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)



X5975CIRE

Product type 8

Cypermethrin

Case Number in R4BP: BC-HT017417-23

Evaluating Competent Authority: FR

Date: May 2018

Table of Contents

[Table of Contents 2](#_Toc503882811)

[*1* CONCLUSION 4](#_Toc503882812)

[*2* ASSESSMENT REPORT 6](#_Toc503882813)

[2.1 Summary of the product assessment 6](#_Toc503882814)

[2.1.1 Administrative information 6](#_Toc503882815)

[2.1.1.1 Identifier of the product / product family 6](#_Toc503882816)

[2.1.1.2 Authorisation holder 6](#_Toc503882817)

[2.1.1.3 Manufacturer of the products of the family 6](#_Toc503882818)

[2.1.1.4 Manufacturer(s) of the active substance(s) 6](#_Toc503882819)

[2.1.2 Product composition and formulation 8](#_Toc503882820)

[2.1.2.1 Identity of the active substance 8](#_Toc503882821)

[2.1.2.2 Candidate(s) for substitution 8](#_Toc503882822)

[2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product 8](#_Toc503882823)

[2.1.2.4 Information on technical equivalence 9](#_Toc503882824)

[2.1.2.5 Information on the substance(s) of concern 9](#_Toc503882825)

[2.1.2.6 Type of formulation 9](#_Toc503882826)

[2.1.3 Hazard and precautionary statements 9](#_Toc503882827)

[2.1.4 Authorised use(s) 10](#_Toc503882828)

[2.1.4.1 Use description 10](#_Toc503882829)

[2.1.4.2 Use-specific instructions for use 11](#_Toc503882830)

[2.1.4.3 Use-specific risk mitigation measures 11](#_Toc503882831)

[2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 11](#_Toc503882832)

[2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging 11](#_Toc503882833)

[2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 11](#_Toc503882834)

[2.1.4.7 Use description 12](#_Toc503882835)

[2.1.4.8 Use-specific instructions for use 12](#_Toc503882836)

[2.1.4.9 Use-specific risk mitigation measures 12](#_Toc503882837)

[2.1.4.10 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 12](#_Toc503882838)

[2.1.4.11 Where specific to the use, the instructions for safe disposal of the product and its packaging 12](#_Toc503882839)

[2.1.4.12 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 12](#_Toc503882840)

[2.1.4.13 Use description 13](#_Toc503882841)

[2.1.4.14 Use-specific instructions for use 13](#_Toc503882842)

[2.1.4.15 Use-specific risk mitigation measures 13](#_Toc503882843)

[2.1.4.16 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 13](#_Toc503882844)

[2.1.4.17 Where specific to the use, the instructions for safe disposal of the product and its packaging 14](#_Toc503882845)

[2.1.4.18 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 14](#_Toc503882846)

[2.1.5 General directions for use 14](#_Toc503882847)

[2.1.5.1 Instructions for use 14](#_Toc503882848)

[2.1.5.2 Risk mitigation measures 14](#_Toc503882849)

[2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 14](#_Toc503882850)

[2.1.5.4 Instructions for safe disposal of the product and its packaging 14](#_Toc503882851)

[2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage 15](#_Toc503882852)

[2.1.6 Other information 15](#_Toc503882853)

[2.1.7 Packaging of the biocidal product 15](#_Toc503882854)

[2.1.8 Documentation 15](#_Toc503882855)

[2.1.8.1 Data submitted in relation to product application 15](#_Toc503882856)

[2.1.8.2 Access to documentation 16](#_Toc503882857)

[2.2 Assessment of the biocidal product 17](#_Toc503882858)

[2.2.1 Intended use(s) as applied for by the applicant 17](#_Toc503882859)

[2.2.2 Physical, chemical and technical properties 19](#_Toc503882860)

[2.2.3 Physical hazards and respective characteristics 25](#_Toc503882861)

[2.2.4 Methods for detection and identification 28](#_Toc503882862)

[2.2.5 Efficacy against target organisms 35](#_Toc503882863)

[2.2.5.1 Function and field of use 35](#_Toc503882864)

[2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected 35](#_Toc503882865)

[2.2.5.3 Effects on target organisms, including unacceptable suffering 35](#_Toc503882866)

[2.2.5.4 Mode of action, including time delay 35](#_Toc503882867)

[2.2.5.5 Efficacy data 36](#_Toc503882868)

[2.2.5.6 Occurrence of resistance and resistance management 37](#_Toc503882869)

[2.2.5.7 Known limitations 38](#_Toc503882870)

[2.2.5.8 Evaluation of the label claims 38](#_Toc503882871)

[2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s) 38](#_Toc503882872)

[2.2.6 Risk assessment for human health 38](#_Toc503882873)

[2.2.6.1 Hazard potential 38](#_Toc503882874)

[2.2.6.2 Human exposure assessment 41](#_Toc503882875)

[2.2.6.3 Risk assessment for human health 48](#_Toc503882876)

[2.2.7 Risk assessment for animal health 52](#_Toc503882877)

[2.2.8 Risk assessment for the environment 53](#_Toc503882878)

[2.2.8.1 Fate and distribution in the environment of the active substance Cypermethrin 53](#_Toc503882879)

[2.2.8.2 Effects on environmental organisms for active substance 57](#_Toc503882880)

[2.2.8.3 Effects on environmental organisms for biocidal product 60](#_Toc503882881)

[2.2.8.4 Environmental exposure assessment 60](#_Toc503882882)

[In a second tier, removal processes was taking into account as described below. 62](#_Toc503882883)

[For the calculation of concentrations in pore water, the soil-water partitioning coefficients are used. 62](#_Toc503882884)

[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. 62](#_Toc503882885)

[The resulting concentrations in soil and pore water taking into account removal processes over Time1 (30 days) and Time 2 (5475 days) are presented below: 62](#_Toc503882886)

[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. 63](#_Toc503882887)

[2.2.8.5 Risk characterisation for the environment 67](#_Toc503882888)

[2.2.9 Measures to protect man, animals and the environment 71](#_Toc503882889)

[*3* Annexes 72](#_Toc503882890)

[3.1 List of studies for the biocidal product family 72](#_Toc503882891)

[3.2 Output tables from exposure assessment tools 74](#_Toc503882892)

[3.2.1 Toxicology and metabolism –active substance 74](#_Toc503882893)

[3.2.2 Toxicology – biocidal product 75](#_Toc503882894)

[3.2.3 Safety for professional operators 76](#_Toc503882895)

[3.2.4 Safety for non-professional operators and the general public 77](#_Toc503882896)

[3.3 Residue behaviour 78](#_Toc503882897)

[3.4 Efficacy of the active substance from its use in the biocidal product (\*) 79](#_Toc503882898)

# CONCLUSION

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

The formulation X5975CIRE 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 transparent liquid, with a beeswax-like odour. It is not explosive and has no oxidizing properties. The product is considered flammable and has a flash point of 32.7°C. It has a self-ignition temperature higher than 270°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed.

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in tin-plate can.

Its technical characteristics are acceptable for an AL formulation.

The formulation is classified H304 and H226.

H304: May be fatal if swallowed and enters airways.

H226: Flammable liquid and vapor.

An analytical method for the determination of active substance in the formulation X5975CIRE was provided and validated.

Analytical method for the determination of cypermethrin residues in plants, animal food, soil, water and air were provided and validated at EU level.

Cypermethrin is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in animal and human body fluids and tissues is not required.

**Conclusion on efficacy**

French competent authorities (FR CA) assessed that the product X5975CIRE, has shown a sufficient efficacy:

* For preventive treatment when used by superficial application (spraying and brushing) of wood used in use class 1 against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and* *Lyctus brunneus),* and against termites *(Reticulitermes spp.),* at the application rate of at 200 g of product X5975CIRE / m² of wood*.*
* For curative treatment when used by superficial application (spraying and brushing) of wood in service in conditions of use class 1 against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and* *Lyctus brunneus)* and termites *(Reticulitermes spp.),* at the application rate of 300 g of product X5975CIRE / m² of wood*.*

**Conclusion on risk assessment for human health**

Risks related to the use of X5975 CIRE by professionals and non-professionals are considered acceptable for all the intended uses mentioned above.

- The risk is acceptable for industrial uses by a professional with gloves during application.

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

- The risk is acceptable for spray application by a professional with PPE (gloves and coated coverall 10%) during application phase.

- The risk is acceptable for brush and spray application by non-professionals, without PPE.

Risks related to a secondary exposure to treated wood are considered acceptable for all scenarios.

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

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses. Wood treated with X5975CIRE must contain label restrictions against use in contact with livestock, food and feed.

**Conclusion on risk assessment for the environment**

In order to avoid any possible risk to the environment the following will be stated on the label for industrial use (short-dipping):

* 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;
* Any contaminated water/soil shall be collected, contained and treated as hazardous waste.

# ASSESSMENT REPORT

Summary of the product assessment

Administrative information

#### Identifier of the product / product family

| **Identifier[[1]](#footnote-1)** | **Country (if relevant)** |
| --- | --- |
| X5975CIREBricorama Traitement Spécial Meubles, Xylophene Curatif SC 2000, Xylophène Meubles & Objets Anciens, Axton Traitement Meubles et Parquets, Xylophène Meuble,Xylophène Meubles, Objets et Parquets, Xylophène Industrie Xylobati SC 2000, Traitement Meubles Nuance, Boisilor Traitement Meubles | France  |
| Tratamento Moveis Nuance, Axton Tratamento Madeira Deteriorada Interior  | Portugal |
| Axton Trattamento Old Wood Interno | Italy  |
| Axton Tratamiento Madera Deteriorada Interior | Spain |
| ΘΕΡΑΠΕΙΑ ΓΙΑ ΞΥΛΙΝΑ ΔΑΠΕΔΑ ΚΑΙ ΕΠΙΠΛΑ | Greece |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | PPG AC - France SA |
| **Address** | 1 rue de l'UnionImmeuble Union Square, CS1005592565 Rueil-MalmaisonFrance  |
| **Authorisation number** | **FR-2018-0030** |
| **Date of the authorisation** | **31/05/2018** |
| **Expiry date of the authorisation** | **30/05/2028** |

#### Manufacturer of the products of the family

|  |  |
| --- | --- |
| **Name of manufacturer** | PPG AC - France SA, Dyrup S.A.S. |
| **Address of manufacturer** | Immeuble Union Square, 1 rue de l'Union92565 Rueil-MalmaisonFrance |
| **Location of manufacturing sites** | ZI Montplaisir, 25 rue Jean le Rond d'Alembert81000 AlbiFrance |

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

|  |  |
| --- | --- |
| **Active substance** | Cyperméthrine |
| **Name of manufacturer** | Arysta LifeScience Benelux SPRL  |
| **Address of manufacturer** | Rue de Renory 26/14102 OugréeBelgium |
| **Location of manufacturing sites** | **1/ Dr Reddys Laboratories Limited\***Steanard Lane, Mirfield, West Yorkshire, WF14 8QB, United Kingdom **2/ Gharda Ltd**D, ½, MIDC, LOTE PARSHURAM TAL. KHED DIST. RATNAGIRI 415 722, MAHARASHTRA, India |

*\* Initially, the location manufacturing site was Mitchell Cotts Chemical*

### Product composition and formulation

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

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

Yes [ ]

No [x]

#### Identity of the active substance

|  |
| --- |
| **Main constituent(s)** |
| **ISO name** | Cypermethrin cis:trans/40:60 |
| **IUPAC or EC name** | (RS)-α-cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate |
| **EC number** | 257-842-9 |
| **CAS number** | 52315-07-8 |
| **Index number in Annex VI of CLP** |  |
| **Minimum purity / content** | 920 g/kg |
| **Structural formula** |  |

#### Candidate(s) for substitution

The active substance cypermethrin contained in the biocidal product X5975CIRE is 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 (%)** |
| --- | --- | --- | --- | --- | --- |
| Cypermethrine | (RS)-α-cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance (pure) | 52315-07-8 | 257-842-9 | 0.07 |
| Hydrocarbons, C9-C11, nalkanes,isoalkanes,cyclics, < 2% aromatics | Hydrocarbons, C9-C11, nalkanes,isoalkanes, cyclics,< 2% aromatics | solvent |  | 919-857-5 | >95 |

#### Information on technical equivalence

Not relevant.

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

Please see the confidential annex for further details.

