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)



X6122B1

Product type 8

Cypermethrin

Tebuconazole

Propiconazole

IPBC

Case Number in R4BP: BC-JL017423-44

Evaluating Competent Authority: FR

Date: April 2018

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Updated September 2023

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**Note to the reader:**

This consolidated PAR for the minor change application of the product authorisation is based on the PAR of the first authorisation, in which all necessary addenda have been included.

In this consolidated PAR, each section contains the initial assessment and the subsequent successive assessments (minor change, major change, post authorisation data...) the assessments related to the renewal of the product are at the end of each section and are highlighted in grey.

* **Minor change application**

Following the X6122B1 first authorisation, changes claimed in the frame of a minor change application are:

* change of conditions of use : preventive treatment for wood in use class from 1 to 3.1.
* addition of a trade name
* addition of a manufacturing site

1. **History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | *FR* | BC-JL017423-44 | 08.04.2019 | Initial assessment : X6122B1 |
| NA-MIC | *FR* | BC-VY051280-08 | 30/10/2019 | Minor change application |
| NA-AAT | *FR* |  |  | Removal of non professional uses from the SPC |

# CONCLUSION

*The biocidal product X6122B1 is a PT8 intended to be used for preventive and curative wood treatment for use class 1, 2 and 3.1 containing 0.075% cypermethrin, 0.15% propiconazole, 0.0475% tebuconazole and 0.049% IPBC. Contents are the ones related to pure active ingredients*

*The product is a ready-to-use product to be used by professional, non-professional and industrial users and applied by brushing, spraying, dipping or injection.*

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

X6122B1 is not considered to be potentially explosive or to contain an oxidising agent. The product is not intended to be used in combination with other products. The product is not expected to be flammable. Its technical properties indicate that no specific issues are to be expected when it is handled, stored or applied as recommended.

The product is classified H304 Cat 1. It is stable 24 months at ambient temperature in its commercial packaging. It should not be stored at a temperature higher than 20°C and it should be protected from light when the product is sold in HDPE packaging.

**Conclusion on Efficacy**

French competent authorities (FR CA) assessed that the product X6122B1, has shown a sufficient efficacy for

* For the preventive treatment: superficial application at 200 g of product / m² of wood used in use class 1 against wood boring beetles and termites (*Reticulitermes spp.*).
* For the curative treatment when used by superficial application for wood in service (not exposed to weathering and leaching) against wood boring beetles and termites (Reticulitermes spp.), at 300 g of product/m² that could be completed by injection application at 180 mL /m² if need be.

FR CA considers that the efficacy data are not sufficient to demonstrate the efficacy of the product X6122B1 against wood rotting fungi. Indeed, at the application rate claimed by the applicant, the efficacy is not demonstrated against all the mandatory fungi strains of the EN 113 after an ageing following the EN 73.

* **Minor change application for X612B1 - 2019 :**

French competent authorities (FR CA) assessed that the product X6122B1, has shown a sufficient efficacy for:

* The preventive treatment by superficial application at 200 g of product / m² of wood (softwood and hardwood) used in use classes 2 to 3.1 against wood rotting fungi (brown rot and white rot fungi). For use class 3.1, a top coat is needed.
* The preventive treatment by superficial application at 200 g of product / m² of wood (softwood and hardwood) used in use class 1 to 3.1 against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and Lyctus brunneus*) and termites (*Reticulitermes spp.*).

**Conclusion on Human health**

Risks related to the use of X6122B1 by professionals and non-professionals are acceptable for all the intended uses, except spraying combined with injection for non-professional users.

Risks related to a secondary exposure to treated wood are acceptable.

**Conclusion on risk for consumers via residues in food**

Regarding consumer health protection, there are no objections against the intended uses. Wood treated with X6122B1 must contain label restrictions against use in contact with livestock, food and feed.

**Conclusion on environmental risk assessment**

For preventive treatment of wood classes 1 and 2, emissions are considered negligible. The risks for the application phase and service life are therefore acceptable for treatment of wood in classes 1 and 2.

For an outdoor application in curative treatment, risks are acceptable only if emissions to the aquatic and terrestrial compartments are prevented whatever the type of treatment. Therefore, the product should not be applied above or near surface water and the ground has to be covered with an appropriate plastic sheet to prevent any emission to the terrestrial compartment during in situ brushing. For spraying application, the risk mitigation measure for the soil compartment is considered as unappropriate.

For the service-life phase of treated wood, risks can be considered acceptable for all the compartments whatever the type of treatment with the use of appropriate risk mitigation measures.

Finally, for the curative treatment, wood must not be exposed to weathering and leaching.

**Overall conclusion**

**The product X6122B1 can be authorized *for preventive wood treatment for use class 1 only (professional, non-professional and industrial users) and for curative treatment* (wood not exposed to weathering and leaching)** ***(professional, non-professional users). Appropriate RMMs (detailed in the SPC) have to be implemented.***

**Overall conclusion – Minor change for X6122B1 – 2019:**

The product X6122B1 can be authorized for preventive wood treatment for use class 1 to 3.1 (professional, non-professional and industrial users) and for curative treatment (wood not exposed toweathering and leaching) (professional, non-professional users). Appropriate RMMs (detailed in the SPC) have to be implemented.

**2023 : NA-AAT removal of non professional uses**

Considering the BPC opinion on propiconaole approval renewal[[1]](#footnote-1), propiconazole meets the criteria to be defined as an endocrine disruptor. Product X6122B1 contains 0.16% of propiconazole and is also endocrine disruptors.

Following article 19.4.d of the BPR, the product X6122B1 cannot be used by the general public. The authorisation of the BPF has thus been modified.

The SPC.xml has been modified. The assessment report (setion 2 of the PAR) has not been modified : a full revision of the PAR will be made in the course of the renewal of the product.

# ASSESSMENT REPORT

## Summary of the product assessment – Minor change application for X6122B1 – 2019

### Administrative information

#### Identifier of the product

| **Identifier[[2]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| X6122B1  France  Xylophene Expert Xylo Extrême  Xylophène Professionnel SOR40  Xylophene Curatif SORX 2000  Xylophène Industrie Xylobati SORX 2000  Xylophene Préventif SGR 2002  Xylophène Industrie Xyloprotect SGR 2002  Xylophène Xylo Extrême  Spain :  Xylophène S.O.R. 40,  Xylophène S.O.R. 2 EXTREME  Bondex Classic Fondo Matacarcomas  Portugal :  Xylophène S.O.R. 40  Xylophène S.O.R. 2 EXTREME  Greece : Gori 22  Italy : Gori 22  Switzerland : Gori 22  Belgium : Madurox Bi-Activ I  Luxembourg : Madurox Bi-Activ  UK : Gori 22  Denmark : Gori Stop Svamp & Insekt  Norway : Gori Stop Svamp & Insekt  Sweden : Gori Stop Svamp & Insekt  Hungary : LAZURÁN UNIVERZÁLIS FAANYAGVÉDŐSZER  Romania : LAZURÁN UNIVERZÁLIS FAANYAGVÉDŐSZER  Czech Republic : PRIMALEX Syntétické Fungicidni NAPOUŠTĚDLO Na DŘEVO  Slovakia : PRIMALEX Syntétické Fungicidni NAPOUŠTĚDLO Na DŘEVO | France |

As no fungi efficacy claim is accepted, commercial names that refer to this activy have to be modified.

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | PPG AC - France SA |
| **Address** | 1 rue de l'Union  Immeuble Union Square, CS10055  92565 Rueil-Malmaison |
| **Authorisation number** | **FR-2019-0021** | |
| **Date of the authorisation** | **08/04/2019** | |
| **Expiry date of the authorisation** | **07/04/2024** | |

#### Manufacturer of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | PPG AC - France SA, Dyrup S.A.S. |
| **Address of manufacturer** | Immeuble Union Square,  1 rue de l'Union  92565 Rueil-Malmaison  France |
| **Location of manufacturing sites** | ZI Montpaisir, 25 rue Jean le Rond d'Alembert 81000 Albi France |

#### 

|  |  |
| --- | --- |
| **Name of manufacturer** | PPG Trilak Kft. |
| **Address of manufacturer** | 4, Grassalkovitch ut.  Budapest 1238  Hungary |
| **Location of manufacturing sites** | 4, Grassalkovitch ut.  Budapest 1238  Hungary |

#### Manufacturers of the active substances

|  |  |
| --- | --- |
| **Active substance** | Cyperméthrine |
| **Name of manufacturer** | Arysta LifeScience Benelux SPRL |
| **Address of manufacturer** | Rue de Renory 26/1  4102 Ougrée  Belgique |
| **Location of manufacturing sites** | 1/ Mitchell Cotts Chemicals,  Steanard Lane, Mirfield,  West Yorkshire,  WF14 8QB,  UK  2/ Gharda Ltd;  D, ½, MIDC,  LOTE PARSHURAM TAL. KHED DIST. RATNAGIRI 415 722, MAHARASHTRA,  India |

|  |  |
| --- | --- |
| **Active substance** | Propiconazole |
| **Name of manufacturer** | Janssen Pharmaceutica NV |
| **Address of manufacturer** | Turnhoutseweg 30  2340 Beerse  Belgium |
| **Location of manufacturing sites** | Dongsha ChemZone,  Zhangjiagang  215600 Jiangsu  China |

|  |  |
| --- | --- |
| **Active substance** | Tebuconazole |
| **Name of manufacturer** | Lanxess Deutschland GmbH |
| **Address of manufacturer** | 51369 Leverkusen  Germany |
| **Location of manufacturing sites** | Bayer CropScience Corp. P.O. Box 4913  64120-001 Kansas City  United States |

|  |  |
| --- | --- |
| **Active substance** | IPBC |
| **Name of manufacturer** | Troy Chemical Company BV |
| **Address of manufacturer** | 8 Vreeland Road, 07932 Florham Park, NJ, US |
| **Location of manufacturing sites** | One Avenue L  07105 Newark  United States |

### 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 substances on the Union list of approved active substances under Regulation No. 528/2012?

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituents** | |
| **ISO name** | Cypermethrin |
| **IUPAC or EC name** | (RS)-α-cyano-3phénoxybenzyl-(1RS)- cis,trans-3-(2,2-dichlorovinyl)-2,2-diméthylcyclopropanecarboxylate |
| **EC number** | 257-842-9 |
| **CAS number** | 52315-07-8 |
| **Index number in Annex VI of CLP** |  |
| Minimum purity / content | 920 g/kg |
| **Structural formula** |  |

|  |  |
| --- | --- |
| **Main constituents** | |
| **ISO name** | Propiconazole |
| **IUPAC or EC name** | 1-[[2-(2,4-dichlorophényl)-  4-propyl-1,3-dioxolane-2-  yl]méthyl]-1H-1,2,4-triazole |
| **EC number** | 262-104-4 |
| **CAS number** | 60207-90-1 |
| **Index number in Annex VI of CLP** |  |
| **Minimum purity / content** | 930 g/kg |
| **Structural formula** |  |

|  |  |
| --- | --- |
| **Main constituents** | |
| **ISO name** | Tebuconazole |
| **IUPAC or EC name** | 1-(4-chlorophényl)-4,4-  diméthyl-3-(1,2,4-triazole-  1-ylméthyl)pentane-  3-ol |
| **EC number** | 403-640-2 |
| **CAS number** | 107534-96-3 |
| **Index number in Annex VI of CLP** |  |
| **Minimum purity / content** | 950 g/kg |
| **Structural formula** |  |

|  |  |
| --- | --- |
| **Main constituents** | |
| **ISO name** | IPBC |
| **IUPAC or EC name** | Butylcarbamate de  3-iodo-2-propynyle |
| **EC number** | 259-627-5 |
| **CAS number** | 55406-53-6 |
| **Index number in Annex VI of CLP** |  |
| **Minimum purity / content** | 980 g/kg |
| **Structural formula** |  |

#### Candidate for substitution

The active substance tebuconazole contained in the biocidal product X6122B1 is candidate for substitution in accordance with Article 10 of BPR because it fulfills the following 2 of the PBT criteria: vP and T.

The active substances cypermethrin, propiconazole and IPBC contained in the biocidal product X6122B1 are not candidate for substitution in accordance with Article 10 of BPR.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%) (technical)** |
| --- | --- | --- | --- | --- | --- |
| Cypermethrin | (RS)-α-cyano-3phenoxybenzyl-(1RS)- cis, trans-3-(dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52315-07-8 | 257-842-9 | 0.08 |
| Propiconazole | 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 | 0.16 |
| Tebuconazole | 1-(4-chlorophenyl)-4,4- dimethyl-3-(1,2,4-triazol-1-ylmethyl)pentan-3-ol | Active substance | 107534-96-3 | 403-640-2 | 0.05 |
| IPBC | 3-iodo-2-  propynylbutylcarbamate | Active substance | 55406-53-6 | 259-627-5 | 0.05 |
| Solvent naphta | Hydrocarbons, C10-C13, n-alkanes,  isoalkanes, cyclics,  < 2% aromatics | Solvent |  | 918-481-9 | 97.15 |

#### Information on technical equivalence

Not applicable.

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

The coforrmulant Hydrocarbons, C10-C13, n-alkanes, isoalkanes,cyclics triggers a classification Asp Tox. Cat 1 - H304 of product. This coformulant is considered substance of concern.

The substance of concern is the solvent which is present at a significant content in the product. Consequently, a method in order to monitor the content of naphta solvent in the product is not relevant.

#### Assessment of endocrine disruption (ED) properties of co-formulants in biocidal products

According to our assessment, none of the co-formulants contained in the biocidal product X6122B1 are identified as endocrine disruptors.

Please refer to Confidential Annex.

#### Type of formulation

|  |
| --- |
| Any other liquid |

### Hazard and precautionary statements

#### Classification of the active substances

The current classification can be displayed here as appropriate.

|  |  |
| --- | --- |
| **Classification - Regulation (EC) 1272/2008** | **Tebuconazole** |
| Hazard statement | Acute Tox 4 – H302  Repr 2 – H361d  H400 – Toxic to aquatic life  H410 – Very toxic to aquatic life with long lasting effects (chronic M-factor = 10) |
| Precautionary statements | P273 – Avoid release to the environment  P391 – Collect spillage  P501 - Dispose of contents/container in accordance with local/ regional/national/international regulation (to be specified). |

|  |  |
| --- | --- |
| **Classification - Regulation (EC) 1272/2008** | **Propiconazole** |
| Hazard statement | Acute Tox 4 – H302  Skin Sens 1 – H317  H400 – Very toxic to aquatic life  H410 – Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P273 – Avoid release to the environment  P391 – Collect spillage  P501 - Dispose of contents/container in accordance with local/ regional/national/international regulation (to be specified). |

**Remark:** a RAC opinion[[3]](#footnote-3) is available for propiconazole. This opinion adds to the current harmonised classification the classification Reprotox 1B, H360D.

|  |  |
| --- | --- |
| **Classification - Regulation (EC) 1272/2008** | **Cypermethrin** |
| Hazard statement | Acute Tox 4 – H302  Acute Tox 4 – H332  STOT SE 3 – H335  H400 – Very toxic to aquatic life  H410 – Very toxic to aquatic life with long lasting effects  M-factor = 1000 |
| Precautionary statements | P273 – Avoid release to the environment  P391 – Collect spillage  P501 - Dispose of contents/container in accordance with local/ regional/national/international regulation (to be specified). |

|  |  |
| --- | --- |
| **Classification - Regulation (EC) 1272/2008** | **IPBC** |
| Hazard statement | Acute Tox 4 – H302  Skin Sens 1 – H317  Eye Irrit 1 – H318  Acute Tox 3 - H331  STOT RE 1 - H372  H400– – Very toxic to aquatic life |
| Precautionary statements | P273 – Avoid release to the environment  P391 – Collect spillage  P501 - Dispose of contents/container in accordance with local/ regional/national/international regulation (to be specified). |

#### Classification of the biocidal product

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

|  |  |
| --- | --- |
| **Classification** | |
| Hazard category | Asp Tox Cat 1  Aquatic acute 1  Aquatic chronic 1 |
| Hazard statement | H304 May be fatal if swallowed and enters airways,  H400 – Very toxic to aquatic life  H410 – Very toxic to aquatic life with long lasting effects |
| Pictograms | Résultat de recherche d'images pour "logo H410" |
|  | |
| **Labelling** | |
| Signal words | Danger |
| Hazard statements | H304: May be fatal if swallowed and enters airways  H410 – Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand.  P102: Keep out of reach of children.  P103: Read label before use  P301 +P310: F SWALLOWED: Immediately call a POISON CENTER or doctor/physician.  P331: Do NOT induce vomiting.  P405: Store locked up.  P273 – Avoid release to the environment  P391 – Collect spillage  P501 - Dispose of contents/container in accordance with local/ regional/national/international regulation (to be specified). |
|  | |
| Note | EUH 066: Repeated exposure may cause skin dryness or cracking  EUH 208: Contains propiconazole. May produce an allergic reaction |

### Authorised use(s)

#### Use description

Use # 1 – Preventive treatment for wood in use class 1, 2 and 3.1 - Professional

|  |  |
| --- | --- |
| **Product Type** | 8 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** | Preventive treatment for wood in use 1, 2 and 3.1 |
| **Target organism(s) (including development stage)** | Wood rotting fungi (brown rot and white rot fungi)  Wood boring insects   * House longhorn beetle (*Hylotrupes bajulus*) * Common furniture beetle (*Anobium punctatum*) * Powder post beetles (*Lyctus brunneus*)   Termites (*Reticulitermes spp.*) |
| **Field(s) of use** | Preventive treatment for wood in use class 1,2 and 3.1  (Softwood and hardwood) |
| **Application method(s)** | Superficial application / brush / roller /pad treatment  Superficial application / spray treatment |
| **Application rate(s) and frequency** | The product is ready to use  The product is applied by superficial application, the application rate is   * UC 1 to 3.1: 200 g of product /m² |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Can /Tin, Metal: , 0.75, 1, 2.5, 5, 25, 30, 55, 200 L  IBC (intermediate bulk container), Plastic: HDPE , 1000 L  The 30 L can is internally coated with an epoxyphenolic lacquer.  Tin-plate can up to 200 L and HDPE 1000 L IBC for professionnal users. Hermetically closed with a cap. |

#### Use-specific instructions for use

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| --- |
| * For preventive superficial application on wood for use class 3.1, a top coat has to be applied. |

#### Use-specific risk mitigation measures

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| --- |
| **Professional user only:** For brushing, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and coated coverall (category IV type 6) during application phase.  **Professional user only:** For spraying, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and impermeable coverall (category IV type 4) during spraying, gloves, and coated coverall (category IV type 6) during cleaning phase.   * For outdoor treatment, apply only by brushing and cover the ground with an appropriate plastic sheet to prevent any emission to the terrestrial compartment. * Do not apply where the product can reach surface water during outdoor application * Treated wood should not be used near an aquatic environment |

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

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

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

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#### Use description

Use # 2 – Preventive treatment for wood in use class 1, 2 and 3.1 - Non-Professional

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| --- | --- |
| **Product Type** | 8 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** | Preventive treatment for wood in use class 1,2 and 3.1 |
| **Target organism(s) (including development stage)** | Wood rotting fungi (brown rot and white rot fungi)  Wood boring insects   * House longhorn beetle (*Hylotrupes bajulus*) * Common furniture beetle (*Anobium punctatum*) * Powder post beetles (*Lyctus brunneus*)   Termites (*Reticulitermes spp.*) |
| **Field(s) of use** | Preventive treatment for wood in use class 1, 2 and 3.1  (Softwood and hardwood) |
| **Application method(s)** | Superficial application / brush / roller /pad treatment  Superficial application / spray treatment |
| **Application rate(s) and frequency** | The product is ready to use  The product is applied by superficial application, the application rate is   * UC 1 to 3.1: 200 g of product /m² |
| **Category(ies) of users** | Non-professional |
| **Pack sizes and packaging material** | Can /Tin, Metal: , 0.75, 1, 2.5, 5, 25, 30, 55, 200 L  IBC (intermediate bulk container), Plastic: HDPE , 1000 L  The 30 L can is internally coated with an epoxyphenolic lacquer.  Tin-plate can up to 30 L for non-professional users.  Packagings for non-professional users are hermetically closed with a cap and fitted with a child-resistant fastening and a tactile warning of danger |

#### Use-specific instructions for use

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| --- |
| * For preventive superficial application on wood for use class 3.1, a top coat has to be applied. |

#### Use-specific risk mitigation measures

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| --- |
| * For outdoor treatment, apply only by brushing and cover the ground with an appropriate plastic sheet to prevent any emission to the terrestrial compartment. * Do not apply where the product can reach surface water during outdoor application. * Treated wood should not be used near an aquatic environment. |

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

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

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

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#### Use description

Use # 3 – curative treatment for wood in service - Professional

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| --- | --- |
| **Product Type** | 8 |
| **Where relevant, an exact description of the authorised use** | Curative treatment for wood in service |
| **Target organism(s) (including development stage)** | Wood boring insects   * House longhorn beetle (*Hylotrupes bajulus*) * Common furniture beetle (*Anobium punctatum*) * Powder post beetles (*Lyctus brunneus*)   Termites (*Reticulitermes spp.*) |
| **Field(s) of use** | Curative treatment for wood in service (wood not exposed to weathering and leaching)  Softwood and hardwood |
| **Application method(s)** | Superficial application / brush / roller /pad treatment  Superficial application / spray treatment  Injection (combinated with a superficial application) |
| **Application rate(s) and frequency** | The product is ready to use.  For the treatment with a superficial application, the application rate is :   * 300 g of product / m² of wood   When the application is performed by injection (always combined with superficial application), the application rate is :   * 180 mL of product / m² of wood (equivalent to 145 g of product /m² of wood) (+ 300 g of product / m² of wood) |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | Can /Tin, Metal: , 0.75 L, 1, 2.5, 5, 25, 30, 55 and 200 L  IBC (intermediate bulk container), Plastic: HDPE , 1 000 L  The 30 L tin-plate can is internally coated with an epoxyphenolic lacquer.  Tin-plate can up to 200 L and HDPE 1000 L IBC for professionnal users. Hermetically closed with a cap. |

#### Use-specific instructions for use

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| * Curative treatments performed by injection must always be combined with curative treatments applied by surperficial application. * Use only for the treatement of wood not be exposed to weathering and leaching |

#### Use-specific risk mitigation measures

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| * **Professional user only:** For brushing, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and coated coverall (category IV type 6) during application phase. * **Professional user only:** For spraying, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and impermeable coverall (category IV type 4) during spraying and gloves and coated coverall (category IV type 6) during cleaning phase. * **Professional user only:** For injection combined to brushing, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and coated coverall (category IV type 6) during application by brushing and gloves during injection. * **Professional user only** For injection combined to spraying, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and impermeable coverall (category IV type 4) during application by spraying, gloves during injection and gloves and coated coverall (category IV type 6) during cleaning of equipments. * For outdoor treatment, apply only by brushing and cover the ground with an appropriate plastic sheet to prevent any emission to the terrestrial compartment * Do not apply where the product can reach surface water during outdoor application * Treated wood should not be used near an aquatic environment. |

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

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

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

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#### Use description

Use # 4 – curative treatment for wood in service – Non-professional

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| --- | --- |
| **Product Type** | 8 |
| **Where relevant, an exact description of the authorised use** | Curative treatment for wood in service |
| **Target organism(s) (including development stage)** | Wood boring insects   * House longhorn beetle (*Hylotrupes bajulus*) * Common furniture beetle (*Anobium punctatum*) * Powder post beetles (*Lyctus brunneus*)   Termites (*Reticulitermes spp.*) |
| **Field(s) of use** | Curative treatment for wood in service (wood not exposed to weathering and leaching)  Softwood and hardwood |
| **Application method(s)** | Superficial application / brush / roller /pad treatment  Superficial application / spray treatment  Injection (combinated with brush application) |
| **Application rate(s) and frequency** | The product is ready to use.  For the treatment with a superficial application, the application rate is :   * 300 g of product / m² of wood   When the application is performed by injection (always combined with superficial application by brushing), the application rate is :  180 mL of product / m² of wood (equivalent to 145 g of product /m² of wood) (+ 300 g of product / m² of wood) |
| **Category(ies) of users** | Non professional users |
| **Pack sizes and packaging material** | Can /Tin, Metal: , 0.75 L, 1, 2.5, 5, 25, 30, 55 and 200 L  IBC (intermediate bulk container), Plastic: HDPE , 1 000 L  The 30 L tin-plate can is internally coated with an epoxyphenolic lacquer. Tin-plate can up to 30 L for non-professional users.  Packagings for non-professional users are hermetically closed with a cap and fitted with a child-resistant fastening and a tactile warning of danger. |

#### Use-specific instructions for use

|  |
| --- |
| * Curative treatments performed by injection must always be combined with curative treatments applied by surperficial application (only with brushing application). * Use only for the treatement of wood not be exposed to weathering and leaching |

#### Use-specific risk mitigation measures

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| --- |
| * For outdoor treatment, apply only by brushing and cover the ground with an appropriate plastic sheet to prevent any emission to the terrestrial compartment * Do not apply where the product can reach surface water during outdoor application * Treated wood should not be used near an aquatic environment. |

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

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

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

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#### Use description

Use # 5 – industrial treatment

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| --- | --- |
| **Product Type** | 8 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** | Preventive treatment for wood in use class 1, 2 et 3.1 |
| **Target organism(s) (including development stage)** | Wood rotting fungi (brown rot and white rot fungi)  Wood boring insects   * House longhorn beetle (*Hylotrupes bajulus*) * Common furniture beetle (*Anobium punctatum*) * Powder post beetles (*Lyctus brunneus*)   Termites (*Reticulitermes spp.*) |
| **Field(s) of use** | Preventive treatment for wood in use classes 1 to 3.1  (Softwood and hardwood) |
| **Application method(s)** | Superficial application / short dipping treatment |
| **Application rate(s) and frequency** | The product is ready to use  When the application is performed by short dipping, the application rate is :   * UC 1 to 3.1: 200 g of product /m² |
| **Category(ies) of users** | Industrial |
| **Pack sizes and packaging material** | IBC (intermediate bulk container), Plastic: HDPE, 1000 L or tinplate, 200L, Hermetically closed with a cap. |

#### Use-specific instructions for use

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| * For preventive superficial application on wood for use class 3.1, a top coat has to be applied. |

#### Use-specific risk mitigation measures

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| --- |
| * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and clothes (category IV type 6) during mixing and loading and gloves during application. * Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber. * Industrial application shall be conducted within a contained area on impermeable hard standing with bunding * During the application phase, prevent any release of cleaning water (after cleaning of floors, tanks, containers) to the environment (sewer, soil, water). * Freshly treated timber shall be stored after treatment under shelter and on impermeable hard standing to prevent losses to soil, sewer, or water, and any losses from the application of the product shall be collected for reuse or disposal. Before use, store the timber in an area sheltered from the weather. * Any contaminated water/soil shall be collected, contained and treated as hazardous waste. * Treated wood should not be used near an aquatic environment. |

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

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

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

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### General directions for use

#### Instructions for use

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

#### Risk mitigation measures

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| * Do not apply on wood likely to be in contact with food, feed, drinks and livestock. |

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

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

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

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

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

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| * Shelf life: 24 months * Do not store at a temperature higher than 20°C * Protect from light (only bulk containers). |

### Other information

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| * The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA) * Treated wood should not be intended for uses involving contact with food, feed or livestock. |

### Packaging of the biocidal product

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| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Can | 0.75 L, 1 L, 2.5 L, 5 L, 25 L, 30 L, 55 L and 200 L | Metal (tin plate, with an internal epoxyphenolic lacquer only for the 30L container) | Hermetically closed | professional | Y |
| Bulk containers | 1000L | HDPE |  |
| Bulk containers | 1000L | HDPE |  | industrial | Y |
| Can | 200 L | Metal (tin plate) | Hermetically closed |
| Can | 0.75 L, 1 L, 2.5 L, 5 L, 25 L and 30 L | Metal (tin plate). An internal epoxyphenolic lacquer is added only for the 30L container. | Hermetically closed | Non-professional | Y |

### Documentation

#### Data submitted in relation to product application

**Physical, chemical and technical properties of the product**

Physico-chemical properties studies and analytical methods on the biocidal product X6122B1 were provided by PPG.

**Efficacy data**

* Laboratory efficacy study conducted according to the standard EN 113[[4]](#footnote-4), with the product X6122B1 after ageing following EN 73[[5]](#footnote-5) (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 113, with the product X6122B1 after ageing following EN 84[[6]](#footnote-6) (leaching procedure);
* Laboratory efficacy study conducted according to the standard EN 118[[7]](#footnote-7), with the product X6122B1, after ageing following EN 73 (evaporating procedure) against *Reticulitermes flavipes*;
* Laboratory efficacy study conducted according to the standard EN 118, with the product X6122B1, after ageing following EN 84 (leaching procedure) against *Reticulitermes flavipes*;
* Laboratory efficacy study conducted according to the standard EN 46-1[[8]](#footnote-8), with the product X6122B1, after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 46-1, with the product X6122B1, after ageing following EN 84 (leaching procedure);
* Laboratory efficacy study conducted according to the standard EN 49-1[[9]](#footnote-9), with the product X6122B1, after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 49-1, with the product X6122B1, after ageing following EN 84 leaching procedure);
* Laboratory efficacy study conducted according to the standard EN 20-1[[10]](#footnote-10), with the product X6122B1, after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 1390[[11]](#footnote-11), with the product X6122B1;
* Laboratory efficacy study conducted according to the standard EN 48[[12]](#footnote-12), with the product X6122B1;
* **Minor change application for X6122B1 - 2019 :**
* 2 Laboratory efficacy studies conducted according to the standard EN 113, with the product X6122B1, against *Poria placenta* only, after ageing following EN73 (evaporating procedure);

#### Access to documentation

PPG has access to analytical methods:

* On the active substance Cypermethrin with a Letter of Access of Agriphar.
* On the active substance propiconazole with a Letter of Access of Janssen PMP
* On the active substance tebuconazole with a Letter of Access of Lanxess
* On the active substance IPBC with a Letter of Access of Troy Chemical

## Assessment of the biocidal product

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

Intended use # 1 – Preventive\_Softwood

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| --- | --- |
| Product Type(s) | PT8 |
| Where relevant, an exact description of the authorised use | Softwood: Preventive treatment - Use class 1. Indoor. |
| Target organism (including development stage) | Hylotrupes bajulus L.-Larvae-House longhorn beetle  Anobium punctatum De Geer-Larvae-Common furniture beetle Lyctus brunneus-Larvae-Powder post beetles  Reticulitermes sp.-soldiers, nymphs and workers-Subterranean termites |
| Field of use | Indoor |
| Application method(s) | superficial application -  Superficial application / brush / roller / pad treatment Superficial application / spray treatment |
| Application rate(s) and frequency | 200 g/m² |
| Category(ies) of user(s) | Professional  General public (non-professional) |
| Pack sizes and packaging material | Can /Tin, Metal: , 0.75, 1, 2.5, 5, 25, 30, 55, 200 L  IBC (intermediate bulk container), Plastic: HDPE , 1000 L  The 30 L can is internally coated with an epoxyphenolic lacquer.  Tin-plate can up to 30 L for non-professional users.  Tin-plate can up to 200 L and HDPE 1000 L IBC for professionnal users. Hermetically closed with a cap.  Packagings for non-professional users are hermetically closed with a cap and fitted with a child-resistant fastening and a tactile warning of danger |

Intended use # 2 – Preventive\_Hardwood

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| --- | --- |
| Product Type(s) | PT8 |
| Where relevant, an exact description of the authorised use | Hardwood: Preventive treatment - Use classes 1, 2 and 3.1. Indoor and outdoor.  Treated wood intended to be used outdoor and exposed to weathering must be protected with a topcoat. |
| Target organism (including development stage) | Hylotrupes bajulus L.-Larvae-House longhorn beetle  Anobium punctatum De Geer-Larvae-Common furniture beetle  Lyctus brunneus-Larvae-Powder post beetles  Reticulitermes sp.-soldiers, nymphs and workers-Subterranean termites Basidiomycetes:-No data-Brown rot fungi  Basidiomycetes:-No data-White rot fungi |
| Field of use | Indoor, Outdoor |
| Application method(s) | superficial application -  Superficial application / brush / roller / pad treatment Superficial application / spray treatment |
| Application rate(s) and frequency | 200 g/m |
| Category(ies) of user(s) | Professional, General public (nonprofessional) |
| Pack sizes and packaging material | Can /Tin, Metal: , 0.75, 1, 2.5, 5, 25, 30, 55, 200 L  IBC (intermediate bulk container), Plastic: HDPE , 1000 L  The 30 L can is internally coated with an epoxyphenolic lacquer.  Tin-plate can up to 30 L for non-professional users.  Tin-plate can up to 200 L and HDPE 1000 L IBC for professionnal users. Hermetically closed with a cap.  Packagings for non-professional users are hermetically closed with a cap and fitted with a child-resistant fastening and a tactile warning of danger |

Intended use # 3 – Curative

|  |  |
| --- | --- |
| Product Type(s) | PT8 |
| Where relevant, an exact description of the authorised use | Curative treatment / wood in service.  Wood not exposed to weathering and leaching. |
| Target organism (including development stage) | Hylotrupes bajulus L.-Larvae-House longhorn beetle  Anobium punctatum De Geer-Larvae-Common furniture beetle Lyctus brunneus-Larvae-Powder post beetles  Reticulitermes sp.-soldiers, workers and nymphs-Subterranean termites |
| Field of use | Indoor, Outdoor |
| Application method(s) | superficial application -  Superficial application / brush / roller / pad treatment Superficial application / spray treatment  Injection (only for curative treatment, always done with a superficial treatment) |
| Application rate(s) and frequency | 300 g/m² for superficial application, and 180 mL/m² or 145 g/m² for injection (20 mL per hole, 9 holes/m²) - - -  Three layers of the product are applied, with at least 1 hour of drying between each layer. However, the product is applied only once. If applied according to the instructions for use, and if the treated wood is used in the correct field of use, the preservative efficacy is guaranteed for at least 10 years (CTB-P+ certification). |
| Category(ies) of user(s) | Professional  General public (non-professional) |
| Pack sizes and packaging material | Can /Tin, Metal: , 0.75 L, 1, 2.5, 5, 25, 30, 55 and 200 L  IBC (intermediate bulk container), Plastic: HDPE , 1 000 L  The 30 L tin-plate can is internally coated with an epoxyphenolic lacquer. Tin-plate can up to 30 L for non-professional users.  Tin-plate can up to 200 L and HDPE 1000 L IBC for professionnal users. Hermetically closed with a cap.  Packagings for non-professional users are hermetically closed with a cap and fitted with a child-resistant fastening and a tactile warning of danger. |

Intended use # 4 – Industry\_Softwood

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| --- | --- |
| Product Type(s) | PT8 |
| Where relevant, an exact description of the authorised use | This product is used by industrial users, by short-time dipping, for preventive treatment.  The application rate is 200 g/m². This corresponds to a dipping during 3 minutes, with a mean intake of 15 to 20 litres of the product per m3 (for traditional framework) |
| Target organism (including development stage) | Hylotrupes bajulus L.-Larvae-House longhorn beetle  Anobium punctatum De Geer-Larvae-Common furniture beetle Lyctus brunneus-Larvae-Powder post beetles  Reticulitermes sp.-soldiers, workers and nymphs-Subterranean termites |
| Field of use | Indoor |
| Application method(s) | Open system: dip treatment |
| Application rate(s) and frequency | 200 g/m²  The product is applied once. If applied according to the instructions for use, and if the treated wood is used in the correct field of use, the preservative efficacy is guaranteed for at least 10 years. The product is certified as CTB-P+. |
| Category(ies) of user(s) | Industrial |
| Pack sizes and packaging material | IBC (intermediate bulk container), Plastic: HDPE, 1000 L Hermetically closed with a cap. |

* **Minor change application for X6122B1 – 2019 :**

Intended use # 1 – Preventive treatment for wood in use class 1 to 3.1 - Professional

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| --- | --- |
| Product Type(s) | PT8 |
| Where relevant, an exact description of the authorised use | Preventive treatment for wood in use classes 1 to 3.1 |
| Target organism (including development stage) | *Hylotrupes bajulus L.*  House longhorn beetle  *Anobium punctatum De Geer*  Common furniture beetle  *Lyctus brunneus*  Powder post beetles  *Reticulitermes sp.*  Termites  *Basidiomycetes:*  Brown rot fungi  *Basidiomycetes:*  White rot fungi |
| Field of use | Indoor  Outdoor  Preventive treatment for wood in use class 1 to 3.1  Softwood and hardwood |
| Application method(s) | superficial application  Superficial application / brush / roller /pad treatment  Superficial application / spray treatment |
| Application rate(s) and frequency | 200 g/m² |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | Can /Tin, Metal: , 0.75, 1, 2.5, 5, 25, 30, 55, 200 L  IBC (intermediate bulk container), Plastic: HDPE , 1000 L  The 30 L can is internally coated with an epoxyphenolic lacquer.  Tin-plate can up to 30 L for non-professional users.  Tin-plate can up to 200 L and HDPE 1000 L IBC for professionnal users. Hermetically closed with a cap. |

Intended use # 2 – Preventive treatment for wood in use class1 to 3.1 Non Professional

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| --- | --- |
| Product Type(s) | PT8 |
| Where relevant, an exact description of the authorised use | Preventive treatment for wood in use classes 1 to 3.1 |
| Target organism (including development stage) | *Hylotrupes bajulus L.*  House longhorn beetle  *Anobium punctatum De Geer*  Common furniture beetle  *Lyctus brunneus*  Powder post beetles  *Reticulitermes sp.*  Termites  *Basidiomycetes:*  *Brown rot fungi*  *Basidiomycetes:*  White rot fungi |
| Field of use | Indoor  Outdoor  Preventive treatment for wood in use class 1 to 3.1  Softwood and hardwood |
| Application method(s) | superficial application  Superficial application / brush / roller /pad treatment  Superficial application / spray treatment |
| Application rate(s) and frequency | 200 g/m² |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | Can /Tin, Metal: , 0.75, 1, 2.5, 5, 25, 30, 55, 200 L  IBC (intermediate bulk container), Plastic: HDPE , 1000 L  The 30 L can is internally coated with an epoxyphenolic lacquer.  Tin-plate can up to 30 L for non-professional users.  Packagings for non-professional users are hermetically closed with a cap and fitted with a child-resistant fastening and a tactile warning of danger |

Intended use # 3 – Curative treatment for wood in service Professional

|  |  |
| --- | --- |
| Product Type(s) | PT8 |
| Where relevant, an exact description of the authorised use | Curative treatment for wood in service |
| Target organism (including development stage) | *Hylotrupes bajulus L.*  House longhorn beetle  *Anobium punctatum De Geer*  Common furniture beetle  *Lyctus brunneus*  Powder post beetles  *Reticulitermes sp.*  Termites |
| Field of use | Indoor  Outdoor  Curative treatment for wood in service (wood not exposed to weathering and leaching)  Softwood and hardwood |
| Application method(s) | superficial application  Superficial application / brush / roller /pad treatment  Superficial application / spray treatment  Injection ( always combinated with a superficial application) |
| Application rate(s) and frequency | 300 g/m² |
| Category(ies) of user(s) | Professional |
| Pack sizes and packaging material | Can /Tin, Metal: , 0.75 L, 1, 2.5, 5, 25, 30, 55 and 200 L  IBC (intermediate bulk container), Plastic: HDPE , 1 000 L  The 30 L tin-plate can is internally coated with an epoxyphenolic lacquer.  Tin-plate can up to 200 L and HDPE 1000 L IBC for professionnal users. Hermetically closed with a cap. |

Intended use # 4 – Curative treatment for wood in service Non Professional

|  |  |
| --- | --- |
| Product Type(s) | PT8 |
| Where relevant, an exact description of the authorised use | Curative treatment for wood in service |
| Target organism (including development stage) | *Hylotrupes bajulus L.*  House longhorn beetle  *Anobium punctatum De Geer*  Common furniture beetle  *Lyctus brunneus*  Powder post beetles  *Reticulitermes sp.*  Termites |
| Field of use | Indoor  Outdoor  Curative treatment for wood in service (wood not exposed to weathering and leaching)  Softwood and hardwood |
| Application method(s) | superficial application  Superficial application / brush / roller /pad treatment  Superficial application / spray treatment  Injection ( always combinated with a superficial application) |
| Application rate(s) and frequency | 300 g/m² |
| Category(ies) of user(s) | General public (non-professional) |
| Pack sizes and packaging material | Can /Tin, Metal: , 0.75 L, 1, 2.5, 5, 25, 30, 55 and 200 L  IBC (intermediate bulk container), Plastic: HDPE , 1 000 L  The 30 L tin-plate can is internally coated with an epoxyphenolic lacquer. Tin-plate can up to 30 L for non-professional users.  Packagings for non-professional users are hermetically closed with a cap and fitted with a child-resistant fastening and a tactile warning of danger. |

Intended use # 5 – industrial treatment

|  |  |
| --- | --- |
| Product Type(s) | PT8 |
| Where relevant, an exact description of the authorised use | Preventive treatment for wood in use classes 1 to 3.1 |
| Target organism (including development stage) | *Hylotrupes bajulus L.*  House longhorn beetle  *Anobium punctatum De Geer*  Common furniture beetle  *Lyctus brunneus*  Powder post beetles  *Reticulitermes sp.*  Termites  *Basidiomycetes:*  Brown rot fungi  *Basidiomycetes:*  White rot fungi |
| Field of use | Indoor  Outdoor  Preventive treatment for wood in use class 1 to 3.1  Softwood and hardwood |
| Application method(s) | Open system: dip treatment  Superficial application / short dipping treatment |
| Application rate(s) and frequency | 200 g/m² |
| Category(ies) of user(s) | Industrial |
| Pack sizes and packaging material | IBC (intermediate bulk container), Plastic: HDPE, 1000 L or tinplate, 200L, Hermetically closed with a cap. |

### Physical, chemical and technical properties

**Identity, composition of the biocidal product, packaging**

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. Active substances are supplied in premixes.

The product contains 0.07% of pure cypermethrin (cis:trans/ 40:60), 0.15% of pure propiconazole, 0.049% of pure IPBC and 0.0475% of pure tebuconazole.

The product contains 0.08% of technical cypermethrin, 0.16% of technical propiconazole, 0.05% of technical IPBC and 0.05% of technical tebuconazole.

The product does not contain PT6 conservative.

Formulation type: Another Liquid (AL), ready to use

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

**Physico-chemical properties**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | METDESCR | X6122B1  Lot/batch No.: PaP V 83.2 | Liquid, transparent, no deposit, no phase partition | Acceptable | Simon F. 2015  150313/PaPV93.8  Legay S 2015  402/14/1095F/abc-e |
| Colour at 20 °C and 101.3 kPa | pale yellow, transparent at initial time and yellow, transparent |
| Odour at 20 °C and 101.3 kPa | White spirit like odour |
| Acidity / alkalinity |  |  | Not required as X6122B1 is a non-aqueous ready-to-use product. | Acceptable. Not required for non-aqueous liquid which are not applied as dilution. |  |
| Relative density / bulk density | OECD 109 | X6122B1  Lot/batch No.: PaP V 83.2 | According to OECD No.109 (pycnometers method), the mean relative density of X6122B1 was:  D (21.3°C / 4°C) = 0.803 | Acceptable | Legay S 2015  402/14/1095F/abc-e |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  (8 weeks at 40 ± 2ºC in commercial packaging)  Analytical method validated in report 402/13/1139F/ab-e (see point 2.2.3) and 635281-1 (for PBC but not sufficiently validated) | X6122B1  Lot/batch No.: PaP V 83.2 | Packaging: 5L in HDPE and 1 L bottle in metal without lacquer  The product X6122B1 was found to be a pale yellow, transparent liquid at initial time and a yellow, transparent liquid after 8 weeks at 40 ± 2°C. No deposit or phase partition was observed after 8 weeks at 40 ± 2°C. The appearance of X6122B1 was considered to be stable after an accelerated storage procedure at 40 ± 2°C for 8 weeks.  The appearance of the packaging materials (5 L bottle in HDPE and 1 L bottle in metal) were considered to be stable after an accelerated storage procedure for 8 weeks at 40 ± 2°C. No significant weight change were observed (-1.8% for the HDPE packaging and -1.2% for the metal packaging). No sign of corrosion were noted.  MASS CHANGES  - Initial total mass (product + packaging): 4376 g for the HDPE packaging, 857.27 g for the metal packaging  - Mass at sampling (product + packaging): after storage: 4297 g for the HDPE packaging, 847.37 g for the metal packaging  The cypermethrin content was 0.074% w/w at initial time and 0.073% w/w after 8 weeks at 40 ± 2°C.  The IPBC content was 0052% w/w at initial time and 0.040% w/w after 8 weeks at 40 ± 2°C.  The tebuconazole content was 0.049% w/w at initial time and 0.049% w/w after 8 weeks at 40 ± 2°C.  The propiconazole content was 0.159% w/w at initial time and 0.160% w/w after 8 weeks at 40 ± 2°C.  With a variation of -1.4% for cypermethrin, no variation for tebuconazole and a variation of +0.6% for propiconazole vs. the values at initial time, the test item was considered to be stable after the accelerated storage procedure. The variation was - 23.1% for IPBC. PBC was identified as degradation product.  Determination of degradation product from IPBC has been performed in report M. Klamer 2016:  Before storage: 0.052% w/w IPBC and no PCB found (<LOQ)  After storage: 0.038% w/w IPBC and 0.011% PBC | The product compatible with metal box and HDPE container.  Variation of IPBC after storage is higher than 10%. A study has been performed to identify PBC as the degradation product. Its content after storage was found to be 0.011%w/w, which corresponds to the loss of IPBC. Validation data are reported in the section “analytical method”. The method is not completely validated. However, it is clear that IPBC will degrade into PBC. In order to accept such variations, a fully validated method and justification that the degradation products do not lead to human health concern and do not affect the efficacy should be provided as stated in Echa guidance on the BPR.  With the available data, since the variations after storage is higher than 10%, the product is not considered stable at 40°C and should not be stored at a temperature higher than 20°C (temperature of the shelf life study). | Legay S 2015  402/14/1095F/abc-e  M. Klamer 2016  Report no. 635281-1 rev1 |
| Storage stability test – **long term storage at ambient temperature** | Technical Monograph No.17, 2nd edition, CropLife International  Analytical method validated in report 402/13/1139F/ab-e (see point 2.2.3) | X6122B1  Lot/batch No XVIII 193 NDF | The long term storage study at ambient temperature during 24 months has been performed with the product X6122B1 in its commercial packaging (1L tin plate cans without internal varnish, which is the worst case for metallic packaging).  **Appearance**  The appearance of X6122B1 was considered to be stable after 6, 12, 18 and 24 months of storage at ambient temperature (colourless, limpid liquid and initial time and after 6 months, light yellow, transparent liquid after 12/18/24 months, with no deposit or phase partition).  **Packaging stability**  The appearance of the packaging material (1L metal packaging) was considered to be stable after 6,12, 18, 24 months of storage at ambient temperature (no sign of corrosion or degradation). No significant weight change was observed after 6 and 12 months of storage (-0.49% after 6 months, -0.84% after 12 months, -1.30% after 18 months, -1.93% after 24 months).  **Active ingredient contents**  The cypermethrin content was 0.070% w/w at initial time and 0.071% w/w after 24 months. With variations of +1.4% after 24 months vs. the value at initial time, the test item was considered to be stable after 24 months of storage at ambient temperature.  The propiconazole content was 0.160% w/w at initial time and 0.166% w/w after 24 months. With variations +3.8% after 24 months vs. the value at initial time, the test item was considered to be stable after 24 months of storage at ambient temperature.  The tebuconazole content was 0.050% w/w at initial time, 0.050% w/w after 24 months. With no variation after 24 months vs. the value at initial time, the test item was considered to be stable after 24 months of storage at ambient temperature.  The IPBC content was 0.048% w/w at initial time, 0.050% w/w after 24 months. With a variation of +4.2% after 24 months vs. the value at initial time, the test item was considered to be stable 24 months of storage at ambient temperature. | The product is considered stable when stored 2 years.  Test has only been performed with tinplate can without internal lacquer. Compatibility with HDPE has been demonstrated during the accelerated storage stability study. | Legay S. 2013  13/1139F/c  Legay S 2016  Final report No.402/13/1139F/c-e |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3  (7 days at 0 ± 1ºC in closed glass bottle) | X6122B1  Lot/batch No.: PaP V 83.2 | The test item was physically stable after storage at 0 ± 2°C for 7 days in HDPE bottles. No deposit or phase partition was observed. No change regarding the appearance of the product has been noted. | Acceptable. The preparation is stable after storage 7 days at 0°C. | Legay S. 2015  402/14/1095F/defgh-e |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Not required as the biocidal product is packed in opaque commercial packagings. Moreover, active substances are not sensitive to light. | Not acceptable. Cypermethrin is sensitive to light and one packaging (HDPE) is not a barrier to the light. Therefore, the product should be stored away from light. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | The test item X6122B1 was not considered to be stable after 8 weeks at 40 ± 2°C but stable after 7 days at 0 ± 2°C.  The individual commercial packagings are hermetically closed with a cap. With their closure systems, the packagings are leak-tight. | The product is not considered stable at 40°C. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | The product is compatible with metal can and HDPE containers (see results of the accelerated storage stability and shelf life study). Therefore no further data are required. | Acceptable. |  |
| Wettability |  |  | Not applicable | Not applicable |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not applicable | Not applicable |  |
| Wet sieve analysis and dry sieve test |  |  | Not applicable | Not applicable |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not applicable | Not applicable |  |
| Disintegration time |  |  | Not applicable | Not applicable |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not applicable | Not applicable |  |
| Persistent foaming |  |  | Not applicable | Not applicable |  |
| Flowability/Pourability/Dustability |  |  | Not applicable | Not applicable |  |
| Burning rate — smoke generators |  |  | Not applicable | Not applicable |  |
| Burning completeness — smoke generators |  |  | Not applicable | Not applicable |  |
| Composition of smoke — smoke generators |  |  | Not applicable | Not applicable |  |
| Spraying pattern — aerosols |  |  | Not applicable | Not applicable |  |
| Physical compatibility |  |  | Not applicable | Not applicable | The product is not intended to be mixed and is a RTU formulation. Compability with packaging has been demonstrated with the material HDPE and tinplate can. Consequently, no further data are necessary. |
| Chemical compatibility |  |  | Not applicable | Not applicable |
| Degree of dissolution and dilution stability |  |  | Not applicable | Not applicable |  |
| Surface tension | EEC A5  OECD Guideline 115 (Surface Tension of Aqueous Solutions) | X6122B1  Lot/batch No PaP V83.2 | According to EC A.5 and OECD No.115 (ring method), X6122B1 was considered as surface-active (mean surface tension at 20.8°C of the pure test item: 25.47 mN/m). | Acceptable | Legay S. 2015  402/14/1095F/defgh-e |
| Viscosity | OECD 114 | X6122B1  Lot/batch No PaP V83.2 | According to OECD No.114, the mean kinematic viscosity of X6122B1, determined using a flow cup method was the following:  < 6.62 mm²/s at 20.0 ± 0.5°C  < 6.62 mm²/s at 40.0 ± 0.5°C | Acceptable. As the product contains H304 compounds at a content >10%, the formulation is classified H304 Cat1, SGH08 | Legay S. 2015  402/14/1095F/defgh-e |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | |  | | --- | | D.S.C./ (Q)SAR | | X6122B1  Lot/batch No PaP V83.2  Expert statement | According to the evaluation of propiconazole, cypermethrin cis:trans / 40:60, IPBC and tebuconazole under Biocidal Products Directive, these active substances (0.32% w/w total) have no potential explosive properties.  Based on data available in literature, safety data sheet and/or on their structure, all other ingredients (99.56% w/w) are not expected to have explosive properties.  Moreover, according to Differential Scanning Calorimetry (DSC) graphs, no exothermic reaction was observed in the temperature range from 20°C to 500°C. Only two endothermic reactions noted with an energy of 92J/g and 49J/g respectively Therefore, the test item is unlikely to be explosive and the test on explosive properties according to UN Test series 1 to 3 described in Part I of the UN-MTC should not be performed. | Acceptable. The product is not explosive. | Raphalen E., Legay S. 2015  402/14/1095F/i-e  Detrimont H., Ambrosi D. 2015 Report 15/06 |
| Flammable gases |  |  | Not applicable | Not applicable |  |
| Flammable aerosols |  |  | Not applicable | Not applicable |  |
| Oxidising gases |  |  | Not applicable | Not applicable |  |
| Gases under pressure |  |  | Not applicable | Not applicable |  |
| Flammable liquids | EEC A9 (closed cup) | X6122B1  Lot/batch No PaP V83.2 | According to EC A.9 method (Pensky-Martens apparatus), the product X6122B1 is not flammable (flash point: 62.8 degree C). | Acceptable. The product is not flammable. | Legay S. 2015  402/14/1095F/defgh-e |
| Flammable solids |  |  | Not applicable | Not applicable |  |
| Self-reactive substances and mixtures | Expert statement |  | According to Regulation (EC) No.1272/2008, homogeneous mixtures of organic substances  should be considered for classification in this hazard class unless their exothermic decomposition energy is  less than 300 J/g. As no exothermic reaction was observed in the temperature range used from 20°C to 500°C (DSC graphs), testing is considered as unnecessary. | Acceptable. As no exothermic decomposition has been observed, the product is not considered self-reactive. |  |
| Pyrophoric liquids |  |  | Not required as experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperature. | Acceptable. |  |
| Pyrophoric solids |  |  | Not applicable | Not applicable |  |
| Self-heating substances and mixtures | D.S.C. / (Q)SAR | X6122B1  Lot/batch No PaP V83.2  Expert statement | Based on most recent approach of structural formulas, 98.78% of the formulants are not considered to have potential self-reactive properties unlike the pure components propiconazole, cypermethrin cis:trans / 40:60, IPBC and tebuconazole (0.32% w/w total).  Data are lacking to conclude on the self-reactivity for one formulant (0.89% w/w).  Bases on these data, it is not expected that the product is a self heating mixture. | Acceptable. Based on the composition and on the DSC results, the preparation is not a self-heating substance. | Raphalen E., Legay S. 2015  402/14/1095F/i-e  Detrimont H., Ambrosi D. 2015 Report 15/06 |
| Substances and mixtures which in contact with water emit flammable gases |  |  | Not required as experience in handling and use shows that the product does not react with water. | Not applicable |  |
| Oxidising liquids | (Q)SAR | Expert statement | Considering the high proportion of not-oxidising ingredients (in total 99.10% w/w), the product X6122B1 is not expected to present a significant hazard for oxidising properties, and testing is considered as unnecessary. | Acceptable. Based on the composition, the product is not an oxidizing liquid. | Detrimont H., Ambrosi D. 2015  15/06 |
| Oxidising solids |  |  | Not applicable | Not applicable |  |
| Organic peroxides |  |  | Not applicable | Not applicable |  |
| Corrosive to metals |  |  | Not required as no ingredient is classified as corrosive to metals and experience in handling and use shows that the product is not corrosive to metals.  Moreover, compatibility of the product with metal can has been demonstrated during the accelerated and shelf life study. | Acceptable |  |
| Auto-ignition temperatures of products (liquids and gases) | (Q)SAR | Expert statement | As 99.99% of ingredients are not-auto-flammable, the product X6122B1 is not expected to present a significant hazard for auto-flammability, and testing is considered as unnecessary. | Acceptable. The product is not expected to be auto-flammable in the conditions of use. | Detrimont H., Ambrosi D. 2015  15/06 |
| Relative self-ignition temperature for solids |  |  | Not applicable | Not applicable |  |
| Dust explosion hazard |  |  | Not applicable | Not applicable |  |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The formulation X6122B1 is Another Liquid (AL) formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of yellow transparent liquid, with a white spirit like odour. It is not explosive and has no oxidizing properties. The product is not considered flammable and has a flash point of 62.8°C. It is not auto-flammable in the conditions of use. The viscosity of the preparation at 40°C is 6.62mm2/s. Since the product contains H304 compounds at a content >10%, the formulation is classified H304 Cat 1, SGH08.  There is an effect of high temperature on the stability of the formulation since after 8 weeks at 40°C in HDPE container and metal can, the active ingredient content of IPBC decreased from more than 10% and degrades into PBC. Others active substance contents and technical properties were unchanged. The product is not considered stable at 40°C. There is no effect of low temperature on the stability of the formulation since after 7 days at 0°C, there are no modification of the properties of the product. The product is stable 2 years at 20°C when stored in tinplate can.Compatibility has been demonstrated with HDPE packaging during the accelerated storage stability. The product should be stored away from light (only for HDPE bulk containers, metal tinplate are considered as barriers to light) and should not be stored at a temperature higher than 20°C. Its technical characteristics are acceptable for an AL formulation.  Shelf life: 2 years  Do not store at a temperature higher than 20°C  Protect from light (only bulk containers). |

### Methods for detection and identification

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

Physical and chemical properties of the active substances and analytical methods for determination of active ingredients in the technical active ingredient have already been evaluated at EU level and are presented in the CAR of the active substances. The notifier PPG of the product X6122B1 is not the applicant that supported the annex I inclusion dossier of the active substances but it has a letter of access to these data.

