Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR MINOR CHANGE APPLICATIONS**

(submitted by the evaluating Competent Authority)



PPG\_Class3\_WB

Product type 8

Cypermethrin

Tebuconazole

Propiconazole

IPBC

Case Number in R4BP for NA-APP: [BC-AP017518-34](https://echa-access.echa.europa.eu/r4bp-web-authority/case/,DanaInfo=r4bp-main.echa.europa.eu,SSL+na-app.xhtml?id=BC-AP017518-34)

Case Number in R4BP for NA-MIC: BC-VK052065-31

Evaluating Competent Authority: FR

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**Note to the reader:**

This consolidated PAR has been prepared for the assessment of the post authorisation data and is based on the last version of the PAR which includes the minor change of PPG\_Class3\_WB. The minor change decision was delivered on 29/01/2020 with the following request:

“To provide a long term stability study for the product X6119C (META RCP 1) in HDPE packaging in order to confirm the stability of IPBC before the 21st of January. The results of this study will be extrapolated for the meta-SPC2.”

In this consolidated PAR, the assessments related to the post authorisation data of the product are at the end of the concerned sections and are highlighted in grey.

The SPC (in the first section of the PAR) corresponds to the currently authorised uses in France.

* **Minor change application for PPG CLASS3 WB – 2019 :**

Change claimed in the frame of the minor change application is:

* A change of composition and classification.
* An addition of of a trade name.
* An addition of a manufacturing site.

**History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | *FR* | BC-AP017518-34 | 04/06/2019 | Initial assessment |
| NA-MIC | *FR* | BC-VK052065-31 | 29/01/2020 | Minor change application |
|  | Post authorisation data assessment |

# CONCLUSION

The biocidal product family PPG-CLASS3\_WB is a PT8 intended to be used for preventive and curative wood treatment containing 0.1%-1.2% cypermethrin, 0.15%-2.2% propiconazole, 0.05%-0.74% tenuconazole and 0.05%-0.74% IPBC.

The BPF is initially structured into 3 meta SPCs:

* Products of meta SPC 1 are emulsion concentrates to be used after dilution by professional and industrial users for the preventive treatment of wood for use class 1, 2 and 3.1
* Products of meta SPC 2 are emulsion concentrates to be used after dilution by industrial users for the preventive treatment of wood for use class 1, 2 and 3.1
* Products of meta SPC 3 are ready-to-use product to be used by professional and non professional users for the preventive treatment of wood for use class 1, 2 and 3.1 and curactive treatment of wood in place.

Meta SPC 3 contains two products for which the target organisms are slightly different. Hence FR CA has split the meta SCP 3 in two, and has created a meta SPC 4, with the same uses as meta SPC 3, but different target organisms.

***Physico chemical properties***

***Meta SPC1***

Products of meta SPC 1 (X6119CJ and X6119C) are emulsion oil in water (EW to be diluted) formulation. They are not classified regarding safety properties. However, they are classified by default corrosive to metals H290 Corr. 1.

Products are considered stable 1 year at ambient temperature and they should not be stored at a temperature higher than 22°C. Moroever, products should be stirred before and during application. In order to confirm the stability of IPBC, a new shelf life study is required and should be provided for the worst case, i.e for the product X6119C in HDPE packaging.Compatibility has been demonstrated with HDPE and f-HDPE packaging during the long term storage stability. The products should be stored away from light.

***Meta SPC2***

Products of meta SPC 2 (X6119C1 and X6119B1) have compositions similar to formulation X6119C (meta SPC 1). They are oil in water formulation (EW to be diluted) Products are not classified regarding safety properties. However, they are classified by default corrosive to metals H290 Corr. 1. Technical properties are acceptable. However, viscosity for X6119C1 is missing and should have been provided**.** Nevertheless, the product X6119C1 is not authorized due to efficacy results, so no further data are required.As for products of meta SPC1, products are considered stable 7 days at 0°C, one year at ambient temperature (22°C) in commercial packaging (HDPE) and they should be stored away from light.

***Meta SPC3***

Products of meta SPC 3 (X6119M2 and X6119CR) are ready to use formulations (EW: emulsion oil in water, ready to use). The products are not classified regarding safety properties. However, they are classified by default metals H290 Corr. 1. Products are stable 2 years at ambient temperature in commercial packaging (tin plate and HDPE). The products should not be stored at a temperature higher than 40°C and should be protected from light.

***Meta SPC4***

The only product of meta SCP 4 (X6236) is a ready to use formulation (EW: emulsion oil in water, ready to use). The product is not classified regarding safety properties. However, it is classified by default metals H290 Corr. 1. There is no effect of temperature on the stability of the formulation after 7 days at 0°C, 8 weeks at 40°C and 2 years at ambient temperature in commercial packaging (tin plate can). The product should not be stored at a temperature higher than 40°C.

***Analytical methods***

Analytical methods have been provided and found acceptable for the determination of active substances in the products. However, specificity is missing for the product X6119CR.

Analytical methods for the determination of active substances residues in the environment are available in the CAR of the active substances. The applicant has an access to this data with letters of access.

Post-AMM requirements:

A new shelf life study for X6119C in HDPE packaging is required in post authorisation within 1 year to confirm the stability of IPBC.

Results will be extrapolated to the product of Meta SPC2.

* **Minor change application for PPG CLASS3 WB - 2019:**

The conclusions of the physico chemical properties and analytical methods remain unchanged following the assessment of the minor change submitted. Please refer to the confidential annex for details.

* **Post authorisation data for PPG CLASS3 WB - 2021:**

*Following first authorisation of the family PPG CLASS3 WB, a post-authorisation requirement was identified regarding stability of IPBC on storage for products belonging to Meta SPC 1 and Meta SPC 2. According to the results provided for the first authorisation, X6119C was identified as a worst case and a new storage stability study for this product was requested in order to confirm the shelf life for products of Meta SPC 1 and Meta SPC 2. The applicant has informed ANSES on the 10th March 2021 that products X6119C and X6119CJ (Meta SPC 1) and X6119B1 (Meta SPC 2) will not be manufactured anymore and no further stability study was launched to cover the post-authorisation data requirement. Furthermore, the applicant has stated that both Meta SPC 1 and Meta SPC 2 could be removed from the PPG\_Class 3\_WB family.*

***Conclusion on Efficacy:***

French competent authorities (FR CA) assessed that the family (PPG\_CLASS3\_WB), separated in four META-SPCs has shown a sufficient efficacy as following:

* In META-SPC1:
* The data presented in the dossier demonstrated for the products X6119CJ and X6119C:
  + The preventive efficacy of the product when used by superficial application of wood used in use class 1 against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.),* on softwood and hardwood*,* at the application rate of 100 g of 5 % v/v diluted product / m² of wood*.*
  + The preventive efficacy of the product when used by superficial application of wood used in use classes 2 to 3.1:
    - against wood rotting fungi (brown rot fungi, softwood and hardwood for use class 2, and softwood only for use class 3.1),
    - against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.)* on softwood and hardwood, at the application rate of 165 g of 5 % v/v diluted product / m² of wood*.*

For the use class 3.1, a top coat is needed.

* Following request for additional information on efficacy by eCA, the use of the product at the concentration of 8.33 % v/v for curative treatment has been withdrawn by the applicant.

The product is applied by industrial and professional users.

* In META-SPC 2:
* The data presented in the dossier demonstrated for the product X6119B1:
  + The preventive efficacy of the product when used by superficial application of wood used in use class 1 against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.)* on softwood and hardwood*,* at the application rate of 100 g of 10 % v/v diluted product / m² of wood *.*
  + The preventive efficacy of the product when used by superficial application of wood used in use classes 2 to 3.1
    - against wood rotting fungi (brown rot fungi, softwood and hardwood for use class 2, and softwood only for use class 3.1),
    - against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.)* on softwood and hardwood, at the application rate of 165 g of 10 % v/v diluted product / m² of wood*.*

For the use class 3.1, a top coat is needed.

* The efficacy of the product X6119C1 is not demonstrated.

The product is applied by industrial users.

* In META-SPC 3
* The data presented in the dossier demonstrated for the product X6119M2:
  + The preventive efficacy of the product when used by superficial application of wood used in use class 1, at the application rate of 200 g product/m² of wood, against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*) and against termites (*Reticulitermes spp.* and *Heterotermes spp.)* on softwood and hardwood.
  + The preventive efficacy of the product when used by superficial application of wood used in use class 2, at the application rate of 200 g product/m² of wood, against wood rotting fungi (brown rot fungi), against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*) and against termites (*Reticulitermes spp.* and *Heterotermes spp.)* on softwood and hardwood.
  + The preventive efficacy of the product when used by superficial application of wood used in use class 3.1, at the application rate of 200 g product/m² of wood against:
    - wood rotting fungi (brown rot fungi) on softwood,
    - wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.)* on softwood and hardwood*.*

For the use class 3.1, a top coat is needed.

* + The curative efficacy of the product when used by superficial application (that could be completed by injection) of wood in service in condition of use classes 1 and 2, at the application rate of 300 g product/m² of wood, against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.* and *Heterotermes spp.)* on softwood and hardwood.
* The efficacy of the product X6119CR is not demonstrated.
* Given the composition variation, the product X6236 cannot be included in the meta SPC 3, it should be separated in another meta SPC.

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

* In META-SPC 4
* The data presented in the dossier demonstrated for the product X6236:
  + The preventive efficacy of the product when used by superficial application of wood used in use classes 1 to 3.1, at the application rate of 200 g product/m² of wood,
  + against wood rotting fungi (brown rot fungi, softwood and hardwood for use class 2, and softwood only for use class 3.1),
  + against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.* and *Heterotermes spp.)* on softwood and hardwood*.*

For the use class 3.1, a top coat is needed.

* + The curative efficacy of the product when used by superficial application (that could be completed by injection) of wood in service in condition of use classes 1 and 2, at the application rate of 300 g product/m² of wood, against wood boring beetles (*Anobium punctatum)* and against termites *(Reticulitermes spp.* and *Heterotermes spp.),* on softwood and hardwood

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

* **Minor Change application for PPG CLASS 3 WB – 2019 :**

The efficacy assessment remained unchanged.

**Conclusion on Human Health**

**Meta SPC 1 and 2**

The risk is acceptable for professional users if the following RMM are applied:

* For industrial use: wear gloves and clothes during mixing and loading and gloves and impermeable coverall during application
* For brush application: wear gloves during mixing and loading.
* For spraying application: wear gloves and coated coverall during application and no ppe during cleaning.
* For injection combined to brushing: wear gloves during mixing and loading and injection.
* For injection combined to spraying: wear gloves and coated coverall during application by spraying, gloves during injection, gloves and coated coverall during cleaning of injection equipment and no PPE during cleaning of spray equipment.

The risk linked to secondary exposure is acceptable.

**Meta SPC 3**

**X6119 M2**

The risk is acceptable for professional if the following RMM are applied:

* For spraying application: wear gloves and coated coverall during application and no ppe during cleaning.
* For injection combined to brushing: wear gloves during injection.
* For injection combined to spraying: wear gloves and coated coverall during application by spraying, gloves during injection and no PPE during cleaning of spray equipments.

The risk is acceptable for non professional users (brushing, spraying and injection).

The risk linked to secondary exposure is acceptable.

**X6119 CR**

The risk for spraying application by a professional is unacceptable.

The risk is acceptable for professional if the following RMM are applied:

* For brush application: wear *g*loves during loading, gloves and coated coverall during application and no PPE during cleaning.
* For injection combined to brushing: gloves during mixing and loading, gloves and coated coverall during application by brush, gloves during injection, gloves and coated coverall during cleaning of injection equipment and no PPE during cleaning of brush.

The risk linked to secondary exposure is acceptable.

**For meta SPC 4**

**X6236**

The risk is acceptable for professional if the following RMM are applied:

* For spraying application: wear gloves and coated coverall during application and no ppe during cleaning.
* For injection combined to brushing: wear gloves during injection.
* For injection combined to spraying: wear gloves and coated coverall during application by spraying, gloves during injection and no PPE during cleaning of spray equipments.

The risk is acceptable for non professional users (brushing, spraying and injection).

The risk linked to secondary exposure is acceptable.

* **Minor Change application for PPG CLASS3 WB - 2019:**

The classification and labelling of meta SPCs 3 and 4 has been updated and no new substance of concern has been identified. The conclusions remain unchanged.

***Conclusions on Risk for consumers via residues***

Regarding consumer health protection, there are no objections against the intended uses. Wood treated with PPG CLASS 3 products must contain label restrictions against use in contact with livestock, food and feed.

**Conclusion on environmental risk assessment**

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

For an outdoor application phase for wood in class 3, risks are acceptable only if emissions to the aquatic and terrestrial compartments are prevented whatever the type of treatment. Therefore, the product should not be applied above or near surface and the ground has to be covered with an appropriate plastic sheet to prevent any emission to the terrestrial compartment during in situ brushing. For spraying application, the risk mitigation measure for the soil compartment is considered as unappropriate

For the service-life phase of treated wood (class 3), risks can be considered acceptable for all the compartments whatever the type of treatment with the use of appropriate risk mitigation measures.

On the other hand, exposure levels for environmental organisms don’t take into account of the use of a topcoat and unacceptable risks were found for sediment dwelling-organisms. Consequently, treated wood exposed to weathering must be protected with a topcoat. Moreover, it should be noted that for the use class 3.1, the wood and wood-based products will not remain wet for long periods. Water will not accumulate. In these conditions, risks to the aquatic environment for the service-life stage should be lower than calculated.

* **Minor change application for PPG CLASS3 WB - 2019:**

The change in the composition does not change the classification of the product for the environment and no new substance of concern has been identified. The conclusions of the environmental assessment remain unchanged.

**Overall conclusion**

**The BPF PPG\_Class3\_WB containing 4 meta SPCs can be authorized. Details of the conditions of uses and risk mitagion measures are given in the SPC.**

* **Post authorisation data for PPG\_Class3\_WB - 2021:**

**Considering the non submission of the post authorisation data assessment, only 2 meta SPCs in the BPF PPG\_Class3\_WB family (meta SPC3 and meta SPC4) can still be authorized. Details of the conditions of uses and risk mitigation measures are given in the SPC (cf section 2.1).**

The conclusions regarding the intended uses for PPG\_Class3\_WB biocidal products family are:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Meta SPC** | **Field of use** | **Target organisms** | **Application rate** | **Users** | **Conclusions** |
| Meta SPC 1 | Preventive treatment in use classes 1 to 3.1. | Wood rotting fungi (brown rot fungi)  Wood boring beetles:  *Hylotrupes bajulus* *Anobium punctatum* *Lyctus brunneus*  Termites *Reticulitermes spp.* | The treatment is performed by superficial application:  UC 1: 100 g of 5 % diluted product / m² of wood (against insects only)  UC 2 to 3.1: 165 g of 5 % diluted product / m² of wood (against insects and fungi). | Industrial users  Professional users | **Unacceptable**  The post authorisation confirmatory stability data have not been provided |
| Meta SPC 2 | Preventive treatment in use classes 1 to 3.1. | The treatment is performed by superficial application:  UC 1: 100 g of 10 % diluted product / m² of wood  UC 2 to 3.1: 165 g of 10 % diluted product / m² of wood. | Industrial users | **Unacceptable**  The post authorisation confirmatory stability data have not been provided |
| Meta SPC 3 | Preventive treatment in use classes 1 to 3.1. | The treatment is performed by superficial application:  UC 1 to 3.1: 200 g product / m² of wood | Professional and non-professional users | **Acceptable** |
| Curative treatment for wood in service (wood not exposed to weathering and frequent wetting) softwood and hardwood | Wood boring insects   * House longhorn beetle (*Hylotrupes bajulus*) \_ Larvae * Common furniture beetle (*Anobium punctatum*) \_ Larvae * Powder post beetles (*Lyctus brunneus*) \_ Larvae   Termites (*Reticulitermes spp.* and *Heterotermes spp.*) | The product is ready to use.  When the treatment is performed by superficial application, the application rate is :   * 300 g of product / m² of wood   When the application is performed by injection (combined with superficial application), the application rate is :  180 g of product / m² of wood (+ 300 g of product / m² of wood) | Professional and non-professional users |
| Meta SPC 4 | Preventive treatment in use classes 1 to 3.1. | Wood rotting fungi (brown rot fungi)  Wood boring beetles:  *Hylotrupes bajulus* *Anobium punctatum* *Lyctus brunneus*  Termites *Reticulitermes spp.* | The treatment is performed by superficial application:  UC 1 to 3.1: 200 g product / m² of wood | Professional and non-professional users | **Acceptable** |
| Curative treatment for wood (wood not exposed to weathering and leaching) on softwood and hardwood | Wood boring insects   * *Anobium punctatum*   Termites *Reticulitermes spp.* and *Heterotermes spp.* | The product is ready to use.  When the treatment is performed by superficial application, the application rate is :   * 300 g of product / m² of wood   When the application is performed by injection (combined with superficial application), the application rate is :  180 g of product / m² of wood (+ 300 g of product / m² of wood) |

# ASSESSMENT REPORT

## Summary of the product assessment

**Part I – First information level**

### Administrative information

#### Identifier of the product family

| **Identifier[[1]](#footnote-1)** | **Country (if relevant)** |
| --- | --- |
| PPG\_Class3\_WB | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | PPG AC - France SA |
| **Address** | Immeuble Union Square  1 rue de l'Union  CS10055  92565 Rueil-Malmaison  France |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### Manufacturer of the products of the family

|  |  |
| --- | --- |
| **Name of manufacturer** | PPG AC - France SA |
| **Address of manufacturer** | Immeuble Union Square  1 rue de l’Union  CS 10055  92565 Rueil Malmaison  France |
| **Location of manufacturing sites** | ZI Montplaisir, 25 rue Jean le Rond d'Alembert  81000 Albi  France |
|  | PPG Trilak Kft.  4, Grassalkovich ut.  Budapest 1238  Hungary |
|  | ZI DE RUITZ,  BP 83  62620 RUITZ  FRANCE |
|  | DYRUP A/S,  GLADSAXEVEJ 300  2860 SØBORG  DENMARK |
|  | PPG DECO POLSKA SP. Z O.O.,  UL. KWIDZYŃSKA 8  51-416 WROCŁAW  POLAND |
|  | BERKEM DEVELOPPEMENT SAS,  MARAIS OUEST  24680 GARDONNE  FRANCE |
|  | PPG ROMANIA,  33 CATANOAIA STREET, SECTOR 3  032903 BUCHAREST  ROMANIA |

#### Manufacturers of the active substances

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

|  |  |
| --- | --- |
| **Active substance** | Propiconazole |
| **Name of manufacturer** | Janssen Pharmaceutica NV |
| **Address of manufacturer** | Turnhoutseweg  302340 Beerse  Belgium |
| **Location of manufacturing sites** | Dongsha ChemZone  Zhangjiagang  215600 Jiangsu  China |

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

|  |  |
| --- | --- |
| **Active substance** | IPBC |
| **Name of manufacturer** | Troy Chemical Company BV |
| **Address of manufacturer** | Uiverlaan 12e  3145 XN Maassluis  Netherlands |
| **Location of manufacturing sites** | One Avenue L  07105 Newark  United States |

### Product family 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 substances

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

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

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

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

#### Candidates for substitution

The active substance tebuconazole contained in the biocidal product family PPG\_Class3\_WB is candidate for substitution in accordance with Article 10 of BPR because it fulfills the following 2 of the PBT criteria: vP and T.

The active substances cypermethrin, propiconazole and IPBC contained in the biocidal product PPG\_Class3\_WB are not candidate for substitution in accordance with Article 10 of BPR.

#### Information on technical equivalence

Not applicable.

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

Please see the confidential annex for further details.

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

According to our assessment, none of the co-formulants contained in the biocidal product family PPG\_ Class3\_WB are identified as endocrine disruptors.

Please refer to Confidential Annex.

#### Qualitative and quantitative information on the composition of the family

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)**  **(technical)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Cypermethrin | (RS)-α-cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52315-07-8 | 257-842-9 | 0.11 | 0.11 |
| Propiconazole | 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole | Active substance | 60207-90-1 | 262-104-4 | 0.16 | 0.16 |
| Tebuconazole | (RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol. | Active substance | 107534-96-3 | 403-640-2 | 0.05 | 0.05 |
| IPBC | 3-iodo-2-propynyl butyl carbamate | Active substance | 55406-53-6 | 259-627-5 | 0.05 | 0.05 |
| BIT | 1,2-benzisothiazol-3(2H)-one | preservative | 2634-33-5 | 220-120-9 | 0.026 | 0.026 |
| CMIT MIT | Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) | preservative | 55965-84-9 | 611-341-5 | 0.00135 | 0.00135 |

#### Formulation type

| **Formulation(s)** |
| --- |
| Emulsion oil in water (ready to use or to be diluted in water) |

### Meta SPC 3 administrative information

#### Meta SPC 3 identifier

| **Identifier** | Meta-SPC 3 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |
| **Number** |  |

#### Product type

| **Product type** | PT08 |
| --- | --- |

### Meta SPC 3 composition

#### Qualitative and quantitative information on the composition of the meta SPC 3

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%) (technical)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Cypermethrin | (RS)-α-cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52315-07-8 | 257-842-9 | 0.11 | 0.11 |
| Propiconazole | 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole | Active substance | 60207-90-1 | 262-104-4 | 0.16 | 0.16 |
| Tebuconazole | (RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol. | Active substance | 107534-96-3 | 403-640-2 | 0.05 | 0.05 |
| IPBC | 3-iodo-2-propynyl butyl carbamate | Active substance | 55406-53-6 | 259-627-5 | 0.05 | 0.05 |
| BIT | 1,2-benzisothiazol-3(2H)-one | preservative | 2634-33-5 | 220-120-9 | 0.026 | 0.026 |
| CMIT MIT | Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) | preservative | 55965-84-9 | 611-341-5 | 0.00135 | 0.00135 |

#### Type of formulation of the meta SPC 3

| **Formulation** | Emulsion (oil in water) ready to use |
| --- | --- |
|  |  |

### Hazard and precautionary statements of the meta SPC 3

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr. 1  Aquatic acute 1  Aquatic chronic 1 |
| Hazard statement | H290: May be corrosive to metals  H400 – Very toxic to aquatic life  H410 – Very toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Pictograms | Résultat de recherche d'images pour "logo H410" |
| Hazard statements | H290: May be corrosive to metals  H410 – Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P273 – Avoid release to the environment  P501 - Dispose of content/container in accordance with local/ regional/national/international regulation (to be specified).  P391: collect spillage |
|  |  |
|  | |
| Note | X6119 M2:  EUH 208: Contains propiconazole, 1,2-benzisothiazolin-3-one 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one. May produce an allergic reaction. |

### Authorised use of the meta SPC 3

#### Use description

Use # 1 – Preventive treatment

|  |  |
| --- | --- |
| **Product Type** | PT08 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism(s) (including development stage)** | Wood rotting fungi (brown rot fungi) (on softwood and hardwood for UC 2 and on softwood in UC3.1)  Wood boring beetles (on softwood and hardwood)  House longhorn beetle (*Hylotrupes bajulus*) \_ Larvae  Common furniture beetle (*Anobium punctatum*) \_ Larvae  Powder post beetle (*Lyctus brunneus*) \_ Larvae  Termites (*Reticulitermes spp.,* in use classes 1 to 3.1 on softwood and hardwood,and *Heterotermes spp* in use classes 1 and 2 on softwood and hardwood)  Workers, soldiers and nymphs. |
| **Field(s) of use** | Preventive treatment in use classes 1 to 3.1. |
| **Application method(s)** | Superficial application / spray treatment  Superficial application / brush / roller / pad treatment |
| **Application rate(s) and frequency** | The treatment is performed by superficial application:  UC 1 to 3.1: 200 g product / m² of wood |
| **Category(ies) of users** | Professional and non-professional users |
| **Pack sizes and packaging material** | For professional users:  - 0.5 L and 2 L HDPE bottles  - 0.75 L and 1 L metal bottles (tin plate can with epoxy phenolic varnish)  - 1 L fluorinated HDPE bottles  - 2.5 L, 5 L and 6 L metal cans (tin plate can with epoxy phenolic varnish)  - 5 L, 6 L and 25 L HDPE jerry cans  - 25 L and 30 L metal pails (tin plate can with epoxy phenolic varnish)  - 30 L HDPE pails  - 200 L HDPE drums  - 1000 HDPE intermediate bulk containers.  For non professional users:  - 0.5 L and 2 L HDPE bottles  - 0.75 L and 1 L metal bottles (tin plate can with epoxy phenolic varnish)  - 1 L fluorinated HDPE bottles  - 2.5 L, 5 L and 6 L metal cans (tin plate can with epoxy phenolic varnish)  - 5 L and 25 L HDPE jerry cans  - 20 L, 24L, 25 L and 30 L metal pails (tin plate can with epoxy phenolic varnish) |

##### Use-specific instructions for use

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

##### Use-specific risk mitigation measures

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

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

#### Use description

Use # 2 – Curative treatment

|  |  |
| --- | --- |
| **Product Type** | 8 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** | Curative treatment for wood in service |
| **Target organism(s) (including development stage)** | Wood boring insects   * House longhorn beetle (*Hylotrupes bajulus*) \_ Larvae * Common furniture beetle (*Anobium punctatum*) \_ Larvae * Powder post beetles (*Lyctus brunneus*) \_ Larvae   Termites (*Reticulitermes spp.* et *Heterotermes spp.*)  Workers, soldiers and nymphs |
| **Field(s) of use** | Curative treatment for wood in service (wood not exposed to weathering and frequent wetting) softwood and hardwood |
| **Application method(s)** | Superficial application / brush / roller / pad  Superficial application / spray  Injection (combined with a superficial application) |
| **Application rate(s) and frequency** | The product is ready to use.  When the treatment is performed by superficial application, the application rate is :   * 300 g of product / m² of wood   When the application is performed by injection (combined with superficial application), the application rate is :   * 180 g of product / m² of wood (+ 300 g of product / m² of wood) |
| **Category(ies) of users** | Professional and non-professional users |
| **Pack sizes and packaging material** | For professional users:  - 0.5 L and 2 L HDPE bottles  - 0.75 L and 1 L metal bottles (tin plate can with epoxy phenolic varnish)  - 1 L fluorinated HDPE bottles  - 2.5 L, 5 L and 6 L metal cans (tin plate can with epoxy phenolic varnish)  - 5 L, 6 L and 25 L HDPE jerry cans  - 25 L and 30 L metal pails (tin plate can with epoxy phenolic varnish)  - 30 L HDPE pails  - 200 L HDPE drums  - 1000 HDPE intermediate bulk containers.  For non professional users:  - 0.5 L and 2 L HDPE bottles  - 0.75 L and 1 L metal bottles (tin plate can with epoxy phenolic varnish)  - 1 L fluorinated HDPE bottles  - 2.5 L, 5 L and 6 L metal cans (tin plate can with epoxy phenolic varnish)  - 5 L and 25 L HDPE jerry cans  - 20 L, 24L, 25 L and 30 L metal pails (tin plate can with epoxy phenolic varnish) |

##### Use-specific instructions for use

|  |
| --- |
| * Curative treatments performed by injection must always be combined with curative treatments applied by superficial application. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * **PROFESSIONAL USERS** For injection combined to brush application, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during injection. * **PROFESSIONAL USERS** For injection combined to spray application, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and coated coverall (category III type 6) during application by spraying and gloves during injection |

##### 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 of the meta SPC 3

#### Instructions for use

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

#### Risk mitigation measures

|  |
| --- |
| * Do not apply on wood likely to be in contact with food, feed, drinks and livestock. * **PROFESSIONAL USERS** For spray application, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and coated coverall (category III type 6) during application . |

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

|  |
| --- |
| * 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. * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Contact poison treatment specialist if symptoms occur. * 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: Wash out mouth with water. Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities. * Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately. * Keep the container or label available. |

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

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

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

|  |
| --- |
| * Shelf life: 24 months * Do not store at a temperature higher than 40°C * Protect from direct sunlight (except for can containers) |

### Other information

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

### Third information level: individual products in the meta SPC 3

#### Trade names, authorisation number and specific composition of each individual product

| **Trade name** | X6119M2  Bricorama Traitement Bois Extérieurs  Xylophene Curatif CE 2006  Xylophène Industrie Xylobati CE 2006  Bricorama Traitement Multi-Usages  Xylophène Multi-Usages  Xylophène Universel  Traitement du Bois Universel  Veraxyl Universel Traitement Du Bois  Xylophène Bois Extérieurs  Xylophene Expert Xylo Total  Xylophène Professionnel M2000  Colours Traitement Multi-Usages  Boisilor Traitement Multi-Usages  Inventiv' Protec Traitement Multi-Usages  Boisilor Traitement Bois Extérieurs  Xylophène Bois Extérieur  Traitement Bois Extérieur Nuance  Traitement Multi-Usages Nuance  Axton Traitement Universel  Flexell Traitement Universel  Xylophène Xylo Total  Xylophène Hydro, Spain  Bondex Tratamiento Multiuso Para Madera, Spain  Bondex Multitratamiento, Spain  Xylophène Hydro, Portugal  Bondex Tratamento Multi-Usos Para Madeira, Portugal  Tratamento Madeiras Exterior Nuance, Portugal  Tratamento  Multiusos Nuance, Portugal  Gori 11, Italy  Bondex Preserve III, Italy  Axton Trattamento Antitarlo Universale Interno & Esterno, Italy  Bondex Long Life Wood Preservative, Greece  Bondex Preserve III, Greece  ΘΕΡΑΠΕΙΑ ΞΥΛΟΥ ΓΙΑ ΕΣΩΤΕΡΙΚΗ/ΕΞΩΤΕΡΙΚΗ ΧΡΗΣΗ, Greece  Gori 11, Switzerland  Bondex Preserve III, Switzerland  Gori 11, UK  Madurox Sanio 3, Belgium  Madurox Sanio 3, Luxembourg  LAZURÁN OLDÓSZERMENTES FAANYAGVÉDŐ, Hungary  LAZURÁN OLDÓSZERMENTES FAANYAGVÉDŐ, Romania  BALAKRYL NAPOUŠTĚDLO, CZ Republic  BALAKRYL NAPOUŠTĚDLO, Slovakia  Bondex Preserve, Slovakia  Bondex Preserve III, Slovenia  Bondex Preserve III, Croatia | | | | |
| --- | --- | --- | --- | --- | --- |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%) (technical)** |
| Cypermethrin | (RS)-α-cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52315-07-8 | 257-842-9 | 0.11 |
| Propiconazole | 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole | Active substance | 60207-90-1 | 262-104-4 | 0.16 |
| Tebuconazole | (RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol. | Active substance | 107534-96-3 | 403-640-2 | 0.05 |
| IPBC | 3-iodo-2-propynyl butyl carbamate | Active substance | 55406-53-6 | 259-627-5 | 0.05 |
| BIT | 1,2-benzisothiazol-3(2H)-one | preservative | 2634-33-5 | 220-120-9 | 0.026 |
| CMIT MIT | Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) | preservative | 55965-84-9 | 611-341-5 | 0.00135 |
| 1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-C8-18(even numbered) acyl derivs., hydroxides, inner salts | 1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-C8-18(even numbered) acyl derivs., hydroxides, inner salts | Surfactant | 97862-59-4 | 931-296-8 | 0.0 |

### Meta SPC 4 administrative information

#### Meta SPC 4 identifier

| **Identifier** | Meta-SPC 4 |
| --- | --- |

#### Suffix to the authorisation number

|  |  |
| --- | --- |
| **Number** |  |

#### Product type

| **Product type** | PT08 |
| --- | --- |

### Meta SPC 4 composition

#### Qualitative and quantitative information on the composition of the meta SPC 4

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%) (technical)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Cypermethrin | (RS)-α-cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52315-07-8 | 257-842-9 | 0.11 | 0.11 |
| Propiconazole | 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole | Active substance | 60207-90-1 | 262-104-4 | 0.16 | 0.16 |
| Tebuconazole | (RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol. | Active substance | 107534-96-3 | 403-640-2 | 0.05 | 0.05 |
| IPBC | 3-iodo-2-propynyl butyl carbamate | Active substance | 55406-53-6 | 259-627-5 | 0.05 | 0.05 |
| BIT | 1,2-benzisothiazol-3(2H)-one | preservative | 2634-33-5 | 220-120-9 | 0.026 | 0.026 |
| CMIT MIT | Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) | preservative | 55965-84-9 | 611-341-5 | 0.00135 | 0.00135 |

#### Type of formulation of the meta SPC 4

| **Formulation** | Emulsion (oil in water) ready to use |
| --- | --- |
|  |  |

### Hazard and precautionary statements of the meta SPC 4

| **Classification** | |
| --- | --- |
| Hazard category | Met. Corr cat. 1  Aquatic acute 1  Aquatic chronic 1 |
| Hazard statement | H290: May be corrosive to metals  H400 – Very toxic to aquatic life  H410 – Very toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Pictogram | Résultat de recherche d'images pour "logo H410" |
| Hazard statements | H290: May be corrosive to metals  H410 – Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P273 – Avoid release to the environment  P501 - Dispose of content/container in accordance with local/ regional/national/international regulation (to be specified).  P391: Collect spillage |
|  | |
| Note | EUH 208: Contains propiconazole, 1,2-benzisothiazolin-3-one 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one. May produce an allergic reaction. |

### Authorised use of the meta SPC 4

#### Use description

Use # 1 – Preventive treatment-

|  |  |
| --- | --- |
| **Product Type** | PT08 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism(s) (including development stage)** | Wood rotting fungi (brown rot fungi) (on softwood and hardwood for UC 2 and on softwood for UC3.1)  Wood boring beetles (on softwood and hardwood)  House longhorn beetle (*Hylotrupes bajulus*) \_ Larvae  Common furniture beetle (*Anobium punctatum*) \_ Larvae  Powder post beetle (*Lyctus brunneus*) \_ Larvae  Termites (*Reticulitermes spp.* and *Heterotermes spp*) (on softwood and hardwood)  Workers, soldiers and nymphs. |
| **Field(s) of use** | Preventive treatment in use classes 1 to 3.1 |
| **Application method(s)** | Superficial application / spray treatment  Superficial application / brush / roller / pad treatment |
| **Application rate(s) and frequency** | The treatment is performed by superficial application:  UC 1 to 3.1: 200 g product / m² of wood |
| **Category(ies) of users** | Professional and non-professional users |
| **Pack sizes and packaging material** | For professional users:  - 1 L metal bottles (tin plate can with epoxy phenolic varnish)  - 5 L metal cans (tin plate can with epoxy phenolic varnish)  - 20 L metal pails (tin plate can with epoxy phenolic varnish).  For non professional users:  - 1 L metal bottles (tin plate can with epoxy phenolic varnish)  - 5 L and 6 L metal cans (tin plate can with epoxy phenolic varnish)  - 20 L and 24 L metal pails (tin plate can with epoxy phenolic varnish). |

##### Use-specific instructions for use

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

##### Use-specific risk mitigation measures

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

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

|  |
| --- |
|  |

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

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| --- |
|  |

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

|  |
| --- |
|  |

#### Use description

Use # 2 – Curative treatment

|  |  |
| --- | --- |
| **Product Type** | 8 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism(s) (including development stage)** | Wood boring insects   * Common furniture beetle (*Anobium punctatum*) \_ Larvae   Termites (*Reticulitermes spp.* et *Heterotermes spp.*)  Workers, soldiers and nymphs |
| **Field(s) of use** | Curative treatment for wood (wood not exposed to weathering and leaching) on softwood and hardwood |
| **Application method(s)** | Superficial application / brush / roller / pad  Superficial application / spray  Injection (combined with a superficial application) |
| **Application rate(s) and frequency** | The product is ready to use.  When the treatment is performed by superficial application, the application rate is :   * 300 g of product / m² of wood   When the application is performed by injection (combined with superficial application), the application rate is :   * 180 g of product / m² of wood (+ 300 g of product / m² of wood) |
| **Category(ies) of users** | Professional and non-professional users |
| **Pack sizes and packaging material** | For professional users  - 1 L metal bottles (tin plate can with epoxy phenolic varnish)  - 5 L metal cans (tin plate can with epoxy phenolic varnish)  - 20 L metal pails (tin plate can with epoxy phenolic varnish).  For non professional users  - 1 L metal bottles (tin plate can with epoxy phenolic varnish)  - 5 L and 6 L metal cans (tin plate can with epoxy phenolic varnish)  - 20 L and 24 L metal pails (tin plate can with epoxy phenolic varnish). |

##### Use-specific instructions for use

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| --- |
| * Curative treatments performed by injection must always be combined with curative treatments applied by superficial application. |

##### Use-specific risk mitigation measures

|  |
| --- |
| * PROFESSIONAL USERS: For injection combined to brush application, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during injection. * PROFESSIONAL USERS : For spray application, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and coated coverall (category III type 6) during application * PROFESSIONAL USERS: For injection combined to spray application, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and coated coverall (category III type 6) during application by spraying and gloves during injection. |

##### 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 of the meta SPC 4

#### Instructions for use

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

#### Risk mitigation measures

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

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

|  |
| --- |
| * 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. * Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Contact poison treatment specialist if symptoms occur. * 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: Wash out mouth with water. Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities. * Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately. * Keep the container or label available. |

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

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

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

|  |
| --- |
| * Shelf life: 24 months * Do not store at a temperature higher than 40°C |

### Other information

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

### Third information level: individual products in the meta SPC 4

#### Trade names, authorisation number and specific composition of each individual product

| **Trade name** | X6236  Xylophène Premium Gel Actif Monocouche Multi-Usages  Xylophène Hydro Gel, Spain  Xylophène Hydro Gel, Portugal  Gori 21, Greece | | | | |
| --- | --- | --- | --- | --- | --- |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%) (technical)** |
| Cypermethrin | (RS)-α-cyano-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52315-07-8 | 257-842-9 | 0.11 |
| Propiconazole | 1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl]-1H-1,2,4-triazole | Active substance | 60207-90-1 | 262-104-4 | 0.16 |
| Tebuconazole | (RS)-1-(4-chlorophenyl)-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol.Ratio (1:1) | Active substance | 107534-96-3 | 403-640-2 | 0.05 |
| IPBC | 3-iodo-2-propynyl butyl carbamate | Active substance | 55406-53-6 | 259-627-5 | 0.05 |
| BIT | 1,2-benzisothiazol-3(2H)-one | preservative | 2634-33-5 | 220-120-9 | 0.026 |
| CMIT MIT | Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) | preservative | 55965-84-9 | 611-341-5 | 0.00135 |
| 1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-C8-18(even numbered) acyl derivs., hydroxides, inner salts | 1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-C8-18(even numbered) acyl derivs., hydroxides, inner salts | Surfactant | 97862-59-4 | 931-296-8 | 0.0 |

### Packaging of the biocidal product

All packagings are hermetically closed with a cap.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Family group** | **Product** | **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Meta SPC1 | X6119CJ | Intermediate bulk containers | 1000L | HDPE | Industrial | Yes |
| X6119C | Drums  Intermediate bulk container | 50L and 200L  1000L | HDPE  HDPE | Industrial | Yes |
| Jerry cans | 5L | f-HDPE | Professional | Yes |
| Meta SPC2 | X6119C1 | drums | 200L | HDPE | Industrial | Yes |
| X6119B1 | Drums  Intermediate bulk containers | 200L  1000L | HDPE  HDPE | Industrial | Yes |
| Meta SPC3 | X6119CR | Pails  Sachets | 20L  20L | Tin plate pails with internal epoxyphenolic varnish  LDPE sachets  (packed in 20L tin plate pails with internal epoxyphenolic varnish pails) | Professional | Yes |
| X6119M2 | Bottles  Bottles  Bottles  Cans  Jerry cans  Pails  Pails  Drums  Intermediate bulk containers | 0.5 and 2L  0.75 and 1L  1L  2.5, 5 and 6L  5, 6 and 25L  25 and 30L  30L  200L  1000L | HDPE  Tin plate bottles with internal epoxyphenolic varnish  f-HDPE  Tin plate cans with internal epoxyphenolic varnish  HDPE  Tin plate pails with internal epoxyphenolic varnish  HDPE  HDPE  HDPE | Professional | Yes |
| Bottles  Bottles  Bottles  Cans  Jerry cans  pails | 0.5 and 2L  0.75 and 1L  1L  2.5, 5 and 6L  5 and 25L  20, 24, 25, 30L | HDPE  Tin plate bottles with internal epoxyphenolic varnish  f-HDPE  Tin plate cans with internal epoxyphenolic varnish  HDPE  Tin plate pails with internal epoxyphenolic varnish | Non professional | Yes |
| Meta-SPC4 | X6236 | Bottles  Cans  Pails | 1L  5L  20L | Tin plate bottles with internal epoxyphenolic varnish  Tin plate cans with internal epoxyphenolic varnish  Tin plate pails with internal epoxyphenolic varnish | Professional | Yes |
| Bottles  Cans  pails | 1L  5 and 6L  20 and 24L | Tin plate bottles with internal epoxyphenolic varnish  Tin plate cans with internal epoxyphenolic varnish  Tin plate pails with internal epoxyphenolic varnish | Non professional | Yes |

### Documentation

#### Data submitted in relation to product application

***Physico-chemistry***

Physico-chemical properties studies and analytical methods on the biocidal products X6119CJ, X6119C, X6119M2 and X6236 were provided by PPG. For others formulations, the applicant has submitted a bridging or reduced data. This point is discussed in each meta SPC.

***Efficacy:***

Data submitted in relation to product application

The following efficacy studies were submitted:

* For META SPC 1:
* Laboratory efficacy study conducted according to the standard EN 113[[2]](#footnote-2), with a 5 % v/v dilution of the product X6119CJ after ageing following EN 73[[3]](#footnote-3) (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 113, with a 5 % v/v dilution of the product X6119CJ after ageing following EN 84[[4]](#footnote-4) (leaching procedure);
* Laboratory efficacy study conducted according to the standard EN 118[[5]](#footnote-5), with a 5 % v/v dilution of the product X6119CJ, after ageing following EN 73 (evaporating procedure) against *Reticulitermes flavipes*;
* Laboratory efficacy study conducted according to the standard EN 118, with a 5 % v/v dilution of the product X6119CJ, after ageing following EN 84 (evaporating procedure) against *Reticulitermes flavipes*;
* Laboratory efficacy study conducted according to the standard EN 46-1[[6]](#footnote-6), with a 5 % v/v dilution of the product X6119CJ, after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 49-1[[7]](#footnote-7), with a 5 % v/v dilution of the product X6119CJ, after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 20-1[[8]](#footnote-8), with a 5 % v/v dilution of the product X6119CJ, after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 118[[9]](#footnote-9), with a 3 % v/v dilution of the product X6119C, after ageing following EN 73 (evaporating procedure) against *Reticulitermes flavipes*;
* Laboratory efficacy study conducted according to the standard EN 46-1[[10]](#footnote-10), with a 3 % v/v dilution of the product X6119C, after ageing following EN 73 (evaporating procedure);
* For META SPC 2:

No efficacy studies was conducted with products included in this META SPC

* For META SPC 3:
  + Laboratory efficacy study conducted according to the standard EN 113, with the product X6119M2 after ageing following EN 73 (evaporating procedure);
  + Laboratory efficacy study conducted according to the standard EN 113, with the product X6119M2 after ageing following EN 84 (leaching procedure);
  + Laboratory efficacy study conducted according to the standard EN 118, with the product X6119M2, after ageing following EN 73 (evaporating procedure) against *Reticulitermes flavipes*;
  + Laboratory efficacy study conducted according to the standard EN 118, with the product X6119M2, after ageing following EN 73 (evaporating procedure) against *Heterotermes tenuis*;
  + Laboratory efficacy study conducted according to the standard EN 118, with the product X6119M2, after ageing following EN 84 (evaporating procedure) against *Reticulitermes flavipes*;
  + Laboratory efficacy study conducted according to the standard EN 118, with the product X6119M2, after ageing following EN 84 (evaporating procedure) against *Heterotermes tenuis;*
  + Laboratory efficacy study conducted according to the standard EN 46-1, with the product X6119M2, after ageing following EN 73 (evaporating procedure);
  + Laboratory efficacy study conducted according to the standard EN 46-1, with the product X6119M2, after ageing following EN 84 (evaporating procedure);
  + Laboratory efficacy study conducted according to the standard EN 49-1, with the product X6119M2, after ageing following EN 73 (evaporating procedure);
  + Laboratory efficacy study conducted according to the standard EN 49-1, with the product X6119M2, after ageing following EN 84 (evaporating procedure);
  + Laboratory efficacy study conducted according to the standard EN 20-1, with the product X6119M2, after ageing following EN 73 (evaporating procedure);
  + Laboratory efficacy study conducted according to the standard EN 1390, with the product X6119M2;
  + Laboratory efficacy study conducted according to the standard EN 48, with the product X6119M2.
* For META SPC 4:
  + Laboratory efficacy study conducted according to the standard EN 113, with the product X6236 after ageing following EN 73 (evaporating procedure);
  + Laboratory efficacy study conducted according to the standard EN 113, with the product X6236 after ageing following EN 84 (leaching procedure);
  + Laboratory efficacy study conducted according to the standard EN 118, with the product X6236, after ageing following EN 73 (evaporating procedure) against *Reticulitermes flavipes*;
  + Laboratory efficacy study conducted according to the standard EN 118, with the product X6236, after ageing following EN 73 (evaporating procedure) against *Heterotermes tenuis*;
  + Laboratory efficacy study conducted according to the standard EN 118, with the product X6236, after ageing following EN 84 (evaporating procedure) against *Reticulitermes flavipes*;
  + Laboratory efficacy study conducted according to the standard EN 118, with the product X6236, after ageing following EN 84 (evaporating procedure) against *Heterotermes tenuis;*
  + Laboratory efficacy study conducted according to the standard EN 46-1, with the product X6236, after ageing following EN 73 (evaporating procedure);
  + Laboratory efficacy study conducted according to the standard EN 46-1, with the product X6236, after ageing following EN 84 (evaporating procedure);
  + Laboratory efficacy study conducted according to the standard EN 49-1, with the product X6236, after ageing following EN 73 (evaporating procedure);
  + Laboratory efficacy study conducted according to the standard EN 49-1, with the product X6236, after ageing following EN 84 (evaporating procedure);
  + Laboratory efficacy study conducted according to the standard EN 20-1, with the product X6236, after ageing following EN 73 (evaporating procedure);
  + Laboratory efficacy study conducted according to the standard EN 1390, with the product X6236;
  + Laboratory efficacy study conducted according to the standard EN 48, with the product X6236,

**Residues data**

No specific residue data were submitted in the context of this dossier. The product family PPG Class 3 WB is intended to be used as preventive and curative treatment of interior and exterior woods. It is not intended to be used on wood that can get into contact with food or feed. Therefore residues in food or feed are not expected. Considering the intended uses no data is required.

#### Access to documentation

PPG has access to analytical methods:

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

## Assessment of the biocidal product family

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

**Intended uses for Meta-SPC 1**

Use # 1 – Industry\_Preventive\_3% (X6119C)

|  |  |
| --- | --- |
| **Product Type** | PT08 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** | Concentrate product applied by short dipping, spraying, flow coat or aspersion (in an aspersion cabin). |
| **Target organism(s) (including development stage)** | Wood rotting basidiomycetes (brown rot fungi)  Wood boring insects, larvae  Subterranean termites (genus Reticulitermes), Workers, soldiers and nymphs |
| **Field(s) of use** | Softwood, solid wood  Preventive treatment  Use classes 1 and 2  Indoor |
| **Application method(s)** | Superficial application / short dipping treatment  Superficial application / spray treatment  Superficial application / flow coat / aspersion (aspersion cabin) |
| **Application rate(s) and frequency** | 3% dilution  150 g of diluted product/m² |
| **Category(ies) of users** | Industrial users |
| **Pack sizes and packaging material** | - 50 L and 200 L HDPE drums  - 1000 L HDPE intermediate bulk container.  All packagings are hermetically closed with a cap.  Specifications and description of these packagings are presented in Section 12.3 of the IUCLID file. |

Use # 2 – Industry\_Preventive\_5% (X6119C and X6119CJ)

|  |  |
| --- | --- |
| **Product Type** | PT08 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** | Concentrate products applied by short dipping, spraying, flow coat or aspersion (in an aspersion cabin). |
| **Target organism(s) (including development stage)** | Wood rotting basidiomycetes (brown rot fungi)  Wood boring insects (house longhorn beetle, common furniture beetle and powder post beetles), larvae  Subterranean termites (genus Reticulitermes), Workers, soldiers and nymphs |
| **Field(s) of use** | Softwood, solid wood  Preventive treatment  Use classes 1, 2 and 3.1  Indoor and Outdoor  Treated wood intended to be used outdoor and exposed to weathering must be protected with a topcoat. |
| **Application method(s)** | Superficial application / short dipping treatment (X6119C and X6119CJ)  Superficial application / spray treatment (X6119C)  Superficial application / flow coat / aspersion (aspersion cabin) (X6119C) |
| **Application rate(s) and frequency** | X6119C :  5% dilution  100 g of diluted product/m² against insects (use class 1)  150 g of diluted product/m² against insects and fungi (use classes 2 and 3.1)  X6119CJ :  5% dilution  150 g of diluted product/m² |
| **Category(ies) of users** | Industrial users |
| **Pack sizes and packaging material** | X6119C :  - 50 L and 200 L HDPE drums  - 1000 L HDPE intermediate bulk container  X6119CJ :  - 1000 L HDPE intermediate bulk container  All packagings are hermetically closed with a cap.  Specifications and description of these packagings are presented in Section 12.3 of the IUCLID file. |

**Table 4.1.3 Use # 3 – Professional\_Preventive\_5% (X6119C)**

|  |  |
| --- | --- |
| **Product Type** | PT08 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** | Concentrate product applied by brush / roller / pad or spray treatment |
| **Target organism(s) (including development stage)** | Wood rotting basidiomycetes (brown rot fungi)  Wood boring insects (house longhorn beetle, common furniture beetle and powder post beetles), larvae  Subterranean termites (genus Reticulitermes), Workers, soldiers and nymphs |
| **Field(s) of use** | Softwood, solid wood  Preventive treatment  Use classes 1, 2 and 3.1  Indoor and Outdoor  Treated wood intended to be used outdoor and exposed to weathering must be protected with a topcoat. |
| **Application method(s)** | Superficial application / brush / roller / pad treatment  Superficial application / spray treatment |
| **Application rate(s) and frequency** | 5% dilution  100 g of diluted product/m² against insects (use class 1)  150 g of diluted product/m² against insects and fungi (use classes 2 and 3.1) |
| **Category(ies) of users** | Professional users |
| **Pack sizes and packaging material** | - 5 L fluorinated HDPE jerry cans  All packagings are hermetically closed with a cap.  Specifications and description of these packagings are presented in Section 12.3 of the IUCLID file. |

Use # 4 – Professional\_Curative\_8.33% (X6119C)

|  |  |
| --- | --- |
| **Product Type** | PT08 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** | Concentrate product applied by brush / roller / pad or spray treatment. Can also be applied by injection (in combination with superficial application) |
| **Target organism(s) (including development stage)** | Wood boring insects (house longhorn beetle), larvae |
| **Field(s) of use** | Softwood and hardwood, solid wood  Curative treatment / wood in service  Indoor  Wood not exposed to weathering and leaching (risk class 2) |
| **Application method(s)** | Superficial application / brush / roller / pad treatment  Superficial application / spray treatment  Injection (in combination with superficial application) |
| **Application rate(s) and frequency** | 8.33% dilution  300 g of diluted product/m² (brush, roller, pad, spray)  180 g/m² of diluted product (20 mL per hole, 9 holes/m², for injection) |
| **Category(ies) of users** | Professional users |
| **Pack sizes and packaging material** | - 5 L fluorinated HDPE jerry cans  All packagings are hermetically closed with a cap.  Specifications and description of these packagings are presented in Section 12.3 of the IUCLID file. |

**Intended uses for Meta-SPC 2**

**Use # 1 – Industry\_Preventive (X6119C1, X6119B and X6119B1)**

|  |  |
| --- | --- |
| **Product Type** | PT08 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** | Concentrate products applied by short dipping, spraying, flow coat or aspersion (in an aspersion cabin). |
| **Target organism(s) (including development stage)** | Wood rotting basidiomycetes (brown rot fungi)  Wood boring insects (house longhorn beetle, common furniture beetle and powder post beetles), larvae  Subterranean termites (genus Reticulitermes), Workers, soldiers and nymphs |
| **Field(s) of use** | Softwood, solid wood  Preventive treatment  Use classes 1, 2 and 3.1  Indoor and Outdoor  Treated wood intended to be used outdoor and exposed to weathering must be protected with a topcoat. |
| **Application method(s)** | Superficial application / short dipping treatment (X6119B and X6119B1)  Superficial application / spray treatment (X6119B1)  Superficial application / flow coat / aspersion (aspersion cabin) (X6119C1) |
| **Application rate(s) and frequency** | X6119C1 :  5% dilution  150 g of diluted product/m²  X6119B1:  10% dilution  150 g of diluted product/m |
| **Category(ies) of users** | Industrial users |
| **Pack sizes and packaging material** | X6119C1 :  - 200 L HDPE drums.  X6119B1 :  - 200 L HDPE drums  - 1000 L HDPE intermediate bulk containers.  All packagings are hermetically closed with a cap.  Specifications and description of these packagings are presented in Section 12.3 of the IUCLID file. |

**Intended uses for Meta-SPC 3**

**Use # 1 – Preventive**

|  |  |
| --- | --- |
| **Product Type** | PT08 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** | Ready-for-use products applied by brush / roller / pad treatment or spray treatment. |
| **Target organism(s) (including development stage)** | Wood rotting basidiomycetes (brown rot fungi)  Wood boring insects (house longhorn beetle, common furniture beetle and powder post beetles), larvae  Subterranean termites (genus Reticulitermes), Workers, soldiers and nymphs |
| **Field(s) of use** | Softwood and hardwood (Use class 1), solid wood  Preventive treatment  Use classes 1, 2 and 3.1  Indoor and Outdoor  Treated wood intended to be used outdoor and exposed to weathering must be protected with a topcoat. |
| **Application method(s)** | Superficial application / brush / roller / pad treatment  Superficial application / spray treatment |
| **Application rate(s) and frequency** | 200 g product/m² |
| **Category(ies) of users** | Profesionnal (X6119CR, X6119M2 and X6236) and non-professional (X6119M2 and X6236) users |
| **Pack sizes and packaging material** | X6119CR:  - 20 L tin-plate pails with internal epoxyphenolic varnish  - 20 L LDPE sachets (packaged in 20 L tin-plate pails with internal epoxyphenolic varnish).    X6119M2:  - 0.5 L and 2 L HDPE bottles  - 0.75 L and 1 L tin-plate bottles with internal epoxyphenolic varnish  - 1 L fluorinated HDPE bottles  - 2.5 L, 5 L and 6 L tin-plate cans with internal epoxyphenolic varnish  - 5 L, 6 L and 25 L HDPE jerry cans  - 25 L and 30 L tin-plate pails with internal epoxyphenolic varnish  - 30 L HDPE pails  - 200 L HDPE drums  - 1000 HDPE intermediate bulk containers.  X6236:  - 1 L tin-plate bottles with internal epoxyphenolic varnish  - 5 L tin-plate cans with internal epoxyphenolic varnish  - 20 L tin-plate pails with internal epoxyphenolic varnish.  All packagings are hermetically closed with a cap. |

**Use # 2 – Curative (X6119CR, X6119M2 and X6236)**

|  |  |
| --- | --- |
| **Product Type** | PT08 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** | Ready-for-use products applied by brush / roller / pad treatment or spray treatment.  Also applied by injection, in combination with a superficial treatment. |
| **Target organism(s) (including development stage)** | Wood rotting basidiomycetes (brown rot fungi)  Wood boring insects (house longhorn beetle, common furniture beetle and powder post beetles), larvae  Subterranean termites (genus Reticulitermes), Workers, soldiers and nymphs |
| **Field(s) of use** | Softwood and hardwood (Use class 1), solid wood  Curative treatment / wood in service  Wood not exposed to weathering and leaching (risk class 2) |
| **Application method(s)** | Superficial application / brush / roller / pad treatment  Superficial application / spray treatment  Injection (in combination with superficial application) (not X6236) |
| **Application rate(s) and frequency** | Superficial application: 300 g product/m²  Injection: 180 g product/m² (20 mL per hole, 9 holes/m²) |
| **Category(ies) of users** | Professional (X6119CR, X6119M2 and X6236) and non-professional (X6119M2 and X6236) users |
| **Pack sizes and packaging material** | X6119CR:  - 20 L tin-plate pails with internal epoxyphenolic varnish  - 20 L LDPE sachets.    X6119M2 for professional users:  - 0.5 L and 2 L HDPE bottles  - 0.75 L and 1 L tin-plate bottles with internal epoxyphenolic varnish  - 1 L fluorinated HDPE bottles  - 2.5 L, 5 L and 6 L tin-plate cans with internal epoxyphenolic varnish  - 5 L, 6 L and 25 L HDPE jerry cans  - 25 L and 30 L tin-plate pails with internal epoxyphenolic varnish  - 30 L HDPE pails  - 200 L HDPE drums  - 1000 HDPE intermediate bulk containers.  X6119M2 for non-profesionnal users:  - 0.5 L and 2 L HDPE bottles  - 0.75 L and 1 L tin-plate bottles with internal epoxyphenolic varnish  - 1 L fluorinated HDPE bottles  - 2.5 L, 5 L and 6 L tin-plate cans with internal epoxyphenolic varnish  - 5 L and 25 L HDPE jerry cans  - 20 L, 24L, 25 L and 30 L tin-plate pails with internal epoxyphenolic varnish  X6236 for profesionnal users:  - 1 L tin-plate bottles with internal epoxyphenolic varnish  - 5 L tin-plate cans with internal epoxyphenolic varnish  - 20 L tin-plate pails with internal epoxyphenolic varnish.  X6236 for non-profesionnal users:  - 1 L tin-plate bottles with internal epoxyphenolic varnish  - 5 L and 6 L tin-plate cans with internal epoxyphenolic varnish  - 20 L and 24 L tin-plate pails with internal epoxyphenolic varnish  All packagings are hermetically closed with a cap. |

### Physical, chemical and technical properties

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

The biocidal family product Class 3 WB does not contain products which have already been assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC. The composition of the family product and of each product is confidential and is presented in a confidential annex. Active substances are supplied in premixes for cypermethrin and propiconazole. The contents of active ingredients can differ in each product. This is summarized in the following table.

Cypermethrin is already sold in the premix Cypress 50% PM (cypermethrin min 48%) and propiconazole in Wocosen 50TK (propiconazole min 50%).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Family group** | **product** | **Active substances** | **Content pure AI (% w/w)** | **Content technical AI (%w/w)** | **Purity of AI (%)** |
| Meta SPC1 | X6119CJ | Cypermethrin  IPBC  Propiconazole  Tebuconazole | 1.20  0.74  2.20  0.74 | 1.29  0.76  2.37  0.78 | 92  98  98  95 |
| X6119C | Cypermethrin  IPBC  Propiconazole  Tebuconazole | 1.20  0.74  2.20  0.74 | 1.29  0.76  2.37  0.78 | 92  98  98  95 |
| Meta SPC 2 | X6119C1 | Cypermethrin  IPBC  Propiconazole  Tebuconazole | 1.20  0.74  2.20  0.74 | 1.29  0.76  2.37  0.78 | 92  98  98  95 |
| X6119B1 | Cypermethrin  IPBC  Propiconazole  Tebuconazole | 0.60  0.37  1.10  0.37 | 0.65  0.38  1.18  0.39 | 92  98  98  95 |
| Meta SPC 3 | X6119CR | Cypermethrin  IPBC  Propiconazole  Tebuconazole | 0.10  0.05  0.15  0.05 | 0.11  0.05  0.16  0.05 | 92  98  98  95 |
| X6119M2 | Cypermethrin  IPBC  Propiconazole  Tebuconazole | 0.10  0.05  0.15  0.05 | 0.11  0.05  0.16  0.05 | 92  98  98  95 |
| X6236 | Cypermethrin  IPBC  Propiconazole  Tebuconazole | 0.10  0.05  0.15  0.05 | 0.11  0.05  0.16  0.05 | 92  98  98  95 |

The products contain conservatives which are authorised or currently assessed as PT6.

Formulation type: EW (to be diluted in water) or ready to used product

|  |  |  |  |
| --- | --- | --- | --- |
| **Family group** | **product** | **Use rates proposed** | **Method of application** |
| Meta SPC1 | X6119CJ | 5% in water | dipping |
| X6119C | 3 to 5% in water (only the use rate at 5% will be authorised) | Dipping, spraying, aspersion, injection, brush/roller/pad treatment |
| Meta SPC 2 | X6119C1 | 5% in water (product not authorised) | aspersion |
| X6119B1 | 10% in water | Dipping, spraying |
| Meta SPC 3 | X6119CR | Ready to use (product not authorised) | Brush/roller/pad treatment, spraying, injection |
| X6119M2 | Ready to use | Brush/roller/pad treatment, spraying, injection |
| X6236 | Ready to use | Brush/roller/pad treatment, spraying |

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

**Post authorisation data for PPG CLASS3 WB - 2021:**

*Following first authorisation of the family PPG CLASS3 WB, a post-authorisation requirement was identified regarding stability of IPBC on storage for products belonging to Meta SPC 1 and Meta SPC 2. According to the results provided for the first authorisation, X6119C was identified as a worst case and a new storage stability study for this product was requested in order to confirm the shelf life for products of Meta SPC 1 and Meta SPC 2. The applicant has informed ANSES that products X6119C and X6119CJ (Meta SPC 1) and X6119B1 (Meta SPC 2) will not be manufactured anymore and no further stability study was launched to cover the post authorisation data requirement. Furthermore, the applicant has stated that both Meta SPC 1 and Meta SPC 2 could be removed from the PPG\_Class 3\_WB family.*

**Physico-chemical properties**

**Meta SPC 1**

**Product X6119CJ (dilution rate: 5%w/w; packaging claimed: HDPE containers)**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa |  | X6119CJ  XIX 1 NDF  X6119C  PaP V 83.1 | opaque liquid  no deposit of phase partition was observed. | Acceptable | Legay S. 2013  13/1141F/ad  GLP  Simon, F. 2015  150313/PaPV93.2  GLP |
| Colour at 20 °C and 101.3 kPa | yellow |
| Odour at 20 °C and 101.3 kPa | detergent-like odour |
| Acidity / alkalinity | CIPAC MT 75.3 | X6119CJ  PaP V 83.1 | According to CIPAC MT 75.3, the mean pH value of X6119CJ at 1% in water was 5.87 at 19.1°C before the accelerated storage procedure and 5.47 at 20.2°C after the accelerated storage procedure. The pH value was considered to be stable after the accelerated storage procedure. | Acceptable | Legay S. 2015  402/14/1100F/abcdefg-e  GLP |
| Relative density / bulk density | OECD 109 | X6119CJ  PaP V 83.1 | According to OECD No.109 (pycnometers method), the mean relative density of X6119CJ was:  D (20.6°C / 4°C) = 1.042 | Acceptable | Legay S. 2015  402/14/1100F/hijkl-e  GLP |
| Storage stability test – **accelerated storage (8 weeks at 40°C)** | CIPAC MT 46.3 | X6119CJ  PaP V 83.1 | **Appearance**  The appearance of X6119CJ was slightly different after an accelerated storage procedure for 8 weeks at 40 ± 2°C.  - Changes in colour: from yellow opaque to orange opaque  - Changes in clarity: none  - Changes in texture: none  - Other changes: deposit and phase partition  **Packaging**  The appearance of the packaging material (5L bottle in HDPE) was considered to be stable after an accelerated storage procedure for 8 weeks at 40 ± 2°C. No significant weight change was observed (-0.04%). No sign of corrosion or degradation.  **pH (CIPAC MT 75.3)**  before storage: 5.87 (pure test item)  after storage 8 weeks at 40°C: 5.47 (pure test item)  The pH of the pure test item X6119CJ was considered to be stable after an accelerated storage procedure for 8 weeks at 40 ± 2°C with only a slight decrease of the pH value (- 0.40 pH units).  **Emulsion stability at 5%w/w (CIPAC MT 36.3)**  Before storage  Initial emulsification: uniform emulsion  Emulsion stability on standing: no free oil, cream, solid matter after standing for 30 min, 2h, 24h  Re-emulsification after standing for 24 h: no free oil, cream, solid matter after standing for 30 s;  uniform emulsion  Final emulsion stability: no free oil, cream, solid matter after standing for 30 min  **after storage**  Initial emulsification: uniform emulsion  Emulsion stability on standing: no free oil, cream after standing for 30 min, 2h, 24h; presence of solid matter after standing for 30 min, 2h, 24h;  Re-emulsification after standing for 24 h: no free oil, cream after standing for 30 s; presence of solid matter after standing for 30 s; uniform emulsion  Final emulsion stability: no free oil, cream after standing for 30 min ; presence of solid matter after standing for 30min  The emulsion characteristics and re-emulsification properties of X6119CJ diluted at 5% w/w in standard waters A and D were different before and after an accelerated storage procedure with the presence of solid matter after 8 weeks at 40 ± 2°C. This presence of solid matter was most probably due to the deposit observed in the concentrated product after the accelerated storage procedure.  **Persistent foaming (CIPAC MT 47.2) at 5% v/v**  Before storage: Volume of foam : 73 mL after 1 minute  After storage: Volume of foam : 72 mL after 1 minute  **Active ingredient contents (method validated; performed with inert packaging = glass bottle)**   |  |  |  | | --- | --- | --- | | **a.i content (%)** | **Initial** | **T 8 weeks at 40°C** | | **Cypermethrin** | 1.25 | 1.14 (-8.8%) | | **IPBC** | 0.70 | 0.67 (-4.3%) | | **Propiconazole** | 2.45 | 2.35 (-4.1%) | | **tebuconazole** | 0.72 | 0.70 (-2.8%) | | After storage, the product is not still homogeneous. Deposit is also noticed after re-emulsification (30min) which can be due to the colorants introduced. Therefore, the product must be stirred before and during application.  The volume of foam is not in acceptable limits before and after storage.The applicant states that “the product is used only by industrial users and dilutions are made automatically with devices such as Dosatrons without any direct handling by operators. Therefore, there is no mixing of the product in water in the dipping tank done by operators. No foam is produced in these conditions, very different from the conditions tested in the laboratory study mentioned. Mixing of the solution is achieved when the wood piles are dipped. The dipping is done with a conveyor with a trolley supporting the wood piles. The trolley can go down in the diluted product, and then up, and the wood piles drain on the tank. The wood piles are then coveyed on the drying area. At no time the operators are in close contact with the diluted product “.  Considering the application (dipping) and the fact that the conditions of the CIPAC test are very different from the ones in real conditions (no agitation), eCa considers that data are sufficient. Moreover no exposition is expected according to human health section.  The variation of cypermethrin content after storage 8 weeks at 40°C is higher than 5% but less than 10%. Degradation products were not identified by the applicant. However, after long term storage, no variation higher than 10% were observed for cypermethrin. Therefore this allows to confirm that the product remains stable. However it should be mentioned on the label to store the product below 40°C. | Legay S. 2015  402/14/1100F/abcdefg-e  GLP |
| Storage stability test – **long term storage at ambient temperature** | Technical Monograph 17 | X6119CJ  XIX 1 NDF | **Appearance**  The appearance of X6119CJ was considered to be stable after 6 and 12 months of storage at ambient temperature (liquid, opaque yellow). However phase separation was noticed, which disappear after shaking. After 18 and 24 months, the appearance of X6119CJ was a yellow and opaque liquid, without deposit nor partition.  **Packaging**  The appearance of the packaging material (5L HDPE packaging) was considered to be stable after 6, 12, 18 and 24 months of storage at ambient temperature (no sign of corrosion or degradation). No significant weight changes were observed (0% after 6 months, + 0.1% after 12 months, 0% after 18 months and 24months).  **Active ingredient contents (analytical method validated, HDPE packaging)**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **a.i content (%)** | **Initial** | **T6** | **T12** | **T18** | **T24** | | **Cypermethrin** | 1.248 | 1.153  (-7.6%) | 1.219  (-2.3%) | 1.170  (-6.3%) | 1.142  (-8.5%) | | **IPBC** | 0.695 | 0.612  (-11.9%) | 0.588  (-15.4%) | 0.686  (-1.3%) | 0.650  (-6.5%) | | **Propiconazole** | 2.265 | 2.150  (-5.1%) | 2.163  (-4.5%) | 2.253  (-0.5%) | 2.257  (-0.4%) | | **tebuconazole** | 0.774 | 0.76  (-1.8%) | 0.777  (+0.4%) | 0.718  (-7.2%) | 0.744  (-3.9%) |   The samples of X6119CJ stored after 6 and 12 months were analysed for IPBC and PBC contents by another facility (Danish technological institute). Content of IPBC was found to be 0.74%w/w while PBC content was always found below 0.01%w/w.  **pH value**  before storage: 6.2 at 18.7°C  after 24 months: 5.7 at 19.1°C  **Emulsion stability at 5%w/w (CIPAC MT 36.3)**  Before storage  Initial emulsification: uniform emulsion  Emulsion stability on standing: no free oil, cream, solid matter after standing for 30 min, 2h, 24h  Re-emulsification after standing for 24 h: no free oil, cream, solid matter after standing for 30 s;  uniform emulsion  Final emulsion stability: no free oil, cream, solid matter after standing for 30 min  after storage 24 months at ambient temperature  Initial emulsification: uniform emulsion  Emulsion stability on standing: no free oil, cream after standing for 30 min, 2h, 24h; slight deposit after standing for 2h, 24h;  Re-emulsification after standing for 24 h: no free oil, cream but a slight deposit (solid matter) after standing for 30 s; uniform emulsion  Final emulsion stability: no free oil, cream after standing for 30 min but a slight deposit (solid matter)  **Persistent foaming at 5%w/w (CIPAC MT 47.2)**  Before storage: Volume of foam : 73 mL after 1 minute  After storage 24 months at ambient temperature: Volume of foam : 40 mL after 1 minute (69mL after 10s) | Since a phase partition is sometimes observed, it should be mentioned to stir the product before using. Deposit is also noticed after emulsion stability test and remains 30min after re-emulsification. This may be due to the colorant introduced. In order to get a homogeneous application, the product should be stirred during applicantion.  The volume of foam is not in acceptable limits before storage. Based on the previous explanation (see accelerated storage), no further data are required.    The variations of IPBC content after 6 and 12 months are higher than 10% while variations are in acceptable limits after 18 and 24 months. The applicant asked another laboratoty to demonstrate that IPBC was converted into PBC. Nevertheless, results given with the Danish Institute were not in accordance with results obtained by FCBA. IPBC was found stable and no PBC was detected. No validation data were provided by the Danish Institute. The applicant states that difference observed between the two facilities can be explained by the instability of the ratio IPBC/PBC in the product.  **eCA considers that this answer is not sufficient and that the results are not reliable. Results provided do not allow to conclude on the stability of IPBC since variations are not coherent with a possible degradation of the active substance.**  **According to the results of the accelerated storage, a two year shelf life is acceptable. Since results for other active substances are also acceptable after 24 months, shelf life is also supported. However, in order to confirm stability for IPBC, a new shelf life is required in post authorisation.** | Legay S, 2016  report 402/13/1141F/ad-e  GLP |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 | X6119CJ  PaP V 83.1 | **Appearance**  The test item was physically stable after storage at 0 ± 2°C for 7 days in HDPE bottle (5L). No deposit or phase partition was observed.  **Emulsion stability at 3% w/w and 8.33% w/w after low storage (CIPAC MT 36.3)**  Initial emulfisication:uniform emulsion  Emulsion stability on standing:no free oil, cream, solid matter after standing for 30min, 2h, 24h  Re-emulsificaiton after standing for 24h: no free oil, cream, solid matter after standing for 30s, uniform emulsion  Final emulsion stability: no free oil, cream, solid matter after standing for 30min  The emulsions at 3 and 8.33% w/w in standard waters A and D were considered to be stable after storage at 0 ± 2°C for 7 days. | Acceptable. The product is stable after 7 days at 0°C. | Legay S. 2015  402/14/1100F/hijkl-e  GLP |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Justification for non submission proposed by the applicant:  Not required as the biocidal product is packed in opaque commercial packagings. | Not acceptable. Packaging are not considered to be barrier to light. Since cypermethrin is sensitive to sunlight (DT50 photostability in water: 12.4-14.8d), it is recommended to store the product away from light. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | The test item X6119CJ was considered to be stable after 8 weeks at 40 ± 2°C regarding the active substances contents except for cypermethrin for which the variation was between 5 and 10%. However after long term storage, cypermethrin contents remains in acceptable limits (variations <10%) indicating that the product is stable.  After 6 and 12 months, variations of active ingredient contents are in acceptable limits except for IPBC. After 18 and 24 months, IPBC was stable.    The test item X6119CJ was considered to be stable after 7 days at 0 ± 2°C.  The individual commercial packagings are hermetically closed with a cap. With their closure systems, the packagings are leak-tight. | The product was considered stable after 8 weeks at 40°C.  **According to the results of the accelerated storage, a two year shelf life is acceptable. Since results for other active substances are also acceptable after 24 months, shelf life is also supported. However, in order to confirm the stability of IPBC, a new shelf life is required in post authorisation. See previous comment in shelf life section.**  The product is considered stable after 7 days at 0°C. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | The product is compatible with HDPE packaging as demonstrated during the storage stability. | Acceptable. |  |
| Wettability |  |  | Not applicable | Not relevant |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not applicable | Not relevant |  |
| Wet sieve analysis and dry sieve test |  |  | Not applicable | Not relevant |  |
| Emulsifiability, re-emulsifiability and emulsion stability | CIPAC MT 36.3 | X6119CJ  PaP V 83.1 | **At 5% w/w in standard waters A and D at 20 ± 2°C:**  Initial emulsification: uniform emulsion  Emulsion stability on standing: no free oil, cream, solid matter after standing for 30 min, 2h, 24h  Re-emulsification after standing for 24 h: no free oil, cream, solid matter after standing for 30 s; uniform emulsion  Final emulsion stability: no free oil, cream, solid matter after standing for 30 min | Acceptable. | Legay S. 2015  402/14/1100F/abcdefg-e  Legay S. 2015  402/14/1100F/hijkl-e  GLP |
| Disintegration time |  |  | Not applicable | Not relevant |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not applicable | Not relevant |  |
| Persistent foaming | CIPAC MT 47.2 | X6119CJ  PaP V 83.1 | The persistent foaming of X6119CJ was determined according to CIPAC MT 47.2 method (5% w/w in standard water D).  The volume of foam produced after 30 inversions of the test item at 20 ± 2°C was:  - at initial time : 73 mL after 1 min of standing | The volume of foam is not in acceptable limits. The applicant states that “the product is used only by industrial users and dilutions are made automatically with devices such as Dosatrons without any direct handling by operators. Therefore, there is no mixing of the product in water in the dipping tank done by operators. No foam is produced in these conditions, very different from the conditions tested in the laboratory study mentioned. Mixing of the solution is achieved when the wood piles are dipped. The dipping is done with a conveyor with a trolley supporting the wood piles. The trolley can go down in the diluted product, and then up, and the wood piles drain on the tank. The wood piles are then coveyed on the drying area. At no time the operators are in close contact with the diluted product “.  Considering the application (dipping) and the fact that the conditions of the CIPAC test are very different from the ones in real conditions (no agitation), eCa considers that data are sufficient. Moreover exposition is acceptable with the wear of personal protective equipements as recommended by human health section. | Legay S. 2015  402/14/1100F/abcdefg-e  GLP |
| Flowability/Pourability/Dustability |  |  | Not applicable | Not relevant |  |
| Burning rate — smoke generators |  |  | Not applicable | Not relevant |  |
| Burning completeness — smoke generators |  |  | Not applicable | Not relevant |  |
| Composition of smoke — smoke generators |  |  | Not applicable | Not relevant |  |
| Spraying pattern — aerosols |  |  | Not applicable | Not relevant |  |
| Physical compatibility |  |  | Not applicable. The product is not intended to be used in conjunction with any other products or active substances. Hence, no data on the physical and chemical compatibility of X6119CJ with other biocidal products, chemicals or active substances is required. | Not applicable. |  |
| Chemical compatibility |  |  | Not applicable. The product is not intended to be used in conjunction with any other products or active substances. Hence, no data on the physical and chemical compatibility of X6119CJ with other biocidal products, chemicals or active substances is required. | Not applicable. |  |
| Degree of dissolution and dilution stability |  |  | Not applicable | Not relevant for EW formulation. |  |
| Surface tension | OECD 115 and E.U method A.5 | X6119CJ  PaP V 83.1 | According to EC A.5 and OECD No.115 (ring method), X6119CJ was considered as surface-active (mean surface tension at 20.1°C of the pure test item: 29.72 mN/m). | Acceptable. The product is surface active. | Legay S. 2015  402/14/1100F/hijkl-e  GLP |
| Viscosity | OECD 114 | X6119CJ  PaP V 83.1 | The test item showed a non-Newtonian behaviour both at 20 and 40 ± 0.2°C using a rotational viscometer Brookfield.  The dynamic viscosity varied as follows:  - at 20.0 ± 0.2°C, from 720.0 mPa\*s at 0.3 rpm to 165.6 mPa\*s at 30 rpm.  - at 40.0 ± 0.2°C, from 520.0 mPa\*s at 0.3 rpm to 87.2 mPa\*s at 30 rpm. | Acceptable. The product is a non Newtonien fluid. | Legay S. 2015  402/14/1100F/hijkl-e  GLP |