#### Type of formulation

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

### Hazard and precautionary statements

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

| **Classification** |
| --- |
| Hazard category | Asp. Tox. 1 STOT SE 3 Flam. Liq. 3Aquatic Acute 1Aquatic Chronic 1 |
| Hazard statement | H226: Flammable liquid and vapour H304: May be fatal if swallowed and enters airwaysH336 May cause drowsiness or dizzinessH400 – Very toxic to aquatic lifeH410 – Very toxic to aquatic life with long lasting effectsEUH066: Repeated exposure may cause skin dryness or cracking |
|  |
| **Labelling** |
| Pictograms: | GHS02GHS07GHS08GHS09Résultat de recherche d'images pour "pictogram ghs02"Résultat de recherche d'images pour "pictogram ghs07" Etiquettes de produits dangereux sur carte "Risque mutagène, respiratoire, cancérigène ou pour la reproduction" |
| Signal words: | Danger |
| Hazard statements | H336 May cause drowsiness or dizzinessH304: May be fatal if swallowed and enters airwaysH226: Flammable liquid and vapour EUH066 – H410 – Very toxic to aquatic life with long lasting effectsEUH066: Repeated exposure may cause skin dryness or cracking |
| Precautionary statements | P102 - Keep out of reach of children.P103 - Read label before use.P210 - Keep away from heat/sparks/open flames/hot surfaces. — No smoking.P233 - Keep container tightly closedP240 - Ground/bond container and receiving equipment.P241 - Use explosion-proof electrical/ventilating/lighting/…/equipment.P242 - Use only non-sparking tools.P243 - Take precautionary measures against static discharge.P261 – Avoid breathing dust/fume/gas/mist/vapours/sprayP271 – Use only outdoors or in a well-ventilated areaP273 – Avoid release to the environmentP280 – Wear protective gloves/protective clothing/eye protection/face protection.P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER/doctor/…P303 + P361+ P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin withwater/shower.P304 + P340 – IF INHALED: Remove person to fresh air and keep comfortable for breathingP312 – Call a POISON CENTER/doctor/…/if you feel unwellP331 – Do NOT induce vomitingP370 + P378 - In case of fire: Use … for extinction.P391 – Collect spillageP403 + P233 – Store in a well-ventilated place. Keep container tightly closed.P405 – Store locked upP501 - Dispose of contents/container in accordance with local regulation. |
|  |
| Note | EUH066 - Repeated exposure may cause skin dryness or cracking |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Preventive treatment

|  |  |
| --- | --- |
| **Product Type** | PT8 |
| **Where relevant, an exact description of the authorised use** | preventive treatment of use class 1 wood |
| **Target organism (including development stage)** | House longhorn beetle (*Hylotrupes bajulus L.*) : LarvaeCommon furniture beetle (*Anobium punctatum De Geer*) : LarvaePowder post beetles (*Lyctus brunneus*) : LarvaeSubterranean termites (*Reticulitermes sp*.) : soldiers, nymphs and workers |
| **Field of use** | Use class 1 on softwood and hardwood |
| **Application method(s)** | Superficial application by spraying or brushing |
| **Application rate(s) and frequency** | Ready to use product: application by spraying or brushingUC1 : 200 g/m²  |
| **Category(ies) of users** | Professional, General public (non professional) |
| **Pack sizes and packaging material** | Metal\* bottles or cans: 0.5L, 1L , 2.5L and 5L*\*tin-plate without internal varnish layer* |

#### Use-specific instructions for use

|  |
| --- |
|  |

#### Use-specific risk mitigation measures

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

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

#### Use description

Table 2. Use # 2 – Curative treatment

|  |  |
| --- | --- |
| **Product Type** | PT8 |
| **Where relevant, an exact description of the authorised use** | curative treatment for solid wood, in conditions of use class 1. |
| **Target organism (including development stage)** | House longhorn beetle (*Hylotrupes bajulus L.*) : LarvaeCommon furniture beetle (*Anobium punctatum De Geer*) : LarvaePowder post beetles (*Lyctus brunneus*) : LarvaeSubterranean termites (*Reticulitermes sp*.) : soldiers, nymphs and workers |
| **Field of use** | Curative treatmentWood in conditions of use class 1, on softwood and hardwood.  |
| **Application method(s)** | Superficial application by spraying or brushing |
| **Application rate(s) and frequency** | Ready to use product: application by spraying or brushing300 g/m² |
| **Category(ies) of users** | Professional, General public (non professional) |
| **Pack sizes and packaging material** | Metal\* bottles or cans: 0.5L, 1L , 2.5L and 5L*\*tin-plate without internal varnish layer* |

#### Use-specific instructions for use

|  |
| --- |
|  |

#### Use-specific risk mitigation measures

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

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

#### Use description

Table 3. Use # 3 – Preventive treatment in industry

|  |  |
| --- | --- |
| **Product Type** | PT8 |
| **Where relevant, an exact description of the authorised use** | Preventive treatment of use class 1 wood |
| **Target organism (including development stage)** | House longhorn beetle (*Hylotrupes bajulus L.*) : LarvaeCommon furniture beetle (*Anobium punctatum De Geer*) : LarvaePowder post beetles (*Lyctus brunneus*) : LarvaeSubterranean termites (*Reticulitermes sp*.) : soldiers, nymphs and workers |
| **Field of use** | Use class 1 on softwood and hardwood |
| **Application method(s)** | Short dip treatment |
| **Application rate(s) and frequency** | Ready to use product: application by short dip treatment.UC1: 200 g/m² |
| **Category(ies) of users** | Industrial  |
| **Pack sizes and packaging material** | Metal\* cans: 5LMetal\* barrel: 200L*\*tin-plate without internal varnish layer* |

#### Use-specific instructions for use

|  |
| --- |
|  |

#### Use-specific risk mitigation measures

|  |
| --- |
| Industrial use:* Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during dipping treatment.
* 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;
* Any contaminated water/soil shall be collected, contained and treated as hazardous waste.
 |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

 General directions for use

#### Instructions for use

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

#### Risk mitigation measures

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

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

|  |
| --- |
| * Impaired consciousness: do not give fluids or induce vomiting; place in recovery position and seek medical advice immediately.
* Keep the container or label available.
* Inhalation: Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
* Mouth contact/Ingestion: Wash out mouth with water. Seek medical advice immediately if symptoms occur and/or in case of mouth contact with large quantities.
* Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Get medical attention 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.
 |

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

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

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

|  |
| --- |
| Shelf life: 2 years |

Other information

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

Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging**  | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle / Can | 0.5L1L2.5L5L | Tin-plate (with no internal varnish layer) | Hermetically closed | Professional and Non-professional | Yes |
| Can / Barrel | 5L200L | Tin-plate (with no internal varnish layer) | Hermetically closed | Industrial | Yes |

Documentation

#### Data submitted in relation to product application

**Efficacy data**

* Laboratory efficacy study conducted according to the standard EN 118[[2]](#footnote-2), with the product X6122B1 with or without fungicidal active substances, after ageing following EN 73[[3]](#footnote-3) (evaporating procedure) against *Reticulitermes flavipes*;
* Laboratory efficacy study conducted according to the standard EN 118, with the product X6122B1, after ageing following EN 73[[4]](#footnote-4) (evaporating procedure) against *Reticulitermes flavipes*;
* Laboratory efficacy study conducted according to the standard EN 46-1[[5]](#footnote-5), with the product X6122B1, after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 49-1[[6]](#footnote-6), with the product X6122B1, after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 20-1[[7]](#footnote-7), with the product X6122B1, after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 1390[[8]](#footnote-8), with the product X6122B1;
* Laboratory efficacy study conducted according to the standard EN 48[[9]](#footnote-9), with the product X6122B1;

**Physico-chemical properties studies and analytical methods**

Physico-chemical properties studies and analytical methods on the biocidal product X5975CIRE were provided by PPG.

**Residues data**

No specific residue data were submitted in the context of this dossier. The product X5975CIRE is intended to be used for the preventive and curative treatment of interior woods. These preventive and curative treatments are done by professionals and non-professionals by brush application and spray application. The product can also be used by industrial users to treat wood by short dipping.

It will not get into contact with food, feed or livestock. Residues in food, feed or livestock are not expected. Considering the intended uses no data is required.

**Ecotoxicology data**

No specific data were submitted.

**Human health data**

No acute toxicity study (oral, dermal or inhalation) has been submitted for the product. No skin or eye irritation study has been submitted for the product. No skin sensitisation study has been submitted for the product. The classification has been established by calculation.

Following study has been conducted with the product X5975CIR:

In vitro dermal absorption study conducted according to the “OECD guideline for the testing of chemicals: test No.428”.

#### Access to documentation

PPG has access to analytical methods on the active substance Cypermethrin with a Letter of Access from Agriphar.

Assessment of the biocidal product

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

The product X5975CIRE is intended to be used for the preservation of wood in service used in use class 1 (preventive treatment) by superficial application against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and Lyctus brunneus*) and termites (*Reticulitermes spp*.), at the application rate of 200 g of product X5975CIRE / m² of wood.

This product is also intended to be used for the curative treatment of wood against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum,* and *Lyctus brunneus* and termites (*Reticulitermes spp.),* indoor at the application rate of 300 g of product X5975CIRE / m² of wood.

Table 4. Intended use # 1 – Preventive treatment

|  |  |
| --- | --- |
| Product Type | PT8 |
| Where relevant, an exact description of the authorised use | The product X5975CIRE is used as a use class 1 preventive and curative treatment for solid wood, against termites and woodboring beetles (house longhorn beetle, furniture beetle and Lyctus). It can be used indoors, on both softwood and hardwood.The application rate is 200 g/m² for preventive use, with 1 or 2 layers of the product.For professionals and nonprofessionals users, the product can be applied by brushing or spraying. |
| Target organism (including development stage) | House longhorn beetle (*Hylotrupes bajulus L.*) : LarvaeCommon furniture beetle (*Anobium punctatum De Geer*) : LarvaePowder post beetles (*Lyctus brunneus*) : LarvaeSubterranean termites (*Reticulitermes sp*.) : soldiers, nymphs and workers |
| Field of use | Indoor |
| Application method(s) | Spraying, Painting |
| Application rate(s) and frequency | Spraying : 200 g/m²Painting : 200 g/m² for preventive useTwo 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 theinstructions 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 |
| Category(ies) of user(s) | Professional, General public (nonprofessional) |
| Pack sizes and packaging material | Tinplate can (without intern varnish layer). Hermetically closed with a cap.Bottle / Tinplate : Metal 0.5 LBottle / Tinplate : Metal 1 LCan / Tinplate : Metal 2.5 LCan / Tinplate : Metal 5 L |

Table 5. Intended use # 2 – Curative treatment

|  |  |
| --- | --- |
| Product Type | PT8 |
| Where relevant, an exact description of the authorised use | The product X5975CIRE is used as a preventive and curative treatment for solid wood, against termites and woodboring beetles (house longhorn beetle, furniture beetle and Lyctus). It can be used indoors, on both softwood and hardwood.The application rate is 300 g/m² for curative use, with 3 layers of the product.For professionals and nonprofessionals users, the product can be applied by brushing or spraying. |
| Target organism (including development stage) | House longhorn beetle (*Hylotrupes bajulus L.*) : LarvaeCommon furniture beetle (*Anobium punctatum De Geer*) : LarvaePowder post beetles (*Lyctus brunneus*) : LarvaeSubterranean termites (*Reticulitermes sp*.) : soldiers, nymphs and workers |
| Field of use | Indoor |
| Application method(s) | Spraying |
| Application rate(s) and frequency | 300 g/m²Three 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. |
| Category(ies) of user(s) | Professional, General public (nonprofessional) |
| Pack sizes and packaging material | Tinplate can (without intern varnish layer). Hermetically closed with a cap.Bottle / Tinplate : Metal 0.5 LBottle / Tinplate : Metal 1 LCan / Tinplate : Metal 2.5 LCan / Tinplate : Metal 5 L |

Table 6. Intended use # 3 – Industrial use

|  |  |
| --- | --- |
| Product Type | PT8 |
| Where relevant, an exact description of the authorised use | The product X5975CIRE is used as a class 1 preventive and curative treatment for solid wood, against termites and woodboring beetles (house longhorn beetle, furniture beetle and Lyctus). It can be used indoors, on both softwood and hardwood.This product can be used by industrial users, by shorttime 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) | House longhorn beetle (*Hylotrupes bajulus L.*) : LarvaeCommon furniture beetle (*Anobium punctatum De Geer*) : LarvaePowder post beetles (*Lyctus brunneus*) : LarvaeSubterranean termites (*Reticulitermes sp*.) : soldiers, nymphs and workers |
| Field of use | Indoor |
| Application method(s) | Open system: dip treatment |
| Application rate(s) and frequency | 200 g/m²The 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. |
| Category(ies) of user(s) | Industrial  |
| Pack sizes and packaging material | Tinplate can (without intern varnish layer). Hermetically closed with a cap.Can or barrel / Tinplate : Metal 5 L, 200L |

### 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. The product contains 0.07% of pure cypermethrin (cis:trans/ 40:60) and 0.08% of technical cypermethrin.

The product does not contain PT6 conservative and it is used undiluted.

