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)



[X6019 CIR]

Product type [8]

[Cypermethrin as included in the Union list of approved active substances]

Case Number in R4BP: [BC-EK017441-53]

Evaluating Competent Authority: [FR]

Date: [26/04/2018]

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# CONCLUSION

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

The formulation X6019 CIR is an Aerosol dispenser (AE) 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 classified H222. The internal pressure is 15 bars. It has a self-ignition temperature superior of 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 metal can (commercial packaging). Its technical characteristics are acceptable for an AE formulation.

The formulation is classified H304, H229 and H222.

H304: May be fatal if swallowed and enters airways

H229: Pressurized container: may burst if heated

H222: Extremely flammable aerosol

An analytical method for the determination of active substance in the formulation X6019CIR 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 X6019 CIR, has shown a sufficient efficacy for

* For curative treatment when used by injection for wood furniture against wood boring beetles (*Hylotrupes bajulus*), at 180 g of product/m².

**Conclusion on risk assessment for human health**

Risks related to the use of X6019 CIR by professionals and non-professionals are considered acceptable for all the intended uses mentioned above.

- The risk is acceptable for injecting application by a professional or a non-professional without PPE.

- The risk is acceptable for combination of spray application and injection by a professional with PPE.

- The risk is acceptable for combination of spray application and injection by a non-professional without PPE.

- The risk is acceptable for combination of brush application and injection by a professional or a non-professional, without PPE.

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

**Conclusion on risk for consumers via residues**

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses. Wood treated with X6019 CIR must contain label restrictions against use in contact with livestock, food and feed.

**Conclusion on risk assessment for the environment**

No emissions in the environmental compartments are predicted when using the product X6019 CIR for curative indoor treatments and then no risk assessment for the environment is deemed necessary.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### **Identifier of the product**

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| X6019 CIR  Xylophène Meubles & Objets Anciens Aérosol  Xylophène Meuble Aérosol  Xylophène Meubles, Objets et Parquets Aérosol  Bricorama Traitement Spécial Meubles Aérosol  Boisilor Traitement Meubles Aérosol  Aérosol Traitement Meubles Nuance  Axton Traitement Meubles et Parquets (Spray) | France |
| Axton Trattamento Old Wood Interno (Spray) | Italy |
| Xylophène S.O.R. 2 SPRAY,  Axton Tratamiento Madera Deteriorada Interior (Spray) | Spain |
| Xylophène S.O.R. 2 SPRAY  Tratamento Moveis Aerossol Nuance  Axton Tratamento Madeira Deteriorada Interior (Spray) | Portugal |
| Xylophène Spécial Meubles  ΘΕΡΑΠΕΙΑ ΓΙΑ ΞΥΛΙΝΑ ΔΑΠΕΔΑ ΚΑΙ ΕΠΙΠΛΑ (Spray) | Greece |

#### **Authorisation holder**

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | PPG AC – France SA |
| **Address** | 10 rue Henri Sainte Claire Deville  92565 Rueil-Malmaison  France |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### **Manufacturer of the product**

|  |  |
| --- | --- |
| **Name of manufacturer** | PPG AC – France SA |
| **Address of manufacturer** | Immeuble Union Square  1 rue de l'Union  CS 10055  92565 Rueil Malmaison cedex  France |
| **Location of manufacturing sites** | ZI Montplaisir, 25 rue Jean le Rond d'Alembert  81000 Albi  France |

#### **Manufacturers of the active substance**

|  |  |
| --- | --- |
| **Active substance** | Cypermethrin |
| **Name of manufacturer** | Arysta LifeScience Benelux SPRL |
| **Address of manufacturer** | 26 rue de Renory  14102 Ougrée  Belgium |
| **Location of manufacturing sites** | Dr Reddys Laboratories Limited\*  Steanard Lane, Mirfield,  West Yorkshire,  WF14 8QB, UK |
| 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

#### **Identity of the active substance**

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

#### **Candidate(s) for substitution**

The active substance cypermethrin contained in the biocidal product X6019 CIR 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 (%)** |
| --- | --- | --- | --- | --- | --- |
| Cyperméthrine | (RS)-α-cyano-3phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52315-07-8 | 257-842-9 | 0.05 |
| Hydrocarbons, C9-C11, nalkanes,  isoalkanes,  cyclics, < 2% aromatics | Hydrocarbons, C9-C11, nalkanes,  isoalkanes, cyclics,  < 2% aromatics | Non-active substance | - | 919-857-5 | >65 |

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

Please see the confidential annex for further details.

#### **Type of formulation**

|  |
| --- |
| Aerosol dispenser (AE) |

### Hazard and precautionary statements

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

|  |  |
| --- | --- |
| **Classification** | |
| Hazard category | Flam. Aerosol 1  Asp. Tox. 1  STOT SE 3  Aquatic Acute 1  Aquatic Chronic 1 |
| Hazard statement | H222 – Extremely flammable aerosol.  H229 – Pressurized container, may burst when heated.  H304 – May be fatal if swallowed and enters airways  H336 – May cause drowsiness or dizziness  H400 – Very toxic to aquatic life  H410 – Very toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Danger  Résultat de recherche d'images pour "GHS02"ghs07 Résultat de recherche d'images pour "GHS09" |
| Hazard statements | H222 – Extremely flammable aerosol.  H229 – Pressurized container, may burst when heated.  H336 – May cause drowsiness or dizziness.  H410 – Very toxic to aquatic life with long lasting effects |
| 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.  P211: Do not spray on an open flame or other ignition source.  P251: Pressurized container: Do not pierce or burn, even after use.  P261: Avoid breathing dust/fume/gas/mist/vapours/spray  P271: Use only outdoors or in a well-ventilated area  P273: Avoid release to the environment  P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing  P312: Call a POISON CENTER/doctor/…/if you feel unwell  P391: Collect spillage  P403 + P233: Store in a well-ventilated place. Keep container tightly closed.  P410 + P412: Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F. |
|  | |
| Note | EUH066: Repeated exposure may cause skin dryness or cracking |

