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

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR MINOR CHANGE OF NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



TERMIPROTECT FILM ANTI-TERMITES NEW

Product type(s) 18

Permethrin as included in the Union list of approved active substances

Case Number NA-APP in R4BP: BC-PP023938-11

Case Number NA-MIC in R4BP: BC-GA048580-60

Evaluating Competent Authority: France

Date: 20 July 2018

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**Note to the reader:**

This consolidated PAR for the minor change of the product authorisation TERMIPROTECT FILM ANTI-TERMITES NEW is based on the PAR of the first authorisation, in which all addenda have been included.

In part 2.1 of this consolidated PAR, the summary of product characteristics is pointed out and corresponds to the decision for the major/minor change application.

In part 2.2 of this consolidated PAR, each section contains the initial assessment and the subsequent successive assessments (major change and post authorisation data), the assessments related to the minor change of the product are at the end of each section and are highlighted in grey.

* **Minor change 2019**

Change claimed in the frame of the minor change application is a change of composition: modification of pigments.

**History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | *FR* | BC-PP023938-11 | 21/08/18 | Initial assessment : TERMIFILM |
| NA-BBS | *FR* | BC-HH043902-46 | 02/01/19 | Same product : TERMIPROTECT FILM ANTI-TERMITES NEW |
| NA-MIC | *FR* | BC-GA048580-60 | 07/06/2019 | Minor change application : change of pigments |

# CONCLUSION

The product TERMIFILM is a Low Density PolyEthylene (LDPE) film, thickness of 150 μm, green, in which 1% w/w of permethrin is added during its production process. The product TERMIFILM is a ready-to-use anti-termites physico-chemical barrier used in pre-construction, for protection of buildings. It is intended to be applied as preventive treatment by professional users.

Regarding the name of the product TERMIFILM UV+ initialy claimed, the proposal UV+ is not acceptable by the FR CA because of the lack of property against UV. Furthermore, the risk mitigation measure “Do not expose to adverse weather conditions during application” must be indicate. Therefore, the name TERMIFILM UV+ has been changed by the applicant during the assessment stage by TERMIFILM.

***Physico-chimical properties***

The relative density of the product is 0.799.

Regarding the stability of the product TERMIFILM , there is no effect of low and high temperature, since after 7 days at 0 °C and after 14 days at 54 °C, neither the active ingredient content nor the product aspect were changed.

The stability data indicate a shelf life of at least 2 years when stored in LDPE.

The biocidal product TERMIFILM is not explosive and has no oxidising properties. It is not flammable and contains no substance associated with self-heating.

Regarding the method of analysis, the method using GC-MS and HPLC-UV is fully validated for the determination of Permethrin in the biocidal product TERMIFILM/TERMIFILM

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 LANXESS Deutschland GmbH and Tagros Chemicals India Ltd. are available.

* **Minor Change 2019**

Based on the new claimed composition, the product is expected to be blue and black. The physico-chemical properties and analytical methods don’t change with this minor change.

***Efficacy***

French competent authorities (FR CA) consider that the efficacy of the product TERMIFILM, used as physico-chemical barrier (total application) to protect buildings is demonstrated against subterranean termites (*Reticulitermes spp., Coptotermes spp., Heterotermes spp., and Prorhinotermes spp*.) and tree termites (*Nasutitermes spp. and Cryptotermes spp*.) is demonstrated. Efficacy is demonstrated against European and tropical species of termites.

* **Minor change 2019**

This demand consist in the replacement of the pigments by other pigments. As pigment have no impact on the efficacy, the efficacy conclusions remain valid.

***Human health risk assessement***

Regarding the primary exposure the risk for professional users is considered as acceptable taking into account the protective equipment (wear of gloves).

Regarding the secondary exposure, exposures for workers after application and for people living or working in the building are considered as negligible, the risk is considered as acceptable.

* **Minor Change 2019**

Based on the new claimed composition (exchanging pigments), the Human Health risk assessment can be considered as equivalent to the reference assessment.

***Dietary risk***

Regarding the use, food or feed contamination is not expected. As a consequence, the exposure via food, livestock exposure or via transfer of biocidal active substances is considered as negligible. Therefore, 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.

***Environmental risk assessment***

* Construction step

Following indirect releases to the environment via the STP, all calculated PEC/PNEC ratios were < 1 for soil and groundwater. Thus the risk for these environmental compartments is acceptable. Nevertheless, regarding the exposure of the STP, surface water and sediment, RCR values were > 1 indicating unacceptable risk to these environmental compartments.

Following direct releases to the environment, calculated RCR values were > 1 for the exposure of soil. Thus, the risk for these environmental compartments is unacceptable.

A risk mitigation measure is proposed to prevent the exposure of the aquatic and terrestrial compartments during the construction phase of the building: ***During its application step, do not expose the film to rain***. The application of this risk mitigation measure preventing emissions to the environment would achieve acceptable risks.

* Service life

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

* **Minor Change 2019**

Based on the new claimed composition (exchanging pigments), the environmental risk assessment can be considered as equivalent to the reference assesment.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

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

| **Trade name** | TERMIPROTECT FILM ANTI-TERMITES NEW |
| --- | --- |
|  |  |

#### 

#### **Authorisation holder**

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | BERKEM DEVELOPPEMENT |
| **Address** | Marais Ouest  24680 Gardonne  FRANCE |
| **Authorisation number** | FR-2018-0058 | |
| *Suffixes to the authorisation number linked to trade names[[1]](#footnote-1)* |  | |
| *R4BP asset reference number* |  | |
| **Date of the authorisation** | 21/08/2018 | |
| **Expiry date of the authorisation** | 20/08/2028 | |

#### 

#### **Manufacturer(s) of the products of the family**

|  |  |
| --- | --- |
| **Name of manufacturer** | SARPAP & CECIL INDUSTRIES sas - BERKEM Group |
| **Address of manufacturer** | Marais Ouest  24680 Gardonne  France |
| **Location of manufacturing sites** | Marais Ouest  24680 Gardonne  France |

#### 

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

|  |  |
| --- | --- |
| **Active substance** | Permethrin |
| **Name of manufacturer** | LANXESS Deutschland GmbH |
| **Address of manufacturer** | Kennedyplatz 1, D-50568 Köln, GERMANY |
| **Location of manufacturing sites** | Bayer Vapi Private Limited  Plot # 306/3 II Phase, GIDC ,  Vapi – 396 195 Gujarat  India |
| **Active substance** | Permethrin |
| **Name of manufacturer** | TAGROS Chemicals India Ltd |
| **Address of manufacturer** | 72 Marshalls road,  Egmore,  Chennai-600 008,  Tamil Nadu,  INDIA |
| **Location of manufacturing sites** | A4 / 1 & 2 SIPCOT Industrial Complex, Pachayankuppam ,  607 005 CUDDALORE, Tamil Nadu,  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 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 product TERMIFILM 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**

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | **Content (g/m2)** |
| --- | --- | --- | --- | --- | --- | --- |
| Permethrin technical  Permetrin (pure) | 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2- dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52645-53-1 | 258-067-9 | 1.08\*  1 | 1.30\*\*  1.20\*\*\* |

\*the content of technical substance expressed in %w/w is calculated taking into account the minimum purity of 93%.

\*\*the content of technical substance expressed in g/m² is calculated taking into account the minimum purity of 93%.

\*\*\* the content of pure substance expressed in g/m² is calculated taking into account the density of the product (120g/m²)

Content of pure active substance: content corresponding to the active substance alone (without impurities)

Content of technical active substance: content corresponding to the active substance and all its impurities

#### **Information on technical equivalence**

Not concerned

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

Not concerned .

* **Minor change 2019**

**Assessment of endocrine disruption (ED) properties of the biocidal product**

According to our assessment, none of the co-formulants contained in the product TERMIPROTECT FILM ANTI-TERMITES NEW is regulatory identified as endocrine disruptor.

However, one co-formulant shows indications of endocrine activity (refer to confidential annex).

Based on available information, it is not possible to conclude whether this co-formulant should be considered to have ED properties or not. This should be further assessed in the frame of REACH Regulation. In case where this co-formulant is finally identified as ED, the biocidal product will be considered as ED and authorisation will have to be revised accordingly.

#### **Type of formulation**

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

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Skin sensitisation, cat.1  Aquatic Acute Cat 1;  Aquatic Chronic Cat 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/soap  P333 + P313: If skin irritation or a rash occurs: Get medical advice/attention.  P321: Specific treatment (see first aid instruction on this label)  P391:Collect spillage  P501: Dispose of contents/container to …hazardous or special waste collection point in accordance with local/regional/national/international regulation |
|  | |
| Note | **-** |

### Authorised use(s)

#### **Use description**

**Table 1. Use # 1 –Preventive treatement before construction**

|  |  |
| --- | --- |
| **Product Type** | 18: Insecticides, acaricides and products to control others arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product TERMIPROTECT FILM ANTI-TERMITES NEWis a ready-to-use anti-termites physico-chemical barrier used in pre-construction, for protection of buildings. |
| **Target organism (including development stage)** | Subterranean termites (*Reticulitermes spp., Coptotermes spp., Heterotermes spp., and Prorhinotermes spp.)*  Tree termites *(Nasutitermes spp.and Cryptotermes spp*.)  Workers, soldiers, nymphs |
| **Field of use** | Outdoor: preventive treatment before the construction |
| **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 1,08 % w/w permethrin  One application during the construction of the building |
| **Category(ies) of users** | Professional and trained professional |
| **Pack sizes and packaging material** | LDPE[[2]](#footnote-2) roller of 30 m² (width: 6 m; length: 5 m)  LDPE roller of 75 m² (width: 3 m; length: 25 m)  LDPE roller of 150 m² (width: 6 m; length: 25 m)  Packaging material is a transparent plastic film LDPE |

#### Use-specific instructions for use

|  |
| --- |
| - |

#### Use-specific risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

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| - |

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

|  |
| --- |
| - |

### General directions for use

#### Instructions for use

|  |
| --- |
| * 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. * Inform the registration holder if the treatment is ineffective |

#### **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 its application step, do not expose the film to rain. |

#### **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. |

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

|  |
| --- |
|  |

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

|  |
| --- |
| * Shelf-life of the product: 2 years. |

### 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. * Inform the registration holder if the treatment is ineffective |

### Packaging of the biocidal product

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Transparent plastic film | 30 m² | LDPE | Professional | Yes |
| Transparent plastic film | 75 m² | LDPE | Professional | Yes |
| Transparent plastic film | 150 m² | LDPE | Professional | Yes |

### Documentation

#### Data submitted in relation to product application

***Physico-chimical properties***

Physico-chemical properties studies and analytical methods on the biocidal product were provided. See the annex 3.1.

***Efficacy data:***

* ***Laboratory tests:***
* A laboratory efficacy study conducted according to an adaptation of the experimental standard XP X41-541[[3]](#footnote-3), with the product TERMIFILM (1 % w/w permethrin), in alkaline conditions, on termites *(Reticulitermes santonensis)*;
* A laboratory efficacy study conducted according to the experimental standard XP X 41-540[[4]](#footnote-4), with the product TERMIFILM (1 % w/w permethrin), after artificial ageing (leaching) according to the protocol XP X 41-542[[5]](#footnote-5), on termites (*Reticulitermes flavipes)*;
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550[[6]](#footnote-6), with the product TERMIFILM (1 % w/w permethrin), after natural weathering (UV – vertical (3 months) according to the protocol CTBA BIO-E-016[[7]](#footnote-7), on termites (*Coptotermes gestroi*);
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product TERMIFILM (1 % w/w permethrin), after natural weathering (UV – horizontal (8 weeks)) according to the protocol CTBA BIO-E-016, on termites (*Coptotermes gestroi*);
* ***Field tests :***
* A field efficacy study, with the product TERMIFILM (1 % w/w permethrin), performed in France (Oleron Island), according to an internal method, with 22 years of exposure to termites (*Reticulitermes santonensis*);
* A field efficacy study, with the product TERMIFILM (1 % w/w permethrin), performed in France (Guyane), according to the in-house concrete slab methodology, with 3.5 years of exposure to termites (*Coptotermes testaceux, Heterotermes tenuis, Nasutitermes spp.* and *Cryptotermes spp.*);
* A field efficacy study, with the product TERMIFILM (1 % w/w permethrin), performed in Australia, in wet/dry tropical climate (Coalinga) and humid tropical (Brisban), following the concrete slab methodology (CSIRO[[8]](#footnote-8),[[9]](#footnote-9)) with 6 years of exposure to termites (*Mastotermes darwiniensis, Coptotermes acinaciformis, Heterotermes spp., Microcerotermes spp.* and *Schedorhinotermes spp.*)

**Toxicology**

The applicant has provided one study performed on the formulation TERMIFILM for skin sensitisation.

**Ecotoxicology**

The applicant has provided one study performed on the formulation TERMIFILM.

#### **Access to documentation**

A letter of acces (LoA) has been submitted. It grants acces to the complete BPR 98/8/EC dossier submitted by LANXESS Deutschland GmbH and TAGROS Chemicals India Ltd to the European Commission for the listing of Permethrin

## Assessment of the biocidal product (family)

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

**Table 1. Intended use # 1 – name of the use**

|  |  |
| --- | --- |
| **Product Type** | PT18 - Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product TERMIFILM is a ready-to-use anti-termites physico-chemical barrier used in pre-construction, for protection of buildings |
| **Target organism (including development stage)** | |  |  | | --- | --- | | **Target organism(s)** | **development stage** | | *Heterotermes* sp. (Termites) | Adults | | *Nasutitermes* sp. (Termites) | Adults | | *Cryptotermes* sp. (Termites) | Adults | | *Reticulitermes* sp. (Termites) | Adults | | *Coptotermes* sp. (Termites) | Adults | | *Prorhinotermes* sp. (Termites) | Adults | |
| **Field of use** | Outdoor |
| **Application method(s)** | Installation before construction |
| **Application rate(s) and frequency** | 1 application. |
| **Category(ies) of users** | Professional |
| **Pack sizes and packaging material** | LDPE roller of 30 m² (width: 6m; length: 5 m)  LDPE roller of 75 m² (width: 3m; length: 25 m)  LDPE roller of 150 m² (width: 6m; length: 25 m)  Packaging material is a transparent plastic film LDPE |

### Physical, chemical and technical properties

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Product** | **Pur content of active substance (%)** | **Technical content of active substance (%)** | **Pur content of active substance (g/m2)** | **Technical content of active substance (g/m2)** |
| TERMIFILM | 1 | 1.08\* | 1.20\*\* | 1.30\*\*\* |

\*the content of technical substance expressed in %w/w is calculated taking into account the minimum purity of 93%.

\*\*the content of pure substance expressed in g/m2 is calculated taking into account the minimum purity of 93%.

\*\*\* the content of technical substance expressed in g/m2 is calculated taking into account the density of the product (120g/m2)

Note:

The applicant indicates that 1%w/w pure permethrine is equivalent to 1.45 g/m² pure permethrin. However, according to eCA, 1%w/w pure permethrine is equivalent to 1.20 g/m² pure permethrin obtained by calculation.

After commenting phase the applicant confirmed tha this data has been measured according to EN 1849-2 (see test report send with our dossier N°15/159-1 of CSTC (Centre Scientifique et Technique de la Construction) dated 03/09/2015).