Formulation type: Another Liquid (AL)

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

The product X5975CIRE is packaged in tinplate metal bottles/cans/barrels hermetically closed with a cap.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | METDESCR | **X5975CIRE** **Lot/batch No.: 1418200053** | **transparent liquid** | **Acceptable** | Raphalen E. 2015Report N° 402/14/1092F/abc-eSimon F., 2015150313/PaPV93.9 |
| Colour at 20 °C and 101.3 kPa | **colourless** |
| Odour at 20 °C and 101.3 kPa | **beeswax-like odour** |
| Acidity / alkalinity | pH: CIPAC MT 75.3 Acidity: CIPAC MT 31.2.3 |  | **Not required as X5975CIRE is a non-aqueous ready-to-use product.**As the product is an organic solution, the determination of pH and acidity/alkalinity are scientifically unjustified. In the Guidance on the BPR, Vol. 1, Part A, it is specified on point 3.3 that *"In the case of solid and* ***non-aqueous liquid biocidal products*** *which are to be* ***applied as aqueous dilutions or dispersions*** *the pH of a 1% dilution or dispersion of the product should be determined and reported"*. As the product X5975CIRE is a **non-aqueous ready-to-use** product, it is not intended to be applied as aqueous solutions (see document "S13\_uses\_PT08\_X5975CIRE\_update20160607), therefore the determination of pH in 1% aqueous solution is not justified.Moreover, the guidance specifies that "*The acidity/alkalinity must be determined when the pH of the biocidal product as formulated or its 1% dilution or dispersion is < 4 or > 10*". Taking into account that the determination of pH in 1% aqueous solution is not justified and that the product X5975CIRE is a non-aqueous ready-to-use product, the determination of acidity/alkalinity is also unjustified. | **Acceptable** |  |
| Relative density / bulk density | CIPAC MT 3.2.1  | **X5975CIRE** **Lot/batch No.: 1418200053** | **D20 = 0.787** | **Acceptable** | Raphalen E. 2015Report N° 402/14/1092F/defgh-e |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 (14 days at 54 ± 2ºC in commercial packaging)  | **X5975CIRE** **Lot/batch No.: 1418200053** |

|  |  |  |
| --- | --- | --- |
| Test | Initial | After 14 days storage at 54°C |
| Appearance of test item | Transparent, colourless and liquid. No deposit, no phase partition, no surface skin, no visual impurities, no foreign ingredients. |
| Cypermethrin content (% w/w) | 0.074 | 0.078 (+5.4%) |
| Appearance and weight of test packaging | Metal can, no sign of corrosion or degradation541.43g | Metal can, no sign of corrosion or degradation514.68g (-4.98%) |

 | **Acceptable** | Raphalen E. 2015Report N° 402/14/1092F/abc-e**HPLC method : 402/13/1140F/ab-e** |
| Storage stability test – **long term storage at ambient temperature** | Shelf-life (2years at ambient temperature) | **X5975CIRE** **Lot/batch No.: XIX 5 NDF**  | The long term storage study at ambient temperature during 24 months, with the product X5975CIRE in its commercial packaging (metal can)

|  |  |  |  |
| --- | --- | --- | --- |
| Test | Initial | After 12 months storage at 20°C in 1L tin-plate can | After 24 months storage at 20°C in 1L tin-plate can |
| Appearance of test item | Transparent, colourless and liquid. No deposit, no phase partition, no surface skin, no visual impurities, no foreign ingredients. |
| Cypermethrin content (% w/w) | 0.062 | 0.064 (+3.23%) | 0.063(+1.6%) |
| Appearance and weight of test packaging | 1L metal can, no sign of corrosion or degradation | No sign of corrosion or degradation Loss of weight : 3.52% | No sign of corrosion or degradation Loss of weight : 6.3% |

 | **The long term storage study is acceptable.** | Legay S., 2013Study plan N° 13/1140F/c**HPLC method : 402/13/1140F/ab-e** |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 (7 days at 0 ± 1ºC in closed glass bottle)  | **X5975CIRE** **Lot/batch No.: 1418200053** |

|  |  |  |
| --- | --- | --- |
| Test | Initial | After 7 days storage at 0°C |
| Appearance of test item | Transparent, colourless and liquid. No deposit, no phase partition, no surface skin, no visual impurities, no foreign ingredients. |

 | **Acceptable** | Raphalen E. 2015Report N° 402/14/1092F/defgh-e |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Not required |  |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | Not required |  |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | See “Storage stability test – **long term storage at ambient temperature”** |  |  |
| Wettability |  |  | Not required |  |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not required |  |  |
| Wet sieve analysis and dry sieve test |  |  | Not required |  |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not required |  |  |
| Disintegration time |  |  | Not required |  |  |
| Particle size distribution, content of dust/fines, attrition, friability | *Only for powders and granules*  |  | **Not applicable** |  |  |
| Persistent foaming | CIPAC MT 47.2  |  | Not required |  |  |
| Flowability/Pourability/Dustability |  |  | Not required |  |  |
| Burning rate — smoke generators |  |  | Not applicable |  |  |
| Burning completeness — smoke generators |  |  | Not applicable |  |  |
| Composition of smoke — smoke generators |  |  | Not applicable |  |  |
| Spraying pattern — aerosols |  |  | Not applicable |  |  |
| Physical compatibility |  |  | Not applicable |  |  |
| Chemical compatibility |  |  | Not applicable |  |  |
| Degree of dissolution and dilution stability |  |  | Not applicable |  |  |
| Surface tension | METTENS (equivalent to EEC A5)  | **X5975CIRE** **Lot/batch No.: 1418200053** | **24.27 mN/m at 21.4°C on the pure test item** | **Acceptable****Surface active substance****The product is classified H304.** | Raphalen E. 2015Report N° **402/14/1092F/defgh-e** |
| Viscosity | METVISCO (Pesticide Research Dept) [equivalent to OECD 114]  | **X5975CIRE** **Lot/batch No.: 1418200053** |

|  |  |
| --- | --- |
| Temperature (°C) | Kinematic viscosity (mm²/s) |
| 20.0 | <6.62 |
| 40.0 | <6.62 |

 | **Acceptable****The product is classified H304.** | Raphalen E. 2015Report N° **402/14/1092F/defgh-e** |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives |

|  |
| --- |
|  EEC A14  |

 | **X5975CIRE** **Lot/batch No.: 1418200053** | According to Differential Scanning Calorimetry (DSC) graphs, two endothermic reactions and one exothermic reaction were observed in the temperature range from 20°C to 500°C. The exothermic decomposition energy at 334°C was less than 500 J/g. Therefore, the test item X5975CIRE 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** | **Raphalen E., Legay S.** Report N° 2015402/14/1092F/i-e |
| Flammable gases |  |  | Not applicable |  |  |
| Flammable aerosols |  |  | Not applicable |  |  |
| Oxidising gases |  |  | Not applicable |  |  |
| Gases under pressure |  |  | Not applicable |  |  |
| Flammable liquids | CIPAC MT 12.2 (equivalent to EEC A9)  | **X5975CIRE** **Lot/batch No.: 1418200053** | **Flash point : 32.7°C** | **Acceptable****The product is considered as flammable and classified H226.** | Raphalen E. 2015Report N° **402/14/1092F/defgh-e** |
| Flammable solids |  |  | Not applicable |  |  |
| Self-reactive substances and mixtures |  |  | Not required |  |  |
| 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. | This test is required with the CLP regulation. Nevertheless, as there are no ingredients classified H250 (category 1), it considered acceptable. |  |
| Pyrophoric solids |  |  | Not applicable |  |  |
| Self-heating substances and mixtures |  |  | Not required |  |  |
| Substances and mixtures which in contact with water emit flammable gases |  |  | Not applicable |  |  |
| Oxidising liquids |  | **X6019CIR** | Considering the high proportion of non-oxidising ingredients (in total 99.99% w/w, 0.01% of perfume), the product X6019CIR is not expected to present a significant hazard for oxidising properties, and testing is considered as unnecessary. Considering that X5975CIRE and the liquid extracted from the X6019CIR aerosol are identical, X5975CIRE is not expected to present a significant hazard for oxidizing properties. | **Acceptable**The statement was performed on the formulation X6019CIR which does not contain more or less oxidising properties than X5975CIRE formulation. | **Detrimont H., Ambrosi D., 2015**Report N° **15/03** |
| Oxidising solids |  |  | Not applicable |  |  |
| Organic peroxides |  |  | 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. |  |  |
| Auto-ignition temperatures of products (liquids and gases) | EEC A15  | **X6019CIR** | **>270°C** | **Acceptable** The statement was performed on the formulation X6019CIR which does not contain less flammable properties than X5975CIRE formulation. | **Detrimont H., Ambrosi D., 2015**Report N° **15/03** |
| Relative self-ignition temperature for solids |  |  | Not applicable |  |  |
| Dust explosion hazard |  |  | Not applicable |  |  |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The formulation X5975CIRE 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 transparent liquid, with a beeswax-like odour. It is not explosive and has no oxidizing properties. The product is considered flammable and has a flash point of 32.7°C. It has a self-ignition temperature higher than 270°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in tin-plate can. Its technical characteristics are acceptable for an AL formulation.**The formulation is classified H304 and H226.****H304: May be fatal if swallowed and enters airways****H226: Flammable liquid and vapour** |

### 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 substance 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 substance cypermethrin (2013). The notifier PPG of the product X5975CIRE is not the applicant that supported the annex I inclusion dossier of the active substance (Agriphar) but it has a letter of access to these data.

**Summary for Cypermethrin:**

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

**Summary:**

|  |  |
| --- | --- |
| Soil (principle of method and LOQ) | Cypermethrin 40:60 cis:transGC-MS**LOQ 0.05 mg/kg**  |
| Air (principle of method and LOQ) | Cypermethrin 40:60 cis:transGC-MS**LOQ 0.375 μg/m3** |
| Water (principle of method and LOQ) | Cypermethrin 40:60 cis:transGC-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:transGC-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:transGC-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.

**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 (X5975CIRE): Validation of analytical method and chemical analysis of active ingredient declared in the test item, Chemical analysis of active ingredient in a wood preservative |
| Document No | 402/13/1140F/ab-e  |
| Test facility |  |
| Guidelines: | SANCO/3030/99 rev.4.  |
| GLP | Yes |

**Preparation of accuracy samples:**

The blank formulation 13/1140F/4 (matrix blank) is weighted in order to obtain an aliquot of around 0.417 g. The sample is placed in a volumetric flask of 5 mL and then, a known amount of a stock solution containing the active ingredients in acetone is added. The volumetric flask of 5 mL is completed with acetone.

**Validation of the analytical method:**

|  |  |
| --- | --- |
| Specificity | No interference at the selected wavelength (210nm) was detected at the retention time of the active ingredient in HPLC-UV in blank formulation samples diluted in acetone. No interference from other substances present in the preparation should not contribue than 3% to the total peak area measured for the active substance. Chromatograms were provided. |
| Linearity | 2 linearity ranges were studied by carrying out five calibration spots with single determination, over a concentration range at the “target value” ±20%. A linear regression and its correlation coefficient were calculated. |
| Compound | Linearity (working range) mg/L |
| Cypermethrin  | 40 to 60 mg/L Y = 5.644\*104 X – 1.327\*104R2 = 0.99740N=5 |
| Cypermethrin | 40 to 60 mg/L Y = 5.650\*104 X – 1.139\*104R2 = 0.99978N=5 |
| Precision | Repeatability was evaluated with 12 independent determinations of cypermethrin in the formulated product, no outlier. |
| Compound | Repeatability (RSD) |
| Cypermethrin  | RSDr = 0.5719% < 4.09% (RSDr calculated with modified equation of Horwitz)RSDR = 0.7750% < 6.11% (RSDR calculated with modified equation of Horwitz) |
| 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.  |
| Compound | Accuracy (recovery ) |
| Cypermethrin | 99.23% |

**Specificity, linearity, precision and accuracy were checked and are found acceptable.**

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

|  |
| --- |
| **Analytical methods for monitoring** |
| **Analyte (type of analyte e.g. active substance)** | **Matrix** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| cypermethrin | Oilseed rape (seed) | GC-ECD | 0.05 mg/kg / 5 | 0.05 to 1.5 mg/Ln N=5, r²>0.98 | the mean concentrations of the interfering components in the control samples did not exceed 30% of the LOQ | 80-94 | 89 | 6.6 | 0.05 | Wimbush, J (2003); 40/037-D2149 |
| 0.5 mg/kg / 5 | 80-91 | 85 | 5.7 |
| Oilseed rape (oil) | 0.05 mg/kg / 5 | 87-94 | 89 | 3.0 |
| 0.5 mg/kg / 5 | 76-82 | 79 | 3.4 |
| cypermethrin | Wheat grain | GC-ECD | 0.025 mg/kg / 5 | 71-93 | 84 | 9.7 | 0.025 |
| 0.25 mg/kg / 5 | *79-92* | *87* | *5.6* |
| Wheat straw | 0.025 mg/kg / 5 | *104-117* | *110* | *4.3* |
| 0.25 mg/kg / 5 | *84-95* | *90* | *4.8* |
| cypermethrin | Oilseed rape (seed) | GC-ECD | 0.05 mg/kg / 5 | *75-85* | *79* | *4.8* | 0.05 | *ILV**Devine H., 2003 ; CLE 0040/037-03RO* |
| 0.5 mg/kg / 5 | *78-88* | *85* | *5.1* |
| Oilseed rape (oil) | 0.05 mg/kg / 5 | *87-113* | *100* | *11.4* |
| 0.5 mg/kg / 5 | *69-88* | *78* | *9.5* |
| Wheat grain | 0.025 mg/kg / 5 | *69-80* | *77* | *6.0* | 0.025 |
| 0.25 mg/kg / 5 | *64-80* | *72* | *9.1* |
| cypermethrin | Oilseed rape (seed) | GC-ECD | 0.05 mg/kg / 5 | *93-106* | *98* | *5.9* | 0.05 | Confirmatory method of Wimbush, J (2003) by column replacement |
| 0.5 mg/kg / 5 | *88-97* | *92* | *5.2* |
| Oilseed rape (oil) | 0.05 mg/kg / 5 | *73-80* | *75* | *3.8* |
| 0.5 mg/kg / 5 | *76-82* | *78* | *3.4* |
| Wheat grain | 0.025 mg/kg / 5 | *101-106* | *105* | *2.0* | 0.025 |
| 0.25 mg/kg / 5 | *87-102* | *98* | *6.5* |
| Wheat straw | 0.025 mg/kg / 5 | *90-98* | *94* | *3.4* |
| 0.25 mg/kg / 5 | *93-105* | *97* | *5.3* |
| cypermethrin | Bovine muscle | GC-MSD | 0.05 mg/kg / 5 | 0.01 to 1 mg/LN=6R²>0.98 | No interference > 30% of LOQ in the control matrices.  | *86-91* | *87* | *2.5* | *0.05* | Wimbush, J (2003); 40/041-D2149Ion m/z 207 |
| 0.5 mg/kg / 5 | *80-84* | *81* | *2.2* |
| Bovine kidney | 0.05 mg/kg / 5 | *95-103* | *100* | *3.0* |
| 0.5 mg/kg / 5 | *84-89* | *87* | *2.3* |
| Bovine liver | 0.05 mg/kg / 5 | *83-87* | *85* | *2.1* |
| 0.5 mg/kg / 5 | *81-90* | *86* | *4.5* |
| Bovine fat | 0.05 mg/kg / 5 | *78-84* | *82* | *3.5* |
| 0.5 mg/kg / 5 | *93-101* | *97* | *3.7* |
| Eggs | 0.01 mg/kg / 5 | *80-87* | *83* | *3.9* | *0.01* |
| 0.1 mg/kg / 5 | *87-94* | *91* | *3.1* |
| Milk | 0.005 mg/kg / 5 | *84-106* | *92* | *9.7* | *0.005* |
| 0.05 mg/kg / 5 | *62-90* | *77* | *15.1* |
| cypermethrin | Bovine muscle | GC-MSD | 0.05 mg/kg / 5 | 0.01 to 1 mg/LN=6R²>0.98 | No interference > 30% of LOQ in the control matrices. | *82-85* | *83* | *1.3* | *0.05* | *ILV**Devine H., 2003 ; CLE 0040/041-03R* |
| 0.5 mg/kg / 5 | *78-89* | *85* | *5.2* |
| Bovine fat | 0.05 mg/kg / 5 | *92-101* | *96* | *4.1* |
| 0.5 mg/kg / 5 | *72-86* | *79* | *6.5* |
| Eggs | 0.01 mg/kg / 5 | *98-102* | *101* | *1.9* | *0.01* |
| 0.1 mg/kg / 5 | *84-86* | *85* | *1.1* |
| Milk | 0.005 mg/kg / 5 | *73-88* | *82* | *6.8* | *0.005* |
| 0.05 mg/kg / 5 | *91-101* | *96* | *4.3* |
| cypermethrin | Bovine muscle | GC-MSD | 0.05 mg/kg / 5 | 0.01 to 1 mg/LN=6R²>0.98 | No interference > 30% of LOQ in the control matrices. | *87-92* | *89* | *2.6* | *0.05* | Wimbush, J (2003); 40/041-D2149Ion m/z 209 |
| 0.5 mg/kg / 5 | *79-84* | *81* | *2.5* |
| Bovine kidney | 0.05 mg/kg / 5 | *97-106* | *103* | *3.3* |
| 0.5 mg/kg / 5 | *85-89* | *87* | *2.1* |
| Bovine liver | 0.05 mg/kg / 5 | *83-104* | *92* | *9.2* |
| 0.5 mg/kg / 5 | *87-91* | *89* | *1.8* |
| Bovine fat | 0.05 mg/kg / 5 | *80-88* | *83* | *3.7* |
| 0.5 mg/kg / 5 | *91-99* | *95* | *5.2* |
| Eggs | 0.01 mg/kg / 5 | *80-84* | *82* | *2.5* | *0.01* |
| 0.1 mg/kg / 5 | *85-97* | *91* | *5.2* |
| Milk | 0.005 mg/kg / 5 | *82-105* | *90* | *10.8* | *0.005* |
| 0.05 mg/kg / 5 | *62-88* | *76* | *14.5* |