**Physical hazards and respective characteristics of X6119CJ**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | DSC and theorical assessment | X6119CJ  PaP V 83.1 | According to Differential Scanning Calorimetry (DSC) graphs, no exothermic reaction was observed in the temperature range from 20°C to 500°C. Therefore, the test item is unlikely to be explosive and the test on explosive properties according to UN Test series 1 to 3 described in Part I of the UN-MTC should not be performed.  According to the evaluation of propiconazole, cypermethrin cis:trans / 40:60, tebuconazole and IPBC under Biocidal Products Directive, these active substances (4.88% w/w total) have no potential explosive properties.  Based on data available in literature, safety data sheet and/or on their structure, 21.11% of formulants are not expected to be explosive.  The product X6119CJ contains 42.57% w/w of an inert ingredient.  Data are lacking to conclude on the explosive properties of some formulants (4.00% w/w total).  According to data available in literature, safety data sheet and/or on their structure, all other ingredients (27.44% w/w total) have potential explosive properties.  However, the Differential Scanning Calorimetry (DSC) graphs do not show any exothermic decomposition, what demonstrates that the product X6119CJ is unlikely to be explosive, and testing is considered as unnecessary. | Acceptable. No exothermic reaction has been noticed during the DSC analysis. The product is not explosive. | Raphalen E., Legay S. 2015  402/14/1100F/m-e  Detrimont H., Ambrosi D. 2015 |
| Flammable gases |  |  | Not applicable | Not applicable |  |
| Flammable aerosols |  |  | Not applicable | Not applicable |  |
| Oxidising gases |  |  | Not applicable | Not applicable |  |
| Gases under pressure |  |  | Not applicable | Not applicable |  |
| Flammable liquids | EEC A.9 (closed cup) | X6119CJ  PaP V 83.1 | According to EC A.9 method (Pensky-Martens apparatus), the product X6119CJ is not flammable (flash point: 94.4 deg C). | Acceptable. The product is not flammable. | Legay S. 2015  402/14/1100F/hijkl-e  GLP |
| Flammable solids |  |  | Not applicable | Not applicable |  |
| Self-reactive substances and mixtures | D.S.C. | X6119CJ  PaP V 83.1 | Based on most recent approach of structural formulas, (2-methoxymethylethoxy)propanol, some formulants (22.57% w/w total) are not considered to have potential self-reactive properties unlike the components propiconazole, cypermethrin cis:trans / 40:60, tebuconazole, IPBC and one formulant (8.38% w/w total).  Data are lacking to conclude on the self-reactivity some compounds (26.48% w/w total).  The product X6119CJ contains 42.57% w/w of inert ingredient.  However, according to Regulation (EC) No.1272/2008, homogeneous mixtures of organic substances should be considered for classification in this hazard class unless their exothermic decomposition energy is less than 300 J/g. As no exothermic reaction was observed in the temperature range used from 20°C to 500°C (DSC graphs), testing is considered as unnecessary | Acceptable. No exothermic reaction has been noticed during the DSC analysis. The product is not considered as self reactive. | Raphalen E., Legay S. 2015  402/14/1100F/m-e  Detrimont H., Ambrosi D. 2015  15/04 |
| Pyrophoric liquids |  |  | Not required as X6119CJ contains around 43% w/w water and as experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperature | Acceptable. |  |
| Pyrophoric solids |  |  | Not applicable | Not applicable |  |
| Self-heating substances and mixtures |  |  | No test was provided. | Not acceptable. Nevertheless, accoding to the composition, the product is not expected to be a self heating liquid. |  |
| Substances and mixtures which in contact with water emit flammable gases |  |  | Not required as X6119CJ contains around 43% w/w water. | Acceptable. |  |
| Oxidising liquids | method O.2 (Part III, section 34.4.2, United Nations Recommendations on the Transport of Dangerous Goods - Manual of Tests and Criteria - Fifth revised edition (2009)) | X6119CJ  PaP V 83.1 | Considering the proportion of components with unknown properties (about 26.5% w/w total), it is not possible to conclude regarding oxidising properties of X6119CJ, and testing is considered as necessary.  A study according to method O.2 (Part III, section 34.4.2, United Nations Recommendations on the Transport of Dangerous Goods - Manual of Tests and Criteria - Fifth revised edition (2009)) was performed.  The test item is mixed in a ratio 1 to 1 by weight with dried fibrous cellulose and introduced into a pressure vessel. If during mixing or filling spontaneous ignition occurs, no further testing is necessary and the test item is considered as an oxidizer.  If spontaneous ignition does not occur, the full test is carried out. The mixture is heated in a pressure vessel and the mean time taken for the pressure to rise from 690 kPa to 2070 kPa above atmospheric pressure is determined. This is compared with the mean pressure rise time of three reference substances, each one mixed in 1:1 proportion with the dried fibrous cellulose. According to the pressure rise times obtained, the test item is classified in different packing groups.  **Mean pressure rise time for reference items:**  50% perchloric acid solution/cellulose: 105ms  40% aqueous sodium chlorate solution/cellulose: 1015ms  65% aqueous nitric acid solution/cellulose: 3012ms  **Mean pressure rise time for test item:**  For one assay, the pressure rise time from atmospheric pressure to 2070 kPa was 35014ms. For 4 other essays, no pressure rise time obtained with the test item / cellulose mixture was recorded. Therefore, the product is not considered as oxidizing. | Acceptable. The product has no oxidizing properties. | Demangel B. 2015  15-904015-001  Detrimont H., Ambrosi D. 2015  15/04 |
| Oxidising solids |  |  | Not applicable | Not applicable |  |
| Organic peroxides |  |  | Not applicable | Not applicable |  |
| Corrosive to metals |  |  | As the product X6119CJ contains an ingredient which is classified as corrosive and as no C1 test according to UN RTDG has been performed, the product X6119CJ is classified as corrosive to metals, Met. Corr. 1, H290. | Acceptable. The product is classified by default corrosive to metals H290 Corr.1. |  |
| Auto-ignition temperatures of products (liquids and gases) | EU A15 | X6119CJ  XIX 1 NDF | The mean auto-ignition temperature of the test item was 445 ± 6°C. | Acceptable. The product is not auto flammable up to 445°C. | Demangel B. 2014  14-904015-003  GLP |
| Relative self-ignition temperature for solids |  |  | Not applicable | Not applicable |  |
| Dust explosion hazard |  |  | Not applicable | Not applicable |  |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product X6119CJ** |
| The formulation X6119CJ is an emulsion oil in water (EW) formulation. All studies have been performed in accordance with the current requirements. The appearance of the product is that of yellow opaque liquid, with a detergent like odour. It is not explosive and has no oxidizing properties. The product is not considered flammable and has a flash point of 94.4°C. It is not auto-flammable in the conditions of use (temperature of auto-ignition: 445°C). The preparation is classified by default corrosive to metals H290 Corr. 1. The pH of the neat formulation is 5.87 at 20°C. The viscosity of the product at 20°C is from 720mPa.s (0.3RPM) to 165.6mPa.s (30RPM).  There is an effect of high temperature on the stability of the formulation since after 8 weeks at 40°C in HDPE container, the active ingredient content of cypermethrin decreased from more 8.8%. Degradation products were not identified. However, after 2 years storage at ambient temperature, variations of cypermethrin content remain below 10% and allow to confirm that the product can be considered stable regarding cypermethrin content. Other active substance contents and technical properties were unchanged. Only the appearance of the formulation changes after storage (phase partition and slight deposit after emulsion and re-emulsification test) and it is recommended to stirr the product before and during application. It should also be indicated on the label that the product should be stored below 40°C.  There is no effect of low temperature on the stability of the formulation since after 7 days at 0°C, there are no modification of the properties of the product.  Emulsion stability and re-emulsification at 5%w/w have been provided and demonstrate that the product forms stable emulsions. Persitent foaming at 5% w/w is not acceptable since more than 60mL of foam are formed. However, the applicant has provided further details on the application of the product (dilution of the product using dosatron system, without any contact of the solution with operators, and then dipping of the wood into tanks). Moreover, conditions of the CIPAC method are different from the ones in real conditions (no agitation) and exposition is acceptable with the wear of personal protective equipments as recommended by human health section. Therefore, eCA considers that data provided are sufficient to cover this issue.  Results of the shelf life study of the formulation X6119CJ in HDPE packaging were provided after 6, 12, 18 and 24 months. Content of propiconazole, cypermethrin and tebuconazole were stable on storage. However, IPBC contents at intermediate times (6 and 12 months) were not in accordance with results obtained at 18 and 24 months. For the two first intermediate points, variations were higher than 10% but this was not the case after 18 and 24 months. Samples stored 6 and 12 months were analysed a second time, not under GLP, with another test facility (DTI), providing inconsistent results with the previous one (FBCA) obtained under GLP. Indeed, DTI concludes that no degradation occured in samples: IPBC remained stable and no PBC was found. **eCA considers that results provided do not allow to conclude on the stability of IPBC since variations are not coherent with a possible degradation of the active substance. According to the results of the accelerated storage, a two year shelf life is acceptable. Since results for other active substances are also acceptable after 24 months, shelf life is also supported. However, in order to confirm the stability of IPBC, a new shelf life is required in post authorisation.**  Compatibility has been demonstrated with HDPE packaging during the long term storage stability, no further data are required.  Effect of light has not been studied. Packagings made of HDPE are not considered to be barrier to light. Since cypermethrin is sensitive to sunlight (DT50 (photostability in water: 12.4-14.8d), it is recommended to store the product away from light.  Its technical characteristics are acceptable for an emulsion formulation. |

**Product X6119C (dilution rate: 3 to 5%; packaging claimed: HDPE and HDPE-f containers, only dilution rate at 5% is authorised)**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa |  | X6119C  XIX 2 NDF  X6119C  1502700018 | Translucent liquid  No deposit of phase partition was observed. | Acceptable | Legay S. 2013  13/1136F/cd  GLP  Simon, F. 2015  150313/PaPV93.1  GLP |
| Colour at 20 °C and 101.3 kPa | yellow |
| Odour at 20 °C and 101.3 kPa | detergent-like odour |
| Acidity / alkalinity | CIPAC MT 75.3 | X6119C  XIX 2 NDF | the mean pH value of X6119C (pure) was 7.53 at 19.0°C before the long term storage procedure. | Acceptable | Legay S. 2013  13/1136F/cd  GLP |
| Relative density / bulk density | OECD 109 | X6119C  1502700018 | According to OECD No.109 (pycnometers method), the mean relative density of X6119C was:  D (20.9°C / 4°C) = 1.036 | Acceptable | Legay S 2015  402/14/1099F/a-e  GLP |
| Storage stability test – **accelerated storage (8 weeks at 40°C)** |  |  | No results were provided. The products X6119C and X6119CJ have very close compositions, only the dye present in product X6119CJ is replaced by an inert ingredient in product X6119C. Therefore, the storage stability of X6119C, after 8 weeks at 40 °C, is expected to be the same as the storage stability of X6119CJ. | The bridging is not acceptable.  However, after long term storage of formulation X6119C, results are different from the one expected. Variations of cypermethrin content in X6119CJ after storage 8 weeks at 40°C is higher than 5% but below 10%. Stability in formulation X6119C is not confirmed since after 18 and 24 months storage, content of cypermethrin is higher than 10% and the decrease is linear. Therefore, eCA considers that extrapolation cannot be made between both formulations without explanations. The product X6119C should not be stored at a temperature higher than 22°C (maximum temperature tested during shelf life study).  Persistent foaming and emulsion stability have been performed at 3 and 8.33% w/w during the long term storage stability. | **/** |
| Storage stability test – **long term storage at ambient temperature** | Technical Monograph 17 | X6119C  XIX 2 NDF | **Appearance**  The appearance of X6119C was considered to be stable after 6, 12, 18 and 24 months of storage at ambient temperature (liquid, translucent yellow-orange).  **Packaging**  The appearance of the packaging material (5L HDPE and f-HDPE packaging) was considered to be stable after 6, 12, 18 and 24 months of storage at ambient temperature (no sign of corrosion or degradation). No significant weight changes were observed (0% after 6 months, + 0% after 12 months, 0.04% after 18 months and -0.06% 24months).  **Active ingredient contents (analytical method validated)**  **HDPE packaging**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **a.i content (%)** | **Initial** | **T6** | **T12** | **T18** | **T24** | | **Cypermethrin** | 1.210 | 1.12  (-7.6%) | 1.10  (-8.3%) | 1.052  (-13.1%) | 1.018  (-15.9%) | | **IPBC** | 0.751 | 0.757  (+0.8%) | 0.667  (-11.2%) | 0.697  (-7.2%) | 0.567  (-24.5%) | | **Propiconazole** | 2.216 | 2.16  (-2.5%) | 2.104  (-5.1%) | 2.135  (-3.7%) | 2.237  (+0.95%) | | **tebuconazole** | 0.781 | 0.753  (-3.6%) | 0.729  (-6.7%) | 0.723  (-7.4%) | 0.774  (-0.90%) |   The sample of X6119C stored after 12 months was analysed for IPBC and PBC contents by another facility (Danish technological institute). Content of IPBC was found to be 0.74%w/w while PBC content was always found below 0.01%w/w.  **f-HDPE packaging**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **a.i content (%)** | **Initial** | **T6** | **T12** | **T18** | **T24** | | **Cypermethrin** | 1.210 | 1.111  (-8.2%) | 1.128  (-6.8%) | 1.059  (-12.5%) | 1.030  (-14.9%) | | **IPBC** | 0.751 | 0.708  (-5.7%) | 0.701  (-6.7%) | 0.697  (-7.2%) | 0.581  (-22.6%) | | **Propiconazole** | 2.16 | 2.159  (-2.6%) | 2.126  (-4.1%) | 2.131  (-3.8%) | 2.239  (+1.0%) | | **tebuconazole** | 0.781 | 0.751  (-3.8%) | 0.736  (-5.8%) | 0.722  (-7.6%) | 0.778  (-0.4%) |   The sample of X6119C stored after 12 months was analysed for IPBC and PBC contents by another facility (Danish technological institute). Content of IPBC was found to be 0.74%w/w while PBC content was always found below 0.01%w/w.  **pH value**  before storage: 7.5 at 19.0°C  after 24 months: 6.8 at 18.9°C  **Emulsion stability (CIPAC MT 36.3)**  After 6 months at ambient temperature  At 5%w/w  Initial emulsification: uniform emulsion  Emulsion stability on standing: no free oil, cream, solid matter after standing for 30 min, 2h, 24h  Re-emulsification after standing for 24 h: no free oil, cream, solid matter after standing for 30 s; uniform emulsion  Final emulsion stability: no free oil, cream, solid matter after standing for 30 min  after storage 24 months at ambient temperature   * at 3%w/w   Initial emulsification: uniform emulsion  Emulsion stability on standing: no free oil, cream , solide after standing for 30 min, 2h, 24h  Re-emulsification after standing for 24 h: no free oil, cream, solid matter after standing for 30 s; uniform emulsion  Final emulsion stability: no free oil, cream, solid matter after standing for 30min   * at 8.33%w/w   Initial emulsification: uniform emulsion  Emulsion stability on standing: no free oil, cream , solide after standing for 30 min, 2h, 24h  Re-emulsification after standing for 24 h: no free oil, cream, solid matter after standing for 30 s; uniform emulsion  Final emulsion stability: no free oil, cream, solid matter after standing for 30min  **Persistent foaming (CIPAC MT 47.2)**  After 6 months at ambient temperature and at 5%w/w: Volume of foam : no foam after 1 min  After storage 24 months at ambient temperature, at 3% and 8.33% w/w : Volume of foam : no foam observed after 1 min. | Cypermethrin content decreases linearly from t0 to t24 months. Results are only acceptable up to 12 months storage. Such loss was not observed for the colouring version (X6119CJ) and for other products of the family (containing lower content of cypermethrin). The applicant has explained this specific loss in X6119C due to the pH of this product which is slightly higher than for other products of the family. According to the assessment report, cypermethrin is degraded slightly under neutral conditions (major metabolites are DCVC acid and 3-PBA). This may explain the difference with other products.  The variation of IPBC content after 12 and 24 months is higher than 10% while variations were in acceptable limits after 6 and 18 months. The applicant asked another laboratoty to demonstrate that IPBC was converted into PBC. Nevertheless, results given with the Danish Institute were not in accordance with results obtained by FCBA. IPBC was found stable after 12 months storage and no PBC was detected. It should be noted that no validation data were provided by the Danish Institute. The applicant states that difference observed between the two facilities can be explained by the instability of the ratio IPBC/PBC in the product.  **eCA considers that this answer is not sufficient and that the results are not reliable. Results provided do not allow to conclude on the stability of IPBC since variations are not coherent with a possible degradation of the active substance.**  **According to the results obtained for other active substances, only a 12 months shelf life can be granted. However, in order to confirm stability for IPBC, a new shelf life is required in post authorisation.**  Technical properties were tested at 5%w/w after 6months and at 3 and 8%w/w after 24 months and found acceptable.  Persistent foaming results are very different between formulations X6119C and X6119CJ. The applicant explains that these differences are due to the foaming properties of colouring agent premix (containing 8% of dispersing agent) which are not present in formulation X6119C. | Legay S, 2016  Report 402/13/1136F/cd-e  GLP |
| Storage stability test – **low temperature stability test for liquids** |  |  | The product X6119C has the same composition than X6119CJ without colouring agents which are replaced by an inert ingredient.  Considering that the major change is the suppression of colouring agents in the product X6119C, and that this change does not affect the emulsion stability, it is not expected that the composition change has any significant impact on the physical stability after 7 days at 0 °C.  Therefore, the storage stability of X6119C, after 7 days at 0 °C, is expected to be the same as the storage stability of X6119CJ. | The bridging is acceptable. The formulation X6119C is considered stable after low temperature storage. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Justification for non submission proposed by the applicant:  Not required as the biocidal product is packed in opaque commercial packagings. | Not acceptable. Packaging are not considered to be barrier to light. Since cypermethrin is sensitive to sunlight (DT50 (photostability in water: 12.4-14.8d) , it is recommended to store the product away from light. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | The test item X6119CJ was considered to be stable after 8 weeks at 40 ± 2°C regarding the active substances contents except for cypermethrin for which the variation was between 5 and 10%. However after long term storage, cypermethrin content remains in acceptable limits (variations <10%) indicating that the product is stable.  After 24 months storage of the product X6119C, variations of active ingredient contents are in acceptable limits except for cypermethrin after 18 months and 24 months and for IPBC after 12 and 24 months. The content of cypermethrin decreases linearly from t0 to t24 while this is not the case for IPBC.    The test item X6119CJ was considered to be stable after 7 days at 0 ± 2°C.  The individual commercial packagings are hermetically closed with a cap. With their closure systems, the packagings are leak-tight. | Bridging from X6119CJ to X6119C is acceptable to consider the product stable after low temperature storage but not after accelerated storage.  **According to the results obtained for other active substances, only a 12 months shelf life can be granted. However, in order to confirm stability for IPBC, a new shelf life is required in post authorisation.**  **See previous comment in shelf life section.** | Legay S, 2016  Report 402/13/1136F/cd-e  GLP |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | The product is compatible with HDPE and f-HDPE packaging as demonstrated during the storage stability. No degradation, leakage, deformation were noticed after storage. | Accepable. | Legay S, 2016  Report 402/13/1136F/cd-e  GLP |
| Wettability |  |  | Not applicable | Not relevant |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not applicable | Not relevant |  |
| Wet sieve analysis and dry sieve test |  |  | Not applicable | Not relevant |  |
| Emulsifiability, re-emulsifiability and emulsion stability | CIPAC MT 36.3 | X6119C  XIX 2 NDF | Before the long-term storage procedure, 5% w/w in standard waters A and D at 20 ± 2°C:  Initial emulsification: uniform emulsion  Emulsion stability on standing: no free oil, cream, solid matter after standing for 30 min, 2h, 24h  Re-emulsification after standing for 24 h: no free oil, cream, solid matter after standing for 30 s; uniform emulsion  Final emulsion stability: no free oil, cream, solid matter after standing for 30 min  After 6 months at ambient temperature  At 5%w/w  Initial emulsification: uniform emulsion  Emulsion stability on standing: no free oil, cream, solid matter after standing for 30 min, 2h, 24h  Re-emulsification after standing for 24 h: no free oil, cream, solid matter after standing for 30 s;  uniform emulsion  Final emulsion stability: no free oil, cream, solid matter after standing for 30 min  after storage 24 months at ambient temperature   * at 3%w/w   Initial emulsification: uniform emulsion  Emulsion stability on standing: no free oil, cream , solide after standing for 30 min, 2h, 24h  Re-emulsification after standing for 24 h: no free oil, cream, solid matter after standing for 30 s; uniform emulsion  Final emulsion stability: no free oil, cream, solid matter after standing for 30min   * at 8.33%w/w   Initial emulsification: uniform emulsion  Emulsion stability on standing: no free oil, cream , solide after standing for 30 min, 2h, 24h  Re-emulsification after standing for 24 h: no free oil, cream, solid matter after standing for 30 s; uniform emulsion  Final emulsion stability: no free oil, cream, solid matter after standing for 30min | Acceptable. Based on the results provided, the product is considered to form stable emulsion. | Legay S. 2013  13/1136F/cd  GLP  Legay S, 2016  Report 402/13/1136F/cd-e  GLP |
| Disintegration time |  |  | Not applicable | Not relevant |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not applicable | Not relevant |  |
| Persistent foaming | CIPAC MT 47.2 | X6119C  XIX 2 NDF | Before the long term storage procedure (at 5% w/w in standard water D)  The volume of foam produced after 30 inversions of the test item at 20 ± 2°C was 0 mL after 1 min of standing.  This result is within the acceptable limit of 60 mL of foam after 1 min.  After 6 months at ambient temperature and at 5%w/w: Volume of foam : no foam after 1 min  After storage 24 months at ambient temperature, at 3% and 8.33% w/w : Volume of foam : no foam observed after 1 min | Acceptable. Based on the results provided, the product is considered to be non foaming.  Persistent foaming results are very different between formulations X6119C and X6119CJ. The applicant explains that these differences are due to the foaming properties of one colouring agent premix (dispersing agent at a content of 8% in the premix) which are not present in formulation X6119C. | Legay S. 2013  13/1136F/cd  GLP  Legay S, 2016  Report 402/13/1136F/cd-e  GLP |
| Flowability/Pourability/Dustability |  |  | Not applicable | Not relevant |  |
| Burning rate — smoke generators |  |  | Not applicable | Not relevant |  |
| Burning completeness — smoke generators |  |  | Not applicable | Not relevant |  |
| Composition of smoke — smoke generators |  |  | Not applicable | Not relevant |  |
| Spraying pattern — aerosols |  |  | Not applicable | Not relevant |  |
| Physical compatibility |  |  | Not applicable. The product is not intended to be used in conjunction with any other products or active substances. Hence, no data on the physical and chemical compatibility of X6119C with other biocidal products, chemicals or active substances is required. | Not applicable |  |
| Chemical compatibility |  |  | Not applicable. The product is not intended to be used in conjunction with any other products or active substances. Hence, no data on the physical and chemical compatibility of X6119C with other biocidal products, chemicals or active substances is required. | Not applicable |  |
| Degree of dissolution and dilution stability |  |  | Not applicable | Not relevant for EW formulation. |  |
| Surface tension |  |  | No results were provided.  The product X6119C has the same composition than X6119CJ without colouring agents (- 3.30% w/w) which are replaced by an inter ingredient.  Considering that the product X6119CJ already contains 42.57% w/w of the same inert ingredient, and that the major change is the suppression of colouring agents in the product X6119C, it is not expected that the composition change has any significant impact on surface tension.  Therefore, the surface tension of X6119C is expected to be in the same range as the surface tension of X6119CJ, and to be considered as surface-active. | The bridging is acceptable. |  |
| Viscosity |  |  | No results were provided.  The product X6119C has the same composition than X6119CJ without colouring agents (- 3.30% w/w) which are replaced by an inter ingredient.  Considering that the product X6119CJ already contains 42.57% w/w of the same inert ingredient, and that the major change is the suppression of colouring agents in the product X6119C, it is not expected that the composition change has any significant impact on viscosity.  Therefore, the viscosity of X6119C is expected to be in the same range as the viscosity of X6119CJ, and to be considered to have non-Newtonian properties. | The bridging is acceptable. |  |

**Physical hazards and respective characteristics of X6119C**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | **/** | **/** | No results were provided. The product X6119C has the same composition than X6119CJ without colouring agents (- 3.30% w/w) which are replaced by an inert ingredient..  Considering the DSC graphs and explosive properties of the product X6119CJ which already contains 42.57% w/w of the same inter ingredient, and that the major change is the suppression of colouring agents in the product X6119C, it is not expected that this composition change has any significant impact on the DSC profile and explosive properties.  Therefore, X6119C is not expected to present a significant hazard for explosive properties. | The bridging is acceptable. The product is not explosive. |  |
| Flammable gases |  |  | Not applicable | Not applicable |  |
| Flammable aerosols |  |  | Not applicable | Not applicable |  |
| Oxidising gases |  |  | Not applicable | Not applicable |  |
| Gases under pressure |  |  | Not applicable | Not applicable |  |
| Flammable liquids | **/** | **/** | No results were provided. The product X6119C has the same composition than X6119CJ without colouring agents (- 3.30% w/w) which are replaced by an inert ingredient.  Considering the flash point of the product X6119CJ which already contains 42.57% w/w of the same inert ingredient, and that the major change is the suppression of colouring agents in the product X6119C, it is expected that this composition change has any significant impact on the flash point.  Therefore, the flash point of X6119C (94.4 deg C) is expected to be similar or higher than the one obtained with X6119CJ; the products are not classified as flammable products following CLP regulation. | The bridging is acceptable. The product is not flammable. |  |
| Flammable solids |  |  | Not applicable | Not applicable |  |
| Self-reactive substances and mixtures | **/** | **/** | No results were provided. The product X6119C has the same composition than X6119CJ without colouring agents (- 3.30% w/w) which are replaced by an inert ingredient.  Considering the DSC graphs and self-reactive properties of the product X6119CJ which already contains 42.57% w/w of the same inert ingredient, and that the major change is the suppression of colouring agents in the product X6119C, it is not expected that this composition change has any significant impact on the DSC profile and self-reactive properties.  Therefore, X6119C is not expected to present a significant hazard for self-reactive properties. | The bridging is acceptable. The product is not a self reactive mixture. |  |
| Pyrophoric liquids | **/** | **/** | Not required as X6119CJ contains around 43% w/w of inert ingredient and as experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperature | Acceptable |  |
| Pyrophoric solids |  |  | Not applicable | Not applicable |  |
| Self-heating substances and mixtures | **/** | **/** | No test was provided. | Not acceptable. Nevertheless, accoding to the composition of the product, X6119C is not expected to be a self heating liquid. |  |
| Substances and mixtures which in contact with water emit flammable gases | **/** | **/** | Not required as X6119CJ contains around 43% w/w of inert ingredient. | Acceptable. |  |
| Oxidising liquids | **/** | **/** | No results were provided. The product X6119C has the same composition than X6119CJ without colouring agents (- 3.30% w/w) which are replaced by an inert ingredient.  Considering the oxidizing properties of the product X6119CJ which already contains 42.57% w/w of the same inert ingredient, and that the major change is the suppression of colouring agents in the product X6119C, it is not expected that this composition change has any significant impact on the oxidizing properties.  Therefore, the oxidizing properties of X6119C are expected to be in the same range as the oxidizing properties of X6119CJ; the products are not classified as an oxidising liquid following CLP regulation. | The bridging is acceptable. The product is not oxidising. |  |
| Oxidising solids |  |  | Not applicable | Not applicable |  |
| Organic peroxides |  |  | Not applicable | Not applicable |  |
| Corrosive to metals | **/** | **/** | As the product X6119CJ contains an ingredient which is classified as corrosive and as no C1 test according to UN RTDG has been performed, the product X6119CJ is classified as corrosive to metals, Met. Corr. 1, H290. | Acceptable. The product is classified by default corrosive to metals H290 Corr.1. |  |
| Auto-ignition temperatures of products (liquids and gases) | **/** | **/** | No results were provided. The product X6119C has the same composition than X6119CJ without colouring agents (- 3.30% w/w) which are replaced by an inert ingredient.  Considering the auto-ignition temperature of the product X6119CJ which already contains 42.57% w/w of the same inert ingredient, and that the major change is the suppression of colouring agents in the product X6119C, it is not expected that this composition change has any significant impact on the auto-ignition temperature.  Therefore, the auto-ignition temperature of X6119C(445°C) is expected to be similar or higher than the one obtained with X6119CJ. | The bridging is acceptable. The product X6119C is not expected to be autoflammable up to 445°C. |  |
| Relative self-ignition temperature for solids |  |  | Not applicable | Not applicable |  |
| Dust explosion hazard |  |  | Not applicable | Not applicable |  |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product X6119C** |
| The formulation X6119C is an emulsion oil in water (EW) formulation. All studies have been performed in accordance with the current requirements. The appearance of the product is that of translucent yellow liquid, with a detergent like odour. It is not explosive and has no oxidizing properties. The product is not considered flammable and has a flash point of 94.4°C. It is not auto-flammable in the conditions of use (temperature of auto-ignition: 445°C). The product is classified by default corrosive to metals H290 Corr. 1. The pH of the neat formulation is 7.5 at 19°C. The viscosity of the product at 20°C is from 720mPa.s (0.3RPM) to 165.6mPa.s (30RPM).The product is considered surface active.  No accelerated storage stability and low storage stability studies were provided. Since the compositions of X6119CJ and X6119C are very similar, results obtained with X6119CJ should be considered applicable to X6119C. However, there is an effect of high temperature on the stability of the formulation X6119CJ since after 8 weeks at 40°C in HDPE container, the active ingredient content of cypermethrin decreases from more 8.8%. Degradation products were not identified. After 2 years storage of X6119C at ambient temperature, cypermethrin content decreases linearly and variations are higher than 10% from 18 months, but this was not the case for the formulation X6119CJ. Other active substance contents and technical properties were unchanged (except persistent foaming). Therefore, accelerated storage with formulation X6119CJ cannot be extrapolated to X6119C since long term storage does not confirm the stability of cypermethrin content. The formulation X6119C should not be stored at a temperature higher than 22°C (maximum temperature tested during shelf life study).  There is no effect of low temperature on the stability of the formulation since after 7 days at 0°C, there are no modification of the properties of the product.  Emulsion stability and re-emulsification at 3%, 5% and 8.33% have been provided and demonstrate that the product forms stable emulsions.  At 3%w/w, 5% w/w and 8.33% w/w, no foam was observed, demonstrating that the formulation X6119C is not a foaming product. Significant differences were noticed between formulations X6119CJ (>60mL after 1 min) and X6119C (no foam after 1min). According to the applicant, differences may be due to one colouring premix (containing dispersing agent at 8%) added in formulation X6119CJ which may have foaming properties.  Results of the shelf life study of the formulation X6119C in HDPE and f-HDPE packaging were provided after 6, 12, 18 and 24 months. Content of propiconazole, and tebuconazole were stable on storage. However, cypermethrin content decreases linearly on storage and results were not in acceptable limits after 18 months. Such loss was not observed for the colouring version (X6119CJ) and for other products of the family (containing lower content of cypermethrin). The applicant has explained this specific loss in X6119C due to the pH of this product which is slightly higher than for other products of the family. According to the assessment report, cypermethrin is degraded slightly under neutral conditions (major metabolites are DCVC acid and 3-PBA). This may explain the difference with other products.  Moreover, IPBC contents at intermediate times (6 and 18 months) were not in accordance with results obtained at 12 and 24 months. After 6 and 18 months, variations were below than 10% which was not the case after 18 and 24 months. Samples stored 12 months were analysed a second time, not under GLP, with another test facility (DTI), providing inconsistent results with the previous one (FBCA) obtained under GLP. Indeed, DTI concludes that no degradation occured in samples: IPBC remained stable and no PBC was found. **eCA considers that results provided do not allow to conclude on the stability of IPBC since variations are not coherent with a possible degradation of the active substance. According to the results obtained for other active substances, only a 12 months shelf life can be granted. However, in order to confirm the stability of IPBC, a new shelf life is required in post authorisation.**  Compatibility has been demonstrated with HDPE and f-HDPE packaging during the long term storage stability, no further data are required.  Effect of light has not been studied. Packagings made of HDPE are not considered to be barrier to light. Since cypermethrin is sensitive to sunlight (DT50 photostability in water: 12.4-14.8d) , it is recommended to store the product away from light.  Its technical characteristics are acceptable for an emulsion formulation. |

**Conclusion on Meta SPC1**

Physico chemical studies were provided for both X6119CJ and X6119C and covered this SPC.Products of this meta SPC are emulsion oil in water (EW) formulation. All studies have been performed in accordance with the current requirements. The appearance of the products is that of yellow (opaque or translucent) liquid, with a detergent like odour. Products are not classified regarding physico chemical products. However, they are classified by default corrosive to metals H290 Corr. 1. The pH of the neat formulation is 5.87 at 20°C for X6119CJ and 7.2 at 19°C for X6119C. The decrease of the pH can be explained by one colouring agent which has a pH of 4.5-5.5. Both formulations are surface active and are considered to be non newtonien fluid.

There is no effect of low temperature on the stability of the formulation since after 7 days at 0°C, there are no modification of the properties of the products.

Extrapolation between X6119C and XC119CJ cannot be made regarding the accelerated storage stability. Variation of cypermethrin content is higher than 5% in X6119CJ after 8 weeks at 40°C and phase partition (maybe due to pigments sedimentation) was observed. Long term study allows to confirm stability of cypermethrin in X6119CJ after 24 months while this is not the case for the formulation XC6119C since cypermethrin degrades linearly in X6119C.

For each formulation, content of IPBC is not stable and results are not in accordance at the intermediate time (6, 12, 18, 24 months). Samples stored 6 and 12 months were analysed a second time, not under GLP, with another test facility (DTI), providing inconsistent results with the previous one (FBCA) obtained under GLP. Indeed, DTI concludes that no degradation occured in samples: IPBC remained stable and no PBC was found. No conclusion on IPBC stability can be set with the available data. Moreover, for the formulation X6119C, content of cypermethrin decreases linearly and variations were higher than 10% after 18months and 24 months. Such loss was not observed for the colouring version (X6119CJ) and for other products of the family (containing lower content of cypermethrin). This may be explained by a higher pH of the formulation and the slight degradation of cypermethrin in neutral conditions.

Based on the worst case, given that products in the same meta SPC should have the same classification and labelling, products are considered stable 1 year at ambient temperature and they should not be stored at a temperature higher than 22°C. Moroever, products should be stirred before and during application. **However, in order to confirm the stability of IPBC, a new shelf life study is required and should be provided for the worst case, i.e for the product X6119C in HDPE packaging.**

Compatibility has been demonstrated with HDPE and f-HDPE packaging (no degradation, deformation, or leakage) during the long term storage stability, no further data are required.

Effect of light has not been studied. Packagings made of HDPE are not considered to be barrier to light. Since cypermethrin is sensitive to sunlight (DT50 (photostability in water: 12.4-14.8d) , it is recommended to store the product away from light.

Technical characteristics are acceptable for an EC formulation. Tests were performed at the recommended use rates for each product (5%w/w for X6119CJ, 3% w/w and 8.33% w/w for X6119C). Only persistent foaming was different between both formulations.. According to the applicant, differences may be due to the presence of the colouring premixes in formulation X6119CJ which may have foaming properties. However, full composition of the premix should be provided.

For X6119CJ, persistent foaming at 5% w/w is not acceptable since more than 60mL of foam are produced. However, the applicant has provided further details on the application of the product (dilution of the product using dosatron system, without any contact of the solution with operators, and then dipping of the wood into tanks). Moreover, conditions of the CIPAC method are different from the ones in real conditions (no agitation). Additionally, this issue is covered with the wear of personal protective equipments as recommended by human health section.

**Shelf life:** one year

**Mitigation measure:** do not store at a temperature higher than 22°C. Store away from light. Stir before and during application.

**Classification:** H290 corrosive to metals

**Post authorisation data:** a shelf life study of one year for the product X6119C in HDPE packaging should be provided to confirm the stability of IPBC.

**Post authorisation data for PPG CLASS3 WB - 2021:** The meta SPC 1 is not anymore claimed by the applicant. The data gap regarding a new storage stability study for X6119C is not anymore relevant.

**Meta SPC 2**

This meta SPC is related to products X6119C1 and X6119B1. Products are intended to be diluted in water (5% for X6119C1 and 10% ofr X6119B1) and used for industrial purpose.

Packaging claimed for these products: HDPE packaging.

These products have compositions which are similar to formulation X6119C (meta SPC 1). Bridgings have been performed regarding stability data which are discussed in confidential annex. However, for technical properties, physico chemical tests were required and are reported below.

**X6119C1**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Emulsifiability, re-emulsifiability and emulsion stability | CIPAC MT 36.3 | X6119C1, batch 1600600033 | Before the long-term storage procedure, 5% w/w in standard waters A and D at 20 ± 2°C:  Initial emulsification: uniform emulsion  Emulsion stability on standing: no free oil, cream, solid matter after standing for 30 min, 2h, 24h  Re-emulsification after standing for 24 h: no free oil, cream, solid matter after standing for 30 s; uniform emulsion  Final emulsion stability: no free oil, cream, solid matter after standing for 30 min | Acceptable. Based on the results provided, the product is considered to form stable emulsion. | E. RAPHALEN, 2016  Report 402/16/1076F-e  GLP |
| Persistent foaming | CIPAC MT 47.2 | X6119C1, batch 1600600033 | At 5%w/w: no foam observed after 1min | Acceptable. The product is not a foaming product. | E. RAPHALEN, 2016  Report 402/16/1076F-e  GLP |
| Surface tension | OECD 115 | X6119C1, batch 1600600033 | Surface tension of the pure test item: 23.29mN/m at 19.5°C | Acceptable. The product is considered to be surface active. | E. RAPHALEN, 2016  Report 402/16/1076F-e  GLP |

**X6119B1**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Emulsifiability, re-emulsifiability and emulsion stability | CIPAC MT 36.3 | X6119B1, batch PaP V 132.1 | Before the long-term storage procedure, 10% w/w in standard waters A and D at 20 ± 2°C:  Initial emulsification: uniform emulsion  Emulsion stability on standing: no free oil, cream, solid matter after standing for 30 min, 2h, 24h  Re-emulsification after standing for 24 h: no free oil, cream, solid matter after standing for 30 s; uniform emulsion  Final emulsion stability: no free oil, cream, solid matter after standing for 30 min | Acceptable. Based on the results provided, the product is considered to form stable emulsion. | E. RAPHALEN, 2016  Report 402/16/1075F-e  GLP |
| Persistent foaming | CIPAC MT 47.2 | X6119B1, batch PaP V 132.1 | At 10%w/w: no foam observed after 1min | Acceptable. The product is not a foaming product. | E. RAPHALEN, 2016  Report 402/16/1075F-e  GLP |
| Surface tension | OECD 115 | X6119B1, batch PaP V 132.1 | Surface tension of the pure test item: 23.02mN/m at 19.3°C | Acceptable. The product is considered to be surface active. | E. RAPHALEN, 2016  Report 402/16/1075F-e  GLP |
| Viscosity | OECD 114 | X6119B1, batch PaP V 132.1 | The kinematic viscosity was determined using a flow cup method.  20.0°C: <6.62mm2/s  40°C: <6.62mm2/s | Acceptable. However, no details were provided at different RPM. It can be assumed as for X6119C that the product has non Newtonian properties. | E. RAPHALEN, 2016  Report 402/16/1075F-e  GLP |

In order to support a shelf life of 12 months which is claimed and to confirm the extrapolation made from products of meta SPC1 to X6119B1, the applicant has submitted control quality data including contents of each active ingredient using method based on HPLC-UV (C18 column):



For the 3 analysed batches, aged between 20 and 22 months, the active substances' content has not varied by more than +/- 10%. FR considers that data are sufficient to propose only a shelf life of 12 months as claimed by the applicant. Indeed, since these results consist of QC data and not to a formal shelf life study, FR is not of the opinion to grant a longer shelf life.

**Conclusion on meta SPC 2**

This meta SPC covers X6119C1 and X6119B1.

Products of meta SPC 2 are emulsion oil in water (EW) formulation. All studies have been performed in accordance with the current requirements.The appearance of the product is that of yellow (translucent) liquid, with a detergent like odour. It is not explosive and has no oxidizing properties. Both products are not considered flammable and have a flash point of 94.4°C. They are not auto-flammable in the conditions of use (temperature of auto-ignition: 445°C). The products are classified by default corrosive to metals H290 Corr. 1. The pH of the neat formulations is approx 7at 19°C. Both formulations are surface active. X6119B1 is considered to be non newtonien fluid. **However, viscosity for X6119C1 should be provided.**

There is no effect of low temperature on the stability of the formulations since after 7 days at 0°C, there are no modifications of the properties of the products.

Extrapolations have been found acceptable between formulation X6119C and X6119C1/X6119B1 since compositions are very similar or modifications consist in dilution of X6119C. Therefore storage stability data provided for X6119C have been used for formulations of meta SPC2. As for X6119C, it is recommended to store the products at a temperature below 22°C (maximum temperature tested during shelf life study of X6119C). **According to the results obtained for the formulation X6119C and QC data provided for X6119B1, a 12 months shelf life can be granted for X6119C1 and X6119B1. However, in order to confirm the stability of IPBC, a new shelf life is required in post authorisation. Data required for X6119C in HDPE packaging will cover data gap for products of meta SPC2.**

Compatibility has been demonstrated with HDPE and f-HDPE packaging (no degradation, deformation, or leakage) during the long term storage stability, no further data are required.

Effect of light has not been studied. Packagings made of HDPE are not considered to be barrier to light. Since cypermethrin is sensitive to sunlight (DT50 photostability in water: 12.4-14.8d) , it is recommended to store the product away from light.

Technical characteristics are acceptable for an emulsion formulation. Tests were performed at the recommended use rate for each product (5%w/w for X6119C1, 10% for X6119B1).

**Shelf life:** one year

**Mitigation measure:** do no store at a temperature higher than 22°C. Store away from light.

**Classification:** H290 corrosive to metals

**Post authorisation data:** a shelf life study for the product X6119C in HDPE packaging of one year results should be provided to confirm the stability of IPBC. Viscosity of X6119C1 should be provided.

* **Post authorisation data for PPG CLASS3 WB - 2021:**

**T**he meta SPC 2 is not anymore claimed by the applicant. The data gap regarding a new storage stability study for X6119C is not anymore relevant.

**Meta SPC 3 and Meta SPC 4**

**Product X6119M2 (ready to use EW formulation, packaging claimed: HDPE, f-HDPE and tinplate can with internal epoxy phenolic varnish) / meta SPC 3**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa |  | X6119M2  Lot/batch No1502600020 | colourless, transparent liquid at initial time and a very slightly yellow | Acceptable | Legay S. 2015  402/14/1096F/abcd-e  GLP |
| Colour at 20 °C and 101.3 kPa | Colourless, transparent |
| Odour at 20 °C and 101.3 kPa | detergent-like odour |
| Acidity / alkalinity | CIPAC MT 75.3 | X6119M2  Lot/batch No1502600020 | The mean pH value of X6119M2 (pure test item) was 7.02 at 19.8°C | Acceptable | Legay S. 2015  402/14/1096F/abcd-e  GLP |
| Relative density / bulk density | OECD 109 | X6119M2  Lot/batch No.: 1502600020 | According to OECD No.109 (pycnometers method), the mean relative density of X6119M2 was:  D (19.8°C / 4°C) = 1.002 | Acceptable | Legay S. 2015  402/14/1096F/efgh-e  GLP |
| Storage stability test – **accelerated storage (8 weeks at 40°C)** | CIPAC MT 46.3 | X6119M2  Lot/batch No1502600020 | **Appearance**  - Changes in colour: from colourless transparent to very slightly yellow transparent  - Changes in clarity: none  - Changes in texture: none  - Other changes: none  **Packaging**  The appearances of the packaging materials (5 L bottle in HDPE and 1 L bottle in tinplate can with internal epoxy phenolic varnish) were considered to be stable after an accelerated storage procedure for 8 weeks at 40 ± 2°C. No significant weight changes were observed (-0.02% for the 5 L bottle in HDPE and -0.01% for the 1L bottle in tinplate metal can). No sign of corrosion or degradation.  **pH (CIPAC MT 75.3)**  before storage: 7.02 (pure test item)  after storage: 6.96 (pure test item)  **Active ingredient contents (method validated; performed with inert packaging = glass bottle)**   |  |  |  | | --- | --- | --- | | **a.i content (%)** | **Initial** | **T 8 weeks at 40°C** | | **Cypermethrin** | 0.101 | 0.097 (-4.0%) | | **IPBC** | 0.047 | 0.045 (-4.3%) | | **Propiconazole** | 0.149 | 0.149 (0%) | | **tebuconazole** | 0.048 | 0.049 (+2.1%) | | Acceptable. The product is stable in HDPE bottle and metal can (tin plate can with epoxy phenolic varnish) after 8 weeks at 40°C. | Legay S. 2015  402/14/1096F/abcd-e  GLP |
| Storage stability test – **long term storage at ambient temperature** | Technical Monograph 17 | X6119M2  Lot/batch No.: XVIII 195 NDF | **Appearance**  The appearance of X6119M2 was considered to be stable after 6, 12, 18 and 24 months of storage at ambient temperature (colourless, limpid liquid). No phase separation or deposit were noticed.  **Packaging**  The appearance of the packaging materials (5L HDPE and 1L tin plate can with internal epoxy phenolic varnish) was considered to be stable after 6 and 12 months of storage at ambient temperature (no sign of corrosion or degradation). No significant weight changes were observed (0% after 6 months, 0% after 12 months, -0.04% after 18 months, -0.12% after 24 months for the 5L HDPE packaging, 0% after 6 months and +0.01% after 12 months, +0.01% after 18 months, no variations after 24 months for the 1L metal packaging).  **Active substance contents (validated method)**  Results in HDPE packaging   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **a.i content (%)** | **Initial** | **T6** | **T12** | **T18** | **T24** | | **Cypermethrin** | 0.095 | 0.092  (-3.2%) | 0.094  (-1.1%) | 0.091  (-4.2%) | 0.088  (-7.4%) | | **IPBC** | 0.047 | 0.043  (-8.5%) | 0.048 (+2.1%) | 0.046  (-2.1%) | 0.043  (-8.5%) | | **Propiconazole** | 0.144 | 0.142  (-1.4%) | 0.142  (-1.4%) | 0.143  (-0.7%) | 0.144  (0.0%) | | **tebuconazole** | 0.047 | 0.047 (0.0%) | 0.046  (-2.1%) | 0.047 (0.0%) | 0.045  (-4.3%) |   Results in tin plate can with internal epoxy phenolic varnish   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **a.i content** | **Initial** | **T6** | **T12** | **T18** | **T24** | | **Cypermethrin** | 0.095 | 0.092  (-3.2%) | 0.093  (-2.1%) | 0.090  (-5.3%) | 0.086  (-9.5%) | | **IPBC** | 0.047 | 0.044  (-6.4%) | 0.044  (-6.4%) | 0.045  (-4.3%) | 0.043  (-8.5%) | | **Propiconazole** | 0.144 | 0.141  (-2.1%) | 0.139  (-3.5%) | 0.14  (-2.8%) | 0.14  (-2.8%) | | **tebuconazole** | 0.047 | 0.047  (0.0%) | 0.046  (-2.4%) | 0.046  (-2.1%) | 0.045  (-4.3%) |   **pH**  HDPE packaging  At t0:7.1 at 18.9°C  At t24: 7.0 at 20.4°C  Tin plate can  At t0: 7.0 at 18.9°C  At t24: 6.8 at 20.4°C  **Emulsion stability (performed on the neat product)**  HDPE  After 6 months:  Initial emulsification: uniform emulsion  Emulsion stability on standing: no oil, cream or solid matter after 30min, 2h and 24h  Re-emulsification after 24h: no oil, cream or solid matter after 30 sec; uniform emulsion  Final emulsion stability: no oil, cream or solid matter after 30min  Tin plate can  After 6 months:  Initial emulsification: uniform emulsion  Emulsion stability on standing: no oil, cream or solid matter after 30min, 2h and 24h  Re-emulsification after 24h: no oil, cream or solid matter after 30 sec; uniform emulsion  Final emulsion stability: no oil, cream or solid matter after 30min | The product is stable 2 year at ambient temperature in HDPE and tin plate can with internal epoxyphenolic varnish. Since HDPE is a worst case, the product is also considered compatible with f-HDPE. | Legay S. 2016  Report 402/13/1134F/cd-e  GLP |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 | X6119M2  Lot/batch No.: 1502600020 | The test item was physically stable after storage at 0 ± 2°C for 7 days. No deposit or phase partition was observed. | Acceptable. The product is stable after 7 days at 0°C. | Legay S. 2015  402/14/1096F/efgh-e  GLP |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Justification of non submission provided by the applicant:  Not required as the biocidal product is packed in opaque commercial packagings. | Not acceptable. Packaging are not considered to be barrier to light. Since cypermethrin is sensitive to sunlight (DT50 photostability in water: 12.4-14.8d) , it is recommended to store the product away from light (except for metal cans). |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | The test item X6119M2 was considered to be stable after 8 weeks at 40 ± 2°C and after 7 days at 0 ± 2°C  The individual commercial packagings are hermetically closed with a cap. With their closure systems, the packagings are leak-tight. | Acceptable. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | Compatibility with HDPE container and tin plate can has been demonstrated with the storage stability studies. | Acceptable |  |
| Wettability |  |  | Not applicable | Not applicable |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not applicable | Not applicable |  |
| Wet sieve analysis and dry sieve test |  |  | Not applicable | Not applicable |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not applicable (ready to use EW formulation) | Acceptable. The product is ready to use. |  |
| Disintegration time |  |  | Not applicable | Not applicable |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not applicable | Not applicable |  |
| Persistent foaming |  |  | Not applicable (ready to use) | Acceptable. The product is ready to use. |  |
| Flowability/Pourability/Dustability |  |  | Not applicable | Not applicable |  |
| Burning rate — smoke generators |  |  | Not applicable | Not applicable |  |
| Burning completeness — smoke generators |  |  | Not applicable | Not applicable |  |
| Composition of smoke — smoke generators |  |  | Not applicable | Not applicable |  |
| Spraying pattern — aerosols |  |  | Not applicable | Not applicable |  |
| Physical compatibility |  |  | Not applicable. The product is not designed to be used in conjunction with any other products or active substances. Hence, no data on the physical and chemical compatibility of X6119M2 with other biocidal products, chemicals or active substances is required. | Not applicable |  |
| Chemical compatibility |  |  | Not applicable. The product is not designed to be used in conjunction with any other products or active substances. Hence, no data on the physical and chemical compatibility of X6119M2 with other biocidal products, chemicals or active substances is required. | Not applicable |  |
| Degree of dissolution and dilution stability |  |  | Not applicable | Not applicable |  |
| Surface tension | EU method A.5  OECD 115 | X6119M2  Lot/batch No.: 1502600020 | According to EC A.5 and OECD No.115 (ring method), X6119M2 was considered as surface-active (mean surface tension at 20.4°C of the pure test item: 27.36 mN/m). | Acceptable. | Legay S. 2015  402/14/1096F/efgh-e  GLP |
| Viscosity | OECD 114 | X6119M2  Lot/batch No.: 1502600020 | According to OECD No.114, the mean kinematic viscosity of X6119M2, determined using a flow cup method was the following:  < 6.62 mm²/s at 20.0 ± 0.5°C  < 6.62 mm²/s at 40.0 ± 0.5°C | Acceptable. | Legay S. 2015  402/14/1096F/efgh-e  GLP |

**Physical hazards and respective characteristics of X6119M2**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives |  |  | The products X6119M2 and X6236 have very close compositions, with the following differences.Three formulants (1.87% w/w) and a part of one formulant (- 2.00% w/w), are replaced in product X6119M2 by an inert ingredient already present (+ 3.87% w/w).  Considering the explosive properties of the product X6236, which already contains 92.25% w/w of inert ingredient, and that the total composition change from X6236 to X6119M2 is only 3.87% w/w with exclusively an increase of inert ingredient content and decreases of formulants, it is not expected that this composition change has any significant impact on the explosive properties.  Therefore, X6119M2 is not expected to present a significant hazard for explosive properties. | The bridging is acceptable. The product X6119M2 is not explosive. |  |
| Flammable gases |  |  | Not applicable | Not applicable |  |
| Flammable aerosols |  |  | Not applicable | Not applicable |  |
| Oxidising gases |  |  | Not applicable | Not applicable |  |
| Gases under pressure |  |  | Not applicable | Not applicable |  |
| Flammable liquids |  |  | The products X6119M2 and X6236 have very close compositions, with the following differences.Three formulants (1.87% w/w) and a part of one formulant (- 2.00% w/w), are replaced in product X6119M2 by an inert ingredient already present (+ 3.87% w/w).  Considering the flammable hazard of the product X6236, which already contains 92.25% w/w of inert ingredient, and that the total composition change from X6236 to X6119M2 is only 3.87% w/w with exclusively an increase of inert ingredient content and decreases of formulants, it is not expected that this composition change has any significant impact on the flash point.  Therefore, X6119M2 is not expected to present a significant hazard for flammable properties. | The bridging is acceptable. The product X6119M2 is not flammable. |  |
| Flammable solids |  |  | Not applicable | Not applicable |  |
| Self-reactive substances and mixtures |  |  | The products X6119M2 and X6236 have very close compositions, with the following differences.Three formulants (1.87% w/w) and a part of one formulant (- 2.00% w/w), are replaced in product X6119M2 by an inert ingredient already present (+ 3.87% w/w).  Considering the self-reactive properties of the product X6236, which already contains 92.25% w/w of inert ingredient, and that the total composition change from X6236 to X6119M2 is only 3.87% w/w with exclusively an increase of inert ingredient content and decreases of formulants, it is not expected that this composition change has any significant impact on the self-reactive properties.  Therefore, X6119M2 is not expected to present a significant hazard for self-reactive properties. | The bridging is acceptable. Moreover, the decomposition energy of the product X6236 is low (62g/J). Therefore, the product X6119M2 is not a self reactive mixture. |  |
| Pyrophoric liquids |  |  | The products X6119M2 and X6236 have very close compositions, with the following differences.Three formulants (1.87% w/w) and a part of one formulant (- 2.00% w/w), are replaced in product X6119M2 by an inert ingredient already present (+ 3.87% w/w).  Considering that the product X6236 is not a pyrophoric liquid and already contains 92.25% w/w of inert ingredient, and that the total composition change from X6236 to X6119M2 is only 3.87% w/w with exclusively an increase of inert ingredient content and decreases of formulants, it is not expected that this composition change has any significant impact on the pyrophoricity.  Therefore, X6119M2 is not expected to be a pyrophoric liquid. | The bridging is acceptable. The product X6119M2 is not a pyrophoric liquid. |  |
| Pyrophoric solids |  |  | Not applicable | Not applicable |  |
| Self-heating substances and mixtures |  |  | No results were provided. | Not acceptable. Nevertheless, since the product contains around 96% of inert ingredient, the product X6119M2 is not expected to be a self heating liquid. |  |
| Substances and mixtures which in contact with water emit flammable gases |  |  | Not required as X6119M2 contains around 96% w/w of inert ingredient and foeCA a stable mixture. | Acceptable. |  |
| Oxidising liquids |  |  | The products X6119M2 and X6236 have very close compositions, with the following differences.Three formulants (1.87% w/w) and a part of one formulant (- 2.00% w/w), are replaced in product X6119M2 by an inert ingredient already present (+ 3.87% w/w).  Considering the oxidising properties of the product X6236, which already contains 92.25% w/w of inert ingredient, and that the total composition change from X6236 to X6119M2 is only 3.87% w/w with exclusively an increase of inert ingredient content and decreases of formulants, it is not expected that this composition change has any significant impact on the oxidising properties.  Therefore, X6119M2 is not expected to present a significant hazard for oxidising properties. | The bridging is acceptable. The product X6119M2 has no oxidising properties. |  |
| Oxidising solids |  |  | Not applicable | Not applicable |  |
| Organic peroxides |  |  | Not applicable | Not applicable |  |
| Corrosive to metals |  |  | As the product X6119CJ contains an ingredient which is classified as corrosive and as no C1 test according to UN RTDG has been performed, the product X6119CJ is classified as corrosive to metals, Met. Corr. 1, H290. | Acceptable. The product is classified by default corrosive to metals H290 Corr.1. |  |
| Auto-ignition temperatures of products (liquids and gases) |  |  | The products X6119M2 and X6236 have very close compositions, with the following differences.Three formulants (1.87% w/w) and a part of one formulant (- 2.00% w/w), are replaced in product X6119M2 by an inert ingredient already present (+ 3.87% w/w).  Considering the auto-ignition temperature of the product X6236, which already contains 92.25% w/w inert ingredient , and that the total composition change from X6236 to X6119M2 is only 3.87% w/w with exclusively an increase of inert ingredient content and decreases of formulants, it is not expected that this composition change has any significant impact on the auto-ignition temperature.  Therefore, the auto-ignition temperature of X6119M2 is expected to be similar or higher than the one obtained with X6236. | The bridging is acceptable. The auto-ignition temperature is expected to be similar or higher than the one determined for the product X6236 (480°C). |  |
| Relative self-ignition temperature for solids |  |  | Not applicable | Not applicable |  |
| Dust explosion hazard |  |  | Not applicable | Not applicable |  |

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| **Conclusion on the physical, chemical and technical properties of the product X6119M2** |
| The formulation X6119M2 is a ready to use formulation (EW: emulsion oil in water ready to use). 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 a colourless, transparent liquid with a detergent-like odour. It is not explosive and has no oxidizing properties. The product is not considered flammable. It is not auto-flammable in the conditions of use (temperature of auto-ignition: 480°C). The pH of the neat formulation is 7.02 at 19.8°C. The viscosity of the preparation at 20.0 ± 0.2°C, is < 6.62 mm²/s at 20.0 ± 0.5°C and < 6.62 mm²/s at 40.0 ± 0.5°C. The product is classified by default metals H290 Corr. 1.  There is no effect of temperature on the stability of the formulation X6119M2 since after 8 weeks at 40°C in HDPE container and tin plate can with internal epoxy phenolic varnish and 7 days at 0°C, there are no modifications of active substance contents and technical properties remain unchanged. The product should not be stored at a temperature higher than 40°C.  The product is stable after 24 months storage in tinplate can with epoxy phenolic varnish. Variations regarding active substances contents, appearance, emulsion stability and aspect of the packaging have been found acceptable.  Compatibility with HDPE and f-HDPE containers and tin plate can with internal varnish with epoxy phenolic varnish has been demonstrated during the accelerated and long term storage stability study. Effect of light has not been studied. Packagings made of HDPE are not considered to be barrier to light. Since cypermethrin is sensitive to sunlight (DT50 (photostability in water: 12.4-14.8d) , it is recommended to store the product away from light (except for metal cans). |

No physico chemical studies were provided for the formulation X6119CR. Instead, the applicant has provided a bridging with formulation X6119M2 and X6236. The bridging for each formulation is discussed in confidential part. Only surface tension and viscosity were provided.

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| --- | --- | --- | --- | --- | --- |
| Property | Guideline and Method | Purity of the test substance (% (w/w) | Results | Comments | Reference |
| Surface tension | EU method A.5  OECD 115 | X6119CR  Lot/batch No.: PaP V 131.2 | The measurement was not performed because the pure test item did not show any adherence or wetting process to the plate. The plate penetrated into the test item and then was not removed. The place out without creating a film because there was no adherence between the metal of the plate and the test item. Due to its behaviour, no measurement was possible on the test item. | Since the product contains more thickening agent, viscosity is higher than for X6236. According to OECD 115, the method is suitable for aqueous solution with a viscosity approximately up to 200mPa.s, which can explained why the measurement was not possible. Nevertheless, considering that X6236 is surface active and that X6119CR contains more surface active substances, it can be assumed that X6119CR will also be surface active. | Legay S. 2016  402/16/1077F-e  GLP |
| Viscosity | OECD 114 | X6119CR  Lot/batch No.: PaP V 131.2 | According to OECD No.114, the mean kinematic viscosity of X6119M2, determined using a flow cup method was the following:  At 20°C: from 470 000 mPa\*s at 0.3rpm to 5.352 mPa\*s at 100rpm  At 40°C: from 316 000 mPa\*s at 0.3 rpm to 3492 mPa\*s at 100rpm | Acceptable. The product is a non newtonien fluid. | Legay S. 2016  402/16/1077F-e  GLP |

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| **Conclusion on the physical, chemical and technical properties of the product X6119CR** |
| The formulation X6119CR is a ready to use formulation (EW: emulsion oil in water ready to use). 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 a slight yellow opaque gel with essential oil odour. It is not explosive and has no oxidizing properties. The product is not considered flammable. It is not auto-flammable in the conditions of use (temperature of auto-ignition: 480°C). The pH of the neat formulation is expected to be near 7 at 20°C. The viscosity of the preparation at 20.0 ± 0.2°C, is from 470 000 mPa\*s at 0.3rpm to 5.352 mPa\*s at 100rpm. The product is classified by default metals H290 Corr. 1.  Storage stability were not performed with X6119CR. However bridgings with formulation X6236 and X6119M2 have been found acceptable (see confidential section for more details). Therefore, the same conclusion for X6236 applies for X6119CR : The formulation is considered stable after storage 8 weeks at 40°C. There is no effect of low temperature on the stability of the formulation since after 7 days at 0°C, there are no modifications of the properties of the product. The product should not be stored at a temperature higher than 40°C. The product is stable after 24 months storage in tinplate can with epoxy phenolic varnish and HDPE packaging. Variations regarding active substances contents, appearance, emulsion stability and aspect of the packaging have been found acceptable.  Compatibility with metal can (tinplate with internal epoxy phenolic varnish) and HDPE has been demonstrated during the accelerated storage and long term storage stability study. The product is also considered stable in LDPE packaging since results were found acceptable in HDPE.  Effect of light has not been studied. Packagings made of HDPE are not considered to be barrier to light. Since cypermethrin is sensitive to sunlight (DT50 photostability in water: 12.4-14.8d) , it is recommended to store the product away from light (except for metal cans). |

**Product X6236 (ready to use product; packaging claimed: tin plate metal can with an internal epoxy phenolic varnish) / meta SPC 4**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa |  | X6236  Lot/batch No1502300036 | Opaque gel, no deposit, no phase partition | Acceptable | Legay S. 2015  402/14/1097F/abcd-e  GLP |
| Colour at 20 °C and 101.3 kPa | white |
| Odour at 20 °C and 101.3 kPa | detergent-like odour |
| Acidity / alkalinity | CIPAC MT 75.3 | X6236  Lot/batch No1502300036 | The mean pH value of X6236 (pure test item) was 7.11 at 19.2°C before the accelerated storage procedure and 7.11 at 20.2°C after the accelerated storage procedure. The pH value was considered to be stable after the accelerated storage procedure. | Acceptable | Legay S. 2015  402/14/1097F/abcd-e  GLP |
| Relative density / bulk density | OECD 109 (pycnometers method) | X6236  Lot/batch No1502300036 | According to OECD No.109 (pycnometers method), the mean relative density of X6236 was:  D (20.8°C / 4°C) = 1.001 | Acceptable | Legay S. 2015  402/14/1097F/efgh-e  GLP |
| Storage stability test – **accelerated storage (8 weeks at 40°C)** | CIPAC MT 46.3 | X6236  Lot/batch No1502300036 | **Appearance**  The appearance of the packaging material (1 L bottle in tin plate with an internal epoxyphenolic varnish) was considered to be stable after an accelerated storage procedure for 8 weeks at 40 ± 2°C. No weight change was observed.  - Changes in colour: yes: white opaque to cream opaque  - Changes in clarity: none  - Changes in texture: none  **Packaging (1L bottle in metal)**  No significant sign of corrosion or degradation was observed. The appearance of the packaging material (1 L bottle in metal) was considered to be stable after an accelerated storage procedure for 8 weeks at 40 ± 2°C. No weight change was observed.  **pH (CIPAC MT 75.3)**  before storage: 7.11 at 19.2°C (pure)  after storage: 7.11 at 20.2°C (pure)  **Viscosity (OECD 114)**  Before storage  The test item showed a non-newtonian behaviour both at 20 and 40 ± 0.2°C using a rotational viscometer Brookfield.  The dynamic viscosity varied as following:  - at 20.0 ± 0.2°C, from 96800 mPa\*s at 0.3 rpm to 771.6 mPa\*s at 100 rpm.  - at 40.0 ± 0.2°C, from 48800 mPa\*s at 0.3 rpm to 718.8 mPa\*s at 100 rpm.  After storage  The test item showed a non-newtonian behaviour both at 20 and 40 ± 0.2°C using a rotational viscometer Brookfield.  The dynamic viscosity varied as following:  - at 20.0 ± 0.2°C, from 96400 mPa\*s at 0.3 rpm to 694.8 mPa\*s at 100 rpm.  - at 40.0 ± 0.2°C, from 38000 mPa\*s at 0.3 rpm to 699.8 mPa\*s at 100 rpm.  **Active ingredient contents (method validated; performed with inert packaging = glass bottle)**   |  |  |  | | --- | --- | --- | | **a.i content (%)** | **Initial** | **T 8 weeks at 40°C** | | **Cypermethrin** | 0.1 | 0.098 (-2%) | | **IPBC** | 0.049 | 0.045 (-8.2%) | | **Propiconazole** | 0.147 | 0.148% (+0.7%) | | **tebuconazole** | 0.048 | 0.049 (+2.1%) | | The variation of IPBC content after storage 8 weeks at 40°C is higher than 5%. Degradation products were not idenfitied. However, since after 2 years storage, the product is stable (ie variations of active substances contents are <10%), this confirms that the product is stable. It should be indicated on the label to store the product at a temperature below 40°C. | Legay S. 2015  402/14/1097F/abcd-e  GLP |
| Storage stability test – **long term storage at ambient temperature** | Technical Monograph 17 | X6236  Lot/batch No.: PaP V29.1 | **Appearance**  The appearance of X6236 was considered to be stable after 6, 12, 18 and 24 months of storage at ambient temperature (opaque, white liquid). No changes (no deposit, no phase partition) were noticed.  **Packaging**  The appearance of the packaging material (1L tin plate can with internal epoxy phenolic varnish) was considered to be stable after 6, 12, 18 and 24 months of storage at ambient temperature (no sign of corrosion or degradation). No weight change was observed after 24 months of storage.  **Active ingredient contents (method validated; tinplate can with internal epoxy phenolic varnish**)   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **a.i content (%)** | **Initial** | **T6** | **T12** | **T18** | **T24** | | **Cypermethrin** | 0.099 | 0.096  (-3%) | 0.101  (+2.0%) | 0.103  (+4.0%) | 0.095  (-4.0%) | | **IPBC** | 0.047 | 0.043  (-8.5%) | 0.045  (-4.3%) | 0.045  (-4.3%) | 0.044  (-6.4%) | | **Propiconazole** | 0.148 | 0.145  (-2.0%) | 0.145  (-2.0%) | 0.149  (+0.7%) | 0.148 (0.0%) | | **tebuconazole** | 0.049 | 0.048  (-2.0%) | 0.049  (0.0%) | 0.049  (0.0%) | 0.046  (-6.1%) |   **pH**  at t0: 6.8 at 19°C  after t24 months: 6.8 at 19°C  **Emulsion characteristics**  Initial emulsification: uniform emulsion  Emulsion stability on standing:  no oil, cream or solid matter after 30min, 2h and 24h  Re-emulsification after 24h: no oil, cream or solid matter after 30 sec; uniform emulsion  Final emulsion stability: no oil, cream or solid matter after 30min | Acceptable. The product is considered stable after 24 months storage in commercial packaging (tin plate can with internal epoxy phenolic varnish) | Legay S. 2016  Report 402/13/1138F/ad-e  GLP |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 | X6236  Lot/batch No.: 1502300036 | The test item was physically stable after storage at 0 ± 2°C for 7 days. The product is still an opaque white gel. No deposit or phase partition was observed. | Acceptable. The product is stable after storage 7 days at 0°C. | Legay S. 2015  402/14/1097F/efgh-e  GLP |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Not required as the biocidal product is packed in opaque commercial packagings. | Acceptable (metal can). |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | The test item X6236 was considered to be stable after 8 weeks at 40 ± 2°C. However, IPBC decreases from more than 5%. However, since the product is stable after 2 years at ambient temperature, stability is confirmed.  The test item X6236 was considered to be stable after 7 days at 0 ± 2°    The individual commercial packagings are hermetically closed with a cap. With their closure systems, the packagings are leak-tight. | Acceptable. See comments made in storage stability section. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | Compatibility with metal can (tin plate with epoxy phenolic varnish) has been demonstrated during the accelerated and long term storage stability studies. | Acceptable. |  |
| Wettability |  |  | Not applicable | Not applicable |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not applicable | Not applicable |  |
| Wet sieve analysis and dry sieve test |  |  | Not applicable | Not applicable |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not applicable since the product is ready to use EW formulation | Acceptable. |  |
| Disintegration time |  |  | Not applicable | Not applicable |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not applicable | Not applicable |  |
| Persistent foaming |  |  | Not applicable since the product is ready to use | Acceptable. |  |
| Flowability/Pourability/Dustability |  |  | Not applicable | Not applicable |  |
| Burning rate — smoke generators |  |  | Not applicable | Not applicable |  |
| Burning completeness — smoke generators |  |  | Not applicable | Not applicable |  |
| Composition of smoke — smoke generators |  |  | Not applicable | Not applicable |  |
| Spraying pattern — aerosols |  |  | Not applicable | Not applicable |  |
| Physical compatibility |  |  | Not applicable. The product is not designed to be used in conjunction with any other products or active substances. Hence, no data on the physical and chemical compatibility of X6236 with other biocidal products, chemicals or active substances is required. | Not applicable |  |
| Chemical compatibility |  |  | Not applicable. The product is not designed to be used in conjunction with any other products or active substances. Hence, no data on the physical and chemical compatibility of X6236 with other biocidal products, chemicals or active substances is required. | Not applicable |  |
| Degree of dissolution and dilution stability |  |  | Not applicable | Not applicable |  |
| Surface tension | EU method A.5  OECD 115 | X6236  Lot/batch No.: 1502300036 | X6236 was considered as surface-active (mean surface tension at 20.5°C of the pure test item: 34.54 mN/m). | Acceptable. The product is surface active. | Legay S. 2015  402/14/1097F/efgh-e  GLP |
| Viscosity | OECD 114 | X6236  Lot/batch No.: 1502300036 | The test item showed a non-Newtonian behaviour both at 20 and 40 ± 0.2°C using a rotational viscometer Brookfield.  The dynamic viscosity varied as follows at initial time:  - at 20.0 ± 0.2°C, from 96800 mPa\*s at 0.3 rpm to 771.6 mPa\*s at 100 rpm.  - at 40.0 ± 0.2°C, from 48800 mPa\*s at 0.3 rpm to 718.8 mPa\*s at 100 rpm. | Acceptable. The product is a non-newtonien liquid. | Legay S. 2015  402/14/1097F/efgh-e  GLP  Legay S. 2015  402/14/1097F/abcd-e  GLP |

**Physical hazards and respective characteristics of X6236**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | (DSC)/statement | X6236  Lot/batch No.: 1502300036 | According to the evaluation of propiconazole, cypermethrin cis:trans / 40:60, tebuconazole and IPBC under Biocidal Products Directive, these active substances (0.35% w/w total) have no potential explosive properties.  Based on data available in literature, safety data sheet and/or on their structure, some formulants (3.78% w/w total) are not expected to be explosive.  The product X6236 contains 92.25% w/w of an inert ingredient.  Data are lacking to conclude on the explosive properties of some formulants (2.84% w/w total).  According to data available in literature, safety data sheet and/or on their structure, all other ingredients (0.77% w/w total) have potential explosive properties. Only one compound (0.01% w/w) does not present an explosive hazard in the product X6236 due to the formulation (liquid).  In addition, the Differential Scanning Calorimetry (DSC) graphs show an exothermic decomposition at about 313°C with a decomposition energy less than 500 J/g (62J/g), what demonstrates that the product X6236 is unlikely to be explosive, and testing is considered as unnecessary. | Acceptable. The product is not explosive. | Raphalen E., Legay S 2015  402/14/1097F/i-e  Detrimont H., Ambrosi D. 2015  15/09 |
| Flammable gases |  |  | Not applicable | Not applicable |  |
| Flammable aerosols |  |  | Not applicable | Not applicable |  |
| Oxidising gases |  |  | Not applicable | Not applicable |  |
| Gases under pressure |  |  | Not applicable | Not applicable |  |
| Flammable liquids |  |  | Not required as X6236 contains around 92% w/w of inert ingredient and less than 0.5% of components classified as flammable. | Acceptable. Based on the composition, the product is not considered flammable. |  |
| Flammable solids |  |  | Not applicable | Not applicable |  |
| Self-reactive substances and mixtures | D.S.C. / statement | X6236  Lot/batch No.: 1502300036 | Based on most recent approach of structural formulas, some formulants (0.78% w/w total) are not considered to have potential self-reactive properties unlike the components propiconazole, cypermethrin cis:trans / 40:60, tebuconazole, IPBC and one formulant (1.03% w/w total).  Data are lacking to conclude on the self-reactivity of several compounds (5.93% w/w total).  The product X6236 contains 92.25% w/w of an inert ingredient.  In addition, according to Regulation (EC) No.1272/2008, homogeneous mixtures of organic substances should be considered for classification in this hazard class unless their exothermic decomposition energy is less than 300 J/g. As an exothermic reaction was observed around 313°C with a decomposition energy less than 300 J/g (62J/g), testing is considered as unnecessary. | Acceptable. The product is not a self reactive mixture. | Raphalen E., Legay S 2015  402/14/1097F/i-e  Detrimont H., Ambrosi D. 2015  15/09 |
| Pyrophoric liquids |  |  | Not required as X6236 contains around 92% w/w of inert ingredient and as experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperature. | Acceptable |  |
| Pyrophoric solids |  |  | Not applicable | Not applicable |  |
| Self-heating substances and mixtures |  |  | No results were provided. | Not acceptable. Nevertheless, since the formulation contains more than 90% of inert ingredient, the product is not considered as a self heating mixture. |  |
| Substances and mixtures which in contact with water emit flammable gases |  |  | Not required as X6236 contains around 92% w/w of inert ingredient. | Acceptable. |  |
| Oxidising liquids | statement |  | Considering the high proportion of non-oxidising ingredients (in total 96.93% w/w), the product X6236 is not expected to present a significant hazard for oxidising properties, and testing is considered as unnecessary | Acceptable. The product has no oxidizing properties. | Detrimont H., Ambrosi D. 2015  15/09 |
| Oxidising solids |  |  | Not applicable | Not applicable |  |
| Organic peroxides |  |  | Not applicable | Not applicable |  |
| Corrosive to metals |  |  | As the product contains an ingredient which is classified as corrosive and as no C1 test according to UN RTDG has been performed, the product is classified as corrosive to metals, Met. Corr. 1, H290. | Acceptable. The product is classified by default corrosive to metals H290 Corr.1. |  |
| Auto-ignition temperatures of products (liquids and gases) | EEC A15 | X6236  Lot/batch No.: PaP V29.1 | The mean auto-ignition temperature of the test item was 480 ± 6°C. | Acceptable. The product is not autoflammable up to 480°C. | Demangel B. 2014  14-904015-004  GLP |
| Relative self-ignition temperature for solids |  |  | Not applicable | Not applicable |  |
| Dust explosion hazard |  |  | Not applicable | Not applicable |  |

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| **Conclusion on the physical, chemical and technical properties of the product X6236 – Meta SPC 4** |
| The formulation X6236 is a ready to use formulation (EW: emulsion oil in water ready to use). All studies have been performed in accordance with the current requirements. The appearance of the product is that of a white opaque gel with a detergent like odour. It is not explosive and has no oxidizing properties. The product is not considered flammable. It is not auto-flammable in the conditions of use (temperature of auto-ignition: 480°C). The pH of the neat formulation is 7.11 at 20°C. The viscosity of the product at 20.0 ± 0.2°C, is from 96800 mPa\*s at 0.3 rpm to 771.6 mPa\*s at 100 rpm. The product is classified by default metals H290 Corr. 1.  There is an effect of high temperature on the stability of the formulation X6236 since after 8 weeks at 40°C in tin plate container, the active ingredient content of IPBC decreased from 8.2%. Degradation products were not identified. However stability after 24 months was acceptable (ie variations of IPBC<10% after 24 months) and allows to conclude that the product is stable. Other active substance contents and technical properties were unchanged. There is no effect of low temperature on the stability of the formulation since after 7 days at 0°C, there are no modification of the properties of the product. The product should not be stored at a temperature higher than 40°C.  The product is stable after 24 months storage in tinplate can with epoxy phenolic varnish. Variations regarding active substances contents, appearance, emulsion stability and aspect of the packaging have been found found acceptable.  Compatibility with metal can (tinplate with internal epoxy phenolic varnish) has been demonstrated with the accelerated storage and long term storage stability study.  Effect of light has not been studied. However, packaging for meta SPC 4 are barrier to light. Consequently, no mitigation measure is necessary for this meta SPC. |

**Overall conclusion on Meta SPC3 and meta SPC 4**

Physico chemical tests were provided for X6119M2 and X6236. For X6119CR, only data on surface tension and viscosity were submitted. No other data were provided but regarding the composition, tests provided for products of these two meta SPC are sufficient. The appearance of the products is that of a transparent colourless liquid (X6119M2) or white opaque gel (X6236) with a detergent like odour. Products are not classified regarding physico chemical properties. However products are classified H290 Corr 1 by default. pH of neat products are close to 7. The products are considered to have non newtonien properties.