However, for a sample with dimensions 25 m x 6m x150 µm (sample of the test taken in dossier N°15/159-1), by calculation, the density of the product is 120g/m2 taking into account the density of 0.799g/cm3 (that indicated in the GLP study report N°16-919075-003) and a thickness of 150µm.

Another non GLP study (N°15/159-1) was provided indicated a 1,45g/m2 density. The clarification on the discrepancy between both values was not provided and the GLP value will be kept.

However, risk assessments for human health and environment have been made base on a content of 1,45 g/m² according to applicant claim. Based on concentration of 1% pure AS and on technical characteristics of TERMIFILM, calculated technical AS concentration should rather be 1.3 g/m². The concentration claimed by applicant is slightly higher that the calculated one. Hence, the risk assessment performed, based on applicant claim, is the more conservative approach.

Physico-chemical properties of the product are reported below:

| **Property** | **Guideline and Method** | **Purity of the test substance**  **(% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20°C and 101.3 kPa | NBN EN 13956 | - | Solid | CSTC Report n°DE651XM169  15/159-1  CSTC Report n°DE651XM169  15/159-3 |
| Colour at 20°C and 101.3 kPa | NBN EN 13956 | - | Green  **Minor Change 2019**  Based on the new claimed composition the product is expected to be black and blue. The physico-chemical properties and analytical methods don’t change with this minor change. | CSTC Report n°DE651XM169  15/159-1  CSTC Report n°DE651XM169  15/159-3 |
| Odour at 20°C and 101.3 kPa | NBN EN 13956 | - | Odourless | CSTC Report n°DE651XM169  15/159-1  CSTC Report n°DE651XM169  15/159-3 |
| Acidity / alkalinity | - | ~~-~~ | Not applicable | Scientifically unjustified as the product is a treated article in solid form. |
| Relative density / bulk density | OECD Guideline 109 | - | 0.799 at 21°C | Defitraces study report  N°16-919075-003 |
| 120 g/m2 | Calculation taking into account density (0.799g/cm3), the volume and the surface of the product. |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  GC-MS method for permethrin content  **validated in section 2.2.4** | 1.0% w/w | 2 weeks at 54°C  Stored in film bag  After storage, the appearance of test product is unchanged (solid and light green)  Permethrin content (cis and trans)  Day-0: 0.985%  2 weeks: 0.977% (-0.8%)  Stable | MPA study report N°31-16-2781-02 |
| Storage stability test – **long term storage at ambient temperature** | PAP032 BERKEM method (HPLC/UV) | 1.0% w/w | 2 years  Permethrin content (cis and trans)  Day-0: 1.02%  2 years: 0.99%  Packaging: LDPE  Information on the appareance of the packaging is not reported in the IUCLID. Nevertheless, the appareance of the product before and after storage in the accelerated study is light green and solid. By extrapolation, the same observation is applicable for the ambient storage study.  Note:  -The substance active permetrhine has 4 stereoisomers.  The monitoring of these isomers was not performed (no chiral method was provided) during the storage. | BERKEM study report BK\_2015\_STLG\_TERMIFILM\_10\_2015 |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3  GC-MS method for permethrin content  **validated in section 2.2.4** | 1.0% w/w | 1 week at 0°C  Stored in film bag  After storage, the appearance of test product is unchanged (solid and light green)  Permethrin content (cis and trans)  Day-0: 0.985%  1 week: 0.990%  Stable | MPA study report N°31-16-2781-01 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | A justification was provided during the commenting phase by the applicant: “The packaging of TERMIFILM (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.  So, 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 TERMIFILM, two efficacy studies after exposure of the product to the sunlight, respectively 8 weeks and 100 days according to XPX 41-550 (June 2009), are presented. After exposure to sunlight during 8 weeks and 100 days, 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” | - |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | The product was considered to be stable after 2 weeks at 54°C and storage at ambient temperature.  The individual commercial packaging is sealed. With this closure system, the packaging is leak-tight. | BERKEM study report BK\_2015\_STLG\_TERMIFILM\_10\_2015  MPA study report N°31-16-2781-02 |
| 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 LDPE.  . | BERKEM study report BK\_2015\_STLG\_TERMIFILM\_10\_2015  MPA study report N°31-16-2781-02 |
| Wettability |  |  | Not applicable |  |
| Suspensibility, spontaneity and dispersion stability | - | - | Not applicable | - |
| Wet sieve analysis and dry sieve test | - | - | Not applicable | - |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not applicable | - |
| Disintegration time | - | - | Not applicable | - |
| Particle size distribution, content of dust/fines, attrition, friability | - | - | Not applicable | - |
| Persistent foaming | - | - | Not applicable | - |
| Flowability/Pourability/Dustability | - | - | Not applicable | - |
| Burning rate — smoke generators | - | - | Not applicable | - |
| Burning completeness — smoke generators | - | - | Not applicable | - |
| Composition of smoke — smoke generators | - | - | Not applicable | - |
| Spraying pattern — aerosols | - | - | Not applicable | - |
| Physical compatibility | - | - | Not applicable | - |
| Chemical compatibility | - | - | Not applicable | - |
| Degree of dissolution and dilution stability | - | - | Not applicable | - |
| Surface tension | - | - | Not applicable | - |
| Viscosity | - | - | Not applicable | - |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The biocidal product TERMIFILM is a solid chemical-physical barrier containing 1 % w/w permethrin (pure). It is a green LDPE (Low Density PolyEthylene) film, without odour.  The relative density of the product is 0.799.  There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and after 14 days at 54 °C, neither the active ingredient content nor the product aspect were changed.  The stability data indicate a shelf life of at least 2 years when stored in LDPE. |

* **Minor Change 2019**

Based on the new claimed composition the product is expected to be black and blue. The physico-chemical properties and analytical methods don’t change with this minor change.

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | - | - | The product is based on LDPE which is known to be non explosive. | Data scientifically unjustified |
| Flammable gases | - | - | Not applicable | - |
| Flammable aerosols | - | - | Not applicable | - |
| Oxidising gases |  |  | Not applicable | - |
| Gases under pressure | - | - | Not applicable | - |
| Flammable liquids | - | - | Not applicable | - |
| Flammable solids | - | - | The product is based on LDPE which is known to be non flammable. | Data scientifically unjustified |
| Self-reactive substances and mixtures | - | - | There are no chemical groups present in TERMIFILM associated with explosive or self- reactive properties. | Data scientifically unjustified |
| Pyrophoric liquids | - | - | Not applicable |  |
| Pyrophoric solids | - | - |  | Data scientifically unjustified |
| Self-heating substances and mixtures | - | - | There are no chemical groups present in TERMIFILM associated with self-heating. | Data scientifically unjustified |
| Substances and mixtures which in contact with water emit flammable gases | - | - | The chemical structure of the components contained in TERMIFILM does not contain metals or metalloids.  Experience in production or handling shows that TERMIFILM does not react with water. | Data scientifically unjustified |
| Oxidising liquids | - | - | Not applicable | - |
| Oxidising solids | - | - | The product based on LDPE which is known to be non oxidising. | Data scientifically unjustified |
| Organic peroxides | - | - | TERMIFILM doesn’t contain any component with the bivalent -O-O- structure. | Data scientifically unjustified |
| Corrosive to metals | - | - | TERMIFILM doesn’t contain any component classified as H290 (May be corrosive to metals).  The formulation of TERMIFILM doesn’t contain any component which by chemical action will materially damage, or even destroy, metals. | Data scientifically unjustified |
| Auto-ignition temperatures of products (liquids and gases) | - | - | Not applicable | - |
| Relative self-ignition temperature for solids | - | - | There are no chemical groups present in TERMIFILM associated with explosive, with self-reactive or with self-heating properties. | Data scientifically unjustified |
| Dust explosion hazard | - | - | Not applicable | - |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The biocidal product TERMIFILM is not explosive and has no oxidising properties. The product is not flammable and contains no substance associated with self-heating. |

### Methods for detection and identification

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 | Manual cut blank film sample are extracted with acetone by using ultrasonic bath and shaking. The filtered clear solution is then diluted with acetone and analysed by GC-MS. | Extracts of blank film (matrix) were spiked in duplicate at a level of 80%, 100% and 120% with the calibration substances –  data are not relevant because the fortification is performed on extract solution (fortification is performed after extraction)  Recoveries of the method are given from precision data | R=0.9997  From 10.14 to 28.08 µg/mL  n=6 | No interferences from matrix detected  Note: In the chromatogram, we can observe permethrine cis and permetrine trans with sufficient resolution.  No validation data is reported in the study report for each isomers. | 97.2 – 99.8 | 98.50 | 1.24  n=6 | Not relevant | Annex: Validation of GC-method from MPA study reports No 31/16/2781/01 & 31/16/2781/02 |
| Permethrin | Pieces of film are introduced in a cutting mill and crushed for several minutes. Acetonitrile is added and ultrasound extraction is followed for 2 hours. The solution is then analysed by HPLC/UV (260 nm). | 5 groups of 3  *(recovery measurements were obtained from the linearity study)* | R²=0.98  From 0.3 to 0.75 mg/mL  n=5 (triplicate)  R²=0.98  From 0.3 to 0.75 mg/mL  n=5 (triplicate) | *Permethrine trans*  No interferences from matrix detected  *Permethrine cis*  No interferences from matrix detected  Note: In the chromatogram, we can observe permethrine cis and permetrine trans with sufficient resolution.  No validation data is reported in the study report for each isomers. | 93,62 – 98,65 | 96,14 | 1.5  n=6 | 0,1128 mg/ml | RAPPORT DE VALIDATION ANALYTIQUE  POUR LE CONTROLE DE LA PERMETHRINE DANS LE TERMIFILM |

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| **Conclusion on the methods for detection and identification of the product** |
| The method using GC-MS and HPLC-UV is fully validated for the determination of Permethrin in the treated article TERMIFILM.  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 LANXESS Deutschland GmbH and Tagros Chemicals India Ltd. are available. |

### 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**

According to the use claimed by the applicant, the product TERMIFILM is a ready to use physico-chemical barrier (Low Density PolyEthylene (LDPE) film, thickness of 150 µm, green) for the preventive protection of new buildings against termites.

The manufacturing process leads to 1 % w/w permethrin. The product is applied by professional in surface application, directly applied on the ground or embankment, before pouring the slab.

The application rate recommended by the applicant is the following:

* The amount of applied active substance is 1 % w/w permethrin. One application takes place during the building construction.

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

According to the claims, the product TERMIFILM is intended to protect buildings against subterranean termites (*Reticulitermes spp., Coptotermes spp., Heterotermes spp., and Prorhinotermes spp.)* and tree termites *(Nasutitermes spp., Cryptotermes spp*.) for European and overseas territories.

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 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**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **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  Preventive anti-termites barrier | TERMIFILM  1 % w/w  permethrin | Subterranean termites  (*Reticulitermes santonensis*) | Efficacy according to XP X41-541 (lab test) after alkaline ageing | Film previously worn by exposure to alkalinity  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 | All the devices (control and test) are made in quadruplet.  According to the methodology, the test is considered as valid if the survival rate in the control is higher than 50 % and if all the bait woods are ranked with a quotation of 4.  But in this study, the mean survival rate in the control is only22 % (6, 15, 9, 57)  Supportive data confirmed by efficacy in the field. | Ansard D. and Paulmier I.  BIOTEC/IP/DA – 145/95R/3  IC3 |
| Insecticide  Preventive anti-termites barrier | TERMIFILM  1 % w/w permethrin | Subterranean termites  (*Reticulitermes santonensis*) | Efficacy according to XP X 41-540 (lab test) after ageing according X41-542 (effect of water) | Film previously worn by exposure to alkalinity  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 | All the devices (control and test) are made in quintuple.  For the control, all the survival rates are higher than 50 % (57.7 %) and penetration of 50 mm by the termites is observed.  In the test devices, all the bait woods are protected (quotation 0) | Serment M.-M. 1995  BIOTEC/IP/DA-145/95F  IC2 |
| Insecticide  Preventive anti-termites barrier | TERMIFILM  1 % w/w permethrin | *Coptotermes gestroi* | Efficacy according to XP X 41-550 after ageing according to CTBA BIO-E-016 (effect of the natural light) (lab test)  (vertical 102 days) | 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 % (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. | Vuillemin J 2010  12/09Fb  IC 1 |
| Insecticide  Preventive anti-termites barrier | TERMIFILM  1 % w/w permethrin | *Coptotermes gestroi* | Efficacy according to XP X 41-550 after ageing according to CTBA BIO-E-016 (effect of the natural light) (lab test)  (horizontal 8 weeks) | Film previously worn by exposure to solar radiation (exposed horizontally during 8 weeks, 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 % (63.4 %), 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. | Vuillemin J. and Paviel F. 2014  04-13  IC 1 |
| Insecticide  Preventive anti-termites barrier | TERMIFILM  1 % w/w permethrin | Subterranean termites  (*Reticulitermes santonensis, Reticulitermes lucifugus*)  (Oleron Island, france) | In house method (field: similar to CTBA-BIO-E-008/4)  5 test devices with TERMIFILM  1 control device | Study area: Saint-Trojan-Les Bains  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: 21 years  Replicates: 5 replicates of 2 devices (one with a PVC pipe and one with an electrical conduit).  Controls: 1 | 2 years after the installation, the control device has been colonized by termites that valid the test.  The field test is visited every year since 1994. Most of the time termites are observed in the control device.  19 years after the beginning of the test, one test device has been penetrated by termites and the test wood in the device was attacked. | BIOTEC/AMP - 145.2-5/95R  BIOTEC/AMP - 145.3-5/95R  BIOTEC/AMP - 145.4-5/95R  BIOTEC/AMP - 145.5-5/95R  PC/66/010/03F  PC/66/209/04F  401/10/222F  401/10/222F/c  401/10/222F/d  401/10/222F/e  IC1 |
| Insecticide  Preventive anti-termites barrier | TERMIFILM  1 % w/w permethrin | Subterranean termites  *Coptotermes testaceus*  *Heterotermes tenuis*  Tree termites  *Nasutitermes spp. Cryptotermes spp.*  *(Guyane)* | In house method  Field: concrete slab  3 tests devices with TERMIFILM  1 control device (poplar wood)  1 control device  (tropical wood)  The test is made in duplicate | According to the methodology | 6 months after the beginning of the test, in one control device, the presence of *Coptotermes testaceus* is recorded. The presence of *Heterotermes tenuis* is also recorded after 3.5 years.  All the test devices remained unpenetrated 5.5 years after the beginning of the test | Fouquet D. 2005  Compte rendu essai de champ Guyane (Cirad)  IC1 |
| Insecticide  Preventive anti-termites barrier | TERMIFILM  1 % w/w permethrin | **Darwin (Coolalinga) wet dry tropical. (2 sites)**  *Mastotermes darwiniensis*  *Coptotermes acinaciformis*  *Heterotermes spp.*  **Brisban (humid tropical)**  *Coptotermes acinaciformis*  *Microcerotermes spp.*  *Schedorhinotermes spp.* | Concrete slab  (Cisro) | According to the methodology | **Darwin :**  Site 1: After one year, one of the ten  control device was penetrated by *Mastotermes darwiniensis* and after 6 years all the control devices were penetrated.  Under the test device, the presence of *Mastotermes darwiniensis* , *Heterotermes spp* and *Coptotermes acinaciformis* is noted. After 5.5 years, the test devices remained protected.  Site 2: after 1 year all the control devices were penetrated by *Coptotermes acinaciformis*.  Under the test devices, the presence of *Schedorhinotermes spp.*, *Microcerotermes ssp.* and *Coptotermes acinaciformis* is noted/ After 5.5 years, the test devices remained protected.  **Brisban:**  Some control devices are penetrated 1 year after the beginning of the test and after 2 years, all the controls have been penetrated.  Under the test devices, the presence of *Coptotermes acinaciformis*, *Schedorhinotermes spp*. and *Microcerotermes spp* are noted. After 5.5 years, the test devices remained protected | Termite Group  Report 2005/14  (Cisro)  Termite Group  Report 2006/13  (Cisro)  IC 1 |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| Some species of tropical termites, (*Heterotermes spp.*, *Nasutitermes spp*. and *Cryptotermes spp*.), at the time of the dossier, are very difficult or impossible to breed in laboratory, reason why no laboratory test has been submitted on these species. It is also commonly accepted, in the frame of the French certification, that lab tests are needed on *Reticulitermes spp.* for Europe and *Coptetermes spp.* for oversea departments, with field tests included others species claimed. Indeed these two species are considered as the most representative of economical consequences from termites attacks.  Regarding the demonstration of the efficacy of the product against *Prorhinotermes* spp., efficacy against several subterranean termites genus (*Reticulitermes spp., Coptotermes spp. Heterotermes spp., Microcerotermes spp. and Schedorhinotermes spp.*) is demonstrated in the field. Therefore, FR CA is of the opinion that efficacy against a sufficient number of different subterranean termites is proven to also cover *Prorhinotermes spp*.  For information, in France, *Prorhinotermes* spp. is a target of interest from an economical point of view for at least one oversee department Mayotte.  A list of locations, where the product has been applied with success has been presented by the applicant. In this list, several applications were performed in locations where the presence of Prorhinotermes was noted.  Additionnaly according to litterature *Prorhinotermes spp.* seems to be very closed to *Coptotermes* spp. from an entomological point of view.  French competent authorities (FR CA) consider that in accordance with the elements presented in the dossier and the requirements of the TNsG on PT18 (2012)[[10]](#footnote-10), the efficacy of the product TERMIFILM, used as physico-chemical barrier (total application) to protect buildings is demonstrated against subterranean termites (*Reticulitermes spp., Coptotermes spp., Heterotermes spp., and Prorhinotermes spp.)* and tree termites *(Nasutitermes spp*. and *Cryptotermes spp.*).  The application rate validated is the following: the concentration of active substance in the product is 1 % w/w. One application of the product takes place during the building construction.   * **Minor change 2019:**   This demand consist in the replacement of the pigments by other pigments. As pigment have no impact on the efficacy, the efficacy conclusions remain valid. |

