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\_CLASS1\_WB

Product type 8

Cypermethrin

Case Number in R4BP for NA-APP: [BC-CC017499-50]

Case Number in R4BP for NA-MIC: [BC-GR051951-24]

Evaluating Competent Authority: France

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**Note to the reader:**

This consolidated PAR for the minor change of the product authorisation PPG\_CLASS1\_WB is based on the PAR of the first authorisation, in which all addenda have been included.

The part 2.1 of this consolidated PAR corresponds to the summary of product characteristics which is proposed for authorisation for the minor change application.

In part 2.2 of this consolidated PAR, each section contains the initial assessment and the subsequent successive assessments (major change and post authorisation data).

The assessments related to the minor change of the product are at the end of each section and are highlighted in grey.

* **Minor change 2019**

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

* The change of composition (Meta SPC 1,2 and 3) and classification (Meta SPC 2 and 3).
* The addition of two trade names

**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-CC017499-50 | 12.06.2018 | Initial assessment |
| NA-MIC | *FR* | BC-GR051951-24 | 29/01/2020 | Minor change application |

# CONCLUSION

**Conclusion on the physicochemical and technical properties of the product**

The physico-chemical characteristics of the PPG\_CLASS1\_WB family have been described and are considered to be compliant under the conditions of use specified in the annexed Meta SPCs.

Analytical methods are considered to be compliant.

* **Minor Change application for PPG CLASS1 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.

**Conclusion on Efficacy**

French competent authorities (FR CA) assessed that the product family (PPG\_CLASS1\_WB). Based on the information given by the applicant and the uses claimed for the products belonging to the family, the family was separated in 3 meta-SPC:

* In META-SPC1:
* The data presented in the dossier demonstrated for the product X6089CR:
  + 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.).*
  + 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.)*

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

* In META-SPC 2:
* The data presented in the dossier demonstrated for the product X6089HA1:
  + 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.).*
  + 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.).*

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

* In META-SPC 3
* The data presented in the dossier demonstrated for the product X6235:
  + 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.).*
  + the curative efficacy of the product when used by superficial application of wood in service against wood boring beetles (*Anobium punctatum)* and termites (*Reticulitermes spp.* and *Heterotermes spp.*)*.*

During the assessment of the dossier, the applicant has withdrawn his claim against *Hylotrupes bajulus.* According to the EN 14128, an efficacy against *Lyctus brunneus* could be accepted only if the curative efficacy of the product is demonstrated against both *Hylotrupes bajulus* and *Anobium punctatum*. Therefore the curative effect against *Lyctus* for the product X6235 is not demonstrated.

The product is applied by non-professional users.

* **Minor Change application for PPG CLASS 1 WB - 2019:**

The efficacy assessment remained unchanged**.**

**Conclusion on risk assessment for human health**

For product X6089CR, the risk is acceptable without PPE for application by brushing and brushing combined to injection. The risk is acceptable for spraying and spraying combined to injection when gloves and coated coverall are worn.

For product X6089HA1, the risk is acceptable without PPE for application by brushing and brushing combined to injection. The risk is acceptable for spraying when gloves and coated coverall are worn. The risk is acceptable for spraying combined to injection when gloves and impermeable coverall are worn.

PPE is required only for professionals. The risk is acceptable without PPE for non-professionals.

For product X6235, the risk is acceptable.

* **Minor Change application for PPG CLASS 1 WB - 2019:**

The classification and labelling of meta SPCs 2 and 3 has been updated and no new substance of concern has been identified. The conclusions remain unchanged.

**Conclusion on risk for consumers via residues**

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses. Wood treated with PPG\_CLASS1\_WB must contain label restrictions against use in contact with livestock, food and feed.

**Conclusion on risk assessment for the environment**

No emissions in the environmental compartments are predicted when using the products X6089CR, X6089HA1 and X6235 for curative indoor treatments and then no risk assessment for the environment is deemed necessary.

* **Minor change application for PPG CLASS1 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.

# ASSESSMENT REPORT

# Part I - First information level

## Summary of the product assessment

### Administrative information

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

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| PPG\_CLASS1\_WB | France |

#### **Authorisation holder**

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | PPG AC – France SA |
| **Address** | 10 rue Henri Sainte Claire Deville  92565 Rueil-Malmaison  France |
| **Authorisation number** | **FR-2018-0042** | |
| **Date of the authorisation** | **12/06/2018** | |
| **Expiry date of the authorisation** | **12/06/2028** | |

#### **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 cedex  France |
| **Location of manufacturing sites** | ZI Montplaisir, 25 rue Jean le Rond d'Alembert  81000 Albi  France |

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

|  |  |
| --- | --- |
| **Active substance** | Cypermethrin |
| **Name of manufacturer** | Arysta LifeScience Benelux SPRL |
| **Address of manufacturer** | 26 rue de Renory  14102 Ougrée  Belgium |
| **Location of manufacturing sites** | Dr Reddys Laboratories Limited,  Steanard Lane, Mirfield,  West Yorkshire,  WF14 8QB, UK |
| Gharda Ltd; D, ½,  MIDC, LOTE PARSHURAM TAL. KHED DIST.  RATNAGIRI 415 722,  MAHARASHTRA, INDIA |

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

### Product 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 substance**

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

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

The active substance cypermethrin contained in the biocidal products of the PPG\_Class1\_WB family is not candidate for substitution in accordance with Article 10 of BPR.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Cypermethrin (pure) |  |  |  |  |  | | (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 |  |  |  |  |  | |
| alcohols, C11-14-iso-, C13-rich, ethoxylated propoxylated | alcools, C11-14-iso-, C13-rich, ethoxylés propoxylés | Non-ionic surfactant | 78330-23-1 | - | 0.00 | 0.108 |

#### 

#### **Type of formulation**

|  |
| --- |
| Another Liquid (AL) |

# Part II.- Second information level - meta SPC 1

## 1. Meta SPC 1 administrative information

## 

## 1.1. Meta SPC identifier

| **X6089CR** |  |
| --- | --- |

## 

## 1.2. Suffix to the authorisation number

|  |  |
| --- | --- |
| **Number 1** |  |

## 1.3. Product type(s)

| **Product type(s)** | PT08 |
| --- | --- |

## 2. Meta SPC 1 composition

## 2.1. Qualitative and quantitative information on the composition of the meta SPC 1

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Cypermethrin (technical) |  |  |  |  |  | | (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 |  |  |  |  |  | |
| alcohols, C11-14-iso-, C13-rich, ethoxylated propoxylated | alcools, C11-14-iso-, C13-rich, ethoxylés propoxylés | Non-ionic surfactant | 78330-23-1 | - | 0.054 | 0.108 |

## 2.2. Type(s) of formulation of the meta SPC 1

| **Formulation** |  |
| --- | --- |
| Another Liquid (AL) |  |

## 3. Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1

| **Classification** | |
| --- | --- |
| Hazard category | Eye Irrit. 2  Aquatic Acute 1  Aquatic Chronic 1 |
| Hazard statement | H319 - Causes serious eye irritation  H400 – Very toxic to aquatic life  H410 – Very toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Warning  Résultat de recherche d'images pour "GHS09" |
| Hazard statements | H319 - Causes serious eye irritation  H410 – Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P102: Keep away from children  P264: Wash … thoroughly after handling  P273: Avoid release to the environment  P280: Wear protective gloves/protective clothing/eye protection/face protection.  P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P337 + P313: If eye irritation persists: Get medical advice/ attention.  P391: Collect spillage  P501: Dispose of contents/container in accordance with local regulation. |
|  | |
| Note | EUH208: Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. |

## 4. Authorised use(s) of the meta SPC 1

**4.1. Use description**

Table 1. Use # 1 – Preventive X6089CR

|  |  |
| --- | --- |
| **Product Type** | PT08 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism(s) (including development stage)** | Wood boring beetles  House longhorn beetle (*Hylotrupes bajulus*) \_ Larvae  Common furniture beetle (*Anobium punctatum*) \_ Larvae  Powder post beetle (*Lyctus brunneus*) \_ Larvae  Subterranean Termites (*Reticulitermes spp.*) \_ Workers, soldiers and nymphs |
| **Field(s) of use** | UC1 on softwood and hardwood. |
| **Application method(s)** | Superficial application / brush / roller / pad treatment  Superficial application / spray treatment |
| **Application rate(s) and frequency** | Application rate in the analytical zone:  Preventive treatment – use class 1: 200 g/m² |
| **Category(ies) of users** | Non-professionals  Professionals |
| **Pack sizes and packaging material** | - 4 L, 15 L tin-plate cans, 20 L tin-plate pails  - 20 L LDPE sachet.  The tin-plate cans and pails are coated inside with an epoxyphenolic varnish.  All packagings are hermetically closed with a cap. |

## 4.1.1. Use-specific instructions for use

|  |
| --- |
| - |

## 

## 4.1.2 Use-specific risk mitigation measures

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## 

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

|  |
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| - |

## 

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

|  |
| --- |
| - |

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

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| --- |
| - |

**4.2. Use description**

Table 2. Use # 2 – Curative X6089CR

|  |  |
| --- | --- |
| **Product Type** | PT08 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism(s) (including development stage)** | Wood boring beetles  House longhorn beetle (*Hylotrupes bajulus*) \_ Larvae  Common furniture beetle (*Anobium punctatum*) \_ Larvae  Powder post beetle (*Lyctus brunneus*) \_ Larvae  Subterranean Termites (*Reticulitermes spp.*)  Workers, soldiers and nymphs |
| **Field(s) of use** | Curative treatment  wood in situation of use class 1, on softwood and hardwood. |
| **Application method(s)** | Superficial application / brush / roller / pad treatment  Superficial application / spray treatment  Injection (in combination with superficial application) |
| **Application rate(s) and frequency** | Application rate in the analytical zone: (wood in service)  300 g/m² for curative treatment by superficial application,  In combination with injection if need be:  180 g/m² for injection (20 mL per hole, 9 holes/m²). |
| **Category(ies) of users** | Non-professionals  Professionals |
| **Pack sizes and packaging material** | X6089CR:  - 4 L, 15 L tin-plate cans, 20 L tin-plate pails  - 20 L LDPE sachet.  The tin-plate cans and pails are coated inside with an epoxyphenolic varnish.  All packagings are hermetically closed with a cap. |

## 4.2.1. Use-specific instructions for use

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

# 

## 4.2.2 Use-specific risk mitigation measures

|  |
| --- |
| **-** |

# 

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

|  |
| --- |
| **-** |

# 

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

|  |
| --- |
| **-** |

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

|  |
| --- |
| - |

## 5. General directions for use of the meta SPC 1

## 

## *5.1. Instructions for use*

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

## *5.2. Risk mitigation measures*

|  |
| --- |
| * Do not apply on wood likely to be in contact with food, feed, drinks and livestock. * For professional, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and a coated coverall (category III Type 6) during the application phase of the product by spraying and injection combined with spraying. |

## *5.3. 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. * Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. Do not give fluids or induce vomiting. * Inhalation (of spray mist): Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. * In case of impaired consciousness place in recovery position and seek medical advice immediately. * Keep the container or label available. |

## 

## *5.4. Instructions for safe disposal of the product and its packaging*

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

## 

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

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

## 6. Other information

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

# Part III - Third information level: individual products in the meta SPC 1

## 1. Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | X6089CR  Koatec Hydrogel  Xylophene Curatif WI100G  Xylophène Industrie Xylobati WI100G  Xylophène Professionnel CGX  Xylophene Expert Xylo Profond  Xylophène Xylo Profond  Spain:  Corpol Gel Plus | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Cypermethrin (technical) |  |  |  |  |  | | (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 |
| alcools, C11-14-iso-, C13-rich, ethoxylés propoxylés | alcools, C11-14-iso-, C13-rich, ethoxylés propoxylés | Non-ionic surfactant | 78330-23-1 | - | 0.054-0.108 |

# Part II.- Second information level - meta SPC 2

## 1. Meta SPC 2 administrative information

## 1.1. Meta SPC identifier

| **X6089HA1** |  |
| --- | --- |

## 1.2. Suffix to the authorisation number

|  |  |
| --- | --- |
| **Number 2** |  |

## 1.3. Product type(s)

| **Product type(s)** | PT08 |
| --- | --- |

## 2. Meta SPC 2 composition

## 2.1. Qualitative and quantitative information on the composition of the meta SPC 2

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Cypermethrin (pure) |  |  |  |  |  | | (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 |  |  |  |  |  | |

## 2.2. Type(s) of formulation of the meta SPC 2

| **Formulation** |  |
| --- | --- |
| Another Liquid (AL) |  |

## 3. Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2

| **Classification** | |
| --- | --- |
| Hazard category | Aquatic Acute 1  Aquatic Chronic 1 |
| Hazard statement | H400 – Very toxic to aquatic life  H410 – Very toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Warning  Résultat de recherche d'images pour "GHS09" |
| Hazard statements | H410 – Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P273: Avoid release to the environment  P391: Collect spillage  P501: Dispose of contents/container in accordance with local regulation. |
|  | |
| Note | EUH208: Contains 1,2-benzisothiazol-3(2H)-one and a mixture of 5-chloro-2methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction. |

## 4. Authorised use(s) of the meta SPC 2

**4.1. Use description**

Table 1. Use # 1 – Preventive X6089HA1

|  |  |
| --- | --- |
| **Product Type** | PT08 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism(s) (including development stage)** | Wood boring beetles  House longhorn beetle (*Hylotrupes bajulus*) \_ Larvae  Common furniture beetle (*Anobium punctatum*) \_ Larvae  Powder post beetle (*Lyctus brunneus*) \_ Larvae  Subterranean Termites (*Reticulitermes spp. and Heterotermes spp.*)  Workers, soldiers and nymphs |
| **Field(s) of use** | Use class 1 on softwood and hardwood. |
| **Application method(s)** | Superficial application / brush / roller / pad treatment  Superficial application / spray treatment |
| **Application rate(s) and frequency** | Application rate in the analytical zone:  Preventive treatment – use class 1: 200 g/m² |
| **Category(ies) of users** | Non-professionals  Professionals |
| **Pack sizes and packaging material** | X6089HA1:  - 1 L, 5 L, 6 L 20 L, 24 L, 25 L and 30 L tin-plate cans  - 30 L HDPE pail  - 55 L tin-plate drum  - 200 L HDPE drum  - 1000 L HDPE intermediate bulk container  The tin-plate cans and drums are coated inside with an epoxyphenolic varnish.  All packagings are hermetically closed with a cap. |

## 4.1.1. Use-specific instructions for use

|  |
| --- |
| - |

## 4.1.2 Use-specific risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

**4.2. Use description**

Table 2. Use # 2 – Curative X6089HA1

|  |  |
| --- | --- |
| **Product Type** | PT08 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism(s) (including development stage)** | Wood boring beetles  House longhorn beetle (*Hylotrupes bajulus*) \_ Larvae  Common furniture beetle (*Anobium punctatum*) \_ Larvae  Powder post beetle (*Lyctus brunneus*) \_ Larvae  Subterranean Termites (*Reticulitermes spp. and Heterotermes spp.*)  Workers, soldiers and nymphs |
| **Field(s) of use** | Curative treatment  wood in situation of use class 1, on softwood and hardwood. |
| **Application method(s)** | Superficial application / brush / roller / pad treatment  Superficial application / spray treatment  Injection (in combination with superficial application) |
| **Application rate(s) and frequency** | Application rate in the analytical zone: (wood in service)  300 g/m² for curative treatment by superficial application,  In combination with injection if need be:  180 g/m² for injection (20 mL per hole, 9 holes/m²). |
| **Category(ies) of users** | Non-professionals  Professionals |
| **Pack sizes and packaging material** | X6089HA1:  - 1 L, 5 L, 6 L 20 L, 24 L, 25 L and 30 L tin-plate cans  - 30 L HDPE pail  - 55 L tin-plate drum  - 200 L HDPE drum  - 1000 L HDPE intermediate bulk container.  The tin-plate cans and drums are coated inside with an epoxyphenolic varnish.  All packagings are hermetically closed with a cap. |

## 4.2.1. Use-specific instructions for use

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

## 4.2.2 Use-specific risk mitigation measures

|  |
| --- |
| **-** |

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

|  |
| --- |
| **-** |

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

|  |
| --- |
| **-** |

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

|  |
| --- |
| - |

## 5. General directions for use of the meta SPC 2

## *5.1. Instructions for use*

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

## *5.2. Risk mitigation measures*

|  |
| --- |
| * Do not apply on wood likely to be in contact with food, feed, drinks and livestock. * For professional, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and a coated coverall (category III Type 6) during the application phase of the product by spraying. * For professional, wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) and an impermeable coverall (category III Type 3 or 4) during the application phase of the product by injection combined with spraying. |

## *5.3. 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. * Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. Do not give fluids or induce vomiting. * Inhalation (of spray mist): Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. * In case of impaired consciousness place in recovery position and seek medical advice immediately. * Keep the container or label available. |

## *5.4. Instructions for safe disposal of the product and its packaging*

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

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

|  |
| --- |
| * Do not store more than 18 months. * Do not store above 40°C. |

## 6. Other information

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

# Part III - Third information level: individual products in the meta SPC 2

## 1. Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **X6089HA1**  Xylophène Poutres & Charpentes  Xylophène Boiseries & Parquets  Veraxyl Charpente Traitement du Bois  Xylophène Charpente  Xylophène Professionnel C2000  Xylophene Expert Xylo Structure  Colours Traitement Poutres et Charpentes  Inventiv' Protec Traitement Poutres et Charpentes  Boisilor Traitement Poutres & Charpentes  Bricorama Traitement Poutres Et Charpentes  Xylophene Curatif CE 2000  Xylophène Industrie Xylobati CE 2000  Traitement Poutres et Charpentes Nuance  Xylophène Xylo Structure  Denmark:  Gori Stop Insekt  Protox Insekt  A-Tox+  Borup Møbel- & Træbeskyttelse  Juliana Woodrefresher | | | | |
| **Authorisation number** |  | | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Cypermethrin (technical) |  |  |  |  |  | | (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 | |

# Part II.- Second information level - meta SPC 3

## 1. Meta SPC 3 administrative information

## 1.1. Meta SPC identifier

| **X6235** |  |
| --- | --- |

## 1.2. Suffix to the authorisation number

|  |  |
| --- | --- |
| **Number 3** |  |

## 1.3. Product type(s)

| **Product type(s)** | PT08 |
| --- | --- |

## 2. Meta SPC 3 composition

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Cypermethrin (technical) |  |  |  |  |  | | (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 |  |  |  |  |  | |
| alcohols, C11-14-iso-, C13-rich, ethoxylated propoxylated | alcools, C11-14-iso-, C13-rich, ethoxylés propoxylés | Non-ionic surfactant | 78330-23-1 | - | 0.0147 | 0.0294 |

## 2.2. Type(s) of formulation of the meta SPC 3

| **Formulation** |  |
| --- | --- |
| Another Liquid (AL) |  |

## 3. Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 3

| **Classification** | |
| --- | --- |
| Hazard category | Aquatic Acute 1  Aquatic Chronic 1 |
| Hazard statement | H400 – Very toxic to aquatic life  H410 – Very toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Warning  Résultat de recherche d'images pour "GHS09" |
| Hazard statements | H410 – Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P273: Avoid release to the environment  P391: Collect spillage  P501: Dispose of contents/container in accordance with local regulation. |
|  | |
| Note | EUH208: Contains 1,2-benzisothiazol-3(2H)-one and a mixture of 5-chloro-2methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction. |

## 4. Authorised use(s) of the meta SPC 3

**4.1. Use description**

Table 1. Use # 1 – Preventive X6235

|  |  |
| --- | --- |
| **Product Type** | PT08 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism(s) (including development stage)** | Wood boring beetles  House longhorn beetle (*Hylotrupes bajulus*) \_ Larvae  Common furniture beetle (*Anobium punctatum*) \_ Larvae  Powder post beetle (*Lyctus brunneus*) \_ Larvae  Subterranean Termites (*Reticulitermes spp*. and *Heterotermes spp.*)  Workers, soldiers and nymphs |
| **Field(s) of use** | Use class 1 on softwood and hardwood. |
| **Application method(s)** | Superficial application / brush / roller / pad treatment  Superficial application / spray treatment |
| **Application rate(s) and frequency** | Application rate in the analytical zone:  Preventive treatment – use class 1: 200 g/m² |
| **Category(ies) of users** | Non-professionals |
| **Pack sizes and packaging material** | X6235:  - 1 L, 5 L, 6 L, 20 L, 24 L and 25 L tin-plate cans  The tin-plate cans are coated inside with an epoxyphenolic varnish.  All packagings are hermetically closed with a cap. |