There are no effects on the stability of the products after storage 8 weeks at 40°C, 7 days at 0°C and 2 years at ambient temperature in HDPE, LDPE and tin plate can with internal epoxy phenolic varnish. Effect of light has not been studied. Packagings made of HDPE are not considered to be barrier to light. Since cypermethrin is sensitive to sunlight (DT50 photostability in water: 12.4-14.8d), it is recommended to store the products X6119CR and X6119M2 away from light. Physico chemical properties are acceptable for ready to use emulsion formulation.

**Shelf life:** two years

**Mitigation measure:**

For meta SPC3: do no store at a temperature higher than 40°C. Store away from light (except for metal cans).

For meta SPC 4: do no store at a temperature higher than 40°C.

**Classification:** H290 corrosive to metals

* **Minor Change application for PPG\_Class3\_WB - 2019 :**

The conclusions of the physico chemical properties and analytical methods remain unchanged following the assessment of the minor change submitted. Please refer to the confidential annex for details.

### Methods for detection and identification

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

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

**Summary for Propiconazole:**

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

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

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

**Summary for Cypermethrin:**

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

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

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

**Summary for IPBC:**

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

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| Soil (principle of method and LOQ) | HPLC-MS/MS, LOQ = 0.01 mg/kg |
| Air (principle of method and LOQ) | Not necessary, IPBC is not volatile |
| Water (principle of method and LOQ) | Both for surface water, ground water and drinking water. HPLC-MS/MS, LOQ = 0.1 µg/L |
| Body fluids and tissues (principle of method and LOQ) | AM in body fluids and tissues to be submitted at the product evaluation stage. |
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) | Not necessary, IPBC-based wood preservation products or materials treated with such products are not used in a manner which may cause contact with such materials. |
| Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) | Not necessary, IPBC-based wood preservation products or materials treated with such products are not used in a manner which may cause contact with such materials. |

Since the active substance is toxic, an analytical method for body fluids and tissues is required. Analytical methods for body fluids and tissues have been provided in the CAR ot PT6. Methods for food and feeding stuffs of plant origin are not required since the use pattern of product will not result in any contact with food or feeding stuff of plant origin.

**Summary for tebuconazole:**

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

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

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

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

**Meta SPC 1**

**Product X6119C and X6119CJ**

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| --- | --- |
| **Report:** | **Raphalen E. 2013** |
| Title: | Physico-chemical tests on a concentrated aqueous emusion (X6119C/ X6119CJ): Validation of analytical method and chemical analysis of active ingredients declared in the test items, Chemical analysis of active ingredients in two wood preservatives |
| Document No | 402/13/1136F/ab-e |
| Test facility |  |
| Guidelines: | SANCO/3030/99 rev.4. |
| GLP | Yes |

**Principle:** a quantity of test item was accurately weighed in order to obtain a concentration near 90 mg/L in propiconazole, 50 mg/L in cypermethrin, 30 mg/L tebuconazole and IPBC. The product was diluted in acetonitrile. Samples were analysed by HPLC-UV.

**Material**

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

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

Column temperature: 30°C

Mobile phase:

A: acetonitrile

B: water

Gradient:

Time (minutes) % A % B

0.0 52 48

2.0 52 48

5.0 45 55

9.0 90 10

20.0 90 10

21.0 52 48

23.0 52 48

Flow rate: 1 mL/min

Injection volume: 10 µL

UV detector: UV set at 210 nm for propiconazole, cypermethrin and tebuconazole, UV set at 260 nm for IPBC

**Retention times:**

Propiconazole: approximately 4.39 min

Cypermethrin 1: approximately 10.96 minutes

Cypermethrin 2: approximately 10.89 minutes

Cypermethrin 3: approximately 10.99 minutes

Tebuconazole: approximately 3.24 minutes

IPBC: approximately 2.2 minutes

**Reference items:**

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

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

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

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

**Test items:**

**1/Name of test material: X6119C (FCBA reference: 13/1136F/1)**

Composition of test material, percentage of components:

Propiconazole CAS No.60207-90-1, 2.20% w/w (nominal content)

Cypermethrin CAS No.52315-07-8, 1.20% w/w (nominal content)

Tebuconazole CAS No.107534-96-3, 0.74% w/w (nominal content)

IPBC CAS No.55406-53-6, 0.74% w/w (nominal content)

Batch No: XIX 2 NDF

Manufacturing date: 27 June 2013

Blank formulation: batch PaP V31.4, manufacturing date: 8 July 2013 (FCBA reference: 13/1141F/3)

**2/Name of test material: X6119CJ (FCBA reference: 13/1141F/1)**

Composition of test material, percentage of components:

Propiconazole CAS No.60207-90-1, 2.20% w/w (nominal content)

Cypermethrin CAS No.52315-07-8, 1.20% w/w (nominal content)

Tebuconazole CAS No.107534-96-3, 0.74% w/w (nominal content)

IPBC CAS No.55406-53-6, 0.74% w/w (nominal content)

Batch No.: XIX 1 NDF

Manufacturing date: 27 June 2013

Blank formulation: PaP V31.5, manufacturing date: 8 July 2013 (FCBA reference: 13/1136F/2)

**Validation of the analytical method:**

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| --- | --- |
| Specificity | Chromatograms were provided for calibration standards, blank formulation of X6119CJ and X6119C, test items and spiked test item. No interference at the selected wavelengths (210 nm for propiconazole and 260 nm for cypermethrin, tebuconazole and IPBC) was detected at the retention time of each active substance in HPLC-UV in blank formulation samples of X6119C and X6119CJ diluted in acetone. The applied method to quantify each active substance in the test items X6119C and X6119CJ is considered as specific. |
| Linearity | 5 calibration standards were used for the determination of the linearity. 2 series were performed with each substance.  **Propiconazole**  5 calibration standards from 72 to 108mg/L  Serie 1:the linear function corresponds to y = 3.037292\*104\*x - 1.406169\*105(y = peak area, x = propiconazole content in mg/L)  The determination coefficient r² is equal to 0.996071 so the correlation coefficient r is equal to 0.9980 showing a good linearity.  Serie 2:the linear function corresponds to y = 2.792873\*104\*x + 5.835127\*104(y = peak area, x = propiconazole content in mg/L)  The determination coefficient r² is equal to 0.999683 so the correlation coefficient r is equal to 0.9998 showing a good linearity.  **Cypermethrin**  5 calibrations standards from 40 to 60mg/L  Serie 1:the linear function corresponds to y = 5.417572\*104\*x + 7.139752\*104(y = peak area, x = cypermethrin content in mg/L)  The determination coefficient r² is equal to 0.997087 so the correlation coefficient r is equal to 0.9985 showing a good linearity.  Serie 2:the linear function corresponds to y = 5.950726\*104\*x - 1.940215\*105(y = peak area, x = cypermethrin content in mg/L)  The determination coefficient r² is equal to 0.997379 so the correlation coefficient r is equal to 0.9987 showing a good linearity  **Tebuconazole**  5 calibrations standards from 24 to 36mg/L  Serie 1:the linear function corresponds to y = 1.717261\*104\*x – 2.055625\*104(y = peak area, x = tebuconazole content in mg/L)  The determination coefficient r² is equal to 0.998838 so the correlation coefficient r is equal to 0.9994 showing a good linearity.  Serie 2:the linear function corresponds to y = 1.568435\*104\*x – 6.402389\*103(y = peak area, x = tebuconazole content in mg/L)  The determination coefficient r² is equal to 0.999315 so the correlation coefficient r is equal to 0.9997 showing a good linearity.  **IPBC**  5 calibration standards from 24 to 36mg/L  Serie 1:the linear function corresponds to y = 3.795521\*102\*x – 1.004830\*103(y = peak area, x = IPBC content in mg/L)  The determination coefficient r² is equal to 0.998827 so the correlation coefficient r is equal to 0.9994 showing a good linearity.  Serie 2:the linear function corresponds to y = 3.919380\*102\*x – 1.703092\*103(y = peak area, x = IPBC content in mg/L)  The determination coefficient r² is equal to 0.993955 so the correlation coefficient r is equal to 0.9970 showing a good linearity.  The applied method to quantify each active substance at the declared value in both test items 13/1136F/1 and 13/1141F/1 is considered as linear on the calibration range. |
| Precision | Precision was performed with 6 samples of the test items  **X6119C**  **Propiconazole**  RSD=0.45% (RSDr=2.38% with C=0.022)  **Cypermethrin**  RSD=0.41% (RSDr=2.61% with C=0.0120)  **Tebuconazole**  RSD=0.38% (RSDr=2.80% with C=0.0074)  **IPBC**  RSD=2.00% (RSDr=2.80% with C=0.0074)  **X6119CJ**  **Propiconazole**  RSD=0.44% (RSDr=2.38% with C=0.022)  **Cypermethrin**  RSD=0.56% (RSDr=2.61% with C=0.0120)  **Tebuconazole**  RSD=0.78% (RSDr=2.80% with C=0.0074)  **IPBC**  RSD=1.15% (RSDr=2.80% with C=0.0074) |
| Accuracy | Accuracy was determined by analysis of 12 independent determinations in which known amounts of the reference substance were added to a blank formulation. 0.208g of blank formulation of X6119C was weighted in a 50mL flask and was spiked with active substance solutions and diluted into acetonitrile with the following concentrations:   * 50mg/L for cypermethrin (eq to 1.20% cypermethrin/reconstituted product X6119C) * 91.5mg/L for propiconazole (eq to 2.2% propiconazole/reconstituted product X6119C) * 30.8mg/L for tebuconazole (eq to 0.72% tebuconazole/reconstituted product X6119C) * 30.8mg/L for IPBC (eq to 0.72% IPBC/reconstituted product X6119C)   **Propiconazole**  Mean recovery rate = 99.81% (n = 12), RSD=0.61%  **Cypermethrin**  Mean recovery rate = 100.8% (n = 12), RSD=0.62%  **Tebuconazole**  Mean recovery rate = 100.3% (n = 12), RSD=0.73%  **IPBC**  Mean recovery rate = 101.8% (n = 12), RSD=1.4%  No results were provided for formulation X6119CJ. Nevertheless, the only difference with X6119C is the addition of colouring agent and specificity has been demonstrated for both formulations. Therefore, data are considered sufficient. |
| Conclusion | Specificity, linearity, accuracy and precision are found acceptable. The method is validated.  **Method is validated for all products of the Meta SPC1.** |

**Meta SPC 2**

**Product X6119C1**

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| **Report:** | **Raphalen E. 2015** |
| Title: | Validation according to SANCO 3030/99 rev. 4 for the chemical analysis of the active substances in the biocidal product X6119C1 |
| Document No | 15/1069F/ab-e |
| Test facility |  |
| Guidelines: | SANCO/3030/99 rev.4. |
| GLP | Yes |

**Principle:** a quantity of test item was accurately weighed in order to obtain a concentration near 90 mg/L in propiconazole, 50 mg/L in cypermethrin, 30 mg/L tebuconazole and IPBC. The product was diluted in acetonitrile. Samples were analysed by HPLC-UV.

**Material**

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

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

Column temperature: 30°C

Mobile phase:

A: acetonitrile

B: water

Gradient:

Time (minutes) % A % B

0.0 55 45

2.0 55 45

3.0 90 10

7.0 90 10

8.0 55 45

10.00 55 45

25.00 55 45

Flow rate: 1 mL/min

Injection volume: 10 µL

UV detector: UV set at 210 nm for propiconazole, cypermethrin and tebuconazole, UV set at 260 nm for IPBC

**Retention times:**

Propiconazole: approximately 3.79 min

Cypermethrin 1: approximately 5.62 minutes

Cypermethrin 2: approximately 5.71 minutes

Tebuconazole: approximately 2.93 minutes

IPBC: approximately 2.05 minutes

**Reference items:**

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

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

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

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

**Test items:**

**1/Name of test material: X6119C1 (FCBA reference: 15/1069F/1)**

Composition of test material, percentage of components:

Propiconazole CAS No.60207-90-1, 2.20% w/w (nominal content)

Cypermethrin CAS No.52315-07-8, 1.20% w/w (nominal content)

Tebuconazole CAS No.107534-96-3, 0.74% w/w (nominal content)

IPBC CAS No.55406-53-6, 0.74% w/w (nominal content)

Batch No: PaP V 101.1

Manufacturing date: 13 May 2015

Blank formulation: matrice X6119C1, FCBA reference 15/1069F/2, batch PaP V 101.2, manufacturing date: 13 May 2015

**Validation of the analytical method:**

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| --- | --- |
| Specificity | Chromatograms were provided for calibration standards, blank formulation of X6119C1, test items and spiked test item. No interference at the selected wavelengths (210 nm for propiconazole and 260 nm for cypermethrin, tebuconazole and IPBC) was detected at the retention time of each active substance in HPLC-UV in blank formulation samples of X6119C1 diluted in acetone. The applied method to quantify each active substance in the test items X6119C1 is considered as specific. |
| Linearity | 5 calibration standards were used for the determination of the linearity. 2 series were performed with each substance and covered the target value +/-20%.  **Propiconazole**  5 calibration standards from 72 to 108mg/L  The linear function corresponds to y = 2.338534\*104\*x – 3.059631\*103(y = peak area, x = propiconazole content in mg/L)  The determination coefficient r² is equal to 0.999912 so the correlation coefficient r is equal to 0.999956 showing a good linearity.  **Cypermethrin**  5 calibrations standards from 40 to 60mg/L  The linear function corresponds to y = 4.958071\*104\*x + 7.139752\*104(y = peak area, x = cypermethrin content in mg/L)  The determination coefficient r² is equal to 0.999106 so the correlation coefficient r is equal to 0.999553 showing a good linearity.  **Tebuconazole**  5 calibrations standards from 24 to 36mg/L  The linear function corresponds to y = 1.710021\*104\*x – 3.862852\*104(y = peak area, x = tebuconazole content in mg/L)  The determination coefficient r² is equal to 0.996760 so the correlation coefficient r is equal to 0.998379 showing a good linearity.  **IPBC**  5 calibration standards from 24 to 36mg/L  The linear function corresponds to y = 3.45102\*102\*x – 6.277323\*102(y = peak area, x = IPBC content in mg/L)  The determination coefficient r² is equal to 0.990175 so the correlation coefficient r is equal to 0.995076 showing a good linearity.  The applied method to quantify each active substance at the declared value is considered as linear on the calibration range. |
| Precision | Precision was performed with 6 samples of the test items  **X6119C1**  **Propiconazole**  RSD=0.16% (RSDr=2.38% with C=0.022)  **Cypermethrin**  RSD=0.47% (RSDr=2.61% with C=0.0120)  **Tebuconazole**  RSD=0.81% (RSDr=2.80% with C=0.0074)  **IPBC**  RSD=1.46% (RSDr=2.80% with C=0.0074) |
| Accuracy | Accuracy was determined by analysis of 6 independent determinations in which known amounts of the reference substance were added to a blank formulation. 0.1g of blank formulation of X6119C1 was weighted in a 25mL flask and was spiked with active substance solutions and diluted into acetonitrile with the following concentrations:   * 48mg/L for cypermethrin (eq to 1.20% cypermethrin/reconstituted product X6119C) * 88mg/L for propiconazole (eq to 2.2% propiconazole/reconstituted product X6119C) * 29.6mg/L for tebuconazole (eq to 0.73% tebuconazole/reconstituted product X6119C) * 29.6mg/L for IPBC (eq to 0.73% IPBC/reconstituted product X6119C)   **Propiconazole**  Mean recovery rate = 97.6% (n = 6), RSD=0.16%  **Cypermethrin**  Mean recovery rate = 97.0% (n = 6), RSD=0.47%  **Tebuconazole**  Mean recovery rate = 96.6% (n = 6), RSD=0.81%  **IPBC**  Mean recovery rate = 99.7% (n = 6), RSD=1.46% |
| Conclusion | Specificity, linearity, accuracy and precision are found acceptable. The method is validated.  **Method is validated for X6119C1** |

**Product X6119B1**

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| **Report:** | **Raphalen E. 2015** |
| Title: | Content of active substances in the biocidal product X6119B1 after a method validation according to SANCO 3030/99 rev. 4 |
| Document No | 15/1068F/ab-e |
| Test facility |  |
| Guidelines: | SANCO/3030/99 rev.4. |
| GLP | Yes |

**Principle:** a quantity of test item was accurately weighed in order to obtain a concentration near 90 mg/L in propiconazole, 50 mg/L in cypermethrin, 30 mg/L tebuconazole and IPBC. The product was diluted in acetonitrile. Samples were analysed by HPLC-UV.

**Material**

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

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

Column temperature: 30°C

Mobile phase:

A: acetonitrile

B: water

Gradient:

Time (minutes) % A % B

0.0 55 45

2.0 55 45

3.0 90 10

7.0 90 10

8.0 55 45

10.00 55 45

25.00 55 45

Flow rate: 1 mL/min

Injection volume: 10 µL

UV detector: UV set at 210 nm for propiconazole, cypermethrin and tebuconazole, UV set at 260 nm for IPBC

**Retention times:**

Propiconazole: approximately 3.79 min

Cypermethrin 1: approximately 5.62 minutes

Cypermethrin 2: approximately 5.71 minutes

Tebuconazole: approximately 2.93 minutes

IPBC: approximately 2.05 minutes

**Reference items:**

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

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

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

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

**Test items:**

**1/Name of test material: X6119B1 (FCBA reference: 15/1068F/1)**

Composition of test material, percentage of components:

Propiconazole CAS No.60207-90-1, 1.10% w/w (nominal content)

Cypermethrin CAS No.52315-07-8, 0.60% w/w (nominal content)

Tebuconazole CAS No.107534-96-3, 0.37% w/w (nominal content)

IPBC CAS No.55406-53-6, 0.37% w/w (nominal content)

Batch No: 1513317

Manufacturing date: 13 May 2015

Blank formulation: matrice X6119B1, FCBA reference 15/1068F/2, batch PaP V 101.15, manufacturing date: 13 May 2015

**Validation of the analytical method:**

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| --- | --- |
| Specificity | Chromatograms were provided for calibration standards, blank formulation of X6119B1, test items and spiked test item. No interference at the selected wavelengths (210 nm for propiconazole and 260 nm for cypermethrin, tebuconazole and IPBC) was detected at the retention time of each active substance in HPLC-UV in blank formulation samples of X6119B1 diluted in acetone. The applied method to quantify each active substance in the test items X6119B1 is considered as specific. |
| Linearity | 5 calibration standards were used for the determination of the linearity. 2 series were performed with each substance and covered the target value +/-20%.  **Propiconazole**  5 calibration standards from 72 to 108mg/L  The linear function corresponds to y = 2.338534\*104\*x + 3.059631\*103(y = peak area, x = propiconazole content in mg/L)  The determination coefficient r² is equal to 0.999912 so the correlation coefficient r is equal to 0.999956 showing a good linearity.  **Cypermethrin**  5 calibrations standards from 40 to 60mg/L  The linear function corresponds to y = 4.958071\*104\*x + 7.056564\*104(y = peak area, x = cypermethrin content in mg/L)  The determination coefficient r² is equal to 0.999106 so the correlation coefficient r is equal to 0.999553 showing a good linearity.  **Tebuconazole**  5 calibrations standards from 24 to 36mg/L  The linear function corresponds to y = 1.710021\*104\*x – 3.862852\*104(y = peak area, x = tebuconazole content in mg/L)  The determination coefficient r² is equal to 0.996760 so the correlation coefficient r is equal to 0.998379 showing a good linearity.  **IPBC**  5 calibration standards from 24 to 36mg/L  The linear function corresponds to y = 3.45102\*102\*x – 6.277323\*102(y = peak area, x = IPBC content in mg/L)  The determination coefficient r² is equal to 0.990175 so the correlation coefficient r is equal to 0.995076 showing a good linearity.  The applied method to quantify each active substance at the declared value is considered as linear on the calibration range. |
| Precision | Precision was performed with 6 samples of the test item  **X6119B1**  **Propiconazole**  RSD=0.81% (RSDr=2.64% with C=0.011)  **Cypermethrin**  RSD=0.83% (RSDr=2.89% with C=0.006)  **Tebuconazole**  RSD=1.07% (RSDr=3.11% with C=0.0037)  **IPBC**  RSD=0.79% (RSDr=3.11% with C=0.0037) |
| Accuracy | Accuracy was determined by analysis of 6 independent determinations in which known amounts of the reference substance were added to a blank formulation. 0.2g of blank formulation of X6119B1 was weighted in a 25mL flask and was spiked with active substance solutions and diluted into acetonitrile with the following concentrations:   * 48mg/L for cypermethrin (eq to 0.6% cypermethrin/reconstituted product X6119C) * 88mg/L for propiconazole (eq to 1.1% propiconazole/reconstituted product X6119C) * 29.6mg/L for tebuconazole (eq to 0.37% tebuconazole/reconstituted product X6119C) * 29.6mg/L for IPBC (eq to 0.37% IPBC/reconstituted product X6119C)   **Propiconazole**  Mean recovery rate = 97.4% (n = 6), RSD=0.23%  **Cypermethrin**  Mean recovery rate = 97.1% (n = 6), RSD=0.26%  **Tebuconazole**  Mean recovery rate = 95.3% (n = 6), RSD=0.42%  **IPBC**  Mean recovery rate = 96.8% (n = 6), RSD=0.84% |
| Conclusion | Specifcity, linearity, accuracy and precision are found acceptable. The method is validated.  **Method is validated for X6119B1** |

**Conclusion Meta SPC2**

Analytical methods are validated for the determination of cypermethrin, propiconazole, tebuconazole and IPBC in the product X6119C1 and X6119B1.

**Meta SPC 3 and Meta SPC 4**

**Product X6119M2 – Meta SPC3**

|  |  |
| --- | --- |
| **Report:** | **Raphalen E. 2013** |
| Title: | Physico-chemical tests on a ready-to-use aqueous emulsion (X6119M2/ X6089HA1): Validation of analytical method and chemical analysis of active ingredients declared in the test items, Chemical analysis of active ingredients in two wood preservatives |
| Document No | 402/13/1134F/ab-e |
| Test facility |  |
| Guidelines: | SANCO/3030/99 rev.4. |
| GLP | Yes |

**Principle:**

A quantity of test item was accurately weighed in order to obtain a concentration near 75 mg/L in propiconazole, 50 mg/L in cypermethrin, 25 mg/L tebuconazole and IPBC. The product was diluted in acetonitrile and the solution was shaken.

Samples were analysed by HPLC-UV.

**Material**

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

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

Column temperature: 30°C

Mobile phase:

A: acetonitrile

B: water

Gradient:

Time (minutes) % A % B

0.0 52 48

1.0 52 48

2.0 55 45

5.0 65 35

9.0 90 10

20.0 90 10

21.0 52 48

23.0 52 48

Flow rate: 1 mL/min

Injection volume: 10 µL

UV detector: UV set at 230 nm

Retention times:

Propiconazole: approximately 4.13 min

Cypermethrin 1: approximately 9.9 minutes

Cypermethrin 2: approximately 10.02 minutes

Cypermethrin 3: approximately 10.07 minutes

Tebuconazole: approximately 3.25 minutes

IPBC: approximately 2.2 minutes

**Reference items:**

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

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

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

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

**Test items:**

Name of test material: X6119M2 (FCBA reference: 13/1134F/1)

Composition of test material, percentage of components:

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

Cypermethrin CAS No.52315-07-8: 0.10% w/w (nominal content)

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

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

Batch No.: XVIII 195 NDF

Manufacturing date: 20 June 2013

Blank formulation: batch PaP V31.3 (FCBA 13/1134F/3)

**Validation of the analytical method:**

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| --- | --- |
| Specificity | Chromatograms were provided for calibration standards, blank formulation, test item and spiked test item. No interference at the selected wavelength (230 nm) was detected at the retention time of each active substance in HPLC-UV in blank formulation samples of product X6119M2 diluted in acetonitrile.  The applied method to quantify each active substance in test item X6119M2 is considered as specific. |
| Linearity | 5 calibration standards were used for the determination of the linearity. 2 series were performed with each substance.  **Propiconazole**  5 calibration standards ranging from 60 to 90mg/L  Serie 1:the linear function corresponds to y = 1.189334\*104\*x + 2.152619\*104(y = peak area, x = propiconazole content in mg/L)  The determination coefficient r² is equal to 0.999510 so the correlation coefficient r is equal to 0.9998 showing a good linearity.  Serie 2:the linear function corresponds to y = 1.234962\*104\*x – 2.952965\*104(y = peak area, x = propiconazole content in mg/L)  The determination coefficient r² is equal to 0.999482 so the correlation coefficient r is equal to 0.9997 showing a good linearity.  **Cypermethrin**  5 calibration standards ranging from 40 to 60mg/L  Serie 1:the linear function corresponds to y = 2.487745\*104\*x + 1.922258\*104(y = peak area, x = cypermethrin content in mg/L)  The determination coefficient r² is equal to 0.999030 so the correlation coefficient r is equal to 0.9995 showing a good linearity.  Serie 2:the linear function corresponds to y = 2.481036\*104\*x – 4.834926\*103(y = peak area, x = cypermethrin content in mg/L)  The determination coefficient r² is equal to 0.997831 so the correlation coefficient r is equal to 0.9989 showing a good linearity.  **Tebuconazole**  5 calibration standards ranging from 20 to 30mg/L  Serie 1:the linear function corresponds to y = 3.929212\*103\*x – 3.261595\*103(y = peak area, x = tebuconazole content in mg/L)  The determination coefficient r² is equal to 0.996840 so the correlation coefficient r is equal to 0.9984 showing a good linearity.  Serie 2:the linear function corresponds to y = 3.538290\*103\*x + 2.088050\*103(y = peak area, x = tebuconazole content in mg/L)  The determination coefficient r² is equal to 0.996459 so the correlation coefficient r is equal to 0.9982 showing a good linearity.  **IPBC**  5 calibration standards ranging from 20 to 30mg/L  Serie 1:the linear function corresponds to y = 1.030824\*103\*x – 3.025141\*101(y = peak area, x = IPBC content in mg/L)  The determination coefficient r² is equal to 0.991560 so the correlation coefficient r is equal to 0.9958 showing a good linearity.  Serie 2:the linear function corresponds to y = 9.987331\*102\*x – 6.19986\*101(y = peak area, x = IPBC content in mg/L)  The determination coefficient r² is equal to 0.995693 so the correlation coefficient r is equal to 0.9978 showing a good linearity.  The applied method to quantify each active substance at the declared value in test item X6119M2 is considered as linear on the calibration range. |
| Precision | Precision was performed with 6 samples of the test item.  **Propiconazole**  RSD=0.69% (RSDr=3.57% with C=0.0015)  **Cypermethrin**  RSD=1.05% (RSDr=3.79% with C=0.001)  **Tebuconazole**  RSD=2.13% (RSDr=4.2% with C=0.0005)  **IPBC**  RSD=4.26% (RSDr=4.2% with C=0.0005) |
| Accuracy | Accuracy was determined by analysis of 12 independent determinations in which known amounts of the reference substance were added to a blank formulation of X6119M2 and diluted in 5 mL of acetonitrile. The fortification levels in the final solution were:  - 75 mg/L for propiconazole (eq to 0.15% w/w propiconazole/reconstituted product X6119M2)  - 50 mg/L for cypermethrin (eq to 0.10% w/w cypermethrine/reconstituted product X6119M2)  - 25 mg/L for tebuconazole (eq to 0.05% w/w tebuconazole/reconstituted product X6119M2)  - 25 mg/L for IPBC (eq to 0.05% w/w IPBC/reconstituted product X6119M2)  **Propiconazole**  Mean recovery rate = 100.4% (n = 12), RSD=0.5791%  **Cypermethrin**  Mean recovery rate = 100.9% (n = 12), RSD=0.6263%  **Tebuconazole**  Mean recovery rate = 99.91% (n = 12), RSD=0.8391%  **IPBC**  Mean recovery rate = 99.48% (n = 12), RSD=1.688% |
| Conclusion | Specificity, linearity, accuracy and precision are found acceptable. The method is validated. |

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| **Report:** | **Raphalen E. 2013** |
| Title: | Physico-chemical tests on a ready-to-use aqueous emulsion (X6236): Validation of analytical method and chemical analysis of active ingredients declared in the test items, Chemical analysis of active ingredients in two wood preservatives |
| Document No | 402/13/1137F/ab-e |
| Test facility |  |
| Guidelines: | SANCO/3030/99 rev.4. |
| GLP | Yes |

**Principle:**

A quantity of test item was accurately weighed in order to obtain a concentration near 75 mg/L in propiconazole, 50 mg/L in cypermethrin, 25 mg/L tebuconazole and IPBC. The product was diluted in acetonitrile and the solution was shaken.

Samples were analysed by HPLC-UV.

**Material**

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

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

Column temperature: 30°C

Mobile phase:

A: acetonitrile

B: water

Gradient:

Time (minutes) % A % B

0.0 52 48

1.0 52 48

2.0 55 45

5.0 65 35

9.0 90 10

20.0 90 10

21.0 52 48

23.0 52 48

Flow rate: 1 mL/min

Injection volume: 10 µL

UV detector: UV set at 230 nm

Retention times:

Propiconazole: approximately 4.13 min

Cypermethrin 1: approximately 9.9 minutes

Cypermethrin 2: approximately 10.02 minutes

Cypermethrin 3: approximately 10.07 minutes

Tebuconazole: approximately 3.25 minutes

IPBC: approximately 2.2 minutes

**Reference items:**

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

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

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

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

**Test item:**

Name of test material: X6236 (FCBA reference: 13/1138F/1)

Composition of test material, percentage of components:

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

Cypermethrin CAS No.52315-07-8, 0.10% w/w (nominal content)

Tebuconazole CAS No.10753-96-3, 0.05% w/w (nominal content)

IPBC CAS No.55406-53-6, 0.05% w/w (nominal content)

Batch No.: PaP V29.1

Manufacturing date: 03 July 2013

Blank formulation: batch PaP V31.2, manufacturing date 8 July 2013 (FCBA reference 13/1137F/2)

**Validation of the analytical method:**

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| --- | --- |
| Specificity | Chromatograms were provided for calibration standards, blank formulation, test item and spiked test item. No interference at the selected wavelength (230 nm) was detected at the retention time of each active substance in HPLC-UV in blank formulation samples diluted in acetonitrile.  The applied method to quantify each active substance in test item X6236 is considered as specific. |
| Linearity | 5 calibration standards were used for the determination of the linearity. 2 series were performed with each substance.  **Propiconazole**  Serie 1:the linear function corresponds to y = 1.189334\*104\*x + 2.152619\*104(y = peak area, x = propiconazole content in mg/L)  The determination coefficient r² is equal to 0.999510 so the correlation coefficient r is equal to 0.9998 showing a good linearity.  Serie 2:the linear function corresponds to y = 1.243013\*104\*x – 2.301857\*104(y = peak area, x = propiconazole content in mg/L)  The determination coefficient r² is equal to 0.998512 so the correlation coefficient r is equal to 0.9993 showing a good linearity.  **Cypermethrin**  Serie 1:the linear function corresponds to y = 2.487745\*104\*x + 1.922258\*104(y = peak area, x = cypermethrin content in mg/L)  The determination coefficient r² is equal to 0.999030 so the correlation coefficient r is equal to 0.9995 showing a good linearity.  Serie 2:the linear function corresponds to y = 2.493219\*104\*x + 3.052713\*102(y = peak area, x = cypermethrin content in mg/L)  The determination coefficient r² is equal to 0.997409 so the correlation coefficient r is equal to 0.9987 showing a good linearity.  **Tebuconazole**  Serie 1:the linear function corresponds to y = 3.929212\*103\*x – 3.261595\*103(y = peak area, x = tebuconazole content in mg/L)  The determination coefficient r² is equal to 0.996840 so the correlation coefficient r is equal to 0.9984 showing a good linearity.  Serie 2:the linear function corresponds to y = 3.701968\*103\*x + 3.770048\*102(y = peak area, x = tebuconazole content in mg/L)  The determination coefficient r² is equal to 0.997598 so the correlation coefficient r is equal to 0.9988 showing a good linearity  **IPBC**  Serie 1:the linear function corresponds to y = 1.030824\*103\*x – 3.025141\*101(y = peak area, x = IPBC content in mg/L)  The determination coefficient r² is equal to 0.991560 so the correlation coefficient r is equal to 0.9958 showing a good linearity.  Serie 2:the linear function corresponds to y = 1.007651\*103\*x + 3.640597\*102(y = peak area, x = IPBC content in mg/L)  The determination coefficient r² is equal to 0.994214 so the correlation coefficient r is equal to 0.9971 showing a good linearity. |
| Precision | Precision was performed with 6 samples of the test item.  **Propiconazole**  RSD=0.68% (RSDr=3.57% with C=0.0015)  **Cypermethrin**  RSD=1.01% (RSDr=3.79% with C=0.001)  **Tebuconazole**  RSD=0.00% (RSDr=4.2% with C=0.0005)  **IPBC**  RSD=2.13% (RSDr=2.13% with C=0.0005) |
| Accuracy | Accuracy was determined by analysis of 12 independent determinations in which known amounts of the reference substance were added to a blank formulation of X6236 and diluted in 5 mL of acetonitrile. The fortification levels in the final solution were:  - 75 mg/L for propiconazole (eq to 0.15% w/w propiconazole/reconstituted product X6236)  - 50 mg/L for cypermethrin (eq to 0.1% w/w cypermethrine/reconstituted product X6236)  - 25 mg/L for tebuconazole (eq to 0.05% w/w tebuconazole/reconstituted product X6236)  - 25 mg/L for IPBC (eq to 0.05% w/w IPBC/reconstituted product X6236)  **Propiconazole**  Mean recovery rate = 100.3% (n = 12), RSD=0.4715%  **Cypermethrin**  Mean recovery rate = 100.1% (n = 12), RSD=1.058%  **Tebuconazole**  Mean recovery rate = 99.97% (n = 12), RSD=2.009%  **IPBC**  Mean recovery rate = 98.66% (n = 12), RSD=0.9474% |
| Conclusion | Specificity, linearity, accuracy and precision are found acceptable. The method is validated. |

**Product X6119CR (meta SPC3)**

**No results were provided for the determination of the active ingredients in the formulation X6119CR. Since the contents of active substances and the composition is similar to X6119M2 and X6236, a full validation is not required. Nevertheless, as new formulants are present in the formulation X6119CR, specificity must at least be demonstrated to confirm there are no interferences at the retention time of the active substances. According to the applicant, a new study is on going. Data are requested in post authorisation to confirm the specificity of the method.**

**Conclusion Meta SPC3 and meta SPC 4**

Analytical methods for the determination of cypermethrin, propiconazole, tebuconazole and IPBC in products of meta SPC 3 or meta SPC 4 are validated. **However for the formulation X6119CR, specificity should be demonstrated. However this product is not authorised.**

### Efficacy against target organisms

#### Function and field of use

MG 02: preservatives

Product Type 08: wood preservative

The products of the family (PPG\_Class1\_WB) are liquid water based wood preservative products. The family was separated in 4 META-SPC:

* META-SPC 1: the products of the META-SPC1 are intended to be used for preventive treatments by superficial application. The product is applied by industrial and professional users.
* META-SPC 2: the products of the META-SPC2 are intended to be used for preventive treatments by superficial application. The product is applied by industrial users only.
* META-SPC 3: the products of the META-SPC3 are intended to be used for preventive treatments by superficial application and for curative treatments by superficial application (that could be completed by injection for curative treatments). The product is applied by professional and non-professional users.
* META-SPC 4: the products of the META-SPC4 are intended to be used for preventive treatments by superficial application and for curative treatments by superficial application (that could be completed by injection for curative treatments). The product is applied by professional and non-professional users.

*Based on applicant proposal, meta SPC 3 and meta SPC 4 were merged. Nevertheless, eCA considers that one of the product of the meta SPC could not be grouped with other ones and should separated. Technical explanations are given here below*

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

The products of the family (PPG\_Class3\_WB) are intended to be used by superficial application for preventive treatments for wood in use classes 1 to 3.1. Products of meta SPC 3 and 4 are also intended to be used for curative treatments by superficial application (that could be completed by injection), for wood in service in situation of use classes 1 and 2.

* in META SPC 1, the application rates recommended by the applicant are the following:

- Preventive treatments: superficial application at:

* + - * 200 g of 3 % v/v diluted product / m² of wood and at 100 g of 3 % v/v diluted product /m² of wood in use class 1 against wood boring beetles and termites;
      * 165 g of 5 % v/v diluted product / m² of wood in use classes 2 to 3.1 against wood rotting fungi (brown rot fungi), wood boring beetles and termites;
      * 100 g of 5 % v/v diluted product /m² of wood in use class 1 against wood boring beetles and termites.
* in META SPC2, the application rates recommended by the applicant are the following:

- Preventive treatments: superficial application at:

* + - * 165 g of 5 % v/v diluted product / m² of wood in use classes 2 to 3.1 against wood rotting fungi (brown rot fungi), wood boring beetles and termites;
      * 100 g of 5 % v/v diluted product /m² of wood in use class 1 against wood boring beetles and termites;
      * 165 g of 10 % v/v diluted product / m² of wood in use classes 2 to 3.1 against wood rotting fungi (brown rot fungi), wood boring beetles and termites;
      * 100 g of 10 % v/v diluted product /m² of wood for use in use class 1 against wood boring beetles and termites.

The dilutions are product dependent

* in META SPC3, the application rates recommended by the applicant are the following:

- Preventive treatments: superficial application at 200 g of product / m² of wood in use classes 1 to 3.1 against wood rotting fungi (brown rot fungi), wood boring beetles and termites;

- Curative treatment: superficial application at 300 g of product / m² of wood (+ injection 180 g of product / m² of wood if need be (20 mL per hole, 9 holes /m²)) against wood boring beetles and termites.

* in META SPC4, the application rates recommended by the applicant are the following:

- Preventive treatments: superficial application at 200 g of product / m² of wood in use classes 1 to 3.1 against wood rotting fungi (brown rot fungi), wood boring beetles and termites;

- Curative treatment: superficial application at 300 g of product / m² of wood (+ injection 180 g of product / m² of wood if need be (20 mL per hole, 9 holes /m²)) against wood boring beetles and termites.

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

According to the uses claimed by the applicant, the products of the family (PPG\_Class3\_WB) are intended to be used against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*), wood rotting fungi (brown rot fungi)and termites *(Reticulitermes spp*. and *Heterotermes spp*.) on softwood and hardwood

The development stages for insects claimed are larvae and adults.

#### Mode of action, including time delay

Cypermethrin is a synthetic pyrethroid with contact and stomach action. It acts by preventing the transmission of impulses along the nervous system of the insect. It is thought that this is achieved by blocking the sodium channels in nerve membranes, thus preventing action potentials passing down the nerve axon (see AR for Cypermethrin PT08, 12/07/2012).

As other triazole fungicides, tebuconazole and propiconazole are DMIs (DeMethylation Inhibitors). These substances inhibit the C14 demethylation step in the ergosterol biosynthesis of fungi (Fungicide Resistance Action Committee, FRAC2).

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

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

Regarding the curative insecticidal efficacy, based on the elements presented in the dossier, the product of the META-SPC 3 has demonstrated a slow action on *Hylotrupes bajulus* and a fast action on *Anobium punctatum.* The product of the META-SPC4 has demonstrated a fast action on *Anobium punctatum*.

#### Efficacy data

* **For META-SPC1: this META-SPC includes X6119CJ and X6119C formulations.**

The tests have been performed with a 5 % v/v dilution of product X6119CJ

French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the product X6119CJ according to the uses and the applications rates claimed:

* Regarding the preventive claim against wood rotting fungi, for superficial application, the product X6119CJ is efficient according to EN 113 (+EN73 and EN84), against wood destroying basidiomycetes (excluding *C. versicolor*), when diluted at 5 %, v/v at the application rate of 165 g/m². Then for use class 2 an efficacy on softwood and hardwood is validated. For use class 3.1, only an efficacy on softwood is validated.

Moreover, as for use class 3.1, the demonstration of the efficacy is based on the EN 113 standard, the EN-599[[11]](#footnote-11) requires the use of a top coat (§5.2.17 & §5.2.18). Then it can be concluded that when applied by superficial application for use class 3.1, a top coat has to be applied.

* Regarding the preventive efficacy claim against wood boring beetles, for superficial application, the product X6119CJ is efficient according to respectively EN 46 (+EN73 and EN84), EN 49 (+EN73 and EN84) and EN 20-1 (+EN73), against *Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus* at the application rate of 100 g of 5 % v/v diluted product X6119CJ / m² of wood in use classes 1 to 3.1 on softwood and hardwood.
* Regarding the preventive efficacy claim against termites, for superficial application, the product X6119CJ is efficient according to EN 118 (+EN73 and EN84), against *Reticulitermes spp.*, at the application rate of 100 g of 5 % v/v diluted product X6119CJ / m² of wood in use classes 1 to 3.1 on softwood and hardwood.

Additional tests were also presented in this META SPC with a 3 % v/v dilution of the product X6119C:

* Regarding the preventive efficacy claim against wood boring beetles, for superficial application, the product X6119C is efficient according to EN 46 (+EN73) against *Hylotrupes bajulus* for use class 1 at the application rate of 100 g of 3 % diluted product X6119C / m² of wood. Nevertheless, no data was presented to demonstrate that *Hylotrupes bajulus* is the most tolerant beetle. Indeed no determination of the brv (biological reference value) was performed during the efficacy assessment of the product X6119CJ. Then, at the application rate of 100 g of 3 % diluted product X6119C / m² of wood, it is only possible to validate an efficacy against *Hylotrupes bajulus,* and not against wood boring beetles in use class 1.
* Regarding the preventive efficacy claim against termites, for superficial application, the product X6119C is efficient according to EN 118 (+73) against *Reticulitermes spp*., for use class 1 at the application rate of 200 g of 3 % v/v diluted product X6119C / m² of wood.

In a same META SPC, all the products should demonstrate an efficacy for all the claims mentioned in the SPC. For the dilution at 3 % v/v, the demonstration of the efficacy is not demonstrated for all the claims, and then the dilution of 3 % v/v of the product X6119C cannot be validated.

At the application dilution of 5% v/v, according to the Annex A of the EN 599 §A.2.3 e), no new biological testing is required for changes in pigments to an equal or lower pigment content of the product. The differences between X6119CJ and X6119C formulations are only on pigments. The tests have been performed with the colored product X6119CJ and the product X6119C is colorless. Therefore a read-across between the formulations X6119CJ and X6119C is acceptable. Then at the dilution of 5 % v/v, the efficacy demonstrated for the product X6119CJ is applicable to the product X6119C.

After the consultation of the applicant, the use of the product at the concentration 8.33 % v/v has been withdrawn.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC1 & 2** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6119CJ  cypermethrin 1.23% w/w,  propiconazole 2.35% w/w, tebuconazole 0.74% w/w and IPBC 0.74% w/w.  Tested after 5% v/v dilution in water | Brown rot fungi: *Coniophora puteana, Gloeophyllum trabeum* and *Poria placenta* | Laboratory test.  EN 113 after EN 73 (evaporation). | Following the recommendation of the standard:  On scots pine blocks ,the targeted retentions of test product were 0-20-40-60 and 80 kg/m3 of wood, corresponding to 0.0, 2.68, 5.36, 6.70, 8.04 and 10.71 % w/w.  The product was applied by vacuum impregnation  - 6 blocks tested for each treatment and each fungal strain. *C. puteana*, *G. trabeum* and *P. placenta* are tested on pine.  - Number of replicates: 6 replicates for each treatment and each fungal strain.  CONTROLS  - Untreated controls: yes, one non-treated control block included with the treated block in each test. There are also 6 virulence control blocks for each fungal strain.  The effects investigated is mass loss of the test blocks, induced by the fungal development  The method for recording / scoring effects is the individual weighting of the test blocks at the beginning and at the end of the exposure period.  - Intervals of examination: one time, after 4 months exposure of the blocks to the fungal strains | The study is validated as more than 20 % of mass loss is observed in the control (>30 % in each control)  Mid toxic values of the test product X6119CJ 5 %:  - *C. puteana*: 61.56-81.77: 62.2 kg/m3 of wood  - *G. trabeum* 20.65-41.09 : 60.9 kg/m3 of wood  - *P. placenta*: 61.32-81.97:71.6 kg/m3 of wood  **The study demonstrates the efficacy of the product X6119CJ at the application rate of 71.6 kg of the 5 % v/v diluted product X6119 CJ /m3 of wood. It corresponds to an application rate of 143.2 g of 5 % v/v diluted X6119CJ / m² of wood.** | Schumacher P. and Fennert E.- M., 2015  32/14/9800/03  6,7\_01  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6119CJ  cypermethrin 1.23% w/w,  propiconazole 2.35% w/w, tebuconazole 0.74% w/w and IPBC 0.74% w/w.  Tested after 5% v/v dilution in water | Brown rot fungi: *Coniophora puteana, Gloeophyllum trabeum* and *Poria placenta* | Laboratory test.  EN 113 after EN 84 (leaching). | Following the recommendation of the standard:  On scots pine blocks, the targeted retentions of test product were 0-20-40-60 and 80 kg/m3 of wood, corresponding to 0.0, 2.68, 5.36, 6.70, 8.04 and 10.71 % w/w.  The product was applied by vacuum impregnation  - 6 blocks tested for each treatment and each fungal strain. *C. puteana*, *G. trabeum* and *P. placenta* are tested on pine.  - Number of replicates: 6 replicates for each treatment and each fungal strain.  CONTROLS  - Untreated controls: yes, one non-treated control block included with the treated block in each test. There are also 6 virulence control blocks for each fungal strain.  The effects investigated is mass loss of the test blocks, induced by the fungal development  The method for recording / scoring effects is the individual weighting of the test blocks at the beginning and at the end of the exposure period.  - Intervals of examination: one time, after 4 months exposure of the blocks to the fungal strains | The study is validated as more than 20 % of mass loss is observed in the control (>30 % in each control)  Mid toxic values of the test product X6119CJ 5 %:  - *C. puteana*: 20.73-40.91: 30.8 kg/m3 of wood  - *G. trabeum* 41.25-51.84 : 46.5 kg/m3 of wood  - *P. placenta*: 81.89 kg/m3 of wood  **The study demonstrates the efficacy of the product X6119CJ at the application rate of 81.9 kg of the 5 % v/v diluted product X6119 CJ /m3 of wood. It corresponds to an application rate of 163.8 g of 5 % v/v diluted X6119CJ / m² of wood.** | Schumacher P. and Fennert E.- M., 2015  32/14/9800/04  S6.7\_02  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6119CJ  cypermethrin 1.20% w/w,  propiconazole 2.20% w/w, tebuconazole 0.74% w/w and IPBC 0.74% w/w.  Tested after 5% v/v dilution in water | *Reticulitermes flavipes* | EN118 + EN 73 | The product X6119CJ concentrate diluted at 5 % v/v is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation) at three application rates 100, 150 et 200 g/m².  For the lowest application rate, the quantity really applied on each test block varied between 100 g/m² and 103.6 g/m² (mean 101.2 g/m²).  worker, nymph and soldier termites were used for each test block.  5 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 % (52.7 %) and the control test blocks are ranked 4.  **The treated blocks are ranked (1,1,1,2,1,1) at the end of the study which demonstrates the efficacy of the 5 % v/v diluted product X6119CJ against *Reticulitermes flavipes* at the application rate of 101.2 g of 5 % v/v diluted product / m² of wood.** | Brunet C. and Paulmier I., 2015  401/15/118F  6.7\_03  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6119CJ  cypermethrin 1.23% w/w,  propiconazole 2.35% w/w, tebuconazole 0.74% w/w and IPBC 0.74% w/w.  Tested after 5% v/v dilution in water | *Reticulitermes flavipes* | EN118 + EN 84 | The product X6119CJ concentrate diluted at 5 % v/v is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 84 standard method (leaching) at the application rate of 100, g/m².  The quantity really applied on each test block varied between 98.9 g/m² and 100.1 g/m² (mean 99.5 g/m²).  worker, nymph and soldier termites were used for each test block.  5 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 % (63 %) and the control test blocks are ranked 4.  **The treated blocks are ranked (1,1,2,1,1,1) at the end of the study which demonstrates the efficacy of the 5 % v/v diluted product X6119CJ against *Reticulitermes flavipes* at the application rate of 99.5 g of 5 % v/v diluted product / m² of wood.** | Ansard D. and Paulmier I., 2015  401/14/133F/d-e  6.7\_04  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6119CJ  cypermethrin 1.23% w/w,  propiconazole 2.35% w/w, tebuconazole 0.74% w/w and IPBC 0.74% w/w.  Tested after 5% v/v dilution in water | House longhorn beetle: *Hylotrupes bajulus* (L.) | EN 46 + EN 73 (evaporation) | The product X6119CJ concentrate diluted at 5 % v/v 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 98.4 g/m² and 100.0 g/m² (mean 98.8 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 % (90 % and 83.3 % solvent control).  On the treated test blocks, 100 % of the larvae were dead and had not tunnelled.  **This study demonstrated the efficacy of the product at 98.8 g of 5 % v/v diluted product / m² of wood against *Hylotrupes bajulus* larvae** | Schumacher P. and Fennert E.- M., 2015  32/14/9800/01  6.7\_05  IC2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6119CJ  cypermethrin 1.23% w/w,  propiconazole 2.35% w/w, tebuconazole 0.74% w/w and IPBC 0.74% w/w.  Tested after 5% v/v dilution in water | House longhorn beetle: *Hylotrupes bajulus* (L.) | EN 46 + EN 84 (leaching) | The product X6119CJ concentrate diluted at 5 % v/v is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 84 standard method (leaching).  The quantity really applied on each test block varied between 98.4 g/m² and 100.0 g/m² (mean 98.9 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 % (90 % and 86.7 % solvent control).  On the treated test blocks, 100 % of the larvae were dead and had not tunnelled.  **This study demonstrated the efficacy of the product at 98.9 g of 5 % v/v diluted product / m² of wood against *Hylotrupes bajulus* larvae** | Schumacher P. and Fennert E.- M., 2014  32/14/9800/02  6.7\_06 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6119CJ  cypermethrin 1.23% w/w,  propiconazole 2.2% w/w, tebuconazole 0.74% w/w and IPBC 0.74% w/w.  Tested after 5% v/v dilution in water | Common furniture beetle:  *Anobium punctatum* | EN 49 + EN 73  (evaporation) | The product X6119CJ concentrate diluted at 5 % v/v 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 98.9 g/m² and 101.2 g/m² (mean 99.4 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 (59) 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 at 98.9 g of 5 % v/v diluted product / m² of wood against *Anobium punctatum*** | Brunet C. and Paulmier I., 2017  401/14/133F/a and b-e  6.7\_07  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6119CJ  cypermethrin 1.23% w/w,  propiconazole 2.2% w/w, tebuconazole 0.74% w/w and IPBC 0.74% w/w.  Tested after 5% v/v dilution in water | Common furniture beetle:  *Anobium punctatum* | EN 49 + EN 84  (leaching) | The product X6119CJ concentrate diluted at 5 % v/v is applied by brushing on hardwood test blocks (*Quercus petrae*) and followed by an artificial weathering according to the EN 84 standard method (leaching).  The quantity really applied on each test block varied between 99.6 g/m² and 101.3 g/m² (mean 100 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 (52) 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 at 100 g of 5 % v/v diluted product / m² of wood against *Anobium punctatum*** | Brunet C. and Paulmier I., 2017  401/14/133F/a and b-e  6.7\_08  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6119CJ  cypermethrin 1.23% w/w,  propiconazole 2.2% w/w, tebuconazole 0.74% w/w and IPBC 0.74% w/w.  Tested after 5% v/v dilution in water | Powder post beetle: *Lyctus brunneus* | EN 20-1 + EN 73 (evaporation) | The product X6119CJ concentrate diluted at 5 % v/v 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 98.4 g/m² and 99.9 g/m² (mean 99.0 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 at 99 g of 5 % v/v diluted product /m² of wood against *Lyctus brunneus.*** | Brunet C. and Paulmier I., 2017  401/14/133F/c/e  6.7\_09  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6119C  cypermethrin 1.20% w/w,  propiconazole 2.20% w/w, tebuconazole 0.74% w/w and IPBC 0.74% w/w.  Tested after 3% v/v dilution in water | *Reticulitermes flavipes* | EN118 + EN 73 | The product X6119C concentrate diluted at 3 % v/v is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation) at three application rates 100, 150 et 200 g/m².  For the lowest application rate, the quantity really applied on each test block varied between 200.2 g/m² and 201.7 g/m² (mean 200.9 g/m²).  worker, nymph and soldier termites were used for each test block.  5 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 % (53.3 %) and the control test blocks are ranked 4.  **The treated blocks are ranked (1,1,1,1,1,0) at the end of the study which demonstrates the efficacy of the 3 % v/v diluted product X6119C against *Reticulitermes flavipes* at the application rate of 101.2 g of 3 % v/v diluted product X6119C/ m² of wood.** | Ansard D. and Paulmier I., 2015  401/15/047F  6.7-10  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6119C  cypermethrin 1.28% w/w,  propiconazole 2.23% w/w, tebuconazole 0.75% w/w and IPBC 0.77% w/w.  Tested after 3% v/v dilution in water | House longhorn beetle: *Hylotrupes bajulus* (L.) | EN 46 + EN 73 (evaporation) | The product X6119C concentrate diluted at 3 % v/v 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 98.4 g/m² and 100.0 g/m² (mean 99.6 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 % (93 %).  On the treated test block, 100 % of the larvae was dead and had not tunnelled.  **This study demonstrated the efficacy of the product X6119C at 99.6 g of 3 % v/v diluted product / m² of wood against *Hylotrupes bajulus* larvae** | Schumacher P. and Fennert E.- M., 2015  32/15/9850/01  6.7\_11  IC1 |

* **For META-SPC2: this META-SPC includes X6119C1, X6119B1 and X6119B formulations.**

No test was performed with the products contained in the META SPC 2.

Following the consultation of the applicant, the product X6119B has been withdrawn.

For both products of the META-SPC 2 (X6119C1 and X6119B1), read across have been performed with another formulation X6119CJ from meta SPC 1 (please refer to the confidential PAR):

* + - * For the product X6119C1: After comparison of the formulations, it appears that for several compounds, the variations are outside the variations acceptable to avoid new biological testing according to the Annex A of the Standard EN 599-1. Indeed for two surfactants, the variations are higher than 2 % w/w (Annex A:§A.2.3.g) and for a resin, the variation is higher than 1.8 % w/w (Annex A:§A.2.3.c)

Then the read-across between both formulations is not acceptable and then the efficacy of the product X6119 C1 is not demonstrated.

* + - * For the product X6119B1: the product X6119B1 is a dilution 1:1 of the formulation X6119CJ, except for colouring agents which have been replaced by water in the formulation X6119B1. According to the Annex A of the standard EN 599-1, section A2.3.b, no new biological testing is required for change involving the addition or the deletion of a soluble dyestuff. Then the read across between both formulations is accepted. As the efficacy of the of the product X6119CJ has been demonstrated with a 5 % v/v dilution of the formulation and as the product X6119B1 is 1:1 dilution of the formulation X6119CJ, the efficacy demonstrated is applicable for a 10 % v/v dilution of the product X6119B1. Please refer to the META SPC 1 efficacy evaluation for the relevant tests.
* **For META-SPC3: this META-SPC includes initially, X6119CR, X6119M2 and X6236 formulations.**
  + - * The tests have been performed with the formulation X6119M2

French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the product X6119M2 according to the uses and application rates claimed:

* Regarding the preventive claim against wood rotting fungi, for superficial application, the product X6119M2 is efficient according to EN 113 (+EN 73 and EN 84), against wood destroying basidiomycetes (excluding *C. versicolor*), at the application rate of 100 g/m². The preventive efficacy claimed against wood rotting fungi on softwood is validated. Moreover as for use class 3.1, the demonstration of the efficacy is based on the EN 113 standard, the EN-599 requires the use of a top coat (§5.2.17 & §5.2.18). Then when applied by superficial application for use class 3.1, a top coat has to be applied. Furthermore regarding the wood species, the EN 599 states that:
  + *Coriolus versicolor* is not required for product intended only for use class 2 (§5.2.13),
  + For products intended for use class 3, efficacy shall be tested using *Coriolus versicolor* if an efficacy is claimed for hardwood (§5.2.19)

Then for use class 2 an efficacy on softwood and hardwood is validated. For use class 3.1, only an efficacy on softwood is validated.

* Regarding the preventive efficacy claim against wood boring beetles, for superficial application, the product X6119M2 is efficient according to respectively EN 46 (+EN73 and EN84), EN 49 (+EN73 and EN84) and EN 20-1 (+EN73), against *Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus* at the application rate of 200 g of product X6119M2 / m² of wood in use classes 1 to 3.1 on softwood and hardwood.
* Regarding the preventive efficacy claim against termites, for superficial application, the product X6119M2 is efficient according to EN 118 (+EN73 and EN84), against *Reticulitermes spp.*, at the application rate of 200 g of X6119M2 / m² of wood in use classes 1 to 3.1, and is efficient according to EN 118 (+EN73), against *Heterotermes spp.*, at the application rate of 200 g of X6119M2 / m² of wood in use classes 1 and 2 only as no efficacy test according to EN118 (+EN84) has been submitted for *Heterotermes spp*. An efficacy on softwood and hardwood is validated.
* Regarding the curative efficacy claim against wood boring beetles (*Hylotrupes bajulus*, *Anobium punctatum* *and Lyctus brunneus*), for superficial application, the product X6119M2 is efficient according to respectively, EN 1390 against *Hylotrupes bajulus* with a slow action activity and EN 48 against *Anobium punctatum* with a fast action activity, at the application rate of 300 g of product X6119M2 / m² of wood. According to EN 14128[[12]](#footnote-12), if curative treatment against *Lyctus brunneus* is required, a curative wood preservative "for *Hylotrupes* bajulus and *Anobium punctatum*" should be applied. The curative efficacy against wood boring beetles for wood in service in situation of use classes 1 and 2, on softwood and hardwood, is then validated.
* Regarding the curative efficacy claim against termites (*Reticulitermes spp.* and *Heterotermes spp.*), no curative efficacy standard are available against termites. However, the objective of curative products are, as for the preventive treatments against termites (tested following the standard EN 118 + EN73), to protect wood against termites and to eliminate termites in the wood. Indeed, their function is not to destroy the entire colony (which is not in the wood). Moreover the target stages in the preventive and in the curative efficacy treatments are the same, which means the dose of active substance in both treatments are the same. Then the efficacy demonstrated in the preventive efficacy test can be extrapolated for a curative application for wood in service in situation of use classes 1 and 2 on softwood and hardwood.
* Regarding the curative efficacy claim against wood boring beetles, by injection, this treatment is always performed in combination with superficial application. Then, efficacy demonstrated for superficial treatment is sufficient and no additional data is needed. Curative treatment by injection in combination with a superficial treatment, at the application rate of 180 g of product X6119M2 / m² of wood is validated on softwood and hardwood.
  + - * No test has been performed with the product X6119CR and a read-across has been performed with two other formulations X6089CR and X6236:

For the insecticidal efficacy of the product X6119CR, a read-across with the formulation X6089CR has been done: after comparison of the formulations and according to the Annex A of the EN 599, the read-across is acceptable (please refer to the confidential PAR).

For the fungicidal efficacy of the product X6119CR, a read across with the formulation X6236 has been done: the difference on the content of penetrating agent is outsite of the variations (2 % w/w) acceptable to avoid new biological testing according to the §A2.3.g of the Annex A of the EN 599. Then the read-across between the formulations X6119CR and X6236 is rejected.

Therefore the read-across is then not acceptable and the efficacy of the product X6119CR is not demonstrated.

* + - * After evaluation of the efficacy data submitted for the product X6236, it has been concluded that this product should be part of another META-SPC (named META-SPC4) since validated target and application rates are not the same as the uses claimed for META-SPC3 (the curative efficacy against some species is not demonstrated for product X6236) . The assessment has been presented below.

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC 3** | | | | | | | | | | | | |
| **Function** | | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | | | **Test system / concentrations applied / exposure time** | | **Test results: effects** | **Reference** | |
| MG 02: preservatives | Wood preservative  Preventive treatment | | X6119M2  cypermethrin 0.1% w/w,  propiconazole 0.151% w/w, tebuconazole 0.051% w/w and IPBC 0.051% w/w. | Brown rot fungi: *Coniophora puteana, Gloeophyllum trabeum* and *Poria placenta* | | Laboratory test.  EN 113 after EN 73 (evaporation). | Following the recommendation of the standard:  The targeted retentions of test product were 0-20-40-60-80 and 100 kg/m3 of wood corresponding :  on scots pine blocks, to 0.0, 2.68, 5.36, 6.70, 8.04 and 10.71 kg % w/w.  On beech blocks, to 0.0, 3.10, 6.2, 9.30, 12.4, 15.50 % w/w  The product was applied by vacuum impregnation  - 6 blocks tested for each treatment and each fungal strain. *C. puteana*, *G. trabeum* and *P. placenta* are tested on pine and *C. versicolor* on beech.  - Number of replicates: 6 replicates for each treatment and each fungal strain.  CONTROLS  - Untreated controls: yes, one non-treated control block included with the treated block in each test. There are also 6 virulence control blocks for each fungal strain.  The effects investigated is mass loss of the test blocks, induced by the fungal development  The method for recording / scoring effects is the individual weighting of the test blocks at the beginning and at the end of the exposure period.  - Intervals of examination: one time, after 4 months exposure of the blocks to the fungal strains | | The study is validated as more than 20 % of mass loss is observed in the control (>30 % in each control)  Mid toxic values of the test product X6119M2:  - *C. puteana*: 41.77-62.61: 52.2 kg/m3 of wood  - *G. trabeum* 20.95 – 41.42 : 31.2 kg/m3 of wood  - *P. placenta*: 41.27 – 61.73 : 51.5 kg/m3 of wood  - C. versicolor: >98.33  🡪 brv : 52,2 kg X6119M2/m3 of wood  **The study demonstrates the efficacy of the product X6119M2 at the application rate of 52.2 kg of product X6119M2/m3 of wood. It corresponds to an application rate of 104.4 g X6119M2 / m² of wood.** | | | Schumacher P. and Fennert E.- M., 2015  32/14/9802/03  6,7\_13  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | | X6119M2  cypermethrin 0.1% w/w,  propiconazole 0.151% w/w, tebuconazole 0.051% w/w and IPBC 0.051% w/w. | Brown rot fungi: *Coniophora puteana, Gloeophyllum trabeum* and *Poria placenta* | | Laboratory test.  EN 113 after EN 84 (leaching). | Following the recommendation of the standard:  The targeted retentions of test product were 0-20-40-60-80 and 100 kg/m3 of wood corresponding:  On scots pine blocks to 0.0, 2.68, 5.36, 6.70, 8.04, 10.71 and 13.39 % w/w  On beech blocks, to 0.0, 3.10, 6.2, 9.30, 12.4 and 15.50 % w/w    The product was applied by vacuum impregnation  - 6 blocks tested for each treatment and each fungal strain. *C. puteana*, *G. trabeum* and *P. placenta* are tested on pine ad *C. versicolor* on beech  - Number of replicates: 6 replicates for each treatment and each fungal strain.  CONTROLS  - Untreated controls: yes, one non-treated control block included with the treated block in each test. There are also 6 virulence control blocks for each fungal strain.  The effects investigated is mass loss of the test blocks, induced by the fungal development  The method for recording / scoring effects is the individual weighting of the test blocks at the beginning and at the end of the exposure period.  - Intervals of examination: one time, after 4 months exposure of the blocks to the fungal strains | | The study is validated as more than 20 % of mass loss is observed in the control (>30 % in each control)  Mid toxic values of the test product X6119M2:  - *C. puteana*: <20.8 kg/m3 of wood  - *G. trabeum* <20.8 kg/m3 of wood  - *P. placenta*: 40.67 - 61.70: 51.2 kg/m3 of wood  *C. versicolor*: >96.0 kg/m3  **The study demonstrates the efficacy of the product X6119M2 at the application rate of 51.2 kg of product X6119M2/m3 of wood. It corresponds to an application rate of 102.4 g X6119M2 / m² of wood.** | | | Schumacher P. and Fennert E.- M., 2015  32/14/9802/04  S6.7\_14  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | | X6119M2  cypermethrin 0.1% w/w,  propiconazole 0.15% w/w, tebuconazole 0.05% w/w and IPBC 0.05% w/w. | *Reticulitermes flavipes* | | EN118 + EN 73  (evaporation) | The product X6119M2 is applied by paintbrush application on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation) at the application rate of 200 g/m².  The quantity really applied on each test block varied between 198.8 g/m² and 200.8 g/m² (mean 200.1 g/m²).  worker, nymph and soldier termites were used for each test block.  5 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 % (61.3 %) and the control test blocks are ranked 4.  **The treated blocks are ranked (1,1,1,1,1,1) at the end of the study which demonstrates the efficacy of the product X6119M2 against *Reticulitermes flavipes* at the application rate of 200.1 g of product X6119M2 / m² of wood.** | | | Ansard D. and Paulmier I., 2015  401/14/133F/e-e  6.7\_15  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | | X6119M2  cypermethrin 0.1% w/w,  propiconazole 0.15% w/w, tebuconazole 0.05% w/w and IPBC 0.05% w/w. | *Heterotermes tenuis* | | EN118 + EN 73  (evaporation) | The product X6119M2 is applied by paintbrush application on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation) at the application rate of 200 g/m².  The quantity really applied on each test block varied between 199.8 g/m² and 201.6 g/m² (mean 200.5 g/m²).  worker, nymph and soldier termites were used for each test block.  5 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 % (76 %) and the control test blocks are ranked 4.  **The treated blocks are ranked (1,1,1,1,1,1) at the end of the study which demonstrates the efficacy of the product X6119M2 against *Heterotermes tenuis* at the application rate of 200.5 g of product X6119M2 / m² of wood.** | | | Ansard D. and Paulmier I., 2015  401/16/075F/b-e  6.7\_15bis  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | | X6119M2  cypermethrin 0.1% w/w,  propiconazole 0.15% w/w, tebuconazole 0.05% w/w and IPBC 0.05% w/w. | *Reticulitermes flavipes* | | EN118 + EN 84  (leaching) | The product X6119M2 is applied by paintbrush application on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 84 standard method (leaching) at the application rate of 200 g/m².  The quantity really applied on each test block varied between 198.1 g/m² and 199.4 g/m² (mean 198.8 g/m²).  worker, nymph and soldier termites were used for each test block.  5 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 % (63.7 %) and the control test blocks are ranked 4.  **The treated blocks are ranked (1,1,1,1,1,1) at the end of the study which demonstrates the efficacy of product X6119M2 against *Reticulitermes flavipes* at the application rate of 198.8 g product X6119M2 / m² of wood.** | | | Ansard D. and Paulmier I., 2015  401/14/135F/d-e  6.7\_16  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | | X6119M2  cypermethrin 0.1% w/w,  propiconazole 0.15% w/w, tebuconazole 0.05% w/w and IPBC 0.05% w/w. | House longhorn beetle: *Hylotrupes bajulus* (L.) | | EN 46 + EN 73 (evaporation) | The product X6119M2 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 200 g/m² (mean 198.8 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 % (83.3 %).  On the treated test block, 100 % of the larvae was dead and had not tunnelled.  **This study demonstrated the efficacy of the product X6119M2 at 198.8 g product / m² of wood against *Hylotrupes bajulus* larvae** | | | Schumacher P. and Fennert E.- M., 2015  32/14/9802/01  6.7\_17  IC2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | | X6119M2  cypermethrin 0.1% w/w,  propiconazole 0.15% w/w, tebuconazole 0.05% w/w and IPBC 0.05% w/w. | House longhorn beetle: *Hylotrupes bajulus* (L.) | | EN 46 + EN 84 (leaching) | The product X6119M2 is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 84 standard method (leaching).  The quantity really applied on each test block varied between 200 g/m² and 197.6 g/m² (mean 199.1 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 % (83.3 % and 93.3 for the solvent control)  On the treated test block, 100 % of the larvae were dead and had not tunnelled.  **This study demonstrated the efficacy of the product X6119M2 at 199.1 g product / m² of wood against *Hylotrupes bajulus* larvae** | | | Schumacher P. and Fennert E.- M., 2015  32/14/9802/02  6.7\_18  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | | X6119M2  cypermethrin 0.1% w/w,  propiconazole 0.15% w/w, tebuconazole 0.05% w/w and IPBC 0.05% w/w. | Common furniture beetle:  *Anobium punctatum* | | EN 49 + EN 73  (evaporation) | The product X6119M2 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 198.2 g/m² and 200.7 g/m² (mean 199.5 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 X6119M2 at the application rate of 199.5 g / m² of wood against *Anobium punctatum*** | | | Brunet C. and Paulmier I., 2017  401/14/135F/a and b-e  6.7\_19  IC2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | | X6119M2  cypermethrin 0.1% w/w,  propiconazole 0.15% w/w, tebuconazole 0.05% w/w and IPBC 0.05% w/w. | Common furniture beetle:  *Anobium punctatum* | | EN 49 + EN 84  (leaching) | The product X6119M2 is applied by brushing on hardwood test blocks (*Quercus petrae*) and followed by an artificial weathering according to the EN 84 standard method (leaching).  The quantity really applied on each test block varied between 198.6 g/m² and 201.7 g/m² (mean 199.6 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 (231) 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 X6119M2 at 199.6 g product / m² of wood against *Anobium punctatum*** | | | Brunet C. and Paulmier I., 2017  401/14/135F/a and b-e  6.7\_20  IC2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | | X6119M2  cypermethrin 0.1% w/w,  propiconazole 0.15% w/w, tebuconazole 0.05% w/w and IPBC 0.05% w/w. | Powder post beetle: *Lyctus brunneus* | | EN 20-1 + EN 73 (evaporation) | The product X6119M2 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 194.3 g/m² and 196.5 g/m² (mean 196.0 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 at 196 g of product X6119M2/m² of wood against *Lyctus brunneus.*** | | | Brunet C. and Paulmier I., 2017  401/14/135F/c/e  6.7\_21  IC1 |
| MG 02: preservatives | Wood preservative  Curative treatment | | X6119M2  cypermethrin 0.1% w/w,  propiconazole 0.15% w/w, tebuconazole 0.05% w/w and IPBC 0.05% w/w | House longhorn beetle: *Hylotrupes bajulus (L.)* | | EN 1390 | The ready to use product 06 LBCEOL 20/2 PT is applied by brushing on sapwood test blocks (*Pinus sylvestris*)  The quantity really applied on each test block varied between 296 g/m² and 298.9 g/m² (mean 294.4 g/m²).  6 larvae of *Hylotrupes bajulus* were used for each test block.  10 replicates for the treated block and 2 replicates for the control are performed.  The investigated effects are the mortality of the larvae.  - Method for recording / scoring effects: recovery of the insects and count of the dead and alive larvae. Calculation of the percentage of mortality.  - Intervals of examination: one time, 25 weeks after exposure of the larvae in the wood block to the tested product.  The efficacy criterion according to the EN 14128 is a mortality higher than 80 % | | The study is validated as the survival rate in the control is higher than 75 % (100%).  **The mortality observed in the treated block is lower than 80 % (78 %) and for three replicates the mortality is lower than 70 %.**  **This study does not demonstrate the curative efficacy of the product X6119M2 at the application rate of 297.4 g/m² against longhorn beetle (*Hylotrupes bajulus)*.** | | | Schumacher P. and Fennert E.- M., 2015  32/14/9802/05A  6.7\_22  IC 3 |
| MG 02: preservatives | Wood preservative  Curative treatment | | X6119M2  cypermethrin 0.11% w/w,  propiconazole 0.165% w/w, tebuconazole 0.055% w/w and IPBC 0.054% w/w | House longhorn beetle: *Hylotrupes bajulus (L.)* | | EN 1390 | The ready to use product X6119M2 is applied by brushing on sapwood test blocks (*Pinus sylvestris*)  The quantity really applied on each test block varied between 299.8 mL/m² and 300.1 mL/m² (mean 300.0 g/m²).  6 larvae of *Hylotrupes bajulus* were used for each test block.  10 replicates for the treated block and 2 replicates for the control are performed.  The investigated effects are the mortality of the larvae.  - Method for recording / scoring effects: recovery of the insects and count of the dead and alive larvae. Calculation of the percentage of mortality.  - Intervals of examination: one time, 25 weeks after exposure of the larvae in the wood block to the tested product.  The efficacy criterion according to the EN 14128 is a mortality higher than 80 % | | The study is validated as the survival rate in the control is higher than 75 % (100%).  **The mortality observed in the treated block is higher than 80 % (82.4 %) which validated the low action efficacy of the product X6119M2, at the application rate of 300 ml of product / m² of wood, 24 weeks after is application.** | | | Brunet C. and Paulmier I., 2017  401/16/119F/3/e  6.7\_22bis  IC 1 |
| MG 02: preservatives | Wood preservative  Curative treatment | | X6119M2  cypermethrin 0.1% w/w,  propiconazole 0.15% w/w, tebuconazole 0.05% w/w and IPBC 0.05% w/w | Common furniture beetle:  *Anobium punctatum (L)* | | EN48 | The ready to use product X6119M2 is applied by brushing on sapwood test blocks (*Pinus sylvestris*)  The quantity really applied on each test block varied between 300.9 g/m² and 302.3 g/m² (mean 301.6g/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 % (81.3 %) validated the efficacy of the product X6119M2, at the application rate of 300 g of product / m² of wood.** | | | Brunet C. and Paulmier I., 2016  401/14/135/f-e  6.7\_23  IC1 |

* **For META-SPC 4:**

The tests have been performed with the formulation (X6236)

French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the product X6236:

* Regarding the preventive claim against wood rotting fungi, for superficial application, the product X6236 is efficient according to EN 113 (+EN 73 and EN 84), against wood destroying basidiomycetes (excluding *C. versicolor*), at the application rate of 200 g/m². The preventive efficacy claimed against wood rotting fungi on softwood is validated. Moreover as for use class 3.1, the demonstration of the efficacy is based on the EN 113 standard, the EN-599 requires the use of a top coat (§5.2.17 & §5.2.18). Then it can be concluded that when applied by superficial application for use class 3.1, a top coat has to be applied. Furthermore regarding the wood species, the EN 599 states that:
  + *Coriolus versicolor* is not required for product intended only for use class 2 (§5.2.13),
  + For products intended for use class 3, efficacy shall be tested using *Coriolus versicolor* if an efficacy is claimed for hardwood (§5.2.19)

Then for use class 2 an efficacy on softwood and hardwood is validated. For use class 3.1, only an efficacy on softwood is validated.