**Summary for Propiconazole:**

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

|  |  |
| --- | --- |
| Soil (principle of method and LOQ) | GLC-NPD; LOQ : 0.02 mg/kg (parent compound)  GLC-ECD; LOQ : 0.05 mg/kg (total; 2,4-DCBA)  HPLC-UV; LOQ : 0.01 mg/kg as 1,2,4-triazole (total; 1,2,4-triazole)  LC-LC-ESI/MS/MS; LOQ : 0.005 mg/kg (CGA 118 244)  HPLC-LC/MS/MS; LOQ: 0.005 mg/kg as parent compound and its degradation products CGA 21795, CGA 91305, CGA 118244, CGA 118245, CGA 136735 and CGA 71019 (1,2,4-triazole) |
| Air (principle of method and LOQ) | GLC-NPD; LOQ : 10 μg/m3 (parent compound) GC-MS; LOQ : 10 μg/m3 (parent compound) |
| Water (principle of method and LOQ) | GLC-ECD; LOQ : 0.05 μg/l (parent compound in potable water) GC-MS : 0.05 μg/l (parent compound in potable water and surface water) Sediment HPLC-LC/MS/MS: 0.010 mg/kg (parent compound and its degradation products CGA 217495, CGA 91305 and CGA 136735) |
| Body fluids and tissues (principle of method and LOQ) | Not applicable (not toxic or very toxic substance) |
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) | Not applicable |
| Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) | Not applicable |

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 Cypermethrin:**

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

|  |  |
| --- | --- |
| Soil (principle of method and LOQ) | Cypermethrin 40:60 cis:trans  GC-MS  **LOQ 0.05 mg/kg** |
| Air (principle of method and LOQ) | Cypermethrin 40:60 cis:trans  GC-MS  **LOQ 0.375 μg/m3** |
| Water (principle of method and LOQ) | Cypermethrin 40:60 cis:trans  GC-electron capture  **LOQ 0.01 µg/L** |
| Body fluids and tissues (principle of method and LOQ) | Not required as Cypermethrin is not classified as toxic or highly toxic |
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) | Cypermethrin 40:60 cis:trans  GC-electron capture  **LOD 0.05 mg/kg** (oilseed rape) **0.025 mg/kg** (wheat) |
| Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) | Cypermethrin 40:60 cis:trans  GC-MS  **LOQ 0.05 mg/kg** for bovine tissues, **0.005 mg/kg** for milk, **0.01 mg/kg** for eggs |

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 IPBC:**

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

|  |  |
| --- | --- |
| Soil (principle of method and LOQ) | IPBC/PBC: HPLC-MS/MS, LOQ = 0.01 mg/kg |
| Air (principle of method and LOQ) | Not necessary, IPBC is not volatile and spray applications only involve non-respirable particles. |
| Water (principle of method and LOQ) | IPBC/PBC: Both for surface water, ground water and drinking water. HPLC-MS/MS, LOQ = 0.1 µg/L |
| Body fluids and tissues (principle of method and LOQ) | Relevant residues for monitoring human body fluid and tissues were PBC and IPBC. In blood and muscle IPBC degraded rapidly (to PBC) and it was not possible to determine IPBC residues above 70%. Analysis was done by HPLC using reversedphase liquid chromatography and a water / methanol gradient on a C18-column. Detection was made with a MS/MS system using positive electrospray ionisation. LOQ for PBC and IPBC in urine and blood at 0.05 mg/L. LOQ for PBC and IPBC in meat at 0.1 mg/L. |
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) | Not necessary, IPBC-based wood preservation products or materials treated with such products are not used in a manner which may cause contact with such materials. |
| Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) | Not necessary, IPBC-based wood preservation products or materials treated with such products are not used in a manner which may cause contact with such materials. |

Since the active substance is toxic, an analytical method for body fluids and tissues is required and is available in the CAR of the active substance. Methods for food and feeding stuffs of plant origin are not required since the use pattern of product will not result in any contact with food or feeding stuff of plant origin.

**Summary for tebuconazole:**

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

|  |  |
| --- | --- |
| Soil (principle of method and LOQ) | The DFG Method S 19 describes the analytical procedures for the determination of tebuconazole in soil. The extraction from soil is performed with acetone followed by the clean-up procedures of gel permeation chromatography (GPC) on Bio Beads S-X3 polystyrene gel. Tebuconazole is analysed by gas chromatography on fused silica gel with a nitrogen/phosphorus detector or mass specific detector. Evaluation is carried out with external standard. Limit of quantification (LOQ): 0.01mg/kg |
| Air (principle of method and LOQ) | Air is sucked through Tenax or XAD-2 adsorption tubes at a rate of 2 l/min during a period of 6 hours. The adsorbed active ingredient is extracted with ethyl acetate and determined after gas chromatographic separation by means of a nitrogen and phosphorous selective detector (GC-NPD). A confirmatory procedure is based on gas chromatography using mass selective detection (GCMSD). No deviation from the described Tenax sampling and extraction technique is necessary. The same crude extracts could be investigated by both different GC methods. Evaluation is carried out with external standard. Limit of quantification (LOQ): 0.001 mg a.i./ m3 air |
| Water (principle of method and LOQ) | Determination for tebuconazole in surfacewater is performed according to DFG Method W 5. Water samples are analysed by means of gas chromatography on fused silica gel after extraction with dichloromethane and clean up by gel permeation chromatography on Bio Beads S-X3 polystyrene gel. For detection a mass selective detector (MSD) is used. Evaluation is carried out with external standard. Limit of quantification (LOQ) surface- ground- and drinking water: 0.05 µg/l |
| Body fluids and tissues (principle of method and LOQ) | Relevant only for toxic substances. |
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) | Not relevant |
| Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) | Not relevant |

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.

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

|  |  |
| --- | --- |
| **Report:** | **Raphalen E., 2013** |
| Title: | Physico-chemical tests on a ready-to-use solvent based product (X6122B1): Validation of analytical method and chemical analysis of active ingredients declared in the test item, Chemical analysis of active ingredients in a wood preservative |
| Document No | 402/13/1139F/ab-e |
| Test facility |  |
| Guidelines: | SANCO/3030/99 rev.4. |
| GLP | Yes |

**Preparation of accuracy samples:**

The active substances contents in X6122B1 are determined using a liquid chromatography method with UV detection at 235 nm for propiconazole and 210 nm for cypermethrin, tebuconazole and IPBC (HPLC-UV). Quantification is performed using external standard calibration.

A quantity of test item was accurately weighed in order to obtain a concentration near 75 mg/L in propiconazole, 35 mg/L in cypermethrin, 25 mg/L tebuconazole and IPBC. The product was diluted in acetone and the solution was shaken. The active substances contents in X6122B1 are determined using a liquid chromatography method with UV detection at 235 nm for propiconazole and 210 nm for cypermethrin, tebuconazole and IPBC (HPLC-UV). Quantification is performed using external standard calibration.

Material

Instrument: HPLC Alliance Waters or equivalent, UV PDA Waters 2998 or equivalent

Column: Ascentis Express C18 or equivalent, length of 10 cm, internal diameter of 4.6 mm, particle size of 5 µm

Column temperature: 30°C

Mobile phase:

A: acetonitrile

B: water

Gradient:

Time (minutes) % A % B

0.0 50 50

3.0 50 50

6.0 45 55

10.0 90 10

20.0 90 10

Flow rate: 1 mL/min

Injection volume: 10 µL

UV detector: UV set at 235 nm for propiconazole, UV set at 210 nm for cypermethrin, tebuconazole and IPBC

Retention times:

Propiconazole: approximately 5.10 min

Cypermethrin 1: approximately 11.91 minutes

Cypermethrin 2: approximately 11.97 minutes

Cypermethrin 3: approximately 12.02 minutes

Tebuconazole: approximately 3.75 minutes

IPBC: approximately 2.44 minutes

Reference items:

Propiconazole CAS No.60207-90-1, batch SZE8059X, purity: 98.9%, expiry date: February 28, 2014, supplier: Sigma

Cypermethrin CAS No.52315-07-8, batch SZBC047XV, purity: 94.3%, expiry date: February 16, 2017, supplier: Sigma

Tebuconazole CAS No.107534-96-3, batch SZBB055XV, purity: 99.5%, expiry date: February 24, 2016, supplier: Sigma

IPBC CAS No.55406-53-6, batch I2LBG, purity: 98.1%, expiry date: August 28, 2014, supplier: TCI

Test item: X6122B1, Batch No.: XVIII 193 NDF, Manufacturing date: 18 June 2013

Propiconazole CAS No.60207-90-1: 0.15% w/w (nominal content)

Cypermethrin CAS No.52315-07-8: 0.07% w/w (nominal content)

Tebuconazole CAS No.107534-96-3: 0.05% w/w (nominal content)

IPBC CAS No.55406-53-6: 0.05% w/w (nominal content) Batch No.: XVIII 193 NDF

**Validation of the analytical method:**

|  |  |
| --- | --- |
| Specificity | No interference at the selected wavelengths (235 nm for propiconazole and 210 nm for cypermethrin, tebuconazole and IPBC) was detected at the retention time of each active substance in HPLC-UV in blank formulation samples diluted in acetone. The applied method to quantify each active substance in the test item 13/1139F/1 is considered as specific. |
| Linearity | 5 calibration standards were used for the determination of the linearity. 2 series were performed with each substance.  **Propiconazole**  Serie 1:the linear function corresponds to y = 2.464581\*103\*x + 9.797599\*103(y = peak area, x = propiconazole content in mg/L)  The determination coefficient r² is equal to 0.993179 so the correlation coefficient r is equal to 0.9966 showing a good linearity.  Serie 2:the linear function corresponds to y = 2.559888\*103\*x – 1.153212\*103(y = peak area, x = propiconazole content in mg/L)  The determination coefficient r² is equal to 0.998901 so the correlation coefficient r is equal to 0.9995 showing a good linearity.  **Cypermethrin**  Serie 1:the linear function corresponds to y = 5.289900\*104\*x + 1.133484\*105 (y = peak area, x = cypermethrin content in mg/L)  The determination coefficient r² is equal to 0.990089 so the correlation coefficient r is equal to 0.9950 showing a good linearity.  Serie 2:the linear function corresponds to y = 5.768062\*104\*x – 2.804116\*104 (y = peak area, x = cypermethrin content in mg/L)  The determination coefficient r² is equal to 0.998963 so the correlation coefficient r is equal to 0.9995 showing a good linearity.  **Tebuconazole**  Serie 1:the linear function corresponds to y = 1.532965\*104\*x + 3.271327\*104(y = peak area, x = tebuconazole content in mg/L)  The determination coefficient r² is equal to 0.991533 so the correlation coefficient r is equal to 0.9958 showing a good linearity.  Serie 2:the linear function corresponds to y = 1.790398\*104\*x – 3.099961\*104(y = peak area, x = tebuconazole content in mg/L)  The determination coefficient r² is equal to 0.996142 so the correlation coefficient r is equal to 0.9981 showing a good linearity.  **IPBC**  Serie 1:the linear function corresponds to y = 1.555349\*103\*x + 2.681051\*101(y = peak area, x = IPBC content in mg/L)  The determination coefficient r² is equal to 0.996143 so the correlation coefficient r is equal to 0.9981 showing a good linearity.  Serie 2:the linear function corresponds to y = 1.639031\*103\*x – 3.214651\*103(y = peak area, x = IPBC content in mg/L)  The determination coefficient r² is equal to 0.998027 so the correlation coefficient r is equal to 0.9990 showing a good linearity.  The applied method to quantify each active substance at the declared value in the test item 13/1139F/1 is considered as linear on the calibration range. |
| Precision | Precision was performed with 6 samples of the test item.  **Propiconazole**  RSD=1.25% (RSDR=3.56% with C=0.0015)  **Cypermethrin**  RSD=1.43% (RSDR=3.99% with C=0.0007)  **Tebuconazole**  RSD=2.00% (RSDR=4.21% with C=0.0005)  **IPBC**  RSD=2.08% (RSDR=4.21% with C=0.0005) |
| Accuracy | Accuracy was determined by analysis of 12 independent determinations in which known amounts of the reference substance were added to a blank formulation. The accuracy results are expressed as the recovery rate. The matrix was spiked at following active substance concentrations:   * 35mg/L for cypermethrin * 75mg/L for propiconazole * 25mg/L for tebuconazole * 25mg/L for IPBC   **Propiconazole**  Mean recovery rate = 101.9% (n = 12),  **Cypermethrin**  Mean recovery rate = 100.6% (n = 12)  **Tebuconazole**  Mean recovery rate = 101.0% (n = 12)  **IPBC**  Mean recovery rate = 104.4% (n = 12) |

Specificity, linearity, precision and accuracy were checked and are found acceptable. Another method has been provided below (E. Jacobsen, M.Klamer, 2016) but it is not sufficiently validated. Method (Raphalen E, 2013) is sufficient.

|  |  |
| --- | --- |
| **Report:** | **E. Jacobsen, M.Klamer, 2016** |
| Title: | Method report IPBC/PBC |
| Document No | 635281\_650541 |
| Test facility | Danish Technological Institute, Aarhus Laboratory for Chemistry and Microbiology |
| Guidelines: | SANCO/3030/99 rev.4. |
| GLP | Yes |

**Principle:** the method involves dilution with methanol. Samples are shaken for 30 min, placed in an ultrasonic bath for 15min and then filtered at 45µm. Analysis by reversed phase HPLC with diode aray detection and by using an external standard.

Analytical conditions

Agilent HPLC-DAD 1260

Column: Kinetex C18, 100A, 150 mm, 4,6 mm, 5 μm, Phenomenex

Column temperature: 32 °C

Program: Gradient with mobile phases of MilliQ-water (pH 3 with phosphor acid) and acetonitrile, 65%:35% to 0%:100% in 16 min, 0%:100% to 65%:35% in 3 min. Total time 20 min.

Flow: 0.75 mL/min.

Injection volume 25 μL

Detection: DAD, 200 nm

**Findings**

**Specificity**

Chromatograms have been provided for calibration standards, test item before and after storage and for blank formulation. No interferences at the retention time of IPBC and PBC were noticed. Specificity is acceptable.

**Linearity**

Calibration has been performed with 8 standards (duplicate) ranging from 0.5 to 140µg/mL (or to 150µg/mL for PBC). Regressions are liner for PBC and IPBC with a correlation coefficient >0.99. Linearity is acceptable.

**Accuracy**

Accuracy has been performed with test item fortified at one level:

IPBC: fortification at 41.63µg/mL – mean recovery=102% (n=2)

PBC: fortification at 11.17µg/mL – mean recovery=103% (n=2)

Mean recoveries are in acceptable limit. Nevertheless, two fortification levels should have been tested.

**Precision**

Precision has been performed with duplicate determination on the test item before and after storage. However, number of samples for the determination of the mean recovery is insufficient. At least 5 samples should have been determined.

Before storage

IPBC content: 0.0507/0.0522 % (RSD= 1.50%)

After storage

IPBC content: 0.0378/0.0382% (RSD=0.61%)

PBC content: 0.0199/0.0203% (RSD=1.50%)

Precision should have been performed on 5 independent samples. A RSD calculated using two measurements is not reliable. Precision is not fully demonstrated.

**LOQ**

No LOQ can be set since accuracy and precision data are insufficient.

**Conclusion**The method is not fully validated according to guidance SANCO3030/99/rev.4. Precision and accuracy data are insufficient. Since another method is available (Raphalen E, 2013), no further data will be required.

### Efficacy against target organisms

#### Function and field of use

MG 02: preservatives

Product Type 08: wood preservative

The product X6122B1 is a solvent-based ready for use wood preservative product. The product is intended to be used by superficial application for preventive and curative treatments by superficial application (that could be completed by injection).

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

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

The product X6122B1 is intended to be used by superficial application for preventive treatment for wood used in use classes 1 to 3.1 and is also intended to be used for curative treatment by superficial application (that could be completed by injection), for wood in service

The application rates recommended by the applicant are the following:

- Preventive treatment: superficial application at 200 g of product / m² of wood

- Curative treatment: superficial application at 300 g of product / m² of wood, completed by injection if need be at 180 mL/m²

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

According to the uses claimed by the applicant, the product X6122B1 is intended to be used for the preservation of wood used in use classes 1 to 3.1 by superficial application against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*), wood rotting fungi (*Coniophora puteana, Gloeophyllum trabeum, Poria Placenta* and *Coriolus versicolor*) and subterranean termites (*Reticulitermes spp.*).

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 subterranean termites (*Reticulitermes spp*.), by superficial application, completed by injection if need be.

The development stages claimed are larvae and adults.

* **Results of the efficacy data**
* Regarding the claim against wood rotting fungi, for superficial application, the product X6122B1 is efficient, according to EN 113+EN84, against wood rotting fungi (including *C. Versicolor*) for use classes 2 and 3.1 at the application rate of 200 g of product X6122B1 / m² of wood. Nevertheless, the product is not efficient, according to the efficacy criteria of EN 113+EN73, against wood rotting fungi. Indeed for one fungi (*Poria placenta*), the efficacy is not demonstrated at the highest concentration tested where the mean mass loss reduction in the treated blocks is higher than maximum value authorized by the efficacy criteria of the standard (3%).

The applicant argued that for *P. placenta* is responsible for brown rot only on softwood and *C. versicolor* is responsible for white rot only on hardwood (EN113: annex D), then a preventive efficacy against wood rotting fungi can be claimed only for hardwood.

FR CA do not agree with this argumentation, indeed:

* according to EN 599, for use class 2, the efficacy of the product should be demonstrated according to EN 113 + EN 73 whereas for use class 3, the efficacy should be demonstrated according to both EN 113 + EN73 and EN 113 + EN 84.
* a demonstration of the efficacy on brown rot with the three model fungi of the EN 113 + EN 73 and/or EN 84 (*Coniophora puteana*, *Poria placenta* and *Gloeophyllum trabeum)* tested on the representative wood category softwoodis a minimum to claim an efficacy against wood rotting fungi for use class 2 and 3.
* the demonstration of efficacy on white rot with the model fungi of the EN 113 + EN 73 and/or EN 84 *C. versicolor* on the representative wood categories softwood and/or hardwood is only an option from UC3 (as an additional biological test), to complete the claim “wood rotting fungi”, tested on softwood and/or hardwood.

Then minimum requirements for a claim against wood rotting fungi (i.e efficacy on brown rot tested on the representative wood category softwood) are not achieved for UC 2 and 3, and the reasoning of the applicant (selecting only fungi that would attack hardwood) is not allowed by EN 599 norm.

Note that as for use class 3.1, the demonstration of the efficacy is based on the EN 113 standard, the EN 599[[13]](#footnote-13) requires the use of a top coat (§5.2.17 & §5.2.18). Then it means that when applied by superficial application, for use class 3.1, a top coat would have to be applied, if the claim against wood rotting fungi was accepted.

* Regarding the preventive efficacy claim against wood boring beetles, for superficial application, the product X6122B1 is efficient according to respectively EN 46 (+EN73/84), EN 49 (+EN73/84) and EN 20-1 (+EN73), against *Hylotrupes bajulus, Anobium punctatum and* *Lyctus brunneus* at the application rate of 200 g of product X6122B1 / m² of wood.
* Regarding the preventive efficacy claim against termites (*Reticulitermes spp.*), for superficial application, the product X6222B1 is efficient according to EN 118 (+EN73/84), against *Reticulitermes spp.*, at the application rate of 200 g of product X6122B1 / m² of wood.
* Regarding the curative efficacy claim against wood boring beetles (*Hylotrupes bajulus*, *Anobium punctatum* and *Lyctus brunneus*), for superficial application, the product X6122B1 is efficient according to respectively EN 1390 and EN 48 against *Hylotrupes bajulus* and *Anobium punctatum* with a slow action activity, at the application rate of 300 g of product X6122B1 / m² of wood. According to EN 14128[[14]](#footnote-14), if curative treatment against *Lyctus brunneus* is required, a curative wood preservative "for *Hylotrupes* *bajulus* and *Anobium* punctatum" should be applied. The curative efficacy against wood boring beetles is then validated.
* Regarding the curative efficacy claim against termites (*Reticulitermes spp.*), 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. Indeed, their function is not to destroy the entire colony (which is not in the wood). Moreover the target stages in the preventive and in the curative efficacy treatments are the same, which means the dose of active substance in both treatments are the same. Then the efficacy demonstrated in the preventive efficacy test can be extrapolated for a curative application.
* Regarding the curative efficacy claim against wood boring beetles, by injection, this treatment is always performed in combination with superficial application. Then, efficacy demonstrated for superficial treatment is sufficient and no additional data is needed. Curative treatment by injection, in combination with a superficial treatment, at the application rate of 180 mL of product X6122B1 / m² of wood is validated.
* **Minor change application for X6122B1 2019:**

Regarding the preventive efficacy against wood boring beetles, for superficial application, based on the efficacy data already submitted in the dossier, the product is efficient against (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*) and against termites (*Reticulitermes spp.*) at the application rate of 200 g/ m² of wood in uses classes 1 to 3.1 on softwood and hardwood.

Regarding the preventive efficacy claim against wood rotting fungi, for superficial application, (following the submission of to additional efficacy studies performed according to EN 113 + EN 73) against *Poria placenta),* the product X6122B1 is efficient according to EN 113 (+EN73 and EN84), against wood destroying basidiomycetes (including *C. versicolor*), at the application rate of 200 g/m². The preventive efficacy claimed against wood rotting fungi on softwood and hardwood is validated. Moreover as for use class 3.1, the demonstration of the efficacy is based on the EN 113 standard and the EN-599,therefore the use of a top coat is required in reference to the EN-599 (§5.2.17 & §5.2.18). Then it can be concluded that when applied by superficial application for use class 3.1, a top coat has to be applied.

#### 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).

IPBC has a Carbamate structure. The target sites of Carbamates in fungi are cell membrane permeability and fatty acids (according to the information provided by FRAC (Fungicide Resistance Action Committee).

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 fast acting on *Anobium punctatum.*

#### Efficacy data

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch Pap V 129.2 | *C. puteana*  *G.trabeum*  *P.placenta*  *C.versicolor* | EN 113 after EN 73 (evaporation) | Following the recommendation of the standard:  The targeted retentions of test product were 0-20-40-60-80 and 100 kg/m3 of wood. This retentions correspond to the following target concentrations tested  On scots pine blocks, the targeted concentrations to be tested were 0.0, 4.3, 8.55, 12.82, 17.09 and 21.37 %w/w.  On beech blocks, the targeted concentrations to be tested were 0.0, 5.63, 11.27, 16.90, 22.53 and 28.16 % w/w.  The product was applied by vacuum impregnation  - 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  - Number of replicates: 6 replicates for each treatment and each fungal strain.  CONTROLS  - 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.  The effects investigated is mass loss of the test blocks, induced by the fungal development  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.  - 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)  Mid toxic values of the test product X6122B1:  - *C. puteana*: 58.28 kg/m3  - *G. trabeum* 19.58-39.07 : 29.33 kg/m3  - *C. versicolor*: 79.5 – 98.59: 89.05 kg/m3  For P. placenta the efficacy is not demonstrated at the highest concentration tested 21.37% which mean that the brv is higher than 97.24 kg product/m3 of wood  **Thus, the biological reference value of the test product X6122B1 after evaporative ageing procedure, cannot be determined.** | Schumacher P. and Fennert E.M., 2017  S6.7\_01  32/16/9803/03  IC 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch Pap V 129.2 | *C. puteana*  *G.trabeum*  *P.placenta*  *C.versicolor* | EN 113 After EN 84 (leaching) | Following the recommendation of the standard:  The targeted retentions of test product were 0-20-40-60-80 and 100 kg/m3 of wood. This retentions correspond to the following target concentrations tested  On scots pine blocks, the targeted concentrations to be tested were 0.0, 4.3, 8.55, 12.82, 17.09 and 21. % w/w.  On beech blocks, the targeted concentrations to be tested were 0.0, 5.63, 11.27, 16.90, 22.53 and % w/w of product/m3 of wood.  - 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  The product was applied by vacuum impregnation  - Number of replicates: 6 replicates for each treatment and each fungal strain.  CONTROLS  - 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.  The effects investigated is mass loss of the test blocks, induced by the fungal development  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.  - 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 (>20 % in each control)  **The study demonstrates the efficacy of the product X6122B1 at the application rate of 69 kg/m3 on *C. puteana, G. trabeum, P. placenta* and 90.08 kg/m3 for *C. versicolor*. It corresponds to an application rate of 180.16 g of X6122B1 / m² of wood.** | Schumacher P. and Fennert E.M., 2017  S6.7\_02  32/16/9803/02  IC 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch 1405900037 | Subterranean termite: *Reticulitermes flavipes* | EN 118 + EN 73 (evaporation) | The ready to use product X6122B1 is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test block varied between 245.9 mL/m² and 248.6 mL/m² (mean 247.2 mL/m²).  250 workers, 4 nymphs and 1 soldier termite were used for each test block.  5 replicates for the treated block and 5 replicates for the control are performed.  The investigated effects are the mortality of the insects.  Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack).  - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (65.3 %) and the control test blocks are ranked 4.  **All the treated blocks are ranked 1 (except 1) at the end of the study which demonstrates the efficacy of the product X6122B1 at the application rate of 247 mL (equivalent to 199.45 g) of product / m² of wood.** | Ansard D. and  Paulmier I.,  2015  S6.7\_03  401/14/136F/e-e  IC 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch Pap V 129.2 | European subterranean termite: *Reticulitermes grassei* | EN 118 + EN 84 (leaching) | The ready to use X6122B1 is applied by brushing on sapwood test blocks (Pinus sylvaticus) and followed by an artificial weathering according to the EN 84 standard method (leaching).  The quantity really applied on each test block varied between 248.6 mL/m² and 250 mL/m² (mean 249.33 mL/m²).  250 workers, 4 nymphs and 1 soldier termite were used for each test block.  5 replicates for the treated block and 5 replicates for the control are performed.  The investigated effects are the mortality of the insects.  Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack).  - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (70.3 %) and the control test blocks are ranked 4.  **All the treated blocks are ranked 0 or 1 at the end of the study which demonstrates the efficacy of the product X6122B1 at the application rate of 247 ml (199.45 g) of product / m² of wood.** | Ansard D. and Paulmier I.,  2016  S6.7\_04  401/16/039F/b-e  IC 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch 1405900037 | House longhorn beetle: *Hylotrupes bajulus* (L.) | EN 46 + EN 73 (evaporation) | The ready to use product X6122B1 is applied by dipping on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test block varied between 197.6 g/m² and 199.2 g/m² (mean 198.5 g/m²).  10 recently hatched larvae of *H. bajulus* for each are used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The effect investigated is the mortality of insect’s larvae.  The method for recording / scoring effects is the recovery of the insects and count of dead and alive larvae and count of dead larvae having tunneled or not.  - Intervals of examination: one time, after 1 month exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 70 % (100%).  On the treated test block, 100 % or the larvae was dead and had not tunnelled.  **This study demonstrated the efficacy of the product at 198.5 g of product X6122B1 / m² of wood against *Hylotrupes bajulus* larvae** | Schumacher P. and Fennert E.-M., 2015  S6.7\_05  32/14/9803/01  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch Pap V 129.2 | House longhorn beetle: *Hylotrupes bajulus* (L.) | EN 46 + EN 84 (leaching) | The ready to use X6122B1 is applied by dipping on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 84 standard method (leaching).  The quantity really applied on each test block varied between 198.2 g/m² and 199.2 g/m² (mean 198.9 g/m²).  6 replicates for the treated block and 3 replicates for the control are performed.  The effect investigated is the mortality of insect’s larvae.  The method for recording / scoring effects is the recovery of the insects and count of dead and alive larvae and count of dead larvae having tunneled or not.  - Intervals of examination: one time, after 1 month exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 70 % (90%).  On the treated test block, 100 % or the larvae was dead and had not tunnelled.  **This study demonstrated the efficacy of the product at 198.9 g of product X6122B1 / m² of wood against *Hylotrupes bajulus* larvae** | Brunet C. and Paulmier I.,  2016  S6.7\_06  401/16/039F/a-e  IC 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch 1405900037 | Common furniture beetle | EN 49 + EN 73  (evaporation) | The ready to use product X6122B1 is applied by dipping on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test block varied between 199.1 g/m² and 201.7 g/m² (mean 200.3 g/m²).  5 replicates for the treated block and for the control are performed.  The efficacy of the product is based on the comparison of egg laying, eggs emergence and mortality larvae between control blocks and treated blocks.  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.  On the treated block, 100% of mortality is observed  **This study demonstrated the efficacy of the product at 200.3 g of product X6122B1 / m² of wood against *Anobium punctatum*** | Brunet C.and Paulmier I., 2017  S6.7\_07  401/14/136F/a,b,e  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch 1405900037 | Common furniture beetle | EN 49 + EN 84  (leaching) | The ready to use product 06 X6122B1 is applied by dipping on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 84 standard method (leaching).  The quantity really applied on each test block varied between 198.9 g/m² and 201.2 g/m² (mean 200 g/m²).  5 replicates for the treated block and for the control are performed.  The efficacy of the product is based on the comparison of egg laying, eggs emergence and mortality larvae between control blocks and treated blocks.  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  On the treated block, 100% of moratility is observed  **This study demonstrated the efficacy of the product at 200 g of product X6122B1 / m² of wood against *Anobium punctatum*** | Brunet C.and Paulmier I., 2017  S6.7\_08  401/14/136F/a,b,e  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch 1405900037 | Powder post beetle: *Lyctus brunneus* | EN 20-1 + EN 73 (evaporation) | The ready to use product X6122B1 is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test block varied between 196.1 g/m² and 198.1 g/m² (mean 197.1 g/m²).  10 recently hatched larvae of *L. bruneus* for each are used for each test block.  5 replicates for the treated block and 5 replicates for the control are performed.  The investigated effects are the mortality of the insects.  The method for recording / scoring effects is the recovery and the counting of the insects (alive/dead) and the number of drilled openings.  - Intervals of examination is one examination, 20 weeks after beginning of exposure of the adults. | The study is validated as:   * At least, for each control, 20 insects are found * Adult emergence has started at the end test in the control and at least 85 % (95.3 %) of the insects are found alive   In the test block 100 % of mortality is observed.  **This study demonstrated the efficacy of the product at 197.1 g of product X6122B1/ m²of wood against *Lyctus brunneus*** | Brunet C. and Paulmier I.,  2016  S6.7\_09  401/14/136F/c/e  IC1 |
| MG 02: preservatives | Wood preservative  Curative treatment | X6122B1  batch Pap V 129.2 | House longhorn beetle: *Hylotrupes bajulus (L.)* | EN 1390 | The ready to use product X6122B1is applied by brushing on sapwood test blocks (*Pinus sylvestris*)  The quantity really applied on each test block varied between 299.4 mL/m² and 300.4 mL/m² (mean 299.9 mL/m²).  6 larvae of *Hylotrupes bajulus* were used for each test block.  10 replicates for the treated block and 2 replicates for the control are performed.  The investigated effects are the mortality of the larvae.  - Method for recording / scoring effects: recovery of the insects and count of the dead and alive larvae. Calculation of the percentage of mortality.  - Intervals of examination: one time, 25 weeks after exposure of the larvae in the wood block to the tested product.  The efficacy criterion according to the EN 14128 is a mortality higher than 80 % | The study is validated as the survival rate in the control is higher than 75 % (100%).  **The mortality observed in the treated block is higher than 80 % (96.6 %) which validated the slow action efficacy of the product at the application rate of 300 ml of product X6122B1 / m² of wood, 24 weeks after is application.** | Brunet C. and Brunet C. and Paulmier I.,  2015  S6.7\_10  401/16/039F/c-e  IC 1 |
| MG 02:  preservatives | Wood preservative  Curative treatment | X6122B1  batch 1405900037 | Common furniture beetle:  *Anobium punctatum (L)* | EN48 | The ready to use product X6122B1 is applied by brushing on sapwood test blocks (*Pinus sylvestris*)  The quantity really applied on each test block varied between 300.5 g/m² and 301.8 g/m² (mean 301g/m²).  12 larvae of *Anobium punctatum* were used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The investigated effects are the mortality of the larvae.  - Method for recording / scoring effects: recovery of the insects and count of the dead and alive larvae. Calculation of the percentage of mortality.  - Intervals of examination: one time, 8 weeks after exposure of the larvae in the wood block to the tested product.  The efficacy criterion according to the EN 14128 is mortality higher than 80 %. | The study is validated as the survival rate in the control is higher than 70 % (100%).  **The mortality observed in the treated block is higher than 80 % (90.9 %) validated the efficacy of the product, at the application rate of 300 g of product X6122B1/ m² of wood.** | Brunet C. and Paulmier I., 2016  S6.7\_11  401/14/136F/e/e  IC1 |

* **Minor change application for X6122B1- 2019 :**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| MG 02:  preservatives | Wood preservative  Preventive treatment | X6122B1, batch Pap V 168.1 | P. placenta | EN 113 after EN73 (evaporation) | The targeted retentions of test product were 0-60-70-80-90 and 100 kg/m3 of wood. This retentions correspond to the following target concentrations tested  On scots pine blocks, the measured retentions were 0.0, 62.5, 77.9, 84.5, 90 and 102.3 Kg/m3.  The product was applied by vacuum impregnation  - Number of replicates: 3 to 6 replicates for each treatment.  - 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.  The effects investigated is mass loss of the test blocks, induced by the fungal development  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.  - 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 (>20 % in each control)  Mid toxic values of the test product X6122B1:  - *P. placenta* <62.5 kg/m3  The choice of the tested concentration does not follow the requirement of the standard.  This study demonstrates the efficacy of the product against *P. placenta* at the application rate of 125 g of product X6122B1 / m² of wood. | Le Bayon I., 2018  S6.7\_01bis  401/17/151F/1/e  IC2 |
| MG 02:  preservatives | Wood preservative  Preventive treatement | X6122B1, batch Pap V 168.2 | P. placenta | EN 113 after EN73 (evaporation) | The targeted retentions of test product were 0-60-70-80-90 and 100 kg/m3 of wood. This retentions correspond to the following target concentrations tested  On scots pine blocks, the measured retentions were 0.0, 60, 73, 85.7, 94 and 109.1 Kg/m3.  The product was applied by vacuum impregnation  - Number of replicates: 4 to 6 replicates for each treatment.  - 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.  The effects investigated is mass loss of the test blocks, induced by the fungal development  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.  - 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 (>20 % in each control)  Mid toxic values of the test product X6122B1:  - *P. placenta* <62.5 kg/m3  The choice of the tested concentration does not follow the requirement of the standard.  This study demonstrates the efficacy of the product against *P. placenta* at the application rate of 120 g of product X6122B1 / m² of wood. | Le Bayon I., 2018  S6.7\_01ter  401/17/151F/2/e  IC2 |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) assessed that the product X6122B1, has shown a sufficient efficacy for   * For the preventive treatment: superficial application at 200 g of product / m² of wood used in use class 1 against wood boring beetles and termites (*Reticulitermes spp.*), on softwood and hardwood * For the curative treatment when used by superficial application for wood in service (not exposed to weathering and leaching) against wood boring beetles and termites (Reticulitermes spp.), at 300 g of product/m² that could be completed by injection application at 180 mL /m² if need be, on softwood and hardwood.   FR CA considers that the efficacy data are not sufficient to demonstrate the efficacy of the product X6122B1 against wood rotting fungi. Indeed, at the application rate claimed by the applicant, the efficacy is not demonstrated against all the mandatory fungi strains of the EN 113 after an ageing following the EN 73. |

* **Minor change application for X6122B1 – 2019 :**

French competent authorities (FR CA) assessed that the product X6122B1, has shown a sufficient efficacy for

* The preventive treatment by superficial application at 200g of product/m² of wood (softwood and hardwood) used in use classes 2 to 3.1 against wood rotting fungi (brown rot and white rot fungi). For use class 3.1, a top coat is needed.
* The preventive treatment by superficial application at 200 g of product / m² of wood (softwood and hardwood) used in use class 1 to 3.1 against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and Lyctus brunneus*) and termites (*Reticulitermes spp.*).

#### Occurrence of resistance and resistance management

Resistance to pyrethroid insecticides such as cypermethrin has been reported for a number of pests both in ariculture 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 considered generally wise to  
accept 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.

The risk of resistance formation against Carbamate fungicides is regarded to be low to medium by FRAC (Fungicide Resistance Action Committee. This applies to the use of Carbamate fungicides in agriculture, where yearly applications to the same fields are possible (even more than one application per season is possible).

With regard to the use of Carbamates in wood preservation, resistance formation constitutes an even smaller problem: The number of treatments to a wooden structure is generally low (in many cases, only one application is made per lifetime of timber structures), resulting in a low selection pressure.

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.

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the product X6122B1 has shown a sufficient efficacy for the control of wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*) and termites (*Reticulitermes spp.*).

However, regarding the claim against wood rotting fungi, FR CA considers that the efficacy data are not sufficient to demonstrate the efficacy of the product X6122B1. Indeed, at the application rate claimed by the applicant, the efficacy is not demonstrated against all the mandatory fungi strains of the EN 113 after an ageing following the EN 73. Consequently this claim is not proposed for an authorization and then the preventive efficacy in use classes 2 and 3 is not demonstrated.

The application rates validated are the following:

- Preventive treatment against wood boring beetles and termites: superficial application at 200 g of product / m² of wood

- Curative treatment against wood boring beetles and termites: superficial application at 300 g of product / m² of wood, completed by injection if need be at 180 mL/m²

* **Minor change application for X6122B1 – 2019 :**

French competent authorities (FR CA) assessed that the product X6122B1, has shown a sufficient efficacy for:

* The preventive treatment by superficial application at 200 g of product / m² of wood (softwood and hardwood) used in use classes 2 to 3.1 against wood rotting fungi (brown rot and white rot fungi). For use class 3.1, a top coat is needed.
* The preventive treatment by superficial application at 200 g of product / m² of wood ( softwood and hardwood) used in use class 1 to 3.1 against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and Lyctus brunneus*) and termites (*Reticulitermes spp.*).

The application rate validated remained unchanged.

### Risk assessment for human health

#### Hazard potential

##### Toxicology of the active substances

The toxicology of the active substances were examined extensively according to standard requirements. The results of this toxicological assessment can be found in the CAR[[15]](#footnote-15).

The threshold limits and labelling regarding human health risks listed in Annex 4 „Toxicology and metabolism” must be taken into consideration.

See the Assessment Reports of the active substances.

The relevant critical endpoints are summarised in the following table:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference dose** | **Value**  **(mg/kg bw/day)** | **Study** | **NOAEL**  **(mg/kg bw/day)** | **Uncertainty Factor** | **Oral absorption** |
| **Cypermethrine** | | | | | |
| Long-term AEL | 0.022 | 2-year rat study | 5 | 100 | 44% (animal)  57% (human) |
| Medium-term AEL | 0.055 | 90-days dog | 12.5 | 100 | 44% (animal)  57% (human) |
| Short-term AEL | 0.088 | Acute delayed neurotoxicity in rat | 20 | 100 | 44% (animal)  57% (human) |
| **Propiconazole** | | | | | |
| Long-term AEL | 0.04 | 2-year rat study | 3.6 | 100 | 86% (100%) |
| Medium-term AEL | 0.08 | 2-generation rat study | 8 | 100 | 86% (100%) |
| Short-term AEL | 0.3 | developmental toxicity study in rat | 30 | 100 | 86% (100%) |
| **Tebuconazole** | | | | | |
| Long-term AEL | 0.03 | 1-year dog study | 3 | 100 | 100% |
| Medium-term AEL | 0.03 | 1-year dog study | 3 | 100 | 100% |
| Short-term AEL | 0.03 | 1-year dog study | 3 | 100 | 100% |
| **IPBC** | | | | | |
| Long-term AEL | 0.2 | 2-year rat study | 20 | 100 | >90% (100%) |
| Medium-term AEL | 0.35 | 90-day rat study | 3.5 | 100 | >90% (100%) |
| Short-term AEL | 0.35 | 90-day rat study | 3.5 | 100 | >90% (100%) |

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

The coforrmulant Hydrocarbons, C10-C13, n-alkanes, isoalkanes,cyclics (EC number: 918-481-9) triggers a classification Asp Tox. Cat 1 - H304 of product. This coformulant is considered substance of concern.

##### Toxicology of the biocidal product

X6122B1 is not a representative product of one active substance assessed during the EU- review program for inclusion of the active substance in Annex I of Directive 98/8/EC.

The toxicology of the biocidal product was examined appropriately according to standard requirements.

The basis for the health assessment of the biocidal product is laid out in Annex 5 ”Toxicology – biocidal product”

###### PERCUTANEOUS ABSORPTION

In order to complete the human risk assessment for the formulation X6122B1, three *in vitro* dermal absorption studies were performed to determine the dermal penetration potency of cypermethrin, propiconazole and tebuconazole.

**Dermal absorption of cypermethrin in formulation X6122B1[[16]](#footnote-16)**

The absorption profile and the distribution of the test item cypermethrin in formulation X6122B1 subsequent to the application on human skin was analysed using an *in vitro* flow-through diffusion cell. Cypermethrin was tested at one concentration corresponding to the content of the pure product (0.07% w/w) for a contact time of 8 hours (corresponding to a normal working day) and followed by an exposure time of 24 hours. The study was performed according to the “OECD guideline for the testing of chemicals: Test No.428: Skin Absorption: *in vitro* method (13 April 2004)”. The study was also designed using the Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665) The dermal absorption of the test item was expressed as percentage of the recovered amount per chamber.

Eight replicates were reported. One replicate was excluded considering its as outlier due to strongly deviating of absorption rate (outlier according to Nalimov). The mean recovery rate was <95% since several replicates had a recovery < 95%. In this context, a correction of recovery was realised.

The mean value of total absorption at 12 h was below 75%, therefore the stratum corneum (strips 3 - ∞) were taken into account to determine absorption.

Considering the amount in stratum corneum, skin, receptor fluid (RF), gauze and chamber wash RF, a dermal absorption of 24.88% with a standard deviation of 10.93% is obtained.

As the standard deviation is superior to 25% of mean absorption, it is added to mean dermal absoption.

To conclude a dermal absorption value of 36% is proposed.

**Dermal absorption of propiconazole in formulation X6122B1**

The absorption profile and the distribution of the test item propiconazole in formulation X6122B1 subsequent to the application on human skin was analysed using an *in vitro* flow-through diffusion cell. Propiconazole was tested at one concentration corresponding to the content of the pure product for a contact time of 8 hours (corresponding to a normal working day) and followed by an exposure time of 24 hours. The study was performed according to the “OECD guideline for the testing of chemicals: Test No.428: Skin Absorption: *in vitro* method. The study was also designed using the Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665).

The dermal absorption of the test item was expressed as percentage of the recovered amount per chamber.

Nine replicates were reported and used for evaluation.

A correction of recovery was realised.

The mean value of total absorption at 12 h was inferior to 75%, therefore the stratum corneum (strips 3 - ∞) were taken into account to determine absorption. For two cells, all strips of stratum corneum were removed with strip 1-2. In this context, the strip 1-2 were taken into consideration to determine the dermal absorption.

Considering the amount in stratum corneum, skin, receptor fluid (RF), gauze and chamber wash RF, a dermal absorption of 14.88% with a standard deviation of 11% is obtained.

As the standard deviation is superior to 25% of mean absorption, it is added to mean dermal absoption.

To conclude a dermal absorption value of 26% is proposed.

**Dermal absorption of tebuconazole in formulation X6122B1**

The absorption profile and the distribution of the test item tebuconazole in formulation X6122B1 subsequent to the application on human skin was analysed using an *in vitro* flow-through diffusion cell. Tebuconazole was tested at one concentration corresponding to the content of the pure product for a contact time of 8 hours (corresponding to a normal working day) and followed by an exposure time of 24 hours.

The study was performed according to the “OECD guideline for the testing of chemicals: Test No.428: Skin Absorption: *in vitro* method (13 April 2004)”. The study was also designed using the Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665). The dermal absorption of the test item is expressed as percentage of the recovered amount per chamber.

Nine replicates were reported and used for evaluation.

A correction of recovery was realised.

The mean value of total absorption at 12 h was inferior to 75%, therefore the stratum corneum (strips 3 - ∞) were taken into account to determine absorption. For four cells, all strips of stratum corneum were removed with strip 1-2. In this context, the strip 1-2 were taken into consideration to determine the dermal absorption.

Considering the amount in stratum corneum, skin, receptor fluid (RF), gauze and chamber wash RF, a dermal absorption of 23.82% with a standard deviation of 7% is obtained.

As the standard deviation is superior to 25% of mean absorption, it is added to mean dermal absoption.

To conclude a dermal absorption value of 31% is proposed.

**Dermal absorption of IPBC in formulation X6122B1**

No dermal absorption study was provided for this active substance. Considering a concentration of 0.05% in the product, the default value of 75% proposed in the EFSA guidance on dermal absorption[[17]](#footnote-17) is used.

###### Acute toxicity

The formulation X6122B1 is a ready-for-use solvent-based product containing 0.08% w/w cypermethrin, 0.16% w/w propiconazole, 0.05% w/w tebuconazole and 0.05% w/w IPBC (technical active susbtances content). In order to avoid unnecessary animal experiment, no acute oral toxicity study was conducted. Therefore, the classification is determined by calculation according to the CLP regulation for oral, dermal and inhaltion routes.

According to the criteria of Annex I to Regulation (EC) No.1272/2008, the proposed classification for the formulation X6122B1 on acute toxicity is: not classified.

###### Irritation and corrosivity

In order to avoid unnecessary animal experiment, no a study was conducted. Therefore, the classification is determined by calculation according to the CLP regulation.

According to the criteria of Annex I to Regulation (EC) No.1272/2008, the proposed classification for the formulation X6122B1 on dermal and eyes irritation is: not classified.

###### Sensitisation

In order to avoid unnecessary animal experiment, no study was conducted. Therefore, the classification is determined by calculation according to the CLP regulation.

According to the criteria of Annex I to Regulation (EC) No.1272/2008, the proposed classification for the formulation X6122B1 on sensitisation is: not classified.

###### Other studies

No other study has been submitted.

According to the CLP Regulation and based on the available data on active substances and co-formulants, the product should be classified:

* Asp Tox. Cat 1 - H304 May be fatal if swallowed and enters airways.
* EUH 066: Repeated exposure may cause skin dryness or cracking.
* EUH 208: Contains propiconazole. May produce an allergic reaction.

The classification “Asp Tox. Cat 1 - H304” and the labelling EUH 066: Repeated exposure may cause skin dryness or cracking are linked to the co-formulant: Hydrocarbons, C10-C13.

Therefore, Hydrocarbons, C10-C13 is considered as a SOC. According to the Guidance on the Biocidal Products Regulation Volume III HH parts b+C, this SOC is allocated to BAND A. Application of P-statements associated to H statement is considered appropriate to manage the risk linked to this substance.

According to the PT07-AR of tebuconazole (2013), the PT07-AR of propiconazole (2013), the PT08-AR of cypermethrin (2013), the PT13-AR of IPBC (2015) no definite conclusions can be drawn concerning the endocrine disruption activity of each active substance.

Nevertheless, a number of scientific publications mention potential endocrine disruption activity of propiconazole and tebuconazole. These effects will be assessed more in details at the renewal stage of these biocidal active substances approval in the frame of the EU Regulation No 528/2012 (scheduled in 2019), and according to the criteria mentioned in the future *Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009.* In case these active substances were identified as ED, the conditions for the product authorisation will have to be revised.

#### Human exposure assessment

The product X6122B1 is a ready-for-use solvent-based wood preservative for industrial, professional and non-professional uses. The product contains 0.08% w/w cypermethrin, 0.16% propiconazole, 0.05% w/w tebuconazole and 0.05% w/w IPBC (technical active susbtances content.

The product X6122B1 is intended to be used for the preventive and curative treatment of interior and exterior woods.

