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 NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



[**TERMIPROTECT**]

Product type [18]

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

Case Number in R4BP: [BC-ES023513-36]

Evaluating Competent Authority: [FR]

Date: [29/03/2018]

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# CONCLUSION

TERMIPROTECT is a biocidal product family that comprise 3 Meta-SPCs:

Meta-SPC 1 contains 2 products:

* Xylophène Professionnel Termiprotect Film Anti-Termites (other commercial name Cultisol Isofilma Anti-Termites), product code **X6232-001**.
* SIKA Anti Termites film NEW, product code **X6232-001bis**.

Meta-SPC 2 contains 1 product:

* Xylophène Professionnel Termiprotect Périfilm Anti-Termites, product code **X6232-002**.

Meta-SPC 3 contains 1 product:

* Xylophène Professionnel Termiprotect Périfilm AD Anti-Termites, product code **X6240**.

The different products are physico-chemical barriers with LDPE 3 layers films against termites to protect buildings.

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

Regarding the stability of the products TERMIPROTECT, the different products are considered to be stable to light exposure.

There is no effect of high temperature, since after 8 weeks at 40°C, neither the active ingredient content nor the product aspect were changed for the products of the meta-SPC 1 and 2. The following management measure should be added: Do not store at temperatures higher than 40°C.

The stability data indicate a shelf life of at least 2 years when stored in LDPE for the products of the meta-SPC 1 and 2. The results after 24 months of the long term storage stability study performed on the product X6232-001 should be provided in post-authorization.

The product of the Meta-SPC 3 must be protected from high temperatures because of the presence of a bituminous layer. As no accelerated storage test has been provided on the product, the following management measure has to be added: do not store at temperatures higher than 22°C. Based on the data provided for the long term storage stability study, only a shelf life of 6 months is accepted.

All the products TERMIPROTECT are not explosive and have no oxidising properties. It is not flammable and contains no substance associated with self-heating.

Regarding the method of analysis, the chiral method using HPLC-UV is fully validated for the determination of Permethrin in the biocidal products TERMIPROTECT.

As the product is not intended to come into contact with food, drink and animal feeding stuffs, analytical methods for the determination of residues of permethrin in food of plant and animal origin are not required.

Acceptable validated methods were provided for residues of permethrin in soil, water and in air in the CAR of the active substance. Letters of access from Tagros Chemicals India Ltd. is available.

**Conclusion on Efficacy**

French competent authorities considered that in accordance with the submitted tests and the requirements of TNsG on PT18[[1]](#footnote-1), the efficacy of the products of the TERMIPROTECT family, used as physico-chemical barrier (surface or peripheral application) to protect buildings is demonstrated against European subterranean termites (*Reticulitermes spp.*)

**Conclusion on risk assessment for human health**

The risk for human health is considered acceptable for professionals considering the use of gloves when manipulating the product.

The exposure of workers after application or of people living or working in the building is considered negligible.

**Conclusion on risk for consumers via residues**

Regarding the use, food or feed contamination is not expected. As a consequence the exposure via food, via livestock exposure or via transfer of biocidal active substances is considered as negligible, and no dietary risk assessment was performed. Nevertheless the following risk mitigation measure is proposed to avoid any food and feed contamination:

* Avoid any contamination of food, feed or drinks.

**Conclusion on risk assessment for the environment**

* Construction step:

For the exposure of soil, groundwater, STP following direct or indirect releases to the environment, all calculated RCR values were < 1, indicating an acceptable risk to these environmental compartments.

For the exposure of surface water and sediment following indirect releases via the STP, RCR values were > 1, indicating unacceptable risk to these environmental compartments. A risk mitigation measure is proposed to prevent the exposure of the aquatic compartment when a release to the STP is foreseen: ***During the application step of the film, if the treated zone is connected to a rainwater collection system or sewer, do not expose the film to rain***. The application of this risk mitigation measure preventing emissions to the STP would achieve acceptable risks.

* Service life:

For the exposure of STP, surface water, sediment, soil and groundwater, all calculated RCR values were < 1, indicating an acceptable risk to the environmental compartments.

# ASSESSMENT REPORT

## Summary of the product assessment

# 

# Part I - First information level

### Administrative information

#### Identifier of the product family

| **Identifier[[2]](#footnote-2)** | **Country (if relevant)** |
| --- | --- |
| TERMIPROTECT | France |

#### Authorisation holder

|  |  |  |  |
| --- | --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | |  | | --- | | PPG AC - France | |
| **Address** | Immeuble Union Square  1 rue de l'Union  CS 10055  92565 Rueil Malmaison cedex  France |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### Manufacturer of the products of the family

|  |  |
| --- | --- |
| **Name of manufacturer** | Granger Frères |
| **Address of manufacturer** | BP 25 ZI des Taillas  43600 Sainte Sigolene  France |
| **Location of manufacturing sites** | BP 25 ZI des Taillas  43600 Sainte Sigolene  France |

#### Manufacturer of the active substance

|  |  |
| --- | --- |
| **Active substance** | Permethrin |
| **Name of manufacturer** | Tagros Chemicals India Ltd. |
| **Address of manufacturer** | "Jhaver Centre", Rajah Annamalai Building  IV Floor, 72, Marshalls Road  Egmore  Chennai-600 008  India |
| **Location of manufacturing sites** | Tagros Chemicals India Ltd.  A-4/1&2, Sipcot Industrial Complex  Pachayankuppam  Cuddalore – 607 005, Tamilnadu  India |

### 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** | Permethrin |
| **IUPAC or EC name** | 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2- dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate |
| **EC number** | 258-067-9 |
| **CAS number** | 52645-53-1 |
| **Minimum purity / content** | ≥ 93% w/w sum of all Permethrin isomers |
| **Structural formula** | Afficher l'image d'origine |

#### Candidate(s) for substitution

The active substance Permethrin does not meet any exclusion criteria listed in Article 5 of Regulation (EU) No.528/2012 (CMR Cat. 1A or 1B, endocrine disruptor, vPvB) or two of the criteria for being PBT in accordance with Annex XIII of Regulation (EC) No.1907/2009. Therefore, Permethrin contained in the biocidal family products TERMIPROTECT is not a candidate for substitution in accordance with Article 10 of Regulation (EU) No.528/201.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Permethrin  (technical) | 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2- dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52645-53-1 | 258-067-9 | 0.11 | 1.08 |
| Permethrin  (Pure) | 0.1 | 1.0 |

#### 

#### Information on technical equivalence

The plant location used in this biocide product dossier was evaluated in the CAR of the active substance permethrin and is authorized at EU level.

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

TERMIPROTECT family doesn’t contain any substance of concern.

#### Type of formulation

|  |
| --- |
| XX: other (film) |

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

## 

## 1. Meta SPC 1 administrative information

## 1.1. Meta SPC identifier

| **X6232-001**  **X6232-001bis** |  |
| --- | --- |

## 

## 1.2. Suffix to the authorisation number

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

## 1.3. Product type(s)

| **Product type(s)** | PT18 |
| --- | --- |

## 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** |
| Permethrin  (technical)  Permethrin  (Pur) | 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2- dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52645-53-1 | 258-067-9 | 1.08  1.0 | 1.08  1.0 |

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

| **Formulation** |  |
| --- | --- |
| XX: other (film) |  |

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

| **Classification** | |
| --- | --- |
| Hazard category | Skin Sens 1  Aquatic Acute 1  Aquatic Chronic 1 |
| Hazard statement | H317: May cause an allergic skin reaction  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long-lasting effects |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H317: May cause an allergic skin reaction  H410: Very toxic to aquatic life with long-lasting effects |
| Precautionary statements | P261: Avoid breathing dust/fumes/gas/mist/vapours/spray  P272: Contaminated work clothing should not be allowed out of the workplace  P273: Avoid release to the environment  P280: Wear protective gloves/protective clothing/eye protection/face protection  P302 + P352: IF ON SKIN: Wash with plenty of water/…  P333 + P313: If skin irritation or a rash occurs: Get medical advice/attention  P321: Specific treatment (see … on this label)  P363: Wash contaminated clothing before reuse.  P391: Collect spillage.  P501: Dispose of content and container to… |
|  | |
| Note | **-** |

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

**4.1. Use description**

Table 1. Use # 1 – **Film - surface application**

|  |  |
| --- | --- |
| **Product Type** | PT18: Insecticides, acaricides and products to control others arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The products of the Termiprotect family are ready-to-use anti-termites physico-chemical barriers used in pre-construction, for protection of buildings. |
| **Target organism (including development stage)** | Subterranean termites: *Reticulitermes spp*.  Workers, soldiers, nymphs |
| **Field of use** | Preventive treatment, during the construction  Outdoor use |
| **Application method(s)** | Before pouring the slab: direct application of the film on the ground or embankment |
| **Application rate(s) and frequency** | Ready-to-use product, containing 1 % permethrin  One application during the construction of the building |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | The rolls of X6232-001 (film size 5 m \* 33 m or 2.5 m \* 33 m), are packed in 120 µm, transparent, LDPE sacks.  The rolls of X6232-001bis (film size 5 m \* 28 m or 2.5 m \* 28 m), are packed in 120 µm, transparent, LDPE sacks. |

## 4.1.1. Use-specific instructions for use

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## 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

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| - |

## 4.1.5. 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

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## *5.1. Instructions for use*

|  |
| --- |
| * To ensure a satisfactory level of efficacy and avoid the development of resistance in susceptible insect populations, the following recommendations have to be implemented: * Always read the label or leaflet before use and respect follow all the instructions provided. * The users should inform if the treatment is ineffective and report straightforward to the registration holder. |

## *5.2. Risk mitigation measures*

|  |
| --- |
| * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during the handling of the product. * Do not apply on surfaces likely to be in direct contact with food, feed or drinks. * During the application step of the film, if the treated zone is connected to a rainwater collection system or sewer, do not expose the film to rain. |

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

|  |
| --- |
| * Skin contact: Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur. * Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs. * Mouth contact: Wash out mouth with water. Contact poison treatment specialist. * Keep the container or label available. |

## 

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

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|  |

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

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

## 6. Other information

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| --- |
| * The results after 24 months of the long term stability study performed on the product X6232-001 should be provided in post authorization within two years. * The authorization holder has to report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management. * Efficacy has only been demonstrated on European subterranean termites (*Reticulitermes* spp.). The product cannot be used in overseas departments. |

# 

# 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)** | **X6232-001**  Xylophène Professionnel Termiprotect Film Anti-Termites  Cultisol Isofilma Anti-Termites | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Permethrin  (technical)  Permethrin  (pur) | 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2- dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52645-53-1 | 258-067-9 | 1.08  1.0 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **X6232-001bis**  SIKA Anti Termites film NEW | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Permethrin  (technical)  Permethrin  (pur) | 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2- dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52645-53-1 | 258-067-9 | 1.08  1.0 |

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

## 1. Meta SPC 2 administrative information

## 1.1. Meta SPC identifier

| **X6232-002** |  |
| --- | --- |

## 1.2. Suffix to the authorisation number

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

## 1.3. Product type(s)

| **Product type(s)** | PT18 |
| --- | --- |

## 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** |
| Permethrin  (technical)  Permethrin  (pur) | 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2- dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52645-53-1 | 258-067-9 | 1.08  1.0 | 1.08  1.0 |

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

| **Formulation** |  |
| --- | --- |
| XX: other (film) |  |

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

| **Classification** | |
| --- | --- |
| Hazard category | Skin Sens 1  Aquatic Acute 1  Aquatic Chronic 1 |
| Hazard statement | H317: May cause an allergic skin reaction  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long-lasting effects |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H317: May cause an allergic skin reaction  H410: Very toxic to aquatic life with long-lasting effects |
| Precautionary statements | P261: Avoid breathing dust/fumes/gas/mist/vapours/spray  P272: Contaminated work clothing should not be allowed out of the workplace  P273: Avoid release to the environment  P280: Wear protective gloves/protective clothing/eye protection/face protection  P302 + P352: IF ON SKIN: Wash with plenty of water/…  P333 + P313: If skin irritation or a rash occurs: Get medical advice/attention.  P321: Specific treatment (see … on this label)  P363: Wash contaminated clothing before reuse.  P501: Dispose of content and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulations |
|  | |
| Note | **-** |

## 

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

**4.1. Use description**

Table 1. Use # 1 – **Perifilm - peripheral application**

|  |  |
| --- | --- |
| **Product Type** | PT18: Insecticides, acaricides and products to control others arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The products of the Termiprotect family are ready-to-use anti-termites physico-chemical barriers used in pre-construction, for protection of buildings. |
| **Target organism (including development stage)** | Subterranean termites: *Reticulitermes spp*.  Workers, soldiers, nymphs |
| **Field of use** | Preventive treatment, during the construction  Outdoor use |
| **Application method(s)** | Before pouring the slab: direct application of the perifilm on the periphery of the future slab (horizontal) and along the foundations (vertical). After pouring the slab: application of the film placed flat on the slab along the outer edges of the construction. |
| **Application rate(s) and frequency** | Ready-to-use product, containing 1 % permethrin  One application during the construction of the building |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | The rolls of X6232-002 (film size 0.5 m \* 100 m), are packed in 120 µm, transparent, LDPE sacks. |

## 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

|  |
| --- |
|  |

## 

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

## *5.1. Instructions for use*

|  |
| --- |
| * To ensure a satisfactory level of efficacy and avoid the development of resistance in susceptible insect populations, the following recommendations have to be implemented: * Always read the label or leaflet before use and respect follow all the instructions provided. * The users should inform if the treatment is ineffective and report straightforward to the registration holder. |

## *5.2. Risk mitigation measures*

|  |
| --- |
| * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during the handling of the product. * Avoid any contamination of food, feed or drinks. * During the application step of the film, if the treated zone is connected to a rainwater collection system or sewer, do not expose the film to rain. |

## 

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

|  |
| --- |
| * Skin contact: Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur. * Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs. * Mouth contact: Wash out mouth with water. Contact poison treatment specialist. * Keep the container or label available. |

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

|  |
| --- |
|  |

## 

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

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

## 6. Other information

|  |
| --- |
| * The results after 24 months of the long term stability study performed on the product X6232-001 and use to X6232-002 should be provided in post authorization within two years. * The authorization holder has to report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management. * Efficacy has only been demonstrated on European subterranean termites (*Reticulitermes spp.*). The product cannot be used in overseas departments. |

# 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)** | **X6232-002**  Xylophène Professionnel Termiprotect Périfilm Anti-Termites | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Permethrin  (technical)  Permethrin  (pur) | 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2- dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52645-53-1 | 258-067-9 | 1.08  1.0 |

# 

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

## 1. Meta SPC 3 administrative information

## 1.1. Meta SPC identifier

| **X6240** |  |
| --- | --- |

## 1.2. Suffix to the authorisation number

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

## 1.3. Product type(s)

| **Product type(s)** | PT18 |
| --- | --- |

## 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** |
| Permethrin  (technical)  Permethrin  (pur) | 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2- dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52645-53-1 | 258-067-9 | 0.11  0.1 | 0.11  0.1 |

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

| **Formulation** |  |
| --- | --- |
| XX: other (film) |  |

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

| **Classification** | |
| --- | --- |
| Hazard category | None |
| Hazard statement | None |
|  | |
| **Labelling** | |
| Signal words | None |
| Hazard statements | None |
| Precautionary statements | None |
|  | |
| Note | EUH 208: Contains Permethrin. May produce an allergic reaction. |

## 

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

**4.1. Use description**

Table 1. Use # 1– **Perifilm - peripheral application**

|  |  |
| --- | --- |
| **Product Type** | PT18: Insecticides, acaricides and products to control others arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The products of the Termiprotect family are ready-to-use anti-termites physico-chemical barriers used in pre-construction, for protection of buildings. |
| **Target organism (including development stage)** | Subterranean termites: *Reticulitermes spp*.  Workers, soldiers, nymphs |
| **Field of use** | Preventive treatment, during the construction  Outdoor use |
| **Application method(s)** | Before pouring the slab: direct application of the perifilm on the periphery of the future slab (horizontal) and along the foundations (vertical). After pouring the slab: application of the film placed flat on the slab along the outer edges of the construction |
| **Application rate(s) and frequency** | Ready-to-use product, containing 0,1 % permethrin  One application during the construction of the building |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | On X6240, the bitumen layer is covered with a protective PE sheet coated with silicone, removed during application. The rolls of X6240 (size 0.1 m \* 20 m or 0.2 m \* 20 m or 0.4 m \* 20 m), are packed in 120 µm, transparent, LDPE sacks. |

## 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

|  |
| --- |
| - |

## 

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

## *5.1. Instructions for use*

|  |
| --- |
| * To ensure a satisfactory level of efficacy and avoid the development of resistance in susceptible insect populations, the following recommendations have to be implemented: * Always read the label or leaflet before use and respect follow all the instructions provided. * The users should inform if the treatment is ineffective and report straightforward to the registration holder. |

## *5.2. Risk mitigation measures*

|  |
| --- |
| * Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during the handling of the product. * Avoid any contamination of food, feed or drinks. * During the application step of the film, if the treated zone is connected to a rainwater collection system or sewer, do not expose the film to rain. |

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

|  |
| --- |
| * Skin contact: Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur. * Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs. * Mouth contact: Wash out mouth with water. Contact poison treatment specialist. * Keep the container or label available. |

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

|  |
| --- |
|  |

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

|  |
| --- |
| * Do not store at temperatures higher than 22°C. * Shelf-life: 6 months. |

## 6. Other information

|  |
| --- |
| * The authorization holder has to report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management. * Efficacy has only been demonstrated on European subterranean termites (*Reticulitermes spp.*). The product cannot be used in overseas departments. |

# 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)** | **X6240**  Xylophène Professionnel Termiprotect Périfilm AD Anti-Termites | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Permethrin  (technical)  Permethrin  (pur) | 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2- dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52645-53-1 | 258-067-9 | 0.11  0.1 |

### Packaging of the biocidal product

The family is composed of 3 Meta-SPCs. The packaging of the different products for the different meta-SPCs is reported below.

Meta-SPC 1:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Product** | **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| X6232-001 | Transparent sack, 120 μm | For 5 m \* 33 m rolls and 2.5 m \* 33 m rolls | LDPE | n.a. | professional | Yes |
| X6232-001bis | Transparent sack, 120 μm | For 5 m \* 28 m rolls  For 2,5 m \* 28 m | LDPE | n.a. | professional | Yes |

Meta-SPC 2:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Product** | **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| X6232-002 | Transparent sack, 120 μm | For 0.5 m \* 100 m rolls | LDPE | n.a. | professional | Yes |

Meta-SPC 3:

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Product** | **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| X6240 | Transparent sack, 120 μm | For 0.1 m \* 20 m rolls, 0.2 \* 20 m rolls and 0.4 m \* 20 m rolls | LDPE | n.a. | professional | Yes |

### Documentation

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

**Identity, physicochemical and analytical method data**

Physico-chemical properties studies and analytical methods on the biocidal products X6232-001, X6232-001bis, X6232-002 and X6240 were provided. See the annex 3.1.

**Efficacy data:**

* ***Laboratory tests:***
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550[[3]](#footnote-3), with the product X6232 (1 % w/w permethrin), without ageing, on termites (*Reticulitermes flavipes)*;
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product X6232 (1 % w/w permethrin), after artificial ageing (leaching) according to the protocol XP ENV 1250-2[[4]](#footnote-4), on termites (*Reticulitermes flavipes)*;
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product X6232 (1 % w/w permethrin), after natural weathering (UV – vertical (3 months) according to the protocol CTBA BIO-E-016[[5]](#footnote-5), on termites (*Reticulitermes flavipes)*;
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product X6232 (1 % w/w permethrin), after natural weathering (UV - horizontal) according to the protocol CTBA BIO-E-016, on termites (*Reticulitermes flavipes)*;
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product X6232 (1 % w/w permethrin), in alkaline condition (alkaline contact) according to the protocol CTBA BIO-E-007[[6]](#footnote-6), on termites (*Reticulitermes flavipes)*;
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product X6232 (1 % w/w permethrin), after ageing (freezing) according to the protocol NF X41-580-3[[7]](#footnote-7), on termites (*Reticulitermes flavipes)*;
* ***Field tests :***
* A field efficacy study, with the product X6232 (1 % w/w permethrin), performed in France (Oleron island), according to the methodology CTBA BIO-E-008[[8]](#footnote-8), with a 4 years exposure to termites (*Reticulitermes santonensis)*;

**Toxicology data, Residues data, Ecotoxicology data**

No study was provided.