* Regarding the preventive efficacy claim against wood boring beetles, for superficial application, the product X6236 is efficient according to respectively EN 46 (+EN73 and EN84), EN 49 (+EN73 and EN84) and EN 20-1 (+EN73), against *Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus* at the application rate of 200 g / m² of wood in use classes 1 to 3.1 on softwood and hardwood.
* Regarding the preventive efficacy claim against termites, for superficial application, the product X6236 is efficient according to EN 118 (+EN73 and EN84), against *Reticulitermes spp.* and *Heterotermes spp.*, at the application rate of 200 g of X6236 / m² of wood in use classes 1 to 3.1 on softwood and hardwood.
* Regarding the curative efficacy claim against wood boring beetles (*Hylotrupes bajulus*, *Anobium punctatum* and *Lyctus brunneus*), for superficial application, the product X6236 is efficient according to EN 48 against *Anobium punctatum* with a fast action activity, at the application rate of 300 g of product X6236 / m² of wood for wood in service in situation of use classes 1 and 2 on softwood and hardwood. Regarding the curative efficacy claim against *Hylotrupes bajulus*, a mortality of 75% is observed after 22 weeks of exposure in the study submitted. According to EN 1390 standard, the duration of exposure should be normally 24 weeks with a mortality of 80 %. Then the efficacy criterion of 80 % is not met and the efficacy against *Hylotrupes bajulus* is not demonstrated.

According to EN 14128, if curative treatment against *Lyctus brunneus* is required, a curative wood preservative "for *Hylotrupes* bajulus and *Anobium punctatum*" should be applied. Then curative efficacy against *Lyctus brunneus* is not validated.

* Regarding the curative efficacy claim against termites (*Reticulitermes spp.* and *Heterotermes spp.*), no curative efficacy standard are available against termites. However, the objective of curative products are, as for the preventive treatments against termites (tested following the standard EN 118 + EN73/84), to protect wood against termites and to eliminate termites in the wood. Indeed, their function is not to destroy the entire colony (which is not in the wood). Moreover the target stages in the preventive and in the curative efficacy treatments are the same, which means the dose of active substance in both treatments are the same. Then the efficacy demonstrated in the preventive efficacy test can be extrapolated for a curative application for wood in service in situation of use classes 1 and 2 on softwood and hardwood.
* Regarding the curative efficacy claim against wood boring beetles, by injection, this treatment is always performed in combination with superficial application. Then, efficacy demonstrated for superficial treatment is sufficient and no additional data is needed. As only an efficacy against *Anobium punctatum* has been demonstrated by superficial application, only the curative treatment by injection in combination with a superficial treatment against *Anobium punctatum*, at the application rate of 180 g of product X6236 / m² of wood is validated on softwood and hardwood.

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| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC 4** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6236  cypermethrin 0.099% w/w,  propiconazole 0.149% w/w, tebuconazole 0.049% w/w and IPBC 0.049% w/w. | Brown rot fungi: *Coniophora puteana, Gloeophyllum trabeum* and *Poria placenta* | Laboratory test.  EN 113 after EN 73 (evaporation). | Following the recommendation of the standard:  The targeted retentions of test product were 0-20-40-60-80 and 100 kg/m3 of wood corresponding:  On scots pine blocks, to the targeted concentrations to be tested were 0.0, 2.68, 5.36, 8.04, 10.71 and 13.39 % w/w.  On beech blocks, to the target concentrations to be tested were 0.0, 3.10, 6.2, 9.30, 12.4, 15.50 % w/w  The product was applied by vacuum impregnation  - 6 blocks tested for each treatment and each fungal strain. *C. puteana*, *G. trabeum* and *P. placenta* are tested on pine and *C. versicolor* on beech.  - Number of replicates: 6 replicates for each treatment and each fungal strain.  CONTROLS  - Untreated controls: yes, one non-treated control block included with the treated block in each test. There are also 6 virulence control blocks for each fungal strain.  The effects investigated is mass loss of the test blocks, induced by the fungal development  The method for recording / scoring effects is the individual weighting of the test blocks at the beginning and at the end of the exposure period.  - Intervals of examination: one time, after 4 months exposure of the blocks to the fungal strains | The study is validated as more than 20 % of mass loss is observed in the control (>30 % in each control)  Mid toxic values of the test product X6236:  - *C. puteana*: 61.01-82.36: 71.7 kg/m3 of wood  - *G. trabeum* 61.43 – 82.70 : 72.1 kg/m3 of wood  - *P. placenta*: 61.81 – 82.22 : 72.0 kg/m3 of wood  - C. versicolor: >98.79  🡪 brv : 72.0 kg X6236/m3 of wood  **The study demonstrates the efficacy of the product X6236 at the application rate of 72.1 kg of product X6236/m3 of wood. It corresponds to an application rate of 144.2 g X6236 / m² of wood.** | Schumacher P. and Fennert E.- M., 2015  32/14/9801/03  6,7\_24  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6236  cypermethrin 0.099% w/w,  propiconazole 0.149% w/w, tebuconazole 0.049% w/w and IPBC 0.049% w/w. | Brown rot fungi: *Coniophora puteana, Gloeophyllum trabeum* and *Poria placenta* | Laboratory test.  EN 113 after EN 84 (leaching). | Following the recommendation of the standard:  The targeted retentions of test product were 0-20-40-60-80 and 100 kg/m3 of wood corresponding:  On scots pine blocks, to the targeted concentrations to be tested were 0.0, 2.68, 5.36, 8.04, 10.71 and 13.39 % w/w.  On beech blocks, to the target concentrations to be tested were 0.0, 3.10, 6.2, 9.30, 12.4, 15.50 % w/w    The product was applied by vacuum impregnation  - 6 blocks tested for each treatment and each fungal strain. *C. puteana*, *G. trabeum* and *P. placenta* are tested on pine ad *C. versicolor* on beech  - Number of replicates: 6 replicates for each treatment and each fungal strain.  CONTROLS  - Untreated controls: yes, one non-treated control block included with the treated block in each test. There are also 6 virulence control blocks for each fungal strain.  The effects investigated is mass loss of the test blocks, induced by the fungal development  The method for recording / scoring effects is the individual weighting of the test blocks at the beginning and at the end of the exposure period.  - Intervals of examination: one time, after 4 months exposure of the blocks to the fungal strains | The study is validated as more than 20 % of mass loss is observed in the control (>30 % in each control)  Mid toxic values of the test product X6236:  - *C. puteana*: 20.77 - 40.84 : 30.81 kg/m3 of wood  - *G. trabeum* 20.83 - 41.15 : 31 kg/m3 of wood  - *P. placenta*: 81.91 - 103.06 : 92.49 kg/m3 of wood  - C. versicolor >98.37 kg/m3  **The study demonstrates the efficacy of the product X6236 at the application rate of 92.5 kg of product /m3 of wood. It corresponds to an application rate of 185 g X6236 / m² of wood.** | Schumacher P. and Fennert E.- M., 2015  32/14/9801/04  S6.7\_25  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6236  cypermethrin 0.09% w/w,  propiconazole 0.14% w/w, tebuconazole 0.04% w/w and IPBC 0.04% w/w. | *Reticulitermes falvipes* | EN118 + EN 73  (evaporation) | The product X6236 is applied by paintbrush application on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation) at the application rate of 200 g/m².  The quantity really applied on each test block varied between 197.5 g/m² and 199.5 g/m² (mean 198.4 g/m²).  worker, nymph and soldier termites were used for each test block.  5 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 % (61.3 %) and the control test blocks are ranked 4.  **The treated blocks are ranked (1,1,0,0,1,1) at the end of the study which demonstrates the efficacy of the product X6236 against *Reticulitermes flavipes* at the application rate of 198.4 g of product X6236/m² of wood.** | Ansard D. and Paulmier I., 2015  401/14/134F/e-e  6.7\_26  IC2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6236  cypermethrin 0.09% w/w,  propiconazole 0.14% w/w, tebuconazole 0.04% w/w and IPBC 0.04% w/w. | *Heterotermes tenuis* | EN118 + EN 73  (evaporation) | The product X6236 is applied by paintbrush application on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 73 standard method (evaporation) at the application rate of 200 g/m².  The quantity really applied on each test block varied between 200 g/m² and 201.2 g/m² (mean 200.6 g/m²).  worker, nymph and soldier termites were used for each test block.  5 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 % (76 %) and the control test blocks are ranked 4.  **The treated blocks are ranked (1,1,1,1,1,1) at the end of the study which demonstrates the efficacy of the product X6236 against *Reticulitermes flavipes* at the application rate of 200.6 g of product X6236/m² of wood.** | Ansard D. and Paulmier I., 2017  401/16/075F/b-e  6.7\_26 bis  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6236  cypermethrin 0.09% w/w,  propiconazole 0.14% w/w, tebuconazole 0.04% w/w and IPBC 0.04% w/w. | *Reticulitermes flavipes* | EN118 + EN 84  (leaching) | The product X6236 is applied by paintbrush application on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 84 standard method (leaching) at the application rate of 200 g/m².  The quantity really applied on each test block varied between 198.0 g/m² and 199.5 g/m² (mean 198.6 g/m²).  worker, nymph and soldier termites were used for each test block.  5 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 % (63.7 %) and the control test blocks are ranked 4.  **The treated blocks are ranked (1,1,1,1,1,1) at the end of the study which demonstrates the efficacy of product X6236 against *Reticulitermes flavipes* at the application rate of 198.6 g product X6236 / m² of wood.** | Ansard D. and Paulmier I., 2015  401/14/134F/d-e  6.7\_27  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6236  cypermethrin 0.1% w/w,  propiconazole 0.15% w/w, tebuconazole 0.05% w/w and IPBC 0.05% w/w. | *Heterotermes tenuis* | EN118 + EN 84  (leaching) | The product X6236 is applied by paintbrush application on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 84 standard method (leaching) at the application rate of 200 g/m².  The quantity really applied on each test block varied between 199.8 g/m² and 201.4 g/m² (mean 200.4 g/m²).  worker, nymph and soldier termites were used for each test block.  5 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 % (73.7 %) and the control test blocks are ranked 4.  **The treated blocks are ranked (1,1,1,1,2,1) at the end of the study which demonstrates the efficacy of product X6236 against *Reticulitermes flavipes* at the application rate of 200.4 g product X6236 / m² of wood.** | Ansard D. and Paulmier I., 2015  401/16/075F/a-e  6.7\_27bis  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6236  cypermethrin 0.099% w/w,  propiconazole 0.149% w/w, tebuconazole 0.049% w/w and IPBC 0.049% w/w. | House longhorn beetle: *Hylotrupes bajulus* (L.) | EN 46 + EN 73 (evaporation) | The product X6236 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 200 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 % (80.0 %).  On the treated test block, 100 % of the larvae was dead and had not tunnelled.  **This study demonstrated the efficacy of the product X6236 at 198.5 g product / m² of wood against *Hylotrupes bajulus* larvae** | Schumacher P. and Fennert E.- M., 2015  32/14/9801/01  6.7\_28  IC2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6236  cypermethrin 0.099% w/w,  propiconazole 0.149% w/w, tebuconazole 0.049% w/w and IPBC 0.049% w/w. | House longhorn beetle: *Hylotrupes bajulus* (L.) | EN 46 + EN 84 (leaching) | The product X6236 is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) and followed by an artificial weathering according to the EN 84 standard method (leaching).  The quantity really applied on each test block varied between 200 g/m² and 197.6 g/m² (mean 199.1 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 % (83.3 % and 93.3 for the solvent control)  On the treated test block, 100 % of the larvae was dead and had not tunnelled.  **This study demonstrated the efficacy of the product X6236 at 198.7 g product / m² of wood against *Hylotrupes bajulus* larvae** | Schumacher P. and Fennert E.- M., 2014  32/14/9801/02  6.7\_29  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6236  cypermethrin 0.099% w/w,  propiconazole 0.149% w/w, tebuconazole 0.049% w/w and IPBC 0.049% w/w. | Common furniture beetle:  *Anobium punctatum* | EN 49 + EN 73  (evaporation) | The product X6236 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 g/m² and 200.6 g/m² (mean 199.8 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 X6236 at the application rate of 199.5 g / m² of wood against *Anobium punctatum*** | Brunet C. and Paulmier I., 2017  401/14/134F/a and b-e  6.7\_30  IC2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6236  cypermethrin 0.099% w/w,  propiconazole 0.149% w/w, tebuconazole 0.049% w/w and IPBC 0.049% w/w. | Common furniture beetle:  *Anobium punctatum* | EN 49 + EN 84  (leaching) | The product X6236 is applied by brushing on hardwood test blocks (*Quercus petrae*) and followed by an artificial weathering according to the EN 84 standard method (leaching).  The quantity really applied on each test block varied between 198.9 g/m² and 200.4 g/m² (mean 199.9 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 (231) 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 X6236 at 199.9 g product / m² of wood against *Anobium punctatum*** | Brunet C. and Paulmier I., 2017  401/14/134F/a and b-e  6.7\_31  IC2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6236  cypermethrin 0.1% w/w,  propiconazole 0.15% w/w, tebuconazole 0.05% w/w and IPBC 0.05% w/w. | Powder post beetle: *Lyctus brunneus* | EN 20-1 + EN 73 (evaporation) | The product X6236 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 199.5 g/m² (mean 197.5 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 at 197.5 g of product X6236/m² of wood against *Lyctus brunneus.*** | Brunet C. and Paulmier I., 2017  401/14/134F/c/e  6.7\_32  IC1 |
| MG 02: preservatives | Wood preservative  Curative treatment | X6236  cypermethrin 0.1% w/w,  propiconazole 0.15% w/w, tebuconazole 0.05% w/w and IPBC 0.05% w/w. | House longhorn beetle: *Hylotrupes bajulus (L.)* | EN 1390 | The ready to use product X6236 is applied by brushing on sapwood test blocks (*Pinus sylvestris*)  The quantity really applied on each test block varied between 297.2 mL/m² and 298.8 mL/m² (mean 298 g/m²).  6 larvae of *Hylotrupes bajulus* were used for each test block.  10 replicates for the treated block and 2 replicates for the control are performed.  The investigated effects are the mortality of the larvae.  - Method for recording / scoring effects: recovery of the insects and count of the dead and alive larvae. Calculation of the percentage of mortality.  - Intervals of examination: one time, 25 weeks after exposure of the larvae in the wood block to the tested product.  The efficacy criterion according to the EN 14128 is a mortality higher than 80 % | The study is validated as the survival rate in the control is higher than 75 % (100%).  **The mortality observed in the treated block is lower than 80 % (75 %) which did not validate the low action efficacy of the product X6236, 22 weeks after is application.** | Schumacher P. and Fennert E.- M., 2015  32/14/9801/05A  6.7\_33  IC 1 |
| MG 02: preservatives | Wood preservative  Curative treatment | X6236  cypermethrin 0.1% w/w,  propiconazole 0.15% w/w, tebuconazole 0.05% w/w and IPBC 0.05% w/w. | Common furniture beetle:  *Anobium punctatum (L)* | EN48 | The ready to use product X6236 is applied by brushing on sapwood test blocks (*Pinus sylvestris*)  The quantity really applied on each test block varied between 298.8 g/m² and 300.4 g/m² (mean 299.7 g/m²).  12 larvae of *Anobium punctatum* were used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The investigated effects are the mortality of the larvae.  - Method for recording / scoring effects: recovery of the insects and count of the dead and alive larvae. Calculation of the percentage of mortality.  - Intervals of examination: one time, 8 weeks after exposure of the larvae in the wood block to the tested product.  The efficacy criterion according to the EN 14128 is mortality higher than 80 %. | The study is validated as the survival rate in the control is higher than 70 % (100%).  **The mortality observed in the treated block is higher than 80 % (91 %) validated the efficacy of the product X6236, at the application rate of 299.7 g of product / m² of wood.** | Brunet C. and Paulmier I., 2016  401/14/134F/f/e  6.7\_34  IC1 |

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| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) assessed that the family (PPG\_CLASS3\_WB), separated in four META-SPC has shown a sufficient efficacy as following:   * In META-SPC1: * The data presented in the dossier demonstrated for the products X6119CJ and X6119C:   + The preventive efficacy of the product when used by superficial application of wood used in use class 1 against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.),* on softwood and hardwood*,* at the application rate of 100 g of 5 % v/v diluted product / m² of wood*.*   + The preventive efficacy of the product when used by superficial application of wood used in use classes 2 to 3.1:     - against wood rotting fungi (brown rot fungi, softwood and hardwood for use class 2, and softwood only for use class 3.1),     - against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.)* (softwood and hardwood), at the application rate of 165 g of 5 % v/v diluted product / m² of wood*.*   For the use class 3.1, a top coat is needed.   * + Following the consultation of the applicant, the use of the product at the concentration of 8.33 % v/v has been withdrawn.   The product is applied by industrial and professional users.   * In META-SPC 2: * The data presented in the dossier demonstrated for the product X6119B1:   + The preventive efficacy of the product when used by superficial application of wood used in use class 1 against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.)* on softwood and hardwood*,* at the application rate of 100 g of 10 % v/v diluted product / m² of wood *.*   + The preventive efficacy of the product when used by superficial application of wood used in use classes 2 to 3.1:     - against wood rotting fungi (brown rot fungi, softwood and hardwood for use class 2, and softwood only for use class 3.1),     - against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.)* on softwood and hardwood, at the application rate of 165 g of 10 % v/v diluted product / m² of wood*.*   For the use class 3.1, a top coat is needed.   * The efficacy of the product X6119C1 is not demonstrated. * Following the consultation of the applicant, the product X6119B has been withdrawn.   The product is applied by industrial users.   * In META-SPC 3 * The data presented in the dossier demonstrated for the product X6119M2:   + The preventive efficacy of the product when used by superficial application of wood used in use class 1, at the application rate of 200 g product/m² of wood, against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*) and against termites (*Reticulitermes spp.* and *Heterotermes spp.)* on softwood and hardwood.   + The preventive efficacy of the product when used by superficial application of wood used in use class 2, at the application rate of 200 g product/m² of wood, against wood rotting fungi (brown rot fungi), against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*) and against termites (*Reticulitermes spp.* and *Heterotermes spp.)* on softwood and hardwood.   + The preventive efficacy of the product when used by superficial application of wood used in use class 3.1, at the application rate of 200 g product/m² of wood against:     - wood rotting fungi (brown rot fungi) on softwood,     - wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.)* on softwood and hardwood*.*   For the use class 3.1, a top coat is needed.   * + The curative efficacy of the product when used by superficial application (that could be completed by injection) of wood in service in condition of use classes 1 and 2, at the application rate of 300 g product/m² of wood, against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.* and *Heterotermes spp.)* on softwood and hardwood*.* * The efficacy of the product X6119CR is not demonstrated.   The product is applied by professional and non-professional users.   * In META-SPC 4 * The data presented in the dossier demonstrated for the product X6236:   + The preventive efficacy of the product when used by superficial application of wood used in use classes 1 to 3.1, at the application rate of 200 g product/m² of wood,     - against wood rotting fungi (brown rot fungi, softwood and hardwood for use class 2, and softwood only for use class 3.1),     - against wood boring beetles (Hylotrupes bajulus, Anobium punctatum and Lyctus brunneus) and against termites (Reticulitermes spp. and Heterotermes spp.) on softwood and hardwood.   For the use class 3.1, a top coat is needed.   * + The curative efficacy of the product when used by superficial application (that could be completed by injection) of wood in service in condition of use classes 1 and 2, at the application rate of 300 g product/m² of wood, against wood boring beetles (*Anobium punctatum)* and against termites *(Reticulitermes spp.* and *Heterotermes spp.)* on softwood and harwood   The product is applied by professional and non-professional users. |

* **Minor Change application for PPG CLASS3 WB – 2019:**

In X6119M2 (Meta SPC 3) and X6236 (Meta SPC 4), one formulant is replaced  
by a similar one (same function, same content and same physical properties). According to Annex A of EN 599, no new biological testing is required for this variation. Efficacy assessment remained unchanged.

#### Occurrence of resistance and resistance management

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

Tebuconazole and Propiconazole are DeMethylation Inhibitor (DMI) fungicides within Sterol Biosynthesis Inhibitor (SBI) Class I. According to the FRAC Code List, DMI fungicides show no cross resistance to other SBI classes. There are big differences in the activity spectra of DMI fungicides. Resistance to DMI fungicides is known in various fungal species. Several resistance mechanisms are known incl. target site mutations in cyp51 (erg 11) gene, e.g. V136A, Y137F, A379G, I381V; cyp51 promotor; ABC transporters and others. It is considered generally wise to accept that cross resistance is present between DMI fungicides active against the same fungus, and the risk of resistance formation against DMI fungicides is regarded to be medium (Resistance management required).

For wood preservation with tebuconazole-and propiconazole-containing products, cases of resistances are not reported or known up to the time being.

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

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

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

#### Known limitations

None.

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the family (PPG\_CLASS3\_WB), separed in four META-SPC has shown a sufficient efficacy as following:

* In META-SPC1:
* The data presented in the dossier demonstrated for the products X6119CJ and X6119C:
  + The preventive efficacy of the product when used by superficial application of wood in use class 1 against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.)* on softwood and hardwood*.*
  + The preventive efficacy of the product when used by superficial application of wood used in use classes 2 to 3.1 against wood rotting fungi (brown rot fungi), against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.)* (softwood and hardwood for use class 2, and hardwood for use class 3.1)*. Moreover,* for the use class 3.1, a top coat is needed.

The application rates validated are the following:

- Preventive treatments in use class 1 against termites and wood boring beetles: superficial application at 100 g of 5 % v/v diluted product X6119C or X6119CJ / m² of wood.

- Preventive treatment in use classes 2 to 3.1: superficial application at 165 g of 5 % v/v diluted product X6119C or X6119CJ / m² of wood. For use in use class 3, a top coat must be applied.

* In META-SPC 2:
* The data presented in the dossier demonstrated for the product X6119B1:
  + The preventive efficacy of the product when used by superficial application of wood used in use class 1 against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.)* on softwood and hardwood*.*
  + The preventive efficacy of the product when used by superficial application of wood used in use classes 2 to 3.1:
    - against wood rotting fungi (brown rot fungi, softwood and hardwood for use class 2, and softwood only for use class 3.1),
    - against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.)* on softwood and hardwood*.*

For the use class 3.1, a top coat is needed.

The application rates validated are the following:

Preventive treatments in use class 1 against termites and wood boring beetles: superficial application at 100 g of 10 % v/v diluted product X6119B1 / m² of wood.

Preventive treatment in use classes 2 to 3.1: superficial application at 165 g of 10 % diluted product X6119B1 / m² of wood. For use in use class 3, a top coat must be applied.

* In META-SPC 3
* The data presented in the dossier demonstrated for the product X6119M2:
  + The preventive efficacy of the product when used by superficial application of wood used in use class 1 against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus*) and against termites (*Reticulitermes spp.* and *Heterotermes spp)* on softwood and hardwood*.*
  + The preventive efficacy of the product when used by superficial application of wood used in use class 2 against wood rotting fungi (brown rot fungi), against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.* and *Heterotermes ssp.),* on softwood and hardwood*.*
  + The preventive efficacy of the product when used by superficial application of wood used in use class 3.1 against:
    - wood rotting fungi (brown rot fungi) on softwood
    - wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus),* against termites *(Reticulitermes spp.)* on softwood and hardwood

For the use class 3.1, the use of a top coat is needed*.*

* + The curative efficacy of the product when used by superficial application (that could be completed by injection) of wood in service against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and termites *(Reticulitermes spp.* and *Heterotermes spp.)* for wood in service in situation of use classes 1 and 2 on softwood and hardwood.

The application rates validated are the following:

Preventive treatment in use classes 1 to 3.1: superficial application at 200 g product / m² of wood. For use in use class 3, a top coat must be applied.

Curative treatment: superficial application at 300 g of product / m² of wood in service in situation of uses classes 1 and 2 (injection 180 g of product / m² of wood if need be) (20 mL per hole, 9 holes/m²).

* In META-SPC 4
* The data presented in the dossier demonstrated for the product X6236:
  + The preventive efficacy of the product when used by superficial application of wood used in use classes 1 to 3.1
    - against wood rotting fungi (brown rot fungi, softwood and hardwood for use class 2, and softwood only for use class 3.1),
    - against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum* and *Lyctus brunneus)* and against termites *(Reticulitermes spp.* and *Heterotermes spp.)* on softwood and hardwood(except in use class 3.1 on softwood only)*.*
  + The curative efficacy of the product when used by superficial application (that could be completed by injection) of wood in service in situation of use classes 1 and 2 against wood boring beetles (*Anobium punctatum)* and termites *(Reticulitermes spp.* and *Heterotermes spp.)* on softwood and harwood

The application rates validated are the following:

Preventive treatment in use classes 1 to 3.1: superficial application at 200 g product / m² of wood. For use in use class 3, a top coat must be applied.

Curative treatment: superficial application at 300 g of product / m² of wood in service in situation of uses classes 1 and 2 (injection 180 g of product / m² of wood if need be) (20 mL per hole, 9 holes/m²).

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

* **Minor Change application for PPG CLASS3 WB – 2019:**

Efficacy Assessment remained unchanged.

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

### Risk assessment for human health

The assessment for human health was based on the initial uses claimed by the applicant. The applicant reviewed its uses after that the human health assessment was finished:

For meta SPC 1,

For industrial use :

- replacement of the application rate of 150 g/m2 for the dilution at 3% by an application rate between 100 and 200 g/m2

- replacement of the application rate of 150 g/m2 for the dilution at 5% by an application rate at 165 g/m2

For professional use :

* replacement of the application rate of 150 g/m2 for the dilution at 5% by an application rate at 165 g/m2
* withdrawal of the dilution at 8.33% (cure treatment) (worst case)

For meta SPC 2,

For industrial use :

- replacement of the application rate of 150 g/m2 for the dilution at 5% by an application rate between 100 and 165 g/m2

- replacement of the application rate of 150 g/m2 for the dilution at 10% by an application rate between 100 and 165 g/m2.

Considering that the human health assessment covered the new claimed uses, the assessment for human health was not reviewed.

Indeed, for meta SPC 1and 2,

* the primary exposure assessment was performed considering active substances concentrations at (propiconazole: 0.2%, cypermethrine: 0.11%, tebuconazole: 0.06% and IPBC: 0.06%). These concentrations cover the dilution at 3% and 5% of the different products of meta SPC1 and 2. The application rate has no impact on the determination of primary exposure.
* The secondary exposure was performed considering active substances concentrations at (propiconazole: 0.2%, cypermethrine: 0.11%, tebuconazole: 0.06% and IPBC: 0.06%) and an application rate of 480 g/m2. This scenario covers all dilutions and application rate.

In the family product, three meta-SPC are proposed by applicant:

* Meta-SPC 1 which contains 2 products: X6119 C and X6119CJ
* Meta-SPC 2 which contains 2 products: X6119 C1 and X6119 B1
* Meta-SPC 3 which contains 3 products: X6119 CR, X6119 M2 and X6236.

Meta SPC 3 has been split into two meta SPC (3 and 4) by FR CA (see reason in the Efficacy section)

The products contained in the meta-SPC 1 and 2 are concentrate water-based products which have to be diluted before application.

The products contained in the meta-SPC 3 are ready to use products.

#### Hazard potential

##### Toxicology of the active substance

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

See the Assessment Reports of the active substances.

The relevant critical endpoints are summarised in the following table:

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

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

**Meta SPC 1**:

For the products X6119 C and X6119 CJ, the following co-formulants are considered substances of concern due to their proposed classifcation including in the submitted MSDSs and their impact on the classification of the products:

* mixture of 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one or (C(M)IT/MIT);
* 1,2-benzisothiazolin-3-one or (BIT);
* 1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-C8-18(even numbered) acyl derivs., hydroxides, inner salts,.

They lead to a classification **Skin Irrit 2 – H315**, **Eye Irrit 1 – H318** and **Skin Sens 1 H317** of the products.

Therefore, according to the BPR Guidance Volume III Human health – Part B Risk Assessment, the BAND A and B evaluation scheme are applied. In this context, a qualitative risk assessment associated with the application of P and H statements is performed.

**Meta SPC 2**:

For the product X6119 B1, the following co-formulants are considered substances of concern, due to their proposed classifcation including in the submitted MSDSs and their impact on the classification of the products:

* mixture of 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one or (C(M)IT/MIT);
* 1,2-benzisothiazolin-3-one or (BIT);
* 1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-C8-18(even numbered) acyl derivs., hydroxides, inner salts

They lead to a classification **Skin Irrit 2 – H315**, **Eye Irrit 1 – H318** and **Skin Sens 1 H317** of the product.

Therefore, according to the BPR Guidance Volume III Human health – Part B Risk Assessment, the BAND A and B evaluation scheme are applied. In this context, a qualitative risk assessment associated with the application of P and H statements is performed.

For the product X6119 C1, the following co-formulants are considered substances of concern, due to their proposed classifcation including in the submitted MSDSs and their impact on the classification of the products:

* mixture of 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one or (C(M)IT/MIT);
* 1,2-benzisothiazolin-3-one or (BIT);

They lead to a classification **Skin Irrit 2 – H315**, **Eye Irrit 1 – H318** and **Skin Sens 1 H317** of the product.

Therefore, according to the BPR Guidance Volume III Human health – Part B Risk Assessment, the BAND A and B evaluation scheme are applied. In this context, a qualitative risk assessment associated with the application of P and H statements is performed.

**Meta SPC 3 and 4:**

For the products X6119 M2 and X6236, the co-formulant Simulsol SL 8 is considered substance of concern, due to its proposed classifcation including in the submitted MSDSs and its impact on the classification of the products.

It leads to a classification **Eye Irrit 2 – H319** of the products. Therefore, according to the BPR Guidance Volume III Human health – Part B Risk Assessment, the BAND A evaluation scheme are applied. In this context, a qualitative risk assessment associated with the application of P and H statements is performed.

For the product X6119 CR, the co-formulant Rheovis AS1188 is considered substance of con

cern, due to its proposed classifcation including in the submitted MSDSs and its impact on the classification of the products.

It leads to a classification **Eye Irrit 2 – H319** of the product. Therefore, according to the BPR Guidance Volume III Human health – Part B Risk Assessment, the BAND A evaluation scheme are applied. In this context, a qualitative risk assessment associated with the application of P and H statements is performed.

#### Toxicology of the biocidal product

The toxicology of the biocidal product was examined appropriately according to standard requirements. The products were not the representative 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 5 ”Toxicology – biocidal product”.

##### Percutaneous absorption

In order to complete the human risk assessment for the Meta-SPC 1 and the Meta-SPC 2 of the PPG\_Class3\_WB family, three *in vitro* dermal absorption studies were performed with the representative formulation X6119CJ diluted at 3% to determine the dermal penetration potency of cypermethrin, propiconazole and tebuconazole.

The bridging justifications for X6119C, X6119C1 and X6119B1 from formulation X6119CJ and values used for risk assessment are presented at the end of this section.

**Dermal absorption of cypermethrin in formulation X6119CJ**

In this study, the dermal absorption of cypermethrin formulated in X6119CJ was investigated using human skin *in vitro*. Cypermethrin was tested at one concentration representing a 3% dilution of the commercial product in water (corresponding to 0.0345 % w/w of pure active substance). The study procedures described in this report were based on the most recent guidelines.

For the X6119CJ formulation, less than 75% of the total absorption (material in the receptor fluid at the end of the study) occurred within half the duration of the total sampling period. Therefore, only tape strips 1 and 2 were excluded from absorption calculation.

The *in vitro* dermal absorption of cypermethrin in the X6119CJ formulation was 5% (s.d. 2%).

As standard deviation is superior to 25% of the mean of the absorption, this value is added to the mean value to determine a dermal absorption value **of 7%** for **Cypermethrine**.

**Dermal absorption of propiconazole in formulation X6119CJ**

In this study, the dermal absorption of propiconazole formulated in X6119CJ was investigated using human skin *in vitro*. Propiconazole was tested at one concentration representing a 3% dilution of the commercial product in water (corresponding to 0.066 % w/w of pure active substance).

The study procedures described in this report were based on the most recent guidelines.

For the X6119CJ formulation, more than 75% of the total absorption (material in the receptor fluid at the end of the study) occurred within half the duration of the total sampling period. Therefore, all tape strips were excluded from absorption calculation.

The *in vitro* dermal absorption of propiconazole in the X6119CJ formulation was 7% (s.d. 2%).  
As standard deviation is superior to 25% of the mean of the absorption, this value is added to the mean value to determine a dermal absorption value of **9% for Propiconazole**.

**Dermal absorption of tebuconazole in formulation X6119CJ**

In this study, the dermal absorption of tebuconazole formulated in X6119CJ was investigated using human skin in vitro. Tebuconazole was tested at one concentration representing a 3% dilution of the commercial product in water (corresponding to 0.0222 % w/w of pure active substance).

The study procedures described in this report were based on the most recent guidelines.

For the X6119CJ formulation, more than 75% of the total absorption (material in the receptor fluid at the end of the study) occurred within half the duration of the total sampling period. Therefore, all tape strips were excluded from absorption calculation.

The *in vitro* dermal absorption of tebuconazole in the X6119CJ formulation was 6% (s.d. 2%).

As standard deviation is superior to 25% of the mean of the absorption, this value is added to the mean value to determine a dermal absorption value of **8% for Tebuconazole**.

**Dermal absorption of IPBC in formulation X6119CJ**

No study is available. Consequently, the default dermal absorption value of 75% (as proposed for substance at concentration inferior to 5% in the product in the EFSA guidance on dermal absorption of 2012[[13]](#footnote-13)) is proposed.

**Dermal absorption values:**

The proposed dermal absorption values for product X6119 CJ diluted at 3% are as follows:

|  |  |
| --- | --- |
| Cypermethrine | 7% |
| Propiconazole | 9% |
| Tebuconazole | 8% |
| IPBC | 75% |

For the product X6119 CJ:

The product X6119 CJ could be manipulated concentrated or diluted at 3 or 5%.

Except for IPBC (75% default value), the three *in vitro* dermal absorption studies with tebuconazole, propiconazole and cypermethrin on human skin were performed with the most diluted concentration (3%).

Therefore, the dermal absorption value was extrapolated to the higher concentrations and concentrate product, considering this approach as a worst case (according to the EFSA guidance on dermal absorption).

Comparaison of the concentration in active substances (%)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **X6119 CJ 3%**  **Tested in the dermal absorption study** | **X61169 CJ** | **X6119 CJ 5%** |
| Propiconazole | **0.07** | 2.37 | 0.12 |
| Cypermethrine | **0.04** | 1.29 | 0.06 |
| Tebuconazole | **0.02** | 0.78 | 0.04 |
| IPBC | **0.02** | 0.76 | 0.04 |

For the product X6119 C:

As mentioned below, the product X6119 C could be manipulated concentrated or diluted at 3%, 5% or 8.33%.

The concentrations of active substances are the same in X6119 CJ and X6119 C.

The difference between both compositions is the presence of a dying agent in X6119 CJ.

This difference will have no impact on the dermal absorption (moreover, the tested product contains these dying agent). Therefore, the read across between X6119 CJ and X6119 C is considered acceptable.

The dermal absorption values performed with a product diluted of 3% were extrapolated to the the higher concentrations and concentrated product as a worst case.

Comparaison of the concentration in active substances (%)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **X6119 CJ 3%**  **Tested in the dermal absorption study** | **X6119 C** | **X6119 C 3%** | **X6119 C 5%** | **X6119 C 8.33%** |
| Propiconazole | **0.07** | 2.37 | 0.07 | 0.12 | 0.20 |
| Cypermethrine | **0.04** | 1.29 | 0.04 | 0.06 | 0.11 |
| Tebuconazole | **0.02** | 0.78 | 0.02 | 0.04 | 0.06 |
| IPBC | **0.02** | 0.76 | 0.02 | 0.04 | 0.06 |

For the product X6119 B1:

The product can be manipulated concentrated or diluted at 10%. The concentrations of active substances are lower in the product B1 compared to the product X6119 CJ. However, the concentrations of active substances in the concentrated product (X6119 B1) and in the diluted product at 10% are superior to the concentrations of active substances tested in the dermal absorption. The tested formulation is therefore considered as a worst-case for the concentrated product X6119 B1 and its dilution at 10%.

Concerning the co formulants, the product X6119 B1 contains less binder, surfactant, organic solvent, preservative and anti-foaming agent than the product X6119 CJ. Therefore, the read across between X6119 B1 and X6119 CJ is considered acceptable.

The dermal absorption values performed with a product diluted of 3% were extrapolated to X6119 B1.

Comparaison of the concentration in active substances (%)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **X6119 CJ 3%**  **Tested in the dermal absorption study** | **X6119 B1** | **X6119 B1 10%** |
| Propiconazole | **0.07** | 1.18 | 0.12 |
| Cypermethrine | **0.04** | 0.65 | 0.06 |
| Tebuconazole | **0.02** | 0.39 | 0.04 |
| IPBC | **0.02** | 0.38 | 0.04 |

For the product X6119 C1:

The product can be manipulated concentrated or diluted at 5%.

The concentrations of active substances are the same in X6119 CJ and X6119 C1.

Concerning the co-formulants, the product X6119 C1 contains less binder, organic solvent and preservative than the product X6119 CJ.

A surfactant present in X6119 CJ (12.5%) is replaced by another surfactant at a higher content (+5%) and water.

The anti-foaming agent of X6119CJ (0.70%) is replaced by 1.40% of another anti-foaming agent in X6119C. These variations are considered without impact on the dermal absorption.

Therefore, the read across between X6119 C1 and X6119 CJ is deemed acceptable.

The dermal absorption values performed with a product diluted of 3% were extrapolated to X6119 C1.

Comparaison of the concentration in active substances (%)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **X6119 CJ 3%**  **Tested in the dermal absorption study** | **X61169 C1** | **X6119 C1 5%** |
| Propiconazole | **0,07** | 2.37 | 0.12 |
| Cypermethrine | **0,04** | 1.29 | 0.06 |
| Tebuconazole | **0,02** | 0.78 | 0.04 |
| IPBC | **0,02** | 0.76 | 0.04 |

To conclude, the following dermal absorption values will be used for all the products and the related dilutions of meta SPC 1 and meta SPC 2.

|  |  |
| --- | --- |
| **Cypermethrine** | **7%** |
| **Propiconazole** | **9%** |
| **Tebuconazole** | **8%** |
| **IPBC** | **75%** |

In order to complete the human risk assessment for the Meta-SPC 3 of the PPG\_Class3\_WB family, three *in vitro* dermal absorption studies were performed with the representative formulation X6236 to determine the dermal penetration potency of cypermethrin, propiconazole and tebuconazole.

**Dermal absorption of cypermethrin in formulation X6236**

In this study, the dermal absorption of cypermethrin formulated in X6236 was investigated using human skin *in vitro*. Cypermethrin was tested at one concentration in a X6236 formulation mixed with [14C]- cypermethrin (1.0 g cypermethrin/kg). The study procedures described in this report were based on the most recent guidelines.

For the X6236 formulation, less than 75% of the total absorption (material in the receptor fluid at the end of the study) occurred within half the duration of the total sampling period. Therefore, only tape strips 1 and 2 were excluded from absorption calculation.

The *in vitro* dermal absorption of cypermethrin in the X6236 formulation was 5% (s.d. 2%).

As standard deviation is superior to 25% of the mean of the absorption, this value is added to the mean value to determine a dermal absorption value of **7% for Cypermethrine**.

**Dermal absorption of propiconazole in formulation X6236**

In this study, the dermal absorption of propiconazole formulated in X6236 was investigated using human skin *in vitro*. Propiconazole was tested at one concentration in a X6236 formulation mixed with [14C]- propiconazole (1.5 g propiconazole/kg). The study procedures described in this report were based on the most recent guidelines.

For the X6236 formulation, less than 75% of the total absorption (material in the receptor fluid at the end of the study) occurred within half the duration of the total sampling period. Therefore, only tape strips 1 and 2 were excluded from absorption calculation.

After normalisation, the results for the dermal absorption are summarised below:

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Disc 10 | Disc 1 | Disc 2 | Disc 3 | Disc 1 | Disc 2 | Disc 3 | Disc 1 | Disc 2 | **Mean** | **SD** |
| **Total % potentially absorbed (excluding tape strips 1&2)**  **After normalization** | 2.32 | 2.74 | 1.00 | 1.21 | 3.39 | 3.31 | 3.91 | 3.12 | 5.09 | **2.90** | **1.28** |

Therefore, the *in vitro* dermal absorption of propiconazole in the X6236 formulation was 3% (s.d. 1%).

As standard deviation is superior to 25% of the mean of the absorption, this value is added to the mean value to determine a dermal absorption value of **4% for Propiconazole**.

**Dermal absorption of tebuconazole in formulation X6236**

In this study, the dermal absorption of tebuconazole formulated in X6236 was investigated using human skin *in vitro*. Tebuconazole was tested at one concentration in a X6236 formulation mixed with [14C]- tebuconazole (0.5 g tebuconazole/kg). The study procedures described in this report were based on the most recent guidelines.

For the X6236 formulation, over 75% of the total absorption (material in the receptor fluid at the end of the study) occurred within half the duration of the total sampling period. Therefore, all tape strips were excluded from absorption calculation.

The *in vitro* dermal absorption of tebuconazole in the X6236 formulation was 2% (s.d. 0.8%).

As standard deviation is superior to 25% of the mean of the absorption, this value is added to the mean value to determine a dermal absorption value of **3% for Tebuconazole**.

**Dermal absorption of IPBC in formulation X6236**

No study is available. Consequently, the default dermal absorption value of 75% (as proposed for substance at concentration inferior to 5% in the product in the EFSA guidance on dermal absorption of 2012[[14]](#footnote-14)) is proposed.

**Dermal absorption values:**

To conclude the proposed dermal absorption values for product X6236 diluted at 3% are:

|  |  |
| --- | --- |
| **Cypermethrine** | **7%** |
| **Propiconazole** | **4%** |
| **Tebuconazole** | **3%** |
| **IPBC** | **75%** |

For the product X6119 M2

No dermal absorption study is provided. A read across with the values obtained for X6236 is proposed by applicant.

The concentrations in active substances are similar between both formulations.

X6119 M2 contains less penetrating agent, thickening agent and pH regulator but more of water than the product X6236.

In this context, the tested formulation covers the formulation of X6119 M2. The read across between X6116 M2 and X6236 is considered acceptable.

Comparaison of the concentration in active substances

|  |  |  |
| --- | --- | --- |
|  | **X6119 M2** | **X6236** |
| Propiconazole | **0.16** | **0.16** |
| Cypermethrine | **0.11** | **0.11** |
| Tebuconazole | **0.05** | **0.05** |
| IPBC | **0.05** | **0.05** |

For the product X6119 CR

No dermal absorption study is provided. A read across with the values obtained with X6236 is proposed by applicant.

The concentrations in active substances are similar between both formulations.

However, the differences between co formulants are important.

The product X6119 CR contains for example more surfactant (6.85% in X6119 CR vs 4.28% in X6236), more thickening agent (1.80% in X6119 CR vs 1.71% in X6236).

The variation in surfactant between both formulations is superior to 25%. In this context, according to the EFSA guidance on dermal absorption, the read across is considered unacceptable.

For this product, the default value of 75% will be used for each active substance.

Comparaison of the concentration in active substances

|  |  |  |
| --- | --- | --- |
|  | **X6119 CR** | **X6236** |
| Propiconazole | 0.16 | 0.16 |
| Cypermethrine | 0.11 | 0.11 |
| Tebuconazole | 0.05 | 0.05 |
| IPBC | 0.05 | 0.05 |

To conlude the following dermal absorption values will be used for the products **X6236 and X6119 M2**.

|  |  |
| --- | --- |
| **Cypermethrine** | **7%** |
| **Propiconazole** | **4%** |
| **Tebuconazole** | **3%** |
| **IPBC** | **75%** |

For the product **X6119 CR**, the following dermal absorption values will be used:

|  |  |
| --- | --- |
| **Cypermethrine** | **75%** |
| **Propiconazole** | **75%** |
| **Tebuconazole** | **75%** |
| **IPBC** | **75%** |

##### Acute toxicity

In order to avoid unnecessary animal experiment, no acute oral toxicity study was conducted.

Therefore, the classification is determined by calculation according to the CLP regulation for oral, dermal and inhalation routes.

According to the criteria of Annex I to Regulation (EC) No.1272/2008, the proposed classification for all the products are: **not classified.**

##### Irritation and corrosivity

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

According to the criteria of Annex I to Regulation (EC) No.1272/2008, the proposed classification for the products on dermal and eyes irritation are:

* For **products X6119 C and X61169CJ (meta SPC1)**:
  + **H315:** Causes skin irritation.
  + **H318:** Causes serious eye damage.

The classification H315 is linked in particular to the presence of co-formulant Acticide SPX and Acticide B20 (classified H314) at concentration superior to 1%.

The classification H318 is linked in particular to the presence of coformulant 1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-C8-18(even numbered) acyl derivs., hydroxides, inner salts (classified H318) at concentration superior to 3% and sum of coformulant Acticide SPX and Acticide B20 (classified H314) at concentration superior to 3%.

* For products **X6119 B1 (meta SPC2)**:
  + **H315:** Causes skin irritation.
  + **H318:** Causes serious eye damage.

The classification H315 is linked in particular to the presence of coformulant Acticide B20 (classified H314) at concentration superior to 1%.

The classification H318 is linked in particular to the presence of coformulant 1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-C8-18(even numbered) acyl derivs., hydroxides, inner salts (classified H318) at concentration superior to 3% .

* For products **X6119 C1 (meta SPC2)**:
  + **H315:** Causes skin irritation.
  + **H318:** Causes serious eye damage.

The classification H315 is linked in particular to the presence of coformulant Acticide SPX and Acticide B20 (classified H314) at concentration superior to 1%.

The classification H318 is linked in particular to the sum of coformulant Acticide SPX and Acticide B20 (classified H314) at concentration equal to 3% .

* For products **X6119 M2 and X6236 (meta SPC3 and meta SPC 4)**:
  + **H319:** Causes serious eye irritation.

The classification H319 is linked in particular to the presence of coformulant Simulsol SL 8 (classified H318) at concentration superior to 1%.

* For products **X6119 CR (meta SPC3)**:
  + **H319:** Causes serious eye irritation.

The classification H319 is linked in particular to the presence of coformulant Rheovis AS1188 (classified H318) at concentration superior to 1%.

##### Sensitisation

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

According to the criteria of Annex I to Regulation (EC) No.1272/2008, the proposed classification for the products on sensitisation are:

* For products **X6119 C and X61169CJ (meta SPC1)**:
  + **H317**: May cause an allergic skin reaction.

The classification H317 is linked in particular to the presence of propiconazole and coformulants Acticide SPX and Acticide B20 (classified H317) at concentration superior to 1%.

The labelling should mentionned: ”Contain: propiconazole, IPBC, BIT, CMIT/MIT and 2-[(3-aminopropyl)methylamino]ethanol”.

* For products **X6119 B1 (meta SPC2)**:
  + **H317**: May cause an allergic skin reaction.

The classification H317 is linked in particular to the presence of propiconazole and coformulants Acticide B20 (classified H317) at concentration superior to 1% and the presence of mixture of C(M)IT/MIT at concentration superior to 0.0015% (0.0147%).

The labelling should mentionned: ”contain: propiconazole, IPBC, BIT, CMIT/MIT and 2-[(3-aminopropyl)methylamino]ethanol”.

* For products **X6119 C1 (meta SPC2)**:
  + **H317**: May cause an allergic skin reaction.

The classification H317 is linked in particular to the presence of propiconazole and coformulants Acticide B20 and Acticide SPX (classified H317) at concentration superior to 1%.

Moreover, the labelling should mentionned: ”contain: propiconazole, IPBC, BIT, CMIT/MIT and 2-[(3-aminopropyl)methylamino]ethanol”.

* For products **X6119 M2 and X6236 (meta SPC3 and meta SPC 4)**:

**Not classified** for this endpoint is required.

However, the labelling should mentionned: ” **EUH 208** contains: propiconazole, 1,2-benzisothiazolin-3-one (BIT) and Mixture of 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one (C(M)IT/MIT”. May produce an allergic reaction.

* For products **X6119 CR (meta SPC3)**:

**Not classified** for this endpoint is required.

However, the labelling should mentionned: ” **EUH 208** contains: propiconazole and coformulants Mergal (containing notably 1,2-benzisothiazolin-3-one), Norasystem (containing notably citral, linalool) and Clove ext”. May produce an allergic reaction.

##### Other studies

No other study has been submitted.

According to the CLP Regulation and based on the available data on active substances and co-formulants, the products of the family should be classified as folows:

|  |  |
| --- | --- |
| Meta SPC 1 (X6119 C and X61169CJ) | H315  H318  H317  H360d[[15]](#footnote-15)  The labelling should mention: ” contain: propiconazole, IPBC, BIT, CMIT/MIT and 2-[(3-aminopropyl)methylamino]ethanol |
| Meta SPC 2 (X6119 B1 X6119 C1) | H315  H318  H317  H360d15  The labelling should mentionned: ” contain: propiconazole, IPBC, BIT, CMIT/MIT and 2-[(3-aminopropyl)methylamino]ethanol |
| X6119 M2 and X6236 (meta SPC3 and meta SPC 4) | H319  EUH 208: Contains propiconazole, 1,2-benzisothiazolin-3-one 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one. May produce an allergic reaction. |
| X6119 CR (meta SPC3) | H319  EUH 208: Contains propiconazole and 1,2-benzisothiazolin-3-one), citral, linalool and Clove ext. May produce an allergic reaction. |

* **Minor Change application for PPG CLASS3 WB – 2019:**

For the products X6119M2 and X6236, one formulant (0.05% w/w) was replaced by a similar formulant (0.05% w/w) with the same function. Both formulants are not classified for human health. Therefore, this minor change does not impact the classification by calculation rules of the products of the BPF.

***Eye damage and irritation (meta SPC 3 and 4)***

A study according to OECD 438 (eye irritation on isolated chicken eye) has been conducted with the representative product of the meta SPC 3 (X6119M2).

The conclusions of this study is as follow:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table of in vitro studies on serious eye damage and eye irritation** | | | | | |
|  | | | | | |
| **Method, Guideline,**  **GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks** *(e.g. major deviations)* | **Reference** |
| Isolated Chicken Eyes OECD 438 (2018);  GLP: yes  Reliability: 1 | X6119M2, Batch No: 4908609349,  30 µL of undiluted test item were applied on the entire surface of the cornea | Exposure: 10 seconds.  Observation and measurement: 30, 75, 120, 180, 240 minutes post-treatment.  The enucleated eye test with isolated eyes of chicken is a validated *in vitro* test system. It represents a test system nearest to the *in vivo* test, without the need to use live animals. In the Isolated Chicken Eye (ICE) test, the tested compound is applied in one single dose onto the cornea of isolated eyes (in three replicates) and corneal effects are evaluated during 4 hours. | No corneal opacity occurs during the observation period (all scores equal to zero); corresponding to ICE Class I.  Slight fluorescein retention change (score 1) was noted on all three eyes at the 30 min observation time point; corresponding to ICE Class II.  No significant corneal swelling (mean % of the three eyes at any time point ≤ 5% ) was observed during the four hour observation period; corresponding to ICE Class I.  🡪The overall ICE Class was: 2xI, 1xII.  Based on this *in vitro* eye irritation study in isolated chicken eyes with X6119M2 , **no** classification for eye irritation and serious eye damage is needed. | None | T. Barré, 2019  Report: ICE-PH-19/0188 |

* **For META-SPC3:**

No classification for Eye damage and irritation is required for the representative product of the meta SPC 3 (X6119M2).

* **For META-SPC4:**

The study has been performed with the representative product of the meta SPC 3 (X6119M2) which is different than the representative product of the META-SPC4 (X6236). The bridging between the two formulations is presented below:

The products X6119M2 and X6236 are ready-for-use products and contain the same active substances.

The products X6119M2 and X6236 have similar compositions, with the following differences:

* The penetrating agent with no toxicological classification is increased in the product X6236. No impact on the local effect of the product is expected by the content difference.
* Two thickening agents are added in the product X6236. One has no toxicological classification and the other is classified for Eye damage .
* One pH regulator classified for eye (and dermal) irritation is added in the product X6236.
* The content in water content in X6236 is thus slightly decreased.
* Other component are in the same content.

Taking into account these elements and considering that the most impacting content changes are very slight, the eye local toxicological properties of the product X6236 are not expected to be different from the one of X6119M2.

In conclusion, the read-across between the compositions of the representative products X6119M2 (meta SPC 3) and X6236 (meta SPC 4) are acceptable.

Thus, the results of the study described above are considered relevant for the representative product X6236 (meta SPC 4): no classification for Eye damage and irritation is required.

Please refer to the confidential annex for the detailed comparison between the compositions of X6119M2 and X6236.

***Toxicology of substance of concern (meta SPC 3 and 4)***

For the products X6119 M2 and X6236, the co-formulant Simulsol SL 8 (D-Glucopyranose, oligomers, decyl octyl glycosides, EC: 500- 220-1) was considered substance of concern, due to its proposed classifcation included in the submitted MSDSs and its impact on the classification of the products.

This identification is no longer relevant in the frame of minor change application.

No new SOC has been identified.

#### Human exposure assessment

**META SPC 1 and 2**

The products X6119C, X6119CJ, X6119C1 and X6119B1 are concentrate water-based wood  
preservatives for industrial and professional uses.

**X6119 C** (propiconazole: 2.37%, cypermethrine: 1.29%, tebuconazole: 0.78% and IPBC: 0.76%; technical active substance content)

The product can be used by industrial for preventive treatment of wood by dipping treatement, spray treatment and flow coat/aspersion with product diluted at 3% or 5%. The rate of application is 150 g of diluted product / m2 for 3% dilution and 100/150 g of diluted product / m2 for 5% dilution.

The product can also be used by professional for preventive and curative treatement by brush/roller/pad and spray superficial. For preventive treatment, application is performed with product diluted at 5% and for curative treatment, application is performed with product diluted at 8.33%. The rate of application is 100/150 g of diluted product / m2 for 5% dilution for preventive treatment.The rate of application for curative treatment is 300 g of diluted product / m2 for 8.33% dilution. Injection in combination with superficial application can also be performed with product diluted at 8.33%. The rate of application is 180g of diluted product / m2 for 8.33% dilution.

As the dermal absorption values are the same for all the dilutions, for this product, risk characterisation will be realised:

* For industrial, considering an automated treatment with product X6119 C diluted at 5% (worst case) (propiconazole: 0.12%, cypermethrine: 0.06%, tebuconazole: 0.04% and IPBC: 0.04%). This assessment covers treatment with product diluted at 3% (propiconazole: 0.07%, cypermethrine: 0.04%, tebuconazole: 0.02% and IPBC: 0.02%).
* For professional, considering brush application, spray application and injection with product X6119 C diluted at 8.33% (worst case) (propiconazole: 0.2%, cypermethrine: 0.11%, tebuconazole: 0.06% and IPBC: 0.06%). This assessment covers treatment with product diluted at 5% (propiconazole: 0.12%, cypermethrine: 0.06%, tebuconazole: 0.04% and IPBC: 0.04%).
* For secondary exposure, an application of 480 g of diluted product at 8.33% will be performed. This scenario is the worst case scenario considering the highest concentration and the highest rate of application).

**X6119 CJ** (propiconazole: 2.37%, cypermethrine: 1.29%, tebuconazole: 0.78% and IPBC: 0.76%)

The product can be used by industrial for preventive treatment of wood by dipping treatement with product diluted at 5%(propiconazole: 0.12%, cypermethrine: 0.06%, tebuconazole: 0.04% and IPBC: 0.04%). The rate of application is 150 g of diluted product / m2 for 5% dilution.

Considering that the dermal absorption values are the same for all the products and all the dilutions, and that the concentrations in active substances are similar between X6119 C and X6119 CJ, the risk assessment for this use is covered by the risk assessment performed for industrial uses of X6119 C diluted at 5% (propiconazole: 0.12%, cypermethrine: 0.06%, tebuconazole: 0.04% and IPBC: 0.04%).

For secondary exposure, the risk is also covered by the risk assessment performed for X6119C.

**X6119 C1** (propiconazole: 2.37%, cypermethrine: 1.29%, tebuconazole: 0.78% and IPBC: 0.76%)

The product can be used by industrial for preventive treatment of wood by flow coat/aspersion treatement with product diluted at 5% (propiconazole: 0.12%, cypermethrine: 0.06%, tebuconazole: 0.04% and IPBC: 0.04%). The rate of application is 150 g of diluted product / m2 for 5% dilution.

Considering that the dermal absorption values are the same for all the products and all the dilutions, and that the concentrations in active substances are similar between X6119 C and X6119 C1, the risk assessment for this use is covered by the risk assessment performed for industrial uses of X6119 C diluted at 5% (propiconazole: 0.12%, cypermethrine: 0.06%, tebuconazole: 0.04% and IPBC: 0.04%).

For secondary exposure, the risk is also covered by the risk assessment performed for X6119C.

**X6119 B1** (propiconazole: 1.18%, cypermethrine: 0.65%, tebuconazole: 0.39% and IPBC: 0.38%)

The product can be used by industrial for preventive treatment of wood by dipping and spray treatement with product diluted at 10% (propiconazole: 0.12%, cypermethrine: 0.06%, tebuconazole: 0.04% and IPBC: 0.04%). The rate of application is 150 g of diluted product / m2 for 10% dilution.

Considering that the dermal absorption values are the same for all the products and all the dilutions, that the concentration in active substance for the concentrate products is inferior in X6119 B1 product and that the concentrations in active substances for the diluted products are similar between X6119 C and X6119 B1, the risk assessment for this use is covered by the risk assessment performed for industrial uses of X6119 C diluted at 5% (propiconazole: 0.12%, cypermethrine: 0.06%, tebuconazole: 0.04% and IPBC: 0.04%).

For secondary exposure, the risk is also covered by the risk assessment performed for X6119C.

**For META SPC 1 and 2, the risk assessment is performed for product X6119 C, which covers all products of uses for product in meta SPC 1 and meta SPC 2.**

**META SPC 3**

The Meta-SPC 3 of the PPG\_Class3\_WB family contains the products X6119CR, X6119M2 and X6236 which are ready-for-use water-based wood preservatives for professional and non-professional uses.

**X6119M2** (propiconazole: 0.16%, cypermethrine: 0.11%, tebuconazole: 0.05% and IPBC: 0.05%)

The product can be used for preventive treatement by brush/roller/pad and spray application. The rate of application is 200 g of product / m2.

The product can be used for curative treatement by brush/roller/pad and spray superficial application. The rate of application is 300 g of product / m2. Injection in combination with superficial application can also be performed at a rate of application of 180g of product / m2.

For this product, the risk characterisation will be performed:

* For professional, considering brush application, spray application and injection with product X6119M2. The assessments of brush and spray application are similar for curative or preventive treatment.
* For non-professional, considering brush application, spray application and injection with product X6119M2. The assessments of brush and spray application are similar for curative or preventive treatment.
* For secondary exposure, an application rate of 480 g of product should be performed.

**X6236** (propiconazole: 0.16%, cypermethrine: 0.11%, tebuconazole: 0.05% and IPBC: 0.05%)

As the active substances concentrations, dermal absorption values and uses are similar with the product X6119 M2, no additional risk characterization will be performed. The risk is covered by the risk assessment made for X6119M2.

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**X6119 CR** (propiconazole: 0.16%, cypermethrine: 0.11%, tebuconazole: 0.05% and IPBC: 0.05%)

The active substances concentrations and uses are the same as for X6119M2. Howsever, dermal absorption values are different. Therefore, the risk characterisation will be performed:

* For professional, considering brush application, spray application and injection with product X6119CR. The assessments of brush and spray application are similar for curative or preventive treatment.
* For secondary exposure with an application rate of 480 g of product.

**For META SPC 3 and META SPC 4 , the risk assessment is performed for product X6119M2 and X6119CR**

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

For the primary exposure to the product, only professional and non-professional users are in contact with the product during mixing and loading, application and cleaning of the equipment. Dermal and inhalation routes were considered as the main exposure routes during the primary exposure.

For the secondary exposure, consumers and also professionals might be in contact with the product. Exposure may occur soon after application with a short exposure period (acute phase) or exposure may be long-term and repeated (chronic phase).

**Table 1: Summary of main paths of human epxosure**

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

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Active Substance** | **Molecular weight**  **(g/mol)** | **Vapor Pressure**  **(Pa)** | **Inhalation absorption** | **Oral absorption** |
| **Cypermethrin** | 416 | 2.3\*10-7 (20°C) 6\*10-7 (25°C) | 100% | 57% |
| **Tebuconazole** | 308 | 1.7\*10-6 | 100% | 100% |
| **Propiconazole** | 342 | 5.6\*10-5 | 100% | 86%  (100%) |
| **IPBC** | 281 | 2,36-4,5 \*10-3 | 100% | >90%  (100%) |

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

##### META SPC 1 and 2

###### Exposure of industrial users

*In Annex 3.2 “Output tables from exposure assessment tools”, the results of the exposure calculations for the active substance and the substance of concern for the professional user are laid out.*

X6119 C can be used by industrial for preventive treatment of wood by dipping treatement, spray treatment and flow coat/aspersion with product diluted at 3% or 5%. The rate of application is 150 g of diluted product / m2 for 3% dilution and 100/150 g of diluted product / m2 for 5% dilution.

Risk characterisation will be realised considering an automated treatment with product X6119 C diluted at 5% (worst case).

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

The product is decanted; this will often be a full or semi-automatic process with limited exposure to the operator. The “*mixing and loading model 7*” from the TNsG part 2 p. 142 is used with the manual pouring data as a worst case approach to determine this exposure.

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

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

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

|  | Active substance | Inhalation Exposure  (mg/kg bw/j) | Dermal Exposure  (mg/kg bw/d) | Total Exposure (mg/kg bw/d) |
| --- | --- | --- | --- | --- |
| Automated treatment – without PPE except gloves during application | | | | |
| Transfer of product | Cyperméthrine | 4.21E-05 | 1.52E-02 | 1.52E-02 |
| Propiconazole | 7.74E-05 | 3.59E-02 | 3.60E-02 |
| Tébuconazole | 2.55E-05 | 1.05E-02 | 1.05E-02 |
| IPBC | 2.48E-05 | 9.60E-02 | 9.60E-02 |
| Automated dipping | Cyperméthrine | 1.02E-04 | 2.90E-02 | 2.91E-02 |
| Propiconazole | 1.88E-04 | 6.86E-02 | 6.88E-02 |
| Tébuconazole | 6.18E-05 | 2.01E-02 | 2.01E-02 |
| IPBC | 6.02E-05 | 1.83E-01 | 1.83E-01 |
| Transfer + Application | Cyperméthrine | 1.44E-04 | 4.42E-02 | 4.44E-02 |
| Propiconazole | 2.65E-04 | 1.05E-01 | 1.05E-01 |
| Tébuconazole | 8.72E-05 | 3.06E-02 | 3.07E-02 |
| IPBC | 8.50E-05 | 2.79E-01 | 2.79E-01 |
| Automated treatment – with gloves/clothes during M&L and gloves and impermeable coverall during application | | | | |
| Transfer of product | Cyperméthrine | 4.21E-05 | 1.52E-04 | 1.94E-04 |
| Propiconazole | 7.74E-05 | 3.59E-04 | 4.36E-04 |
| Tébuconazole | 2.55E-05 | 1.05E-04 | 1.30E-04 |
| IPBC | 2.48E-05 | 9.60E-04 | 9.84E-04 |
| Automated dipping | Cyperméthrine | 1.02E-04 | 4.54E-03 | 4.64E-03 |
| Propiconazole | 1.88E-04 | 1.07E-02 | 1.09E-02 |
| Tébuconazole | 6.18E-05 | 3.14E-03 | 3.20E-03 |
| IPBC | 6.02E-05 | 2.87E-02 | 2.87E-02 |
| Transfer + Application | Cyperméthrine | 1.44E-04 | 4.69E-03 | 4.84E-03 |
| Propiconazole | 2.65E-04 | 1.11E-02 | 1.13E-02 |
| Tébuconazole | 8.72E-05 | 3.24E-03 | 3.33E-03 |
| IPBC | 8.50E-05 | 2.96E-02 | 2.97E-02 |

###### Exposure of professional users

The product can be used by professional for preventive and curative treatement by brush/roller/pad and spray superficial.

For preventive treatment, application is performed with product diluted at 5% and for curative treatment, application is performed with product diluted at 8.33%.

The rate of application for preventive treatment is 100/150 g of diluted product / m2 for 5% dilution. For curative treatment, it is 300 g of diluted product / m2 for 8.33% dilution.

Injection in combination with superficial application can also be performed with product diluted at 8.33%. The rate of application is 180g of diluted product / m2 for 8.33% dilution.

Risk characterisation will be performed considering brush application, spray application and injection with product X6119 C diluted at 8.33% (worst case). The assessment of exposure during curative treatment covers the preventive treatment.

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

***Brush application***

A dilution of prouct is needed before application. In this context, this exposure is estimated via the use of model mixing and loading 4.

Professional exposure during the application phase has been considered using “*Non-professional application of paints by brushing and rolling*” from the Recommendation no. 10 of the BPC Ad hoc Working Group on Human Exposure[[16]](#footnote-16).

Exposure during the cleaning of equipment (brush) has been assessed with the exposure model from the Opinion no. 11 of HEEG[[17]](#footnote-17).

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Dermal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Brushing 300g/m2 – without PPE** | | | | |
| Mixing and loading | Cyperméthrine | na | 7.83E-03 | 7.83E-03 |
| Propiconazole | na | 1.85E-02 | 1.85E-02 |
| Tébuconazole | na | 5.41E-03 | 5.41E-03 |
| IPBC | na | 4.94E-02 | 4.94E-02 |
| Product application phase | Cyperméthrine | 1.45E-04 | 1.80E-03 | 1.94E-03 |
| Propiconazole | 2.68E-04 | 4.26E-03 | 4.52E-03 |
| Tébuconazole | 8.83E-05 | 1.25E-03 | 1.34E-03 |
| IPBC | 8.56E-05 | 1.13E-02 | 1.14E-02 |
| Brush cleaning phase | Cyperméthrine | na | 3.97E-04 | 3.97E-04 |
| Propiconazole | na | 6.19E-04 | 6.19E-04 |
| Tébuconazole | na | 3.47E-04 | 3.47E-04 |
| IPBC | na | 1.26E-03 | 1.26E-03 |
| Mixing and loading + application + cleaning | Cyperméthrine | **1.45E-04** | **1.00E-02** | **1.02E-02** |
| Propiconazole | **2.68E-04** | **2.34E-02** | **2.36E-02** |
| Tébuconazole | **8.83E-05** | **7.00E-03** | **7.09E-03** |
| IPBC | **8.56E-05** | **6.20E-02** | **6.21E-02** |
| **Brushing 300g/m2 – with gloves during mixing and loading and no PPE during application and cleaning of the brush** | | | | |
| Mixing and loading | Cyperméthrine | na | 7.83E-04 | 7.83E-04 |
| Propiconazole | na | 1.85E-03 | 1.85E-03 |
| Tébuconazole | na | 5.41E-04 | 5.41E-04 |
| IPBC | na | 4.94E-03 | 4.94E-03 |
| Product application phase | Cyperméthrine | 1.45E-04 | 1.80E-03 | 1.94E-03 |
| Propiconazole | 2.68E-04 | 4.26E-03 | 4.52E-03 |
| Tébuconazole | 8.83E-05 | 1.25E-03 | 1.34E-03 |
| IPBC | 8.56E-05 | 1.13E-02 | 1.14E-02 |
| Brush cleaning phase | Cyperméthrine | na | 3.97E-04 | 3.97E-04 |
| Propiconazole | na | 6.19E-04 | 6.19E-04 |
| Tébuconazole | na | 3.47E-04 | 3.47E-04 |
| IPBC | na | 1.26E-03 | 1.26E-03 |
| Mixing and loading + application + cleaning | Cyperméthrine | **1.45E-04** | **2.98E-03** | **3.12E-03** |
| Propiconazole | **2.68E-04** | **6.72E-03** | **6.99E-03** |
| Tébuconazole | **8.83E-05** | **2.14E-03** | **2.22E-03** |
| IPBC | **8.56E-05** | **1.75E-02** | **1.76E-02** |

***Spray application***

Professional exposure during the mixing and loading and the application phase has been considered using “*the spraying model 2*” according to the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure[[18]](#footnote-18).

Exposure during the cleaning of equipment has been assessed with the BEAT scenario “*Cleaning of the spray equipment*” from TNsG second version of 2007[[19]](#footnote-19).