### Authorised use(s)

#### **Use description**

Table 1. Use # 1 – Curative treatment

|  |  |
| --- | --- |
| **Product Type** | 8 |
| **Where relevant, an exact description of the authorised use** | Wood preservative |
| **Target organism (including development stage)** | Wood boring insects: *Hylotrupes bajulus* |
| **Field of use** | Curative treatment / wood in service  Indoor |
| **Application method(s)** | Injection |
| **Application rate(s) and frequency** | 180 g product/m² |
| **Category(ies) of users** | Professional and Non professional |
| **Pack sizes and packaging material** | 0.4 L tinplate can (without intern varnish layer) |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

### 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. * For professionals, in case of complementary application with superficial treatment, wear gloves. |

#### **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

|  |
| --- |
| - |

### 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)** |
| Aerosol Can | 0.4 L | Tinplate | PP cap | Professional and non-professional | Yes |

### Documentation

#### **Data submitted in relation to product application**

**Identity, physicochemical and analytical method data**

Physico-chemical properties studies and analytical methods on the biocidal product X6019CIR were provided by PPG.

**Efficacy data**

Following study has been conducted with the product X6019CIR:

- Laboratory efficacy study conducted according to the methodology of the standard EN 1390, with the product X6019CIR;

Following studies have been conducted with the product X6122B1 (bridging with the product X5975CIRE, equivalent to X6019CIR without propellant):

- Laboratory efficacy study conducted according to the standard EN 118, with the product X6122B1 with or without fungicidal active substances, after ageing following EN 73 (evaporating procedure) against *Reticulitermes flavipes*;

- Laboratory efficacy study conducted according to the standard EN 118, with the product X6122B1, after ageing following EN 73 (evaporating procedure) against *Reticulitermes flavipes*;

- Laboratory efficacy study conducted according to the standard EN 46-1 , with the product X6122B1, after ageing following EN 73 (evaporating procedure);

- Laboratory efficacy study conducted according to the standard EN 49-1 , with the product X6122B1, after ageing following EN 73 (evaporating procedure);

- Laboratory efficacy study conducted according to the standard EN 20-1 , with the product X6122B1, after ageing following EN 73 (evaporating procedure);

- Laboratory efficacy study conducted according to the standard EN 1390, with the product X6122B1;

- Laboratory efficacy study conducted according to the standard EN 48, with the product X6122B1;

**Toxicology 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 X5975CIRE equivalent to X6019CIR without propellant:

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

**Residues data**

No specific residue data were submitted in the context of this dossier. The product X6019CIR is intended to be used as curative treatment for interior solid woods. This curative treatment is done by professionals and non-professionals by injection. 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 study was provided.

#### **Access to documentation**

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

## Assessment of the biocidal product

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

Table 1. Intended use # 1 – Curative treatment

|  |  |
| --- | --- |
| Product Type(s) | 8 |
| Where relevant, an exact description of the authorised use | Wood preservative |
| Target organism (including development stage) | Wood boring insects (house longhorn beetle, common furniture beetle and powder post beetles)  Subterranean termites (genus *Reticulitermes*) |
| Field of use | Curative treatment / wood in service  Indoor |
| Application method(s) | Injection |
| Application rate(s) and frequency | 180 g product/m² |
| Category(ies) of user(s) | Professional and Non professional |
| Pack sizes and packaging material | 0.4 L tinplate bottle (without intern varnish layer) |

### Physical, chemical and technical properties

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 0.10% of premix, which corresponds to 0.05% of pure cypermethrin (cis:trans/ 40:60) and 0.054% of technical cypermethrin.

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

Formulation type: Aerosol dispenser (AE)