These preventive and curative treatments are done by professionals and non-professionals by brush application, spray application or injection. The product can also be used by industrial users to treat wood by short dipping.

The application doses are 200 g/m² for preventive treatment and 300 g/m² for curative treatment. The maximum application dose of 300 g/m² used for curative treatments is considered a worst-case exposure and therefore will be taken into account for the human risk assessment.

For products intended to be applied by injection, the dose of application is 145 g/m².

##### Identification of main paths of human exposure towards active substance from its use in biocidal product

The active substances cypermethrin, tebuconazole, propiconazole and IPBC were assessed for exposure of humans when dipping, brushing and spraying (indoor and/or outdoor).

For the primary exposure to the product, only professional and non-professional users are in contact with the product during mixing and loading, application (dipping, 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 1: Summary of main paths of human exposure

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

Physico-chemical and toxicological data of cypermethrine, tebuconazole, propiconazole and IPBC are summarized in the following table:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Active Substance | Concentration in technical active substance  (% w/w) | Molecular weight  (g/mol) | Vapor Pressure  (Pa) | Inhalation absorption | Dermal absorption | Oral absorption |
| Cypermethrin | 0.08 | 416 | 2.3\*10-7 (20°C)  6\*10-7 (25°C) | 100% | 36% | 57% |
| Tebuconazole | 0.05 | 308 | 1.7\*10-6 | 100% | 31% | 100% |
| Propiconazole | 0.16 | 342 | 5.6\*10-5 | 100% | 26% | 86% (100%) |
| IPBC | 0.05 | 281 | 2,36-4,5 \*10-3 | 100% | 75% | >90% (100%) |

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

Industrial, professional and non-professional uses are claimed.

Industrial:

* Automated dipping (an application dose of 200 g/m2)

Professional:

* Brushing (an application dose of 200 g/m2 for preventive treatment and 300 g/m2 for curative treatment)
* Spraying (an application dose of 200 g/m2 for preventive treatment and 300 g/m2 for curative treatment).
* Injection in combination with superficial treatment (brush or spray) for curative treatment (an application dose of 145 g/m2).

Non-professional:

* Brushing (an application dose of 300 g/m2 for curative treatment)
* Spraying (an application dose of 300 g/m2 for curative treatment).
* Injection in combination with superficial treatment (brush or spray) for curative treatment (an application dose of 145 g/m2).

###### Exposure of professional users

*Safety for professional operators summary is page 205 of the PAR.*

X6122B1 is a RTU product that can be applied by dipping at an application dose of 200 g/m2, brushing or spraying at an application dose of 200 g/m2 for preventive treatment and 300 g/m2 for curative treatment. An application dose of 145 g/m2 is considered for injection, in combination with superficial treatment (brush or spray) for curative treatment.

A dermal and inhalation exposure to the product containing 0.08% (w/w) of cypermethrine, 0.16% (w/w) of propiconazole, 0.05% (w/w) of tebuconazole and 0.05% (w/w) of IPBC (technical active susbtances content) can occur during the mixing and loading, the application and the equipment’s cleaning.

The assessment of exposure during curative treatment is presented below and it covers the preventive treatment.

Exposure of Industrial users

**Industrial uses – automated dipping application**

This product is a RTU and should not be diluted before use. There may be a preparatory phase in which the product is decanted, this will often be a full or semi-automatic process with limited exposure to the operator. The “*mixing and loading model 7*” from the TNsG part 2 p. 142 is used with the manual pouring data as a worst case approach to determine this exposure.

To predict exposure for this primary exposure scenario, the indicative exposure values from the “*Handling Model 1*” are used: Recommendation 6 of HEAd hoc WG (TNsG part 2, p. 160 and User Guidance p.26), considering 4 cycles per day. The percentiles proposed in the user guidance were used.

There is no generic model in the TNsG for cleaning of internal surfaces of dipping tanks. To predict exposure for this scenario, the indicative exposure values from the “*Handling Model 1*” are used (TNsG user Guidance 2004, p.26), considering 1 cycles per day. Thus, this assessment is covered by assessment of application (for which 4 cycles are considered).

The cleaning is not realised every day. Therefore, the exposure during this task will not add to the exposure during decanting and application.

|  | Active substance | Inhalation Exposure  (mg/kg bw/j) | Dermal Exposure  (mg/kg bw/d) | Total Exposure (mg/kg bw/d) |
| --- | --- | --- | --- | --- |
| Automated dipping 200g/m2 – without PPE except gloves during application | | | | |
| Transfer of product | Cyperméthrine | 2,61E-06 | 4,85E-03 | 4,85E-03 |
| Propiconazole | 5,22E-06 | 7,00E-03 | 7,01E-03 |
| Tébuconazole | 1,63E-06 | 2,61E-03 | 2,61E-03 |
| IPBC | 1,63E-06 | 6,31E-03 | 6,31E-03 |
| Automated dipping | Cyperméthrine | 4,00E-05 | 8,03E-03 | 8,07E-03 |
| Propiconazole | 8,00E-05 | 1,16E-02 | 1,17E-02 |
| Tébuconazole | 2,50E-05 | 4,32E-03 | 4,34E-03 |
| IPBC | 2,50E-05 | 1,05E-02 | 1,05E-02 |
| Transfer + Application | Cyperméthrine | - | | 1,29E-02 |
| Propiconazole | - | | 1,87E-02 |
| Tébuconazole | - | | 6,96E-03 |
| IPBC | - | | 1,68E-02 |
| Automated dipping 200g/m2 – with gloves/clothes during M&L and gloves during application | | | | |
| Transfer of product | Cyperméthrine | 2,61E-06 | 4,85E-05 | 5,11E-05 |
| Propiconazole | 5,22E-06 | 7,00E-05 | 7,52E-05 |
| Tébuconazole | 1,63E-06 | 2,61E-05 | 2,77E-05 |
| IPBC | 1,63E-06 | 6,31E-05 | 6,48E-05 |
| Automated dipping | Cyperméthrine | 4,00E-05 | 8,03E-03 | 8,07E-03 |
| Propiconazole | 8,00E-05 | 1,16E-02 | 1,17E-02 |
| Tébuconazole | 2,50E-05 | 4,32E-03 | 4,34E-03 |
| IPBC | 2,50E-05 | 1,05E-02 | 1,05E-02 |
| Transfer + Application | Cyperméthrine | - | | 8,12E-03 |
| Propiconazole | - | | 1,17E-02 |
| Tébuconazole | - | | 4,37E-03 |
| IPBC | - | | 1,05E-02 |

Exposure of professional users

***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[[18]](#footnote-18). 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[[19]](#footnote-19).

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Dermal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Brushing 300g/m2 – without PPE** | | | | |
| M&L | n.a | | | |
| Product application phase | Cyperméthrine | 1,09E-04 | 9,49E-03 | 9,60E-03 |
| Propiconazole | 2,17E-04 | 1,37E-02 | 1,39E-02 |
| Tébuconazole | 6,79E-05 | 5,11E-03 | 5,18E-03 |
| IPBC | 6,79E-05 | 1,24E-02 | 1,24E-02 |
| Brush cleaning phase | Cyperméthrine | - | 7,17E-04 | 7,17E-04 |
| Propiconazole | - | 9,32E-04 | 9,32E-04 |
| Tébuconazole | - | 4,94E-04 | 4,94E-04 |
| IPBC |  | 8,63E-04 | 8,63E-04 |
| Application + cleaning | Cyperméthrine | - | | 1,03E-02 |
| Propiconazole | - | | 1,49E-02 |
| Tébuconazole | - | | 5,67E-03 |
| IPBC | - | | 1,33E-02 |
| Brushing 300g/m2 – with gloves and coated coverall during application and no PPE during cleaning | | | | |
| M&L | n.a | | | |
| Product application phase | Cyperméthrine | 1,09E-04 | 1,05E-03 | 1,16E-03 |
| Propiconazole | 1,09E-04 | 1,52E-03 | 1,74E-03 |
| Tébuconazole | 2,17E-04 | 5,67E-04 | 6,34E-04 |
| IPBC | 6,79E-05 | 1,37E-03 | 1,44E-03 |
| Brush cleaning phase | Cyperméthrine | 6,79E-05 | 7,17E-04 | 7,17E-04 |
| Propiconazole | - | 9,32E-04 | 9,32E-04 |
| Tébuconazole | - | 4,94E-04 | 4,94E-04 |
| IPBC | - | 8,63E-04 | 8,63E-04 |
| Application + cleaning | Cyperméthrine | - | | 1,88E-03 |
| Propiconazole | - | | 2,67E-03 |
| Tébuconazole | - | | 1,13E-03 |
| IPBC | - | | 2,30E-03 |

***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[[20]](#footnote-20).

Exposure during the cleaning of equipment has been assessed with the BEAT scenario “*Cleaning of the spray equipment*” from TNsG second version of 2007[[21]](#footnote-21).

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Spraying 300g/m2 – without PPE** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 1,90E-03 | 2,14E-01 | 2,16E-01 |
| Propiconazole | 3,80E-03 | 3,09E-01 | 3,13E-01 |
| Tébuconazole | 1,19E-03 | 1,15E-01 | 1,16E-01 |
| IPBC | 1,19E-03 | 2,78E-01 | 2,80E-01 |
| Cleaning of the spray equipment | Cyperméthrine | - | 2,46E-03 | 2,46E-03 |
| Propiconazole | - | 3,56E-03 | 3,56E-03 |
| Tébuconazole | - | 1,33E-03 | 1,33E-03 |
| IPBC | - | 3,21E-03 | 3,21E-03 |
| Appli + cleaning | Cyperméthrine |  |  | 2,18E-01 |
| Propiconazole |  |  | 3,16E-01 |
| Tébuconazole |  |  | 1,18E-01 |
| IPBC |  |  | 2,83E-01 |
| **Spraying 300g/m2 – with gloves and impermeable coverall during spraying and gloves and coated coverall during cleaning** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 1,90E-03 | 8,16E-03 | 1,01E-02 |
| Propiconazole | 3,80E-03 | 1.18E-02 | 1,56E-02 |
| Tébuconazole | 1,19E-03 | 4.39E-03 | 5.58E-03 |
| IPBC | 1,19E-03 | 1.06E-02 | 1.18E-02 |
| Cleaning of the spray equipment | Cyperméthrine | - | 3,21E-04 | 3,21E-04 |
| Propiconazole | - | 4.63E-04 | 4.63E-04 |
| Tébuconazole | - | 1,73E-04 | 1,73E-04 |
| IPBC | - | 4,18E-04 | 4,18E-04 |
| Appli (PPE)+ cleaning | Cyperméthrine |  |  | 1,04E-02 |
| Propiconazole |  |  | 1,61E-02 |
| Tébuconazole |  |  | 5.75E-03 |
| IPBC |  |  | 1.23E-02 |

***Injection***

An injection can be performed in combination with superficial application.

In first step, exposure during this injection phase is determined according to the subsoil treatment model 2, as recommended in the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure[[22]](#footnote-22).

Exposure during the cleaning of equipment has been assessed with the BEAT scenario “*Cleaning of the spray equipment*” from TNsG second version of 2007[[23]](#footnote-23).

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Injection 145 g/m2 – with gloves during injection and no PPE during cleaning** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 1.27E-05 | 3.07E-03 | 3.08E-03 |
| Propiconazole | 2.53E-05 | 4.44E-03 | 4.46E-03 |
| Tébuconazole | 7.92E-06 | 1.65E-03 | 1.66E-03 |
| IPBC | 7.92E-06 | 4.00E-03 | 4.01E-03 |
| Cleaning of the equipment | Cyperméthrine | NA | 2.65E-03 | 2.46E-03 |
| Propiconazole | NA | 3.82E-03 | 3.56E-03 |
| Tébuconazole | NA | 1.42E-03 | 1.33E-03 |
| IPBC | NA | 3.45E-03 | 3.21E-03 |
| Appli + cleaning | Cyperméthrine | 1.27E-05 | 5.72E-03 | 5.55E-03 |
| Propiconazole | 2.53E-05 | 8.26E-03 | 8.02E-03 |
| Tébuconazole | 7.92E-06 | 3.08E-03 | 2.99E-03 |
| IPBC | 7.92E-06 | 7.45E-03 | 7.22E-03 |
| **Injection 145g/m2 – with gloves during injection and gloves and coated coverall during cleaning** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 1.27E-05 | 3.07E-03 | 3.08E-03 |
| Propiconazole | 2.53E-05 | 4.44E-03 | 4.46E-03 |
| Tébuconazole | 7.92E-06 | 1.65E-03 | 1.66E-03 |
| IPBC | 7.92E-06 | 4.00E-03 | 4.01E-03 |
| Cleaning of the equipment | Cyperméthrine | NA | 3.57E-04 | 3.21E-04 |
| Propiconazole | NA | 5.16E-04 | 4.63E-04 |
| Tébuconazole | NA | 1.92E-04 | 1.73E-04 |
| IPBC | NA | 4.65E-04 | 4.18E-04 |
| Appli + cleaning | Cyperméthrine | 1.27E-05 | 3.43E-03 | 3.41E-03 |
| Propiconazole | 2.53E-05 | 4.95E-03 | 4.93E-03 |
| Tébuconazole | 7.92E-06 | 1.85E-03 | 1.83E-03 |
| IPBC | 7.92E-06 | 4.47E-03 | 4.43E-03 |

Then, as the injection is performed in combination with superficial treatment, the exposure determined above is combined with the exposure during the application by brushing and spraying.

Injection combined with brush treatment

| **Scenario** | **Active substance** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- |
| **Injection 145 g/m2 in combination with brush treatment at 300 g/m2**  **With gloves and coated coverall during application by brushing , gloves during injection and no PPE during cleaning** | | |
| Brush treatment | Cyperméthrine | 1.88E-03 |
| Propiconazole | 2.67E-03 |
| Tébuconazole | 1.13E-03 |
| IPBC | 2,30E-03 |
| Injection | Cyperméthrine | 5.55E-03 |
| Propiconazole | 8.02E-03 |
| Tébuconazole | 2.99E-03 |
| IPBC | 7.22E-03 |
| Brush + injection | Cyperméthrine | 7.43E-03 |
| Propiconazole | 1.07E-02 |
| Tébuconazole | 4.12E-03 |
| IPBC | 9.52E-03 |

Injection combined with spray treatment

| **Scenario** | **Active substance** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- |
| **Injection 145 g/m2 in combination with spray treatment at 300 g/m2**  **With gloves and impermeable coverall during spraying, gloves during injection and gloves and coated coverall during cleaning of equipments.** | | |
| Spray treatment | Cyperméthrine | 1,04E-02 |
| Propiconazole | 1,61E-02 |
| Tébuconazole | 5.77E-03 |
| IPBC | 1.23E-02 |
| Injection | Cyperméthrine | 3.41E-03 |
| Propiconazole | 4.93E-03 |
| Tébuconazole | 1.83E-03 |
| IPBC | 4.43E-03 |
| Spray + injection | Cyperméthrine | 1.38E-02 |
| Propiconazole | 2.10E-02 |
| Tébuconazole | 7.60E-03 |
| IPBC | 1.67E-02 |

###### Exposure of non-professional users

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[[24]](#footnote-24). Considering the heavy packaging for non professional (up to 30L), a pouring phase is considered. The exposure is determined according to the mixing and loading model 4.

Exposure during the cleaning of equipment (brush) has been assessed with the exposure model from the Opinion no. 11 of HEEG[[25]](#footnote-25).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Scenario | Active substance | Inhalation Exposure  (mg/kg bw/j) | Dermal Exposure  (mg/kg bw/d) | Total Exposure (mg/kg bw/d) |
| Brushing 300g/m2 | | | | |
| M&L | Cyperméthrine | - | 1,93E-03 | 1,93E-03 |
| Propiconazole | - | 2,78E-03 | 2,78E-03 |
| Tébuconazole | - | 1,04E-03 | 1,04E-03 |
| IPBC |  | 2,51E-03 | 2,51E-03 |
| Product application phase | Cyperméthrine | 1,09E-04 | 9,49E-03 | 9,60E-03 |
| Propiconazole | 2,17E-04 | 1,37E-02 | 1,39E-02 |
| Tébuconazole | 6,79E-05 | 5,11E-03 | 5,18E-03 |
| IPBC | 6,79E-05 | 1,24E-02 | 1,24E-02 |
| Brush cleaning phase | Cyperméthrine | - | 7,17E-04 | 7,17E-04 |
| Propiconazole | - | 9,32E-04 | 9,32E-04 |
| Tébuconazole | - | 4,94E-04 | 4,94E-04 |
| IPBC | - | 8,63E-04 | 8,63E-04 |
| M&L + appli + cleaning | Cyperméthrine |  |  | 1,22E-02 |
| Propiconazole |  |  | 1,76E-02 |
| Tébuconazole |  |  | 6,71E-03 |
| IPBC |  |  | 1,58E-02 |

***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. Mixing and loading phases are considered for brush and injection. To determine these exposures, the mixing and loading model 4 is used.

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/j) | Demal Exposure  (mg/kg bw/d) | Total Exposure (mg/kg bw/d) |
| Brushing 300 g/m2 + injection 145 g/m2 | | | | |
| M&L phase (brush and injection) | Cyperméthrine |  | 3,85E-03 | 3,85E-03 |
| Propiconazole |  | 5,57E-03 | 5,57E-03 |
| Tébuconazole |  | 2,07E-03 | 2,07E-03 |
| IPBC |  | 5,02E-03 | 5,02E-03 |
| Product application phase | Cyperméthrine | 2,17E-04 | 1,90E-02 | 1,92E-02 |
| Propiconazole | 4,35E-04 | 2,74E-02 | 2,79E-02 |
| Tébuconazole | 1,36E-04 | 1,02E-02 | 1,04E-02 |
| IPBC | 1,36E-04 | 2,47E-02 | 2,49E-02 |
| Cleaning phase (brush) | Cyperméthrine | - | 7,17E-04 | 7,17E-04 |
| Propiconazole | - | 9,32E-04 | 9,32E-04 |
| Tébuconazole | - | 4,94E-04 | 4,94E-04 |
| IPBC | - | 8,63E-04 | 8,63E-04 |
| Cleaning phase (spray) | Cyperméthrine | - | 2,46E-03 | 2,46E-03 |
| Propiconazole | - | 3,56E-03 | 3,56E-03 |
| Tébuconazole | - | 1,33E-03 | 1,33E-03 |
| IPBC | - | 3,21E-03 | 3,21E-03 |
| M&L + appli + cleaning | Cyperméthrine |  |  | 2,62E-02 |
| Propiconazole |  |  | 3,79E-02 |
| Tébuconazole |  |  | 1,42E-02 |
| IPBC |  |  | 3,39E-02 |

***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. The correction by density (0.803) has been considered.

Exposure during the cleaning of equipment has been assessed with the BEAT scenario “*Cleaning of the spray equipment*” from TNsG second version of 2007[[26]](#footnote-26).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Scenario | Active substance | Inhalation Exposure  (mg/kg bw/j) | Demal Exposure  (mg/kg bw/d) | Total Exposure (mg/kg bw/d) |
| Spraying 300g/m2 – without PPE | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 1,03E-03 | 4,56E-02 | 4,67E-02 |
| Propiconazole | 2,05E-03 | 6,57E-02 | 6,78E-02 |
| Tébuconazole | 6,41E-04 | 2,45E-02 | 2,51E-02 |
| IPBC | 6,41E-04 | 5,93E-02 | 5,99E-02 |
| Cleaning of the spray equipment | Cyperméthrine | - | 2,65E-03 | 2,65E-03 |
| Propiconazole | - | 3,82E-03 | 3,82E-03 |
| Tébuconazole | - | 1,42E-03 | 1,42E-03 |
| IPBC | - | 3,45E-03 | 3,45E-03 |
| Appli + cleaning | Cyperméthrine |  |  | 4,93E-02 |
| Propiconazole |  |  | 7,16E-02 |
| Tébuconazole |  |  | 2,66E-02 |
| IPBC |  |  | 6,33E-02 |

***Spray application + injection***

No specific exposure model for injection is available.

In this context, exposure is determined considering:

* Exposure during spraying,
* Similar exposure during cleaning of spray equipment and injection equipment,
* The exposure during injection combined to spraying is not higher than the exposure during injection combined to brushing. Therefore, the exposure linked to the injection in the scenario injection combined to brush is added to the exposure during spraying. A mixing and loading step of injection equipment is considered. The mixing and loqing model 4 is used.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Scenario | Active substance | Inhalation Exposure  (mg/kg bw/j) | Demal Exposure  (mg/kg bw/d) | Total Exposure (mg/kg bw/d) |
| Spraying 300g/m2 + injection 145g/m2 – without PPE | | | | |
| Loading of injection equipment | Cyperméthrine |  | 1,93E-03 | 1,93E-03 |
| Propiconazole |  | 2,78E-03 | 2,78E-03 |
| Tébuconazole |  | 1,04E-03 | 1,04E-03 |
| IPBC |  | 2,51E-03 | 2,51E-03 |
| Product application phase - spray | Cyperméthrine | 1,03E-03 | 4,56E-02 | 4,67E-02 |
| Propiconazole | 2,05E-03 | 6,57E-02 | 6,78E-02 |
| Tébuconazole | 6,41E-04 | 2,45E-02 | 2,51E-02 |
| IPBC | 6,41E-04 | 5,93E-02 | 5,99E-02 |
| Product application phase - injection | Cyperméthrine | 1,09E-04 | 9,49E-03 | 9,60E-03 |
| Propiconazole | 2,17E-04 | 1,37E-02 | 1,39E-02 |
| Tébuconazole | 6,79E-05 | 5,11E-03 | 5,18E-03 |
| IPBC | 6,79E-05 | 1,24E-02 | 1,24E-02 |
| Cleaning phase | Cyperméthrine | - | 5,29E-03 | 5,29E-03 |
| Propiconazole | - | 7,65E-03 | 7,65E-03 |
| Tébuconazole | - | 2,85E-03 | 2,85E-03 |
| IPBC | - | 6,89E-03 | 6,89E-03 |
| Loading + application + cleaning | Cyperméthrine |  |  | 6,35E-02 |
| Propiconazole |  |  | 9,21E-02 |
| Tébuconazole |  |  | 3,42E-02 |
| IPBC |  |  | 8,17E-02 |

##### 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 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, 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***

As a worst-case, it has been considered that the wood was treated with a total application dose of 445g/m2, corresponding to a curative treatment by brushing or spraying followed by injection.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **Substances** | **Dermal Exposure**  **(mg/kg pw/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** | Cyperméthrine | 2,69E-03 | 1,24E-05 | - | 2,70E-03 |
| Propiconazole | 3,89E-03 | 2,49E-05 | - | 3,91E-03 |
| Tébuconazole | 1,45E-03 | 7,77E-06 | - | 1,46E-03 |
| IPBC | 3,50E-03 | 7,77E-06 | - | 3,51E-03 |
| **Infant chewing wood composites chips (450g/m2)** | Cyperméthrine | - | - | 9,74E-03 | 9,74E-03 |
| Propiconazole | - | - | 3,42E-02 | 3,42E-02 |
| Tébuconazole | - | - | 1,07E-02 | 1,07E-02 |
| IPBC | - | - | 1,07E-02 | 1,07E-02 |

***Chronic secondary exposure scenario***

As a worst-case, it has been considered that the wood was treated with a total application dose of 445g/m2, corresponding to a curative treatment by brushing or spraying and injection.

Exposure was determined according to the scenario proposed in the User guidance, except for exposure to volatile residue. For this scenario a modelisation by ConsExpo was realised to determine the amount of active substance /m3 air.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **Substances** | **Dermal Exposure**  **(mg/kg pw/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** | Cyperméthrine | 2,69E-03 | 7,46E-05 | - | 2,77E-03 |
| Propiconazole | 3,89E-03 | 1,49E-04 | - | 4,04E-03 |
| Tébuconazole | 1,45E-03 | 4,66E-05 | - | 1,50E-03 |
| IPBC | 3,50E-03 | 4,66E-05 | - | 3,55E-03 |
| **Inhalation of volatilizing residues indoors (Adult)** | Cyperméthrine | - | 3,28E-09 | - | 3,28E-09 |
| Propiconazole | - | 1,60E-06 | - | 1,60E-06 |
| Tébuconazole | - | 1,52E-08 | - | 1,52E-08 |
| IPBC | - | 4,03E-05 | - | 4,03E-05 |
| **Inhalation of volatilizing residues indoors (Infant)** | Cyperméthrine | - | 6,642E-09 | - | 6,642E-09 |
| Propiconazole | - | 3,24E-06 | - | 3,24E-06 |
| Tébuconazole | - | 3,07E-08 | - | 3,07E-08 |
| IPBC | - | 8,15E-05 | - | 8,15E-05 |
| **Child playing on playground structure outdoors** | Cyperméthrine | 1,03E-03 | - | - | 1,03E-03 |
| Propiconazole | 1,48E-03 | - | - | 1,48E-03 |
| Tébuconazole | 5.52E-04 | - | - | 5.52E-04 |
| IPBC | 1.34E-03 | - | - | 1.34E-03 |
| **Infant playing on weathered (playground) structure and mouthing (450 g/m2)** | Cyperméthrine | 1,54E-03 | - | 3,04E-03 | 4,58E-03 |
| Propiconazole | 2,22E-03 | - | 1,07E-02 | 1,29E-02 |
| Tébuconazole | 8,28E-04 | - | 3,34E-03 | 4,17E-03 |
| IPBC | 2,00E-03 | - | 3,34E-03 | 5,34E-03 |

##### 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/j) | Secondary exposure (inhalation of volatilized residues)  (mg/kg bw/d) | Total exposure  (mg/kg bw/d) |
| --- | --- | --- | --- | --- |
| Dipping  (gloves and protective clothes during M&l and gloves during application) | Cyperméthrine | 8,12E-03 | 3,28E-09 | 8,12E-03 |
| Propiconazole | 1,17E-02 | 1,60E-06 | 1,17E-02 |
| Tébuconazole | 4,37E-03 | 1,52E-08 | 4,37E-03 |
| IPBC | 1,05E-02 | 4,03E-05 | 1,06E-02 |
| Brushing  (gloves and coated coverall during application and without PPE during cleaning) | Cyperméthrine | 1,88E-03 | 3,28E-09 | 1,88E-03 |
| Propiconazole | 2,67E-03 | 1,60E-06 | 2,67E-03 |
| Tébuconazole | 1,13E-03 | 1,52E-08 | 1,13E-03 |
| IPBC | 2,30E-03 | 4,03E-05 | 2,34E-03 |
| Spraying  (gloves and impermeable coverall during spraying and gloves and coated coverall during cleaning) | Cyperméthrine | 1,04E-02 | 3,28E-09 | 1.04E-02 |
| Propiconazole | 1,61E-02 | 1,60E-06 | 1.61E-02 |
| Tébuconazole | 5.75E-03 | 1,52E-08 | 5.75E-03 |
| IPBC | 1.23E-02 | 4,03E-05 | 1.23E-02 |
| Brushing + injecting (gloves and coated coverall during application and without PPE during cleaning) | Cyperméthrine | 7.43E-03 | 3,28E-09 | 7.43E-03 |
| Propiconazole | 1.07E-02 | 1,60E-06 | 1.07E-02 |
| Tébuconazole | 4.12E-03 | 1,52E-08 | 4.12E-03 |
| IPBC | 9.52E-03 | 4,03E-05 | 9.56E-03 |
| Spraying + injecting  (gloves and impermeable coverall during spraying and gloves and coated coverall during cleaning) | Cyperméthrine | 1.38E-02 | 3,28E-09 | 1.38E-02 |
| Propiconazole | 2.10E-02 | 1,60E-06 | 2.10E-02 |
| Tébuconazole | 7.60E-03 | 1,52E-08 | 7.60E-03 |
| IPBC | 1.67E-02 | 4,03E-05 | 1.67E-02 |

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

|  |  |  |  |
| --- | --- | --- | --- |
| Active substance | Infant playing on a wood strucure + mouthing  (mg/kg bw/d) | Secondary exposure (inhalation of volatilized residues)  (mg/kg bw/d) | Total exposure  (mg/kg bw/d) |
| Cyperméthrine | 4,58E-03 | 6,64E-09 | 4,58E-03 |
| Propiconazole | 1,29E-02 | 3,24E-06 | 1,29E-02 |
| Tébuconazole | 4,17E-03 | 3,07E-08 | 4,17E-03 |
| IPBC | 5,34E-03 | 8,15E-05 | 5,42E-03 |

#### Risk assessment for human health

##### Risk for direct exposure

###### Professional users

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Tébuconazole** | **Propiconazole** | **IPBC** |
| **Long term AEL**  **(mg/kg bw/d)** | 0.022 | 0.03 | 0.04 | 0.2 |

The product contains 4 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[[27]](#footnote-27)

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 and a refinement is needed.

INDUSTRIAL users

**Industrial uses – automated dipping application**

*Tier 1 (acceptability of each substance)*

|  |  |  |  |
| --- | --- | --- | --- |
| Scenario | AEL  (mg/kg pc/j) | Exposure  (mg/kg pc/j) | % AEL |
| Automated dipping 200g/m2 – without PPE except gloves during application | | | |
| Transfer phase | Cyperméthrine  0.022 | 4,85E-03 | 22.05 |
| Propiconazole : 0.04 | 7,01E-03 | 17.5 |
| Tébuconazole : 0.03 | 2,61E-03 | 8.7 |
| IPBC  0.2 | 6,31E-03 | 3.2 |
| Product application phase | Cyperméthrine  0.022 | 8,07E-03 | 36.7 |
| Propiconazole : 0.04 | 1,17E-02 | 29.2 |
| Tébuconazole : 0.03 | 4,34E-03 | 14.5 |
| IPBC  0.2 | 1,05E-02 | 5.2 |
| Transfer + application | Cyperméthrine  0.022 | 1,29E-02 | 58.7 |
| Propiconazole : 0.04 | 1,87E-02 | 46.7 |
| Tébuconazole : 0.03 | 6,96E-03 | 23.2 |
| IPBC  0.2 | 1,68E-02 | 8.4 |
| Automated dipping 200g/m2 – with gloves/clothes during M&L and gloves during application | | | |
| Transfer phase | Cyperméthrine  0.022 | 5,11E-05 | 0.23 |
| Propiconazole : 0.04 | 7,52E-05 | 0.19 |
| Tébuconazole : 0.03 | 2,77E-05 | 0.09 |
| IPBC  0.2 | 6,48E-05 | 0.03 |
| Product application phase | Cyperméthrine  0.022 | 8,07E-03 | 36.7 |
| Propiconazole : 0.04 | 1,17E-02 | 29.2 |
| Tébuconazole : 0.03 | 4,34E-03 | 14.5 |
| IPBC  0.2 | 1,05E-02 | 5.2 |
| Transfer + application | Cyperméthrine  0.022 | 8,12E-03 | 36.9 |
| Propiconazole : 0.04 | 1,17E-02 | 29.4 |
| Tébuconazole : 0.03 | 4,37E-03 | 14.6 |
| IPBC  0.2 | 1,05E-02 | 5.3 |

*Tier 2 (additivity)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Cyperméthrine | Propiconazole | Tébuconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | | | |
| without PPE except gloves during application | 0.59 | 0.47 | 0.23 | 0.08 | 1.37 | Unacceptable |
| With gloves/clothes during M&L and gloves during application | 0.37 | 0.29 | 0.15 | 0.05 | 0.86 | Acceptable |

* The risk is acceptable (HI < 1) when gloves/clothes during M&L and gloves during application are worn.

The cleaning of tank is not realised every day. This exposure is considered as acute exposure contrary to the treatment which is performed every day and considered as chronic exposure. Therefore, the exposure during the cleaning will not add to the exposure during decanting and application to characterise the risk.

Since 1 cycle is considered to determine the exposure during cleaning whereas 4 cycles are considered for application, the assessment of cleaning is covered by assessment of application. Therefore, the same PPEs than those used during application are required for cleaning.

Professional users

***Brush application***

*Tier 1 (acceptability of each substance)*

|  |  |  |  |
| --- | --- | --- | --- |
| Scenario | AEL  (mg/kg pc/j) | Exposure  (mg/kg pc/j) | % AEL |
| Brushing 300g/m2 – without PPE | | | |
| M&L | n.a | | |
| Product application phase | Cyperméthrine : 0.022 | 9,60E-03 | 43.6 |
| Propiconazole : 0.04 | 1,39E-02 | 34.8 |
| Tébuconazole : 0.03 | 5,18E-03 | 17.3 |
| IPBC : 0.2 | 1,24E-02 | 6.2 |
| Brush cleaning phase | Cyperméthrine : 0.022 | 7,17E-04 | 3.3 |
| Propiconazole : 0.04 | 9,32E-04 | 2.3 |
| Tébuconazole : 0.03 | 4,94E-04 | 1.6 |
| IPBC : 0.2 | 8,63E-04 | 0.4 |
| Appli + cleaning | Cyperméthrine : 0.022 | 1,03E-02 | 46.9 |
| Propiconazole : 0.04 | 1,49E-02 | 37.1 |
| Tébuconazole : 0.03 | 5,67E-03 | 18.9 |
| IPBC : 0.2 | 1,33E-02 | 6.6 |
| Brushing 300g/m2 – with gloves and coated coverall during application and no PPE during cleaning | | | |
| M&L | n.a | | |
| Product application phase | Cyperméthrine : 0.022 | 1,16E-03 | 5.3 |
| Propiconazole : 0.04 | 1,74E-03 | 4.3 |
| Tébuconazole : 0.03 | 6,34E-04 | 2.1 |
| IPBC : 0.2 | 1,44E-03 | 0.7 |
| Brush cleaning phase | Cyperméthrine : 0.022 | 7,17E-04 | 3.3 |
| Propiconazole : 0.04 | 9,32E-04 | 2.3 |
| Tébuconazole : 0.03 | 4,94E-04 | 1.6 |
| IPBC : 0.2 | 8,63E-04 | 0.4 |
| Appli + cleaning | Cyperméthrine : 0.022 | 1,88E-03 | 8.5 |
| Propiconazole : 0.04 | 2,67E-03 | 6.7 |
| Tébuconazole : 0.03 | 1,13E-03 | 3.8 |
| IPBC : 0.2 | 2,30E-03 | 1,2 |

*Tier 2 (additivity)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Cyperméthrine | Propiconazole | Tébuconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | | | |
| Without PPE | 0.47 | 0.37 | 0.19 | 0.07 | 1.1 | Unacceptable |
| With gloves and coated coverall during application and no PPE during cleaning | 0.09 | 0.07 | 0.04 | 0.01 | 0.21 | Acceptable |

* The risk is acceptable (HI < 1) when gloves and coated coverall during application and no PPE during cleaning are worn.

***Spray application***

*Tier 1 (acceptability of each substance)*

| Scenario | AEL  (mg/kg pc/j) | Exposure  (mg/kg pc/j) | % AEL | Risk |
| --- | --- | --- | --- | --- |
| Spraying 300g/m2 – without PPE | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine : 0.022 | 2,16E-01 | 981 | Unacceptable |
| Propiconazole : 0.04 | 3,13E-01 | 782 | Unacceptable |
| Tébuconazole : 0.03 | 1,16E-01 | 388 | Unacceptable |
| IPBC : 0.2 | 2,80E-01 | 140 | Unacceptable |
| Cleaning spray equipment | Cyperméthrine  0.022 | 2,46E-03 | 11.2 |  |
| Propiconazole : 0.04 | 3,56E-03 | 8.9 |  |
| Tébuconazole : 0.03 | 1,33E-03 | 4.4 |  |
| IPBC : 0.2 | 3,21E-03 | 1.6 |  |
| Appli + cleaning | Cyperméthrine  0.022 | 2,18E-01 | 992 | Unacceptable |
| Propiconazole : 0.04 | 3,16E-01 | 791 | Unacceptable |
| Tébuconazole : 0.03 | 1,18E-01 | 392 | Unacceptable |
| IPBC : 0.2 | 2,83E-01 | 141 | Unacceptable |
| Spraying 300g/m2 –with gloves and impermeable coverall during spraying and gloves and coated coverall during cleaning | | | | |
| M&L | Included in the model | | | |
| Application phase | Cyperméthrine  0.022 | 1,01E-02 | 45.8 |  |
| Propiconazole : 0.04 | 1,56E-02 | 39.0 |  |
| Tébuconazole : 0.03 | 5.58E-03 | 18.6 |  |
| IPBC  0.2 | 1.18E-02 | 5.9 |  |
| Cleaining equipement | Cyperméthrine  0.022 | 3,21E-04 | 1.5 |  |
| Propiconazole : 0.04 | 4.63E-04 | 1.2 |  |
| Tébuconazole : 0.03 | 1,73E-04 | 0.6 |  |
| IPBC  0.2 | 4,18E-04 | 0.2 |  |
| Appli + cleaning | Cyperméthrine  0.022 | 1,04E-02 | 47.2 |  |
| Propiconazole : 0.04 | 1,61E-02 | 40.1 |  |
| Tébuconazole : 0.03 | 5.75E-03 | 19.2 |  |
| IPBC  0.2 | 1.23E-02 | 6.1 |  |

* The risk is unacceptable for spray application by a professional without PPE.

*Tier 2 (additivity)*

|  | Cyperméthrine | Propiconazole | Tébuconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| --- | --- | --- | --- | --- | --- | --- |
| HQ (Exposure/AEL) | | | | |
| with gloves and impermeable coverall during spraying and gloves and coated coverall during cleaning | 0.47 | 0.40 | 0.19 | 0.06 | 1.13 | HI >1 |

* HI > 1, a refinement is needed.

A Tier 3B approach is considered since the 4 active substances have target organs in common.

The liver is a target organ common to cypermethrine, propiconazole, tebuconazole and IPBC.

The kidney is a target organ common to cypermethrine, propiconazole and IPBC.

Blood is a target organ common to cypermethrine, propiconazole and tebuconazole.

The adrenal is a target organ common to propiconazole and tebuconazole.

The lung is a target organ common to cypermethrine and IPBC.

Specific target organ AELS can be derived for each active substance based on the available data in the CARs.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Tébuconazole** | **Propiconazole** | **IPBC** |
| **General long term AEL** | 0.022 | 0.03 | 0.04 | 0.2 |
| **Specific AEL: liver** | 0.18 | 0.06 | 0.08 | 0.2 |
| **Specific AEL: kidney** | 0.022 | - | 0.5 | 0.35 |
| **Specific AEL: Hemato** | 0.022 | 0.3 | 0.761 |  |
| **Specific AEL: adrenals** |  | 0.03 | 0.04 |  |
| **Specific AEL: lungs** | 0.07 |  |  | 0.2 |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** |
| combined exposure appli cleaning and residue | | | | |  |
| Exposure with gloves and impermeable coverall during spraying and gloves and coated coverall during cleaning | 1,04E-02 | 1,61E-02 | 5.75E-03 | 1.23E-02 |  |
|  |  |  |  |  |  |
| AEL liver | 0.18 | 0.08 | 0.06 | 0.2 | **HI** |
| %AEL | 6% | 20% | 10% | 6% | **0.42** |
|  |  |  |  |  |  |
| AEL kidney | 0.022 | 0.5 |  | 0.35 |  |
| %AEL | 47% | 3% |  | 4% | **0.54** |
|  |  |  |  |  |  |
| AEL hematology | 0.022 | 0.761 | 0.3 |  |  |
| %AEL | 47% | 2% | 2% |  | **0.51** |
|  |  |  |  |  |  |
| AEL adrenals |  | 0.036 | 0.03 |  |  |
| %AEL |  | 45% | 19% |  | **0.64** |
|  |  |  |  |  |  |
| AEL Lung | 0.07 |  |  | 0.2 |  |
| %AEL | 15% |  |  | 6% | **0.21** |

HI is inferior to 1 for all common organs. The risk should be considered as acceptable.

***Injection***

| Scenario | AEL  (mg/kg pc/j) | Exposure  (mg/kg pc/j) | % AEL |
| --- | --- | --- | --- |
| **Injection 145 g/m2 – with gloves during injection and no PPE during cleaning** | | | |
| M&L | Included in the model | | |
| Application phase | Cyperméthrine : 0.022 | 3.08E-03 | 14 |
| Propiconazole : 0.04 | 4.46E-03 | 11 |
| Tébuconazole : 0.03 | 1.66E-03 | 6 |
| IPBC : 0.2 | 4.01E-03 | 2 |
| Cleaning equipment | Cyperméthrine : 0.022 | 2.46E-03 | 11 |
| Propiconazole : 0.04 | 3.56E-03 | 8.9 |
| Tébuconazole : 0.03 | 1.33E-03 | 4.4 |
| IPBC : 0.2 | 3.21E-03 | 1.6 |
| Appli + cleaning | Cyperméthrine : 0.022 | 5.55E-03 | 25 |
| Propiconazole : 0.04 | 8.02E-03 | 20 |
| Tébuconazole : 0.03 | 2.99E-03 | 10 |
| IPBC : 0.2 | 7.22E-03 | 4 |
| **Injection 145g/m2 – with gloves during injection and gloves and coated coverall during cleaning** | | | |
| M&L | Included in the model | | |
| Application phase | Cyperméthrine : 0.022 | 3.08E-03 | 14 |
| Propiconazole : 0.04 | 4.46E-03 | 11 |
| Tébuconazole : 0.03 | 1.66E-03 | 6 |
| IPBC : 0.2 | 4.01E-03 | 2 |
| Cleaning equipement | Cyperméthrine : 0.022 | 3.21E-04 | 1.4 |
| Propiconazole : 0.04 | 4.63E-04 | 1.2 |
| Tébuconazole : 0.03 | 1.73E-04 | 0.6 |
| IPBC : 0.2 | 4.18E-04 | 0.2 |
| Appli + cleaning | Cyperméthrine : 0.022 | 3.41E-03 | 15 |
| Propiconazole : 0.04 | 4.93E-03 | 12 |
| Tébuconazole : 0.03 | 1.83E-03 | 6 |
| IPBC : 0.2 | 4.43E-03 | 2 |

*Tier 2 (additivity)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Cyperméthrine | Propiconazole | Tébuconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | | | |
| **with gloves during injection and no PPE during cleaning** | 0.25 | 0.20 | 0.10 | 0.04 | 0.59 | Acceptable |
| **with gloves during injection and gloves and coated coverall during cleaning** | 0.15 | 0.12 | 0.06 | 0.02 | 0.35 | Acceptable |

* The risk is acceptable (HI < 1).

***Brush application + injection***

*Tier 1 (each substance)*

|  |  |  |  |
| --- | --- | --- | --- |
| Scenario | AEL  (mg/kg pc/j) | Exposure  (mg/kg pc/j) | % AEL |
| **Injection 145 g/m2 in combination with brush treatment at 300 g/m2**  **With gloves and coated coverall during application by brushing , gloves during injection and no PPE during cleaning** | | | |
| Appli + cleaning | Cyperméthrine : 0.022 | 7.43E-03 | 34 |
| Propiconazole : 0.04 | 1.07E-02 | 27 |
| Tébuconazole : 0.03 | 4.12E-03 | 14 |
| IPBC : 0.2 | 9.52E-03 | 5 |

*Tier 2 (additivity)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Cyperméthrine | Propiconazole | Tébuconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | | | |
| **With gloves and coated coverall during application by brushing , gloves during injection and no PPE during cleaning** | 0.34 | 0.27 | 0.14 | 0.05 | 0.80 | Acceptable |

* The risk is acceptable (HI < 1) when gloves and coated coverall during application, gloves during injection and no PPE during cleaning are worn.

***Spray application + injection***

*Tier 1 (acceptability of each substance)*

|  |  |  |  |
| --- | --- | --- | --- |
| Scenario | AEL  (mg/kg pc/j) | Exposure  (mg/kg pc/j) | % AEL |
| **Injection 145 g/m2 in combination with spray treatment at 300 g/m2**  **With gloves and impermeable coverall during spraying, gloves during injection and gloves and coated coverall during cleaning of equipments.** | | | |
| Appli + cleaning | Cyperméthrine : 0.022 | 1.38E-02 | 63 |
| Propiconazole : 0.04 | 2.10E-02 | 53 |
| Tébuconazole : 0.03 | 7.60E-03 | 25 |
| IPBC : 0.2 | 1.67E-02 | 8 |

*Tier 2 (additivity)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Cyperméthrine | Propiconazole | Tébuconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | | | |
| **With gloves and impermeable coverall during spraying, gloves during injection and gloves and coated coverall during cleaning of equipments** | 0.63 | 0.53 | 0.25 | 0.08 | 1.49 | See Tier 3B |

* HI > 1, a refinement is needed.

A Tier 3B approach is considered since the 4 active substances have target organs in common.

The liver is a target organ common to cypermethrine, propiconazole, tebuconazole and IPBC.

The kidney is a target organ common to cypermethrine, propiconazole and IPBC.

Blood is a target organ common to cypermethrine, propiconazole and tebuconazole.

The adrenal is a target organ common to propiconazole and tebuconazole.

The lung is a target organ common to cypermethrine and IPBC.

Specific target organ AELS can be derived for each active substance based on the available data in the CARs.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Tébuconazole** | **Propiconazole** | **IPBC** |
| **General long term AEL** | 0.022 | 0.03 | 0.04 | 0.2 |
| **Specific AEL: liver** | 0.18 | 0.06 | 0.08 | 0.2 |
| **Specific AEL: kidney** | 0.022 | - | 0.5 | 0.35 |
| **Specific AEL: Hemato** | 0.022 | 0.3 | 0.761 |  |
| **Specific AEL: adrenals** |  | 0.03 | 0.04 |  |
| **Specific AEL: lungs** | 0.07 |  |  | 0.2 |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** |
| combined exposure appli cleaning and residue | | | | |  |
| Exposure **With gloves and impermeable coverall during spraying, gloves during injection and gloves and coated coverall during cleaning of equipments** | 1.38E-02 | 2.10E-02 | 7.60E-03 | 1.67E-02 |  |
|  |  |  |  |  |  |
| AEL liver | 0.18 | 0.08 | 0.06 | 0.2 | **HI** |
| %AEL | 8% | 26% | 13% | 8% | **0.55** |
|  |  |  |  |  |  |
| AEL kidney | 0.022 | 0.5 |  | 0.35 |  |
| %AEL | 63% | 4% |  | 5% | **0.72** |
|  |  |  |  |  |  |
| AEL hematology | 0.022 | 0.761 | 0.3 |  |  |
| %AEL | 63% | 3% | 3% |  | **0.68** |
|  |  |  |  |  |  |
| AEL adrenals |  | 0.036 | 0.03 |  |  |
| %AEL |  | 58% | 25% |  | **0.84** |
|  |  |  |  |  |  |
| AEL Lung | 0.07 |  |  | 0.2 |  |
| %AEL | 20% |  |  | 8% | **0.28** |

HI is inferior to 1 for all common organs. The risk should be considered as acceptable.

###### Non-professional users

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Tébuconazole** | **Propiconazole** | **IPBC** |
| **Short term AEL**  **(mg/kg bw/d)** | 0.088 | 0.03 | 0.3 | 0.35 |

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 pc/j) | Exposure  (mg/kg pc/j) | % AEL |
| Brushing 300g/m2 | | | |
| M&L | Cyperméthrine  0.088 | 1,93E-03 | 2 |
| Propiconazole : 0.3 | 2,78E-03 | 1 |
| Tébuconazole : 0.03 | 1,04E-03 | 3 |
| IPBC  0.35 | 2,51E-03 | 1 |
| Application phase | Cyperméthrine  0.088 | 9,60E-03 | 10.9 |
| Propiconazole : 0.3 | 1,39E-02 | 4.6 |
| Tébuconazole : 0.03 | 5,18E-03 | 17.3 |
| IPBC  0.35 | 1,24E-02 | 3.6 |
| Brush cleaning | Cyperméthrine  0.088 | 7,17E-04 | 0.82 |
| Propiconazole : 0.3 | 9,32E-04 | 0.31 |
| Tébuconazole : 0.03 | 4,94E-04 | 1.65 |
| IPBC  0.35 | 8,63E-04 | 0.25 |
| Appli + cleaning | Cyperméthrine  0.088 | 1,22E-02 | 13.9 |
| Propiconazole : 0.3 | 1,76E-02 | 5.9 |
| Tébuconazole : 0.03 | 6,71E-03 | 22.4 |
| IPBC  0.35 | 1,58E-02 | 4.5 |

*Tier 2 (additivity)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Cyperméthrine | Propiconazole | Tébuconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | |  |
| 0.14 | 0.06 | 0.22 | 0.05 | 0.47 | Acceptable |

* HI < 1, the risk is acceptable.

***Spray application***

*Tier 1 (acceptability of each substance)*

|  |  |  |  |
| --- | --- | --- | --- |
| Scenario | AEL  (mg/kg pc/j) | Exposure  (mg/kg pc/j) | % AEL |
| Spraying 300g/m2 | | | |
| M&L | Included in the model | | |
| Application phase | Cyperméthrine  0.088 | 4,67E-02 | 53.0 |
| Propiconazole : 0.3 | 6,78E-02 | 22.6 |
| Tébuconazole : 0.03 | 2,51E-02 | 83.8 |
| IPBC  0.35 | 5,99E-02 | 17.1 |
| Cleaning spray equipment | Cyperméthrine  0.088 | 2,65E-03 | 3.0 |
| Propiconazole : 0.3 | 3,82E-03 | 1.3 |
| Tébuconazole : 0.03 | 1,42E-03 | 4.8 |
| IPBC  0.35 | 3,45E-03 | 0.98 |
| Appli + cleaning | Cyperméthrine  0.088 | 4,93E-02 | 56 |
| Propiconazole : 0.3 | 7,16E-02 | 23.9 |
| Tébuconazole : 0.03 | 2,66E-02 | 88.5 |
| IPBC  0.35 | 6,33E-02 | 18.1 |

*Tier 2 (additivity)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Cyperméthrine | Propiconazole | Tébuconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | |  |
| 0.56 | 0.24 | 0.89 | 0.18 | 1.9 | see Tierr 3B |

* HI > 1, the risk is unacceptable, a refinement is needed.

A Tier 3B approach is considered since the 4 active substances have target organs in common in the short term toxicity study.

The liver is a target organ common to cypermethrine, propiconazole, tebuconazole and IPBC.

The kidney is a target organ common to propiconazole and IPBC.

Blood is a target organ common to propiconazole and tebuconazole.

Specific target organ short term AELS can be derived for each active substance based on the available data in the CARs.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Tébuconazole** | **Propiconazole** | **IPBC** |
| **General long term AEL** | 0.088 | 0.03 | 0.3 | 0.35 |
| **Specific AEL: liver** | 0.11 | 0.3 | 0.3 | 0.35 |
| **Specific AEL: kidney** | - | - | 0.5 | 0.35 |
| **Specific AEL: Hemato** | - | 0.3 | 1.5 | - |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** |
| combined exposure appli cleaning and residue | | | | |  |
| Exposure | 4.93E-02 | 7.16E-02 | 2.66E-02 | 6.33E-02 |  |
|  |  |  |  |  | **HI** |
| %AEL (liver) | 43 | 24 | 9 | 18 | **0.94** |
|  |  |  |  |  |  |
| %AEL (kidney) |  | 14 |  | 18 | **0.32** |
|  |  |  |  |  |  |
| %AEL (hemato) |  | 5 | 9 |  | **0.14** |

* HI is inferior to 1 for all common organs. The risk is acceptable.

***Brush application + injection***

*Tier 1 (acceptability of each substance)*

|  |  |  |  |
| --- | --- | --- | --- |
| Scenario | AEL  (mg/kg pc/j) | Exposure  (mg/kg pc/j) | % AEL |
| Brushing 300g/m2 and Injecting 145g/m2 | | | |
| M&L phase (brush and injection) | Cyperméthrine  0,088 | 3,85E-03 | 4 |
| Propiconazole : 0.3 | 5,57E-03 | 2 |
| Tébuconazole : 0,03 | 2,07E-03 | 7 |
| IPBC  0.35 | 5,02E-03 | 1 |
| Application phase | Cyperméthrine  0,088 | 1,92E-02 | 21.8 |
| Propiconazole : 0.3 | 2,79E-02 | 9.3 |
| Tébuconazole : 0,03 | 1,04E-02 | 34.5 |
| IPBC  0.35 | 2,49E-02 | 7.1 |
| Brush cleaning | Cyperméthrine  0,088 | 7,17E-04 | 0.82 |
| Propiconazole : 0.3 | 9,32E-04 | 0.31 |
| Tébuconazole : 0.03 | 4,94E-04 | 1.65 |
| IPBC  0.35 | 8,63E-04 | 0.25 |
| Injector cleaning | Cyperméthrine  0,088 | 2,46E-03 | 2.8 |
| Propiconazole : 0.3 | 3,56E-03 | 1.2 |
| Tébuconazole : 0.03 | 1,33E-03 | 4.4 |
| IPBC  0.35 | 3,21E-03 | 0.9 |
| M&L + appli + cleaning | Cyperméthrine  0,088 | 2,62E-02 | 29.8 |
| Propiconazole : 0.3 | 3,79E-02 | 12.6 |
| Tébuconazole : 0.03 | 1,42E-02 | 47.5 |
| IPBC  0.35 | 3,39E-02 | 9.7 |

*Tier 2 (additivity)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Cyperméthrine | Propiconazole | Tébuconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | |  |
| 0.298 | 0.126 | 0.475 | 0.097 | 0.99 | Acceptable |

* HI < 1, the risk is acceptable.