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Spraying 300g/m2 – without PPE** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 2.26E-03 | 4.94E-02 | 5.17E-02 |
| Propiconazole | 4.16E-03 | 1.17E-01 | 1.21E-01 |
| Tébuconazole | 1.37E-03 | 3.43E-02 | 3.57E-02 |
| IPBC | 1.33E-03 | 3.12E-01 | 3.13E-01 |
| Cleaning of the spray equipment | Cyperméthrine | NA | 6.88E-04 | 6.88E-04 |
| Propiconazole | NA | 1.63E-03 | 1.63E-03 |
| Tébuconazole | NA | 4.78E-04 | 4.78E-04 |
| IPBC | NA | 4.34E-03 | 4.34E-03 |
| Appli + cleaning | Cyperméthrine | **2.26E-03** | **5.01E-02** | **5.24E-02** |
| Propiconazole | **4.16E-03** | **1.19E-01** | **1.23E-01** |
| Tébuconazole | **1.37E-03** | **3.48E-02** | **3.62E-02** |
| IPBC | **1.33E-03** | **3.16E-01** | **3.18E-01** |
| **Spraying 300g/m2 – with gloves and coated coverall during application and no PPE during cleaning** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 2.26E-03 | 3.00E-03 | 5.25E-03 |
| Propiconazole | 4.16E-03 | 7.09E-03 | 1.13E-02 |
| Tébuconazole | 1.37E-03 | 2.08E-03 | 3.45E-03 |
| IPBC | 1.33E-03 | 1.89E-02 | 2.02E-02 |
| Cleaning of the spray equipment | Cyperméthrine | na | 6.88E-04 | 6.88E-04 |
| Propiconazole | na | 1.63E-03 | 1.63E-03 |
| Tébuconazole | na | 4.78E-04 | 4.78E-04 |
| IPBC | na | 4.34E-03 | 4.34E-03 |
| Appli + cleaning | Cyperméthrine | **2.26E-03** | **3.68E-03** | **5.94E-03** |
| Propiconazole | **4.16E-03** | **8.72E-03** | **1.29E-02** |
| Tébuconazole | **1.37E-03** | **2.56E-03** | **3.93E-03** |
| IPBC | **1.33E-03** | **2.32E-02** | **2.46E-02** |

***Injection***

An injection can be performed in combination with superficial application.

In first step, exposure during this injection phase is determined according to the subsoil treatment model 2, as recommended in the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure[[20]](#footnote-20).

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

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Injection 180 g/m2 – with gloves during injection and no PPE during cleaning** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 1.69E-05 | 7.99E-04 | 8.16E-04 |
| Propiconazole | 3.12E-05 | 1.89E-03 | 1.92E-03 |
| Tébuconazole | 1.03E-05 | 5.55E-04 | 5.65E-04 |
| IPBC | 9.98E-06 | 5.04E-03 | 5.05E-03 |
| Cleaning of the equipment | Cyperméthrine | NA | 6.88E-04 | 6.88E-04 |
| Propiconazole | NA | 1.63E-03 | 1.63E-03 |
| Tébuconazole | NA | 4.78E-04 | 4.78E-04 |
| IPBC | NA | 4.34E-03 | 4.34E-03 |
| Appli + cleaning | Cyperméthrine | **1.69E-05** | **1.49E-03** | **1.50E-03** |
| Propiconazole | **3.12E-05** | **3.52E-03** | **3.55E-03** |
| Tébuconazole | **1.03E-05** | **1.03E-03** | **1.04E-03** |
| IPBC | **9.98E-06** | **9.38E-03** | **9.39E-03** |
| **Injection 180 g/m2 – with gloves during injection and gloves and coated coverall during cleaning** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 1.69E-05 | 7.99E-04 | 8.16E-04 |
| Propiconazole | 3.12E-05 | 1.89E-03 | 1.92E-03 |
| Tébuconazole | 1.03E-05 | 5.55E-04 | 5.65E-04 |
| IPBC | 9.98E-06 | 5.04E-03 | 5.05E-03 |
| Cleaning of the equipment | Cyperméthrine | NA | 9.29E-05 | 9.29E-05 |
| Propiconazole | NA | 2.20E-04 | 2.20E-04 |
| Tébuconazole | NA | 6.45E-05 | 6.45E-05 |
| IPBC | NA | 5.86E-04 | 5.86E-04 |
| Appli + cleaning | Cyperméthrine | **1.69E-05** | **8.92E-04** | **9.09E-04** |
| Propiconazole | **3.12E-05** | **2.11E-03** | **2.14E-03** |
| Tébuconazole | **1.03E-05** | **6.19E-04** | **6.29E-04** |
| IPBC | **9.98E-06** | **5.63E-03** | **5.64E-03** |

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

Injection combined with brush treatment

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Injection 180 g/m2 in combination with brush treatment at 300 g/m2**  **With gloves during mixing and loading, no PPE during application except gloves during injection and no PPE during cleaning** | | | | |
| Brush treatment | Cyperméthrine | **1.45E-04** | **2.98E-03** | **3.12E-03** |
| Propiconazole | **2.68E-04** | **6.72E-03** | **6.99E-03** |
| Tébuconazole | **8.83E-05** | **2.14E-03** | **2.22E-03** |
| IPBC | **8.56E-05** | **1.75E-02** | **1.76E-02** |
| Injection | Cyperméthrine | **1.69E-05** | **1.49E-03** | **1.50E-03** |
| Propiconazole | **3.12E-05** | **3.52E-03** | **3.55E-03** |
| Tébuconazole | **1.03E-05** | **1.03E-03** | **1.04E-03** |
| IPBC | **9.98E-06** | **9.38E-03** | **9.39E-03** |
| Brush + injection | Cyperméthrine | **1.62E-04** | **4.46E-03** | **4.63E-03** |
| Propiconazole | **2.99E-04** | **1.02E-02** | **1.05E-02** |
| Tébuconazole | **9.86E-05** | **3.17E-03** | **3.27E-03** |
| IPBC | **9.56E-05** | **2.69E-02** | **2.70E-02** |

Injection combined with spray treatment

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Injection 180 g/m2 in combination with spray treatment at 300 g/m2**  **With gloves and coated coverall during application by spraying, gloves during injection, gloves and coated coverall during cleaning of injection equipment and no PPE during cleaning of spray equipment** | | | | |
| Spray treatment | Cyperméthrine | **2.26E-03** | **3.68E-03** | **5.94E-03** |
| Propiconazole | **4.16E-03** | **8.72E-03** | **1.29E-02** |
| Tébuconazole | **1.37E-03** | **2.56E-03** | **3.93E-03** |
| IPBC | **1.33E-03** | **2.32E-02** | **2.46E-02** |
| Injection | Cyperméthrine | **1.69E-05** | **8.92E-04** | **9.09E-04** |
| Propiconazole | **3.12E-05** | **2.11E-03** | **2.14E-03** |
| Tébuconazole | **1.03E-05** | **6.19E-04** | **6.29E-04** |
| IPBC | **9.98E-06** | **5.63E-03** | **5.64E-03** |
| Spray + injection | Cyperméthrine | 2.28E-03 | 4.57E-03 | 6.85E-03 |
| Propiconazole | 4.19E-03 | 1.08E-02 | 1.50E-02 |
| Tébuconazole | 1.38E-03 | 3.18E-03 | 4.56E-03 |
| IPBC | 1.34E-03 | 2.88E-02 | 3.02E-02 |

##### META SPC 3 and META SPC 4

The products X6119CR, X6119M2 and X6236 are ready-for-use water-based wood preservatives for professional and non-professional (only X6119M2 and X6236) uses.

###### Exposure of professional users

*In Annex 3.2 “Output tables from exposure assessment tools”, the results of the exposure calculations for the active substance and the substance of concern for the professional user are laid out.*

**X6119 M2**

The product can be used by professional for preventive treatement by brush/roller/pad and spray application. The rate of application is 200 g of product / m2.

The product can be used by professional for curative treatement by brush/roller/pad and spray superficial application. The rate of application is 300 g of product / m2. Injection in combination with superficial application can also be performed at a rate of application of 180g of product / m2.

The assessment of exposure during curative treatment covers the preventive treatment.

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

***Brush application***

A decanting of prouct is needed before application. In this context, this exposure is estimated via the use of model mixing and loading 4.

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[[22]](#footnote-22).

Exposure during the cleaning of equipment (brush) has been assessed with the exposure model from the Opinion no. 11 of HEEG[[23]](#footnote-23).

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Dermal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Brushing 300g/m2 – without PPE** | | | | |
| Mixing and loading | Cyperméthrine | na | 6.67E-04 | 6.67E-04 |
| Propiconazole | na | 5.55E-04 | 5.55E-04 |
| Tébuconazole | na | 1.30E-04 | 1.30E-04 |
| IPBC | na | 3.25E-03 | 3.25E-03 |
| Product application phase | Cyperméthrine | 1.45E-04 | 1.80E-03 | 1.94E-03 |
| Propiconazole | 2.17E-04 | 1.54E-03 | 1.75E-03 |
| Tébuconazole | 6.79E-05 | 3.60E-04 | 4.28E-04 |
| IPBC | 6.79E-05 | 9.00E-03 | 9.07E-03 |
| Brush cleaning phase | Cyperméthrine | na | 3.97E-04 | 3.97E-04 |
| Propiconazole | na | 3.73E-04 | 3.73E-04 |
| Tébuconazole | na | 2.67E-04 | 2.67E-04 |
| IPBC | na | 1.05E-03 | 1.05E-03 |
| Mixing and loading + application + cleaning | Cyperméthrine | **1.45E-04** | **2.86E-03** | **3.01E-03** |
| Propiconazole | **2.17E-04** | **2.46E-03** | **2.68E-03** |
| Tébuconazole | **6.79E-05** | **7.57E-04** | **8.25E-04** |
| IPBC | **6.79E-05** | **1.33E-02** | **1.34E-02** |

***Spray application***

Professional exposure during the mixing and loading and the application phase has been considered using “*the spraying model 2*” according to the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure[[24]](#footnote-24).

Exposure during the cleaning of equipment has been assessed with the BEAT scenario “*Cleaning of the spray equipment*” from TNsG second version of 2007[[25]](#footnote-25).

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Spraying 300g/m2 – without PPE** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 2.54E-03 | 5.56E-02 | 5.82E-02 |
| Propiconazole | 3.80E-03 | 4.75E-02 | 5.13E-02 |
| Tébuconazole | 1.19E-03 | 1.11E-02 | 1.23E-02 |
| IPBC | 1.19E-03 | 2.78E-01 | 2.80E-01 |
| Cleaning of the spray equipment | Cyperméthrine | NA | 6.88E-04 | 6.88E-04 |
| Propiconazole | NA | 5.88E-04 | 5.88E-04 |
| Tébuconazole | NA | 1.38E-04 | 1.38E-04 |
| IPBC | NA | 3.45E-03 | 3.45E-03 |
| Appli + cleaning | Cyperméthrine | **2.54E-03** | **5.63E-02** | **5.88E-02** |
| Propiconazole | **3.80E-03** | **4.81E-02** | **5.19E-02** |
| Tébuconazole | **1.19E-03** | **1.13E-02** | **1.25E-02** |
| IPBC | **1.19E-03** | **2.82E-01** | **2.83E-01** |
| **Spraying 300g/m2 – with gloves and coated coverall during application and no PPE during cleaning** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 2.54E-03 | 3.37E-03 | 5.91E-03 |
| Propiconazole | 3.80E-03 | 2.88E-03 | 6.68E-03 |
| Tébuconazole | 1.19E-03 | 6.75E-04 | 1.86E-03 |
| IPBC | 1.19E-03 | 1.69E-02 | 1.81E-02 |
| Cleaning of the spray equipment | Cyperméthrine | na | 6.88E-04 | 6.88E-04 |
| Propiconazole | na | 5.88E-04 | 5.88E-04 |
| Tébuconazole | na | 1.38E-04 | 1.38E-04 |
| IPBC | na | 3.45E-03 | 3.45E-03 |
| Appli + cleaning | Cyperméthrine | **2.54E-03** | **4.06E-03** | **6.60E-03** |
| Propiconazole | **3.80E-03** | **3.47E-03** | **7.27E-03** |
| Tébuconazole | **1.19E-03** | **8.13E-04** | **2.00E-03** |
| IPBC | **1.19E-03** | **2.03E-02** | **2.15E-02** |

***Injection***

An injection can be performed in combination with superficial application.

In first step, exposure during this injection phase is determined according to the subsoil treatment model 2, as recommended in the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure[[26]](#footnote-26).

Exposure during the cleaning of equipment has been assessed with the BEAT scenario “*Cleaning of the spray equipment*” from TNsG second version of 2007[[27]](#footnote-27).

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Injection 180 g/m2 – with gloves during injection and no PPE during cleaning** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 1.69E-05 | 7.99E-04 | 8.16E-04 |
| Propiconazole | 2.53E-05 | 6.83E-04 | 7.08E-04 |
| Tébuconazole | 7.92E-06 | 1.60E-04 | 1.68E-04 |
| IPBC | 7.92E-06 | 4.00E-03 | 4.01E-03 |
| Cleaning of the equipment | Cyperméthrine | NA | 6.88E-04 | 6.88E-04 |
| Propiconazole | NA | 5.88E-04 | 5.88E-04 |
| Tébuconazole | NA | 1.38E-04 | 1.38E-04 |
| IPBC | NA | 3.45E-03 | 3.45E-03 |
| Appli + cleaning | Cyperméthrine | **1.69E-05** | **1.49E-03** | **1.50E-03** |
| Propiconazole | **2.53E-05** | **1.27E-03** | **1.30E-03** |
| Tébuconazole | **7.92E-06** | **2.98E-04** | **3.06E-04** |
| IPBC | **7.92E-06** | **7.45E-03** | **7.45E-03** |

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

Injection combined with brush treatment

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Injection 180 g/m2 in combination with brush treatment at 300 g/m2**  **No PPE during application except gloves during injection and no PPE during cleaning** | | | | |
| Brush treatment | Cyperméthrine | **1.45E-04** | **2.86E-03** | **3.01E-03** |
| Propiconazole | **2.17E-04** | **2.46E-03** | **2.68E-03** |
| Tébuconazole | **6.79E-05** | **7.57E-04** | **8.25E-04** |
| IPBC | **6.79E-05** | **1.33E-02** | **1.34E-02** |
| Injection | Cyperméthrine | **1.69E-05** | **1.49E-03** | **1.50E-03** |
| Propiconazole | **2.53E-05** | **1.27E-03** | **1.30E-03** |
| Tébuconazole | **7.92E-06** | **2.98E-04** | **3.06E-04** |
| IPBC | **7.92E-06** | **7.45E-03** | **7.45E-03** |
| Brush + injection | Cyperméthrine | **1.62E-04** | **4.35E-03** | **4.51E-03** |
| Propiconazole | **2.43E-04** | **3.74E-03** | **3.98E-03** |
| Tébuconazole | **7.58E-05** | **1.05E-03** | **1.13E-03** |
| IPBC | **7.58E-05** | **2.07E-02** | **2.08E-02** |

Injection combined with spray treatment

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Injection 180 g/m2 in combination with spray treatment at 300 g/m2**  **With gloves and coated coverall during application by spraying, gloves during injection** | | | | |
| Spray treatment | Cyperméthrine | **2.54E-03** | **4.06E-03** | **6.60E-03** |
| Propiconazole | **3.80E-03** | **3.47E-03** | **7.27E-03** |
| Tébuconazole | **1.19E-03** | **8.13E-04** | **2.00E-03** |
| IPBC | **1.19E-03** | **2.03E-02** | **2.15E-02** |
| Injection | Cyperméthrine | **1.69E-05** | **1.49E-03** | **1.50E-03** |
| Propiconazole | **2.53E-05** | **1.27E-03** | **1.30E-03** |
| Tébuconazole | **7.92E-06** | **2.98E-04** | **3.06E-04** |
| IPBC | **7.92E-06** | **7.45E-03** | **7.45E-03** |
| Brush + injection | Cyperméthrine | 2.56E-03 | 5.55E-03 | 8.10E-03 |
| Propiconazole | 3.83E-03 | 4.74E-03 | 8.57E-03 |
| Tébuconazole | 1.20E-03 | 1.11E-03 | 2.31E-03 |
| IPBC | 1.20E-03 | 2.78E-02 | 2.90E-02 |

**X6119 CR** (propiconazole: 0.16%, cypermethrine: 0.11%, tebuconazole: 0.05% and IPBC: 0.05%)

The product can be used by professional for preventive treatement by brush/roller/pad and spray application. The rate of application is 200 g of product / m2.

The product can be used by professional for curative treatement by brush/roller/pad and spray superficial application. The rate of application is 300 g of product / m2. Injection in combination with superficial application can also be performed at a rate of application of 180g of product / m2.

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

***Brush application***

For roller application, a loading of paint in a support is needed before application. In this context, this exposure is estimated via the use of model mixing and loading 4.

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[[28]](#footnote-28).

Exposure during the cleaning of equipment (brush) has been assessed with the exposure model from the Opinion no. 11 of HEEG[[29]](#footnote-29).

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Dermal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Brushing 300g/m2 – without PPE** | | | | |
| Loading of the paint in a support | Cyperméthrine | na | 6.88E-03 | 6.88E-03 |
| Propiconazole | na | 1.00E-02 | 1.00E-02 |
| Tébuconazole | na | 3.13E-03 | 3.13E-03 |
| IPBC | na | 3.13E-03 | 3.13E-03 |
| Product application phase | Cyperméthrine | 1.49E-04 | 1.90E-02 | 1.92E-02 |
| Propiconazole | 2.17E-04 | 2.77E-02 | 2.79E-02 |
| Tébuconazole | 6.79E-05 | 8.66E-03 | 8.72E-03 |
| IPBC | 6.79E-05 | 8.66E-03 | 8.72E-03 |
| Brush cleaning phase | Cyperméthrine | na | 1.96E-03 | 1.96E-03 |
| Propiconazole | na | 2.74E-03 | 2.74E-03 |
| Tébuconazole | na | 1.02E-03 | 1.02E-03 |
| IPBC | na | 1.02E-03 | 1.02E-03 |
| Loading + application + cleaning | Cyperméthrine | **1.49E-04** | **2.79E-02** | **2.80E-02** |
| Propiconazole | **2.17E-04** | **4.04E-02** | **4.07E-02** |
| Tébuconazole | **6.79E-05** | **1.28E-02** | **1.29E-02** |
| IPBC | **6.79E-05** | **1.28E-02** | **1.29E-02** |
| Brushing 300g/m2 – with gloves during loading, gloves and coated coverall during application and no PPE during cleaning | | | | |
| Loading of the paint in a support | Cyperméthrine | na | 6.88E-04 | 6.88E-04 |
| Propiconazole | na | 1.00E-03 | 1.00E-03 |
| Tébuconazole | na | 3.13E-04 | 3.13E-04 |
| IPBC | na | 3.13E-04 | 3.13E-04 |
| Product application phase | Cyperméthrine | 1.49E-04 | 2.47E-03 | 2.61E-03 |
| Propiconazole | 2.17E-04 | 3.59E-03 | 3.80E-03 |
| Tébuconazole | 6.79E-05 | 1.12E-03 | 1.19E-03 |
| IPBC | 6.79E-05 | 1.12E-03 | 1.19E-03 |
| Brush cleaning phase | Cyperméthrine | na | 1.96E-03 | 1.96E-03 |
| Propiconazole | na | 2.74E-03 | 2.74E-03 |
| Tébuconazole | na | 1.02E-03 | 1.02E-03 |
| IPBC | na | 1.02E-03 | 1.02E-03 |
| Application + cleaning | Cyperméthrine | **1.49E-04** | **5.11E-03** | **5.26E-03** |
| Propiconazole | **2.17E-04** | **7.33E-03** | **7.54E-03** |
| Tébuconazole | **6.79E-05** | **2.45E-03** | **2.52E-03** |
| IPBC | **6.79E-05** | **2.45E-03** | **2.52E-03** |
| Brushing 300g/m2 – with gloves during loading, gloves and impermeable coverall during application and no PPE during cleaning | | | | |
| Loading of the paint in a support | Cyperméthrine | na | 6.88E-04 | 6.88E-04 |
| Propiconazole | na | 1.00E-03 | 1.00E-03 |
| Tébuconazole | na | 3.13E-04 | 3.13E-04 |
| IPBC | na | 3.13E-04 | 3.13E-04 |
| Product application phase | Cyperméthrine | 1.49E-04 | 1.62E-03 | 1.77E-03 |
| Propiconazole | 2.17E-04 | 2.36E-03 | 2.58E-03 |
| Tébuconazole | 6.79E-05 | 7.38E-04 | 8.06E-04 |
| IPBC | 6.79E-05 | 7.38E-04 | 8.06E-04 |
| Brush cleaning phase | Cyperméthrine | na | 1.96E-03 | 1.96E-03 |
| Propiconazole | na | 2.74E-03 | 2.74E-03 |
| Tébuconazole | na | 1.02E-03 | 1.02E-03 |
| IPBC | na | 1.02E-03 | 1.02E-03 |
| Application + cleaning | Cyperméthrine | **1.49E-04** | **4.27E-03** | **4.42E-03** |
| Propiconazole | **2.17E-04** | **6.10E-03** | **6.32E-03** |
| Tébuconazole | **6.79E-05** | **2.07E-03** | **2.14E-03** |
| IPBC | **6.79E-05** | **2.07E-03** | **2.14E-03** |

***Spray application***

Professional exposure during the mixing and loading and the application phase has been considered using “*the spraying model 2*” according to the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure[[30]](#footnote-30).

Exposure during the cleaning of equipment has been assessed with the BEAT scenario “*Cleaning of the spray equipment*” from TNsG second version of 2007[[31]](#footnote-31).

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Spraying 300g/m2 – without PPE** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 2.61E-03 | 6.13E-01 | 6.15E-01 |
| Propiconazole | 3.80E-03 | 8.91E-01 | 8.95E-01 |
| Tébuconazole | 1.19E-03 | 2.78E-01 | 2.80E-01 |
| IPBC | 1.19E-03 | 2.78E-01 | 2.80E-01 |
| Cleaning of the spray equipment | Cyperméthrine | NA | 7.58E-03 | 7.58E-03 |
| Propiconazole | NA | 1.10E-02 | 1.10E-02 |
| Tébuconazole | na | 3.45E-03 | 3.45E-03 |
| IPBC | NA | 3.45E-03 | 3.45E-03 |
| Appli + cleaning | Cyperméthrine | **2.61E-03** | **6.20E-01** | **6.23E-01** |
| Propiconazole | **3.80E-03** | **9.02E-01** | **9.06E-01** |
| Tébuconazole | **1.19E-03** | **2.82E-01** | **2.83E-01** |
| IPBC | **1.19E-03** | **2.82E-01** | **2.83E-01** |
| **Spraying 300g/m2 – with gloves and coated coverall during spraying and no PPE during cleaning of spray equipment** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 2.61E-03 | 3.71E-02 | 3.97E-02 |
| Propiconazole | 3.80E-03 | 5.40E-02 | 5.78E-02 |
| Tébuconazole | 1.19E-03 | 1.69E-02 | 1.81E-02 |
| IPBC | 1.19E-03 | 1.69E-02 | 1.81E-02 |
| Cleaning of the spray equipment | Cyperméthrine | na | 7.58E-03 | 7.58E-03 |
| Propiconazole | na | 1.10E-02 | 1.10E-02 |
| Tébuconazole | na | 3.45E-03 | 3.45E-03 |
| IPBC | na | 3.45E-03 | 3.45E-03 |
| Appli + cleaning | Cyperméthrine | **2.61E-03** | **4.47E-02** | **4.73E-02** |
| Propiconazole | **3.80E-03** | **6.50E-02** | **6.88E-02** |
| Tébuconazole | **1.19E-03** | **2.03E-02** | **2.15E-02** |
| IPBC | **1.19E-03** | **2.03E-02** | **2.15E-02** |
| **Spraying 300g/m2 – with gloves and impermeable coverall during spraying and no PPE during cleaning of spray equipment** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 2.61E-03 | 2.34E-02 | 2.60E-02 |
| Propiconazole | 3.80E-03 | 3.40E-02 | 3.78E-02 |
| Tébuconazole | 1.19E-03 | 1.06E-02 | 1.18E-02 |
| IPBC | 1.19E-03 | 1.06E-02 | 1.18E-02 |
| Cleaning of the spray equipment | Cyperméthrine | na | 7.58E-03 | 7.58E-03 |
| Propiconazole | na | 1.10E-02 | 1.10E-02 |
| Tébuconazole | na | 3.45E-03 | 3.45E-03 |
| IPBC | na | 3.45E-03 | 3.45E-03 |
| Appli (PPE)+ cleaning | Cyperméthrine | **2.61E-03** | **3.10E-02** | **3.36E-02** |
| Propiconazole | **3.80E-03** | **4.51E-02** | **4.89E-02** |
| Tébuconazole | **1.19E-03** | **1.41E-02** | **1.53E-02** |
| IPBC | **1.19E-03** | **1.41E-02** | **1.53E-02** |

***Injection***

An injection can be performed in combination with superficial application.

In first step, exposure during this injection phase is determined according to the subsoil treatment model 2, according to the Recommendation no. 6 of the BPC Ad hoc Working Group on Human Exposure[[32]](#footnote-32).

Exposure during the cleaning of equipment has been assessed with the BEAT scenario “*Cleaning of the spray equipment*” from TNsG second version of 2007[[33]](#footnote-33).

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Injection 180 g/m2 – with gloves during injection and no PPE during cleaning** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 1.74E-05 | 8.80E-03 | 8.82E-03 |
| Propiconazole | 2.53E-05 | 1.28E-02 | 1.28E-02 |
| Tébuconazole | 7.92E-06 | 4.00E-03 | 4.01E-03 |
| IPBC | 7.92E-06 | 4.00E-03 | 4.01E-03 |
| Cleaning of the equipment | Cyperméthrine | NA | 7.58E-03 | 7.58E-03 |
| Propiconazole | NA | 1.10E-02 | 1.10E-02 |
| Tébuconazole | NA | 3.45E-03 | 3.45E-03 |
| IPBC | NA | 3.45E-03 | 3.45E-03 |
| Appli + cleaning | Cyperméthrine | **1.74E-05** | **1.64E-02** | **1.64E-02** |
| Propiconazole | **2.53E-05** | **2.38E-02** | **2.39E-02** |
| Tébuconazole | **7.92E-06** | **7.45E-03** | **7.45E-03** |
| IPBC | **7.92E-06** | **7.45E-03** | **7.45E-03** |
| **Injection 180 g/m2 – with gloves during injection and gloves and coated coverall during cleaning** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 1.74E-05 | 8.80E-03 | 8.82E-03 |
| Propiconazole | 2.53E-05 | 1.28E-02 | 1.28E-02 |
| Tébuconazole | 7.92E-06 | 4.00E-03 | 4.01E-03 |
| IPBC | 7.92E-06 | 4.00E-03 | 4.01E-03 |
| Cleaning of the equipment | Cyperméthrine | NA | 1.02E-03 | 1.02E-03 |
| Propiconazole | NA | 1.49E-03 | 1.49E-03 |
| Tébuconazole | NA | 4.65E-04 | 4.65E-04 |
| IPBC | NA | 4.65E-04 | 4.65E-04 |
| Appli + cleaning | Cyperméthrine | **1.74E-05** | **9.82E-03** | **9.84E-03** |
| Propiconazole | **2.53E-05** | **1.43E-02** | **1.43E-02** |
| Tébuconazole | **7.92E-06** | **4.47E-03** | **4.47E-03** |
| IPBC | **7.92E-06** | **4.47E-03** | **4.47E-03** |

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

The combination with the exposure during spraying was not performed because the risk is ever unacceptable just during spraying.

Injection combined with brush treatment

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Injection 180 g/m2 in combination with brush treatment at 300 g/m2**  **With gloves during mixing and loading, gloves and coated coverall during application by brush, gloves during injection, gloves and coated coverall during cleaning of injection equipment and no PPE during cleaning of brush** | | | | |
| Brush treatment | Cyperméthrine | **1.49E-04** | **5.11E-03** | **5.26E-03** |
| Propiconazole | **2.17E-04** | **7.33E-03** | **7.54E-03** |
| Tébuconazole | **6.79E-05** | **2.45E-03** | **2.52E-03** |
| IPBC | **6.79E-05** | **2.45E-03** | **2.52E-03** |
| Injection | Cyperméthrine | **1.74E-05** | **9.82E-03** | **9.84E-03** |
| Propiconazole | **2.53E-05** | **1.43E-02** | **1.43E-02** |
| Tébuconazole | **7.92E-06** | **4.47E-03** | **4.47E-03** |
| IPBC | **7.92E-06** | **4.47E-03** | **4.47E-03** |
| Brush + injection | Cyperméthrine | 1.67E-04 | 1.49E-02 | 1.51E-02 |
| Propiconazole | 2.43E-04 | 2.16E-02 | 2.19E-02 |
| Tébuconazole | 7.58E-05 | 6.92E-03 | 6.99E-03 |
| IPBC | 7.58E-05 | 6.92E-03 | 6.99E-03 |

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

*In Annex 3.2 “Output tables from exposure assessment tools”, the results of the exposure calculations for the active substance and the substance of concern for the non-professional user and the general public are laid out.*

**X6119 M2** (propiconazole: 0.16%, cypermethrine: 0.11%, tebuconazole: 0.05% and IPBC: 0.05%)

The product can be used by non-professional for preventive treatement by brush/roller/pad and spray application. The rate of application is 200 g of product / m2.

The product can be used by non-professional for curative treatement by brush/roller/pad and spray superficial application. The rate of application is 300 g of product / m2. Injection in combination with superficial application can also be performed at a rate of application of 180g of product / m2.

The assessments of brush and spray application are similar for curative or preventive treatment.

For roller application, a loading of paint in a support is needed before application. In this context, this exposure is estimated via the use of model mixing and loading 4. 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[[34]](#footnote-34).

Exposure during the cleaning of equipment (brush) has been assessed with the exposure model from the Opinion no. 11 of HEEG[[35]](#footnote-35).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Dermal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| **Brushing 300g/m2** | | | | |
| Loading of the paint in a support | Cyperméthrine | na | 6.42E-04 | 6.42E-04 |
| Propiconazole | na | 5.33E-04 | 5.33E-04 |
| Tébuconazole | na | 1.25E-04 | 1.25E-04 |
| IPBC | na | 3.13E-03 | 3.13E-03 |
| Product application phase | Cyperméthrine | 1.49E-04 | 1.78E-03 | 1.93E-03 |
| Propiconazole | 2.17E-04 | 1.48E-03 | 1.69E-03 |
| Tébuconazole | 6.79E-05 | 3.46E-04 | 4.14E-04 |
| IPBC | 6.79E-05 | 8.66E-03 | 8.72E-03 |
| Brush cleaning phase | Cyperméthrine | na | 3.95E-04 | 3.95E-04 |
| Propiconazole | na | 3.68E-04 | 3.68E-04 |
| Tébuconazole | na | 2.66E-04 | 2.66E-04 |
| IPBC | na | 1.02E-03 | 1.02E-03 |
| Loading + application + cleaning | Cyperméthrine | **1.49E-04** | **2.81E-03** | **2.96E-03** |
| Propiconazole | **2.17E-04** | **2.38E-03** | **2.60E-03** |
| Tébuconazole | **6.79E-05** | **7.37E-04** | **8.05E-04** |
| IPBC | **6.79E-05** | **1.28E-02** | **1.29E-02** |

***Brush application + injection***

No specific exposure model for injection is available.

In a conservative approach, the exposure values set in the “*Non-professional application of paints by brushing and rolling*” from the Recommendation no. 10 of the BPC Ad hoc Working Group on Human Exposure, has been used and multiplied by two in order to simulate an application by brush and injection.

For the cleaning of the equipment, exposure during the cleaning of an equipment spray (as presented for the spray application) has been added to the cleaning of a brush scenario, in order to simulate the cleaning of both apparatus.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| **Brushing 300 g/m2 + injection 180 g/m2** | | | | |
|  | Cyperméthrine | na | 6.42E-04 | 6.42E-04 |
| Propiconazole | na | 5.33E-04 | 5.33E-04 |
| Tébuconazole | na | 1.25E-04 | 1.25E-04 |
| IPBC | na | 3.13E-03 | 3.13E-03 |
| Product application phase | Cyperméthrine | 2.99E-04 | 3.55E-03 | 3.85E-03 |
| Propiconazole | 4.35E-04 | 2.95E-03 | 3.39E-03 |
| Tébuconazole | 1.36E-04 | 6.92E-04 | 8.28E-04 |
| IPBC | 1.36E-04 | 1.73E-02 | 1.74E-02 |
| Cleaning phase (brush) | Cyperméthrine | na | 3.95E-04 | 3.95E-04 |
| Propiconazole | na | 3.68E-04 | 3.68E-04 |
| Tébuconazole | na | 2.66E-04 | 2.66E-04 |
| IPBC | na | 1.02E-03 | 1.02E-03 |
| Cleaning phase (spray) | Cyperméthrine | na | 7.08E-04 | 7.08E-04 |
| Propiconazole | na | 5.88E-04 | 5.88E-04 |
| Tébuconazole | na | 1.38E-04 | 1.38E-04 |
| IPBC | na | 3.45E-03 | 3.45E-03 |
| Appli + cleaning | Cyperméthrine | **2.99E-04** | **5.30E-03** | **5.60E-03** |
| Propiconazole | **4.35E-04** | **4.44E-03** | **4.88E-03** |
| Tébuconazole | **1.36E-04** | **1.22E-03** | **1.36E-03** |
| IPBC | **1.36E-04** | **2.49E-02** | **2.50E-02** |

***Spray application***

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

Exposure during the cleaning of equipment has been assessed with the BEAT scenario “*Cleaning of the spray equipment*” from TNsG second version of 2007[[36]](#footnote-36).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| **Spraying 300g/m2 – without PPE** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cyperméthrine | 9.93E-05 | 1.17E-02 | 1.18E-02 |
| Propiconazole | 1.69E-03 | 9.73E-03 | 1.14E-02 |
| Tébuconazole | 4.51E-05 | 2.28E-03 | 2.33E-03 |
| IPBC | 4.51E-05 | 5.70E-02 | 5.70E-02 |
| Cleaning of the spray equipment | Cyperméthrine | na | 7.08E-04 | 7.08E-04 |
| Propiconazole | na | 5.88E-04 | 5.88E-04 |
| Tébuconazole | na | 1.38E-04 | 1.38E-04 |
| IPBC | na | 3.45E-03 | 3.45E-03 |
| Appli + cleaning | Cyperméthrine | **9.93E-05** | **1.24E-02** | **1.25E-02** |
| Propiconazole | **1.69E-03** | **1.03E-02** | **1.20E-02** |
| Tébuconazole | **4.51E-05** | **2.42E-03** | **2.46E-03** |
| IPBC | **4.51E-05** | **6.04E-02** | **6.05E-02** |

***Spray application + injection***

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| **Spraying 300g/m2 + injection 150g/m2 – without PPE** | | | | |
| M&L | n.a | | | |
| Product application phase | Cyperméthrine | 1.99E-04 | 2.34E-02 | 2.36E-02 |
| Propiconazole | 3.38E-03 | 1.95E-02 | 2.28E-02 |
| Tébuconazole | 9.03E-05 | 4.56E-03 | 4.65E-03 |
| IPBC | 9.03E-05 | 1.14E-01 | 1.14E-01 |
| Cleaning phase | Cyperméthrine | na | 1.42E-03 | 1.42E-03 |
| Propiconazole | na | 1.18E-03 | 1.18E-03 |
| Tébuconazole | na | 2.76E-04 | 2.76E-04 |
| IPBC | na | 6.89E-03 | 6.89E-03 |
| Appli + cleaning | Cyperméthrine | **1.99E-04** | **2.48E-02** | **2.50E-02** |
| Propiconazole | **3.38E-03** | **2.06E-02** | **2.40E-02** |
| Tébuconazole | **9.03E-05** | **4.84E-03** | **4.93E-03** |
| IPBC | **9.03E-05** | **1.21E-01** | **1.21E-01** |

**X6236** (propiconazole: 0.16%, cypermethrine: 0.11%, tebuconazole: 0.05% and IPBC: 0.05%)

As the active substances concentrations, dermal absorption values and uses (except lacking of injection here) are similar with the product X6119 M2, no additional risk characterization will be performed. The risk is covered by the risk assessment performed for X6119 M2 product.

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

As mentioned above (2.7.2), secondary exposure is performed for product X6119 C applied at 480 g of diluted product at 8.33%. This corresponds to the first efficacy doses proposed by applicant.

During the assessment, the applicant claimed a reduction of efficacy doses. As risk assessments for secondary exposure with the first doses are acceptable the assessment was not revised with the new efficacy doses. This risk covers secondary exposure of all applications for this product, applications of all products of meta SPC 1and 2 and applications of products X6119M2 and X6236 of meta SPC 3.

Another risk assessment for secondary exposure is performed for product X6119 CR as justified above (2.7.2).

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 |

***Acute secondary exposure scenario***

For all products (except X6119 CR), as a worst-case, it has been considered that the wood was treated with a total application dose of 480g/m2 of diluted product at 8.33%, corresponding to a curative treatment by brushing or spraying followed by injection.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **Substances** | **Dermal Exposure**  **(mg/kg pw/d)** | **Inhalation Exposure**  **(mg/kg bw/d** | **Oral Exposure**  **(mg/kg bw/d** | **Total Exposure**  **(mg/kg bw/d)** |
| **Adult amateur sanding/processing of treated wood composites** | Cyperméthrine | 7.55E-04 | 1.79E-05 | nr | 7.73E-04 |
| Propiconazole | 1.79E-03 | 3.30E-05 | nr | 1.82E-03 |
| Tébuconazole | 5.24E-04 | 1.09E-05 | nr | 5.35E-04 |
| IPBC | 4.76E-03 | 1.06E-05 | nr | 4.77E-03 |
| **Infant chewing wood composites chips (450g/m2)** | Cyperméthrine | nr | nr | 1.41E-02 | 1.41E-02 |
| Propiconazole | nr | nr | 4.54E-02 | 4.54E-02 |
| Tébuconazole | nr | nr | 1.50E-02 | 1.50E-02 |
| IPBC | nr | nr | 1.45E-02 | 1.45E-02 |

For X6119 CR product, it has been considered that the wood was treated with a total application dose of 480g/m2 of product, corresponding to a curative treatment by brushing or spraying followed by injection.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **Substances** | **Dermal Exposure**  **(mg/kg pw/d)** | **Inhalation Exposure**  **(mg/kg bw/d** | **Oral Exposure**  **(mg/kg bw/d** | **Total Exposure**  **(mg/kg bw/d)** |
| **Adult amateur sanding/processing of treated wood composites** | Cyperméthrine | 8.09E-03 | 1.79E-05 | nr | 8.11E-03 |
| Propiconazole | 1.21E-02 | 2.68E-05 | nr | 1.21E-02 |
| Tébuconazole | 3.78E-03 | 8.38E-06 | nr | 3.79E-03 |
| IPBC | 3.78E-03 | 8.38E-06 | nr | 3.78E-03 |
| **Infant chewing wood composites chips (450g/m2)** | Cyperméthrine | nr | nr | 1.85E-02 | 1.85E-02 |
| Propiconazole | nr | nr | 3.69E-02 | 3.69E-02 |
| Tébuconazole | nr | nr | 1.15E-02 | 1.15E-02 |
| IPBC | nr | nr | 1.15E-02 | 1.15E-02 |

***Chronic secondary exposure scenario***

For all products (except X6119 CR), as a worst-case, it has been considered that the wood was treated with a total application dose of 480g/m2 of diluted product at 8.33%, corresponding to a curative treatment by brushing or spraying and injection.

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **Substances** | **Dermal Exposure**  **(mg/kg pw/d)** | **Inhalation Exposure**  **(mg/kg bw/d** | **Oral Exposure**  **(mg/kg bw/d** | **Total Exposure**  **(mg/kg bw/d)** |
| **Adult professional sanding/processing of treated wood composites** | Cyperméthrine | 7.55E-04 | 1.08E-04 | nr | 8.63E-04 |
| Propiconazole | 1.79E-03 | 1.98E-04 | nr | 1.99E-03 |
| Tébuconazole | 5.24E-04 | 6.53E-05 | nr | 5.90E-04 |
| IPBC | 4.76E-03 | 6.33E-05 | nr | 4.83E-03 |
| **Inhalation of volatilizing residues indoors (Adult)** | Cyperméthrine | nr | *3.28E-09* | nr | *3.28E-09* |
| Propiconazole | nr | *8.91E-07* | nr | *8.91E-07* |
| Tébuconazole | nr | 1.52E-08 | nr | 1.52E-08 |
| IPBC | nr | 3.57E-05 | nr | 3.57E-05 |
| **Inhalation of volatilizing residues indoors (Infant)** | Cyperméthrine | nr | *6.642E-09* | nr | *6.642E-09* |
| Propiconazole | nr | *1.80E-06* | nr | *1.80E-06* |
| Tébuconazole | nr | 3.07E-08 | nr | 3.07E-08 |
| IPBC | nr | 7.24E-05 | nr | 7.24E-05 |
| **Child playing on playground structure outdoors** | Cyperméthrine | 2.88E-04 | nr | nr | 2.88E-04 |
| Propiconazole | 6.81E-04 | nr | nr | 6.81E-04 |
| Tébuconazole | 2.00E-04 | nr | nr | 2.00E-04 |
| IPBC | 1.81E-03 | nr | nr | 1.81E-03 |
| **Infant playing on weathered (playground) structure and mouthing (450 g/m2)** | Cyperméthrine | 4.31E-04 | nr | 4.39E-03 | 4.82E-03 |
| Propiconazole | 1.02E-03 | nr | 1.42E-02 | 1.52E-02 |
| Tébuconazole | 3.00E-04 | nr | 4.68E-03 | 4.98E-03 |
| IPBC | 2.72E-03 | nr | 4.54E-03 | 7.26E-03 |

For X6119 CR product, it has been considered that the wood was treated with a total application dose of 480g/m2 of product, corresponding to a curative treatment by brushing or spraying followed by injection.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **Substances** | **Dermal Exposure**  **(mg/kg pw/d)** | **Inhalation Exposure**  **(mg/kg bw/d** | **Oral Exposure**  **(mg/kg bw/d** | **Total Exposure**  **(mg/kg bw/d)** |
| **Adult professional sanding/processing of treated wood composites** | Cyperméthrine | 8.09E-03 | 1.08E-04 | nr | 8.20E-03 |
| Propiconazole | 1.21E-02 | 1.61E-04 | nr | 1.23E-02 |
| Tébuconazole | 3.78E-03 | 5.03E-05 | nr | 3.83E-03 |
| IPBC | 3.78E-03 | 5.03E-05 | nr | 3.83E-03 |
| **Inhalation of volatilizing residues indoors (Adult)** | Cyperméthrine | nr | *3.28E-09* | nr | *3.28E-09* |
| Propiconazole | nr | *8.91E-07* | nr | *8.91E-07* |
| Tébuconazole | nr | 1.52E-08 | nr | 1.52E-08 |
| IPBC | nr | 3.57E-05 | nr | 3.57E-05 |
| **Inhalation of volatilizing residues indoors (Infant)** | Cyperméthrine | nr | *6.642E-09* | nr | *6.642E-09* |
| Propiconazole | nr | *1.80E-06* | nr | *1.80E-06* |
| Tébuconazole | nr | 3.07E-08 | nr | 3.07E-08 |
| IPBC | nr | 7.24E-05 | nr | 7.24E-05 |
| **Child playing on playground structure outdoors** | Cyperméthrine | 3.08E-03 | nr | nr | 3.08E-03 |
| Propiconazole | 4.61E-03 | nr | nr | 4.61E-03 |
| Tébuconazole | 2.16E-03 | nr | nr | 2.16E-03 |
| IPBC | 2.16E-03 | nr | nr | 2.16E-03 |
| **Infant playing on weathered (playground) structure and mouthing (450 g/m2)** | Cyperméthrine | 4.62E-03 | nr | 4.39E-03 | 9.01E-03 |
| Propiconazole | 6.91E-03 | nr | 1.15E-02 | 1.84E-02 |
| Tébuconazole | 2.16E-03 | nr | 3.60E-03 | 5.76E-03 |
| IPBC | 2.16E-03 | nr | 3.60E-03 | 5.76E-03 |

* **Minor Change application for PPG CLASS3 WB – 2019:**

The exposure assessment for human health remains unchanged.

#### Risk assessment for human health

##### Risk for direct exposure

###### META SPC 1 and 2

Industrial and professional users

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

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

The product contains 4 different active substances; therefore a risk assessment from combined exposure to several active substances should be performed according to the Guidance on the Biocidal Product Regulation, Part B of 2015[[37]](#footnote-37)

The first step (Tier 1) of this approach is to verify acceptability for each substance used in the product, corresponding to the comparison of the exposure values to the AEL of each substance as stated above and leading to the calculation of Hazard Quotients (HQ), corresponding to estimation of exposure/AEL. If for one substance, the exposure is above the AEL, risk is unacceptable

In a Tier 2, additive effects were considered by summing up the HQ of each active substance, leading to the calculation of a HI (Hazard Index).

**If HI ≤ 1** the risk related to use of the mixture will be considered acceptable;

**If HI > 1** a refinement is needed.

**Industrial users**

5% dilution (covers 3% dilution)

|  | **AEL**  **(mg/kg/d)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| --- | --- | --- | --- |
| Automated treatment – without PPE except gloves during application | | | |
| Transfer of product | Cyperméthrine  0.022 | 1.52E-02 | 69% |
| Propiconazole : 0.04 | 3.60E-02 | 90% |
| Tébuconazole : 0.03 | 1.05E-02 | 35% |
| IPBC  0.2 | 9.60E-02 | 48% |
| Automated dipping | Cyperméthrine  0.022 | 2.91E-02 | 132% |
| Propiconazole : 0.04 | 6.88E-02 | 172% |
| Tébuconazole : 0.03 | 2.01E-02 | 67% |
| IPBC  0.2 | 1.83E-01 | 92% |
| Transfer + Application | Cyperméthrine  0.022 | 4.44E-02 | **202%** |
| Propiconazole : 0.04 | 1.05E-01 | **262%** |
| Tébuconazole : 0.03 | 3.07E-02 | **102%** |
| IPBC  0.2 | 2.79E-01 | **140%** |
| Automated treatment – with gloves/clothes during M&L and gloves and impermeable coverall during application | | | |
| Transfer of product | Cyperméthrine  0.022 | 1.94E-04 | 1% |
| Propiconazole : 0.04 | 4.36E-04 | 1% |
| Tébuconazole : 0.03 | 1.30E-04 | 0.4% |
| IPBC  0.2 | 9.84E-04 | 0.5% |
| Automated dipping | Cyperméthrine  0.022 | 4.64E-03 | 21% |
| Propiconazole : 0.04 | 1.09E-02 | 27% |
| Tébuconazole : 0.03 | 3.20E-03 | 11% |
| IPBC  0.2 | 2.87E-02 | 14% |
| Transfer + Application | Cyperméthrine  0.022 | 4.84E-03 | **22%** |
| Propiconazole : 0.04 | 1.13E-02 | **28%** |
| Tébuconazole : 0.03 | 3.33E-03 | **11%** |
| IPBC  0.2 | 2.97E-02 | **15%** |

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cypermethrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
|  | **(∑ HQ a.s)** |
| Without PPE | 2.02 | 2.62 | 1.02 | 1.40 | 7.06 | Unacceptable |
| With gloves/clothes during M&L and gloves **and impermeable coverall** during application | 0.22 | 0.28 | 0.11 | 0.15 | 0.76 | Acceptable |

* **Considering the mixture approach, the risk is unacceptable (HI > 1) without PPE but it is acceptable (HI < 1) when gloves/clothes during M&L and gloves and impermeable coverall during application are worn.**

**Professional users**

8.33% dilution (covers 5% dilution)

Brush application

| **Scenario** | **AEL**  **(mg/kg/d)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| --- | --- | --- | --- |
| **Brushing 300g/m2 – without PPE** | | | |
| Mixing and loading | Cyperméthrine  0.022 | 7.83E-03 | 36% |
| Propiconazole : 0.04 | 1.85E-02 | 46% |
| Tébuconazole : 0.03 | 5.41E-03 | 18% |
| IPBC  0.2 | 4.94E-02 | 25% |
| Product application phase | Cyperméthrine  0.022 | 1.94E-03 | 9% |
| Propiconazole : 0.04 | 4.52E-03 | 11% |
| Tébuconazole : 0.03 | 1.34E-03 | 4% |
| IPBC  0.2 | 1.14E-02 | 6% |
| Brush cleaning phase | Cyperméthrine  0.022 | 3.97E-04 | 2% |
| Propiconazole : 0.04 | 6.19E-04 | 2% |
| Tébuconazole : 0.03 | 3.47E-04 | 1% |
| IPBC  0.2 | 1.26E-03 | 0.6% |
| Mixing and loading + application + cleaning | Cyperméthrine  0.022 | **1.02E-02** | **46%** |
| Propiconazole : 0.04 | **2.36E-02** | **59%** |
| Tébuconazole : 0.03 | **7.09E-03** | **24%** |
| IPBC  0.2 | **6.21E-02** | **31%** |
| **Brushing 300g/m2 – with gloves during mixing and loading and no PPE during application and cleaning of the brush** | | | |
| Mixing and loading | Cyperméthrine  0.022 | 7.83E-04 | 4% |
| Propiconazole : 0.04 | 1.85E-03 | 5% |
| Tébuconazole : 0.03 | 5.41E-04 | 2% |
| IPBC  0.2 | 4.94E-03 | 3% |
| Product application phase | Cyperméthrine  0.022 | 1.94E-03 | 9% |
| Propiconazole : 0.04 | 4.52E-03 | 11% |
| Tébuconazole : 0.03 | 1.34E-03 | 4% |
| IPBC  0.2 | 1.14E-02 | 6% |
| Brush cleaning phase | Cyperméthrine  0.022 | 3.97E-04 | 2% |
| Propiconazole : 0.04 | 6.19E-04 | 2% |
| Tébuconazole : 0.03 | 3.47E-04 | 1% |
| IPBC  0.2 | 1.26E-03 | 1% |
| Mixing and loading + application + cleaning | Cyperméthrine  0.022 | **3.12E-03** | **14%** |
| Propiconazole : 0.04 | **6.99E-03** | **17%** |
| Tébuconazole : 0.03 | **2.22E-03** | **7%** |
| IPBC  0.2 | **1.76E-02** | **9%** |

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI**  **(∑ HQ a.s)** | **Risk** |
| **HQ (Exposure/AEL)** | | | | |
| Without PPE | 0.46 | 0.59 | 0.24 | 0.31 | **1.60** | Unacceptable |
| Without PPE, except gloves during mixing and loading | 0.14 | 0.17 | 0.07 | 0.09 | **0.48** | **Acceptable** |

* **The risk is unacceptable (HI > 1) without PPE but it is acceptable (HI < 1) when gloves are worn during mixing and loading.**

Spray application

| **Scenario** | **AEL**  **(mg/kg/d)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| --- | --- | --- | --- |
| **Spraying 300g/m2 – without PPE** | | | |
| M&L | Included in the model | | |
| Product application phase | Cyperméthrine  0.022 | 5.17E-02 | 235% |
| Propiconazole : 0.04 | 1.21E-01 | 303% |
| Tébuconazole : 0.03 | 3.57E-02 | 119% |
| IPBC  0.2 | 3.13E-01 | 157% |
| Cleaning of the spray equipment | Cyperméthrine  0.022 | 6.88E-04 | 3% |
| Propiconazole : 0.04 | 1.63E-03 | 4% |
| Tébuconazole : 0.03 | 4.78E-04 | 2% |
| IPBC  0.2 | 4.34E-03 | 2% |
| Appli + cleaning | Cyperméthrine  0.022 | **5.24E-02** | **238%** |
| Propiconazole : 0.04 | **1.23E-01** | **307%** |
| Tébuconazole : 0.03 | **3.62E-02** | **121%** |
| IPBC  0.2 | **3.18E-01** | **159%** |
| **Spraying 300g/m2 – with gloves and coated coverall during application and no PPE during cleaning** | | | |
| M&L | Included in the model | | |
| *Product application phase* | *Cyperméthrine*  *0.022* | 5.25E-03 | *24%* |
| *Propiconazole : 0.04* | 1.13E-02 | *28%* |
| *Tébuconazole : 0.03* | 3.45E-03 | *12%* |
| *IPBC*  *0.2* | 2.02E-02 | *10%* |
| *Cleaning of the spray equipment* | *Cyperméthrine*  *0.022* | 6.88E-04 | *3%* |
| *Propiconazole : 0.04* | 1.63E-03 | *4%* |
| *Tébuconazole : 0.03* | 4.78E-04 | *2%* |
| *IPBC*  *0.2* | 4.34E-03 | *2%* |
| *appli + cleaning* | *cyperméthrine*  *0.022* | **5.94E-03** | ***27%*** |
| *propiconazole : 0.04* | **1.29E-02** | ***32%*** |
| *tébuconazole : 0.03* | **3.93E-03** | ***13%*** |
| *ipbc*  *0.2* | **2.46E-02** | ***12%*** |

###### The risk is unacceptable without PPE.

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | | | | **(∑ HQ a.s)** |
| **without PPE** | **2.38** | **3.07** | **1.21** | **1.59** | **9.26** | **Unacceptable** |
| With gloves and coated coverall during spraying and no PPE during cleaning | **0.27** | **0.32** | **0.13** | **0.12** | **0.85** | **Acceptable** |

###### **The risk is acceptable when gloves and coated coverall during application and no ppe during cleaning are worn.**

Injection application

| **Scenario** | **AEL**  **(mg/kg/d)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| --- | --- | --- | --- |
| **Injection 180 g/m2 – with gloves during injection and no PPE during cleaning** | | | |
| M&L | Included in the model | | |
| Product application phase | Cyperméthrine  0.022 | 8.16E-04 | 4% |
| Propiconazole : 0.04 | 1.92E-03 | 5% |
| Tébuconazole : 0.03 | 5.65E-04 | 2% |
| IPBC  0.2 | 5.05E-03 | 3% |
| Cleaning of the equipment | Cyperméthrine  0.022 | 6.88E-04 | 3% |
| Propiconazole : 0.04 | 1.63E-03 | 4% |
| Tébuconazole : 0.03 | 4.78E-04 | 2% |
| IPBC  0.2 | 4.34E-03 | 2% |
| Appli + cleaning | Cyperméthrine  0.022 | **1.50E-03** | **7%** |
| Propiconazole : 0.04 | **3.55E-03** | **9%** |
| Tébuconazole : 0.03 | **1.04E-03** | **3%** |
| IPBC  0.2 | **9.39E-03** | **5%** |
| **Injection 180 g/m2 – with gloves during injection and gloves and coated coverall during cleaning** | | | |
| M&L | Included in the model | | |
| Product application phase | Cyperméthrine  0.022 | 8.16E-04 | 4% |
| Propiconazole : 0.04 | 1.92E-03 | 5% |
| Tébuconazole : 0.03 | 5.65E-04 | 2% |
| IPBC  0.2 | 5.05E-03 | 3% |
| Cleaning of the equipment | Cyperméthrine  0.022 | 9.29E-05 | 0.4% |
| Propiconazole : 0.04 | 2.20E-04 | 1% |
| Tébuconazole : 0.03 | 6.45E-05 | 0.2% |
| IPBC  0.2 | 5.86E-04 | 0.3% |
| Appli + cleaning | Cyperméthrine  0.022 | **9.09E-04** | **4%** |
| Propiconazole : 0.04 | **2.14E-03** | **5%** |
| Tébuconazole : 0.03 | **6.29E-04** | **2%** |
| IPBC  0.2 | **5.64E-03** | **3%** |

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | | | | **(∑ HQ a.s)** |
| **with gloves during application and without PPE during cleaning** | **0.07** | **0.09** | **0.03** | **0.05** | **0.24** | **Acceptable** |

* The risk is acceptable (HI < 1) when no PPE (except gloves during injection) are worn.

However, injection is performed in combination with brushing and spraying.

Injection combined with brush treatment

| **Scenario** | **AEL**  **(mg/kg/d)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| --- | --- | --- | --- |
| **Injection 180 g/m2 in combination with brush treatment at 300 g/m2**  **With gloves during mixing and loading, no PPE during application except gloves during injection and no PPE during cleaning** | | | |
| Brush treatment | Cyperméthrine  0.022 | **3.12E-03** | **14%** |
| Propiconazole : 0.04 | **6.99E-03** | **17%** |
| Tébuconazole : 0.03 | **2.22E-03** | **7%** |
| IPBC  0.2 | **1.76E-02** | **9%** |
| Injection | Cyperméthrine  0.022 | **1.50E-03** | **7%** |
| Propiconazole : 0.04 | **3.55E-03** | **9%** |
| Tébuconazole : 0.03 | **1.04E-03** | **3%** |
| IPBC  0.2 | **9.39E-03** | **5%** |
| Brush + injection | Cyperméthrine  0.022 | **4.63E-03** | **21%** |
| Propiconazole : 0.04 | **1.05E-02** | **26%** |
| Tébuconazole : 0.03 | **3.27E-03** | **11%** |
| IPBC  0.2 | **2.70E-02** | **14%** |

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | | | | **(∑ HQ a.s)** |
| **With gloves during mixing and loading, no PPE during application except gloves during injection and no PPE during cleaning** | **0.21** | **0.26** | **0.11** | **0.14** | **0.72** | **Acceptable** |

* **For injection in combination withsuperficial application by brushing** the risk is acceptable (HI < 1) when **gloves during mixing and loading, gloves during injection are worn.**

Injection combined with spray treatment

| **Scenario** | **AEL**  **(mg/kg/d)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| --- | --- | --- | --- |
| **Injection 180 g/m2 in combination with spray treatment at 300 g/m2**  **With gloves and coated coverall during application by spraying, gloves during injection, gloves and coated coverall during cleaning of injection equipment and no PPE during cleaning of spray equipment** | | | |
| Spray treatment | Cyperméthrine  0.022 | **5.94E-03** | ***27%*** |
| Propiconazole : 0.04 | **1.29E-02** | ***32%*** |
| Tébuconazole : 0.03 | **3.93E-03** | ***13%*** |
| IPBC  0.2 | **2.46E-02** | ***12%*** |
| Injection | Cyperméthrine  0.022 | **9.09E-04** | **4%** |
| Propiconazole : 0.04 | **2.14E-03** | **5%** |
| Tébuconazole : 0.03 | **6.29E-04** | **2%** |
| IPBC  0.2 | **5.64E-03** | **3%** |
| Spray + injection | Cyperméthrine  0.022 | 6.85E-03 | 31% |
| Propiconazole : 0.04 | 1.50E-02 | 38% |
| Tébuconazole : 0.03 | 4.56E-03 | 15% |
| IPBC  0.2 | 3.02E-02 | 15% |

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | | | | **(∑ HQ a.s)** |
| **With gloves and coated coverall during application by spraying, gloves during injection , gloves and coated coverall during cleaning of injection equipment and no PPE during cleaning of spray equipment** | 0.31 | 0.38 | 0.15 | 0.15 | **0.99** | **Acceptable** |

* **For injection in combination withsuperficial application by spraying, the risk is acceptable (HI < 1) when gloves and coated coverall during application by spraying, gloves during injection, gloves and coated coverall during cleaning of injection equipment and no PPE during cleaning of spray equipment are worn.**

**Summary of conclusion**

|  |  |
| --- | --- |
| **Scenario** | **Conclusion** |
| **Industrial** | Gloves and clothes during mixing and loading and gloves and impermeable coverall during application |

|  |  |
| --- | --- |
| **Scenario** | **Conclusion** |
| **Brush /Roller application** | Gloves during mixing and loading. |
| **Spraying application** | Gloves and coated coverall during application and no ppe during cleaning |
| **Injection** | Gloves during injection |
| **Injection combined to brushing** | Gloves during mixing and loading and injection |
| **Injection combined to spraying** | Gloves and coated coverall during application by spraying, gloves during injection, gloves and coated coverall during cleaning of injection equipment and no PPE during cleaning of spray equipment |

###### META SPC 3

Professional users

The same Toxicological Reference Values than for meta SPC 1 and 2 are used.

**X6119 M2 and X6236**

Brush application

| **Scenario** | **AEL**  **(mg/kg/d)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| --- | --- | --- | --- |
| **Brushing 300g/m2 – without PPE** | | | |
| Mixing and loading | Cyperméthrine  0.022 | 6.67E-04 | 3% |
| Propiconazole : 0.04 | 5.55E-04 | 1% |
| Tébuconazole : 0.03 | 1.30E-04 | 0.4% |
| IPBC  0.2 | 3.25E-03 | 2% |
| Product application phase | Cyperméthrine  0.022 | 1.94E-03 | 9% |
| Propiconazole : 0.04 | 1.75E-03 | 4% |
| Tébuconazole : 0.03 | 4.28E-04 | 1% |
| IPBC  0.2 | 9.07E-03 | 5% |
| Brush cleaning phase | Cyperméthrine  0.022 | 3.97E-04 | 2% |
| Propiconazole : 0.04 | 3.73E-04 | 0.9% |
| Tébuconazole : 0.03 | 2.67E-04 | 0.9% |
| IPBC  0.2 | 1.05E-03 | 0.5% |
| Mixing and loading + application + cleaning | Cyperméthrine  0.022 | **3.01E-03** | **14%** |
| Propiconazole : 0.04 | **2.68E-03** | **7%** |
| Tébuconazole : 0.03 | **8.25E-04** | **3%** |
| IPBC  0.2 | **1.34E-02** | **7%** |

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | | | | **(∑ HQ a.s)** |
| Without PPE | 0.14 | 0.07 | 0.03 | 0.07 | **0.31** | Acceptable |

* **Considering the mixture approach, the risk is acceptable (HI < 1) without PPE.**

Spray application

| **Scenario** | **AEL**  **(mg/kg/d)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| --- | --- | --- | --- |
| **Spraying 300g/m2 – without PPE** | | | |
| M&L | Included in the model | | |
| Product application phase | Cyperméthrine  0.022 | 5.82E-02 | 264% |
| Propiconazole : 0.04 | 5.13E-02 | 128% |
| Tébuconazole : 0.03 | 1.23E-02 | 41% |
| IPBC  0.2 | 2.80E-01 | 140% |
| Cleaning of the spray equipment | Cyperméthrine  0.022 | 6.88E-04 | 3% |
| Propiconazole : 0.04 | 5.88E-04 | 1% |
| Tébuconazole : 0.03 | 1.38E-04 | 0% |
| IPBC  0.2 | 3.45E-03 | 2% |
| Appli + cleaning | Cyperméthrine  0.022 | **5.88E-02** | **267%** |
| Propiconazole : 0.04 | **5.19E-02** | **130%** |
| Tébuconazole : 0.03 | **1.25E-02** | **42%** |
| IPBC  0.2 | **2.83E-01** | **142%** |
| **Spraying 300g/m2 – with gloves and coated coverall during application and no PPE during cleaning** | | | |
| M&L | Included in the model | | |
| Product application phase | Cyperméthrine  0.022 | 5.91E-03 | 27% |
| Propiconazole : 0.04 | 6.68E-03 | 17% |
| Tébuconazole : 0.03 | 1.86E-03 | 6% |
| IPBC  0.2 | 1.81E-02 | 9% |
| Cleaning of the spray equipment | Cyperméthrine  0.022 | 6.88E-04 | 3% |
| Propiconazole : 0.04 | 5.88E-04 | 1% |
| Tébuconazole : 0.03 | 1.38E-04 | 0% |
| IPBC  0.2 | 3.45E-03 | 2% |
| Appli + cleaning | Cyperméthrine  0.022 | **6.60E-03** | **30%** |
| Propiconazole : 0.04 | **7.27E-03** | **18%** |
| Tébuconazole : 0.03 | **2.00E-03** | **7%** |
| IPBC  0.2 | **2.15E-02** | **11%** |

###### The risk is unacceptable without ppe.

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | | | | **(∑ HQ a.s)** |
| **without PPE** | **2.67** | **1.30** | **0.42** | **1.42** | **5.81** | **Unacceptable** |
| With gloves and coated coverall during spraying and no PPE during cleaning | **0.30** | **0.18** | **0.07** | **0.11** | **0.66** | **Acceptable** |

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

Injection application

| **Scenario** | **AEL**  **(mg/kg/d)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| --- | --- | --- | --- |
| **Injection 180 g/m2 – with gloves during injection and no PPE during cleaning** | | | |
| M&L | Included in the model | | |
| Product application phase | Cyperméthrine  0.022 | 8.16E-04 | 4% |
| Propiconazole : 0.04 | 7.08E-04 | 2% |
| Tébuconazole : 0.03 | 1.68E-04 | 1% |
| IPBC  0.2 | 4.01E-03 | 2% |
| Cleaning of the equipment | Cyperméthrine  0.022 | 6.88E-04 | 3% |
| Propiconazole : 0.04 | 5.88E-04 | 1% |
| Tébuconazole : 0.03 | 1.38E-04 | 0% |
| IPBC  0.2 | 3.45E-03 | 2% |
| Appli + cleaning | Cyperméthrine  0.022 | **1.50E-03** | 7% |
| Propiconazole : 0.04 | **1.30E-03** | 3% |
| Tébuconazole : 0.03 | **3.06E-04** | 1% |
| IPBC  0.2 | **7.45E-03** | 4% |

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | | | | **(∑ HQ a.s)** |
| **with gloves during application and without PPE during cleaning** | **0.07** | **0.03** | **0.01** | **0.04** | **0.15** | **Acceptable** |

* Considering the mixture approach, the risk is acceptable (HI < 1) when no PPE (except gloves during injection) are worn.

However, injection is performed in combination with brushing and spraying.

Injection combined with brush treatment

| **Scenario** | **AEL**  **(mg/kg/d)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| --- | --- | --- | --- |
| **Injection 180 g/m2 in combination with brush treatment at 300 g/m2**  **No PPE during application and cleaning however gloves during injection** | | | |
| Brush treatment | Cyperméthrine  0.022 | **3.01E-03** | **14%** |
| Propiconazole : 0.04 | **2.68E-03** | **7%** |
| Tébuconazole : 0.03 | **8.25E-04** | **3%** |
| IPBC  0.2 | **1.34E-02** | **7%** |
| Injection | Cyperméthrine  0.022 | **1.50E-03** | 7% |
| Propiconazole : 0.04 | **1.30E-03** | 3% |
| Tébuconazole : 0.03 | **3.06E-04** | 1% |
| IPBC  0.2 | **7.45E-03** | 4% |
| Brush + injection | Cyperméthrine  0.022 | **4.51E-03** | **21%** |
| Propiconazole : 0.04 | **3.98E-03** | **10%** |
| Tébuconazole : 0.03 | **1.13E-03** | **4%** |
| IPBC  0.2 | **2.08E-02** | **10%** |

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | | | | **(∑ HQ a.s)** |
| **No PPE during application and cleaning however gloves during injection** | **0.21** | **0.1** | **0.04** | **0.1** | **0.45** | **Acceptable** |

* Considering the mixture approach, the risk is acceptable (HI < 1) when **no PPE during application except gloves during injection and no PPE during cleaning are worn.**

Injection combined with spray treatment

| **Scenario** | **AEL**  **(mg/kg/d)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| --- | --- | --- | --- |
| **Injection 180 g/m2 in combination with spray treatment at 300 g/m2**  **With gloves and coated coverall during application by spraying, gloves during injection, no PPE during cleaning of spray and injection equipment** | | | |
| Spray treatment | Cyperméthrine  0.022 | **6.60E-03** | **30%** |
| Propiconazole : 0.04 | **7.27E-03** | **18%** |
| Tébuconazole : 0.03 | **2.00E-03** | **7%** |
| IPBC  0.2 | **2.15E-02** | **11%** |
| Injection | Cyperméthrine  0.022 | **1.50E-03** | 7% |
| Propiconazole : 0.04 | **1.30E-03** | 3% |
| Tébuconazole : 0.03 | **3.06E-04** | 1% |
| IPBC  0.2 | **7.45E-03** | 4% |
| Spray + injection | Cyperméthrine  0.022 | 8.10E-03 | 37% |
| Propiconazole : 0.04 | 8.57E-03 | 21% |
| Tébuconazole : 0.03 | 2.31E-03 | 8% |
| IPBC  0.2 | 2.90E-02 | 14% |

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Cyperméthrine | Propiconazole | Tébuconazole | IPBC | **HI** | **Risk** |
| HQ (Exposure/AEL) |  |  |  |  | **(∑ HQ a.s)** |
| With gloves and coated coverall coverall during application by spraying and gloves during injection. No PPE during cleaning of spray and injection equipment | 0.37 | 0.21 | 0.08 | 0.14 | **0.80** | **Acceptable** |

* Considering the mixture approach, the risk is acceptable (HI < 1) when **gloves and coated coverall during application by spraying and gloves during injection are worn. No PPE during cleaning of spray and injection equipment are required.**

**Summary of conclusion**

|  |  |
| --- | --- |
| **Scenario** | **Conclusion** |
| **Brush /Roller application** | No PPE |
| **Spraying application** | Gloves and coated coverall during application and no ppe during cleaning |
| **Injection** | Gloves during injection |
| **Injection combined to brushing** | Gloves during injection |
| **Injection combined to spraying** | Gloves and coated coverall during application by spraying, gloves during injection, no PPE during cleaning of equipments |

**X6119 CR**

Brush application

| **Scenario** | **AEL**  **(mg/kg/d)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| --- | --- | --- | --- |
| **Brushing 300g/m2 – without PPE** | | | |
| Loading of the paint in a support | Cyperméthrine  0.022 | 6.88E-03 | 31% |
| Propiconazole : 0.04 | 1.00E-02 | 25% |
| Tébuconazole : 0.03 | 3.13E-03 | 10% |
| IPBC  0.2 | 3.13E-03 | 2% |
| Product application phase | Cyperméthrine  0.022 | 1.92E-02 | 87% |
| Propiconazole : 0.04 | 2.79E-02 | 70% |
| Tébuconazole : 0.03 | 8.72E-03 | 29% |
| IPBC  0.2 | 8.72E-03 | 4% |
| Brush cleaning phase | Cyperméthrine  0.022 | 1.96E-03 | 9% |
| Propiconazole : 0.04 | 2.74E-03 | 7% |
| Tébuconazole : 0.03 | 1.02E-03 | 3% |
| IPBC  0.2 | 1.02E-03 | 1% |
| Loading + application + cleaning | Cyperméthrine  0.022 | **2.80E-02** | **127%** |
| Propiconazole : 0.04 | **4.07E-02** | **102%** |
| Tébuconazole : 0.03 | **1.29E-02** | **43%** |
| IPBC  0.2 | **1.29E-02** | **6%** |
| Brushing 300g/m2 – with gloves during loading, gloves and coated coverall during application and no PPE during cleaning | | | |
| Loading of the paint in a support | Cyperméthrine  0.022 | 6.88E-04 | 3% |
| Propiconazole : 0.04 | 1.00E-03 | 3% |
| Tébuconazole : 0.03 | 3.13E-04 | 1% |
| IPBC  0.2 | 3.13E-04 | 0.2% |
| Product application phase | Cyperméthrine  0.022 | 2.61E-03 | 12% |
| Propiconazole : 0.04 | 3.80E-03 | 10% |
| Tébuconazole : 0.03 | 1.19E-03 | 4% |
| IPBC  0.2 | 1.19E-03 | 1% |
| Brush cleaning phase | Cyperméthrine  0.022 | 1.96E-03 | 9% |
| Propiconazole : 0.04 | 2.74E-03 | 7% |
| Tébuconazole : 0.03 | 1.02E-03 | 3% |
| IPBC  0.2 | 1.02E-03 | 1% |
| Application + cleaning | Cyperméthrine  0.022 | **5.26E-03** | **24%** |
| Propiconazole : 0.04 | **7.54E-03** | **19%** |
| Tébuconazole : 0.03 | **2.52E-03** | **8%** |
| IPBC  0.2 | **2.52E-03** | **1%** |
| Brushing 300g/m2 – with gloves during loading, gloves and impermeable coverall during application and no PPE during cleaning | | | |
| Loading of the paint in a support | Cyperméthrine  0.022 | 6.88E-04 | 3% |
| Propiconazole : 0.04 | 1.00E-03 | 3% |
| Tébuconazole : 0.03 | 3.13E-04 | 1% |
| IPBC  0.2 | 3.13E-04 | 0.2% |
| Product application phase | Cyperméthrine  0.022 | 1.77E-03 | 8% |
| Propiconazole : 0.04 | 2.58E-03 | 6% |
| Tébuconazole : 0.03 | 8.06E-04 | 3% |
| IPBC  0.2 | 8.06E-04 | 0.4% |
| Brush cleaning phase | Cyperméthrine  0.022 | 1.96E-03 | 9% |
| Propiconazole : 0.04 | 2.74E-03 | 7% |
| Tébuconazole : 0.03 | 1.02E-03 | 3% |
| IPBC  0.2 | 1.02E-03 | 1% |
| Application + cleaning | Cyperméthrine  0.022 | **4.42E-03** | **20%** |
| Propiconazole : 0.04 | **6.32E-03** | **16%** |
| Tébuconazole : 0.03 | **2.14E-03** | **7%** |
| IPBC  0.2 | **2.14E-03** | **1%** |

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | | | | **(∑ HQ a.s)** |
| **with gloves during m&L** |  |  |  |  |  |  |
| Without PPE | 0.99 | 0.79 | 0.34 | 0.05 | **2.17** | Unacceptable |
| With gloves and coated coverall during application and no PPE during cleaning | 0.24 | 0.19 | 0.08 | 0.01 | **0.52** | **Acceptable** |
| *With gloves and impermeable coverall during application and no PPE during cleaning* | *0.20* | *0.16* | *0.07* | *0.01* | ***0.44*** | ***Acceptable*** |

* Considering the mixture approach, HI is inferior to 1 when gloves during loading, gloves and coated coverall during application and no PPE during cleaning are worn.