## 4.1.1. Use-specific instructions for use

|  |
| --- |
| - |

## 4.1.2 Use-specific risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

**4.2. Use description**

Table 2. Use # 2 – Curative X6235

|  |  |
| --- | --- |
| **Product Type** | PT08 – Wood preservatives |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism(s) (including development stage)** | Wood boring beetles  Common furniture beetle (*Anobium punctatum*) \_ Larvae  Subterranean Termites (*Reticulitermes spp.* and *Heterotermes spp.*) \_ Workers, soldiers and nymphs |
| **Field(s) of use** | Curative treatment  wood in situation of use class 1, on softwood and hardwood. |
| **Application method(s)** | Superficial application / brush / roller / pad treatment  Superficial application / spray treatment |
| **Application rate(s) and frequency** | Application rate in the analytical zone: (wood in service)  300 g/m² for curative treatment by superficial application |
| **Category(ies) of users** | Non-professionals |
| **Pack sizes and packaging material** | X6235:  - 1 L, 5 L, 6 L, 20 L, 24 L and 25 L tin-plate cans  The tin-plate cans are coated inside with an epoxyphenolic varnish.  All packagings are hermetically closed with a cap. |

## 4.2.1. Use-specific instructions for use

|  |
| --- |
| - |

## 4.2.2 Use-specific risk mitigation measures

|  |
| --- |
| **-** |

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

|  |
| --- |
| **-** |

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

|  |
| --- |
| **-** |

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

|  |
| --- |
| - |

## 5. General directions for use of the meta SPC 3

## *5.1. Instructions for use*

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

## *5.2. Risk mitigation measures*

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

## *5.3. 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. * Ingestion: Wash out mouth with water. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested. Do not give fluids or induce vomiting. * Inhalation (of spray mist): Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled. * In case of impaired consciousness place in recovery position and seek medical advice immediately. * Keep the container or label available. |

## *5.4. Instructions for safe disposal of the product and its packaging*

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

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

|  |
| --- |
| * Do not store above 40°C. * Shelf life: 2 years |

## 6. Other information

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

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

## 1. Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | X6235  Xylophène Premium Gel Actif Monocouche Poutres & Charpentes  Axton Traitement Poutres et Charpentes  Flexell Traitement Poutres et Charpentes | | | | |
| **Authorisation number** |  | | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Cypermethrin (technical) |  |  |  |  |  | | (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 | |
| alcohols, C11-14-iso-, C13-rich, ethoxylated propoxylated | alcools, C11-14-iso-, C13-rich, ethoxylés propoxylés | Non-ionic surfactant | 78330-23-1 | - | 0.0147 – 0.0294 | |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| ***X6089CR*** | 4L  15L  20L | Tin-plate (with an epoxyphenol varnish layer) | Hermetically closed | Professional and non-professional | Yes |
| 20L | LDPE |
| ***X6089HA1*** | 1L  5L  6L  20L  24L  25L  30L  55L | Tin-plate (with an epoxyphenol varnish layer) | Professional and non-professional |
| 30L  200L  1000L | HDPE |
| ***X6235*** | 1L  5L  6L  20L  24L  25L | Tin-plate (with an epoxyphenol varnish layer) | non-professional |

### Documentation

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

**Identity, physicochemical and analytical method data**

Physico-chemical properties studies and analytical methods on the biocidal products X6089CR, X6089HA1 and X6235 were provided by PPG. See the annex 3.1.

**Efficacy data**

The following efficacy studies were submitted:

* For X6089CR:
* Laboratory efficacy study conducted according to the standard EN 118[[1]](#footnote-1), with the product X6089CR, after ageing following EN 73[[2]](#footnote-2) (evaporating procedure) against *Reticulitermes flavipes*;
* Laboratory efficacy study conducted according to the standard EN 46-1[[3]](#footnote-3), with the product X6089CR, after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 49-1[[4]](#footnote-4), with the product X6089CR, after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 20-1[[5]](#footnote-5), with the product X6089CR, after ageing following EN 73 (evaporating procedure);
* Laboratory efficacy study conducted according to the standard EN 1390[[6]](#footnote-6), with the product X6089CR;
* Laboratory efficacy study conducted according to the standard EN 48[[7]](#footnote-7), with the product X6089CR;
* For X6089HA1:
* Laboratory efficacy study conducted according to the standard EN 118[[8]](#footnote-8), 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 46-1, 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 73 (evaporating procedure) and after ageing following EN 84[[9]](#footnote-9) (leaching 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[[10]](#footnote-10), with the product X6119M2
* For X6235:
  + 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 46-1, 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 73 (evaporating procedure) and after ageing following EN 84 (leaching 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 48, with the product X6236;

**Toxicology data**

No study was provided.

* **Minor Change application for PPG CLASS1 WB - 2019  :**

**Toxicology data**

The applicant submitted a study according to OECD 438 (eye irritation on isolated chicken eye) conducted with the product X6119M2 (a formulated biocidal PT08 product containing 0.10% Cypermethrin (pure), composition in Confidential Annex).

**Residues data**

No specific residue data were submitted in the context of this dossier. The product PPG\_CLASS1\_WB is intended to be used as preventive and curative treatment for interior woods. These preventive and curative treatments are done by professionals and non-professionals by brush/roller/pad/superficial application, spray application or injection. It will not get into contact with food, feed or livestock. Residues in food, feed or livestock are not expected. Considering the intended uses no data is required.

**Ecotoxicology data**

No study was provided.

#### **Access to documentation**

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

## Assessment of the biocidal product family

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

Table 1. Intended use # 1 – X6089CR

|  |  |
| --- | --- |
| Product Type(s) | 8 |
| Where relevant, an exact description of the authorised use |  |
| Target organism (including development stage) | Wood boring insects (house longhorn beetle, common furniture beetle and powder post beetles)  Subterranean termites (genus *Reticulitermes spp*) |
| Field of use | Use class 1  Indoor |
| Application method(s) | Preventive treatment - use class 1  Curative treatment / wood in service indoor |
| Application rate(s) and frequency | Superficial application / brush / roller / pad treatment  Superficial application / spraying treatment  Injection (in combination with superficial application)  Rate:  200 g/m² for preventive treatment,  300 g/m² for curative treatment by superficial application,  180 g/m² for injection (20 mL per hole, 9 holes/m²) |
| Category(ies) of user(s) | Professional Non professional / general public |
| Pack sizes and packaging material | - 5 L and 6 L metal cans  - 25 L and 30 L metal pails  - 30 L HDPE pail  - 55 L metal drum  - 200 L HDPE drum  - 1000 L HDPE intermediate bulk container.  All packagings are hermetically closed with a cap. |

Table 2. Intended use # 2 – X6089HA1

|  |  |
| --- | --- |
| Product Type(s) | 8 |
| Where relevant, an exact description of the authorised use |  |
| Target organism (including development stage) | Wood boring insects (house longhorn beetle, common furniture beetle and powder post beetles)  Subterranean termites (*Reticulitermes spp.* and *Heterotermes spp.*) |
| Field of use | Use class 1  Indoor |
| Application method(s) | Preventive treatment - use class 1  Curative treatment / wood in service indoor |
| Application rate(s) and frequency | Superficial application / brush / roller / pad treatment  Superficial application / spraying treatment  Injection (in combination with superficial application)  Rate:  200 g/m² for preventive treatment,  300 g/m² for curative treatment by superficial application,  180 g/m² for injection (20 mL per hole, 9 holes/m²) |
| Category(ies) of user(s) | Professional  Non professional / general public |
| Pack sizes and packaging material | - 1 L, 5 L and 6 L metal cans  - 20 L, 24 L, 25 L and 30 L metal pails  All packagings are hermetically closed with a cap. |

Table 3. Intended use # 3 – X6235

|  |  |
| --- | --- |
| Product Type(s) | 8 |
| Where relevant, an exact description of the authorised use |  |
| Target organism (including development stage) | Wood boring insects (house longhorn beetle, common furniture beetle and powder post beetles)  Subterranean termites (*Reticulitermes spp. and Heterotermes spp.*) |
| Field of use | Use class 1  Indoor |
| Application method(s) | Preventive treatment - use class 1  Curative treatment / wood in service indoor |
| Application rate(s) and frequency | Superficial application / brush / roller / pad treatment  Superficial application / spraying treatment  Rate:  200 g/m² for preventive treatment,  300 g/m² for curative treatment by superficial application |
| Category(ies) of user(s) | Non professional / general public |
| Pack sizes and packaging material | - 1 L, 5 L and 6 L metal cans  - 20 L, 24 L, 25 L and 30 L metal pails  All packagings are hermetically closed with a cap. |

### Physical, chemical and technical properties

**PPG\_CLASS1\_WB is a biocidal product family containing one meta SPC and 3 products: X6089CR (AL), X6089HA1 (AL) and X6235 (AL).**

***After assessment by eCA, Based on information given by the applicant and based on claimed uses for each products, the composition range with the family has been restricted and the meta SPC has been split into three meta-SPC. Each meta SPC contain only one product.***

* ***Meta SPC 1 : X6089CR***
* ***Meta SPC 2 : X6089HA1***
* ***Meta SPC 3 : X6235***

X6089CR, X6112M2 and X6236 (respectively equivalent to X6089HA1 and X6235) were tested. All of composition comparisons are given in confidential annex.

The biocidal products are not the same as the one assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC.

The products contain 0.20 % of premix, which corresponds to 0.11% of technical cypermethrin and 0.10% of pure cypermethrin (cis:trans/ 40:60).

The family of products does not contain PT6 conservative and it is used undiluted. Its physico-chemical properties are covered.

Formulation type: Another Liquid (AL)

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

The product X6089CR is packaged in 4L tinplate can, 15L tinplate pail, 20L LDPE sachet and 20L tinplate pail.

The product X6089HA1 is packaged in 1L, 5L and 6L tinplate cans, 20L, 24L, 25L and 30L tinplate pails, 30L HDPE pail, 55L tinplate drum, 200L HDPE drum, 1000L HDPE intermediate bulk container.

The product X6235 is packaged in 1L, 5L and 6L tinplate cans, 20L, 24L and 25L tinplate pails.

All packagings are hermetically closed with a cap.

**Properties of the biocidal product X6089CR**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa |  | **X6089CR** **Lot/batch No.: 1407600021** | **semi-pasty liquid** | **Acceptable** | Raphalen E., 2015  Report N° 402/14/1094F/abcdef-e |
| Colour at 20 °C and 101.3 kPa | **milky white** |
| Odour at 20 °C and 101.3 kPa | **floral-like odour** | Simon F., 2015  Report N° 150313/PaPV93.11 |
| Acidity / alkalinity | pH: CIPAC MT 75.3  Acidity: CIPAC MT 31.2.3 |  | **Neat product:**  **pH=6.41 at 19.6°C** | **Acceptable** | Raphalen E., 2015  Report N° 402/14/1094F/abcdef-e |
| Relative density / bulk density | CIPAC MT 3.2.1 | **X6089CR** **Lot/batch No.: 1407600021** | **D20 = 0.995** | **Acceptable** | Raphalen E. 2015  Report N° 402/14/1094F/ghijk-e |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  (14 days at 54 ± 2ºC in tinplate can)  HPLC method : N°94 (CTBA-IBC/67/1170/05F/BPL-e) | **X6089CR** **Lot/batch No.: 1407600021** | |  |  |  | | --- | --- | --- | | **Test** | **Initial** | **After 14 days storage at 54°C** | | **Appearance of test item** | Semi-pasty milky white colour  Small rust spots on the surface of the product | Semi-pasty milky white colour  No phasing  No deposit  No impurities | | **Cypermethrin content (% w/w)** | 0.10 | 0.11 (+10.0%) | | **Appearance and weight of test packaging** | Metal can, no sign of corrosion or degradation  5615 g | Non-adherent deposit due to water condensation occurring rust on the metal inside the can  Rust spots on the edge of the cover and around the inside perimeter of the container  small signs of corrosion  5615 g (-0%) | | **pH** | 6.41 at 19.6°C | 6.29 at 20.3°C | | **Emulsion characteristics and re-emulsification properties of pure test item** | **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 | | | **Signs of degradation (slight brown sports at the surface of product and the top border of packaging) are observed after storage in metal can. More justifications with photos of packaging before and after storage (with automatic closing) were provided. Very small signs of corrosion are observed at the interface lid/can but empty metal can shows no signs of corrosion. Therefore, the study is considered acceptable.** | Raphalen E., 2015  Report N° 402/14/1094F/abcdef-e  **P. Poveda, 2017 – Report 5006501** |
| Storage stability test – **long term storage at ambient temperature** | Shelf-life (2years at ambient temperature)  HPLC method : N°94 (CTBA-IBC/67/1170/05F/BPL-e) | **X6089CR** **Lot/batch No.: PaP V 29.2**  **PaP V 31.1** | The long term storage study at ambient temperature during 24 months, with the product X6089CR in its commercial packaging (tinplate can) is described below:   |  |  |  | | --- | --- | --- | | **Test** | **Initial** | **After 24 months storage at 20°C in tinplate can** | | **Appearance of test item** | White semi-pasty homogeneous | White semi-pasty homogeneous - No deposit – No phase partition | | **Cypermethrin content (% w/w)** | 0.101 | 0.100 (-1.0%) | | **Appearance and weight of test packaging** | 1L tinplate can, No potential sign of corrosion, deformation, leakage or degradation | Sign of corrosion are observed inside the container, around the opening and on the top of the product especially after 18 months, no deformation or leakage or degradation (inside and outside)  -0.00% weight change | | **pH at 19.6°C** | 6.33 | 6.31 | | **Emulsion stability after 6 months storage** | **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 | | | **Signs of degradation (slight brown sports at the surface of product and the top border of packaging) are observed after 6, 12, 18 and 24 months of storage in metal can. More justifications with photos of packaging before and after storage (with automatic closing) were provided. Very small signs of corrosion are observed at the interface lid/can but empty metal can shows no signs of corrosion. Therefore, the study is considered acceptable.** | Legay S., 2015  Study plan N° 402/13/1096F/ab-e  **P. Poveda, 2017 – Report 5006501** |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3  (7 days at 0 ± 1ºC in closed glass bottle) | **X6089CR** **Lot/batch No.: 1407600021** | |  |  |  |  | | --- | --- | --- | --- | | **Test** | **Initial** | **After 7 days storage at 0°C** | | | **Appearance of test item** | Opaque white  No deposit or phase partition was observed | | | | **pH** | 6.14 | | 6.27 | | **Emulsion stability** | **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** | Raphalen E. 2015  Report N° 402/14/1094F/ghijk-e |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Not required |  |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | Not required |  |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | See ”Storage stability test – **long term storage at ambient temperature”** |  |  |
| Wettability |  |  | Not applicable |  |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not applicable |  |  |
| Wet sieve analysis and dry sieve test |  |  | Not applicable |  |  |
| Emulsifiability, re-emulsifiability and emulsion stability | CIPAC MT 36.3 | **X6089CR** **Lot/batch No.: 1407600021** | **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** | Raphalen E., 2015  Report N° 402/14/1094F/abcdef-e |
| Disintegration time |  |  | Not required |  |  |
| Particle size distribution, content of dust/fines, attrition, friability | *Only for powders and granules* |  | Not applicable |  |  |
| Persistent foaming | CIPAC MT 47.2 |  | Not required |  |  |
| Flowability/Pourability/Dustability |  |  | Not applicable |  |  |
| Burning rate — smoke generators |  |  | Not applicable |  |  |
| Burning completeness — smoke generators |  |  | Not applicable |  |  |
| Composition of smoke — smoke generators |  |  | Not applicable |  |  |
| Spraying pattern — aerosols |  |  | - |  |  |
| Physical compatibility |  |  | Not applicable |  |  |
| Chemical compatibility |  |  | Not applicable |  |  |
| Degree of dissolution and dilution stability |  |  | Not applicable |  |  |
| Surface tension | EEC A5 | **X6089CR** **Lot/batch No.: 1407600021** | **Due to the viscous consistency of the test item, a measurement of the surface tension was not possible.** | **Acceptable as the product is a ready-to-use formulation.** | Raphalen E. 2015  Report N° 402/14/1094F/ghijk-e |
| Viscosity | OECD 114 | **X6089CR** **Lot/batch No.: 1407600021** | |  |  | | --- | --- | | **Temperature (°C)** | **Kinematic viscosity (mPa/s)** | | **20.0** | **4248 to 296000 from 0.3 rpm to 100 rpm** | | **40.0** | **4164 to 346 000 from 0.3 rpm to 100 rpm** | | **Acceptable** | Raphalen E. 2015  Report N° 402/14/1094F/ghijk-e |

**Properties of the biocidal product X6089HA1**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa |  | **X6089HA1**  **Lot/batch No.: PaP V32.1** | **Transparent liquid** | **Acceptable** | Legay S., 2016  Report N° COA-402/13/1135F/ad-e |
| Colour at 20 °C and 101.3 kPa | **Very light yellow** |
| Odour at 20 °C and 101.3 kPa | **Detergent like odour** | Simon F., 2015  Report N° 150313/PaPV93.10 |
| Acidity / alkalinity | pH: CIPAC MT 75.3  Acidity: CIPAC MT 31.2.3 | **X6112M2**  **Lot/batch No1502600020** | **Neat product:**  **pH = 7.02 at 19.8°C** | **Acceptable**  The test was performed on X6112M2 product but it is considered as similar to X6089HA1. | Legay S., 2015  Report N° 402/14/1096F/abcd-e |
| Relative density / bulk density | CIPAC MT 3.2.1 | **X6112M2**  **Lot/batch No1502600020** | **D20 = 1.003** | **Acceptable**  The test was performed on X6112M2 product but it is considered as similar to X6089HA1. | Legay S., 2015  Report N° 402/14/1096F/efgh-e |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3    HPLC method : N°283-e available and validated | **X6112M2**  **Lot/batch No1502600020** | |  |  |  | | --- | --- | --- | | **Test** | **Initial** | **After 8 weeks storage at 40°C** | | **Appearance of test item** | Liquid, colourless, transparent  No deposit  No phase partition | Liquid, very slightly yellow, transparent  No deposit  No impurities | | **Cypermethrin content (% w/w)** | 0.101 | 0.097 (-4.0%) | | **Appearance and weight of test packaging** | HDPE can, no sign of corrosion or degradation  5093 g | HDPE can, no sign of corrosion or degradation  5092 g (-0.02%) | | Metal can, no sign of corrosion or degradation  1129.5 g | Metal can, no sign of corrosion or degradation  1129.4 g (-0.01%) | | **pH** | 7.02 at 19.8°C | 6.96 at 20.0°C | | **Acceptable**  The test was performed on X6112M2 product but it is considered as similar to X6089HA1.  **The product does not storage above 40°C.** | Legay S., 2015  Report N° 402/14/1096F/abcd-e |
| Storage stability test – **long term storage at ambient temperature** | Shelf-life (2years at ambient temperature)  HPLC method : N°284-e available and validated | **X6089HA1**  **Lot/batch No.: PaP V 32.1** | The long term storage study at ambient temperature during 24 months, with the product X6089HA1 in its commercial packaging (tinplate and HDPE cans) is described below:   |  |  |  |  | | --- | --- | --- | --- | | **Test** | **Initial** | **After 24 months storage at 20°C in tinplate can** | **After 24 months storage at 20°C in HDPE can** | | **Appearance of test item** | Liquid, colourless, transparent | Liquid, very pale yellow, transparent  No deposit  No impurities | Liquid, very light yellow, transparent  No deposit  No impurities | | **Cypermethrin content (% w/w)** | 0.095 | **After 18 months:** 0.087% (-8.4%)  **After 24 months:** 0.080 (-15.8 %) | **After 18 months**: 0.087% (-8.4%)  **After 24 months**: 0.083 (-12.6 %) | | **pH at 19°C** | 7.3 | 7.3 | 7.2 | | **Appearance and weight of test packaging** | 5L HDPE can, no sign of corrosion or degradation | - | No potential sign of corrosion or degradation  Loss of weight :  -0.08% | | 5L metal can, no sign of corrosion or degradation | No potential sign of corrosion or degradation  Loss of weight :  -0.02% | - | | **Emulsion stability after 6 months storage** | **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 not stable after 24 months. As the results are acceptable after 18 months, the mention “do not storage more than 18 months” on the label should be noted.** | Legay S., 2016  Study plan N° COA-402/13/1135F/ad-e |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3  (7 days at 0 ± 1ºC in closed glass bottle) | **X6112M2**  **Lot/batch No1502600020** | |  |  |  | | --- | --- | --- | | **Test** | **Initial** | **After 7 days storage at 0°C** | | **Appearance of test item** | Liquid, colourless, transparent  No deposit or phase partition was observed | | | **Acceptable**  The test was performed on X6112M2 product but it is considered as similar to X6089HA1. | Legay S., 2015  Report N° 402/14/1096F/efgh-e |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Not required |  |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | Not required |  |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | See ”Storage stability test – **long term storage at ambient temperature”** |  |  |
| Wettability |  |  | Not applicable |  |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not applicable |  |  |
| Wet sieve analysis and dry sieve test |  |  | Not applicable |  |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not applicable |  |  |
| Disintegration time |  |  | Not required |  |  |
| Particle size distribution, content of dust/fines, attrition, friability | *Only for powders and granules* |  | Not applicable |  |  |
| Persistent foaming |  |  | Not required |  |  |
| Flowability/Pourability/Dustability |  |  | Not applicable |  |  |
| Burning rate — smoke generators |  |  | Not applicable |  |  |
| Burning completeness — smoke generators |  |  | Not applicable |  |  |
| Composition of smoke — smoke generators |  |  | Not applicable |  |  |
| Spraying pattern — aerosols |  |  | - |  |  |
| Physical compatibility |  |  | Not applicable |  |  |
| Chemical compatibility |  |  | Not applicable |  |  |
| Degree of dissolution and dilution stability |  |  | Not applicable |  |  |
| Surface tension | EEC A5 | **X6112M2**  **Lot/batch No1502600020** | 27.36 mN/m undiluted at 20.4°C  Surface Active product | **Acceptable**  The test was performed on X6112M2 product but it is considered as similar to X6089HA1. | Legay S., 2015  Report N° 402/14/1096F/efgh-e |
| Viscosity | OECD 114 | **X6112M2**  **Lot/batch No1502600020** | |  |  | | --- | --- | | **Temperature (°C)** | **Kinematic viscosity (mm²/s)** | | **20.0** | **<6.62** | | **40.0** | **<6.62** | | **Acceptable**  The test was performed on X6112M2 product but it is considered as similar to X6089HA1. | Legay S., 2015  Report N° 402/14/1096F/efgh-e |