|  |
| --- |
| **Analytical methods for soil** |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| cypermethrin | GC-MSDIon m/z 207 | 0.05 mg/kg / 5 | 0.005 to 1.0 mg/L, n=6, r²>0.999 | No significant matrix interference (control values < 30% LOQ) | 99-105 | 101 | 2.3 | 0.05 | Wimbush, J (2003); 40/039-D2149 |
| 0.5 mg/kg / 5 | 99-101 | 100 | 1.0 |
| GC-MSDIon m/z 209 | 0.05 mg/kg / 5 | 98-104 | 101 | 2.4 |
| 0.5 mg/kg / 5 | *98-101* | *100* | *1.3* |

|  |
| --- |
| **Analytical methods for water** |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| cypermethrin | GC-ECD | 0.01 µg/L / 5 | 0.005 to 0.5 mg/L, n=6, r²>0.99 | No significant matrix interference (control values < 30% LOQ) | 94-116 | 101 | 8.4 | 0.01 µg/L | Wimbush, J (2002); 40/040-D2149 |
| 0.1 µg/L / 5 | 84-94 | 89 | 4.6 |
| GC-MSD | 0.01 µg/L / 5 | 89-108 | 93 | 7.6 |
| 0.1 µg/L / 5 | 79-97 | 88 | 7.8 |

|  |
| --- |
| **Analytical methods for air** |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| cypermethrin | GC-MSD(Ambient conditions) | 0.375 µg/m3 | 0.01 to 0.3 µg/mL, n=6, r²≥0.98 | No significant matrix interference (control values < 30% LOQ) | - | 80 | 8.6 | 0.375 µg/m3 | Wimbush, J (2005); 1669/016-D2149 |
| 3.75 µg/m3 | - | 110 | 12.0 |
| GC-MSD(Elevated conditions) | 0.375 µg/m3 | - | 89 | 11.0 |
| 3.75 µg/m3 | - | 99 | 3.9 |

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

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| **Analytical method with its ILV (Wimbush, J, 2003 and Devine H, 2003) using GC-ECD was provided at EU level for the determination of cypermethrin residues in oily and dry matrices with a LOQ = 0.05 mg/kg (oilseed rape) and 0.025 mg/kg (wheat).****Analytical method with its ILV (Wimbush, J, 2003 and Devine H, 2003) using GC/MS was provided at EU level for the determination of cypermethrin residues in animal products matrices with a LOQ = 0.05 mg/Kg (bovine tissue), 0.005 mg/Kg (bovine milk), 0.01 mg/Kg (hen eggs).****Analytical method (Wimbush, J, 2003) using GC/MS was provided at EU level for the determination of cypermethrin residues in soil with a LOQ = 0.05 mg/kg.****Analytical method (Wimbush, J, 2002) using GC-ECD and confirmation by GC/MS was provided at EU level for the determination of cypermethrin residues in surface water with a LOQ = 0.01 µg/L.****Analytical method (Wimbush, J, 2005) using GC-ECD was provided at EU level for the determination of cypermethrin residues in air with a LOQ = 0.375μg/m3.****Cypermethrin is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in animal and human body fluids and tissues is not required.** |

### Efficacy against target organisms

#### Function and field of use

MG 02: preservatives

Product Type 08: wood preservative

The product X5975CIRE 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.

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 X5975CIRE is intended to be used by superficial application for preventive treatment for wood used in use class 1 and is also intended to be used for curative treatments by superficial application, for wood in service, indoor.

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

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

According to the uses claimed by the applicant, the product X5975CIRE is intended to be used for the preservation of wood in service used in use class 1 (preventive treatment) by superficial application against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and Lyctus brunneus*) and termites (*Reticulitermes spp.*).

This product is also intended to be used for the curative treatment of wood in conditions of use class 1, against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum,* and *Lyctus brunneus* and termites (*Reticulitermes spp.),* indoor.

The development stages claimed are larvae and adults.

#### 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).

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

Regarding the curative insecticidal efficacy, based on the elements presented in the dossier, the product X5975CIRE has demonstrated a slow action on *Hylotrupes bajulus* and a rapid effect on *Anobium punctatum.*

#### Efficacy data

Please refer to section 3.4 “Efficacy of the active substance from its use in the biocidal product”.

* **Bridging data with the product X6122B1:**

No efficacy trials according to European standards were conducted with the product X5975CIRE. A bridging was prepared from the results obtained with product X6122B1 and from an internal test showing that removal of the fungicidal active substances in a formulation does not affect its insecticidal efficacy:

The products X5975CIRE and X6122B1 have close compositions. The major differences are the presence of three additional fungicidal active substances in the product X6122B1, and the replacement of the principal solvent by another one (with content adjustments for other minor solvents) in the product X5975CIRE.

Annex A of the standard EN 599-1 describes if re-testing is needed when variations occur in product formulation:

* According to section A.3.2.a, no new biological tests are required when the change involves deletion of fungicides from a product tested against insects, if data exist which confirm no effect of the removal on the efficacy of the remaining actives substances. The product X6122B1 contains three fungicidal actives substances, which have no insecticidal activity. In the product X5975CIRE, these fungicidal active substances are absent, and the only active substance is cypermethrin with the same concentration than in the product X6122B1. Moreover, efficacy tests according to a EN 118-like protocol have been conducted, comparing the efficacy of product X6122B1, to a formulation containing only the fungicidal actives substances and a formulation containing only cypermethrin (as X5975CIRE): the results showed that the complete formulation and the formulation with only the insecticidal active substance are both effective against termites, with a similar level of efficacy. On the contrary, the formulation with only the fungicide active substances has no efficacy on termites. Thus it can be concluded that the suppression of these fungicidal active substances has no effect on the insecticidal efficacy of the product X5975CIRE.
* According to section A.2.2.a, no new biological testing is required for changes involving substitution of any co-formulant by one which is chemically equivalent, from another supplier. Therefore the replacement of the principal solvent by another one chemically equivalent in the product X5975CIRE is acceptable from an efficacy point of view.
* According to section A.2.2.h, no new biological testing is required for replacing a co-formulant provided that the additive constitutes less than 2% of the total formulation and physical properties are not affected.

Content adjustments for these other minor solvents is less than 2%.

Moreover, physical properties and stability of the product X5975CIRE have been confirmed and penetration is not expected to be affected.

Therefore efficacy results of the product X6122B1 are considered as applicable for efficacy of the rpoduct X5975CIRE and no new biological tests should be required for X5975CIRE.

* **Results of the efficacy data**

The tests have been performed with the product X6122B1.

* Regarding the preventive efficacy claim against wood boring beetles, for superficial application, the product X6122B1 is efficient according to respectively EN 46 (+EN73), EN 49 (+EN73) and EN 20-1 (+EN73), against *Hylotrupes bajulus, Anobium punctatum and* *Lyctus brunneus* for use class 1 at the application rate of 200 g of product X6122B1 / m² of wood.
* Regarding the preventive efficacy claim against termites (*Reticulitermes spp.*), for superficial application, the product X6122B1 is efficient according to EN 118 (+EN73), against *Reticulitermes spp.*, for use class 1, 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* with a slow action activity and against *Anobium punctatum* with a rapid action activity, at the application rate of 300 g of product X6122B1 / m² of wood. According to EN 14128[[10]](#footnote-10), 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), 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.

French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the product X5975CIRE according to the uses and the applications rates claimed.

All efficacy studies are presented in annex 3.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) assessed that the product X5975CIRE, has shown a sufficient efficacy:* For preventive treatment when used by superficial application of wood used in use class 1 against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and* *Lyctus brunneus),* and against termites *(Reticulitermes spp.),* at the application rate of at 200 g of product X5975CIRE / m² of wood*.*
* For curative treatment when used by superficial application of wood in service in conditions of use class 1 against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and* *Lyctus brunneus)* and termites *(Reticulitermes spp.,* at the application rate of 300 g of product X5975CIRE / m² of wood.*).*
 |

#### Occurrence of resistance and resistance management

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

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.

#### Known limitations

None

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the product X5975CIRE has shown a sufficient efficacy for the preservation of wood in service used by industrial, professional and non-professional users:

* For the preventive efficacy of the product when used by superficial application of wood in service used in use class 1 against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and* *Lyctus brunneus),* and against termites *(Reticulitermes spp.).*
* For the curative efficacy of the product when used by superficial application against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and* *Lyctus brunneus)* and against termites *(Reticulitermes spp.).*

The application rates validated are the following:

* Preventive treatments: superficial application at 200 g of product X5975CIRE / m² of wood
* Curative treatment: superficial application at 300 g of product X5975CIRE / m² of wood

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

None.

### Risk assessment for human health

The product X5975CIRE is a wood preservative which is a ready-for-use formulation for industrial, professional and non-professional uses. The product contains 0.076% w/w cypermethrin.

#### Hazard potential

##### Toxicology of the active substance

The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in the CAR. The threshold limits and labelling regarding human health risks listed in Annex 3.2.1 „Toxicology and metabolism” must be taken into consideration.

see Assessment Report or CAR of cypermethrine.

The summary of Toxicological Reference Values is presented below:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Reference dose** | **Value** **(mg/kg bw/day)** | **Study** | **NOAEL****(mg/kg bw/day)** | **Uncertainty Factor** | **Oral absorption****Animal** | **Oral absorption****Human** |
| Long-term AEL | 0.022 | 2-year rat study  | 5 | 100 | 44% | 57% |
| Medium-term AEL | 0.055 | 90-days dog | 12.5 | 100 | 44% | 57% |
| Short-term AEL | 0.088 | Acute delayed neurotoxicity in rat | 20 | 100 | 44% | 57% |

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

The coformulant Hydrocarbons, C9-C11,n-alkanes, isoalkanes, cyclics triggers a classification Asp Tox. Cat 1 - H304 and STOT SE 3 – H336 and EUH066 of product. In this context, the coformulant is considered substance of concern.

##### Toxicology of the biocidal product

 The toxicology of the biocidal product was examined appropriately according to standard requirements. The product was not a dummy product in the EU- review program for inclusion of the active substance in Annex I of Directive 98/8/EC.

The basis for the health assessment of the biocidal product is laid out in Annex 3.2.2 ”Toxicology – biocidal product”

###### Percutaneous absorption

The absorption profile and the distribution of the test item cypermethrin in formulation X5975CIRE subsequent to the application on human skin was analysed using an *in vitro* flow-through diffusion cell. Hereby, the test item cypermethrin in formulation X5975CIRE was tested at one concentration corresponding to the content of the pure product (0.07% w/w of pure active substance) 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)” which recommends to use a radiolabelled substance to perform this absorption study. The study was also designed using the Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665).

Single values for 9 replicates, mean and standard deviation are listed. In the total absorption the activity of skin, receptor fluid, gauze and chamber wash is included. Strips 1-2 were excluded for all replicates, also strips 3 - ∞ were excluded as mean value of total absorption at 12h was above 75%.

Nine replicates were reported, but only seven replicates were used for evaluation, since two replicates were defined as outlier according to Nalimov concerning the absorption rate.

Dermal absorption is expressed as a percentage of the total amount recovered by chamber.

Mean recovery rate was 98.4% for cypermethrin in formulation X5975CIRE, single values ranging from 91.7% to 108%. Deviations between samples in recovery might be caused by the oily characteristics of the test item.