Spray application

| **Scenario** | **AEL**  **(mg/kg/d)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| --- | --- | --- | --- |
| **Spraying 300g/m2 – without PPE** | | | |
| M&L | Included in the model |  |  |
| Product application phase | Cyperméthrine  0.022 | 6.15E-01 | 2796% |
| Propiconazole : 0.04 | 8.95E-01 | 2237% |
| Tébuconazole : 0.03 | 2.80E-01 | 932% |
| IPBC  0.2 | 2.80E-01 | 140% |
| Cleaning of the spray equipment | Cyperméthrine  0.022 | 7.58E-03 | 34% |
| Propiconazole : 0.04 | 1.10E-02 | 28% |
| Tébuconazole : 0.03 | 3.45E-03 | 11% |
| IPBC  0.2 | 3.45E-03 | 2% |
| Appli + cleaning | Cyperméthrine  0.022 | **6.23E-01** | **2831%** |
| Propiconazole : 0.04 | **9.06E-01** | **2265%** |
| Tébuconazole : 0.03 | **2.83E-01** | **944%** |
| IPBC  0.2 | **2.83E-01** | **142%** |
| **Spraying 300g/m2 – with gloves and coated coverall during spraying and no PPE during cleaning of spray equipment** | | | |
| M&L | Included in the model |  |  |
| Product application phase | Cyperméthrine  0.022 | 3.97E-02 | 181% |
| Propiconazole : 0.04 | 5.78E-02 | 145% |
| Tébuconazole : 0.03 | 1.81E-02 | 60% |
| IPBC  0.2 | 1.81E-02 | 9% |
| Cleaning of the spray equipment | Cyperméthrine  0.022 | 7.58E-03 | 34% |
| Propiconazole : 0.04 | 1.10E-02 | 28% |
| Tébuconazole : 0.03 | 3.45E-03 | 11% |
| IPBC  0.2 | 3.45E-03 | 2% |
| Appli + cleaning | Cyperméthrine  0.022 | **4.73E-02** | **215%** |
| Propiconazole : 0.04 | **6.88E-02** | **172%** |
| Tébuconazole : 0.03 | **2.15E-02** | **72%** |
| IPBC  0.2 | **2.15E-02** | **11%** |
| **Spraying 300g/m2 – with gloves and impermeable coverall during spraying and no PPE during cleaning of spray equipment** | | | |
| M&L | Included in the model |  |  |
| Product application phase | Cyperméthrine  0.022 | 2.60E-02 | 118% |
| Propiconazole : 0.04 | 3.78E-02 | 95% |
| Tébuconazole : 0.03 | 1.18E-02 | 39% |
| IPBC  0.2 | 1.18E-02 | 6% |
| Cleaning of the spray equipment | Cyperméthrine  0.022 | 7.58E-03 | 34% |
| Propiconazole : 0.04 | 1.10E-02 | 28% |
| Tébuconazole : 0.03 | 3.45E-03 | 11% |
| IPBC  0.2 | 3.45E-03 | 2% |
| Appli (PPE)+ cleaning | Cyperméthrine  0.022 | **3.36E-02** | **153%** |
| Propiconazole : 0.04 | **4.89E-02** | **122%** |
| Tébuconazole : 0.03 | **1.53E-02** | **51%** |
| IPBC  0.2 | **1.53E-02** | **8%** |

* When the risk is assessed substance by substance, the risk is **unacceptable** even if gloves and impermeable coverall during spraying are worn. In this context, no additional risk characterization is performed.

***Injection***

| **Scenario** | **AEL**  **(mg/kg/d)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| --- | --- | --- | --- |
| **Injection 180 g/m2 – with gloves during injection and no PPE during cleaning** | | | |
| M&L | Included in the model |  |  |
| Product application phase | Cyperméthrine  0.022 | 8.82E-03 | 40% |
| Propiconazole : 0.04 | 1.28E-02 | 32% |
| Tébuconazole : 0.03 | 4.01E-03 | 13% |
| IPBC  0.2 | 4.01E-03 | 2% |
| Cleaning of the equipment | Cyperméthrine  0.022 | 7.58E-03 | 34% |
| Propiconazole : 0.04 | 1.10E-02 | 28% |
| Tébuconazole : 0.03 | 3.45E-03 | 11% |
| IPBC  0.2 | 3.45E-03 | 2% |
| Appli + cleaning | Cyperméthrine  0.022 | **1.64E-02** | **75%** |
| Propiconazole : 0.04 | **2.39E-02** | **60%** |
| Tébuconazole : 0.03 | **7.45E-03** | **25%** |
| IPBC  0.2 | **7.45E-03** | **4%** |
| **Injection 180 g/m2 – with gloves during injection and gloves and coated coverall during cleaning** | | | |
| M&L | Included in the model |  |  |
| Product application phase | Cyperméthrine  0.022 | 8.82E-03 | 40% |
| Propiconazole : 0.04 | 1.28E-02 | 32% |
| Tébuconazole : 0.03 | 4.01E-03 | 13% |
| IPBC  0.2 | 4.01E-03 | 2% |
| Cleaning of the equipment | Cyperméthrine  0.022 | 1.02E-03 | 5% |
| Propiconazole : 0.04 | 1.49E-03 | 4% |
| Tébuconazole : 0.03 | 4.65E-04 | 2% |
| IPBC  0.2 | 4.65E-04 | 0.2% |
| Appli + cleaning | Cyperméthrine  0.022 | **9.84E-03** | **45%** |
| Propiconazole : 0.04 | **1.43E-02** | **36%** |
| Tébuconazole : 0.03 | **4.47E-03** | **15%** |
| IPBC  0.2 | **4.47E-03** | **2%** |

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | | | | **(∑ HQ a.s)** |
| **with gloves during application and without PPE during cleaning** | **0.75** | **0.60** | **0.25** | **0.04** | **1.63** | **Unacceptable** |
| **with gloves during application and with PPE during cleaning** | **0.45** | **0.36** | **0.15** | **0.02** | **0.98** | **Acceptable** |

* Considering the mixture approach, the risk is acceptable (HI < 1) when **gloves during injection and gloves and coated coverall during cleaning are worn.**

Injection combined with brush treatment

| **Scenario** | **AEL**  **(mg/kg/d)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| --- | --- | --- | --- |
| **Injection 180 g/m2 in combination with brush treatment at 300 g/m2**  **With gloves during mixing and loading, gloves and coated coverall during application by brush, gloves during injection, gloves and coated coverall during cleaning of injection equipment and no PPE during cleaning of brush** | | | |
| Brush treatment | Cyperméthrine  0.022 | **5.26E-03** | **24%** |
| Propiconazole : 0.04 | **7.54E-03** | **19%** |
| Tébuconazole : 0.03 | **2.52E-03** | **8%** |
| IPBC  0.2 | **2.52E-03** | **1%** |
| Injection | Cyperméthrine  0.022 | **9.84E-03** | **45%** |
| Propiconazole : 0.04 | **1.43E-02** | **36%** |
| Tébuconazole : 0.03 | **4.47E-03** | **15%** |
| IPBC  0.2 | **4.47E-03** | **2%** |
| Brush + injection | Cyperméthrine  0.022 | 1.51E-02 | 69% |
| Propiconazole : 0.04 | 2.19E-02 | 55% |
| Tébuconazole : 0.03 | 6.99E-03 | 23% |
| IPBC  0.2 | 6.99E-03 | 3% |

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | | | | **(∑ HQ a.s)** |
|  | **0.69** | **0.55** | **0.23** | **0.03** | **1.50** | **Unacceptable** |

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

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

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

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

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

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

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

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Tébuconazole** | **Propiconazole** | **IPBC** |
| **General long term AEL** | 0.022 | 0.03 | 0.04 | 0.2 |
| **Specific AEL: liver** | 0.18 (3 weeks rat) | 0.06 (24 months mice) | 0.08 (2 generation rat) | 0.2 (90 days rat) |
| **Specific AEL: kidney** | 0.022 (90 days rat) | - | 0.5 (28 days rat) | 0.35 (90 days rat) |
| **Specific AEL: Hemato** | 0.022 (24 months rat) | 0.3 (28 days rat) | 0.761 (90 days rat) |  |
| **Specific AEL: adrenals** |  | 0.03 (1 year dog) | 0.04 (24 months rat) |  |
| **Specific AEL: lungs** | 0.07 (90 days dog) |  |  | 0.2 (24 months rat) |

The comparison of the exposure values with the specific AELs leads to the following results:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** |  |
|  | | | | |  |
| Combined exposure | 1.51E-02 | 2.19E-02 | 6.99E-03 | 6.99E-03 |  |
|  |  |  |  |  |  |
| AEL liver | 0.18 | 0.08 | 0.06 | 0.2 | **HI** |
| %AEL | 8% | 27% | 12% | 3% | 0.51 |
|  |  |  |  |  |  |
| AEL kidney | 0.022 | 0.5 |  | 0.35 |  |
| %AEL | 69% | 4% |  | 2% | 0.75 |
|  |  |  |  |  |  |
| AEL hematology | 0.022 | 0.761 | 0.3 |  |  |
| %AEL | 69% | 3% | 2% |  | 0.74 |
|  |  |  |  |  |  |
| AEL adrenals |  | 0.036 | 0.03 |  |  |
| %AEL |  | 61% | 23% |  | 0.84 |
|  |  |  |  |  |  |
| AEL Lung | 0.07 |  |  | 0.2 |  |
| %AEL | 21% |  |  | 3% | 0.25 |

HI is inferior to 1 for all organs. In this context, the risk is considered acceptable when **gloves during mixing and loading, gloves and coated coverall during application by brush, gloves during injection, gloves and coated coverall during cleaning of injection equipment and no PPE during cleaning of brush are worn.**

Injection combined with spray treatment

The combination with the exposure during spraying was not performed because the risk is ever unacceptable just during spraying.

**Summary of conclusion**

|  |  |
| --- | --- |
| **Scenario** | **Conclusion** |
| **Brush /Roller application** | Gloves during loading, gloves and coated coverall during application and no PPE during cleaning |
| **Spraying application** | Unacceptable |
| **Injection** | Gloves during injection and gloves and coated coverall during injection |
| **Injection combined to brushing** | Gloves during mixing and loading, gloves and coated coverall during application by brush, gloves during injection, gloves and coated coverall during cleaning of injection equipment and no PPE during cleaning of brush |
| **Injection combined to spraying** | Not relevant |

Non professional users

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

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

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

**X6119 M2**

Brush application

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| **Brushing 300g/m2** |  |  |  |
| Loading of the paint in a support | Cyperméthrine  0.088 | 6.42E-04 | 1% |
| Propiconazole : 0.3 | 5.33E-04 | 0.2% |
| Tébuconazole : 0.03 | 1.25E-04 | 0.4% |
| IPBC  0.35 | 3.13E-03 | 1% |
| Product application phase | Cyperméthrine  0.088 | 1.93E-03 | 2% |
| Propiconazole : 0.3 | 1.69E-03 | 1% |
| Tébuconazole : 0.03 | 4.14E-04 | 1% |
| IPBC  0.35 | 8.72E-03 | 2% |
| Brush cleaning phase | Cyperméthrine  0.088 | 3.95E-04 | 0.4% |
| Propiconazole : 0.3 | 3.68E-04 | 0.1% |
| Tébuconazole : 0.03 | 2.66E-04 | 1% |
| IPBC  0.35 | 1.02E-03 | 0.3% |
| Loading + application + cleaning | Cyperméthrine  0.088 | **2.96E-03** | **3%** |
| Propiconazole : 0.3 | **2.60E-03** | **1%** |
| Tébuconazole : 0.03 | **8.05E-04** | **3%** |
| IPBC  0.35 | **1.29E-02** | **4%** |

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | | | | **(∑ HQ a.s)** |
| Without PPE (sans MetL° | 0.03 | 0.01 | 0.03 | 0.04 | **0.11** | Acceptable |

* HI < 1, the risk is acceptable for brush application by a non-professional.

Brush application + injection

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| **Brushing 300 g/m2 + injection 180 g/m2** | | | |
| Loading of the paint in a support | Cyperméthrine  0.088 | 6.42E-04 | 1% |
| Propiconazole : 0.3 | 5.33E-04 | 0.2% |
| Tébuconazole : 0.03 | 1.25E-04 | 0.4% |
| IPBC  0.35 | 3.13E-03 | 1% |
| Product application phase | Cyperméthrine  0.088 | 3.85E-03 | 4% |
| Propiconazole : 0.3 | 3.39E-03 | 1% |
| Tébuconazole : 0.03 | 8.28E-04 | 3% |
| IPBC  0.35 | 1.74E-02 | 5% |
| Cleaning phase (brush) | Cyperméthrine  0.088 | 3.95E-04 | 0.4% |
| Propiconazole : 0.3 | 3.68E-04 | 0.1% |
| Tébuconazole : 0.03 | 2.66E-04 | 0.9% |
| IPBC  0.35 | 1.02E-03 | 0.3% |
| Cleaning phase (spray) | Cyperméthrine  0.088 | 7.08E-04 | 1% |
| Propiconazole : 0.3 | 5.88E-04 | 0.2% |
| Tébuconazole : 0.03 | 1.38E-04 | 0.5% |
| IPBC  0.35 | 3.45E-03 | 1% |
| Appli + cleaning | Cyperméthrine  0.088 | **5.60E-03** | **6%** |
| Propiconazole : 0.3 | **4.88E-03** | **2%** |
| Tébuconazole : 0.03 | **1,36E-03** | **5%** |
| IPBC  0.35 | **2,50E-02** | **7%** |

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | | | | **(∑ HQ a.s)** |
| Without PPE | 0.06 | 0.02 | 0.05 | 0.07 | **0.20** | Acceptable |

* HI < 1, the risk is acceptable for injection combined to brush application by a non-professional.

Spray application

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| **Spraying 300g/m2 – without PPE** | | | |
| M&L | Included in the model |  |  |
| Product application phase | Cyperméthrine  0.088 | 1.18E-02 | 13% |
| Propiconazole : 0.3 | 1.14E-02 | 4% |
| Tébuconazole : 0.03 | 2.33E-03 | 8% |
| IPBC  0.35 | 5.70E-02 | 16% |
| Cleaning of the spray equipment | Cyperméthrine  0.088 | 7.08E-04 | 1% |
| Propiconazole : 0.3 | 5.88E-04 | 0.2% |
| Tébuconazole : 0.03 | 1.38E-04 | 0.5% |
| IPBC  0.35 | 3.45E-03 | 1% |
| Appli + cleaning | Cyperméthrine  0.088 | **1.25E-02** | **14%** |
| Propiconazole : 0.3 | **1.20E-02** | **4%** |
| Tébuconazole : 0.03 | **2.46E-03** | **8%** |
| IPBC  0.35 | **6.05E-02** | **17%** |

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | | | | **(∑ HQ a.s)** |
| Without PPE | 0.14 | 0.04 | 0.08 | 0.17 | **0.44** | Acceptable |

* HI < 1, the risk is acceptable for spray application by a non-professional.

Spray application + injection

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** |
| **Spraying 300g/m2 + injection 150g/m2 – without PPE** | | | |
| M&L | n.a | | |
| Product application phase | Cyperméthrine  0.088 | 2.36E-02 | 27% |
| Propiconazole : 0.3 | 2.28E-02 | 8% |
| Tébuconazole : 0.03 | 4.65E-03 | 16% |
| IPBC  0.35 | 1.14E-01 | 33% |
| Cleaning phase | Cyperméthrine  0.088 | 1.42E-03 | 2% |
| Propiconazole : 0.3 | 1.18E-03 | 0.4% |
| Tébuconazole : 0.03 | 2.76E-04 | 1% |
| IPBC  0.35 | 6.89E-03 | 2% |
| Appli + cleaning | Cyperméthrine  0.088 | **2.50E-02** | **28%** |
| Propiconazole : 0.3 | **2.40E-02** | **8%** |
| Tébuconazole : 0.03 | **4.93E-03** | **16%** |
| IPBC  0.35 | **1.21E-01** | **35%** |

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | | | | **(∑ HQ a.s)** |
| Without PPE | 0.28 | 0.08 | 0.16 | 0.35 | **0.87** | Acceptable |

* HI < 1, the risk is acceptable for injection combined to spray application by a non-professional.

|  |  |
| --- | --- |
| **Scenario** | **Conclusion** |
| **Brush /Roller application** | Acceptable |
| **Spraying application** | Acceptable |
| **Injection combined to brushing** | Acceptable |
| **Injection combined to spraying** | Acceptable |

X6236

The risk is covered by the risk assessment performed for X6119 M2 product.

##### Risk for indirect exposure

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

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

***Acute Exposure***

**All products (except X6119 CR)**

Tier 1 (acceptability of each substance)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Adult amateur sanding/processing of treated wood composites** | Cyperméthrine  0,088 | 7.73E-04 | 0.9% | Acceptable |
| Propiconazole : 0.3 | 1.82E-03 | 0.6% | Acceptable |
| Tébuconazole : 0,03 | 5.35E-04 | 2% | Acceptable |
| IPBC 0.35 | 4.77E-03 | 1% | Acceptable |
| **Infant chewing wood composites chips (450g/m2)** | Cyperméthrine  0,088 | 1.41E-02 | 16% | Acceptable |
| Propiconazole : 0.3 | 4.54E-02 | 15% | Acceptable |
| Tébuconazole : 0,03 | 1.50E-02 | 50% | Acceptable |
| IPBC 0.35 | 1.45E-02 | 4% | Acceptable |

* When the risk is assessed substance by substance, the risk is acceptable for adult sanding/processing of treated wood composites and Infant chewing wood composites chips.

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
|  | **HQ (Exposure/AEL)** | | |  | **(∑ HQ a.s)** |
| **Sanding** | 0.01 | 0.01 | 0.02 | **0.01** | **0.05** | **Acceptable** |
| **Chewing** | 0.16 | 0.15 | 0.50 | **0.04** | **0.85** | **Acceptable** |

* HI < 1, the risk is then acceptable.

**X6119 CR**

Tier 1 (acceptability of each substance)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Adult amateur sanding/processing of treated wood composites** | Cyperméthrine  0,088 | 8.11E-03 | 9% | Acceptable |
| Propiconazole : 0.3 | 1.21E-02 | 4% | Acceptable |
| Tébuconazole : 0,03 | 3.79E-03 | 13% | Acceptable |
| IPBC 0.35 | 3.78E-03 | 1% | Acceptable |
| **Infant chewing wood composites chips (450g/m2)** | Cyperméthrine  0,088 | 1.85E-02 | 21% | Acceptable |
| Propiconazole : 0.3 | 3.69E-02 | 12% | Acceptable |
| Tébuconazole : 0,03 | 1.15E-02 | 38% | Acceptable |
| IPBC 0.35 | 1.15E-02 | 3% | Acceptable |

* When the risk is assessed substance by substance, the risk is acceptable for adult sanding/processing of treated wood composites and Infant chewing wood composites chips.

Tier 2 (additivity)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
|  | **HQ (Exposure/AEL)** | | |  | **(∑ HQ a.s)** |
| **Sanding** | 0.09 | 0.04 | 0.13 | **0.01** | **0.27** | **Acceptable** |
| **Chewing** | 0.21 | 0.12 | 0.38 | **0.03** | **0.75** | **Acceptable** |

* HI < 1, the risk is then acceptable.

***Chronic secondary exposure scenario***

**All products (except X6119 CR)**

Tier 1 (acceptability of each substance)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Adult professional sanding/processing of treated wood composites** | Cyperméthrine  0.022 | 8.63E-04 | 4% | Acceptable |
| Propiconazole : 0.04 | 1.99E-03 | 5% | Acceptable |
| Tébuconazole : 0.03 | 5.90E-04 | 2% | Acceptable |
| IPBC 0.2 | 4.83E-03 | 2% | Acceptable |
| **Inhalation of volatilizing residues indoors (Adult)** | Cyperméthrine  0.022 | *3.28E-09* | *0.000015%* | Acceptable |
| Propiconazole : 0.04 | *8.91E-07* | *0.0022%* | Acceptable |
| Tébuconazole : 0.03 | 1.52E-08 | 0.00005% | Acceptable |
| IPBC 0.2 | 3.57E-05 | 0.02% | Acceptable |
| **Inhalation of volatilizing residues indoors (Infant)** | Cyperméthrine  0.022 | *6.642E-09* | *0.000030%* | Acceptable |
| Propiconazole : 0.04 | *1.80E-06* | *0.0045%* | Acceptable |
| Tébuconazole : 0.03 | 3.07E-08 | 0.000102% | Acceptable |
| IPBC 0.2 | 7.24E-05 | 0.04% | Acceptable |
| **Child playing on playground structure outdoors** | Cyperméthrine  0.022 | 2.88E-04 | 1% | Acceptable |
| Propiconazole : 0.04 | 6.81E-04 | 2% | Acceptable |
| Tébuconazole : 0.03 | 2.00E-04 | 1% | Acceptable |
| IPBC 0.2 | 1.81E-03 | 1% | Acceptable |
| **Infant playing on weathered (playground) structure and mouthing (450 g/m2)** | Cyperméthrine  0.022 | 4.82E-03 | 22% | Acceptable |
| Propiconazole : 0.04 | 1.52E-02 | 38% | Acceptable |
| Tébuconazole : 0.03 | 4.98E-03 | 17% | Acceptable |
| IPBC 0.2 | 7.26E-03 | 4% | Acceptable |

* When the risk is assessed substance by substance, the risk is acceptable for chronic exposure scenarios.

*Tier 2 (additivity)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | |  | **(∑ HQ a.s)** |
| **Adult professional sanding/processing of treated wood composites** | | | | | |
| 0.04 | 0.05 | 0.02 | **0.02** | **0.13** | **Acceptable** |
| **Adult: inhalation of volatilised residues, indoors** | | | | | |
| 0.0000 | 0.00 | 0.00 | **0.00** | **0.00** | **Acceptable** |
| **Infant: inhalation of volatilised residues, indoors** | | | | | |
| 0.0000 | 0.00 | 0.00 | **0.00** | **0.00** | **Acceptable** |
| **Child playing on playground structure outdoors** | | | | | |
| 0.01 | 0.02 | 0.01 | **0.01** | **0.05** | **Acceptable** |
| **Infant playing on playground structure outdoors and mouthing** | | | | | |
| **(wood treated at 480g/m2)** | | | | | |
| 0.22 | 0.38 | 0.17 | **0.04** | **0.81** | **Acceptable** |

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

**X6119 CR**

Tier 1 (acceptability of each substance)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Adult professional sanding/processing of treated wood composites** | Cyperméthrine  0.022 | 8.20E-03 | 37% | Acceptable |
| Propiconazole : 0.04 | 1.23E-02 | 31% | Acceptable |
| Tébuconazole : 0.03 | 3.83E-03 | 13% | Acceptable |
| IPBC 0.2 | 3.83E-03 | 2% | Acceptable |
| **Inhalation of volatilizing residues indoors (Adult)** | Cyperméthrine  0.022 | *3.28E-09* | *0.000015%* | Acceptable |
| Propiconazole : 0.04 | *8.91E-07* | *0.0022%* | Acceptable |
| Tébuconazole : 0.03 | 1.52E-08 | 0.00005% | Acceptable |
| IPBC 0.2 | 3.57E-05 | 0.02% | Acceptable |
| **Inhalation of volatilizing residues indoors (Infant)** | Cyperméthrine  0.022 | *6.642E-09* | *0.000030%* | Acceptable |
| Propiconazole : 0.04 | *1.80E-06* | *0.0045%* | Acceptable |
| Tébuconazole : 0.03 | 3.07E-08 | 0.0001% | Acceptable |
| IPBC 0.2 | 7.24E-05 | 0.04% | Acceptable |
| **Child playing on playground structure outdoors** | Cyperméthrine  0.022 | 3.08E-03 | 14% | Acceptable |
| Propiconazole : 0.04 | 4.61E-03 | 12% | Acceptable |
| Tébuconazole : 0.03 | 2.16E-03 | 7% | Acceptable |
| IPBC 0.2 | 2.16E-03 | 1% | Acceptable |
| **Infant playing on weathered (playground) structure and mouthing (450 g/m2)** | Cyperméthrine  0.022 | 9.01E-03 | 41% | Acceptable |
| Propiconazole : 0.04 | 1.84E-02 | 46% | Acceptable |
| Tébuconazole : 0.03 | 5.76E-03 | 19% | Acceptable |
| IPBC 0.2 | 5.76E-03 | 3% | Acceptable |

* When the risk is assessed substance by substance, the risk is acceptable for chronic exposure scenarios.

*Tier 2 (additivity)*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** | **HI** | **Risk** |
| **HQ (Exposure/AEL)** | | |  | **(∑ HQ a.s)** |
| **Adult professional sanding/processing of treated wood composites** | | | | | |
| 0.37 | 0.31 | 0.13 | **0.02** | **0.83** | **Acceptable** |
| **Adult: inhalation of volatilised residues, indoors** | | | | | |
| 0.0000 | 0.00 | 0.00 | **0.00** | **0.00** | **Acceptable** |
| **Infant: inhalation of volatilised residues, indoors** | | | | | |
| 0.0000 | 0.00 | 0.00 | **0.00** | **0.00** | **Acceptable** |
| **Child playing on playground structure outdoors** | | | | | |
| 0.14 | 0.12 | 0.07 | **0.01** | **0.34** | **Acceptable** |
| **Infant playing on playground structure outdoors and mouthing** | | | | | |
| **(wood treated at 480g/m2)** | | | | | |
| 0.41 | 0.46 | 0.19 | **0.03** | **1.09** | **Unacceptable** |

* HI < 1 for all scenario except the scenario of an infant playing on treated structure. For this scenario refinement is needed.

A Tier 3B approach is considered since the 4 active substances have target organs in common. The same AEL of organs than above are used.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Cyperméthrine** | **Propiconazole** | **Tébuconazole** | **IPBC** |  |
|  | | | | |  |
| Combined exposure | 9.01E-03 | 1.84E-02 | 5.76E-03 | 5.83E-03 |  |
|  |  |  |  |  |  |
| AEL liver | 0.18 | 0.08 | 0.06 | 0.2 | **HI** |
| %AEL | 5% | 23% | 10% | 3% | 41% |
|  |  |  |  |  |  |
| AEL kidney | 0.022 | 0.5 |  | 0.35 |  |
| %AEL | 41% | 4% |  | 2% | 46% |
|  |  |  |  |  |  |
| AEL hematology | 0.022 | 0.761 | 0.3 |  |  |
| %AEL | 41% | 2% | 2% |  | 45% |
|  |  |  |  |  |  |
| AEL adrenals |  | 0.036 | 0.03 |  |  |
| %AEL |  | 51% | 19% |  | 70% |
|  |  |  |  |  |  |
| AEL Lung | 0.07 |  |  | 0.2 |  |
| %AEL | 13% |  |  | 3% | 16% |

HI is inferior to 1 for all organs. In this context, the risk is considered acceptable.

**Local risk assessment:**

The products are classified for local effect.

Meta SPC 1 (H315/H318/H317) 🡪 PRO: Considering the conclusion of the systemic risk assessment and P sentences linked to the classification, PPE are required. Therefore, local risk assessment is considered acceptable.

Meta SPC 2 (H315/H318/H317)🡪 PRO: Considering the conclusion of the systemic risk assessment and P sentences linked to the classification, PPE are required. Therefore, local risk assessment is considered acceptable.

Meta SPC 3 and 4 (H319)🡪 PRO and non- PRO:

For non-pro: Exposure of eyes is expected only for application by spraying. Considering that exposure is less than 1 hour per day, the risk is acceptable.

For pro: Exposure of eyes is expected only for application by spraying. Chemical goggles are required by P sentence. Therefore, the risk is acceptable.

* **Minor Change application for PPG CLASS3 WB – 2019:**

**Local risk assessment**

On the frame of the minor change application, only the products of the Meta SPC 1 and 2 are classified for local effects.

Therefore, the local risk characterization performed according to the guidance on BPR Volume III part B/C is only relevant for the meta SPC1 and 2.

No local risk characterization is required for the meta SPC 3 and 4.

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

* **Minor Change application for PPG CLASS3 WB – 2019:**

The conclusions remained unchanged.

***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.

### Risk assessment for the environment

* **Minor change application for PPG CLASS3 WB - 2019:**

The conclusions of the environmental assessment remain unchanged.

The new co-formulant is not a substance of concern for the environment and does not change the classification of the product. Therefore it will not change the environmental assessment.

#### Fate and distribution in the environment of the actives substances

The products X6119C, X6119CJ, X6119C1 and X6119B1 belong to Meta-SPC 1 and 2 of the PPG\_Class3\_WB family. **X6119C** is considered as the representative product for the environmental risk assessment taking into account its in-use a.s. concentrations, and its intended professional and industrial uses.

The products X6119CR and X6119M2 belong to Meta-SPC 3 of the PPG\_Class3\_WB family. **X6119M2** is considered as the representative product for the environmental risk assessment taking into account its in-use a.s. concentrations, and its intended professional and non-professional uses.

The product X6236 belong to Meta-SPC 3/4 of the PPG\_Class3\_WB family. **X6236** is evaluated separately for the environmental risk assessment taking into account its in-use a.s. concentrations, and its intended professional and non-professional uses.

A summary of the environmental behaviour of the active substances and their relevant metabolites is presented below.

Table 2.2‑1 Summary of the physico-chemical, environmental fate and behaviour parameters for each active substance and their relevant metabolites used by FR-CA for the product-environmental risk assessment according to the list of endpoints validated at EU level

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Parameter / Variable** | **Unit** | **Cyper-**  **methrin** | **Tebuco-**  **nazole** | **Propico-**  **nazole** | **1,2,4-triazole(\*)** | **IPBC** | **PBC(\*\*\*)** | **Iodine (\*\*\*\*)** |
| Molar mass | [g.mol-1] | 416.3 | 307.8 | 342.2 | 69.1 | 281.1 | 155.2 | 253.81 |
| Vapour pressure | [Pa] | 6.00E-07 | 1.70E-06 | 5.60E-05 | 0.220 | 2.36E-03 | 1.88E+01 | 40.7 |
| Water solubility | [mg.l-1] | 4.00E-03 | 29 | 100 | 700 | 168 | 2860 | 290 |
| Koc | [l.kg-1] | 575 000 | 992 | 944 | 89 | 134.5 | 198.1 |  |
| DT50 (soil) | [d at 12°C] | 17.2 | 77 | 82 | 114.7 (\*\*) | 1.96E-01 | 9.50 | n.r. |
| DT50 (surface water) | [d at 12°C] | 0.95 | 43 | 12 | n.r. | 1.29E-01 | 31.2 | n.r. |
| DT50 (water/sediment whole system) | [d at 12°C] | 18.5 | 198  (degradation in water) | 1206 | n.r. | 2.04E-01 | 31.4 | n.r. |
| BCF in fish | [l.kg-1] | 417 | n.r. | n.r. | n.r. | n.r. | n.r. | n.r. |
| BCF in earthworm | [l.kg-1] | 3380 | n.r. | n.r. | n.r. | n.r. | n.r. | n.r. |
| STP fraction | | | | | | | | |
| FSTP, water | [-] | 0.091 | 0.89 | 0.9 | n.r. | 0.963 | 0.967 | 0.80 |
| FSTP, sludge | [-] | 0.909 | 0.109 | 0.1 | n.r. | 0.0364 | 0.0241 | 0.20 |
| n.r. – Not relevant for the environmental risk assessement of the product  (\*) – Relevant metabolite of tebuconazole and propiconazole in soil with a maximum of 9% and 43.23 % of applied radioactivity, respectively.  (\*\*) – Calculated according to the Arrhenius equation with a DT50 at 20°C of 60.5 days.  (\*\*\*) – Relevant metabolite of IPBC in all environmental compartments assuming 100% of applied radioactivity.  (\*\*\*\*) – Relevant metabolite of IPBC in all environmental compartments with a transformation rate in:   * Surface water – iodine to iodide 100% - iodine to iodate 100% * Soil *via* the STP- iodine to iodide 14% - iodine to iodate 100% * Soil *via* direct release - iodine to iodide 100% - iodine to iodate 100% | | | | | | | | |

#### Effects on environmental organisms

The calculated PNECs are summarised in the following Table for actives substance and relevant metabolites.

Table 2.2‑2 Summary of the PNEC values for each active substance and their relevant metabolites used by FR-CA for the product-environmental risk assessment according to the list of endpoints validated at EU level

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **PNEC** | **Unit** | **Cyper-**  **methrin** | **Tebuco-**  **nazole** | **Propico-**  **nazole** | **1,2,4-triazole** | **IPBC** | **PBC** |
| **PNECSTP** | [mg.l-1] | 1.63E+00 | 3.20E-01 | 1.00E+02 | n.r. | 0.44 | 0.44 |
| **PNECwater** | [mg.l-1] | 4.00E-06 (1) | 1.00E-03 | 6.80E-03 | n.r. | 5.00E-04 | 4.13E-02 |
| **PNECsediment** | [mg.kgwwt-1] | 5.00E-02(2) | 5.50E-01 | 5.40E-02 | n.r. | n.r. | 2.10E-01 |
| **PNECsoil** | [mg.kgwwt-1] | 9.18E-02 | 1.00E-01 | 1.00E-01 | 8.20E-03 | 4.40E-03 | 1.49E-01 |
| **PNECoral,bird** | [mg.kgfood] | 3.33E+01 | n.r. | n.r. | n.r. | n.r. | n.r. |
| **PNECoral,mammals** | [mg.kgfood] | 3.33E+00 | n.r. | n.r. | n.r. | n.r. | n.r. |

n.r: not relevant

(1) According to the WGIV2016, a robust NOEC fish of 0.4 µg.l-1 is considered to derive the PNECwater for Cypermethrin with an assessment factor of 100.

(2) EPM – A factor of 10 has to be added to the PEC/PNEC ratios

Iodine and iodine compounds are ubiquitously distributed and there is a natural cycle of iodine species in the environment. Consequently, natural background levels have to be taken into account in the environmental risk assessment. Literature data were compiled in the CAR of Iodine. Environmental background values as presented in the table below:

Table 2.2‑3 Summary table of background levels for Iodine

|  |  |
| --- | --- |
| Compartment | Background level (Iodine and cover the iodine compounds) |
| Freshwater (river and lake) | 0.5 - 20 µg.l-1 |
| Freshwater sediment | 6 mg.kg wwt-1 |
| Soil | 0.565-22.6 mg.kg wwt-1 with extremes up to 110.74 mg.kg wwt-1 |
| Groundwater | < 1 - 70 µg.l-1L with extremes up to 400 µg.l-1 |

##### PBT and ED Assessment

**PBT-assessment:**

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

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

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

According to the PT13-AR of IPBC (2015), IPBC and PBC do not fulfil the PBT nor the vPvB criteria.

**ED-assessment:**

According to the PT07-AR of tebuconazole (2013), the PT07-AR of propiconazole (2013), the PT08-AR of cypermethrin (2013), the PT13-AR of IPBC (2015) no definite conclusions can be drawn concerning the endocrine disruption activity of each active substance.Nevertheless, a number of scientific publications mention potential endocrine disruption activity of propiconazole and tebuconazole. These effects will be assessed more in details at the renewal stage of these biocidal active substances approval in the frame of the EU Regulation No 528/2012 (scheduled in 2019), and according to the criteria mentioned in the future *Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009.* In case these active substances were identified as ED, the conditions for the product authorisation will have to be revised.

#### Effects on environmental organisms for the substance(s) of concern

According to the BPC guidance document Vol IV Part B+C, and the part 8 for the assessment of substances of concern,

* CMIT/MIT is an active substance from other product types for which a draft final Competent Authority Report is available. Nevertheless, this substance is present in the biocidal product at a concentration < 0.1%. Moreover the PNECwater for cypermethrin is lower than the PNECwater for CMIT/MIT. Finally if we look the relative toxic unit for algae (most sensitive specie), the percentage of CMIT/MIT in the product toxicity is only of 6% (acute) and 18% (chronic) compared to the toxicity percentage of actives substances of 79% (acute) and 67% (chronic). Consequently this substance is not considered as SoC.
* BIT is an active substances from other product types for which a draft final Competent Authority Report is not available. BIT is still under review for PT06 (moreover BIT is used in this product as preservative). No risk assessment for BIT in PT06 is available. This substance is present in the biocidal product at a concentration > 0.1%. On the other hand the PNECwater for BIT is not lower than the PNECwater of actives substances. Finally if we look the relative toxic unit for algae (most sensitive specie), the percentage of CMIT/MIT in the product toxicity is only of 14% (acute) and 13% (chronic) compared to the toxicity percentage of actives substances of 79% (acute) and 67% (chronic).

Finally the conclusions of risk assessment will not be modified considering RMMs already proposed. Consequently BIT and CMIT/MIT are not considered as SoCs.

#### Effects on environmental organisms for biocidal product

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

#### Environmental exposure assessment

##### Meta SPC1 & 2: Emissions to the environment for the representative product for X6119C

This environmental exposure assessment covers the products X6119C, X6119CJ, X6119C1 and X6119B1 belonging to Meta-SPC1 and 2 of the PPG\_Class3\_WB family. The product X6119C was considered to be the representative product considering a similar composition between products. Moreover the product X6119C has the highest concentrations of active substances.

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

The product X6119C is used at a 3% and a 5% dilution in water. This risk assessment is based on the 5% solution as a worst-case approach. The performed semi-field leaching study was also performed on this solution.

Industrial applications

Based on the industrial application the following scenario can be considered:

* Emission scenario for automated spraying (ESD 4.1.1)
* Emission scenario for industrial dipping process (ESD 4.1.2)

No risk assessment has been conducted for the industrial application (including storage), based on mandatory risk mitigation measures for wood treatment plants: ‘*Industrial application shall be conducted within a contained area on impermeable hard standing with bunding and freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal’.* This will be stated on the label.

Emissions from treated wood in service after treatment (Use class 3) have been considered using the following scenarios:

* House – ESD 4.3.3.1 (groundwater according to FOCUS/PEARL)
* Noise Barrier - ESD 4.3.3.3
* Bridge over Pond – ESD 4.3.3.4

In situ brushing and spraying by professionals

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

* Brushing (House scenario according to ESD 4.2.4.1 for the soil compartment and groundwater (pore water) and Bridge over pond for the surface water and sediment, ESD 4.2.4.3)
* Spraying (House scenario for outdoor spraying, ESD 4.4.5)

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

* House – ESD 4.3.3.1 (groundwater according to FOCUS/PEARL)
* Bridge over Pond – ESD 4.3.3.4
* Noise barrier – ESD 4.3.3.3

##### Meta SPC1 & 2: Calculation of leaching rates from the semi-field leaching study (X6119C)

The leaching values used in the calculation of emissions are derived from the leaching study results. The study has been carried out with the **X6119C** product during 457 days and from a surface application. The results of the semi-field study were recalculated by FR-CA by expressing the leaching in losses per mm rain incident on the panels for the standard rain year, instead of time, as the variability with time is of secondary interest due to the natural variability of rainfall. The results are presented over calendar years and over standard rain years (700 mm rain, in 365 days, *i.e.* 1.92 mm rain per day).

The applicant performed this leaching study using the product without topcoat.

For each active substance and to estimation the Q\*leach, time, the best goodness of the fit (with the r² value closest to 1) is obtained by fitting the cumulative quantities leached versus cumulative rain fall plot using a linear regression:

Q\*leach,time = a\*mm + b

Q\*leach, time values are calculated for:

* TIME1 = 30 days, equivalent to 30 \* 1.92 = 57.53 mm of accumulated rain;
* TIME2 = 15 years, equivalent to 5475 \* 1.92 = 10512 mm of accumulated rain.

It is worth noting that the limit of quantification for IPBC and for Cypermethrin is 0.02 mg/L instead of 0.01 mg/L (as indicated by the registrant). This value was used as input for the leaching estimation.

The leaching values obtained from an application by brushing at 300.1 g.m-² without topcoat have been normalized for an application dose of 200 g.m-2 and to 700 mm of rainfall per year for each active substance are summarized in the following table:

Table 2.2‑4 Leaching values obtained from surface application at 200 g/m² without topcoat (X6119C)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Equations used for calculations** | **Q\*leach [mg.m-2]** | |
| **TIME 1 (30d)** | **TIME 2 (15y)**  **Industrial** |
| Propiconazole | Q\*leach = 0.023 \* mm + 46.179 **(r² = 0.97)** | 31.66 | 191.91 |
| Tebuconazole | Q\*leach = 0.008 \* mm + 17.779 **(r² = 0.98)** | 12.15 | 67.51 |
| Cypermethrin | Q\*leach = 0.0015 \* mm + 19 **(r² = 0.97)** | 0.183 | 10.50 |
| IPBC | Q\*leach = 0.0041 \* mm + 20.874 **(r² = 0.97)** | 14.07 | 42.80 |

Moreover IPBC is rapidly degraded in water with a DT50 of 3.1 h at 12°C and in soil with a DT50 of 4.7 h at 12°C. Therefore, emissions of PBC (degradation product of IPBC) are also calculated assuming 100% formation fraction of IPBC to PBC at time 0, using the ratio between the molar mass of PBC and IPBC of 0.552 in water and in soil.

The assessment of 1,2,4-triazole was proposed only for emission to soil. The emission calculation for the metabolite takes into account the maximal level of formation fraction of the substances in soil (9% and 43% for tebuconazole and propiconazole respectively, as defined for the approval of these substances) and the molar mass of each component. An assessment of PBC in water and in soil and an assessment of 1,2,4-triazole is also proposed for soil compartment.

Table 2.2‑5 Relevant metabolites - Leaching values obtained from surface application at 200 g/m² without topcoat (X6119C)

|  |  |  |
| --- | --- | --- |
|  | **Q\*leach [mg.m-2]** | |
| **TIME 1 (30d)** | **TIME 1 (15y)**  **Industrial** |
| **Equations:**  Q\*leach, time1  = ( Q\*leach time 1/time2 \* DEGrate \* Molar mass metabolite/Molar mass parent) | | |
| 1,2,4-triazole | 2.99 | 18.03 |
| PBC | 7.77 | 23.63 |

Table 2.2‑6 : The relevant environmental compartments for each substance and identified metabolites are specified in the table below (X6119C):

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Phase | STP | Surface water | | Sediment | | Soil | | Groundwater | | Secondary Poisoning |
| Direct Release | *Via* STP | Direct Release | *Via* STP | Direct Release | *Via* STP | Direct Release | *Via* STP |
| Propiconazole | Y | Y | Y | Y | Y | Y | Y | Y | Y | N |
| Tebuconazole | Y | Y | Y | Y | Y | Y | Y | Y | Y | N |
| Cypermethrin | Y | Y | Y | Y | Y | Y | Y | N | N | Y |
| IPBC | Y | Y | N | N | N | Y | N | Y | N | N |
| PBC | Y | Y | Y | Y | Y | Y | Y | Y | Y | N |
| 1,2,4-triazole | N | N | N | N | N | Y | N | Y | Y | N |

##### Meta SPC1 & 2: Estimation of emissions

Industrial application: automated spraying and dipping (storage phase only).

The applicant proposed an assessment for the storage phase of the industrial application. Nevertheless, FR-CA considers not relevant the carry out of risk assessment for the industrial application phase (including storage), based on mandatory risk mitigation measures for wood treatment plants. Storage must only take place on sealed places or under cover to prevent direct release to soil. This will be stated on the label.

##### Industrial application: Treated wood in-service.

Emissions from treated house - service-life of industrial treated wood (X6119C)

**HOUSE - treated wood *in service*– industrial surface application**

|  |  |  |
| --- | --- | --- |
| **Symbol** | **Value** | **Unit** |
| ***Inputs*** | | |
| Application | Industrial | [-] |
| AREA house | 125 | [m²] |
| TIME1 | 30 | [d] |
| TIME2 | 5475 | [d] |
| Q\*leach,TIME1 | See leaching values above | [mg.m-2] |
| Q\*leach,TIME2 | [mg.m-2] |
| DT50 soil | See Table 2.2‑1 | [d-1] |
| V soil | 13 | [m3] |
| RHO soil | 1700 | [kgwwt.m-3] |
| ***Outputs*** | | |
|  | **Qleach, TIME1 (30d) [kg]** | **Qleach, TIME2 (15y)  [kg]** |
| Propiconazole | 3.96E-03 | 2.40E-02 |
| Tebuconazole | 1.52E-03 | 8.44E-03 |
| Cypermethrin | 2.29E-05 | 1.31E-03 |
| IPBC | 1.76E-03 | 5.35E-03 |
| PBC | 9.71E-04 | 2.95E-03 |
| 1,2,4-triazole | 3.74E-04 | 2.25E-03 |

Emissions from treated noise barrier - service-life of industrial treated wood (X6119C)

**NOISE BARRIER – treated wood in-service – industrial surface application**

|  |  |  |
| --- | --- | --- |
| **Symbol** | **Value** | **Unit** |
| ***Inputs*** | | |
| Application | Industrial | [-] |
| AREA noise-barrier | 3000 | [m²] |
| TIME1 | 30 | [d] |
| TIME2 | 5475 | [d] |
| Q\*leach,TIME1 | See leaching values above | [mg.m-2] |
| Q\*leach,TIME2 | [mg.m-2] |
| DT50 soil | See Table 2.2‑1 | [d-1] |
| V soil | 250 | [m3] |
| RHO soil | 1700 | [kgwwt.m-3] |
| F SOIL | 0.3 | [-] |
| F STP | 0.7 | [-] |
| ***Outputs*** | | |
| ***Direct emissions to soil*** | | |
|  | **Qleach, TIME1 (30d) [kg]** | **Qleach, TIME2 (15y)  [kg]** |
| Propiconazole | 2.85E-03 | 1.73E-01 |
| Tebuconazole | 1.09E-02 | 6.08E-02 |
| Cypermethrin | 1.65E-04 | 9.45E-03 |
| IPBC | 1.27E-02 | 3.85E-02 |
| PBC | 6.99E-03 | 2.13E-02 |
| 1,2,4-triazole | 2.70E-03 | 1.62E-02 |
| ***Emissions to STP*** | | |
|  | **ESTP TIME1 (30d) [kg.d-1]** | **ESTP TIME2 (15y)  [ kg.d-1]** |
| Propiconazole | 2.22E-03 | 7.36E-05 |
| Tebuconazole | 8.51E-04 | 2.59E-05 |
| Cypermethrin | 1.28E-05 | 4.03E-06 |
| IPBC | 9.85E-04 | 1.64E-05 |
| PBC | 5.44E-04 | 9.06E-06 |
| 1,2,4-triazole | 2.10E-04 | 6.91E-06 |

Emissions from bridge over pond - service-life of industrial treated wood (X6119C)

**BRIDGE OVER POND – treated wood in-service – industrial surface application**

|  |  |  |
| --- | --- | --- |
| **Symbol** | **Value** | **Unit** |
| ***Inputs*** | | |
| Application | Industrial | [-] |
| AREA bridge | 10 | [m²] |
| TIME1 | 30 | [d] |
| TIME2 | 5475 | [d] |
| Q\*leach,TIME1 | See leaching values above | [mg.m-2] |
| Q\*leach,TIME2 | [mg.m-2] |
| DT50 soil | See Table 2.2‑1 | [d-1] |
| V water | 1 000 | [m3] |
| ***Outputs*** | | |
| ***Direct emissions to water*** | | |
|  | **Qleach, TIME1 (30d) [kg]** | **Qleach, TIME2 (15y)  [kg]** |
| Propiconazole | 3.17E-04 | 1.92E-03 |
| Tebuconazole | 1.22E-04 | 6.75E-04 |
| Cypermethrin | 1.83E-06 | 1.05E-04 |
| IPBC | 1.41E-04 | 4.28E-04 |
| PBC | 7.77E-05 | 2.36E-04 |
| 1,2,4-triazole | 2.99E-05 | 1.80E-04 |

*In-situ* application: application and wood in-service

Considering the actives susbstances’s contents of the representative product X6119C and the leaching values from surface application, the calculations of the emissions during the application stage and during the wood in service step, permitted to achieve at the same conclusions that for the representative product, X6119M2, of the meta SPC 3.

Consequently, only the calculation for the meta-SPC 3 with the representative product, X6119M2, is described (see below) and covers the evaluation for meta-SPC1 & 2 for an *in-situ* application.

##### Meta SPC 3: Emissions to the environment for the representative product, X6119M2

*In-situ* brushing and spraying by professionals and non-professionals – Use class 3

This environmental exposure assessment covers the products X6119CR and X6119M2 belonging to Meta-SPC 3 of the PPG\_Class3\_WB family. The product X6119M2 was considered to be the representative product considering a similar composition between products. Moreover the product X6119M2 has the highest concentrations of active substances.

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

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

* Brushing (House scenario according to ESD 4.2.4.1 for the soil compartment and groundwater (pore water) and Bridge over pond for the surface water and sediment, ESD 4.2.4.3)
* Spraying (House scenario for outdoor spraying, ESD 4.4.5)

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

* House – ESD 4.3.3.1 (groundwater according to FOCUS/PEARL)
* Bridge over Pond – ESD 4.3.3.4
* Noise barrier – ESD 4.3.3.3

##### Meta SPC 3: Calculation of leaching rates from the semi-field leaching study (X6119M2)

The leaching values used in the calculation of emissions are derived from the leaching study results. The study has been carried out with the X6119M2 product during 421 days and from a surface application. The results of the semi-field study were recalculated by FR-CA by expressing the leaching in losses per mm rain incident on the panels for the standard rain year, instead of time, as the variability with time is of secondary interest due to the natural variability of rainfall. The results are presented over calendar years and over standard rain years (700 mm rain, in 365 days, *i.e.* 1.92 mm rain per day).

The applicant performed leaching study using the product without topcoat.

For each active substance and to estimation the Q\*leach, time, the best goodness of the fit (with the r² value closest to 1) is obtained by fitting the cumulative quantities leached versus cumulative rain fall plot using a linear regression:

Q\*leach,time = a\*mm + b

Q\*leach, time values are calculated for:

* TIME1 = 30 days, equivalent to 30 \* 1.92 = 57.53 mm of accumulated rain;
* TIME2 = 15 years, equivalent to 5475 \* 1.92 = 10512 mm of accumulated rain.

It is worth noting that the limit of quantification for IPBC and for Cypermethrin is 0.02 µg.ml-1 instead of 0.01 µg.ml-1 (as indicated by the registrant). This value was used as input for the leaching estimation.

The leaching values obtained from an application by brushing at 305.7 g.m-² without topcoat have been normalized for an application dose of 200 g.m-2 and to 700 mm of rainfall per year for each active substance are summarized in the following table:

Table 2.2‑7 Leaching values obtained from surface application at 200 g/m² without topcoat (X6119M2)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Equations used for calculations** | **Q\*leach [mg.m-2]** | |
| **TIME 1 (30d)** | **TIME 2 (5y)**  ***In situ*** |
| Propiconazole | Q\*leach = 0.0404 \* mm + 72.438 **(r² = 0.99)** | 48.91 | 140 |
| Tebuconazole | Q\*leach = 0.0128 \* mm + 24.377 **(r² = 0.99)** | 16.43 | 45.32 |
| Cypermethrin | Q\*leach = 0.0018 \* mm + 21.284 **(r² = 0.97)** | 14 | 18 |
| IPBC | Q\*leach = 0.0082 \* mm + 29.987 **(r² = 0.98)** | 19.93 | 38.39 |

Moreover IPBC is rapidly degraded in water with a DT50 of 3.1 h at 12°C and in soil with a DT50 of 4.7 h at 12°C. Therefore, emissions of PBC (degradation product of IPBC) are also calculated assuming 100% of formation fraction of IPBC to PBC at time 0, using the ratio between the molar mass of PBC and IPBC of 0.552 in water and in soil.

The assessment of 1,2,4-triazole was proposed only for emission to soil. The emission calculation for the metabolite takes into account the maximal level of formation fraction of the substances in soil (9% and 43.23% for tebuconazole and propiconazole respectively as defined for the approval of these substances) and the molar mass of each component. An assessment of PBC in water and in soil and an assessment of 1,2,4-triazole in soil are also proposed.

Table 2.2‑8 Relevant metabolites - Leaching values obtained from surface application at 200 g/m² without topcoat (X6119M2)

|  |  |  |
| --- | --- | --- |
|  | **Q\*leach [mg.m-2]** | |
| **TIME 1 (30d)** | **TIME2 (5y)**  ***In situ*** |
| **Equations:**  Q\*leach, time1  = ( Q\*leach time 1/time2 \* formation fraction\* Molar mass metabolite/Molar mass parent) | | |
| 1,2,4-triazole | 4.58 | 13.06 |
| PBC | 11 | 21.2 |

The relevant environmental compartments for each substance and identified metabolites are specified in the table below (X6119M2):

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Phase | STP | Surface water | | Sediment | | Soil | | Groundwater | | Secondary Poisoning |
| Direct Release | *Via* STP | Direct Release | *Via* STP | Direct Release | *Via* STP | Direct Release | *Via* STP |
| Propiconazole | Y | Y | Y | Y | Y | Y | Y | Y | Y | N |
| Tebuconazole | Y | Y | Y | Y | Y | Y | Y | Y | Y | N |
| Cypermethrin | Y | Y | Y | Y | Y | Y | Y | N | N | Y |
| IPBC | Y | Y | N | N | N | Y | N | Y | N | N |
| PBC | Y | Y | Y | Y | Y | Y | Y | Y | Y | N |
| 1,2,4-triazole | N | N | N | N | N | Y | N | Y | Y | N |

##### Meta SPC 3: Estimation of emissions - X6119M2

In-situ application - X6119M2

For the risk assessment, the technical active substance content has to be considered.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Expression of the active substance’s content | Cypermethrin | Tebuconazole | Propiconazole | IPBC |
| Pure (%w/w) | 0.10 | 0.05 | 0.15 | 0.05 |
| Technical (%w/w) | 0.21 | 0.05 | 0.30 | 0.05 |

According to the technical Agreements for Biocides (June 2016), the house-scenario is the worst case scenario and would therefore be sufficient. Consequently, the fence scenario has been deleted.

An assessment of PBC in water and in soil and an assessment of 1,2,4-triazole in soil are proposed (see above).

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

Emission from in-situ brushing application (X6119M2)

|  |  |  |
| --- | --- | --- |
| **Outputs – in situ application by brush - House scenario - 200 g.m-2** | | |
|  | Professional | Non professional |
| **Emission of substance to soil – E soil [kg.d-1]** | | |
| Propiconazole | 2.25E-03 | 3.75E-03 |
| Tebuconazole | 3.75E-04 | 6.25E-04 |
| Cypermethrin | 1.58E-03 | 2.63E-03 |
| IPBC | 3.75E-04 | 6.25E-04 |
| PBC | 2.07E-04 | 3.45E-04 |
| 1,2,4-triazole | 2.04E-04 | 3.40E-04 |
| **Outputs – in situ application by brush - Bridge scenario - 200 g.m-2** | | |
| **Emission of substance to water – E water [kg.d-1]** | | |
|  | Professional | Non professional |
| Propiconazole | 1.80E-04 | 3.00E-04 |
| Tebuconazole | 3.00E-05 | 5.00E-05 |
| Cypermethrin | 1.26E-04 | 2.10E-04 |
| IPBC | 3.00E-05 | 5.00E-05 |
| PBC | 1.66E-05 | 2.76E-05 |

Emissions from in-situ spraying application (X6119M2)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Outputs – in situ application by spray - House scenario** | | | | |
| **Emission of substance to soil after application (run-off) – E soil [kg.d-1]** | | | | |
| Propiconazole | 1.50E-02 | | | |
| Tebuconazole | 2.50E-03 | | | |
| Cypermethrin | 1.05E-02 | | | |
| IPBC | 2.50E-03 | | | |
| PBC | 1.38E-03 | | | |
| 1,2,4-triazole | 1.35E-03 | | | |
| **Emission of substance to soil after application (drift Tier 1) – E soil [kg.d-1]** | | | | |
| Propiconazole | 7.50E-03 | | | |
| Tebuconazole | 1.25E-03 | | | |
| Cypermethrin | 5.25E-03 | | | |
| IPBC | 1.25E-03 | | | |
| PBC | 6.90E-04 | | | |
| 1,2,4-triazole | 6.76E-04 | | | |
| **Emission of substance to soil after application (drift Tier 2) – E soil [kg.d-1]** | | | | |
| Propiconazole | 2.48E-03 | | | |
| Tebuconazole | 4.13E-04 | | | |
| Cypermethrin | 1.73E-03 | | | |
| IPBC | 4.13E-04 | | | |
| PBC | 2.28E-04 | | | |
| 1,2,4-triazole | 2.23E-04 | | | |
| **Inputs - – in situ application by spray - Bridge scenario - 200 g.m-2** | | | | |
| **Parameter/variable** | | **Symbol** | **Value** | **Unit** |
| Treated wood area | | AREAbridge | 10 | [m².d-1] |
| Application rate of the product | | Qapplic.product | 0.2 | [l.m-2] |
| Content of the active substances | | fai | See above | [-] |
| Density of the product | | RHOproduct | 1000 | [kg.m-3] |
| Fraction of product lost to water during application by drift and by run-off | | Fwater,spray | 0.3 | [-] |
| Water volume under bridge | | Vwater | 1000 | [m²] |
| **Outputs - in situ application by spray - Bridge scenario - 200 g.m-2** | | | | |
| **Emission of substance to water after application – E water [kg.d-1]** | | | | |
| Propiconazole | 1.80E-03 | | | |
| Tebuconazole | 3.00E-04 | | | |
| Cypermethrin | 1.26E-03 | | | |
| IPBC | 3.00E-04 | | | |
| PBC | 1.66E-04 | | | |

##### In situ treated wood in-service - X6119M2

**NOISE BARRIER – treated wood in-service – in situ application**

|  |  |  |
| --- | --- | --- |
| **Symbol** | **Value** | **Unit** |
| **Inputs** | | |
| Application | *In situ application* | [-] |
| AREA noise-barrier | 3000 | [m²] |
| TIME1 | 30 | [d] |
| TIME2 | 1825 | [d] |
| Q\*leach,TIME1 | See leaching values above | [mg.m-2] |
| Q\*leach,TIME2 | [mg.m-2] |
| DT50 soil | See Table 2.2‑1 | [d-1] |
| V soil | 250 | [m3] |
| RHO soil | 1700 | [kgwwt.m-3] |
| F SOIL | 0.3 | [-] |
| F STP | 0.7 | [-] |
| **Outputs** | | |
| ***Direct emissions to soil*** | | |
|  | **Qleach, TIME1 (30d) [kg]** | **Qleach, TIME2 (5y)  [kg]** |
| Propiconazole | 4.40E-02 | 1.26E-01 |
| Tebuconazole | 1.48E-02 | 4.08E-02 |
| Cypermethrin | 1.26E-02 | 1.62E-02 |
| IPBC | 1.79E-02 | 3.46E-02 |
| PBC | 9.90E-03 | 1.91E-02 |
| 1,2,4-triazole | 4.12E-03 | 1.18E-02 |
| ***Emissions to STP*** | | |
|  | **ESTP TIME1 (30d) [kg.d-1]** | **ESTP TIME2 (5y)  [kg.d-1]** |
| Propiconazole | 3.42E-03 | 1.61E-04 |
| Tebuconazole | 1.15E-03 | 5.22E-05 |
| Cypermethrin | 9.80E-04 | 2.07E-05 |
| IPBC | 1.39E-03 | 4.42E-05 |
| PBC | 7.70E-04 | 2.44E-05 |
| 1,2,4-triazole | 3.20E-04 | 1.50E-05 |

**HOUSE – treated wood in-service – in situ application**

|  |  |  |
| --- | --- | --- |
| **Symbol** | **Value** | **Unit** |
| **Inputs** | | |
| Application | *In situ application* | [-] |
| AREA house | 125 | [m²] |
| TIME1 | 30 | [d] |
| TIME2 | 1825 | [d] |
| Q\*leach,TIME1 | See leaching values above | [mg.m-2] |
| Q\*leach,TIME2 | [mg.m-2] |
| DT50 soil | See Table 2.2‑1 | [d-1] |
| V soil | 13 | [m3] |
| RHO soil | 1700 | [kgwwt.m-3] |
| **Outputs** | | |
|  | **Qleach, TIME1(30d) [kg]** | **Qleach, TIME2 (5y)  [kg]** |
| Propiconazole | 6.11E-03 | 1.75E-02 |
| Tebuconazole | 2.05E-03 | 5.67E-03 |
| Cypermethrin | 1.75E-03 | 2.25E-03 |
| IPBC | 2.49E-03 | 4.80E-03 |
| PBC | 1.38E-03 | 2.65E-03 |
| 1,2,4-triazole | 5.72E-04 | 1.63E-03 |

**BRIDGE OVER POND – treated wood in-service – in situ application**

|  |  |  |
| --- | --- | --- |
| **Symbol** | **Value** | **Unit** |
| **Inputs** | | |
| Application | *In situ application* | [-] |
| AREA bridge | 10 | [m²] |
| TIME1 | 30 | [d] |
| TIME2 | 5475 | [d] |
| Q\*leach,TIME1 | See leaching values above | [mg.m-2] |
| Q\*leach,TIME2 | [mg.m-2] |
| DT50 soil | See Table 2.2‑1 | [d-1] |
| V water | 1 000 | [m3] |
| **Outputs** | | |
| ***Direct emissions to water*** | | |
|  | **Qleach, TIME1 (30d) [kg]** | **Qleach, TIME2 (5y)  [kg]** |
| Propiconazole | 4.89E-04 | 1.40E-03 |
| Tebuconazole | 1.64E-04 | 4.53E-04 |
| Cypermethrin | 1.40E-04 | 1.80E-04 |
| IPBC | 1.99E-04 | 3.84E-04 |
| PBC | 1.10E-04 | 2.12E-04 |
| 1,2,4-triazole | 4.58E-05 | 1.31E-04 |

##### Meta SPC 4: Emissions to the environment for the representative product : X6236

Meta SPC 3: In situ brushing and spraying by professionals and non-professionals - Use class 3

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

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

* Brushing (House scenario according to ESD 4.2.4.1 for the soil compartment and groundwater (pore water) and Bridge over pond for the surface water and sediment, ESD 4.2.4.3)
* Spraying (House scenario for outdoor spraying, ESD 4.4.5)

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

* House – ESD 4.3.3.1 (groundwater according to FOCUS/PEARL)
* Bridge over Pond – ESD 4.3.3.4
* Noise barrier

##### Meta SPC 4: Calculation of leaching rates from the semi-field leaching study (X6236)

The leaching values used in the calculation of emissions are derived from the leaching study results. The study has been carried out with the X6236 product during 457 days and from a surface application. The results of the semi-field study were recalculated by FR-CA by expressing the leaching in losses per mm rain incident on the panels for the standard rain year, instead of time, as the variability with time is of secondary interest due to the natural variability of rainfall. The results are presented over calendar years and over standard rain years (700 mm rain, in 365 days, *i.e.* 1.92 mm rain per day).

The applicant performed leaching study using the product without topcoat.

For each active substance and to estimation the Q\*leach, time, the best goodness of the fit (with the r² value closest to 1) is obtained by fitting the cumulative quantities leached versus cumulative rain fall plot using a linear regression:

Q\*leach,time = a\*mm + b

Q\*leach, time values are calculated for:

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

It worth noting that the limit of quantification for IPBC and for Cypermethrin is 0.02 µg.ml-1 instead of 0.01 µg.ml-1 (as indicated by the registrant). This value was used as input for the leaching estimation.

The leaching values obtained from an application by brushing at 304.8 g.m-² without topcoat have been normalized for an application dose of 200 g.m-2 and to 700 mm of rainfall per year for each active substance are summarized in the following table:

Table 2.2‑9 Leaching values obtained from surface application at 200 g/m² without topcoat (X6236)

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Equations used for calculations** | **Q\*leach [mg.m-2]** | |
| **TIME 1 (30d)** | **TIME 2 (5y)**  ***In situ*** |
| Propiconazole | Q\*leach = 0.0406 \* mm + 65.025 **(r² = 0.99)** | 44.20 | 128 |
| Tebuconazole | Q\*leach = 0.0126 \* mm + 25.634 **(r² = 0.99)** | 17.30 | 45.76 |
| Cypermethrin | Q\*leach = 0.0016 \* mm + 18.066 **(r² = 0.97)** | 11.91 | 15.51 |
| IPBC | Q\*leach = 0.0071 \* mm + 32.994 **(r² = 0.98)** | 21.92 | 37.96 |

Moreover IPBC is rapidly degraded in water with a DT50 of 3.1 h at 12°C and in soil with a DT50 of 4.7 h at 12°C. Therefore, emissions of PBC (degradation product of IPBC) are also calculated assuming 100% of formation fraction of IPBC to PBC at time 0, using the ratio between the molar mass of PBC and IPBC of 0.552 in water and in soil.

The assessment of 1,2,4-triazole was proposed only for emission to soil. The emission calculation for the metabolite takes into account the maximal formation fraction of the substances in soil (9% and 43.23% for tebuconazole and propiconazole respectively, as defined for the approval of these substances) and the molar mass of each component.

An assessment of PBC in water and in soil and an assessment of 1,2,4-triazole in soil are also proposed.

Table 2.2‑10 Relevant metabolites - Leaching values obtained from surface application at 200 g/m² without topcoat (X6236)

|  |  |  |
| --- | --- | --- |
|  | **Q\*leach [mg.m-2]** | |
| **TIME 1 (30d)** | **TIME2 (5y)**  ***In situ*** |
| **Equations:**  Q\*leach, time1  = ( Q\*leach time 1/time2 \* DEGrate \* Molar mass metabolite/Molar mass parent) | | |
| 1,2,4-triazole | 4.19 | 12.04 |
| PBC | 12.10 | 20.96 |

The relevant environmental compartments for each substance and identified metabolites are specified in the table below (X6236):

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Phase | STP | Surface water | | Sediment | | Soil | | Groundwater | | Secondary Poisoning |
| Direct Release | *Via* STP | Direct Release | *Via* STP | Direct Release | *Via* STP | Direct Release | *Via* STP |
| Propiconazole | Y | Y | Y | Y | Y | Y | Y | Y | Y | N |
| Tebuconazole | Y | Y | Y | Y | Y | Y | Y | Y | Y | N |
| Cypermethrin | Y | Y | Y | Y | Y | Y | Y | N | N | Y |
| IPBC | Y | Y | N | N | N | Y | N | Y | N | N |
| PBC | Y | Y | Y | Y | Y | Y | Y | Y | Y | N |
| 1,2,4-triazole | N | N | N | N | N | Y | N | Y | Y | N |

##### Meta SPC 3: Estimation of emissions - In-situ application (X6236)

FR-CA agrees with the registrant’s inputs used for the estimation of releases from *in situ* brush and spray application of the product according to the “house” scenario described in the PT08-ESD, except for the input “content of active substance in the product”, expressed in pure active substance instead of technical active substance. For the risk assessment, the technical active substance content has to be considered.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Expression of the active substance’s content | Cypermethrin | Tebuconazole | Propiconazole | IPBC |
| Pure (%w/w) | 0.10 | 0.05 | 0.15 | 0.05 |
| Technical (%w/w) | 0.21 | 0.05 | 0.30 | 0.05 |

According to the technical Agreements for Biocides (June 2016), the house-scenario is the worst case scenario and would therefore be sufficient. Consequently, the fence scenario has been deleted.

An assessment of PBC in water and in soil and an assessment of 1,2,4-triazole in soil are proposed (see above).

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

Emission from in-situ brushing application (X6236)

|  |  |  |
| --- | --- | --- |
| **Outputs - House scenario – in situ brush application - 200 g.m-2** | | |
|  | Professional | Non professional |
| **Emission of substance to soil – E soil [kg.d-1]** | | |
| Propiconazole | 2.25E-03 | 3.75E-03 |
| Tebuconazole | 3.75E-04 | 6.25E-04 |
| Cypermethrin | 1.58E-03 | 2.63E-03 |
| IPBC | 3.75E-04 | 6.25E-04 |
| PBC | 2.07E-04 | 3.45E-04 |
| 1,2,4-triazole | 2.04E-04 | 3.40E-04 |
| **Outputs - Bridge scenario - in situ brush application - 200 g.m-2** | | |
| **Emission of substance to water – E water [kg.d-1]** | | |
|  | Professional | Non professional |
| Propiconazole | 1.80E-04 | 3.00E-04 |
| Tebuconazole | 3.00E-05 | 5.00E-05 |
| Cypermethrin | 1.26E-04 | 2.10E-04 |
| IPBC | 3.00E-05 | 5.00E-05 |
| PBC | 1.66E-05 | 2.76E-05 |

Emissions from in-situ spraying application (X6236)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Outputs- House scenario – in situ spray application - 200 g.m-2** | | | | |
| **Emission of substance to soil after application (run-off) – E soil [kg.d-1]** | | | | |
| Propiconazole | | 1.50E-02 | | |
| Tebuconazole | | 2.50E-03 | | |
| Cypermethrin | | 1.05E-02 | | |
| IPBC | | 2.50E-03 | | |
| PBC | | 1.38E-03 | | |
| 1,2,4-triazole | | 1.36E-03 | | |
| **Emission of substance to soil after application (drift Tier 1) – E soil [kg.d-1]** | | | | |
| Propiconazole | | 7.50E-03 | | |
| Tebuconazole | | 1.25E-03 | | |
| Cypermethrin | | 5.25E-03 | | |
| IPBC | | 1.25E-03 | | |
| PBC | | 6.90E-04 | | |
| 1,2,4-triazole | | 6.80E-04 | | |
| **Emission of substance to soil after application (drift Tier 2) – E soil [kg.d-1]** | | | | |
| Propiconazole | | 2.48E-03 | | |
| Tebuconazole | | 4.13E-04 | | |
| Cypermethrin | | 1.73E-03 | | |
| IPBC | | 4.13E-04 | | |
| PBC | | 2.28E-04 | | |
| 1,2,4-triazole | | 2.24E-04 | | |
| **Inputs: Bridge scenario** | | | | |
| **Parameter/variable** | **Symbol** | | **Value** | **Unit** |
| Treated wood area | AREAbridge | | 10 | [m².d-1] |
| Application rate of the product | Qapplic.product | | 0.2 | [L.m-2] |
| Content of the active substances | fai | | See above | [-] |
| Density of the product | RHOproduct | | 1000 | [kg.m-3] |
| Fraction of product lost to water during application by drift and by run-off | Fwater,spray | | 0.3 | [-] |
| Water volume under bridge | Vwater | | 1000 | [m²] |
| **Outputs - Bridge scenario – in situ spray application - 200 g.m-2** | | | | |
| **Emission of substance to water after application – E water,bridge [kg.d-1]** | | | | |
| Propiconazole | | 1.80E-03 | | |
| Tebuconazole | | 3.00E-04 | | |
| Cypermethrin | | 1.26E-03 | | |
| IPBC | | 3.00E-04 | | |
| PBC | | 1.66E-04 | | |

Emissions from in situ treated wood in-service

**NOISE BARRIER – Wood in service**

|  |  |  |  |
| --- | --- | --- | --- |
| **Symbol** | **Value** | | **Unit** |
| ***Inputs*** | | | |
| Application | *In situ application* | | [-] |
| AREA noise-barrier | 3000 | | [m²] |
| TIME1 | 30 | | [d] |
| TIME2 | 1825 | | [d] |
| Q\*leach,TIME1 | See leaching values above | | [mg.m-2] |
| Q\*leach,TIME2 | [mg.m-2] |
| DT50 soil | See Table 2.2‑1 | | [d-1] |
| V soil | 250 | | [m3] |
| RHO soil | 1700 | | [kgwwt.m-3] |
| F SOIL | 0.3 | | [-] |
| F STP | 0.7 | | [-] |
| **Outputs** | | | |
| ***Direct emissions to soil*** | | | |
|  | **Qleach, TIME1 (30d) [kg]** | **Qleach, TIME2 (5y)  [kg]** | |
| Propiconazole | 3.98E-02 | 1.15E-01 | |
| Tebuconazole | 1.56E-02 | 4.12E-02 | |
| Cypermethrin | 1.07E-02 | 1.40E-02 | |
| IPBC | 1.97E-02 | 3.42E-02 | |
| PBC | 1.09E-02 | 1.89E-02 | |
| 1,2,4-triazole | 3.77E-03 | 1.08E-02 | |
| ***Emissions to STP*** | | | |
|  | **ESTP TIME1 (30d) [kg.d-1]** | **ESTP TIME2 (5y)  [ kg.d-1]** | |
| Propiconazole | 3.09E-03 | 1.47E-04 | |
| Tebuconazole | 1.21E-03 | 5.27E-05 | |
| Cypermethrin | 8.34E-04 | 1.78E-05 | |
| IPBC | 1.53E-03 | 4.37E-05 | |
| PBC | 8.47E-04 | 2.41E-05 | |
| 1,2,4-triazole | 2.93E-04 | 1.39E-05 | |

**HOUSE – Wood in service**

|  |  |  |
| --- | --- | --- |
| **Symbol** | **Value** | **Unit** |
| ***Inputs*** | | |
| Application | *In situ application* | [-] |
| AREA house | 125 | [m²] |
| TIME1 | 30 | [d] |
| TIME2 | 1825 | [d] |
| Q\*leach,TIME1 | See leaching values above | [mg.m-2] |
| Q\*leach,TIME2 | [mg.m-2] |
| DT50 soil | See Table 2.2‑1 | [d-1] |
| V soil | 13 | [m3] |
| RHO soil | 1700 | [kgwwt.m-3] |
| **Outputs** | | |
|  | **Qleach, TIME1(30d) [kg]** | **Qleach, TIME2 (5y)  [kg]** |
| Propiconazole | 5.53E-03 | 1.60E-02 |
| Tebuconazole | 2.16E-03 | 5.72E-03 |
| Cypermethrin | 1.49E-03 | 1.94E-03 |
| IPBC | 2.74E-03 | 4.74E-03 |
| PBC | 1.51E-03 | 2.62E-03 |
| 1,2,4-triazole | 5.23E-04 | 1.50E-03 |

**BRIDGE OVER POND –Wood in service**

|  |  |  |
| --- | --- | --- |
| **Symbol** | **Value** | **Unit** |
| ***Inputs*** | | |
| Application | *In situ application* | [-] |
| AREA bridge | 10 | [m²] |
| TIME1 | 30 | [d] |
| TIME2 | 5475 | [d] |
| Q\*leach,TIME1 | See leaching values above | [mg.m-2] |
| Q\*leach,TIME2 | [mg.m-2] |
| DT50 soil | See Table 2.2‑1 | [d-1] |
| V water | 1 000 | [m3] |
| **Outputs** | | |
| ***Direct emissions to water*** | | |
|  | **Qleach, TIME1 (30d) [kg]** | **Qleach, TIME2 (5y)  [kg]** |
| Propiconazole | 4.42E-04 | 1.28E-03 |
| Tebuconazole | 1.73E-04 | 4.58E-04 |
| Cypermethrin | 1.19E-04 | 1.55E-04 |
| IPBC | 2.19E-04 | 3.80E-04 |
| PBC | 1.21E-04 | 2.10E-04 |
| 1,2,4-triazole | 4.19E-05 | 1.20E-04 |

#### PECs for the relevant product : X6119C

##### PEC in the aquatic compartment (including sediment): X6119C

Direct emissions during service life - Bridge over the pond scenario after industrial surface application

The emissions in local water were calculated for the service life of treated wood phase.