#### **Access to documentation**

A letter of access of Limaru/Tagros grants acces to data concerning permethrin technical.

## Assessment of the biocidal product family

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

Table 1. Intended use # 1 – Film - surface application (Meta-SPC 1)

|  |  |
| --- | --- |
| **Product Type** | PT18 – Insecticides |
| **Where relevant, an exact description of the authorised use** | The products of the Termiprotect family are ready-to-use anti-termites physico-chemical barriers used in pre-construction, for protection of buildings.  The film is used for surface application. |
| **Target organism (including development stage)** | Subterranean termites (genus *Reticulitermes, Heterotermes, Rhinotermes* and *Coptotermes*)  Tree termites (genus *Nasutitermes*)  Workers, soldiers and nymphs |
| **Field of use** | Outdoor use |
| **Application method(s)** | Before pouring the slab, direct application of the film on the ground or embankment. |
| **Application rate(s) and frequency** | Once, at the time of construction of the building. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Please see the relevant section (paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file). |



Table 2. Intended use # 2 – Perifilm - peripheral application (Meta-SPCs 2 and 3)

|  |  |
| --- | --- |
| **Product Type** | PT18 – Insecticides |
| **Where relevant, an exact description of the authorised use** | The products of the Termiprotect family are ready-to-use anti-termites physico-chemical barriers used in pre-construction, for protection of buildings.  The perifilms are used for peripheral application. |
| **Target organism (including development stage)** | Subterranean termites (genus *Reticulitermes, Heterotermes, Rhinotermes* and *Coptotermes*)  Tree termites (genus *Nasutitermes*)  Workers, soldiers and nymphs |
| **Field of use** | Outdoor use |
| **Application method(s)** | Before pouring the slab: direct application of the perifilm on the ground, on the periphery of the future slab (horizontal) and along the foundations (vertical).  After pouring the slab: application of the film placed flat on the slab along the outer edges of the construction. |
| **Application rate(s) and frequency** | Once, at the time of construction of the building. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Please see the relevant section (paragraph 2.1.7 of this document and Section 12.3 of the IUCLID file). |

### Physical, chemical and technical properties

The family is composed of 3 Meta-SPCs:

Meta-SPC 1 contains 2 products:

* Xylophène Professionnel Termiprotect Film Anti-Termites (other commercial name Cultisol Isofilma Anti-Termites), product code **X6232-001**.
* SIKA Anti Termites film NEW, product code **X6232-001bis**.

Meta-SPC 2 contains 1 product:

* Xylophène Professionnel Termiprotect Périfilm Anti-Termites, product code **X6232-002**.

Meta-SPC 3 contains 1 product:

* Xylophène Professionnel Termiprotect Périfilm AD Anti-Termites, product code **X6240**.

The different products are LDPE 3 layers films. The compositions of the 4 formulations are very similar:

* a lower 37.5 µm black layer, containing the active substance permethrin,
* an intermediate 75 µm uncoloured layer, also containing the active substance
* an upper 37.5 µm coloured layer (blue/red/yellow depending on the product), without active substance.

These 3 layers make up a physico-chemical barrier of 150 µm. For the Meta-SPC 3, the lower layer is also coated with a self-adhesive bitumen coating (refer to section 3.6 for composition).

Pure and technical content of the active substance permethrin in the different products in % and in g/m2 have been reported in the table below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product** | **Pure content of active substance (%)** | **Technical content of active substance (%)** | **Pure content of active substance (g/m2)** | **Technical content of active substance (g/m2)** |
| X6232-001, X6232-001bis and X6232-002 | 1 | 1.08 | 1.39 | 1.50 |
| X6240 | 0.1 | 0.11 | 1.53 | 1.68 |

The contents of active substance in g/m2 have been calculated taking into account the density of the products provided in the physico-chemical properties (139g/m2 for products X6232-001, X6232-001bis and X6232-002 and 1529g/m2 for product X6240).

The physical, chemical and technical properties of each formulation are detailed in the tables below.

Some tests have been performed with the product X6232 which is not part of the BPF. Its composition is detailed is the confidential annex. The only difference between product X6232 with the products X6232-001, X6232-001bis and X6232-002 is the colour of the upper layer.

Table 2.2.2/01. Physical, chemical and technical properties - Meta-SPC 1 – Products X6232-001 and X6232-001bis

| **Property** | **Guideline and Method** | **Purity of the test substance**  **(% w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20°C and 101.3 kPa | Visual observation |  | The test item X6232-001 is a PE film with one side black and one side blue and has a faint odour. | Material data sheet of CULTISOL ISOFILMA FILM ANTI-TERMITES & XYLOPHENE PROFESSIONNEL TERMIPROTECT FILM ANTI-TERMITES |
| Colour at 20°C and 101.3 kPa |
| Odour at 20°C and 101.3 kPa | The test item X6232-001bis is a PE film with one side black and one side yellow and has a faint odour. | Material data sheet of SIKA ANTI TERMITES FILM NEW |
| Acidity / alkalinity |  |  | Not required |  |
| Relative density / bulk density | EN 1848-2 |  | The surface mass of the PE film of X6232-001 is 139 g/m².  The products X6232-001 and X6232-001bis have very close compositions, as only the dye agents are different between the two products. Then the surface mass of the PE film of X6232-001bis is expected to be 139 g/m². | Fiche technique du produit TERMIPROTECT® Film Anti-Termites |
| Storage stability test – **accelerated storage** | NF X 41-580-1: 2008 (accelerated testing, 8 weeks at 40 ± 3°C)  **Method for measure of permethrin validated in section 2.2.4** | Product X6232  Batch number: 270312  Containing 0.95% w/w of permethrin (1.32 g/m²) | The products X6232 and X6232-001 (and X6232-001bis) have very close compositions. It was demonstrated that accelerated storage stability can be extrapolated from studies obtained with X6232.   |  |  |  | | --- | --- | --- | | Test | At initial time | After 8 weeks at 40±3°C in glass flask | | Appearance of the test item | PE film with one side black and one side brown | PE film with one side black and one side brown | | Permethrin content | 0.95% w/w  1.32 g/m² | 0.95% w/w  1.32 g/m² |   Stable 2 years pending the results of the long term storage stability study.  The following management measure should be added: Do not store at temperatures higher than 40°C. | FCBA Report No. 402/12/033F/abc-e |
| Storage stability test – **long term storage at ambient temperature** | Technical Monograph No.17, 2nd edition, CropLife International | Product X6232-001  Batch number: 4515376252  Containing 1.00% w/w of permethrin (1.39 g/m²) | The long term storage study at ambient temperature with the product X6232-001 in its commercial packaging (roll packaged in LDPE transparent sack) is still on-going, started on 2016/04/25.  Intermediate results at 6 and 12 months have been provided:   |  |  |  |  | | --- | --- | --- | --- | | Test | T0 | T6months | T12months | | Appearance of the test item | Smooth and gloss film with a black face and a blue face | Smooth and gloss film with a black face and a blue face | Film smooth and gloss with a black face and a blue face | | Packaging | - | No potential signs of degradation | | | Weight changes | - | Loss: -0.008% w/w | Gain: 0.06% | | Permethrin content | 0.97% w/w  1.33 g/m²  Ratio cis/trans: 25.8/74.2% | 0.93% w/w  1.29 g/m²  Ratio cis/trans: 26.1%/73.9% | 0.94 % w/w  1.28 g/m²  Ratio cis/trans: 26.2%/73.8% |   Results are acceptable after 6 and 12 months (< -4.1% variation of active substance content and the ratio is constant).  The results after 24 months of storage at 20 ± 2°C, related to the appearance of the test item X6232-001, the aspect and weight of the commercial packaging (roll packaged in LDPE transparent sack) and analytical quantification of the active substance should be provided in post-authorization.  As the products X6232-001 and X6232-001bis have very close compositions, the long term storage stability of the product X6232-001bis can be extrapolated from studies obtained with X6232-001. | Study plan No. 15/1169F/c  Certificate of analysis COA-402/15/1169F/ab-e  Certificate of analysis COA-402/15/1169F/1/c/T6M-e  Certificate of analysis COA-402/15/1169F/1/c/T12M-e |
| Storage stability test – **low temperature stability test for liquids** |  |  | Not required |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | XPX 41-550 (June 2009) | Product X6232  Batch number: 270312  Containing 0.95% w/w of permethrin | The packaging of X6232-001 and X6232-001bis (roll packaged in LDPE transparent sack) is transparent to the light; nevertheless the active substance permethrin is not known to be sensible to light effect. According to Assessment Report permethrin Product-type 18 (April 2014), permethrin does not absorb > 290 nm, which indicates that the molecule is not susceptible to breakdown by light.  As the product is conditioned in the form of a roll, only the circumference can be exposed to light. Furthermore the product contains an UV-protective film and the layer, which contains the active substance, is within the product.  Taking to account all these precisions, it is expected that the light has no effect on the product and its active substance content.  It is unclear whether the UV-protective film refers to a supplementary barrier or an additive added to prevent the degradation of the film. However, as the active substance permethrin is not light sensitive, no further data is required.  Moreover in order to confirm that the light has no influence on the stability of both products, two efficacy studies after exposure of the product X6232 to the sunlight, respectively 15 days and 3 months according to XPX 41-550 (June 2009), are presented. After exposure to sunlight during 15 days and 3 months, the film has not been crossed by the termites. These results confirm the stability of the product to light exposure, as the product efficacy is not affected by the sunlight exposure.  As the products X6232 and X6232-001 (and X6232-001bis) have very close compositions, it was demonstrated that stability at light can be extrapolated from studies obtained with X6232. | FCBA report No. 401/12/033F/1/h (15 days)  FCBA report No. 401/12/033F/1/i (3 months) |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | The test items X6232-001 and X6232-001bis were considered to be stable after 8 weeks at 40 ± 3°C.  The individual commercial packaging (roll packaged in LDPE transparent sack) is sealed. With this closure system, the packaging is leak-tight. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | See the storage stability tests: no change in appearance and permethrin content when stored in glass flask  The long term storage study at ambient temperature with the product X6232-001 in its commercial packaging (roll packaged in LDPE transparent sack) is still on-going. |  |
| Wettability |  |  | Not required |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not required |  |
| Wet sieve analysis and dry sieve test |  |  | Not required |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not required |  |
| Disintegration time |  |  | Not required |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not required |  |
| Persistent foaming |  |  | Not required |  |
| Flowability/Pourability/Dustability |  |  | Not required |  |
| Burning rate — smoke generators |  |  | Not required |  |
| Burning completeness — smoke generators |  |  | Not required |  |
| Composition of smoke — smoke generators |  |  | Not required |  |
| Spraying pattern — aerosols |  |  | Not required |  |
| Physical compatibility |  |  | Not applicable. X6232-001 and X6232-001bis are ready-to-use products and are not intended to be used in conjunction with any other products or active substances. |  |
| Chemical compatibility |  |  | Not applicable. X6232-001 and X6232-001bis are ready-to-use products and are not intended to be used in conjunction with any other products or active substances. |  |
| Degree of dissolution and dilution stability |  |  | Not required |  |
| Surface tension |  |  | Not required |  |
| Viscosity |  |  | Not required |  |

Table 2.2.2/02. Physical, chemical and technical properties - Meta-SPC 2 – Product X6232-002

| **Property** | **Guideline and Method** | **Purity of the test substance**  **(% w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20°C and 101.3 kPa | Visual observation |  | The test item X6232-002 is a PE film with one side black and one side red and has a faint odour. | Material data sheet of XYLOPHENE PROFESSIONNEL TERMIPROTECT PERIFILM ANTI-TERMITES |
| Colour at 20°C and 101.3 kPa |
| Odour at 20°C and 101.3 kPa |
| Acidity / alkalinity |  |  | Not required |  |
| Relative density / bulk density | EN 1848-2 |  | The surface mass of the PE film of X6232-002 is 139 g/m². | Product technical sheet TERMIPROTECT Périfilm AD Anti-Termites |
| Storage stability test – **accelerated storage** | NF X 41-580-1: 2008 (accelerated testing, 8 weeks at 40 ± 3°C)  **Method for measure of permethrin validated in section 2.2.4** | Product X6232  Batch number: 27 03 12  Containing 0.95% w/w of permethrin (1.32 g/m²) | The products X6232 and X6232-002 have very close compositions. It was demonstrated that accelerated storage stability can be extrapolated from studies obtained with X6232.   |  |  |  | | --- | --- | --- | | Test | At initial time | After 8 weeks at 40±3°C in glass flask | | Appearance of the test item | PE film with one side black and one side brown | PE film with one side black and one side brown | | Permethrin content | 0.95% w/w  1.32 g/m² | 0.95% w/w  1.32 g/m² |   Stable 2 years pending the results of the long term storage stability study.  The following management measure should be added: Do not store at temperatures higher than 40°C. | FCBA Report No. 402/12/033F/abc-e |
| Storage stability test – **long term storage at ambient temperature** | Technical Monograph No.17, 2nd edition, CropLife International | Product X6232-001  Batch number: 4515376252  Containing 1.00% w/w of permethrin (1.39 g/m²) | The products X6232-001 and X6232-002 have very close compositions. It was demonstrated that long term storage stability can be extrapolated from studies obtained with X6232-001.  The long term storage study at ambient temperature with the product X6232-001 in its commercial packaging (roll packaged in LDPE transparent sack) is still on-going, started on 2016/04/25.  Intermediate results at 6 and 12 months have been provided:   |  |  |  |  | | --- | --- | --- | --- | | Test | T0 | T6 months | T12 months | | Appearance of the test item | Smooth and gloss film with a black face and a blue face | Smooth and gloss film with a black face and a blue face | Film smooth and gloss with a black face and a blue face | | Packaging | - | No potential signs of degradation | | | Weight changes | - | Loss: -0.008% w/w | Gain: 0.06% | | Permethrin content | 0.97% w/w  1.33 g/m²  Ratio cis/trans: 25.8/74.2% | 0.93% w/w  1.29 g/m²  Ratio cis/trans: 26.1%/73.9% | 0.94% w/w  1.28 g/m²  Ratio cis/trans: 26.2%/73.8% |   Results are acceptable after 6 and 12 months (< -4.1% variation of active substance content and the ratio is constant).  The results after 24 months and intermediate results of storage at 20 ± 2°C, related to the appearance of the test item X6232-001, the aspect and weight of the commercial packaging (roll packaged in LDPE transparent sack) and analytical quantification of the active substance should be provided in post-authorization. | Study plan No. 15/1169F/c  Certificate of analysis COA-402/15/1169F/ab-e  Certificate of analysis COA-402/15/1169F/1/c/T6M-e  Certificate of analysis COA-402/15/1169F/1/c/T12M-e |
| Storage stability test – **low temperature stability test for liquids** |  |  | Not required |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | XPX 41-550 (June 2009) | Product X6232  Batch number: 27 03 12  Containing 0.95% w/w of permethrin (1.32 g/m²) | The packaging of X6232-002 (roll packaged in LDPE transparent sack) is transparent to the light; nevertheless the active substance permethrin is not known to be sensible to light effect. According to Assessment Report permethrin Product-type 18 (April 2014), permethrin does not absorb > 290 nm, which indicates that the molecule is not susceptible to breakdown by light.  As the product is conditioned in the form of a roll, only the circumference can be exposed to light. Furthermore the product contains an UV-protective film and the layer, which contains the active substance, is within the product.  Taking to account all these precisions, it is expected that the light has no effect on the product and its active substance content.  It is unclear whether the UV-protective film refers to a supplementary barrier or an additive added to prevent the degradation of the film. However, as the active substance permethrin is not light sensitive, no further data is required.  Moreover, in order to confirm that the light has no influence on the stability of product X6232-002, two efficacy studies after exposure of the product X6232 to the sunlight, respectively 15 days and 3 months according to XPX 41-550 (June 2009), are presented.  After exposure to sunlight during 15 days and 3 months, the barrier of the product has not been crossed by the termites. These results confirm the stability of the product to light exposure, as the product efficacy is not affected by the sunlight exposure.  As the products X6232 and X6232-002 have very close compositions. It was demonstrated that stability at light can be extrapolated from studies obtained with X6232. | FCBA report No 401/12/033F/1/h (15 days)  FCBA report No 401/12/033F/1/i (3 months) |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | The test item X6232-002 was considered to be stable after 8 weeks at 40 ± 3°C.  The individual commercial packaging (roll packaged in LDPE transparent sack) is sealed. With this closure system, the packaging is leak-tight. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | See the storage stability tests: : no change in appearance and permethrin content when stored in glass flask  The long term storage study at ambient temperature with the product X6232-001 in its commercial packaging (roll packaged in LDPE transparent sack) is still on-going. |  |
| Wettability |  |  | Not required |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not required |  |
| Wet sieve analysis and dry sieve test |  |  | Not required |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not required |  |
| Disintegration time |  |  | Not required |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not required |  |
| Persistent foaming |  |  | Not required |  |
| Flowability/Pourability/Dustability |  |  | Not required |  |
| Burning rate — smoke generators |  |  | Not required |  |
| Burning completeness — smoke generators |  |  | Not required |  |
| Composition of smoke — smoke generators |  |  | Not required |  |
| Spraying pattern — aerosols |  |  | Not required |  |
| Physical compatibility |  |  | Not applicable. X6232-002 is a ready-to-use product and is not intended to be used in conjunction with any other products or active substances. |  |
| Chemical compatibility |  |  | Not applicable. X6232-002 is a ready-to-use product and is not intended to be used in conjunction with any other products or active substances. |  |
| Degree of dissolution and dilution stability |  |  | Not required |  |
| Surface tension |  |  | Not required |  |
| Viscosity |  |  | Not required |  |