***Spray application + injection***

*Tier 1 (acceptability of each substance)*

| Scenario | AEL  (mg/kg pc/j) | Exposure  (mg/kg pc/j) | % AEL | Risk |
| --- | --- | --- | --- | --- |
| Spraying 300g/m2 + injecting 145 mg/m2 | | | | |
| Loading of injection equipment | Cyperméthrine  0,088 | 1,93E-03 | 2 | Acceptable |
| Propiconazole : 0.3 | 2,78E-03 | 1 | Acceptable |
| Tébuconazole : 0.03 | 1,04E-03 | 3 | Acceptable |
| IPBC  0.35 | 2,51E-03 | 1 | Acceptable |
| Application phase - spray | Cyperméthrine  0,088 | 4,67E-02 | 53.0 | Acceptable |
| Propiconazole : 0.3 | 6,78E-02 | 22.6 | Acceptable |
| Tébuconazole : 0.03 | 2,51E-02 | 83.8 | Acceptable |
| IPBC  0.35 | 5,99E-02 | 17.1 | Acceptable |
| Application phase - injection | Cyperméthrine  0,088 | 9,60E-03 | 11 | Acceptable |
| Propiconazole : 0.3 | 1,39E-02 | 4.6 | Acceptable |
| Tébuconazole : 0.03 | 5,18E-03 | 17 | Acceptable |
| IPBC  0.35 | 1,24E-02 | 3.5 | Acceptable |
| Cleaning spray equipment | Cyperméthrine  0.088 | 5,29E-03 | 6 | Acceptable |
| Propiconazole : 0.3 | 7,65E-03 | 3 | Acceptable |
| Tébuconazole : 0.03 | 2,85E-03 | 10 | Acceptable |
| IPBC  0.35 | 6,89E-03 | 2 | Acceptable |
| Appli + cleaning | Cyperméthrine  0.088 | 6,35E-02 | 72 | Acceptable |
| Propiconazole : 0.3 | 9,21E-02 | 31 | Acceptable |
| Tébuconazole : 0.03 | 3,42E-02 | 114 | Unacceptable |
| IPBC  0.35 | 8,17E-02 | 23 | Acceptable |

* The risk is unacceptable for spray + injection application by a non-professional for tebuconazole.

##### Risk for indirect exposure

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Tébuconazole** | **Propiconazole** | **IPBC** |
| **Long term AEL**  **(mg/kg bw/d)** | 0.022 | 0.03 | 0.04 | 0.2 |
| **Short term AEL**  **(mg/kg bw/d)** | 0.088 | 0.03 | 0.3 | 0.35 |

***Acute Exposure***

*Tier 1 (acceptability of each substance)*

|  |  |  |  |
| --- | --- | --- | --- |
| Scenario | AEL  (mg/kg pc/j) | Exposure  (mg/kg pc/j) | % AEL |
| Adult amateur sanding/processing of treated wood composites | Cyperméthrine  0,088 | 2,70E-03 | 3.1 |
| Propiconazole : 0.3 | 3,91E-03 | 1.3 |
| Tébuconazole : 0,03 | 1,46E-03 | 4.9 |
| IPBC 0.35 | 3,51E-03 | 1.0 |
| Infant chewing wood composites chips | Cyperméthrine  0,088 | 9,74E-03 | 11.1 |
| Propiconazole : 0.3 | 3,42E-02 | 11.4 |
| Tébuconazole : 0,03 | 1,07E-02 | 35.6 |
| IPBC 0.35 | 1,07E-02 | 3.1 |

*Tier 2 (additivity)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Cyperméthrine | Propiconazole | Tébuconazole | IPBC | HI  (∑ HQ a.s) | Risk |
|  | HQ (Exposure/AEL) | | |  |
| Sanding | 0.03 | 0.01 | 0.05 | 0.01 | 0.1 | Acceptable |
| Chewing | 0.11 | 0.11 | 0.36 | 0.03 | 0.6 | Acceptable |

* HI < 1, the risk is then acceptable.

***Chronic Exposure***

*Tier 1 (acceptability of each substance)*

|  |  |  |  |
| --- | --- | --- | --- |
| Scenario | AEL  (mg/kg pc/j) | Exposure  (mg/kg pc/j) | % AEL |
| Adult professional sanding/processing of treated wood composites | Cyperméthrine : 0.022 | 2,77E-03 | 12.6 |
| Propiconazole : 0.04 | 4,04E-03 | 10.1 |
| Tébuconazole : 0.03 | 1,50E-03 | 5.0 |
| IPBC : 0.2 | 3,55E-03 | 1.8 |
| Adult: inhalation of volatilised residues, indoors | Cyperméthrine : 0.022 | 3,28E-09 | <0.01 |
| Propiconazole : 0.04 | 1,60E-06 | <0.01 |
| Tébuconazole : 0.03 | 1,52E-08 | <0.01 |
| IPBC : 0.2 | 4,03E-05 | 0.02 |
| Infant: inhalation of volatilised residues, indoors | Cyperméthrine : 0.022 | 6,64E-09 | <0.01 |
| Propiconazole : 0.04 | 3,24E-06 | <0.01 |
| Tébuconazole : 0.03 | 3,07E-08 | <0.01 |
| IPBC : 0.2 | 8,15E-05 | 0.04 |
| Child playing on playground structure outdoors | Cyperméthrine : 0.022 | 1,03E-03 | 4.7 |
| Propiconazole : 0.04 | 1,48E-03 | 3.7 |
| Tébuconazole : 0.03 | 5.52E-04 | 1.8 |
| IPBC : 0.2 | 1.34E-03 | 0.7 |
| Infant playing on playground structure outdoors and mouthing | Cyperméthrine : 0.022 | 4,58E-03 | 20.8 |
| Propiconazole : 0.04 | 1,29E-02 | 32.2 |
| Tébuconazole : 0.03 | 4,17E-03 | 13.9 |
| IPBC : 0.2 | 5,34E-03 | 2.7 |

*Tier 2 (additivity)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Cyperméthrine | Propiconazole | Tébuconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | |  |
| Adult professional sanding/processing of treated wood composites | | | | | |
| 0.13 | 0.1 | 0.05 | 0.02 | 0.3 | Acceptable |
| Adult: inhalation of volatilised residues, indoors | | | | | |
| <0.0001 | <0.0001 | <0.0001 | 0.0002 | 0.0002 | Acceptable |
| Infant: inhalation of volatilised residues, indoors | | | | | |
| <0.0001 | <0.0001 | <0.0001 | 0.0004 | 0.0005 | Acceptable |
| Child playing on playground structure outdoors | | | | | |
| 0.05 | 0.04 | 0.02 | 0.01 | 0.12 | Acceptable |
| Infant playing on playground structure outdoors and mouthing  (wood treated at 200 g/m2) | | | | | |
| 0.21 | 0.32 | 0.14 | 0.03 | 0.7 | Acceptable |

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

##### Risk for combined exposure

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Tébuconazole** | **Propiconazole** | **IPBC** |
| **Long term AEL**  **(mg/kg bw/d)** | 0.022 | 0.03 | 0.04 | 0.2 |

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

*Tier 1 (acceptability of each substance)*

|  |  |  |  |
| --- | --- | --- | --- |
| Scenario | AEL  (mg/kg pc/j) | Exposure  (mg/kg pc/j) | % AEL |
| Adult combined expo : Dipping  (gloves and protective clothes during M&l and gloves during application) | Cyperméthrine  0.022 | 8,12E-03 | 36.9 |
| Propiconazole : 0.04 | 1,17E-02 | 29.4 |
| Tébuconazole : 0.03 | 4,37E-03 | 14.6 |
| IPBC  0.2 | 1,06E-02 | 5.3 |
| Adult combined expo : Brushing  (gloves and coated coverall during application and without PPE during cleaning) | Cyperméthrine  0.022 | 1,88E-03 | 8.54 |
| Propiconazole : 0.04 | 2,67E-03 | 6.7 |
| Tébuconazole : 0.03 | 1,13E-03 | 3.8 |
| IPBC  0.2 | 2,34E-03 | 1.2 |
| Adult combined expo : spraying  (gloves and impermeable coverall during spraying and gloves and coated coverall during cleaning) | Cyperméthrine  0.022 | 1.04E-02 | 47.2 |
| Propiconazole : 0.04 | 1.61E-02 | 40.1 |
| Tébuconazole : 0.03 | 5.75E-03 | 19.2 |
| IPBC  0.2 | 1.23E-02 | 6.1 |
| Adult combined expo : Brushing + injecting  (gloves and coated coverall during application by brushing , gloves during injection and no PPE during cleaning) | Cyperméthrine  0.022 | 7.43E-03 | 34 |
| Propiconazole : 0.04 | 1.07E-02 | 27 |
| Tébuconazole : 0.03 | 4.12E-03 | 14 |
| IPBC  0.2 | 9.56E-03 | 5 |
| Adult combined expo : spraying + injecting  (gloves and impermeable coverall during spraying, gloves during injection and gloves and coated coverall during cleaning of equipments.) | Cyperméthrine  0.022 | 1.38E-02 | 63 |
| Propiconazole : 0.04 | 2.10E-02 | 53 |
| Tébuconazole : 0.03 | 7.60E-03 | 25 |
| IPBC  0.2 | 1.67E-02 | 8 |

*Tier 2 (additivity)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Cyperméthrine | Propiconazole | Tébuconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | |  |
| Adult combined expo : Dipping | | | | | |
| 0.34 | 0.29 | 0.15 | 0.05 | 0.83 | Acceptable |
| Adult combined expo : Brushing | | | | | |
| 0.09 | 0.07 | 0.04 | 0.01 | 0.21 | Acceptable |
| Adult combined expo : spraying | | | | | |
| 0.47 | 0.40 | 0.19 | 0.06 | 1.13 | Tier 3B |
| Adult combined expo : Brushing + injecting | | | | | |
| 0.34 | 0.27 | 0.14 | 0.05 | 0.80 | Acceptable |
| Adult combined expo : spraying + injecting | | | | | |
| 0.63 | 0.53 | 0.25 | 0.08 | 1.49 | Tier 3B |

* HI < 1, except for spraying combined with injection. Therefore, the risk is acceptable for combined chronic exposure scenarios (adult), except for spraying combined with injection.

A Tier 3B approach is considered since the 4 active substances have target organs in common.

The liver is a target organ common to cypermethrine, propiconazole, tebuconazole and IPBC.

The kidney is a target organ common to cypermethrine, propiconazole and IPBC.

Blood is a target organ common to cypermethrine, propiconazole and tebuconazole.

The adrenal is a target organ common to propiconazole and tebuconazole.

The lung is a target organ common to cypermethrine and IPBC.

Specific target organ long term AELS can be derived for each active substance based on the available data in the CARs.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Tébuconazole** | **Propiconazole** | **IPBC** |
| **General long term AEL** | 0.022 | 0.03 | 0.04 | 0.2 |
| **Specific AEL: liver** | 0.18 | 0.06 | 0.08 | 0.2 |
| **Specific AEL: kidney** | 0.022 | - | 0.5 | 0.35 |
| **Specific AEL: Hemato** | 0.022 | 0.3 | 0.761 |  |
| **Specific AEL: adrenals** |  | 0.03 | 0.04 |  |
| **Specific AEL: lungs** | 0.07 |  |  | 0.2 |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** |
| combined exposure appli cleaning and residue | | | | |  |
| Exposure with gloves and impermeable coverall during spraying and gloves and coated coverall during cleaning | 1,04E-02 | 1,61E-02 | 5.75E-03 | 1.23E-02 |  |
|  |  |  |  |  |  |
| AEL liver | 0.18 | 0.08 | 0.06 | 0.2 | **HI** |
| %AEL | 6% | 20% | 10% | 6% | **0.42** |
|  |  |  |  |  |  |
| AEL kidney | 0.022 | 0.5 |  | 0.35 |  |
| %AEL | 47% | 3% |  | 4% | **0.54** |
|  |  |  |  |  |  |
| AEL hematology | 0.022 | 0.761 | 0.3 |  |  |
| %AEL | 47% | 2% | 2% |  | **0.51** |
|  |  |  |  |  |  |
| AEL adrenals |  | 0.036 | 0.03 |  |  |
| %AEL |  | 45% | 19% |  | **0.64** |
|  |  |  |  |  |  |
| AEL Lung | 0.07 |  |  | 0.2 |  |
| %AEL | 15% |  |  | 6% | **0.21** |

HI is inferior to 1 for all common organs. The risk should be considered as acceptable.

The comparison of the exposure values during the application by spraying combined to injection and the cleaning with the specific AELs leads to the following results:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** |
| combined exposure appli cleaning and residue | | | | |  |
| Exposure **With gloves and impermeable coverall during spraying, gloves during injection and gloves and coated coverall during cleaning of equipments** | 1.38E-02 | 2.10E-02 | 7.60E-03 | 1.67E-02 |  |
|  |  |  |  |  |  |
|  |  |  |  |  | **HI** |
| %AEL (liver) | 8% | 26% | 13% | 8% | **0.55** |
|  |  |  |  |  |  |
| %AEL (kidney) | 63% | 4% |  | 5% | **0.72** |
|  |  |  |  |  |  |
| %AEL (hemato) | 63% | 3% | 3% |  | **0.68** |
|  |  |  |  |  |  |
| %AEL (adrenals) |  | 58% | 25% |  | **0.84** |
|  |  |  |  |  |  |
| %AEL (ling) | 20% |  |  | 8% | **0.28** |

HI is inferior to 1 for all common organs. The risk should be considered as acceptable.

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

*Tier 1 (each substance)*

|  |  |  |  |
| --- | --- | --- | --- |
| Scenario | AEL  (mg/kg pc/j) | Exposure  (mg/kg pc/j) | % AEL |
| Infant combined exposure | Cyperméthrine  0.022 | 4,58E-03 | 20.8 |
| Propiconazole : 0.04 | 1,29E-02 | 32.3 |
| Tébuconazole : 0.03 | 4,17E-03 | 13.9 |
| IPBC  0.2 | 5,42E-03 | 2.7 |

*Tier 2 (additivity)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Cyperméthrine | Propiconazole | Tébuconazole | IPBC | HI  (∑ HQ a.s) | Risk |
| HQ (Exposure/AEL) | | | |
| 0.21 | 0.32 | 0.14 | 0.03 | 0.7 | Acceptable |

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

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

**Risks related to the use of X6122B1 by professionals and non-professionals are considered acceptable for all the intended uses, except the use of the product by spraying combined with injection for non-professional users**

**Risks related to a secondary exposure to treated wood are acceptable.**

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

In Annex 4 “Residue behaviour”, the results of the residue assessment are laid out.

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 X6122B1 must contain label restrictions against use in contact with livestock, food and feed.

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

Not relevant

### Risk assessment for the environment

|  |
| --- |
| FR-CA box 1  Please notice that the environmental risk assessment (section 2.8) is reported as provided by the applicant. The FR CA position is presented in green evaluation boxes. |

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

The product X6122B1 is a Use Class 3.1 product (outdoor, not covered, not in ground contact) intended for the preventive treatment of interior woods (beams, frames…) and exterior woods (shutters, doors, gates, cladding…). Treated wood intended to be used outdoor and exposed to weathering must be protected with a topcoat. It can also be used as a curative treatment on wood not exposed to weathering and leaching (risk class 2). It is used by brushing and spraying by professionals and non-professionals and by industrial dipping. For curative treatment, it can be applied by injection to complement the superficial application.

The environmental fate and behaviour of the product X6122B1 is presented in Section 10 of the IUCLID file. Based on the intended uses of the product and on the nature of the substances, on their physico-chemical properties and on their relations structure/function, the main foreseen route of entry in the environment are soil, surface water and groundwater.

For the assessment of the environmental fate and behaviour of the active substances contained in the biocidal product X6122B1, please refer to the chapters on fate and distribution in the environment (see Assessment Reports, cypermethrin cis:trans / 40:60 PT08, 12/07/2013; propiconazole PT09, 12/07/2013; tebuconazole PT10, 27/09/2013 and IPBC PT06, 27/09/2013) and environmental effects assessment of each active substance in Document II-A (see Letters of Access from Agriphar, Janssen, Lanxess and Troy in Section 13 of the active substances' datasets).

A summary of the environmental behaviour of the active substances and their relevant metabolites is presented below. All the data are coming from the Assessment Reports for the active substances.

* **Environmental behaviour of cypermethrin**

|  |  |  |  |
| --- | --- | --- | --- |
| Degradation | |  | |
| * Hydrolysis | In acidic conditions and at pH 7, cypermethrin is relatively stable (DT50 > 29 days at pH 7, 25°C and DT50 > 1 year and of 4.73 days respectively at pH 4 and 7, 50°C). It is degraded under alkaline conditions at pH 9 (DT50 of 1.9 hours at 50°C). The increase in temperature increases the degradation rate of cypermethrin.  At 12°C (environmental conditions), the derived DT50 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 14C phenoxy label and 12.4 days for 14C 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 DT50 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, DT50 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 DT50 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 DT50 values for the degradation of cypermethrin is within the range 6 to 24 days following incubation at 20 ± 2°C (mean DT50 = 13.5 days at 20°C). In soil PT 102, incubated at 10 ± 2°C, the DT50 value for the degradation of cypermethrin is 52 days. The corresponding DT50 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 DT50 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 Koc values ranging from 80 653 to 574 360. Koc 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 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 DT50 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 DT50 of around 9.3 days and  CGA 118 245 having DT50 of around 1 day at 20 °C. | |
|  |  | |
| Distribution |  | |
| * Adsorption   desorption | With an arithmetic mean value of Koc = 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 Koc 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. | |

* **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 DT50 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 Koc = 992 L/kg (arithmetic mean value).  The triazole metabolite has a high mobility potential, the Koc 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 IPBC**

The metabolites iodine and iodate are not taken in account in this assessment. In fact iodine is a biocidal active substance used as a disinfectant and was evaluated at European level by Sweden. The environmental risk assessment presented in the Assessment Report of IPBC showed that no risk to environmental compartments is foreseen for iodine and iodate. Therefore, no effect and risk assessment on these substances will be performed here.

|  |  |
| --- | --- |
| Degradation |  |
| * Hydrolysis | IPBC is stable to hydrolysis. |
|  |  |
| * Photolysis | Direct photodegradation of IPBC in water is low and the substance may be considered photolysis stable in water. |
|  |  |
| * Biodegradation | IPBC is not readily biodegradable but is primary biodegradable according to Zahn-Wellens test. |
| *In water*  */sediment* | The biodegradation half-life in surface water is estimated to about 3.1 hour at 12°C.  In anaerobic aquatic environments (sediment/water), IPBC was degraded in PBC (propargyl butyl carbamate) which was degraded to 2-propenyl butylcarbamate (2-PBC) and 2 unidentified degradates (less than 10%), CO2 and possibly CH4. |
| *In soil* | IPBC is metabolised rapidly in soil in laboratory experiments, the half-life is estimated to be 4.7 hours at 12°C. The primary degradate in aerobic soil was PBC. In soil, PBC was degraded to CO2, bound soil residues and an unidentified metabolite. |
|  |  |
| Distribution |  |
| * Adsorption   desorption | IPBC has a medium to high mobility potential with a Koc value of 126. |
|  |  |
| * Volatilisation | Air will not be an environmental compartment of concern for IPBC because of the low vapour pressure of this compound. It should also be noted that the calculated DT50 of IPBC in air is only about 15 hours and is therefore not considered persistent in air. |
|  |  |
| * Bioaccumulation | The bioaccumulation potential is not significant based on a log Kow value of 2.8. |

The physico-chemical and fate and behaviour data on the 4 active substances are summarised in the following Table. The numbers *in italic* are used for the environmental risk assessment.

Table 2.2‑1: Environmental data on the active substances

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Data | Cypermethrin | Propiconazole | Tebuconazole | IPBC and relevant metabolite |
| Reference | AR for cypermethrin  PT08, 12/07/2013 | AR for propiconazole PT08, 29-11-2007 and AR for propiconazole PT09, 12/07/2013 | AR for tebuconazole PT08, 29/11/2007 | AR for IPBC PT08, 22/02/2008 and AR for IPBC PT06, 27/09/2013 |
| Molecular weight (g/mol) | *416.3* | *342.2* | *307.8* | *281.1* |
| Melting point [°C] | Onset: 41.2  Peak: 47.3 | no data | 105 | 65.8 – 66.5 |
| Boiling point [°C] | Not measurable, decomposes | > 250 | Not measurable, decomposes | No boiling point, decomposes |
| Vapour Pressure (Pa) | *2.3\*10-7* at 20°C  6\*10-7 at 25°C | 5.6\*10-5 at 25°C  *3.97\*10–5* at 20°C | *1.7\*10-6* at 20°C | 2.36 - 4.5\*10-3 at 25°C  *3.19\*10–3 at 20°C* |
| Henry´s law constant (Pa m3 mol-1) | *2.4-\*10-2* at 20°C | *9.2\*10-5* | *1\*10-5* | 3.38 - *6.45\*10-3* at 25°C |
| Solubility in water at 20°C (mg/L) | *4\*10-3* at 20°C | *100* at 20°C | *29* at 20°C, pH = 7 | *168* at 20°C, pH 7 |
| Partition coefficient  log Kow | *5.45 at 25°C*  TDCVC: 2.672 (calculated)  CDCVC: 2.672 (calculated) | *3.72* at 25°C | *3.49* at 20°C | *2.81 at 25°C*  PBC: 1.64 |
| Hydrolysis DT50 [d] | 12°C, pH 4: DT50 = 7 631 d  12°C, pH 7: DT50 = 98.9 d  12°C, pH 9: DT50 = 1.65 d | Stable at 70°C after 28 days | Stable at 25°C after 28 days | 702 at 12°C, pH 7 |
| Photolytic / photo-oxidative degradation in water (DT50) [d] | At 20°C, pH 4:  DT50 = 12.4 - 14.7 d | Stable at 25°C after 30 days | Stable at pH 7 | Stable to direct and indirect photolysis |
| Degradation in water/sediment  (DT50) [d] | In water:  0.95 d at 12°C  In sediment:  20.7 – 27 d at 12°C  In whole system:  6.6 - *18.5 d* at 12°C  3-PBA:  24.5 d at 12°C (whole system)  TDCVC:  152 – 274 d at 12°C (whole system)  CDCVC:  18 – 356 d at 12°C (whole system) | In water:  6.4 d at 20°C (dissipation)  DT50 degradation has not been determined  In whole system:  *1206 d* at 12°C (degradation) | In water:  *198 d* (degradation); 43 d (dissipation)  In sediment:  365 d (dissipation)  In whole system:  46 d (dissipation) | In whole system (anaerobic):  *3.1 h* (0.129 d) at 12°C  PBC In whole system (anaerobic):  26 d at 12°C  In water:  31.2 d at 12°C  In sediment:  31.4 d at 12°C |
| Degradation in soil (DT50) [d] | In aerobic conditions:  *17.2* at 12°C  (geometric mean)  In anaerobic conditions:  87.2 at 12°C | *129* (dissipation) (maximal DT50 in field studies)  1,2,4-triazole:  9.3 d at 20°C  CGA 118 245:  1 d at 20°C | Laboratory study:  > 365 at 20°C  Field study:  *77* at 12°C (dissipation)  1,2,4-triazole:  10 d (dissipation) | In aerobic conditions:  *4.7 h* (0.196 d) at 12°C  PBC:  10 d at 12°C |
| Soil photolysis (DT50) [d] | 29.6  (soil photolysis is considered as a minor route of degradation) | Stable | Stable | not required |
| Photo-oxidative degradation in air (DT50) | 18 h | < 2 days | > 2 days (3.8 days) | 15 h |
| Adsorption / desorption Koc [L/kg] | *574 360* | *944* (arithmetic mean value)  1,2,4-triazole:  69 (arithmetic mean value)  CGA 118 245:  29 (arithmetic mean value) | *992* (arithmetic mean value)  1,2,4-triazole:  89 (source: AR for PT10) | *126*  PBC:  198.1 (estimated) |
| Absorption to sludge [%] | - | - | *21* | - |
| BCF in fish | 417  TDCVC: 37.25 (calculated)  CDCVC:  37.25 (calculated) | 180 | 78 | not relevant |
| Depuration rate constant (fish) [d-1] | 1.58\*10-3 L/h | 0.48 | 0.44 | not relevant |
| BCF in earthworms | - | 64 (calculated with TGD, formula 82d) | 28 (estimated) | not relevant |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 2  Summary of the physico-chemical, environmental fate and behaviour 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** | **Cyper-**  **methrin** | **Tebuco-**  **nazole** | **Propico-**  **nazole** | **1,2,4-triazole(\*)** | **IPBC** | **PBC(\*\*\*)** | | Molar mass | [g.mol-1] | 416.3 | 307.8 | 342.2 | 69.1 | 281.1 | 155.2 | | Vapour pressure | [Pa] | 6.00E-07 | 1.70E-06 | 5.60E-05 | 0.220 | 2.36E-03 | 1.88E+01 | | Water solubility | [mg.L-1] | 4.00E-03 | 29 | 100 | 700 | 168 | 2860 | | Koc | [L.kg-1] | 575 000 | 992 | 944 | 89 | 134.5 | 198.1 | | DT50 (soil) | [d at 12°C] | 17.2 | 77 | 82 | 114.7 (\*\*) | 1.96E-01 | 9.50 | | DT50 (surface water) | [d at 12°C] | 0.95 | 43 | 12 | n.r. | 1.29E-01 | 31.2 | | DT50 (water/sediment whole system) | [d at 12°C] | 18.5 | 198 | 1206 | n.r. | 2.04E-01 | 31.4 | | K soil-water | [m3.m-3] | 1.73E+04 | 3.00E+01 | 2.85E+01 | n.r. | 4.24E+00 | 6.14E+00 | | BCF in fish | [L.kg-1] | 417 | n.r. | n.r. | n.r. | n.r. | n.r. | | BCF in earthworm | [L.kg-1] | 3380 | n.r. | n.r. | n.r. | n.r. | n.r. | | STP fraction | | | | | | | | | FSTP, water | [-] | 0.091 | 0.89 | 0.9 | n.r. | 0.963 | 0.967 | | FSTP, sludge | [-] | 0.909 | 0.109 | 0.1 | n.r. | 0.0364 | 0.0241 | | 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 Arrhenius equation with a DT50 at 20°C of 60.5 days.  (\*\*\*) – Relevant metabolite of IPBC in all environmental compartments assuming 100% of applied radioactivity. | | | | | | | |   Moreover IPBC is quickly degraded in the environment in iodine, released as iodine radical, which is not stable in soil or water and can be considered as a “transient metabolites”. The final reaction end-products would be iodide and iodate. According to the conclusions of the AR for IPBC PT06 (27/09/2013), a quantitative assessment should not be a requirements for the final reaction end-products of IPBC. Moreover this present evaluation is covered by the qualitative assessment proposed in the AR for IPBC PT06. |

#### Effects on environmental organisms for active substance

##### Aquatic compartment (including sediments)

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 in Section 13 of the active substances datasets).

The relevant ecotoxicological data and the calculated PNECs (see Assessment Reports) are summarised in the following Table:

Table 2.2‑2: 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** | **IPBC** **and relevant metabolite (4)** |
| LC50 fish [mg/L] | *Mortality (96 h):*  2.83\*10-3 | *Mortality (96 h):* 4.4  1,2,4-triazole: 498 | *Mortality (96 h)* 2.6 | *Mortality (96 h)*: 0.067  PBC: Mortality 96 h: 85.0 |
| NOEC fish [mg/L] | *Fry survival, body length/weight (28 d):* **1\*10-5(1)** | *(21 d semi-static)* **0.010**  *(83 d ELS, flow-through)* 0.012 | *(100 d)* **0.068** | *Larval growth (length and weight*  0.0084 |
| EC50 aquatic invertebrates [mg/L] | *Immobilisation (48 h):* 4.71\*10-3 | *Immobilisation (48 h):* 2.8  *Mortality (48 h):* 4.2  1,2,4-triazole: > 100 | *Mortality (96 h)* 0.51 | *Mortality (48 h): 0.160*  PBC: Mortality 48 h: 60.0 |
| NOEC aquatic invertebrates [mg/L] | *Immobilisation (21 d):* 4\*10-5 | *Immobilisation (21 d):* 0.01 | *Immobilisation (28 d)* 0.11 | *Mortality, reproduction and growth effects (21 d)* 0.050 |
| ErC50 algae [mg/L] | *Growth rate (96 h):*  > 33\*10-3 | *Growth rate (72 h):* 5.3  1,2,4-triazole: > 31 | *Growth rate (72 h)* 9.0 | *72 h: 0.053*  **PBC: 96 h: > 41.3** |
| EbC50 algae [mg/L] | *Biomass (96 h):*  > 33\*10-3 | *Biomass (72 h):* 1.96 | no data | *72 h:* 0.022  PBC: 96 h: > 41.3 |
| NOEC algae [mg/L] | *Biomass (96 h):*  > 33\*10-3 | *(72h)* 0.56 | *Biomass (72 h)* 0.46 | *72 h:* **0.0046**  PBC: 96 h: 21.2 |
| **PNECwater [mg/L]** | **1.10-6 (AF = 10)** | **1\*10-3 (AF=10)** | **6.8\*10-3 (AF=10)** | **5\*10-4 (AF = 10)**  **PBC: 0.0413**  **(AF = 1000)** |
| NOEC Sediment dwelling organism | - | *(28 d)* **54.5 mg/kg** | *Emergence (28 d)*  **5.4 mg/kgwwt**  (= 25 mg/kgdwt)  *Development (28 d)* 10.8 mg/kgwwt  (= 50 mg/kgdwt) | *-* |
| **PNECsediment [mg/kgwwt]** | **0.125 (equilibrium partitioning method(2))** | **0.55 (AF=100)** | **0.054 (AF=100)** | **0.00176 (equilibrium partitioning method(5))** |
| EC50 Microorganisms [mg/L] | *Respiration inhibition  (3 h):* **163** | *Respiration inhibition (30 min):* **> 32** | *Respiration inhibition  (3 h)* **> 100** | *Respiration inhibition* (3h): **44** |
| **PNECSTP [mg/L]** | **1.63 (AF = 100)** | **0.32 (AF=100)** | **100 (3)** | **0.44 (AF = 100)**  **PBC: 0.44 (6)** |

(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 Koc of 575 000 (to calculate Ksup-water),

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

(4) QSAR estimation indicates a toxicity of the metabolite 2-PBC comparable to that found for IPBC. Therefore, no experimental ecotoxicological data for this metabolite is required.

(5) The PNEC for the sediment is calculated using the equilibrium partitioning method. However, the risk to the sediment is the same that described for surface water. Therefore the risk of the sediment will not be considered further.

(6) For the PNECSTP of the metabolite PBC, the value determined for IPBC is used as a worst-case.

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

##### 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 Letters of Access in Section 13 of the active substances datasets).

- 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 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.

- Data on tebuconazole

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

- Data on IPBC

No data is available because IPBC is considered not relevant for the air compartment based on its physico-chemical properties (low vapour pressure). It should also be noted that the calculated DT50 of IPBC in air is only about 15 hours and IPBC is therefore not considered persistent in air.

##### 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 in Section 13 of the active substances datasets).

The relevant ecotoxicological data and the PNEC (see Assessment Report) are presented in the following Tables:

Table 2.2‑3: Ecotoxicological data on active substances for the terrestrial compartment

| **Ecotoxicity on terrestrial organisms** | **Cypermethrin *cis:trans* / 40:60** | **Tebuconazole** | **Propiconazole and relevant metabolites** | **IPBC and relevant metabolite** |
| --- | --- | --- | --- | --- |
| EC50 earthworm [mg/kg] | *(14 d)* > 100 mg/kgdwt | *Mortality (14 d):*  470 mg/kgdwt | *Mortality (14 d):* 205 mg/kgwwt(= 686 mg/kgdwt)  1,2,4-triazole: > 299 mg/kgwwt (> 1000 mg/kgdwt)  CGA 118 245: > 299 mg/kgwwt (> 1000 mg/kgdwt) | *Mortality (14 d): > 1000 mg/kgdwt* |
| NOEC earthworm [mg/kg] | *Mortality (56 d):* > 100 mg/kgdwt  *Biomass (56 d):* 30.8 mg/kgdwt  *Reproduction (56 d):* **5.20 mg/kgdwt** | *Reproduction (56 d):* **5.70 mg/kgdwt** | *Reproduction (56 d):* **0.998 mg/kgwwt** | *-* |
| LC50 plants [mg/kg] | Not expected to be phytotoxic | *Emergence (14 d):* > 100 mg/kgdwt | no data | - |
| EC50 plants [mg/kg] | Not expected to be phytotoxic | *Growth (14 d):* 24 mg/kgdwt | *Seedling emergence and survival:* 4.32 mg/kgwwt | *Fresh weight reduction: 4.92 mg/kgdwt* |
| NOEC plants [mg/kg] | Not expected to be phytotoxic | no data | *Reproduction:* 1.69 mg/kgwwt(0.96 mg/kgdwt) | *-* |
| EC50 Mineralization [mg/kg] | - | *Nitrogen and carbon mineralisation (28 d):*  > 8.30 mg/kgdwt | *Nitrogen mineralisation:* > 2.16 mg/kgwwt(> 1.67 mg/kgdwt)  1,2,4-triazole: > 0.82 mg/kgwwt (> 0.33 mg/kgdwt) | *Carbon mineralisation: 312.5 mg/kgdwt* |
| NOEC Mineralization [mg/kg] | *Nitrogen mineralisation:* 52 mg/kgdwt | *Nitrogen and carbon mineralisation (28 d):*  8.30 mg/kgdwt | *Nitrogen mineralisation:* 2.16 mg/kgwwt(1.67 mg/kgdwt)  1,2,4-triazole: 0.82 mg/kgwwt (0.33 mg/kgdwt) | *-* |
| **PNECsoil** | **0.0918 mg/kgwwt (AF = 50)**  (0.104 mg/kgdwt) | **0.1 mg/kgwwt (AF=50)**  (0.114 mg/kgdwt) | **0.1 mg/kgwwt (AF=10)** | **0.0044 mg/kgwwt (AF = 1000)**  **(5\*10-3 mg/kgdwt)**  **PBC: 0.149 mg/kgwwt (0.169 mg/kgdwt)**  **(eq. method) (1)** |
| LD50 bird [mg/kg b.w.] (acute) | Not determined. | 1988 | - | *-* |
| LC50 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 | - | *-* |
| LD50 mammal  [mg/kg b.w.] (acute) | 1945 | 1700 (female)  4000 (male) | - | *-* |

‘(1) The PNECsoil for the metabolite PBC is calculated from PNEC water.

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

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

* **Data on cypermethrin**

As cypermethrin has a log Kow > 3 (log Kow = 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.

PNECoral, bird and PNECoral, 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/kgfood. The PNECoral, bird is then derived from this NOEC according to formula 79 of the guidance:

PNECoral, bird = NOECbird / AForal.

According to the Table 26 of the guidance, the assessment factor (AForal) is equal to 30 because a chronic study on birds is available.

PNECoral,bird = 1000 / 30

**PNECoral,bird = 33.3 mg/kgfood**

\* A 2 years study on rats *via* oral route has been performed and the NOAEL reported in the Assessment Report is 5 mg/kgbw/d. This NOAEL is converted in NOEC expressed in mg/kgfood according to the formula 78 of the guidance:

NOECmammal = NOAELmammal, oral \* CONVmammal

where CONVmammal 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.

NOECmammal = 5 \* 20 = 100 mg/kgfood.

Then, the PNECoral, small mammal is derived from this NOEC according to formula 79 of the guidance:

PNECoral, small mammal = NOECmammal / 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.

PNECoral,small mammal = 100 / 30

**PNECoral,small mammal = 3.33 mg/kgfood**

* **Data on propiconazole**

The log Pow of propiconazole is 3.72 at 25°C implying slight bioaccumulation potential. In the bioaccumulation study, the mean steady-state BCF of propiconazole was 180 and depuration half-life 0.48 days for the whole fish. Additionally, an estimated BCF of 64 was determined for terrestrial organisms. Then propiconazole is considered as not bioaccumulative to aquatic or 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). The assessment of the active substance data does not warrant conclusion of endocrine disruption potential for propiconazole. In the toxicity tests with mammals there were no effects in test animals which could be related to possible endocrine disruption.

Therefore, there is no need to perform an assessment of secondary poisoning for propiconazole.

* **Data on tebuconazole**

The log Pow of tebuconazole is 3.49 at 20°C implying slight bioaccumulation potential. However, tebuconazole showed a low bioconcentration potential in aquatic and terrestrial organisms (BCFfish of 78 L/kg and BCF in earthworm of 28 estimated according to TGD) and it did not undergo biomagnification through the food chain. Moreover, tebuconazole did not represent a risk to birds due to the low toxicity of the active substance.

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 does not need to be performed as the risk of contamination of the environment is very limited when using the product according to the recommendations.

* **Data on IPBC**

The bioaccumulation potential of IPBC is not significant based on its log Pow value of 2.81 at 25°C, which results in bioconcentration factor (BCF) below 2000. Moreover IPBC has a proposed classification as Acute Tox 3, Eye Dam. 1, Acute Tox 4, Skin Sens. 1, STOT SE3 with H331, H318, H302, H317, H335, (T, R22-23-37-41-43). Hence the toxicological classification does not meet the criteria to perform a risk assessment for the bioaccumulation and secondary poisoning. Furthermore IPBC is not included in the EU list of potential endocrine disruptors.

Therefore, there is no need to perform an assessment of secondary poisoning for IPBC.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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** | **Cyper-**  **methrin** | **Tebuco-**  **nazole** | **Propico-**  **nazole** | **1,2,4-triazole** | **IPBC** | **PBC** | | **PNECSTP** | [mg/L] | 1.63E+00 | 3.20E-01 | 1.00E+02 | n.r. | 0.44 | 0.44 | | **PNECwater** | [mg/L] | 4.00E-06(1) | 1.00E-03 | 6.80E-03 | n.r. | 5.00E-04 | 4.13E-02 | | **PNECsediment** | [mg/kgwwt] | 5.00E-02 | 5.50E-01 | 5.40E-02 | n.r. | n.r. | 2.10E-01 | | **PNECsoil** | [mg/kgwwt] | 9.18E-02 | 1.00E-01 | 1.00E-01 | 8.20E-03 | 4.40E-03 | 1.49E-01 | | **PNECoral,bird** | [mg/kgfood] | 3.33E+01 | n.r. | n.r. | n.r. | n.r. | n.r. | | **PNECoral,mammals** | [mg/kgfood] | 3.33E+00 | n.r. | n.r. | n.r. | n.r. | n.r. |   n.r: not relevant  ’(1) According to the WGIV2016, a robust NOEC fish of 0.4 µg.L-1 is considered to derive the PNECwater for Cypermethrin with an assessment factor of 100. |

##### 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.  According to the PT13-AR of IPBC (2015), IPBC and PBC do not fulfil the PBT nor the vPvB criteria.  **ED-assessment:**  According to the PT07-AR of tebuconazole (2013), the PT07-AR of propiconazole (2013), the PT08-AR of cypermethrin (2013), the PT13-AR of IPBC (2015) no definite conclusions can be drawn concerning the endocrine disruption activity of each active substance.  Nevertheless, a number of scientific publications mention potential endocrine disruption activity of propiconazole and tebuconazole. These effects will be assessed more in details at the renewal stage of these biocidal active substances approval in the frame of the EU Regulation No 528/2012 (scheduled in 2019), and according to the criteria mentioned in the future *Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009.* In case these active substances were identified as ED, the conditions for the product authorisation will have to be revised. |

#### Effects on environmental organisms for biocidal product

|  |
| --- |
| FR-CA box 5  No data on ecotoxicity of the product has been provided by the applicant. |

#### Environmental exposure assessment

Calculations of emissions are performed only for preventive treatments by industrial dipping and for preventive treatments by professional and non-professional by brushing and spraying.

Indeed, as curative treatments are intended for the treatment of wood in risk class 2, no emission into the environment is foreseen during the application or during the service-life of the wood.

The choice of emission scenarios and calculations follows the Revised Emission Scenario Document (ESD) for Wood Preservatives (ENV/JM/MONO (2013)21).

Based on the industrial application the following scenario has been considered:

- Emission scenario for industrial dipping process (ESD 4.1.2)

Based on the application techniques the following scenarios have been considered for the *in-situ* application:

- Brushing (House and Fence scenario according to ESD 4.2.4.1 and ESD 4.2.4.2 for the soil compartment and groundwater (pore water) and Bridge over pond for the surface water and sediment, ESD 4.2.4.3)

- Spraying (House scenario for outdoor spraying, ESD 4.4.5)

Emissions from treated wood in service after treatment have been considered using the following scenarios:

- House – ESD 4.3.3.1 (groundwater according to FOCUS/PEARL)

- Fence – ESD 4.3.3.2

- Noise Barrier - ESD 4.3.3.3

- Bridge over Pond – ESD 4.3.3.4

All calculations were performed using all decimals. However, in the tables in this report only two decimals are shown. This may result in minor deviations between the results in the tables and the calculated examples.

##### Emission from industrial treatment

For the industrial dipping application emission during storage are considered. Although it is a solvent based product, emission to air is not considered as the active substances have a vapour pressure below 0.005 Pa (ESD 4.1.1.4).

Emission to the facility drain is omitted according to ESD (p.46): “The release of wood preservatives from the treating installation or where the treated timber is stored into a surface water drain or drain connected to an STP is not permitted and so any installation where this occurs is in contravention of environmental protection legislation and the license to operate the treatment process”.

Table 2.2‑4: Emission during storage after industrial dipping

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| INPUTS | | | | |
| Effective surface area of treated wood, considered to be exposed to rain, per 1 m2 storage area (i.e. soil) | *AREAwood-expo* | 11 | [m2/m2] | D |
| Duration of the initial assessment period | *Time 1* | 30 | [d] | D |
| Duration of a longer assessment period | *Time 2* | 5475 | [d] | D |
| Average daily flux i.e. the average quantity of a substance that is daily leached out of 1 m² of treated wood during 14 day storage period | *FLUXstorage,dipp* | 1.7\*10-7 (IPBC)  6.8\*10-7 (propiconazole)  3.0\*10-7 (tebuconazole)  2.0\*10-9 (cypermethrin) | [kg/m2.d] | D |
| Bulk density of wet soil | *RHOsoil* | 1700 | [kg.m-2] | D |
| Soil depth | *DEPTHsoil* | 0.5 | [m] | D |
| Fraction of rainwater running off the storage site | *Frunoff* | 0.5 | [-] | D |
| Flow rate of a small creek | *FLOWsurfacewater* | 0.3 | [m3/s] | D |
| OUTPUTS | | | | |
| Volume of (wet) soil | Vsoil | 350 | [m3] | O |
| Cumulative quantity of a substance, leached due to rainfall from stored treated wood, over the initial assessment period | *Qleachstorage,time1* | 3.7\*10-2 (IPBC)  0.16 (propiconazole)  6.9\*10-2 (tebuconazole)  4.4\*10-4 (cypermethrin) | [kg] | O |
| Cumulative quantity of a substance, leached due to rainfall from stored treated wood, over a longer assessment period | *Qleachstorage,time2* | 7.0 (IPBC)  29 (propiconazole)  13 (tebuconazole)  8\*10-2 (cypermethrin) | [kg] | O |
| Local concentration in soil at storage place at the end of the initial assessment period | *Clocalsoil,time1* | 0.03 (IPBC)  0.13 (propiconazole)  0.06 (tebuconazole)  3.7\*10-4 (cypermethrin) | [mg/kgwwt] | O |
| Local concentration in soil at storage place at the end of a longer assessment period | *Clocalsoil,time2* | 5.95 (IPBC)  24.13 (propiconazole)  10.58 (tebuconazole)  0.07 (cypermethrin) | [mg/kgwwt] | O |
| Local emission rate in surface water resulting from leaching from stored treated wood due to rain run-off, over the initial assessment period | *Elocalsurfacewater,time1* | 6.5\*10-4 (IPBC)  2.6\*10-3 (propiconazole)  1.2\*10-3 (tebuconazole)  7.3\*10-6 (cypermethrin) | [kg/d] | O |
| Local emission rate in surface water resulting from leaching from stored treated wood due to rain run-off, over a longer assessment period | *Elocalsurfacewater,Time2* | 6.5\*10-4 (IPBC)  2.6\*10-3 (propiconazole)  1.2\*10-3 (tebuconazole)  7.3\*10-6 (cypermethrin) | [kg/d] | O |
| Local concentration in surface water over the initial assessment period | *Clocalsurfacewater,time1* | 0.03 (IPBC)  0.10 (propiconazole)  0.04 (tebuconazole)  2.8\*10-4 (cypermethrin) | [µg/L] | O |
| Local concentration in surface water over a longer assessment period | *Clocalsurfacewater,time2* | 2.5\*10-2 (IPBC)  0.10 (propiconazole)  4.4\*10-2 (tebuconazole)  2.8\*10-4 (cypermethrin) | [µg/L] | O |

Calculations (IPBC used as an example)

Vsoil = *AREAstorage \* DEPTHsoil*

Vsoil = 700 \* 0.5

Vsoil = 350 m3

As the leaching behaviour for this product is described by a linear function for the first year of exposure the FLUXstorage,dipp can be estimated by using the Q\*leach, time 1 value from the leaching study (se section 3.3.2.3) for both Time 1 and 2 estimation.

*FLUXstorage,dipp = Q\*leachtime1/Time1*

*FLUXstorage,dipp = 5.04 / 30*

*FLUXstorage,dipp =* 1.7\*10-7 [kg/m2/d]

*Qleachstorage,time1 = FLUXstorage,dipp \* AREAwood-expo \*AREAstorage \* Time 1*

*Qleachstorage,time1 = 1.7\*10-7 \* 11 \* 700 \* 30*

*Qleachstorage,time1 =* 0.039 [kg]

*Clocalsoil,time1 = (Qleachstorage,time1 \* (1 – Frunoff)) / (Vsoil \* RHOsoil)*

*Clocalsoil,time1* = 0.039 \* (1 – 0.5)) / (350 \* 1700)

*Clocalsoil,time1 =* 0.033 [mg/kgwwt]

*Elocalsurfacewater,time1 =* (*Qleachstorage,time1 \* Frunoff)) / Time 1*

*Elocalsurfacewater,time1 =* (0.039 \* 0.5) / 30

*Elocalsurfacewater,time1 =* 0.00065 [kg/d]

*Clocalsurfacewater,time1 = Elocalsurfacewater,time1 / FLOWsurfacewater*

*Clocalsurfacewater,time1 =* (0.00065 */* 0.3) \* 11.57 (conversion factor for transforming m3/s into L/d and kg/d into µg/d)

*Clocalsurfacewater,time1 =* 0.025 [µg/L]

In a second tier removal processes in soil were taking into account as described for the House scenario.

Table 2.2‑5: Concentration in soil and in pore-water from storage after industrial dipping taking removal into account.

| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** |
| --- | --- | --- | --- | --- |
| Local concentration in soil at storage place at the end of the initial assessment period | *Clocalsoil,time1* | 3.2\*10-5 (IPBC)  0.12 (propiconazole)  0.05 (tebuconazole)  2.1\*10-4 (cypermethrin) | [mg/kgwwt] | O |
| Local concentration in soil at storage place at the end of a longer assessment period | *Clocalsoil,time2* | 3.3\*10-5 (IPBC)  0.82 (propiconazole)  0.21 (tebuconazole)  3.0\*10-4 (cypermethrin) | [mg/kgwwt] | O |
| Average concentrations in pore water over the initial assessment period (30d) | Clocalpore,time1 | 13.9 (IPBC)  7.9 (propiconazole)  3.3 (tebuconazole)  3.7\*10-5 (cypermethrin) | [µg.L-1] | O |
| Average concentration in pore water over a longer  duration (1825d) | Clocalpore,time2 | 2541 (IPBC)  1438 (propiconazole)  600 (tebuconazole)  0.01 (cypermethrin) | [µg.L-1] | O |

The average concentration in the pore water can be calculated as:

Clocalpore,time1 = Clocalsoil,time1 \* RHOsoil / ksoil-water

Clocalpore,time1 = 3.3\*10-2 \* 1700 / 3.98

Clocalpore,time1 = 13.93 µg.L-1

##### Emission from in-situ treatments

For the *in situ* brushing application the following scenarios were considered:

* House (ESD 4.2.4.1)
* Fence (ESD 4.2.4.2)
* Bridge over Pond (ESD 4.2.4.3)

For the *in-situ* spraying application the House scenario for outdoor spraying was used (ESD 4.4.5).

Default values and formula are taken from the Revised Emission Scenario Document for Wood Preservatives (ESD) and the Technical Guidance Document (TGD).

For the applications foreseen, where a risk assessment is needed for this product the application rate of 200 g/m2 for preventive treatments is used. Indeed, as curative treatments are intended for the treatment of wood used in risk class 2, no emission into the environment is foreseen during the application or during the service life of the wood.