### Properties of the biocidal product X6235

| **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 No.: 1502300036** | **Opaque gel** | **Acceptable**  The test was performed on X6236 product but it is considered as similar to X6235. | Legay S., 2014  Report N° COA- 402/14/1097F/abcd-e |
| Colour at 20 °C and 101.3 kPa | **White** |
| Odour at 20 °C and 101.3 kPa | **Oil-like odour** | Simon F., 2015  Report N° 150313/PaPV93.7 |
| Acidity / alkalinity | pH: CIPAC MT 75.3  Acidity: CIPAC MT 31.2.3 | **X6236**  **Lot/batch No.: 1502300036** | **Neat product:**  **pH = 7.1 at 19.2°C** | **Acceptable**  The test was performed on X6236 product but it is considered as similar to X6235. | Legay S., 2015  Report N° 402/14/1097F/abcd-e |
| Relative density / bulk density | CIPAC MT 3.2.1 | **X6236**  **Lot/batch No.: 1502300036** | **D20 = 1.003** | **Acceptable**  The test was performed on X6236 product but it is considered as similar to X6235. | Legay S., 2015  Report N° 402/14/1097F/efgh-e |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3    HPLC method : N°285-e  available and validated | **X6236**  **Lot/batch No.: 1502300036** | |  |  |  | | --- | --- | --- | | **Test** | **Initial** | **After 8 weeks storage at 40°C** | | **Appearance of test item** | Gel white opaque  No deposit  No phase partition | Gel cream opaque  No deposit  No impurities | | **Cypermethrin content (% w/w)** | 0.100 | 0.098 (-2.0%) | | **Appearance and weight of test packaging** | metal can, no sign of corrosion or degradation  583 g | metal can, no sign of corrosion, leakage or degradation  583 g (-0.0%) | | **pH** | 7.11 at 19.2°C | 7.11 at 20.2°C | | **Viscosity** | - From 96800 mPa\*s at 0.3 rpm to 772 mPa\*s at 100 rpm at 20°C  - From 48800 mPa\*s at 0.3 rpm to 719 mPa\*s at 100 rpm at 40°C | - From 96400 mPa\*s at 0.3 rpm to 695 mPa\*s at 100 rpm at 20°C  - From 38000 mPa\*s at 0.3 rpm to 700 mPa\*s at 100 rpm at 40°C | | **Acceptable**  The test was performed on X6236 product but it is considered as similar to X6235.  **The product does not storage above 40°C.** | Legay S., 2015  Report N° 402/14/1097F/abcd-e  HPLC method : N°285-e |
| Storage stability test – **long term storage at ambient temperature** | Technical monograph N°17  Shelf-life (2years at ambient temperature)  HPLC method : N°285-e  available and validated | **X6236**  **Lot/batch No.: 1502300036** | The long term storage study at ambient temperature during 24 months, with the product X6236 in its commercial packaging (tinplate can) is described below:   |  |  |  | | --- | --- | --- | | **Test** | **Initial** | **After 24 months storage at 20°C in tinplate can** | | **Appearance of test item** | Liquid white and opaque  No deposit  No impurities | Liquid, light beige and opaque  No deposit  No impurities | | **Cypermethrin content (% w/w)** | 0.099 | 0.095 (-4 %) | | **Appearance and weight of test packaging** | 5L metal can, no sign of corrosion or degradation | No potential sign of corrosion, leakage or degradation  Loss of weight : 0.0% | | **pH** | 6.8 at 19.2°C | 6.8 at 19.1°C | | **Emulsion stability after 6 months storage** | **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 test was performed on X6236 product but it is considered as similar to X6235.  **The product is stable after 2 years at ambient temperature in commercial packaging.** | Legay S., 2016  Study plan N° 402/13/1138F/ad-e |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3  (7 days at 0 ± 1ºC in closed glass bottle) | **X6236**  **Lot/batch No.: 1502300036** | |  |  |  | | --- | --- | --- | | **Test** | **Initial** | **After 7 days storage at 0°C** | | **Appearance of test item** | Gel opaque white  No deposit or phase partition was observed | | | **Acceptable**  The test was performed on X6236 product but it is considered as similar to X6235. | Legay S., 2015  Report N° 402/14/1097F/efgh-e |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** |  |  | Not required |  |  |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | Not required |  |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | See ”Storage stability test – **long term storage at ambient temperature”** |  |  |
| Wettability |  |  | Not applicable |  |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not applicable |  |  |
| Wet sieve analysis and dry sieve test |  |  | Not applicable |  |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not applicable |  |  |
| Disintegration time |  |  | Not required |  |  |
| Particle size distribution, content of dust/fines, attrition, friability | *Only for powders and granules* |  | Not applicable |  |  |
| Persistent foaming |  |  | Not required |  |  |
| Flowability/Pourability/Dustability |  |  | Not applicable |  |  |
| Burning rate — smoke generators |  |  | Not applicable |  |  |
| Burning completeness — smoke generators |  |  | Not applicable |  |  |
| Composition of smoke — smoke generators |  |  | Not applicable |  |  |
| Spraying pattern — aerosols |  |  | - |  |  |
| Physical compatibility |  |  | Not applicable |  |  |
| Chemical compatibility |  |  | Not applicable |  |  |
| Degree of dissolution and dilution stability |  |  | Not applicable |  |  |
| Surface tension | EEC A5 | **X6236**  **Lot/batch No.: 1502300036** | 34.54 mN/m undiluted at 20.4°C  Surface Active product | **Acceptable**  The test was performed on X6236 product but it is considered as similar to X6235. | Legay S., 2015  Report N° 402/14/1097F/efgh-e |
| Viscosity | OECD 114 | **X6236**  **Lot/batch No.: 1502300036** | |  |  | | --- | --- | | **Temperature (°C)** | **Kinematic viscosity (mm²/s)** | | **20.0** | **from 96800 at 0.3rpm to 771.6 at 100rpm** | | **40.0** | **from 48800 at 0.3rpm to 718.8 at 100rpm** | | **Acceptable**  The test was performed on X6236 product but it is considered as similar to X6235. | Legay S., 2015  Report N° 402/14/1097F/efgh-e |

### Physical hazards and respective characteristics

**Properties of the biocidal product X6089CR**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | |  | | --- | | EEC A14 | | **X6089CR** **Lot/batch No.: 1407600021** | Considering the high proportion of water and of not-explosive ingredients (in total 98.22% w/w), the product X6089CR is not expected to present a significant hazard for explosivity.    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. | **Acceptable** | Raphalen E., Legrand G., 2015  Report N° 402/14/1094F/l-e  Detrimont H., Ambrosi D., 2015  Report N°: 15/05 |
| Flammable gases |  |  | Not applicable |  |  |
| Flammable aerosols |  |  | Not applicable |  |  |
| Oxidising gases |  |  | Not applicable |  |  |
| Gases under pressure |  |  | Not applicable |  |  |
| Flammable liquids |  |  | The product X6089CR is not flammable. Test is not required as X6089CR contains around 90% w/w water and less than 0.5% of components classified as flammable. | **Acceptable** |  |
| Flammable solids |  |  | Not applicable |  |  |
| Self-reactive substances and mixtures |  | **X6089CR** **Lot/batch No.: 1407600021** | According to the literature review and considering the high proportion of water, the product X6089CR is not expected to present a significant hazard for self-reactivity.    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 self-reactive and the test on self-reactive properties according to UN Test series A to H described in Part II of the UN-MTC should not be performed. | **Acceptable** | Raphalen E., Legrand G., 2015  Report N° 402/14/1094F/l-e  Detrimont H., Ambrosi D., 2015  Report N°: 15/05 |
| Pyrophoric liquids |  |  | Not required as X6089CR contains around 90% 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. | This test is required with the CLP regulation. Nevertheless, as there are no ingredients classified H250 (category 1), it considered acceptable. |  |
| Pyrophoric solids |  |  | Not applicable |  |  |
| Self-heating substances and mixtures |  |  | Not required |  |  |
| Substances and mixtures which in contact with water emit flammable gases |  |  | Not applicable |  |  |
| Oxidising liquids |  | **X6089CR** **Lot/batch No.: 1407600021** | Considering the high proportion of water and of not-oxidising ingredients (in total 98.27% w/w), the product X6089CR is not expected to present a significant hazard for oxidising properties, and testing is considered as unnecessary. | **Acceptable** | Detrimont H., Ambrosi D., 2015  Report N°: 15/05 |
| Oxidising solids |  |  | Not applicable |  |  |
| Organic peroxides |  |  | Not applicable |  |  |
| Corrosive to metals |  |  | Not required as no ingredient is classified as corrosive to metals and experience in handling and use shows that the product is not corrosive to metals. |  |  |
| Auto-ignition temperatures of products (liquids and gases) | EEC A15 | **X6089CR** **Lot/batch No.: PaP V 29.2** | 437 ± 5°C | **Acceptable** | Demangel B.  Report N° 14-904015-002 |
| Relative self-ignition temperature for solids |  |  | Not applicable |  |  |
| Dust explosion hazard |  |  | Not applicable |  |  |

**Properties of the biocidal products X6089HA1 and X6235**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Comments** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | |  | | --- | | EEC A14 | | **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.  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, what demonstrates that the product X6236 is unlikely to be explosive, and testing is considered as unnecessary.  A confidential statement are given in confidential part. | **Acceptable**  The test and statement were performed on X6236 product but it is considered as similar to X6089HA1 and X6235. | Raphalen E., Legay S., 2015  Report N° 402/14/1097F/i-e  Detrimont H., Ambrosi D., 2015  Report N°: 15/09 |
| Flammable gases |  |  | Not applicable |  |  |
| Flammable aerosols |  |  | Not applicable |  |  |
| Oxidising gases |  |  | Not applicable |  |  |
| Gases under pressure |  |  | Not applicable |  |  |
| Flammable liquids |  |  | The product X6089CR is not flammable. Test is not required as X6089XR contains around 90% w/w water and less than 0.5% of components classified as flammable. | **Acceptable** |  |
| Flammable solids |  |  | Not applicable |  |  |
| Self-reactive substances and mixtures |  | **X6236**  **Lot/batch No.: 1502300036** | 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 (DSC graphs), testing is considered as unnecessary.  A confidential statement is given in confidential part. | **Acceptable**  The test and statement were performed on X6236 product but it is considered as similar to X6089HA1 and X6235. | Raphalen E., Legay S., 2015  Report N° 402/14/1097F/i-e  Detrimont H., Ambrosi D., 2015  Report N°: 15/09 |
| Pyrophoric liquids |  |  | Not required as X6236 contains around 92% 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. | This test is required with the CLP regulation. Nevertheless, as there are no ingredients classified H250 (category 1), it considered acceptable. |  |
| Pyrophoric solids |  |  | Not applicable |  |  |
| Self-heating substances and mixtures |  |  | Not required |  |  |
| Substances and mixtures which in contact with water emit flammable gases |  |  | Not applicable |  |  |
| Oxidising liquids |  | **X6236**  **Lot/batch No.: 1502300036** | Considering the high proportion of not-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 test and statement were performed on X6236 product but it is considered as similar to X6089HA1 and X6235. | Detrimont H., Ambrosi D., 2015  Report N°: 15/09 |
| Oxidising solids |  |  | Not applicable |  |  |
| Organic peroxides |  |  | Not applicable |  |  |
| Corrosive to metals |  |  | Not required as no ingredient is classified as corrosive to metals and experience in handling and use shows that the product is not corrosive to metals. |  |  |
| Auto-ignition temperatures of products (liquids and gases) | EEC A15 | **X6236**  **Lot/batch No.: 1502300036** | 480 ± 6°C | **Acceptable**  The test was performed on X6236 product but it is considered as similar to X6089HA1 and X6235. | Demangel B.  Report N° 14-904015-004 |
| Relative self-ignition temperature for solids |  |  | Not applicable |  |  |
| Dust explosion hazard |  |  | Not applicable |  |  |

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| --- |
| **Conclusion on the physical, chemical and technical properties of the META SPC 1: product** **X6089CR** |
| The formulation X6089CR is an Another Liquid (AL) formulation use undiluted. 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 milky white semi-pasty liquid, with a floral-like odour. It is not explosive and has no oxidizing properties. The product is not considered flammable. It has a self-ignition temperature at 437°C.There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 24 months at ambient temperature when stored in metal can (commercial packaging). Its technical characteristics are acceptable for an AL formulation.  **Implication concerning labelling:** None |

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| **Conclusion on the physical, chemical and technical properties of the META SPC 2: product** **X6089HA1** |
| The formulation X6089HA1 is an Another Liquid (AL) formulation use undiluted. 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 very light yellow transparent liquid, with a detergent-like odour. It is not explosive and has no oxidizing properties. The product is not considered flammable. It has a self-ignition temperature at 480°C.There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at 18 months at ambient temperature when stored in HDPE and metal can (commercial packagings). Its technical characteristics are acceptable for an AL formulation.  **Implication concerning labelling:**  Do not store above 40°C.  Do not store more than 18 months. |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the META SPC 3: product** **X6235** |
| The formulation X6235 is an Another Liquid (AL) formulation use undiluted. 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 white opaque gel, with an oil-like odour. It is not explosive and has no oxidizing properties. The product is not considered flammable. It has a self-ignition temperature at 480°C.There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 8 weeks at 40°C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 24 months at ambient temperature when stored in HDPE and metal can (commercial packagings). Its technical characteristics are acceptable for an AL formulation.  **Implication concerning labelling:** Do not store above 40°C. |

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| --- |
| **Conclusion on the physical, chemical and technical properties of the family products** |
| All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. It is not explosive and has no oxidizing properties. The products are not considered flammable. There is no effect of low and high temperature on the stability of the formulations, since after 7 days at 0°C, 14 days at 54°C (for META SPC1) and 8 weeks at 40°C (for META SPC 2&3), neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 18 months for META SPC 2 and 24 months for META SPC 1&3 at ambient temperature when stored in HDPE and metal can (commercial packagings). Its technical characteristics are acceptable. |

* **Minor Change application for PPG CLASS1 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**

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

**Summary for Cypermethrin:**

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

**Summary:**

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

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

**Analytical method for determining the active substance and relevant component in the biocidal product X6089CR**

|  |  |
| --- | --- |
| **Report:** | **Yrieix C., 2006** |
| Title: | Chemical tests on a ready to use water based preservative (X6089CR): Validation of the analytical method and chemical analysis of cypermethrin in the test item |
| Document No | CTBA-IBC/67/1170/05F/BPL-e  Analytical protocol N°94 version 1 |
| Test facility | Chemistry laboratory  Timber, Construction and Industry Group  Centre Technique du Bois et de l'Ameublement (CTBA)  Allée de Boutaut - BP 227  33028 Bordeaux cedex  FRANCE |
| Guidelines: | SANCO/3030/99 rev.4. |
| GLP | Yes |

**Preparation of accuracy samples:**

The product is diluted in water, manual stirring during 30 sec and passed in an ultra-sonic bath during 10 min before to analyse by HPLC-UV.

**Validation of the analytical method:**

|  |  |  |
| --- | --- | --- |
| Specificity | No interference at the selected wavelength (210 nm) was detected at the retention time of the active ingredient in HPLC-UV in blank formulation samples diluted in acetonitrile.  No interference from other substances present in the preparation should not contribue than 3% to the total peak area measured for the active substance. Chromatograms were provided. | |
| Linearity | Linearity was studied by carrying out five calibration spots with single determination, over a concentration range at the “target value” ± 20%. A linear regression and its correlation coefficient were calculated. | |
| Compound | Linearity (working range) mg/L |
| Cypermethrin | 5.0 to 50 mg/L  Y = 5.597\*104 X – 5.812\*102 R2 = 0.9999  N=5 |
| Precision | Repeatability was evaluated with 12 independent determinations of cypermethrin in the formulated product, no outlier. | |
| Compound | Repeatability (RSD) |
| Cypermethrin | RSDr = 3.95% < 7.58% (RSDr calculated with modified equation of Horwitz)  RSDR = 4.63% < 11.31% (RSDR calculated with modified equation of Horwitz) |
| Accuracy | Accuracy was determined by analysis of 12 independent determinations in which known amounts of the reference substance were added to a blank formulation. The accuracy results are expressed as the recovery rate. | |
| Compound | Accuracy (recovery ) |
| Cypermethrin (0.1% w/w) | 91.6% |

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

The analytical method for the determination of cypermethrin in the product X6089CR can be considered as validated.

**Analytical method for determining the active substance and relevant component in the biocidal product X6089HA1**

|  |  |
| --- | --- |
| **Report:** | **Raphaelen 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 |
| Document No | 402/13/1134F/ab-e  Analytical protocol N°283-e for X6119M2 and N°284-e for X6089HA1 |
| Test facility | Chemistry laboratory  Timber, Construction and Industry Group  Centre Technique du Bois et de l'Ameublement (CTBA)  Allée de Boutaut - BP 227  33028 Bordeaux cedex  FRANCE |
| Guidelines: | SANCO/3030/99 rev.4. |
| GLP | Yes |

**Preparation of accuracy samples:**

The blank formulation 13/1134F/3 (matrix blank) is weighted in order to obtain an aliquot of around 0.25 g. The sample is placed in a volumetric flask of 5 mL and then, a known amount of a stock solution containing the active ingredients in acetonitrile is added. The volumetric flask of 5 mL is completed with acetonitrile.

**Validation of the analytical method:**

|  |  |  |
| --- | --- | --- |
| Specificity | No interference at the selected wavelength (230nm) was detected at the retention time of the active ingredient in HPLC-UV in blank formulation samples diluted in acetonitrile.  No interference from other substances present in the preparation should not contribue than 3% to the total peak area measured for the active substance. Chromatograms were provided. | |
| Linearity | Linearity was studied by carrying out five calibration spots with single determination, over a concentration range at the “target value” ±20%. A linear regression and its correlation coefficient were calculated. | |
| Compound | Linearity (working range) mg/L |
| Cypermethrin | 40 to 60 mg/L  Y = 2.488\*104 X + 1.922\*104 R2 = 0.9990  N=5 |
|  | Cypermethrin | 40 to 60 mg/L  Y = 2.481\*104 X – 4.835\*103 R2 = 0.9978  N=5 |
| Precision | Repeatability was evaluated with 12 independent determinations of cypermethrin in the formulated product, no outlier. | |
| Compound | Repeatability (RSD) |
| Cypermethrin | RSDr = 0.626% < 3.79% (RSDr calculated with modified equation of Horwitz)  RSDR = 1.25% < 5.66% (RSDR calculated with modified equation of Horwitz) |
| Accuracy | Accuracy was determined by analysis of 12 independent determinations in which known amounts of the reference substance were added to a blank formulation. The accuracy results are expressed as the recovery rate. | |
| Compound | Accuracy (recovery ) |
| Cypermethrin (0.1% w/w) | 100.9% |

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

The analytical method for the determination of cypermethrin in the product X6089HA1 can be considered as validated.