Table 2.2.2/03. Physical, chemical and technical properties - Meta-SPC 3 – Product X6240

| **Property** | **Guideline and Method** | **Purity of the test substance**  **(% w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20°C and 101.3 kPa | Visual observation |  | The test item X6240 is a PE film with one side red and one side black and is odourless. | Material data sheet of Xylophène Professionnel Termiprotect Perifilm AD Anti-Termites |
| Colour at 20°C and 101.3 kPa |
| Odour at 20°C and 101.3 kPa |
| Acidity / alkalinity |  |  | Not required |  |
| Relative density / bulk density | EN 1848-2 | Product X6240  Batch number: G0058/07515  Containing 0.1% w/w of permethrin (1.59 g/m²) | The surface mass of the PE film of X6240 is 1529 g/m². | FCBA report No. 402/16/1014F/ab-e |
| Storage stability test – **accelerated storage** |  |  | As the product X6240 is a ready-to-use solid PE film with a bituminous layer, the product must be protect from high temperature to avoid the melting of the bituminous layer. As no accelerated storage test has been provided on the product, the following management measure has to be added: do not store at temperatures higher than 22°C. |  |
| Storage stability test – **long term storage at ambient temperature** | Technical Monograph No.17, 2nd edition, CropLife International  1 year at 20°C  Analytical method FCBA Chimie No.324-e version 3 | Product X6240  Batch number: G0058/07515  Containing 0.1% w/w of permethrin (1.59 g/m²)  Packaging: plastic film in LDPE | The long term storage study at ambient temperature (20± 2°C) during 1 year with the product X6240 in its commercial packaging (film in LDPE) has been provided.  Intermediate results at 6 months and final results at 12 months have been provided:   |  |  |  |  | | --- | --- | --- | --- | | Test | T0 | T6months | T12months | | Appearance of the test item | Film with bituminous layer:  Film: Red face smooth and gloss Bituminous layer: black face, smooth and gloss | Film with bituminous layer:  Film: Red face, smooth and gloss, Bituminous layer: black face, sticky, soft and gloss | | | Packaging | No signs of degradation (no signs of discoloration or deformation) | | | | Weight changes | - | Loss: -0.1% w/w | Gain: 0.08% w/w | | Permethrin content | 0.098% w/w  1.55 g/m²  Ratio cis/trans: 26.1/73.9% | 0.095% w/w  1.42 g/m²  Ratio cis/trans: 24.7%/75.3% | 0.085% w/w  1.25 g/m²  Ratio cis/trans: 25.5%/74.5% |   Results are acceptable after 6 months (-3.1% variation of active substance content and the ratio is constant). However the result after 1 year is not acceptable (-13.3%).  Therefore only a shelf-life of 6 months at 20°C± 2°C is accepted. | FCBA report No. 402/16/1014F/ab-e  FCBA report No. 402/16/1014F/c-e |
| Storage stability test – **low temperature stability test for liquids** |  |  | Not required |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | XPX 41-550 (June 2009) | Product X6232  Batch number: 27 03 12  Containing 0.95% w/w of permethrin (1.32 g/m²) | The packaging of X6240 (roll packaged in LDPE transparent sack) is transparent to the light; nevertheless the active substance permethrin is not known to be sensible to light effect. According to Assessment Report permethrin Product-type 18 (April 2014), permethrin does not absorb > 290 nm, which indicates that the molecule is not susceptible to breakdown by light.  As the product is conditioned in the form of a roll, only the circumference can be exposed to light. Furthermore the product contains an UV-protective film and the layer, which contains the active substance, is within the product.  Taking to account all these precisions, it is expected that the light has no effect on the product and its active substance content.  It is unclear whether the UV-protective film refers to a supplementary barrier or an additive added to prevent the degradation of the film. However, as the active substance permethrin is not light sensitive, no further data is required.  Moreover in order to confirm that the light has no influence on the stability of product X6240, two efficacy studies after exposure of the product to the sunlight, respectively 15 days and 3 months according to XPX 41-550 (June 2009), are presented.  After exposure to sunlight during 15 days and 3 months, the barrier of the product X6232 has not been crossed by the termites. These results confirm the stability of the product to light exposure, as the product efficacy is not affected by the sunlight exposure.  The products X6232 and X6240 have very close compositions. It was demonstrated that stability at light can be extrapolated from studies obtained with X6232. | FCBA report No 401/12/033F/1/h (15 days)  FCBA report No 401/12/033F/1/i (3 months) |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  |  | As the product X6240 is a ready-to-use solid PE film with a bituminous layer, the product must be protect from high temperature to avoid the melting of the bituminous layer. As no accelerated storage test has been provided on the product, the following management measure has to be added: do not store at temperatures higher than 22°C.  The individual commercial packaging (roll packaged in LDPE transparent sack) is sealed. With this closure system, the packaging is leak-tight. |  |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  |  | The long term storage study at ambient temperature with the product X6240 in its commercial packaging (roll packaged in LDPE transparent sack) is provided. See results reported above. |  |
| Wettability |  |  | Not required |  |
| Suspensibility, spontaneity and dispersion stability |  |  | Not required |  |
| Wet sieve analysis and dry sieve test |  |  | Not required |  |
| Emulsifiability, re-emulsifiability and emulsion stability |  |  | Not required |  |
| Disintegration time |  |  | Not required |  |
| Particle size distribution, content of dust/fines, attrition, friability |  |  | Not required |  |
| Persistent foaming |  |  | Not required |  |
| Flowability/Pourability/Dustability |  |  | Not required |  |
| Burning rate — smoke generators |  |  | Not required |  |
| Burning completeness — smoke generators |  |  | Not required |  |
| Composition of smoke — smoke generators |  |  | Not required |  |
| Spraying pattern — aerosols |  |  | Not required |  |
| Physical compatibility |  |  | Not applicable. X6240 is a ready-to-use product and is not intended to be used in conjunction with any other products or active substances. |  |
| Chemical compatibility |  |  | Not applicable. X6240 is a ready-to-use product and is not intended to be used in conjunction with any other products or active substances. |  |
| Degree of dissolution and dilution stability |  |  | Not required |  |
| Surface tension |  |  | Not required |  |
| Viscosity |  |  | Not required |  |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| **Meta-SPC 1:**  The two products are PE films with :   * For the product X6232-001, one side black and one side blue with a faint odour. * For the product X6232-001bis, one side black and one side yellow with a faint odour.   It was demonstrated that physico-chemical properties of this Meta-SPC can be extrapolated from studies performed with X6232.  The product X6232 is considered to be stable to light exposure. After exposure to sunlight during 15 days and 3 months, the barrier of the product X6232 is not expected to be crossed by the termites. These results confirm the stability of the biocidal products to light exposure, as the product efficacy is not affected by the sunlight exposure.  There is no effect of high temperature on the stability of the product X6232, since after 8 weeks at 40 °C, neither the active ingredient content nor the aspect of the product were changed. Thus, the products X6232-001 and X6232-001bis are considered to be stable after accelerated storage at 40°C. The following management measure should be added: Do not store at temperatures higher than 40°C.  For the products X6232-001 and X6232-001bis, a shelf-life of 24 months is accepted. The results after 24 months of the long term storage stability study performed on the product X6232-001 should be provided in post-authorization.  **Meta-SPC 2:**  The product X6232-002 is PE film with one side black and one side red with a faint odour  It was demonstrated that physico-chemical properties of this product family can be extrapolated from studies performed with X6232.  The product X6232 is considered to be stable to light exposure. After exposure to sunlight during 15 days and 3 months, the barrier of the product X6232 is not expected to be crossed by the termites. These results confirm the stability of the biocidal products to light exposure, as the product efficacy is not affected by the sunlight exposure.  There is no effect of high temperature on the stability of the product X6232, since after 8 weeks at 40 °C, neither the active ingredient content nor the aspect of the product were changed. Thus, the product X6232-002 is considered to be stable after accelerated storage at 40°C. The following management measure should be added: Do not store at temperatures higher than 40°C.  For the product X6232-002 a shelf-life of 24 months is accepted under condition the results after 24 months of the long term storage stability study performed on the product X6232-001 should be provided in post-authorization.  **Meta-SPC 3:**  The product X6240 is PE film with one side red and one side black and odourless  It was demonstrated that physico-chemical properties of this product family can be extrapolated from studies performed with X6232. The product X6232 is considered to be stable to light exposure. After exposure to sunlight during 15 days and 3 months, the barrier of the product X6232 is not expected to be crossed by the termites. These results confirm the stability of the biocidal products to light exposure, as the product efficacy is not affected by the sunlight exposure.  The product X6240 must be protected from high temperatures because of the presence of a bituminous layer. As no accelerated storage test has been provided on the product, the following management measure has to be added: do not store at temperatures higher than 22°C.  For the product X6240, based on the data provided on the long term storage stability study, a shelf life of 6 months is accepted. |

### Physical hazards and respective characteristics

Table 2.2.3/01. Physical hazards and respective characteristics - Meta-SPC 1 and Meta-SPC 2

| **Property** | **Guideline and Method** | **Purity of the test substance (% w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | The product is not explosive. Test is not required as the product is a polymer matrix formulated as a film and containing minimum 90% w/w polyethylene which is not classified as explosive. Furthermore, the active substance permethrin and the others components of the product are not also classified as explosive. | | | |
| Flammable gases | Not required | | | |
| Flammable aerosols | Not required | | | |
| Oxidising gases | Not required | | | |
| Gases under pressure | Not required | | | |
| Flammable liquids | Not required | | | |
| Flammable solids | The product is not flammable. Test is not required as the product is a polymer matrix formulated as a film and containing minimum 90% w/w polyethylene which is not classified as flammable. Furthermore, the active substance permethrin and the others components of the product are not also classified as flammable. | | | |
| Self-reactive substances and mixtures | The product is not a self-reactive mixture. Test is not required as the product is a polymer matrix formulated as a film and containing minimum 90% w/w polyethylene which is not classified as self-reactive substance. Furthermore, the active substance permethrin and the others components of the product are not also classified as self-reactive substances. | | | |
| Pyrophoric liquids | Not required | | | |
| Pyrophoric solids | The product is not a pyrophoric solid. Test is not required as experience in manufacture and handling shows that the product does not ignite spontaneously on coming into contact with air at normal temperature. | | | |
| Self-heating substances and mixtures | The product is not a self-heating mixture. Test is not required as the product is a polymer matrix formulated as a film and containing minimum 90% w/w polyethylene which is not classified as self-heating substance. Furthermore, the active substance permethrin and the others components of the product are not also classified as self-heating substances. | | | |
| Substances and mixtures which in contact with water emit flammable gases | The product does not emit flammable gases when in contact with water. Test is not required as the product is a polymer matrix formulated as a film and containing minimum 90% w/w polyethylene which does not emit flammable gases in contact with water. Furthermore, the active substance permethrin and the others components of the product do not also emit flammable gases in contact with water. | | | |
| Oxidising liquids | Not required | | | |
| Oxidising solids | The product is not oxidising. Test is not required as the product is a polymer matrix formulated as a film and containing minimum 90% w/w polyethylene which is not classified as oxidising substance. Furthermore, the active substance permethrin and the others components of the product are not also classified as oxidising substances. | | | |
| Organic peroxides | Not required | | | |
| Corrosive to metals | The product is not corrosive to metal. Test is not required as the product is a polymer matrix formulated as a film and containing minimum 90% w/w polyethylene which is not classified as corrosive to metals. Furthermore, the active substance permethrin and the others components of the product are not also classified as corrosive to metals. | | | |
| Auto-ignition temperatures of products (liquids and gases) | Not required | | | |
| Relative self-ignition temperature for solids | The product is not expected to present a significant hazard for self-ignition. Test is not required as the product is a polymer matrix formulated as a film and containing minimum 90% w/w polyethylene which does not easily ignite (auto-ignition temperature > 300°C according to safety data sheet). | | | |
| Dust explosion hazard | Not required | | | |

Table 2.2.3/02. Physical hazards and respective characteristics - Meta-SPC 3

| **Property** | **Guideline and Method** | **Purity of the test substance (% w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | The product X6240 is not explosive. Test is not required as the product X6240 is formulated as a polyethylene film with a bituminous waterproofing membrane and as this main component (minimum 91% w/w) is not classified as explosive. | | | |
| Flammable gases | Not required | | | |
| Flammable aerosols | Not required | | | |
| Oxidising gases | Not required | | | |
| Gases under pressure | Not required | | | |
| Flammable liquids | Not required | | | |
| Flammable solids | The product X6240 is not flammable. Test is not required as the product X6240 is formulated as a polyethylene film with a bituminous waterproofing membrane and as this main component (minimum 91% w/w) is not classified as flammable. | | | |
| Self-reactive substances and mixtures | The product X6240 is not a self-reactive mixture. Test is not required as the product X6240 is formulated as a polyethylene film with a bituminous waterproofing membrane and as this main component (minimum 91% w/w) is not classified as self-reactive substance. | | | |
| Pyrophoric liquids | Not required | | | |
| Pyrophoric solids | The product X6240 is not a pyrophoric solid. Test is not required as experience in manufacture and handling shows that the product X6240 does not ignite spontaneously on coming into contact with air at normal temperature. | | | |
| Self-heating substances and mixtures | The product X6240 is not a self-heating mixture. Test is not required as the product X6240 is formulated as a polyethylene film with a bituminous waterproofing membrane and as this main component (minimum 91% w/w) is not classified as self-heating substance. | | | |
| Substances and mixtures which in contact with water emit flammable gases | The product X6240 does not emit flammable gases when in contact with water. Test is not required as the product X6240 is formulated as a polyethylene film with a bituminous waterproofing membrane and as this main component (minimum 91% w/w) does not emit flammable gases in contact with water. | | | |
| Oxidising liquids | Not required | | | |
| Oxidising solids | The product X6240 is not oxidising. Test is not required as the product X6240 is formulated as a polyethylene film with a bituminous waterproofing membrane and as this main component (minimum 91% w/w) is not classified as oxidising substance. | | | |
| Organic peroxides | Not required | | | |
| Corrosive to metals | The product X6240 is not corrosive to metal. Test is not required as the product X6240 is formulated as a polyethylene film with a bituminous waterproofing membrane and as this main component (minimum 91% w/w) is not classified as corrosive to metals. | | | |
| Auto-ignition temperatures of products (liquids and gases) | Not required | | | |
| Relative self-ignition temperature for solids | The product X6240 is not expected to present a significant hazard for self-ignition. Test is not required as the product X6240 is formulated as a polyethylene film with a bituminous waterproofing membrane and as this main component (minimum 91% w/w) does not easily ignite (auto-ignition temperature > 300°C according to safety data sheet). | | | |
| Dust explosion hazard | Not required | | | |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| Due to their formulation as a polymer matrix containing minimum 90% w/w polyethylene, the products of Meta-SPCs 1 and 2 have no explosive properties, flammability, self-reactivity, oxidising properties and auto-flammability.  Due to its formulation as a polyethylene film (equivalent to the X6232-002 product) with a bituminous waterproofing membrane as main component (minimum 91% w/w), the products of Meta-SPC 3 have no explosive properties, flammability, self-reactivity, oxidising properties and auto-flammability. |

### Methods for detection and identification

An analytical method for the determination of permethrin content in the test item X6232 was validated during the GLP study No.402/12/033F/abc-e.

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| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | | |
| **Analyte** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Precision** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Permethrin* (permethrin I and II) | Permethrin is analysed after extraction from samples of the formulation by ASE (Accelerated Solvent Extraction) with acetone and quantified by Liquid Chromatography using a reverse phase column and a UV detector (210 nm).  Quantification was performed using external standard calibration. | Accuracy was obtained by spiking 2 \* 6 times the matrix with 20 mg/mL permethrin. | Calibration range: 16.0 to 24.0 mg/L of permethrin  (n=5, 80-120% range)  r = 0.9998  r² = 0.9997 | Retention time for permethrin peaks (permethrin I and II) matches between reference item, formulation blank spiked with reference item and test item, confirming the identity of the analyte.  No interference was observed in formulation blank at the retention time of permethrin. | 81.05 - 100.30 | 94.85  (n=12)  The mean recovery result is slightly lower than the Guidelines requirements for formulations containing between 1% and 10% of an active substance (97 - 103%). | 5.65  (n=12)  for blank formulation spiked with reference item | RSD = 1.89%  < modified Horwitz 2.68%  Mean average content = 0.95% w/w (n=6) | Not relevant | GLP study No. 402/12/033F/ abc-e |

Permethrin I refers to Trans-permethrin and Permerthrin II refers to Cis-permethrin.

Specificity of the method for the products X6232-001, X6232-001bis and X6232-002 has been provided in the study No.402/15/1169F/ab-e with the analysis of the balls with the different dyes used in the products:

LDPE balls with blue dye (for product X6232-001) and LDPE balls with yellow dye (for product X6232-001bis) have been analysed to check the specificity. Then LDPE balls with red dye (for product X6232-002) has been analysed to check the specificity.

The three matrices have been extracted with solvent. Chromatograms have been provided and no interference more than 3% was observed at the retention times of the active substance permethrin.

Validation data of the method have been provided for the product X6240 study No.402/16/1014F/ab-e:

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| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | | |
| **Analyte** | **Analytical method** | **Specificity** | **Linearity** | **Fortification range / Number of measurements** | **Recovery rate (%)** | | | **Precision** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *Permethrin* (permethrin I and II) | Permethrin is analysed after freezing the sample in order to separate bituminous coating and PE film and extraction from samples of the formulation by ASE (Accelerated Solvent Extraction) with acetone  Quantification with Liquid Chromatography using a reverse phase column and a UV detector (210 nm).  Quantification was performed using external standard calibration. | Retention time for permethrin peaks (permethrin I and II) matches between reference item, formulation blank spiked with reference item and test item, confirming the identity of the analyte.  No interference was observed in blank solvent and blank extraction. No interference more than 3% after extraction of matrix at the retention time of permethrin | Calibration range: 16.0 to 24.0 mg/L of permethrin  (n=5, 80-120% range)  r = 0.9998  r² = 0.9995 | Accuracy was obtained by spiking 1 \* 6 matrix samples with 20 mg/mL permethrin. | 98.3 – 103.1 | 100.6  (n=6) | 1.61%  (n=6)  for blank formulation spiked with reference item | RSD = 1.61% | Not relevant | GLP study No.402/16/1014F/ab-e |

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| **Analytical methods for monitoring** |
| Analytical method for permethrin residues in soil, air and water are available in Assessment Report permethrin Product-type 18 (April 2014). Please, refer to Letter of Access from Tagros. |

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| **Analytical methods for soil** |
| A validated method using HPLC/MS/MS was supplied in the CAR of the active substance for analysis of residues of permethrin with a LOQ = 5.0 μg/kg in soil.  Soil samples were extracted in a microwave extractor with a mixture of acetonitrile/water and ammonium formate. The sample was cleaned up by centrifugation. Identification and quantification of the test item was done using HPLC MS/MS detection in the Multiple Reaction Monitoring mode.  The method was validated using a slit loam soil (Höfchen) and a sandy loam soil (Laacher Hof). |

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| **Analytical methods for air** |
| A validated method using HPLC/MS/MS was supplied in the CAR of the active substance for analysis of residues of permethrin in air with a LOQ = 5 μg/m3 air.  Air is sucked through XAD adsorption tubes at about 1.5 L/min for 6 hours (total air sampling volume about 0.5 m3). Subsequently, the adsorption material is extracted with acetone. The extract is diluted with methanol/water (1/2 v/v) and analysed by HPLC/MS/MS, monitoring two parent-daughter ion transitions.  Another validated method using GC/ECD was supplied in the CAR of the active substance for analysis of residues in air with a LOQ = 0.0001 mg/m3 air.  Air is sucked through adsorption tubes at about 1.8 L/min for 6 hours at 35°C. Subsequently, the adsorption material is extracted with acetone. The extract was analysed for permethrin using GC/ECD. GC-MS/MS was used as a confirmatory method (three ions with an m/z > 100). |

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| **Analytical methods for water** |
| A validated method using HPLC/MS/MS was supplied in the CAR of the active substance for analysis of residues of permethrin with a LOQ = 0.05 µg/L for drinking and surface water.  Acidified water samples are diluted with acetonitrile and analysed by HPLC-MS/MS using positive ionisation mode without further clean-up. Concentrations were quantified using external matrix-matched standard solutions. |

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| **Analytical methods for animal and human body fluids and tissues** |
| As the active substance permethrin is not classified Toxic or Very Toxic, an analytical method for the determination of permethrin residue in human body fluids and tissues is unnecessary. |

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| **Analytical methods for monitoring of active substances and residues in food and feeding stuff** |
| As the products (Meta-SPCs 1, 2 and 3) are not intended to be used with surface in contact with food/feed of plant and animal origin, analytical method for the determination of permethrin residue in food/feed of plant and animal origin is unnecessary. |

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| **Conclusion on the methods for detection and identification of the product** |
| A chiral method of analysis using HPLC-UV for the active substance in the formulation X6232 was provided and fully validated. Specificity of the method has been demonstrated for the products X6232-001, X6232-001bis, X6232-002. Moreover complete validation data which are acceptable have been provided for the product X6240.  Since the proposal is for non-crop use then analytical methods for residues in food of plant and animal origin are not required.  Acceptable validated methods were provided in Assessment Report permethrin Product-type 18 (April 2014) for residues of permethrin in soil, water and in air. |

### Efficacy against target organisms

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

MG 03: Pest control

Product Type 18: Insecticides, acaricides and products to control other arthropods.

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

The products of the TERMIPROTECT family are ready-to-use anti-termites physico-chemical barriers (polyethylene films containing permethrin) used in pre-construction, for protection of buildings against the infestation of subterranean termites in metropolitan France. The products are applied by professional users only. The lower black layer containing the active substance is laid down on the ground or embankment, or around the possible pipe crossing.

Depending on the situation, different products of the TERMIPROTECT family are used, with different modes of application.

* In META-SPC 1, the products are applied in **surface application.** The film is applied directly on the ground or embankment, before pouring of the slab. This is the case generally for large-scale building.
* In META-SPCs 2 and 3, the products are applied in **peripheral application**. The perifilm can be applied before or after pouring of the slab. Before pouring of the slab, the perifilm is applied directly on the ground, on the periphery of the future slab (horizontal) and along the foundations (vertical). After pouring of the slab, it is applied flat on the slab along the outer edges of the construction.

The application rate recommended by the applicant are the following:

Whatever the product of the family, the amount of active substance applied is always the same: 1% / m². One application of the product takes place during the building construction.

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

According to the claims, the products of the TERMIPROTECT family are used to protect buildings against European subterranean termites (*Reticulitermes spp.*) and overseas subterranean termites (*Coptotermes spp.*).

After request for additional data (September 2016), the applicant has withdrawn the claims in oversea departments against *Heterotermes ssp*., *Rhinotermes spp*., *Coptotermes spp* and *Nasutitermes ssp*. Therefore the data presented in the IUCLID dossier on these species have not been taken into account.

The termites are killed after contact with the film containing permethrin.

The development stages claimed are larvae, nymphs and adults.