- *In-situ* brushing application

Table 2.2‑6: Calculations of emissions from *in-situ* brushing.

| Parameter/variable | Nomenclature | Value | Unit | Origin |
| --- | --- | --- | --- | --- |
| INPUTS | | | | |
| Treated wood area | AREAhouse  AREAfence  AREAbridge | 125  2  10 | [m2/d] | D |
| Application rate of the product | Qapplic,product | 0.200 | [kg/m²] | A |
| Content of active substance in the product | fa.i. | 0.05% IPBC  0.15% propiconazole  0.05% tebuconazole  0.07% cypermethrin | [%] | A |
| Density of product | RHOproduct | Not relevant | [kg/L] | A |
| Fraction of product lost to soil during application | Fsoil,brush | 0.03 (professional)  0.05 (non-professional) | [-] | D |
| Fraction of product lost to water during application | Fwater,brush | 0.03 (professional)  0.05 (non-professional) | [-] | D |
| Volume of contaminated water | Vwater bridge | 1000 | [m3] | D |
| Volume of contaminated soil | Vsoil house  Vsoil fence | 13  0.25 | [m3] | D |
| Bulk density of (wet) soil | RHOsoil | 1700 | [kgwwt.m-3] | D |
| OUTPUTS | | | | |
| Emission of active substance to soil during the day of application (house, professional application) | Esoil,brush | 3.8\*10-4 (IPBC)  1.1\*10-3 (propiconazole)  3.8\*10-4 (tebuconazole)  5.3\*10-4 (cypermethrin) | [kg/d] | O |
| Emission of active substance to soil during the day of application (house, non-professional application) | Esoil,brush | 6.3\*10-4 (IPBC)  1.9\*10-3 (propiconazole)  6.3\*10-4 (tebuconazole)  8.8\*10-4 (cypermethrin) | [kg/d] | O |
| Emission of active substance to soil during the day of application (fence, professional application) | Esoil,brush | 6.0\*10-6 (IPBC)  1.8\*10-5 (propiconazole)  6.0\*10-6 (tebuconazole)  8.4\*10-6 (cypermethrin) | [kg/d] | O |
| Emission of active substance to soil during the day of application (fence, non-professional application) | Esoil,brush | 1.0\*10-5 (IPBC)  3.0 \*10-5 (propiconazole)  1.0\*10-5 (tebuconazole)  1.4\*10-5 (cypermethrin) | [kg/d] | O |
| Emission of active substance to water during the day of application (Bridge, professional application) | Ewater,brush | 3.0\*10-5 (IPBC)  9.0\*10-5 (propiconazole)  3.0\*10-5 (tebuconazole)  4.2\*10-5 (cypermethrin | [kg/d] | O |
| Emission of active substance to water during the day of application (Bridge, non-professional application) | Ewater,brush | 5.0\*10-5 (IPBC)  1.5\*10-4 (propiconazole)  5.0\*10-5 (tebuconazole)  7.0\*10-5 (cypermethrin) | [kg/d] | O |
| Concentration in local soil at the end of the day of application (house, professional application) | Clocalsoil,brush | 1.7\*10-2 (IPBC)  5.1\*10-2 (propiconazole)  1.7\*10-2 (tebuconazole)  2.4\*10-2 (cypermethrin) | [mg/kgwwt] | O |
| Concentration in local soil at the end of the day of application (house, non-professional application) | Clocalsoil,brush | 2.8\*10-2 (IPBC)  8.5\*10-2 (propiconazole)  2.8\*10-2 (tebuconazole)  4.0\*10-2 (cypermethrin) | [mg/kgwwt] | O |
| Concentration in local soil at the end of the day of application (fence, professional application) | Clocalsoil,brush | 1.4\*10-2 (IPBC)  4.2\*10-2 (propiconazole)  1.4\*10-2 (tebuconazole)  2.0\*10-2 (cypermethrin) | [mg/kgwwt] | O |
| Concentration in local soil at the end of the day of application (fence, non-professional application) | Clocalsoil,brush | 2.4\*10-2 (IPBC)  7.1\*10-2 (propiconazole)  2.4\*10-2 (tebuconazole)  3.3\*10-2 (cypermethrin) | [mg/kgwwt] | O |
| Concentration in local water at the end of the day of application (bridge, professional application) | Clocalwater,brush | 3.0\*10-2 (IPBC)  9.0\*10-2 (propiconazole)  3.0\*10-2 (tebuconazole)  4.2\*10-2 (cypermethrin) | [µg/L] | O |
| Concentration in local water at the end of the day of application (bridge, non-professional application) | Clocalwater,brush | 5.0\*10-2 (IPBC)  0.15 (propiconazole)  5.0\*10-2 (tebuconazole)  5.0\*10-2 (cypermethrin) | [µg/L] | O |

D = default, A = based on information of applicant, O = output

Calculations (IPBC and non-professional application used as an example)

- House scenario:

Esoil,brush = AREAhouse \* Qapplic,product \* fa.i. \* Fsoil,brush

Esoil,brush = 125 \* 0.200 \* 0.05 \* 0.05 /100

Esoil,brush = 6.3\*10-4 kg/d

Clocalsoil,brush = Esoil,brush / (Vsoil \*RHOsoil)

Clocalsoil,brush = 0.00063 / (13 \* 1700)

Clocalsoil,brush = 2.8\*10-8 kg/kgwwt = 0.028 mg/kgwwt

- Fence scenario:

Esoil,brush = AREAfence \* Qapplic,product \* fa.i. \* Fsoil,brush

Esoil,brush = 2 \* 0.200 \* 0.05 \* 0.05 /100

Esoil,brush = 1.0\*10-5 kg/d

Clocalsoil,brush = Esoil,brush / (Vsoil \*RHOsoil)

Clocalsoil,brush = 0.00001 / (0.25 \* 1700) \* 106 (mg/kg conversion factor)

Clocalsoil,brush =2.4\*10-8 kg/kgwwt = 0.024 mg/kgwwt

- Bridge over pond scenario:

Ewater,brush = AREAbridge \* Qapplic,product \* fa.i. \* Fwater,brush

Ewater,brush = 10 \* 0.200 \* 0.05 \* 0.05 / 100

Ewater,brush = 5.0\*10-5 kg/d

Clocalwater,brush = Ewater,brush /Vwater

Clocalwater,brush = 0.00005 / 1000

Clocalwater,brush = 5\*10-8 mg/m3 = 0.05 µg/L

- *In-situ* spraying application

Table 2.2‑7: Calculations of emissions from *in situ* spraying, house

| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** |
| --- | --- | --- | --- | --- |
| **INPUTS** | | | | |
| Treated wood area | AREAhouse | 125 | [m2/d] | D |
| Application rate of the product | Qapplic,product | 0.200 | [kg/m²] | A |
| Content of active substance in the product | fa.i. | 0.05 % IPBC  0.15 % propiconazole  0.05 % tebuconazole  0.07 % cypermethrin | [%] | A |
| Density of product | RHOproduct | - | [kg/L] | A |
| Fraction of product lost to soil during application  by spray drift | Fdrift | 0.1 | [-] | D |
| Fraction of product lost to soil during application  by run-off | Frunoff | 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) | Fdep | 0.33 | [-] | D |
| Run-off: Soil volume adjacent to treated surface  Drift: volume to which deposition occurs in tier 1 | Vsoil,runoff , drift- tier1 | 13 | [m3] | D |
| Drift: volume to which deposition occurs in tier 2 | Vsoil,drift-tier2 | 15 | [m3] | D |
| Bulk density of (wet) soil | RHOsoil | 1700 | [kgwwt.m-3] | D |
| **OUTPUTS** | | | | |
| Emission of active substance to soil during the day of application by runoff (tier 1) | Esoil,runoff tier 1 | 2.5\*10-3 (IPBC)  7.5\*10-3 (propiconazole)  2.5\*10-3 (tebuconazole)  3.5\*10-3 (cypermethrin) | [kg/d] | O |
| Emission of substance to soil during the day of application by spray drift (tier 1) | *Esoil,spray\_drift\_tier 1* | 1.3\*10-3 (IPBC)  3.8\*10-3 propiconazole)  1.3\*10-3 (tebuconazole)  1.8\*10-3 (cypermethrin) | [kg/d] | O |
| Emission of substance to soil during the day of application by spray drift (tier 2) | *Esoil,spray\_drift\_tier 2* | 3.6\*10-4 (IPBC)  1.1\*10-3 propiconazole)  3.6\*10-4 (tebuconazole)  5.0\*10-4 (cypermethrin) | [kg/d] | O |
| Concentration in local soil at the end of the day of application due to run-off (tier 1) | Clocalsoil,runoff tier 1 | 0.11 (IPBC)  0.34 (propiconazole)  0.11 (tebuconazole)  0.16 (cypermethrin) | [mg/kgwwt] | O |
| Concentration in local soil at the end of the day of application due to spray drift (tier 1) | Clocalsoil,spray\_drift\_tier 1 | 5.7\*10-2 (IPBC)  0.17 (propiconazole)  5.7\*10-2 (tebuconazole)  7.9\*10-2 (cypermethrin) | [mg/kgwwt] | O |
| Concentration in local soil at the end of the day of application due to spray drift (tier 2) | Clocalsoil,spray\_drift\_tier 2 | 1.6\*10-2 (IPBC)  4.9\*10-2 (propiconazole)  1.6\*10-2 (tebuconazole)  2.3\*10-2 (cypermethrin) | [mg/kgwwt] | O |
| Total concentration in local soil at the end of the day of application due to spray drift (tier 1) and run-off | Clocalsoil,total tier 1 | 0.17 (IPBC)  0.51 (propiconazole)  0.17 (tebuconazole)  0.24 (cypermethrin) | [mg/kgwwt] | O |
| Total concentration in local soil at the end of the day of application due to spray drift (tier 2) and run-off | Clocalsoil,total tier 2 | 1.6\*10-2 (IPBC)  4.9\*10-2 (propiconazole)  1.6\*10-2 (tebuconazole)  2.3\*10-2 (cypermethrin) | [mg/kgwwt] | O |

D = default, A = based on information of applicant, O = output

Calculations (IPBC used as an example):

Esoil,runoff tier 1 = AREAhouse \* Qapplic,product \* fa.i. \* Frunoff

Esoil,runoff tier 1 = 125 \* 0.200 \* 0.05/100 \* 0.2

Esoil,runoff tier 1 = 2.5\*10-3 kg/d

Esoil,spray\_drift\_tier1 = AREAhouse \* Qapplic,product \* fa.i. \* Fdrift

Esoil,spray\_drift\_tier1 = 125 \* 0.200 \* 0.05/100 \* 0.1

Esoil,spray\_drift\_tier1 = 1.3\*10-3 kg/d

Esoil,spray\_drift\_tier2 = AREAhouse \* Qapplic,product \* fa.i. \* Fdrift \* Fdep

Esoil,spray\_drift\_tier2 = 125 \* 0.200 \* 0.05/100 \* 0.1 \* 0.33

Esoil,spray\_drift\_tier2 = 3.6\*10-4 kg/d

Clocalsoil,runoff tier 1 = Esoil,runoff / (Vsoil,runoff , drift- tier1 \*RHOsoil)

Clocalsoil,runoff tier 1 = 0.0025 / (13 \* 1700)

Clocalsoil,runoff tier 1 = 1.13\*10-7 kg/kgwwt = 0.11mg/kgwwt

Clocalsoil,spray\_drift\_tier 1 = Esoil,spray\_drift\_tier1 / (Vsoil,runoff , drift- tier1 \*RHOsoil)

Clocalsoil,spray\_drift\_tier 1 = 0.0013 / (13 \* 1700)

Clocalsoil,spray\_drift\_tier 1 = 5.7\*10-8 kg/kgwwt = 5.7\*10-2mg/kgwwt

Clocalsoil,spray\_drift\_tier 2 = Esoil,spray\_drift\_tier2 / (Vsoil,drift-tier2 \*RHOsoil)

Clocalsoil,spray\_drift\_tier 2 = 0.00041 / (15 \* 1700)

Clocalsoil,spray\_drift\_tier 2 = 1.6\*10-8 kg/kgwwt = 1.6\*10-2mg/kgwwt

*Clocalsoil,total tier 1* = Clocalsoil,runoff tier 1 + Clocalsoil,spray drift\_tier 1

*Clocalsoil,total tier 1* = 0.11 + 0.06 = 0.17 mg/kgwwt

##### Emissions from treated wood in-service

As basis for the calculations of emissions from treated wood in service, a semi-field leaching study according to NT Build 509 (2005): *Leaching of Active Ingredients from Preservative-Treated Timber – Semi-Field Testing* was conducted (see study summary in IUCLID Section 10.3).

In this study, cypermethrin was not detected at any sampling occasions. At all sample occasions, cypermethrin was below the limit of quantification of 0.01 µg/mL. This value was used as input for the leaching estimation for the long-term assessment period and must be considered a worst-case approach.

The leaching study was performed with an average application rate of 301.5 g/m2 in order to cover all possible application scenarios. In fact the dose of 300 g/m² is for curative treatment which is only done for risk class 2 woods (no emission foreseen). The dose of 200 g/m² is used for preventive treatments indoors and outdoors. Thus, considering the applications foreseen, the risk assessment is done at the dose of 200 g/m2. Therefore, the leaching data obtained is multiplied by this factor:

Fapplic rate = 200 / 301.5 = 0.663.

Both IPBC and the major metabolite, PBC, were measured. The content of PBC in the leachate was transformed to the corresponding concentration of IPBC, so the total concentration of IPBC in each sample was calculated by this formula:

[Total IPBC] = [IPBC] + [molar mass of IPBC] / [molar mass of PBC] × [PBC]

[Total IPBC] = [IPBC] + 281.09/155.19 × [PBC]

In the following IPBC is used as an example. The calculations are based on 700 mm of rain per year. The best curve fit for all four active substances with the data available so far is a linear function (Q\*leach,time = a\*t + b), given r2 values between 0.97 and 0.99.

Time 1 = 30 days is calculated as follows:

Q\*leach time 1 is determined based on a linear regression of the first six data points:

Q\*leach time 1 = 0.0077 \* [time] + 7.3643.

Inserting time = 30 days gives:

Q\*leach time 1 = 7.595 mg/m2.

The daily flux between 0 and 30 days is 7.595/30 = 0.253 mg/m2/day.

Then a new linear regression between zero and Q\*leach time 1 is performed and this equation is used to determine Q\*leach time 1 taken the reduced application rate into account:

Q\*leach time 1 = 0.253 \* [time] \* Fapplic rate

Q\*leach time 1 = 0.253 \* 30 \* 0.663

Q\*leach time 1 = 5.04 mg/m2.

Time 2 = 1825 days is calculated based on a linear regression of the first six data points taken the reduced application rate into account:

Q\*leach time 2 = (0.0077 \* [time] + 7.3643) \* Fapplic rate

Q\*leach time 2 = (0.0077 \* 1825 + 7.3643) \* 0.663

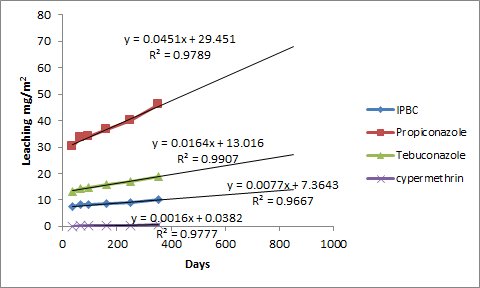
Q\*leach time 2 = 14.20 mg/m2.

Time 2 = 5475 days is calculated based on a linear regression of the first six data points taken the reduced application rate into account:

Q\*leach time 2 = (0.0077 \* [time] + 7.3643) \* Fapplic rate

Q\*leach time 2 = (0.0077 \* 5475 + 7.3643) \* 0.663

Q\*leach time 2 = 32.85 mg/m2.



*Figure 1: Linear regression of the leaching data*

###### House scenario, in-service of industrial treated wood

Table 2.2‑8: Calculation of emissions from treated house in-service.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| **INPUTS** | | | | | |
| Leachable wood area | AREAhouse | 125 | [m²/d] | 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 (30d) | Q\*leach, time 1 | 5.04 (IPBC)  20.44 (propiconazole)  8.96 (tebuconazole)  0.06 (cypermethrin) | [mg.m-2] | A |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the longer assessment period (5475d) | Q\*leach, time 2 | 32.98 (IPBC)  183.34 (propiconazole)  68.30 (tebuconazole)  5.84 (cypermethrin) | [mg.m-2] | A |
| Volume of (wet) soil | Vsoil | 13 | [m3] | D |
| Bulk density of (wet) soil | RHOsoil | 1700 | [kg.m-3] | D |
| **OUTPUT EMISSIONS** | | | | | |
| Cumulative quantity of active substance, leached over the initial assessment period (30d) | Qleach, time 1 | 630 (IPBC)  2554 (propiconazole)  1120 (tebuconazole)  7.1 (cypermethrin) | [mg] | O |
| Cumulative quantity of active substance, leached over the longer assessment period (5475d) | Qleach, time 2 | 4107 (IPBC)  22918 (propiconazole)  8525 (tebuconazole)  730 (cypermethrin) | [mg] | O |
| Concentration in local soil at the end of the initial assessment period (30d) | Clocalsoil,leach,time1 | 2.8\*10-2 (IPBC)  0.12 (propiconazole)  0.05 (tebuconazole)  3.2\*10-4 (cypermethrin) | [mg.kgwwt-1] | O |
| Concentration in local soil at the end of the longer assessment period (5475d) | Clocalsoil,leach,time2 | 0.19 (IPBC)  1.04 (propiconazole)  0.39 (tebuconazole)  0.03 (cypermethrin) | [mg.kgwwt-1] | O |

D=default, A=based on information of applicant, O=output

Calculations (IPBC used as an example):

Qleach, time1 = AREAhouse \* Q\*leach, time1

Qleach, time1 = 125 \* 5.04

Qleach, time1 = 630 mg

Qleach, time2 = AREAhouse \* Q\*leach, time2

Qleach, time2 = 125 \* 32.98

Qleach, time2 = 4107 mg

Clocalsoil,leach, time1 = Qleach, time1/ (Vsoil \*RHOsoil)

Clocalsoil,leach, time1= 630 / (13 \* 1700)

Clocalsoil,leach, time1= 0.0285 mg/kgwwt

Clocalsoil,leach, time2 = Qleach, time2 / (Vsoil \*RHOsoil)

Clocalsoil,leach, time2 = 4107 / (13 \* 1700)

Clocalsoil,leach, time2 = 0.19 mg/kgwwt

###### Fence scenario, in-service of industrial treated wood

Table 2.2‑9: Calculation of emissions from treated fence in-service.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| **INPUTS** | | | | |
| Leachable wood area | AREAfence | 2 | [m²/d] | 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 (30d) | Q\*leach, time 1 | 5.04 (IPBC)  20.44 (propiconazole)  8.96 (tebuconazole)  0.06 (cypermethrin) | [mg.m-2] | A |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the longer assessment period (5475d) | Q\*leach, time 2 | 32.98 (IPBC)  183.34 (propiconazole)  68.30 (tebuconazole)  5.84 (cypermethrin) | [mg.m-2] | A |
| Volume of (wet) soil | Vsoil | 0.25 | [m3] | D |
| Bulk density of (wet) soil | RHOsoil | 1700 | [kg.m-3] | D |
| **OUTPUT EMISSIONS** | | | | |
| Cumulative quantity of active substance, leached over the initial assessment period (30d) | Qleach, time 1 | 10.08 (IPBC)  40.87 (propiconazole)  17.92 (tebuconazole)  0.11 (cypermethrin) | [mg] | O |
| Cumulative quantity of active substance, leached over the longer assessment period (5475d) | Qleach, time 2 | 65.70 (IPBC)  366.69 (propiconazole)  136.40 (tebuconazole)  11.67 (cypermethrin) | [mg] | O |
| Concentration in local soil at the end of the initial assessment period (30d) | Clocalsoil,leach,time 1 | 0.02 (IPBC)  0.10 (propiconazole)  0.04 (tebuconazole)  2.7\*10-4 (cypermethrin) | [mg.kgwwt-1] | O |
| Concentration in local soil at the end of the longer assessment period (5475d) | Clocalsoil,leach,time 2 | 0.15 (IPBC)  0.86 (propiconazole)  0.32 (tebuconazole)  2.7\*10-2 (cypermethrin) | [mg.kgwwt-1] | O |

D=default, A=based on information of applicant, O=output

Calculations (IPBC used as an example):

Qleach, time1 = AREAfence \* Q\*leach, time1

Qleach, time1 = 2 \* 5.04

Qleach, time1 = 10.08 mg

Qleach, time2 = AREAfence \* Q\*leach, time2

Qleach, time2 = 2 \* 32.98

Qleach, time2 = 65.70 mg

Clocalsoil,leach, time1 = Qleach, time1 / (Vsoil \*RHOsoil)

Clocalsoil,leach, time1= 10.08 / (0.25 \* 1700)

Clocalsoil,leach, time1= 2.4\*10-2 mg/kgwwt

Clocalsoil,leach, time2 = Qleach, time2 / (Vsoil \*RHOsoil)

Clocalsoil,leach, time2 = 65.70 / (0.25 \* 1700)

Clocalsoil,leach, time2 = 0.15 mg/kgwwt

###### Noise Barrier scenario, in-service of industrial treated wood

Table 2.2‑10: Calculation of emissions from treated noise barrier in-service.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** |
| **INPUTS** | | | | | |
| Leachable wood area | AREAnoise-barrier | 3000 | [m²/d] | 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 (30d) | Q\*leach, time 1 | 5.04 (IPBC)  20.44 (propiconazole)  8.96 (tebuconazole)  0.06 (cypermethrin) | [mg.m-2] | A |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the longer assessment period (5475d) | Q\*leach, time 2 | 32.98 (IPBC)  183.34 (propiconazole)  68.30 (tebuconazole)  5.84 (cypermethrin) | [mg.m-2] | A |
| Volume of (wet) soil | Vsoil | 250 | [m3] | D |
| Bulk density of (wet) soil | RHOsoil | 1700 | [kg.m-3] | D |
| Fraction released to soil | Fsoil | 0.3 | [-] | D |
| Fraction released to the STP | FSTP | 0.7 | [-] | D |
| **OUTPUT EMISSIONS** | | | | | |
| Cumulative quantity of active substance, leached over the initial assessment period (30d) | Qleach, time 1 | 4536 (IPBC)  18296 (propiconazole)  8065 (tebuconazole)  51 (cypermethrin) | [mg] | O |
| Cumulative quantity of active substance, leached over the longer assessment period (5475d) | Qleach, time 2 | 29567 (IPBC)  165010 (propiconazole)  61381 (tebuconazole)  5253 (cypermethrin) | [mg] | O |
| Concentration in local soil at the end of the initial assessment period (30d) | Clocalsoil,leach ,time 1 | 0.01 (IPBC)  0.04 (propiconazole)  0.02 (tebuconazole)  1.2\*10-4 (cypermethrin) | [mg.kgwwt-1] | O |
| Concentration in local soil at the end of the longer assessment period (5475d) | Clocalsoil,leach, time 2 | 0.07 (IPBC)  0.39 (propiconazole)  0.14 (tebuconazole)  0.01 (cypermethrin) | [mg.kgwwt-1] | O |
| Local daily emission rate to the STP following leaching from treated wood during the initial  assessment period | *ESTP,time1* | 352.8 (IPBC)  1431 (propiconazole)  627 (tebuconazole)  4.0 (cypermethrin) | [mg.d-1] | O |
| Local daily emission rate to the STP following leaching from treated wood during the longer  assessment period | *ESTP,time2* | 12.6 (IPBC)  70.3 (propiconazole)  26.2 (tebuconazole)  2.24 (cypermethrin) | [mg.d-1] | O |
| Local concentration in STP water over the initial assessment period (30d) without removal | Clocalinf time1 | 0.18 (IPBC)  0.72 (propiconazole)  0.31 (tebuconazole)  1.0\*10-3 (cypermethrin) | [µg.L-1] | O |
| Local concentration in STP water over a longer assessment period (5475d) without removal | Clocalinf, time2 | 0.01 (IPBC)  0.03 (propiconazole)  0.01 (tebuconazole)  1.1\*10-3 (cypermethrin) | [µg.L-1] | O |

D=default, A=based on information of applicant, O=output

Calculations (IPBC used as an example):

Emission to soil:

Qleach, time 1 = AREAnoise-barrier \* Fsoil \* Q\*leach, time 1

Qleach, time 1 = 3000 \* 0.3 \* 5.04

Qleach, time 1 = 4536 [mg]

Clocalsoil,leach,time 1 = Qleach, time 1 / (Vsoil \* RHOsoil)

Clocalsoil,leach,time 1 = 4536 / 250 \* 1700

Clocalsoil,leach,time 1 = 0.011 [mg/kgwwt-1]

Emission to STP:

*ESTP,time1 =* AREAnoise-barrier \* FSTP \* Q\*leach, time 1 / TIME1

*ESTP,time1 =* 3000 \* 0.7 \* 5.04 / 30

*ESTP,time1* = 352.8 [mg/d]

The influent to the STP can be calculated based on the model calculations in EUSES:

EFFLUENTlocal stp=Nlocal\*Qstp (Eq 651 EUSES 2.1)

Nlocal = 10.000 eq (Tabel III-192 EUSES 2.1)

Qstp = 0.2 [m3.eq-1.d-1] (Tabel III-192 EUSES 2.1)

EFFLUENTlocalSTP = Nlocal \* QSTP

EFFLUENTlocalSTP = 0.2 \* 10000

EFFLUENTlocalSTP = 2000 [m3/d]

Clocalinf = *ESTPtime1 /* EFFLUENTlocalSTP (Eq 649 EUSES 2.1)

Clocalinf time1 = 352.8 / 2000

Clocalinf time1 = 0.18 [µg/L]

###### Bridge over Pond scenario, in-service of industrial treated wood

Table 2.2‑11: Calculation of emissions from treated bridge over pond in-service.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** |
| **INPUTS** | | | | |
| Leachable wood area | AREAbridge | 10 | [m²/d] | 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 (30d) | Q\*leach, time 1 | 5.04 (IPBC)  20.44 (propiconazole)  8.96 (tebuconazole)  0.06 (cypermethrin) | [mg.m-2] | A |
| Cumulative quantity of active substance, leached out of 1 m² of treated wood over the longer assessment period (5475d) | Q\*leach, time 2 | 32.98 (IPBC)  183.34 (propiconazole)  68.30 (tebuconazole)  5.84 (cypermethrin) | [mg.m-2] | A |
| Water volume under bridge | Vwater | 1000 | [m3] | D |
| **OUTPUT EMISSIONS** | | | | |
| Cumulative quantity of active substance, leached over the initial assessment period (30d) | Qleach, time 1 | 50.4 (IPBC)  204.4 (propiconazole)  89.6 (tebuconazole)  0.6 (cypermethrin) | [mg] | O |
| Cumulative quantity of active substance, leached over the longer assessment period (5475d) | Qleach, time 2 | 329.8 (IPBC)  1833.4 (propiconazole)  683.0 (tebuconazole)  58.4 (cypermethrin) | [mg] | O |
| Concentration in local water at the end of the initial assessment period (30d) | Clocalwater leach,time1 | 0.05 (IPBC)  0.02 (propiconazole)  0.09 (tebuconazole)  5.7\*10-4 (cypermethrin) | [µg.L-1] | O |
| Concentration in local water at the end of the longer assessment period (5475d) | Clocalwater,leach,time 2 | 0.33 (IPBC)  1.83 (propiconazole)  0.68 (tebuconazole)  0.06 (cypermethrin) | [µg.L-1] | O |

D=default, A=based on information of applicant, O=output

Calculations (IPBC used as an example):

Qleach, time1 = AREAbridge \* Q\*leach, time1

Qleach, time1 = 10 \* 5.04

Qleach, time1 = 50.4 mg

Qleach, time2 = AREAbridge \* Q\*leach, time2

Qleach, time2 = 10 \* 32.98

Qleach, time2 = 329.8 mg

Clocalwater,leach, time1 = Qleach, time1/ Vwater

Clocalwater,leach, time1= 50.4 / 1000

Clocalwater,leach, time1= 0.05 mg/m3 = 0.05 µg.L-1

Clocalwater,leach, time2 = Qleach, time2 / Vwater

Clocalwater,leach, time2 = 329.8 / 1000

Clocalwater,leach, time2 = 0.330 mg/m3 = 0.33 µg.L-1

###### House scenario, in-service of in-situ treated wood

The emissions to soil from treated wood in service following *in-situ* treatment are calculated according to the equations provided for the house scenario.

###### Fence scenario, in-service of in-situ treated wood

The emissions to soil from treated wood in service following *in-situ* treatment are calculated according to the equations provided for the house scenario.

###### Bridge over Pond scenario, in-service of in-situ treated wood

The emissions to soil from treated wood in service following *in-situ* treatment are calculated according to the equations provided for the house scenario.

###### Spraying scenario (House), in-service of in-situ treated wood

The emissions to soil from treated wood in service following spraying application, are calculated according to the equations provided for the house scenario.

##### Emissions from industrial treated wood in service taken removal into account

For industrially pre-treated wood, emissions during application do not end up in the same compartment as during service-life of the treated wood. It is consequently not necessary to sum up the emissions from application phase and service-life. In this section removal during service-life is considered for house, fence, noise barrier and bridge over pond for industrial treated wood.

For the calculation of concentrations in pore water the soil-water partitioning coefficients are used.

For the calculation of concentrations in soil and in pore water taken removal into account the first order rate constants for removal from soil are used.

The resulting concentrations in soil and pore water taking into account removal processes over Time1 (30 days) and Time2 (1825 days) are presented below:

Table 2.2‑12: Soil-water partitioning coefficients and first order rate constants for removal from soil.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Soil-water partitioning coefficients | *K*soil-water | 3.98 (IPBC)  29 (propiconazole)  30 (tebuconazole)  17231 (cypermethrin) | [m3. m-3] | S |
| First order rate constants for removal from soil | *k* | 3.54 (IPBC)  5.3\*10-3 (propiconazole)  9.0\*10-3 (tebuconazole)  4.0\*10-2 (cypermethrin) | [d-1] | S |

where:

**Ksoil-water** = Fairsoil \* Kair-soil + Fwater soil + Fsolidsoil \* Kpsoil \* RHOsolid / 1000 (Eq. 24 TGD)

Table 2.2‑13: Default values from TGD.

|  |  |  |
| --- | --- | --- |
| Symbol | Value | Unit |
| Fairsoil | 0.2 | [mair3.msoil-3] |
| Fwater soil | 0.2 | [mwater3.msoil-3] |
| Fsolidsoil | 0.6 | [msolid3.msoil-3] |
| R | 8.314 | [Pa·m3·mol-1] |
| Temp | 285 | [K[ |
| Focsoil | 0.02 | [kg/kg] |
| Koc | 126 | [L/kg] |
| RHOsolid | 2500 | [kgsolid.msolid-3] |

Example for IPBC:

Ksoil-water = Fairsoil \* Henry / R \* Temp+ Fwater soil + Fsolidsoil \* Focsoil \* Koc \* RHOsolid / 1000

Ksoil-water = 0.2 \* 0.00645 / 8.314 \* 285 + 0.2 + 0.6 \* 0.02 \* 126 \* 2500 /1000

Ksoil-water = 3.98 m3/m3.

###### House scenario, concentrations from in-service of industrial treated wood with removal

In a second tier, soil and pore-water concentrations taking removal into account were calculated. In the ESD, section 3.4.1.2, a model is described to estimate the time dependent concentration in soil based on a single emission during application followed by an average leaching rate from the wood in service. When *in-situ* application is used equation 3.7 and 3.8 are recommended.

The use of other models for higher tier estimation is also suggested in the ESD (paragraph 54).

In the TGD, section 2.3.8.5, a general model for removal processes is described. This model is derived from pesticide use in the agriculture and describes the *in-situ* application of biocides:

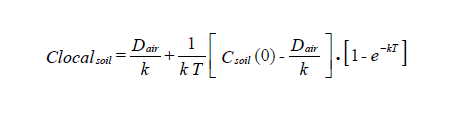
                    (Eq. 53 TGD)

Setting Dair = 0 implies that all the biocide is degraded in the soil. This is a worst-case assumption. Then eq. 53 TGD is reduced to:

This equation can be used to describe the removal process of the biocides applied *in-situ*:

Clocalsoil,brush rem= Clocalsoil,brush \* e-kt

During service life, the emission to the soil is described by a constant flux, so an average concentration over a certain time period can be assumed, consequently the average concentration over that time period can be estimated by the following equation:

(Eq. 55 TGD)

Dair = 0 will reduce eq. 55 to:

The combined concentration in soil taken removal processes into account can be described by the following equation:

Clocalsoil,total, rem (t)= Clocalsoil,brush rem +

Clocalsoil,total, rem (t)= Clocalsoil,brush \* e-kt + (Clocalsoil (t) / kt)\*(1- e-k t)

where:

k = ln2 / DT50soil

Clocalsoil,brush: the *in-situ* concentration in soil at the day of application.

Clocalsoil in service (t): the average concentration in the soil during the assessment period.

Table 2.2‑14: Concentration in soil and pore-water, in-service of industrial treated wood (house) taking removal into account.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomencla­ture | Value | Unit | Origin |
| **OUTPUT EMISSION** | | | | |
| Average concentrations in soil over the initial assessment period (30d) | Clocalsoil,total, time1 | 2.8\*10-5 (IPBC)  0.11 (propiconazole)  0.04 (tebuconazole)  1.8\*10-4 (cypermethrin) | [mg.kgwwt-1] | O |
| Average concentrations in soil over a longer  duration (5475d) | Clocalsoil total, time2 | 8.6\*10-7 (IPBC)  0.03 (propiconazole)  0.01 (tebuconazole)  1.5\*10-4 (cypermethrin) | [mg.kgwwt-1] | O |
| Average concentrations in pore water over the initial assessment period (30d) | Clocalpore,time1 | 0.01 (IPBC)  6.35 (propiconazole)  2.51 (tebuconazole)  1.8\*10-5 (cypermethrin) | [µg.L-1] | O |
| Average concentration in pore water over a longer  duration (5475d) | Clocalpore,time2 | 3.7\*10-4 (IPBC)  1.87 (propiconazole)  0.39 (tebuconazole)  1.4\*10-5 (cypermethrin) | [µg.L-1] | O |

Calculations (IPBC used as an example):

The average concentration in the pore water can be calculated as (equation 3.9 of the ESD):

Clocalpore,time1 = Clocalsoil,total, time1 \* RHOsoil / Ksoil-water

Clocalpore,time1 = 2.8\*10-5 \* 1700 / 3.98

Clocalpore,time1 = 0.01 µg/L

###### Fence scenario, concentrations from in-service of industrial treated wood with removal

The same calculations as for the house scenario were performed for the fence scenario.

Table 2.2‑15: Concentration in soil and pore-water, in-service of industrial treated wood (Fence) taking removal into account.

| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** |
| --- | --- | --- | --- | --- |
| **OUTPUT EMISSION** | | | | |
| Average concentrations in soil over the initial assessment period (30d) | Clocalsoil,total, rem time1 | 2.4\*10-5 (IPBC)  0.09 (propiconazole)  0.04 (tebuconazole)  1.5\*10-4 (cypermethrin) | [mg.kgwwt-1] | O |
| Average concentrations in soil over a longer  duration (5475d) | Clocalsoil,total, rem, time2 | 7.2\*10-7 (IPBC)  2.6\*10-2 (propiconazole)  5.7\*10-3 (tebuconazole)  1.4\*10-4 (cypermethrin) | [mg.kgwwt-1] | O |
| Average concentrations in pore water over the initial assessment period (30d) | Clocalpore,time1 | 0.01 (IPBC)  5.28 (propiconazole)  2.09 (tebuconazole)  1.5\*10-5 (cypermethrin) | [µg.L-1] | O |
| Average concentration in pore water over a longer  duration (5475d) | Clocalpore,time2 | 3.1\*10-4 (IPBC)  1.56 (propiconazole)  0.32 (tebuconazole)  1.2\*10-5 (cypermethrin) | [µg.L-1] | O |

Calculations (IPBC and non-professional application used as an example):

The average concentration in the pore water can be calculated as:

Clocalpore,time1 = Clocalsoil,total, rem time1 \* RHOsoil / ksoil-water

Clocalpore,time1 = 2.4\*10-5 \* 1700 / 3.98

Clocalpore,time1 = 0.01 µg.L-1

###### Noise Barrier scenario, concentrations from in-service of industrial treated wood with removal

The same calculations as for the house scenario were performed for the noise barrier scenario.

Table 2.2‑16: Concentration in soil from in-service of industrial treated wood (Noise Barrier) taken removal into account.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** |
| **OUTPUT EMISSION** | | | | |
| Average concentrations in soil over the initial assessment period (30d) | Clocalsoil,leach ,time 1 | 1.1\*10-5 (IPBC)  0.04 (propiconazole)  0.02 (tebuconazole)  6.9\*10-5 (cypermethrin) | [mg.kgwwt-1] | O |
| Average concentrations in soil over a longer  duration (5475d) | Clocalsoil,leach ,time 2 | 3.2\*10-7 (IPBC)  1.2\*10-2 (propiconazole)  2.5\*10-3 (tebuconazole)  5.5\*10-5 (cypermethrin) | [mg.kgwwt-1] | O |
| Average concentrations in pore water over the initial assessment period (30d) | Clocalpore,time1 | 4.5\*10-3 (IPBC)  2.38 (propiconazole)  0.94 (tebuconazole)  6.8\*10-6 (cypermethrin) | [µg.L-1] | O |
| Average concentration in pore water over a longer  duration (5475d) | Clocalpore,time2 | 1.4\*10-4 (IPBC)  0.70 (propiconazole)  0.14 (tebuconazole)  5.4\*10-6 (cypermethrin) | [µg.L-1] | O |

Calculations (IPBC used as an example):

The average concentration in the pore water can be calculated as:

Clocalpore,time1 = Clocalsoil leach time1 \* RHOsoil / ksoil-water

Clocalpore,time1 = 1.1\*10-5 \* 1700 / 3.98

Clocalpore,time1 = 4.5\*10-3 µg.L-1

###### Bridge over pond scenario, concentrations from in-service of industrial treated wood with removal

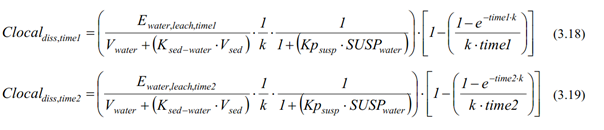
In a second tier, concentrations in water taking removal into account were calculated based on the model described in section 3.4.2.1 of the revised ESD (equation 3.18 and 3.19).

For releases into a static water body, the removal from the water column due to adsorption onto sus­pended matter and into sediment can be significant. To take this phenomenon into account, equation 3.18 and 3.19 of the ESD was adapted.

The resulting water concentrations taking into account removal processes over Time1 (30 days) and Time2 (5475 days) are presented below.

Table 2.2‑17: Concentration in surface water from in-service of industrial treated wood taking removal into account (bridge over pond).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Parameter/variable** | **Nomencla-ture** | **Value** | **Unit** | **Origin** |
| **INPUTS** | | | | |
| Volume of sediment compartment | Vsed | 1.5 | [m3] | D |
| Total sediment – water partitioning coefficients | Ksed-water | 3.95 (IPBC)  24.40 (propiconazole)  25.60 (tebuconazole)  14376 (cypermethrin) | [m3.m-3] | S |
| Concentrations of suspended matter in the surface water | SUSPwater | 15\*10-3 | [kg.m-3] | D |
| Solids-water partitioning coefficients for suspended matter | Kpsusp | 12.6\*10-3 (IPBC)  94.4\*10-3 (propiconazole)  99.2\*10-3 (tebuconazole)  57.5 (cypermethrin) | [mg.m-2] | O |
| **OUTPUT EMISSION** | | | | |
| Average concentrations in surface water over the initial assessment period (30d) | *Clocaldiss, time1* | 3.1\*10-4 (IPBC)  9.8\*10-2 (propiconazole)  4.2\*10-2 (tebuconazole)  4.8\*10-6 (cypermethrin) | [µg.L-1] | O |
| Average concentrations in surface water over a longer  duration (5475d) | *Clocaldiss, time2* | 1.1\*10-5 (IPBC)  3.9\*10-1 (propiconazole)  3.2\*10-2 (tebuconazole)  6.7\*10-6 (cypermethrin) | [µg.L-1] | O |



where:

Vsed = Vwater \* Depthsed / Depthpond.

Default depth of sediment: 3 mm; depth of pond: 2 m (ESD Jetty in the lake scenario).

Vsed = 1000 \* 0.003 / 2

Vsed = 1.5 [m3]

Ksed-water = Fwater sed + Fsolid sed \* Kpsed \* RHOsolid / 1000 (Eq. 24 TGD)

where:

Kpsed = Focsed \* Koc [L/kg]

Kpsusp = Focsusp \* Koc [m3/kg]

In equation 24, the following input was used:

Table 2.2‑18: Default values from TGD.

|  |  |  |
| --- | --- | --- |
| Symbol | Value | Unit |
| Fwater sed | 0.8 | [mwater3.msed-3] |
| Fsolid-sed | 0.2 | [msolid3.msed-3] |
| Focsed | 0.05 | [kg/kg] |
| Focsusp | 0.1 | [kg/kg] |
| Koc | 126 | [L/kg] |
| RHOsolid | 2500 | [kgsolid.msolid-3] |

Using IPBC as an example:

Ksed-water = 0.8 + 0.2 \* 0.05 \* 126 \* 2500 / 1000

Ksed-water = 3.95 [m3/m3]

*k* = ln2 / DT50 water

*Clocaldiss,time1* = (((1.6810-6 / (1000 + 3.95\*1.5)) \* (1/5.3663) \* (1 /(1 + (12.6\*103 \* 15\*10-3)) \* (1 - ((1 - e-30\*5.3663)/(5.3663\*30))

*Clocaldiss,time1* = 3.1\*10-4 [µg/L-1]

\* Combined concentrations in sediment

The combined concentrations in sediment were calculated according to the equilibrium partitioning method, based on formulas 18, 24 and 50 in the Technical Guidance Document on Risk Assessment (TGD):

Clocalsed,total, time1 = *K*susp-water \* Clocalwater,total, time1 \* 1000 / RHOsusp (Eq. 50)

where:

Ksusp-water = Fairsusp \* Kair-water + Fwater susp + Fsolidsusp \* Kpsusp \* RHOsolid / 1000 (Eq. 24)

In equation 24 the following input were used:

Table 2.2‑19: Default values from TGD.

|  |  |  |
| --- | --- | --- |
| Symbol | Value | Unit |
| Fairsusp | 0.2 | [mair3.msusp-3] |
| Fwater susp | 0.9 | [mwater3.msusp-3] |
| Fsolidsusp | 0.1 | [msolid3.msusp-3] |
| R | 8.314 | [Pa·m3·mol-1] |
| Temp | 285 | K |
| RHOsolid | 2500 | [kgsolid.msolid-3] |

Using IPBC and non-professional application with removal as an example:

Kair-water = Henry / (R \* Temp)

Kair-water = 6.45\*10-3 / 8.314 \* 285

Kair-water = 2.72\*10-6 m3/m3

Kpsusp = focsusp \* Kocsediment

Kpsusp = 0.1 \* 126

Kpsusp = 12.6 L/kg

RHOsusp = Fsolidsusp \* RHOsolid + Fwatersusp \* RHOwater + Fairsusp\* RHOair (Eq. 18)

RHOsusp = 0.1 \* 2500 + 0.9 \* 1000

RHOsusp = 1150 kg/m3

Ksusp-water = Fairsusp \* Kair-water + Fwater susp + Fsolidsusp \* Kpsusp \* RHOsolid / 1000

Ksusp-water = 0.2 \* 2.72\*10-6 + 0.9 + 0.1 \* 12.6 \* 2500 /1000

Ksusp-water = 4.05 m3/m3

Clocalsed,total, time1 = *K*susp-water \* Clocalwater,total, time1 \* 1000 / RHOsusp

Clocalsed,total, time1 = 4.05 \* 3.13\*10-5  / 1150

Clocalsed,total, time1 = 1.10\*10-7  mg/kgwwt

Table 2.2‑20: Concentration in sediment from in-service of industrial treated wood (bridge over pond) taking removal into account.

| **Parameter/variable** | **Nomencla-ture** | **Value** | **Unit** | **Origin** |
| --- | --- | --- | --- | --- |
| **OUTPUT EMISSION** | | | | |
| Average concentrations in sediment over the initial assessment period (30d) | Clocalsed,total, time1 | 1.1\*10-6 (IPBC)  2.1\*10-3 (propiconazole)  9.3\*10-4 (tebuconazole)  6.0\*10-5 (cypermethrin) | [mg.kgwwt-1] | O |
| Average concentrations in sediment over a longer duration (5475d) | Clocalsed,total, time2 | 3.9\*10-8 (IPBC)  8.3\*10-3 (propiconazole)  7.2\*10-4 (tebuconazole)  8.4\*10-5 (cypermethrin) | [mg.kgwwt-1] | O |

###### Combined concentrations in soil and in pore-water from in-situ treatment and in-service

The combined concentrations for *in-situ* application (professional and non-professional application) and in service emissions are presented in the following sections. In a first tier, removal is not taken into account, while the second tier is also considering removal processes.

House scenario, combined concentrations in soil and in pore-water from in-situ treatment and in-service

**- Combined concentrations not taking removal into account, House scenario**

Table 2.2‑21: Combined concentration in soil and in soil pore-water from brushing in-situ and in-service based on the house scenario, removal not considered.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** |
| **OUTPUT EMISSION** | | | | |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (30d), professional application | Clocalsoil,total, time1 | 0.05 (IPBC)  0.17 (propiconazole)  0.07 (tebuconazole)  0.02 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (30d), non-professional application | Clocalsoil,total, time1 | 0.06(IPBC)  0.20 (propiconazole)  0.08 (tebuconazole)  0.04 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (1825d), professional application | Clocalsoil,total, time2 | 0.10 (IPBC)  0.47 (propiconazole)  0.18 (tebuconazole)  0.03 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (1825d), non-professional application | Clocalsoil total, time2 | 0.11 (IPBC)  0.50 (propiconazole)  0.19 (tebuconazole)  0.05 (cypermethrin) | [mg.kgwwt-1] | O |
| Average concentrations in pore water over the initial assessment period (30d), professional application | Clocalpore,time1 | 19.42 (IPBC)  9.92 (propiconazole)  3.84 (tebuconazole)  2.4\*10-3 (cypermethrin) | [µg.L-1] | O |
| Average concentrations in pore water over the initial assessment period (30d), non-professional application | Clocalpore,time1 | 24.25 (IPBC)  11.95 (propiconazole)  4.48 (tebuconazole)  3.9\*10-3 (cypermethrin) | [µg.L-1] | O |
| Average concentration in pore water over a longer  duration (1825d), professional application | Clocalpore,time2 | 41.57 (IPBC)  28.03 (propiconazole)  10.11 (tebuconazole)  3.4\*10-3 (cypermethrin) | [µg.L-1] | O |
| Average concentration in pore water over a longer  duration (1825d), non-professional application | Clocalpore,time2 | 46.40 (IPBC)  30.05 (propiconazole)  10.75 (tebuconazole)  5.0\*10-3 (cypermethrin) | [µg.L-1] | O |

Calculations (IPBC used as an example):

Clocalsoil,total, time1 = Clocalsoil,brush + Clocalsoil,leach,time 1

Clocalsoil,total, time1 = 0.028 + 0.029

Clocalsoil,total, time1 = 0.05 mg/kgwwt

The average concentration in the pore water can be calculated as (equation 3.9 of the ESD):

Clocalpore,time1 = Clocalsoil,total, time1 \* RHOsoil / Ksoil-water

Clocalpore,time1 = 0.05 \* 1700 / 3.98

Clocalpore,time1 = 19.42 µg/L

**- Combined concentrations taking removal into account, House scenario**

In a second tier, soil and pore-water concentrations taking removal into account were calculated. The calculations are described in section 3.3.2.4.1.

Table 2.2‑22: Combined concentration in soil and in pore-water from in-situ brushing and in-service (House) taking removal into account.

| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** |
| --- | --- | --- | --- | --- |
| **OUTPUT EMISSION** | | | | |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (30d), professional application | Clocalsoil,total, rem time1 | 2.8\*10-5 (IPBC)  0.15 (propiconazole)  0.06 (tebuconazole)  0.01 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (30d), non-professional application | Clocalsoil,total, rem time1 | 2.8\*10-5 (IPBC)  0.18 (propiconazole)  0.07 (tebuconazole)  0.01 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (1825d), professional application | Clocalsoil,total, rem, time2 | 8.6\*10-7 (IPBC)  0.03 (propiconazole)  0.01 (tebuconazole)  1.5\*10-4 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (1825d), non-professional application | Clocalsoil,total, rem, time2 | 8.6\*10-7 (IPBC)  0.03 (propiconazole)  0.01 (tebuconazole)  1.5\*10-4 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in pore water over the initial assessment period (30d), professional application | Clocalpore,time1 | 0.01 (IPBC)  8.91 (propiconazole)  3.24 (tebuconazole)  6.9\*10-4 (cypermethrin) | [µg.L-1] | O |
| Combined concentrations in pore water over the initial assessment period (30d), non-professional application | Clocalpore,time1 | 0.01 (IPBC)  10.63 (propiconazole)  3.72 (tebuconazole)  1.1\*10-3 (cypermethrin) | [µg.L-1] | O |
| Combined concentration in pore water over a longer  duration (1825d), professional application | Clocalpore,time2 | 3.7\*10-4 (IPBC)  1.87 (propiconazole)  0.39 (tebuconazole)  1.4\*10-5 (cypermethrin) | [µg.L-1] | O |
| Combined concentrations in pore water over the initial assessment period (1825d), non-professional application | Clocalpore,time2 | 3.7\*10-4 (IPBC)  1.87 (propiconazole)  0.39 (tebuconazole)  1.4\*10-5 (cypermethrin) | [µg.L-1] | O |

The average concentration in the pore water can be calculated as:

Clocalpore,time1 = Clocalsoil,total, rem time1 \* RHOsoil / ksoil-water

Clocalpore,time1 = 2.8\*10-5 \* 1700 / 3.98

Clocalpore,time1 = 0.01 µg.L-1

Fence scenario, combined concentrations in soil and in pore-water from in-situ treatment and in-service

The combined concentrations in soil resulting from application (brushing) and leaching of treated wood in-service based on the fence scenario are presented in the following tables.

**- Combined concentrations not taking removal into account, Fence scenario**

Table 2.2‑23: Combined concentration in soil and in pore-water from *in-situ* (brushing) and in-service based on the fence scenario, removal not considered.

| Parameter/variable | Nomenclature | Value | Unit | Origin |
| --- | --- | --- | --- | --- |
| **OUTPUT EMISSION** | | | | |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (30d), professional application | Clocalsoil,total, time1 | 0.04 (IPBC)  0.14 (propiconazole)  0.06 (tebuconazole)  0.02 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (30d), non-professional application | Clocalsoil,total, time1 | 0.05 (IPBC)  0.17 (propiconazole)  0.07 (tebuconazole)  0.03 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (1825d), professional application | Clocalsoil,total, time2 | 0.08 (IPBC)  0.39 (propiconazole)  0.15 (tebuconazole)  0.03 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (1825d), non-professional application | Clocalsoil,total, time2 | 0.09 (IPBC)  0.42 (propiconazole)  0.16 (tebuconazole)  0.04 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in pore water over the initial assessment period (30d), professional application | Clocalpore,time1 | 16.16 (IPBC)  8.26 (propiconazole)  3.19 (tebuconazole)  2.0\*10-3 (cypermethrin) | [µg.L-1] |  |
| Combined concentrations in pore water over the initial assessment period (30d), non-professional application | Clocalpore,time1 | 20.18 (IPBC)  9.94 (propiconazole)  3.73 (tebuconazole)  3.3\*10-3 (cypermethrin) | [µg.L-1] | O |
| Combined concentration in pore water over a longer duration (1825d), professional application | Clocalpore,time2 | 34.59 (IPBC)  23.32 (propiconazole)  8.41 (tebuconazole)  2.9\*10-3 (cypermethrin) | [µg.L-1] |  |
| Combined concentration in pore water over a longer duration (1825d), non-professional application | Clocalpore,time2 | 38.61 (IPBC)  25.00 (propiconazole)  8.94 (tebuconazole)  4.2\*10-3 (cypermethrin) | [µg.L-1] | O |

Calculations (IPBC and non-professional application used as an example):

Clocalsoil,total, time1 = Clocalsoil,brush + Clocalsoil,leach,time 1

Clocalsoil,total, time1 = 0.016 + 0.024

Clocalsoil,total, time1 = 0.04 mg/kgwwt

The average concentration in the pore water can be calculated as:

Clocalpore,time1 = Clocalsoil,total time1 \* RHOsoil / ksoil-water

Clocalpore,time1 = 0.04 \* 1700 / 3.98

Clocalpore,time1 = 16.16 µg.L-1

**- Combined concentrations taking removal into account, Fence scenario**

In a second tier, soil and pore-water concentrations taking removal into account were calculated. The calculations are described in section 3.3.2.4.1.

The resulting soil and pore-water concentrations taking into account removal processes over Time1 (30 days) and Time2 (1825 days) are presented below:

Table 2.2‑24: Combined concentration in soil and pore-water from *in-situ* (brushing) and *in-service* (Fence) taking removal into account.

| Parameter/variable | Nomencla-ture | Value | Unit | Origin |
| --- | --- | --- | --- | --- |
| **OUTPUT EMISSION** | | | | |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (30d), professional application | Clocalsoil,total, rem time1 | 2.4\*10-5 (IPBC)  0.12 (propiconazole)  0.05 (tebuconazole)  5.8\*10-3 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (30d), non-professional application | Clocalsoil,total, rem time1 | 2.4\*10-5 (IPBC)  0.15 (propiconazole)  0.05 (tebuconazole)  9.6\*10-3 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (1825d), professional application | Clocalsoil,total, rem, time2 | 7.2\*10-7 (IPBC)  0.03 (propiconazole)  0.01 (tebuconazole)  1.2\*10-4 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (1825d), non-professional application | Clocalsoil,total, rem, time2 | 7.2\*10-7 (IPBC)  0.03 (propiconazole)  0.01 (tebuconazole)  1.2\*10-4 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil water over the initial assessment period (30d), professional application | Clocalpore,time1 | 0.01 (IPBC)  7.42 (propiconazole)  2.69 (tebuconazole)  5.7\*10-4 (cypermethrin) | [µg.L-1] | O |
| Combined concentrations in soil water over the initial assessment period (30d), non-professional application | Clocalpore,time1 | 0.01 (IPBC)  8.84 (propiconazole)  3.10 (tebuconazole)  9.5\*10-4 (cypermethrin) | [µg.L-1] | O |
| Combined concentration in pore water over a longer  duration (1825d), professional application | Clocalpore,time2 | 3.1\*10-4 (IPBC)  1.56 (propiconazole)  0.32 (tebuconazole)  1.2\*10-5 (cypermethrin) | [µg.L-1] | O |
| Combined concentration in pore water over a longer  duration (1825d), non-professional application | Clocalpore,time2 | 3.1\*10-4 (IPBC)  1.56 (propiconazole)  0.32 (tebuconazole)  1.2\*10-5 (cypermethrin) | [µg.L-1] | O |

Calculations (IPBC and non-professional application used as an example):

The average concentration in the pore water can be calculated as:

Clocalpore,time1 = Clocalsoil,total, rem time1 \* RHOsoil / ksoil-water

Clocalpore,time1 = 2.4\*10-5 \* 1700 / 3.98

Clocalpore,time1 = 0.01 µg.L-1

Bridge over Pond, combined concentrations from in-situ (brushing) treatment and in-service

The combined concentrations in water resulting from application *in-situ* (brushing) and leaching of treated wood *in-service* based on the bridge over pond scenario are shown in the following tables.