**Analytical method for determining the active substance and relevant component in the biocidal product X6235**

|  |  |
| --- | --- |
| **Report:** | **Raphaelen E., 2013** |
| Title: | Physico-chemical tests on a ready-to-use aqueous emulsion (X6235/X6236): Validation of analytical method and chemical analysis of active ingredients declared in the test items |
| Document No | 402/13/1137F/ab-e  Analytical protocol N°285-e for X6236 and N°286-e for X6235 |
| Test facility | Chemistry laboratory  Timber, Construction and Industry Group  Centre Technique du Bois et de l'Ameublement (CTBA)  Allée de Boutaut - BP 227  33028 Bordeaux cedex  FRANCE |
| Guidelines: | SANCO/3030/99 rev.4. |
| GLP | Yes |

**Preparation of accuracy samples:**

The blank formulation 13/1137F/2 (matrix blank) is weighted in order to obtain an aliquot of around 0.25 g. The sample is placed in a volumetric flask of 5 mL and then, a known amount of a stock solution containing the active ingredients in acetonitrile is added. The volumetric flask of 5 mL is completed with acetonitrile.

**Validation of the analytical method:**

|  |  |  |
| --- | --- | --- |
| Specificity | No interference at the selected wavelength (230nm) was detected at the retention time of the active ingredient in HPLC-UV in blank formulation samples diluted in acetonitrile.  No interference from other substances present in the preparation should not contribue than 3% to the total peak area measured for the active substance. Chromatograms were provided. | |
| Linearity | Linearity was studied by carrying out five calibration spots with single determination, over a concentration range at the “target value” ±20%. A linear regression and its correlation coefficient were calculated. | |
| Compound | Linearity (working range) mg/L |
| Cypermethrin | 40 to 60 mg/L  Y = 2.488\*104 X + 1.922\*104 R2 = 0.9990  N=5 |
|  | Cypermethrin | 40 to 60 mg/L  Y = 2.493\*104 X – 3.053\*102 R2 = 0.9974  N=5 |
| Precision | Repeatability was evaluated with 12 independent determinations of cypermethrin in the formulated product, no outlier. | |
| Compound | Repeatability (RSD) |
| Cypermethrin | RSDr = 1.06% < 3.79% (RSDr calculated with modified equation of Horwitz)  RSDR = 1.78% < 5.66% (RSDR calculated with modified equation of Horwitz) |
| Accuracy | Accuracy was determined by analysis of 12 independent determinations in which known amounts of the reference substance were added to a blank formulation. The accuracy results are expressed as the recovery rate. | |
| Compound | Accuracy (recovery ) |
| Cypermethrin (0.1% w/w) | 100.1% |

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

The analytical method for the determination of cypermethrin in the product X6235 can be considered as validated.

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

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

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

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

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

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

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

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

### Efficacy against target organisms

#### **Function and field of use**

MG 02: preservatives

Product Type 08: wood preservative

The products of the family (PPG\_CLASS1\_WB) are water-based wood preservative products ready to use. Based on the information given by the applicant and the uses claimed for the products belonging to the family, the family was separated in 3 meta-SPC:

* META-SPC1 comprises the product X6089CR. It is intended to be used for preventive and 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-SPC2 comprises X6089HA1. The product is intended to be used by superficial application for preventive and 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-SPC3 comprises the product X6235. It is intended to be used by superficial application for preventive and curative treatments by superficial application. The product is applied by non-professional users only.

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

The products of the family (PPG\_CLASS1\_WB) are intended to be used by superficial application for preventive treatment for wood used in use class 1 and is also intended to be used for curative treatments by superficial application (that could be completed by injection), for wood in service, indoor.

* in META SPC1 and 2, the application rates recommended by the applicant are the following:

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

- 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, every 33 cm in staggered rows)).

* 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,

- Curative treatment: superficial application at 300 g of product / m² of wood.

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

According to the uses claimed by the applicant, the products of the family (PPG\_CLASS1\_WB) are intended to be used for the preservation of wood used in use class 1 by superficial application against:

META SPC1: wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and Lyctus brunneus*) and termites (*Reticulitermes spp*.)

META SPC2: wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and Lyctus brunneus*) and termites (*Reticulitermes spp*. and *Heterotermes spp*.)

META SPC3: wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and Lyctus brunneus*) and termites (*Reticulitermes spp*. and *Heterotermes spp*.)

These products of the family are also intended to be used for the curative treatment of wood in service (indoor) against:

META SPC1: wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and Lyctus brunneus*) and termites (*Reticulitermes spp*.)

META SPC2: wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and Lyctus brunneus*) and termites (*Reticulitermes spp*. and *Heterotermes spp*.)

META SPC3: wood boring beetles (*Anobium punctatum and Lyctus brunneus*) and termites (*Reticulitermes spp*. and *Heterotermes spp*.)

The development stages claimed are larvae and adults for wood boring beetles and workers, soldiers and nymphs for termites.

#### **Mode of action, including time delay**

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

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

Regarding the curative insecticidal efficacy, based on the elements presented in the dossier, the products of the META-SPC 1 and 2 have demonstrated a slow action on *Hylotrupes bajulus* and a fast acting on *Anobium punctatum.* For the product of the META SPC-3, only a differed effect on *Anobium punctatum* is noticed.

#### **Efficacy data**

* **For META-SPC1:**

The tests have been performed with the product X6089CR

French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the product X6089CR according to the uses and the applications rates claimed:

* Regarding the preventive efficacy claim against wood boring beetles, for superficial application, the product X6089CR is efficient according to respectively EN 46 (+EN73), EN 49 (+EN73) and EN 20-1 (+EN73), against *Hylotrupes bajulus, Anobium punctatum and* *Lyctus brunneus* for use class 1 at the application rate of 200 g of product X6089CR / m² of wood.
* Regarding the preventive efficacy claim against termites, for superficial application, the product X6089CR is efficient according to EN 118 (+EN73), against *Reticulitermes spp.*, for use class 1, at the application rate of 200 g of product X6089CR / m² of wood.
* Regarding the curative efficacy claim against wood boring beetles (*Hylotrupes bajulus*, *Anobium punctatum* and *Lyctus brunneus*), for superficial application, the product X6089CR is efficient according to respectively EN 1390 and EN 48 against *Hylotrupes bajulus* with a slow action activity and against *Anobium punctatum with a fast action activity*, at the application rate of 300 g of product X6089CR / m² of wood. According to EN 14128[[11]](#footnote-11), if curative treatment against *Lyctus brunneus* is required, a curative wood preservative "for *Hylotrupes* bajulus and *Anobium punctatum*" should be applied. The curative efficacy against wood boring beetles is then validated.
* Regarding the curative efficacy claim against termites (*Reticulitermes spp.*), no curative efficacy standard are available against termites. However, the objective of curative products are, as for the preventive treatments against termites (tested following the standard EN 118 + EN73), to protect wood against termites and to eliminate termites in the wood. Indeed, their function is not to destroy the entire colony (which is not in the wood). Moreover the target stages in the preventive and in the curative efficacy treatments are the same, which means the dose of active substance in both treatments are the same. Then the efficacy demonstrated in the preventive efficacy test can be extrapolated for a curative application.
* Regarding the curative efficacy claim against wood boring beetles, by injection, this treatment is always performed in combination with superficial application. Efficacy demonstrated for superficial treatment is sufficient and no additional data is needed. Curative treatment by injection in combination with a superficial treatment, at the application rate of 180 g of product X6089CR / m² of wood is validated.

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| **Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC1** | | | | | | | |
| **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 | X6089CR | *Reticulitermes flavipes* | EN118 + EN 73 | The ready to use product X6089CR  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 200.1 g/m² and 201.3 g/m² (mean 200.5 g/m²).  worker, nymph and soldier termites were used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The investigated effects are the mortality of the insects.  Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack).  - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (59.7 %) and the control test blocks are ranked 4.  **All the treated blocks are ranked 0 at the end of the study which demonstrates the efficacy of the product X6089CR against *Reticulitermes flavipes* at the application rate of 200.5 g of product / m² of wood.** | Ansard D. and Paulmier I., 2016  401/16/040F/b-e  6.7\_01  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6089CR | House longhorn beetle: *Hylotrupes bajulus* (L.) | EN 46 + EN 73 (evaporation) | The ready to use product X6089CR 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 199 g/m² and 200.5 g/m² (mean 199.9 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 % (92 % and 96 % solvent control).  On the treated test block, 100 % or the larvae was dead and had not tunnelled.  **This study demonstrated the efficacy of the product at 199.9 g of product / m² of wood against *Hylotrupes bajulus* larvae**  Note:  No solvent control has been performed as the product is a water-based formulation. | Brunet C. and Paulmier I., 2016  401/16/040F/a-e  6.7\_02  IC2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6089CR | Common furniture beetle:  *Anobium punctatum* | EN 49 + EN 73  (evaporation) | The ready to use product X6089CR 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 198.9 g/m² and 200.60 g/m² (mean 199.7 g/m²).  5 replicates for the treated block and for the control are performed.  The efficacy of the product is based on the comparison of egg laying, eggs emergence and mortality larvae between control blocks and treated blocks.  The method for recording / scoring effects is the count of eggs laid, eggs hatched and alive larvae found. | The study is validated as more than 50 (172) alive larvae in total are found in the control and as alive larvae are found in each control block.  In the treated blocks 100 % of larvae are dead at the end of the test.  **This study demonstrated the efficacy of the product at 200 g of product / m² of wood against *Anobium punctatum***  Note:  No solvent control has been performed as the product is a water-based formulation. | Brunet C. and Paulmier I., 2017  401/14/137F/a-e  6.7\_03  IC2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6089CR | Powder post beetle: *Lyctus brunneus* | EN 20-1 + EN 73 (evaporation) | The ready to use product X6089CR is applied by brushing on hardwood test blocks (*Quercus spp.*) and followed by an artificial weathering according to the EN 73 standard method (evaporation).  The quantity really applied on each test block varied between 197.1 g/m² and 199.5 g/m² (mean 198.0 g/m²).  6 replicates for the treated block and 3 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 198 g of product/m² of wood against *Lyctus brunneus.***  Note:  No solvent control has been performed as the product is a water-based formulation. | Brunet C. and Paulmier I., 2015  401/14/137F/b/e  6.7\_04  IC2 |
| MG 02: preservatives | Wood preservative  Curative treatment | X6089CR | House longhorn beetle: *Hylotrupes bajulus (L.)* | EN 1390 | The ready to use product X6089CR is applied by brushing on sapwood test blocks (*Pinus sylvestris*)  The quantity really applied on each test block varied between 299.6 mL/m² and 300.3 mL/m² (mean 300 mL/m²).  6 larvae of *Hylotrupes bajulus* were used for each test block.  10 replicates for the treated block and 2 replicates for the control are performed.  The investigated effects are the mortality of the larvae.  - Method for recording / scoring effects: recovery of the insects and count of the dead and alive larvae. Calculation of the percentage of mortality.  - Intervals of examination: one time, 25 weeks after exposure of the larvae in the wood block to the tested product.  The efficacy criterion according to the EN 14128 is mortality higher than 80 %. | The study is validated as the survival rate in the control is higher than 75 % (100 %).  **The mortality observed in the treated block is higher than 80 % (80.7 %) and the contact time of 24 weeks validated the low action efficacy of the product X6089CR against *Hylotrupes bajulus* larvae, at the application rate of 300 ml of product / m² of wood.** | Brunet C. and Paulmier I., 2017  401/16/040F/c-e  6.7-05  IC2 |
| MG 02: preservatives | Wood preservative  Curative treatment | X6089CR | Common furniture beetle:  *Anobium punctatum (L)* | EN48 | The ready to use product X6089CR is applied by brushing on sapwood test blocks (*Pinus sylvestris*)  The quantity really applied on each test block varied between 299.4 g/m² and 301.2 g/m² (mean 300.2 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 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 % (85 %) validated the efficacy (fast action) of the product X6089CR, at the application rate of 300 g of product / m² of wood.** | Brunet C. and Paulmier I., 2015  401/14/137F/c/e  6.7-06  IC1 |

* **For META-SPC2:**

The tests have been performed with a different formulation (X6119M2) than the representative product of the META-SPC2 (X6089HA1). The bridging between the two formulations is presented below:

The products X6089HA1 and X6119M2 are liquid water-based ready-for-use products, containing 0.10 w/w cypermethrin. X6119M2 contains also fungicidal active substances.

The products X6089HA1 and X6119M2 have close compositions, with the following differences:

* The three fungicidal active substances are replaced by water in the product X6089HA1
* A solvent is replaced by water in the product X6089HA1, (with content adjustment for other minor solvent).

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

* According to section A.3.2.a, no new biological tests are required when the change involves deletion of fungicides from a product tested against insects, if data exist which confirm no effect of the removal on the efficacy of the remaining active substances.

The product X6119M2 contains three fungicidal active substances, which have no insecticidal activity. In the product X6089HA1, these fungicidal active substances are absent, and the only active substance is cypermethrin with the same concentration than in the product X6119M2.

Moreover, two additional efficacy tests performed according to EN 118-like protocol without ageing procedure, one with the X6119M2 containing the insecticidal and the fungicidal active substances and one with the product X6119M2 which contains only the insecticidal active substance. The results showed that at the application rate claimed, no difference of efficacy between the two formulations is observed. It confirms that the fungicidal active substance has no impact on the insecticidal efficacy. Then the read-across is acceptable.

* In case of an emulsion, according to the section A.2.4b, no new biological testing is required for replacing or adding co-solvent up to 5 % of the total formulation provided that the physical properties are not affected.

Physical properties and stability of the product X6086H1 have been confirmed and penetration is not expected to be affected.

Therefore efficacy results of the product X6119M2 are considered as applicable for efficacy of the product X6089HA1 and no new biological tests should be required for X6089HA1.

French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the product X6089HA1 according to the uses and the applications rates claimed:

* Regarding the preventive efficacy claim against wood boring beetles, for superficial application, the product X6119M2 is efficient according to respectively EN 46 (+EN73), EN 49 (+EN73/EN84) and EN 20-1 (+EN73), against *Hylotrupes bajulus, Anobium punctatum and* *Lyctus brunneus* for use class 1 at the application rate of 200 g of product X6119M2 / m² of wood.
* Regarding the preventive efficacy claim against termites, for superficial application, the product X6119M2 is efficient according to EN 118 (+EN73), against *Reticulitermes spp* and *Heterotermes spp*., for use class 1, at the application rate of 200 g of product X6119M2 / m² of wood.
* 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 and EN 48 against *Hylotrupes bajulus* with a slow action activity and 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, if curative treatment against *Lyctus brunneus* is required, a curative wood preservative "for *Hylotrupes* *bajulus* and *Anobium punctatum*" should be applied. The curative efficacy against wood boring beetles is then validated.
* Regarding the curative efficacy claim against termites (*Reticulitermes spp.* 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. Their function is not to destroy the entire colony (which is not in the wood). Moreover the target stages in the preventive and in the curative efficacy treatments are the same, which means the dose of active substance in both treatments are the same. Then the efficacy demonstrated in the preventive efficacy test can be extrapolated for a curative application.
* Regarding the curative efficacy claim against wood boring beetles, by injection, this treatment is always performed in combination with superficial application. Efficacy demonstrated for superficial treatment is sufficient and no additional data is needed. Curative treatment by injection and in combination with a superficial treatment, at the application rate of 180 g of product X6089HA1 / m² of wood is validated.

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| **Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC2** | | | | | | | |
| **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 | *Reticulitermes flavipes* | EN118 + EN 73 | The ready to use 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 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.  6 replicates for the treated block and 3 replicates for the control are performed.  The investigated effects are the mortality of the insects.  Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack).  - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (61.3 %) and the control test blocks are ranked 4.  **All the treated blocks are ranked 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 / m² of wood.** | Ansard D. and Paulmier I., 2015  401/14/135F/e-e  6.7-15  IC2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6119M2 | *Heterotermes tenuis* | EN118 + EN 73 | The ready to use 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 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.  6 replicates for the treated block and 3 replicates for the control are performed.  The investigated effects are the mortality of the insects.  Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack).  - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (76 %) and the control test blocks are ranked 4.  **All the treated blocks are ranked 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 / m² of wood.** | Ansard D. and Paulmier I., 2017  401/16/075F/1/b-e  6.7-15bis  IC2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6119M2 | House longhorn beetle: *Hylotrupes bajulus* (L.) | EN 46 + EN 73 (evaporation) | The ready to use 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 198.4 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 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 % or the larvae was dead and had not tunnelled.  **This study demonstrated the efficacy of the product X6119M2 at 198.8 g of product / m² of wood against *Hylotrupes bajulus* larvae**  Note:  No solvent control has been performed as the product is a water-based formulation. | Schumacher P. and Fennert E.-, 2015  32/14/9802/01  6.7-17  IC2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6119M2 | Common furniture beetle:  *Anobium punctatum* | EN 49 + EN 73  (evaporation)  EN 49 + EN84  (leaching) | The ready to use product X6119M2 is applied by brushing on hardwood test blocks (*Quercus petrae*) and followed for some specimens by an artificial weathering according to the EN 73 standard method (evaporation) and for some others by an artificial weathering according to the EN 84 standard method (leaching).  The quantity really applied on each test block varied between 198.2 g/m² and 200.7 g/m² (mean 199.6 g/m²) for EN73 and between 198.6 g/m² and 200.7 g/m² (mean 199.5 g/m²) for EN 84  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 for EN73 and 231 for EN84) 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 both tests.  **This study demonstrated the efficacy of the product X6119M2 at 200 g of product / m² of wood against *Anobium punctatum***  Note:  No solvent control has been performed as the product is a water-based formulation. | Brunet C. and Paulmier I., 2017  401/14/135F/a /b-e  6.7-19  IC2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6119M2 | Powder post beetle: *Lyctus brunneus* | EN 20-1 + EN 73 (evaporation) | The ready to use product X6119M2 is applied by brushing on hardwood test blocks (*Quercus spp.*) 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 X6119M2 at 196 g of product/m² of wood against *Lyctus brunneus.***  Note:  No solvent control has been performed as the product is a water-based formulation. | Brunet C. and Paulmier I., 2015  401/14/135F/c/e  6.7-21  IC2 |
| MG 02: preservatives | Wood preservative  Curative treatment | X6119M2 | House longhorn beetle: *Hylotrupes bajulus (L.)* | EN 1390 | The ready to use product X6089CR 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 300.31 mL/m² (mean 300 mL/m²).  6 larvae of *Hylotrupes bajulus* were used for each test block.  10 replicates for the treated block and 2 replicates for the control are performed.  The investigated effects are the mortality of the larvae.  - Method for recording / scoring effects: recovery of the insects and count of the dead and alive larvae. Calculation of the percentage of mortality.  - Intervals of examination: one time, 25 weeks after exposure of the larvae in the wood block to the tested product.  The efficacy criterion according to the EN 14128 is a mortality higher than 80 %. | The study is validated as the survival rate in the control is higher than 75 % (100%).  **The mortality observed in the treated block is higher than 80 % (82.4 %) and the contact time of 24 weeks validated the low action efficacy of the product X6119M2 against *Hylotrupes bajulus* larvae, at the application rate of 300 mL of product / m² of wood.** | Brunet C. and Paulmier I., 2017  401/16/199F/3/e  6.7-22bis  IC2 |
| MG 02: preservatives | Wood preservative  Curative treatment | X6119M2 | 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 301.2 g/m² and 302.3 g/m² (mean 301.5 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 a 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 (fast action) of the product X6119M2, at the application rate of 301.5 g of product / m² of wood.** | Brunet C. and Paulmier I., 2015  401/14/135F/f/e  6.7-23  IC1 |
| MG 02: preservatives | Wood preservative  Curative treatment | X6119M2 | *Reticulitermes flavipes* | EN118-LIKE | The ready to use product X6119M2  is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) without initial ageing step.  The quantity really applied on each test block varied between 200 g/m² and 219 g/m² (mean 206.5 g/m²).  worker, nymph and soldier termites were used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The investigated effects are the mortality of the insects.  Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack).  - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (59 %) and the control test blocks are ranked 4.  **All the treated blocks are ranked 0 or 1 at the end of the study which demonstrates the efficacy of the product X6119M2 against *Reticulitermes flavipes* at the application rate of 206.5 g of product / m² of wood without ageing.** | LAFRAGETTE D., 2015  AD 001.S01 |
| MG 02: preservatives | Wood preservative  Curative treatment | X6119M2 without the fungicidal active substances | *Reticulitermes flavipes* | EN118-LIKE | The ready to use product X6119M2  is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) without initial ageing step.  The quantity really applied on each test block varied between 199 g/m² and 203 g/m² (mean 200.5 g/m²).  worker, nymph and soldier termites were used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The investigated effects are the mortality of the insects.  Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack).  - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (59 %) and the control test blocks are ranked 4.  **All the treated blocks are ranked 1 at the end of the study which demonstrates the efficacy of the product X6119M2 against *Reticulitermes flavipes* at the application rate of 200.5 g of product / m² of wood without ageing.** | LAFRAGETTE D., 2015  AD 001.S01 |

* **For META-SPC3:**

The tests have been performed with a different formulation (X6236) than the representative product of the META-SPC3 (X6235). The bridging between the two formulations is presented below:

Bridging data for efficacy for X6235 from X6236:

The product X6235 and X6236 are liquid water-based ready-for-use products, containing 0.10 % w/w cypermethrin. X6236 contains also fungicidal actives substances.