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

Permethrin is a type I axonic poison. It exerts its effects by means of hyperexcitation of both the peripheral and central nervous systems of target insects. This hyperexcitation occurs due to a prolongation of the Na+ current during membrane excitation causing an extended depolarisation of the synapse resulting in convulsions and eventual paralysis of the insect.

Pyrethroids act on the insect nervous system by slowing action potential decay and thereby initiating repetitive discharges in motor and sensory axons. Electrophysiological studies have suggested that these phenomena result from modification of the gating kinetics of neuronal, voltage-sensitive Na channels. Single channel studies have been conducted which have shown that pyrethroids slow the kinetics of opening and closing of Na channels.

Pyrethroids show high potency and selectivity for insects over mammals. The negative temperature dependence of pyrethroid action is partly responsible for the low mammalian toxicity of these compounds. Type 1 pyrethroids produce a distinct poisoning syndrome characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. The effects are generated largely by effects in the central nervous system. Permethrin also induces hepatic microsomal enzymes.

Permethrin exerts its effect directly and immediately on the insect’s nervous system. A time delay mechanism is not involved in its mode of action.

#### **Efficacy data**

Preamble: All the efficacy tests have been performed with the product X6232.

Regarding the META SPC1:

* The films X6232 and X6232-001 only differ by the colour of their upper layer and a very slight difference in the amount of the binder. These two variations of the formulation are not considered to impact the efficacy of the product and then a read-across between both formulations is acceptable.
* The films X6232 and X6232-001bis differ by the colour of their upper layer. This variation of the formulation is not considered to impact the efficacy of the product and then the read-across between both formulations is acceptable.

Regarding the META SPC 2, the films X6232 and X6232-002 differ by the colour of their upper layer. This variation of the formulation is not considered to impact the efficacy of the product and then the read across between both formulations is acceptable.

Regarding the META SPC 3, the films X6232 and X6240 differ by the colour of their upper layer and by the addition (in the formulation X6240) of a layer of bitumen. The layer of bitumen can be gone through by termites which then arrive in contact with the film (equivalent to X6232 except for the colour as already described). Then a read across between both formulations is acceptable.

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| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide | Outdoor | X6232  (permethrin 1% w/w) | *Reticulitermes flavipes*  150 workers, 3  nymphs and 2 soldiers per replicate | XP X 41-550 | Each test device is composed of the lower part of sand with a pine sapwood bait wood block and of the higher part of floral foam. The film (tested film or control non-treated film) is placed between these two parts, with its lower (inferior) layer in contact with the floral foam. Four holes (0.8 mm diameter) are pierced on the film. At the beginning of exposure, the termites are disposed on the floral foam.  Exposure: 4 weeks  Replicates: 4  Controls: 4 | Survival rate in the control higher than 50 % (76 %), all the control blocks are ranked 4  Damages rate in the test blocks: 0  No passing through the film in all the test devices. Efficacy criterion matched. | Brunet C. and Paulmier I.  2012  S6.7\_01  IC1 |
| Insecticide | Outdoor | X6232  (permethrin 1% w/w) | *Reticulitermes flavipes*  150 workers, 3  nymphs and 2 soldiers per replicate | FCBA- BIO-E-  046 and  XP X 41-550 | Film previously worn by immersion, according to standard FCBA-BIO-E-046 (adaptation of XP ENV 1250-2).  Each test device is composed of the lower part of sand with a pine sapwood bait wood block and of the higher part of floral foam. The film (tested film or control non-treated film) is placed between these two parts, with its lower (inferior) layer in contact with the floral foam. Four holes (0.8 mm diameter) are pierced on the film. At the beginning of exposure, the termites are disposed on the floral foam.  Exposure: 4 weeks  Replicates: 4  Controls: 4 | Survival rate in the control higher than 50 % (72.3 %), all the control blocks are ranked 4  Damages rate in the test blocks: 0  No passing through the film in all the test devices. Efficacy criterion matched. | Brunet C. and Paulmier I.  2012  S6.7\_02  IC1 |
| Insecticide | Outdoor | X6232  (permethrin 1% w/w) | *Reticulitermes flavipes*  150 workers, 3  nymphs and 2 soldiers per replicate | CTBA- BIO-E-  016 and  XP X 41-550 | Film previously worn by exposure to solar radiation (exposed horizontally during 15 days, according to standard CTBA-BIO-E-016).  Each test device is composed of the lower part of sand with a pine sapwood bait wood block and of the higher part of floral foam. The film (tested film or control non-treated film) is placed between these two parts, with its lower (inferior) layer in contact with the floral foam. Four holes (0.8 mm diameter) are pierced on the film. At the beginning of exposure, the termites are disposed on the floral foam.  Exposure: 4 weeks  Replicates: 4  Controls: 4 | Survival rate in the control higher than 50 % (50.7 %), all the control blocks are ranked 4  Damages rate in the test blocks: 0  No passing through the film in all the test devices. Efficacy criterion matched. | Brunet C. and Paulmier I.  2013  S6.7\_03  IC1 |
| Insecticide | Outdoor | X6232  (permethrin 1% w/w) | *Reticulitermes flavipes*  150 workers, 3  nymphs and 2 soldiers per replicate | CTBA- BIO-E-  016 and  XP X 41-550 | Film previously worn by exposure to solar radiation (exposed vertically during 3 months, according to standard CTBA-BIO-E-016).  Each test device is composed of the lower part of sand with a pine sapwood bait wood block and of the higher part of floral foam. The film (tested film or control non-treated film) is placed between these two parts, with its lower (inferior) layer in contact with the floral foam. Four holes (0.8 mm diameter) are pierced on the film. At the beginning of exposure, the termites are disposed on the floral foam.  Exposure: 4 weeks  Replicates: 4  Controls: 4 | Survival rate in the control higher than 50 % (62.6 %)  the control blocks are ranked 4  Damages rate in the test blocks: 0  No passing through the film in the test devices.  Efficacy criterion matched. | Brunet C. and Paulmier I.  2013  S6.7\_04  IC1 |
| Insecticide | Outdoor | X6232  (permethrin 1% w/w) | *Reticulitermes flavipes*  150 workers, 3  nymphs and 2 soldiers per replicate | CTBA- BIO-E-  007 and  XP X 41-550 | Film previously worn by exposure to an alkaline medium, according to standard CTBA-BIO-E-007. Each test device is composed of the lower part of sand with a pine sapwood bait wood block and of the higher part of floral foam. The film (tested film or control non-treated film) is placed between these two parts, with its lower (inferior) layer in contact with the floral foam. Four holes (0.8 mm diameter) are pierced on the film. At the beginning of exposure, the termites are disposed on the floral foam.  Exposure: 4 weeks  Replicates: 4  Controls: 4 | Survival rate in the control higher than 50 % (85.8 %)  the control blocks are ranked 4  Damages rate in the test blocks: 0  No passing through the film in the test devices.  Efficacy criterion matched. | Ansard D. and Paulmier I.  2012  S6.7\_05  IC1 |
| Insecticide | Outdoor | X6232  (permethrin 1% w/w) | *Reticulitermes flavipes*  150 workers, 3  nymphs and 2 soldiers per replicate | NF X41- 580  (part 3) and XP X 41-  550 | Film previously worn by exposure to frost, according to standard NF X41-580 (part 3).  Each test device is composed of the lower part of sand with a pine sapwood bait wood block and of the higher part of floral foam. The film (tested film or control non-treated film) is placed between these two parts, with its lower (inferior) layer in contact with the floral foam. Four holes (0.8 mm diameter) are pierced on the film. At the beginning of exposure, the termites are disposed on the floral foam.  Exposure: 4 weeks  Replicates: 4  Controls: 4 | Survival rate in the control higher than 50 % (50.7 %)  the control blocks are ranked 4  Damages rate in the test blocks: 0  No passing through the film in all the test devices. Efficacy criterion matched. | Brunet C. and Paulmier I.  2013  S6.7\_06  IC1 |
| Insecticide | Outdoor | X6232  (permethrin 1% w/w) | *Reticulitermes flavipes* workers, nymphs and soldiers | CTBA- BIO-E- 008/4 | Study area: Saint-Trojan-Les Bains (Charente- Maritime, France)  The test device is composed of susceptible bait wood (*Pinus sylvestris* sapwood), shut up in a concrete manhole riser (40\*40\*40 cm) half-buried and closed by a cover. The concrete manhole riser is set on the film applied on soil. A PVC pipe or an electrical conduit is buried in the soil through the middle of the film. The film is closely tight to the pipe or duct.  Exposure: 10 years  Replicates: 5 replicates of 2 devices (one with a PVC pipe and one with an electrical conduit).  Controls: 5 | After 4 years, termites have penetrated 2 control devices on 5 installed  The study is validated.  In all the test devices after 4 years of exposure to termites (*Reticulitermes flavipes*), nor damage on the test product nor the presence of termites inside the test devices is observed. | Brunet C. and Paulmier I.  2017  S6.7\_12  IC1 |

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| **Conclusion on the efficacy of the product** |
| French competent authorities considered that in accordance with the submitted tests and the requirements of the TNsG on PT18, the efficacy of the products of the TERMIPROTECT family, used as physico-chemical barrier (surface and peripheral application) to protect buildings is demonstrated against European subterranean termites (*Reticulitermes spp.*)  The application rate validated is the following:  The concentration of active substance in the products is 1 % /m². One application of the product takes place during the building construction. |

#### **Occurrence of resistance and resistance management**

Resistance to permethrin has been reported for a number of pests both in agriculture and public health (German cockroach (Atkinson et al., 1991), house fly (Shen and Plapp, 1990), stable fly (Cilek and Greena, 1994), *Culex* mosquitos (Wan-Norafilack et al., 2013), *Aedes* mosquitos (Saavedra-Rodriguez et al., 2008), *Anopheles* mosquitos (Müller et al., 2008)…), when permethrin has been used as a general insecticide (PT18 use). In general, pyrethroid resistance has been attributed to reduced neural sensitivity, enhanced metabolism, and reduced penetration ratio in many insects. A substantial degree of resistance remaining after synergism suggests the presence of other resistance mechanisms (see Assessment Report permethrin, PT08, April 2014).

However, resistance of termites to permethrin, is not reported up to date in the scientific literature.

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

- Always read the label or leaflet before use and respect follow all the instructions provided.

- The users should inform if the treatment is ineffective and report straightforward to the registration holder.

Moreover, the authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

#### **Known limitations**

*None*

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

French competent authorities (FR CA) assessed that the products of the TERMIPROTECT family have shown a sufficient efficacy as a physico-chemical barrier (for META SPC1 in surface application and in META SPCs 2 and 3 in peripheral application) to protect building against European subterranean termites (*Reticulitermes spp*.).

The application rate validated is the following:

Whatever the product of the family, the concentration of the active substance in the product is always the same 1 % /m². One application of the product takes place during the building construction.

### Risk assessment for human health

The products of the TERMIPROTECT family are ready-to-use anti-termites physico-chemical barriers used in pre-construction, for protection of buildings. They are applied outdoor by direct application of the film on the ground, once, before construction of the building.

The products are intended to be applied by professional users.

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

No acute toxicity study (oral, dermal and inhalation), nor skin and eye irritation study neither skin sensitisation study has been performed on any product of the TERMIPROTECT family.

Classification of the products has been carried out according to the calculation rules laid down in the CLP regulation.

***Skin corrosion and irritation***

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| **Data waiving** | |
| Information requirement | Skin corrosion and irritation |
| Justification | No study has been performed on any products of the TERMIPROTECT family.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for skin irritation. |

***Eye irritation***

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| **Data waiving** | |
| Information requirement | Eye irritation |
| Justification | No study has been performed on any products of the TERMIPROTECT family.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for eye irritation. |

***Respiratory tract irritation***

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| **Data waiving** | |
| Information requirement | Respiratory tract irritation |
| Justification | No study has been performed on any products of the TERMIPROTECT family.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory tract irritation. |

***Skin sensitization***

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| **Data waiving** | |
| Information requirement | Skin sensitization |
| Justification | No study has been performed on any products of the TERMIPROTECT family.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, a classification Skin Sens 1 – H317 is required for products in Meta SPC 1 and 2.  For meta SPC 3, the hazard mention EUH 208 ”Contains Permethrin. May produce an allergic reaction” should be applied on the label. |

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| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | - |
| Justification for the value/conclusion | In meta SPC 1 and 2, the content of a.s classified H317 is higher than 1% (general concentration limit), leading to a classification of the products as skin sensitizer.  In meta SPC 3, the content of a.s is below 1% but higher than 0.1% (threshold limit for elicitation), therefore a mention EUH 208 is required. |
| Classification of the product according to CLP | Skin Sens 1 – H317 for meta SPC 1 and 2  EUH 208: Contains Permethrin. May produce an allergic reaction for meta SPC 3 |

***Respiratory sensitization (ADS)***

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| **Data waiving** | |
| Information requirement | Respiratory sensitization |
| Justification | No study has been performed on any products of the TERMIPROTECT family.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for respiratory sensitization. |

***Acute toxicity***

*Acute toxicity by oral route*

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| **Data waiving** | |
| Information requirement | Oral acute toxicity |
| Justification | No study has been performed on any products of the TERMIPROTECT family.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for oral acute toxicity. |

*Acute toxicity by inhalation*

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| **Data waiving** | |
| Information requirement | Inhalation acute toxicity |
| Justification | No study has been performed on any products of the TERMIPROTECT family.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for inhalation acute toxicity. |

*Acute toxicity by dermal route*

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| **Data waiving** | |
| Information requirement | Dermal acute toxicity |
| Justification | No study has been performed on any products of the TERMIPROTECT family.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, no classification is required for dermal acute toxicity. |

***Information on dermal absorption***

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| **Data waiving** | |
| Information requirement | Dermal absorption |
| Justification | The dermal absorption value of 3% set in the CAR of the active substance permethrin has been used for the risk assessment.  The dermal absorption value set in the CAR for a liquid formulation (EC formulation) is considered as a worst case for the product TERMIPROTECT. |

***Available toxicological data relating to non active substance(s) (i.e. substance(s) of concern)***

According to the definition of a substance of concern laid down in the Guidance on the BPR Volume III Human Health – Part B and C Risk Assessment, TERMIPROTECT family does not contain any substance of concern.

***Available toxicological data relating to a mixture***

Not applicable.

***Other***

Not applicable.

#### **Exposure assessment**

All the TERMIPROTECT films are composed of 3 LDPE layers films:

* a lower 37.5 µm black layer, containing the active substance permethrin,
* an intermediate 75 µm uncoloured layer, also containing the active substance
* an upper 37.5 µm coloured layer (blue/red/yellow depending on the product), without active substance.

These 3 layers make up a physico-chemical barrier of 150 µm.

Regarding the product of Meta-SPC 3, the lower layer is also coated with a self-adhesive bitumen coating.

The lower black layer is laid down on the ground, embankment or slab, or around the possible pipe crossings.

Depending on the type of building, different products of the TERMIPROTECT family are used, with different mode of application.

* **in case of surface application**, the film is applied directly on the ground or embankment, before pouring of the slab. This is the case generally for large-scale building.
* **in the case of peripheral application**, the perifilm can be applied before or after pouring of the slab. Before pouring of the slab, the perifilm is applied directly on the ground, on the periphery of the future slab (horizontal) and along the foundations (vertical). After pouring of the slab, it is applied flat on the slab along the outer edges of the construction.

The products are intended to be applied by professional users.

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

| **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 | n.a | no | n.a | n.a | no | no | No |
| Dermal | n.a | yes | n.a | n.a | negligible | no | No |
| Oral | n.a | no | n.a | n.a | no | no | No |

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| 1. SSurface application | Dermal contact with the membrane during surface application of the film on the ground | **Primary exposure – dermal**  The film is deposited on the foundations of building.  It is unroll and cut according to the area to be protected.  Operator could be exposed through skin contact.  During application of the product, the professional will have multiple contacts with membranes. Assessing the amount of contact or the total surface during use is very uncertain. A reverse reference scenario is thus developed. | Professionals |
| 1. Peripheral Application | Dermal contact with membrane during peripheral application of the perifilm | **Primary exposure – dermal**  The film is deposited on the foundations of building.  It is unroll and cut according to the area to be protected.  Operator could be exposed through skin contact.  During application of the product, the professional will have multiple contacts with the membrane when applying the product on the house ground surface. | Professionals |

***Industrial exposure***

Not applicable.

***Professional exposure***

*Scenario [1]: Surface application – Dermal contact with membrane*

| **Description of Scenario [1]** | | | |
| --- | --- | --- | --- |
| During application of the product, the professional will have multiple contacts with membranes. Assessing the amount of contact or the total surface during use is very uncertain. A reverse reference scenario is thus developed.  Regarding the use of the product and the volatility of permethrin and the fact that the application is made outdoor, exposure via inhalation route (and oral route) is considered as negligible.  Only the dermal exposure *via* handling of the product will be assessed.  ***Assessment of maximum acceptable contact surface***  It can be assumed that up to a depth of 0.1 mm residues of the treated film are relevant for transfer to the skin.  So surface loading can be calculated as follow:  = (0.168 mg a.s./cm2 ÷ 0.015 cm) \* 0.01 cm  = **0.112 mg a.s./cm2**  A default value of 3% is used for transfer coefficients from membrane to skin is used *(Biocides Human Health Exposure Methodology).*  The long term AEL is used to derive the reverse exposure scenario as the exposure is chronic.  The parameters to assess dermal exposure are summarised in the table below. | | | |
|  | Parameters1 | Value | Source |
| Tier 1 | Impregnation concentration a.s (mg/cm2) | 0.168 | Applicant’s data |
| Relevant depth for transfer (mm) | 0.1 | - |
| Surface loading (mg/cm2) | 0.102 | - |
| Transfer coefficient layer/skin | 3% | Biocides Human Health Exposure Methodology |
| Dislodgeable active substance (mg/cm2) | 3.36E-03 | - |
| Gloves penetration factor | 100% | HEEG Opinion 9 |
| AEL long term (mg/kg) | 0.05 | - |
| Body weight (kg) | 60 | HEAD Hoc recommendation 14 |
| Dermal absorption | 3% | Active substance data |
| Tier 22 | Gloves penetration factor | 5% | HEEG Opinion 9 |

1 Include generic parameters (e.g. respiration rates, exposed skin areas, exposure times) and protection/penetration rates for PPE. Use footnotes for references and justifications.

2 Only include the parameters changed with respect to the previous Tier.

**Calculations for Scenario [1]: Reverse calculations**

| **Summary table: Maximum acceptable contact surface (m2)** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **AELlong term**  **(mg/kg bw/d)** | **Maximum acceptable contact surface (m2)** |
| Scenario [1] | Tier 1/no PPE | 0.05 | 2.98 |
| Scenario [1] | Tier 2/gloves | 0.05 | 59.5 |

**Further information and considerations on scenario [1]**

None

*Scenario [2]: Peripheral application – Dermal contact with the membrane*

Regarding the structure of TERMIPROTECT, 3 LPDE layer films, the exposure scenario of the peripheral application is considered covered by the exposure scenario of surface application.

**Further information and considerations on scenario [2]**

None

*Combined scenarios*

Not applicable

***Non-professional exposure***

Not applicable.

***Exposure of the general public***

Regarding secondary exposure, it could not occur as TERMIPROTECT will be below a concrete slab and/or buried.

According to the method of application, TERMIPROTECT will be not accessible to people during its service life.

***Monitoring data***

No data submitted.

***Dietary exposure***

In the Opinion on approval of permethrin under PT 18 (8 April 2014), it is stated at point 2.4. “Elements to be taken into account when authorizing products”, that “*an assessment of the risk in food and feed areas may be required at product authorisation where use of the product may lead to contamination of food and feeding stuffs”*.

Biocide products of meta-SPC 1 are intended to be used in pre-construction with surface application on the ground or embankment before pouring the slab. Regarding this use, food or feed contamination is not expected.

Biocide products of meta-SPC 2 and 3 are intended to be used in pre-construction with peripheral application:

* on the ground on the periphery of the future slab (horizontal) and along the foundations (vertical) before pouring the slab.
* on the slab along the outer edges of the construction (vertical) after pouring the slab.

Regarding the characteristics of the biocidal products (formulation of the films, films watertight) and the low migration properties of permethrin (AR section Environment, IR 2014), it can be concluded that no emissions into the soil are foreseen after the application. Therefore no contamination of alimentary commodities growing on soil from home gardening is expected.