- **Combined concentrations not taking removal into account, Bridge over pond scenario**

Table 2.2‑25: Combined concentration in water from *in-situ* (brushing) and *in-service* (bridge over pond).

| Parameter/variable | Nomenclature | Value | Unit | Origin |
| --- | --- | --- | --- | --- |
| **OUTPUT EMISSION** | | | | |
| Combined concentrations in local water resulting from application (brushing) and leaching of treated wood (30d), professional application | Clocalwater,total, time1 | 0.08 (IPBC)  0.29 (propiconazole)  0.12 (tebuconazole)  0.04 (cypermethrin) | [µg.L-1] | O |
| Combined concentrations in local water resulting from application (brushing) and leaching of treated wood (30d), non-professional application | Clocalwater,total, time1 | 0.10 (IPBC)  0.35 (propiconazole)  0.14 (tebuconazole)  0.07 (cypermethrin) | [µg.L-1] | O |
| Combined concentrations in local water resulting from application (brushing) and leaching of treated wood (1825d), professional application | Clocalwater,total, time2 | 0.17 (IPBC)  0.83 (propiconazole)  0.31 (tebuconazole)  0.06 (cypermethrin) | [µg.L-1] | O |
| Combined concentrations in local water resulting from application (brushing) and leaching of treated wood (1825d), non-professional application | Clocalwater,total, time2 | 0.19 (IPBC)  0.89 (propiconazole)  0.33 (tebuconazole)  0.09 (cypermethrin) | [µg.L-1] | O |

Calculations (IPBC and non-professional application used as an example):

Clocalwater,total, time1 = Clocalwater,brush + Clocalwater,leach,time 1

Clocalwater,total, time1 = 0.05 + 0.05

Clocalwater,total, time1 = 0.10 µg/L.

- **Combined concentrations taking removal into account, Bridge over pond scenario**

\* Combined concentrations in surface water

In a second tier, concentrations in water taking removal into account were calculated based on the model described in section 3.4.2.1 of the revised ESD (equation 3.18 and 3.19).

For releases into a static water body, the removal from the water column due to adsorption onto sus­pended matter and into sediment can be significant. To take this phenomenon into account, equation 3.18 and 3.19 of the ESD was adapted.

The calculations are shown in section 3.3.2.4.4 and the resulting water concentrations taking into account removal processes over Time1 (30 days) and Time2 (1825 days) are presented below.

Table 2.2‑26: Combined concentration in water from *in-situ* (brushing) and *in-service* taking removal into account (bridge over pond).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Parameter/variable | Nomenclature | Value | Unit | Origin |
| **INPUTS** | | | | |
| Volume of sediment compartment | Vsed | 1.5 | [m3] | D |
| Total sediment – water partitioning coefficients | Ksed-water | 3.95 (IPBC)  24.4 (propiconazole)  25.6 (tebuconazole)  14376 (cypermethrin) | [m3.m-3] | S |
| Concentrations of suspended matter in the surface water | SUSPwater | 15\*10-3 | [kg.m-3] | D |
| Solids-water partitioning coefficients for suspended matter | Kpsusp | 12.6\*10-3 (IPBC)  94.4\*10-3 (propiconazole)  99.2\*10-3 (tebuconazole)  57.436 (cypermethrin) | [mg.m-2] | O |
| **OUTPUT EMISSION** | | | | |
| Combined concentrations in local water resulting from application (brushing) and leaching of treated wood (30d), professional application | *Clocaldiss, time1* | 4.9\*10-4 (IPBC)  0.14 (propiconazole)  0.06 (tebuconazole)  3.6\*10-4 (cypermethrin) | [µg.L-1] | O |
| Combined concentrations in local water resulting from application (brushing) and leaching of treated wood (30d), non-professional application | *Clocaldiss, time1* | 6.2\*10-4 (IPBC)  0.17 (propiconazole)  0.06 (tebuconazole)  6.0\*10-4 (cypermethrin) | [µg.L-1] | O |
| Combined concentrations in local water resulting from application (brushing) and leaching of treated wood (1825d), profess­sio­nal application | *Clocaldiss, time2* | 1.7\*10-5 (IPBC)  0.29 (propiconazole)  0.04 (tebuconazole)  2.1\*10-5 (cypermethrin) | [µg.L-1] | O |
| Combined concentrations in local water resulting from application (brushing) and leaching of treated wood (1825d), non-professional application | *Clocaldiss,time2* | 1.9\*10-5 (IPBC)  0.31 (propiconazole)  0.04 (tebuconazole)  3.1\*10-5 (cypermethrin) | [µg.L-1] | O |

\* Combined concentrations in sediment

The combined concentrations in sediment were calculated according to the equilibrium partitioning method, based on formulas 18, 24 and 50 in the Technical Guidance Document on Risk Assessment (TGD). The calculations are shown in section 3.3.2.4.4 and the results in the table below.

Table 2.2‑27: Combined concentration in sediment from *in-situ* (brushing) and *in-service* (bridge over pond) taking removal into account

| Parameter/variable | Nomenclature | Value | Unit | Origin |
| --- | --- | --- | --- | --- |
| **OUTPUT EMISSION** | | | | |
| Combined concentrations in sediment resulting from application (brushing) and leaching of treated wood (30d), professional application | Clocalsed,total, time1 | 1.7\*10-6 (IPBC)  3.0\*10-3 (propiconazole)  1.2\*10-3 (tebuconazole)  4.5\*10-3 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in sediment resulting from application (brushing) and leaching of treated wood (30d), non-professional application | Clocalsed,total, time1 | 2.2\*10-6 (IPBC)  3.6\*10-3 (propiconazole)  1.4\*10-3 (tebuconazole)  7.5\*10-3 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in sediment resulting from application (brushing) and leaching of treated wood (1825d), professional application | Clocalsed,total, time2 | 6.1\*10-8 (IPBC)  6.2\*10-3 (propiconazole)  8.9\*10-3 (tebuconazole)  6.6\*10-4 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in sediment resulting from application (brushing) and leaching of treated wood (1825d), non-professional application | Clocalsed,total, time2 | 6.9\*10-8 (IPBC)  6.6\*10-3 (propiconazole)  9.5\*10-4 (tebuconazole)  3.8\*10-4 (cypermethrin) | [mg.kgwwt-1] | O |

Spraying, combined concentrations from in-situ treatment and in-service

The combined concentrations in soil and pore-water resulting from *In-situ* treatment (spraying) and *in-service* (House) of treated wood are presented below.

**- Combined concentrations not taking removal into account**

Table 2.2‑28: Combined concentration in soil from *in-situ* (spraying) and in-service (house) Tier 1 and Tier 2.

| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** |
| --- | --- | --- | --- | --- |
| **OUTPUT EMISSION** | | | | |
| Combined concentrations in soil resulting from application (spraying) and leaching of treated wood (30d) | Clocalsoil,total, time1 tier1 | 0.20 (IPBC)  0.62 (propiconazole)  0.22 (tebuconazole)  0.24 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (spraying) and leaching of treated wood (1825d) | Clocalsoil,total, time2 tier1 | 0.25 (IPBC)  0.93 (propiconazole)  0.33 (tebuconazole)  0.25 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (spraying) and leaching of treated wood (30d) Tier 2 | Clocalsoil,total, time1 tier2 | 0.04 (IPBC)  0.16 (propiconazole)  0.07 (tebuconazole)  0.02 (cypermethrin) | [mg.kgwwt-1] | O |

Calculations (IPBC and tier 1 application used as an example):

Clocalsoil,total, time1 tier1 = Clocalsoil, tier 1 + Clocalsoil,leach,time 1

Clocalsoil,total, time1 tier1 = 0.17 + 0.028

Clocalsoil,total, time1 tier1 = 0.20 mg/kgwwt

**- Combined concentrations taking removal into account**

In a second tier, soil and pore-water concentrations taking removal into account were calculated. The calculations are described in section 3.3.2.4.1.

The resulting soil and pore-water concentrations taking into account removal processes over Time1 (30 days) and Time2 (1825 days) are presented below.

Table 2.2‑29: Combined concentration in soil and pore-water from in-situ (spraying) and in-service (house) taking removal into account Tier 1 and Tier 2.

| Parameter/variable | Nomenclature | Value | Unit | Origin |
| --- | --- | --- | --- | --- |
| **OUTPUT EMISSION** | | | | | |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (30d), tier 1 | Clocalsoil,total, rem, time1 tier 1 | 2.8\*10-5 (IPBC)  0.54 (propiconazole)  0.17 (tebuconazole)  0.07 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (brushing) and leaching of treated wood (1825d), tier 1 | Clocalsoil,total, rem, time2 tier 1 | 8.6\*10-7 (IPBC)  0.03 (propiconazole)  0.01 (tebuconazole)  1.5\*10-4 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (spraying) and leaching of treated wood (30d) Tier 2 | Clocalsoil,total, rem, time1 tier2 | 2.8\*10-5 (IPBC)  0.15 (propiconazole)  0.06 (tebuconazole)  0.01 (cypermethrin) | [mg.kgwwt-1] | O |
| Combined concentrations in soil resulting from application (spraying) and leaching of treated wood (1825d) Tier 2 | Clocalsoil,total, rem, time2 tier2 | 8.6\*10-7 (IPBC)  0.03 (propiconazole)  0.01 (tebuconazole)  1.5\*10-4 (cypermethrin) | [mg.kgwwt-1] | O |
| Average concentrations in pore water over the initial assessment period (30d), tier 1 | Clocalpore,time1 tier1 | 0.01 (IPBC)  32.03 (propiconazole)  9.79 (tebuconazole)  6.7\*10-3 (cypermethrin) | [µg.L-1] | O |
| Average concentration in pore water over a longer duration (1825 d), tier 1 | Clocalpore,time2 tier1 | 3.7\*10-4 (IPBC)  1.87 (propiconazole)  0.39 (tebuconazole)  1.4\*10-5 (cypermethrin) | [µg.L-1] | O |
| Average concentrations in pore water over the initial assessment period (30d), tier 2 | Clocalpore,time1 tier2 | 0.01 (IPBC)  8.79 (propiconazole)  3.79 (tebuconazole)  0.002 (cypermethrin) | [µg.L-1] | O |
| Average concentration in pore water over a longer duration (1825 d), tier 2 | Clocalpore,time2 tier2 | 3.7\*10-4 (IPBC)  1.87 (propiconazole)  0.39 (tebuconazole)  1.4\*10-5 (cypermethrin) | [µg.L-1] | O |

The average concentration in the pore water can be calculated as (IPBC used as an example):

Clocalpore,time1 tier 1 = Clocalsoil,total, time1 tier1 \* RHOsoil / ksoil-water

Clocalpore,time1 tier 1 = 2.8\*10-5 \* 1700 / 3.98

Clocalpore,time1 tier 1 = 0.01 µg.L-1

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 6   1. 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 study has been carried out with the X6122B1 product during 421 days and from a surface application. 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 without topcoat.  For each active substance and to estimation the Q\*leach, time, the best goodness of the fit (with the r² value closest to 1) is obtained by fitting the cumulative quantities leached versus cumulative rain fall plot using a linear regression:  Q\*leach,time = a\*mm + b  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; * TIME2 = 15 years, equivalent to 5475 \* 1.92 = 10512 mm of accumulated rain.   Noted that the limit of quantification for IPBC and for Cypermethrin is 0.02 µg/mL instead of 0.01 µg/mL (as indicated by the registrant). This value was used as input for the leaching estimation.  The leaching values obtained from an application by brushing at 300.1 g.m-² without topcoat have been normalized for an application dose of 200 g.m-2 and have been 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 without topcoat.**   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Equations used for calculations** | **Q\*leach**  **[mg.m-2]** | | | | **TIME 1 (30d)** | **TIME 2 (5y)**  ***In situ*** | **TIME 2 (15y)**  **Industrial** | | Propiconazole | Q\*leach = 24.884 \* mm + 28656  **(r² = 0.99)** | 19.96 | 76.78 | 192.33 | | Tebuconazole | Q\*leach = 9.001 \* mm + 12738  **(r² = 0.99)** | 8.79 | 29.35 | 71.14 | | Cypermethrin | Q\*leach = 1.768 \* mm + 25.327  **(r² = 0.97)** | 8.42E-02 | 4.12 | 12.33 | | IPBC | Q\*leach = 6.033 \* mm + 7250.4  **(r² = 0.98)** | 5.04 | 18.82 | 46.83 |   Moreover IPBC is rapidly degraded in water with a DT50 of 3.1 h at 12°C and in soil with a DT50 of 4.7 h at 12°C. Therefore, emissions of PBC (degradation product of IPBC) are also calculated assuming 100% transformation of IPBC to PBC at time 0, using the ratio between the molar mass of PBC and IPBC of 0.552 in water and in soil.  The assessment of 1,2,4-triazole was proposed only for emission to soil. 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. An assessment of PBC in water and in soil and an assessment of 1,2,4-triazole is also proposed for soil compartment.  **Relevant metabolites - Leaching values obtained from surface application at 200 g/m² without topcoat.**   |  |  |  |  | | --- | --- | --- | --- | |  | **Q\*leach**  **[mg.m-2]** | | | | **TIME 1 (30d)** | **TIME2 (5y)**  ***In situ*** | **TIME 1 (15y)**  **Industrial** | | **Equations:**  Q\*leach, time1  = ( Q\*leach time 1/time2 \* DEGrate \* Molar mass metabolite/Molar mass parent) | | | | | 1,2,4-triazole | 1.92 | 7.29 | 18.23 | | PBC | 2.78 | 10.39 | 25.86 |   The relevant environmental compartments for each substance and identified metabolites are specified in the table below:   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Phase | STP | Surface water | | Sediment | | Soil | | Groundwater | | Secondary Poisoning | | Direct Release | *Via* STP | Direct Release | *Via* STP | Direct Release | *Via* STP | Direct Release | *Via* STP | | Propiconazole | Y | Y | Y | Y | Y | Y | Y | Y | Y | N | | Tebuconazole | Y | Y | Y | Y | Y | Y | Y | Y | Y | N | | Cypermethrin | Y | Y | Y | Y | Y | Y | Y | N | N | Y | | IPBC | Y | Y | N | N | N | Y | N | Y | N | N | | PBC | Y | Y | Y | Y | Y | Y | Y | Y | Y | N | | 1,2,4-triazole | N | N | N | N | N | Y | N | Y | Y | N |  1. Estimation of emissions – Industrial Dipping (storage phase only)   FR-CA agrees with the registrant’s inputs used for the estimation of releases from industrial treatment (storage phase) according to the “industrial dipping process” scenario described in the PT08-ESD. However the average daily flux (*FLUXstorage,dipp)* for each substance have been recalculated from the new Q\*leach, time 1 values (see above). Moreover, for the service life for the longer storage period on a storage place, i.e. Time 2, a default value of 7300 days (i.e. 20 years) must be used, which corresponds to the average life span of an industrial treatment plant.  For the application phase, no emission estimations were provided by the applicant based on mandatory risk mitigation measures for wood treatment plants.   |  |  |  | | --- | --- | --- | | Nomenclature | Value | Unit | | FLUX storage, dipp (considering 30 days leaching) | | [kg.m-2.d-1] | | Tebuconazole | 2.93E-07 | | Propiconazole | 6.65E-07 | | Cypermethrin | 2.81E-09 | | IPBC | 1.68E-07 | | PBC | 9.28E-08 | | 1,2,4-triazole | 6.40E-08 | | *Qleachstorage,time1* | | [kg] | | Tebuconazole | 6.77E-02 | | Propiconazole | 1.54E-01 | | Cypermethrin | 6.48E-04 | | IPBC | 3.88E-02 | | PBC | 2.14E-02 | | 1,2,4-triazole | 1.48E-02 | | *Qleachstorage,time 2* | | [kg] | | Tebuconazole | 1.65E+01 | | Propiconazole | 3.74E+01 | | Cypermethrin | 1.58E-01 | | IPBC | 9.44E+00 | | PBC | 5.21E+00 | | 1,2,4-triazole | 3.60E+00 | | *Elocalsurfacewater,time1* | | [kg.d-1] | | Tebuconazole | 1.13E-03 | | Propiconazole | 2.56E-03 | | Cypermethrin | 1.08E-05 | | IPBC | 6.47E-04 | | PBC | 3.57E-04 |  1. Estimation of emissions - In-situ application   FR-CA agrees with the registrant’s inputs used for the estimation of releases from brush and 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 instead of technical active substance.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Expression of the active substance’s content | Cypermethrin | Tebuconazole | Propiconazole | IPBC | | Pure (%w/w) | 0.07 | 0.05 | 0.15 | 0.05 | | Technical (%w/w) | 0.08 | 0.05 | 0.16 | 0.05 |   According to the technical Agreements for Biocides (June 2016), the house-scenario is the worst case scenario and would therefore be sufficient. Consequently, the fence scenario has been deleted.  An assessment of PBC in water and in soil and an assessment of 1,2,4-triazole in soil is proposed (see above).  According to the ESD-PT08, no scenario is currently available for estimating direct release to surface water from outdoor spraying application. Therefore, the ESD-TP08 scenario “bridge over pond” was adapted by considering the fraction of product lost to water during application as the sum of releases due to run-off (Frunoff = 0.2) and drift (Fdrift = 0.1) described in the section 4.4.5 of the ESD-PT08 (2013).   * 1. Emission from in-situ brushing application  |  |  |  | | --- | --- | --- | | ***Outputs- House scenario-200 g/m2*** | | | |  | Professional | Non professional | | **Emission of substance to soil – E soil,brush\_house [kg.d-1]** | | | | Tebuconazole | 3.75E-04 | 6.25E-04 | | Propiconazole | 1.20E-03 | 2.00E-03 | | Cypermethrin | 6.00E-04 | 1.00E-03 | | IPBC | 3.75E-04 | 6.25E-04 | | PBC | 2.07E-04 | 3.45E-04 | | 1,2,4-triazole | 1.12E-04 | 1.87E-04 | | ***Outputs- Bridge scenario*** | | | | **Emission of substance to water – E water,brush\_bridge [kg.d-1]** | | | |  | Professional | Non professional | | Tebuconazole | 3.00E-05 | 5.00E-05 | | Propiconazole | 9.60E-05 | 1.60E-04 | | Cypermethrin | 4.80E-05 | 8.00E-05 | | IPBC | 3.00E-05 | 5.00E-05 | | PBC | 1.66E-05 | 2.76E-05 |  * 1. Emissions from in-situ spraying application   **Inputs – calculations of emissions from application by spraying – bridge scenario**   |  |  |  |  | | --- | --- | --- | --- | | ***Inputs:*** | | | | | **Parameter/variable** | **Symbol** | **Value** | **Unit** | | Treated wood area | AREAbridge | 10 | [m².d-1] | | Application rate of the product | Qapplic.product | 0.2 | [L.m-2] | | Content of the active substances | fai | See above | [-] | | Density of the product | RHOproduct | 1 | [kg.l-3] | | Fraction of product lost to water during application by drift and by run-off | Fwater,spray | 0.03 | [-] | | Water volume under bridge | Vwater | 1000 | [m3] |   **Emission from in-situ spraying application**   |  |  | | --- | --- | | ***Outputs- House scenario*** | | | **Emission of substance to soil after application (run-off) – E soil,runoff [kg.d-1]** | | | Tebuconazole | 2.50E-03 | | Propiconazole | 8.00E-03 | | Cypermethrin | 4.00E-03 | | IPBC | 2.50E-03 | | PBC | 1.38E-03 | | 1,2,4-triazole | 7.49E-03 | | **Emission of substance to soil after application (drift Tier 1) – E soil,spray\_drift, tier 1 [kg.d-1]** | | | Tebuconazole | 1.25E-03 | | Propiconazole | 4.00E-03 | | Cypermethrin | 2.00E-03 | | IPBC | 1.25E-03 | | PBC | 6.90E-04 | | .90E-041,2,4-triazole | 3.73E-04 | | **Emission of substance to soil after application (drift Tier 2) – E soil, spray\_drift, tier 2 [kg.d-1]** | | | Tebuconazole | 4.13E-04 | | Propiconazole | 1.32E-03 | | Cypermethrin | 6.60E-04 | | IPBC | 4.13E-04 | | PBC | 2.28E-04 | | 1,2,4-triazole | 1.23E-04 | | ***Outputs- Bridge scenario*** | | | **Emission of substance to water after application – E water,spray\_bridge [kg.d-1]** | | | Tebuconazole | 3.00E-05 | | Propiconazole | 9.60E-05 | | Cypermethrin | 4.80E-05 | | IPBC | 3.00E-05 | | PBC | 1.66E-05 |  1. Emissions from treated wood in-service    1. Emissions from treated house in-service of industrial / *in situ* treated wood   **HOUSE - treated wood in service– industrial / *in-situ* application - Inputs**   |  |  |  |  | | --- | --- | --- | --- | | **Symbol** | **Value** | | **Unit** | | *Inputs* | | | | | | Application | Industrial | *In situ* | [-] | | AREA house | 125 | | [m²] | | TIME1 | 30 | | [d] | | TIME2 | 5475 | 1825 | [d] | | Q\*leach,TIME1 | See leaching values in section 1 | | [mg.m-2] | | Q\*leach,TIME2 | [mg.m-2] | | DT50 soil | See FR-CA box 2 | | [d-1] | | V soil | 13 | | [m3] | | RHO soil | 1700 | | [kgwwt.m-3] |   **HOUSE - treated wood in service (industrial / in situ application 200 g/m2) - Outputs**   |  |  |  |  | | --- | --- | --- | --- | |  | **Industrial & *In situ* application** | ***In situ* application** | **Industrial application** | | **Qleach, TIME1(30d) [kg]** | **Qleach, TIME2 (5y)  [kg]** | **Qleach, TIME2 (15y)  [kg]** | | Propiconazole | 2.50E-03 | 9.60E-03 | 2.40E-02 | | Tebuconazole | 1.10E-03 | 3.67E-03 | 8.89E-03 | | Cypermethrin | 1.05E-05 | 5.15E-04 | 1.54E-03 | | IPBC | 6.30E-04 | 2.35E-03 | 5.85E-03 | | 1,2,4-triazole | 2.40E-04 | 9.12E-04 | 2.28E-03 | | PBC | 3.48E-04 | 1.30E-03 | 3.23E-03 |  * 1. Emissions from treated noise barrier in-service of industrial treated wood   **NOISE BARRIER - treated noise barrier in-service – industrial application - Inputs**   |  |  |  | | --- | --- | --- | | **Symbol** | **Value** | **Unit** | | *Inputs* | | | |  | Industrial |  | | AREA noise-barrier | 3000 | [m²] | | TIME1 | 30 | [d] | | TIME2 | 5475 | [d] | | Q\*leach,TIME1 | See leaching values in section 1 | [mg.m-2] | | Q\*leach,TIME2 | [mg.m-2] | | DT50 soil | See FR-CA box 2 | [d-1] | | V soil | 250 | [m3] | | RHO soil | 1700 | [kgwwt.m-3] | | F SOIL | 0.3 | [-] | | F STP | 0.7 | [-] |   **NOISE BARRIER - treated noise barrier in-service – industrial application – Outputs**   |  |  |  | | --- | --- | --- | |  | **Industrial application** | **Industrial application** | | ***Direct emissions to soil*** | | | |  | **Qleach, TIME1 (30d) [kg]** | **Qleach, TIME2 (15y)  [kg]** | | Propiconazole | 1.80E-02 | 1.73E-01 | | Tebuconazole | 7.91E-03 | 6.40E-02 | | Cypermethrin | 7.58E-05 | 1.11E-02 | | IPBC | 4.54E-03 | 4.21E-02 | | PBC | 2.50E-03 | 2.33E-02 | | 1,2,4-triazole | 1.73E-03 | 1.64E-02 | | ***Emissions to STP*** | | | |  | **ESTP TIME1 (30d) [kg.d-1]** | **ESTP TIME2 (15y)  [ kg.d-1]** | | Propiconazole | 1.40E-03 | 7.38E-05 | | Tebuconazole | 6.15E-04 | 2.73E-05 | | Cypermethrin | 5.89E-06 | 4.73E-06 | | IPBC | 3.53E-04 | 1.80E-05 | | PBC | 1.95E-04 | 9.92E-06 | | 1,2,4-triazole | 1.34E-04 | 6.99E-06 | |

#### Local PECs

In the following tables, PEC values for treatment and in-service with and without removal are listed. Also the combination of PEC values from *in-situ* treatment and in-service is shown.

The *in-situ* treatment is based on both the professional and non-professional calculations.

##### PEC industrial application, dipping

* PEC in surface water

Table 2.2‑30: PEC in surface water, industrial application, storage.

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cypermethrin** |
| --- | --- | --- | --- | --- |
| **Dipping (surface water)** |  |  |  |  |
| PEC in surface water over the initial assessment period [µg.L-1] | 0.03 | 0.10 | 0.04 | 2.8\*10-4 |
| PEC in surface water over a longer assessment period [µg.L-1] | 2.5\*10-2 | 1.0\*10-1 | 4.4\*10-2 | 2.8\*10-4 |

* PEC in soil and pore water

Table 2.2‑31: PEC in soil and pore water, industrial application, storage.

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cypermethrin** |
| --- | --- | --- | --- | --- |
| **Dipping (soil)** |  |  |  |  |
| PEC in soil at storage place at the end of the initial assessment period [mg.kgwwt-1] | 0.03 | 0.13 | 0.06 | 3.7\*10-4 |
| PEC in soil at storage place at the end of a longer assessment period  [mg.kgwwt-1] | 5.95 | 24.13 | 10.58 | 0.07 |
|  |  |  |  |  |
| PEC in soil at storage place at the end of the initial assessment period with removal [mg.kgwwt-1] | 3.2\*10-5 | 0.12 | 0.05 | 2.1\*10-4 |
| PEC in soil at storage place at the end of a longer assessment period with removal [mg.kgwwt-1] | 3.3\*10-5 | 0.82 | 0.21 | 3.0\*10-4 |
| **Dipping (pore water)** |  |  |  |  |
| PEC local with removal Time 1 (30 days) [µg/L] | 0.01 | 7.26 | 2.87 | 2.1\*10-5 |
| PEC local with removal Time 2 (1825 days) [µg/L] | 1.4\*10-2 | 49 | 12 | 3.0\*10-5 |

##### PEC in-situ application, brushing and spraying

* PEC in surface water

Table 2.2‑32: PEC in surface water, in-situ application.

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cypermethrin** |
| --- | --- | --- | --- | --- |
| **Bridge over Pond (surface water)** |  |  |  |  |
| PEC local in water at the end of the day of application (bridge, professional application) [µg.L-1] | 0.03 | 0.09 | 0.03 | 0.04 |
| PEC local in water at the end of the day of application (bridge, non-professional application) [µg.L-1] | 0.05 | 0.15 | 0.05 | 0.07 |

* PEC in soil

Table 2.2‑33: PEC in soil, in-situ application.

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cypermethrin** |
| --- | --- | --- | --- | --- |
| **House (brushing, soil)** |  |  |  |  |
| PEC local in soil at the end of the day of application (house, professional application) [mg.kgwwt-1] | 0.02 | 0.05 | 0.02 | 0.02 |
| PEC local in soil at the end of the day of application (house, non-professional application) [mg.kgwwt-1] | 0.03 | 0.09 | 0.03 | 0.04 |
| **Fence (brushing, soil)** |  |  |  |  |
| PEC local in soil at the end of the day of application (fence, professional application) [mg.kgwwt-1] | 0.01 | 0.04 | 0.01 | 0.02 |
| PEC local in soil at the end of the day of application (fence, non-professional application) [mg.kgwwt-1] | 0.02 | 0.07 | 0.02 | 0.03 |
| **House (spraying, soil)** |  |  |  |  |
| PEC local in soil at the end of the day of application due to spray drift (tier 1) and run-off | 0.17 | 0.51 | 0.17 | 0.24 |
| PEC local in soil at the end of the day of application due to spray drift (tier 2) and run-off | 0.02 | 0.05 | 0.02 | 0.02 |

##### PEC in STP, surface water and sediment

Table 2.2‑34: PEC in STP, surface water and sediment, industrial dipping, in-service.

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cypermethrin** |
| --- | --- | --- | --- | --- |
| **Noise Barrier (STP influent)** | | | | |
| PEC local without removal [µg/L] Time 1 | 0.18 | 0.72 | 0.31 | 2.0\*10-3 |
| PEC local without removal [µg/L] Time 2 (5475 days) | 0.01 | 0.03 | 0.01 | 1.1\*10-3 |
|  | | | | |
| **Bridge over Pond (surface water)** | | | | |
| PEC local without removal [µg/L] Time 1 | 0.05 | 0.20 | 0.09 | 5.7\*10-4 |
| PEC local without removal [µg/L] Time 2 (5475 days) | 0.33 | 1.83 | 0.68 | 0.06 |
| PEC local with removal, [µg/L] Time 1 (30 days) | 3.1\*10-4 | 9.8\*10-2 | 4.2\*10-2 | 4.8\*10-6 |
| PEC local with removal, [µg/L] Time 2 (1825 days) | 1.1\*10-5 | 3.9\*10-1 | 3.2\*10-2 | 6.7\*10-6 |
|  | | | | |
| **Bridge over Pond (sediment)** | | | | |
| PEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 1.1\*10-6 | 2.1\*10-3 | 9.3\*10-4 | 6.0\*10-5 |
| PEC local with removal [mg.kgwwt-1] Time 2 (1825 days) | 3.9\*10-8 | 8.3\*10-3 | 7.2\*10-4 | 8.4\*10-5 |

Table 2.2‑35: PEC in surface water and sediment, professional application.

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cypermethrin** |
| --- | --- | --- | --- | --- |
| **Bridge over Pond (surface water)** | | | | |
| PEC local without removal [mg.kgwwt-1] Time 1 | 0.08 | 0.29 | 0.12 | 0.04 |
| PEC local without removal [mg.kgwwt-1] Time 2 (1825 days) | 0.17 | 0.83 | 0.31 | 0.06 |
| PEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 4.9\*10-4 | 0.14 | 0.06 | 3.6\*10-4 |
| PEC local with removal [mg.kgwwt-1] Time 2 (1825 days) | 1.7\*10-5 | 0.29 | 0.04 | 2.1\*10-5 |
|  | | | | |
| **Bridge over Pond (sediment)** | | | | |
| PEC local without removal [mg.kgwwt-1] Time 1 | 2.8\*10-4 | 6.3\*10-3 | 2.7\*10-3 | 5.3\*10-1 |
| PEC local without removal [mg.kgwwt-1] Time 2 (1825 days) | 6.1\*10-4 | 0.02 | 0.01 | 0.77 |
| PEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 1.7\*10-6 | 3.0\*10-3 | 1.2\*10-3 | 4.5\*10-3 |
| PEC local with removal [mg.kgwwt-1] Time 2 (1825 days) | 6.1\*10-8 | 6.2\*10-3 | 8.9\*10-4 | 2.6\*10-4 |

Table 2.2‑36: PEC in surface water and sediment, non-professional application.

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cypermethrin** |
| --- | --- | --- | --- | --- |
| **Bridge over Pond (surface water)** | | | | |
| PEC local without removal [mg.kgwwt-1] Time 1 | 0.10 | 0.35 | 0.14 | 0.07 |
| PEC local without removal [mg.kgwwt-1] Time 2 (1825 days) | 0.19 | 0.89 | 0.33 | 0.09 |
| PEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 6.2\*10-4 | 0.17 | 0.06 | 6.0\*10-4 |
| PEC local with removal [mg.kgwwt-1] Time 2 (1825 days) | 1.9\*10-5 | 0.31 | 0.04 | 3.1\*10-5 |
|  | | | | |
| **Bridge over Pond (sediment)** | | | | |
| PEC local without removal [mg.kgwwt-1] Time 1 | 3.5\*10-4 | 0.01 | 3.1\*10-3 | 0.88 |
| PEC local without removal [mg.kgwwt-1] Time 2 (1825 days) | 6.8\*10-4 | 0.02 | 0.01 | 1.12 |
| PEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 2.2\*10-6 | 3.6\*10-3 | 1.4\*10-3 | 7.5\*10-3 |
| PEC local with removal [mg.kgwwt-1] Time 2 (1825 days) | 6.9\*10-8 | 6.6\*10-3 | 9.5\*10-4 | 3.8\*10-4 |

##### PEC in air

The following conclusions concerning the air compartment are taken from the AR:

**IPBC**

Air will not be an environmental compartment of concern for IPBC used in wood preservatives because of the low vapour pressure of this compound. It should also be noted that the calculated DT50 of IPBC in air is only about 15 hours and is therefore not considered persistent in air.

**Propiconazole and tebuconazole**:

According to the vapour pressure and the Henry’s law constant of propiconazole and tebuconazole the atmosphere is not a compartment of concern for these compounds.

**Cypermethrin**:

Cypermethrin has a low volatility and emissions to the air compartment are expected to be low.

Based on the above conclusions from the AR, risk assessment to air is not performed.

##### PEC in soil, pore water and groundwater

Table 2.2‑37: PEC in soil, industrial dipping, in-service.

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cypermethrin** |
| --- | --- | --- | --- | --- |
| **House (soil)** | | | | |
| PEC local without removal [mg.kgwwt-1] Time 1 (30 days) | 0.03 | 0.12 | 0.05 | 3.2\*10-4 |
| PEC local without removal [mg.kgwwt-1] Time 2 (1825 days) | 0.19 | 1.04 | 0.39 | 0.03 |
| PEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 2.8\*10-5 | 0.11 | 0.04 | 1.8\*10-4 |
| PEC local with removal [mg.kgwwt-1] Time 2 (1825 days) | 8.6\*10-7 | 0.03 | 0.01 | 1.5\*10-4 |
|  | | | | |
| **Fence (soil)** | | | | |
| PEC local without removal [mg.kgwwt-1] Time 1 (30 days) | 2.4\*10-2 | 0.10 | 0.04 | 2.7\*10-4 |
| PEC local without removal [mg.kgwwt-1] Time 2 (1825 days) | 0.15 | 0.86 | 0.32 | 2.7\*10-2 |
| PEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 2.4\*10-5 | 0.09 | 0.04 | 1.5\*10-4 |
| PEC local with removal [mg.kgwwt-1] Time 2 (1825 days) | 7.2\*10-7 | 2.6\*10-2 | 5.7\*10-3 | 1.2\*10-4 |
|  | | | | |
| **Noise Barrier (soil)** | | | | |
| PEC local without removal [mg.kgwwt-1] Time 1 (30 days) | 0.01 | 0.04 | 0.02 | 1.2\*10-4 |
| PEC local without removal [mg.kgwwt-1] Time 2 (1825 days) | 0.07 | 0.39 | 0.14 | 0.01 |
| PEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 1.1\*10-5 | 0.04 | 0.02 | 6.9\*10-5 |
| PEC local with removal [mg.kgwwt-1] Time 2 (1825 days) | 3.2\*10-7 | 1.2\*10-2 | 2.6\*10-3 | 5.5\*10-5 |

Table 2.2‑38: PEC in soil, brushing, professional application.

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cypermethrin** |
| --- | --- | --- | --- | --- |
| **House (brushing, soil)** | | | | |
| PEC local without removal [mg.kgwwt-1] Time 1 (30 days) | 0.05 | 0.17 | 0.07 | 0.02 |
| PEC local without removal [mg.kgwwt-1] Time 2 (1825 days) | 0.10 | 0.47 | 0.18 | 0.03 |
| PEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 2.8\*10-5 | 0.15 | 0.06 | 0.01 |
| PEC local with removal [mg.kgwwt-1] Time 2 (1825 days) | 8.6\*10-7 | 0.03 | 0.01 | 1.5\*10-4 |
|  | | | | |
| **Fence (brushing, soil)** | | | | |
| PEC local without removal [mg.kgwwt-1] Time 1 (30 days) | 3.8\*10-2 | 0.14 | 0.06 | 2.0\*10-2 |
| PEC local without removal [mg.kgwwt-1] Time 2 (1825 days) | 0.08 | 0.39 | 0.15 | 2.9\*10-2 |
| PEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 2.4\*10-5 | 0.12 | 0.05 | 5.8\*10-3 |
| PEC local with removal [mg.kgwwt-1] Time 2 (1825 days) | 7.2\*10-7 | 2.6\*10-2 | 5.7\*10-3 | 1.2\*10-4 |

Table 2.2‑39: PEC in soil, brushing, non-professional application.

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cypermethrin** |
| --- | --- | --- | --- | --- |
| **House (brushing, soil)** | | | | |
| PEC local without removal [mg.kgwwt-1] Time 1 (30 days) | 0.06 | 0.20 | 0.08 | 0.04 |
| PEC local without removal [mg.kgwwt-1] Time 2 (1825 days) | 0.11 | 0.50 | 0.19 | 0.05 |
| PEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 2.8\*10-5 | 0.18 | 0.07 | 0.01 |
| PEC local with removal [mg.kgwwt-1] Time 2 (1825 days) | 8.6\*10-7 | 0.03 | 0.01 | 1.5\*10-4 |
|  | | | | |
| **Fence (brushing, soil)** | | | | |
| PEC local without removal [mg.kgwwt-1] Time 1 (30 days) | 4.7\*10-2 | 0.17 | 0.07 | 3.3\*10-2 |
| PEC local without removal [mg.kgwwt-1] Time 2 (1825 days) | 0.09 | 0.42 | 0.16 | 4.2\*10-2 |
| PEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 2.4\*10-5 | 0.15 | 0.05 | 9.6\*10-3 |
| PEC local with removal [mg.kgwwt-1] Time 2 (1825 days) | 7.2\*10-7 | 2.6\*10-2 | 5.7\*10-3 | 1.2\*10-4 |

Table 2.2‑40: PEC in soil, spraying.

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cypermethrin** |
| --- | --- | --- | --- | --- |
| **House (spraying, Tier 1, soil)** | | | | |
| PEC local without removal [mg.kgwwt-1] Time 1 (30 days) | 0.20 | 0.62 | 0.22 | 0.24 |
| PEC local without removal [mg.kgwwt-1] Time 2 (1825 days) | 0.25 | 0.93 | 0.33 | 0.25 |
| PEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 2.8\*10-5 | 0.54 | 0.17 | 0.07 |
| PEC local with removal [mg.kgwwt-1] Time 2 (1825 days) | 8.6\*10-7 | 0.03 | 0.01 | 1.5\*10-4 |
|  | | | | |
| **House (spraying, Tier 2, soil)** | | | | |
| PEC local without removal [mg.kgwwt-1] Time 1 (30 days) | 0.04 | 0.16 | 0.07 | 0.02 |
| PEC local without removal [mg.kgwwt-1] Time 2 (1825 days) | 0.10 | 0.47 | 0.18 | 0.03 |
| PEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 2.8\*10-5 | 0.15 | 0.06 | 0.01 |
| PEC local with removal [mg.kgwwt-1] Time 2 (1825 days) | 8.6\*10-7 | 0.03 | 0.01 | 1.5\*10-4 |

Table 2.2‑41: PEC in pore water, industrial dipping, in-sevice.

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cypermethrin** |
| --- | --- | --- | --- | --- |
| **House (pore water)** | | | | |
| PEC local with removal [µg/L] Time 1 (30 days) | 0.01 | 6.35 | 2.51 | 1.8\*10-5 |
| PEC local with removal [µg/L] Time 2 (1825 days) | 3.7\*10-4 | 1.87 | 0.39 | 1.4\*10-5 |
|  | | | | |
| **Fence (pore water)** | | | | |
| PEC local with removal [µg/L] Time 1 (30 days) | 0.01 | 5.28 | 2.09 | 1.5\*10-5 |
| PEC local with removal [µg/L] Time 2 (1825 days) | 3.1\*10-4 | 1.56 | 0.32 | 1.2\*10-5 |
|  | | | | |
| **Noise Barrier (pore water)** | | | | |
| PEC local with removal [µg/L] Time 1 (30 days) | 4.5\*10-3 | 2.38 | 0.94 | 6.8\*10-6 |
| PEC local with removal [µg/L] Time 2 (1825 days) | 1.4\*10-4 | 0.70 | 0.14 | 5.4\*10-6 |

Table 2.2‑42: PEC in pore water, brushing, professional application.

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cypermethrin** |
| --- | --- | --- | --- | --- |
| **House (brushing, pore water)** | | | | |
| PEC local without removal [µg/L] Time 1 (30 days) | 19.42 | 9.92 | 3.84 | 2.4\*10-3 |
| PEC local without removal [µg/L] Time 2 (1825 days) | 41.57 | 28.03 | 10.11 | 3.4\*10-3 |
| PEC local with removal [µg/L] Time 1 (30 days) | 0.01 | 8.91 | 3.24 | 6.9\*10-4 |
| PEC local with removal [µg/L] Time 2 (1825 days) | 3.7\*10-4 | 1.87 | 0.39 | 1.4\*10-5 |
|  | | | | |
| **Fence (brushing, pore water)** | | | | |
| PEC local without removal [µg/L] Time 1 | 16.16 | 8.26 | 3.19 | 2.0\*10-3 |
| PEC local without removal [µg/L] Time 2 (1825 days) | 34.59 | 23.32 | 8.41 | 2.9\*10-3 |
| PEC local with removal [µg/L] Time 1 (30 days) | 0.01 | 7.42 | 2.69 | 5.7\*10-4 |
| PEC local with removal [µg/L] Time 2 (1825 days) | 3.1\*10-4 | 1.56 | 0.32 | 1.2\*10-5 |

Table 2.2‑43: PEC in pore water, brushing, non-professional application.

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cypermethrin** |
| --- | --- | --- | --- | --- |
| **House (brushing, pore water)** | | | | |
| PEC local without removal [µg/L] Time 1 (30 days) | 24 | 12 | 4.48 | 3.9\*10-3 |
| PEC local without removal [µg/L] Time 2 (1825 days) | 46 | 30 | 10.75 | 5.0\*10-3 |
| PEC local with removal [µg/L] Time 1 (30 days) | 0.01 | 11 | 3.72 | 1.1\*10-3 |
| PEC local with removal [µg/L] Time 2 (1825 days) | 3.7\*10-4 | 1.87 | 0.39 | 1.4\*10-5 |
|  | | | | |
| **Fence (brushing, pore water)** | | | | |
| PEC local without removal [µg/L] Time 1 | 20 | 10 | 3.73 | 3.3\*10-3 |
| PEC local without removal [µg/L] Time 2 (1825 days) | 39 | 25 | 8.94 | 4.2\*10-3 |
| PEC local with removal [µg/L] Time 1 (30 days) | 0.01 | 8.84 | 3.10 | 9.5\*10-4 |
| PEC local with removal [µg/L] Time 2 (1825 days) | 3.1\*10-4 | 1.56 | 0.32 | 1.2\*10-5 |

Table 2.2‑44: PEC in pore water, spraying.

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cypermethrin** |
| --- | --- | --- | --- | --- |
| **House (spraying, Tier 1, pore water)** | | | | |
| PEC local with removal [µg/L] Time 1 (30 days) | 0.01 | 32 | 9.79 | 6.7\*10-3 |
| PEC local with removal [µg/L] Time 2 (1825 days) | 3.7\*10-4 | 1.87 | 0.39 | 1.4\*10-5 |
|  | | | | |
| **House (spraying, Tier 2, pore water)** | | | | |
| PEC local with removal [µg/L] Time 1 (30 days) | 0.01 | 9 | 3.20 | 6.6\*10-4 |
| PEC local with removal [µg/L] Time 2 (1825 days) | 3.7\*10-4 | 3.02 | 0.52 | 1.4\*10-5 |

#### Assessment for groundwater

For IPBC and cypermethrin, PECporewater values are below the limit for drinking water (0.1 µg/L) for all scenarios when taking removal processes into account. Therefore, a higher tier for groundwater assessment is not relevant for these two substances.

For propiconazole and tebuconazole, PECs in pore water are above the threshold value of 0.1 µg/L, even when removal is taken into account. Moreover, according to the document "*Groundwater exposure assessment for wood preservatives"* (endorsed at the 24th CA meeting) leaching to groundwater must be evaluated if Koc < 500 L/kg or DT50 > 21 days and both propiconazole and tebuconazole meet these criteria. Therefore, a groundwater risk assessment was performed according to FOCUS PEARL 4.4.4 for propiconazole and tebuconazole.

A groundwater risk assessment of PBC and 1,2,4-triazole was also performed since these metabolites may be present in amounts close to or above 10% of the mother molecule.

For 1,2,4-triazole the combined contribution from propiconazole (32.2%) and tebuconazole (9%) was used as input for the model calculation.

The following data were used as input to the FOCUS PEARL model calculations:

According to the ESD Appendix 4, a density of 16 houses per hectare is assumed and Fweatherside = 0.5 for *in-service* since the leaching rates are derived from semi-field testing. The grassland scenario and spraying was used in all cases. The applications occurred at the following dates: 10.01, 15.02, 24.03, 29.04, 05.06, 11.07, 17.08, 22.09, 29.10 and 04.12.

Additional assumptions: no interception, fallow soil, no plant uptake, assessment of standard 26 years (6 years warm-up period plus 20 years simulation period).

As input to the model, a worst-case approximation was used based on the sum of the following two contributions:

For the *in-situ* estimation, the leaching value from the spraying scenario (tier 1) was used, combined run off and drift:

Q\* time 2in situ = (Esoil run off tier 1 + Esoil spray drift tier 1)/ Areahouse, [kg/m2]

For the *in-service* leaching, the total loss during 5 years of service-life estimated (based on the semi-field leaching study) was used.

When converting total leaching in [kg/m2] to [kg/ha] the following equation was used for *in-situ* treatment:

Q\* time 2 [kg/ha]in-situ = (Q\* time 2in situ \* Area house per hectare) / (Time 2 \* Annual deposits)

Where the following default values are used:

Areahouse per hectare = 2000 [m2 /ha]

Time 2 [years] = 5 years

Annual deposits [-] = 10

Using propiconazole as an example:

Q\* time 2 [kg/ha]in-situ = (5.0\*10-3 + 3.8\*10-3/125) \* 2000) / (5 \* 10)

Q\* time 2 [kg/ha]in-situ = 3.6\*10-3

When converting total leaching (Q\* time 2) in [kg/m2] to [kg/ha] the following equation was used for *in-service*:

Q\* time 2 [kg/ha]in service = (Q\*leach time2 \* Area house per hectare) / (Time 2 \* Annual deposits) \* Fweatherside)

Q\* time 2 [kg/ha]in service = ((74.14\*10-6 \* 2000) / (5 \* 10)) \* 0.5

Q\* time 2 [kg/ha]in service = 1.5\*10-3

Total input to the model:

Q\* time 2 [kg/ha]in-situ + Q\* time 2 [kg/ha]in service

The input parameters and results of the model calculations are presented below.

Table 2.2‑45: PEC estimation to groundwater using the PEARL FOCUS model

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Parameter/variable** | **PBC** | **Propiconazole** | **Tebuconazole** | **1,2,4-triazole** |
| **INPUTS** | | | | |
| Reference | AR for PT08 | AR for PT08 | AR for PT08 | AR for PT08 |
| Application rate: Estimated from the leaching rate converted to 10 equal applications per annum  (kg ha-1) | 0.0010 | 0.0063 | 0.0021 | - |
| Kom or Koc (L. kg-1) | 198.1 (Koc) | 397 (Kom) | 992 (Koc) | 51.6 (Kom) |
| Freundlich exponent assumed as 0.9 (unless laboratory data known) mean values | 0.9 | 0.88(1) | 0.9 | 0.92(1) |
| DT50 (days, note °C) | 10 (12°C) | 43(1) (20°C). | 56.9 (12°C)  Mean of 4 experiments in Northern Europe | 6.4(1) |
| Molecular Mass (g mol-1) | 155.2 | 342.2 | 307.8 | 69.1 |
| Water solubility (mg L-1, note °C) | 0.49\*104 (20°C) | 100 (20°C) | 29 (20°C) | 700000 (20°C) |
| Vapour pressure (Pa, note °C) | 47 (20°C) | 0.56\*10-4 (25°C) | 1.70\*10-6 (20°C) | 0.22 (25°C) |
| Proportion (% applied) of parent compound that is metabolised | 100% of IPBC is metabolised (from leaching studies | Worst case for soil 32.2% of propiconazole is metabolised to 1,2,4-triazole in soil compartment | 9% of tebuconazole is metabolised to 1,2,4-triazole | - |
| The ratio in molecular weight between the mother molecule and the metabolite [metabolite/mother molecule] | 0.552117 | 0.2019 | 0.224496 | - |
| **OUTPUT EMISSIONS at target depth** | | | | |
| Châteaudun (µg.L-1) | 0.000 | 0.000 | 0.000 | 0.000 |
| Hamburg (µg.L-1) | 0.000 | 0.000 | 0.000 | 0.000 |
| Jokioinen (µg.L-1) | 0.000 | 0.000 | 0.000 | 0.000 |
| Kremsmünster (µg.L-1) | 0.000 | 0.000 | 0.000 | 0.000 |
| Okehampton (µg.L-1) | 0.000 | 0.000 | 0.000 | 0.000 |
| Piacenza (µg.L-1) | 0.000 | 0.000 | 0.000 | 0.000 |
| Porto (µg.L-1) | 0.000 | 0.000 | 0.000 | 0.000 |
| Seville (µg.L-1) | 0.000 | 0.000 | 0.000 | 0.000 |
| Thiva (µg.L-1) | 0.000 | 0.000 | 0.000 | 0.000 |

(1) Communication from Janssen, e-mail dated 19.03.2015.

##### Non-compartmental-specific exposure relevant to the food chain (secondary poisoning)

- Cypermethrin

As cypermethrin has a log Kow > 3 (log Kow = 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 0.09 µg/L. This concentration is obtained in the bridge over pond scenario following *in situ* application by non-professional and leaching during the whole assessment period of 1825 days (see Table 3.3.2.5.3-1). The calculated concentration in fishes has to be considered as a worst case. Indeed, it is stated on the label to restrict the use of the product close to water-ways. Therefore no emission into the surface water can occur during the *in situ* application. Moreover, the concentration in surface water of 0.09 µg/L is calculated without taking into account removal processes.

The concentration in earthworm is calculated using the worst case concentration in soil (*i.e*. the concentration of 0.25 mg/kgwwt. This concentration is obtained in the tier 1 of the spraying scenario following *in situ* application by spraying and leaching during the whole assessment period of 1825 days (see Table 3.3.2.5.4-1). The calculated concentration in earthworm has to be considered as a worst case. Indeed, it is stated on the label to cover the soil during the application, therefore no emission occur during *in situ* application by spraying. Moreover, the concentration in soil of 0.25 mg/kgwwt is calculated without taking into account removal processes.

Table 2.2‑46: PEC of cypermethrin in fish and earthworm

|  |  |  |
| --- | --- | --- |
|  | Concentration in fish | Concentration in earthworm |
| Cypermethrin | 0.0187 mg/kgwet fish | 0.0502 mg/kgwet earthworm |

- As stated in section 2.2.6.2 there is no need to perform an assessment of secondary poisoning for propiconazole, tebuconazole and IPBC.

##### Relevant metabolites

IPBC:

According to the AR for IPBC, PBC was identified as a relevant metabolite of IPBC in water, sediment and soil, because it was found in degradation studies at above the limit value of 10%. Due to a relative short half-life of PBC (T½ of 31.2; 31.4 and 9.5 days at 12oC in water, sediment and soil, respectively) PBC can be regarded as a transient metabolite. In addition, the ecotoxicity of PBC is a factor of 300 – 1000 lower for fish, invertebrates and algae compared to IPBC.

In this report PBC was included in the calculation, by transforming the measured amount of PBC to the corresponding amount of IPBC and use the total as input parameter. This must be considered a worst-case approach.

Propiconazole:

In the soil laboratory studies there were two degradation products of propiconazole accounting for more than 10% of the active substance: CGA 118 245 and 1,2,4-triazole. Both are degraded in soil faster than the parent substance CGA 118 245 having DT50 of around 1 day and 1,2,4-triazole having DT50 of around 9.3 days at 20 °C. Both degradation products are also more mobile in soil than propiconazole CGA 118 245 having the arithmetic mean Koc of 129 from 3 soils and 1,2,4-triazole having the arithmetic mean Koc of 69 from 10 soils.