Concentrations were calculated over the assessment periods (*i.e.* 30 days for TIME1 and 5475 days for the TIME2), with the dissipation half-life from water (DT50water) of each active substance in order to take into account degradation and adsorption processes (c.f. Table 2.2‑1) using equations 3.16 and 3.17 for static water bodies.

Concentrations in sediment were calculated using the degradation half-life of each active substances (eq. 3.16 and 3.17) in the whole water-sediment system (DT50whole system), and the partition coefficient organic carbon-water (Koc).

|  |  |  |
| --- | --- | --- |
| **Bridge over the pond – Wood in service - PEC local surface water** | | |
|  | **TWA over the TIME 1 assessment period (30 days)**  **[µg.l-1]** | **TWA over the TIME 2 assessment period (15 years)**  **[µg.l-1]** |
| Propiconazole | 9.59E-02 | 6.05E-03 |
| Tebuconazole | 5.20E-02 | 7.56E-03 |
| Cypermethrin | 7.98E-05 | 2.63E-05 |
| IPBC | 8.67E-04 | 1.45E-05 |
| PBC | 3.15E-02 | 1.93E-03 |
| **Bridge over the pond – Wood in service - PEC local sediment** | | |
|  | **TIME 1 assessment period (30 days)**  **[mg.kg-1wwt]** | **TIME 2 assessment period**  **(15 years)**  **[mg.kg-1wwt]** |
| Propiconazole | 3.35E-03 | 9.04E-03 |
| Tebuconazole | 1.31E-03 | 7.46E-04 |
| Cypermethrin | 8.13E-03 | 6.37E-03 |
| PBC | 1.60E-04 | 9.87E-06 |

Indirect emissions via the STP - Noise barrier scenario

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

|  |  |  |
| --- | --- | --- |
| **NOISE BARRIER – Wood in service - PECSTP** | | |
|  | **TIME1**  **[mg.l-1]** | **TIME2**  **[mg.l-1]** |
| Propiconazole | 9.97E-04 | 3.31E-05 |
| Tebuconazole | 3.78E-04 | 1.15E-05 |
| Cypermethrin | 5.86E-07 | 1.84E-07 |
| IPBC | 4.74E-04 | 7.90E-06 |
| PBC | 2.63E-04 | 4.38E-04 |

Indirect emissions to surface water and sediment via the STP were calculated according to the equations 45 and 50 of the ECHA Guidance Vol.IV, par B (2015).

|  |  |  |
| --- | --- | --- |
| **NOISE BARRIER – Wood in service - PECwater\_via\_STP** | | |
|  | **TIME1**  **[µg.l-1]** | **TIME2**  **[µg.l-1]** |
| Propiconazole | 9.96E-02 | 3.31E-03 |
| Tebuconazole | 3.78E-02 | 1.15E-03 |
| Cypermethrin | 3.15E-05 | 9.89E-06 |
| IPBC | 4.74E-02 | 7.90E-04 |
| PBC | 2.63E-02 | 4.38E-04 |
| **NOISE BARRIER – Wood in service - PECsediment\_via\_STP** | | |
|  | **TIME1**  [**mg.kg-1wwt**] | **TIME2**  [**mg.kg-1wwt**] |
| Propiconazole | 2.12E-03 | 7.05E-05 |
| Tebuconazole | 8.45E-04 | 2.57E-05 |
| Cypermethrin | 3.93E-04 | 1.24E-04 |
| PBC | 1.34E-04 | 2.23E-06 |

PEC in the aquatic compartment for iodine (transformation product from IPBC)

The environmental risk assessment for iodine was carried out only for the worst case scenarios (highest IPBC output value for Estp time 1). The used molar fraction of iodine from IPBC is 0.451. Further it is assumed that all iodine is transformed either to iodide or iodate. The molar fraction between iodine and iodide is 1 and between iodine and iodate is 1.38.

ESTP, iodine, Time 1 = ESTP, IPBC, Time 1 \* 0.451 \* 80% = 4.44E-04 kg.d-1

With ESTP, IPBC = 9.85E-04 kg.d-1 (Noise barrier, wood in service, 30 days). According to the CAR for iodine (2013) only 80% of the emission *via* STP is discharged to the surface water.

PEC STP, iodine = 1.78E-04 mg.L-1

PEC surface water, iodine = = 1.77E-05 mg.L-1

PEC surface water, iodide = PEC surface water, iodine \* 1 = 1.77E-05 mg.L-1

PEC surface water, iodiate = PEC surface water, Iodine \* 1.38 = 2.45E-05 mg.L-1

The sediment compartment is not relevant (cover by surface water).

##### PEC in air: X6119C

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

IPBC

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

Propiconazole and tebuconazole:

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

Cypermethrin:

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

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

##### PEC in the soil compartment - X6119C

Direct emissions to soil - Service life of treated wood

Twa concentrations are calculated (with eq. 3.7 and 3.8 of the PT08 ESD) taking into account the degradation process with the half-life in soil (DT50soil).

|  |  |  |
| --- | --- | --- |
| **House – Wood in service - PEC LOCAL SOIL** | | |
|  | **TWA concentration**  **TIME1**  **[mg.kg-1wwt]** | **TWA concentration**  **TIME2**  **[mg.kg-1wwt]** |
| Propiconazole | 8.24E-02 | 2.64E-02 |
| Tebuconazole | 3.15E-02 | 8.81E-03 |
| Cypermethrin | 3.59E-04 | 2.71E-04 |
| IPBC | 7.43E-04 | 1.25E-05 |
| PBC | 1.19E-02 | 3.78E-04 |
| 1,2,4-triazole | 7.98E-03 | 3.46E-03 |
| **Noise barrier – Wood in service (direct release) - PEC LOCAL SOIL** | | |
|  | **TWA concentration**  **TIME1**  **[mg.kg-1wwt]** | **TWA concentration**  **TIME2**  **[mg.kg-1wwt]** |
| Propiconazole | 3.09E-02 | 9.87E-03 |
| Tebuconazole | 1.18E-02 | 3.30E-03 |
| Cypermethrin | 1.35E-04 | 1.01E-04 |
| IPBC | 2.78E-04 | 4.70E-06 |
| PBC | 4.47E-03 | 1.42E-04 |
| 1,2,4-triazole | 2.99E-03 | 1.29E-03 |

Indirect emissions to soil (via the STP) - Noise barrier scenario

Indirect emissions to soil via spreading of STP sludge onto soil were used to calculate concentrations in soil according to the equations of the ECHA Guidance Vol.IV, par B (2015), with the following inputs.

|  |  |  |
| --- | --- | --- |
| **Noise barrier - Wood-in-service only - PEC LOCAL SOIL via STP** | | |
|  | **TIME1**  **[mg.kg-1wwt]** | **TIME 2**  **[mg.kg-1wwt]** |
| Propiconazole | 3.81E-04 | 1.26E-05 |
| Tebuconazole | 1.57E-04 | 4.77E-06 |
| Cypermethrin | 1.26E-05 | 3.95E-06 |
| PBC | 9.86E-06 | 1.64E-07 |

PEC in the terrestrial compartment for iodine (transformation product from IPBC)

The environmental risk assessment for iodine was carried out only for the worst case scenarios = PEC soil, IPBC of 2.42E-01 mg.kgwwt-1 (House scenario, direct emission to soil, estimation without degradation, 15 years). The used molar fraction of iodine and IPBC is 0.451. Further it is assumed that all iodine is transformed either to iodide or iodate. The molar fraction between iodine and iodide is 1 and between iodine and iodate is 1.38.

PEC soil, iodine = PEC soil, IPBC \* 0.451 = 1.09E-01 mg.kgwwt-1

PEC soil, iodide = PEC soil, Iodine \* 1 = 1.09E-01 mg.kgwwt-1

PEC soil, iodate = PEC soil, Iodine \* 1.38 = 1.51E-01 mg.kgwwt-1

##### PECs for the groundwater compartment: X6119C

The estimations of releases of active substances, and their relevant degradation products to the groundwater compartment, were calculated with the FOCUS PEARL v.4.4.4 software.

According to the paragraph 578 of the PT08-ESD (2013), the estimation of releases to groundwater is relevant for susbstance with:

* Koc < 500 l.kg-1 and
* DT50soil > 21 d**.**

Considering that:

|  |  |  |  |
| --- | --- | --- | --- |
| **Substance** | **Koc [l.kg-1]** | **DT50soil,12°C [d]** | |
| Tebuconazole | 992 | 77 | |
| Propiconazole | 944 | 82 | |
| 1,2,4-triazole (\*) | 89 | 114.7 (\*\*) | |
| Cypermethrin | 575000 | 17.2 | |
| IPBC | 134.5 | 1.96E-01 | |
| PBC(\*\*\*) | 198.1 | 9.50 | |
| (\*) – Relevant degradation product of tebuconazole and propiconazole in soil, with a maximum formation fration of 9% and 43.23% of applied radioactivity, respectively.  (\*\*) – Calculated according to the arrhenius equation with a DT50 at 20°C of 60.5 days.  (\*\*\*) – Relevant metabolite of IPBC in all environmental compartments assuming 100% of applied radioactivity. | | |

Estimations of releases to groundwater is considered relevant by FR-CA for the following substances:

* Tebuconazole;
* Propiconazole;
* IPBC;
* PBC;
* 1,2,4-triazole.

According to the PT08-ESD (2013), a groundwater assessment is only necessary for the house scenario, which can be considered to be the worst case for soil exposure, thus covering all other scenarios. Emissions into the soil during the service-life of the treated wood due to leaching are taken into account to estimate the contamination of the groundwater.

The scenario for the groundwater exposure assessment for wood preservatives described in the supplement of the appendix 4 of the PT08-ESD, based on leaching values.

| **Input parameter** | **Unit** | **Value** | | | | |
| --- | --- | --- | --- | --- | --- | --- |
|  | | **Tebuco-nazole** | **Propico-nazole** | **IPBC** | **PBC** | **1,2,4-triazole** |
| **Physicochemical parameters** | | | | | | |
| Molar mass | g.mol-1 | 307.8 | 342.2 | 281.1 | 155.2 | 69.1 |
| Water solubility (25 °C) | mg.l-1 | 29 | 100 | 168 | 2860 | 700 000 |
| Molar enthalpy of dissolution | kJ.mol-1 | 27 | | | | |
| Saturated vapour pressure | Pa | 1.70E-06 (20°C) | 5.60E-05  (25°C) | 2.36E-03  (25°C) | 1.88E+01  (25°C) | 2.20E-01  (20°C) |
| Molar enthalpy of vaporisation | kJ.mol-1 | 95 | | | | |
| Diffusion coefficient in water (20 °C) | m².d-1 | 4.3E-05 | | | | |
| Diffusion coefficient in air (20 °C) | m².d-1 | 0.43 | | | | |
| **Degradation parameters** | | | | | | |
| Half-life (12°C, pF2) | d | 77 | 82 | 1.96E-01 | 9.50 | 114.7 |
| Arrhenius activation energy | kJ.mol-1 | 65.4 | | | | |
| Exponent of moisture correction function | - | 0.7 | | | | |
| **Sorption parameters** | | | | | | |
| Koc value | l.kg-1 | 992 | 944 | 134.5 | 198.1 | 89 |
| Komvalue (20°C) | ml.g-1 | 575.41 | 547.56 | 78.02 | 114.91 | 51.62 |
| Freundlich exponent 1/n | - | 1 | | | | |
| Method of subroutine description | - | pH independent | | | | |
| **Crop related parameters** | | | | | | |
| Crop uptake factor | - | 0 | | | | |
| **Application Schemes** | | | | | | |
| Q\*leach, TIME2  (15 years) | kg.m-2 | 6.75E-05 | 1.92E-04 | 4.28E-05 | n.r. | n.r. |
| Total leachable area | m².ha-1 | 2 000 | | | | |
| Fraction of house surface exposed to weather | - | 0.5 | | | | |
| Service life | year | 5 | | | | |
| Number of application per year | - | 10 | | | | |
| Dosage per FOCUS application | kg.ha-1.applicaton-1 | 1.35E-03 | 3.84E-03 | 8.56E-04 | n.r. | n.r. |
| Fraction transformed | - | n.r. | n.r. | n.r. | 1  (IPBC) | 0.09 (Tebuconazole) 0.43  (Propiconazole) |
| Application type | - | To the soil surface | | | | |
| Repeat interval for years | - | 1 | | | | |
| Date | - | 10/01/1901 | | | | |
| 15/02/1901 | | | | |
| 24/03/1901 | | | | |
| 29/04/1901 | | | | |
| 05/06/1901 | | | | |
| 11/07/1901 | | | | |
| 17/08/1901 | | | | |
| 22/09/1901 | | | | |
| 29/10/1901 | | | | |
| 04/12/1901 | | | | |
| **Crops Application** | | | | | | |
| Crop(s) | - | Grassland | | | | |
| Selected Locations | | CHATEAUDUN | | | | |
| HAMBURG | | | | |
| JOIKIONEN | | | | |
| KREMSMUENSTER | | | | |
| OKEHAMPTON | | | | |
| PIACENZA | | | | |
| PORTO | | | | |
| SEVILLA | | | | |
| THIVA | | | | |

n.r.: not relevant

The results are listed in the table below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **Tebuconazole [µg.l-1]** | **Propiconazole [µg.l-1]** | **1,2,4-triazole (\*) [µg.l-1]** | **IPBC**  **[µg.l-1]** | **PBC**  **[µg.l-1]** |
| CHATEAUDUN | < 0.001 | < 0.001 | 0.057 | < 0.001 | < 0.001 |
| HAMBURG | < 0.001 | < 0.001 | 0.097 | < 0.001 | < 0.001 |
| JOIKIONEN | < 0.001 | < 0.001 | 0.078 | < 0.001 | < 0.001 |
| KREMSMUENSTER | < 0.001 | < 0.001 | 0.062 | < 0.001 | < 0.001 |
| OKEHAMPTON | < 0.001 | < 0.001 | 0.079 | < 0.001 | < 0.001 |
| PIACENZA | < 0.001 | < 0.001 | 0.060 | < 0.001 | < 0.001 |
| PORTO | < 0.001 | < 0.001 | 0.047 | < 0.001 | < 0.001 |
| SEVILLA | < 0.001 | < 0.001 | 0.026 | < 0.001 | < 0.001 |
| THIVA | < 0.001 | < 0.001 | 0.031 | < 0.001 | < 0.001 |

\* sum of the concentrations from tebuconazole and propiconazole modellings

##### Secondary poisoning: X6119C

FR-CA considers that secondary poisoning is relevant only for the active substance cypermethrin.

For the aquatic food chain**,** the scenario “direct emissions during service life - Bridge over the pond scenario after industrial application” is taken into account with a Clocalwater,TWA\_TIME1 of 7.98E-05 µg.L-1.

For the terrestrial food chain, the scenario “Direct emissions to soil – House - Service life of treated wood” is taken into account with a Clocalsoil,TWA\_TIME1 of 3.59E-04 mg.kg-1wwt.

In accordance with the equations of the ECHA guidance vol.IV, part B (2015), PECoral,predator for both food chain were calculated as followed:

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter / variable** | **Symbol** | **Unit** | **Value** |
| ***Aquatic food chain:*** | | | |
| Predicted environmental concentration during episode | PEClocal,water | [mg.l-1] | 7.98E-08 |
| Bioconcentration factor for fish on wet weight basis | BCFfish | [l.kg-1wet fish] | 417 |
| Biomagnification factor in fish | BMF | [-] | 2 |
| **Predicted environmental concentration in food (considering that predators feed at 50% on local level)** | **PECoral,predator** | **[mg.kg-1wet fish]** | **3.33E-05** |
| ***Terrestrial food chain :*** |  |  |  |
| log of partition coefficient n-octanol-water | Log Kow | [-] | 5.45 |
| Bioconcentration factor for earthworm on wet weight basis | BCFearthworm | [l.kg-1wet earthworm] | 3.38E+03 |
| Concentration in porewater | Cporewater | [mg.l-1] | 2.14E-05 |
| Concentration in soil | Csoil | [mg.kg-1wwt] | 3.59E-04 |
| Fraction of gut loading in worm | Fgut | [kgdwt.kg-1wwt] | 0.1 |
| Conversion factor for soil concentration wet-dry weight soil | CONVsoil | [kgwwt.kg-1dwt] | 1.13 |
| **Predicted environmental concentration in food (considering that predators feed at 50% on local level)** | **PECoral,predator** | **[mg.kg-1wet earthworm]** | **1.38E-05** |

#### PECs for the relevant product : X6119M2

##### PEC in the aquatic compartment (including sediment): X6119M2

Direct emission to the aquatic compartment - Bridge over the pond scenario

The emissions in local water were calculated for the outdoor application phase at the application rate of 200 g product/m² of wood , and in for the service life of treated wood phas e.

The initial concentrations in water were defined on the day of application for the application phase (PT08-ESD eq. 4.42). For service-life, concentrations were calculated over the assessment periods (*i.e.* 30 days for TIME1 and 1825 days for the TIME2), with the dissipation half-life from water (DT50water) of each active substance in order to take into account degradation and adsorption processes (c.f. Table 2.2‑1) using equations 3.16 and 3.17 for static water bodies. Application and service-life were calculated separately.

The concentrations in sediment were calculated using the equation 50 of the ECHA GUIDANCE vol.IV,Part B (2015). For service-life, concentrations in local water were calculated using the degradation half-life of each active substances (eq. 3.16 and 3.17) in the whole water-sediment system (DT50whole system), and the partition coefficient organic carbon-water (Koc).

Application Phase - Bridge over the pond

|  |  |  |
| --- | --- | --- |
| **Application - Bridge over the pond - Treatment by brushing** | | |
|  | Professional | Non-professional |
| **PEC local surface water, initial concentration after application** [µg.l-1] | | |
| Propiconazole | 1.80E-01 | 3.00E-01 |
| Tebuconazole | 3.00E-02 | 5.00E-02 |
| Cypermethrin | 1.26E-01 | 2.10E-01 |
| IPBC | 3.00E-02 | 5.00E-02 |
| PBC | 1.66E-02 | 2.76E-02 |
| **PEC local sediment after application** [mg.kg-1wwt] | | |
| Propiconazole | 3.83E-03 | 6.39E-03 |
| Tebuconazole | 6.70E-04 | 1.12E-03 |
| Cypermethrin | 1.58E+00 | 2.63E+00 |
| PBC | 8.43E-05 | 1.40E-04 |
| **Application - Bridge over the pond - Treatment by spraying** | | |
| **PEC local surface water, initial concentration after application** [µg.l-1] | | |
| Propiconazole | 1.80E+00 | |
| Tebuconazole | 3.00E-01 | |
| Cypermethrin | 1.26E+00 | |
| IPBC | 3.00E-01 | |
| PBC | 1.66E-01 | |
| **PEC local sediment after application** [mg.kg-1wwt] | | |
| Propiconazole | 3.83E-02 | |
| Tebuconazole | 6.70E-03 | |
| Cypermethrin | 1.58E+01 | |
| PBC | 8.43E-04 | |

Service life - Bridge over the pond

|  |  |  |
| --- | --- | --- |
| **PEC local surface water** | | |
|  | TWA over the TIME 1 assessment period (30 days)  [µg.l-1] | TWA over the TIME 2 assessment period [µg.l-1] |
| Propiconazole | 1.48E-01 | 1.31E-02 |
| Tebuconazole | 7.04E-02 | 1.49E-02 |
| Cypermethrin | 6.10E-03 | 1.35E-04 |
| IPBC | 1.23E-03 | 3.91E-05 |
| PBC | 4.46E-02 | 5.10E-03 |
| **PEC local sediment** | | |
|  | TWA over the TIME 1 assessment period (30 days)  [mg.kg-1wwt] | TWA over the TIME 2 assessment period [mg.kg-1wwt] |
| Propiconazole | 5.18E-03 | 1.08E-02 |
| Tebuconazole | 1.77E-03 | 1.34E-03 |
| Cypermethrin | 6.22E-01 | 3.24E-02 |
| PBC | 2.27E-04 | 2.61E-05 |

Indirect emissions via the STP - Noise barrier scenario

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

|  |  |  |
| --- | --- | --- |
| Outputs: | | |
| **PECSTP** | | |
|  | **TIME1**  [mg.l-1] | **TIME2**  [mg.l-1] |
| Tebuconazole | 5.12E-04 | 2.32E-05 |
| Propiconazole | 1.54E-03 | 7.24E-05 |
| Cypermethrin | 4.48E-05 | 9.48E-07 |
| IPBC | 6.72E-04 | 2.13E-05 |
| PBC | 3.72E-04 | 1.18E-05 |

Indirect emissions to surface water and sediment via the STP were calculated according to the equations 45 and 50 of the ECHA Guidance Vol.IV, par B (2015).

|  |  |  |
| --- | --- | --- |
| **Wood-in-service – Noise barrier - Treated wood in service only** | | |
| **PECwater\_via\_STP** | | |
|  | **TIME1**  [µg.l-1] | **TIME2**  [µg.l-1] |
| Tebuconazole | 5.11E-02 | 2.32E-03 |
| Propiconazole | 1.54E-01 | 7.23E-03 |
| Cypermethrin | 2.41E-03 | 5.09E-05 |
| IPBC | 6.71E-02 | 2.13E-03 |
| PBC | 3.72E-02 | 1.18E-03 |
| **PECsediment\_via\_STP** | | |
|  | **TIME1**  [**mg.kg-1wwt**] | **TIME2**  [**mg.kg-1wwt**] |
| Tebuconazole | 1.14E-03 | 5.18E-05 |
| Propiconazole | 3.28E-03 | 1.54E-04 |
| Cypermethrin | 3.01E-02 | 6.36E-04 |
| PBC | 1.89E-04 | 6.00E-06 |

PEC in the aquatic compartment for iodine (transformation product from IPBC)

The environmental risk assessment for iodine was carried out only for the worst case scenarios (highest IPBC output value for Estp time 1). The used molar fraction of iodine from IPBC is 0.451. Further it is assumed that all iodine is transformed either to iodide or iodate. The molar fraction between iodine and iodide is 1 and between iodine and iodate is 1.38.

ESTP, iodine, Time 1 = ESTP, IPBC, Time 1 \* 0.451 \* 80% = 6.27E-04 kg.d-1

With ESTP, IPBC = 1.39E-03 kg.d-1 (Noise barrier, wood in service, 30 days). According to the CAR for iodine (2013) only 80% of the emission *via* STP is discharged to the surface water.

PEC STP, iodine = 2.51E-04 mg.L-1

PEC surface water, iodine = = 2.50E-05 mg.L-1

PEC surface water, iodide = PEC surface water, iodine \* 1 = 2.50E-05 mg.L-1

PEC surface water, iodiate = PEC surface water, Iodine \* 1.38 = 3.45E-05 mg.L-1

The sediment compartment is not relevant (cover by surface water).

##### PEC in air: X6119M2

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

IPBC

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

Propiconazole and tebuconazole:

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

Cypermethrin:

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

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

##### PEC in the soil compartment : X6119M2

Direct emissions to soil - *In situ* application

Initial concentrations are presented (eq. 4.38 for brush, 4.120 for spray Tier 1 and 4.121 for spray Tier 2 of the PT08 ESD).

|  |  |  |
| --- | --- | --- |
| **Application – House - Treatment by brushing** | | |
|  | Professional | Non-professional |
| **PEC local soil**, **initial concentrations in local soil** [mg.kg-1wwt] | | |
| Propiconazole | 1.02E-01 | 1.70E-01 |
| Tebuconazole | 1.70E-02 | 2.83E-02 |
| Cypermethrin | 7.13E-02 | 1.19E-01 |
| IPBC | 1.70E-02 | 2.83E-02 |
| PBC | 9.37E-03 | 1.56E-02 |
| 1,2,4-triazole | 9.18E-03 | 1.53E-02 |
| **Application – House - Treatment by spraying** | | |
| **PEC local soil**, **initial concentrations in local soil** [mg.kg-1wwt] | | |
|  | Tier 1 (Runoff + Drift) | Tier 2 (Drift) |
| Propiconazole | 1.02E+00 | 9.71E-02 |
| Tebuconazole | 1.70E-01 | 1.62E-02 |
| Cypermethrin | 7.13E-01 | 6.79E-02 |
| IPBC | 1.70E-01 | 1.62E-02 |
| PBC | 9.37E-02 | 8.93E-03 |
| 1,2,4-triazole | 9.18E-02 | 8.75E-03 |

Direct emissions to soil - Service life of treated wood (without considering application phase)

Twa concentrations are calculated (with eq. 3.7 and 3.8 of the PT08 ESD) taking into account the degradation process with the half-life in soil (DT50soil).

|  |  |  |
| --- | --- | --- |
| **PEC LOCAL SOIL – House scenario** | | |
|  | **TWA concentration**  **TIME1**  [**mg.kg-1wwt**] | **TWA concentration**  **TIME2**  [**mg.kg-1wwt**] |
| Propiconazole | 1.27E-01 | 6.38E-02 |
| Tebuconazole | 4.26E-02 | 1.96E-02 |
| Cypermethrin | 2.75E-02 | 1.99E-03 |
| IPBC | 1.05E-03 | 3.38E-05 |
| PBC | 1.69E-02 | 1.08E-03 |
| 1,2,4-triazole | 1.22E-02 | 8.24E-03 |
| **PEC LOCAL SOIL – Noise barrier** | | |
|  | **TWA concentration**  **TIME1**  [**mg.kg-1wwt**] | **TWA concentration**  **TIME2**  [**mg.kg-1wwt**] |
| Propiconazole | 4.77E-02 | 2.39E-02 |
| Tebuconazole | 1.59E-02 | 7.34E-03 |
| Cypermethrin | 1.03E-02 | 7.45E-04 |
| IPBC | 3.94E-04 | 1.27E-05 |
| PBC | 6.33E-03 | 4.06E-04 |
| 1,2,4-triazole | 4.57E-03 | 3.08E-03 |

Direct emissions to soil - *In situ* Application + Service life of treated wood - House

|  |  |  |
| --- | --- | --- |
| **Brush application + Treated wood in service** | | |
| **PEC LOCAL SOIL,** **TWA concentration, TIME 1** [mg.kg-1wwt] | | |
|  | ***Professional*** | ***Non professional*** |
| Propiconazole | 2.17E-01 | 2.77E-01 |
| Tebuconazole | 5.74E-02 | 6.73E-02 |
| Cypermethrin | 6.88E-02 | 9.64E-02 |
| IPBC | 1.21E-03 | 1.32E-03 |
| PBC | 2.07E-02 | 2.32E-02 |
| 1,2,4-triazole | 2.06E-02 | 2.62E-02 |
| **PEC LOCAL SOIL,** **TWA concentration, TIME 2** [mg.kg-1wwt] | | |
| Propiconazole | 6.89E-02 | 7.23E-02 |
| Tebuconazole | 2.04E-02 | 2.09E-02 |
| Cypermethrin | 2.28E-03 | 2.47E-03 |
| IPBC | 3.38E-05 | 3.38E-05 |
| PBC | 1.09E-03 | 1.10E-03 |
| 1,2,4-triazole | 2.06E-02 | 9.40E-03 |
| **Spray application + Treated wood in service** | | |
| **PEC LOCAL SOIL,** **TWA concentration, TIME 1 - Tier 1** [mg.kg-1wwt] | | |
| Propiconazole | 1.03E+00 | |
| Tebuconazole | 1.91E-01 | |
| Cypermethrin | 4.41E-01 | |
| IPBC | 2.65E-03 | |
| PBC | 5.49E-02 | |
| 1,2,4-triazole | 9.62E-02 | |
| **PEC LOCAL SOIL,** **TWA concentration, TIME 2 - Tier 1** [mg.kg-1wwt] | | |
| Propiconazole | 1.15E-01 | |
| Tebuconazole | 2.75E-02 | |
| Cypermethrin | 4.88E-03 | |
| IPBC | 3.38E-05 | |
| PBC | 1.16E-03 | |
| 1,2,4-triazole | 1.52E-02 | |

Indirect emissions to soil (via the STP) - Noise barrier scenario:

Indirect emissions to soil via spreading of STP sludge onto soil were used to calculate concentrations in soil according to the equations of the ECHA Guidance Vol.IV, par B (2015), with the following inputs.

|  |  |  |
| --- | --- | --- |
| **Wood-in-service – Noise barrier- Treated wood in service only** | | |
| **PECsoil\_via\_STP [mg.kg-1wwt]** | **TIME1** | **TIME 2** |
| Propiconazole | 5.88E-04 | 2.77E-05 |
| Tebuconazole | 2.12E-04 | 9.61E-06 |
| Cypermethrine | 9.62E-04 | 2.04E-05 |
| PBC | 1.40E-05 | 4.42E-07 |
| 1,2,4-triazole | 5.87E-04 | 2.75E-05 |

PEC in the terrestrial compartment for iodine (transformation product from IPBC)

The environmental risk assessment for iodine was carried out only for the worst case scenarios (highest IPBC output values = PEC soil, IPBC of 2.17E-01 mg.kgwwt-1 for House scenario, direct emission to soil during service-life, estimation without degradation, 5 years) . The used molar fraction of iodine and IPBC is 0.451. Further it is assumed that all iodine is transformed either to iodide or iodate. The molar fraction between iodine and iodide is 1 and between iodine and iodate is 1.38.

PEC soil, iodine = PEC soil, IPBC \* 0.451 = 9.79E-02 mg.kgwwt-1

PEC soil, iodide = PEC soil, Iodine \* 1 = 9.79E-02 mg.kgwwt-1

PEC soil, iodate = PEC soil, Iodine \* 1.38 = 1.35E-01 mg.kgwwt-1

##### PECs for the groundwater compartment: X6119M2

The estimations of releases of active substances, and their relevant degradation products for the groundwater compartment, were calculated with the FOCUS PEARL v.4.4.4 software.

According to the paragraph 578 of the PT08-ESD (2013), the estimation of releases to groundwater is relevant for susbstance with:

* Koc < 500 l.kg-1 and
* DT50soil > 21 d**.**

Considering that:

|  |  |  |  |
| --- | --- | --- | --- |
| **Substance** | **Koc [l.kg-1]** | **DT50soil,12°C [d]** | |
| Tebuconazole | 992 | 77 | |
| Propiconazole | 944 | 82 | |
| 1,2,4-triazole (\*) | 89 | 114.7 (\*\*) | |
| Cypermethrin | 575000 | 17.2 | |
| IPBC | 134.5 | 1.96E-01 | |
| PBC(\*\*\*) | 198.1 | 9.50 | |
| (\*) – Relevant degradation product of tebuconazole and propiconazole in soil, with a maximum formation rate of 9% and 43.23% of applied radioactivity, respectively.  (\*\*) – Calculated according to the arrhenius equation with a DT50 at 20°C of 60.5 days.  (\*\*\*) – Relevant metabolite of IPBC in all environmental compartments assuming 100% of applied radioactivity. | | |

Estimations of releases to groundwater is considered relevant by FR-CA for the following substances:

* Tebuconazole;
* Propiconazole;
* IPBC;
* PBC;
* 1,2,4-triazole.

According to the PT08-ESD (2013), a groundwater assessment is only necessary for the house scenario, which can be considered to be the worst case for soil exposure, thus covering all other scenarios.

Consequently to the environmental risk assessment performed for the application phase, it is recommended on the label to cover the soil during the application by brushing or spraying. Then, no emission into the soil occurs during the application. Therefore, only emissions into the soil during the service-life of the treated wood due to leaching are taken into account to estimate the contamination of the groundwater.

The scenario for the groundwater exposure assessment for wood preservatives described in the supplement of the appendix 4 of the PT08-ESD, based on leaching values.

| **Input parameter** | **Unit** | **Value** | | | | |
| --- | --- | --- | --- | --- | --- | --- |
|  | | **Tebuco-nazole** | **Propico-nazole** | **IPBC** | **PBC** | **1,2,4-triazole** |
| **Physicochemical parameters** | | | | | | |
| Molar mass | g.mol-1 | 307.8 | 342.2 | 281.1 | 155.2 | 69.1 |
| Water solubility (25 °C) | mg.l-1 | 29 | 100 | 168 | 2860 | 700 000 |
| Molar enthalpy of dissolution | kJ.mol-1 | 27 | | | | |
| Saturated vapour pressure | Pa | 1.70E-06 (20°C) | 5.60E-05  (25°C) | 2.36E-03  (25°C) | 1.88E+01  (25°C) | 2.20E-01  (20°C) |
| Molar enthalpy of vaporisation | kJ.mol-1 | 95 | | | | |
| Diffusion coefficient in water (20 °C) | m².d-1 | 4.3E-05 | | | | |
| Diffusion coefficient in air (20 °C) | m².d-1 | 0.43 | | | | |
| **Degradation parameters** | | | | | | |
| Half-life (12°C, pF2) | d | 77 | 82 | 1.96E-01 | 9.50 | 114.7 |
| Arrhenius activation energy | kJ.mol-1 | 65.4 | | | | |
| Exponent of moisture correction function | - | 0.7 | | | | |
| **Sorption parameters** | | | | | | |
| Koc value | l.kg-1 | 992 | 944 | 134.5 | 198.1 | 89 |
| Komvalue (20°C) | ml.g-1 | 575.41 | 547.56 | 78.02 | 114.91 | 51.62 |
| Freundlich exponent 1/n | - | 1 | | | | |
| Method of subroutine description | - | pH independent | | | | |
| **Crop related parameters** | | | | | | |
| Crop uptake factor | - | 0 | | | | |
| **Application Schemes** | | | | | | |
| Q\*leach, TIME2 (5 years) | kg.m-2 | 4.53E-05 | 1.40E-04 | 3.84E-05 | n.r. | n.r. |
| Total leachable area | m².ha-1 | 2 000 | | | | |
| Fraction of house surface exposed to weather | - | 0.5 | | | | |
| Service life | year | 5 | | | | |
| Number of application per year | - | 10 | | | | |
| Dosage per FOCUS application | kg.ha-1.applicaton-1 | 9.06E-04 | 2.80E-03 | 7.68E-04 | n.r. | n.r. |
| Fraction transformed | - | n.r. | n.r. | n.r. | 1  (IPBC) | 0.09 (Tebuconazole) 0.43  (Propiconazole) |
| Application type | - | To the soil surface | | | | |
| Repeat interval for years | - | 1 | | | | |
| Date | - | 10/01/1901 | | | | |
| 15/02/1901 | | | | |
| 24/03/1901 | | | | |
| 29/04/1901 | | | | |
| 05/06/1901 | | | | |
| 11/07/1901 | | | | |
| 17/08/1901 | | | | |
| 22/09/1901 | | | | |
| 29/10/1901 | | | | |
| 04/12/1901 | | | | |
| **Crops Application** | | | | | | |
| Crop(s) | - | Grassland | | | | |
| Selected Locations | | CHATEAUDUN | | | | |
| HAMBURG | | | | |
| JOIKIONEN | | | | |
| KREMSMUENSTER | | | | |
| OKEHAMPTON | | | | |
| PIACENZA | | | | |
| PORTO | | | | |
| SEVILLA | | | | |
| THIVA | | | | |

n.r.: not relevant

The results are listed in the table below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **Tebuconazole [µg.l-1]** | **Propiconazole [µg.l-1]** | **1,2,4-triazole (\*) [µg.l-1]** | **IPBC**  **[µg.l-1]** | **PBC**  **[µg.l-1]** |
| CHATEAUDUN | < 0.001 | < 0.001 | 0.04 | < 0.001 | < 0.001 |
| HAMBURG | < 0.001 | < 0.001 | 0.07 | < 0.001 | < 0.001 |
| JOIKIONEN | < 0.001 | < 0.001 | 0.06 | < 0.001 | < 0.001 |
| KREMSMUENSTER | < 0.001 | < 0.001 | 0.04 | < 0.001 | < 0.001 |
| OKEHAMPTON | < 0.001 | < 0.001 | 0.06 | < 0.001 | < 0.001 |
| PIACENZA | < 0.001 | < 0.001 | 0.04 | < 0.001 | < 0.001 |
| PORTO | < 0.001 | < 0.001 | 0.03 | < 0.001 | < 0.001 |
| SEVILLA | < 0.001 | < 0.001 | 0.019 | < 0.001 | < 0.001 |
| THIVA | < 0.001 | < 0.001 | 0.022 | < 0.001 | < 0.001 |

##### Secondary poisoning: X6119M2

FR-CA agreed with the applicant for considering that secondary poisoning is relevant only for the active substance cypermethrin. As a consequence, the secondary poisoning was assessed for the TIME2 assessment period of service life considering as a worst case:

* for the aquatic food chain**,** the scenario Bridge “surface treatment (eq. to 200 g.m-2) – treated wood in service only” with a Clocalwater,TWA\_TIME2 of 1.34E-04 µg.L-1;
* for the terrestrial food chain, the scenario “spray application (Tier1 – runoff + drift) + treated wood in service” with a Clocalsoil,TWA\_TIME2 of 4.88E-03 mg.kg-1wwt.

In accordance with the equations of the ECHA guidance vol.IV, part B (2015), PECoral,predator for both food chain were calculated as followed:

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter / variable** | **Symbol** | **Unit** | **Value** |
| ***Aquatic food chain:*** | | | |
| Predicted environmental concentration during episode | PEClocal,water | [mg.l-1] | 1.34E-07 |
| Bioconcentration factor for fish on wet weight basis | BCFfish | [l.kg-1wet fish] | 417 |
| Biomagnification factor in fish | BMF | [-] | 2 |
| **Predicted environmental concentration in food (considering that predators feed at 50% on local level)** | **PECoral,predator** | **[mg.kg-1wet fish]** | **5.63E-05** |
| ***Terrestrial food chain :*** |  |  |  |
| log of partition coefficient n-octanol-water | Log Kow | [-] | 5.45 |
| Bioconcentration factor for earthworm on wet weight basis | BCFearthworm | [l.kg-1wet earthworm] | 3.38E+03 |
| Concentration in porewater | Cporewater | [mg.l-1] | 2.91E-04 |
| Concentration in soil | Csoil | [mg.kg-1wwt] | 4.88E-03 |
| Fraction of gut loading in worm | Fgut | [kgdwt.kg-1wwt] | 0.1 |
| Conversion factor for soil concentration wet-dry weight soil | CONVsoil | [kgwwt.kg-1dwt] | 1.13 |
| **Predicted environmental concentration in food (considering that predators feed at 50% on local level)** | **PECoral,predator** | **[mg.kg-1wet earthworm]** | **2.48E-04** |

#### PECs for the relevant product : X6236

##### PEC in the aquatic compartment (including sediment): X6236

Direct emission to the aquatic compartment - Bridge over the pond scenario

The emissions in local water were calculated for the outdoor application phase, and in for the service life of treated wood phase.

The initial concentrations in water were defined on the day of application for the application phase (PT08-ESD eq. 4.42). For service-life, concentrations were calculated over the assessment periods (*i.e.* 30 days for TIME1 and 1825 days for the TIME2), with the dissipation half-life from water (DT50water) of each active substance in order to take into account degradation and adsorption processes (c.f. Table 2.2‑1) using equations 3.16 and 3.17 for static water bodies. Application and service-life were calculated separately.

The concentrations in sediment were calculated using the equation 50 of the ECHA GUIDANCE vol.IV,Part B (2015). For service-life, concentrations in local water were calculated using the degradation half-life of each active substances (eq. 3.16 and 3.17) in the whole water-sediment system (DT50whole system), and the partition coefficient organic carbon-water (Koc).

Application Phase - Bridge over the pond scenario

|  |  |  |
| --- | --- | --- |
| **Application - Bridge over the pond - Treatment by brushing** | | |
|  | Professional | Non-professional |
| **PEC local surface water, initial concentration after application** [µg.l-1] | | |
| Propiconazole | 1.80E-01 | 3.00E-01 |
| Tebuconazole | 3.00E-02 | 5.00E-02 |
| Cypermethrin | 1.26E-01 | 2.10E-01 |
| IPBC | 3.00E-02 | 5.00E-02 |
| PBC | 1.66E-02 | 2.76E-02 |
| **PEC local sediment after application** [mg.kg-1wwt] | | |
| Propiconazole | 3.83E-03 | 6.39E-03 |
| Tebuconazole | 6.70E-04 | 1.12E-03 |
| Cypermethrin | 1.58E+00 | 2.63E+00 |
| PBC | 8.43E-05 | 1.40E-04 |
| **Application - Bridge over the pond - Treatment by spraying** | | |
| **PEC local surface water, initial concentration after application** [µg.l-1] | | |
| Propiconazole | 1.80E+00 | |
| Tebuconazole | 3.00E-01 | |
| Cypermethrin | 1.26E+00 | |
| IPBC | 3.00E-01 | |
| PBC | 1.66E-01 | |
| **PEC local sediment after application** [mg.kg-1wwt] | | |
| Propiconazole | 3.83E-02 | |
| Tebuconazole | 6.70E-03 | |
| Cypermethrin | 1.58E+01 | |
| PBC | 8.43E-04 | |

Service life - Bridge over the pond

|  |  |  |
| --- | --- | --- |
| **PEC local surface water** | | |
|  | TWA over the TIME 1 assessment period (30 days)  [µg.l-1] | TWA over the TIME 2 assessment period [µg.l-1] |
| Propiconazole | 1.34E-01 | 1.20E-02 |
| Tebuconazole | 7.41E-02 | 1.50E-02 |
| Cypermethrin | 5.19E-03 | 1.16E-04 |
| IPBC | 1.35E-03 | 3.87E-05 |
| PBC | 4.90E-02 | 5.04E-03 |
| **PEC local sediment** | | |
|  | TWA over the TIME 1 assessment period (30 days)  [mg.kg-1wwt] | TWA over the TIME 2 assessment period [mg.kg-1wwt] |
| Propiconazole | 4.68E-03 | 9.90E-03 |
| Tebuconazole | 1.87E-03 | 1.35E-03 |
| Cypermethrin | 5.29E-01 | 2.79E-02 |
| PBC | 2.50E-04 | 2.58E-05 |

Indirect emissions via the STP - Noise barrier scenario

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

|  |  |  |
| --- | --- | --- |
| Outputs: | | |
| **PECSTP** | | |
|  | **TIME1**  [mg.l-1] | **TIME2**  [mg.l-1] |
| Propiconazole | 1.39E-03 | 6.63E-05 |
| Tebuconazole | 5.39E-04 | 2.34E-05 |
| Cypermethrin | 3.82E-05 | 8.16E-07 |
| IPBC | 7.39E-04 | 2.10E-05 |
| PBC | 4.10E-04 | 1.17E-05 |

Indirect emissions to surface water and sediment via the STP were calculated according to the equations 45 and 50 of the ECHA Guidance Vol.IV, par B (2015).

|  |  |  |
| --- | --- | --- |
| **Wood-in-service – Noise barrier - Treated wood in service only** | | |
| **PECwater\_via\_STP** | | |
|  | **TIME1**  [µg.l-1] | **TIME2**  [µg.l-1] |
| Propiconazole | 1.39E-01 | 6.62E-03 |
| Tebuconazole | 5.38E-02 | 2.34E-03 |
| Cypermethrin | 2.05E-03 | 4.38E-05 |
| IPBC | 7.39E-02 | 2.10E-03 |
| PBC | 4.09E-02 | 1.17E-03 |
| **PECsediment\_via\_STP** | | |
|  | **TIME1**  [**mg.kg-1wwt**] | **TIME2**  [**mg.kg-1wwt**] |
| Propiconazole | 2.96E-03 | 1.41E-04 |
| Tebuconazole | 1.20E-03 | 5.23E-05 |
| Cypermethrin | 2.56E-02 | 5.48E-04 |
| PBC | 2.08E-04 | 5.93E-06 |

PEC in the aquatic compartment for iodine (transformation product from IPBC)

The environmental risk assessment for iodine was carried out only for the worst case scenarios (highest IPBC output value for Estp time 1). The used molar fraction of iodine from IPBC is 0.451. Further it is assumed that all iodine is transformed either to iodide or iodate. The molar fraction between iodine and iodide is 1 and between iodine and iodate is 1.38.

ESTP, iodine, Time 1 = ESTP, IPBC, Time 1 \* 0.451 \* 80% = 6.90E-04 kg.d-1

With ESTP, IPBC = 1.53E-03 kg.d-1 (Noise barrier, wood in service, 30 days). According to the CAR for iodine (2013) only 80% of the emission *via* STP is discharged to the surface water.

PEC STP, iodine = 2.76E-04 mg.L-1

PEC surface water, iodine = = 2.75E-05 mg.L-1

PEC surface water, iodide = PEC surface water, iodine \* 1 = 2.75E-05 mg.L-1

PEC surface water, iodiate = PEC surface water, Iodine \* 1.38 = 3.80E-05 mg.L-1

The sediment compartment is not relevant (cover by surface water).

##### PEC in air: X6236

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

IPBC

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

Propiconazole and tebuconazole:

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

Cypermethrin:

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

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

##### PEC in the soil compartment: X6236

Direct emissions to soil - *In situ* application

Initial concentrations are presented (eq. 4.38 for brush, 4.120 for spray Tier 1 and 4.121 for spray Tier 2 of the PT08 ESD).

|  |  |  |  |
| --- | --- | --- | --- |
| **Application – House -Treatment by brushing** | | | |
|  | Professional | | Non-professional |
| **PEC local soil**, **initial concentrations in local soil** [mg.kg-1wwt] | | | |
| Propiconazole | 1.02E-01 | | 1.70E-01 |
| Tebuconazole | 1.70E-02 | | 2.83E-02 |
| Cypermethrin | 7.13E-02 | | 1.19E-01 |
| IPBC | 1.70E-02 | | 2.83E-02 |
| PBC | 9.37E-03 | | 1.56E-02 |
| 1,2,4-triazole | 9.23E-03 | | 1.54E-02 |
| **Application – House - Treatment by spraying** | | | |
| **PEC local soil**, **initial concentrations in local soil** [mg.kg-1wwt] | | | |
|  | | Tier1 (Runoff + Drift) | Tier 2 (Drift) |
| Propiconazole | | 1.02E+00 | 9.71E-02 |
| Tebuconazole | | 1.70E-01 | 1.62E-02 |
| Cypermethrin | | 7.13E-01 | 6.79E-02 |
| IPBC | | 1.70E-01 | 1.62E-02 |
| PBC | | 9.37E-02 | 8.93E-03 |
| 1,2,4-triazole | | 9.23E-02 | 8.80E-03 |

Direct emissions to soil - Service life of treated wood (without considering application phase)

Twa concentrations are calculated (with eq. 3.7 and 3.8 of the PT08 ESD) taking into account the degradation process with the half-life in soil (DT50soil).

|  |  |  |
| --- | --- | --- |
| **PEC LOCAL SOIL – House scenario** | | |
|  | **TWA concentration**  **TIME1**  [**mg.kg-1wwt**] | **TWA concentration**  **TIME2**  [**mg.kg-1wwt**] |
| Propiconazole | 1.15E-01 | 5.82E-02 |
| Tebuconazole | 4.48E-02 | 2.00E-02 |
| Cypermethrin | 2.34E-02 | 1.71E-03 |
| IPBC | 1.16E-03 | 3.34E-05 |
| PBC | 1.86E-02 | 1.09E-03 |
| 1,2,4-triazole | 1.12E-02 | 7.58E-03 |
| **PEC LOCAL SOIL – Noise barrier** | | |
|  | **TWA concentration**  **TIME1**  [**mg.kg-1wwt**] | **TWA concentration**  **TIME2**  [**mg.kg-1wwt**] |
| Propiconazole | 4.31E-02 | 2.18E-02 |
| Tebuconazole | 1.68E-02 | 7.49E-03 |
| Cypermethrin | 8.76E-03 | 6.39E-04 |
| IPBC | 4.33E-04 | 1.25E-05 |
| PBC | 6.96E-03 | 4.09E-04 |
| 1,2,4-triazole | 4.18E-03 | 2.84E-03 |

Direct emissions to soil - In situ Application + Service life of treated wood - House

|  |  |  |
| --- | --- | --- |
| **Brush application + Treated wood in service** | | |
| **PEC LOCAL SOIL,** **TWA concentration, TIME 1** [mg.kg-1wwt] | | |
|  | ***Professional*** | ***Non professional*** |
| Propiconazole | 2.05E-01 | 2.65E-01 |
| Tebuconazole | 5.97E-02 | 6.96E-02 |
| Cypermethrin | 6.47E-02 | 9.23E-02 |
| IPBC | 1.32E-03 | 1.42E-03 |
| PBC | 2.24E-02 | 2.49E-02 |
| 1,2,4-triazole | 1.96E-02 | 2.52E-02 |
| **PEC LOCAL SOIL,** **TWA concentration, TIME 2** [mg.kg-1wwt] | | |
| Propiconazole | 6.33E-02 | 6.67E-02 |
| Tebuconazole | 2.08E-02 | 2.13E-02 |
| Cypermethrin | 2.00E-03 | 2.19E-03 |
| IPBC | 3.34E-05 | 3.34E-05 |
| PBC | 1.10E-03 | 1.11E-03 |
| 1,2,4-triazole | 8.28E-03 | 8.74E-03 |
| **Spray application + Treated wood in service** | | |
| **PEC LOCAL SOIL,** **TWA concentration, TIME 1 - Tier 1** [mg.kg-1wwt] | | |
| Propiconazole | 1.01E+00 | |
| Tebuconazole | 1.93E-01 | |
| Cypermethrin | 4.37E-01 | |
| IPBC | 2.76E-03 | |
| PBC | 5.66E-02 | |
| 1,2,4-triazole | 9.56E-02 | |
| **PEC LOCAL SOIL,** **TWA concentration, TIME 2 - Tier 1** [mg.kg-1wwt] | | |
| Propiconazole | 1.09E-01 | |
| Tebuconazole | 2.79E-02 | |
| Cypermethrin | 4.60E-03 | |
| IPBC | 3.34E-05 | |
| PBC | 1.17E-03 | |
| 1,2,4-triazole | 1.46E-02 | |

Indirect emissions to soil (via the STP) - Noise barrier scenario:

Indirect emissions to soil via spreading of STP sludge onto soil were used to calculate concentrations in soil according to the equations of the ECHA Guidance Vol.IV, par B (2015), with the following inputs.

|  |  |  |
| --- | --- | --- |
| **Wood-in-service – Noise barrier- Treated wood in service only** | | |
| **PECsoil\_via\_STP [mg.kg-1wwt]** | **TIME1** | **TIME 2** |
| Propiconazole | 5.32E-04 | 2.53E-05 |
| Tebuconazole | 2.23E-04 | 9.70E-06 |
| Cypermethrine | 8.19E-04 | 1.75E-05 |
| PBC | 1.54E-05 | 4.37E-07 |
| 1,2,4-triazole | 5.37E-04 | 2.54E-05 |

PEC in the terrestrial compartment for iodine (transformation product from IPBC)

The environmental risk assessment for iodine was carried out only for the worst case scenarios (highest IPBC output values = PEC soil, IPBC of 2.15E-01 mg.kgwwt-1 for House scenario, direct emission to soil during service-life, estimation without degradation, 5 years) . The used molar fraction of iodine and IPBC is 0.451. Further it is assumed that all iodine is transformed either to iodide or iodate. The molar fraction between iodine and iodide is 1 and between iodine and iodate is 1.38.

PEC soil, iodine = PEC soil, IPBC \* 0.451 = 9.68E-02 mg.kgwwt-1

PEC soil, iodide = PEC soil, Iodine \* 1 = 9.68E-02 mg.kgwwt-1

PEC soil, iodate = PEC soil, Iodine \* 1.38 = 1.34E-01 mg.kgwwt-1

##### PECs for the groundwater compartment: X6236

The estimations of releases of active substances, and their relevant degradation products for the groundwater compartment, were calculated with the FOCUS PEARL v.4.4.4 software.

According to the paragraph 578 of the PT08-ESD (2013), the estimation of releases to groundwater is relevant for susbstance with:

* Koc < 500 l.kg-1 and
* DT50soil > 21 d**.**

Considering that:

|  |  |  |  |
| --- | --- | --- | --- |
| **Substance** | **Koc [l.kg-1]** | **DT50soil,12°C [d]** | |
| Tebuconazole | 992 | 77 | |
| Propiconazole | 944 | 82 | |
| 1,2,4-triazole (\*) | 89 | 114.7 (\*\*) | |
| Cypermethrin | 575000 | 17.2 | |
| IPBC | 134.5 | 1.96E-01 | |
| PBC(\*\*\*) | 198.1 | 9.50 | |
| (\*) – Relevant degradation product of tebuconazole and propiconazole in soil, with a maximum of 9% and 43.23% of applied radioactivity, respectively.  (\*\*) – Calculated according to the arrhenius equation with a DT50 at 20°C of 60.5 days.  (\*\*\*) – Relevant metabolite of IPBC in all environmental compartments assuming 100% of applied radioactivity. | | |

Estimations of releases to groundwater is considered relevant by FR-CA for the following substances:

* Tebuconazole;
* Propiconazole;
* IPBC;
* PBC;
* 1,2,4-triazole.

According to the PT08-ESD (2013), a groundwater assessment is only necessary for the house scenario, which can be considered to be the worst case for soil exposure, thus covering all other scenarios.

Consequently to the environmental risk assessment performed for the application phase, it is recommended on the label to cover the soil during the application by brushing or spraying. Then, no emission into the soil occurs during the application. Therefore, only emissions into the soil during the service-life of the treated wood due to leaching are taken into account to estimate the contamination of the groundwater.

The scenario for the groundwater exposure assessment for wood preservatives described in the supplement of the appendix 4 of the PT08-ESD, based on leaching values.

| **Input parameter** | **Unit** | **Value** | | | | |
| --- | --- | --- | --- | --- | --- | --- |
|  | | **Tebuco-nazole** | **Propico-nazole** | **IPBC** | **PBC** | **1,2,4-triazole** |
| **Physicochemical parameters** | | | | | | |
| Molar mass | g.mol-1 | 307.8 | 342.2 | 281.1 | 155.2 | 69.1 |
| Water solubility (25 °C) | mg.L-1 | 29 | 100 | 168 | 2860 | 700 000 |
| Molar enthalpy of dissolution | kJ.mol-1 | 27 | | | | |
| Saturated vapour pressure | Pa | 1.70E-06 (20°C) | 5.60E-05  (25°C) | 2.36E-03  (25°C) | 1.88E+01  (25°C) | 2.20E-01  (20°C) |
| Molar enthalpy of vaporisation | kJ.mol-1 | 95 | | | | |
| Diffusion coefficient in water (20 °C) | m².d-1 | 4.3E-05 | | | | |
| Diffusion coefficient in air (20 °C) | m².d-1 | 0.43 | | | | |
| **Degradation parameters** | | | | | | |
| Half-life (12°C, pF2) | d | 77 | 82 | 1.96E-01 | 9.50 | 114.7 |
| Arrhenius activation energy | kJ.mol-1 | 65.4 | | | | |
| Exponent of moisture correction function | - | 0.7 | | | | |
| **Sorption parameters** | | | | | | |
| Koc value | l.kg-1 | 992 | 944 | 134.5 | 198.1 | 89 |
| Komvalue (20°C) | mL.g-1 | 575.41 | 547.56 | 78.02 | 114.91 | 51.62 |
| Freundlich exponent 1/n | - | 1 | | | | |
| Method of subroutine description | - | pH independent | | | | |
| **Crop related parameters** | | | | | | |
| Crop uptake factor | - | 0 | | | | |
| **Application Schemes** | | | | | | |
| Q\*leach, TIME2 (5 years) | kg.m-2 | 4.58E-05 | 1.28E-04 | 3.80E-05 | n.r. | n.r. |
| Total leachable area | m².ha-1 | 2 000 | | | | |
| Fraction of house surface exposed to weather | - | 0.5 | | | | |
| Service life | year | 5 | | | | |
| Number of application per year | - | 10 | | | | |
| Dosage per FOCUS application | kg.ha-1.applicaton-1 | 9.15E-04 | 2.56E-03 | 7.59E-04 | n.r. | n.r. |
| Fraction transformed | - | n.r. | n.r. | n.r. | 1  (IPBC) | 0.09 (Tebuconazole) 0.43  (Propiconazole) |
| Application type | - | To the soil surface | | | | |
| Repeat interval for years | - | 1 | | | | |
| Date | - | 10/01/1901 | | | | |
| 15/02/1901 | | | | |
| 24/03/1901 | | | | |
| 29/04/1901 | | | | |
| 05/06/1901 | | | | |
| 11/07/1901 | | | | |
| 17/08/1901 | | | | |
| 22/09/1901 | | | | |
| 29/10/1901 | | | | |
| 04/12/1901 | | | | |
| **Crops Application** | | | | | | |
| Crop(s) | - | Grassland | | | | |
| Selected Locations | | CHATEAUDUN | | | | |
| HAMBURG | | | | |
| JOIKIONEN | | | | |
| KREMSMUENSTER | | | | |
| OKEHAMPTON | | | | |
| PIACENZA | | | | |
| PORTO | | | | |
| SEVILLA | | | | |
| THIVA | | | | |

n.r.: not relevant

The results are listed in the table below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **Tebuconazole [µg.l-1]** | **Propiconazole [µg.l-1]** | **1,2,4-triazole (\*) [µg.l-1]** | **IPBC**  **[µg.l-1]** | **PBC**  **[µg.l-1]** |
| CHATEAUDUN | < 0.001 | < 0.001 | 0.038 | < 0.001 | < 0.001 |
| HAMBURG | < 0.001 | < 0.001 | 0.065 | < 0.001 | < 0.001 |
| JOIKIONEN | < 0.001 | < 0.001 | 0.052 | < 0.001 | < 0.001 |
| KREMSMUENSTER | < 0.001 | < 0.001 | 0.041 | < 0.001 | < 0.001 |
| OKEHAMPTON | < 0.001 | < 0.001 | 0.053 | < 0.001 | < 0.001 |
| PIACENZA | < 0.001 | < 0.001 | 0.040 | < 0.001 | < 0.001 |
| PORTO | < 0.001 | < 0.001 | 0.031 | < 0.001 | < 0.001 |
| SEVILLA | < 0.001 | < 0.001 | 0.017 | < 0.001 | < 0.001 |
| THIVA | < 0.001 | < 0.001 | 0.021 | < 0.001 | < 0.001 |

##### Secondary poisoning: X6236

FR-CA agreed with the applicant for considering that secondary poisoning is relevant only for the active substance cypermethrin. As a consequence, the secondary poisoning was assessed for the TIME2 assessment period of service life considering as a worst case:

* for the aquatic food chain**,** the scenario Bridge “surface treatment (eq. to 200 g.m-2) – treated wood in service only” with a Clocalwater,TWA\_TIME2 of 1.16E-04 µg.L-1;
* for the terrestrial food chain, the scenario “spray application (Tier1 – runoff + drift) + treated wood in service” with a Clocalsoil,TWA\_TIME2 of 4.60E-03 mg.kg-1wwt.

In accordance with the equations of the ECHA guidance vol.IV, part B (2015), PECoral,predator for both food chain were calculated as followed:

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter / variable** | **Symbol** | **Unit** | **Value** |
| ***Aquatic food chain:*** | | | |
| Predicted environmental concentration during episode | PEClocal,water | [mg.l-1] | 1.16E-07 |
| Bioconcentration factor for fish on wet weight basis | BCFfish | [l.kg-1wet fish] | 417 |
| Biomagnification factor in fish | BMF | [-] | 2 |
| **Predicted environmental concentration in food (considering that predators feed at 50% on local level)** | **PECoral,predator** | **[mg.kg-1wet fish]** | **4.85E-05** |
| ***Terrestrial food chain :*** |  |  |  |
| log of partition coefficient n-octanol-water | Log Kow | [-] | 5.45 |
| Bioconcentration factor for earthworm on wet weight basis | BCFearthworm | [l.kg-1wet earthworm] | 3.38E+03 |
| Concentration in porewater | Cporewater | [mg.l-1] | 2.74E-04 |
| Concentration in soil | Csoil | [mg.kg-1wwt] | 4.46E-03 |
| Fraction of gut loading in worm | Fgut | [kgdwt.kg-1wwt] | 0.1 |
| Conversion factor for soil concentration wet-dry weight soil | CONVsoil | [kgwwt.kg-1dwt] | 1.13 |
| **Predicted environmental concentration in food (considering that predators feed at 50% on local level)** | **PECoral,predator** | **[mg.kg-1wet earthworm]** | **2.34E-04** |

#### Risk characterisation for the environment

##### Risk characterisation for the relevant product: X6119C (Industrial application only)

For the *in-situ* application, the calculation for the meta-SPC 3 with the representative product, X6119M2 covers the evaluation for meta-SPC1 & 2 for an *in-situ* application.

###### Risk characterisation for the aquatic compartment (including STP and sediment): X6119C

Direct emission to the aquatic compartment – industrial application, storage

For the industrial application phase, no emission estimations were provided by the applicant based on mandatory risk mitigation measures for wood treatment plants.

Direct emission to the aquatic compartment - Bridge over the pond scenario –service life

The risk characterisation for the aquatic compartment including sediment has been performed considering PEC calculated for the bridge scenario, and compared to PNECwater and PNECsediment of each active substance for the service life of the treated wood.

|  |  |
| --- | --- |
| **Bridge over the pond - Treated wood in service only – Industrial application - TIME 1** | |
| **SURFACE WATER** | **PEC/PNEC** |
| Propiconazole | 1.41E-02 |
| Tebuconazole | 5.20E-02 |
| Cypermethrin | 2.00E-02 |
| IPBC | 1.73E-03 |
| PBC | 7.63E-04 |
| **∑PEC/PNEC\*\*** | 8.78E-02 |
| **SEDIMENT** | **PEC/PNEC** |
| Propiconazole | 6.20E-02 |
| Tebuconazole | 2.38E-03 |
| Cypermethrin\* | **1.63E+00** |
| PBC | 7.64E-04 |
| **∑PEC/PNEC\*\*** | **1.69E+00** |
| **Bridge over the pond - Treated wood in service only – Industrial application - TIME 2** | |
| **SURFACE WATER** | **PEC/PNEC** |
| Propiconazole | 8.90E-04 |
| Tebuconazole | 7.56E-03 |
| Cypermethrin | 6.58E-03 |
| IPBC | 2.90E-05 |
| PBC | 4.67E-05 |
| **∑PEC/PNEC\*\*** | 1.51E-02 |
| **SEDIMENT** | **PEC/PNEC** |
| Propiconazole | 1.67E-01 |
| Tebuconazole | 1.36E-03 |
| Cypermethrin\* | **1.27E+00** |
| PBC | 4.61E-05 |
| **∑PEC/PNEC\*\*** | **1.44E+00** |

\* An additional factor of 10 has been considered as PNECsed was defined using the EPM method

\*\* Sum of PEC/PNEC for parents substances

Considering that all PEC/PNEC ratios for surface water and sediment are below 1 except for the cypermethrin in sediment at the TIME 1 and TIME 2 (industrial application). Calculated sums of PEC/PNEC ratios are above 1 for sediment. No use of treated wood near aquatic compartment should be allowed.

Indirect emissions via the STP - Noise barrier scenario

The risk characterisation for the STP has been performed considering PEC calculated for the noise barrier scenario of the PT08-ESD, and compared to PNECSTP of each active substance for the service life of treated wood.

|  |  |
| --- | --- |
| **Noise barrier - Treated wood in service only – Industrial application – TIME 1** | |
| **STP** | **PEC/PNEC** |
| Propiconazole | 9.97E-06 |
| Tebuconazole | 1.18E-03 |
| Cypermethrin | 3.60E-07 |
| IPBC | 1.08E-03 |
| PBC | 5.98E-04 |
| **∑PEC/PNEC\*** | 2.27E-03 |
| **Noise barrier - Treated wood in service only – Industrial application – TIME 2** | |
| **STP** | **PEC/PNEC** |
| Propiconazole | 3.31E-07 |
| Tebuconazole | 3.59E-05 |
| Cypermethrin | 1.13E-07 |
| IPBC | 1.80E-05 |
| PBC | 9.95E-06 |
| **∑PEC/PNEC\*** | 5.43E-05 |

\* Sum of PEC/PNEC for parents substances

Considering that all PEC/PNEC ratios and aggregated PEC/PNEC ratios for STP are below 1, the risk for the STP is considered acceptable.

The risk characterisation for indirect releases via STP to the aquatic compartment including sediment has been performed considering PEC calculated for the noise barrier scenario, and compared to PNECwater and PNECsediment of each active substance for the service life of the treated wood.

|  |  |
| --- | --- |
| **Noise barrier - Treated wood in service only – Industrial application – TIME 1** | |
| **SURFACE WATER**  **(*via STP*)** | **PEC/PNEC** |
| Propiconazole | 1.46E-02 |
| Tebuconazole | 3.78E-02 |
| Cypermethrin | 7.88E-03 |
| PBC | 6.37E-04 |
| **∑PEC/PNEC\*\*** | 6.10E-02 |
| **SEDIMENT**  **(*via STP*)** | **PEC/PNEC** |
| Propiconazole | 3.93E-02 |
| Tebuconazole | 1.54E-03 |
| Cypermethrin | 7.86E-02 |
| PBC | 6.38E-04 |
| **∑PEC/PNEC\*\*** | 1.20E-01 |
| **Noise barrier - Treated wood in service only – Industrial application – TIME 2** | |
| **SURFACE WATER**  **(*via STP*)** | **PEC/PNEC** |
| Propiconazole | 4.87E-04 |
| Tebuconazole | 1.15E-03 |
| Cypermethrin | 2.47E-03 |
| PBC | 1.06E-05 |
| **∑PEC/PNEC\*\*** | 4.12E-03 |
| **SEDIMENT**  **(*via STP*)** | **PEC/PNEC** |
| Propiconazole | 1.31E-03 |
| Tebuconazole | 4.67E-05 |
| Cypermethrin | 2.48E-02 |
| PBC | 1.06E-05 |
| **∑PEC/PNEC\*\*** | 2.62E-02 |

\* An additional factor of 10 has been considered as PNECsed was defined using the EPM method

\*\* Sum of PEC/PNEC for parents substances

Considering that all PEC/PNEC ratios for surface water and sediment are below 1, as well as the aggregated values, the risk for the aquatic compartment (including sediment) exposed to indirect releases via the STP is considered acceptable during the service life of treated wood with the product.

**Environmental risk characterisation for Iodine**

**STP**

PNECSTP for Iodine = 2.9 mg.l-1.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PEC/PNEC** | **Worst case scenario** | **Iodine (I2)** | **Iodate (IO3-)** | **Iodide (I-)** |
| STP | Noise barrier, 30 days | 6.13E-05 | - | - |

An acceptable risk is found for the STP when considering the worst case scenario.

**Surface water**

Background level in freshwater (river an lake) = 0.5-20 µg.l-1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PEC** | **Worst case scenario** | **Iodine (I2)** | **Iodate (IO3-)** | **Iodide (I-)** |
| Surface water | Noise barrier, 30 days | 1.77E-02 | 1.77E-02 | 2.45E-02 |

The calculated iodine/iodide/iodate concentrations are below the reported background level for iodine in freshwater.

###### Risk characterisation for the terrestrial compartment: X6119C

Industrial dipping and storage

The risk for the storage phase after industrial application is considered acceptable for the terrestrial compartment, only if the freshly treated timber is stored after treatment under shelter and on impermeable hard standing.to prevent releases to soil.

For the industrial application phase, no emission estimations were provided by the applicant based on mandatory risk mitigation measures for wood treatment plants:

* Prevent any release to the environment during the product application phase as well as during the storage and the transport of treated timber;
* During the application phase, prevent any release of cleaning water (after cleaning of floors, tanks, containers) to the environment (sewer, soil, water);
* Freshly treated timber shall be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water, and that any losses of the product shall be collected for reuse or disposal. Before use, store the timber in an area sheltered from the weather;
* Any contaminated water/soil shall be collected, contained and treated as hazardous waste.

Service life of treated wood – Direct releases

Concerning the service-life phase of treated wood, the risk characterisation for the terrestrial compartment has been performed considering PEC calculated for the house scenario of the PT08-ESD, and compared to PNECsoil of each active substance for the service life of the treated wood.

Considering the unacceptable risk for the terrestrial compartment calculated for all intended type of application, the risk characterisation for the terrestrial compartment during the service life of treated wood taking into account also the application phase was not calculated.

|  |  |  |
| --- | --- | --- |
| **Wood-in service – House – Treated wood in service only** | | |
| **SOIL** | **TIME 1** | **TIME 2** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | 8.24E-01 | 2.64E-01 |
| Tebuconazole | 3.15E-01 | 8.81E-02 |
| Cypermethrin | 3.91E-03 | 2.95E-03 |
| IPBC | 1.69E-01 | 2.84E-03 |
| PBC | 7.99E-02 | 2.54E-03 |
| 1,2,4-triazole | 9.73E-01 | 4.22E-01 |
| **∑PEC/ PNEC\*** | **1.31E+00** | 3.58E-01 |
| **Wood-in service – Noise barrier – Treated wood in service only** | | |
| **SOIL** | **TIME 1** | **TIME 2** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | 3.09E-01 | 9.87E-02 |
| Tebuconazole | 1.18E-01 | 3.30E-02 |
| Cypermethrin | 1.47E-03 | 1.10E-03 |
| IPBC | 6.32E-02 | 1.07E-03 |
| PBC | 3.00E-02 | 9.53E-04 |
| 1,2,4-triazole | 3.64E-01 | 1.58E-01 |
| **∑PEC/ PNEC\*** | 4.91E-01 | 1.34E-01 |

\* Sum of the ratios for the active substances

Considering that calculated **∑**PEC/PNEC ratio for terrestrial compartment is above 1 only in TIME 1 for the house scenario, the risks are considered acceptable during the service life of treated wood.

Indirect emissions via the STP during serfice lif of treated wood - Noise barrier scenario

Concerning the service-life of treated wood, the risk characterisation for indirect releases via STP (*i.e.* spreading of STP sludge on soil) to the terrestrial compartment has been performed considering PEC calculated for the noise barrier scenario of the PT08-ESD, and compared to PNECsoil of each active substance for the service life of the treated wood.

|  |  |  |
| --- | --- | --- |
| **Wood-in-service – Noise barrier- Treated wood in service only** | | |
| **SOIL (via STP)** | **TIME 1** | **TIME 2** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | 3.81E-03 | 1.26E-04 |
| Tebuconazole | 1.57E-03 | 4.77E-05 |
| Cypermethrin | 1.37E-04 | 4.30E-05 |
| PBC | 6.62E-05 | 1.10E-06 |
| 1,2,4-triazole | 4.68E-02 | 1.54E-03 |
| **∑PEC/ PNEC\*** | 5.58E-03 | 2.18E-04 |

\* Sum of the ratios for the actives substances

Considering that all PEC/PNEC ratios for terrestrial compartment are below 1, the risk for the terrestrial compartment is considered acceptable during the service life of treated wood following indirect emissions *via* the STP.

**Terrestrial risk characterisation for Iodine**

Background level in soil = 0.565-22.6 mg.kgwwt-1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PEC** | **Worst case scenario** | **Iodine (I2)** | **Iodate (IO3-)** | **Iodide (I-)** |
| Soil | House, 5 years without degradation | 0.109 | 0.109 | 0.151 |

The calculated iodine/iodide/iodate concentrations are below the reported background level for iodine in soil.

###### Risk characterisation for the groundwater: X6119C

The estimated concentrations of active substances, and their relevant degradation products, in the groundwater compartment, were calculated with the FOCUS PEARL v.4.4.4 software.

The calculated PECgroudwater have been compared to the drinking water standard for pesticides (set at 0.1 μg/l) for each relevant substance. For all 9 EU scenarios, PECgroundwater are all below 0.1 µg/l.

Based on these results, it can be concluded that the use of the product will not pose a significant risk of groundwater contamination.

###### Risk characterisation for the atmospheric compartment: X6119C

Not relevant.

###### Risk characterisation for the secondary poisonning: X6119C

Secondary poisoning is relevant only for the active substance cypermethrin. Therefore, the secondary poisoning was assessed for the TIME2 assessment period of the service life for wood treated by surface treatment, considered as a worst case. PEC and risk ratios for the risk of secondary poisoning for birds and mammals are summarised in the following table.

|  |  |  |
| --- | --- | --- |
|  | **PEC/PNECbirds**  (PNECoral,bird = 33.3 mg/kg food) | **PEC/PNECmammals**  (PNECoral,small mammal = 3.33 mg/kg food) |
| *Via* fish | 3.94E-04 | 3.94E-03 |
| *Via* earthworm | 4.14E-07 | 4.14E-06 |

Based on these PEC/PNEC ratios, it can be concluded that the use of the product will not pose a significant risk to the top predators.

##### Risk characterisation for the relevant product : X6119M2

For the *in-situ* application, the calculation for the meta-SPC 3 with the representative product, X6119M2 covers the evaluation for meta-SPC1 & 2 for an *in-situ* application.

###### Risk characterisation for the aquatic compartment (including STP and sediment): X6119M2

Direct emission during application - Bridge over the pond scenario

For the application phase, the risk characterisation for the aquatic compartment including sediment has been performed considering PEC calculated for the bridge over pond scenario of the PT08-ESD, and compared to PNECwater and PNECsediment of each active substance.

|  |  |  |
| --- | --- | --- |
| **Application - Bridge over the pond - Treatment by brushing** | | |
| **SURFACE WATER** | **Professional** | **Non-professional** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | 2.65E-02 | 4.41E-02 |
| Tebuconazole | 3.00E-02 | 5.00E-02 |
| Cypermethrin | **3.15E+01** | **5.25E+01** |
| IPBC | 6.00E-02 | 1.00E-01 |
| PBC | 4.02E-04 | 6.68E-04 |
| **∑PEC/PNEC\*\*** | **3.16E+01** | **5.27E+01** |
| **SEDIMENT** | **Professional** | **Non-professional** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | 7.09E-02 | 1.18E-01 |
| Tebuconazole | 1.22E-03 | 2.04E-03 |
| Cypermethrin\* | **3.16E+02** | **5.26E+02** |
| PBC | 4.01E-04 | 6.67E-04 |
| **∑PEC/PNEC** | **3.16E+02** | **5.26E+02** |
| **Application - Bridge over the pond - Treatment by spraying** | | |
| **SURFACE WATER** | **PEC/PNEC** | |
| Propiconazole | 2.65E-01 | |
| Tebuconazole | 3.00E-01 | |
| Cypermethrin | **3.15E+02** | |
| IPBC | 6.00E-01 | |
| PBC | 4.02E-03 | |
| **∑PEC/PNEC\*\*** | **3.16E+02** | |
| **SEDIMENT** | **PEC/PNEC** | |
| Propiconazole | 7.09E-01 | |
| Tebuconazole | 1.22E-02 | |
| Cypermethrin\* | **3.16E+03** | |
| PBC | 4.01E-03 | |
| **∑PEC/PNEC** | **3.16E+03** | |

\* An additional factor of 10 has been considered as PNECsed was defined using the EPM method

\*\* Sum of the ratios for the active substances

Whatever the application method (brushing and spraying), all the calculated sums of PEC/PNEC ratios are above 1 for surface water and sediment.