The products X6235 and X6236 have close compositions, with the following differences:

* The three fungicidal active substances are replaced by water in the product X6235;
* A solvent is replaced by water in the product X6235, (with content adjustment for other minor solvent).

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

* According to section A.3.2.a, no new biological tests are required when the change involves deletion of fungicides from a product tested against insects, if data exist which confirm no effect of the removal on the efficacy of the remaining active substances.

The product X6236 contains three fungicidal active substances, which have no insecticidal activity. In the product X6235, these fungicidal active substances are absent, and the only active substance is cypermethrin with the same concentration than in the product X6236.

Moreover, two additional efficacy tests performed according to EN 118-like protocol without ageing procedure performed with another formulation X6119M2 containing the insecticidal and the fungicidal active substances and one with the product X6119M2 which contains only the insecticidal active substance. The results showed that at the application rate claimed, no difference of efficacy between the two formulations is observed. It confirms that the fungicidal active substance has no impact on the insecticidal active substance. Then the read-across is acceptable

* In case of an emulsion, according to the section A.2.4b, no new biological testing is required for replacing or adding co-solvent up to 5 % of the total formulation provided that the physical properties are not affected.

Therefore efficacy results of the product X6236 are considered as applicable for efficacy of the product X6235 and no new biological tests should be required for X6235.

French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the product X6235 according to the uses and the applications rates claimed:

* Regarding the preventive efficacy claim against wood boring beetles, for superficial application, the product X6236 is efficient according to respectively EN 46 (+EN73), EN 49 (+EN73/EN84) and EN 20-1 (+EN73), against *Hylotrupes bajulus, Anobium punctatum and* *Lyctus brunneus* for use class 1 at the application rate of 200 g of product X6236 / m² of wood.
* Regarding the preventive efficacy claim against termites, for superficial application, the product X6236 is efficient according to EN 118 (+EN73), against *Reticulitermes spp* and *Heterotermes spp*., for use class 1, at the application rate of 200 g of product X6236 / m² of wood.
* Regarding the curative efficacy claim against wood boring beetles (*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. 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. But as the efficacy against *Hylotrupes bajulus* has been withdrawn, the efficacy against *Lyctus brunneus* cannot be validated. Then curative efficacy is only validated for *Anobium punctatum*.
* 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. 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.

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| **Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC3** | | | | | | | |
| **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 | *Reticulitermes flavipes* | EN118 + EN 73 | The ready to use product X62336  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 197.5 g/m² and 199.5 g/m² (mean 198.4 g/m²).  worker, nymph and soldier termites were used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The investigated effects are the mortality of the insects.  Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack).  - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (61.3 %) and the control test blocks are ranked 4.  **All the treated blocks are ranked 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 / m² of wood.** | Ansard D. and Paulmier I., 2015  401/14/134F/e-e  6.7-26  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6236 | *Heterotermes tenuis* | EN118 + EN 73 | The ready to use 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 200 g/m² and 201.2 g/m² (mean 200.6 g/m²).  worker, nymph and soldier termites were used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The investigated effects are the mortality of the insects.  Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack).  - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (76 %) and the control test blocks are ranked 4.  **All the treated blocks are ranked 1 at the end of the study which demonstrates the efficacy of the product X6236 against *Heterotermes tenuis* at the application rate of 200.6 g of product / m² of wood.** | Ansard D. and Paulmier I., 2015  401/16/075F/2/b-e  6.7-26bis  IC1 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6236 | House longhorn beetle: *Hylotrupes bajulus* (L.) | EN 46 + EN 73 (evaporation) | The ready to use 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 198.5 g/m²).  10 recently hatched larvae of *H. bajulus* for each are used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The effect investigated is the mortality of insect’s larvae.  The method for recording / scoring effects is the recovery of the insects and count of dead and alive larvae and count of dead larvae having tunneled or not.  - Intervals of examination: one time, after 1 month exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 70 % (80%).  On the treated test block, 100 % or the larvae was dead and had not tunnelled.  **This study demonstrated the efficacy of the product X6236 at 198.5 g of product / m² of wood against *Hylotrupes bajulus* larvae**  Note:  No solvent control has been performed as the product is a water-based formulation. | Schumacher P. and Fennert E.-, 2015  32/14/9801/01  6.7-28  IC2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6236 | Common furniture beetle:  *Anobium punctatum* | EN 49 + EN 73  (evaporation)  EN 49 + EN84  (leaching) | The ready to use product X6119M2 is applied by brushing on hardwood test blocks (*Quercus petrae*) and followed for some specimens by an artificial weathering according to the EN 73 standard method (evaporation) and for some others by an artificial weathering according to the EN 84 standard method (leaching).  The quantity really applied on each test block varied between 199 g/m² and 200.6 g/m² (mean 200 g/m²) for EN73 and between 198.9 g/m² and 200.4 g/m² (mean 199.9 g/m²) for EN 84  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 for EN73 and 231 for EN84) 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 both tests.  **This study demonstrated the efficacy of the product X6236 at 200 g of product / m² of wood against *Anobium punctatum***  Note:  No solvent control has been performed as the product is a water-based formulation. | Brunet C. and Paulmier I., 2017  401/14/134F/a b-e  6.7-30  IC2 |
| MG 02: preservatives | Wood preservative  Preventive treatment | X6236 | Powder post beetle: *Lyctus brunneus* | EN 20-1 + EN 73 (evaporation) | The ready to use product X6236 is applied by brushing on hardwood test blocks (*Quercus spp.*) 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 196 g of product X6236/m² of wood against *Lyctus brunneus.***  Note:  No solvent control has been performed as the product is a water-based formulation. | Brunet C. and Paulmier I., 2015  401/14/134F/c/e  6.7-32  IC2 |
| MG 02: preservatives | Wood preservative  Curative treatment | X6236 | 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 298.8 g/m² and 300.4 g/m² (mean 299.6 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 a 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 % (91 %) validated the efficacy (fast action) of the product X6236, at the application rate of 299.6 g of product / m² of wood.** | Brunet C. and Paulmier I., 2015  401/14/134F/f/e  6.7-34  IC1 |
| MG 02: preservatives | Wood preservative  Curative treatment | X6119M2 | *Reticulitermes flavipes* | EN118-LIKE | The ready to use product X6119M2  is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) without initial ageing step.  The quantity really applied on each test block varied between 200 g/m² and 219 g/m² (mean 206.5 g/m²).  worker, nymph and soldier termites were used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The investigated effects are the mortality of the insects.  Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack).  - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (59 %) and the control test blocks are ranked 4.  **All the treated blocks are ranked 0 or 1 at the end of the study which demonstrates the efficacy of the product X6119M2 *Reticulitermes flavipes* at the application rate of 206.5 g of product / m² of wood without ageing.** | LAFRAGETTE D., 2015  IC1  AD 001.S01 |
| MG 02: preservatives | Wood preservative  Curative treatment | X6119M2 without the fungicidal active substances | *Reticulitermes flavipes* | EN118-LIKE | The ready to use product X6119M2  is applied by brushing on sapwood test blocks (*Pinus sylvaticus*) without initial ageing step.  The quantity really applied on each test block varied between 199 g/m² and 203 g/m² (mean 200.5 g/m²).  worker, nymph and soldier termites were used for each test block.  6 replicates for the treated block and 3 replicates for the control are performed.  The investigated effects are the mortality of the insects.  Method for recording / scoring effects: recovery of the insects and count of the surviving workers, soldiers and nymphs. Calculation of the percentage of surviving workers. Visual observation of the test blocks and rating (0- no attack, 1- attempted attack, 2- slight attack, 3- average attack, 4- strong attack).  - Intervals of examination: one time, after 8 weeks exposure of the blocks to the insects. | The study is validated as the survival rate in the control is higher than 50 % (59 %) and the control test blocks are ranked 4.  **All the treated blocks are ranked 1 at the end of the study which demonstrates the efficacy of the product X6119M2 against *Reticulitermes flavipes* at the application rate of 200.5 g of product / m² of wood without ageing.** | LAFRAGETTE D., 2015  IC1  AD 001.S01 |

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| --- |
| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) assessed that the family (PPG\_CLASS1\_WB), separed in three META-SPC has shown a sufficient efficacy as following:   * In META-SPC1 (product X6089CR):   + 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.).*   + 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.)* * In META-SPC 2 (X6089HA1):   + 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.).*   + 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.).* * In META-SPC 3 (X6235):   + 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.).*   + the curative efficacy of the product when used by superficial application of wood in service against wood boring beetles (*Anobium punctatum)* and termites (*Reticulitermes spp.* and *Heterotermes spp.*)*.*   Nevertheless, during the assessment of the dossier, the applicant has withdrawn his claim against *Hylotrupes bajulus.* Then according to the EN 14128, an efficacy against *Lyctus brunneus* could be accepted only if the curative efficacy of the product is demonstrated against both *Hylotrupes bajulus* and *Anobium punctatum.* |

* **Minor Change application for PPG CLASS1 WB - 2019 :**

In X6089CR (Meta SPC 1), one perfume (0.01% w/w) is replaced by water. In X6089HA1 (Meta SPC 2) and X6235 (Meta SPC 3), one coformulant 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 these variations. 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 agriculture and public health. However, no data has been found in the literature regarding resistance occurrence to cypermethrin among wood-boring beetle and termites.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the following recommendations have to be implemented:

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

#### **Known limitations**

None

#### **Evaluation of the label claims**

French competent authorities (FR CA) assessed that the products of the family PPG\_CLASS1\_WB have shown a sufficient efficacy for the preservation of wood used by professional and non-professional users:

* META-SPC1:
* For 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.).*
* For the curative efficacy of the product when used by superficial application of wood in service (indoor) (that could be completed by injection) against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and Lyctus brunneus*) and termites (*Reticulitermes spp*.).

The application rates validated are the following:

* Preventive treatments: superficial application at 200 g of product X6089CR / m² of wood
* Curative treatment: superficial application at 300 g of product X6089CR / m² of wood (injection 180 g of product X6089CR / m² of wood if need be) (20 mL per hole, every 33 cm in staggered rows).
* META-SPC2:
* For 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.).*
* For the curative efficacy of the product when used by superficial application of wood in service (indoor) (that could be completed by injection) against wood boring beetles (*Hylotrupes bajulus, Anobium punctatum and* *Lyctus brunneus)* and termites *(Reticulitermes spp.* and *Heterotermes spp.).*

The application rates validated are the following:

* Preventive treatments: superficial application at 200 g of product X6089HA1 / m² of wood
* Curative treatment: superficial application at 300 g of product X6089HA1 / m² of wood (injection 180 g of product HA1 / m² of wood if need be) (20 mL per hole, every 33 cm in staggered rows).
* META-SPC3:
* For 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.).*
* For the curative efficacy of the product when used by superficial application of wood in service (indoor) against wood boring beetles (*Anobium punctatum)* and termites (*Reticulitermes spp.* and *Heterotermes spp.*)*.*

The application rates validated are the following:

* Preventive treatments: superficial application at 200 g of product X6235 / m² of wood
* Curative treatment: superficial application at 300 g of product X6235 / m² of wood
* **Minor Change application for PPG CLASS1 WB – 2019:**

Efficacy Assessment remained unchanged.

### Risk assessment for human health

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

##### Toxicology of the active substance

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

See Assessment Report of Cypermethrin.

A summary of Toxicological reference Values is proposed below:

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

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

X6089CR:

The product contains a coformulant which classify the product as eye irritant. This coformulant is composed of 3-6% of C11-14-iso-C13-rich, ethoxylated propoxylated.

X6089HA1:

The product contains a coformulant which classify the product as eye irritant. This coformulant is composed of 40-60% of D-Glucopyranose, oligomers, decyl octyl glycosides.

X6235:

The product contains a coformulant which classify the product as eye irritant. This coformulant is composed of 40-60% of D-Glucopyranose, oligomers, decyl octyl glycosides.

* **Minor Change application for PPG CLASS 1 - 2019 :**

Since X6089HA1 and X6235 are not classified for eye irritation according to the assay, D-Glucopyranose, oligomers, decyl octyl glycosides is not a SOC for human health.

##### Toxicology of the biocidal product

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

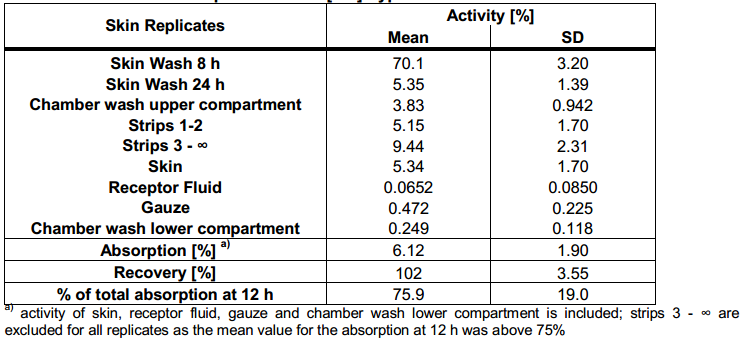
The basis for the health assessment of the biocidal product is laid out in Annex 3.2.2 ”Toxicology – biocidal product”.

###### *Percutaneous absorption*

X6089CR

The absorption profile and the distribution of the test item cypermethrin in formulation X6089CR subsequent to the application on human skin was analysed using an *in vitro* flow-through diffusion cell. Cypermethrin was tested at one concentration corresponding to the content of the pure product (0.10% w/w of pure active substance) for a contact time of 8 hours (corresponding to a normal working day) and followed by an exposure time of 24 hours. The study was performed according to the “OECD guideline for the testing of chemicals: Test No.428: Skin Absorption: *in vitro* method (13 April 2004)” which recommends to use a radiolabelled substance to perform this absorption study. The study was also designed using the Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665).

**Table 2.2.6.1.3.1-1 Mean absorption rates of [14C]-cypermethrin in formulation X6089CR**



In conclusion, in the described percutaneous absorption study under the experimental conditions reported, the test item cypermethrin formulated in X6089CR is considered to permeate through the skin with a total absorption measured at 6.12% (s.d. 1.90%). As the standard deviation is higher than 25% of the mean absorption value, according to the EFSA guidance on dermal absorption (2012), the SD is added to the mean absorption value, leading to 8 %.

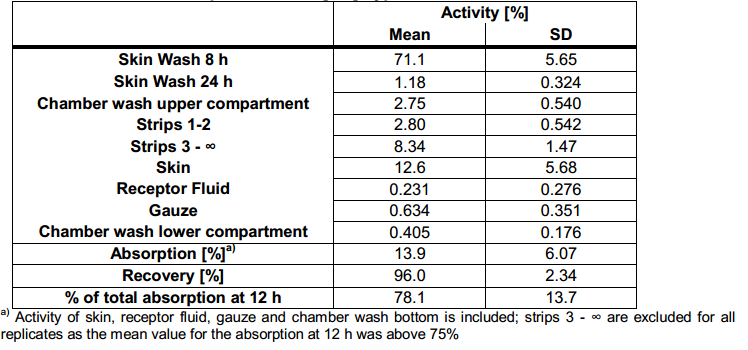
The dermal absorption retained for X6089CR is presented below:

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

X6089HA1

The absorption profile and the distribution of the test item cypermethrin in formulation X6089HA1 subsequent to the application on human skin was analysed using an *in vitro* flow-through diffusion cell. Cypermethrin was tested at one concentration corresponding to the content of the pure product for a contact time of 8 hours (corresponding to a normal working day) and followed by an exposure time of 24 hours. The study was performed according to the “OECD guideline for the testing of chemicals: Test No.428: Skin Absorption: *in vitro* method (13 April 2004)” which recommends to use a radiolabelled substance to perform this absorption study. The study was also designed using the Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665).

**Table 2.2.6.1.3.1-2 Mean absorption rates of [14C]-cypermethrin in formulation X6089HA1**



In conclusion, under the experimental conditions reported, the test item cypermethrin in formulation X6089HA1 is considered to permeate through the skin with a total absorption measured at 13.9% (s.d. 6.07%). As the standard deviation is higher than 25% of the mean absorption value, according to the EFSA guidance on dermal absorption (2012), the SD is added to the mean absorption value, leading to 20 %.

The dermal absorption retained for X6089HA1 is presented below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Guideline/test method** | **Species** | **Route of administration** | **Endpoint/type of test** | **Results**  **(dermal absorption)** |
| OECD 428  *In vitro*  Washing at 8 h / Exposure for 24 h | Human skin | Dermal | Dermal absorption of Cypermethrin | 20% |

X6235

No dermal absorption study has been performed on the product X6235. A read across with the X6236 formulation is proposed. The comparison between the compositions of X6235 and X6236 will demonstrate that the dermal absorption value obtained with X6236 can be extrapolated to X6235.

The absorption profile and the distribution of the test item cypermethrin in formulation X6236 subsequent to the application on human skin was analysed using an *in vitro* flow-through diffusion cell. Cypermethrin was tested at one concentration corresponding to the content of the pure product for a contact time of 8 hours (corresponding to a normal working day) and followed by an exposure time of 24 hours. The study was performed according to the “OECD guideline for the testing of chemicals: Test No.428: Skin Absorption: *in vitro* method (13 April 2004)” which recommends to use a radiolabelled substance to perform this absorption study. The study was also designed using the Guidance on Dermal Absorption (EFSA Journal 2012;10(4):2665).

The mean recovery percentage obtained in the exposure experiment was 90% (s.d. 2%) for the X6236 formulation mixed with [14C]-cypermethrin containing 0.97 mg cypermethrin/g. This was outside the acceptability criteria of 100 ± 5%. Since for all skin discs the recovery was consistently lower than 95% (86%-92%), normalization of the data was performed whereby the dermal absorption was expressed as percentage of the total amount recovered (total % recovery was set to 100%).

**Table 2.2.6.1.3.1-3 Mean corrected absorption rates of [14C]-cypermethrin in formulation X6236**

|  |  |  |
| --- | --- | --- |
| Formulation | X6236 formulation containing cypermethrin 0.1% w/w | |
| Number of human skin discs | 8 | |
| Number of donnors | 5 | |
| ≥ 75% absorbed in receptor fluid in first half of study | No | |
|  | Mean % | Standard deviation |
| **Surface compartment** | | |
| Total skin swab at 8 h | 93 | 2 |
| Material remaining in donor chamber | 0.4 | 0.3 |
| Total % non-absorbed1) | 93 | 2 |
| **Skin compartment** | | |
| Skin | 0.8 | 0.5 |
| Tape strips 1&2 | 1 | 0.3 |
| Stratum corneum  (tape strips excluding 1&2) | 3 | 1 |
| Total % at dose site  (excluding tape strips 1&2) | 4 | 1 |
| **Receptor compartment** | | |
| Receptor fluid  (collected over 24 h) | 1 | 0.5 |
| Receptor fluid terminal | 0.02 | 0.01 |
| Receptor chamber | 0.05 | 0.08 |
| Total % directly absorbed2) | 1 | 0.6 |
| **Overall absorption** | | |
| Total % potentially absorbable  (excluding tape strips 1&2)3) | 5 | 2 |
| Total % absorbed  (excluding all tape strips)4) | 2 | 0.9 |
| Total % recovery | 100 | 0 |

1. % in total skin swabs at 8h + % material remaining in donor chamber
2. % receptor fluid + % receptor fluid terminal + % receptor chamber
3. Total % at dose site (without tape strips 1&2) + total % directly absorbed
4. Total % in receptor fluid, receptor fluid terminal, receptor chamber and skin (excluding all tapes strips)

In conclusion, under the experimental conditions reported, the test item cypermethrin in formulation X6236 is considered to permeate through the skin with a total absorption measured at 5% (s.d. 2%). As the standard deviation is higher than 25% of the mean absorption value, according to the EFSA guidance on dermal absorption (2012), the SD is added to the mean absorption value, leading to 7 %.