#### **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 to permethrin, for termites, 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 data presented in the dossier that allow the demonstration of the efficacy of the product TERMIFILM against termites (*Reticulitermes spp., Coptotermes spp., Heterotermes spp., and Prorhinotermes spp.)* and tree termites *(Nasutitermes spp*. And *Cryptotermes spp.*) for the use claimed by the applicant.

The application rates validated are the following:

The product is used as internal physico-chemical barrier and is directly applied on the ground or embankment, before pouring the slab. The product TERMIFILM contains 1 % w/w permethrin

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

### Risk assessment for human health

TERMIFLM UV+ is a Low Density PolyEthylene (LDPE) film, thickness of 150 μm, green, in which 1% w/w of permethrin (pure) is added in its composition during its production process. Permethrin is expected to be distributed homogeneously and is linked in the matrix of the LDPE film.

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

***Skin corrosion and irritation***

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| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not classified as a skin irritant/corrosive product. |
| Justification for the value/conclusion | No study has been conducted. Based on the calculation method, there is no classified substances for skin irritation/corrosion in the mixture, therefore the product is not classified for this endpoint. |
| Classification of the product according to CLP | Not classified according to Regulation (EC) No 1272/2008 (CLP). |

***Eye irritation***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Not classified as an eye irritant product |
| Justification for the value/conclusion | No study has been conducted. Based on the calculation method taking into account the content of substances classified as eye irritant. |
| Classification of the product according to CLP | Not classified according to Regulation (EC) No 1272/2008 (CLP). |

***Respiratory tract irritation***

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | Not relevant (solid form without any volatile substances) |
| Classification of the product according to CLP and DSD | No classification required. |

***Skin sensitization***

A skin sensitization study (Buehler 3 applications test) has been performed on the biocidal product TERMIFILM . However, Buehler 3 applications test is not considered as sensitive enough to assess the skin sensitisation potential of a product.

| **Summary table of animal studies on skin sensitisation** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline, GLP status, . Reliability** | **Species, Strain, Sex, No/group** | **Test substance, Vehicle,**  **Dose levels,  duration of exposure Route of exposure** *(topical/intradermal, if relevant)* | **Results**  *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)* | **Remarks**  *(e.g. major deviations)* | **Reference** |
| OECD guideline 406 | Guinea pig, Hartley, Charles RIVER | Polyethylene film saturated with insecticide (code E13), buehler 3 applications | Not sensitising by contact with the skin | Buehler 3 applications test is not considered as sensitive enough. | test report T573/6946 done by EVIC France the 23rd of march 1996 |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Classified as a skin sensitizer product. |
| Justification for the value/conclusion | The study is not acceptable (buehler 3 is considered as not enough sensitive).  In this case, a classification based on the calculation method is proposed. The product contains 1% of permethrin classified as a skin sensitizer. Based on the calculation method, the product is classified for this endpoint. |
| Classification of the product according to CLP | H317: May cause an allergic reaction according to Regulation (EC) No 1272/2008 (CLP). |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not classified |
| Justification for the value/conclusion | Not relevant (solid form without any volatile substances) |
| Classification of the product according to CLP | The product does not require classification for respiratory sensitization according to Regulation (EC) No 1272/2008 (CLP). |

***Acute toxicity***

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | ATE mixture = 48000 mg/kg bw |
| Justification for the selected value | According to the composition, the content of the components classified for acute oral toxicity does not trigger classification of the product. |
| Classification of the product according to CLP | Not classified |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | ATE mixture = 150 mg/L |
| Justification for the selected value | According to the composition, the content of the components classified for acute inhalation toxicity does not trigger classification of the product. |
| Classification of the product according to CLP | Not classified |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | - |
| Justification for the selected value | According to the composition, the content of the components classified for acute dermal toxicity does not trigger classification of the product. |
| Classification of the product according to CLP | Not classified |

**CONCLUSION: based on the available data, the product TERMIFILM is classified as skin sensitiser category 1 (H317: May cause an allergic skin reaction) according to CLP Regulation.**

***Information on dermal absorption***

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | Permethrin |
| Value(s) | 3 % |
| Justification for the selected value(s) | Permethrin assessment report, approbation of active substances in the list of Union for the approved active substances, Ireland, April 2014  The dermal absorption value set in the CAR for a liquid formulation (EC formulation) is considered as a worst case for the product TERMIFILM. |

***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, TERMIFILM contains no substance of concern.

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

Not applicable.

#### **Exposure assessment**

Risk assessments for human health have been made base on a content of 1,45 g/m² according to applicant claim.

 Based on concentration of 1% pure AS and on technical characteristics of TERMIFILM, calculated technical AS concentration should rather be 1.3 g/m².

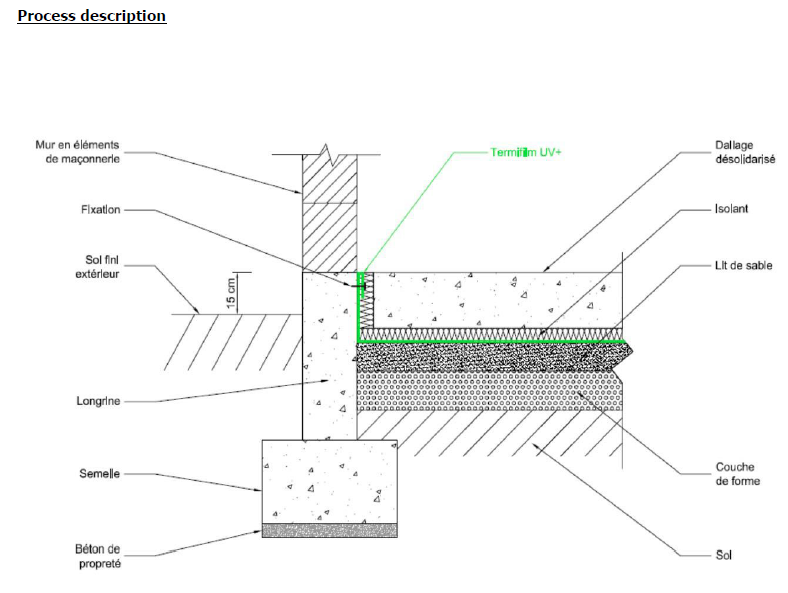
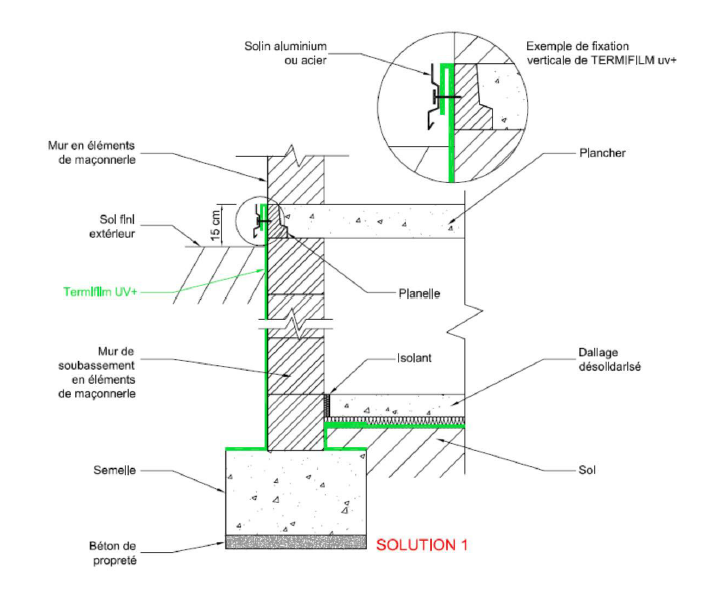
The concentration claimed by applicant is slightly higher that the calculated one. Hence, the risk assessment performed, based on applicant claim, is the more conservative approach.

TERMIFILM is a chemical-physical barrier for the preventive protection of new buildings against termites.

TERMIFLM UV+ is a Low Density PolyEthylene (LDPE) film, thickness of 150μm, green, in which 1% w/w of permethrin is added in its composition during its production process.So Permethrin is expected to be distributed homogeneously.



Application:

TERMIFILM is only for professionals users.

Regarding primary exposure, professional workers could be exposed to TERMIFLM + through skin contact during application.

The activities and the potential for exposure to professional operator are described below:

* **Loading**

The product is delivered as a roll of 30 m² or 75 m² or 150 m².

There is no exposure to the operator as the roll is protected with a plastic foil.

* **Application**

TERMIFILM is unroll and cut according to the area to be protected. Operator could be exposed through skin contact. The wear of gloves and impermeable clothing during handling of the product is recommanded.

There is no standard scenario and models in the TNsGs 2002 or 2007. Consequently, a dedicated scenario was developed considering the dermal contact contact with the product The dermal contact with open edges is negligible due to the width of the roll (6, 3 and 6 meters respectively for the following rolls 30 m², 75 m² and 150 m²).

Due to the very low vapour pressure of permethrin (2.55 x 10-6 Pa; 20ºC), and the fact that the product is applied outdoor, the risk for inhalation exposure to permethrin is considered to be negligible. Hence, concerning primary exposure, the dermal route is regarded to be the main route of exposure.

* **Post-application**

After the treatment there is no contact between the product and operators because there is no handling of TERMIFLM UV+ once it has been applied.

There is no standard scenario and models in the TNsGs 2002 or 2007. Consequently, one scenario was developed for the contact with the membrane

**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) |
| Dermal contact with membrane | Application | Primary exposure. The treated article is deposit on the foundations of building.  Application: Termifilm is unroll and cut according to the area to be protected.  During application of the product, the professional will have multiple contacts with membranes. Assessing the amount of contact or the total surface during application is very uncertain. A reverse reference scenario is thus developed. | Professionals |

***Industrial exposure***

Not applicable.

No industrial exposure is foreseen.

***Professional exposure***

*Scenario [1] 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 developped, considering only dermal exposure via hand manipulation  To assess dermal exposure applying TERMIFILM in a conservative approach We consider that professionals can manage in average 1 building per day, and in average the delay to implement the product in a building is 6 hours for 2 persons.  As a default size, the larger of a private house to be L= 17,5m and l = 7,5m, so 131m² and a larger building to be 5 times longer and larger (L= 87,5m and l = 37,5m, so 3281m² (“Workshop on environmental risk assessment for insecticides, acaricides and products to control other arthropods (Product type 18)” – Brussels, Belgium, 11th of December 2007)  According to exposure assessments done for other substance used in polymer layer (PT9), a depth of 0.1 mm residues of the PET membrane is considered relevant for transfer to the skin.  Considering the thickness of the film (**0.15 mm**) and a depth of 0.1 mm residues, the surface concentration can be calculated as follow:  = (0.145 mg a.s./cm2 ÷ 0.015 cm) \* 0.01 cm  = **0.0967 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. |

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.

|  | Parameters1 | Value |
| --- | --- | --- |
| Tier 1 | Impregnation concentration a.s. (mg/cm2) | 0.145 |
| Relevant depth for transfer (mm) | 0.1 |
| Surface loading (mg/cm2) | 0.097 |
| Transfer coefficient layer/skin | 3 % |
| Dislodgeable active substance (mg/cm2) | 2.90E-03 |
| Gloves penetration factor | 100 % |
| AEL long term (mg/kg) | 0.05 |
| Body weight (kg) | 60 |
| Dermal absorption | 3 % |
| Tier 22 | Gloves penetration factor | 5 % |

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]: Dermal contact with membrane – reverse exposure results**

| **Summary table: Maximum acceptable contact surface (m2)** | | | |
| --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **AEL (mg/kg pc/j)** | **Maximum acceptable contact surface (m²)** |
| Scenario 1 | Tier 1 without PPE | 0.05 | 3,45 |
| Tier 2 with gloves | 0.05 | 68,97 |

*Combined scenarios*

Not applicable.

***Non-professional exposure***

The use of the product is restricted to professionals.

***Exposure of the general public***

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

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

***Monitoring data***

*-*

Not applicable

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

**-**

Not applicable

***Aggregated exposure***

Not applicable

***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 authorising 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”*.

Regarding the intended use, TERMIFILM is a chemical-physical barrier for the preventive protection of new building against termites. Hence 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 PT8  (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.

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

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF** | **Correction for oral absorption** | **Value** |
| AELshort-term | 2-year rat study (oral) | NOAEL = 50 mg/kg bw/day | 100 | - | 0.5 mg/kg bw/day. |
| AELmedium-term | dog 12 month study | NOAEL = 5 mg/kg bw/day | 100 | - | 0.05 mg/kg bw/day. |
| AELlong-term | 12-month dog study | NOAEL = 5 mg/kg bw/day | 100 | - | 0.05 mg/kg bw/day. |
| 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***

**Systemic effects**

|  |  |  |  |
| --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Maximum acceptable contact surface** | **Acceptable**  **(yes/no)** |
| Application – Dermal contact with membrane | 1 without gloves | 3.45 m² | no |
| 2 with gloves | 68.97 m² \* | yes |

For a house of 130 m² with a perimeter of 50 m, the operator therefore does not systematically lay his hands on the total area to be applied. Contacts will be made mainly on the edges when binding two strips with adhesive tape. So considering the conservative assumptions about the concentration in the membrane and transfer the membrane on the skin, the risk upon contact with the membrane is considered acceptable.