For the test item cypermethrin in formulation X5975CIRE the mean total absorption comprising the recovered activity from receptor fluid, skin, chamber wash lower compartment and gauzes was found to be 27.9% (s.d. 9.5%). Strips 3 - ∞ are excluded as the mean value of absorption at 12 h was above 75%.

In conclusion, in the described percutaneous absorption study under the experimental conditions reported, the test item cypermethrin formulated in X5975CIRE is considered to permeate through the skin with a total absorption measured at 27.9% (s.d. 9.5%).

As the standard deviation is higher than 25% of the mean absorption value, according to the EFSA guidance on dermal absorption (2012), the SD is added to the mean absorption value, leading to 37.4% rounded to 37% (also according to the EFSA guidance).

The dermal absorption retained for X5975CIRE is presented below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Guideline/test method** | **Species** | **Route of administration** | **Endpoint/type of test** | **Results****(dermal absorption)** |
| OECD 428*In vitro*Washing at 8 h / Exposure for 24 h | Human skin | Dermal | Dermal absorption of Cypermethrin | 37% |

###### Acute toxicity

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

###### irritation and corrosivity

No skin or eye irritation study has been submitted for the product. The calculation rules of the Regulation 1272/2008 are applied to set the classification of the product for this endpoint. Regarding the content of active substances and co-formulants, no classification is required.

###### Sensitisation

No skin sensitisation study has been submitted for the product. The calculation rules of the Regulation 1272/2008 are applied to set the classification of the product for this endpoint. Regarding the content of active substances and co-formulants, no classification is required.

###### Other studies

No other study has been submitted.

Considering the classification of the active substance and the coformulants (notably hydrocarbons, C9-C11, n-alkanes, isoalkanes, cyclics, < 2% aromatics), the product requires the following toxicological classification:

|  |  |
| --- | --- |
| **Classification - Regulation (EC) 1272/2008** |  |
| Hazard statement | STOT SE 3 – H336 May cause drowsiness or dizzinessAsp. Tox. 1 – H304May be fatal if swallowed and enters airwaysEUH066: Repeated exposure may cause skin dryness or cracking |
| Precautionary statements  | P261, P271, P304 + P340, P312, P403 + P233, P405, P501P301 + P310, P331 |

#### Human exposure assessment

The biocidal product X5975CIRE is a ready-to-use wood preservative product containing 0.076% cypermethrin as active substance.

The product is intended to be used for the preventive and curative treatment of interior woods. These preventive (200 g product /m²) and curative (300 g product/m²) treatments are done by professionals and non-professionals by brush application and spray application. The product can also be used by industrial users to treat preventively wood by short dipping (200 g product/m²).

* For the human risk assessment, exposure is expected for professionals and non-professionals (adults and chidren):Primary exposure for professional
	+ During transfer of product and automated dipping. Professional worker is also occasionally exposed to the formulation when cleaning out the dipping tank,
	+ During professional application by brush or spray indoors.
* Primary exposure for non-professional
	+ During application by brush or spray indoors
* Secondary exposures for professionals and non-professionals (adults and children)

Both categories are exposed to the biocidal product X5975CIRE when they are in contact with the treated woods and/or their residues (acute or chronic exposures). The routes of exposure are expected to be oral, dermal and/or by inhalation.

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Exposure path** | **Industrial use**  | **Professional use** | **General public** | **via the environment** |
| Inhalation | Yes  | Yes | Yes | Yes |
| Dermal | Yes | Yes | Yes | Yes |
| Oral | No | No  | Yes | Yes |

Physico-chemical and toxicological data of cypermethrine are summarized in the following table:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Active Substance** | **Concentration****(% w/w)** | **Molecular weight****(g/mol)** | **Vapor Pressure****(Pa)** | **Log Pow** | **Inhalation absorption** | **Dermal absorption** | **Oral absorption** |
| **Cypermethrin** | 0.076 | 416.3 | 6.10-7 (25°C)2.3.10-7 (20°C) | 5.45 | 100% | 37% | 57% |

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

###### Exposure of professional users

X5975CIRE is RTU product that can be applied by dipping, brushing or spraying at an application dose of 200 g product/m2 for preventive treatment and by brushing or spraying at an application dose of 300 g product/m2 for curative treatment.

A dermal and inhalation exposure to the product containing 0.076% (w/w) of cypermethrin can occur during the mixing and loading, the application and the equipment’s cleaning.

Concerning brush and spraying application, the assessment of exposure during curative treatment is presented below and it covers the preventive treatment.

**Industrial uses – automated dipping**

* Transfer of product

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 TNsG part 2 p. 142 is used with the manual pouring data as a worst case approach.

Task duration: 10 min

* Automated dipping

To predict exposure for this primary exposure scenario, the indicative exposure values from Handling Model 1 are used : Recommendation 6 of HEAd hoc WG (TNsG part 2, p. 160 and User Guidance p.26)

Task duration: 4 cycles per day

| **Scenario** | **Product** | **Inhalation Exposure****(mg/kg bw/j)** | **Dermal Exposure****(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Transfer of product 200 g/m2 – without PPE** | X5975CIRE | 2.48 x 10-6 | 4.73 x 10-3 | 4.74 x 10-3 |
| **Automated dipping 200 g/m2 – with gloves** | 3.8 x 10-5 | 7.84 x 10-3 | 7.87 x 10-3 |
| **Transfer of product + automated dipping** | 4.05 x 10-5 | 1.26 x 10-2 | 1.26 x 10-2 |

* Cleaning dipping tank

There is no generic model in the TNsG for cleaning of internal surfaces of dipping tanks. To predict exposure for this primary exposure scenario, the indicative exposure values from Handling Model 1 are used (TNsG user Guidance 2004, p.26)

Task duration: 1 cycle per day

| **Scenario** | **Product** | **Inhalation Exposure****(mg/kg bw/j)** | **Dermal Exposure****(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Cleaning dipping tank 200 g/m2 – without PPE** | X5975CIRE | 9.5 x 10-6 | 1.96 x 10-3 | 1.97 x 10-3 |

To summary, for automated dipping treatment, two operator exposure scenarios might be assessed:

1. Mixing/loading + automated dipping (chronic exposure)
2. Cleaning out of dipping tank (acute exposure)

**Professional uses**

***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[[11]](#footnote-11). 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[[12]](#footnote-12).

| **Scenario** | **Product** | **Inhalation Exposure****(mg/kg bw/j)** | **Dermal Exposure****(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Brushing 300 g/m2 – without PPE** |
| M&L | X5975CIRE | n.a |
| Product application phase | 1.03 x 10-4 | 9.08 x 10-3 | 9.19 x 10-3 |
| Brush cleaning phase | negligible | 6.97 x 10-4 | 6.97 x 10-4 |
| Application + cleaning | 1.03 x 10-4 | 9.78 x 10-3 | 9.88x 10-3 |

***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[[13]](#footnote-13).

Exposure during the cleaning of equipment has been assessed with the BEAT scenario “*Cleaning of the spray equipment*” from TNsG second version of 2007[[14]](#footnote-14).

| **Scenario** | **Product** | **Inhalation Exposure****(mg/kg bw/j)** | **Dermal Exposure****(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Spraying 300g/m2 – without PPE** |
| M&L | X5975CIRE | Included in the model |
| Product application phase | 1.81 x 10-3 | 2.09 x 10-1 | 2.11 x 10-1 |
| Cleaning of the spray equipment  | negligible | 2.03 x 10-3 | 2.03 x 10-3 |
| Appli + cleaning | 1.81 x 10-3 | 2.11 x 10-1 | 2.13 x 10-1 |
| **Spraying 300g/m2 – with PPE during application phase** |
| M&L | X5975CIRE | Included in the model |
| Product application phase(gloves and coated coverall 10%) | 1.81 x 10-3 | 1.27 x 10-2 | 1.45 x 10-2 |
| Cleaning of the spray equipment (no PPE)  | negligible | 2.03 x 10-3 | 2.03 x 10-3 |
| Appli (PPE)+ cleaning | 1.81 x 10-3 | 1.47x 10-2 | 1.65 x 10-2 |

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

X5975CIRE is RTU product that can be applied by brushing or spraying at an application dose of 200 g product/m2 for preventive treatment and 300 g product/m2 for curative treatment.

A dermal and inhalation exposure to the product containing 0.076% (w/w) of cypermethrin 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.

***Brush application[[15]](#footnote-15)***

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[[16]](#footnote-16). 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[[17]](#footnote-17).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **Product** | **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 | X5975CIRE | 1.03 x 10-4 | 9.08 x 10-3 | 9.19 x 10-3 |
| Brush cleaning phase | negligible | 6.96 x 10-4 | 6.96 x 10-4 |
| Appli + cleaning | 1.03 x 10-4 | 9.78 x 10-3 | 9.88 x 10-3 |

***Spray application***

Non-professional exposure during the mixing and loading and the application phase has been considered using the “*Consumer spraying and dusting Model 3*” taken from the TNsG second version of 2007.

Exposure during the cleaning of equipment has been assessed with the BEAT scenario “*Cleaning of the spray equipment*” from TNsG second version of 2007[[18]](#footnote-18).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **Product** | **Inhalation Exposure****(mg/kg bw/j)** | **Dermal 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 | X5975CIRE  | 6.86x 10-5 | 4.27 x 10-2 | 4.28 x 10-2 |
| Cleaning of the spray equipment  | negligible | 2.03 x 10-3 | 2.03 x 10-3 |
| Appli + cleaning | 6.86 x 10-5 | 4.48 x 10-2 | 4.48x 10-2 |

##### 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 |

It has been considered that the wood was treated with a total application dose of 300g/m2, corresponding to a curative treatment covering the 200g /m² dose for preventive treatments

***Acute secondary exposure scenario***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **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** | 1.77x 10-3 | 7.96 x 10-6 | - | 1.78 x 10-3 |
| **Infant chewing wood composites chips** | - | - | 6.24 x 10-3 | 6.24 x 10-3 |

***Chronic secondary exposure scenario***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **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** | 1.77 x 10-3 | 4.78 x 10-5 | - | 1.82 x 10-3 |
| **Inhalation of volatilizing residues indoors (Adult)** | - | 2.74 x 10-5 | - | 2.74 x 10-5 |
| **Inhalation of volatilizing residues indoors (Infant)** | - | 5.54 x 10-5 | - | 5.54 x 10-5 |
| **Inhalation of volatilizing residues indoors (Child)** | - | 3.87 x 10-5 | - | 3.87 x 10-5 |
| **Child playing on playground structure outdoors** | 6.75 x 10-4 | - | - | 6.75 x 10-4 |
| **Infant playing on weathered (playground) structure and mouthing** | 1.01 x 10-3 | - | 1.95 x 10-3 | 2.96 x 10-3 |

##### 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 summarised below.

|  |  |  |  |
| --- | --- | --- | --- |
| **Secondary scenario** | **Exposure situation** | **Routes of exposure** | **Exposed population** |
| **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** | **Professional exposure****(mg/kg bw/j)** | **Secondary exposure (inhalation of volatilized residues)****(mg/kg bw/d)** | **Total exposure****(mg/kg bw/d)** |
| Brushing (without PPE) | 9.88 x 10-3 | 2.74 x 10-5 | 9.91x 10-3 |
| Spraying(gloves + coverall 10%) | 1.65 x 10-2 | 2.74 x 10-5 | 1.65 x 10-2 |

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

|  |  |  |
| --- | --- | --- |
| **Infant playing on a wood structure + mouthing** **(mg/kg bw/d)\*** | **Secondary exposure (inhalation of volatilized residues)****(mg/kg bw/d)** | **Total exposure****(mg/kg bw/d)** |
| 2.96 x 10-3 | 5.54 x 10-5 | 3.02 x 10-3 |

#### Risk assessment for human health

##### Risk for direct exposure

###### Professional users

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

|  |  |
| --- | --- |
|  | **Cypermethrin** |
| **Long term AEL****(mg/kg bw/d)** | 0.022 |

**Industrial uses – automated dipping**

Transfer of product + automated dipping

| **Scenario** | **AEL****(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** | **% AEL** | **Risk** |
| --- | --- | --- | --- | --- |
| **Transfer of product 300 g/m2 – without PPE** | 0.022 | 4.74 x 10-3 | 21.53 % | Acceptable |
| **Automated dipping 300 g/m2 – with gloves** | 7.87 x 10-3 | 35.79 % | Acceptable |
| **Transfer of product + automated dipping** | 1.26 x 10-2 | 57.32 % | Acceptable |

Cleaning dipping tank

| **Scenario** | **AEL****(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** | **% AEL** | **Risk** |
| --- | --- | --- | --- | --- |
| **Cleaning dipping tank 300 g/m2 – without PPE** | 0.022 | 1.97 x 10-3 | 2.24 % | Acceptable |

* The risk is acceptable for industrial uses by a professional with gloves during application.

**Brush application**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL****(mg/kg pc/j)** | **Exposure****(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Brushing 300g/m2 – without PPE** |
| M&L | n.a  |
| Product application phase | 0.022 | 9.19 x 10-3 | 41.75 % | Acceptable |
| Brush cleaning phase  | 6.97 x 10-4 | 3.17 % | Acceptable |
| Appli + cleaning | 9.88x 10-3 | 44.92 % | Acceptable |

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

**Spray application**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL****(mg/kg pc/j)** | **Exposure****(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Spraying 300g/m2 – no PPE** |
| M&L | Included in the model |
| Product application phase | 0.022 | 2.11 x 10-1 | 957 % | **Unacceptable** |
| Cleaning spray equipment  | 2.03 x 10-3 | 9.25 % | Acceptable |
| Appli + cleaning | 2.13 x 10-1 | 967 % | **Unacceptable** |
| **Spraying 300g/m2 –PPE during application phase** |
| M&L | Included in the model |
| Application phase(gloves + coated coverall 10%) | 0.022 | 1.45 x 10-2 | 65.72 % | Acceptable |
| Cleaning equipement (no PPE) | 2.03 x 10-3 | 9.25 % | Acceptable |
| Appli (PPE)+ cleaning | 1.65 x 10-2 | 75% | Acceptable |

* The risk is acceptable for spray application by a professional with PPE (gloves and coated coverall 10%) during application phase.