So regarding these uses, food or feed contamination is not expected. As a consequence the exposure via food, via livestock exposure or via transfer of biocidal active substances is considered as negligible.

*Information of non-biocidal use of the active substance*

Residue definitions

Permethrin (sum of isomers)

This active substance is considered “Fat soluble”.

| **Summary table of other (non-biocidal) uses** | | | |
| --- | --- | --- | --- |
|  | **Sector of use1** | **Intended use** | **Reference value(s) 2** |
| 1. | Biocide TP8  (Wood treatment) | EU Reg. 1090/2014: approved active substance for PT 8 and PT 18 | / |
| 2. | Plant protection products | EU Reg. 396/2005: not approved active substance  Permethrin Review Report 13 July 2000:  *”Technical evidence has been provided indicating that limited further use of permethrin in forestry could be allowed whilst research is ongoing in order to find efficient alternatives providing that appropriate risk mitigation measures are taken. To minimise potential risk for aquatic organisms it was proposed by the Rapporteur Member State that a buffer zone should be applied between treated areas and surface waters.*  *In view of the fact that all notifiers of the substance, formally withdrew their support for permethrin within the EU Peer Review Programme and, therefore, no engagements are made to produce the necessary supplementary data, an inclusion of this active substance in Annex I of Directive 91/414 cannot be envisaged”* | Default MRL: Reg. (EU) 2017/623 |
| 3 | Veterinary medicinal products | EU Reg. 470/2009  External application for the control of ectoparasites for cattle | Reg (EU) 37/2010: MRL for bovine:  Muscle, Liver, Kidney, Milk: 50 μg/kg  Fat: 500 μg/kg |

1 e.g. plant protection products, veterinary use, food or feed additives

2 e.g. MRLs. Use footnotes for references.

***Exposure associated with production, formulation and disposal of the biocidal product***

Not applicable

***Aggregated exposure***

Not applicable

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

***Reference values to be used in Risk Characterisation***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** **(mg/kg bw/d)** | **AF** | **Correction for oral absorption** | **Value**  **(mg/kg bw/d)** |
| AELshort-term | 2-year rat study (oral) | 50 | 100 | none | 0.5 |
| AELmedium-term | 1-year dog study (oral) | 5 | 100 | none | 0.05 |
| AELlong-term |
| ARfD | Not allocated | | | | |
| ADI |

***Maximum residue limits or equivalent***

Residue definitions

Permethrin (sum of isomers)

This active substance is considered “Fat soluble”.

|  |  |  |  |
| --- | --- | --- | --- |
| **MRLs or other relevant reference values** | **Reference** | **Relevant commodities** | **Value** |
| Default MRL: Reg. (EU) 2017/623 | Plant protection products | All raw food commodities | 0.05\*-0.10\* mg/kg except bovine commodities (0.05 to 0.5 mg/kg) |
| MRL for bovine : Reg (EU) 37/2010 | Veterinary medicinal products | Bovine commodities | Muscle, Liver, Kidney, Milk: 50 μg/kg  Fat: 500 μg/kg |

***Risk for industrial users***

Not applicable

***Risk for professional users***

|  |  |  |  |
| --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Maximum acceptable contact surface** **(m2)** | **Acceptable**  **(yes/no)** |
| **Surface application -**  **Scenario [1]** | Tier 1/No PPE | 2.98 | no |
| Tier 2/gloves | 59.5 | yes |

**Combined scenarios**

Not applicable

**Local effects**

The product of Meta SPC 1 and 2 are classified as skin sensitizer – H317.

Therefore, RMM and PPE (gloves) have to be taken into consideration during the application of products.

**Conclusion**

For surface application, a maximum surface of contact of 59 m2 has been calculated taking into account gloves.

This surface of contact is considered unrealistic and therefore, the risk is judged acceptable for professionals with gloves.

For peripheral application, the risk is considered covered by the surface application.

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

Not applicable

***Risk for the general public***

As exposures of workers after application or of people living or working in the building are negligible, the risk is therefore considered acceptable.

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

Regarding the use, food or feed contamination is not expected. As a consequence no dietary risk assessment was performed. Nevertheless the following risk mitigation measure is proposed to avoid any food and feed contamination:

* Avoid any contamination of food, feed or drinks.

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

Not applicable

### Risk assessment for animal health

Not applicable

### Risk assessment for the environment

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

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

The products of the TERMIPROTECT family are ready-to-use anti-termites physico-chemical barriers used in pre-construction for protection of buildings. These products contain between 0.10 % and 1.00 % w/w permethrin as active substance (corresponding to 1.39 g permethrin/m2 and 1.53 g permethrin/m2 of PE film).

All the data are coming from the Assessment Report of the active substance (see Assessment Report of permethrin, PT18, April 2014).

**Summary of PNECs of the active substance permethrin and its relevant metabolites DCVA and PBA**

|  |  |  |  |
| --- | --- | --- | --- |
| **Compartment** | **Permethrin** | **DCVA** | **PBA** |
| Freshwater | 4.7E-07 mg/L | 0.015 mg/L | > 0.010 mg/L |
| Freshwater sediment | 2.17E-04 mg/kgwwt | 0.012 mg/kgwwt | 9E-03 mg/kgwwt |
| Soil | > 0.0876 mg/kgwwt | 4.6 mg/kgwwt | 1.44 mg/kgwwt |
| STP | 4.95E-03 mg/L | Not available | Not available |
| Oral bird | ≥ 16.7 mg/kg food | | |
| Oral small mammal | 120 mg/kg food | | |

|  |
| --- |
| BOX 2: FR Opinion  In agreement with the PNEC values proposed. |

***Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required***

There is no ecotoxicological data available for the products of the TERMIPROTECT family. The classification of the products is therefore based on data on the active substance and co-formulants.

The active substance permethrin is classified according to Regulation (EC) No.1272/2008 (CLP) as Aquatic Acute 1, H400 and Aquatic Chronic 1, H410, very toxic to aquatic life with long-lasting effects. Permethrin is assigned an acute M-factor of 100 and a chronic M-factor of 10 000.

Based on the classification and the M-factor values of permethrin, the products of the TERMIPROTECT family are classified according to Regulation (EC) No.1272/2008 (CLP) with the worst-case classification:

Signal Word: Warning

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

The other co-formulants of the products of the TERMIPROTECT family are not classified for the environment and are not considered as substances of concern for the environment. Therefore, the co-formulants are not expected to have a significant impact on the ecotoxicological classification of the products of the TERMIPROTECT family as they are already classified with the worst classification H400/H410 due to the presence of permethrin.

Taking into account all these considerations (i.e. worst case classification of the products based on active substance data and composition of the products not influencing the ecotoxicological properties of the active substance), the classification of the products of the TERMIPROTECT family is based on the active substance data, according to the rules laid down in Regulation (EC) 1272/2008 (CLP) and no further aquatic ecotoxicity data on the products are deemed necessary.

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| BOX 3: FR Opinion  In agreement with the product classification proposed. |

***Further Ecotoxicological studies***

No data is available. As the products of the TERMIPROTECT family don’t contain any substance of concern, the assessment is based on the available ecotoxicological data on permethrin and its metabolites.

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| --- |
| BOX 4: FR Opinion  No further comments. |

***Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)***

No data is available. As the products of the TERMIPROTECT family don’t contain any substance of concern, the assessment is based on the available ecotoxicological data on permethrin and its metabolites.

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| --- |
| BOX 5: FR Opinion  No further comments. |

***Supervised trials to assess risks to non-target organisms under field conditions***

No data is available. This endpoint is relevant only for products in the form of bait or granules. The products of the TERMIPROTECT family are in the form of films acting as physico-chemical barriers.

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| --- |
| BOX 6: FR Opinion  No further comments. |

***Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk***

No data is available. This endpoint is relevant only for products in the form of bait or granules. The products of the TERMIPROTECT family are in the form of films acting as physico-chemical barriers.

|  |
| --- |
| BOX 7: FR Opinion  No further comments. |

***Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)***

No data is available. The products of the TERMIPROTECT family are ready-to-use anti-termites physico-chemical barriers used in pre-construction, for protection of buildings. As the products are used under the buildings, they are not intended to be applied directly in a specific habitat such as water body, wetland, forest or field. No large proportion of specific habitat type will be treated with the products of the TERMIPROTECT family and it can be concluded that no secondary ecological effect is expected when using the products according to the label recommendations.

|  |
| --- |
| BOX 8: FR Opinion  No further comments. |

***Foreseeable routes of entry into the environment on the basis of the use envisaged***

The foreseeable routes of entry in the environment are based on the use envisaged and the behaviour of the products is extrapolated from the information on the active substance itself.

The products of the TERMIPROTECT family are ready-to-use anti-termites physico-chemical barriers used in pre-construction, for protection of buildings. All the TERMIPROTECT films are made of 3 layers:

* a *lower* 37.5 µm black layer, containing the active substance,
* an *intermediate* 75 µm uncoloured layer, also containing the active substance,
* an *upper* 37.5 µm coloured layer (blue/red/yellow depending on the product), without active substance.

These 3 layers make up a physico-chemical barrier.

Regarding the product of Meta-SPC 3, the lower layer is also coated with a self-adhesive bitumen coating.

The different products of the TERMIPROTECT family are used with different mode of application:

* *Before pouring of the slab*, the films can be installed horizontally or vertically.
* In case of a *horizontal installation*, the film is applied directly on the ground or embankment, on the whole surface (Termiprotect Film) or at the periphery of the future slab (Termiprotect Périfilm). The edges of the film are raised and fixed against the vertical walls on a maximum height of 0.3 m.
* In *vertical installation*, the Perifilm is applied along the foundations on a maximum height of 0.3 m.
* *After pouring of the slab*, the products Termiprotect Périfilm or Périfilm AD are applied flat on the slab along the outer edges of the construction. The films are nailed or glued to the slab before being compressed and protected by the paving.

Two steps of the life cycle of the films are considered in the risk assessment: the installation of the films and the service life.

* ***Installation of the films***

The application of the films must take place during a non-rainy day. The film can be exposed to the rain before the slab or the house has been installed above the films. However, the active substance permethrin is incorporated into a solid matrix and all the Termiprotect films are watertight according to the norm NF EN 1928. Moreover, the permethrin has a very low water solubility (< 4.95E-03 mg/l) and a strong adsorption potential (Koc = 26 930 l/kg). It is therefore considered that releases of permethrin through the surface of the films are negligible during the installation step.

The only potential route of release of the active substance could be through the borders of the films. The soil moisture may penetrate the films via the borders that are in direct contact with the soil.

As the borders are very thin, (the thickness of the 2 layers containing the permethrin is 112 µm) releases are expected to be very limited. However, this release pathway is considered in a conservative approach. In urban area the releases are directed to the STP and in rural area the active substance is released directly onto the soil. It is pointed out that the films are never in direct contact with the natural soil but are in contact with either sand or embankment. However it is considered in a very conservative assumption that the soil in contact with the borders of the films is a natural soil.

* ***Service life***

Three release pathways are considered:

* *release through the surface of the film in horizontal position on the whole surface of the house*:

In a very conservative assumption, release of permethrin contained in the whole surface of the applied film is considered, even if the film that is beneath the future house can’t be exposed to rainwater and even if the films are water tight. Indeed, it is considered that soil moisture or water infiltration may be in contact with the whole surface of the film and may lead to the release of the active substance.

However this is not what is recommended in the scenario termite control of the revised ESD for PT08 that indicates (p.100): “The soil volumes and areas treated in phase 1 to 3 are beneath the future house and therefore not subject to wetting as soon as the bottom slab of the future house is set. In addition, biocidal products used for termite control are designed for low mobility in soil. Therefore, the leaching of any substance from treated soil beneath the future house to adjacent un-treated soil after rain is considered negligible”. Nevertheless, as no scenario exists for the assessment of films used in pre­construction, the worst assumptions have been considered.

* *release through the surface of the films in vertical position at the periphery of the house:*

In case of installation before pouring the slab in vertical application or in horizontal application where the edge of the films are raised and fixed against the wall, the lower layer of the film is in direct contact vertically with the soil at the periphery of the house on a maximum height of 0.3 m. Even if the films are water tight it is considered in a conservative assumption that the soil moisture may lead to a release of the active substance out of the films.

* *release through the borders of the films:*

In case of installation after pouring the slab, only the borders of the films are in contact with the soil. The soil moisture may penetrate the films via the borders and may lead to the release of the active substance into the soil.

It is reminded that the films are never in direct contact with the natural soil but are in contact with either sand or embankment. However it is considered in a very conservative assumption that the soil in contact with the films is a natural soil.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| BOX 9: FR Opinion  ***Construction step (installation of the films)***  A time-interval of 2 weeks can be considered between the installation and the slab pouring. During this interval, a short-term exposure of the environment by rainfall events could be considered as relevant.  According to the applicant, emission to the environment is low as the active substance is highly adsorbed with a low solubility. Moreover the active substance is protected by the plastic lining, which presents an impermeable barrier to rainfall. Nevertheless, no leaching data are available to confirm that no releases occur at all.  The only low emission area (due to its low thickness) assumed by the applicant is the open edges (112.5 µm of thickness). Therefore, possible release of the active substance from undamaged product is very limited.  An emission from the open edges of the fibrous layer is taking into account. Two separate theoretical environments can be considered, taking into account rural and urban areas, with 100% of wash-off directed either to soil, or to a sewage treatment plant (STP), respectively.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Step | Area | Environmental compartments (Construction step) | | | | | | Air | STP | Soil | Surface water | Groundwater | | Construction step | Rural | - | - | ++ | - | + | | Urban | - | ++ | + | + | + |   ***Service life of the product***  Due to the level of containment achieved at construction, there would be no exposure to rainfall and interior cleaning during the service-life of the product. Therefore, emission to STP or surface water from either rainwater or cleaning water release to public sewage is considered not relevant. However a potential emission to the soil has been considered.  The use around the external perimeter of a building may result in emission to the adjacent soil around the foundations of the building. The Termiprotect films can be installed underneath a building, covering the whole footprint of the house with a single layer of material. All of the soil beneath the house will therefore be in contact with the product. A layer of insulation is subsequently placed on top of Termiprotect films, followed by a layer of concrete. The product is therefore completely contained once the construction process is complete, and is not exposed to rainfall or interior cleaning. Only releases to soil (and subsequently to groundwater) are relevant from this use.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Step | Area | Environmental compartments (Construction step) | | | | | | Air | STP | Soil | Surface water | Groundwater | | Service-life | Rural | - | - | ++ | - | + | |

***Further studies on fate and behaviour in the environment (ADS)***

No data is available. As the products of the TERMIPROTECT family don’t contain any substance of concern, the assessment is based on the available ecotoxicological data on permethrin and its metabolites.

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| --- |
| BOX 10: FR Opinion  No further comments. |

***Leaching behaviour (ADS)***

The active substance permethrin is incorporated into a solid matrix and as all the Termiprotect films are watertight according to the norm NF EN 1928, the water cannot penetrate into the films. Moreover, the permethrin has a very low water solubility (< 4.95E-03 mg/l) and a strong adsorption potential (Koc = 26 930 l/kg). Therefore a leaching behaviour is not expected.

In the risk assessment it is considered as a worst case that when the surface or the borders of the films are in direct contact with the adjacent soil, the soil moisture may penetrate into the film and may lead to the release of the active substance out of the film.

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| --- |
| BOX 11: FR Opinion  No further comments. |

***Testing for distribution and dissipation in soil (ADS)***

No data is available. As the products of the TERMIPROTECT family don’t contain any substance of concern, the assessment is based on the available ecotoxicological data on permethrin and its metabolites.

|  |
| --- |
| BOX 12: FR Opinion  No further comments. |

***Testing for distribution and dissipation in water and sediment (ADS)***

No data is available. As the products of the TERMIPROTECT family don’t contain any substance of concern, the assessment is based on the available ecotoxicological data on permethrin and its metabolites.

|  |
| --- |
| BOX 13: FR Opinion  No further comments. |

***Testing for distribution and dissipation in air (ADS)***

No data is available. As the products of the TERMIPROTECT family don’t contain any substance of concern, the assessment is based on the available ecotoxicological data on permethrin and its metabolites.

|  |
| --- |
| BOX 14: FR Opinion  No further comments. |

***If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)***

Not relevant.

|  |
| --- |
| BOX 15: FR Opinion  No further comments. |

***If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)***

Not relevant.

|  |
| --- |
| BOX 16: FR Opinion  No further comments. |

#### **Exposure assessment**

|  |  |  |  |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario name** | **Mode of application**  **covered by the scenario** | **Films covered by the**  **scenario** |
| Scenarios for the application step | | | |
| 1 | Release through the borders of the films during the installation step – urban area | All mode of application | Termiprotect Film Termiprotect Périfilm Termiprotect Périfilm AD |
| 2 | Release through the borders of the films during the installation step – rural area | All mode of application | Termiprotect Film Termiprotect Périfilm Termiprotect Périfilm AD |
| Scenarios for the service life | | | |
| 3 | Release through the whole horizontal surface of the film during the service life | Horizontal application on the whole surface before pouring the slab | Termiprotect Film |
| 4 | Release through the vertical surface of the films at the periphery during the service life | Vertical application before pouring the slab | Termiprotect Périfilm |
| 5 | Release through the borders of the films during the service life | Horizontal application after pouring the slab | Termiprotect Périfilm Termiprotect Périfilm AD |

***General information***

|  |  |
| --- | --- |
| Assessed PT | PT 18 |
| Assessed scenarios | Scenario 1: release through the borders of the films during the installation step – urban area  Scenario 2: release through the borders of the films during the installation step – rural area  Scenario 3: release through the whole horizontal surface of the film during the service life  Scenario 4: release through the vertical surface of the films at the periphery during the service life  Scenario 5: release through the borders of the films during the service life |
| ESD(s) used | No emission scenarios are available in the ESDs for insecticides (PT18)[[9]](#footnote-9) or wood preservatives (PT8)[[10]](#footnote-10) regarding the prevalence of preventive termite treatments. Consequently, scenarios were developed by adapting the ESDs PT18 and PT8. |
| Approach | Scenario 1: average consumption  Scenario 2: average consumption  Scenario 3: average consumption  Scenario 4: average consumption  Scenario 5: average consumption |
| Distribution in the environment | Calculated based on TGD 2003 |
| Groundwater simulation | Scenario 3: FOCUS PEARL 4.4.4.  *Considering it as the worst-case scenario*. |
| Confidential Annexes | NO |
| Life cycle steps assessed | Scenario 1 & 2:  Production: No  Formulation No  Use: Yes  Service life: No  Scenario 3, 4 & 5:  Production: No  Formulation No  Use: No  Service life: Yes |

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| BOX 17: FR Opinion  In agreement with the exposure scenario proposed. No further comments. |

***Emission estimation***

**Scenario [1]: Release through the borders of the films during the installation step – Urban area**

**Scenario [2]: Release through the borders of the films during the installation step - Rural Area**

It is considered as a conservative assumption that 100% of the quantity of substance contained in 1 mm of depth of film is released via the borders.

Scenario [1]: It is considered as a worst case that 100% of the releases are directed to the STP through run-off.

Scenario [2]: Release of permethrin through the borders of the films in contact of the soil is considered.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| **Scenario 1: Release through the borders of the films during the installation step – urban area**  **Scenario 2: Release through the borders of the films during the installation step – rural area** | | | |
| Content of permethrin (technical) in the film (fai) | 1.53 | g/m² | - |
| House surface area where leaching occurs (AREA film) | 0.05 | m2 | House perimeter of 50 m and 1 mm of depth of film is released via the borders. |
| Number of treated house per day (Nhouse) | 1 | d-1 | - |
| **Calculation** | | | |
| E local STP = f ai \* AREA film\*Nhouse  E local soil = f ai \* AREA film | | | |
| **Output** | | | |
| Local emission to STP | 7.65E-05 | kg/d |  |
| Local emission to soil | 7.65E-05 | Kg |  |

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| BOX 18: FR Opinion  In worst case approach, a house surface area where leaching occurs of 0.1 m2 was considered in taking into account the external border and the internal border of the films. The content of permethrin (technical) in the film is 1.68 g/m2.   |  |  |  |  | | --- | --- | --- | --- | | **Output** | | | | | Local emission to STP | 1.68E-04 | kg/d |  | | Local emission to soil | 1.68E-04 | Kg |  | |

**Scenario [3]:** **Release through the whole horizontal surface of the film during the service life**

Release of permethrin contained in the whole surface of the applied film is considered. The surface of a standard house of 131.25 m2 (17.5 m \* 7.5 m) is therefore taken into account for the calculation of emissions.