Tebuconazole:

The major metabolite formed in soil from tebuconazole is 1,2,4-triazole.

According to the AR for tebuconazole (PT08), 1,2,4-triazole was identified as a relevant metabolite of tebuconazole in soil, because it was found in soil degradation studies at concentrations up to 9%, which is close to the limit value of 10%. Due to the considerably shorter half-life of 1,2,4-triazole in soil compared to that of tebuconazole, 1,2,4-triazole can be regarded as a transient metabolite. The ecotoxicity of the metabolite is significantly lower than found for tebuconazole for both the aquatic and terrestrial environment and therefore the metabolite will not be considered further.

Cypermethrin:

In the AR three major metabolites were identified in water and soil: 3-phenoxybenzoic acid, TDCVC and CDCVC. However, no data is available for these metabolites and none of these were considered further.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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--- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 7   1. PEC in the aquatic compartment (including sediment)    1. Direct emission to the aquatic compartment – industrial application, storage   Local concentrations in surface water over the initial assessment period and after adsorption on suspended matter have been estimated according to the ESD for PT08.   |  |  | | --- | --- | | Storage – Treatment by industrial dipping | | | PEC local surface water,time1 (after adsorption on suspended matter) [µg.L-1] | | | Tebuconazole | 4.34E-02 | | Propiconazole | 9.87E-02 | | Cypermethrin | 2.24E-04 | | IPBC | 2.49E-02 | | PBC | 1.38E-02 | | PEC local sediment,time1 [mg.kgwwt-1] | | | Tebuconazole | 9.71E-04 | | Propiconazole | 2.10E-03 | | Cypermethrin | 2.80E-03 | | IPBC | 9.24E-05 | | PBC | 7.01E-05 |  * 1. Direct emission to the aquatic compartment - Bridge over the pond scenario   The emissions in local water were calculated for the outdoor application phase, and in 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 (DT50water) 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 (DT50whole system), and the partition coefficient organic carbon-water (Koc).   * + 1. Direct emissions during outdoor – Application Phase  |  |  |  | | --- | --- | --- | | **Application - Bridge over the pond - Treatment by brushing** | | | |  | Professional | Non-professional | | **PEC local surface water, initial concentration after application** [µg.L-1] | | | | Tebuconazole | 3.00E-02 | 5.00E-02 | | Propiconazole | 9.60E-02 | 1.60E-01 | | Cypermethrin | 4.80E-02 | 8.00E-02 | | IPBC | 3.00E-02 | 5.00E-02 | | PBC | 1.66E-02 | 2.76E-02 | | **PEC local sediment after application** [mg.kg-1wwt] | | | | Tebuconazole | 6.70E-04 | 1.12E-03 | | Propiconazole | 2.05E-03 | 3.41E-03 | | Cypermethrin | 6.00E-01 | 1.00E+00 | | PBC | 8.43E-05 | 1.40E-04 |  |  |  | | --- | --- | | **Application - Bridge over the pond - Treatment by spraying** | | | **PEC local surface water, initial concentration after application** [µg.L-1] | | | Tebuconazole | 3.00E-02 | | Propiconazole | 9.60E-02 | | Cypermethrin | 4.80E-02 | | IPBC | 3.00E-02 | | PBC | 1.66E-02 | | **PEC local sediment after application** [mg.kg-1wwt] | | | Tebuconazole | 6.70E-04 | | Propiconazole | 2.05E-03 | | Cypermethrin | 6.00E-01 | | PBC | 8.43E-05 |  * + 1. Direct emissions during service life - Bridge over the pond        1. TIME 1 assessment period (30 days) - After industrial / *in situ* application  |  |  |  |  | | --- | --- | --- | --- | | **PEC local surface water** | | | | |  | **Industrial & *In situ* application**  TWA over the TIME 1 assessment period (30 days)  [µg.L-1] | ***In situ* application**  TWA over the TIME 2 assessment period [µg.L-1] | **Industrial application**  TWA over the TIME 2 assessment period [µg.L-1] | | Tebuconazole | 3.76E-02 | 9.64E-03 | 7.97E-03 | | Propiconazole | 6.05E-02 | 7.21E-03 | 6.06E-03 | | Cypermethrin | 3.67E-05 | 3.09E-05 | 3.09E-05 | | IPBC | 3.11E-04 | 1.92E-05 | 1.59E-05 | | PBC | 1.13E-02 | 2.50E-03 | 2.11E-03 | | **PEC local sediment** | | | | |  | **Industrial & *In situ* application**  TIME 1 assessment period (30 days)  [mg.kg-1wwt] | ***In situ* application**  over the TIME 2 assessment period [mg.kg-1wwt] | **Industrial application**  over the TIME 2 assessment period [mg.kg-1wwt] | | Tebuconazole | 9.49E-04 | 8.66E-04 | 7.86E-04 | | Propiconazole | 2.11E-03 | 5.94-03 | 9.06E-03 | | Cypermethrin | 3.74E-03 | 7.42E-03 | 7.48E-03 | | PBC | 5.75E-05 | 1.28E-05 | 1.08E-05 |  * 1. Indirect emissions via the 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 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 – FSTP,water** [-] | | | | Tebuconazole | 0.89 | | | Propiconazole | 0.9 | | | Cypermethrin | 0.091 | | | IPBC | 0.963 | | | PBC | 0.967 | | | Outputs: | | | | **PECSTP** | | | |  | **Industrial & *In situ* application**  **TIME1**  [mg.L-1] | **Industrial application**  **TIME2**  [mg.L-1] | | Tebuconazole | 2.74E-04 | 1.21E-05 | | Propiconazole | 6.29E-04 | 3.32E-05 | | Cypermethrin | 2.70E-07 | 2.16E-07 | | IPBC | 1.70E-04 | 8.65E-06 | | PBC | 9.42E-05 | 4.79E-06 |   Indirect emissions to surface water and sediment via the STP were calculated according to the equations 45 and 50 of the ECHA Guidance Vol.IV, par B (2015).   |  | | --- | | **Wood-in-service – Noise barrier - Treated wood in service only** |  |  |  |  | | --- | --- | --- | | **PECwater\_via\_STP** | | | |  | **Industrial & *In situ* application**  **TIME1**  [µg.L-1] | **Industrial application**  **TIME2**  [µg.L-1] | | Tebuconazole | 2.73E-02 | 1.21E-03 | | Propiconazole | 6.28E-02 | 3.31E-03 | | Cypermethrin | 1.45E-05 | 1.16E-05 | | IPBC | 1.70E-02 | 8.65E-04 | | PBC | 9.42E-03 | 4.79E-04 | | **PECsediment\_via\_STP** | | | |  | **Industrial & *In situ* application**  **TIME1**  [**mg.kg-1wwt**] | **Industrial application**  **TIME2**  [**mg.kg-1wwt**] | | Tebuconazole | 6.11E-04 | 2.71E-05 | | Propiconazole | 1.34E-03 | 7.06E-05 | | Cypermethrin | 1.81E-04 | 1.45E-04 | | PBC | 4.79E-05 | 2.44E-06 |  1. PEC in the soil compartment    1. Direct emissions to soil       1. Industrial dipping, storage   According to the ESD and considering a continuous release rate in the storage area, an average daily release rate into soil due to leaching over the storage duration is estimated (eq.3.2 for soil of the PT08 ESD).   |  |  | | --- | --- | | Storage – Treatment by industrial dipping | | | PEC local soil, steady-state [mg.kgwwt-1] | | | Tebuconazole | 2.11E-01 | | Propiconazole | 5.09E-01 | | Cypermethrin | 4.51E-04 | | IPBC | 3.07E-04 | | PBC | 8.23E-03 | | 1,2,4-triazole | 6.85E-02 |  * + 1. *In situ* 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).   |  |  |  | | --- | --- | --- | | **Application – House -Treatment by brushing** | | | |  | Professional | Non-professional | | **PEC local soil**, **initial concentrations in local soil** [mg.kg-1wwt] | | | | Tebuconazole | 1.70E-02 | 2.83E-02 | | Propiconazole | 5.43E-02 | 9.05E-02 | | Cypermethrin | 2.71E-02 | 4.52E-02 | | IPBC | 1.70E-02 | 2.83E-02 | | PBC | 9.37E-02 | 1.56E-02 | | 1,2,4-triazole | 5.08E-03 | 8.47E-03 |  |  |  |  | | --- | --- | --- | | **Application – House - Treatment by spraying** | | | | **PEC local soil**, **initial concentrations in local soil** [mg.kg-1wwt] | | | |  | Tier1 (Runoff + Drift) | Tier 2 (Drift) | | Tebuconazole | 1.70E-01 | 1.62E-02 | | Propiconazole | 5.43E-01 | 5.18E-02 | | Cypermethrin | 2.71E-01 | 2.59E-02 | | IPBC | 1.70E-01 | 1.62E-02 | | PBC | 9.37E-02 | 8.93E-03 | | 1,2,4-triazole | 5.08E-02 | 4.85E-03 |  * + 1. Service life of treated wood (without considering application phase)   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 (DT50soil).   |  |  |  |  | | --- | --- | --- | --- | | **PEC LOCAL SOIL – House scenario** | | | | |  | **Industrial & *In situ* application**  **TWA concentration**  **TIME1**  [**mg.kg-1wwt**] | ***In situ* application**  **TWA concentration**  **TIME2**  [**mg.kg-1wwt**] | **Industrial application**  **TWA concentration**  **TIME2**  [**mg.kg-1wwt**] | | Tebuconazole | 2.28E-02 | 1.21E-02 | 8.88E-03 | | Propiconazole | 5.20E-02 | 3.28E-02 | 2.52E-02 | | Cypermethrin | 1.65E-04 | 3.16E-04 | 3.16E-04 | | IPBC | 2.66E-04 | 1.65E-05 | 1.37E-05 | | PBC | 4.27E-03 | 4.86E-04 | 3.81E-04 | | 1,2,4-triazole | 5.12E-03 | 4.30E-03 | 3.32E-03 | | **PEC LOCAL SOIL – Noise barrier** | | | | |  | **Industrial & *In situ* application**  **TWA concentration**  **TIME1**  [**mg.kg-1wwt**] | ***In situ* application**  **TWA concentration**  **TIME2**  [**mg.kg-1wwt**] | **Industrial application**  **TWA concentration**  **TIME2**  [**mg.kg-1wwt**] | | Tebuconazole | 8.52E-03 | 4.55E-03 | 3.33E-03 | | Propiconazole | 1.95E-02 | 1.23E-02 | 9.42E-03 | | Cypermethrin | 6.19E-05 | 1.18E-04 | 1.18E-04 | | IPBC | 9.97E-05 | 6.19E-06 | 5.13E-06 | | PBC | 1.60E-03 | 1.82E-04 | 1.43E-04 | | 1,2,4-triazole | 1.92E-03 | 1.61E-03 | 1.24E-03 |  * + 1. *In situ* Application + Service life of treated wood - House  |  |  |  | | --- | --- | --- | | **Brush application + Treated wood in service** | | | | **PEC LOCAL SOIL,** **TWA concentration, TIME 1** [mg.kg-1wwt] | | | |  | ***Professional*** | ***Non professional*** | | Tebuconazole | 3.76E-02 | 4.75E-02 | | Propiconazole | 9.99E-02 | 1.32E-01 | | Cypermethrin | 1.59E-02 | 2.64E-02 | | IPBC | 4.26E-04 | 5.33E-04 | | PBC | 8.07E-03 | 1.06E-02 | | 1,2,4-triazole | 9.74E-03 | 1.28E-02 | | **PEC LOCAL SOIL,** **TWA concentration, TIME 2** [mg.kg-1wwt] | | | | Tebuconazole | 1.29E-02 | 1.35E-02 | | Propiconazole | 3.55E-02 | 3.73E-02 | | Cypermethrin | 4.26E-04 | 5.00E-04 | | IPBC | 1.65E-05 | 1.65E-05 | | PBC | 4.94E-04 | 4.99E-04 | | 1,2,4-triazole | 4.68E-03 | 4.94E-03 | | **Spray application + Treated wood in service** | | | | **PEC LOCAL SOIL,** **TWA concentration, TIME 1 - Tier 1** [mg.kg-1wwt] | | | | Tebuconazole | 1.71E-01 | | | Propiconazole | 5.32E-01 | | | Cypermethrin | 1.58E-01 | | | IPBC | 1.87E-03 | | | PBC | 4.23E-02 | | | 1,2,4-triazole | 5.16E-02 | | | **PEC LOCAL SOIL,** **TWA concentration, TIME 2 - Tier 1** [mg.kg-1wwt] | | | | Tebuconazole | 2.00E-02 | | | Propiconazole | 6.01E-02 | | | Cypermethrin | 1.42E-03 | | | IPBC | 1.65E-05 | | | PBC | 5.65E-04 | | | 1,2,4-triazole | 8.15E-03 | |  * 1. Indirect emissions to soil (via the STP) - Noise barrier scenario:   Indirect emissions to soil via spreading of STP sludge onto soil were used to calculate concentrations in soil according to the equations of the ECHA Guidance Vol.IV, par B (2015), with the following inputs.   |  |  |  | | --- | --- | --- | | **Wood-in-service – Noise barrier- Treated wood in service only** | | | | **PECsoil\_via\_STP [mg.kg-1wwt]** | **TIME1** | **TIME 2** | | Tebuconazole | 1.13E-04 | 5.03E-06 | | Propiconazole | 2.40E-04 | 1.27E-05 | | Cypermethrine | 5.79E-06 | 4.64E-06 | | PBC | 3.53E-06 | 1.80E-07 |  1. PECs 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:   * Koc < 500 L.kg-1 and * DT50soil > 21 d**.**   Considering that:   |  |  |  |  | | --- | --- | --- | --- | | **Substance** | **Koc [L.kg-1]** | **DT50soil,12°C [d]** | | | Tebuconazole | 992 | 77 | | | Propiconazole | 944 | 82 | | | 1,2,4-triazole (\*) | 89 | 114.7 (\*\*) | | | Cypermethrin | 575000 | 17.2 | | | IPBC | 134.5 | 1.96E-01 | | | PBC(\*\*\*) | 198.1 | 9.50 | | | (\*) – 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 DT50 at 20°C of 60.5 days.  (\*\*\*) – Relevant metabolite of IPBC in all environmental compartments assuming 100% of applied radioactivity. | | |   Estimations of releases to groundwater is considered relevant by FR-CA for the following substances:   * Tebuconazole; * Propiconazole; * IPBC; * PBC; * 1,2,4-triazole.   According to the paragraph 580 of the PT08-ESD (2013), a groundwater assessment is only necessary for the house scenario, which can be considered to be the worst case for soil exposure, thus covering all other scenarios.  Consequently to the environmental risk assessment performed for the application phase, it is recommended on the label to cover the soil during the application by brushing or spraying. 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.  The scenario for the groundwater exposure assessment for wood preservatives described in the supplement of the appendix 4 of the PT08-ESD, based on leaching values.   | **Input parameter** | **Unit** | **Value** | | | | | | --- | --- | --- | --- | --- | --- | --- | |  | | **Tebuco-nazole** | **Propico-nazole** | **IPBC** | **PBC** | **1,2,4-triazole** | | **Physicochemical parameters** | | | | | | | | Molar mass | g.mol-1 | 307.8 | 342.2 | 281.1 | 155.2 | 69.1 | | Water solubility (25 °C) | mg.L-1 | 29 | 100 | 168 | 2860 | 700 000 | | Molar enthalpy of dissolution | kJ.mol-1 | 27 | | | | | | Saturated vapour pressure | Pa | 1.70E-06 (20°C) | 5.60E-05  (25°C) | 2.36E-03  (25°C) | 1.88E+01  (25°C) | 2.20E-01  (20°C) | | Molar enthalpy of vaporisation | kJ.mol-1 | 95 | | | | | | Diffusion coefficient in water (20 °C) | m².d-1 | 4.3E-05 | | | | | | Diffusion coefficient in air (20 °C) | m².d-1 | 0.43 | | | | | | **Degradation parameters** | | | | | | | | Half-life (12°C, pF2) | d | 77 | 82 | 1.96E-01 | 9.50 | 114.7 | | Arrhenius activation energy | kJ.mol-1 | 65.4 | | | | | | Exponent of moisture correction function | - | 0.7 | | | | | | **Sorption parameters** | | | | | | | | Koc value | L.kg-1 | 992 | 944 | 134.5 | 198.1 | 89 | | Komvalue (20°C) | mL.g-1 | 575.41 | 547.56 | 78.02 | 114.91 | 51.62 | | Freundlich exponent 1/n | - | 1 | | | | | | Method of subroutine description | - | pH independent | | | | | | **Crop related parameters** | | | | | | | | Crop uptake factor | - | 0 | | | | | | **Application Schemes** | | | | | | | | Q\*leach, TIME2 (5 years) | kg.m-2 | 2.94E-05 | 7.68E-05 | 1.88E-05 | n.r. | n.r. | | Total leachable area | m².ha-1 | 2 000 | | | | | | Fraction of house surface exposed to weather | - | 0.5 | | | | | | Service life | year | 5 | | | | | | Number of application per year | - | 10 | | | | | | Dosage service-life | kg.ha-1 | 5.88E-04 | 1.54E-03 | 3.76E-04 | n.r. | n.r. | | Fraction transformed | - | n.r. | n.r. | n.r. | 1  (IPBC) | 0.09 (Tebuconazole) 0.43  (Propiconazole) | | Application type | - | To the soil surface | | | | | | Repeat interval for years | - | 1 | | | | | | Date | - | 10/01/1901 | | | | | | 15/02/1901 | | | | | | 24/03/1901 | | | | | | 29/04/1901 | | | | | | 05/06/1901 | | | | | | 11/07/1901 | | | | | | 17/08/1901 | | | | | | 22/09/1901 | | | | | | 29/10/1901 | | | | | | 04/12/1901 | | | | | | **Crops Application** | | | | | | | | Crop(s) | - | Grassland | | | | | | Selected Locations | | CHATEAUDUN | | | | | | HAMBURG | | | | | | JOIKIONEN | | | | | | KREMSMUENSTER | | | | | | OKEHAMPTON | | | | | | PIACENZA | | | | | | PORTO | | | | | | SEVILLA | | | | | | THIVA | | | | |   n.r.: not relevant  The results are listed in the table below.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Scenario** | **Tebuconazole [µg.L-1]** | **Propiconazole [µg.L-1]** | **1,2,4-triazole (\*) [µg.L-1]** | **IPBC**  **[µg.L-1]** | **PBC**  **[µg.L-1]** | | CHATEAUDUN | < 0.001 | < 0.001 | 0.02 | < 0.001 | < 0.001 | | HAMBURG | < 0.001 | < 0.001 | 0.04 | < 0.001 | < 0.001 | | JOIKIONEN | < 0.001 | < 0.001 | 0.03 | < 0.001 | < 0.001 | | KREMSMUENSTER | < 0.001 | < 0.001 | 0.03 | < 0.001 | < 0.001 | | OKEHAMPTON | < 0.001 | < 0.001 | 0.03 | < 0.001 | < 0.001 | | PIACENZA | < 0.001 | < 0.001 | 0.02 | < 0.001 | < 0.001 | | PORTO | < 0.001 | < 0.001 | 0.02 | < 0.001 | < 0.001 | | SEVILLA | < 0.001 | < 0.001 | 0.01 | < 0.001 | < 0.001 | | THIVA | < 0.001 | < 0.001 | 0.01 | < 0.001 | < 0.001 |  1. Secondary poisoning   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 Bridge “surface treatment (eq. to 200 g.m-2) – treated wood in service only” with a Clocalwater,TWA\_TIME2 of 3.09E-05 µg.L-1; * for the terrestrial food chain, the scenario “spray application (Tier1 – runoff + drift) + treated wood in service” with a Clocalsoil,TWA\_TIME2 of 1.42E-03 mg.kg-1wwt.   In accordance with the equations of the ECHA guidance vol.IV, part B (2015), PECoral,predator for both food chain were calculated as followed:   |  |  |  |  | | --- | --- | --- | --- | | **Parameter / variable** | **Symbol** | **Unit** | **Value** | | ***Aquatic food chain:*** | | | | | Predicted environmental concentration during episode | PEClocal,water | [mg.L-1] | 3.09E-08 | | Bioconcentration factor for fish on wet weight basis | BCFfish | [L.kg-1wet fish] | 417 | | Biomagnification factor in fish | BMF | [-] | 2 | | **Predicted environmental concentration in food (considering that predators feed at 50% on local level)** | **PECoral,predator** | **[mg.kg-1wet fish]** | **1.29E-05** | | ***Terrestrial food chain :*** |  |  |  | | log of partition coefficient n-octanol-water | Log Kow | [-] | 5.45 | | Bioconcentration factor for earthworm on wet weight basis | BCFearthworm | [L.kg-1wet earthworm] | 3.38E+03 | | Concentration in porewater | Cporewater | [mg.L-1] | 1.40E-07 | | Concentration in soil | Csoil | [mg.kg-1wwt] | 1.42E-03 | | Fraction of gut loading in worm | Fgut | [kgdwt.kg-1wwt] | 0.1 | | Conversion factor for soil concentration wet-dry weight soil | CONVsoil | [kgwwt.kg-1dwt] | 1.13 | | **Predicted environmental concentration in food (considering that predators feed at 50% on local level)** | **PECoral,predator** | **[mg.kg-1wet earthworm]** | **2.84E-04** | |

#### Risk characterisation for the environment

For the assessment of the environmental fate and behaviour of the active substances contained in biocidal product, refer to the chapter on Fate and Behaviour in the environment Doc. II-A (see Letters of Access from Troy, Janssen, Lanxess and Agriphar).

The environmental risk assessment is performed only for preventive treatments by industrial dipping and for preventive treatments by professional and non-professional by brushing and spraying.

Indeed, as curative treatments are intended for the treatment of wood used in risk class 2 (wood not exposed to weathering and leaching), no emission into the environment is foreseen during the application or during the service-life of the wood.

Modelling based on the revised ESD was used to estimate local PECs for the product X6122B1. In the models, default values (according to the TGD) were used, unless submitted data were available in the dossier. Calculations based on both professionals and non-professionals for brushing, spraying and industrial applications are shown.

The following PNECs are presented in the Assessment Reports of the active substances (see Document II-B point 5, in Section 13 of the IUCLID file):

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cypermethrin** |
| PNECwater [µg/L] | 0.5 | 6.8 | 1 | 0.001 |
| PNECsediment [mg/kgwwt] | 0.00176 | 0.054 | 0.55 | 0.125 |
| PNECSTP [mg/L] | 0.44 | 100 | 0.32 | 1.63 |
| PNECsoil [mg/kgwwt] | 0.0044 | 0.1 | 0.1 | 0.088 |
| Groundwater threshold value[µg/L] | 0.1 | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 8  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** | **Cyper-**  **methrin** | **Tebuco-**  **nazole** | **Propico-**  **nazole** | **1,2,4-triazole** | **IPBC** | **PBC** | | **PNECSTP** | [mg/L] | 1.63E+00 | 3.20E-01 | 1.00E+02 | n.r. | 0.44 | 0.44 | | **PNECwater** | [µg/L] | 4.00E-03(1) | 1.00E+00 | 6.80E+00 | n.r. | 5.00E-01 | 4.13E+01 | | **PNECsediment** | [mg/kgwwt] | 5.00E-02 | 5.50E-01 | 5.40E-02 | n.r. | 1.85E-03 | 2.10E-01 | | **PNECsoil** | [mg/kgwwt] | 9.18E-02 | 1.00E-01 | 1.00E-01 | 8.20E-03 | 4.40E-03 | 1.49E-01 | | **PNECoral,bird** | [mg/kgfood] | 3.33E+01 | n.r. | n.r. | n.r. | n.r. | n.r. | | **PNECoral,mammals** | [mg/kgfood] | 3.33E+00 | n.r. | n.r. | n.r. | n.r. | n.r. |   n.r: not relevant  ’(1) According to the WGIV2016, a robust NOEC fish of 0.4 µg.L-1 is considered to derive the PNECwater for Cypermethrin with an assessment factor of 100. |

##### Aquatic compartment (Including sediments)

**- Substances**

Table 2.2‑47: PEC/PNEC ratios for the aquatic compartment, industrial application, storage

|  | **IPBC** | **Propicona­zole** | **Tebucona­zole** | **Cyperme­thrin** | **Total PEC/PNEC** |
| --- | --- | --- | --- | --- | --- |
| **Dipping (surface water)** |  |  |  |  |  |
| PEC/PNEC in surface water over the initial assessment period [µg.L-1] | 0.05 | 0.01 | 0.04 | 0.28 | 0.39 |
| PEC/PNEC in surface water over a longer assessment period [µg.L-1] | 0.05 | 0.01 | 0.04 | 0.28 | 0.39 |

Table 2.2‑48: PEC/PNEC ratios for the aquatic compartment, *in-situ* application

|  | **IPBC** | **Propicona­zole** | **Tebucona­zole** | **Cyperme­thrin** | **Total PEC/PNEC** |
| --- | --- | --- | --- | --- | --- |
| **Bridge over Pond (surface water)** |  |  |  |  |  |
| PEC/PNEC local in water at the end of the day of application (bridge, professional application) | 0.06 | 0.01 | 0.03 | 42 | 42 |
| PEC/PNEC local in water at the end of the day of application (bridge, non-professional application) | 0.1 | 0.02 | 0.05 | 70 | 70 |

Table 2.2‑49: PEC/PNEC ratios for the aquatic compartment, industrial dipping, in-service

|  | **IPBC** | **Propicon­azole** | **Tebucon­azole** | **Cyperme­thrin** | **Total PEC/PNEC** |
| --- | --- | --- | --- | --- | --- |
| **Noise Barrier (STP influent)** |  |  |  |  |  |
| PEC/PNEC local without removal [µg/L] Time 1 | 4.0\*10-4 | 7.2\*10-6 | 9.8\*10-4 | 1.2\*10-6 | 1.4\*10-3 |
| PEC/PNEC local without removal [µg/L] Time 2 (5475 days) | 1.2\*10-5 | 3.1\*10-7 | 3.6\*10-5 | 6.8\*10-7 | 4.9\*10-5 |
| **Bridge over Pond (surface water)** |  |  |  |  |  |
| PEC/PNEC local without removal [µg/L] Time 1 | 0.10 | 0.03 | 0.09 | 0.57 | 0.79 |
| PEC/PNEC local without removal [µg/L] Time 2 (5475 days) | 0.66 | 0.27 | 0.68 | 58 | 60 |
|  |  |  |  |  |  |
| PEC/PNEC local with removal, [µg/L] Time 1 (30 days) | 6.2\*10-4 | 0.01 | 0.04 | 4.8\*10-3 | 0.06 |
| PEC/PNEC local with removal, [µg/L] Time 2 (5475 days) | 2.2\*10-5 | 0.06 | 0.03 | 0.01 | 0.10 |
| **Bridge over Pond (sediment)** |  |  |  |  |  |
| PEC/PNEC local without removal [mg.kgwwt-1] Time 1 | 0.1 | 0.1 | 3.6\*10-3 | 0.1 | 0.24 |
| PEC/PNEC local without removal [mg.kgwwt-1] Time 2 (5475 days) | 0.7 | 0.7 | 2.8\*10-2 | 5.8 | 7.24 |
|  |  |  |  |  |  |
| PEC/PNEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 6.2\*10-4 | 3.9\*10-2 | 1.7\*10-3 | 4.8\*10-4 | 0.04 |
| PEC/PNEC local with removal [mg.kgwwt-1] Time 2 (5475 days) | 2.2\*10-5 | 0.15 | 1.3\*10-3 | 6.7\*10-4 | 0.16 |

Table 2.2‑50: Combined PEC/PNEC ratios for surface water and sediment, professional application

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cyperme­thrin** | **Total PEC/PNEC** |
| --- | --- | --- | --- | --- | --- |
| **Bridge over Pond (surface water)** |  |  |  |  |  |
| PEC/PNEC local without removal Time 1 (30 days) | 0.16 | 0.04 | 0.12 | 43 | 43 |
| PEC/PNEC local without removal Time 2 (1825 days) | 0.34 | 0.12 | 0.31 | 62 | 62 |
|  |  |  |  |  |  |
| PEC/PNEC local with removal Time 1 (30 days) | 9.9\*10-4 | 0.02 | 0.06 | 3.6\*10-1 | 0.44 |
| PEC/PNEC local with removal Time 2 (1825 days) | 3.5\*10-5 | 0.04 | 0.04 | 2.1\*10-2 | 0.10 |
| **Bridge over Pond (sediment)** |  |  |  |  |  |
| PEC/PNEC local without removal Time 1 (30 days) | 0.2 | 0.1 | 4.9\*10-3 | 4.3 | 4.5 |
| PEC/PNEC local without removal Time 2 (1825 days) | 3.4\*10-1 | 0.3 | 1.3\*10-2 | 6.2 | 6.8 |
|  |  |  |  |  |  |
| PEC/PNEC local with removal Time 1 (30 days) | 9.9\*10-4 | 5.6\*10-2 | 2.3\*10-3 | 3.6\*10-2 | 0.09 |
| PEC/PNEC local with removal Time 2 (1825 days) | 3.5\*10-5 | 1.1\*10-1 | 1.6\*10-3 | 2.1\*10-3 | 0.12 |

Table 2.2‑51: PEC/PNEC ratios for surface water and sediment, non-professional application

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cyperme­thrin** | **Total PEC/PNEC** |
| --- | --- | --- | --- | --- | --- |
| **Bridge over Pond (surface water)** |  |  |  |  |  |
| PEC/PNEC local without removal Time 1 (30 days) | 0.20 | 0.05 | 0.14 | 71 | 71 |
| PEC/PNEC local without removal Time 2 (1825 days) | 0.38 | 0.13 | 0.33 | 90 | 90 |
|  |  |  |  |  |  |
| PEC/PNEC local with removal Time 1 (30 days) | 1.2\*10-3 | 0.02 | 0.06 | 6.0\*10-1 | 0.69 |
| PEC/PNEC local with removal Time 2 (1825 days) | 3.9\*10-5 | 0.05 | 0.04 | 3.1\*10-2 | 0.12 |
| **Bridge over Pond (sediment)** |  |  |  |  |  |
| PEC/PNEC local without removal Time 1 (30 days) | 0.2 | 0.1 | 5.7\*10-3 | 7.0 | 7.40 |
| PEC/PNEC local without removal Time 2 (1825 days) | 0.4 | 0.4 | 1.4\*10-2 | 9.0 | 9.70 |
|  |  |  |  |  |  |
| PEC/PNEC local with removal Time 1 (30 days) | 1.2\*10-3 | 6.7\*10-2 | 2.6\*10-3 | 6.0\*10-2 | 0.13 |
| PEC/PNEC local with removal Time 2 (1825 days) | 3.9\*10-5 | 1.2\*10-1 | 1.7\*10-3 | 3.1\*10-3 | 0.13 |

In the storage scenario following industrial application no risk was identified in surface water for any of the active substances.

In the aquatic compartment, risk was acceptable in both surface water and sediment for IPBC, propiconazole and tebuconazole for industrial application, professional and non-professional use for all scenarios even without taking removal processes into account.

Risk was identified for cypermethrin in all scenarios for both surface water and sediment when removal processes were not taking into account for both professional and non-professional use. When removal processes were taking into account risk was identified at Time 1, while risk was acceptable at Time 2. However, the risk assessment for cypermethrin was based on the LOQ for the leaching study, since it was not detected at any sample occasion, so the above PEC/PNEC values must be considered a very conservative estimate.

**- Metabolites**

PBC was identified as a relevant metabolite of IPBC in water, sediment and soil. Due to a relative short half-life of PBC, it can be regarded as a transient metabolite. In addition, the ecotoxicity of PBC is a factor of 300 – 1000 lower for fish, invertebrates and algae compared to IPBC.

In this report PBC was included in the calculation, by transforming the measured amount of PBC to the corresponding amount of IPBC and use the total as input parameter. This must be considered a worst-case approach. So, no further assessment of this metabolite is needed.

According to the AR for propiconazole, all metabolites amounted to less than 10% of the applied amount of propiconazole in the surface water and sediment systems, so, no further evaluation is needed.

The ecotoxicity of the metabolite 1,2,4-triazole is significantly lower than found for the tebuconazole for both the aquatic and terrestrial environment and therefore the metabolite will not be considered further as concluded for the tebuconazole evaluation in PT08.

In the AR for cypermethrin three major metabolites were identified in water and soil: 3-phenoxybenzoic acid, TDCVC and CDCVC. However, no data is available for these metabolites and none of these are considered further.

For all the above mentioned metabolites, the assessment made for the a.s. cover the risk of the metabolites.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 9  Risk characterisation for the aquatic compartment (including STEP and sediment)   1. **Direct emission to the aquatic compartment – industrial application, storage**   For the storage phase, the risk characterisation for the aquatic compartment including sediment has been performed considering PEC calculated for industrial application (storage) scenario of the PT08-ESD and compared to PNECwater and PNECsediment of each active substance.   |  |  |  | | --- | --- | --- | | Storage – Treatment by industrial dipping | | | | SURFACE WATER | PEC [µg.L-1] | PEC/PNEC | | Tebuconazole | 4.34E-02 | 0.04 | | Propiconazole | 9.87E-02 | 0.01 | | Cypermethrin | 2.24E-04 | 0.06 | | IPBC | 2.49E-02 | 0.05 | | PBC | 1.38E-02 | 3.33E-04 | | PEC/PNEC |  | 0.16 | | SEDIMENT | PEC [mg.kgwwt-1] | PEC/PNEC | | Tebuconazole | 9.71E-04 | 0.002 | | Propiconazole | 2.10E-03 | 0.04 | | Cypermethrin\* | 2.80E-03 | 0.56 | | PBC | 7.01E-05 | 3.33E-04 | | PEC/PNEC |  | 0.60 |   \* An additional factor of 10 has been considered as PNECsed was defined using the EPM method  The calculated sum of PEC/PNEC ratios for sediment is below 1. In the storage scenario following industrial application, no risk was identified in surface water and sediment.  For the industrial application phase, no emission estimations were provided by the applicant based on mandatory risk mitigation measures for wood treatment plants.   1. **Direct emission to the aquatic compartment - Bridge over the pond scenario**   **Direct emissions during outdoor application:**  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, and compared to PNECwater and PNECsediment of each active substance for the application phase.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Application - Bridge over the pond - Treatment by brushing** | | | | | | **SURFACE WATER** | **Professional** | | **Non-professional** | | | **PEC [µg.L-1]** | **PEC/PNEC** | **PEC [µg.L-1]** | **PEC/PNEC** | | Tebuconazole | 3.00E-02 | 3.00E-02 | 5.00E-02 | 5.00E-02 | | Propiconazole | 9.60E-02 | 1.41E-02 | 1.60E-01 | 2.35E-02 | | Cypermethrin | 4.80E-02 | **1.20E+01** | 8.00E-02 | **2.00E+01** | | IPBC | 3.00E-02 | 6.00E-02 | 5.00E-02 | 1.00E-01 | | PBC | 1.66E-02 | 4.01E-04 | 2.76E-02 | 6.68E-04 | | **PEC/PNEC** |  | **12.10** |  | **20.17** | | **SEDIMENT** | **Professional** | | **Non-professional** | | | **PEC [mg.kgwwt-1]** | **PEC/PNEC** | **PEC [mg.kgwwt-1]** | **PEC/PNEC** | | Tebuconazole | 6.70E-04 | 1.22E-03 | 1.12E-03 | 2.03E-03 | | Propiconazole | 2.05E-03 | 3.79E-02 | 3.41E-03 | 6.31E-02 | | Cypermethrin\* | 6.00E-01 | **1.20E+02** | 1.00E+00 | **2.00E+02** | | PBC | 8.43E-05 | 4.01E-04 | 1.40E-04 | 6.68E-04 | | **PEC/PNEC** |  | **120** |  | **200** |   \* An additional factor of 10 has been considered as PNECsed was defined using the EPM method   |  |  |  | | --- | --- | --- | | **Application - Bridge over the pond - Treatment by spraying** | | | | **SURFACE WATER** | **PEC [µg.L-1]** | **PEC/PNEC** | | Tebuconazole | 3.00E-02 | 3.00E-02 | | Propiconazole | 9.60E-02 | 1.41E-02 | | Cypermethrin | 4.80E-02 | **1.20E+01** | | IPBC | 3.00E-02 | 6.00E-02 | | PBC | 1.66E-02 | 4.01E-04 | | **PEC/PNEC** |  | **12.10** | | **SEDIMENT** | **PEC [mg.kgwwt-1]** | **PEC/PNEC** | | Tebuconazole | 6.70E-04 | 1.22E-03 | | Propiconazole | 2.05E-03 | 3.79E-02 | | Cypermethrin\* | 6.00E-01 | **1.20E+02** | | PBC | 8.43E-05 | 4.01E-04 | | **PEC/PNEC** |  | **1 20** |   \* An additional factor of 10 has been considered as PNECsed was defined using the EPM method  Whatever the application method (brushing and spraying) 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 or spraying near surface water leads to unacceptable risk for the aquatic compartment (including sediment) and should be prevented.  **Direct emissions during service life:**  The risk characterisation for the aquatic compartment including sediment has been performed considering PEC calculated for the bridge scenario, and compared to PNECwater and PNECsediment of each active substance for the service life of the treated wood.   |  |  |  | | --- | --- | --- | | **Bridge over the pond - Treated wood in service only – Industrial & *In situ* application** | | | | **SURFACE WATER** | **PEC (TIME 1) [µg.L-1]** | **PEC/PNEC** | | Tebuconazole | 3.76E-02 | 3.76E-02 | | Propiconazole | 6.05E-02 | 8.89E-03 | | Cypermethrin | 3.67E-05 | 9.18E-03 | | IPBC | 3.11E-04 | 6.21E-04 | | PBC | 1.13E-02 | 2.73E-04 | | **PEC/PNEC** |  | 5.66E-02 | | **SEDIMENT** | **PEC (TIME 1) [mg.kgwwt-1]** | **PEC/PNEC** | | Tebuconazole | 9.49E-04 | 1.72E-03 | | Propiconazole | 2.11E-03 | 3.91E-02 | | Cypermethrin\* | 3.74E-03 | 7.48E-01 | | PBC | 5.75E-05 | 2.74E-04 | | **PEC/PNEC** |  | 7.90E-01 | | **Bridge over the pond - Treated wood in service only – Industrial application** | | | | **SURFACE WATER** | **PEC (TIME 2) [µg.L-1]** | **PEC/PNEC** | | Tebuconazole | 7.97E-03 | 7.97E-03 | | Propiconazole | 6.06E-03 | 8.92E-04 | | Cypermethrin | 3.09E-05 | 7.71E-03 | | IPBC | 1.59E-05 | 3.18E-05 | | PBC | 2.11E-03 | 5.10E-05 | | **PEC/PNEC** |  | 1.67E-02 | | **SEDIMENT** | **PEC (TIME 2) [mg.kgwwt-1]** | **PEC/PNEC** | | Tebuconazole | 7.86E-04 | 1.43E-03 | | Propiconazole | 9.06E-03 | 1.68E-01 | | Cypermethrin\* | 7.48E-03 | **1.50E+00** | | PBC | 1.08E-05 | 5.14E-05 | | **PEC/PNEC** |  | **1.66E+00** | | **Bridge over the pond - Treated wood in service only – *In situ* application** | | | | **SURFACE WATER** | **PEC (TIME 2) [µg.L-1]** | **PEC/PNEC** | | Tebuconazole | 9.64E-03 | 9.64E-03 | | Propiconazole | 7.21E-03 | 1.06E-03 | | Cypermethrin | 3.09E-05 | 7.73E-03 | | IPBC | 1.92E-05 | 3.84E-05 | | PBC | 2.50E-03 | 6.05E-05 | | **PEC/PNEC** |  | 1.85E-02 | | **SEDIMENT** | **PEC (TIME 2) [mg.kgwwt-1]** | **PEC/PNEC** | | Tebuconazole | 8.66E-04 | 1.57E-03 | | Propiconazole | 5.94E-03 | 1.10E-01 | | Cypermethrin\* | 7.42E-03 | **1.48E+00** | | PBC | 1.28E-05 | 6.10E-05 | | **PEC/PNEC** |  | **1.60E+00** |   \* 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 except for the cypermethrin in sediment considering long term assessment (TIME2\*) (industrial and in situ application). All the calculated sums of PEC/PNEC ratios are above 1 for surface sediment (in TIME2). No use of treated wood near aquatic compartment should be allowed. Moreover 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.   1. **Indirect emissions via the STP - Noise barrier scenario**   The risk characterisation for the STP has been performed considering PEC calculated for the noise barrier scenario of the PT08-ESD, and compared to PNECSTP of each active substance for the service life of treated wood.   |  |  |  | | --- | --- | --- | | **Noise barrier - Treated wood in service only – Industrial & *In situ* application** | | | | **STP** | **PEC (TIME 1) [mg.L-1]** | **PEC/PNEC** | | Tebuconazole | 2.74E-04 | 8.56E-04 | | Propiconazole | 6.29E-04 | 6.29E-06 | | Cypermethrin | 2.70E-07 | 1.65E-07 | | IPBC | 1.70E-04 | 3.86E-04 | | PBC | 9.42E-05 | 2.14E-04 | | **PEC/PNEC** |  | 1.46E-03 | | **Noise barrier - Treated wood in service only – Industrial application** | | | | **STP** | **PEC (TIME 2) [mg.L-1]** | **PEC/PNEC** | | Tebuconazole | 1.21E-05 | 3.79E-05 | | Propiconazole | 3.32E-05 | 3.32E-07 | | Cypermethrin | 2.16E-07 | 1.33E-07 | | IPBC | 8.65E-06 | 1.97E-05 | | PBC | 4.79E-06 | 1.09E-05 | | **PEC/PNEC** |  | 6.90E-05 | | **Noise barrier - Treated wood in service only – *In situ* application** | | | | **STP** | **PEC (TIME 2) [mg.L-1]** | **PEC/PNEC** | | Tebuconazole | 1.50E-05 | 4.70E-05 | | Propiconazole | 3.98E-05 | 3.98E-07 | | Cypermethrin | 2.17E-07 | 1.33E-07 | | IPBC | 1.04E-05 | 2.37E-05 | | PBC | 5.78E-06 | 1.31E-05 | | **PEC/PNEC** |  | 8.43E-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.  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, and compared to PNECwater and PNECsediment of each active substance for the service life of the treated wood.   |  | | --- | | **Wood-in-service – Noise barrier - Treated wood in service only** |  |  |  |  | | --- | --- | --- | | **Noise barrier - Treated wood in service only – Industrial & *In situ* application** | | | | **SURFACE WATER**  **(*via STP*)** | **PEC (TIME 1) [mg.L-1]** | **PEC/PNEC** | | Tebuconazole | 2.73E-02 | 2.73E-02 | | Propiconazole | 6.28E-02 | 9.23E-03 | | Cypermethrin | 1.45E-05 | 3.62E-03 | | PBC | 9.42E-03 | 2.28E-04 | | **PEC/PNEC** |  | 4.04E-02 | | **SEDIMENT**  **(*via STP*)** | **PEC (TIME 1) [mg.L-1]** | **PEC/PNEC** | | Tebuconazole | 6.11E-04 | 1.11E-03 | | Propiconazole | 1.34E-03 | 2.48E-02 | | Cypermethrin | 1.81E-04 | 3.62E-02 | | PBC | 4.79E-05 | 2.28E-04 | | **PEC/PNEC** |  | 6.23E-02 | | **Noise barrier - Treated wood in service only – Industrial application** | | | | **SURFACE WATER**  **(*via STP*)** | **PEC (TIME 2) [mg.L-1]** | **PEC/PNEC** | | Tebuconazole | 1.21E-03 | 1.21E-03 | | Propiconazole | 3.31E-03 | 4.87E-04 | | Cypermethrin | 1.16E-05 | 2.90E-03 | | PBC | 4.79E-04 | 1.16E-05 | | **PEC/PNEC** |  | 4.62E-03 | | **SEDIMENT**  **(*via STP*)** | **PEC (TIME 2) [mg.L-1]** | **PEC/PNEC** | | Tebuconazole | 2.71E-05 | 4.93E-05 | | Propiconazole | 7.06E-05 | 1.31E-03 | | Cypermethrin | 1.45E-04 | 2.90E-02 | | PBC | 2.44E-06 | 1.16E-05 | | **PEC/PNEC** |  | 3.04E-02 | | **Noise barrier - Treated wood in service only – *In situ* application** | | | | **SURFACE WATER**  **(*via STP*)** | **PEC (TIME 2) [mg.L-1]** | **PEC/PNEC** | | Tebuconazole | 1.50E-03 | 1.50E-03 | | Propiconazole | 3.97E-03 | 5.84E-04 | | Cypermethrin | 1.16E-05 | 2.91E-03 | | PBC | 5.78E-04 | 1.40E-05 | | **PEC/PNEC** |  | 5.01E-03 | | **SEDIMENT**  **(*via STP*)** | **PEC (TIME 2) [mg.L-1]** | **PEC/PNEC** | | Tebuconazole | 3.35E-05 | 6.10E-05 | | Propiconazole | 8.46E-05 | 1.57E-03 | | Cypermethrin | 1.46E-04 | 2.91E-02 | | PBC | 2.94E-06 | 1.40E-05 | | **PEC/PNEC** |  | 3.08E-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 indirect releases via the STP is considered acceptable during the service life of treated wood with the product.  ‘\* A default value of 5 years for an in situ application and 15 years for an industrial application is used as average life span. |

##### Terrestrial compartment

**- Substances**

Table 2.2‑52: PEC/PNEC ratios for the soil compartment, industrial application, storage

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cyperme­thrin** | **Total PEC/PNEC** |
| --- | --- | --- | --- | --- | --- |
| **Dipping (soil)** |  |  |  |  |  |
| PEC/PNEC in soil at storage place at the end of the initial assessment period [mg.kgwwt-1] | 7.41 | 1.32 | 0.58 | 4.2\*10-3 | 9 |
| PEC/PNEC in soil at storage place at the end of a longer assessment period [mg.kgwwt-1] | 1352 | 241 | 106 | 0.77 | 1700 |
|  |  |  |  |  |  |
| PEC/PNEC in soil at storage place at the end of the initial assessment period with removal [mg.kgwwt-1] | 0.01 | 1.22 | 0.51 | 2.4\*10-3 | 1.73 |
| PEC/PNEC in soil at storage place at the end of a longer assessment period with removal [mg.kgwwt-1] | 7.4\*10-3 | 8.18 | 2.14 | 3.4\*10-3 | 10 |

Table 2.2‑53: PEC/PNEC ratios for the soil compartment, *in-situ* application

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cyperme­thrin** | **Total PEC/PNEC** |
| --- | --- | --- | --- | --- | --- |
| **House (brushing, soil)** |  |  |  |  |  |
| PEC/PNEC local in soil at the end of the day of application (house, professional application) | 3.9 | 0.5 | 0.2 | 0.3 | 4.8 |
| PEC/PNEC local in soil at the end of the day of application (house, non-professional application) | 6.4 | 0.8 | 0.3 | 0.4 | 8 |
| **Fence (brushing, soil)** |  |  |  |  |  |
| PEC/PNEC local in soil at the end of the day of application (fence, professional application) | 3.2 | 0.4 | 0.1 | 0.2 | 4 |
| PEC/PNEC local in soil at the end of the day of application (fence, non-professional application) | 5.3 | 0.7 | 0.2 | 0.4 | 6.7 |
| **House (spraying, soil)** |  |  |  |  |  |
| PEC/PNEC local in soil at the end of the day of application due to spray drift (tier 1) and run-off | 39 | 5.1 | 1.7 | 2.7 | 48 |
| PEC/PNEC local in soil at the end of the day of application due to spray drift (tier 2) and run-off | 3.7 | 0.5 | 0.2 | 0.3 | 4.6 |

Table 2.2‑54: PEC/PNEC ratios for the soil compartment, industrial dipping, in-service

|  | **IPBC** | **Propiconazole** | **Tebuconazole** | **Cyperme­thrin** | **Total PEC/PNEC** |
| --- | --- | --- | --- | --- | --- |
| **House (soil)** |  |  |  |  |  |
| PEC/PNEC local without removal [mg.kgwwt-1] Time 1 (30 days) | 6.48 | 1.16 | 0.51 | 3.7\*10-3 | 8.14 |
| PEC/PNEC local without removal [mg.kgwwt-1] Time 2 (5475 days) | 42 | 10.37 | 3.86 | 0.38 | 57 |
|  |  |  |  |  |  |
| PEC/PNEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 0.01 | 1.06 | 0.44 | 2.1\*10-3 | 1.7 |
| PEC/PNEC local with removal [mg.kgwwt-1] Time 2 (5475 days) | 2.0\*10-4 | 0.31 | 0.07 | 1.7\*10-3 | 0.38 |
| **Fence (soil)** |  |  |  |  |  |
| PEC/PNEC local without removal [mg.kgwwt-1] Time 1 | 5.39 | 0.96 | 0.42 | 3.1\*10-3 | 6.78 |
| PEC/PNEC local without removal [mg.kgwwt-1] Time 2 (5475 days) | 35 | 8.63 | 3.21 | 3.1\*10-1 | 47 |
|  |  |  |  |  |  |
| PEC/PNEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 0.01 | 0.89 | 0.37 | 1.7\*10-3 | 1.26 |
| PEC/PNEC local with removal [mg.kgwwt-1] Time 2 (5475 days) | 1.6\*10-4 | 0.26 | 0.06 | 1.4\*10-3 | 0.32 |
| **Noise Barrier (soil)** |  |  |  |  |  |
| PEC/PNEC local without removal [mg.kgwwt-1] Time 1 (30 days) | 2.43 | 0.43 | 0.19 | 1.4\*10-3 | 3.0 |
| PEC/PNEC local without removal [mg.kgwwt-1] Time 2 (5475 days) | 16 | 3.9 | 1.44 | 0.14 | 21 |
|  |  |  |  |  |  |
| PEC/PNEC local with removal [mg.kgwwt-1] Time 1 (30 days) | 2.4\*10-3 | 0.40 | 0.17 | 7.8\*10-4 | 0.57 |
| PEC/PNEC local with removal [mg.kgwwt-1] Time 2 (5475 days) | 7.4\*10-5 | 0.12 | 0.03 | 6.2\*10-4 | 0.14 |

Table 2.2‑55: PEC/PNEC ratios for the soil compartment, brushing, professional application

|  | **IPBC** | **Propiconazole** | **Tebucona­zole** | **Cyperme­thrin** | **Total PEC/PNEC** |
| --- | --- | --- | --- | --- | --- |
| **House (brushing, soil)** |  |  |  |  |  |
| PEC/PNEC local without removal Time 1 (30 days) | 10 | 1.66 | 0.68 | 0.27 | 13 |
| PEC/PNEC local without removal Time 2 (1825 days) | 22 | 4.70 | 1.78 | 0.40 | 29 |
|  |  |  |  |  |  |
| PEC/PNEC local with removal Time 1 (30 days) | 0.01 | 1.50 | 0.57 | 0.08 | 2.15 |
| PEC/PNEC local with removal Time 2 (1825 days) | 2.0\*10-4 | 0.31 | 0.07 | 1.7\*10-3 | 0.38 |
| **Fence (brushing, soil)** |  |  |  |  |  |
| PEC/PNEC local without removal Time 1 (30 days) | 8.60 | 1.39 | 0.56 | 0.23 | 11 |
| PEC/PNEC local without removal Time 2 (1825 days) | 18 | 3.91 | 1.48 | 0.33 | 24 |
|  |  |  |  |  |  |
| PEC/PNEC local with removal Time 1 (30 days) | 0.01 | 1.24 | 0.47 | 0.07 | 1.79 |
| PEC/PNEC local with removal Time 2 (1825 days) | 1.6\*10-4 | 0.26 | 0.06 | 1.4\*10-3 | 0.32 |

Table 2.2‑56: PEC/PNEC ratios for the soil compartment, brushing, non-professional application

|  | **IPBC** | **Propiconazole** | **Tebucon­azole** | **Cyperme­thrin** | **Total PEC/PNEC** |
| --- | --- | --- | --- | --- | --- |
| **House (brushing, soil)** |  |  |  |  |  |
| PEC/PNEC local without removal Time 1 (30 days) | 13 | 2.00 | 0.79 | 0.45 | 16 |
| PEC/PNEC local without removal Time 2 (1825 days) | 25 | 5.04 | 1.89 | 0.58 | 32 |
|  |  |  |  |  |  |
| PEC/PNEC local with removal Time 1 (30 days) | 0.01 | 1.78 | 0.66 | 0.13 | 2.58 |
| PEC/PNEC local with removal Time 2 (1825 days) | 2.0\*10-4 | 0.31 | 0.07 | 1.7\*10-3 | 0.38 |
| **Fence (brushing, soil)** |  |  |  |  |  |
| PEC/PNEC local without removal Time 1 | 11 | 1.67 | 0.66 | 0.38 | 13 |
| PEC/PNEC local without removal Time 2 (1825 days) | 21 | 4.19 | 1.58 | 0.48 | 27 |
|  |  |  |  |  |  |
| PEC/PNEC local with removal Time 1 (30 days) | 0.01 | 1.48 | 0.55 | 0.11 | 2.14 |
| PEC/PNEC local with removal Time 2 (1825 days) | 1.6\*10-4 | 0.26 | 0.06 | 1.4\*10-3 | 0.32 |

Table 2.2‑57: PEC/PNEC ratios for the soil compartment, spraying

|  | **IPBC** | **Propiconazole** | **Tebucon­azole** | **Cyperme­thrin** | **Total PEC/PNEC** |
| --- | --- | --- | --- | --- | --- |
| **House (spraying, Tier 1, soil)** |  |  |  |  |  |
| PEC/PNEC local without removal Time 1 (30 days) | 45 | 6.25 | 2.20 | 2.70 | 56 |
| PEC/PNEC local without removal Time 2 (1825 days) | 57 | 9.28 | 3.31 | 2.83 | 72 |
|  |  |  |  |  |  |
| PEC/PNEC local with removal Time 1 (30 days) | 0.01 | 5.37 | 1.73 | 0.78 | 7.9 |
| PEC/PNEC local with removal Time 2 (1825 days) | 2.0\*10-4 | 0.31 | 0.07 | 1.7\*10-3 | 0.38 |
| **House (spraying, Tier 2, soil)** |  |  |  |  |  |
| PEC/PNEC local without removal Time 1 (30 days) | 10.15 | 1.64 | 0.67 | 0.26 | 13 |
| PEC/PNEC local without removal Time 2 (1825 days) | 22 | 4.68 | 1.77 | 0.38 | 29 |
|  |  |  |  |  |  |
| PEC/PNEC local with removal Time 1 (30 days) | 0.01 | 1.48 | 0.56 | 0.08 | 2.12 |
| PEC/PNEC local with removal Time 2 (1825 days) | 2.0\*10-4 | 0.31 | 0.07 | 1.7\*10-3 | 0.38 |

In the storage scenario following industrial application risk was identified in soil for propiconazole and tebuconazole, when removal processes were taking into account.