**Combined scenarios**

Not applicable.

**Conclusion: based on data and risk assessment presented above, FR CA considers that risk concerning primary exposure during application of the product TERMIFILM is acceptable for professional with the use of gloves.**

* **Minor change 2019**

The minor change consists of exchanging pigments. Since no change of use has been requested, the assessment on human health is covered by the assessment performed in the initial PAR.

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

The use of the product is restricted to professionals.

***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 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

Risk assessments for environment have been made base on a content of 1,45 g/m² according to applicant claim.

 Based on concentration of 1% pure AS and on technical characteristics of TERMIFILM, calculated technical AS concentration should rather be 1.3 g/m².

The concentration claimed by applicant is slightly higher that the calculated one. Hence, the risk assessment performed, based on applicant claim, is the more conservative approach.

|  |
| --- |
| Please notice that the risk assessment for the environment (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**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 1 - FR CA position:**  PNEC values were proposed in the Assessment Report of Permethrin PT18  **PNEC derivation- Active substance**   |  |  | | --- | --- | | **Summary table on PNEC for Permethrin** | | | **Environmental compartment** | **PNEC value** | | STP | 4.95E-03 mg.L-1 | | Surface water | 4.7E-04 µg.L-1 | | Freshwater sediment | 2.17E-04 mg.kgwwt-1 | | Soil | > 8.76E-02 mg.kgwwt-1 | | PNEC oral bird | ≥16.7 mg.kg food | | PNEC oral small mammal | 120 mg.kg food |   **PNEC derivation- Metabolites of active substance**   |  |  | | --- | --- | | **Summary table on PNEC for DCVA** | | | **Environmental compartment** | **PNEC value** | | Surface water | 1.5E-02 mg.L-1 | | Freshwater sediment | 1.2E-02 mg.kgwwt-1 | | Soil | 4.6 mg.kgwwt-1 |  |  |  | | --- | --- | | **Summary table on PNEC for PBA** | | | **Environmental compartment** | **PNEC value** | | Surface water | >1E-02 mg.L-1 | | Freshwater sediment | 9E-03 mg.kgwwt-1 | | Soil | 1.44 mg.kgwwt-1 | |

***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***

According to the ecotoxicity tests done on the product :

- OECD 201 - Algal growth inhibition test (Test report “29257\_EAA” from CIT laboratory, dated 29-04-2005)

- OECD 202 – Acute toxicity in Daphnia magna (Test report “29256\_EAD” from CIT laboratory, dated 29-04-2005)

- OECD 203 – Acute toxicity in the rainbow trout under static conditions (Test report “292224\_EAP” from CIT laboratory, dated 29-04-2005)

The results obtained indicate the product must not be classified for environmental hazards.

Refer to IUCLID dossier on section 9.2

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 2 - FR CA position:**  The studies proposed by the applicant on the product are based on the water accomodated fraction procedure (WAF). The aim of the WAF process is to obtain an aqueous fraction containing the dissolved and/or suspended and/or emulsified fraction of a multi-component substances or a mixture. In the proposed ecotoxicity tests, the test item (green plastic film) was cut in little pieces before addition to the appropriate test solution. Test solutions were stirred during 20 hours and 15 minutes and water soluble fractions were obtained by filtration throught filters of porosity 0.45 µm. Each of these studies are test limits at 100 mg/L of TERMIFILM (equivalent of 1mg/l of permethrin). Chemical analysis were performed during the tests and no permethrin is detected in the tested solutions (neither at the beginning, during nor at the end of tests). Therefore, the organisms tested (algae, daphnids and fish) were probably not exposed to permethrin.  In the other way, in a semi field leaching test proposed by the applicant for the estimation of the PEC, it is shown that more than 23 % of the permethrin leached out from the film after 16 days submitted to rain which shows that, permethrin emissions could occur in the environment and the test under WAF condition is not appropriate for this film product. Therefore, these 3 studies on the product TERMIFILM are not considered as valid.  The biocide product TERMIFILM has the same classification than the active substance (permethrin).  Independently of the acute tests proposed, the chronic classification of the TERMIFILM on the label will always be aquatic chronic 1, H410.   |  |  | | --- | --- | | **Classification of the Active Substance Permethrin** | | | Value/conclusion | Very toxic to aquatic life  Very toxic to aquatic life with long-lasting effects | | Justification for the value/conclusion | Daphnia was the most sensitive aquatic organism with the lowest chronic ecotoxicity endpoint (21d): NOEC4.7E-06 mg/L. | | Classification of the product according to CLP and DSD | The following classification in accordance with the criteria in Regulation (EC) No 1272/2008 is proposed in the AR:  **Aquatic Acute 1; H400; M = 100**  **Aquatic Chronic 1, H410, M = 10000** |  |  |  | | --- | --- | | **Classification of the Product TERMIFILM** | | | Value/conclusion | Aquatic Acute Cat 1; H400  Aquatic Chronic Cat 1; H410 | |

***Further Ecotoxicological studies***

|  |
| --- |
| **Infobox 3 - FR CA position:**  No new data is available. |

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

|  |
| --- |
| **Infobox 4 - FR CA position:**  No new data is available. |

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

|  |
| --- |
| **Infobox 5 - FR CA position:**  No new data is available. |

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

|  |
| --- |
| **Infobox 6 - FR CA position:**  No new data is available. |

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

|  |
| --- |
| **Infobox 7 - FR CA position:**  No new data is available. |

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

|  |
| --- |
| **Infobox 8 - FR CA position:**  No new data is available. |

The exposed environmental compartments that may potentially be impacted during life cycle of TERMIFILM are:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Air (outdoors) | Sewage treatment plant | Surface water and sediment | Soil | Ground  Water\* |
| Application | No | Yes | No | Yes | Yes |
| In service | No | Yes | No | Yes | Yes |

\* Indirect exposure via leaching of the substance in soil

Air: Emissions can occur to the air by evaporation of the active substance contained in TERMIFILM.

The product TERMIFILM is a treated article with a primary biocidal function, containing permethrin as an insecticide.

Permethrin show very low vapour pressure.

Due to the solid form of TERMIFILM and to the very low vapour pressure of Permethrin, it can be concluded that emission to aerial compartment is negligible when using the product.

Water: No direct emission to surface water is foreseen during application phase as TERMIFILM is used as a solid form.

Emission can occur to water by run-off of water from unpaved storage into adjacent surface water body after rain event.

The facility drain is assumed to drain into the public sewage treatment plant (STP).

The emission to sewage treatment plant will be considered.

Concerning the storage, each roll of TERMIFILM is packaged in a plastic foil and must be stored indoor, in a closed storage area.

Soil: Emission can occur to the soil by permethrin leaching due to rainfall.

The product TERMIFILM could be used in contact with soil, therefore, direct soil contamination should be considered.

|  |
| --- |
| **Infobox 9- FR CA position:**  Please see FR position in **Infobox 17 - FR CA position:** |

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

|  |
| --- |
| **Infobox 10- FR CA position:**  No new data is available. |

All the data refer to the chapter 'Fate and distribution in the environment' and 'Effects on environmental organisms' are from Doc IIA as well as from Doc IIB for the active substance Permethrin. A summary is presented below for permethrin.

The technical material supported by the notifiers relates to permethrin as a reaction mass of four stereoisomers (1Rcis, 1Scis, 1Rtrans, and 1Strans), with two pairs of diastereoisomers in a isomeric ratio of 25:75 (cis:trans). Studies were conducted with permethrin 25:75 or with a mixture of isomers where the permethrin samples contain 50-78% of the trans- isomer.

***Leaching behaviour (ADS)***

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 11 - FR CA position:**  A leaching procedure was used by the applicant in order to evaluate the emission of permethrin from the product TERMIFILM. Data used in the environmental assessment are presented below.  In the semi-field leaching test, surface samples of 1 m2 of TERMIFILM treated with 1.453 g/m2 of permethrin are exposed to weather for both horizontal and vertical devices during 6 months.  - After few weeks of weathering exposure, 339.3 mg of permethrin leached out 1 m2 for the horizontal application (23.35 % of the application rate) and 93.5 mg for the vertical application (6.44 % of the application rate). These values are used to set the first application rate event in FOCUS modelling for one house newly constructed and also in the scenarios for the exposure of the film during its installation. Quantities of permethrin leached out at the beginning of the test are presented in the table below.   |  |  |  |  | | --- | --- | --- | --- | | **Parameters used to determine the short-term leaching** | | | | | **Period between two quantitative measures of permethrin (days)** | **Film application** | **Volume of collected water (L)** | **Quantity of permethrin (mg/m2/day)** | |  |  |  |  | | 16 | Vertical | 1.5 | 89.90 | | Horizontal | 13.5 | 333.045 | | 8 | Vertical | 2.5 | 0.38 | | Horizontal | 25 | 2.25 | | 6 | Vertical | 2.5 | 0.18 | | Horizontal | 25 | 1 | | 8 | Vertical | 0.2 | 0.07 | | Horizontal | 2 | 0.6 | | 14 | Vertical | 0.8 | 0.02 | | Horizontal | 6 | 4.50E-04 | | 6 | Vertical | 2.5 | 1.05 | | Horizontal | 24 | 1.2 | | 8 | Vertical | 8 | 1.36 | | Horizontal | 30 | 2.25E-03 | | 5 | Vertical | 8 | 0.56 | | Horizontal | 25 | 1.25 | | **Total over the first period (70 days)** | **Vertical** | **-** | **339.3** | | **Horizontal** | **-** | **93.5** |   - After three months of weathering exposure, the quantity of permethrin leached out from TERMIFILM for the vertical and horizontal application is 0 mg.  In order to considered all leaching potential when permethrin is not detected in the samples, the limit of quantification of the method of analysis set to 0.075 µg/L is used to assess the long-term leaching. On the basis of the available data from the semi-field leaching test, quantities of permethrin are estimated in the table below.   |  |  |  |  | | --- | --- | --- | --- | | **Parameters used to determine the long-term leaching** | | | | | **Period between two quantitative measures of permethrin (days)** | **Film application** | **Volume of collected water (L)** | **Quantity of permethrin (mg/m2/day)** | | 16 | Vertical | 8 | 3.750E-05 | | Horizontal | 25 | 1.172E-04 | | 7 | Vertical | 0.1 | 1.071E-06 | | Horizontal | 1 | 1.071E-05 | | 7 | Vertical | 0.2 | 2.143E-06 | | Horizontal | 8 | 8.571E-05 | | 7 | Vertical | 0.2 | 2.143E-06 | | Horizontal | 3 | 3.214E-05 | | 21 | Vertical | 2 | 7.143E-06 | | Horizontal | 25 | 8.929E-05 | | 7 | Vertical | 0 | 0 | | Horizontal | 2 | 2.143E-05 | | 30 | Vertical | 2.5 | 6.696E-06 | | Horizontal | 12 | 3E-05 | | 19 | Vertical | 5 | 1.974E-05 | | Horizontal | 25 | 9.868E-05 | | **Average over long-term period (183 days)** | **Vertical** | **-** | **9.554E-06** | | **Horizontal** | **-** | **6.064E-05** |   For FOCUS modelling, these average values of 9.55E-06 and 6.06E-05 mg/m2/day for vertical and horizontal device respectively are used to set the application rate events for houses during the service-life. |

See data on permethrin.

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

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| **Infobox 12 - FR CA position:**  No new data is available. |

Degradation of permethrin was investigated under aerobic conditions in several soils. The range of reliable SFO DT50s ranged from 77 d to ~141 d at 12°C. The corresponding geomean DT50 was 106d. The cis isomer degraded more slowly than the trans isomer based on the cis:trans ratio at the time of application changing from 40:60 to 50:50 by day 30 and 78:22 by day 365. The geomean DT50 is derived from permethrin samples containing 50-78% of the trans- isomer. It can be expected that a DT50 value of 106 days is conservative enough to represent the degradation in soil at 12oC of permethrin samples containing a cis:trans ratio of 25:75. Results from another submitted set of studies (giving DT50 values at 12 °C ranging from 11.0 - 21.2 days) are not considered representative of the behaviour of permethrin in soil since the route of degradation was not identified in these latter studies but was shown not to proceed via formation of DCVA and PBA.

The route of degradation of permethrin in soil appears to be dominated by a two-step process. Permethrin breaks down to form DCVA (max 11.3 %AR, SFO DT50 12°C 33.1-~175 d) and PBA (max 15.0 %AR, 1.7-2.5 d at 12°C), and ultimately converts to CO2.

Laboratory test data indicated that NER amounts do not exceed 70% AR after 100 days nor do mineralisation rates fall below 5% AR after 100 days for permethrin.

Permethrin was observed to be relatively stable when exposed to photolysing conditions in soil. A DT50 of 200 d (Florida autumn sunlight) was estimated. However, confidence in the accuracy of this value was low since it was beyond the duration of the test (33 d & 3 hr of Florida autumn sunlight). No transformation product greater than 10 %AR was observed.

Permethrin is strongly adsorbed to soil (Mean Kfoc 73,441 L/kg, Koc 26,930 n = 9). Therefore, leaching is not expected to occur. The two major soil metabolites (DCVA & PBA) are expected to be more mobile. The mean Kfoc for DCVA was 93.2 L/kg (n = 5). For PBA the Kfoc was 141.2 L/kg.

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

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| **Infobox 13 - FR CA position:**  No new data is available. |

Permethrin was observed to be hydrolytically stable between pH 3.0/4.0 to 7.6/7 at 25/50°C respectively. Only at pH 9.0/9.6 was permethrin observed to hydrolyse, with DT50 values for cis- and trans-permethrin estimated at 35 days and 42 days, respectively (at pH 9.6 and 25°C). Permethrin is not readily biodegradable according to OECD 301B (CO2 evolution method)/US EPA OPPTS 835.3110 and OECD 301 F (oxygen consumption). Permethrin (25:75 cis:trans) exhibited inherent primary biodegradability, since its biodegradation was found to be above 20% in a validly conducted test (OECD302 C, BOD test). The results cannot be regarded as evidence of inherent ultimate biodegradability, since biodegradation was not above 70%. An effects study on microorganisms in sewage sludge was provided as a STP simulation test of permethrin degradation (40:60 cis:trans). From the data no clear evidence for degradation is observed. Whilst permethrin as a percentage of radioactivity was observed to decline it is likely that permethrin adsorbed to the sewage sludge (~80% AR) due to the strong adsorption characteristics of the parent compound. The remainder of the parent compound was observed in the supernatant. Permethrin is strongly adsorbed to soil (Mean Kf oc 73,442 L/kg (n= 10)). The two metabolites are more mobile. DCVA exhibited Kfocs ranging from 13.95 L/kg to 356.15 L/kg. Corresponding values for PBA ranged from 70.5 L/kg to 157.3 L/kg.

Permethrin (46:54 and 53:47 cis:trans) was observed to degrade in aerobic water/sediments systems, with whole-system DT50 values of cis- and trans-permethrin calculated at 63.7 days and 27.3 days, respectively at 25°C (equivalent to corresponding values at 12 °C of 180.2 days and 77.2 days). Whole-system first order degradation DT50 values for permethrin (25:75 cis:trans) incubated aerobically in water-sediment systems derived from a creek and a pond, in the dark for 120 days at 20 ± 2 °C were much faster and ranged from 14.3 days to 24.6 days (equivalent to a corresponding range at 12 °C of 27.1 days to 46.7 days). The reason for this difference is not clear.