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

The product X6019 CIR is packaged in 0.4 L tinplate can, fitted with a spraying system and hermetically closed with a PP 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 | **X6019 CIR** **Lot/batch No.: 13052** | **transparent liquid** | **Acceptable** | Legay S. 2013  Report N° 13/1140F/c-e |
| Colour at 20 °C and 101.3 kPa | **colourless** |
| Odour at 20 °C and 101.3 kPa | **beeswax-like odour** | Simon F., 2015  Report N° 150313/PaPV93.10 |
| Acidity / alkalinity | pH: CIPAC MT 75.3  Acidity: CIPAC MT 31.2.3 |  | **Not required as X6019CIR is an aerosol non-aqueous ready-to-use product.** | **Acceptable** |  |
| Relative density / bulk density | CIPAC MT 3.2.1 | **X5975 CIRE** **Lot/batch No.: 1418200053** | **D20 = 0.787** | **Acceptable**  The test was performed on the formulation X5975 CIRE but it considered acceptable because not relevant for an AE formulation. | Raphalen E. 2015  Report N° **402/14/1092F/defgh-e** |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  (14 days at 54 ± 2ºC in commercial packaging) | **X5975 CIRE** **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 degradation  541.43g | Metal can, no sign of corrosion or degradation  514.68g (-4.98%) | | **Acceptable**  The test was performed on the formulation X5975 CIRE but it considered acceptable because interim long term storage is available for X6019 CIR Moreover, X6019 CIR is an aerosol and could be exploded at 54°C. | Raphalen E. 2015  Report 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) | **X6019 CIR** **Lot/batch No.: 13052** | The long term storage study at ambient temperature during 24 months, with the product X6019 CIR in its commercial packaging (metal can) is detailed below   |  |  |  |  | | --- | --- | --- | --- | | **Test** | **Initial** | **After 12 months storage at 20°C in metal can** | **After 24 months storage at 20°C in metal 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)** | 0.059 | 0.054 (-8.5%) | 0.054 (-8.5%) | | **Appearance and weight of test packaging** | 0.4L metal can, no sign of corrosion or degradation | No sign of corrosion or degradation  Loss of weight : 0.29% | No sign of corrosion or degradation  Loss of weight : 0.5% | | **Spray diameter (cm) and spraying pattern** | 8.5  The shape of the spray on the wetted patch was circular | 9.0-9.5  The shape of the spray on the wetted patch was circular | 8.5-9.0  The shape of the spray on the wetted patch was circular | | **Discharge rate (mL/s)** | 1.21  The nozzles of the aerosols were checked and no blocking was observed. | 1.45  The nozzles of the aerosols were checked and no blocking was observed. | 1.33  The nozzles of the aerosols were checked and no blocking was observed. | | **The long term storage study is acceptable.** | Legay S., 2013  Study plan N° **13/1140F/c-e** |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3  (7 days at 0 ± 1ºC in closed glass bottle) | **X5975 CIRE** **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  The test was performed on the formulation X5975 CIRE. The only difference between both formulations is the addition of a propellant mixture in the product X6019 CIR. The propellant contains isobutane, butane and propane with the respective freezing points -159.4°C, -138.3°C and -187.6°C according to the safety data sheet of the propellant mixture.  Consequently, the result of the storage stability at low temperature according CIPAC MT 39.3 for the liquid formulation X6019 CIR, is expected to be the same as for the formulation X5975 CIRE. A specific study for storage stability at low temperature of the product X6019 CIR is not justified. | Raphalen E. 2015  Report 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 applicable |  |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not applicable |  |  |
| Wet sieve analysis and dry sieve test |  |  | Not applicable |  |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not applicable |  |  |
| 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 applicable |  |  |
| Flowability/Pourability/Dustability |  |  | Not applicable |  |  |
| Burning rate — smoke generators |  |  | Not applicable |  |  |
| Burning completeness — smoke generators |  |  | Not applicable |  |  |
| Composition of smoke — smoke generators |  |  | Not applicable |  |  |
| Spraying pattern — aerosols |  |  | 8.5 cm  The shape of the spray on the wetted patch was circular. | **Acceptable** |  |
| Physical compatibility |  |  | Not applicable |  |  |
| Chemical compatibility |  |  | Not applicable |  |  |
| Degree of dissolution and dilution stability |  |  | Not applicable |  |  |
| Surface tension | METTENS  (equivalent to EEC A5) | **X5975 CIRE** **Lot/batch No.: 1418200053** | **24.27 mN/m at 21.4°C on the pure test item** | **Acceptable**  The test was performed on the formulation X5975 CIRE but it considered acceptable because not relevant for an AE formulation.  **Surface active product.**  **The product is classified H304.** | Raphalen E. 2015  Report N° **402/14/1092F/defgh-e** |
| Viscosity | METVISCO (Pesticide Research Dept)  [equivalent to OECD 114] | **X5975 CIRE** **Lot/batch No.: 1418200053** | |  |  | | --- | --- | | **Temperature (°C)** | **Kinematic viscosity (mm²/s)** | | **20.0** | **<6.62** | | **40.0** | **<6.62** | | **Acceptable**  The test was performed on the formulation X5975 CIRE but it considered acceptable because not relevant for an AE formulation.  **The product is classified H304.** | Raphalen E. 2015  Report 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 | | **X5975 CIRE** **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**  The test was performed on the formulation X5975 CIRE but it considered acceptable because not relevant for an AE formulation.  **The product is classified H229.** | Raphalen E., Legay S., 2015  Report N° 402/14/1092F/i-e |
| Flammable gases |  |  | Not applicable |  |  |
| Flammable aerosols |  |  | Not required; the product is classified Flam. Aerosol 1, H222, as it contains more than 85% of flammable components and its chemical heat of combustion is higher than 30 kJ/g. The product is also classified Flam. Aerosol 1, H229 as it is an aerosol. | **Acceptable**  **The product is considered as flammable and classified H222 and H229.** |  |
| Oxidising gases |  |  | Not applicable |  |  |
| Gases under pressure |  |  | ≤3bars at 20°C  ≤10bars at 50°C | **Acceptable** | **Based on the safety data sheet** |
| Flammable liquids |  |  | Not applicable |  |  |
| Flammable solids |  |  | Not applicable |  |  |
| Self-reactive substances and mixtures |  | **X5975 CIRE** **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 heat of decomposition was less than 300 J/g. Therefore, the test item X5975 CIRE is not expected to present a significant hazard for self-reactive properties and the test on self-reactive properties according to UN Test series A to H described in Part II of the UN-MTC should not be performed.  Considering that X5975 CIRE and the liquid extracted from the X6019 CIR aerosol are identical, X6019 CIR is not expected to present a significant hazard for self-reactive properties. | **Acceptable**  The test was performed on the formulation X5975 CIRE but it considered acceptablebecause not relevant for an AE formulation. | Raphalen E., Legay S., 2015  Report N° 402/14/1092F/i-e |
| 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 |  | **X6019 CIR** | Considering the high proportion of non-oxidising ingredients (in total 99.99% w/w, 0.01% of perfume), the product X6019 CIR is not expected to present a significant hazard for oxidising properties, and testing is considered as unnecessary. | **Acceptable** | **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 | **X6019 CIR** | **>270°C** | **Acceptable** | **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 X6019 CIR is an Aerosol dispenser (AE) 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 classified H222. The internal pressure is 15 bars. It has a self-ignition temperature superior of 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 metal can (commercial packaging). Its technical characteristics are acceptable for an AE formulation.  The formulation is classified H304, H229 and H222.  H304: May be fatal if swallowed and enters airways.  H229: Pressurized container: may burst if heated.  H222: Extremely flammable aerosol. |