Based on dermal absorption study performed with X6236, dermal absorption value retained for X6235 is presented below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Guideline/test method** | **Species** | **Route of administration** | **Endpoint/type of test** | **Results**  **(dermal absorption)** |
| OECD 428  *In vitro*  Washing at 8 h / Exposure for 24 h | Human skin | Dermal | Dermal absorption of Cypermethrin | 7% |

###### *Acute toxicity*

X6089CR, X6089HA1, X6235

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

For X6089CR, components classified for acute toxicity are of category 4 and at a content inferior to 1%. Therefore, they are no impact on the acute toxicity.

For X6089HA1, components classified for acute toxicity are of category 4 and at a content inferior to 1%. Therefore, they are no impact on the acute toxicity.

For X6235, components classified for acute toxicity are of category 4 and at a content inferior to 1%. Therefore, they are no impact on the acute toxicity.

###### *Irritation and corrosivity*

X6089CR, X6089HA1, X6235

No skin or eye irritation study has been submitted for the products. The calculation rules of the Regulation 1272/2008 are applied to set the classification of the products for this endpoint, a classification Eye Irrit. Cat.2; H319 is required for each product.

X6089 CR contains, a co-fomulant classified H318 at a content > 1%.

X6089 HA1 contains, a co-fomulant classified H318 at a content > 1%.

X6235 contains, a co-fomulant classified H318 at a content > 1%.

###### *Sensitisation*

X6089CR

No skin sensitisation study has been submitted for the product. The calculation rules of the Regulation 1272/2008 are applied to set the classification of the product for this endpoint, no classification is required. However, BIT is at a content of 0.028%. This substance has a specific threshold of 0.05% for skin sensitization. Therefore, the label of product should mention: EUH208 contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

X6089HA1

No skin sensitisation study has been submitted for the product. The calculation rules of the Regulation 1272/2008 are applied to set the classification of the product for this endpoint, no classification is required. However, BIT and CMI/MIT are at a content of 0.026% and 0.0014% respectively. These substances have specific thresholds of 0.05% and 0.0015% for skin sensitization. Therefore the label of product should mention: EUH208 contains 1,2-benzisothiazol-3(2H)-one and a mixture of 5-chloro-2methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction.

X6235

No skin sensitisation study has been submitted for the product. The calculation rules of the Regulation 1272/2008 are applied to set the classification of the product for this endpoint, no classification is required. However, BIT and CMI/MIT are at a content of 0.026% and 0.0014% respectively. These substances have specific thresholds of 0.05% and 0.0015% for skin sensitization. Therefore, the label of product should mention: EUH208: Contains 1,2-benzisothiazol-3(2H)-one and a mixture of 5-chloro-2methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one. May produce an allergic reaction.

###### *Other studies*

No other study has been submitted.

* **Minor Change application for PPG CLASS 1 – 2019 :**

For the products X6089HA1 and X6235, one formulant (0.05% w/w) was replaced by a similar formulant (0.05% w/w) with the same function. Both co-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.

For the product X6089CR, one co-formulant (perfume, 0.01%) is replaced by water. This change has no impact on the hazard.

***Eye damage and irritation***

A study was provided to justify the classification of Meta SPC2 and 3.

This study has been conducted, according to OECD guideline 438 (eye irritation on isolated chicken eye), with a formulated PT08 product (X6119M2) containing 0,10 %w/w (pure) of cypermetrin.

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 (PT8 formulation with 0,10 %w/w cypermetrin (pure)) 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-SPC2:**

The study has been performed with a different formulation (X6119M2) than the representative product of the META-SPC2 (X6089HA1).

The bridging between the two formulations is presented below:

The products X6089HA1 and X6119M2 are liquid water-based ready-for-use products, containing 0.10% w/w of cypermethrin. X6119M2 contains also fungicidal active substances.

The products X6089HA1 and X6119M2 have close compositions, with the following differences:

* Three fungicidal active substances are replaced by water in the product X6089HA1
* A solvent classified for eye irritation is replaced by water in the product X6089HA1, and a minor content adjustment (decreasing) is performed for another solvent (not classified for eye local toxicity).
* The content in water content in X6089HA1 is thus slightly increased.
* Other component are in the same content.

Therefore, taking into account these elements, the eye local toxicological properties of the product X6089HA1 are not expected to be different from the one of X6119M2.

* **For META-SPC3:**

The study has been performed with a different formulation (X6119M2) than the representative product of the META-SPC3 (X6235). The bridging between the two formulations is presented below:

The products X6235 and X6119M2 are liquid water-based ready-for-use products, containing 0.10% w/w of cypermethrin. X6119M2 contains also fungicidal active substances

The products X6235 and X6119M2 have similar compositions, with the following differences:

* Three fungicidal active substances are replaced by water in the product X6235
* A solvent classified for eye irritation is replaced by water in the product X6235, and a minor content adjustment (decreasing) is performed for another solvent (not classified for eye local toxicity).
* The penetrating agent with no toxicological classification is increased in the product X6235. No impact on the local effect of the product is expected by the content difference.
* Two thickening agents are added in the product X6235. 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 X6235.
* The content in water content in X6235 is thus decreased.
* Other component are in the same content.

Therefore, taking into account these elements and considering that the most impacting content changes are very slight, the eye local toxicological properties of the product X6235 are not expected to be different from the one of X6119M2.

In conclusion, the read-across between the compositions of the product X6119M2 and the representative products X6089HA1 (meta SPC 2) and X6235 (meta SPC 3) are acceptable.

Thus, the results of the study described above are considered relevant for the representative products X6089HA1 (meta SPC 2) and X6235 (meta SPC 3): no classification for Eye damage and irritation is required.

Please refer to the confidential annex for the detailed comparison between the compositions of X6119M2, X6089HA1 and X6235.

#### **Exposure assessment**

The biocidal products X6089CR and X6089HA1 are wood preservatives containing 0.11% cypermethrin as active substances and intended to be used as a ready-to-use product (RTU) without dilution by both professionals and non-professionals.

The biocidal product X6235 is intended to be used by non-professionals only.

**Identification of main paths of human exposure towards active substance and substances of concern from its use in biocidal product**

X6089CR

| **Summary table: relevant paths of human exposure** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | na | yes | yes | na | yes | yes | na |
| Dermal | na | yes | yes | na | yes | yes | na |
| Oral | na | na | yes | na | no | yes | na |

X6089HA1

| **Summary table: relevant paths of human exposure** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | na | yes | yes | na | yes | yes | na |
| Dermal | na | yes | yes | na | yes | yes | na |
| Oral | na | na | yes | na | no | yes | na |

X6235

| **Summary table: relevant paths of human exposure** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | na | na | yes | na | na | yes | na |
| Dermal | na | na | yes | na | na | yes | na |
| Oral | na | na | yes | na | na | yes | na |

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Active Substance** | **Concentration**  **(% w/w)** | **Molecular weight**  **(g/mol)** | **Vapor Pressure**  **(Pa)** | **Log Pow** | **Inhalation absorption** | **Oral absorption** |
| **Cypermethrin** | 0.11 | 416 | 6.10-7 (25°C)  2.3.10-7 (20°C) | 5.45 | 100% | 57% |

Dermal absorptions retained:

|  |  |
| --- | --- |
| **Product name** | **Dermal absorption** |
| X6089CR | 8% |
| X6089HA1 | 20% |
| X6235 | 7% |

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

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

*In Annex 3.2.3„Safety for professional operators“, the results of the exposure calculations for the active substance and the substance of concern for the professional user are laid out.*

X6089CR and X6089HA1 are RTU products that can be applied by brushing or spraying at an application dose of 200 g product/m2 for preventive treatment and 300 g product/m2 for curative treatment. An application dose of 180 g product/m2 is considered for injection, in combination with superficial treatment (brush or spray) in curative treatment.

A dermal and inhalation exposure to the product containing 0.11% (w/w) of cypermethrin can occur during the mixing and loading, the application and the equipment’s cleaning.

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

***Brush application***

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[[12]](#footnote-12). The mixing and loading phase is not considered since the product is a RTU that can be applied directly with a brush.

Exposure during the cleaning of equipment (brush) has been assessed with the exposure model from the Opinion no. 11 of HEEG[[13]](#footnote-13).

| **Scenario** | **Product** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Dermal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Brushing 300 g/m2 – without PPE (0.11% of cypermethrin)** | | | | |
| M&L | X6089CR | n.a | | |
| Product application phase | 1.49 x 10-4 | 2.03x 10-3 | 2.18 x 10-3 |
| Brush cleaning phase | negligible | 4.18 x 10-4 | 4.18 x 10-4 |
| Application + cleaning | 1.49 x 10-4 | 2.45 x 10-3 | 2.60 x 10-3 |
| M&L | X6086HA1 | n.a | | |
| Product application phase | 1.49 x 10-4 | 5.08 x 10-3 | 5.23 x 10-3 |
| Brush cleaning phase | negligible | 6.94 x 10-4 | 6.94 x 10-4 |
| Application + cleaning | 1.49 x 10-4 | 5.77 x 10-3 | 5.92 x 10-3 |

***Brush application + injection***

No specific model for injection is available.

In a conservative approach, the exposure values set in the “*Non-professional application of paints by brushing and rolling*” from the Recommendation no. 10 of the BPC Ad hoc Working Group on Human Exposure, has been used and multiplied by two in order to simulate an application by brush and injection considering that the exposure during injection should not be higher than brush application.

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** | **Product** | **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 – without PPE (0.11% of cypermethrin)** | | | | |
| M&L | X6089CR | n.a | | |
| Product application phase | 2.99 x 10-4 | 4.06 x 10-3 | 4.36 x 10-3 |
| Cleaning phase | negligible | 1.23x 10-3 | 1.23 x 10-3 |
| Appli + cleaning | 2.99 x 10-4 | 5.29 x 10-3 | 5.59 x 10-3 |
| M&L | X6086HA1 | n.a | | |
| Product application phase | 2.99 x 10-4 | 1.02 x 10-2 | 1.05 x 10-2 |
| Cleaning phase | negligible | 2.71 x 10-3 | 2.71 x 10-3 |
| Appli + cleaning | 2.99 x 10-4 | 1.29 x 10-2 | 1.32 x 10-2 |

***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[[14]](#footnote-14).

Exposure during the cleaning of equipment has been assessed with the BEAT scenario “*Cleaning of the spray equipment*” from TNsG second version of 2007[[15]](#footnote-15).

| **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 (0.11% of cypermethrin)** | | | | |
| M&L | X6089CR | Included in the model | | |
| Product application phase | 2.61 x 10-3 | 6.53 x 10-2 | 6.80 x 10-2 |
| Cleaning of the spray equipment | negligible | 8.09 x 10-4 | 8.09 x 10-4 |
| Appli + cleaning | 2.61 x 10-3 | 6.61 x 10-2 | 6.88x 10-2 |
| M&L | X6086HA1 | Included in the model | | |
| Product application phase | 2.61 x 10-3 | 1.63 x 10-1 | 1.66x 10-1 |
| Cleaning of the spray equipment | negligible | 2.02 x 10-3 | 2.02 x 10-3 |
| Appli + cleaning | 2.61 x 10-3 | 1.65 x 10-1 | 1.68x 10-1 |
| **Spraying 300g/m2 – with PPE during application phase (0.11% of cypermethrin)** | | | | |
| M&L | X6089CR | Included in the model | | |
| Product application phase  (gloves and coated coverall 20%[[16]](#footnote-16)) | 2.61 x 10-3 | 6.89 x 10-3 | 9.50 x 10-3 |
| Cleaning of the spray equipment | negligible | 8.09 x 10-4 | 8.09 x 10-4 |
| Appli (EPI)+ cleaning | 2.61 x 10-3 | 7.70x 10-3 | 1.03 x 10-2 |
| M&L | X6086HA1 | Included in the model | | |
| Product application phase  (gloves and coated coverall 20%) | 2.61 x 10-3 | 1.72 x 10-2 | 1.98 x 10-2 |
| Cleaning of the spray equipment | negligible | 2.02 x 10-3 | 2.02 x 10-3 |
| Appli (PPE)+ cleaning | 2.61 x 10-3 | 1.92 x 10-2 | 2.19 x 10-2 |

***Spray application + injection***

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

| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| --- | --- | --- | --- | --- |
| **Spraying 300g/m2 + injection 180g/m2 – with PPE during application (0.11% of cypermethrin)** | | | | |
| M&L | X6089CR | n.a | | |
| Product application phase  (gloves and coated coverall 20%) | 5.23 x 10-3 | 1.38 x 10-2 | 1.90 x 10-2 |
| Cleaning phase | negligible | 1.62 x 10-3 | 1.62 x 10-3 |
| Appli (PPE)+ cleaning | 5.23 x 10-3 | 1.54 x 10-2 | 2.06 x 10-2 |
| M&L | X6086HA1 | n.a | | |
| Product application phase  (gloves and impermeable coverall 5%[[17]](#footnote-17)) | 5.23 x 10-3 | 1.25 x 10-2 | 1.77 x 10-2 |
| Cleaning phase | negligible | 4.04 x 10-3 | 4.04 x 10-3 |
| Appli (PPE)+ cleaning | 5.23 x 10-3 | 1.65 x 10-2 | 2.17 x 10-2 |

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

*In Annex 3.2.4„Safety for non-professional operators“, the results of the exposure calculations for the active substance and the substance of concern for the non-professional user are laid out.*

X6089CR, X6089HA1 and X6235 are RTU products that can be applied by brushing or spraying at an application dose of 200 g product/m2 for preventive treatment and 300 g product/m2 for curative treatment.

An application dose of 180 g product/m2 is considered for injection, in combination with a superficial curative treatment (brush or spray) for X6089CR and X6089HA1 formulations.

A dermal and inhalation exposure to the product containing 0.11% (w/w) of cypermethrin can occur during the mixing and loading, the application and the equipment’s cleaning.

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

Moreover, taking into account that PPE is not authorised for non-professional users, the application rates are the same for the three formulations and based on the fact that X6089HA1 has the highest dermal absorption value, this formulation can be considered as a worst case scenario and covers others formulations.

***Brush application[[18]](#footnote-18)***

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[[19]](#footnote-19). The mixing and loading phase is not considered since the product is a RTU that can be applied directly with a brush.

Exposure during the cleaning of equipment (brush) has been assessed with the exposure model from the Opinion no. 11 of HEEG[[20]](#footnote-20).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 (0.11% of cypermethrin)** | | | | |
| M&L | n.a | | | |
| Product application phase | Cypermethrin | 1.49 x 10-4 | 5.08 x 10-3 | 5.23 x 10-3 |
| Brush cleaning phase | negligible | 6.93 x 10-4 | 6.93 x 10-4 |
| Appli + cleaning | 1.49 x 10-4 | 5.77 x 10-3 | 5.92 x 10-3 |

***Brush application + injection***

No specific exposure model for injection is available.

In a conservative approach, the exposure values set in the “*Non-professional application of paints by brushing and rolling*” from the Recommendation no. 10 of the BPC Ad hoc Working Group on Human Exposure, has been used and multiplied by two in order to simulate an application by brush and injection considering that the exposure during injection should not be higher than brush application.

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 – Without PPE (0.11% of cypermethrin)** | | | | |
| M&L | n.a | | | |
| Product application phase | Cypermethrin | 2.99 x 10-4 | 1.02 x 10-2 | 1.05 x 10-2 |
| Cleaning phase | negligible | 4.83 x 10-4 | 4.83 x 10-4 |
| Appli + cleaning | 2.99 x 10-4 | 1.06 x 10-2 | 1.09 x 10-2 |

***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. This model is based on data from non-professionals spraying a ready for use product indoors, in overhead direction.

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| **Spraying 300g/m2 – without PPE (0.11% of cypermethrin)** | | | | |
| M&L | Included in the model | | | |
| Product application phase | Cypermethrin | 9.93 x 10-5 | 3.34 x 10-2 | 3.35 x 10-2 |
| Cleaning of the spray equipment | negligible | 2.02 x 10-3 | 2.02 x 10-3 |
| Appli + cleaning | 9.93 x 10-5 | 3.55 x 10-2 | 3.56 x 10-2 |

***Spray application + injection***

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **Active substance** | **Inhalation Exposure**  **(mg/kg bw/j)** | **Demal Exposure**  **(mg/kg bw/d)** | **Total Exposure (mg/kg bw/d)** |
| **Spraying 300g/m2 + injection 180g/m2 – without PPE (0.11% of cypermethrin)** | | | | |
| M&L | n.a | | | |
| Product application phase | Cypermethrin | 1.99 x 10-4 | 6.69 x 10-2 | 6.71 x 10-2 |
| Cleaning phase | negligible | 4.04 x 10-3 | 4.04 x 10-3 |
| Appli + cleaning | 1.99 x 10-4 | 7.09 x 10-2 | 7.11 x 10-2 |

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

For secondary exposure, as described in TNsG for Human Exposure (2002 and 2007), it was considered occurring soon after application with a short exposure period (acute phase) or with a long-term and repeated exposure (chronic phase). It concerns:

* for acute phase, scenarios of sanding treated wood (adult) and chewing treated wood offcuts (infant),
* for chronic phase the scenarios of professional sanding, inhalation of volatilizing residues indoors (adult and infant), of child playing on playground structure outdoors and infant playing on weathered (playground) structure and mouthing.

These scenarios which have to be considered for wood preservative treatments are 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***

As a worst-case, it has been considered that the wood was treated with a total application dose of 480 g/m2, corresponding to a curative treatment by brushing or spraying followed by injection. Based on the fact that X6089HA1 has the highest dermal absorption value, this formulation can be considered as a worst case scenario and covers others formulations.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **Product** | **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** | X6089CR | Covered by X6089HA1 | | | |
| X6089HA1 | 2.22 x 10-3 | 1.84 x 10-5 | - | 2.24 x 10-3 |
| X6235 | Covered by X6089HA1 | | | |
| **Infant chewing wood composites chips** | X6089CR | - | - | 1.44 x 10-2 | 1.44 x 10-2 |
| X6089HA1 |
| X6235 |

***Chronic secondary exposure scenario***

As a worst-case, it has been considered that the wood was treated with a total application dose of 480 g/m2, corresponding to a curative treatment by brushing or spraying and injection. Based on the fact that X6089HA1 has the highest dermal absorption value, this formulation can be considered as a worst case scenario and covers others formulations.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **Product** | **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** | X6089CR | Covered by X6089HA1 | | | |
| X6089HA1 | 2.22 x 10-3 | 1.11x 10-4 | - | 2.33 x 10-3 |
| X6235 | Covered by X6089HA1 | | | |
| **Inhalation of volatilizing residues indoors (Adult)** | X6089CR | - | 2.74 x 10-5 | - | 2.74 x 10-5 |
| X6089HA1 |
| X6235 |
| **Inhalation of volatilizing residues indoors (Infant)** | X6089CR | - | 5.54 x 10-5 | - | 5.54 x 10-5 |
| X6089HA1 |
| X6235 |
| **Child playing on playground structure outdoors** | X6089CR | Covered by X6089HA1 | | | |
| X6089HA1 | 8.45 x 10-4 | - | - | 8.45 x 10-4 |
| X6235 | Covered by X6089HA1 | | | |
| **Infant playing on weathered (playground) structure and mouthing** | X6089CR | Covered by X6089HA1 | | | |
| X6089HA1 | 1.27x 10-3 | - | 4.51 x 10-3 | 5.78x 10-3 |
| X6235 | Covered by X6089HA1 | | | |

###### *Combined exposure*

A combined exposure is also considered for an adult (professional exposure + inhalation of volatilizing residues) and an infant (playing on weathered (playground) structure and mouthing + inhalation of volatilizing residues).