###### Non-professional users

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

|  |  |
| --- | --- |
|  | **Cypermethrin** |
| **Short term AEL****(mg/kg bw/d)** | 0.088 |

**Brush application**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL****(mg/kg pc/j)** | **Exposure****(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Brushing 300g/m2 – without PPE** |
| M&L | n.a  |
| Product application phase | 0.088 | 9.19 x 10-3 | 10.44 % | Acceptable |
| Brush cleaning phase  | 6.96 x 10-4 | 0.79 % | Acceptable |
| Appli + cleaning | 9.88 x 10-3 | 11.23 % | Acceptable |

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

**Spray application**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL****(mg/kg pc/j)** | **Exposure****(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Spraying 300g/m2– without PPE** |
| M&L | Included in the model |
| Application phase | 0.088 | 4.28 x 10-2 | 48.65 % | Acceptable |
| Cleaning spray equipment  | 2.03 x 10-3 | 2.31 % | Acceptable |
| Appli + cleaning | 4.48x 10-2 | 51 % | Acceptable |

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

##### Risk for indirect exposure

The exposure values are compared to AELs of active substance.

|  |  |
| --- | --- |
|  | **Cypermethrin** |
| **Long term AEL (mg/kg bw/d)** | 0.022 |
| **Short term AEL (mg/kg bw/d)** | 0.088 |

**Acute Exposure**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL****(mg/kg pc/j)** | **Exposure****(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Adult amateur sanding/processing of treated wood composites** | 0,088 | 1.78 x 10-3 | 2.02 % | Acceptable |
| **Infant chewing wood composites chips** | 6.24 x 10-3 | 7.09 % | Acceptable |

* The risk is acceptable for acute exposure scenarios.

**Chronic Exposure**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL****(mg/kg pc/j)** | **Exposure****(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Adult professional sanding/processing of treated wood composites** | 0.022 | 1.82 x 10-3 | 8.27 % | Acceptable |
| **Adult: inhalation of volatilised residues, indoors** | 2.74 x 10-5 | 0.12 % | Acceptable |
| **Infant: inhalation of volatilised residues, indoors** | 5.54 x 10-5 | 0.25 % | Acceptable |
| **Child: inhalation of volatilised residues, indoors** | 3.87 x 10-5 | 0.18 % | Acceptable |
| **Child playing on playground structure outdoors** | 6.75 x 10-4 | 3.1 % | Acceptable |
| **Infant playing on playground structure outdoors and mouthing****(wood treated at 300 g/m2)** | 2.96 x 10-3 | 13.46 % | Acceptable |

* The risk is acceptable for chronic exposure scenarios.

##### Risk for combined exposure

 The exposure values are compared to AEL below:

|  |  |
| --- | --- |
|  | **Cypermethrin** |
| **Long term AEL****(mg/kg bw/d)** | 0.022 |

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario** | **Exposure****(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Adult combined expo : Brushing** | 9.91x 10-3 | 45.04 | Acceptable |
| **Adult combined expo : spraying** **(gloves +coverall 10%)** | 1.65 x 10-2 | 75.09 | Acceptable |

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario** | **Exposure****(mg/kg pc/j)** | **% AEL** | **Risk** |
| Infant combined exposure | 3.02 x 10-3 | 13.71 | Acceptable |

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

**It should be noted that the notifier claims the use of the X5975CIRE (surface treatment) and X6019CIR (injection treatment) products in association.**

**For risk assessment of the two combined products, please refer to the Product Assessment Report of X6019CIR.**

##### Risk for consumers via residues in food

##### The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses. Wood treated with X5975CIRE must contain label restrictions against use in contact with livestock, food and feed (see Annex 3.3 Residue behaviour).

### Risk assessment for animal health

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 Cypermethrin

The product X5975CIRE is intended for the preventive and curative treatment of interior woods (specifically on furniture) and for preventive treatment by industrial short-dipping. The product is for Use Class 1 (under cover, not exposed to the weather). No risk of contamination of the environment is foreseen for the indoors treatments. For industrial treatment, a risk of contamination can occur during storage even if it is recommended to store the treated wood under shelter and on impermeable hard standing.

The environmental fate and behaviour of the product X5975CIRE 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 routes of entry in the environment are soil, ground water and sediment.

For the assessment of the environmental fate and behaviour of the active substances contained in the biocidal product X5975CIRE, please refer to the chapters on fate and distribution in the environment (see Assessment Reports, cypermethrin cis:trans / 40:60 PT08, 12/07/2013) and environmental effects assessment 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 cypermethrin and its relevant metabolites is presented below.

* **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. |

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

Table 2.2‑1: Physical-chemical and fate and behaviour data on cypermethrin and relevant metabolites

|  |  |
| --- | --- |
| Data | Cypermethrin  |
| Reference | AR for cypermethrinPT08, 12/07/2013 |
| Molecular weight (g/mol) | *416.3* |
| Melting point [°C] | Onset: 41.2Peak: 47.3 |
| Boiling point [°C] | Not measurable, decomposes |
| Vapour Pressure (Pa) | *2.3\*10-7* at 20°C6\*10-7 at 25°C |
| Henry´s law constant (Pa m3 mol-1) | *2.4-\*10-2* at 20°C |
| Solubility in water at 20°C (mg/L) | *4\*10-3* at 20°C |
| Partition coefficient (log Kow) | *5.45 at 25°C*TDCVC: 2.672 (calculated)CDCVC: 2.672 (calculated) |
| Hydrolysis DT50 [d] | 12°C, pH 4: DT50 = 7 631 d12°C, pH 7: DT50 = 98.9 d12°C, pH 9: DT50 = 1.65 d |
| Photolytic / photo-oxidative degradation in water (DT50) [d] | At 20°C, pH 4:DT50 = 12.4 - 14.7 d |
| Degradation in water/sediment (DT50) [d] | In water:0.95 d at 12°CIn sediment:20.7 – 27 d at 12°CIn whole system:6.6 - *18.5 d* at 12°C3-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) |
| Degradation in soil (DT50) [d] | In aerobic conditions:*17.2* at 12°C (geometric mean)In anaerobic conditions:87.2 at 12°C |
| Soil photolysis (DT50) [d]  | 29.6(soil photolysis is considered as a minor route of degradation) |
| Photo-oxidative degradation in air (DT50) | 18 h |
| Adsorption / desorption Koc [L/kg]  | *575 000* |
| Absorption to sludge [%] | - |
| BCF in fish  | 417TDCVC: 37.25 (calculated)CDCVC: 37.25 (calculated) |
| Depuration rate constant (fish) [d-1]  | 1.58\*10-3 L/h |
| BCF in earthworms  | - |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **FR-CA box 2**Summary of the physico-chemical, environmental fate and behaviour parameters for cypermethrin used by FR-CA for the product-environmental risk assessment according to the list of endpoints validated at EU level

|  |  |  |
| --- | --- | --- |
| **Parameter / Variable** | **Unit** | **Cypermethrin** |
| Molar mass | [g.mol-1] | 416.3 |
| Vapour pressure | [Pa] | 6.00E-07 |
| Water solubility | [mg.L-1] | 4.00E-03 |
| Koc | [L.kg-1] | 575 000 |
| DT50 (soil) | [d at 12°C] | 17.2 |
| DT50 (surface water) | [d at 12°C] | 0.95 |
| DT50 (water/sediment whole system) | [d at 12°C] | 18.5 |
| K soil-water | [m3.m-3] | 1.73E+04 |
| BCF in fish | [L.kg-1] | 417 |
| BCF in earthworm | [L.kg-1] | 3380 |
| STP fraction |
| FSTP, water | [-] | 0.091 |
| FSTP, sludge | [-] | 0.909 |

 |

#### 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 Report cypermethrin cis:trans / 40:60 PT08, 12/07/2013) are summarised in the following Table:

Table 2.2‑2: Ecotoxicological data on cypermethrin for the aquatic compartment

|  |  |
| --- | --- |
| **Ecotoxicity on aquatic organisms** | **Cypermethrin *cis:trans* / 40:60** |
| LC50 fish [mg/L] | *Mortality (96 h):* 2.83\*10-3 |
| NOEC fish [mg/L] | *Fry survival, body length/weight (28 d):* **1\*10-5(1)** |
| EC50 aquatic invertebrates [mg/L] | *Immobilisation (48 h):* 4.71\*10-3 |
| NOEC aquatic invertebrates [mg/L] | *Immobilisation (21 d):* 4\*10-5 |
| ErC50 algae [mg/L] | *Growth rate (96 h):* > 33\*10-3 |
| EbC50 algae [mg/L] | *Biomass (96 h):* > 33\*10-3 |
| NOEC algae [mg/L] | *Biomass (96 h):* > 33\*10-3 |
| **PNECwater [mg/L]** | **1.10-6 (AF = 10)** |
| NOEC Sediment dwelling organism | - |
| **PNECsediment [mg/kgwwt]** | **0.125 (equilibrium partitioning method(2))** |
| EC50 Microorganisms [mg/L] | *Respiration inhibition (3 h):* **163** |
| **PNECSTP [mg/L]** | **1.63 (AF = 100)** |

(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).

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 cypermethrin 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.

##### Terrestrial compartment

A summary and evaluation of effect data for the cypermethrin 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 cypermethrin *cis:trans* / 40:60 PT08, 12/07/2013) 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** |
| --- | --- |
| EC50 earthworm [mg/kg] | *(14 d)* > 100 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** |
| LC50 plants [mg/kg] | Not expected to be phytotoxic |
| EC50 plants [mg/kg] | Not expected to be phytotoxic |
| NOEC plants [mg/kg] | Not expected to be phytotoxic |
| EC50 Mineralization [mg/kg] | - |
| NOEC Mineralization [mg/kg] | *Nitrogen mineralisation:* 52 mg/kgdwt |
| **PNECsoil**  | **0.088 mg/kgwwt (AF = 50)**(0.1 mg/kgdwt) |
| LD50 bird [mg/kg b.w.] (acute) | Not determined. |
| LC50 bird [mg/kg feed] (dietary) | *(5 d)* > 5620 mg/kg feed equivalent to> 1376 mg/kg b.w./d |
| NOEC bird [mg/kg feed] | *(21 d)* 1000 mg/kg feed equivalent to92.0 mg/kg b.w./d |
| LD50 mammal [mg/kg b.w.] (acute) | 1945 |

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

A summary and evaluation of effect data for cypermethrin with relevance to non-compartment specific effects can be found in Document II-A (see Letter of Access in Section 13 of the active substance datasets).

**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**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **FR-CA box 3**Summary of the PNEC values for cypermethrin used by FR-CA for the product-environmental risk assessment according to the list of endpoints validated at EU level

|  |  |  |
| --- | --- | --- |
| **PNEC** | **Unit** | **Cypermethrin** |
| **PNECSTP** | [mg/L] | 1.63E+00 |
| **PNECwater** | [mg/L] | 4.00E-06(1) |
| **PNECsediment** | [mg/kgwwt] | 5.00E-02(2) |
| **PNECsoil** | [mg/kgwwt] | 9.18E-02 |
| **PNECoral,bird** | [mg/kgfood] | 3.33E+01 |
| **PNECoral,mammals** | [mg/kgfood] | 3.33E+00 |

’(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.‘(2) EPM – a factor of 10 has to be added to the PEC/PNEC ratios |

##### PBT and ED Assessment

|  |
| --- |
| **FR-CA box 4**PBT and ED assessment**PBT-assessment:**According to the PT08-AR of cypermethrin (2013), cypermethrin does not fulfil the PBT nor the vPvB criteria.**ED-assessment:**According to the PT08-AR of cypermethrin (2013), no definite conclusions can be drawn concerning the endocrine disruption activity of this active substance. |

#### 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

##### Emissions to the environment

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)

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

Although it is a solvent based product, emission to air is not considered as the active substance has 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 licence to operate the treatment process”.

Since this product is only to be used in Use Class 1 (UC1), outdoor storage is very unlikely. However, in order to evaluate the risk for outdoor storage an estimation of the risk was simulated by using 50% emission during Time 1. The FLUX calculated on this basis was also used for estimating emission at Time 2. This must be considered as a very conservative estimate.

###### Emission from storage after industrial dipping

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* | 2.3\*10-6 (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* | 0.54 (cypermethrin) | [kg] | O |
| Cumulative quantity of a substance, leached due to rainfall from stored treated wood, over a longer assessment period  | *Qleachstorage,time2* | 0.098 (cypermethrin) | [kg] | O |
| Local concentration in soil at storage place at the end of the initial assessment period  | *Clocalsoil,time1* | 0.45 (cypermethrin) | [mg/kgwwt] | O |
| Local concentration in soil at storage place at the end of a longer assessment period  | *Clocalsoil,time2* | 83 (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* | 8.9\*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* | 8.9\*10-6 (cypermethrin) | [kg/d] | O |
| Local concentration in surface water over the initial assessment period  | *Clocalsurfacewater,time1* | 0.35 (cypermethrin) | [µg/L] | O |
| Local concentration in surface water over a longer assessment period  | *Clocalsurfacewater,time2* | 0.35 (cypermethrin) | [µg/L] | O |

Calculations (cypermethrin used as an example)

Vsoil = *AREAstorage \* DEPTHsoil*

Vsoil = 700 \* 0.5

Vsoil = 350 m3

As the product contains 0.07% cypermethrin and is used at 200 g/m2 the amount of active substance applied is 0.14 g/m2. So, the value used for Q\*leach, time 1 in this risk assessment is: 0.07 g/m2.