### 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 X6019 CIR 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:trans  GC-MS  **LOQ 0.05 mg/kg** |
| Air (principle of method and LOQ) | Cypermethrin 40:60 cis:trans  GC-MS  **LOQ 0.375 μg/m3** |
| Water (principle of method and LOQ) | Cypermethrin 40:60 cis:trans  GC-electron capture  **LOQ 0.01 µg/L** |
| Body fluids and tissues (principle of method and LOQ) | Not required as Cypermethrin is not classified as toxic or highly toxic |
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) | Cypermethrin 40:60 cis:trans  GC-electron capture  **LOD 0.05 mg/kg** (oilseed rape) **0.025 mg/kg** (wheat) |
| Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) | Cypermethrin 40:60 cis:trans  GC-MS  **LOQ 0.05 mg/kg** for bovine tissues, **0.005 mg/kg** for milk, **0.01 mg/kg** for eggs |

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

**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\*104 R2 = 0.99740  N=5 |
| Cypermethrin | 40 to 60 mg/L  Y = 5.650\*104 X – 1.139\*104 R2 = 0.99978  N=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.**

**Considering that X5975 CIRE and X6019 CIR aerosol are identical formulations, the analytical method for the determination of cypermethrin in the product can be considered as validated for X6019 CIR.**

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

##### **Analytical methods for determining relevant components and/or residues in feed/food of plant and animal origins**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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/L  N=6  R²>0.98 | No interference > 30% of LOQ in the control matrices. | *86-91* | *87* | *2.5* | *0.05* | Wimbush, J (2003); 40/041-D2149  Ion m/z 207 |
| 0.5 mg/kg / 5 | *80-84* | *81* | *2.2* |
| Bovine kidney | 0.05 mg/kg / 5 | *95-103* | *100* | *3.0* |
| 0.5 mg/kg / 5 | *84-89* | *87* | *2.3* |
| Bovine liver | 0.05 mg/kg / 5 | *83-87* | *85* | *2.1* |
| 0.5 mg/kg / 5 | *81-90* | *86* | *4.5* |
| Bovine fat | 0.05 mg/kg / 5 | *78-84* | *82* | *3.5* |
| 0.5 mg/kg / 5 | *93-101* | *97* | *3.7* |
| Eggs | 0.01 mg/kg / 5 | *80-87* | *83* | *3.9* | *0.01* |
| 0.1 mg/kg / 5 | *87-94* | *91* | *3.1* |
| Milk | 0.005 mg/kg / 5 | *84-106* | *92* | *9.7* | *0.005* |
| 0.05 mg/kg / 5 | *62-90* | *77* | *15.1* |
| cypermethrin | Bovine muscle | GC-MSD | 0.05 mg/kg / 5 | 0.01 to 1 mg/L  N=6  R²>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/L  N=6  R²>0.98 | No interference > 30% of LOQ in the control matrices. | *87-92* | *89* | *2.6* | *0.05* | Wimbush, J (2003); 40/041-D2149  Ion 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-MSD  Ion 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-MSD  Ion m/z 209 | 0.05 mg/kg / 5 | 98-104 | 101 | 2.4 |
| 0.5 mg/kg / 5 | *98-101* | *100* | *1.3* |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for water** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| cypermethrin | GC-ECD | 0.01 µg/L / 5 | 0.005 to 0.5 mg/L, n=6, 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 X6019 CIR is a solvent-based ready for use aerosol wood preservative product. The product is intended to be used by injection for curative treatments

According to the applicant, the product X6019 CIR should always be used in conjunction with a superficial application. Nevertheless, in the context of the assessment of the product X6019 CIR, the efficacy of the product X6019 CIR alone, used by infection, should be demonstrated.

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

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

The product X6019 CIR is intended to be used by injection directly in the holes of wood furniture, for curative treatments, indoor.

The application rate recommended by the applicant is the following:

- Curative treatment: injection at 180 g of product / m² of wood

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

According to the uses claimed by the applicant, the product X6019 CIR is intended to be used for the preservation of wood against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum,* and *Lyctus brunneus* and termites (*Reticulitermes spp.),* indoor.

The development stages claimed are larvae and adults.

* **Efficacy by injection alone**

The product X6019 CIR is specifically used by injection, in conjunction with a superficial application and this last one must be sufficiently efficient according to the requirement of PT8 efficacy guidance (2015). Therefore the efficacy of the treatment by injection is normally covered by the efficacy of the superficial treatment and the purpose of product X6019CIR’s treatment is only to be used as an additional treatment linked to service life or damages in depth in the wood.

Nevertheless as the product X6019 CIR will be put on the market alone (even with an instruction of use on the label requested a conjunction with a superficial treatment), requirements of article 19 [1.(b) (i) the biocidal product is sufficiently effective] of the regulation 528/2012/CE shall be fulfilled.

Then a test has been launched with an in-house method adapted from EN 1390 standard. The protocol is described in Annex 9 and the results demonstrated that the product X6019 CIR, applied alone by injection is sufficiently efficient (100 % mortality) against *Hylotrupes bajulus* larvae, at the application rate claimed of 180 g/m².

Moreover curative efficacy of the product X5975 CIRE (bridging data with the product X6122B1, see 2.2.5.5), identical to the product X6019 CIR (except that it a liquid phase without propellant), has been proved against wood boring beetles (*H. bajulus*, *A. punctatum*, *L. brunneus*) according to EN 1390 and EN 48 standards, and against termites (*Reticulitermes spp.)* according to EN 118, with a superficial application at the application rate of 300 g/m². The applicant assumes that “*Hylotrupes bajulus* can be considered as representative of wood-boring insects and thus the biocidal product X6019 CIR has a curative effect on all the larvae of wood-boring insects”. No element was presented for termites.

It has to be noted that no element has been provided in the dossier showing that injection treatment can be assimilated to superficial application and studies for preventive treatment (following EN20, EN46, and EN 49 standards) performed with the product X5975 CIRE (bridging data with the product X6122B1, see Annex 9)don’t allow to confirm the identity of the most resistant target organisms among wood boring beetles (only one application rate at 200 g/m² tested). Therefore FR CA cannot share the conclusions of the applicant to extrapolate the efficacy proved on *Hylotrupes bajulus* to all the wood boring beetles.