During the service life, the soil moisture in contact with the film may lead to a release of the permethrin out of the film. The permethrin will be released progressively over the time. It is therefore considered relevant to perform the assessment considering the whole duration of the service life of the film. The duration of 10 years is considered because it represents the guaranteed duration of protection offered by the products of the TERMIPROTECT family (ten-year construction warranty).

The fraction of 100% of permethrin released over 10 years is considered as worst case assumption. Indeed, laboratory test has demonstrated that after a total immersion in water after at least 79 hours, the film is still efficient. Moreover, the film is still efficient in a field efficacy test after 4 years and 4 months of use in field conditions.

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| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| **Scenario 3: Release through the whole horizontal surface of the film during the service life** | | | |
| Content of permethrin (technical) in the film (fai) | 1.53 | g/m² | - |
| Surface of film considered (AREA film) | 131.25 | m2 | 100% of a standard house |
| Fraction of permethrin contained in the film in contact with the soil that is released over 10 years (frelease, 3650d) | 1 | - | - |
| **Calculation** | | | |
| Elocal soil,3650d= f ai \* AREA film \* f release, 3650d | | | |
| **Output** | | | |
| Cumulative Local emission to soil (3 650 d) | 0.201 | Kg |  |

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| BOX 19: FR Opinion  In agreement with the emission estimation for the scenario 3. Nevertheless, duration of 30 years instead of 10 years is considered. It represents the average lifespan of a house. The content of permethrin (technical) in the film is 1.68 g/m2.   |  |  |  | | --- | --- | --- | | **Output** | | | | Cumulative Local emission to soil (10 950 d) | 0.221 | Kg | |

**Scenario [4]:** **Release through the vertical surface of the films at the periphery during the service life**

Two situations result in a direct contact with the soil of the lower layer of the film in vertical position:

- in case of horizontal application before pouring the slab, the edges of the film are raised and pressed against the vertical walls of the foundations.

- in case of vertical application, before pouring the slab.

In both situations, the films are in contact with the soil on a maximum height of 0.3 m. Considering the peripheral dimension of a standard house ((17.5 + 7.5 m) \* 2), the surface of film in contact with the soil is 15 m2.

During the service life, the soil moisture in contact with the film may lead to a release of the permethrin out of the film. The permethrin will be released progressively over the time. It is therefore considered relevant to perform the assessment considering the whole duration of the service life of the film. The duration of 10 years is considered because it represents the guaranteed duration of protection offered by the products of the TERMIPROTECT family (ten-year construction warranty).

The fraction of 100% of permethrin released over 10 years is considered. This fraction is a worst case assumption, as explained for the scenario 3.

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| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| **Scenario 4: Release through the vertical surface of the films at the periphery during the service life** | | | |
| Content of permethrin (technical) in the film (fai) | 1.53 | g/m² | - |
| Surface of film considered (AREA film) | 15 | m2 | =(17.5+7.5)\*2\*0.3 |
| Fraction of permethrin contained in the film in contact with the soil that is released over 10 years (frelease, 3650d) | 1 | - | - |
| **Calculation** | | | |
| Elocal soil,3650d= f ai \* AREA film \* f release, 3650d | | | |
| **Output** | | | |
| Cumulative Local emission to soil (3 650 d) | 0.0230 | Kg |  |

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| BOX 20: FR Opinion  In accordance with the emission estimation for the scenario 4. Nevertheless, duration of 30 years instead of 10 years is considered. It represents the average lifespan of a house. The content of permethrin (technical) in the film is 1.68 g/m2.   |  |  |  | | --- | --- | --- | | **Output** | | | | Cumulative Local emission to soil (10 950 d) | 0.0252 | Kg | |

**Scenario [5]:** **Release through the borders of the films during the service life**

One mode of application of the films results in a direct contact with the soil of only the borders of the film:

- in case of horizontal application after pouring the slab

It is considered as a conservative assumption that the substance contained in 10 cm of depth of film will be released via the borders during the application step and the service life. Considering the periphery of a standard house (2\* (17.5 m + 7.5m)), this represents a surface of 5 m2.

The permethrin will be released progressively over the time. It is therefore considered relevant to perform the assessment considering the whole duration of the service life of the film. The duration of 10 years is considered because it represents the guaranteed duration of protection offered by the products of the TERMIPROTECT family.

The fraction of 100% of permethrin released over 10 years is considered. This fraction is a worst case assumption, as explained for the scenario 3.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| **Scenario 5: Release through the borders of the films during the service life** | | | |
| Content of permethrin (technical) in the film (fai) | 1.53 | g/m² | - |
| Surface of film considered (AREA film) | 5 | m2 | =(17.5+7.5)\*2\*0.1 |
| Fraction of permethrin contained in the film in contact with the soil that is released over 10 years (frelease, 3650d) | 1 | - | - |
| **Calculation** | | | |
| Elocal soil,3650d= f ai \* AREA film \* f release, 3650d | | | |
| **Output** | | | |
| Cumulative Local emission to soil (3 650 d) | 7.65E-03 | Kg |  |

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| BOX 21: FR Opinion  In accordance with the emission estimation for the scenario 5. Nevertheless, duration of 30 years instead of 10 years is considered. It represents the average lifespan of a house. The content of permethrin (technical) in the film is 1.68 g/m2.   |  |  |  | | --- | --- | --- | | **Output** | | | | Cumulative Local emission to soil (10 950 d) | 8.40E-03 | Kg | |

***Fate and distribution in exposed environmental compartments***

In the scenario 1, emissions in urban area are directed into the STP. STPs are therefore the primary compartment for emissions and surface water bodies (including sediment) as well as the soil compartment (including groundwater) are secondary exposed compartments for residues via sewage treatment plant effluents and sewage sludge applications, respectively.

In scenarios 2, 3, 4 and 5, the soil is the primary receiving compartment. Then, leaching may lead to a contamination of the groundwater. If no data is available, delete the tables and indicate only that no data is available.

|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Scenario 1 | Yes | Yes | No | No | Yes | No | Yes | Yes |
| Scenario 2 | No | No | No | No | No | No | Yes | Yes |
| Scenario 3 | No | No | No | No | No | No | Yes | Yes |
| Scenario 4 | No | No | No | No | No | No | Yes | Yes |
| Scenario 5 | No | No | No | No | No | No | Yes | Yes |

Fate and distribution in the environment of the active substance permethrin is calculated based on the environmental data presented in the following table. These data are coming from the Assessment Report of permethrin, PT18, April 2014. These data are considered sufficient to assess the fate and behaviour of the products as they don’t contain substance of concern. Available fate and behaviour data for the relevant metabolites DCVA and PBA are also reported.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | | | |
| Input | Value | Unit | | Remarks | |
| Molecular weight | 391.29 |  | |  | |
| Melting point | 33 | °C | |  | |
| Boiling point | 305 | °C | |  | |
| Vapour pressure (at 20°C) | 2.155E-06 | Pa | |  | |
| Water solubility (at 20°C) | < 0.00495 | mg/l | |  | |
| Log Octanol/water partition coefficient | 4.67 | Log 10 | |  | |
| Organic carbon/water partition coefficient (Koc) | 73 441 | l/kg | |  | |
| Henry’s Law Constant | 4.6E-03 | Pa/m3/mol | |  | |
| Biodegradability | Not ready biodegradable |  | |  | |
| Rate constant for STP | 0 | h-1 | | EUSES v2.1.2 | |
| DT50 for biodegradation in surface water | 46.7 (whole system) | d (at 12ºC) | |  | |
| DT50 for hydrolysis in surface water | > 365 | d | | Permethrin is hydrolytically stable under environmentally relevant pH and temperature conditions. | |
| DT50 for photolysis in surface water | > 365 | d | | Permethrin is photolytically stable under environmentally relevant pH and temperature conditions. | |
| DT50 for degradation in soil | 106 (geometric mean) | d (at 12°C) | | - | |
| DT50 for degradation in air | 0.701 | d | | Assuming a 24h day and a concentration of hydroxyl radicals of 5\*105 mol/cm3 | |
| BCF in fish | 500-570 (measured) | l/kg | |  | |
| BCF in earthworms | 15 108 (estimated) | l/kg | |  | |
|  | | | | | |
| **DCVA** | | | | | |
| Molecular weight | 209.1 | | g/mol | |  |
| Organic carbon/water partition coefficient (Koc) | 93.2 | | l/kg | | - |
| DT50 for biodegradation in surface water | 26.0 and 49.8 (sum of DCVA isomers) (whole system) | | d | | - |
| DT50 for degradation in soil | 33.1 – 174.8 | | d | | - |
|  | | | | | |
| **PBA** | | | | | |
| Molecular weight | 214.2 | | g/mol | |  |
| Organic carbon/water partition coefficient (Koc) | 141.2 | | l/kg | | - |
| DT50 for biodegradation in surface water | 60.3 – 63.3 (whole system) | | d | | - |
| DT50 for degradation in soil | 1.7 – 2.5 | | d (at 12°C) | | - |

Based on the above data, fate and distribution of permethrin in the STP have been calculated with the model SimpleTreat v4.0.

|  |  |  |
| --- | --- | --- |
| **Calculated fate and distribution in the STP *[if STP is a relevant compartment]*** | | |
| Compartment | Percentage [%] | Remarks |
| Scenario 1 |
| Air | 9.50E-04 |  |
| Water | 10.05 |
| Sludge | 89.95 |
| Degraded in STP | 0 |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| BOX 22: FR Opinion  According to the Document IIB of the active substance, permethrin, the average of Kdoc is more suitable than the Freundlich value for a use in a linear exposure model such as EUSES.   |  |  |  |  | | --- | --- | --- | --- | | **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | | | Input | Value | Unit | Remarks | | Organic carbon/water partition coefficient (Koc) | 26 930 | l/kg |  | | **DCVA** | | | | | Organic carbon/water partition coefficient (Koc) | 188.53 | l/kg | - | | DT50 for degradation in soil | 175 | d (at 12°C) | - | | Percentage metabolite in soil | 11.3 | % |  | | Percentage metabolite in water | 62.6 | % |  | | **PBA** | | | | | Organic carbon/water partition coefficient (Koc) | 37.55 | l/kg | - | | DT50 for degradation in soil | 2.5 | d (at 12°C) | - | | Percentage metabolite in soil | 15 | % |  | | Percentage metabolite in water | 28.8 | % |  |   Fate and distribution of permethrin in the STP are calculated with the model SimpleTreat v3. The v4.0 version was not validated at the level European under Biocide regulation.   |  |  |  | | --- | --- | --- | | **Calculated fate and distribution in the STP *[if STP is a relevant compartment]*** | | | | Compartment | Percentage [%] | Remarks | | Scenario 1 | | Air | 0.0456 |  | | Water | 27.6 | | Sludge | 72.4 | | Degraded in STP | 0 | |

***Calculated PEC values***

*Scenario 1: Release through the borders of the films during the installation step – urban area*

Emissions in urban area are directed into the STP. STP are therefore the primary compartment for emissions and surface water bodies (including sediment) as well as the soil compartment (including groundwater) are secondary exposed compartments for residues *via* sewage treatment plant effluents and sewage sludge applications, respectively.

PEC values were calculated in EUSES v2.1.2, considering a local emission into the STP of 7.65E-05 kg/d, as calculated in section 2.2.8.2.1. Environmental data of the active substance permethrin presented in the above section were used to estimate the fate and behaviour of the substance in the environment and to calculate PEC in the potentially contaminated compartment (*i.e.* STP, freshwater including sediment and soil including groundwater).

No PEC values were derived for the relevant metabolite DCVA and PBA in the aquatic compartment, since toxicity results show that the parent compound is far more toxic and more persistent than these metabolites. These metabolites are therefore not considered as ecotoxicologically relevant.

Initial concentrations of DCVA and PBA in soil following application of sewage sludge to land are estimated as a worst-case assumption to a quantity equivalent to 100% of the parent. PEC soil (DCVA) and PEC soil (PBA) are therefore equal to PEC soil (permethrin) adjusted by a factor of 0.53 and 0.55 respectively to take into account the molecular weights of the compounds.

It should be noted that these PEC value represent extreme worst-case estimate of exposure to soil, since testing data indicate that DCVA and PBA are formed at a maximum of 11.3% and 15% of the parent permethrin respectively. Moreover, degradation of DCVA and PBA in soil has not been taken into account in these calculations.

No PECs in groundwater have been calculated for the metabolites DCVA and PBA for the scenario 1. Indeed, it is considered that the groundwater assessment performed for the scenario 3 covers all other scenarios since the PEC soil calculated in the scenario 3 are highest than the PECs calculated in the other scenarios.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values – scenario 1** | | | | | |
|  | **PECSTP** | **PEC freshwater** | **PEC freshwater sediment** | **PEC soil**  (agric. soil, over 30 days) | **PECGW** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] |
| Permethrin | 3.84E-06 | 3.46E-07 | 5.53E-04 | 1.28E-04 | 6.40E-05 |
| DCVA | Covered by the PECs calculated for the permethrin | | | 6.78E-05 | Covered by the PEC calculated for scenario 3 |
| PBA | 7.04E-05 |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| BOX 23: FR Opinion  *Scenario 1: Release through the borders of the films during the installation step – urban area (releases via the STP only)*  PEC values have been recalculated using Simple Treat v3 (the soil concentrations are calculated taking into account degradation of the substance over the time). Water concentrations and soil concentrations for DCVA and PBA are estimated in taking into account their percentage of formation in each of compartments.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values – scenario 1** | | | | | | |  | **PECSTP** | **PEC freshwater** | **PEC freshwater sediment** | **PEC soil**  (agric. soil, over 30 days) | **PECGW** | | [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] | | Permethrin | 2.32E-05 | 2.23E-06 | 1.31E-03 | 2.26E-04 | 3.08E-04 | | DCVA | NR | 7.45E-07 | 3.64E-06 | 1.60E-05 | 3.42E-03 | | PBA | NR | 3.51E-07 | 5.62E-07 | 2.22E-06 | 4.74E-04 |   NR: Not Relevant |

*Scenario 2: Release through the borders of the films during the installation step – rural area*

In this scenario, the soil is the primary receiving compartment. Then, leaching may lead to a contamination of the groundwater.

The local concentration into the soil is calculated according to the following equation:

PEC local soil = E local soil / (V soil \* RHO soil)

Where:

PEC local soil: Local PEC in soil (kg/kgwwt)

E local soil: Emission into the soil as calculated (7.65\*10-5 kg)

V soil: Volume of soil calculated considering a contamination up to 0.5 m from the house. This represents a soil volume of 13 m3.

RHO soil: Bulk density of wet soil (1700 kgwwt/m3)

As an indication for potential groundwater contamination, the concentration in pore water is calculated from the PEC local soil according to the following formula (equations 67 the GBPR (Guidance on the Biocidal Products Regulation – Volume IV Environment – Part B Risk assessment, active substances, 2015)). It has to be noted that this calculation is a worst-case assumption, neglecting transformation and dilution in deeper soil layers.

PEC local porewater = [PEC local soil \* RHO soil / K soil-water] / 1000

Where:

PEC local porewater: Local PEC in pore water (kg/l)

PEC local soil: Local PEC in soil (kg/kgwwt)

RHO soil: Bulk density of wet soil (1700 kg/m3)

K soil-water: Soil-water partitioning coefficient (2203 m3/m3) (calculated according to equation 24 of the GBPR).

DCVA and PBA soil concentrations are estimated as a worst-case assumption to a quantity equivalent to 100% of the parent. PEC soil (DCVA) and PEC soil (PBA) are therefore equal to PEC soil (permethrin) adjusted by a factor of 0.53 and 0.55 respectively to take into account the molecular weights of the compounds.

No PECs in groundwater have been calculated for the metabolites DCVA and PBA for the scenario 2. Indeed, it is considered that the groundwater assessment performed for the scenario 3 covered all other scenarios since the PEC soil calculated in the scenario 3 are highest than the PECs calculated in the other scenarios.

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| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values – scenario 2** | | | | | |
|  | **PEC STP** | **PEC freshwater** | **PEC freshwater sediment** | **PECinitial soil** | **PECGW** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] |
| Permethrin | NR | NR | NR | 3.46E-03 | 2.67E-03 |
| DCVA | NR | NR | NR | 1.83E-03 | Covered by the PEC calculated for scenario 3 |
| PBA | NR | NR | NR | 1.90E-03 |

NR: Not Relevant

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| BOX 24: FR Opinion  *Scenario 2: Release through the borders of the films during the installation step – rural area (releases to soil only)*  Ksoil-water for permethrin hasn’t been correctly calculated by the applicant. After recalculation with the right K soil-water of 808 m3/m3. Soil concentrations for DCVA and PBA are estimated in taking into account their percentage of formation in soil compartment.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values – scenario 2** | | | | | | |  | **PEC STP** | **PEC freshwater** | **PEC freshwater sediment** | **PECinitial soil** | **PECGW** | | [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] | | Permethrin | NR | NR | NR | 7.60E-03 | 1.60E-02 | | DCVA | NR | NR | NR | 4.59E-04 | **1.33E-01** | | PBA | NR | NR | NR | 6.24E-04 | **8.00E-01** |   NR: Not Relevant |

*Scenario 3: Release through the whole horizontal surface of the film during the service life*

In this scenario, the soil is the primary receiving compartment. Then, leaching may lead to a contamination of the groundwater.

PEC (permethrin) in soil is calculated considering emission values of 0.201 kg over 10 years and a volume of contaminated soil up to 0.5 m deep. This corresponds to a soil volume of 65.625 m3 under the whole horizontal surface.

The concentration is calculated taking into account degradation of the substance over the time.

As an indication for potential groundwater contamination, the concentration of permethrin in pore water is calculated from the PEC local soil according to the equation 67 the GBPR.

DCVA and PBA soil concentrations are estimated from the worst concentration of permethrin calculated in soil over 10 days without taking into account the degradation (equal to 1.80 mg/kgwwt). PEC soil (DCVA) and PEC soil (PBA) are therefore equal to the concentration of permethrin in soil after 10 years without degradation adjusted by a factor of 0.53 and 0.55 respectively to take into account the molecular weights of the compounds.

DCVA concentrations in groundwater have been calculated using the model FOCUS PELMO. The following input data were used:

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Value** | **Remarks** |
| **Name** | **permethrin** | **-** |
| Formula | C21H20Cl2O3 | - |
| Molecular mass | 391.29 g/mol | - |
| Vapour pressure | 2.155 E-06 at 20°C | - |
| Water solubility: | < 0.00495 mg/l at 20°C | - |
| Kfoc | 73441 l/kg | - |
| Freundlich sorption exponent (1/n) | 0.9 | - |
| DT50 soil | 106 days at 12°C | - |
| Q10 | 2.58 | - |
| Coefficient for uptake by plant | 0 | - |
| “Application rate” first year | 200.4 g/ha | Rate of permethrin in film: 1.53 g/m2 Number of treated houses: 1/ha Surface of treated houses: 131 m2  Rate of permethrin on all area: rate of permethrin \* nb of houses \* surface of treated houses = 1.53\*1\*131 = 200.4 g/ha. |
| “Application rate” other years | 1E-06 kg/ha | Default value |

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Value** | **Remarks** |
| **Name** | **DCVA** | **-** |
| Molecular mass | 209.1 g/mol | - |
| Vapour pressure | Data not available | - |
| Water solubility: | Data not available | - |
| Kfoc | 93.2 L/kg | - |
| Freundlich sorption exponent (1/n) | 0.9 | - |
| DT50 soil | 33.1 – 174.8 days at 12°C | - |
| Q10 | 2.58 | - |
| Coefficient for uptake by plant | 0 | - |
| Formation fraction from parent ffM | 0.113  Parent → DCVA → sink | DCVA is formed in the soil at a maximum of 11.3% of the parent permethrin |

The application parameters were as follows for potato applications in November. This represents a worst case because there is no interception in November on a bare soil.