FLUX storage,dipp = Q\*leachtime1/Time1 (50% leached Time 1)

FLUX storage,dipp = 0.07 / 30

FLUX storage,dipp = 2.3\*10-6 [kg/m2/d]

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

Qleachstorage,time1 = 2.3\*10-6 \* 11 \* 700 \* 30

Qleachstorage,time1 = 0.54 [kg]

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

Clocalsoil,time1 = 0.54 \* (1 – 0.5)) / (350 \* 1700)

Clocalsoil,time1 = 0.45 [mg/kgwwt]

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

*Elocalsurfacewater,time1 =* (0.54 \* 0.5) / 30

*Elocalsurfacewater,time1 =* 0.009 [kg/d]

*Clocalsurfacewater,time1 = Elocal surface water,time1 / FLOW surface water*

*Clocalsurfacewater,time1 =* (0.009 */* 0.3) \* 11.57 (conversion factor for transforming m3/s into L/d and kg/d into µg/d)

*Clocalsurfacewater,time1 =* 0.35 [µg/L]

#### In a second tier, removal processes was taking into account as described below.

#### 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 Time 2 (5475 days) are presented below:

Table 2.2‑5: Soil-water partitioning coefficients and first order rate constants for removal from soil.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Soil-water partitioning coefficients | *K*soil-water | 17231 (cypermethrin) | [m3. m-3] | S |
| First order rate constants for removal from soil | *k* | 4.0\*10-2 (cypermethrin) | [d-1] | S |

where:

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

Table 2.2‑6: 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 cypermethrin:

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 \* 575000 \* 2500 /1000

Ksoil-water = 17231 m3/m3.

#### 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:

$Clocal soil\left(t\right)=\frac{D air}{k}-\left[\frac{D air}{k}-Clocal soil\left(t0\right)\right]∙ e^{-kt}$                    (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:

$$Clocal soil\left(t\right)=Clocal soil (t0)∙ e^{-kt}$$

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:

$$Clocal soil in service=\frac{C soil(T) }{kT}\left⌈1-e^{-kT}\right⌉$$

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

Clocalsoil,total, rem (t)= Clocalsoil,brush rem + $Clocal soil in service (t)$

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 2.2‑7: Concentration in soil and pore-water, from storage after industrial dipping 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,total, time1 | 0.26 (cypermethrin) | [mg.kgwwt-1] | O |
| Local concentration in soil at storage place at the end of a longer assessment period | Clocalsoil total, time2 | 0.37 (cypermethrin) | [mg.kgwwt-1] | O |
| Average concentrations in pore water over the initial assessment period (30d) | Clocalpore,time1 | 0.03 (cypermethrin) | [µg.L-1] | O |
| Average concentration in pore water over a longerduration (5475d) | Clocalpore,time2 | 8.16 (cypermethrin) | [µg.L-1] | O |

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 = 0.26 \* 1700 / 17231

Clocalpore,time1 = 0.03 µg/L

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **FR-CA box 6****Estimation of emissions – Industrial Dipping, storage**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, except for the input “content of active substance in the product”. This value must be expressed in technical active substance (0.08 % w/w). 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.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 and eq.3.3 for porewater of the PT08 ESD.As the product contains 0.08% cypermethrin and is used at 200 g.m-2, the amount of active substance applied is 0.16 g.m-2. So, the value used for Q\*leach, time 1 (50% leached) in the risk assessment is = 0.08 g.m -2 (0.16 g.m-2/2).

|  |  |  |
| --- | --- | --- |
| Cypermethrin | Value | Unit |
| FLUX storage, dipp | 2.67E-06 | [kg.m-2.d-1] |
| *Q leach storage time 1* | 6.16E-01 | [kg] |
| *Q leach storage time 2* | 1.50E+02 | [kg] |
| *Clocal soil, steady-state* | 4.28E-01 | [mg.kgwwt-1] |
| *C local porewater, steady-state* | 4.22E-05 | [mg.L-1] |
| *E local surface water,time1* | 1.03E-02 | [kg.d-1] |
| *C local surface water,time1 (before adsorption on suspended matter)* | 3.96E-01 | [µg.L-1] |
| *C local surface water,time1 (after adsorption on suspended matter)* | 2.13E-01 | [µg.L-1] |
| *C local sediment,time1* | 2.66 | [mg.kgwwt-1] |

 |

##### Local PECs

In the following tables the PEC values with and without removal are listed for each active ingredient.

###### PEC industrial application, dipping

* PEC in surface water and sediment

Table 2.2‑8: PEC in surface water, industrial application, storage.

|  | **Cypermethrin** |
| --- | --- |
| **Dipping (surface water)** |  |
| PEC in surface water over the initial assessment period [µg.L-1] | 0.35 |
| PEC in surface water over a longer assessment period [µg.L-1] | 0.35 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **FR-CA box 7**PEC in surface water – Industrial Dipping, storage

|  |  |  |
| --- | --- | --- |
| Cypermethrin | Value | Unit |
| *PECC local surface water,time1 (before adsorption on suspended matter)* | 3.96E-01 | [µg.L-1] |
| *PEC local surface water,time1 (after adsorption on suspended matter)* | 2.13E-01 | [µg.L-1] |
| *PEC local sediment,time1* | 2.66 | [mg.kgwwt-1] |

 |

* PEC in soil and pore water

Table 2.2‑9: PEC in soil and pore water, industrial application, storage.

|  | **Cypermethrin** |
| --- | --- |
| **Dipping (soil)** |
| PEC in soil at storage place at the end of the initial assessment period [mg.kgwwt-1] | 0.45 |
| PEC in soil at storage place at the end of a longer assessment period [mg.kgwwt-1] | 83 |
|  |
| PEC in soil at storage place at the end of the initial assessment period with removal [mg.kgwwt-1] | 0.26 |
| PEC in soil at storage place at the end of a longer assessment period with removal [mg.kgwwt-1] | 0.37 |
| **Dipping (pore water)** |
| PEC local with removal Time 1 (30 days) [µg/L] | 0.03 |
| PEC local with removal Time 2 (1825 days) [µg/L] | 8.16 |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **FR-CA box 8****PEC in soil and pore water, industrial application, storage**

|  |  |  |
| --- | --- | --- |
| Cypermethrin | Value | Unit |
| PEC local soil, stead-state | 4.28E-01 | [mg.kgwwt-1] |
| *PEC local porewater, steady-state* | 4.22E-02 | [µg.L-1] |

 |

###### PEC in air

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

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.

|  |
| --- |
| **FR-CA box 9****PEC in air – Industrial Dipping, storage**FR-CA agrees with the registrant’s approach. |

###### Non-compartmental-specific exposure relevant to the food chain (secondary poisoning)

Cypermethrin:

Cypermethrin is characterized by Log Kow values ranging from 5.3-5.6, which indicate a potential for bioaccumulation. However, cypermethrin is not classified as toxic or harmful to mammalian and, according to the leaching results, leaching from treated wood is very limited resulting in very low PECs in surface water and soil.

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

|  |
| --- |
| **FR-CA box 10****Secondary poisoning – Industrial Dipping, storage**FR-CA agrees with the registrant’s approach. |

###### Relevant metabolites

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.

|  |
| --- |
| **FR-CA box 11****Metabolites – Industrial Dipping, storage**FR-CA agrees with the registrant’s approach. |

#### 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 Agriphar).

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):

|  |  |
| --- | --- |
|  | Cypermethrin |
| PNECwater [µg/L] | 0.001 |
| PNECsediment [mg/kgwwt] | 0.125 |
| PNECSTP [mg/L] | 1.63 |
| PNECsoil [mg/kgwwt] | 0.088 |
| Groundwater threshold value[µg/L] | 0.1 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **FR-CA box 12**Summary of the PNEC values for cypermethrin

|  |  |  |
| --- | --- | --- |
| **PNEC** | **Unit** | **Cypermethrin** |
| **PNEC STP** | [mg/L] | 1.63E+00 |
| **PNEC water** | [mg/L] | 4.00E-06(1) |
| **PNEC sediment** | [mg/kgwwt] | 5.00E-02 |
| **PNEC soil** | [mg/kgwwt] | 9.18E-02 |
| **PNEC oral, bird** | [mg/kg food] | 3.33E+01 |
| **PNEC oral, mammals** | [mg/kg food] | 3.33E+00 |

’(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 2.2‑10: PEC/PNEC ratios for the aquatic compartment, industrial application, storage

|  | **Cypermethrin** |
| --- | --- |
| **Dipping (surface water)** |
| PEC/PNEC in surface water over the initial assessment period [µg.L-1] | 347 |
| PEC/PNEC in surface water over a longer assessment period [µg.L-1] | 347 |

In the storage scenario following industrial application, risk was identified in surface water for cypermethrin.

**- Metabolites**

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 13**PEC/PNEC ratios for the surface water – Industrial Dipping, storage

|  |  |
| --- | --- |
|  | Cypermethrin |
| PEC/PNEC surface water, storage | 53.2 |
| PEC/PNEC sediment, storage\* | 532 |

\* Considering the strong adsorption potential of cypermethrin and as the PNEC sediment value was defined by EPM, a factor of 10 is added to the PEC/PNEC ratio.FR-CA agrees with the registrant’s conclusion. In the storage scenario following industrial application, risk was identified in surface water and sediment for cypermethrin. |

##### Terrestrial compartment

**- Substances**

**Table 2.2-1: PEC/PNEC ratios for the soil compartment, industrial application, storage**

|  | **Total PEC/PNEC** |
| --- | --- |
| **Dipping (soil)** |  |
| PEC/PNEC in soil at storage place at the end of the initial assessment period [mg.kgwwt-1] | 5.15 |
| PEC/PNEC in soil at storage place at the end of a longer assessment period [mg.kgwwt-1] | 939 |
|  |  |
| PEC/PNEC in soil at storage place at the end of the initial assessment period with removal [mg.kgwwt-1] | 2.93 |
| PEC/PNEC in soil at storage place at the end of a longer assessment period with removal [mg.kgwwt-1] | 4.17 |

In the storage scenario following industrial application, risk was identified in soil for cypermethrin, also when removal processes were taking into account.

**- Metabolites**

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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **FR-CA box 14**PEC/PNEC ratios for the soil compartment – Industrial Dipping, storage

|  |  |
| --- | --- |
|  | Cypermethrin |
| PEC/PNEC local soil, stead-state, storage | 4.66 |

FR-CA agrees with the registrant’s conclusion. In the storage scenario following industrial application, risk was identified in soil for cypermethrin. |

##### Groundwater compartment

As an indication for potential groundwater concentrations, the concentrations in pore water have been calculated.

For cypermethrin, PECporewater values are above the limit for drinking water (0.1 μg/L) for the storage scenario when taking removal processes into account.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **FR-CA box 15**

|  |  |  |  |
| --- | --- | --- | --- |
| Cypermethrin | Value | Unit | Origin |
| *PEC local porewater, steady-state* | 4.22E-02 | [µg.L-1] | O |

For cypermethrin, PEC porewater value is below the limit for drinking water (0.1 μg/L) for the storage scenario |

##### Atmospheric compartment

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 X5975CIRE according to the label recommendations.

|  |
| --- |
| **FR-CA box 16****Atmospheric compartment**FR-CA agrees with the registrant’s conclusions. |

##### Non-compartmental specific effects relevant to the food chain (secondary poisoning)

Cypermethrin is not classified as toxic or harmful to mammalian and, according to the leaching results on similar formulation, leaching from treated wood is very limited resulting in very low PECs in surface water and soil.

Therefore, based on the above information, no risk of secondary poisoning is foreseen when using the product as recommended on the label.

|  |
| --- |
| **FR-CA box 17****Secondary poisoning**FR-CA agrees with the registrant’s conclusions. |

##### Conclusion - Remarks

For the industrial applications, risk was identified for both the aquatic and terrestrial compartments for cypermethrin. However, this assessment is built on a very conservative estimate assuming 50% emission during Time 1. Even using this high overestimation, PEC/PNEC ratios for the soil compartment was below 10 when taking removal processes into account.

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.

In order to avoid any possible risk to the environment the following will be stated on the label for industrial use (short-dipping): “Storage must only take place on sealed places or under cover to prevent direct release to soil”.

No risk for the environment is foreseen when the product X5975CIRE is used by professionals and non-professionals for preventive and curative indoor treatments, mainly on furniture (Use Class 1).