Based on the available study performed according to the methodology of EN 1390, FR CA can only conclude on the curative efficacy of the product X6019 CIR alone on *H. bajulus*, at the application rate of 180 g/m², applied by injection.

#### **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).

Regarding the curative insecticidal efficacy, based on the elements presented in the dossier, the product X6019 CIR has demonstrated a fast action on *Hylotrupes bajulus.*

#### **Efficacy data**

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

No efficacy trials according to European standards were conducted with the product X5975 CIRE. 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 X5975 CIRE 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 X5975 CIRE.

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 (like 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 insecticidal active substance 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 are 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 product X5975CIRE and no new biological tests should be required for X5975CIRE.

| **Test substance** | **Test organisms** | **Test system / Concentrations applied / exposure time** | **Test conditions** | **Test results: effects, mode of action, resistance** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| X6019 CIR | House longhorn beetle: *Hylotrupes bajulus (L.)* | EN 1390-like | The ready to use product X6019CIR is applied by injection directly into insects’ exit holes thanks to the injection needle until product rejection on softwood test blocks.  The quantity really applied on each test block varied between 167.8 g/m² and 198 g/m² (mean 186.8 g/m²).  6 larvae of *Hylotrupes bajulus* were used for each test block.  3 replicates for the treated block and 1 replicate for the control are performed.  The investigated effects are the mortality of the larvae.  - Method for recording / scoring effects: recovery of the insects and count of the dead and alive larvae. Calculation of the percentage of mortality.  - Intervals of examination: one time, 12 weeks after exposure of the larvae in the wood block to the tested product.  The efficacy criterion according to the EN 14128 is 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 % (100 %) and the contact time of 12 weeks validated the fast action efficacy of the product X6019 CIR against *Hylotrupes bajulus* larvae, at the application rate of 187 g of product / m² of wood.** | Poveda P., Simon F., 2017  01-01/2015  IC2 |
| X6122B1  X6122B1 without fungicidal AS  X6122B1 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., 2015  RetD AD 001.S01  IC2 |
| X6122B1 | *Reticulitermes flavipes* | EN118 + EN 73 | 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 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., 2016  401/14/136F/e-e  IC1 |
| 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., 2015  32/14/9803/01  IC1 |
| 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., 2017  401/14/136F/a and b-e  IC2 |
| 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., 2016  401/14/137F/c/e  IC2 |
| 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 slow 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., 2017  401/16/039F/c-e  IC2 |
| X6122B1 | 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., 2016  401/14/136F/e/e  IC1 |

#### **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 X6019 CIR has shown a sufficient efficacy for the preservation of furniture wood used by professional and non-professional users:

* For the curative efficacy of the product when used by injection against wood boring beetles (*Hylotrupes bajulus).*

The application rates validated are the following:

* Curative treatment: superficial application at 180 g of product X6019 CIR / m² of wood

According to the claims, the product X6019 CIR is normally used in conjunction with a superficial treatment[[1]](#footnote-1) as the product X5975 CIRE.

#### **Summary of efficacy assessment**

French competent authorities (FR CA) assessed that the product X6019 CIR, has shown a sufficient efficacy for

* For curative treatment when used by injection for wood furniture against wood boring beetles (*Hylotrupes bajulus*), at 180 g of product/m².

### Risk assessment for human health

The product X6019 CIR is a ready-for-use solvent-based wood preservative for professional and non-professional uses. It is formulated as an aerosol, with 70% w/w of the liquid formulation and 30% w/w of butane/propane. The product contains 0.054% w/w cypermethrin ; after vaporation of butane/propane the liquid formulation contains 0.076% w/w cypermethrin.

#### **Assessment of effects on Human Health**

##### 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 of Cypermethrin.

A summary of Toxicological reference Values is proposed 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 reference 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 2.3.2”Toxicology – biocidal product”.

###### *Percutaneous absorption*

In order to complete the human risk assessment for the formulation X6019 CIR, one *in vitro* dermal absorption study was performed with the representative formulation X5975CIRE to determine the dermal penetration potency of cypermethrin. Once applied and the propellant evaporated, the liquid formulation remains on the skin is similar to the formulation X5975CIRE. Therefore, the dermal absorption value of cypermethrin formulated in X5975CIRE might be extrapolated to X6019 CIR.

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 was tested at one concentration corresponding to the content of the pure product in formulation X5975CIRE 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.

**Table 2.2.6.1.3.1‑1 : Mean absorption rates of [14C] - cypermethrin in formulation X5975CIRE**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Skin replicates** | 1b | 2 | 3 | 4 | 5b | 6 | 7 | 8 | 9 |
| **Skin wash 8h** | 31.0 | 38.9 | 56.5 | 57.1 | 51.5 | 45.0 | 33.8 | 32.5 | 44.2 |
| **Skin wash 24h** | 4.08 | 5.25 | 6.25 | 6.53 | 3.87 | 2.85 | 10.2 | 11.0 | 15.3 |
| **Chamber wash upper comp** | 2.28 | 1.98 | 2.42 | 1.48 | 1.58 | 3.16 | 4.89 | 4.08 | 3.69 |
| **Strips 1-2** | 4.66 | 2.71 | 5.67 | 4.52 | 4.11 | 4.53 | 6.42 | 7.03 | 4.71 |
| **Strips 3-∞** | 4.97 | 10.2 | 12.1 | 10.1 | 4.35 | 11.7 | 13.7 | 9.93 | 14.5 |
| **Skin** | 48.3 | 38.2 | 16.0 | 19.5 | 30.6 | 28.2 | 29.4 | 33.4 | 16.1 |
| **Receptor fluid** | 3.93 | 0.579 | 0.150 | 0.112 | 1.15 | 1.5 | 0.202 | 0.195 | 0.466 |
| **Gauze** | 0.452 | 1.15 | 0.511 | 0.395 | 1.66 | 2.06 | 0.969 | 1.19 | 0.453 |
| **Chamber wash lower comp** | 0.340 | 1.04 | 0.469 | 0.286 | 1.15 | 1.02 | 0.426 | 0.667 | 0.657 |
| **Recovery %** | 95.3 | 91.7 | 100 | 94.9 | 119 | 108 | 93.1 | 96.4 | 105 |
| **% of total absorption at 12h** | 72.3 | 93.6 | 88.1 | 91.6 | 86.4 | 85.6 | 98.5 | 91.6 | 97.8 |
| **Absorption %a** | 53.022 | 40.969 | 17.13 | 20.293 | 34.56 | 32.78 | 30.997 | 35.452 | 17.676 |
| **Meanb** | 27.8995714 | | | | | | | | |
| **SDb** | 9.48355417 | | | | | | | | |