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

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

Based on the fact that X6089HA1 has the highest dermal absorption value, this formulation can be considered as a worst case scenario and covers other formulations.

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario** | **Professional exposure**  **(mg/kg bw/j)** | **Secondary exposure (inhalation of volatilized residues)**  **(mg/kg bw/d)** | **Total exposure**  **(mg/kg bw/d)** |
| Brushing (without PPE) | 5.92x 10-3 | 2.74 x 10-5 | 5.95 x 10-3 |
| Spraying  (gloves + coverall 20%) | 2.19 x 10-2 | 2.74 x 10-5 | 2.19 x 10-2 |
| Brushing + injecting (without PPE) | 1.32 x 10-2 | 2.74 x 10-5 | 1.32 x 10-2 |
| Spraying + injecting  (gloves + coverall 5%) | 2.17 x 10-2 | 2.74 x 10-5 | 2.18 x 10-2 |

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

|  |  |  |
| --- | --- | --- |
| **Infant playing on a wood strucure + mouthing**  **(mg/kg bw/d)\*** | **Secondary exposure (inhalation of volatilized residues)**  **(mg/kg bw/d)** | **Total exposure**  **(mg/kg bw/d)** |
| 5.78x 10-3 | 5.54 x 10-5 | 5.84 x 10-3 |

\* wood treated by spraying+injecting with a dose of 480 g/m2

* **Minor Change application for PPG CLASS1 WB – 2019:**

The exposure assessment for human health remained unchanged.

###### *Dietary exposure*

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

#### **Risk characterisation for human health**

##### Risk for direct exposure

###### *Risk for professionals users*

***Brush application***

X6089CR

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Brushing 300g/m2 – without PPE** | | | | |
| M&L | n.a | | | |
| Product application phase | 0.022 | 2.18 x 10-3 | 9.91 | Acceptable |
| Brush cleaning phase | 4.18 x 10-4 | 1.90 | Acceptable |
| Appli + cleaning | 2.60 x 10-3 | 11.81 | Acceptable |

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

X6089HA1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Brushing 300g/m2 – without PPE** | | | | |
| M&L | n.a | | | |
| Product application phase | 0.022 | 5.23 x 10-3 | 23.76 | Acceptable |
| Brush cleaning phase | 6.94 x 10-4 | 3.15 | Acceptable |
| Appli + cleaning | 5.92 x 10-3 | 26.91 | Acceptable |

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

***Brush application + injection***

X6089CR

| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| --- | --- | --- | --- | --- |
| **Brushing 300g/m2 and Injecting 180g/m2 – without PPE** | | | | |
| M&L | n.a | | | |
| Application phase | 0.022 | 4.36 x 10-3 | 19.82 | Acceptable |
| Brush and injector cleaning | 1.23 x 10-3 | 6 | Acceptable |
| Appli + cleaning | 5.59 x 10-3 | 21.72 | Acceptable |

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

X6089HA1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Brushing 300g/m2 and Injecting 180g/m2 – without PPE** | | | | |
| M&L | n.a | | | |
| Application phase | 0.022 | 1.05 x 10-2 | 47.52 | Acceptable |
| Brush and injector cleaning | 2.71 x 10-3 | 12.34 | Acceptable |
| Appli + cleaning | 1.32 x 10-2 | 59.86 | Acceptable |

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

***Spray application***

X6089CR

| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| --- | --- | --- | --- | --- |
| **Spraying 300g/m2 – no PPE** | | | | |
| M&L | Including in the model | | | |
| Product application phase | 0.022 | 6.80 x 10-2 | 309 | **Unacceptable** |
| Cleaning spray equipment | 8.09 x 10-4 | 3.68 | Acceptable |
| Appli + cleaning | 6.88x 10-2 | 313 | **Unacceptable** |
| **Spraying 300g/m2 –PPE during application phase** | | | | |
| M&L | Including in the model | | | |
| Application phase  (gloves + coverall 20%) | 0.022 | 9.50 x 10-3 | 43.20 | Acceptable |
| Cleaning equipement  (no PPE) | 8.09 x 10-4 | 3.68 | Acceptable |
| Appli + cleaning  (gloves + coverall 20% during application) | 1.03 x 10-2 | 46.87 | Acceptable |

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

X6089HA1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Spraying 300g/m2 – no PPE** | | | | |
| M&L | Included in the model | | | |
| Product application phase | 0.022 | 1.66x 10-1 | 754 | **Unacceptable** |
| Cleaning spray equipment | 2.02 x 10-3 | 9.19 | Acceptable |
| Appli + cleaning | 1.68x 10-1 | 764 | **Unacceptable** |
| **Spraying 300g/m2 –PPE during application phase** | | | | |
| M&L | Included in the model | | | |
| Application phase  (gloves + coverall 20%) | 0.022 | 1.98 x 10-2 | 90.18 | Acceptable |
| Cleaning equipement  (no PPE) | 2.02 x 10-3 | 9.19 | Acceptable |
| Appli + cleaning  (gloves + coverall 20% during application) | 2.19 x 10-2 | 99 | Acceptable |

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

***Spray application + injection***

X6089CR

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Spraying 300g/m2 + injecting 180 mg/m2 – PPE during application phase** | | | | |
| M&L | Included in the model | | | |
| Application phase  (gloves + coverall 20%) | 0.022 | 1.90 x 10-2 | 86.39 | Acceptable |
| Cleaning equipment  (no PPE) | 1.62 x 10-3 | 7.35 | Acceptable |
| Appli + cleaning  (gloves + coverall 20% during application) | 2.06 x 10-2 | 94 | Acceptable |

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

X6089HA1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Spraying 300g/m2 + injecting 180 mg/m2 – PPE during application phase** | | | | |
| M&L | Includied in the model | | | |
| Application phase  (gloves + coverall 5%) | 0.022 | 1.77 x 10-2 | 80.45 | Acceptable |
| Cleaning equipment  (no PPE) | 4.04 x 10-3 | 18.38 | Acceptable |
| Appli + cleaning  (gloves + coverall 5% during application) | 2.17 x 10-2 | 98.83 | Acceptable |

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

###### *Risk for non-professional users*

Based on the fact that X6089HA1 has the highest dermal absorption value, this formulation can be considered as a worst case scenario and covers others formulations.

***Brush application***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Brushing 300g/m2** | | | | |
| M&L | n.a | | | |
| Application phase | 0.088 | 5.23 x 10-3 | 5.94 | Acceptable |
| Brush cleaning | 6.93 x 10-4 | 0.79 | Acceptable |
| Appli + cleaning | 5.92 x 10-3 | 6.73 | Acceptable |

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

***Brush application + injection***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Brushing 300g/m2 et Injecting 180g/m2** | | | | |
| M&L | n.a | | | |
| Application phase | 0,088 | 1.05 x 10-2 | 11.88 | Acceptable |
| Brush and injector cleaning | 4.83 x 10-4 | 0.55 | Acceptable |
| Appli + cleaning | 1.09 x 10-2 | 12.43 | Acceptable |

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

***Spray application application***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Spraying 300g/m2** | | | | |
| M&L | Included in the model | | | |
| Application phase | 0.088 | 3.35 x 10-2 | 38.11 | Acceptable |
| Cleaning spray equipment | 2.02 x 10-3 | 2.30 | Acceptable |
| Appli + cleaning | 3.56 x 10-2 | 40.41 | Acceptable |

* The risk is acceptable for spray application by non-professionals. The product could be applied in all premises in a residential housing.

***Spray application + injection***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Spraying 300g/m2 + injecting 180 mg/m2** | | | | |
| M&L | Included in the model | | | |
| Application phase | 0.088 | 6.71 x 10-2 | 76.23 | Acceptable |
| Cleaning spray equipment | 4.04 x 10-3 | 4.60 | Acceptable |
| Appli + cleaning | 7.11 x 10-2 | 80.82 | Acceptable |

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

##### Risk for indirect exposure

***Acute Exposure***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Adult amateur sanding/processing of treated wood composites** | 0,088 | 2.24 x 10-3 | 2.54 | Acceptable |
| **Infant chewing wood composites chips (480g/m²)** | 1.44 x 10-2 | 16.42 | Acceptable |

* The risk is acceptable for chronic exposure scenarios.

***Chronic Exposure***

| **Scenario** | **AEL**  **(mg/kg pc/j)** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| --- | --- | --- | --- | --- |
| **Adult professional sanding/processing of treated wood composites** | 0.022 | 2.33 x 10-3 | 10.58 | Acceptable |
| **Adult: inhalation of volatilised residues, indoors** | 2.74 x 10-5 | 0.12 | Acceptable |
| **Infant: inhalation of volatilised residues, indoors** | 5.54 x 10-5 | 0.25 | Acceptable |
| **Child playing on playground structure outdoors** | 8.45 x 10-4 | 3.8 | Acceptable |
| **Infant playing on playground structure outdoors and mouthing** | 5.78x 10-3 | 26.28 | Acceptable |

* The risk is acceptable for chronic exposure scenarios.

##### Risk for combined exposure

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| **Adult combined expo : Brushing** | 5.95 x 10-3 | 27.04 | Acceptable |
| **Adult combined expo : spraying**  **(gloves +coverall 20%)** | 2.19 x 10-2 | 99.49 | Acceptable |
| **Adult combined expo : Brushing + injecting** | 1.32 x 10-2 | 59.98 | Acceptable |
| **Adult combined expo : spraying + injecting**  **(gloves +coverall 5%)** | 2.18 x 10-2 | 98.96 | Acceptable |

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario** | **Exposure**  **(mg/kg pc/j)** | **% AEL** | **Risk** |
| Infant combined exposure | 5.84 x 10-3 | 26.53 | Acceptable |

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

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

The products are classified Eye irritant of category 2 (H319).

Therefore, a local risk characterization according to the guidance on BPR Volume III part B/C was performed.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | | **Exposure** | | | | | | | **Risk** |
| **Hazard Category** | **Effects in terms of C&L** | **Additional relevant hazard information** | **PT** | **Who is exposed?** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential degree of exposure of eyes** | **Relevant RMM & PPE** | **Conclusion on risk** |
| |  | | --- | | Low | | Eye irrit. 2, H319 | - | 8 | Professional | Pouring and application of product by brushing, spraying and injection | Dermal / inhalation | Until 240 min/day for brushing; 10 min/day for spraying and 480 min/day for injection (worst case situation)  The guidance recommends less than few hours per day.  This recommendation is respected.  Moreover, for brushing and injection, the duration of exposure is of several hours however it is unlikely than eyes are exposed during all the duration for these types of application. | Low | |  | | --- | | Measures to control exposure, such as:  Technics  - Minimisation of manual phases/work tasks,  - Minimisation of splashes and spills;  - Avoidance of contact with contaminated tools and objects;  - Regular cleaning of equipment and work area;  Organisation  - Management/supervision in place to check that the RMMs in place are being used correctly and OCs followed;  - Training for staff on good practice.  - Good standard of personal hygiene |   PPE:  - Chemical goggles | Considering that these recommendations can be followed, the risk is acceptable. |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | | **Exposure** | | | | | | | **Risk** |
| **Hazard Category** | **Effects in terms of C&L** | **Additional relevant hazard information** | **PT** | **Who is exposed?** | **Tasks, uses, processes** | **Potential exposure route** | **Frequency and duration of potential exposure** | **Potential degree of exposure of eyes** | **Relevant RMM & PPE** | **Conclusion on risk** |
| |  | | --- | | Low | | Eye irrit. 2, H319 | - | 8 | Non professional | Pouring and application of product by brushing, spraying and injection | Dermal / inhalation | Until 240 min/day for brushing; 40min/day for spraying and 480 min/day for injection (worst case situation)  The guidance recommends less than one hour per day.  For spraying, this recommendation is respected.  For brushing and injection, the duration of exposure is higher however it is unlikely than eyes are exposed more than 1 hour during these types of application. | Low | Labelling, instructions for use that minimise exposure or possible health effects | Considering that these recommendations can be followed, the risk is acceptable. |

* **Minor Change application for PPG CLASS 1 WB – 2019:**

**Local risk characterization**

Only the products of the Meta SPC 1 are classified Eye irritant of category 2 (H319).

Therefore, the local risk characterization performed for the AMM according to the guidance on BPR Volume III part B/C is only relevant for the meta SPC1.

No local risk characterization is required for the meta SPC 2 and 3.

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

Risks related to the use of PPG\_CLASS1\_WB by professionals and non-professionals are considered acceptable for all the intended uses mentioned above.

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

* **Minor Change application for PPG CLASS1 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. Wood treated with PPG\_CLASS1\_WB must contain label restrictions against use in contact with livestock, food and feed. (See Annex 3.3 Residue Behaviour).

### Risk assessment for animal health

*Not relevant*

### Risk assessment for the environment

|  |
| --- |
| FR-CA box 1  Please notice that the environmental risk assessment (section 2.2.8) is reported as provided by the applicant. The FR CA position is presented in green evaluation boxes. |

* **Minor change application for PPG CLASS1 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.

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

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

The products X6089CR, X6089HA1 and X6235 containing 0.10 % (w/w) cypermethrin are intended for the preventive and curative treatments of interior woods. These products are for Use Class 1 (under cover, not exposed to the weather). No risk of contamination of the environment is foreseen for the indoors treatments.

The environmental fate and behaviour of the products X6089CR, X6089HA1 and X6235 is presented in Section 10 of the IUCLID file. Based on the intended uses of the products and on the nature of the substance, on its physico-chemical properties and on its relations structure/function, the risk of contamination of the environmental compartments can be considered as negligible.

For the assessment of the environmental fate and behaviour of the active substance contained in the biocidal products X6089CR, X6089HA1 and X6235, please refer to the chapters on fate and distribution in the environment (see Assessment Report, cypermethrin cis:trans / 40:60 PT08, 12/07/2013).

A summary of the environmental behaviour of cypermethrin and its relevant metabolites is presented below.

* **Environmental behaviour of cypermethrin**

|  |  |  |  |
| --- | --- | --- | --- |
| Degradation | |  | |
| * Hydrolysis | In acidic conditions and at pH 7, cypermethrin is relatively stable (DT50 > 29 days at pH 7, 25°C and DT50 > 1 year and of 4.73 days respectively at pH 4 and 7, 50°C). It is degraded under alkaline conditions at pH 9 (DT50 of 1.9 hours at 50°C). The increase in temperature increases the degradation rate of cypermethrin.  At 12°C (environmental conditions), the derived DT50 of cypermethrin are  > 7630 days, 98.9 days and 39.71 hours at pH 4, 7 and 9 respectively. | |
|  |  | |
| * Photolysis |  | |
| *In water* | Cypermethrin is degraded by photolysis in water. The half-lives for net photolysis were calculated to be 14.7 days for 14C phenoxy label and 12.4 days for 14C cyclopropane label. The main photolytic degradates were DCVC acid (18% of Applied Radioactivity, AR), 3-phenoxybenzoic acid (15% of AR) and 3-phenoxybenzaldehyde (3% of AR). | |
| *In soil* | Light accelerates the degradation of cypermethrin on a soil surface. However, soil photolysis is a minor route of degradation of the active substance as shown by data on distribution of radioactivity and DT50 for cis- and trans isomers. | |
| *In air* | EPIWIN AOP model gives an indirect half-life of 18h for the photolysis in air (OH) of cypermethrin. | |
|  |  | |
| * Biodegradation | Cypermethrin is not readily biodegradable, not inherently biodegradable, not ultimately biodegradable. | |
| *In water*  */sediment* | Cypermethrin is degradable in a water/sediment compartment. Degradation of cypermethrin was effective in both water-sediment systems. At 12°C, DT50 values were calculated to be between 6.6 and 18.5 days in the whole system, 0.95 days in the water phase and between 20.7 and 27 days in sediments. The significant metabolites were 3-phenoxybenzoic acid (21% AR in water and 11% in sediment), TDCVC (44% AR in water and 20% in sediment) and CDCVC (22% AR in water and 15% in sediment). A further unknown metabolite was identified up to 14% of AR in the units dosed with the cyclopropyl label.  The two main degradation products TDCVC and CDCVC have to be considered as persistent with typical DT50 values > 40 days. | |
| *In soil* | In soil in aerobic conditions, cypermethrin is metabolised to three significant metabolites: 3-phenoxybenzoic acid (10.2% AR at day 7), TDCVC (13.6% of AR at day 7) and CDCVC (3.9% of AR at day 7). Further metabolism of cypermethrin and/or these metabolites lead to bound residues and mineralisation to carbon dioxide. The DT50 values for the degradation of cypermethrin is within the range 6 to 24 days following incubation at 20 ± 2°C (mean DT50 = 13.5 days at 20°C). In soil PT 102, incubated at 10 ± 2°C, the DT50 value for the degradation of cypermethrin is 52 days. The corresponding DT50 at 12°C is calculated to be 17.2 days, based on the geometric mean. Cis cypermethrin degrades at lower rates in comparison to trans cypermethrin.  In anaerobic conditions, cypermethrin is metabolised to three extractable metabolites: 3-PBA (max. 35.1% AR), CDCVC (max. 22.8% AR), TDCVC (max. 31.2% AR) and carbon dioxide (max. 22.8% AR) in the total flooded soil system. The DT50 is estimated to 46 days at 20°C, corresponding to 87.2 days at 12°C. | |
|  |  | |
| Distribution |  | |
| * Adsorption   desorption | Results of the soil adsorption/desorption study provided minimum Koc values ranging from 80 653 to 574 360. Koc for the sediment is minimum 527 972.  These values are indicative of a strong adsorption to the soil particles and sediment. | |
|  |  | |
| * Volatilisation | Due to its low vapour pressure (2.3\*10-7 at 20°C), volatilisation of cypermethrin is not expected. | |
|  |  | |
| * Bioaccumulation | Cypermethrin tends to bioaccumulate in water organisms with a typical bioaccumulation factor (fish) of 417 L/kg. | |

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

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

|  |  |
| --- | --- |
| **Data** | **Cypermethrin** |
| Reference | AR for cypermethrin  PT08, 12/07/2013 |
| Molecular weight (g/mol) | *416.3* |
| Melting point [°C] | Onset: 41.2  Peak: 47.3 |
| Boiling point [°C] | Not measurable, decomposes |
| Vapour Pressure (Pa) | *2.3\*10-7* at 20°C  6\*10-7 at 25°C |
| Henry´s law constant (Pa m3 mol-1) | *2.4-\*10-2* at 20°C |
| Solubility in water at 20°C (mg/L) | *4\*10-3* at 20°C |
| Partition coefficient (log Kow) | *5.45 at 25°C*  TDCVC: 2.672 (calculated)  CDCVC: 2.672 (calculated) |
| Hydrolysis DT50 [d] | 12°C, pH 4: DT50 = 7 631 d  12°C, pH 7: DT50 = 98.9 d  12°C, pH 9: DT50 = 1.65 d |
| Photolytic / photo-oxidative degradation in water (DT50) [d] | At 20°C, pH 4:  DT50 = 12.4 - 14.7 d |
| Degradation in water/sediment (DT50) [d] | **In water**:  0.95 d at 12°C  **In sediment**:  20.7 – 27 d at 12°C  **In whole system**:  6.6 - *18.5 d* at 12°C  3-PBA: 24.5 d at 12°C (whole system)  TDCVC: 152 – 274 d at 12°C (whole system)  CDCVC: 18 – 356 d at 12°C (whole system) |
| Degradation in soil (DT50) [d] | **In aerobic conditions**:  *17.2* at 12°C (geometric mean)  **In anaerobic conditions**:  87.2 at 12°C |
| Soil photolysis (DT50) [d] | 29.6  (soil photolysis is considered as a minor route of degradation) |
| Photo-oxidative degradation in air (DT50) | 18 h |
| Adsorption / desorption Koc [L/kg] | *575 000* |
| Absorption to sludge [%] | - |
| BCF in fish | 417  TDCVC: 37.25 (calculated)  CDCVC: 37.25 (calculated) |
| Depuration rate constant (fish) [d-1] | 1.58\*10-3 L/h |
| BCF in earthworms | - |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **FR-CA box 2**  **Summary of the physico-chemical, environmental fate and behaviour parameters for cypermethrin used by FR-CA for the product-environmental risk assessment according to the list of endpoints validated at EU level**   |  |  |  | | --- | --- | --- | | **Parameter / Variable** | **Unit** | **Cypermethrin** | | Molar mass | [g.mol-1] | 416.3 | | Vapour pressure | [Pa] | 6.00E-07 | | Water solubility | [mg.L-1] | 4.00E-03 | | Koc | [L.kg-1] | 575 000 | | DT50 (soil) | [d at 12°C] | 17.2 | | DT50 (surface water) | [d at 12°C] | 0.95 | | DT50 (water/sediment whole system) | [d at 12°C] | 18.5 | | K soil-water | [m3.m-3] | 1.73E+04 | | BCF in fish | [L.kg-1] | 417 | | BCF in earthworm | [L.kg-1] | 3380 | | STP fraction | | | | FSTP, water | [-] | 0.091 | | FSTP, sludge | [-] | 0.909 | |

##### Effects on environmental organisms for active substance

###### *Aquatic compartment (including water, sediment and stp)*

A summary and evaluation of effect data for the active substances with relevance to the aquatic compartment can be found in Document II-A of the active substance dossier (see Letters of Access in Section 13 of the active substances datasets).