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Value** | |
| FOCUS scenario | Potato | |
| Number of applications | 1 application year 1 (rate 0.2004 kg/ha) 0 application year 2-26 (rate 1e-6 kg/ha) | |
| Stage of application | Bare soil | |
| Rate of application | 1 \* 0.2004 kg a.s./ha | |
| Dates of application (FOCUS, 2000) | Châteaudun | 01/11 |
| Hamburg | 01/11 |
| Jokioinen | 01/11 |
| Kremsmünster | 01/11 |
| Okehampton | 01/11 |
| Piacenza | 01/11 |
| Porto | 01/11 |

|  |  |  |
| --- | --- | --- |
| **Parameter** | **Value** | |
|  | Sevilla | 01/11 |
| Thiva | 01/11 |
| Year | 1=> 0.2004 kg a.s./ha  2,…, 26 => 1 E-6 kg a.s./ha | |
| Application to | On the soil | |
| Crop interception factor | 0% | |
| Amount reaching soil | 1=> 0.2004 kg a.s./ha  2,…, 26 => 1 E-6 kg a.s./ha | |
| Application depth (m) | 0 m | |

As the metabolite PBA is less mobile in soil than DCVA with a Koc of 141.2 L/kg and degrades faster than DCVA with a DT50 of 2.5 days at 12°C, it is considered that the groundwater assessment performed for the DCVA covers the PBA.

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| **Summary table on calculated PEC values over 10 years – scenario 3** | | | | | |
|  | **PECSTP** | **PEC freshwater** | **PECfreshwater sediment** | **PECsoil** | **PECGW** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] |
| Permethrin | NR | NR | NR | 0.0723 | 0.0557 |
| DCVA | NR | NR | NR | 0.954 | max 0.01(1) |
| PBA | NR | NR | NR | 0.990 | Covered by the PEC calculated for DCVA |

‘(1) maximum concentration founded in the Okehampton scenario for the year 9 only.

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| BOX 25: FR Opinion  *Scenario 3: Release through the whole horizontal surface of the film during the service life (to soil only)*  Assuming 100% release to soil over the life span of the house (30 years) provides a worst-case assessment where none of the active substance is lost to other compartments than soil via wash-off.  Termiprotect is installed underneath the building, covering its whole footprint. The total area of Termiprotect installed underneath the house (AREA barrier) is therefore 131.25 m2 (17.5 m × 7.5 m). A soil volume of 65.625 m3 under the whole horizontal surface was considered.  The soil concentrations are calculated taking into account degradation of the substance over the time, to estimate concentrations in soil at the end of the assessment period, assuming continuous release over time (also corresponding to the steady state concentration). Soil concentrations for DCVA and PBA are estimated in taking into account their percentage of formation in soil compartment.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values over 30 years – scenario 3** | | | | | | |  | **PECSTP** | **PEC freshwater** | **PEC freshwater sediment** | **PEC soil** | **PECGW** | | [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] | | Permethrin | NR | | | 2.76E-02 | 5.81E-02 | | DCVA | 2.75E-03 | 7.99E-01 | | PBA | 5.35E-05 | 6.85E-02 |   Refinement of groundwater approach  Such parameters below have been revised.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Parameter** | **Value** | | | **Unit** | | **Name** | **permethrin** | **DCVA** | **PBA** | | Molecular weight | 391.29 | 209.1 | 214.22 | g/mol | | Water solubility (20°C) | 0.18\* | 1000\* | 1000\* | mg/l | | Vapour pressure (20°C) | 2.16E-06 | 0\* | 0\* | Pa | | Koc value | 26 930 | 188.53 | 37.55 | l/kg | | DT50 value (12°C) | 106 | 175 | 2.5 | d | | Freundlich exponent 1/n | 1 | 1 | 1 | - |   \*: Worst-case value  The FOCUS PEARL model has been used.  A more realistic, higher-tier assessment of the potential for groundwater contamination associated with soil applications of permethrin has been carried out using the simulation model FOCUS-PEARL 4.4.4.  The modelling simulates the leaching through the soil profile by release through the whole horizontal surface (scenario 3) and the vertical surface (scenario 4) of the film during the service life. This approach covers the leaching by release through the borders of the films during the service life (scenario 5).  Moreover, release through the borders of the films during the installation step is covered by this simulation given a much lower emission daily loading rate in soil from a single treated house at the installation step.  The leaching potential of permethrin and its metabolite (DCVA and PBA) was investigated by simulating applications of the parent compound to grassland. The grass/alfalfa FOCUS crop was used in the modelling. Simulations were performed for all nine FOCUS scenarios.  The total daily loading rate of permethrin in soil from a single treated house is calculated considering that the product is applied around the external perimeter and underneath a building.  Guidance provided by the Member States Competent Authorities regarding leaching assessments for wood preservatives (PT 8) assumes a default of 16 houses per hectare (Nhouse), (European Commission, undated). The corresponding application rate of permethrin to land can be calculated using the following equation:  Where:   |  |  |  |  | | --- | --- | --- | --- | | **Symbol** | **Value** | **Unit** | **Source** | | *AREA barrier scenario3* | 131.25 | [m2.house-1] | Input | | *AREA barrier scenario4* | 15 | | *TIME* | 10 950 | [d] | Input | | *Qleach 30 years* | 1 680 | [mg.m-2] | Calculated | | *Esoil, leach* | 22.43 | [mg.d-1.house-1] | Output | | *Nhouse* | 16 | house.ha-1 | Default | | *Emission days* | 365 | [d.yr-1] | Default | | *Appl rate* | 131.04 | [g.ha-1.yr-1] | Output |   Ten applications of permethrin were modelled each year during the simulation period (20 years), each at a rate of 13.1 g a.s.ha-1, with applications spaced evenly throughout the year. In accordance with FOCUS guidelines, applications were simulated to the soil surface. Canopy interception was set to 0% in the simulations.  **Relevant input variables in PEARL**   | **Parameter** | **Value** | | --- | --- | | ***Tab Scenario*** | | | Location | All 9 EU scenarios | | Crop Calendar | GRASS | | Irrigation | FOCUS standard irrigation scheme | | Tillage | No tillage | | Repeat interval for application events (years) | 1 | | Deposition | No deposition | | **Substances** | | | Name | Permethrin | | Parent | yes (checked) | | **Transformation scheme editor** | | | To substance | DCVA | | Fraction transformed | 0.113 | | To substance | PBA | | Fraction transformed | 0.15 | | **Absolute Application** | | | Application type | To the soil surface | | Date | 01-Jan  06-Feb  15-Mar  20-Apr  27-May  02-Jul  08-Aug  13-Sep  20-Oct  25-Nov | | Dosage (kg/ha) | 0.013 |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | RESULT\_TEXT | PERMETHRIN | DCVA | PBA | LOCATION | | Conc. closest to the 80th percentile (ug/l) | 0.000 | 0.070 | 0.000 | CHATEAUDUN | | Conc. closest to the 80th percentile (ug/l) | 0.000 | **0.111** | 0.000 | HAMBURG | | Conc. closest to the 80th percentile (ug/l) | 0.000 | 0.067 | 0.000 | JOKIOINEN | | Conc. closest to the 80th percentile (ug/l) | 0.000 | 0.072 | 0.000 | KREMSMUENSTER | | Conc. closest to the 80th percentile (ug/l) | 0.000 | 0.098 | 0.000 | OKEHAMPTON | | Conc. closest to the 80th percentile (ug/l) | 0.000 | **0.104** | 0.000 | PIACENZA | | Conc. closest to the 80th percentile (ug/l) | 0.000 | 0.074 | 0.000 | PORTO | | Conc. closest to the 80th percentile (ug/l) | 0.000 | 0.034 | 0.000 | SEVILLA | | Conc. closest to the 80th percentile (ug/l) | 0.000 | 0.058 | 0.000 | THIVA | |

*Scenario 4: Release through the vertical surface of the films at the periphery during the service life*

In this scenario, the soil is the primary receiving compartment. Then, leaching may lead to a contamination of the groundwater.

PEC (permethrin) in soil is calculated considering emission values of 0.0230 kg over 10 years and a volume of contaminated soil up to 0.5 m wide from the sides of house and up to 0.8 m depth from the house (0.3 m corresponding to the height of the film and 0.5 m corresponding to the default value for migration of substance in soil). This corresponds to a soil volume of 20 m3 adjacent to the vertical surface.

The concentration is calculated taking into account degradation of the substance over the time, using the model described in section 3.4.1.2 of the revised ESD for PT08 (equation 3.8).

As an indication for potential groundwater contamination, the concentration of permethrin in pore water is calculated from the PEC local soil according to the equation 67 the GBPR.

DCVA and PBA soil concentrations are estimated from the worst concentration of permethrin calculated in soil over 10 days without taking into account the degradation (equal to 0.675 mg/kgwwt). PEC soil (DCVA) and PEC soil (PBA) are therefore equal to the concentration of permethrin in soil after 10 years without degradation adjusted by a factor of 0.53 and 0.55 respectively to take into account the molecular weights of the compounds.

No PECs in groundwater have been calculated for the metabolites DCVA and PBA for the scenario 4. Indeed, it is considered that the groundwater assessment performed for the scenario 3 covered all other scenarios since the PEC soil calculated in the scenario 3 are highest than the PECs calculated in the other scenarios.

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| **Summary table on calculated PEC values over 10 years – scenario 4** | | | | | |
|  | **PECSTP** | **PEC freshwater** | **PEC freshwater sediment** | **PEC soil** | **PECGW** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] |
| Permethrin | NR | NR | NR | 0.027 | 0.0209 |
| DCVA | NR | NR | NR | 0.358 | Covered by the PEC calculated for scenario 3 |
| PBA | NR | NR | NR | 0.371 |

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| BOX 26: FR Opinion  *Scenario 4: Release through the vertical surface of the films at the periphery during the service life*  Assuming 100% release to soil over the life span of the house (30 years) provides a worst-case assessment where none of the active substance is lost to other compartments than soil via wash-off.  The soil concentrations are calculated taking into account degradation of the substance over the time, to estimate concentrations in soil at the end of the assessment period, assuming continuous release over time (corresponding to the steady state concentration). Soil concentrations for DCVA and PBA are estimated in taking into account their percentage of formation in soil compartment. A soil volume of 20 m3 was considered.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values – scenario 4** | | | | | | |  | **PECSTP** | **PEC freshwater** | **PEC freshwater sediment** | **PEC soil** | **PECGW** | | [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] | | Permethrin | NR | NR | NR | 1.04E-02 | 2.18E-02 | | DCVA | NR | NR | NR | 1.03E-03 | **3.00E-01** | | PBA | NR | NR | NR | 2.00E-05 | 2.57E-02 | |

*Scenario 5: Release through the borders of the films during the service life*

In this scenario, the soil is the primary receiving compartment. Then, leaching may lead to a contamination of the groundwater.

PEC in soil is calculated considering emission value of 7.65E-03 kg over 10 years and a volume of contaminated soil up to 0.5 m wide and depth from the house. This corresponds to a peripheral soil volume of 13 m3 (default value from the ESD).

The concentration is calculated taking into account degradation of the substance over the time, using the model described in section 3.4.1.2 of the revised ESD for PT08 (equations 3.8).

As an indication for potential groundwater contamination, the concentration of permethrin in pore water is calculated from the PEC local soil according to the equation 67 the GBPR.

DCVA and PBA soil concentrations are estimated from the concentration of permethrin calculated in soil over 10 days without taking into account the degradation (equal to 0.346 mg/kgwwt). PEC soil (DCVA) and PEC soil (PBA) are therefore equal to the concentration of permethrin in soil after 10 years without degradation adjusted by a factor of 0.53 and 0.55 respectively to take into account the molecular weights of the compounds.

No PECs in groundwater have been calculated for the metabolites DCVA and PBA for the scenario 5. Indeed, it is considered that the groundwater assessment performed for the scenario 3 covered all other scenarios since the PEC soil calculated in the scenario 3 are highest than the PECs calculated in the other scenarios.

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| **Summary table on calculated PEC values over 10 years – scenario 5** | | | | | |
|  | **PECSTP** | **PEC freshwater** | **PEC freshwater sediment** | **PECsoil** | **PECGW** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] |
| Permethrin | NR | NR | NR | 0.0139 | 0.0107 |
| DCVA | NR | NR | NR | 0.183 | Covered by the PEC calculated for scenario 3 |
| PBA | NR | NR | NR | 0.190 |

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| BOX 27: FR Opinion  *Scenario 5: Release through the borders of the films during the service life*  Assuming 100% release to soil over the life span of the house (30 years) provides a worst-case assessment where none of the active substance is lost to other compartments than soil via wash-off.  The soil concentrations are calculated taking into account degradation of the substance over the time, to estimate concentrations in soil at the end of the assessment period, assuming continuous release over time (corresponding to the steady state concentration). Soil concentrations for DCVA and PBA are estimated in taking into account their percentage of formation in soil compartment. A soil volume of 13 m3 was considered.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values – scenario 5** | | | | | | |  | **PECSTP** | **PEC freshwater** | **PEC freshwater sediment** | **PEC soil** | **PECGW** | | [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] | | Permethrin | NR | NR | NR | 5.31E-03 | 1.12E-02 | | DCVA | NR | NR | NR | 5.29E-04 | **1.54E-01** | | PBA | NR | NR | NR | 1.03E-05 | 1.32E-02 | |

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning*, i.e.* the direct consumption of the product by birds or mammals is not considered as relevant for the products of the TERMIPROTECT family. Indeed, primary poisoning may mainly occur when a product is applied together with a food attractant or is applied as a granular formulation, which is not the case of the products of the TERMIPROTECT family.

Secondary poisoning

As permethrin has a log Kow > 3 (log Kow = 4.67) and a BCF > 100 (BCF in fish = 570 L/kg and BCF in earthworm = 15 108 L/kg), secondary poisoning may occur via the aquatic food chain and via the terrestrial food chain. The concentration of permethrin in food (i.e. in fish and in earthworm) of fish-eating and worm-eating predators (birds or mammals) has been calculated in EUSES v2.1.2.

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| **Summary table on estimated theoretical exposition (ETE)** | | |
|  | **Concentration in fish** | **Concentration in earthworm** |
| [mg/kg wet fish] | [mg/kg wet earthworm] |
| Scenario 1 | 8.11E-06 | 4.38E-04 |
| Scenario 2 | Not relevant as no contamination of the aquatic compartment is foreseen | 0.0183 |
| Scenario 3 | 0.382 |
| Scenario 4 | 0.143 |
| Scenario 5 | 0.0735 |

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| BOX 28: FR Opinion   |  |  |  | | --- | --- | --- | | **Summary table on estimated theoretical exposition (ETE)** | | | |  | **Concentration in fish** | **Concentration in earthworm** | | [mg/kg wet fish] | [mg/kg wet earthworm] | | Scenario 1 | 6.35E-04 | 2.10E-03 | | Scenario 2 | Not relevant as no contamination of the aquatic compartment is foreseen | 0.1085 | | Scenario 3 | 3.95E-01 | | Scenario 4 | 1.48E-01 | | Scenario 5 | 7.60E-02 | |

#### **Risk characterisation**

***Atmosphere***

Conclusion:According to the specificities and the mode of application of the TERMIPROTECT films, exposure of atmosphere is not expected. Moreover, the volatilisation of permethrin is considered to be negligible based on the vapour pressure (2.155E-06 Pa at 20°C) and Henry constant (4.6E-03 to 4.5E-02 Pa.m3/mol). The fugacity model has shown a distribution of 0.0995% of permethrin in air. In addition, as permethrin is rapidly degraded in the air (DT50= 0.701 day), it would not be transported over large distances in the atmosphere.

Therefore, the risk of contamination of air can be considered as negligible when using the products of the TERMIPROTECT family according to the label recommendations.

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| BOX 29: FR Opinion  In agreement with the conclusions. |

***Sewage treatment plant (STP)***

The STP may be contaminated after the application of the films in urban area. PEC in STP is compared to the PNEC STP of the permethrin.

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| **Summary table on calculated PEC/PNEC values for the STP** | | | |
|  | PNECSTP [mg/l] | PECSTP [mg/l] | PEC/PNECSTP |
| Scenario 1 | 4.95E-03 | 3.84E-06 | 7.77E-04 |

The PEC/PNEC ratio is below the trigger value of 1. Then, risk for STP microorganisms is acceptable when using the products of the TERMIPROTECT family according to the label recommendations.

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| BOX 30: FR Opinion  After recalculation,   |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC/PNEC values for the STP** | | | |  | PNECSTP [mg/l] | PEC/PNECSTP | | Scenario 1 | 4.95E-03 | 4.68E-03 |   Conclusion: Risk for STP microorganisms is acceptable. |

***Aquatic compartment***

The aquatic compartment may be contaminated indirectly *via* STP effluent after the application of the films in urban area. PECs in surface water and sediment are compared to the PNEC surface water and PNEC sediment of the permethrin.

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| **Summary table on calculated PEC/PNEC values for the aquatic compartment** | | | |
| Freshwater | PNEC [mg/l] | PEC [mg/l] | PEC/PNEC |
| Scenario 1 | 4.7E-07 | 3.46E-07 | 0.737 |
| Freshwater sediment | PNEC [mg/kgwwt] | PEC [mg/kgwwt] | PEC/PNEC |
| Scenario 1 | 2.17E-04 | 5.53E-04 | **2.55** |

The PEC/PNEC ratio for the freshwater is below the trigger value of 1. Then, risk for freshwater organisms is acceptable when using the products of the Termiprotect family according to the label recommendations.

The PEC/PNEC ratio for the freshwater sediment is above the trigger value of 1, indicating a risk for the sediment dwelling organisms. However, because there is no available scenario for the assessment of such films, the worst conservative assumptions have been considered. In particular, the assumption that 100% of the emissions are directed to the STP in urban area is not realistic. According to the ESD for PT18, it is considered in urban area that “*the ground surface receiving the emissions will likely consist of non-permeable substrates e.g. paved, concrete, or asphalt ground*”. However, all preconstruction sites where anti-termite films are used are always situated in areas made of sand, embankment or rubble, even when localised in urban area. This is also the case for the products TERMIPROTECT. The run-off of the permethrin to the sewer system is therefore actually negligible when permethrin is released into sand, embankment or rubble. Moreover, it has been considered in this assessment as a very conservative assumption that 100% of the quantity of substance contained in 1 mm of depth of film is released *via* the borders. Based on the results of the efficacy studies, where a laboratory test has demonstrated that after a total immersion of the film in water after at least 79 hours, it is still efficient (see Section S6.7\_02) and also that the film is still efficient in a field efficacy test after 4 years and 4 months of use in field conditions (see Section S6.7\_12), it can be considered that the release of permethrin out of the film is far below the 100% value considered in the risk assessment.

Therefore, even if the RCR for sediment is above 1, it is considered that the risk for sediment dwelling organisms is acceptable when using the products of the TERMIPROTECT family according to the label recommendations.

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| BOX 31: FR Opinion   |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC/PNEC values for the aquatic compartment** | | | | Permethrin | | | | Freshwater | PNEC [mg/l] | PEC/PNEC | | Scenario 1 | 4.70E-07 | **4.74** | | Freshwater sediment | PNEC [mg/kgwwt] | PEC/PNEC | | Scenario 1 | 2.17E-04 | **6.02** | | DCVA | | | | Freshwater | PNEC [mg/l] | PEC/PNEC | | Scenario 1 | 1.50E-02 | 4.97E-05 | | Freshwater sediment | PNEC [mg/kg wwt] | PEC/PNEC | | Scenario 1 | 1.20E-02 | 3.03E-04 | | PBA | | | | Freshwater | PNEC [mg/l] | PEC/PNEC | | Scenario 1 | 1.00E-02 | 3.51E-05 | | Freshwater sediment | PNEC [mg/kg wwt] | PEC/PNEC | | Scenario 1 | 9.00E-03 | 6.24E-05 |   Conclusion: The PEC/PNEC ratio for the freshwater and sediment are above the trigger value of 1 for permethrin, indicating a risk for the freshwater and sediment organisms during the installation step of the film when releases are directed to an STP (urban area).  The exposure assessment has been conducted considering only the releases via the borders of the films (release through the whole horizontal surface or the vertical surface of the films has not been taking into account). Even if the active substance is protected by an upper layer of PE film (which presents an impermeable barrier to rainfall), no leaching studies were provided to confirm that the treated film does not lead to permethrin emission when exposed to water.  Risk mitigation measures are necessary to limit the emission to STP during the installation phase of the TERMIPROTECT product. |

***Terrestrial compartment***

The soil may be contaminated indirectly *via* sewage sludge application after the application of the films in urban area. After the application of the films in rural area and during the service life of the films, the soil may also be directly contaminated.

PECs in soil calculated are compared to the PNEC soil of the permethrin.