a: the total absorption comprising the recovered activity from receptor fluid, skin, chamber wash lower compartment and gauzes

b: replicates 1 and 5 were excluded from evaluation due to strongly deviating absorption rate (outlier according to Nalimov)

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 and X6019 CIR 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 X6019 CIR 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.

#### **Exposure assessment**

The product X6019 CIR is a ready-to-use aerosol which is intended to be used for the curative treatment (180 g product/m2) of interior woods. These curative treatments are done by injection by professionals and non-professionals.

Exposure is expected for professionals and non-professionals (adults and children):

* Primary exposure for professional

During professional application by injection indoors

* Primary exposure for non-professional

During application by injection indoors

Exposure for professional and non-professional primary uses occurs mainly *via* dermal and inhalation routes.

* Secondary exposures for professionals and non-professionals (adults and children)

Both categories are exposed to the biocidal product when they are in contact with the treated woods and/or their residues (acute and 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

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% |

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

NR: not relevant

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

The product X6019 CIR is a ready-for-use solvent-based wood preservative for professional and non-professional uses. It is formulated as an aerosol, with 70% w/w of the liquid formulation and 30% w/w of butane/propane. The product contains 0.054% w/w cypermethrin. Once applied and the propellant evaporated, it remains the liquid formulation which is similar to the formulation X5975CIRE with 0.076% w/w cypermethrin.

The product can be applied by injecting at an application dose of 180 g product/m2 for curative treatment. The product is directly injected, with a tube and a needle, in the holes made by the insects. A dermal and inhalation exposure to the product containing 0.076% (w/w) of cypermethrin can occur during the application.

###### *Exposure of professional users*

***Injection application***

No model is available for injection with an aerosol can. It has been considered that the proposition in HEAdhoc recommendation 6 to use the subsoil treatment model 2 for a classical professional injection can be used. In fact, Subsoil treatment model 2 is a mix of spray and injection events. In an injection process body exposure is not expected, so only hand exposure is considered in recommendation for injection. The model provides only hand exposure inside gloves so it will be considered as a tier 2. Task duration: 40 min

For tier 1 approach without PPE, it will be considered that exposure during an injection process could not be greater than exposure by brush application. So tier 1 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[[2]](#footnote-2). The mixing and loading phase is not considered since the product is a RTU that is applied directly with the aerosol can.

| **Scenario** | **Product** | **Tier** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Dermal Exposure**  **(mg/kg bw/d)** | | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- | --- | --- |
| **Professional Injecting** | | | | | | |
| Product application phase | X6019 CIR | Without gloves | 1.03 x 10-4 | 9.08 x 10-3 | 9.19 x 10-3 | |
| With gloves | 6.02x 10-6 | 1.50 x 10-3 | | 1.51x 10-3 |

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

X6019CIR is RTU product that can be applied by injecting at an application dose of 180 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 application.

***Injection application***

No model is available for injection with an aerosol can for non-professional users. It has been considered that exposure during an injection process could not be greater than exposure by brush application.

Non-professional exposure during the application phase has been considered using “*Non-professional application of paints by brushing and rolling*” from the Recommendation no. 10 of the BPC Ad hoc Working Group on Human Exposure[[3]](#footnote-3). The mixing and loading phase is not considered since the product is a RTU that is applied directly with the aerosol can.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **Product** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Dermal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| **Injecting – Without PPE** | | | | |
| Product application phase | X6019 CIRE | 1.03x 10-4 | 9.08 x 10-3 | 9.19 x 10-3 |

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

For secondary exposure, as described in TNsG for Human Exposure (2002 and 2007), it was considered 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 summarized 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 of180 g/m2, corresponding to a curative treatment.

***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** | 1.06 x 10-3 | 4.78 x 10-6 | - | 1.07 x 10-3 |
| **Infant chewing wood composites chips** | - | - | 3.74 x 10-3 | 3.74 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** | 1.06 x 10-3 | 2.87 x 10-5 | - | 1.09 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** | 4.05 x 10-4 | - | - | 4.05 x 10-4 |
| **Infant playing on weathered (playground) structure and mouthing** | 6.07 x 10-4 | - | 1.17 x 10-3 | 1.78x 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 summarized 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 |

**Professional uses:**

***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)** |
| Injecting  (no PPE) | 9.19x 10-3 | 2.74 x 10-5 | 9.22x 10-3 |

**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)** |
| 1.78 x 10-3 | 5.54 x 10-5 | 1.83 x 10-3 |

**Non-professional uses**

***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)** |
| Injecting | 9.19 x 10-3 | 2.74 x 10-5 | 9.22 x 10-3 |

**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)** |
| 1.78 x 10-3 | 5.54 x 10-5 | 1.83 x 10-3 |

###### *Combined with another use*

The applicant claims the use of the X6019 CIR and X5975CIRE products in association. For risk assessment of the X5975CIRE product, please refer to the Product Assessment Report of X5975CIRE.