The relevant ecotoxicological data and the calculated PNECs (see Assessment Report cypermethrin cis:trans / 40:60 PT08, 12/07/2013) are summarised in the following Table:

**Table 2.2.8‑2: Ecotoxicological data on cypermethrin for the aquatic compartment**

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

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

(2) The PNEC sediment was calculated using the equilibrium partitioning method and a value of Koc of 575 000 (to calculate Ksup-water).

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

###### *Atmosphere*

A summary and evaluation of effect data for the cypermethrin with regard to effects in the atmospheric compartment can be found in Document II-A of the active substance dossier (see Letters of Access in Section 13 of the active substances datasets).

- Data on cypermethrin

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

###### *Terrestrial compartment*

A summary and evaluation of effect data for the cypermethrin with relevance to the terrestrial compartment can be found in Document II-A of the active substance dossier (see Letters of Access in Section 13 of the active substances datasets).

The relevant ecotoxicological data and the PNEC (see Assessment Report cypermethrin *cis:trans* / 40:60 PT08, 12/07/2013) are presented in the following Tables:

**Table 2.2.8‑3: Ecotoxicological data on active substances for the terrestrial compartment**

| **Ecotoxicity on terrestrial organisms** | **Cypermethrin *cis:trans* / 40:60** |
| --- | --- |
| EC50 earthworm [mg/kg] | *(14 d)* > 100 mg/kgdwt |
| NOEC earthworm [mg/kg] | *Mortality (56 d):* > 100 mg/kgdwt  *Biomass (56 d):* 30.8 mg/kgdwt  *Reproduction (56 d):* **5.20 mg/kgdwt** |
| LC50 plants [mg/kg] | Not expected to be phytotoxic |
| EC50 plants [mg/kg] | Not expected to be phytotoxic |
| NOEC plants [mg/kg] | Not expected to be phytotoxic |
| EC50 Mineralization [mg/kg] | - |
| NOEC Mineralization [mg/kg] | *Nitrogen mineralisation:* 52 mg/kgdwt |
| **PNECsoil** | **0.088 mg/kgwwt (AF = 50)**  (0.1 mg/kgdwt) |
| LD50 bird [mg/kg b.w.] (acute) | Not determined. |
| LC50 bird [mg/kg feed] (dietary) | *(5 d)* > 5620 mg/kg feed equivalent to  > 1376 mg/kg b.w./d |
| NOEC bird [mg/kg feed] | *(21 d)* 1000 mg/kg feed equivalent to  92.0 mg/kg b.w./d |
| LD50 mammal [mg/kg b.w.] (acute) | 1945 |

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

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

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

**Data on cypermethrin**

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

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

\* A chronic dietary study on birds has been performed and the NOEC reported in the Assessment Report is 1000 mg/kgfood. The PNECoral, bird is then derived from this NOEC according to formula 79 of the guidance:

PNECoral, bird = NOECbird / AForal.

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

PNECoral,bird = 1000 / 30

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

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

NOECmammal = NOAELmammal, oral \* CONVmammal

where CONVmammal is a conversion factor from NOAEL to NOEC. For rats, when a study of more of 6 weeks is available, the conversion factor is equal to 20 according to the Table 25 of the guidance.

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

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

PNECoral, small mammal = NOECmammal / AForal.

According to the Table 26 of the guidance, the assessment factor (AForal) is equal to 30 because a chronic study (2 years) on rats is available.

PNECoral,small mammal = 100 / 30

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **FR-CA box 3**  **Summary of the PNEC values for cypermethrin used by FR-CA for the product-environmental risk assessment according to the list of endpoints validated at EU level**   |  |  |  | | --- | --- | --- | | **PNEC** | **Unit** | **Cypermethrin** | | **PNECSTP** | [mg/L] | 1.63E+00 | | **PNECwater** | [mg/L] | 4.00E-06(1) | | **PNECsediment** | [mg/kgwwt] | 5.00E-02(2) | | **PNECsoil** | [mg/kgwwt] | 9.18E-02 | | **PNECoral,bird** | [mg/kgfood] | 3.33E+01 | | **PNECoral,mammals** | [mg/kgfood] | 3.33E+00 |   ’(1) According to the WGIV2016, a robust NOEC fish of 0.4 µg.L-1 is considered to derive the PNECwater for Cypermethrin with an assessment factor of 100.  ’(2) – a factor of 10 has to be added to the PEC/PNEC ratios |

###### *PBT and ED Assessment*

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

##### Effects on environmental organisms for biocidal product

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

#### **Exposure assessment**

##### Emissions to the environment

Taking into account the uses of the products, it can be considered that there is no exposure of the environmental compartments when using the products X6089CR, X6089HA1 and X6235 for curative indoor treatments (mainly on beams and frames) and then no risk assessment for the environment is deemed necessary.

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

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

*See Summary of Product Characteristics (SPC)*

### Comparative assessment

*Not relevant.*

# Annexes

## 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** |
| 2.2.2 | 402/14/1094F/abcdef-e | Raphalen E. | 2015 | Physico-chemical properties, technical characteristics and chemical analyses of the biocidal product X6089CR before and after an accelerated storage procedure for 14 days at 54 ± 2oC, in compliance with CIPAC MT 46.3 method (Handbook J, 2000) | DYRUP SAS - PPG |  |  |  |  |
| 2.2.2 | 150313/PaPV93.13 | Simon F. | 2015 | Odour of X6089HA1 | DYRUP SAS - PPG |  |  |  |  |
| 2.2.2 | 150313/PaPV93.11 | Simon F. | 2015 | Odour of X6089CR | DYRUP SAS - PPG |  |  |  |  |
| 2.2.2 | 402/14/1094F/ghijk-e | Raphalen E. | 2015 | Physical, chemical and technical characteristics of the biocidal product X6089CR | DYRUP SAS - PPG |  |  |  |  |
| 2.2.2 | 5006501 | P. Poveda | 2017 | Stability of the biocidal product X6089CR after 14 days storage at 54°C | DYRUP SAS - PPG |  |  |  |  |
| 2.2.2 | 402/13/1096F/ab-e | Legay S. | 2016 | Storage stability during 2 years at ambient temperature according to Technical Monograph No.17 (CropLife) on the wood preservative X6089CR | DYRUP SAS - PPG |  |  |  |  |
| 2.2.2 | 402/14/1096F/efgh-e | Legay S. | 2015 | Physical, chemical and technical characteristics of the biocidal product X6119M2 | DYRUP SAS - PPG |  |  |  |  |
| 2.2.2 | 402/14/1096F/abcd-e | 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) | DYRUP SAS - PPG |  |  |  |  |
| 2.2.2 | COA-402/13/1135F/ad-e | Legay S. | 2016 | Storage stability during 2 years at ambient temperature according to Technical Monograph No.17 (CropLife) on the wood preservative X6089HA1 | DYRUP SAS - PPG |  |  |  |  |
| 2.2.2 | COA- 402/14/1097F/abcd-e | 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) | DYRUP SAS - PPG |  |  |  |  |
| 2.2.2 | 150313/PaPV93.7 | Simon F. | 2015 | Odour of X6236 | DYRUP SAS - PPG |  |  |  |  |
| 2.2.2 | 402/14/1097F/efgh-e | Legay S. | 2015 | Physical, chemical and technical characteristics of the biocidal product X6236 | DYRUP SAS - PPG |  |  |  |  |
| 2.2.2 | 402/13/1138F/ad-e | Legay S. | 2016 | Storage stability during 2 years at ambient temperature according to Technical Monograph No.17 (CropLife) on the wood preservative X6236 | DYRUP SAS - PPG |  |  |  |  |
| 2.2.3 | 402/14/1094F/l-e | Raphalen E. Legrand G. | 2015 | Differential Scanning Calorimetry (DSC) measurement on the test item X6089CR | DYRUP SAS - PPG |  |  |  |  |
| 2.2.3 | 15/05 | Detrimont H., Ambrosi D. | 2015 | Literature review on explosive properties, self-reactivity, oxidising properties of the ingredients of the product X6089CR | DYRUP SAS - PPG |  |  |  |  |
| 2.2.3 | 14-904015-002 | Demangel B. | 2014 | Determination of the auto-ignition temperature of X6089CR | DYRUP SAS - PPG |  |  |  |  |
| 2.2.3 | 402/14/1097F/i-e | Raphalen E., Legay S. | 2015 | Differential Scanning Calorimetry (DSC) measurement on the test item X6236 | DYRUP SAS - PPG |  |  |  |  |
| 2.2.3 | 15/09 | Detrimont H., Ambrosi D. | 2015 | Literature review on explosive properties, self-reactivity, oxidising properties of the ingredients of the product X6236 | DYRUP SAS - PPG |  |  |  |  |
| 2.2.3 | 14-904015-004 | Demangel B. | 2014 | Determination of the auto-ignition temperature of X6236 | DYRUP SAS - PPG |  |  |  |  |
| 2.2.4 | CTBA-IBC/67/1170/05F/BPL-e  Analytical protocol N°94 version 1 | Yrieix C. | 2006 | Chemical tests on a ready to use water based preservative (X6089CR): Validation of the analytical method and chemical analysis of cypermethrin in the test item | DYRUP SAS - PPG |  |  |  |  |
| 2.2.4 | 402/13/1134F/ab-e  Analytical protocol N°283-e for X6119M2 and N°284-e for X6089HA1 | Raphaelen 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 | DYRUP SAS - PPG |  |  |  |  |
| 2.2.4 | 402/13/1137F/ab-e  Analytical protocol N°285-e for X6236 and N°286-e for X6235 | Raphaelen E. | 2013 | Physico-chemical tests on a ready-to-use aqueous emulsion (X6235/X6236): Validation of analytical method and chemical analysis of active ingredients declared in the test items | DYRUP SAS - PPG |  |  |  |  |
| 2.2.2.5 | 401/16/040F/b-e | Ansard D. and Paulmier I. | 2016 | X6089CR. Preventive efficacy against subterranean termites according to NF EN 118 with NF EN 73. | Dyrup SAS |  |  |  |  |
| 2.2.2.5 | 401/16/040F/a-e | Brunet C. and Paulmier I. | 2016 | X6089CR. Preventive efficacy against Hylotrupes bajulus according to NF EN 46-1 with NF EN 73 | Dyrup SAS |  |  |  |  |
| 2.2.2.5 | 401/14/137F/a-e | Brunet C. and Paulmier I. | 2017 | X6089CR. Preventive effectiveness agaisnt Anobium punctatum according to NF EN 49-1 with NF EN 73. | Dyrup SAS |  |  |  |  |
| 2.2.2.5 | 401/14/137F/b/e | Brunet C. and Paulmier I. | 2015 | X6089CR. Determination of the protective effectiveness agaisnt Lyctus brunneus according to NF EN 20-1. | PPG Industries |  |  |  |  |
| 2.2.2.5 | 401/16/040F/c-e | Brunet C. and Paulmier I. | 2017 | X6089CR. Curative action against Hylotrupes bajulus according to NF EN 1390. | Dyrup SAS |  |  |  |  |
| 2.2.2.5 | 401/14/137F/c/e | Brunet C. and Paulmier I. | 2015 | X6089CR. Determination of eradicant action against larvae of Anobium punctatum (De Geer)-laboratory method according to NF EN 48. | PPG Industries |  |  |  |  |
| 2.2.2.5 | 401/14/135F/e-e | Ansard D. and Paulmier I. | 2015 | X6119M2. Preventive action against termites according to NF EN 118 with NF EN 73. | PPG Industries |  |  |  |  |
| 2.2.2.5 | 401/16/075F/1/b-e | Ansard D. and Paulmier I. | 2017 | X6119M2. Preventive efficacy against subterranean termites according to adapted NF EN 118 with NF EN 73. | Dyrup SAS |  |  |  |  |
| 2.2.2.5 | 32/14/9802/01 | Schumacher P. and Fennert E | 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 |  |  |  |  |
| 2.2.2.5 | 401/14/135F/a /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 |  |  |  |  |
| 2.2.2.5 | 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 |  |  |  |  |
| 2.2.2.5 | 401/16/199F/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 SAS |  |  |  |  |
| 2.2.2.5 | 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 |  |  |  |  |
| 2.2.2.5 | AD 001.S01 | LAFRAGETTE D. | 2015 | Efficacy test repport\_EN118-LIKE | - |  |  |  |  |
| 2.2.2.5 | 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 |  |  |  |  |
| 2.2.2.5 | 401/16/075F/2/b-e | Ansard D. and Paulmier I. | 2015 | X6236. Preventive efficacy against subterranean termites according to adapted NF EN 118 with NF EN 73. | Dyrup SAS |  |  |  |  |
| 2.2.2.5 | 32/14/9801/01 | Schumacher P. and Fennert E. | 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 |  |  |  |  |
| 2.2.2.5 | 401/14/134F/a 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 |  |  |  |  |
| 2.2.2.5 | 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 |  |  |  |  |
| 2.2.2.5 | 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

Annex 3.2.1: Toxicology and metabolism –active substance

CYPERMETHRIN

Threshold Limits and other Values for Human Health Risk Assessment

| **Summary** | | | |
| --- | --- | --- | --- |
|  | Value | Study | SF |
| AEL long-term | 0.022 | 2 years rat | 100 |
| AEL medium-term | 0.055 | 90 days dog | 100 |
| AEL acute  ADI  ARfD | 0.088 | Neurotoxicity rat | 100 |
|  | | | |

|  |  |
| --- | --- |
| Inhalative absorption | 100% |
| Oral absorption | 57% (human)/44% (animal) |
| Dermal absorption | X6089CR: 8%  X6089HA1: 20%  X6235: 7% |

| **Classification** | |
| --- | --- |
| with regard to toxicological data (according to the criteria in Reg. 1272/2008) – ATP0 | Acute Tox 4 – H302  Acute Tox 4 – H332  STOT SE 3 – H335 |

Annex 3.2.2: Toxicology – biocidal product

PPG\_CLASS1\_WB

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| General information | | | | | | |
| Formulation Type | | RTU | | | | |
| Active substance(s) (incl. content) | | Cypermethrine 0.1% | | | | |
| Acute toxicity, irritancy and skin sensitisation of the preparation | | | | | | |
| Rat LD50 oral (OECD 420) | | n.a. |  |  |  | |
| Rat LD50 dermal (OECD 402) | | n.a. |  |  |  | |
| Rat LC50 inhalation (OECD 403) | | n.a. |  |  |  | |
| Skin irritation (OECD 404) | | n.a. |  |  |  | |
| Eye irritation (OECD 405) | | Irritant to eyes (calculation method) |  |  |  | |
| Skin sensitisation (OECD 429; LLNA) | | n.a. |  |  |  | |

| Additional toxicological information | | | | |
| --- | --- | --- | --- | --- |
| Short-term toxicity studies | n.a. |  |  |  |
| Toxicological data on active substance(s) (not tested with the preparation) | n.a. |  |  |  |
|  | n.a. |  |  |  |
| Toxicological data on non-active substance(s) (not tested with the preparation) | n.a. |  |  |  |
|  | n.a. |  |  |  |
| Further toxicological information | n.a. | | | |

X6089CR

|  |  |
| --- | --- |
| Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9) | |
| Regulation 1272/2008/EC | GHS07 |
| Warning |
| H319 Causes serious eye irritation  EUH208: Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. |

X6089HA1, X6235

|  |  |
| --- | --- |
| Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9) | |
| Regulation 1272/2008/EC | GHS07 |
| Warning |
| H319 Causes serious eye irritation  EUH208: Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction. |

For X6089HA1 and X6235, the label should mention: Contains a mixture of 5-chloro-2methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one.Annex 3.2.3: Safety for professional operators

PPG\_CLASS1\_WB

Exposure assessment for professional users

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

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

* Brush application: Excel data sheet “Expo IR – Brushing”;
* Spray application: Excel data sheet “Expo IR – Spraying”;
* Brush application + injection: Excel data sheet “Expo IR – Injecting (1);
* Spray application + injection: Excel data sheet “Expo IR – Injecting (2).

Risk assessment

Please see the tables presented in the document section 2.2.6.3.1.1

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

PPG\_CLASS1\_WB

Exposure assessment for Non-professionals

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

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

* Brush application: Excel data sheet “Expo IR – Brushing”;
* Spray application: Excel data sheet “Expo IR – Spraying”;
* Brush application + injection: Excel data sheet “Expo IR – Injecting (1);
* Spray application + injection: Excel data sheet “Expo IR – Injecting (2);

Risk assessment for Non-professionals

Please see the tables presented in the document section 2.2.6.3.1.2;

Exposure assessment for General public (secondary exposure)

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

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

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

Risk assessment for General public (secondary exposure)

Please see the tables presented in the document section 2.2.6.3.2

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## Residue behaviour

**Intended Use (critical application):** intended to be used as preventive and curative treatment for interior woods. These preventive and curative treatments are done by professionals and non-professionals by brush/roller/pad/superficial application, spray application or injection.

**Active substance(s):** cypermethrin

**Formulation of biocidal product:** AL (any other liquid)

**Place of treatment:** indoor

**Target organisms:** Wood boring insects and subterranean termites

**Maximum residue limits or equivalent**

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

PPP: plant protection product

VMP: veterinary medicinal product

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

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

No further data are required concerning the residue behaviour.

## Confidential annex

See separate confidential file.

1. Wood preservatives – Determination of preventive action against *Reticulitermes* species (European termites) (Laboratory method) [↑](#footnote-ref-1)
2. Wood preservatives – Accelerated ageing tests of treated wood prior biological testing – Evaporative ageing procedure. [↑](#footnote-ref-2)
3. Wood preservatives – Determination of the preventive action against *Hylotrupes bajulus (Linnaeus)* – Part 1:Larvicidal effect (Laboratory method). [↑](#footnote-ref-3)
4. Wood preservatives – Determination of the protective effectiveness against *Anobium punctatum (De geer)* – Part 1: Application by surface treatment (Laboratory method). [↑](#footnote-ref-4)
5. Wood preservatives – Determination of the protective effectiveness against *Lyctus brunneus (Stephens)* – Part 1: Application by surface treatment (laboratory method). [↑](#footnote-ref-5)
6. Wood preservatives – Determination of the eradicant action against *Hylotrupes bajulus (Linnaeus)* [↑](#footnote-ref-6)
7. Wood preservatives – Determination of the eradicant action against *larvae of Anobium punctatum (De geer) (Laboartory method)* [↑](#footnote-ref-7)
8. Wood preservatives – Determination of preventive action against *Reticulitermes* species (European termites) (Laboratory method) [↑](#footnote-ref-8)
9. Wood preservatives – Accelerated ageing of treated wood prior to biological testing – Leaching procedure. [↑](#footnote-ref-9)
10. Wood preservatives – Determination of the eradicant action against *larvae of Anobium punctatum (De geer) (Laboratory method)* [↑](#footnote-ref-10)
11. 12 Performance criteria for curative wood preservatives as determined by biological tests (2004) [↑](#footnote-ref-11)
12. “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-12)
13. 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-13)
14. “Methods and models to assess exposure to biocidal product in different product types” version 2, June 2016. [↑](#footnote-ref-14)
15. Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007). [↑](#footnote-ref-15)
16. This protection factor of 80 % is used because the exposure is "light" (i.e.less than 200 mg in-use roduct/minute) on the whole of the body - not including the hands (TNsG 2002, Part 2, p.36). [↑](#footnote-ref-16)
17. The protection factor of 5% corresponds to penetration of an impermeable coverall [↑](#footnote-ref-17)
18. A risk assessment was performed at 240 min considering that this duration covers professional and non professional users. However, a duration of 155 min (as recommended in user guidance of TNsG) could be used to assess the risk for non professional. [↑](#footnote-ref-18)
19. “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-19)
20. 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-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)