The degradation scheme proposed for the behaviour of permethrin in aerobic watersediment systems involves as a first step transformation along parallel pathways to 3-phenoxybenzyl alcohol (PB alcohol) and 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA), followed by transformation of 3-phenoxybenzyl alcohol to 3-phenoxybenzoic acid (PBA), with carbon dioxide and bound residues as terminal products.

Maximum observed levels of DCVA, PBA and PB alcohol in the water compartment were 62.6 %AR, 28.8%AR and 38.2 %AR respectively. DCVA and PBA were also major metabolites in the sediment compartment (21.7 % and 16.4 % respectively). The whole-system first order degradation DT50 values for PB alcohol was measured at 2.7 days for the pond system (5.1 days at 12oC). No reliable DT50 value could be determined for the creek system. Whole-system first order degradation DT50 values for PBA were measured at 31.8 days for the creek system (60.3 days at 12oC) and 33.4.

days for the pond system (63.3 days at 12oC). A reliable DT50 value could not be evaluated for DCVA in either aquatic system since the maximum observed levels occurred towards the end of the study incubations and only showed small declines thereafter. Whilst no reliable DT50 value could be obtained for DCVA in the water/sediment system, the metabolite is common to other pyrethroid chemistry (e.g. cypermethrin) and reliable DT50 values have been reported that provide indicative DT50 values in water/sediment (whole system) from 80-145 days for trans-DCVA and 62 to 188 days for cis-DCVA. Further confirmatory data on the degradation of DCVA in water/sediment systems will need to be supplied by the applicants.

Permethrin was observed to degrade more slowly under anaerobic conditions, with whole-system DT50 values of cis- and trans-permethrin calculated at 179.4 days and 114.5 days, respectively (equivalent to corresponding values at 12 °C of 507.6 days and 323.9 days). A field aquatic dissipation study on a formulated product containing 10.1% w/w permethrin (cis:trans ratio not specified) indicated rapid dissipation from the water phase to sediment for both cis- and trans-permethrin, with DT50 values for the water phase calculated in the range 1.3 days to 3.1 days. Cis- and trans-permethrin appeared to be rather immobile in the sediment, remaining in the upper portion (0-5 cm). DT50 values determined for the cis- and trans-permethrin isomers in the sediment phase ranged from 118 to 256 days and 18 to 62 days, respectively. Metabolites were only detected in the water compartment and had disappeared by 90 days after the last application in the North Carolina test site and 120 days after the last application in the California test site. Based on the above results, biodegradation of Permethrin in freshwater occurred under both aerobic and anaerobic conditions.

Direct photolysis of permethrin (49:51 cis:trans) indicated slow degradation of the test material resulting in a DT50 value of 118 days with 12 hr sunlight per day under outdoor conditions at latitude of 50°N and the fall season. Control experiments revealed that permethrin was stable in water for a period of 32 days under exclusion of light. Slow degradation of permethrin under aqueous photolysis was also confirmed using the ABIWAS computer program. Overall, it is concluded that significant photolysis of permethrin will not occur under environmentally relevant pH and temperature conditions (12°C).

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

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| **Infobox 14 - FR CA position:**  No new data is available. |

Volatilization of permethrin is considered to be negligible based on the vapour pressure (2.155 x 10-6 Pa at 20°C, 25:75 cis:trans) and Henry constant (4.6 x 10-3 - > 4.5 x 10-2 Pa m3 mol-1). Permethrin volatilisation loss from a soil surface over 24 hours to the atmosphere was calculated to be 0.73% assuming a temperature of 25 °C. This calculation was performed by the CA using the Dow method (as detailed under Doc III, A7.3.1); the associated volatilisation constant for permethrin was estimated at 7.31 x 10-3 day-1. The software AOPWIN v1.91, which utilises QSAR methods, was used to calculate an atmospheric half-life value of 0.701d for the gas phase reaction of permethrin with photo-chemically produced hydroxyl radicals (24-hour day and a hydroxyl radical concentration of 5 x 105 radicals/cm3) and 49.27 d for the gas phase reaction of permethrin with ozone (assuming a 24-hour day and an ozone concentration of 7 x 1011 molecules/cm3). The calculations show that reaction with hydroxyl radicals would be expected to be the major contribution to atmospheric degradation of permethrin via gas phase reaction with photo-chemically generated species. Based on the short half-life for this transformation pathway, it is concluded that permethrin is rapidly degraded and would not be transported over large distances in the atmosphere in gaseous phase.

***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)***

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| **Infobox 15 - FR CA position:**  No new data is available. |

***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)***

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| **Infobox 16 - FR CA position:**  Not relevant. |

#### **Exposure assessment**

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| **Infobox 17 - FR CA position:**  **General information**  Risk assessments for environment have been made base on a content of 1,45 g/m² according to applicant claim. Based on concentration of 1% pure AS and on technical characteristics of TERMIFILM, calculated technical AS concentration should rather be 1.3 g/m². The concentration claimed by applicant is slightly higher that the calculated one. Hence, the risk assessment performed, based on applicant claim, is the more conservative approach.   |  |  | | --- | --- | | Assessed PT | PT 18 | | Assessed scenarios | TERMIFILM is a chemical-physical barrier for the preventive protection of new building against termite infestations. TERMIFILM is a Low Density PolyEthylene (LDPE) film, thickness of 150 µm, treated with 1% w/w of permethrin (1.45 g/m2).  The application of TERMIFILM may only be carried out by professionals. The film is placed beneath and around the building during its construction to establishing a barrier to prevent any entrance of the termites inside the building.  Thus, two installation patterns are proposed and are potentially associated:   * Use 1: vertical application   The film may be installed around the external perimeter of a building, as a vertical barrier between the building and the adjoining soil. As a worst case, a maximum height of 100 cm of TERMIFILM is considered installed around the base of the building. Soil is subsequently replaced around the building, covering the TERMIFILM.   * Use 2: horizontal application   The film may be installed underneath a building, covering the whole footprint of the house with a single layer of material. After the installation, the film is covered by the slab.  For the emission calculations, the leaching behaviour of permethrin from the TERMIFIL has been determined using semi-field leaching data. Results obtained are used in the environmental risk assessment of the TERMIFILM. | | ESD(s) used | No information is available in the ESDs for insecticides (PT18) or wood preservatives (PT8) regarding the assessment of preventive termite treatments. However, the environmental risk assessment has been performed considering equations and default values from these two documents with adaptations as described below. | | Approach | Average consumption | | Distribution in the environment | Calculated based on ECHA Guidance on the BPR Vol IV Part B ; April 2015 | | Groundwater simulation | A higher tier model (FOCUS model) is performed | | Confidential Annexes | No | | Life cycle steps assessed | Releases to the environment can take place from the following steps:   * Construction step   A time-interval of 2 weeks can be considered between the TERMIFILM installation and the slab pouring. During this interval, a short-term exposure of the environment by rainfall events is considered as relevant. According to the results of the semi-field leaching test, 23 % of permethrin leached out for the horizontal application whereas 6 % leached out for the vertical application, in the first period of the study. After this first period, no permethrin is detected in the leachates. This leaching data is used in a realistic approach  Two separate theoretical environments can be considered, taking into account rural and urban areas, with emissions directed either to the adjacent soil, or to a sewage treatment plant (STP), respectively.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Step | Area | Environmental compartments (Construction step) | | | | | | Air | STP | Soil | Surface water | Groundwater | | Construction step | Urban | - | ++ | + | + | + | | Rural | - | - | ++ | - | + |  * Service life step   During the service life of the product, due to the level of containment achieved at construction, there is no possible exposure to rainfall or interior cleaning for the both uses (horizontal and vertical). Therefore, emission to STP or surface water from either rainwater or cleaning water release to public sewage is considered not relevant. Consequently, only a potential emission to the soil (and subsequently to groundwater) has been considered.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Step | Area | Environmental compartments (Service life step) | | | | | | Air | STP | Soil | Surface water | Groundwater | | Service-life | Rural | - | - | ++ | - | + |   To conclude, 6 scenarios may be relevant for the environmental risk assessment:  - Scenario 1: During the construction step with vertical application of the product in urban area.  - Scenario 2: During the construction step with horizontal application of the product in urban area.  - Scenario 3: During the construction step with vertical application of the product in rural area.  - Scenario 4: During the construction step with horizontal application of the product in rural area.  - Scenario 5: During the service life with vertical application of the product.  - Scenario 6: During the service life with horizontal application of the product. | | Remarks |  | |

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

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| **Infobox 18 - FR CA position:**  **Active substance: Permethrin**   |  |  |  | | --- | --- | --- | | **Input parameters used in the environmental exposure assessments according to the CAR (April, 2014)** | | | | Input | Value | Unit | | **Permethrin** | | | | CAS number | 52645-53-1 | - | | Molecular weight | 391.29 | g.mol-1 | | Vapour pressure (at 20°C) | 2.16E-06 | Pa | | Water solubility (at 20°C) | 4.95E-03 | mg.L-1 | | Partition coefficient (log POW) (pH 7) | 4.67 | Log 10 | | Biodegradability | Not Ready biodegradable |  | | Degradation in soil (DT50) (at 12°C) | 106 | days | | Adsorption / desorption Koc | 26930 | L.kg-1 | | BCF fish | 570 | L.kg-1 | | BMF fish | 1 | - | | BCF earthworms | 15108 | L.kg-1 | | **Metabolites** | | | | **DCVA** | | | | Molecular weight | 209.07 | g.mol-1 | | Degradation in soil (DT50) (at 12°C) | 175 | days | | Max. % occurrence water | 62.6 | % | | Max. % occurrence soil | 11.3 | % | | Koc | 188.53 | L.kg-1 | | **PBA** | | | | Molecular weight | 214.22 | g.mol-1 | | Degradation in soil (DT50) (at 12°C) | 2.5 | days | | Max. % occurrence water | 28.8 | % | | Max. % occurrence soil | 15 | % | | Koc | 37.55 | L.kg-1 |  |  |  | | --- | --- | | **Calculated fate and distribution of Permethrin in the STP (EUSES model 2.1)** | | | Compartment | Percentage [%] | |  | | Air | 0 | | Water | 27.6 | | Sludge | 72.4 | | Degraded in STP | 0 |   **Calculation method of metabolites emissions**  To estimate PEC in the environmental compartments for the metabolites DCVA and PBA, their own Koc values and DT50 in soil at 12°C have been considered. Following the application of TERMIFILM , concentrations were estimated considering the ratio of the molecular weight of the metabolite compared to the molecular weight of permethrin (0.534 for DCVA and 0.547 for PBA), and considering the metabolite formation fraction (max. % occurrence) for the compartment in question (soil, water…) as presented above. |

***Emission estimation***

In the absence of appropriate scenario, the environmental exposure assessment of Permethrin from TERMIFILM has been determined with Emission Scenario Document (ESD) developed for product type 8 (wood preservatives) by OECD : OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Emission Scenario Document for Wood Preservatives. The emission scenario estimates the emission of wood preservatives from two stages of their life cycle:

• Application phase;

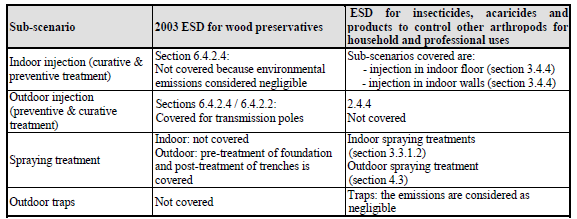
• Service life.

Termite control is an in situ treatment and was formerly described under the respective chapter

for outdoor in situ treatments. It was moved to the additional scenarios since it is not a standard application and only relevant for a limited number of substances.

The objective of termite control is to protect wooden structures against destruction by wood eating termites. Some countries consider therefore termite control as a wood preservation process. Other countries categorise this use as termiticide irrespective of the treated material. This is a regulatory issue and does not influence the potential environmental exposure from the use of these products. Therefore, when the OECD ESD for wood preservatives was prepared, the Biocides Steering Group agreed to include a scenario for this specific treatment in the ESD for wood preservatives.

In parallel, scenarios have been developed in the frame of the OECD ESD (No. 18) for insecticides, acaricides and products to control other arthropods for household and professional uses. The following table, obtained from the OECD ESD for PT18 – No. 18, summarizes emission scenarios for termite treatment covered by the respective ESDs.

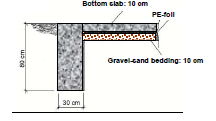


When termites are outside buildings, preventive treatment of all potentially degradable products should be performed. A key element is to build a barrier, which the termites cannot cross. In regions susceptible to the spread of termites, preventive measures should be taken before the construction of a building, by applying the treated article TERMIFILM.

**Preventive pre-construction foundation treatment**

Description of the application : The process aims to create a preventive envelope of biocide barriers for the building to be erected and its foundation. Different construction methods for building foundations exist: deep foundation methods including piles, pile walls, caissons and shallow foundations including pads (isolated footing), strip foundation and rafts. Strip foundation is the most common foundation type and represents the worst case with regard to size of the surface area to be treated. It was therefore used as basis for this emission scenario.

The area between the foundation strips can be partly or totally filled with gravel or soil before the bottom plate is set on the foundation straps in order to create an even surface. Foundations are usually 30 to 50 cm wide and 60 cm to 80 cm deep in order to reach a frost-free foundation depth. Depending on geological properties and frost depth, they can also reach larger depth.



**Environmental release pathways:**

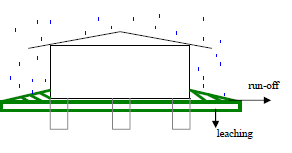
During preventive treatment of foundations, emission could occur to soil in case of rainfall. After treatment, the product which was directly in contact to soil and concrete, may leach to adjacent soil and groundwater.

Environmental compartments receiving emissions are soil from applications during the construction steps of the foundation (in-situ treatment) and adjacent untreated soil after treatment by migration from TERMIFILM (service life).

**Service life**

For horizontal application, TERMIFILM is 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.

For vertical application, the perimeter around the house is not protected by the bottom plat or the future house. This soil band can be exposed to rain and result in movement of the biocide from TERMIFILM to adjacent non-treated soil by leaching and run-off. Hence, for TERMFILM in service, and only for vertical application, emission from the perimeter are considered relevant and covered in the following.



The scenarios provided in the OECD ESD for use class 4a “Wood in contact with ground transmission pole or fence post”, covering emissions to soil from a treated structure (wood or soil) in direct contact with soil, have been adopted to assess the emission from treated to untreated soil in the perimeter.

These scenarios assume that the receiving compartment is a rectangular soil box, around treated material (wood) and the emissions from treated material to adjacent non-treated soil are a result of rainfall events and permanent contact with soil.

According to Permethrin Assessment Report, Inclusion of active substances in the positive list to Regulation (EU) No 528/2012, Ireland, April 2014, the degradation of Permethrin in soil and in the aquatic systems leads to formation of DCVA (2,2-dimethyl-3-(2,2-dichlorovinyl) cyclopropane carboxylic acid) and PBA (3-phenoxybenzoic acid) as the principal metabolites. In this risk assessment, those metabolites have been taken into account in the following observed levels reported in Permethrin Assessment Report:

|  |  |  |
| --- | --- | --- |
|  | **DCVA** | **PBA** |
| **Maximum observed levels in the soil compartment** | 11.3% | 15.0% |
| **Maximum observed levels in the water compartment** | 62.6% | 28.8% |

TERMIFILM is a treated article (Low Density PolylEthylene (LDPE) film), containing 1% w/w or 1,45 g/m² of Permethrin.