**Professional uses:**

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

|  |  |  |
| --- | --- | --- |
| **Product** | **Total exposure**  **(mg/kg bw/d)** | **Exposure of combined uses**  **(mg/kg bw/d)** |
| X6019CIR (injecting) | 9.22 x 10-3 | 2.57 x 10-2 |
| X5975CIRE (spraying worst case) | 1.65 x 10-2 |

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

|  |  |  |
| --- | --- | --- |
| **Product** | **Total exposure**  **(mg/kg bw/d)** | **Exposure of combined uses**  **(mg/kg bw/d)** |
| X6019CIR | 1.83 x 10-3 | 4.85 x 10-3 |
| X5975CIRE | 3.02 x 10-3 |

**Non-professional uses**

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

|  |  |  |
| --- | --- | --- |
| **Product** | **Total exposure**  **(mg/kg bw/d)** | **Exposure of combined uses**  **(mg/kg bw/d)** |
| X6019CIR (injecting) | 9.22 x 10-3 | 5.40 x 10-2 |
| X5975CIRE (spraying) | 4.48 x 10-2 |

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

|  |  |  |
| --- | --- | --- |
| **Product** | **Total exposure**  **(mg/kg bw/d)** | **Exposure of combined uses**  **(mg/kg bw/d)** |
| X6019CIR | 1.83 x 10-3 | 4.85x 10-3 |
| X5975CIRE | 3.02 x 10-3 |

###### *Dietary exposure*

In Annex 3.3 “Residue behaviour”, the results of the residue assessment are laid out.

#### **Risk characterisation 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 |

**Injecting application**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Injecting 180g/m2 –no PPE** | | | | |
| Product application phase without PPE | 0.022 | 9.19 x 10-3 | 42 % | Acceptable |
| Product application phase with gloves | 1.51x 10-3 | 6.84% | Acceptable |

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

###### *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 |

**Injecting application**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Injecting – without PPE** | | | | |
| M&L | n.a | | | |
| Product application phase | 0.088 | 9.19 x 10-3 | 10.44 % | Acceptable |

##### 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 | 1.07 x 10-3 | 1.21 % | Acceptable |
| **Infant chewing wood composites chips** | 3.74 x 10-3 | 4.25 % | 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 | 1.09 x 10-3 | 4.96 % | 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** | 4.05 x 10-4 | 1.8 % | Acceptable |
| **Infant playing on playground structure outdoors and mouthing**  **(wood treated at 300 g/m2)** | 1.78x 10-3 | 8.08 % | 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** |
| **Professional combined expo : injecting** | 9.22x 10-3 | 42 | 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 | 1.83 x 10-3 | 8.33 | Acceptable |

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

##### Combined with another uses

The exposure values are compared to AEL below:

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

**Professional combined exposure (chronic exposure scenario)**

**Combination of spray application and injection**

|  |  |  |
| --- | --- | --- |
| **Product** | **% AEL** | **Risk** |
| X6019 CIR (injection Without PPE) | 42 | Acceptable |
| X5975CIRE (spraying) | 75 | Acceptable |
| X6019 CIR + X5975CIRE | **117** | **Unacceptable** |

Considering X6019 CIR injection with gloves:

|  |  |  |
| --- | --- | --- |
| **Product** | **% AEL** | **Risk** |
| X6019 CIR (injection With gloves) | 6.84 | Acceptable |
| X5975CIRE (spraying) | 75 | Acceptable |
| X6019 CIR + X5975CIRE | 82 | Acceptable |

**Combination of brush application and injection**

|  |  |  |
| --- | --- | --- |
| **Product** | **% AEL** | **Risk** |
| X6019 CIR (injection Without PPE) | 42 | Acceptable |
| X5975CIRE (brushing) | 44.92 | Acceptable |
| X6019 CIR + X5975CIRE | 87 | Acceptable |

**Non Professional combined exposure (acute exposure scenario)**

Only combination of spray application and injection is presented as it covers the combination of brush application and injection

|  |  |  |
| --- | --- | --- |
| **Product** | **% AEL** | **Risk** |
| X6019 CIR (injection) | 10.44 | Acceptable |
| X5975CIRE (spraying) | 51 | Acceptable |
| X6019 CIR + X5975CIRE | 61 | Acceptable |

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

|  |  |  |
| --- | --- | --- |
| **Product** | **% AEL** | **Risk** |
| X6019 CIR | 8.33 | Acceptable |
| X5975CIRE | 13.71 | Acceptable |
| X6019 CIR + X5975CIRE | 22 | Acceptable |

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

Risks related to the use of X6019 CIR by professionals and non-professionals are considered acceptable for all the intended uses mentioned above.

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

If the injection treatment of the product X6019 CIR is combined with superficial application, a risk mitigation measure must be added:

* In case of complementary application with superficial treatment, wear gloves.

##### 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 X6019 CIR 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 2.2.8) is reported as provided by the applicant. The FR CA position is presented in green evaluation boxes. |

#### **Effects assessment on the environment**

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

The product X6019 CIR is intended for the curative treatment of interior woods. 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.

The environmental fate and behaviour of the product X6019 CIR is presented in Section 10 of the IUCLID file. Based on the intended uses of the product and on the nature of the substance, on its physico-chemical properties and on its relations structure/function, no contamination of the environment is foreseen (indoors use only).

For the assessment of the environmental fate and behaviour of the active substance contained in the biocidal product X6019 CIR, please refer to the chapters on fate and distribution in the environment (see Assessment Reports, cypermethrin cis:trans / 40:60 PT08, 12/07/2013).