**Summary table on calculated PEC/PNEC values for the terrestrial compartment**

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| **Summary table on calculated PEC/PNEC values for the soil** | | | |
|  | PNEC soil [mg/kgwwt] | PEC soil [mg/kgwwt] | PEC/PNEC soil |
| **Permethrin** | | | |
| Scenario 1 | 0.0876 | 1.28E-04 | 1.46E-03 |
| Scenario 2 | 3.46E-03 | 0.0395 |
| Scenario 3 | 0.0723 | 0.825 |
| Scenario 4 | 0.0271 | 0.309 |
| Scenario 5 | 0.0139 | 0.159 |
| **DCVA** | | | |
| Scenario 1 | 4.6 | 6.78E-05 | 1.47E-05 |
| Scenario 2 | 1.83E-03 | 3.99E-04 |
| Scenario 3 | 0.954 | 0.207 |
| Scenario 4 | 0.358 | 0.0778 |
| Scenario 5 | 0.183 | 0.0398 |
| **PBA** | | | |
| Scenario 1 | 1.44 | 7.04E-05 | 4.89E-05 |
| Scenario 2 | 1.90E-03 | 1.32E-03 |
| Scenario 3 | 0.990 | 0.688 |
| Scenario 4 | 0.371 | 0.258 |
| Scenario 5 | 0.190 | 0.132 |

The PEC/PNEC ratios for the soil are below the trigger value of 1 for the permethrin and its metabolites DCVA and PBA in all scenarios. Therefore, the risk for the soil is acceptable when using the products of the TERMIPROTECT family according to the label recommendations.

It is highlighted that the risk is acceptable even with the worst conservative assumptions considered because there is no available scenario for the assessment of such films.

Moreover, it is pointed out that the films are never in direct contact with the natural soil but are in contact with sand, embankment or rubble. The contamination of the natural soil is actually negligible.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| BOX 32: FR Opinion  The table below presents the PEC/PNEC ratios after recalculation.   |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC/PNEC values for the soil** | | | |  | PNEC soil [mg/kgwwt] | RCR | | **Permethrin** | | | | Scenario 1 | 0.0876 | 2.58E-03 | | Scenario 2 | 8.68E-02 | | Scenario 3 | 0.315 | | Scenario 4 | 0.118 | | Scenario 5 | 0.061 | | **DCVA** | | | | Scenario 1 | 4.6 | 3.48E-06 | | Scenario 2 | 9.98E-05 | | Scenario 3 | 5.98E-04 | | Scenario 4 | 2.24E-04 | | Scenario 5 | 1.15E-04 | | **PBA** | | | | Scenario 1 | 1.44 | 1.54E-06 | | Scenario 2 | 4.34E-04 | | Scenario 3 | 3.71E-05 | | Scenario 4 | 1.39E-05 | | Scenario 5 | 7.14E-06 |   Conclusion: Risks for the soil are acceptable when using the products of the TERMIPROTECT family according to the label recommendations, for the installation phase of the film as well as during its service-life. |

***Groundwater***

The groundwater may be contaminated following leaching of permethrin, DCVA and PBA from the soil. The PECgroundwater are compared to the threshold value of 0.1 µg/L, the maximum permissible concentration laid down by Directive 98/83/EC.

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values for the groundwater** | | | |
|  | Triggered value [µg/l] | PEC groundwater [µg/l] | RCR |
| **Permethrin** | | | |
| Scenario 1 | 0.1 | 6.4E-05 | 6.4E-04 |
| Scenario 2 | 2.67E-03 | 0.0267 |
| Scenario 3 | 0.0557 | 0.557 |
| Scenario 4 | 0.0209 | 0.209 |
| Scenario 5 | 0.0107 | 0.107 |
| **DCVA** | | | |
| Scenario 1 | 0.1 | Covered by the PEC calculated for scenario 3 | < 1 |
| Scenario 2 | Covered by the PEC calculated for scenario 3 | < 1 |
| Scenario 3 | max 0.01 | max 0.1 |
| Scenario 4 | Covered by the PEC calculated for scenario 3 | < 1 |
| Scenario 5 | Covered by the PEC calculated for scenario 3 | < 1 |
| **PBA** | | | |
| Scenario 1 | 0.1 | Covered by the PEC for DCVA calculated for scenario 3 | < 1 |
| Scenario 2 | < 1 |
| Scenario 3 | < 1 |
| Scenario 4 | < 1 |
| Scenario 5 | < 1 |

All calculated PECgroundwater are below the threshold value of 0.1 µg/l, the maximum permissible concentration laid down by Directive 98/83/EC.

It can therefore be concluded that permethrin and its metabolites DCVA and PBA are not expected to reach groundwater in unacceptable amounts when using the products of the TERMIPROTECT family according to the label recommendations.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| BOX 33: FR Opinion   |  |  |  |  | | --- | --- | --- | --- | | **Summary table on calculated PEC/PNEC values for the groundwater** | | | | |  | Triggered value [µg/l] | PEC groundwater [µg/l] | | | **Permethrin** | | | | | Scenario 1 | 0.1 | 3.08E-04 | | | Scenario 2 | 1.60E-02 | | | Scenario 3 | 5.81E-02 | | | Scenario 4 | 2.18E-02 | | | Scenario 5 | 1.12E-02 | | | **DCVA** | | | | | Scenario 1 | 0.1 | 3.42E-03 | | | Scenario 2 | **1.33E-01** | Covered by the PEC calculated for scenario 3 | | Scenario 3 | **7.99E-01** | **max 0.111\*** | | Scenario 4 | **3.00E-01** | Covered by the PEC calculated for scenario 3 | | Scenario 5 | **1.54E-01** | Covered by the PEC calculated for scenario 3 | | **PBA** | | | | | Scenario 1 | 0.1 | 4.74E-04 | | | Scenario 2 | **8.00E-01** | <0.0000\*  COVERED BY THE PEC CALCULATED FOR SCENARIO 3 | | Scenario 3 | 6.85E-02 | | | Scenario 4 | 2.57E-02 | | | Scenario 5 | 1.32E-02 | |   \*FOCUS PEARL combining scenario 3 and 4, covering scenario 2 and scenario 5.  Conclusion:  Risks for the groundwater are acceptable for the installation step.  Concerning the service life, concentration in groundwater for DCVA is lightly above the limit value of 0.1 µg.l-1 for the Hamburg scenario and the Piacenza scenario (FOCUS model).  Several input parameters influence the leaching of a substance but without sensitivity analysis, it is difficult to determine key parameters for DCVA leaching. Nevertheless, climate conditions can be considered as an influent parameter in overestimating the leaching of the DCVA. Soil in contact with TERMIPROTECT products and adjacent soil are partially protected of the climatic conditions by the house. Consequently and light of the modelling results where only two scenarios show a limit value lightly above 0.1 µg.l-1, risk can be considered as acceptable for groundwater. |

***Primary and secondary poisoning***

Primary poisoning

Primary poisoning*, i.e.* the direct consumption of the product by birds or mammals is not considered as relevant for the products of the TERMIPROTECT family. Indeed, primary poisoning may mainly occur when a product is applied together with food attractant or is applied as granular formulation, which is not the case of the products of the TERMIPROTECT family.

Therefore no risk is foreseen for primary poisoning when using the products according to the label recommendations.

Secondary poisoning

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on secondary poisoning** | | | |
| Scenario | PEC oral predator  (mg/kg wet fish / earthworm) | PEC/PNECbirds  (PNEC oral,bird ≥ 16.7 mg/kg food) | PEC/PNECmammals  (PNECoral,small mammal = 120 mg/kg food) |
| **Secondary poisoning *via* the aquatic food chain** | | | |
| Scenario 1 | 8.11E-06 | 4.86E-07 | 6.76E-08 |
| **Secondary poisoning *via* the terrestrial food chain** | | | |
| Scenario 1 | 4.38E-04 | 2.62E-05 | 3.65E-06 |
| Scenario 2 | 0.0183 | 1.09E-03 | 1.53E-04 |
| Scenario 3 | 0.382 | 0.0229 | 3.18E-03 |
| Scenario 4 | 0.143 | 8.56E-03 | 1.19E-03 |
| Scenario 5 | 0.0735 | 4.40E-03 | 6.125E-04 |

All PEC/PNEC ratios are below 1, therefore the risk of secondary poisoning is acceptable when using the products of the TERMIPROTECT family according to the label recommendations.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| BOX 34: FR Opinion  After recalculation,   |  |  |  | | --- | --- | --- | | **Summary table on secondary poisoning** | | | | Scenario | PEC/PNECbirds  (PNEC oral, bird ≥ 16.7 mg/kg food) | PEC/PNECmammals  (PNEC oral, small mammal = 120 mg/kg food) | | **Secondary poisoning *via* the aquatic food chain** | | | | Scenario 1 | 3.80E-05 | 5.29E-06 | | **Secondary poisoning *via* the terrestrial food chain** | | | | Scenario 1 | 1.26E-04 | 1.75E-05 | | Scenario 2 | 6.50E-03 | 9.04E-04 | | Scenario 3 | 2.37E-02 | 3.29E-03 | | Scenario 4 | 8.86E-03 | 1.23E-03 | | Scenario 5 | 4.55E-03 | 6.33E-04 |   Conclusion: Risk of secondary poisoning is acceptable when using the products of the TERMIPROTECT family according to the label recommendations. |

***Mixture toxicity***

The mixture toxicity assessment is performed according to the Transitional guidance on mixture toxicity assessment for the environment of May 2014.

*Screening step*

Screening Step 1: Identification of the concerned environmental compartments

In the scenario 1, emissions in urban area are directed into the STP. STPs are therefore the primary compartment for emissions and surface water bodies (including sediment) as well as the soil compartment (including groundwater) are secondary exposed compartments for residues *via* sewage treatment plant effluents and sewage sludge applications, respectively.

In scenarios 2, 3 and 4, the soil is the primary receiving compartment. Then, leaching may lead to a contamination of the groundwater.

Screening Step 2: Identification of relevant substances

According to the detailed composition given in Section 2 of the IUCLID file and in the confidential annex in Section 13 of the IUCLID file, the products of the TERMIPROTECT family do not contain any substances of concern or substances classified for the environment and present at a concentration leading the product to be classified.

|  |  |  |
| --- | --- | --- |
| **Summary of relative toxic units** | | |
|  | Relevant component 1  *(active substance)* | Relevant Component n |
| Content in the product [w/w %] | *0.005* | *0.04* |
| Concerned environmental compartment 1 *(Aquatic compartment)* | | |
| Organism 1 *(fish)* | *99.16* | *0.84* |
| Organism 2 *(daphnia)* | *99.58* | *0.42* |
| Organism n *(algae)* | *99.95* | *0.05* |
| Concerned environmental compartment n*(e.g. soil)* | | |
| Organism 1 *(earthworm)* | *13.8* | *86.2* |

Screening Step 3: Screen on synergistic interactions

There are no indications for synergistic effects for the product or its constituents in the literature.

|  |  |
| --- | --- |
| **Screening step** | |
| Significant exposure of environmental compartments? | Yes |
| Number of relevant substances >1? | No |
| Indication for synergistic effects for the product or its constituents in the literature? | No |

Conclusion: the environmental risk assessment of the products of the TERMIPROTECT family is based on the active substance only and no mixture assessment is deemed necessary.

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| BOX 35: FR Opinion  In agreement with the conclusions of the registrant. |

***Aggregated exposure (combined for relevant emmission sources)***

An assessment of aggregated exposure is judged not relevant for the products of the Termiprotect family based on the decision scheme developed by UBA (see Figure 1).

Indeed, as emissions into the environment are negligible, there is no need for estimation of aggregated exposure.



*Figure 1: Decision tree on the need for estimation of aggregated exposure*

|  |
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| **Overall conclusion on the risk assessment for the environment of the product** |
| The products of the TERMIPROTECT family are ready-to-use anti-termites physico-chemical barriers used in pre-construction, for protection of buildings.  After the application of the films in urban area, the STP may be directly contaminated. The aquatic and terrestrial compartments are indirectly contaminated following STP effluent or sewage sludge application respectively. After the application of the films in rural area and during the service life of the films, the soil is directly contaminated and the groundwaters are secondarily exposed after leaching.  Because there is no available scenario for the assessment of such products, the worst conservative assumptions have been considered for the calculations of emissions and PECs.  It is concluded that the risk for all compartments (air, STP, water, sediment, soil and groundwater) and the risk of primary and secondary poisoning are considered acceptable for the active substance and its relevant metabolites when using the products of the TERMIPROTECT family according to the label recommendations.  According to the screening step, there is no need to perform a mixture toxicity assessment. The aggregated assessment can't be performed because there is no guidance available.  Overall, the risk for the environment of the products of the TERMIPROTECT family is acceptable when using the product according to the label recommendations. |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| BOX 36: FR Opinion  **Overall conclusion on the risk assessment for the environment of the product**  Scenario [1]: Release through the borders of the films during the installation step – Urban area  Scenario [2]: Release through the borders of the films during the installation step - Rural Area  Scenario [3]: Release through the whole horizontal surface of the film during the service life  Scenario [4]: Release through the vertical surface of the films at the periphery during the service life  Scenario [5]: Release through the borders of the films during the service life   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Phase | Type of application | STP | Surface water (*Via* STP) | Sediment (*Via* STP) | Soil | | Groundwater | | Secondary Poisoning | | Direct Release | *Via* STP | Direct Release | *Via* STP | | Installation | Scenario [1] | Acceptable | **Unacceptable** | **Unacceptable** | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | | Scenario [2] | n.r. | n.r. | n.r. | Acceptable | n.r. | Acceptable | n.r. | Acceptable | | Service life | Scenario [3] | n.r. | n.r. | n.r. | Acceptable | n.r. | Acceptable | n.r. | Acceptable | | Scenario [4] | | Scenario [5] |   **Conclusion on risk assessment for the environment**   * Construction step:   For the exposure of soil, groundwater, STP following direct or indirect releases to the environment, all calculated RCR values were < 1, indicating an acceptable risk to these environmental compartments.  For the exposure of surface water and sediment following indirect releases via the STP, RCR values were > 1, indicating unacceptable risk to these environmental compartments. A risk mitigation measure is proposed to prevent the exposure of the aquatic compartment when a release to the STP is foreseen: ***During the application step of the film, if the treated zone is connected to a rainwater collection system or sewer, do not expose the film to rain***. The application of this risk mitigation measure preventing emissions to the STP would achieve acceptable risks.   * Service life:   For the exposure of STP, surface water, sediment, soil and groundwater, all calculated RCR values were < 1, indicating an acceptable risk to the environmental compartments. |

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

*See Summary of Product Characteristics (SPC)*

### Assessment of a combination of biocidal products

Not relevant, as the products of the TERMIPROTECT family are not intended to be used with other biocidal products.

### Comparative assessment

*Not relevant.*

# Annexes[[11]](#footnote-11)

## List of studies for the biocidal product family

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** | **Date of first submission** |
| Raphalen E. | 2012 | Physico-chemical tests on a PE anti termite film (X6232): Validation of analytical method and chemical analysis of active ingredient declared in the test item. Stability test according to NF X 41-580-10: 2006 (40°C during 8 weeks)  FCBA Report No. 402/12/033F/abc-e  GLP: Yes | Yes | DYRUP SAS | 2012-08-01 |
| Yrieix C. | 2016 | Certificate of analysis COA-402/15/1169F/ab-e | Yes | DYRUP SAS – PPG industries |  |
| Legay S. | 2016 | Certificate of analysis COA-402/15/1169F/1/c/T6M-e | Yes | DYRUP SAS – PPG industries |  |
| Legay S | 2017 | Certificate of analysis COA-402/15/1169F/1/c/T12M-e | Yes | DYRUP SAS – PPG industries |  |
| Detrimont H. | 2016 | Physico-chemical tests on a anti termite film (X6232-001): technical characteristics of the test item and chemical analysis of declared active substance after a specificity checking  FCBA report No.402/15/1169F/ab-e  GLP: Yes | Yes | DYRUP SAS – PPG industries |  |
| Detrimont H. | 2016 | Physico-chemical tests on a anti termite film with bituminous layer X6240: technical characteristics of the test item and content declared active substance in the test item after method validation according to SANCO/3030/99 rev.4  FCBA report No. 402/16/1014F/ab-e  GLP: Yes | Yes | DYRUP SAS – PPG industries |  |
| Detrimont H. | 2018 | Storage stability during 1 year at ambient temperature according to Technical Monograph No.17 (Croplife) on the anti-termites film with bitumous layer X6240  FCBA report No. 402/16/1014F/c-e  GLP: Yes | Yes | DYRUP SAS – PPG industries |  |
| Paulmier I. | 2013 | X6232 – EFFICACITE ANTI-TERMITE D'UN MATERIAU selon XPX 41-550 après 15 jours d'exposition au rayonnement solaire  FCBA Report No. 401/12/033F/1/h  GLP: No | Yes | DYRUP SAS | 2013-05-31 |
| Paulmier I. | 2013 | X6232 – EFFICACITE ANTI-TERMITE D'UN MATERIAU selon XPX 41-550 après 3 mois d'exposition au rayonnement solaire  FCBA Report No. 401/12/033F/1/i  GLP: No | Yes | DYRUP SAS | 2013-07-03 |
| Brunet C. and Paulmier I. | 2012 | X6232 Efficacité anti-termites d'une barrière physico-chimique selon XP X 41-550 sans vieillissement. | Yes | PPG AC |  |
| Brunet C. and Paulmier I. | 2012 | X6232 Efficacité anti-termites d'une barrière physico-chimique selon XP X 41-550 après immersion | Yes | PPG AC |  |
| Brunet C. and Paulmier I. | 2013 | X6232 – EFFICACITE ANTI-TERMITE D'UN MATERIAU selon XPX 41-550 après 15 jours d'exposition au rayonnement solaire | Yes | PPG AC |  |
| Brunet C. and Paulmier I. | 2013 | X6232 – EFFICACITE ANTI-TERMITE D'UN MATERIAU selon XPX 41-550 après 3 mois d'exposition au rayonnement solaire | Yes | PPG AC |  |
| Ansard D. and Paulmier I. | 2012 | X6232 Efficacité anti-termites d'une barrière physico-chimique selon XP X 41-550 après exposition en milieu alcalin. | Yes | PPG AC |  |
| Brunet C. and Paulmier I. | 2013 | X6232 Efficacité anti-termites d'un matériau selon XP X 41-550 après exposition au gel | Yes | PPG AC |  |
| Brunet C. and Paulmier I. | 2012 - 2016 | X6232 Efficacité anti-termites d'une barrière physico-chimique, Essai de terrain Oléron, installation | Yes | PPG AC |  |

## Output tables from exposure assessment tools



## New information on the active substance

Not relevant

## Residue behaviour

Not relevant

## Summaries of the efficacy studies (B.5.10.1-xx)[[12]](#footnote-12)

Not relevant (IUCLID file available).

## Confidential annex

See separate confidential file.

1. PT18 and PT 19, Guidance to replace part of appendices to chapter 7 (page 187 to 200) from TNsG on Product Evaluation (2012) [↑](#footnote-ref-1)
2. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-2)
3. XP X 41-550: Termites – Determination of the effectiveness against termites of products or material used as barrier designed for ground and/or wall – Laboratory method. [↑](#footnote-ref-3)
4. XP ENV 1250-2: wood preservatives – Methods for measuring losses of active ingredients and other preservative ingredients from treated timber – Part 2: Laboratory method for obtaining samples for analysis to measure losses by leaching into water or synthetic see water. [↑](#footnote-ref-4)
5. CTBA BIO-E-016: CTBA test protocol on exposure of anti-termite barrier to sunlight. [↑](#footnote-ref-5)
6. CTBA BIO-E-007: CTBA test protocol on wear on an anti-termite barrier by the action of an alkalin environment. [↑](#footnote-ref-6)
7. X41-580-3: Wood preservatives - Physicochemical testing Part 3: Resistance to freezing [↑](#footnote-ref-7)
8. CTBA BIO-E-008: CTBA test method - Assessment of the efficacy of a physico-chemical anti-termite barrier – Field test. [↑](#footnote-ref-8)
9. ESD n°18 “Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses”, OECD n°18 (2008) [↑](#footnote-ref-9)
10. ESD n°8 “Emission scenario document for wood preservatives”, OECD n°2 (2013) [↑](#footnote-ref-10)
11. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-11)
12. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-12)