We consider that professionals can manage in average 1 building per day, and in average the delay to implement the product in a building is 6 hours for 2 persons.

**1) Tier 1**

For the emission calculations, as a tier 1, according to the 2nd EU Leaching Workshop, Varese, Italy, June 2013, it was assumed that 50% of active substance has been leached after Time 1 assessment period (considered to be 16 days as a worst case, because after this period TERMIFILM will be covered by slab and/or soil) and that 100% of active substance has been leached after Time 2 assessment period assumed to be 20 years (7300 days).

**Permethrin leaching behavior**

|  |  |  |  |
| --- | --- | --- | --- |
| Product | Active substance | Assessment period  [days] | Emission rate of Permethrin  [Kg/m2.day] |
| TERMIFILM | Permethrin | 16 (Time 1) | 4,5x10-5 |
| 7300 (Time 2) | 2x10-7 |

**For Time 1**

Permethrin application rate: 1.45 g/m²

Emission rate: 1,45 g/m²x0,5/16d = 0,045 g/m²/d= 4,5x10-5 kg/m²/d

**For Time 2**

Permethrin application rate: 1.45 g/m²

Emission rate: 1,45 g/m²/7300d = 2x10-4 g/m²/d= 2x10-7 kg/m²/d

**2) Tier 2**

For the emission calculations, the leaching behaviour of permethrin, from TERMIFILM, has been determined using semi-field leaching data.

In report No. BK\_2012\_SemiFieldLeaching\_TERMIFILM\_05\_2012 from laboratory SARPAP et CECIL INDUSTRIES, in annex of this assessment report, we have obtained results of semi-field leaching tests realized on the product TERMIFILM.

Results used in this risk assessment are represented below in Table 2.2-1.

**Permethrin leaching behavior – Horizontal application**

|  |  |  |  |
| --- | --- | --- | --- |
| Product | Active substance | Assessment period  [days] | Emission rate of Permethrin  [Kg/m2.day] |
| TERMIFILM | Permethrin | 16 (Time 1) | 2x10-5 |
| 7300 (Time 2) | 4,7x10-8 |

For Time 1 of 16 days, result from test duration of 16 days has been taken into account.

For Time 2 of 20 years, result from test duration of 6 months has been taken into account because no leaching of permethrin was observed between the 3rd and the 6th month test duration. Refer to test report No. BK\_2012\_SemiFieldLeaching\_TERMIFILM\_05\_2012.

**For Time 1**

Emission rate: 0,33 g/m²/16d = 2x10-2 g/m²/d= 2x10-5 kg/m²/d

**For Time 2**

Permethrin application rate: 0.2 g/m²

Emission rate: 0,34 g/m²/7300d = 4,7x10-5 g/m²/d= 4,7x10-8 kg/m²/d

**Permethrin leaching behavior – Vertical application**

|  |  |  |  |
| --- | --- | --- | --- |
| Product | Active substance | Assessment period  [days] | Emission rate of Permethrin  [Kg/m2.day] |
| TERMIFILM | Permethrin | 16 (Time 1) | 5,6x10-6 |
| 7300 (Time 2) | 1,3x10-8 |

For Time 1 of 16 days, result from test duration of 16 days has been taken into account.

For Time 2 of 20 years, result from test duration of 6 months has been taken into account because no leaching of permethrin was observed between the 3rd and the 6th month test duration. Refer to test report No. BK\_2012\_SemiFieldLeaching\_TERMIFILM\_05\_2012.

**For Time 1**

Emission rate: 0,09 g/m²/16d = 5,6x10-3 g/m²/d= 5,6x10-6 kg/m²/d

**For Time 2**

Permethrin application rate: 0.2 g/m²

Emission rate: 0,095 g/m²/7300d = 1,3x10-5 g/m²/d= 1,3x10-8 kg/m²/d

**Emission Scenarios for the product application**

**Emission scenario for horizontal application**

**Horizontal application - Tier 1**

***Sewage Treatment Plant (STP)***

***Table: Application phase - STP***

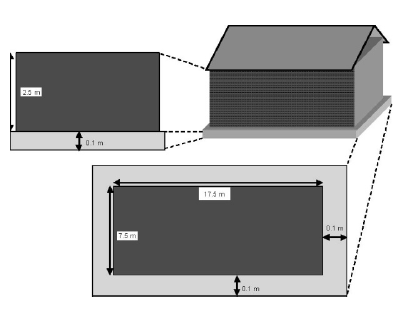
|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** |
|  | | | | |
| **INPUTS** |  |  |  |  |
| Building area treated per day | *AREABuilding-treated* | 144 | [m2.d-1] | A |
| Application rate: quantity of a.i. applied per 1 m2 of building area | *Qai* | 1.45x10-3 | [kg.m-2] | A |
| Fraction released to facility drain  *solubility in water* [mg/L] <0.25 | *Ffacilitydrain* | 0.0001 | [--] | D |
| Fraction released to air  *vapour pressure at 20 °C* [Pa] < 0,005 | *Fair* | 0 | [--] | D |
| Fraction of spray drift deposition | *Fdrift* | 0 | [--] | D |
| **OUTPUTS** |  |  |  |  |
| Local emission rate to air | *Elocalair* | 0 | [kg.d-1] | O |
| Local emission rate to facility drain | *Elocalfacilitydrain* | 2.1x10-5 | [kg.d-1] | O |
| Local facility drain concentration | *Clocalfacilitydrain* | 8.1x10-7 | mg/L | O |

D=default, A=based on information of applicant, O=output

**Calculations:**

o Horizontal application :

According to the “Workshop on environmental risk assessment for insecticides, acaricides and products to control other arthropods (Product type 18)” – Brussels, Belgium, 11th of December 2007”, dimensions”, the default size of a private house are L = 17.5 m and I = 7.5m.



As a worst case, we have considered that the TERMIFILM is apply to the whole surface + 0,5m above to protect the surface of the house.

So the AREA Building-treated = (Lhouse + 0.5) x (lhouse + 0.5)

= (17.5+0.5) x (7.5+0.5)

= 144 [m2.d-1]

- Application rate of a.i. (active ingredient) [kg.m-2]:

Qai = 1% w/w equivalent to 1.45 g/m² = 1.45x10-3 [kg.m-2]

- In situ : Emissions to local air [kg.d-1]

Elocalair = AREA Building-treated x Qai x (Fair +Fdrift)

Elocalair = 144 x 1.45 x10-3 x (0+0) = 0 [kg.d-1]

- In situ : Emissions to facility drain [kg.d-1]

Elocalfacilitydrain = AREA Building-treated x Qai x Ffacilitydrain

Elocalfacilitydrain= 144 x 1.45 x 10-3 x 0.0001 = 2,1x10-5 [kg.d-1]

- PECSTP

Clocalfacilitydrain= Elocalfacilitydrain /FLOW facilitydrain

The OECD ESD does not give a default value of FLOWfacilitydrain. This can be assumed to be a small creek with a flow of 0.3 m3/s.

Clocalfacilitydrain= 2,1x10-5 x 106 / (86400x0.3x103) = 8,1x10-7 mg/L

The facility drain is assumed to drain into the public sewage treatment plant (STP).

***Soil compartment***

***Table Application phase – Soil***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** | |
| **Service life** | | | | | |
| **INPUTS** |  |  |  | |  |
| Treated house area | *AREAtreated perimeter* | 144 | [m2] | | D |
| Cumulative quantity of Permethrin leached out of 1 m2 of TERMIFILM over the initial assessment period | *QAapplic,product* | 1.45x10-3 | [Kg.m-2] | | S |
| Duration of the initial assessment periodA | *TIME* | 16 | [d] | | D |
| Density of (wet) soil | *RHOsoil* | 1700 | [kg.m-3] | | D |
| Volume of untreated soil adjacent to the treated perimeter (distance of 0.1 m) | *VOLUMEhouse,soil* | 14.4 | [m3] | | D |
| **OUTPUTS** |  |  |  | |  |
| Total volume of product leaching out from the treated perimeter | *Totalproduct, leach* | 1.1x10-1 | [Kg] | | O |
| Cumulative quantity of a.i. leaching to the  receiving soil adjacent and below the perimeter | *Qadj house soil* | 6.9x10-3 | [kg.d-1] | | O |
| Concentration of a.i. in the receiving untreated soil | *Cadj house soil* | See below | [kg.kgwwt-1] | | O |

**Calculations :**

For the calculation of the receiving untreated soil volume a dimension box extending horizontally and vertically to a distance of 10 cm from the treated perimeter is considered:

VOLUMEhouse,soil = AREAtreated perimeter x 0.1 = 144 x 0.1 = 14.4 m3

As a tier 1, we have considered that 50% of permethrin will be leach out.

QAapplic,product = 1.45 g/m² / 2 = 7.3x10-4 Kg/m²

Totalproduct,leach = AREAtreatedperimeter x QAapplic,product

= 144 x 7.3x10-4

= 1.1x10-1 Kg

**Emission to soil after treatment:**

Qadj house soil = Totalproduct,leach / Time

= 1.1x10-1 / 16 = 6.9x10-3

Cadj house soil = Qadj house soil / (RHOsoil x Volumehouse,soil)

= 6.9x10-3 / (1700 x 14.4) = 2.8x10-7 kg.kgwwt-1

Due to Permethrin degradation in soil leading to DCVA (observed level: 11.3%) and PBA (observed level 15.0%) as principal metabolites, it has been assumed that 73.7% of Permethrin concentration left in soil.

Permethrin

Concentration of Permethrin in soil = 2.8x10-7 x 73.7% = 2.1x10-7 [kg.kgwwt-1]

DCVA

Concentration of DCVA in soil =

Concentration of Permethrin in Soil \* Molecular weight of DCVA (209.07) \* % metabolite in soil (0.113) / Molecular weight of Permethrin (391.29)

(Refer to LANXESS Permethrin endpoints, Dr. Claudia Bickers, the 3rd of July 2015.)

Concentration of DCVA in soil = (2.8x10-7 x 209.07 x 0.113)/391.29=1.7x10-8 [kg.kgwwt-1]

PBA

Concentration of PBA in soil =

Concentration of Permethrin in Soil \* Molecular weight of PBA (214.22) \* % metabolite in soil (0.15) / Molecular weight of Permethrin (391.29)

(Refer to LANXESS Permethrin endpoints, Dr. Claudia Bickers, the 3rd of July 2015.)

Concentration of PBA in soil = (2.8x10-7 x 214.22 x 0.15)/391.29=2.3x10-8 [kg.kgwwt-1]

**Summary of estimated local concentration in soil from Permethrin:**

|  |  |
| --- | --- |
| **Substance** | **Cadjhouse,soil,withoutFkoc [kg.kgwwt-1]** |
| Permethrin | 2.1x10-7 |
| DCVA | 1.7x10-8 |
| PBA | 2.3x10-8 |

**Horizontal application - Tier 2 – Soil compartment**

***Table Application phase – Soil***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** | |
| **Service life** | | | | | |
| **INPUTS** |  |  |  | |  |
| Treated house area | *AREAtreated perimeter* | 144 | [m2] | | D |
| Cumulative quantity of Permethrin leached out of 1 m2 of TERMIFILM over the initial assessment period | *QAapplic,product* | 9x10-5 | [Kg.m-2] | | S |
| Duration of the initial assessment periodA | *TIME* | 16 | [d] | | D |
| Density of (wet) soil | *RHOsoil* | 1700 | [kg.m-3] | | D |
| Volume of untreated soil adjacent to the treated perimeter (distance of 0.1 m) | *VOLUMEhouse,soil* | 14.4 | [m3] | | D |
| **OUTPUTS** |  |  |  | |  |
| Total volume of product leaching out from the treated perimeter | *Totalproduct, leach* | 4.75x10-2 | [Kg] | | O |
| Cumulative quantity of a.i. leaching to the  receiving soil adjacent and below the perimeter | *Qadj house soil* | 2.9x10-3 | [kg.d-1] | | O |
| Concentration of a.i. in the receiving untreated soil | *Cadj house soil* | See below | [kg.kgwwt-1] | | O |

**Calculations :**

For the calculation of the receiving untreated soil volume a dimension box extending horizontally and vertically to a distance of 10 cm from the treated perimeter is considered :

VOLUMEhouse,soil = AREAtreated perimeter x 0.1 = 144 x 0.1 = 14.4 m3

As a tier 2, we have taking into account the total amount of active ingredient leached out at the end of the assessment period (16 days) for vertical application, obtained according to the semi-field done (Test report N° BK\_2012\_SemiFieldLeaching\_TERMIFILM\_05\_2012).

QAapplic,product = 333 mg/m² = 3.3x10-4 Kg/m²

Totalproduct,leach = AREAtreatedperimeter x QAapplic,product

= 144 x 3.3x10-4

= 4.75x10-2 Kg

Emission to soil after treatment:

Qadj house soil = Totalproduct,leach / Time

= 4.75x10-2 / 16 = 2,9x10-3

Cadj house soil = Qadj house soil / (RHOsoil x Volumehouse,soil)

= 2.9x10-3 / (1700 x 14.4) = 1.2x10-7 kg.kgwwt-1

Due to Permethrin degradation in soil leading to DCVA (observed level: 11.3%) and PBA (observed level 15.0%) as principal metabolites, it has been assumed that 73.7% of Permethrin concentration left in soil.

Permethrin

Concentration of Permethrin in soil = 1.2x10-7 x 73.7% = 8.9x10-8 [kg.kgwwt-1]

DCVA

Concentration of DCVA in soil =

Concentration of Permethrin in Soil \* Molecular weight of DCVA (209.07) \* % metabolite in soil (0.113) / Molecular weight of Permethrin (391.29)

(Refer to LANXESS Permethrin endpoints, Dr. Claudia Bickers, the 3rd of July 2015.)

Concentration of DCVA in soil = (1.2x10-7 x 209.07 x 0.113)/391.29=0.7x10-8 [kg.kgwwt-1]

PBA

Concentration of PBA in soil =

Concentration of Permethrin in Soil \* Molecular weight of PBA (214.22) \* % metabolite in soil (0.15) / Molecular weight of Permethrin (391.29)

(Refer to LANXESS Permethrin endpoints, Dr. Claudia Bickers, the 3rd of July 2015.)