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 2.2.8‑1Physical-chemical and fate and behaviour data on cypermethrin and relevant metabolites**

|  |  |
| --- | --- |
| **Data** | **Cypermethrin** |
| Reference | AR for cypermethrin  PT08, 12/07/2013 |
| Molecular weight (g/mol) | *416.3* |
| Melting point [°C] | Onset: 41.2  Peak: 47.3 |
| Boiling point [°C] | Not measurable, decomposes |
| Vapour Pressure (Pa) | *2.3\*10-7* at 20°C  6\*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 d  12°C, pH 7: DT50 = 98.9 d  12°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°C  **In sediment**:  20.7 – 27 d at 12°C  **In whole system**:  6.6 - *18.5 d* at 12°C  3-PBA: 24.5 d at 12°C (whole system)  TDCVC: 152 – 274 d at 12°C (whole system)  CDCVC: 18 – 356 d at 12°C (whole system) |
| 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 | 417  TDCVC: 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 water, sediment and stp)*

A summary and evaluation of effect data for the active substances with relevance to the aquatic compartment can be found in Document II-A of the active substance dossier (see Letters of Access 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 2.2.8‑2: 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 2.2.8‑3: 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 to  92.0 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) – 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. |

#### **Exposure assessment**

##### Emissions to the environment

It can be considered that there is no exposure of the aquatic or terrestrial compartments when using the product X6019CIR for curative indoor treatments (mainly on furniture) and then no risk assessment for the environment is deemed necessary.

|  |
| --- |
| **FR-CA box 6**  FR-CA agrees with the registrant’s conclusions. |

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

*See Summary of Product Characteristics (SPC)*

### Comparative assessment

*Not relevant.*

# Annexes[[4]](#footnote-4)

## List of studies for the biocidal product

| **Section No** | **Reference No** | **Author** | **Year** | **Title** | **Owner of data** | **Letter of Access** | | **Data protection claimed** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 2.2.2 | 150313/PaPV93.10 | Simon F. | 2015 | Odour of X6019CIR | DYRUP SAS - PPG | **Yes** | **No** | **Yes** | **No** |
| 2.2.2 | 13/1140F/c | Legay S. | 2013&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 |  |  |  |  |
| 2.2.2 | 402/14/1092F/defgh-e | Raphalen E. | 2015 | Physical, chemical and technical characteristics of the biocidal product X5975CIRE | DYRUP SAS - PPG |  |  |  |  |
| 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 |  |  |  |  |
| 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 |  |  |  |  |
| 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 |  |  |  |  |
| 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 |  |  |  |  |
| 2.2.5.5 | 401/14/136F/e-e | Ansard D. and Paulmier I. | 2015 | X6122B1. Preventive action against termites according to NF EN 118 with NF EN 73 |  |  |  |  |  |
|  | 401/16/039F/c-e | Brunet C. and Paulmier I. | 2017 | X6122B1. Curative action against Hylotrupes bajulus according to NF EN 1390. |  |  |  |  |  |
|  |  | Poveda P. | 2017 | Efficacy test report, X6019CIR. Injection according to internal method. |  |  |  |  |  |
|  | 401/14/136F/e/e version 2 | Brunet C. and Paulmier I | 2015 | X6122B1. Determination of eradicant action against larvae of Anobium punctatum (De Geer)-laboratory method according to NF EN 48 |  |  |  |  |  |

## Output tables from exposure assessment tools

Annex 3.2.1 : Toxicology and metabolism –active substance

CYPERMETHRIN

Threshold Limits and other Values for Human Health Risk Assessment

| **Summary** | | | |
| --- | --- | --- | --- |
|  | Value | Study | SF |
| AEL long-term | 0.022 | 2 years rat | 100 |
| AEL medium-term | 0.055 | 90 day dog | 100 |
| AEL acute  ADI  ARfD | 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 – H302  Acute Tox 4 – H332  STOT SE 3 – H335 |

Annex 3.2.2: Toxicology – biocidal product

X6019 CIR

|  |  |
| --- | --- |
| General information | |
| Formulation Type RTU |  |
| Active substance(s) (incl. content) Cypermethrine 0.05% |  |
| Category |  |

| Acute toxicity, irritancy and skin sensitisation of the preparation | | | | |
| --- | --- | --- | --- | --- |
| 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 | | | | |
| --- | --- | --- | --- | --- |
| 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) | |
| Regulation 1272/2008/EC | GHS08  Danger  STOT SE 3 – H336 : May cause drowsiness or dizziness  Asp. Tox. 1 – H304 : May be fatal if swallowed and enters airways  EUH066: Repeated exposure may cause skin dryness or cracking |

Annex 3.2.3: Safety for professional operators

X6019CIR

Exposure assessment for professional users

Please refer to the Excel data sheet attached to the PAR.

* Injecting treatment: Excel data sheet “Expo IR – Injecting”;

Risk assessment

Please see the tables presented in the document section 2.2.6.3.1

Annex 3.2.4 : Safety for non-professional operators and the general public

Exposure assessment for non-professional

Please refer to the Excel data sheet attached to the PAR.

* Injecting treatment: Excel data sheet “Expo IR – Injecting”;

Risk assessment for Non-professionals

Please see the tables presented in the document section 2.2.6.3.2;

Exposure assessment for General public (secondary exposure)

Please refer to the Excel data sheet attached to the PAR.

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

Risk assessment for General public (secondary exposure)

Please see the tables presented in the document section 2.2.6.3.3.

****

## Residue behaviour

**Intended Use (critical application):** intended to be used as curative treatment for interior solid woods. This curative treatment is done by professionals and non-professionals by injection.

**Active substance:** cypermethrin

**Formulation of biocidal product:** AE (aerosol)

**Place of treatment:** indoor

**Target organisms:** Wood boring insects and 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 curative treatment of interior solid woods that do not come in direct contact with food, feedstuff or livestock.

As the product is to be used for 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.

## Confidential annex

See separate confidential file.

1. In consequence, a combined exposure and risk assessment have been performed. [↑](#footnote-ref-1)
2. 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-2)
3. [↑](#footnote-ref-3)
4. [↑](#footnote-ref-4)