Therefore, based on the above calculations and arguments, this product, used as indicated, does not lead to unnecessary risk to the environment.

|  |
| --- |
| **FR-CA box 18****Conclusion**FR-CA agrees with the registrant’s conclusions.In order to avoid any possible risk to the environment the following will be stated on the label for industrial use (short-dipping):* 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.
 |

|  |
| --- |
| **FR-CA box 19****Classification and labelling**FR-CA agrees with the classification and labelling proposed by the registrant. |

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

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

# Annexes

List of studies for the biocidal product family

| **Section No** | **Reference No** | **Author** | **Year** | **Title** | **Owner of data** | **Letter of Access** | **Data protection claimed** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 2.2.2 | 402/14/1092F/abc-e | Raphalen E | 2015 | Physico-chemical properties, technical characteristics and chemical analyses of the biocidal product X5975CIRE before and after an accelerated storage procedure for 14 days at 54 ± 2oC, in compliance with CIPAC MT 46.3 method (Handbook J, 2000) | DYRUP SAS - PPG | **Yes**  | **No** | **Yes**  | **No** |
| 2.2.2 | 150313/PaPV93.9 | Simon F. | 2015 | Odour of X5975CIRE | DYRUP SAS - PPG | **[ ]**  | **[x]**  | **[x]**  | **[ ]**  |
| 2.2.22.2.3 | 402/14/1092F/defgh-e | Raphalen E | 2015 | Physical, chemical and technical characteristics of the biocidal product X5975CIRE | DYRUP SAS - PPG | **[ ]**  | **[x]**  | **[x]**  | **[ ]**  |
| 2.2.2 | 402/13/1140F/1/c-e | Legay S. | 2016 | Storage stability during 2 years at ambient temperature according to Technical Monograph No.17 (CropLife) on the wood preservatives X 5975 CIRE (Liquid) and X 6019 CIR (Aerosol) | DYRUP SAS - PPG | **[ ]**  | **[x]**  | **[x]**  | **[ ]**  |
| 2.2.3 | 402/14/1092F/i-e | Raphalen E., Legay S. | 2015 | Differential Scanning Calorimetry (DSC) measurement on the test item X5975CIRE | DYRUP SAS - PPG | **[ ]**  | **[x]**  | **[x]**  | **[ ]**  |
| 2.2.3 | 15/03 | Detrimont H., Ambrosi D. | 2015 | Literature review on oxidising properties, auto-flammability of the ingredients of the product X6019CIR | DYRUP SAS - PPG | **[ ]**  | **[x]**  | **[x]**  | **[ ]**  |
| 2.2.4 | 402/13/1140F/ab-e | Raphalen E. | 2013 | Physico-chemical tests on a ready-to-use solvent based product (X5975CIRE): Validation of analytical method and chemical analysis of active ingredient declared in the test item, Chemical analysis of active ingredient in a wood preservative | DYRUP SAS - PPG | **[ ]**  | **[x]**  | **[x]**  | **[ ]**  |
| 2.2.5.5 | 401/14/136F/e-e | Ansard D. andPaulmier I. | 2015 | X6122B1. Preventive action against termites according to NFEN 118 with NF EN 73 |  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  |
| 2.2.5.5 | 32/14/9803/01 | Schumacher P.and Fennert E.-M | 2015 | X6122B1. Determination of the preventive action againstrecently hatched larvae of Hylotrupes bajulus (L.) according to EN 46-1 (2009) after evaporative ageing procedure accordingto EN 73 (1988). |  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  |
| 2.2.5.5 | 401/14/136F/a-b-e | Brunet C. andPaulmier I. | 2017 | X6122B1. Preventive effectiveness against Anobiumpunctatum according to NF EN 49-1 with ageing tests |  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  |
| 2.2.5.5 | 401/14/136F/c/eversion 2 | Brunet C. andPaulmier I. | 2015 | X6122B1. Determination of the protective effectivenessagaisnt Lyctus brunneus according to NF EN 20-1. |  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  |
| 2.2.5.5 | 401/16/039F/c-e | Brunet C. andPaulmier I. | 2017 | X6122B1. Curative action against Hylotrupes bajulusaccording to NF EN 1390. |  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  |
| 2.2.5.5 | 401/14/136F/e/eversion 2 | Brunet C. andPaulmier I. | 2015 | X6122B1. Determination of eradicant action against larvae ofAnobium punctatum (De Geer)-laboratory method accordingto NF EN 48. |  | **[ ]**  | **[ ]**  | **[ ]**  | **[ ]**  |

Output tables from exposure assessment tools

Toxicology and metabolism –active substance

CYPERMETHRIN

Threshold Limits and other Values for Human Health Risk Assessment

Date: xx.xx.xxxx

| **Summary**  |
| --- |
|  | Value | Study | SF |
| AEL long-term | 0.022 | 2 years rat | 100 |
| AEL medium-term | 0.055 | 90 day dog | 100 |
| AEL acuteADIARfD  | 0.088 | Neurotoxicity rat | 100 |
|  |

|  |  |
| --- | --- |
| Inhalative absorption | 100% |
| Oral absorption | 57% (homme) 44% (animal) |
| Dermal absorption | 37% |

| **Classification**  |
| --- |
|  |  |
| with regard to toxicological data(according to the criteria in Reg. 1272/2008) – ATP0 | Acute Tox 4 – H302Acute Tox 4 – H332STOT SE 3 – H335 |

Toxicology – biocidal product

X5975CIRE

Date: xx.xx.xxxx

|  |
| --- |
| General information |
| Formulation Type  | RTU |
| Active substance(s) (incl. content) | Cypermethrine 0.07% |
| Category |  |

| 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. |  |  |  |
|  |  |  |  |  |
| Toxicological data on non-active substance(s)(not tested with the preparation) | 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 | GHS08 |
|  | Danger  |
|  | STOT SE 3 – H336 : May cause drowsiness or dizzinessAsp. Tox. 1 – H304 : May be fatal if swallowed and enters airwaysEUH066: Repeated exposure may cause skin dryness or cracking |

 Safety for professional operators

X5975 CIRE

Date: xx.xx.xxxx

Exposure assessment for professional users

Please refer to the Excel data sheet “Expo Pro – X5975 CIRE” attached to the PAR.

This file contains several excel data sheet for each exposure scenario, as follows:

* Short dipping treatment: Excel data sheet “Expo IR – Short dipping treatment”;
* Brush application: Excel data sheet “Expo IR – Brushing”;
* Spray application: Excel data sheet “Expo IR – Spraying”;

Risk assessment

Please see the tables presented in the document section 2.7.3.1.1



Safety for non-professional operators and the general public

X5975 CIRE

Date:xx.xx.xxxx

Exposure assessment for non-professional

Please refer to the Excel data sheet “Expo Non Pro – X5975 CIRE” attached to the PAR.

This file contains several excel data sheet for each exposure scenario, as follows:

* Brush application: Excel data sheet “Expo IR – Brushing”;
* Spray application: Excel data sheet “Expo IR – Spraying”;

Risk assessment for Non-professionals

Please see the tables presented in the document section 2.7.2.2.2;

Exposure assessment for General public (secondary exposure)

Please refer to the Excel data sheet “Expo Pro – PPG” attached to the PAR.

This file contains 2 excel data sheet for secondary exposure scenario, as follows:

* Acute exposure scenario: Excel data sheet “Expo IIR - Acute”;
* Chronic exposure scenario: Excel data sheet “Expo IIR - Chronic”.

Risk assessment for General public (secondary exposure)

Please see the tables presented in the document section 2.7.3.2.



Residue behaviour

cypermethrin

Date: 15/09/2016

**Intended Use (critical application):** preventive and curative treatment of interior woods. These preventive and curative treatments are done by professionals and non-professionals by brush application and spray application. The product can also be used by industrial users to treat wood by short dipping.

**Active substances:** cypermethrin

**Formulation of biocidal product:** AL

**Place of treatment:** indoor

**Target organisms:** wood boring insects, subterranean termites

**Maximum residue limits or equivalent**

|  |  |  |  |
| --- | --- | --- | --- |
| **MRLs or other relevant reference values** | **Reference**  | **Relevant commodities** | **Value** |
| MRL | EU Reg.407/2009 | All ruminant commodities | Cf. EU Reg. 37/2010 |
| EU Reg.396/2005 | All commodities | Cf. Reg. (EU) 2017/626 |

PPP: plant protection product

VMP: veterinary medicinal product

The intended use descriptions of the cypermethrin -containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The product is to be used for preventive and curative treatment of interior woods that do not come in direct contact with food, feedstuff or livestock.

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

No further data are required concerning the residue behaviour.

Efficacy of the active substance from its use in the biocidal product (\*)

| Test substance | Test organisms | Test system / Concentrations applied / exposure time | Test conditions | Test results: effects, mode of action, resistance | Reference |
| --- | --- | --- | --- | --- | --- |
| X6122B1X6122B1 without fungicidal ASX6122B1 without cypermethrin | *Reticulitermes flavipes* | EN118 –like without ageing test | The ready-to-use products are applied by brushing on sapwood test blocks (*Pinus sylvaticus*).The quantity really applied on each test block varied between 198 g/m² and 202 g/m² (mean 199.8 g/m²) for X6122B1; between 199 g/m² and 230 g/m² (mean 205.6 g/m²) for X6122B1 without fungicidal AS; between 198 g/m² and 212 g/m² (mean 302 g/m²) for X6122B1 without cypermethrin.worker, nymph and soldier termites were used for each test block.6 replicates for the treated block and 3 replicates for the control are performed.The investigated effects are the mortality of the insects.Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack). - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (64.7 %) and the control test blocks are ranked 4.**Treated blocks for X6122B1 and X6122B1 without fungicial AS are ranked between 1 and 2 (only 1 block ranked 2) at the end of the study which demonstrates the efficacy of both formulations.****The product X6122B1 without cypermethrin showed no efficacy against termites, therefore fungicidal AS present in the product X6122B1 has no insecticidal efficacy.** | Lafragrette D., 2015RetD AD 001.S01IC2 |
| X6122B1 | *Reticulitermes flavipes* | EN118 + EN 73 | The ready to use product X6122B1is 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 198.4 g/m² and 200.6 g/m² (mean 199.5 g/m²).worker, nymph and soldier termites were used for each test block.6 replicates for the treated block and 3 replicates for the control are performed.The investigated effects are the mortality of the insects.Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack). - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (65.3 %) and the control test blocks are ranked 4.**All the treated blocks are ranked between 1 and 2 (only 1 block ranked 2) at the end of the study which demonstrates the efficacy of the product X6122B1 (and X5975CIRE by read-across) at the application rate of 199.5 g of product / m² of wood.** | Ansard D. and Paulmier I., 2016401/14/136F/e-eIC1 |
| X6122B1 | House longhorn beetle: *Hylotrupes bajulus* (L.)  | EN 46 + 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 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 and 3 replicates for the solvent control are performed.The effect investigated is the mortality of insect’s larvae.The method for recording / scoring effects is the recovery of the insects and count of dead and alive larvae and count of dead larvae having tunneled or not. - Intervals of examination: one time, after 1 month exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 70 % (83%).On the treated test block, 100 % of the larvae were dead and had not tunnelled.**This study demonstrated the efficacy of the product X6122B1(and X5975CIRE by read-across) at 198.5 g of product / m² of wood against *Hylotrupes bajulus* larvae** | Schumacher P. and Fennert E-M., 201532/14/9803/01IC1 |
| X6122B1 | Common furniture beetle:*Anobium punctatum* | EN 49 + EN 73(evaporation) | The ready to use product X6122B1 is applied by brushing on hardwood test blocks (*Quercus petrae*) 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 % (172) alive larvae in total are found in the control and as alive larvae are found in each control block.In the treated blocks 100 % of larvae are dead at the end of the test.**This study demonstrated the efficacy of the product X6122B1(and X5975CIRE by read-across) at 200.3 g of product / m² of wood against *Anobium punctatum*** | Brunet C. and Paulmier I., 2017401/14/136F/a and b-eIC2 |
| X6122B1 | 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).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 treated blocks, 100 % of mortality is observed.**This study demonstrated the efficacy of the product X6122B1 (and X5975CIRE by read-across) at 197.1 g of product/m² of wood against *Lyctus bruneus.*** | Brunet C. and Paulmier I., 2016401/14/137F/c/eIC2 |
| X6122B1 | House longhorn beetle: *Hylotrupes bajulus (L.)* | EN 1390 | 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 299.3 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 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 %) and the contact time of 24 weeks validated the low action efficacy of the product X6122B1 (and X5975CIRE by read-across) against *Hylotrupes bajulus* larvae, at the application rate of 300 ml of product / m² of wood (240 g of product / m² wood).** | Brunet C. and Paulmier I., 2017401/16/039F/c-eIC2 |
| X6089CR | 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 X6122B1 (and X5975CIRE by read-across), at the application rate of 300 g of product / m² of wood.** | Brunet C. and Paulmier I., 2016401/14/136F/e/eIC1 |

*(\*) fill in one table for each MG/PT and/or field of use envisage*

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-1)
2. Wood preservatives – Determination of preventive action against *Reticulitermes* species (European termites) (Laboratory method) [↑](#footnote-ref-2)
3. Wood preservatives – Accelerated ageing tests of treated wood prior biological testing – Evaporative ageing procedure. [↑](#footnote-ref-3)
4. Wood preservatives – Accelerated ageing tests of treated wood prior biological testing – Evaporative ageing procedure. [↑](#footnote-ref-4)
5. Wood preservatives – Determination of the preventive action against *Hylotrupes bajulus (Linnaeus)* – Part 1:Larvicidal effect (Laboratory method). [↑](#footnote-ref-5)
6. Wood preservatives – Determination of the protective effectiveness against *Anobium punctatum (De geer)* – Part 1: Application by surface treatment (Laboratory method). [↑](#footnote-ref-6)
7. Wood preservatives – Determination of the protective effectiveness against *Lyctus brunneus (Stephens)* – Part 1: Application by surface treatment (laboratory method). [↑](#footnote-ref-7)
8. Wood preservatives – Determination of the eradicant action against *Hylotrupes bajulus (Linnaeus)* [↑](#footnote-ref-8)
9. Wood preservatives – Determination of the eradicant action against *larvae of Anobium punctatum (De geer) (Laboratory method)* [↑](#footnote-ref-9)
10. Performance criteria for curative wood preservatives as determined by biological tests (2004) [↑](#footnote-ref-10)
11. “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-11)
12. 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-12)
13. “Methods and models to assess exposureto biocidal product in different product types” version 2, June 2016. [↑](#footnote-ref-13)
14. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-14)
15. Risk assessment was performed at 240 min considering that this duration covers professional and non professional users. However, duration of 155 min (as recommended in user guidance of TNsG) could be used to assess the risk for non professional. [↑](#footnote-ref-15)
16. “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-16)
17. 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-17)
18. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-18)