Concentration of PBA in soil = (1.2x10-7 x 214.22 x 0.15)/391.29=1x10-8 [kg.kgwwt-1]

**Summary of estimated local concentration in soil from Permethrin:**

|  |  |
| --- | --- |
| **Substance** | **Cadjhouse,soil,withoutFkoc [kg.kgwwt-1]** |
| Permethrin | 8.9x10-8 |
| DCVA | 0.7x10-8 |
| PBA | 1x10-8 |

**Emission scenario for vertical application**

**Vertical application - Tier 1**

***Sewage Treatment Plant (STP)***

***Table Application phase - STP***

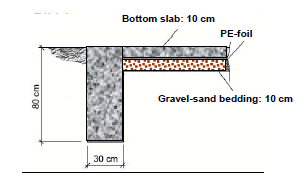
|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** |
|  | | | | |
| **INPUTS** |  |  |  |  |
| Building area treated per day | *AREABuilding-treated* | 50 | [m2.d-1] | A |
| Application rate: quantity of a.i. applied per 1 m2 of building area | *Qai* | 1,45x10-3 | [kg.m-2] | A |
| Fraction released to facility drain  *solubility in water* [mg/L] <0.25 | *Ffacilitydrain* | 0.0001 | [--] | D |
| Fraction released to air  *vapour pressure at 20 °C* [Pa] < 0,005 | *Fair* | 0 | [--] | D |
| Fraction of spray drift deposition | *Fdrift* | 0 | [--] | D |
| **OUTPUTS** |  |  |  |  |
| Local emission rate to air | *Elocalair* | 0 | [kg.d-1] | O |
| Local emission rate to facility drain | *Elocalfacilitydrain* | 7,25x10-6 | [kg.d-1] | O |
| Local facility drain concentration | *Clocalfacilitydrain* | 2,8x10-7 | mg/L | O |

D=default, A=based on information of applicant, O=output

**Calculations:**

*o Vertical application :*

According to the “REVISED EMISSION SCENARIO DOCUMENT FOR WOOD PRESERVATIVES” published by OECD the 27th of September 2013, the area between the foundation strips can be partly or totally filled with gravel or soil before the bottom plate is set on the foundation straps in order to create an even surface. Foundations are usually 30 to 50 cm wide and 60 cm to 80 cm deep in order to reach a frost-free foundation depth. Depending on geological properties and frost depth, they can also reach larger depth.



As a worst case, we have considered that 1m of TERMIFILM is apply to protect the height of the foundation.

According to the “Workshop on environmental risk assessment for insecticides, acaricides and products to control other arthropods (Product type 18)” – Brussels, Belgium, 11th of December 2007”, dimensions”, the default size of a private house are L = 17.5 m and I = 7.5 m.

So the AREABuilding-treated = Perimeter of the house X Height of the foundation

= ((Lhouse + lhouse) x 2) X Height of the foundation

= ((17.5 + 7.5) x 2) X 1

= 50 [m2.d-1]

- Application rate of a.i. (active ingredient) [kg.m-2]:

Qai = 1% w/w equivalent to 1.45 g/m² = 1.45x10-3 [kg.m-2]

- In situ : Emissions to local air [kg.d-1]

Elocalair = AREABuilding-treated x Qai x (Fair +Fdrift)

Elocalair = 50 x 1.45 x10-3 x (0+0) = 0 [kg.d-1]

- In situ : Emissions to facility drain [kg.d-1]

Elocalfacilitydrain = AREABuilding-treated x Qai x Ffacilitydrain

Elocalfacilitydrain= 50 x 1.45 x 10-3 x 0.0001 = 7,25x10-6 [kg.d-1]

- PECSTP

Clocalfacilitydrain= Elocalfacilitydrain /FLOW facilitydrain

The OECD ESD does not give a default value of FLOWfacilitydrain. This can be assumed to be a small creek with a flow of 0.3 m3/s.

Clocalfacilitydrain= 7,25x10-6 x 106 / (86400x0.3x103) = 2,8x10-7 mg/L

The facility drain is assumed to drain into the public sewage treatment plant (STP).

***Soil compartment***

***Table : Application phase – Soil***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** | |
| **Service life** | | | | | |
| **INPUTS** |  |  |  | |  |
| Treated house area | *AREAtreated perimeter* | 50 | [m2] | | D |
| Cumulative quantity of Permethrin leached out of 1 m2 of TERMIFILM over the initial assessment period | *QAapplic,product* | 1.45x10-3 | [Kg.m-2] | | S |
| Duration of the initial assessment periodA | *TIME* | 16 | [d] | | D |
| Density of (wet) soil | *RHOsoil* | 1700 | [kg.m-3] | | D |
| Volume of untreated soil adjacent to the treated perimeter (distance of 0.1 m) | *VOLUMEhouse,soil* | 5 | [m3] | | D |
| **OUTPUTS** |  |  |  | |  |
| Total volume of product leaching out from the treated perimeter | *Totalproduct, leach* | 3.7x10-2 | [Kg] | | O |
| Cumulative quantity of a.i. leaching to the  receiving soil adjacent and below the perimeter | *Qadj house soil* | 2.3x10-3 | [kg.d-1] | | O |
| Concentration of a.i. in the receiving untreated soil | *Cadj house soil* | See below | [kg.kgwwt-1] | | O |

**Calculations :**

For the calculation of the receiving untreated soil volume a dimension box extending horizontally and vertically to a distance of 10 cm from the treated perimeter is considered :

VOLUMEhouse,soil = AREAtreated perimeter x 0.1 = 50 x 0.1 = 5 m3

As a tier 1, we have considered that 50% of permethrin will be leach out.

QAapplic,product = 1.45 g/m² / 2 = 7.3x10-4 Kg/m²

Totalproduct,leach = AREAtreatedperimeter x QAapplic,product

= 50 x 7.3x10-4

= 3.7x10-2 Kg

**Emission to soil after treatment:**

Qadj house soil = Totalproduct,leach / Time

= 3.7x10-2 / 16 = 2.3x10-3

Cadj house soil = Qadj house soil / (RHOsoil x Volumehouse,soil)

= 2.3x10-3 / (1700 x 5) = 2.7x10-7 kg.kgwwt-1

Due to Permethrin degradation in soil leading to DCVA (observed level: 11.3%) and PBA (observed level 15.0%) as principal metabolites, it has been assumed that 73.7% of Permethrin concentration left in soil.

Permethrin

Concentration of Permethrin in soil = 2.7x10-7 x 73.7% = 2x10-7 [kg.kgwwt-1]

DCVA

Concentration of DCVA in soil =

Concentration of Permethrin in Soil \* Molecular weight of DCVA (209.07) \* % metabolite in soil (0.113) / Molecular weight of Permethrin (391.29)

(Refer to LANXESS Permethrin endpoints, Dr. Claudia Bickers, the 3rd of July 2015.)

Concentration of DCVA in soil = (2.7x10-7 x 209.07 x 0.113)/391.29=1.6x10-8 [kg.kgwwt-1]

PBA

Concentration of PBA in soil =

Concentration of Permethrin in Soil \* Molecular weight of PBA (214.22) \* % metabolite in soil (0.15) / Molecular weight of Permethrin (391.29)

(Refer to LANXESS Permethrin endpoints, Dr. Claudia Bickers, the 3rd of July 2015.)

Concentration of PBA in soil = (2.7x10-7 x 214.22 x 0.15)/391.29=2.2x10-8 [kg.kgwwt-1]

**Summary of estimated local concentration in soil from Permethrin:**

|  |  |
| --- | --- |
| **Substance** | **Cadjhouse,soil,withoutFkoc [kg.kgwwt-1]** |
| Permethrin | 2x10-7 |
| DCVA | 1.6x10-8 |
| PBA | 2.2x10-8 |

**Vertical application - Tier 2**

***Soil compartment***

***Table : Application phase – Soil***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** | |
| **Service life** | | | | | |
| **INPUTS** |  |  |  | |  |
| Treated house area | *AREAtreated perimeter* | 50 | [m2] | | D |
| Cumulative quantity of Permethrin leached out of 1 m2 of TERMIFILM over the initial assessment period | *QAapplic,product* | 9x10-5 | [Kg.m-2] | | S |
| Duration of the initial assessment periodA | *TIME* | 16 | [d] | | D |
| Density of (wet) soil | *RHOsoil* | 1700 | [kg.m-3] | | D |
| Volume of untreated soil adjacent to the treated perimeter (distance of 0.1 m) | *VOLUMEhouse,soil* | 5 | [m3] | | D |
| **OUTPUTS** |  |  |  | |  |
| Total volume of product leaching out from the treated perimeter | *Totalproduct, leach* | 4.5x10-3 | [Kg] | | O |
| Cumulative quantity of a.i. leaching to the  receiving soil adjacent and below the perimeter | *Qadj house soil* | 2.8x10-4 | [kg.d-1] | | O |
| Concentration of a.i. in the receiving untreated soil | *Cadj house soil* | See below | [kg.kgwwt-1] | | O |

**Calculations :**

For the calculation of the receiving untreated soil volume a dimension box extending horizontally and vertically to a distance of 10 cm from the treated perimeter is considered :

VOLUMEhouse,soil = AREAtreated perimeter x 0.1 = 50 x 0.1 = 5 m3

As a tier 2, we have taking into account the total amount of active ingredient leached out at the end of the assessment period (16 days) for vertical application, obtained according to the semi-field done (Test report N° BK\_2012\_SemiFieldLeaching\_TERMIFILM\_05\_2012).

QAapplic,product = 89.9 mg/m² = 9x10-5 Kg/m²

Totalproduct,leach = AREAtreatedperimeter x QAapplic,product

= 50 x 9x10-5

= 4.5x10-3 Kg

**Emission to soil after treatment:**

Qadj house soil = Totalproduct,leach / Time

= 4.5x10-3 / 16 = 2,8x10-4

Cadj house soil = Qadj house soil / (RHOsoil x Volumehouse,soil)

= 2.8x10-4 / (1700 x 5) = 3.3x10-8 kg.kgwwt-1

Due to Permethrin degradation in soil leading to DCVA (observed level: 11.3%) and PBA (observed level 15.0%) as principal metabolites, it has been assumed that 73.7% of Permethrin concentration left in soil.

Permethrin

Concentration of Permethrin in soil = 3.3x10-8 x 73.7% = 2.4x10-8 [kg.kgwwt-1]

DCVA

Concentration of DCVA in soil =

Concentration of Permethrin in Soil \* Molecular weight of DCVA (209.07) \* % metabolite in soil (0.113) / Molecular weight of Permethrin (391.29)

(Refer to LANXESS Permethrin endpoints, Dr. Claudia Bickers, the 3rd of July 2015.)

Concentration of DCVA in soil = (3.3x10-8 x 209.07 x 0.113)/391.29=2x10-9 [kg.kgwwt-1]

PBA

Concentration of PBA in soil =

Concentration of Permethrin in Soil \* Molecular weight of PBA (214.22) \* % metabolite in soil (0.15) / Molecular weight of Permethrin (391.29)

(Refer to LANXESS Permethrin endpoints, Dr. Claudia Bickers, the 3rd of July 2015.)

Concentration of PBA in soil = (3.3x10-8 x 214.22 x 0.15)/391.29=2.7x10-9 [kg.kgwwt-1]

**Summary of estimated local concentration in soil from Permethrin:**

|  |  |
| --- | --- |
| **Substance** | **Cadjhouse,soil,withoutFkoc [kg.kgwwt-1]** |
| Permethrin | 2.4x10-8 |
| DCVA | 2x10-9 |
| PBA | 2.7x10-9 |

**Scenario for TERMIFILM in Service life**

**Service life - Horizontal application**

According to the “REVISED EMISSION SCENARIO DOCUMENT FOR WOOD PRESERVATIVES” published by OECD the 27th of September 2013, page 100 :

“Emission to soil: The soil volumes and areas treated 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.”

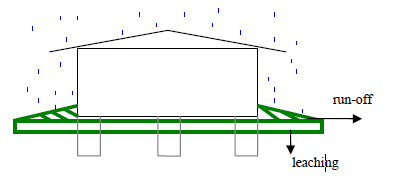
**Service life - Vertical application**

**Service life - Vertical application - Tier 1**

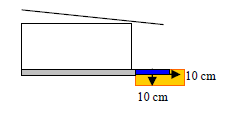
According to the “REVISED EMISSION SCENARIO DOCUMENT FOR WOOD PRESERVATIVES” published by OECD the 27th of September 2013, page 100 :

“The perimeter around the house is not protected by the bottom plat or the future house. This soil band can be exposed to rain and result in movement of the biocide from the treated soil to adjacent non- treated soil by leaching and run-off.”

Hence, for TERMIFILM in service, only emission from the perimeter are considered relevant and covered in the following



Leaching occurs from the treated perimeter. For the calculation of the receiving soil volume, a dimension box extending horizontally and vertically to a distance of 10 cm from the treated perimeter is considered.



Volume of receiving soil :

VOLUMEadj house,soil = ((Lhouse + (0.1x2)) x 0.1 x Height of the foundation) x 2) + (lhouse x 0.1 x Height of the foundation x 2)

= ((17.5 + 0.2) x 0.1 x 1 x 2) + (7.5 x 0.1 x 1 x 2)

= 5,04 m3

As a tier 1, we have considered that 100% of permethrin will be leach out.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** | |
| **Service life** | | | | | |
| **INPUTS** |  |  |  | |  |
| Treated house area | *AREAtreated perimeter* | 50 | [m2] | | D |
| Cumulative quantity of Permethrin leached out of 1 m2 of TERMIFILM over the initial assessment period | *QAapplic,product* | 1.45x103 | [Kg.m-2] | | S |
| Duration of the initial assessment periodA | *TIME* |  | [d] | | D |
| Density of (wet) soil | *RHOsoil* | 1700 | [kg.m-3] | | D |
| Volume of untreated soil adjacent to the treated perimeter (distance of 0.1 m) | *VOLUMEadj house,soil* | 5.04 | [m3] | | D |
| Fraction of product lost to surface adjacent non treated soil by run-off from the upper layer of soil | *Frun-off* | 0.1 | [-] | | D |
| Fraction of product leaching to deeper soil layers, depending on the Koc  > 500 - 2000  > 2000 - 5000  > 5000 | *FKoc* | 0.5  0.1  0 | [-] | | D |
| **OUTPUTS** |  |  |  | |  |
| Total volume of product leaching out from the treated perimeter | *Totalproduct, leach* | 7.25x10-2 | [Kg] | | O |
| Cumulative quantity of a.i. leaching to the  receiving soil adjacent and below the perimeter | *Qadj house soil* | 7.25x10-2 | [kg] | | O |
| Concentration of a.i. in the receiving untreated soil adjacent to perimeter | *Cadj house soil* | See below | [kg.kgwwt-1] | | O |

A) Parameter is provided as information but not further considered in the equations since it is assumed that the total quantity applied is leaching over the assessment period, thus no daily leaching is used for the calculation which would be needed to be multiplied with TIME.

**Calculations :**

As a tier 1, we have considered that 100% of permethrin will be leach out.

QAapplic,product = 1.45 g/m² = 1.45x10-3 Kg/m²

Totalproduct,leach = AREAtreatedperimeter x QAapplic,product

= 50 x 1.45x10-3

= 7.25x10-2 Kg

**Emission to soil after treatment:**

Qadjhouse,soil = Totalproduct,leach

= 7.25x10-2 kg

Concentration of a.i. in the receiving untreated soil adjacent to perimeter, without Fkoc

Cadjhouse,soil,withoutFkoc = (Qadjhouse,soil / (RHOsoil x VOLUMEadjhouse,soil)) x Frunoff

= (7.25x10-2 / (1700 x 5.04)) x 0.1 x 1 = 8.5x10-7 kg.kgwwt-1

Due to Permethrin degradation in soil leading to DCVA (observed level: 11.3%) and PBA (observed level 15.0%) as principal metabolites, it has been assumed that 73.7% of Permethrin concentration left in soil.

Permethrin

Concentration of Permethrin in soil = 8.5x10-7 x 73.7% = 6.3x10-7 [kg.kgwwt-1]

DCVA

Concentration of DCVA in soil =

Concentration of Permethrin in Soil \* Molecular weight of DCVA (209.07) \* % metabolite in soil (0.113) / Molecular weight of Permethrin (391.29)

(Refer to LANXESS Permethrin endpoints, Dr. Claudia Bickers, the 3rd of July 2015.)