Therefore, the application phase by brushing or spraying near surface water is cause of concern for the aquatic compartment (including sediment) and should be prevented.

Direct emissions during service life - Bridge over the pond scenario

The risk characterisation for the aquatic compartment including sediment has been performed considering PEC calculated for the bridge scenario, and compared to PNECwater and PNECsediment of each active substance for the service life of the treated wood.

|  |  |
| --- | --- |
| **Bridge over the pond - Treated wood in service only – TIME 1** | |
| **SURFACE WATER** | **PEC/PNEC** |
| Propiconazole | 2.18E-02 |
| Tebuconazole | 7.04E-02 |
| Cypermethrin | **1.56E+00** |
| IPBC | 2.46E-03 |
| PBC | 1.08E-03 |
| **∑PEC/PNEC\*\*** | **1.62E+00** |
| **SEDIMENT** | **PEC/PNEC** |
| Propiconazole | 9.59E-02 |
| Tebuconazole | 3.22E-03 |
| Cypermethrin\* | **1.24E+02** |
| PBC | 1.08E-03 |
| **∑PEC/PNEC** | **1.24E+02** |
| **Bridge over the pond - Treated wood in service only – TIME 2** | |
| **SURFACE WATER** | **PEC/PNEC** |
| Propiconazole | 1.93E-03 |
| Tebuconazole | 1.49E-02 |
| Cypermethrin | 3.38E-02 |
| IPBC | 7.82E-05 |
| PBC | 1.23E-04 |
| **∑PEC/PNEC\*\*** | 5.07E-02 |
| **SEDIMENT** | **PEC/PNEC** |
| Propiconazole | 2.00E-01 |
| Tebuconazole | 2.44E-03 |
| Cypermethrin\* | **6.49E+00** |
| PBC | 1.24E-04 |
| **∑PEC/PNEC** | **6.69E+00** |

\* An additional factor of 10 has been considered as PNECsed was defined using the EPM method

\*\* Sum of the ratios for the active substances

Considering that all PEC/PNEC ratios for surface water and sediment are below 1 except for the cypermethrin in sediment at the TIME 1 and the TIME 2 (industrial and in situ application). All the calculated sums of PEC/PNEC ratios are above 1 for surface sediment (in TIME 1 and TIME 2). No use of treated wood near aquatic compartment should be allowed. Moreover the application phase of the product above or near water leads to unacceptable risk to the aquatic compartment; no treatment above or near water is allowed.

Indirect emissions via the STP - Noise barrier scenario

The risk characterisation for the STP has been performed considering PEC calculated for the noise barrier scenario of the PT08-ESD, and compared to PNECSTP of each active substance for the service life of treated wood.

|  |  |
| --- | --- |
| **Noise barrier - Treated wood in service only – TIME 1** | |
| **STP** | **PEC/PNEC** |
| Propiconazole | 1.54E-05 |
| Tebuconazole | 1.60E-03 |
| Cypermethrin | 2.75E-05 |
| IPBC | 1.53E-03 |
| PBC | 8.45E-04 |
| **∑PEC/PNEC\*** | 3.17E-03 |
| **Noise barrier - Treated wood in service only – TIME 2** | |
| **STP** | **PEC/PNEC** |
| Propiconazole | 7.24E-07 |
| Tebuconazole | 7.25E-05 |
| Cypermethrin | 5.81E-07 |
| IPBC | 4.84E-05 |
| PBC | 2.68E-05 |
| **∑PEC/PNEC\*** | 1.22E-04 |

\* Sum of the ratios for the active substances

Considering that all PEC/PNEC ratios and aggregated PEC/PNEC ratios for STP are below 1, the risk for the STP is considered acceptable.

The risk characterisation for indirect releases via STP to the aquatic compartment including sediment has been performed considering PEC calculated for the noise barrier scenario, and compared to PNECwater and PNECsediment of each active substance for the service life of the treated wood.

|  |  |
| --- | --- |
| **Noise barrier - Treated wood in service only – TIME 1** | |
| **SURFACE WATER**  **(*via STP*)** | **PEC/PNEC** |
| Propiconazole | 2.26E-02 |
| Tebuconazole | 5.11E-02 |
| Cypermethrin | 6.02E-01 |
| PBC | 9.01E-04 |
| **∑PEC/PNEC** | 6.76E-01 |
| **SEDIMENT**  **(*via STP*)** | **PEC/PNEC** |
| Propiconazole | 6.07E-02 |
| Tebuconazole | 2.07E-03 |
| Cypermethrin | **6.02E+00** |
| PBC | 9.00E-04 |
| **∑PEC/PNEC** | **6.08E+00** |
| **Noise barrier - Treated wood in service only – TIME 2** | |
| **SURFACE WATER**  **(*via STP*)** | **PEC/PNEC** |
| Propiconazole | 1.06E-03 |
| Tebuconazole | 2.32E-03 |
| Cypermethrin | 1.27E-02 |
| PBC | 2.86E-05 |
| **∑PEC/PNEC** | 1.61E-02 |
| **SEDIMENT**  **(*via STP*)** | **PEC/PNEC** |
| Propiconazole | 2.85E-03 |
| Tebuconazole | 9.42E-05 |
| Cypermethrin | 1.27E-01 |
| PBC | 2.86E-05 |
| **∑PEC/PNEC** | 1.30E-01 |

\* An additional factor of 10 has been considered as PNECsed was defined using the EPM method

Considering that all PEC/PNEC ratios for surface water and sediment are below 1 in Time 2, as well as the aggregated values, the risk for the aquatic compartment (including sediment) exposed to indirect releases via the STP is considered acceptable during the long-terme service life of treated wood.

**Environmental risk characterisation for Iodine**

**STP**

PNECSTP for Iodine = 2.9 mg.l-1.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PEC/PNEC** | **Worst case scenario** | **Iodine (I2)** | **Iodate (IO3-)** | **Iodide (I-)** |
| STP | Noise barrier, 30 days | 8.65E-05 | - | - |

An acceptable risk is found for the STP when considering the worst case scenario.

**Surface water**

Background level in freshwater (river an lake) = 0.5-20 µg.l-1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PEC** | **Worst case scenario** | **Iodine (I2)** | **Iodate (IO3-)** | **Iodide (I-)** |
| Surface water | Noise barrier, 30 days | 2.50E-02 | 2.50E-02 | 3.45E-02 |

The calculated iodine/iodide/iodate concentrations are below the reported background level for iodine in freshwater.

The risk for aquatic environment is considered as acceptable.

###### Risk characterisation for the terrestrial compartment: X6119M2

Direct emissions to soil: *In situ* application

The risk characterisation for the terrestrial compartment has been performed considering PEC calculated for the house scenario of the PT08-ESD, and compared to PNECsoil of each active substance for the application phase of preventive and curative treatment.

|  |  |  |
| --- | --- | --- |
| **Application – House -Treatment by brushing** | | |
| **SOIL** | **Professional** | **Non-professional** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | **1.02E+00** | **1.70E+00** |
| Tebuconazole | 1.70E-01 | 2.83E-01 |
| Cypermethrin | 7.77E-01 | **1.30E+00** |
| IPBC | **3.86E+00** | **6.43E+00** |
| PBC | 6.29E-02 | 1.05E-01 |
| 1,2,4-triazole | **1.12E+00** | **1.87E+00** |
| **∑PEC/ PNEC\*** | **5.82E+00** | **9.70E+00** |

\* Sum of the ratios for the active substances

Considering that calculated ∑PEC/PNEC ratios for the active substances and PEC/PNEC ratio for 1,2,4-triazoles are above 1 for soil, brushing application phase is cause of concern for the terrestrial compartment, unless direct releases to soil are prevented by covering the soil during application.

|  |  |  |
| --- | --- | --- |
| **Application – House - Treatment by spraying** | | |
| **SOIL** | **Tier 1 (Runoff + Drift)** | **Tier 2 (Drift)** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | **1.02E+01** | 9.71E-01 |
| Tebuconazole | **1.70E+00** | 1.62E-01 |
| Cypermethrin | **7.77E+00** | 7.40E-01 |
| IPBC | **3.86E+01** | **3.68E+00** |
| PBC | 6.29E-01 | 5.99E-02 |
| 1,2,4-triazole | **1.12E+01** | **1.07E+00** |
| **∑PEC/ PNEC\*** | **5.82E+01** | **5.55E+00** |

\* Sum of the ratios for the active substances

For the terrestrial compartment and considering releases due to run off and drift (TIER1) on soil adjacent to the treated surface (0 to 1 m), PEC/PNEC ratios for tebuconazole, propiconazole, cypermethrin, IPBC and 1,2,4-triazole are above 1 for treatment by spraying.

For the terrestrial compartment and considering releases due to drift only (TIER 2) on soil distant form the treated surface (1 to 1.5 m), ∑PEC/PNEC ratios for the active substances and PEC/PNEC ratio for 1,2,4-triazoles are also above 1 for treatment by spraying.

The risk for the terrestrial compartment after application by spraying is considered acceptable only if the soil is covered during the application, in order to prevent all direct releases to soil *via* run-off and drift.

Direct emissions to soil: Service life of treated wood

Concerning the service-life phase of treated wood, the risk characterisation for the terrestrial compartment has been performed considering PEC calculated for the house scenario of the PT08-ESD, and compared to PNECsoil of each active substance for the service life of the treated wood.

Considering the unacceptable risk for the terrestrial compartment calculated for all intended type of application, the risk characterisation for the terrestrial compartment during the service life of treated wood taking into account also the application phase was not calculated.

|  |  |  |
| --- | --- | --- |
| **Wood-in service – House – Treated wood in service only** | | |
| **SOIL** | **TIME 1** | **TIME 2** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | **1.27E+00** | 6.38E-01 |
| Tebuconazole | 4.26E-01 | 1.96E-01 |
| Cypermethrin | 2.99E-01 | 2.17E-02 |
| IPBC | 2.39E-01 | 7.68E-03 |
| PBC | 1.13E-01 | 7.25E-03 |
| 1,2,4-triazole | **1.49E+00** | **1.00E+00** |
| **∑PEC/ PNEC\*** | **2.24E+00** | 8.64E-01 |
| **Wood-in service – Noise barrier – Treated wood in service only** | | |
| **SOIL** | **TIME 1** | **TIME 2** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | 4.77E-01 | 2.39E-01 |
| Tebuconazole | 1.59E-01 | 7.34E-02 |
| Cypermethrin | 1.12E-01 | 8.12E-03 |
| IPBC | 8.95E-02 | 2.89E-03 |
| PBC | 4.25E-02 | 2.72E-03 |
| 1,2,4-triazole | 5.57E-01 | 3.76E-01 |
| **∑PEC/ PNEC\*** | 8.38E-01 | 3.23E-01 |

\* Sum of the ratios for the active substances

The calculated ∑PEC/PNEC ratio for terrestrial compartment is below 1 in TIME 2 for the house scenario. Consequently, the risks are considered acceptable during the service life of treated wood (also considering that application phases lead to no release to the terrestrial compartment with the application of appropriate risk mitigation measure).

Indirect emissions via the STP during serfice lif of treated wood - Noise barrier scenario

Concerning the service-life of treated wood, the risk characterisation for indirect releases via STP (*i.e.* spreading of STP sludge on soil) to the terrestrial compartment has been performed considering PEC calculated for the noise barrier scenario of the PT08-ESD, and compared to PNECsoil of each active substance for the service life of the treated wood.

|  |  |  |
| --- | --- | --- |
| **Wood-in-service – Noise barrier- Treated wood in service only** | | |
| **SOIL (via STP** | **TIME 1** | **TIME 2** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | 5.88E-03 | 2.77E-04 |
| Tebuconazole | 2.12E-03 | 9.56E-05 |
| Cypermethrin | 1.05E-02 | 2.22E-04 |
| PBC | 9.40E-05 | 2.97E-06 |
| 1,2,4-triazole | 7.15E-02 | 3.36E-03 |
| **∑PEC/ PNEC** | 1.86E-02 | 5.97E-04 |

Considering that all PEC/PNEC ratios for terrestrial compartment are below 1, the risk for the terrestrial compartment is considered acceptable during the service life of treated wood following indirect emissions *via* the STP.

For the metabolite 1,2,4-triazole, the risk assessment conducted for the house scenario covers the noise barrier emissions. Therefore the risks considering this metabolite are also acceptable for indirect releases *via* the STP.

**Terrestrial risk characterisation for Iodine**

Background level in soil = 0.565-22.6 mg.kgwwt-1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PEC** | **Worst case scenario** | **Iodine (I2)** | **Iodate (IO3-)** | **Iodide (I-)** |
| Soil | House, 5 years without degradation | 0.098 | 0.098 | 0.135 |

The calculated iodine/iodide/iodate concentrations are below the reported background level for iodine in soil.

###### Risk characterisation for the groundwater compartment: X6119M2

The estimated concentrations of active substances, and their relevant degradation products, in the groundwater compartment, were calculated with the FOCUS PEARL v.4.4.4 software.

The calculated PECgroudwater have been compared to the drinking water standard for pesticides (set at 0.1 μg/l) for each relevant substance. For all 9 EU scenarios, PECgroundwater are all below 0.1 µg/l.

Based on these results, it can be concluded that the use of the product will not pose a significant risk of groundwater contamination.

###### Risk characterisation for the atmospheric compartment: X6119M2

Not relevant.

###### Risk characterisation for secondary poisonning: X6119M2

Secondary poisoning is relevant only for the active substance cypermethrin. Therefore, the secondary poisoning was assessed for the TIME2 assessment period of the service life for wood treated by surface treatment, considered as a worst case. PEC and risk ratios for the risk of secondary poisoning for birds and mammals are summarised in the following table.

|  |  |  |
| --- | --- | --- |
|  | **PEC/PNECbirds**  (PNECoral,bird = 33.3 mg/kg food) | **PEC/PNECmammals**  (PNECoral,small mammal = 3.33 mg/kg food) |
| *Via* fish | 1.69E-06 | 1.69E-05 |
| *Via* earthworm | 7.45E-06 | 7.45E-05 |

Based on these PEC/PNEC ratios, it can be concluded that the use of the product will not pose a significant risk to the top predators.

##### Risk characterisation for the relevant product : X6236

###### Risk characterisation for the aquatic compartment (including STP and sediment): X6236

Direct emission during outdoor application - Bridge over the pond scenario

For the application phase, the risk characterisation for the aquatic compartment including sediment has been performed considering PEC calculated for the bridge over pond scenario of the PT08-ESD, and compared to PNECwater and PNECsediment of each active substance for the application phase.

|  |  |  |
| --- | --- | --- |
| **Application - Bridge over the pond - Treatment by brushing** | | |
| **SURFACE WATER** | **Professional** | **Non-professional** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | 2.65E-02 | 4.41E-02 |
| Tebuconazole | 3.00E-02 | 5.00E-02 |
| Cypermethrin | **3.15E+01** | **5.25E+01** |
| IPBC | 6.00E-02 | 1.00E-01 |
| PBC | 4.02E-04 | 6.68E-04 |
| **∑PEC/PNEC\*\*** | **3.16E+01** | **5.27E+01** |
| **SEDIMENT** | **Professional** | **Non-professional** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | 7.09E-02 | 1.18E-01 |
| Tebuconazole | 1.22E-03 | 2.04E-03 |
| Cypermethrin\* | **3.16E+02** | **5.26E+02** |
| PBC | 4.01E-04 | 6.69E-04 |
| **∑PEC/PNEC** | **3.16E+02** | **5.26E+02** |
| **Application - Bridge over the pond - Treatment by spraying** | | |
| **SURFACE WATER** | **PEC/PNEC** | |
| Propiconazole | 2.65E-01 | |
| Tebuconazole | 3.00E-01 | |
| Cypermethrin | **3.15E+02** | |
| IPBC | 6.00E-01 | |
| PBC | 4.02E-03 | |
| **∑PEC/PNEC\*\*** | **3.16E+02** | |
| **SEDIMENT** | **PEC/PNEC** | |
| Propiconazole | 7.09E-01 | |
| Tebuconazole | 1.22E-02 | |
| Cypermethrin\* | **3.16E+03** | |
| PBC | 4.01E-03 | |
| **∑PEC/PNEC** | **3.16E+03** | |

\* An additional factor of 10 has been considered as PNECsed was defined using the EPM method

\*\* Sum of the ratios for the active substances

Whatever the application method (brushing and spraying), all the calculated sums of PEC/PNEC ratios for the active substances are above 1 for surface water and sediment.

Therefore, the application phase by brushing or spraying near surface water is cause of concern for the aquatic compartment (including sediment) and should be prevented.

Direct emissions during service life:

The risk characterisation for the aquatic compartment including sediment has been performed considering PEC calculated for the bridge scenario, and compared to PNECwater and PNECsediment of each active substance for the service life of the treated wood.

|  |  |
| --- | --- |
| **Bridge over the pond - Treated wood in service only – TIME 1** | |
| **SURFACE WATER** | **PEC/PNEC** |
| Propiconazole | 1.97E-02 |
| Tebuconazole | 7.41E-02 |
| Cypermethrin | **1.30E+00** |
| IPBC | 2.70E-03 |
| PBC | 1.19E-03 |
| **∑PEC/PNEC\*\*** | **1.40E+00** |
| **SEDIMENT** | **PEC/PNEC** |
| Propiconazole | 8.67E-02 |
| Tebuconazole | 3.40E-03 |
| Cypermethrin\* | **1.06E+02** |
| PBC | 1.19E-03 |
| **∑PEC/PNEC** | **1.06E+02** |
| **Bridge over the pond - Treated wood in service only – TIME 2** | |
| **SURFACE WATER** | **PEC/PNEC** |
| Propiconazole | 1.77E-03 |
| Tebuconazole | 1.50E-02 |
| Cypermethrin | 2.90E-02 |
| IPBC | 7.74E-05 |
| PBC | 1.22E-04 |
| **∑PEC/PNEC\*\*** | 4.60E-02 |
| **SEDIMENT** | **PEC/PNEC** |
| Propiconazole | 1.83E-01 |
| Tebuconazole | 2.45E-03 |
| Cypermethrin\* | **5.59E+00** |
| PBC | 1.23E-04 |
| **∑PEC/PNEC** | **5.77E+00** |

\* An additional factor of 10 has been considered as PNECsed was defined using the EPM method

\*\* Sum of the ratios for the active substances

All the calculated sums of PEC/PNEC ratios for the active substances are above 1 for sediment. No use of treated wood near aquatic compartment should be allowed. Moreover the application phase of the product above or near water leads to unacceptable risk to the aquatic compartment; no treatment above or near water is allowed.

Indirect emissions via the STP - Noise barrier scenario

The risk characterisation for the STP has been performed considering PEC calculated for the noise barrier scenario of the PT08-ESD, and compared to PNECSTP of each active substance for the service life of treated wood.

|  |  |
| --- | --- |
| **Noise barrier - Treated wood in service only – TIME 1** | |
| **STP** | **PEC/PNEC** |
| Propiconazole | 1.39E-05 |
| Tebuconazole | 1.68E-03 |
| Cypermethrin | 2.34E-05 |
| IPBC | 1.68E-03 |
| PBC | 9.32E-04 |
| **∑PEC/PNEC\*** | 4.33E-03 |
| **Noise barrier - Treated wood in service only – TIME 2** | |
| **STP** | **PEC/PNEC** |
| Propiconazole | 6.63E-07 |
| Tebuconazole | 7.31E-05 |
| Cypermethrin | 5.01E-07 |
| IPBC | 4.77E-05 |
| PBC | 2.66E-05 |
| **∑PEC/PNEC\*** | 1.49E-04 |

\* Sum of the ratios for the active substances

Considering that all PEC/PNEC ratios and aggregated PEC/PNEC ratios for STP are below 1, the risk for the STP is considered acceptable.

The risk characterisation for indirect releases via STP to the aquatic compartment including sediment has been performed considering PEC calculated for the noise barrier scenario, and compared to PNECwater and PNECsediment of each active substance for the service life of the treated wood.

|  |  |
| --- | --- |
| **Noise barrier - Treated wood in service only – TIME 1** | |
| **SURFACE WATER**  **(*via STP*)** | **PEC/PNEC** |
| Propiconazole | 2.04E-02 |
| Tebuconazole | 5.38E-02 |
| Cypermethrin | 5.13E-01 |
| PBC | 9.90E-04 |
| **∑PEC/PNEC** | 5.88E-01 |
| **SEDIMENT**  **(*via STP*)** | **PEC/PNEC** |
| Propiconazole | 5.48E-02 |
| Tebuconazole | 2.18E-03 |
| Cypermethrin | **5.12E+00** |
| PBC | 9.90E-04 |
| **∑PEC/PNEC** | **5.18E+00** |
| **Noise barrier - Treated wood in service only – TIME 2** | |
| **SURFACE WATER**  **(*via STP*)** | **PEC/PNEC** |
| Propiconazole | 9.73E-04 |
| Tebuconazole | 2.34E-03 |
| Cypermethrin | 1.10E-02 |
| PBC | 2.83E-05 |
| **∑PEC/PNEC** | 1.44E-02 |
| **SEDIMENT**  **(*via STP*)** | **PEC/PNEC** |
| Propiconazole | 2.61E-03 |
| Tebuconazole | 9.51E-05 |
| Cypermethrin | 1.10E-01 |
| PBC | 2.82E-05 |
| **∑PEC/PNEC** | 1.13E-01 |

\* An additional factor of 10 has been considered as PNECsed was defined using the EPM method

Considering that all PEC/PNEC ratios for surface water and sediment are below 1 in TIME 2, as well as the aggregated values, the risk for the aquatic compartment (including sediment) exposed to indirect releases via the STP is considered acceptable during the service life of treated wood with the product.

**Environmental risk characterisation for Iodine**

**STP**

PNECSTP for Iodine = 2.9 mg.l-1.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PEC/PNEC** | **Worst case scenario** | **Iodine (I2)** | **Iodate (IO3-)** | **Iodide (I-)** |
| STP | Noise barrier, 30 days | 9.52E-05 | - | - |

An acceptable risk is found for the STP when considering the worst case scenario.

**Surface water**

Background level in freshwater (river an lake) = 0.5-20 µg.l-1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PEC** | **Worst case scenario** | **Iodine (I2)** | **Iodate (IO3-)** | **Iodide (I-)** |
| Surface water | Noise barrier, 30 days | 2.75E-02 | 2.75E-02 | 3.80E-02 |

The calculated iodine/iodide/iodate concentrations are below the reported background level for iodine in freshwater.

###### Risk characterisation for the terrestrial compartment: X6236

Direct emissions to soil: *In situ* application

The risk characterisation for the terrestrial compartment has been performed considering PEC calculated for the house scenario of the PT08-ESD, and compared to PNECsoil of each active substance for the application phase of preventive and curative treatment.

|  |  |  |
| --- | --- | --- |
| **Application – House -Treatment by brushing** | | |
| **SOIL** | **Professional** | **Non-professional** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | **1.02E+00** | **1.70E+00** |
| Tebuconazole | 1.70E-01 | 2.83E-01 |
| Cypermethrin | 7.77E-01 | **1.30E+00** |
| IPBC | **3.86E+00** | **6.43E+00** |
| PBC | 6.29E-02 | 1.05E-01 |
| 1,2,4-triazole | **1.13E+00** | **1.88E+00** |
| **∑PEC/ PNEC\*** | **5.82E+00** | **9.70E+00** |

Considering that calculated PEC/PNEC ratios are above 1 for soil, brushing application phase is cause of concern for the terrestrial compartment, unless direct releases to soil is prevented by covering the soil during application.

|  |  |  |
| --- | --- | --- |
| **Application – House - Treatment by spraying** | | |
| **SOIL** | **Tier 1 (Runoff + Drift)** | **Tier 2 (Drift)** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | 1.02E+01 | 9.71E-01 |
| Tebuconazole | **1.70E+00** | 1.62E-01 |
| Cypermethrin | **7.77E+00** | 7.40E-01 |
| IPBC | **3.86E+01** | **3.68E+00** |
| PBC | 6.29E-01 | 5.99E-02 |
| 1,2,4-triazole | **1.13E+01** | **1.07E+00** |
| **∑PEC/ PNEC\*** | **5.82E+01** | **6.68E+00** |

\* Sum of the ratios for the active substances

For the terrestrial compartment and considering releases due to run off and drift (TIER1) on soil adjacent to the treated surface (0 to 1 m), PEC/PNEC ratios for tebuconazole, propiconazole, cypermethrin, IPBC and 1,2,4-triazole are above 1 for treatment by spraying.

For the terrestrial compartment and considering releases due to drift only (TIER 2) on soil distant form the treated surface (1 to 1.5 m), **∑**PEC/PNEC ratios is also above 1 for treatment by spraying.

The risk for the terrestrial compartment after application by spraying is considered acceptable only if the soil is covered during the application, in order to prevent all direct releases to soil *via* run-off and drift.

Direct emissions to soil: Service life of treated wood

Concerning the service-life phase of treated wood, the risk characterisation for the terrestrial compartment has been performed considering PEC calculated for the house scenario of the PT08-ESD, and compared to PNECsoil of each active substance for the service life of the treated wood.

Considering the unacceptable risk for the terrestrial compartment calculated for all intended type of application, the risk characterisation for the terrestrial compartment during the service life of treated wood taking into account also the application phase was not calculated.

|  |  |  |
| --- | --- | --- |
| **Wood-in service – House – Treated wood in service only** | | |
| **SOIL** | **TIME 1** | **TIME 2** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | **1.15E+00** | 5.82E-01 |
| Tebuconazole | 4.48E-01 | 2.00E-01 |
| Cypermethrin | 2.55E-01 | 1.86E-02 |
| IPBC | 2.64E-01 | 7.59E-03 |
| PBC | 1.25E-01 | 7.32E-03 |
| 1,2,4-triazole | **1.36E+00** | 9.24E-01 |
| **∑PEC/ PNEC\*** | **2.12E+00** | 8.08E-01 |
| **Wood-in service – Noise barrier – Treated wood in service only** | | |
| **SOIL** | **TIME 1** | **TIME 2** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | 4.31E-01 | 2.18E-01 |
| Tebuconazole | 1.68E-01 | 7.49E-02 |
| Cypermethrin | 9.54E-02 | 6.96E-03 |
| IPBC | 9.84E-02 | 2.84E-03 |
| PBC | 4.67E-02 | 2.74E-03 |
| 1,2,4-triazole | 5.09E-01 | 3.46E-01 |
| **∑PEC/ PNEC\*** | 7.92E-01 | 3.03E-01 |

\* Sum of the ratios for the active substances

Considering that calculated **∑**PEC/PNEC ratio for terrestrial compartment is above 1 only in TIME 1 for the house scenario, the risks are considered acceptable during the service life of treated wood (also considering that application phases lead to no release to the terrestrial compartment with the application of appropriate risk mitigation measure).

Indirect emissions via the STP during serfice lif of treated wood - Noise barrier scenario

Concerning the service-life of treated wood, the risk characterisation for indirect releases via STP (*i.e.* spreading of STP sludge on soil) to the terrestrial compartment has been performed considering PEC calculated for the noise barrier scenario of the PT08-ESD, and compared to PNECsoil of each active substance for the service life of the treated wood.

|  |  |  |
| --- | --- | --- |
| **Wood-in-service – Noise barrier- Treated wood in service only** | | |
| **SOIL (via STP** | **TIME 1** | **TIME 2** |
| **PEC/PNEC** | **PEC/PNEC** |
| Propiconazole | 5.32E-03 | 2.53E-04 |
| Tebuconazole | 2.23E-03 | 9.70E-05 |
| Cypermethrin | 8.92E-03 | 1.91E-04 |
| PBC | 1.03E-04 | 2.93E-06 |
| 1,2,4-triazole | 6.54E-02 | 3.09E-03 |
| **∑**PEC/ PNEC | 1.66E-02 | 5.44E-04 |

\* Sum of the ratios for the active substances

Considering that all PEC/PNEC ratios for terrestrial compartment are below 1, the risk for the terrestrial compartment is considered acceptable during the service life of treated wood following indirect emissions *via* the STP.

**Terrestrial risk characterisation for Iodine**

Background level in soil = 0.565-22.6 mg.kgwwt-1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **PEC** | **Worst case scenario** | **Iodine (I2)** | **Iodate (IO3-)** | **Iodide (I-)** |
| Soil | House, 5 years without degradation | 0.097 | 0.097 | 0.134 |

The calculated iodine/iodide/iodate concentrations are below the reported background level for iodine in soil.

###### Risk characterisation for the groundwater compartment: X6236

The estimated concentrations of active substances, and their relevant degradation products, in the groundwater compartment, were calculated with the FOCUS PEARL v.4.4.4 software.

The calculated PECgroudwater have been compared to the drinking water standard for pesticides (set at 0.1 μg/l) for each relevant substance. For all 9 EU scenarios, PECgroundwater are all below 0.1 µg/L.

Based on these results, it can be concluded that the use of the product will not pose a significant risk of groundwater contamination.

###### Risk characterisation for the atmospheric compartment: X6236

Not relevant.

Risk characterisation for secondary poisonning: X6236

Secondary poisoning is relevant only for the active substance cypermethrin. Therefore, the secondary poisoning was assessed for the TIME2 assessment period of the service life for wood treated by surface treatment, considered as a worst case. PEC and risk ratios for the risk of secondary poisoning for birds and mammals are summarised in the following table.

|  |  |  |
| --- | --- | --- |
|  | **PEC/PNECbirds**  (PNECoral,bird = 33.3 mg/kg food) | **PEC/PNECmammals**  (PNECoral,small mammal = 3.33 mg/kg food) |
| *Via* fish | 1.46E-05 | 1.46E-04 |
| *Via* earthworm | 7.03E-05 | 7.03E-04 |

Based on these PEC/PNEC ratios, it can be concluded that the use of the product will not pose a significant risk to the top predators.

**Conclusions**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Phase | Type of application / Uses | | STP | Surface water | | | Sediment | | | Soil | | | | Groundwater | | | Secondary Poisoning |
| Direct Release | *Via* STP | | Direct Release | | *Via* STP | Direct Release | | *Via* STP | | Direct Release | | *Via* STP |
| Representative product : **X6119C** (covers Meta SPC1 and Meta SPC 2). | | | | | | | | | | | | | | | | | |
| Application | Industrial application | | No emission estimations based on mandatory risk mitigation measures for wood treatment plants. | | | | | | | | | | | | | | |
| Pro. | | No emission estimations based on risk mitigation measures. | | | | | | | | | | | | | | |
| Wood in service | Use Class 1 and 2 | | Not relevant (releases to the environment not expected). | | | | | | | | | | | | | | |
| Use Class 3 | | Acceptable | Acceptable | Acceptable | | | Acceptable(3) | Acceptable | Acceptable | | Acceptable | | Acceptable | | Acceptable | Acceptable(2) |
| Representative product : **X6119M2** (covers Meta SPC 3). | | | | | | | | | | | | | | | | | |
| Application | | Pro and Non Pro application | No emission estimations based on mrisk mitigation measures. | | | | | | | | | | | | | | |
| Wood in service | | Use Class 1 and 2 | Not relevant (releases to the environment not expected). | | | | | | | | | | | | | | |
| Use Class 3 | Acceptable | Acceptable | | Acceptable | Acceptable(3) | | Acceptable | Acceptable | Acceptable | | Acceptable | | Acceptable | | Acceptable(2) |
| Representative product : **X6236** (covers Meta SPC 4). | | | | | | | | | | | | | | | | | |
| Application | | Pro and Non Pro application | No emission estimations based on mrisk mitigation measures. | | | | | | | | | | | | | | |
| Wood in service | | Use Class 1 and 2 | Not relevant (releases to the environment not expected). | | | | | | | | | | | | | | |
| Use Class 3 | Acceptable | Acceptable | | Acceptable | Acceptable(3) | | Acceptable | Acceptable | Acceptable | | Acceptable | | Acceptable | | Acceptable(2) |

‘(2) For aquatic and terrestrial food chain.

‘(3) Considering the following RMM: *Do not apply where the product can reach surface water during outdoor application* and *Treated wood should not be used near an aquatic environment*

n.r. – not relevant.

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

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

### Assessment of a combination of biocidal products

Not relevant.

### Comparative assessment

Application administrative details

|  |  |
| --- | --- |
| Procedure | NA-APP |
| Purpose | Authorisation |
| Case number in R4BP | [BC-AP017518-34](https://echa-access.echa.europa.eu/r4bp-web-authority/case/,DanaInfo=r4bp-main.echa.europa.eu,SSL+na-app.xhtml?id=BC-AP017518-34) |
| Evaluating Competent Authority | France |
| Applicant | PPG AC - France SA |
| Authorisation holder | PPG AC - France SA |

Administrative information of the Biocidal Product Family

|  |  |
| --- | --- |
| Trade name(s) | PPG\_Class3\_WB |
| Product type(s) | 8 – Wood preservative |
| Active substance(s) | Cypermethrin (CAS: 52315-07-8)  Propiconazole (CAS: 60207-90-1)  Tebuconazole (CAS: 107534-96-3)  IPBC (CAS: CAS: 55406-53-6) |

Active substance as candidate for substitution in the biocidal product family

* **Regulation (UE) 528/2012 regarding substitution criteria**

According to the most recent scientific information available on the active substance in the biocidal product, the wood preservative (PT8) tebuconazole shall be considered as candidate for substitution using the criteria in the regulation (UE) 528/2012, Article 10(1). As this active substance was approved under the Biocidal Products Directive, this information was not mentionned in the Assessment Report. However, as tebuconazole is considered to be toxic (T) and very persistent (vP), it can be considered to meet the criteria listed in Article 10(1)d. It meets two of the criteria for being PBT in accordance with Annex XIII to the regulation (EC) No 1907/2006.

Under Article 23(1) of Regulation 528/2012, Member States evaluating biocidal product family containing at least, one active substance that is a candidate for substitution in accordance with Article 10(1) are required to perform a comparative assessment. FR CA has performed this comparative assessment for the biocidal product family PPG\_Class3\_WB following the EU guidance related to the comparative assessment of the biocidal product family.

The biocidal product family PPG\_Class3\_WB is wood-preservative products containing four active substances as listed above, among which tebuconazole, meets the criteria for substitution under Article 10 of the Biocidal Products Regulation (528/2012). In line with the Note for Guidance, FR CA began the comparative assessment with the screening phase (Annex 1.1 of guidance document) to identify whether the diversity of the active substances - mode of action combination in authorised biocidal products is adequate.

Information of the active substance and the biocidal product family in the application

##### Mode of action of the active substance

The active substance tebuconazole is a fongicide acting on target organisms by interfering with basic metabolism of the fungal cell wall and contents.

##### Intended uses for the relevant Biocidal Product in the application

The product family is to be used by industrial, professional and non-professional users as a preventive and curative treatement for wood, indoor and outdoor. Preventive and curative treatments are performed by superficial application. Curative treatment can also be completed by injection.

**Table 3.1: Intended uses of the biocidal product family – preventive treatment**

|  |  |
| --- | --- |
| Product Type(s) | 8 – Wood preservative |
| Where relevant, an exact description of the authorized use | Preventive treatment for wood on use classes 1, 2 and 3.1 |
| Target organism (including development stage) | Wood rotting fungi (brown rot fungi)  Wood boring beetles:   * House longhorn beetle (*Hylotrupes bajulus*) \_ Larvae * Common furniture beetle (*Anobium punctatum*) \_ Larvae * Powder post beetles (*Lyctus brunneus*) \_ Larvae   Termites (*Reticulitermes spp)* \_ Workers, soldiers and nymphs |
| Field of use | Preventive treatment for wood on use classes 1, 2 and 3.1 |
| Application method(s) | Superficial application / short dipping treatment  Superficial application / spray treatment  Superficial application / flow coat / aspersion  Superficial application / brush / roller / pad treatment |
| Category(ies) of user(s) | Industrial users  Professional users  Non-professional users |

**Table 3.2: Intended uses of the biocidal product family – curative treatment**

|  |  |
| --- | --- |
| Product Type(s) | 8 – Wood preservative |
| Where relevant, an exact description of the authorized use | Curative treatment for wood in service (wood not exposed to weathering and frequent wetting) |
| Target organism (including development stage) | Wood boring insects   * House longhorn beetle (*Hylotrupes bajulus*) \_ Larvae * Common furniture beetle (*Anobium punctatum*) \_ Larvae * Powder post beetles (*Lyctus brunneus*) \_ Larvae   Termites (*Reticulitermes spp.* et *Heterotermes spp.*) \_ Workers, soldiers and nymphs |
| Field of use | Curative treatment for wood in service (wood not exposed to weathering and frequent wetting) softwood and hardwood |
| Application method(s) | Superficial application / brush / roller / pad treatment  Superficial application / spray  Injection (combined with a superficial application) |
| Category(ies) of user(s) | Professional users  Non-professional users |

Mapping of existing alternatives to the relevant Biocidal Product Family

##### Identified eligible alternative Biocidal Products

In order to perform the comparative assessment, FR CA considered all biocidal products authorized on the French market area under the Biocidal Products Directive (BPD) and Biocidal Products Regulation (BPR), and for which the information was available on R4BP3 database, on the 14th of March 2019.

The assessment focused on Biocidal Products addressing the same uses as the relevant Biocidal Product Family. These uses are similar to the ones described in the tables 3.1 and 3.2 above. As tebuconazole is a fungicide, only products with a funcigide activity have been considered for alternative identification.

As there are applications for mutual recognition in parallel for the product family PPG\_Class3\_WB, France as reference member state also discussed the suitability of the Biocidal Products authorized in Concerned Member States’ (cMS) markets.

##### Identified eligible non-chemical alternatives

Considering that tebuconazole was authorized under the BPD, no public consultation was carried out by ECHA in the context of the tebuconazole approval. Consequently, no non-chemical alternatives were proposed to replace the use of this substance.

Screening phase

##### Description of the assessment of the adequate chemical diversity in authorised BPs to minimise the occurence of resistance and conclusion

* + **European context:**

Applications for mutual recognition in parallel for PPG\_Class3\_WB were deposited in 14 Member States: Croatia, Slovenia, United Kingdom, Switzerland, Spain, Slovakia, Romania, Portugal, Luxembourg, Italy, Hungary, Greece, Czech Republic and Belgium.

According to the information available in the R4BP3 database in March 2019, most of the products authorized in the cMS contain the same active substances as the ones found in the composition of product authorized in France. The following active substances are used in the formulation of products not authorized in France (please refer to the table below): benzyl-C8-16-alkyldimethyl, boric acid, boric oxide, dazomet, dichlofluanid, disodium tetraborate, disodium tetraborate pentahydrate, disodium tetraborate decahydrate; disodium octaborate tetrahydrate, fenpropimorph, fenoxycarb, hydrogen cyanide, permethrin, quaternary ammonium compounds, chlorides.

|  |  |  |
| --- | --- | --- |
| **Concerned member States** | **Active substances** | **Number of PT8 authorized products** |
| Croatia | Same as France  +  hydrogen cyanide | 40 |
| Slovenia | Same as France | 11 |
| United-Kingdom | Same as France  +  hydrogen cyanide, disodium tetraborate, boric acid, fenpropimorph, boric oxide, disodium octaborate tetrahydrate , dichlofluanid | 40 |
| Switzerland | Same as France  +  disodium tetraborate pentahydrate, boric acid | 71 |
| Spain | Same as France  +  hydrogen cyanide | 24 |
| Slovakia | Same as France  +  boric acid, fenoxycarb, fenpropimorph, hydrogen cyanide | 48 |
| Romania | Same as France  +  boric acid | 7 |
| Portugal | Same as France | 13 |
| Luxembourg | Same as France | 17 |
| Italy | Same as France | 55 |
| Hungary | Same as France  +  boric acid, disodium tetraborate, disodium tetraborate pentahydrate , disodium tetraborate decahydrate | 45 |
| Greece | Same as France  +  disodium tetraborate decahydrate, boric acid | 50 |
| Czech Republic | Same as France  +  permethrin, hydrogen cyanide, quaternary ammonium compounds, benzyl-C8-16-alkyldimethyl, chlorides | 57 |
| Belgium | Same as France  +  dazomet, boric acid | 22 |

To ensure the accuracy of the information available, FR CA considered that Tier approach should be performed by concerned member states on their own market area.

* + **French context:**

In March 2019 the French CA has granted 38 biocidal products authorised under Product Type 8 (wood preservative) of the BPD and BPR. Each of these biocidal products contains at least one of the following active substances:

* ADBAC/BKC,
* Basic copper carbonate,
* Bifenthrin,
* Creosote
* Permethrin
* Cypermethrin,
* DDAC,
* IPBC (3-iodi-2-propynyl butyl carbamate),
* K-HDO (1-oxyde de cyclohexylhydroxydiazene, sel de potassium),
* Propiconazole,
* Sulfuryl fluoride
* Tebuconazole,
* Thiacloprid
* Fenpropimorph

Among these products, FR CA has identified 23 products with fungicide activity and authorized for preventive or curative treatement. The list is given in the table here below.

Considering that propiconazole will be classified as reprotoxic 1B after 1st december of 2019 accordingly with regulation (EU) 2018/1480, products containing propiconazole are not classified as appropriate alternatives.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **PRODUCT NAME and expiry date of the authorization** | **ACTIVE SUBSTANCES IN THE PRODUCT** | | | **AUTHORIZED USES OF THE PRODUCT** | | | | | **Appropriate alternative** |
| **Active substance** | **CFS ?** | **Mode of action category** | **wood boring larvae inescts and termites** | **wood rotting fungi (brown rot fungi)** | **Curative treatment** | **Preventive treatment** | **Application method** |
| V33 traitement bois multi-usage  09/05/2022 | Cypermethrin, tebuconazole, propiconazole | Yes | PYRETHROIDS  TRIAZOLE | X | X | X | X | Superficial and injection | NO |
| TX204 traitement bois autoclaves vert  09/05/2022 | Cypermethrin, tebuconazole, propiconazole | Yes | PYRETHROIDS  TRIAZOLE | X | X | X | X | Superficial | NO |
| TX204 traitement bois autoclaves brun  09/05/2022 | Cypermethrin, tebuconazole, propiconazole | Yes | PYRETHROIDS  TRIAZOLE | X | X | X | X | Superficial | NO |
| TWP 097i  20/01/2028 | IPBC, propiconazole, perméthrine | Yes | CARBAMATE,  TRIAZOLE  PYRETHROIDS | X | X |  | X | Superficial | NO |
| TWP 092i  21/05/2027 | IPBC, propiconale, cyperméthrine | Yes | CARBAMATE,  TRIAZOLE  PYRETHROIDS | X | X |  | X | Superficial | NO |
| INDULINE SW-900 IT  08/12/2027 | IPBC, propiconazole, cyperméthrine | Yes | CARBAMATE,  TRIAZOLE  PYRETHROIDS | X | X |  | X | Superficial, spraying, dipping | NO |
| Korasit TT product family  31/03/2020 | Propiconazole, Tébuconazole, Thiaclopride | Yes | TRIAZOLE  NEONICOTINOIDS | X | X |  | X | Superficial and inpregnation | NO |
| Tanalith E 3474  03/04/2020 | Carbonate de cuivre basique, propiconazole, tebuconazole | Yes | NON SPECIFIC  TRIAZOLE | X | X |  | X | Impregnation | NO |
| HYDROKOAT 6  24/09/2027 | ADBAC, DDAC, Cyperméthrine | No | QUATERNARY AMMONIUM COMPOUND  PYRETHROIDS | Only insects with wood boring larvae | X |  | X | Superficial | YES |
| Aidol HK-Lasure  30/06/2020 | IPBC | No | CARBAMATE |  | X |  | X | Superficial | YES |
| Aquawood TIM  31/03/2020 | IPBC, propiconazole | Yes | CARBAMATE  TRIAZOLE |  | X |  | X | Superficial | NO |
| Mirecide-TC/94  31/03/2020 | IPBC, propiconazole | Yes | CARBAMATE  TRIAZOLE |  | X |  | X | dipping | NO |
| Induline SW-900  31/03/2020 | IPBC, propiconazole | Yes | CARBAMATE  TRIAZOLE |  | X |  | X | Superficial | NO |
| Koranol grund farblos  31/03/2020 | IPBC, propiconazole | Yes | CARBAMATE  TRIAZOLE |  | X |  | X | Superficial | NO |
| Koralan imprägniergrund farblos  31/03/2020 | IPBC, propiconazole | Yes | CARBAMATE  TRIAZOLE |  | X |  | X | Superficial | NO |
| Primaire protecteur bois  31/03/2020 | IPBC, tebuconazole | Yes | CARBAMATE  TRIAZOLE |  | X |  | X | Superficial | YES |
| TWP 077  31/03/2020 | IPBC, propiconazole | Yes | CARBAMATE  TRIAZOLE |  | X |  | X | Superficial | NO |
| TWP 085  31/03/2020 | IPBC, propiconazole | Yes | CARBAMATE  TRIAZOLE |  | X |  | X | Superficial | NO |
| TWP 21  30/06/2020 | IPBC | No | CARBAMATE |  | X |  | X | Superficial | YES |
| Valtti Akvabase  31/03/2020 | IPBC, propiconazole | Yes | CARBAMATE  TRIAZOLE |  | X |  | X | Superficial | NO |
| Xyligen 30F  30/06/2020 | K-HDO | No | NON SPECIFIC |  | X |  | X | Superficial | YES |
| Axil 2000  31/07/2020 | IPBC, propiconazole, tebuconazole | Yes | CARBAMATE  TRIAZOLE |  | X |  | X | Superficial | NO |
| Axil PAL  31/07/2020 | IPBC, propiconazole, tebuconazole | Yes | CARBAMATE  TRIAZOLE |  | X |  | X | Superficial | NO |

Taking into account elements described above, a few number of product can be considered as appropriate alternative.

* Only one product is auhtorized againts insects and fungi (HYDROKOAT 6). This products is not authorized against termites and is used only for preventive treatment of wood, by industrial users. Consequently there is no appropriate alternative for insecticide activity to consider PPG\_Class3\_WB products as outliers.
* For uses against wood rotting fungi, 5 products have been identified as potential alternatives. The user category corresponding to the authorisations of theses products is given here below. For industrial users,
  + For professional and non professional users, all products contain the same active subtance. Hence, there is not an adequate chemical diversity to consider PPG\_Class3\_WB as an outlier
  + For industrial users, three potential alternatives contain vairous active subtances, but only one product could be used for the same fungicide activity as PPG-Class3 products (on wood of use class 2 and 3)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  | Claims | Industrial | professional | Non professionnal |
| HYDROKOAT 6  24/09/2027 | ADBAC, DDAC, Cyperméthrine | use class 1 and 2) | X |  |  |
| Aidol HK-Lasure  30/06/2020 | IPBC | use class 2 and 3 |  | x |  |
| Primaire protecteur bois  31/03/2020 | IPBC, tebuconazole | use class 2 and 3 |  | x | x |
| TWP 21  30/06/2020 | IPBC | bluestain only | X | x | x |
| Xyligen 30F  30/06/2020 | K-HDO | use class 2 and 3 | X |  |  |

##### Consideration on whether the CFS(s) meet(s) at least one of the exclusion criteria liste in the article 5(1) but can benefit from derogation in accordance with article 5(2) of the BPR

Tebuconazole is not considered as meeting the exclusion criteria according to Article 5(1).

##### Conclusion of the screening phase : stop comparative assessment

In the technical guidance note on comparative assessment of biocidal products, it is stated that :

* a suitable number of available active substances having different modes of action on the harmful organism would be necessary to minimise resistance development or selection ;
* as a general rule, at least three different and independent “active substance/mode of action” combinations should remain available through authorized BPs for a given use in order to consider that chemical diversity is adequate.

The screening phase show that there is not a suitable chemical diversity. Consequently, activity in line with Article 23(3)(b) and the technical guidance note on comparative assessment for professional, non professional and industrial users FR CA stop the comparative assessment and consider that PPG\_Class3\_WB should be authorised.

Since tebuconazole does not meet the exclusion criteria as outlined in Article 5(1), no further assessment is needed at this point. The comparative assessment for PPG\_Class3\_WB can be finalised at the screening stage and the product can be authorised for a period not exceeding 5 years in accordance with Article 23(6) of BPR.

# Annexes

## List of studies for the biocidal product family

| **Section No** | **Reference No** | **Author** | **Year** | **Title** | **Owner of data** | **Letter of Access** | | **Data protection claimed** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  | **Yes** | **No** | **Yes** | **No** |
| S3.1 |  | Simon, F. | 2015 | Odour of X6119C  DYRUP SAS – PPG (Albi, France)  150313/PaPV93.1 | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S3.1 |  | Simon, F. | 2015 | Odour of X6119CJ  DYRUP SAS – PPG (Albi, France)  150313/PaPV93.2 | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S3.1 |  | Simon, F. | 2015 | Odour of X6119M2  DYRUP SAS – PPG (Albi, France)  150313/PaPV93.6 | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S3.1 |  | Simon, F. | 2015 | Odour of X6236  DYRUP SAS – PPG (Albi, France)  150313/PaPV93.7 | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S3.1 |  | Simon F. | 2015 | Type of plastic packaging  DYRUP SAS – PPG (Albi, France) | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S3.1 S3.2 S3.4.1 S3.5 |  | Legay S. | 2016 | Storage stability during 2 years at ambient temperature according to Technical Monograph No.17 (CropLife) on the wood preservative X6119C  FCBA (Bordeaux, France)  402/13/1136F/cd-e | DYRUP SAS - PPG |  | X | X |  |
| S3.1 S3.2 S3.4.1 S3.5 |  | Legay S. | 2016 | Storage stability during 2 years at ambient temperature according to Technical Monograph No.17 (CropLife) on the wood preservative X6119CJ  FCBA (Bordeaux, France)  402/13/1141F/ad-e | DYRUP SAS - PPG |  | X | X |  |
| S3.4.1 |  | Klamer M. and Lindegaard B. | 2016 | Content of IPBC and PBC in X6119C and X6119CJ formulations  696357 (rev1) | DYRUP SAS - PPG |  | X | X |  |
| S3.1 S3.2 S3.4.1 |  | Legay S. | 2016 | Storage stability during 2 years at ambient temperature according to Technical Monograph No.17 (CropLife) on the wood preservative X6119M2  FCBA (Bordeaux, France)  402/13/1134F/cd-e | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S3.1 S3.2 S3.4.1 |  | Legay S. | 2016 | Storage stability during 2 years at ambient temperature according to Technical Monograph No.17 (CropLife) on the wood preservative X6236  FCBA (Bordeaux, France)  402/13/1138F/ad-e | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S3.2 S3.4.1 S3.5 |  | Legay S. | 2015 | Physico-chemical properties, technical characteristics and chemical analyses of the biocidal product X6119CJ before and after an accelerated storage procedure for 8 weeks at 40 ± 2°C, in compliance with CIPAC MT 46.3 method (Handbook J, 2000)  FCBA (Bordeaux, France)  402/14/1100F/abcdefge | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S3.1 S3.2 S3.4.1 |  | Legay S. | 2015 | Physico-chemical properties, technical characteristics and chemical analyses of the biocidal product X6119M2 before and after an accelerated storage procedure for 8 weeks at 40 ± 2oC, in compliance with CIPAC MT 46.3 method (Handbook J, 2000)  FCBA (Bordeaux, France)  402/14/1096F/abcd-e | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S3.1 S3.2 S3.4.1 S3.9 |  | Legay S. | 2015 | Physico-chemical properties, technical characteristics and chemical analyses of the biocidal product X6236 before and after an accelerated storage procedure for 8 weeks at 40 ± 2oC, in compliance with CIPAC MT 46.3 method (Handbook J, 2000)  FCBA (Bordeaux, France)  402/14/1097F/abcd-e | DYRUP SAS - PPG |  | X | X |  |
| S3.3 |  | Legay S. | 2015 | Relative density of the biocidal product X6119C  FCBA (Bordeaux, France)  402/14/1099F/a-e | DYRUP SAS - PPG |  | X | X |  |
| S3.3 S3.4.1 S3.5 S3.8 S3.9 |  | Legay S. | 2015 | Physical, chemical and technical characteristics of the biocidal product X6119CJ  FCBA (Bordeaux, France)  402/14/1100F/hijkl-e | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S3.5 S3.8 |  | Raphalen E. | 2016 | Physico-chemical properties and technical characteristics of the biocidal product X6119C1  FCBA (Bordeaux, France)  402/16/1076F-e | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S3.5 S3.8 S3.9 |  | Raphalen E | 2016 | Physico-chemical properties and technical characteristics of the biocidal product X6119B1  FCBA (Bordeaux, France)  402/16/1075F-e | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S3.5 |  | n.a | 2018 | Quality control data sheet – X6119B1 | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S3.8 S3.9 |  | Raphalen E | 2016 | Physico-chemical properties of the biocidal product X6119CR FCBA (Bordeaux, France)  402/16/1077F-e | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S3.3 S3.4.1 S3.8 S3.9 |  | Legay S. | 2015 | Physical, chemical and technical characteristics of the biocidal product X6119M2  FCBA (Bordeaux, France)  402/14/1096F/efgh-e | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S3.3 S3.4.1 S3.8 |  | Legay S. | 2015 | Physical, chemical and technical characteristics of the biocidal product X6236  FCBA (Bordeaux, France)  402/14/1097F/efgh-e | DYRUP SAS - PPG |  | X | X |  |
| S4.1 S4.17 |  | Raphalen E., Legay S. | 2015 | Differential Scanning Calorimetry (DSC) measurement on the test item X6119CJ  FCBA (Bordeaux, France)  402/14/1100F/m-e | DYRUP SAS - PPG |  | X | X |  |
| S4.1 S4.4 S4.17 |  | Detrimont H., Ambrosi D. | 2015 | Literature review on explosive properties, self-reactivity, oxidising properties of the ingredients of the product X6119CJ  ASC (Chaintré, France)  15/04 | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S4.4 |  | Demangel B. | 2015 | Test for oxidising liquids on X6119CJ in compliance with United Nations Recommendations on the Transport of Dangerous Goods - Manual of Tests and Criteria – Fifth revised edition (2009) - Method O.2 (Part III, Section 34.4.2) EC No.1272/2008 (CLP)  Défitraces (Brindas, France)  15-904015-001 | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S4.1 S4.17 |  | Raphalen E., Legay S. | 2015 | Differential Scanning Calorimetry (DSC) measurement on the test item X6236  FCBA (Bordeaux, France)  402/14/1097F/i-e | DYRUP SAS - PPG |  | X | X |  |
| S4.1 S4.4 S4.17 |  | Detrimont H., Ambrosi D. | 2015 | Literature review on explosive properties, self-reactivity, oxidising properties of the ingredients of the product X6236  ASC (Chaintré, France)  15/09 | DYRUP SAS - PPG |  | X | X |  |
| S4.17.1 |  | Demangel B. | 2014 | Determination of the auto-ignition temperature of X6119CJ  Défitraces (Brindas, France)  14-904015-003 | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S4.17.1 |  | Demangel B. | 2014 | Determination of the auto-ignition temperature of X6236  Défitraces (Brindas, France)  14-904015-004 | DYRUP SAS – PPG (Albi, France) |  | X | X |  |
| S5 |  | Raphalen E. | 2013 | Physico-chemical tests on a concentrated aqueous emusion (X6119C/ X6119CJ): Validation of analytical method and chemical analysis of active ingredients declared in the test items, Chemical analysis of active ingredients in two wood preservatives  FCBA  402/13/1136F/ab-e | DYRUP SAS - PPG |  | X | X |  |
| S5 |  | Raphalen E | 2015 | Validation according to SANCO 3030/99 rev. 4 for the chemical analysis of the active substances in the biocidal product X6119C1  FCBA (Bordeaux, France)  402/15/1069F/ab-e | DYRUP SAS - PPG |  | X | X |  |
| S5 |  | Raphalen E. | 2015 | Content of active substances in the biocidal product X6119B1 after a method validation according to SANCO 3030/99 rev. 4  FCBA (Bordeaux, France)  402/15/1068F/ab-e | DYRUP SAS - PPG |  | X | X |  |
| S5 |  | Raphalen E. | 2013 | Physico-chemical tests on a ready-to-use aqueous emulsion (X6119M2/ X6089HA1): Validation of analytical method and chemical analysis of active ingredients declared in the test items, Chemical analysis of active ingredients in two wood preservatives  FCBA  402/13/1134F/ab-e | DYRUP SAS - PPG |  | X | X |  |
| S5 |  | Raphalen E. | 2013 | Physico-chemical tests on a ready-to-use aqueous emulsion (X6236): Validation of analytical method and chemical analysis of active ingredients declared in the test items, Chemical analysis of active ingredients in two wood preservatives  FCBA  402/13/1137F/ab-e | DYRUP SAS - PPG |  | X | X |  |
| S6.07\_1 | 32/14/9800/03 | Schumacher P. and Fennert E.-  M. | 2015 | Determination of the protective effectiveness against wood  destroying basidiomycetes according to EN 113 (1996) in  combination with leaching procedure according to EN 73  (2014). | Dyrup S.A.S. -  PPG Industries |  |  |  |  |
| S6.07\_2 | 32/14/9800/04 | Schumacher P. and Fennert E.- M. | 2015 | Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (1996) in combination with leaching procedure according to EN 84  (1997). | Dyrup S.A.S. -  PPG Industries |  |  |  |  |
| S6.07\_3 | 401/15/118F | Ansard D. and Paulmier I. | 2015 | X6119CJ. Preventive action against termites according to  NF EN 118 with NF EN 73 | PPG Industries |  |  |  |  |
| S6.07\_4 | 401/14/133F/d-e | Ansard D. and Paulmier I. | 2015 | X6119CJ. Preventive action against termites according to  NF EN 118 with NF EN 84. | PPG Industries |  |  |  |  |
| S6.07\_5 | 32/14/9800/01 | Schumacher P. and Fennert E.- M | 2015 | X6119CJ. Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46-1 (2009) after evaporative ageing procedure according to EN 73 (1988). | Dyrup S.A.S. -  PPG Industries |  |  |  |  |
| S6.07\_6 | 32/14/9800/02 | Schumacher P. and Fennert E.- M | 2014 | X6119CJ. Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46-1 (2009) after leaching procedure according to EN 84 (1997) | Dyrup S.A.S. -  PPG Industries |  |  |  |  |
| S6.07\_7 | 401/14/133F/a and b-e | Brunet C. and Paulmier I. | 2017 | X6119CJ. Preventive effectiveness against Anobium  punctatum according to NF EN 49-1 with ageing tests | PPG Industries |  |  |  |  |
| S6.07\_8 | 401/14/133F/a and b-e | Brunet C. and Paulmier I. | 2017 | X6119CJ. Preventive effectiveness against Anobium punctatum according to NF EN 49-1 with ageing tests | PPG Industries |  |  |  |  |
| S6.07\_9 | 401/14/133F/c/e | Brunet C. and Paulmier I. | 2015 | X6119CJ. Determination of the protective effectiveness against Lyctus brunneus according to NF EN 20-1. | PPG Industries |  |  |  |  |
| S6.07\_10 | 401/15/047F | Brunet C. and Paulmier I. | 2015 | X6119C (3%). Preventive action against termites according to N F EN 118 with NF EN 73 | Dyrup S.A.S. |  |  |  |  |
| S6.07\_11 | 32/15/9850/01 | Schumacher P. and Fennert E.M. | 2015 | Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46-1 (2009) after evaporative ageing procedure according to EN 73 (2014). X6119C | Dyrup S.A.S. -  PPG Industries |  |  |  |  |
| S6.07\_13 | 32/14/9802/03 | Schumacher P. and Fennert E.M. | 2015 | Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (1996) in combination with evaporative ageing procedure according to EN 73 (2014). | Dyrup S.A.S. -  PPG Industries |  |  |  |  |
| S6.07\_15 | 32/14/9802/04 | Schumacher P. and Fennert E.M. | 2015 | Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (1996) in combination with leaching procedure according to EN 84 (1997). | Dyrup S.A.S. -  PPG Industries |  |  |  |  |
| S6.07\_15bis | 401/16/075F/1/b-e | Ansard D. and Paulmier I. | 2015 | X6119M2. Preventive action against termites according to NF EN 118 with NF EN 73. | PPG Industries |  |  |  |  |
| S6.07\_16 | 401/14/135F/d-e | Ansard D. and Paulmier I. | 2017 | X6119M2. Preventive action against termites according to NF EN 118 with NF EN 84. | PPG Industries |  |  |  |  |
| S6.07\_17 | 32/14/9802/01 | Schumacher P. and Fennert E.M. | 2015 | X6119M2. Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46-1 (2009) after evaporative ageing procedure according to EN 73 (1988). | Dyrup S.A.S. -  PPG Industries |  |  |  |  |
| S6.07\_18 | 32/14/9802/02 | Schumacher P. and Fennert E.M. | 2014 | X6119M2. Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46-1 (2009) after leaching procedure according to EN 84 (1997). | Dyrup S.A.S. -  PPG Industries |  |  |  |  |
| S6.07\_19 | 401/14/135F/a and b-e | Brunet C. and Paulmier I. | 2017 | X6119M2. Preventive effectiveness against Anobium punctatum according to NF EN 49-1 with ageing tests. | PPG Industries |  |  |  |  |
| S6.07\_20 | 401/14/135F/a and b-e | Brunet C. and Paulmier I. | 2017 | X6119M2. Preventive effectiveness against Anobium punctatum according to NF EN 49-1 with ageing tests. | PPG Industries |  |  |  |  |
| S6.07\_21 | 401/14/135F/c/e | Brunet C. and Paulmier I. | 2015 | X6119M2. Determination of the protective effectiveness against Lyctus brunneus according to NF EN 20-1. | PPG Industries |  |  |  |  |
| S6.07\_22 | 32/14/9802/05 | Schumacher P. and Fennert E.M. | 2015 | X6119M2. Determination of the eradicant action against larvae of Hylotrupes bajulus (L.) according to EN 1390 (06/2006). | Dyrup S.A.S. -  PPG Industries |  |  |  |  |
| S6.07\_22bis | 401/16/119F/3/e | Brunet C. and Paulmier I. | 2017 | X6119M2 (Batch n° PaP V 148-3). Curative efficacy against Hylotrupes bajulus according to NF EN 1390. | Dyrup S.A.S. |  |  |  |  |
| S6.07\_23 | 401/14/135F/f/e | Brunet C. and Paulmier I. | 2015 | X6119M2. Determination of eradicant action against larvae of Anobium punctatum (De Geer)-laboratory method according to NF EN 48 | PPG Industries |  |  |  |  |
| S6.07\_24 | 32/14/9801/03 | Schumacher P. and Fennert E.M. | 2015 | Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (1996) in combination with leaching procedure according to EN 73 (2014). | Dyrup S.A.S. -  PPG Industries |  |  |  |  |
| S6.07\_25 | 32/14/9801/04 | Schumacher P. and Fennert E.M. | 2015 | Determination of the protective effectiveness against wood destroying basidiomycetes according to EN 113 (1996) in combination with leaching procedure according to EN 84 (1997). | Dyrup S.A.S. -  PPG Industries |  |  |  |  |
| S6.07\_26 | 401/14/134F/e-e | Ansard D. and Paulmier I. | 2015 | X6236. Preventive action against termites according to NF EN 118 with NF EN 73. | PPG Industries |  |  |  |  |
| S6.07\_26bis | 401/16/075F/2/b-e | Ansard D. and Paulmier I. | 2017 | X6236. Preventive efficacy against subterranean termites according to adapted NF EN 118 with NF EN 73. | Dyrup S.A.S. |  |  |  |  |
| S6.07\_27 | 401/14/134F/d-e | Ansard D. and Paulmier I. | 2015 | X6236. Preventive action against termites according to NF EN 118 with NF EN 84. | PPG Industries |  |  |  |  |
| S6.07\_27bis | 401/16/075F/2/a-e | Ansard D. and Paulmier I. | 2016 | X6236. Preventive efficacy against subterranean termites according to adapted NF EN 118 with NF EN 84. | Dyrup S.A.S. |  |  |  |  |
| S6.07\_28 | 32/14/9801/01 | Schumacher P. and Fennert E.M. | 2015 | X6236. Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46-1 (2009) after evaporative ageing procedure according to EN 73 (1988). | Dyrup S.A.S. -  PPG Industries |  |  |  |  |
| S6.07\_29 | 32/14/9801/02 | Schumacher P. and Fennert E.M. | 2014 | X6236. Determination of the preventive action against recently hatched larvae of Hylotrupes bajulus (L.) according to EN 46-1 (2009) after leaching procedure according to EN 84 (1997). | Dyrup S.A.S. -  PPG Industries |  |  |  |  |
| S6.07\_30 | 401/14/134F/a and b-e | Brunet C. and Paulmier I. | 2017 | X6236. Preventive effectiveness against Anobium punctatum according to NF EN 49-1 with ageing test | PPG Industries |  |  |  |  |
| S6.07\_31 | 401/14/134F/a and b-e | Brunet C. and Paulmier I. | 2017 | X6236. Preventive effectiveness against Anobium punctatum according to NF EN 49-1 with ageing test. | PPG Industries |  |  |  |  |
| S6.07\_32 | 401/14/134F/c/e | Brunet C. and Paulmier I. | 2015 | X6236. Determination of the protective effectiveness against Lyctus brunneus according to NF EN 20-1. | PPG Industries |  |  |  |  |
| S6.07\_33 | 32/14/9801/05A | Schumacher P. and Fennert E.M. | 2015 | X6236. Determination of the eradicant action against larvae of Hylotrupes bajulus (L.) according to EN 1390 (06/2006). | Dyrup S.A.S. -  PPG Industries |  |  |  |  |
| S6.07\_34 | 401/14/134F/f/e | Brunet C. and Paulmier I. | 2015 | X6236. Determination of eradicant action against larvae of Anobium punctatum (De Geer)-laboratory method according to NF EN 48. | PPG Industries |  |  |  |  |

## Output tables from exposure assessment tools













## New information on the active substance

Not relevant.

## Residue behaviour

<Active Substance>

Date: 17/02/2017

Intended Use (critical application)

Active substances: tébuconazole, IPBC, cypermethrine and propiconazole

Formulation of biocidal product: concentrate water-based products

Place of treatment: indoor and outdoor

preventive treatment: 150 g to 200 g of diluted product/m²

curative treatment: 180 to 300 g of diluted product/m²

The intended use descriptions of the tebuconazole, IPBC, cypermethrine and propiconazole containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. The products are not intended to be applied on surfaces with possible contact with livestock, feed and foodstuffs. No further data are required concerning the residue behaviour.

## Summaries of the efficacy studies

*see IUCLID*

## Confidential annex

Please refer to the Condidential annex of this PAR.

## Other

Toxicology and metabolism –active substance

<Cypermethrine>

Threshold Limits and other Values for Human Health Risk Assessment

Date: 26/07/2016

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

|  |  |
| --- | --- |
| Inhalative absorption | 100% |
| Oral absorption | 57% (human) and 44% (animal) |
| Dermal absorption | 7% |

| **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 3 – H301  STOT SE 3 – H335  STOT RE 2 – H 373 |

<Propiconazole>

Threshold Limits and other Values for Human Health Risk Assessment

Date: 26/07/2016

| **Summary** | | | |
| --- | --- | --- | --- |
|  | Value | Study | SF |
| AEL long-term | 0.04 | 2 years rat | 100 |
| AEL medium-term | 0.08 | Fertility rat | 100 |
| AEL acute | 0.3 | Developmental rat | 100 |
|  | | | |

|  |  |
| --- | --- |
| Inhalative absorption | 100% |
| Oral absorption | 86% |
| Dermal absorption | 9% ou 4% |

| **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 4 – H302  Skin Sens 1 – H317 |

An opinion of RAC of December 2016 is available for propiconazole, proposing a classification H302, H317 and H360D.

<Tebuconazole>

Threshold Limits and other Values for Human Health Risk Assessment

Date: 26/07/2016

| **Summary** | | | |
| --- | --- | --- | --- |
|  | Value | Study | SF |
| AEL long-term | 0.03 | 1 year dog | 100 |
| AEL medium-term | 0.03 | 1 year dog | 100 |
| AEL acute | 0.03 | 1 year dog | 100 |
|  | | | |

|  |  |
| --- | --- |
| Inhalative absorption | 100% |
| Oral absorption | 100% |
| Dermal absorption | 8% ou 3% |

| **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 4 – H302  Repr 2 – H361d |

<IPBC>

Threshold Limits and other Values for Human Health Risk Assessment

Date: 26/07/2016

| **Summary** | | | |
| --- | --- | --- | --- |
|  | Value | Study | SF |
| AEL long-term | 0.2 | 2 years rat | 100 |
| AEL medium-term | 0.35 | 90 days rat | 100 |
| AEL acute | 0.35 | 90 days rat | 100 |
|  | | | |

|  |  |
| --- | --- |
| Inhalative absorption | 100% |
| Oral absorption | 100% |
| Dermal absorption | 75% |

| **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) | Acute Tox 4 – H302  Acute Tox 3 – H331  Eye dam 1 – H318  Skin Sens 1 – H317  STOT RE 1 – H 372 |

Toxicology – biocidal product

<Biocidal Product>

|  |  |
| --- | --- |
| General information | |
| Formulation Type |  |
| Active substance(s) (incl. content) |  |
| Category |  |

| Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3) | | | | |
| --- | --- | --- | --- | --- |
| No study was provided |  |  |  |  |

| Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7) | | | | |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| No data |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| Further toxicological information |  | | | |

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

|  |  |
| --- | --- |
| X6119 C and X61169CJ (meta SPC1) | H315  H318  H317  The labelling should mention: ”contain: IPBC, 2-[(3 aminopropyl)methylamino]ethanol”. |
| X6119 B1(meta SPC2) | H315  H318  H317  The labelling should mentionned: ”contain: IPBC, 2-[(3-aminopropyl)methylamino]ethanol”. |
| X6119 C1 (meta SPC2) | H315  H318  H317  the labelling should mentionned: ”contain: IPBC, 2-[(3-aminopropyl)methylamino]ethanol”. |
| X6119 M2 and X6236 (meta SPC3) | H319  EUH 208: Contains propiconazole, Acticide B20 (containing notably 1,2-benzisothiazolin-3-one) and Mixture of 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one. May produce an allergic reaction. |
| X6119 CR (meta SPC3) | H319  EUH 208: Contains propiconazole and coformulants Mergal (containing notably 1,2-benzisothiazolin-3-one), Norasystem (containing notably citral, linalool) and Clove ext. May produce an allergic reaction. |

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-1)
2. Wood preservatives – Test method for determining the protective effectiveness against wood destroying basidiomycetes – Determination of the toxic values [↑](#footnote-ref-2)
3. Wood preservatives – Accelerated ageing tests of treated wood prior biological testing – Evaporative ageing procedure. [↑](#footnote-ref-3)
4. Wood preservatives – Accelerated ageing tests of treated wood prior biological testing – leaching procedure. [↑](#footnote-ref-4)
5. Wood preservatives – Determination of preventive action against *Reticulitermes* species (European termites) (Laboratory method) [↑](#footnote-ref-5)
6. Wood preservatives – Determination of the preventive action against *Hylotrupes bajulus (Linnaeus)* – Part 1:Larvicidal effect (Laboratory method). [↑](#footnote-ref-6)
7. Wood preservatives – Determination of the protective effectiveness against *Anobium punctatum (De geer)* – Part 1: Application by surface treatment (Laboratory method). [↑](#footnote-ref-7)
8. Wood preservatives – Determination of the protective effectiveness against *Lyctus brunneus (Stephens)* – Part 1: Application by surface treatment (laboratory method). [↑](#footnote-ref-8)
9. Wood preservatives – Determination of preventive action against *Reticulitermes* species (European termites) (Laboratory method) [↑](#footnote-ref-9)
10. Wood preservatives – Determination of the preventive action against *Hylotrupes bajulus (Linnaeus)* – Part 1:Larvicidal effect (Laboratory method). [↑](#footnote-ref-10)
11. Durability of wood and wood-based products – Efficacy of preventive wood preservatives as determined by biological tests – Part 1: Specification according to use class. [↑](#footnote-ref-11)
12. Performance criteria for curative wood preservatives as determined by biological tests (2004) [↑](#footnote-ref-12)
13. Guidance on dermal absorption. EFSA journal 2012 ; 10(4) :2665 [↑](#footnote-ref-13)
14. Guidance on dermal absorption. EFSA journal 2012 ; 10(4) :2665 [↑](#footnote-ref-14)
15. Propiconazole is classified repr. 1B H360d according to the ATP 13 of CLP regulation. Considering a content in propiconazole superior to 0.3%, a classification repr. 1B H360d of the product is needed. [↑](#footnote-ref-15)
16. “The most appropriate model to used for the scenario of non-professional application of paints by brushing and rolling”, agreed at the HH WG III on 26 May 2016. [↑](#footnote-ref-16)
17. HEEG Opinion on Exposure model ”Primary exposure scenario – washing out of a brush which has been used to apply a paint”, endorsed at TM III 2010. [↑](#footnote-ref-17)
18. “Methods and models to assess exposure to biocidal product in different product types” version 2, June 2016. [↑](#footnote-ref-18)
19. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-19)
20. “Methods and models to assess exposureto biocidal product in different product types” version 2, June 2016. [↑](#footnote-ref-20)
21. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-21)
22. “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-22)
23. HEEG Opinion on Exposure model ”Primary exposure scenario – washing out of a brush which has been used to apply a paint”, endorsed at TM III 2010. [↑](#footnote-ref-23)
24. “Methods and models to assess exposureto biocidal product in different product types” version 2, June 2016. [↑](#footnote-ref-24)
25. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-25)
26. “Methods and models to assess exposureto biocidal product in different product types” version 2, June 2016. [↑](#footnote-ref-26)
27. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-27)
28. “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-28)
29. HEEG Opinion on Exposure model ”Primary exposure scenario – washing out of a brush which has been used to apply a paint”, endorsed at TM III 2010. [↑](#footnote-ref-29)
30. “Methods and models to assess exposureto biocidal product in different product types” version 2, June 2016. [↑](#footnote-ref-30)
31. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-31)
32. “Methods and models to assess exposureto biocidal product in different product types” version 2, June 2016. [↑](#footnote-ref-32)
33. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-33)
34. “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-34)
35. HEEG Opinion on Exposure model ”Primary exposure scenario – washing out of a brush which has been used to apply a paint”, endorsed at TM III 2010. [↑](#footnote-ref-35)
36. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-36)
37. Guidance on the Biocidal product Regulation, Volume III Human Health – Part B risk assessment, 2015. [↑](#footnote-ref-37)