In the soil compartment using the brush application, risk was identified at Time 1 and 2 for IPBC for both the house and fence scenarios and for both professional and non-professional use.

For spray application risk was identified for all a.s. at Time 1 and for IPBC at Time 2.

For the industrial treated wood in service risk was identified for IPBC and propiconazole at Time 1 and for IPBC, propiconazole and tebuconazole at Time 2 when removal was not taking into account for all scenarios. Taking removal into account risk was only identified for propiconazole at Time 1.

For the *in-situ* brushing application risk was identified for the house and the fence scenarios for IPBC, propiconazole and tebuconazole at both Time 1 and 2. Taking removal process into account risk was only identified for propiconazole at Time 1.

Risk was acceptable when taking removal processes into account at Time 2 for both scenarios.

Using the spray application risk was identified at Time 1 and 2 for all 4 a.s. for the house scenario for Tier 1 without taking removal processes into account. Also with removal processes taking into account a risk at Time 1 was identified for propiconazole and tebuconazole.

For Tier 2 risk was identified for IPBC and propiconazole at Time 1 and for IPBC, propiconazole and tebuconazole at Time 2 without removal. When removal processes were taking into account risk was only identified at Time 1 for propiconazole.

Risk was acceptable when taking removal processes into account at Time 2 for both Tier 1 and 2.

**- Metabolites**

PBC was identified as a relevant metabolite of IPBC in water, sediment and soil. Due to a relative short half-life of PBC, it can be regarded as a transient metabolite. In addition, the ecotoxicity of PBC is a factor of 300 – 1000 lower for fish, invertebrates and algae compared to IPBC.

In this report PBC was included in the calculation, by transforming the measured amount of PBC to the corresponding amount of IPBC and use the total as input parameter. This must be considered a worst case approach. Furthermore a groundwater assessment was performed where no risk was identified. So, no further assessment of this metabolite is needed.

In soil two metabolites of propiconazole were above the limit of 10%: 1,2,4-triazole and CGA 118 245, and for tebuconazole 1,2,4-triazole was close to the 10% limit. A groundwater assessment was performed for 1,2,4-triazole without identifying any risk to groundwater. Due to the much lower half-life and lower ecotoxicity these metabolites were not considered further.

In the AR for cypermethrin three major metabolites were identified in soil: 3-phenoxybenzoic acid, TDCVC and CDCVC. However, no data is available for these metabolites and none of these were considered further.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FR-CA box 10  Risk characterisation for the terrestrial compartment   1. **Direct emissions to soil**   **Industrial dipping, storage**  The risk characterisation for the terrestrial compartment has been performed considering PEC calculated for the industrial dipping (storage) of the PT08-ESD, and compared to PNECsoil of each active substance.   |  |  |  | | --- | --- | --- | | Storage – Treatment by industrial dipping | | | | SOIL | PEC [mg.kgwwt-1] | PEC/PNEC | | Tebuconazole | 2.11E-01 | 2.11E+00 | | Propiconazole | 5.09E-01 | 5.09E+00 | | Cypermethrin | 4.51E-04 | 4.91E-03 | | IPBC | 3.07E-04 | 6.99E-02 | | PBC | 8.23E-03 | 5.52E-02 | | 1,2,4-triazole | 6.85E-02 | 8.36E+00 | | PEC/ PNEC |  | 1.57E+01 |   Considering that calculated PEC/PNEC ratio are above 1 for soil, storage of treated wood by industrial dipping phase leads to unacceptable risks to the terrestrial compartment, unless direct releases to soil is prevented by a storage under shelter and on impermeable hard standing.  Therefore, the freshly treated timber must stored after treatment under shelter and on impermeable hard standing to prevent releases to soil.  For the industrial application phase, no emission estimations were provided by the applicant based on mandatory risk mitigation measures for wood treatment plants:   * Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber; * During the application phase, prevent any release of cleaning water (after cleaning of floors, tanks, containers) to the environment (sewer, soil, water); * Freshly treated timber shall be stored after treatment under shelter and on impermeable hard standing to prevent losses to soil, sewer, or water, and any losses from the application of the product shall be collected for reuse or disposal. Before use, store the timber in an area sheltered from the weather; * Any contaminated water/soil shall be collected, contained and treated as hazardous waste.   ***In situ* application**  The risk characterisation for the terrestrial compartment has been performed considering PEC calculated for the house scenario of the PT08-ESD, and compared to PNECsoil of each active substance for the application phase of preventive and curative treatment.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Application – House -Treatment by brushing** | | | | | | **SOIL** | **Professional** | | **Non-professional** | | | **PEC [mg.kgwwt-1]** | **PEC/PNEC** | **PEC [mg.kgwwt-1]** | **PEC/PNEC** | | Tebuconazole | 1.70E-02 | 1.70E-01 | 2.83E-02 | 2.83E-01 | | Propiconazole | 5.43E-02 | 5.43E-01 | 9.05E-02 | 9.05E-01 | | Cypermethrin | 2.71E-02 | 2.96E-01 | 4.52E-02 | 4.93E-01 | | IPBC | 1.70E-02 | **3.86E+00** | 2.83E-02 | **6.43E+00** | | PBC | 9.37E-02 | 6.29E-02 | 1.56E-02 | 1.05E-01 | | 1,2,4-triazole | 5.08E-03 | 6.20E-01 | 8.47E-03 | **1.03E+00** | | **PEC/ PNEC** |  | **5.55** |  | **9.25** |   Considering that calculated PEC/PNEC ratios 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.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Application – House - Treatment by spraying** | | | | | | **SOIL** | **Tier 1 (Runoff + Drift)** | | **Tier 2 (Drift)** | | | **PEC [mg.kgwwt-1]** | **PEC/PNEC** | **PEC [mg.kgwwt-1]** | **PEC/PNEC** | | Tebuconazole | 1.70E-01 | **1.70E+00** | 1.62E-02 | 1.62E-01 | | Propiconazole | 5.43E-01 | **5.43E+00** | 5.18E-02 | 5.18E-01 | | Cypermethrin | 2.71E-01 | **2.96E+00** | 2.59E-02 | 2.82E-01 | | IPBC | 1.70E-01 | **3.86E+01** | 1.62E-02 | **3.68E+00** | | PBC | 9.37E-02 | 6.29E-01 | 8.93E-03 | 5.99E-02 | | 1,2,4-triazole | 5.08E-02 | **6.20E+00** | 4.85E-03 | 5.91E-01 | | **PEC/ PNEC** |  | **55** |  | **5.29** |   For the terrestrial compartment and considering releases due to run off and drift (TIER1) on soil adjacent to the treated surface (0 to 1 m), PEC/PNEC ratios for tebuconazole, propiconazole, cypermethrin, IPBC and 1,2,4-triazole are above 1 for 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 1.5 m), PEC/PNEC ratios is also above 1 for treatment by spraying.  The risk for the terrestrial compartment after 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.  **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, and compared to PNECsoil 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, the risk characterisation for the terrestrial compartment during the service life of treated wood taking into account also the application phase was not calculated.   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Wood-in service – House – Treated wood in service only** | | | | | | | | | | | | **SOIL** | **Industrial & *In situ* application**  **TIME 1** | | | | ***In situ* application**  **TIME 2** | | | **Industrial application TIME 2** | | | | **PEC**  **[mg.kgwwt-1]** | | **PEC/PNEC** | | **PEC**  **[mg.kgwwt-1]** | **PEC/PNEC** | | **PEC**  **[mg.kgwwt-1]** | | **PEC/PNEC** | | Tebuconazole | 2.28E-02 | | 2.28E-01 | | 1.21E-02 | 1.21E-01 | | 8.88E-03 | | 8.88E-02 | | Propiconazole | 5.20E-02 | | 5.20E-01 | | 3.28E-02 | 3.28E-01 | | 2.52E-02 | | 2.52E-01 | | Cypermethrin | 1.65E-04 | | 1.80E-03 | | 3.16E-04 | 3.45E-03 | | 3.16E-04 | | 3.44E-03 | | IPBC | 2.66E-04 | | 6.05E-02 | | 1.65E-05 | 3.76E-03 | | 1.37E-05 | | 3.11E-03 | | PBC | 4.27E-03 | | 2.87E-02 | | 4.86E-04 | 3.26E-03 | | 3.81E-04 | | 2.56E-03 | | 1,2,4-triazole | 5.12E-03 | | 6.24E-01 | | 4.30E-03 | 5.25E-01 | | 3.32E-03 | | 4.05E-01 | | **PEC/ PNEC** |  | | **1.46E+00** | |  | 9.85E-01 | |  | | 7.55E-01 | | **Wood-in service – Noise barrier – Treated wood in service only** | | | | | | | | | | | | **SOIL** | | **Industrial & *In situ* application**  **TIME 1** | | | | | **Industrial application TIME 2** | | | | | **PEC**  **[mg.kgwwt-1]** | | **PEC/PNEC** | | | **PEC**  **[mg.kgwwt-1]** | | **PEC/PNEC** | | | Tebuconazole | | 8.52E-03 | | 8.52E-02 | | | 3.33E-03 | | 3.33E-02 | | | Propiconazole | | 1.95E-02 | | 1.95E-01 | | | 9.42E-03 | | 9.42E-02 | | | Cypermethrin | | 6.19E-05 | | 6.74E-04 | | | 1.18E-04 | | 1.29E-03 | | | IPBC | | 9.97E-05 | | 2.26E-02 | | | 5.13E-06 | | 1.17E-03 | | | PBC | | 1.60E-03 | | 1.07E-02 | | | 1.43E-04 | | 9.58E-04 | | | 1,2,4-triazole | | 1.92E-03 | | 2.34E-01 | | | 1.24E-03 | | 1.52E-01 | | | **PEC/ PNEC** | |  | | 5.47E-01 | | |  | | 2.83E-01 | |   Considering that calculated PEC/PNEC ratio for terrestrial compartment is above 1 only in TIME 1 for the house scenario, the risks are 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).  **Indirect emissions via the STP during service lif of treated wood - Noise barrier scenario**  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, and compared to PNECsoil of each active substance for the service life of the treated wood.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Wood-in-service – Noise barrier- Treated wood in service only** | | | | | | **SOIL (via STP** | **TIME 1** | | **TIME 2** | | | **PEC [mg.kgwwt-1]** | **PEC/PNEC** | **PEC [mg.kgwwt-1]** | **PEC/PNEC** | | Tebuconazole | 1.13E-04 | 1.13E-03 | 5.03E-06 | 5.03E-05 | | Propiconazole | 2.40E-04 | 2.40E-03 | 1.27E-05 | 1.27E-04 | | Cypermethrin | 5.79E-06 | 6.30E-05 | 4.65E-06 | 5.07E-05 | | PBC | 3.53E-06 | 2.37E-05 | 1.80E-07 | 1.21E-06 | | ****PEC/ PNEC |  | 3.62E-03 |  | 2.29E-06 |   Considering that all PEC/PNEC ratios for terrestrial compartment are below 1, 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. |

##### Groundwater compartment

As an indication for potential groundwater concentrations, the concentrations in pore water have been calculated.

For IPBC and cypermethrin, PECporewater values are below the limit for drinking water (0.1 µg/L) for all scenarios when taking removal processes into account.

For propiconazole and tebuconazole, PECs in pore water are above the threshold value of 0.1 µg/L, even when removal is taken into account. Therefore, a groundwater risk assessment was performed according to FOCUS PEARL 4.4.4 for propiconazole and tebuconazole.

A groundwater risk assessment of PBC and 1,2,4-triazole was also performed since these metabolites may be present in amounts close to or above 10% of the mother molecule.

The results of the FOCUS PEARL 4.4.4 calculations showed that tebuconazole, propiconazole and their relevant metabolites are not expected to reach groundwater.

Therefore, no risk for groundwater is expected when using the product according to the label recommendations.

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| FR-CA box 11  **Groundwater compartment**  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.  The calculated PECgroudwater 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. |

##### Atmospheric compartment

IPBC:

Air will not be an environmental compartment of concern for IPBC used in wood preservatives because of the low vapour pressure of this compound. It should also be noted that the calculated DT50 of IPBC in air is only about 15 hours and is therefore not considered persistent in air.

Propiconazole and tebuconazole:

According to the vapour pressure and the Henry’s law constant of propiconazole and tebuconazole the atmosphere is not a compartment of concern for these compounds.

Cypermethrin:

Cypermethrin has a low volatility and emissions to the air compartment are expected to be low.

Therefore, no risk is foreseen for the atmospheric compartment when using the product according to the label recommendations.

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| FR-CA box 12  Atmospheric compartment  FR agrees with the registrant’s conclusions. |

##### Non-compartmental specific effects relevant to the food chain (secondary poisoning)

\* According to the AR for IPBC, secondary poisoning can be excluded due to the log Kow (< 3).

\* In the AR for PT08 it was stated that although propiconazole shows a slight potential for bioaccumulation there is no need to perform an assessment of secondary poisoning.

\* In the AR for PT07 it was stated that tebuconazole showed a low bioconcentration potential in aquatic and terrestrial. So, it is not considered necessary to calculate a PEC for food chain risk assessment.

\* As cypermethrin has a log Kow > 3 (log Kow = 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 Document "S13\_IIB\_PPG\_X6122B1\_update20160606", point 3.3.5, taking into account the worst case concentrations found in surface water and soil. PECs and risk ratios for the risk of secondary poisoning for birds and mammals are summarised in the following table.

**Table 2.2.6-1: PECs and risk ratios for secondary poisoning**

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| --- | --- | --- | --- |
| Concentration in freshwater or soil | PECoral predator | PEC/PNECbirds  (PNECoral,bird  =33.3 mg/kg food) | PEC/PNECmammals  (PNECoral,small mammal  = 3.33 mg/kg food) |
| Worst case PECfreshwater =  0.09 µg/L | 0.0187 mg/kgwet fish | 5.62\*10-4 | 5.62\*10-3 |
| Worst case PECsoil =  0.25 mg/kgwwt | 0.0502 mg/kgwet earthworm | 1.51\*10-3 | 0.0151 |

The RCRs are below 1 for the birds and for mammals.

Therefore, based on the above information, no risk of secondary poisoning is foreseen when using the product as recommended on the label.

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| FR-CA box 13  Risk characterisation for secondary poisonning.  FR-CA agreed with the applicant for considering that secondary poisoning is relevant only for the active substance cypermethrin. Therefore, the secondary poisoning was assessed for the TIME2 assessment period of the service life for wood treated by surface treatment, considered as a worst case. PEC and risk ratios for the risk of secondary poisoning for birds and mammals are summarised in the following table.   |  |  |  | | --- | --- | --- | | **PECoral predator** | **PEC/PNECbirds**  (PNECoral,bird = 33.3 mg/kg food) | **PEC/PNECmammals**  (PNECoral,small mammal = 3.33 mg/kg food) | | 1.29E-05 mg/kgwet fish | 3.87E-07 | 3.87E-06 | | 2.84E-04 mg/kgwet earthworm | 8.54E-06 | 8.54E-05 |   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. |

#### Conclusion - Remarks

For the industrial application, risk was identified for the terrestrial compartment for propiconazole and tebuconazole. Storage must only take place on sealed places or under cover to prevent direct release to soil. This will be stated on the label.

For the *in-situ* application, risk was identified for the aquatic compartment for cypermethrin. For the terrestrial compartment risk was identified for all active substances at spraying (Tier 1) and for IPBC at brushing and spraying. According to CA-Sept14-Doc.5.8 an acceptable risk mitigation measure will be to cover the soil during application and restrict the use of the product close to water-ways. This will be stated on the label.

During service-life, risk was identified for Time 1 and 2 for the aquatic compartment due to cypermethrin. However, taking removal processes into account the risk was acceptable for all scenarios also when looking at the sum of the PEC/PNEC ratios for all 4 substances.

In the terrestrial compartment, risk was identified at Time 1, but at Time 2 risk was acceptable when taking removal processes into account, also when looking at the sum of the PEC/PNEC ratios for all 4 substances.

At the Arona leaching workshop (2005) risk identified at Time 1 was accepted for active substances. The practise was extended to include later product authorisations because a large number of products could not pass the risk assessment at Time 1. This issue was discussed at the second leaching workshop in Varese (2013) and at several following CA meetings (CA-Sept14-Doc.5.8).

A number of new options were suggested at the second leaching workshop, but at this point in time, no decision has been made on how to deal with risk identified at Time 1.

Based on this and the fact that the calculations in this risk assessment was based on worst-case assumptions: the leaching estimation was based on a linear extrapolation and for cypermethrin the LOQ was used in the risk assessment, this product should be treated in the same way as has been the practice with already authorized products: ignoring the risk identified at Time 1.

The 4 active substances in this product meet the criteria for a groundwater risk assessment. However, concentrations of cypermethrin and IPBC in the pore water are below the threshold limit for drinking water (0.1 µg/L), for the calculations for the 'House scenario' when taking removal processes into account. Therefore, a groundwater assessment is not relevant for these two substances.

Groundwater assessment was performed with the FOCUS PEARL model for propiconazole and tebuconazole and the two metabolites, PBC and 1,2,4-triazole. For all these compounds, no risk for groundwater was identified, although a worst-case assumption for release to the environment was used.

Based on the above calculations and arguments, this product, used as indicated, does not lead to unnecessary risk to the environment during application and service-life.

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| FR-CA box 14   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Phase | Type of application / Uses | STP | Surface water | | | Sediment | | | Soil | | | Groundwater | | | Secondary Poisoning | | Direct Release | | *Via* STP | Direct Release | | *Via* STP | Direct Release | | *Via* STP | Direct Release | | *Via* STP | | Application | Industrial Dipping | n.r. | **Unacceptable** | | n.r. | **Unacceptable** | | n.r. | Acceptable(1) | | n.r. | Acceptable | | n.r. | n.r. | | Brush | n.r. | **Unacceptable** | | n.r. | **Unacceptable** | | n.r. | Acceptable(1) | | n.r. | Acceptable | | n.r. | n.r. | | Spray | n.r. | **Unacceptable** | | n.r. | **Unacceptable** | | n.r. | Acceptable(1) | | n.r. | Acceptable | | n.r. | n.r. | | Wood in service | Use Class 1 and 2 | Not relevant (releases to the  environment not expected) | | | | | | | | | | | | | | | Use Class 3(4) | Acceptable | Acceptable | Acceptable | | Acceptable(3) | 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.  ‘(3) Considering the following RMM: *Do not apply where the product can reach surface water during outdoor application*  ‘(4) The risk assessment has been conducted with an application rate of 200 g.m-2. It has been considered that the curative treatment (300 g.m-2) is covered by this assessment with the RMMs phrases proposed. Moreover for the outdoor treatment, wood has not to be exposed to weathering and leaching.  n.r. – not relevant. |

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| For preventive treatment of wood 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 of wood in classes 1 and 2.  For an outdoor application in curative treatment, risks are only acceptable if emissions to aquatic and terrestrial compartments are prevented whatever the type of treatment. Therefore, 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 during in situ brushing. For spraying application, the risk mitigation measure for the soil compartment is considered as unappropriate  For the service-life phase of treated wood, considering that no emissions occurs during application with the use of appropriate risk mitigation measures, risks can be considered acceptable for all the compartments whatever the type of treatment.  Finally, for the curative treatment, wood must not be exposed to weathering and leaching.  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** |  | | Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber; | **Risk mitigation measure mandatory to ensure acceptable risks during industrial application and storage** | | During the application phase, prevent any release of cleaning water (after cleaning of floors, tanks, containers) to the environment (sewer, soil, water) | **Risk mitigation measure mandatory to insure acceptable risks during industrial application phase** | | Industrial application shall be conducted within a contained area on impermeable hard standing with bunding | **Risk mitigation measure mandatory to insure acceptable risks during industrial application phase** | | Freshly treated timber shall be stored after treatment under shelter and on impermeable hard standing to prevent losses to soil, sewer, or water, and any losses from the application of the product shall be collected for reuse or disposal. Before use, store the timber in an area sheltered from the weather; | **Risk mitigation measure mandatory to insure acceptable risks during industrial application and storage** | | Any contaminated water/soil shall be collected, contained and treated as hazardous waste. | 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** | | For outdoor treatment, wood has not to be exposed to weathering and leaching | **Risk mitigation measure mandatory to insure acceptable risks to the aquatic compartment during outdoor service-life 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 | |

### Comparative assessment

*See detail of the comparative assessment in a separate document*

# 2.2.8.1 Application administrative details

|  |  |
| --- | --- |
| Procedure | NA-APP |
| Purpose | Authorisation |
| Case number in R4BP | BC-JL017423-44 |
| Evaluating Competent Authority | France |
| Applicant | PPG AC - France SA |
| Authorisation holder | PPG AC - France SA |

#### Administrative information of the Biocidal Product

|  |  |
| --- | --- |
| Trade name(s) | X6122B1 |
| Product type(s) | 8 – Wood preservative |
| Active substance(s) | Cypermethrin (CAS: 52315-07-8)  Propiconazole (CAS: 60207-90-1)  Tebuconazole (CAS: 107534-96-3)  IPBC (CAS: CAS: 55406-53-6) |

#### Active substance as candidate for substitution in the biocidal product

* **Regulation (UE) 528/2012 regarding substitution criteria**

According to the most recent scientific information available on the active substance in the biocidal product, the wood preservative (PT8) tebuconazole shall be considered as candidate for substitution using the criteria in the regulation (UE) 528/2012, Article 10(1). As this active substance was approved under the Biocidal Products Directive, this information was not mentionned in the Assessment Report. However, as tebuconazole is considered to be toxic (T) and very persistent (vP), it can be considered to meet the criteria listed in Article 10(1)d. It meets two of the criteria for being PBT in accordance with Annex XIII to the regulation (EC) No 1907/2006.

Under Article 23(1) of Regulation 528/2012, Member States evaluating biocidal product containing at least, one active substance that is a candidate for substitution in accordance with Article 10(1) are required to perform a comparative assessment. FR CA has performed it for the biocidal product X6122B1 following the EU guidance[[28]](#footnote-28) regarding the comparative assessment of the biocidal product.

The biocidal product X6122B1 is a wood-preservative product containing four active substances as listed above, among which tebuconazole, meets the criteria for substitution under Article 10 of the Biocidal Products Regulation (528/2012). In line with this Note for Guidance, FR CA began the comparative assessment with the screening phase (Annex 1.1 of guidance document) to identify whether the diversity of the active substances - mode of action combination in authorised biocidal products is adequate.

#### Information of the active substance and the biocidal product in the application

##### Mode of action of the active substance

The active substance tebuconazole is a fongicide acting on target organisms by interfering with basic metabolism of the fungal cell wall and contents.

##### Intended uses for the relevant Biocidal Product in the application

The product is to be used by industrial, professional and non-professional users as a preventive and curative treatement for wood, indoor and outdoor. Preventive and curative treatments are performed by superficial application. Curative treatment can also be completed by injection.

The product was intented to be used also against fungi for preventive treatment of wood class 2 and 3.1. Nevertheless, this claim was not validated by eCA. Hence, this claim is not part of the comparative assessment

Table 3.1**:** Intended uses of the biocidal product – preventive treatment

|  |  |
| --- | --- |
| Product Type(s) | 8 – Wood preservative |
| Where relevant, an exact description of the authorized use | Preventive treatment for wood on use classes 1 |
| Target organism (including development stage) | Wood boring beetles:   * House longhorn beetle (*Hylotrupes bajulus*) * Common furniture beetle (*Anobium punctatum*) * Powder post beetles (*Lyctus brunneus*)   Termites (*Reticulitermes spp)* |
| Field of use | Preventive treatment for wood on use classes 1 |
| Application method(s) | Superficial application / short dipping treatment  Superficial application / spray treatment  Superficial application / brush / roller / pad treatment |
| Category(ies) of user(s) | Industrial users  Professional users  Non-professional users |

**Table 3.2: Intended uses of the biocidal product – curative treatment**

|  |  |
| --- | --- |
| Product Type(s) | 8 – Wood preservative |
| Where relevant, an exact description of the authorized use | Curative treatment for wood in service (indoor) |
| Target organism (including development stage) | Wood boring insects   * House longhorn beetle (*Hylotrupes bajulus*) * Common furniture beetle (*Anobium punctatum*) * Powder post beetles (*Lyctus brunneus*)   Termites (*Reticulitermes spp.* et *Heterotermes spp.*) |
| Field of use | Indoor |
| Application method(s) | Superficial application / brush / roller / pad treatment  Superficial application / spray  Injection (combined with a superficial application) |
| Category(ies) of user(s) | Professional users  Non-professional users |

#### Mapping of existing alternatives to the relevant Biocidal Product

##### Identified eligible alternative Biocidal Products

In order to perform the comparative assessment, FR CA considered all biocidal products authorized on the French market area under the Biocidal Products Directive (BPD) and Biocidal Products Regulation (BPR), and for which the information was available on R4BP3 database, on the 12th of September 2018.

The assessment focused on Biocidal Products addressing the same uses as the relevant Biocidal Product. These uses are similar to the ones described in the tables 3.1 and 3.2 above.

As there are applications for mutual recognition in parallel for the product X6122B1, France as reference member state also discussed the suitability of the Biocidal Products authorized on concerned Member States’ (cMS) markets.

##### Identified eligible non-chemical alternatives

Considering that tebuconazole was authorized under the BPD, no public consultation was carried out by ECHA in the context of the tebuconazole approval. Consequently, no non-chemical alternatives were proposed to replace the use of this substance.

#### Screening phase

##### Description of the assessment of the adequate chemical diversity in authorised BPs to minimise the occurence of resistance and conclusion

French context:

The French CA has granted 70 biocidal products authorised under Product Type 8 (wood preservative) of the BPD and BPR. Each of these biocidal products contains at least one of the following active substances:

* ADBAC/BKC,
* Basic copper carbonate,
* Bifenthrin,
* Creosote
* Permethrin
* Cypermethrin,
* DDAC,
* IPBC (3-iodi-2-propynyl butyl carbamate),
* K-HDO (1-oxyde de cyclohexylhydroxydiazene, sel de potassium),
* Propiconazole,
* Sulfuryl fluoride
* Tebuconazole,
* Thiacloprid

Among these products, 38 products allow the treatment of wood class 1 and 31 products show fongicide and insecticide activities (against insects with wood-boring larvae and termites).

* 27 products contain Cyperméthrine, tébuconazole, propiconazole
* One product contain IPBC, tebuconazol, propiconazol and thiacloprid
* One contain basic copper carbonate, propiconazole, tebuconazole
* One product contain permethrin
* One product contain propiconazol, tébuconazol and thiacloprid

European context:

Applications for mutual recognition in parallel for X6122B1 were deposited in 16 Member States: United-Kingdom, Switzerland, Sweden, Norway, Denmark, Spain, Slovakia, Romania, Portugal, Luxembourg; Ireland, Italy, Hungary, Greece, Czech Republic and Belgium.

According to the information available in the R4BP3 database, most of the products authorized in the cMS contain the same active substances as the ones found in the composition of product authorized in France. The following active substances are used in the formulation of products not authorized in France (please refer to the table below): benzyl-C8-16-alkyldimethyl, boric acid, boric oxide, dazomet, dichlofluanid, disodium tetraborate, disodium tetraborate pentahydrate, disodium tetraborate decahydrate; disodium octaborate tetrahydrate, fenpropimorph, fenoxycarb, hydrogen cyanide, permethrin, quaternary ammonium compounds, chlorides.

|  |  |  |
| --- | --- | --- |
| **Concerned member States** | **Active substances** | **Number of products with an AMM** |
| Croatia | Same as France  +  hydrogen cyanide | 21 |
| Slovenia | Same as France  +  hydrogen cyanide | 42 |
| United-Kingdom | Same as France  +  hydrogen cyanide, disodium tetraborate, boric acid, fenpropimorph, boric oxide, disodium octaborate tetrahydrate , dichlofluanid | 291 |
| Switzerland | Same as France  +  disodium tetraborate pentahydrate, boric acid | 152 |
| Spain | Same as France  +  hydrogen cyanide | 27 |
| Slovakia | Same as France  +  boric acid, fenoxycarb, fenpropimorph, hydrogen cyanide | 42 |
| Romania | Same as France  +  boric acid | 12 |
| Portugal | Same as France | 8 |
| Luxembourg | Same as France | 49 |
| Italy | Same as France | 56 |
| Hungary | Same as France  +  boric acid, disodium tetraborate, disodium tetraborate pentahydrate , disodium tetraborate decahydrate | 89 |
| Greece | Same as France  +  disodium tetraborate decahydrate, boric acid | 34 |
| Czech Republic | Same as France  +  permethrin, hydrogen cyanide, quaternary ammonium compounds, benzyl-C8-16-alkyldimethyl, chlorides | 92 |
| Belgium | Same as France  +  dazomet, boric acid | 34 |
| Sweden | Same as France  +  boric acid, disodium tetraborate, disodium octaborate tetrahydrate, creosote, boric oxide | 77 |
| Norway | Same as France  +  disodium octaborate tetrahydrate, creosote, | 51 |
| Denmark | Same as France  +  permethrin, disodium octaborate tetrahydrate, disodium tetraborate, boric oxide, granulated copper, | 220 |

##### Consideration on whether the CFS(s) meet(s) at least one of the exclusion criteria liste in the article 5(1) but can benefit from derogation in accordance with article 5(2) of the BPR

Tebuconazole is not considered as meeting the exclusion criteria according to Article 5(1).

##### Conclusion of the screening phase: stop comparative assessment

In the technical guidance note on comparative assessment of biocidal products, it is stated that :

* a suitable number of available active substances having different modes of action on the harmful organism would be necessary to minimise resistance development or selection ;
* as a general rule, at least three different and independent “active substance/mode of action” combinations should remain available through authorized BPs for a given use in order to consider that chemical diversity is adequate.

Considering the fungicide activity, the other active substances present in similar products are

* Basic copper carbonate
* Permethrin

Considering the insecticide activity, the other active substances present in similar products are

* Basic copper carbonate
* Permethrin
* Thiacloprid

FR CA concludes that there is no adequate chemical diversity with fungicide and insecticide activity 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 X6122B1 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.

# Annexes[[29]](#footnote-29)

## List of studies for the biocidal product

**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 | X6122B1  batch Pap V 129.2 | *C. puteana*  *G.trabeum*  *P.placenta*  *C.versicolor* | EN 113 after EN 73 (evaporation) | Following the recommendation of the standard:  On scots pine blocks, the targeted concentrations to be tested were 0.0, 4.3, 8.55, 12.82, 17.09 and 21.37 kg of product/m3 of wood.  On beech blocks, the targeted concentrations to be tested were 0.0, 5.63, 11.27, 16.90, 22.53 and 28.16 kg of product/m3 of wood.  The product was applied by vacuum impregnation  - 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  - Number of replicates: 6 replicates for each treatment and each fungal strain.  CONTROLS  - 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.  The effects investigated is mass loss of the test blocks, induced by the fungal development  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.  - 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)  Mid toxic values of the test product X6122B1:  - *C. puteana*: 58.28 kg/m3  - *G. trabeum* 19.58-39.07 : 29.33 kg/m3  - *C. versicolor*: 79.5 – 98.59: 89.05 kg/m3  For P. placenta the efficacy is not demonstrated at the highest concentration tested 21.37% which mean that the brv is higher than 97.24 kg product/m3 of wood  **Thus, the biological reference value of the test product X6122B1 after evaporative ageing procedure, cannot be determined.** | Schumacher P. and Fennert E.M., 2017  S6.7\_01  32/16/9803/03  IC 2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch Pap V 129.2 | *C. puteana*  *G.trabeum*  *P.placenta*  *C.versicolor* | EN 113 After EN 84 (leaching) | Following the recommendation of the standard:  On scots pine blocks, the targeted concentrations to be tested were 0.0, 4.3, 8.55, 12.82, 17.09 and 21.37kg of product/m3 of wood.  On beech blocks, the targeted concentrations to be tested were 0.0, 5.63, 11.27, 16.90, 22.53 and 28.16 kg of product/m3 of wood.  - 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  The product was applied by vacuum impregnation  - Number of replicates: 6 replicates for each treatment and each fungal strain.  CONTROLS  - 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.  The effects investigated is mass loss of the test blocks, induced by the fungal development  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.  - 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 (>20 % in each control)  **The study demonstrates the efficacy of the product X6122B1 is demonstrated at the application rate of 69 kg/m3 on *C. puteana, G. trabeum, P. placenta* and 90.08 kg/m3 for *C. versicolor*. It corresponds to an application rate of 180.16 g of X6122B1 / m² of wood.** | Schumacher P. and Fennert E.M., 2017  S6.7\_02  32/16/9803/02  IC 2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch 1405900037 | Subterranean termite: *Reticulitermes flavipes* | EN 118 + EN 73 (evaporation) | The ready to use product X6122B1 is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test block varied between 245.9 mL/m² and 248.6 mL/m² (mean 247.2 mL/m²).  250 workers, 4 nymphs and 1 soldier termite were used for each test block.  5 replicates for the treated block and 5 replicates for the control are performed.  The investigated effects are the mortality of the insects.  Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack).  - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (65.3 %) and the control test blocks are ranked 4.  **All the treated blocks are ranked 1 (except 1) at the end of the study which demonstrates the efficacy of the product X6122B1 at the application rate of 247 mL (equivalent to 199.45 g) of product / m² of wood.** | Ansard D. and  Paulmier I.,  2015  S6.7\_03  401/14/136F/e-e  IC 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch Pap V 129.2 | European subterranean termite: *Reticulitermes grassei* | EN 118 + EN 84 (leaching) | The ready to use X6122B1 is applied by brushing on sapwood test blocks (Pinus sylvaticus) and followed by an artificial weathering according to the EN 84 standard method (leaching).  The quantity really applied on each test block varied between 248.6 mL/m² and 250 mL/m² (mean 249.33 mL/m²).  250 workers, 4 nymphs and 1 soldier termite were used for each test block.  5 replicates for the treated block and 5 replicates for the control are performed.  The investigated effects are the mortality of the insects.  Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack).  - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (70.3 %) and the control test blocks are ranked 4.  **All the treated blocks are ranked 0 or 1 at the end of the study which demonstrates the efficacy of the product X6122B1 at the application rate of 247 ml (199.45 g) of product / m² of wood.** | Ansard D. and Paulmier I.,  2016  S6.7\_04  401/16/039F/b-e  IC 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch 1405900037 | House longhorn beetle: *Hylotrupes bajulus* (L.) | EN 46 + EN 73 (evaporation) | The ready to use product X6122B1 is applied by dipping on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test block varied between 197.6 g/m² and 199.2 g/m² (mean 198.5 g/m²).  10 recently hatched larvae of *H. bajulus* for each are used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The effect investigated is the mortality of insect’s larvae.  The method for recording / scoring effects is the recovery of the insects and count of dead and alive larvae and count of dead larvae having tunneled or not.  - Intervals of examination: one time, after 1 month exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 70 % (100%).  On the treated test block, 100 % or the larvae was dead and had not tunnelled.  **This study demonstrated the efficacy of the product at 198.5 g of product X6122B1 / m² of wood against *Hylotrupes bajulus* larvae** | Schumacher P. and Fennert E.-M., 2015  S6.7\_05  32/14/9803/01  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch Pap V 129.2 | House longhorn beetle: *Hylotrupes bajulus* (L.) | EN 46 + EN 84 (leaching) | The ready to use X6122B1 is applied by dipping on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 84 standard method (leaching).  The quantity really applied on each test block varied between 198.2 g/m² and 199.2 g/m² (mean 198.9 g/m²).  6 replicates for the treated block and 3 replicates for the control are performed.  The effect investigated is the mortality of insect’s larvae.  The method for recording / scoring effects is the recovery of the insects and count of dead and alive larvae and count of dead larvae having tunneled or not.  - Intervals of examination: one time, after 1 month exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 70 % (90%).  On the treated test block, 100 % or the larvae was dead and had not tunnelled.  **This study demonstrated the efficacy of the product at 198.9 g of product X6122B1 / m² of wood against *Hylotrupes bajulus* larvae** | Brunet C. and Paulmier I.,  2016  S6.7\_06  401/16/039F/a-e  IC 1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch 1405900037 | Common furniture beetle | EN 49 + EN 73  (evaporation) | The ready to use product X6122B1 is applied by dipping on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test block varied between 199.1 g/m² and 201.7 g/m² (mean 200.3 g/m²).  5 replicates for the treated block and for the control are performed.  The efficacy of the product is based on the comparison of egg laying, eggs emergence and mortality larvae between control blocks and treated blocks.  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  **This study demonstrated the efficacy of the product at 200.3 g of product X6122B1 / m² of wood against *Anobium punctatum*** | Brunet C.and Paulmier I., 2017  S6.7\_07  401/14/136F/a,b,e  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch 1405900037 | Common furniture beetle | EN 49 + EN 84  (leaching) | The ready to use product 06 X6122B1 is applied by dipping on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 84 standard method (leaching).  The quantity really applied on each test block varied between 198.9 g/m² and 201.2 g/m² (mean 200 g/m²).  5 replicates for the treated block and for the control are performed.  The efficacy of the product is based on the comparison of egg laying, eggs emergence and mortality larvae between control blocks and treated blocks.  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  **This study demonstrated the efficacy of the product at 200 g of product X6122B1 / m² of wood against *Anobium punctatum*** | Brunet C.and Paulmier I., 2017  S6.7\_08  401/14/136F/a,b,e  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6122B1  batch 1405900037 | Powder post beetle: *Lyctus brunneus* | EN 20-1 + EN 73 (evaporation) | The ready to use product X6122B1 is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test block varied between 196.1 g/m² and 198.1 g/m² (mean 197.1 g/m²).  10 recently hatched larvae of *L. bruneus* for each are used for each test block.  5 replicates for the treated block and 5 replicates for the control are performed.  The investigated effects are the mortality of the insects.  The method for recording / scoring effects is the recovery and the counting of the insects (alive/dead) and the number of drilled openings.  - Intervals of examination is one examination, 20 weeks after beginning of exposure of the adults. | The study is validated as:   * At least, for each control, 20 insects are found * Adult emergence has started at the end test in the control and at least 85 % (95.3 %) of the insects are found alive   In the test block 100 % of mortality is observed.  **This study demonstrated the efficacy of the product at 197.1 g of product X6122B1/ m²of wood against *Lyctus brunneus*** | Brunet C. and Paulmier I.,  2016  S6.7\_09  401/14/136F/c/e |
| MG 02: preservatives | Wood preservative  Curative treatment | X6122B1  batch Pap V 129.2 | House longhorn beetle: *Hylotrupes bajulus (L.)* | EN 1390 | The ready to use product X6122B1is applied by brushing on sapwood test blocks (*Pinus sylvestris*)  The quantity really applied on each test block varied between 299.4 mL/m² and 300.4 mL/m² (mean 299.9 mL/m²).  6 larvae of *Hylotrupes bajulus* were used for each test block.  10 replicates for the treated block and 2 replicates for the control are performed.  The investigated effects are the mortality of the larvae.  - Method for recording / scoring effects: recovery of the insects and count of the dead and alive larvae. Calculation of the percentage of mortality.  - Intervals of examination: one time, 25 weeks after exposure of the larvae in the wood block to the tested product.  The efficacy criterion according to the EN 14128 is a mortality higher than 80 % | The study is validated as the survival rate in the control is higher than 75 % (100%).  **The mortality observed in the treated block is higher than 80 % (96.6 %) which validated the low action efficacy of the product at the application rate of 300 ml of product X6122B1 / m² of wood, 24 weeks after is application.** | Brunet C. and Brunet C. and Paulmier I.,  2015  S6.7\_10  401/16/039F/c-e  IC 1 |
| X6089CR | Wood preservative  Preventive treatment | X6122B1  batch 1405900037 | Common furniture beetle:  *Anobium punctatum (L)* | EN48 | The ready to use product X6122B1 is applied by brushing on sapwood test blocks (*Pinus sylvestris*)  The quantity really applied on each test block varied between 300.5 g/m² and 301.8 g/m² (mean 301g/m²).  12 larvae of *Anobium punctatum* were used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The investigated effects are the mortality of the larvae.  - Method for recording / scoring effects: recovery of the insects and count of the dead and alive larvae. Calculation of the percentage of mortality.  - Intervals of examination: one time, 8 weeks after exposure of the larvae in the wood block to the tested product.  The efficacy criterion according to the EN 14128 is mortality higher than 85 %. | The study is validated as the survival rate in the control is higher than 70 % (100%).  **The mortality observed in the treated block is higher than 80 % (90.9 %) validated the efficacy of the product, at the application rate of 300 g of product X6122B1/ m² of wood.** | Brunet C. and Paulmier I., 2016  S6.7\_11  401/14/136F/e/e  IC1 |

* **Minor change application for X6122B1 – 2019 :**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| MG 02:  preservatives | Wood preservative  Preventive treatment | X6122B1, batch Pap V 168.1 | P. placenta | EN 113 after EN73 (evaporation) | The targeted retentions of test product were 0-60-70-80-90 and 100 kg/m3 of wood. This retentions correspond to the following target concentrations tested  On scots pine blocks, the measured retentions were 0.0, 62.5, 77.9, 84.5, 90 and 102.3 Kg/m3.  The product was applied by vacuum impregnation  - Number of replicates: 3 to 6 replicates for each treatment.  - 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.  The effects investigated is mass loss of the test blocks, induced by the fungal development  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.  - 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 (>20 % in each control)  Mid toxic values of the test product X6122B1:  - P. placenta <62.5 kg/m3  The choice of the tested concentration do not follow the requitement of the standard.  This study demonstrates the efficacy of the product against P. placenta at the application rate of 125 g of product X6122B1 / m² of wood. | Le Bayon I., 2018  S6.7\_01bis  401/17/151F/1/e  IC2 |
| MG 02:  preservatives | Wood preservative  Preventive treatement | X6122B1, batch Pap V 168.2 | P. placenta | EN 113 after EN73 (evaporation) | The targeted retentions of test product were 0-60-70-80-90 and 100 kg/m3 of wood. This retentions correspond to the following target concentrations tested  On scots pine blocks, the measured retentions were 0.0, 60, 73, 85.7, 94 and 109.1 Kg/m3.  The product was applied by vacuum impregnation  - Number of replicates: 4 to 6 replicates for each treatment.  - 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.  The effects investigated is mass loss of the test blocks, induced by the fungal development  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.  - 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 (>20 % in each control)  Mid toxic values of the test product X6122B1:  - P. placenta <62.5 kg/m3  The choice of the tested concentration do not follow the requitement of the standard.  This study demonstrates the efficacy of the product against P. placenta at the application rate of 120 g of product X6122B1 / m² of wood. | Le Bayon I., 2018  S6.7\_01ter  401/17/151F/2/e  IC2 |

## Output tables from exposure assessment tools

## New information on the active substance

## Residue behaviour

cypermethrin, tebuconazole, propiconazole, IPBC

Date: 15/09/2016

**Intended Use (critical application):** preventive and curative treatment for interior and exterior woods. These preventive and curative treatments are done by professionals and non-professionals by brush application, spray application or injection. The product can also be used by industrial users to treat wood by short dipping.

**Active substance(s):** cypermethrin, tebuconazole, propiconazole, IPBC

**Formulation of biocidal product:** AL

**Place of treatment:** indoor and outdoor

**Target organisms:** wood rotting basidiomycetes, wood boring insects, subterranean termites

The intended use descriptions of the cypermethrin, tebuconazole, propiconazole, IPBC-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 do not come in direct contact with food,feedstuff or livestock. No further data are required concerning the residue behaviour.

## Summaries of the efficacy studies (B.5.10.1-xx)[[30]](#footnote-30)

## Confidential annex

Please refer to the Confidendial annex file.

## Other

**Toxicology and metabolism –active substance (annex 5)**

<Cypermethrine>

Threshold Limits and other Values for Human Health Risk Assessment

| **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% (human) 44% (animal) |
| Dermal absorption | 36% |

| **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 4 – H302  Acute Tox 4 – H332  STOT SE 3 – H335 |

**Toxicology and metabolism –active substance**

<Propiconazole>

Threshold Limits and other Values for Human Health Risk Assessment

| **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 | 86% |
| Dermal absorption | 26% |

| **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 4 – H302  Skin Sens 1 – H317 |

<Tebuconazole>

Threshold Limits and other Values for Human Health Risk Assessment

| **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 | 31% |

| **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 4 – H302  Repr 2 – H361d |

<IPBC>

Threshold Limits and other Values for Human Health Risk Assessment

| **Summary** | | | |
| --- | --- | --- | --- |
|  | Value | Study | SF |
| AEL long-term | 0.2 | 2 year rat | 100 |
| AEL medium-term | 0.35 | 90 days rat | 100 |
| AEL acute | 0.35 | 90 days rat | 100 |
|  | | | |

|  |  |
| --- | --- |
| Inhalative absorption | 100% |
| Oral absorption | >90% (100%) |
| Dermal absorption | 75% |

| **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 4 – H302  Skin Sens 1 – H317  Eye Irrit 1 – H318  Acute Tox 3 - H331  STOT RE 1 - H372 |

<X6122B1>

Date: 26/07/2016

|  |  |
| --- | --- |
| General information | |
| Formulation Type | RTU |
| Active substance(s) (incl. content) | Cypermethrine 0.08%  Propiconazole 0.16%  Tebuconazole 0.05%  IPBC 0.05% |

| 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) | n.a |  |  |  |
| Skin sensitisation (OECD 429; LLNA) | n.a |  |  |  |

| 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 |  |  |  |
|  | n.a |  |  |  |
| Toxicological data on non-active substance(s) (not tested with the preparation) | n.a |  |  |  |
|  | 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 | Asp Tox Cat 1 - H304: May be fatal if swallowed and enters airways.  EUH 066: Repeated exposure may cause skin dryness or cracking  EUH 208: Contains propiconazole. May produce an allergic reaction |

**Safety for professional operators**

<X6122B1>

Exposure assessment

Risk assessment

Please refer to the professional Excel data sheet

**Safety for non-professional operators and the general public**

<X6122B1>

Exposure assessment

Risk assessment

Please refer to the non professional Excel data sheets

1. <https://echa.europa.eu/documents/10162/63dfef83-f970-64bf-1896-b74934fff276> [↑](#footnote-ref-1)
2. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
3. Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of propiconazole CLH-O-0000001412-86-139/F Adopted 9 December 2016.

   <https://echa.europa.eu/documents/10162/723fe08d-2ec7-105b-51aa-05064bd91ac3> [↑](#footnote-ref-3)
4. Wood preservatives – Test method for determining the protective effectiveness against wood destroying basidiomycetes – Determination of the toxic values [↑](#footnote-ref-4)
5. Wood preservatives – Accelerated-ageing tests of treated wood prior biological testing – Evaporative ageing procedure. [↑](#footnote-ref-5)
6. Wood preservatives – Accelerated ageing tests of treated wood prior biological testing – leaching procedure. [↑](#footnote-ref-6)
7. Wood preservatives – Determination of preventive action against *Reticulitermes* species (European termites) (Laboratory method) [↑](#footnote-ref-7)
8. Wood preservatives – Determination of the preventive action against *Hylotrupes bajulus (Linnaeus)* – Part 1: Larvicidal effect (Laboratory method). [↑](#footnote-ref-8)
9. Wood preservatives – Determination of the protective effectiveness against *Anobium punctatum (De geer)* – Part 1: Application by surface treatment (Laboratory method). [↑](#footnote-ref-9)
10. Wood preservatives – Determination of the protective effectiveness against *Lyctus brunneus (Stephens)* – Part 1: Application by surface treatment (laboratory method). [↑](#footnote-ref-10)
11. Wood preservatives – Determination of the eradicant action against *Hylotrupes bajulus (Linnaeus)* [↑](#footnote-ref-11)
12. Wood preservatives – Determination of the eradicant action against *larvae of Anobium punctatum (De geer) (Laboratory method)* [↑](#footnote-ref-12)
13. Durability of wood and wood-based products – Efficacy of preventive wood preservatives as determined by biological tests – Part 1: Specification according to use class. [↑](#footnote-ref-13)
14. Performance criteria for curative wood preservatives as determined by biological tests (2004) [↑](#footnote-ref-14)
15. For Propiconazole several CARs exist (for PT 7, 8 and 9). The CAR for PT 8 does not include a long-term AEL, this was found in the more recent PT 9 CAR. [↑](#footnote-ref-15)
16. Dermal absorption of cypermethrin in formulation X6122B1 through human skin in vitro. Eurofins BioPharma. Study n° 150230 [↑](#footnote-ref-16)
17. Guidance on dermal absorption. EFSA Journal 2012 ; 10(4) :2665 [↑](#footnote-ref-17)
18. “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. [↑](#footnote-ref-18)
19. HEEG Opinion on Exposure model” Primary exposure scenario – washing out of a brush which has been used to apply a paint”, endorsed at TM III 2010. [↑](#footnote-ref-19)
20. “Methods and models to assess exposureto biocidal product in different product types” version 2, June 2016. [↑](#footnote-ref-20)
21. Technical Notes for Guidance Human exposure to biocidal products, January 2008 (adopted during CA meeting of 19-20 June of 2007). [↑](#footnote-ref-21)
22. “Methods and models to assess exposureto biocidal product in different product types” version 2, June 2016. [↑](#footnote-ref-22)
23. Technical Notes for Guidance Human exposure to biocidal products, January 2008 (adopted during CA meeting of 19-20 June of 2007). [↑](#footnote-ref-23)
24. “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. [↑](#footnote-ref-24)
25. HEEG Opinion on Exposure model” Primary exposure scenario – washing out of a brush which has been used to apply a paint”, endorsed at TM III 2010. [↑](#footnote-ref-25)
26. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-26)
27. Guidance on the Biocidal product Regulation, Volume III Human Health – Part B risk assessment, 2015. [↑](#footnote-ref-27)
28. Notes for guidance: Comparative assessment of biocidal products – Consolidated version of CA Sept13-Doc.5.1.f & CA-Dec13-Doc5.1.k-Final: Ca-March14-Doc.5.4 [↑](#footnote-ref-28)
29. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-29)
30. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-30)