Concentration of DCVA in soil = (8.5x10-7 x 209.07 x 0.113)/391.29=5.1x10-8 [kg.kgwwt-1]

PBA

Concentration of PBA in soil =

Concentration of Permethrin in Soil \* Molecular weight of PBA (214.22) \* % metabolite in soil (0.15) / Molecular weight of Permethrin (391.29)

(Refer to LANXESS Permethrin endpoints, Dr. Claudia Bickers, the 3rd of July 2015.)

Concentration of PBA in soil = (8.5x10-7 x 214.22 x 0.15)/391.29=7x10-8 [kg.kgwwt-1]

**Summary of estimated local concentration in soil from Permethrin:**

|  |  |
| --- | --- |
| **Substance** | **Cadjhouse,soil,withoutFkoc [kg.kgwwt-1]** |
| Permethrin | 6.3x10-7 |
| DCVA | 5.1x10-8 |
| PBA | 7x10-8 |

*Cadjhouse,soil* **=** *Cadjhouse,soil,withoutFkoc x FKoc*

|  |  |  |  |
| --- | --- | --- | --- |
| **Substance** | **Koc** | **FKoc** | **Cadjhouse,soil**  **[kg.kgwwt-1]** |
| Permethrin | 26930 | 0 | 0 |
| DCVA | 93 | 1 | 5.1x10-8 |
| PBA | 141 | 1 | 7x10-8 |

**Service life - Vertical application - Tier 2**

As a tier 2, we have taking into account the results obtained according to the semi-field done (Test report N° BK\_2012\_SemiFieldLeaching\_TERMIFILM\_05\_2012).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter/variable** | **Nomenclature** | **Value** | **Unit** | **Origin** | |
| **Service life** | | | | | |
| **INPUTS** |  |  |  | |  |
| Treated house area | *AREAtreated perimeter* | 50 | [m2] | | D |
| Cumulative quantity of Permethrin leached out of 1 m2 of TERMIFILM over the initial assessment period | *QAapplic,product* | 9.35x10-5 | [Kg.m-2] | | S |
| Duration of the initial assessment periodA | *TIME* |  | [d] | | D |
| Density of (wet) soil | *RHOsoil* | 1700 | [kg.m-3] | | D |
| Volume of untreated soil adjacent to the treated perimeter (distance of 0.1 m) | *VOLUMEadj house,soil* | 5.04 | [m3] | | D |
| Fraction of product lost to surface adjacent non treated soil by run-off from the upper layer of soil | *Frun-off* | 0.1 | [-] | | D |
| Fraction of product leaching to deeper soil layers, depending on the Koc  > 500 - 2000  > 2000 - 5000  > 5000 | *FKoc* | 0.5  0.1  0 | [-] | | D |
| **OUTPUTS** |  |  |  | |  |
| Total volume of product leaching out from the treated perimeter | *Totalproduct, leach* | 4.7x10-3 | [Kg] | | O |
| Cumulative quantity of a.i. leaching to the  receiving soil adjacent and below the perimeter | *Qadj house soil* | 4.7x10-3 | [kg] | | O |
| Concentration of a.i. in the receiving untreated soil adjacent to perimeter | *Cadj house soil* | See below | [kg.kgwwt-1] | | O |

A) Parameter is provided as information but not further considered in the equations since it is assumed that the total quantity applied is leaching over the assessment period, thus no daily leaching is used for the calculation which would be needed to be multiplied with TIME.

**Calculations :**

As a tier 2, we have taking into account the total amount of active ingredient leached out at the end of the assessment period for vertical application, obtained according to the semi-field done (Test report N° BK\_2012\_SemiFieldLeaching\_TERMIFILM\_05\_2012).

QAapplic,product = 93.509 mg/m² = 9.35x10-5 Kg/m²

Totalproduct,leach = AREAtreatedperimeter x QAapplic,product

= 50 x 9.35x10-5

= 4.7x10-3 Kg

**Emission to soil after treatment:**

Qadjhouse,soil = Totalproduct,leach

= 4.7x10-3 kg

Concentration of a.i. in the receiving untreated soil adjacent to perimeter, without Fkoc

Cadjhouse,soil,withoutFkoc = (Qadjhouse,soil / (RHOsoil x VOLUMEadjhouse,soil)) x Frunoff

= (4.7x10-3 / (1700 x 5.04)) x 0.1 = 5.5x10-8 kg.kgwwt-1

Due to Permethrin degradation in soil leading to DCVA (observed level: 11.3%) and PBA (observed level 15.0%) as principal metabolites, it has been assumed that 73.7% of Permethrin concentration left in soil.

Permethrin

Concentration of Permethrin in soil = 5.5x10-8 x 73.7% = 4.1x10-8 [kg.kgwwt-1]

DCVA

Concentration of DCVA in soil =

Concentration of Permethrin in Soil \* Molecular weight of DCVA (209.07) \* % metabolite in soil (0.113) / Molecular weight of Permethrin (391.29)

(Refer to LANXESS Permethrin endpoints, Dr. Claudia Bickers, the 3rd of July 2015.)

Concentration of DCVA in soil = (5.5x10-8 x 209.07 x 0.113)/391.29=3.3x10-9 [kg.kgwwt-1]

PBA

Concentration of PBA in soil =

Concentration of Permethrin in Soil \* Molecular weight of PBA (214.22) \* % metabolite in soil (0.15) / Molecular weight of Permethrin (391.29)

(Refer to LANXESS Permethrin endpoints, Dr. Claudia Bickers, the 3rd of July 2015.)

Concentration of PBA in soil = (5.5x10-8 x 214.22 x 0.15)/391.29=4.5x10-9 [kg.kgwwt-1]

**Summary of estimated local concentration in soil from Permethrin:**

|  |  |
| --- | --- |
| **Substance** | **PECsoil,leach,time2 [kg.kgwwt-1]** |
| Permethrin | 4.1x10-8 |
| DCVA | 3.3x10-9 |
| PBA | 4.5x10-9 |

*Cadjhouse,soil* **=** *Cadjhouse,soil,withoutFkoc x FKoc*

|  |  |  |  |
| --- | --- | --- | --- |
| **Substance** | **Koc** | **FKoc** | **Cadjhouse,soil**  **[kg.kgwwt-1]** |
| Permethrin | 26930 | 0 | 0 |
| DCVA | 93 | 1 | 3.3x10-9 |
| PBA | 141 | 1 | 4.5x10-9 |

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| **Infobox 19 - FR CA position:**   1. ***Construction step***   The following scenarios consider that the TERMIFILM installation may occur during rainfall events which can cause emissions of active substance in environmental compartments.  In urban area, only releases to STP are foreseen. To calculate the total amount of the active substance reaching the STP, assumptions have to be made about the number of buildings in which TERMIFILM is installed per day, within a typical STP catchment area. No information is available in the ESDs for insecticides (PT18) or wood preservatives (PT8) regarding the prevalence of preventive termite treatments. Therefore this risk assessment has been performed considering a value of 1 house per day where the TERMIFILM product is installed.  In rural area, only releases to the adjacent soil (and groundwater) are foreseen. In the absence of significant soil disturbance, permethrin emitted from the TERMIFILM barrier is likely to remain in the immediate proximity of its release point, with any potential impact highly localised to the layer of soil immediately adjacent to the barrier (based on a distance of 0.5 m vertically and horizontally).  The parameters used in the assessment have been taken from the ESD PT18 (OECD, 2008) or ESD PT8 (OECD, 2013) such as dimensions of house, volume of the receiving soil compartment adjacent to the film.  Scenario 1 and 3: Emission during the construction step with VERTICAL application of the product in urban and rural area  As mentioned by the applicant, TERMIFILM is placed around the entire external perimeter, with a height of 100 cm. The total area of TERMIFILM applied to a single house (*AREAbarrier*) is therefore 50 m2 ((2 × 17.5 m + 2 × 7.5 m) × 1 m). The results of the semi-field leaching test are taken into account considering that the percentage of permethrin leached out from TERMIFILM during the first days of its use when it is applied vertically is 6 %.  Scenario 2 and 4: Emission during the construction step with HORIZONTAL application of the product in urban and rural area  TERMIFILM is installed underneath the building, covering its whole footprint. The total area of film installed underneath the house (AREAbarrier) is therefore 131.25 m2 (17.5 m × 7.5 m). Furthermore, data from the semi-field leaching test show that 23 % of permethrin leached out from TERMIFILM during the first days of its use when it is applied horizontally.  The table below presents input parameters needed to calculate the local emission for the scenario 1,2,3 and 4   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Input parameters for calculating the local emission in scenarios** | | | | | | **Parameter** | **Symbol** | **Value** | **Unit** | **Remarks** | | **INPUTS** | | | | | | Length of the house | Lhouse | 17.5 | [m] | Default value - ESD PT18 | | Width of the house | Whouse | 7.5 | [m] | Default value - ESD PT18 | | Quantity of permethrin in the product applied | Dose | 1.45 | [g.m-2] | - | | **Scenario 1: Emission during the construction step with vertical application of the product in urban area** | | | | | | Depth of the vertical barrier around the building | Dbarrier | 1 | [m] | - | | Area of the vertical barrier around the building | AREAbarrier | 50 | [m2] | - | | Fraction of permethrin leached out from vertical film | Fleach | 0.06 | [-] | See info box 11 | | **OUTPUT SCENARIO 1** | | | | | | Local emission to waste water | Elocal,ww | 4.35E-03 | [kg.d-1] | - | | **Scenario 2: Emission during the construction step with horizontal application of the product in urban area** | | | | | | Area of a house where leaching occurs | AREAhouse | 131.25 | [m2] | - | | Fraction of permethrin leached out from horizontal film | Fleach | 0.23 | [-] | See info box 11 | | **OUTPUT SCENARIO 2** | | | | | | Local emission to waste water | Elocal,ww | 4.38E-02 | [kg.d-1] | - | | **Scenario 3: Emission during the construction step with vertical application of the product in rural area** | | | | | | **OUTPUT SCENARIO 3** | | | | | | Local emission to adjacent soil | Esoil,leach | 4.35E+03 | [mg.d-1] | - | | **Scenario 4: Emission during the construction step with horizontal application of the product in rural area** | | | | | | **OUTPUT SCENARIO 4** | | | | | | Local emission to adjacent soil | Esoil,leach | 4.38E+04 | [mg.d-1] | - |  1. ***Service life step***   Scenario 5: Emission during the service life with VERTICAL application of the product  The use of TERMIFILM around the external perimeter of a building may result in emission to the adjacent soil around the foundations of the building, only due to the level of containment of the film achieved at construction. Any quantity of permethrin emitted from the TERMIFILM barrier is likely to remain in the immediate proximity of its release point, with any potential impact highly localised to the layer of soil immediately adjacent to the barrier.  Assuming 100 % release to soil over the life span of the barrier (30 years) provides a worst-case assessment where no active substance is lost to other compartments via wash-off and considering the leaching values from the semi-field study demonstrating no emission from the film on the long-term period.  As describe previously in the construction step, calculations have been performed based on the dimensions of a typical house defined in the ESD for PT18 (OECD, 2008). TERMIFILM is placed around the entire external perimeter, with a height of 1 m. The total area of TERMIFILM applied to a single house (*AREAbarrier*) is 50 m2. Considering 100 % emission over 30 years and a maximum active substance dose rate of 1.45 g.m-2 for TERMIFILM , the cumulative quantity of permethrin released per m2 over the product lifetime (*Qleach*; mg.m-2) can be calculated as follows:    According to ESD PT8, the continuous daily loading rate of permethrin to soil from a single treated house (Esoil,leach; mg.d-1) is then calculated as:  The table below presents input parameters needed to calculate the local emission for the scenario 5   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Input parameters for calculating the local emission in scenario 5** | | | | | | **Parameter** | **Symbol** | **Value** | **Unit** | **Remarks** | | **Scenario 5: Emission during the service life step with vertical application of the product** | | | | | | **INPUTS** | | | | | | Length of the house | Lhouse | 17.5 | [m] | Default value - ESD PT18 | | Width of the house | Whouse | 7.5 | [m] | Default value - ESD PT18 | | Quantity of permethrin in the product applied | Dose | 1.45 | [g.m-2] | - | | Depth of the vertical barrier around the building | Dbarrier | 1 | [m] | - | | Area of the vertical barrier around the building | AREAbarrier | 50 | [m2] | - | | Expected product life (30years) | TIME | 10950 | [d-1] | - | | **OUTPUT** | | | | | | Quantity of permethrin released per m2 over the product lifetime | Qleach | 1450 | [mg.m-2] | Eq. ESD PT8 | | Local emission to adjacent soil per day over the product lifetime | Esoil,leach | 6.62 | [mg.d-1.house-1] | Eq. ESD PT8 |   Scenario 6: Emission during the service life with HORIZONTAL application of the product  As explain in the scenario 5, the use of TERMIFILM underneath of a building may result in emission to the adjacent soil around the slab of the building only. Any quantity of permethrin emitted from the TERMIFILM layer is likely to remain in the immediate proximity of its release point, with any potential impact highly localised to the layer of soil immediately adjacent to the film. Assuming 100 % release to soil over the life span of the barrier (30 years) provides a worst-case assessment where no active substance is lost to other compartments than soil via wash-off and considering the leaching values from the semi-field study demonstrating no emission from the film on the long-term period.  As previous scenarios, calculations have been performed based on the dimensions of a typical house defined in the ESD for PT18 (OECD, 2008). The total area of TERMIFILM installed underneath the house (AREAhouse) is therefore 131.25 m2. Considering 100% emission over 30 years and a maximum active substance dose rate of 1.45 g.m-2 for TERMIFILM , the cumulative quantity of permethrin released per m2 over the product lifetime (*Qleach*; mg.m-2) can be calculated as showed for the scenario 5.  According to ESD PT8, the continuous, daily loading rate of permethrin in soil from a single treated house (Esoil, leach, time; mg.d-1) is then calculated as described above for the scenario 5.  The table below presents output parameters needed to calculate the local emission for the scenario 6   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Input parameters for calculating the local emission in scenario 6** | | | | | | **Parameter** | **Symbol** | **Value** | **Unit** | **Remarks** | | **Scenario 6: Emission during the service life step with horizontal application of the product** | | | | | | **INPUTS** | | | | | | Length of the house | Lhouse | 17.5 | [m] | Default value - ESD PT18 | | Width of the house | Whouse | 7.5 | [m] | Default value - ESD PT18 | | Quantity of permethrin in the product applied | Dose | 1.45 | [g.m-2] | - | | Area of a house where leaching occurs | AREAhouse | 131.25 | [m2] | - | | Expected product life (30years) | TIME | 10950 | [d-1] | - | | **OUTPUT** | | | | | | Quantity of permethrin released per m2 over the product lifetime | Qleach | 1450 | [mg.m-2] | Eq. ESD PT8 | | Local emission to adjacent soil per day over the product lifetime | Esoil,leach | 1.74E+01 | [mg.d-1.house-1] | Eq. ESD PT8 | |

***Calculated PEC values***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **Infobox 20 - FR CA position:**  Scenario 1: Emission during the construction step with vertical application of the product in urban area (releases to STP only)  The concentrations in the different environmental compartments following releases to the STP for the active substance (permethrin) and metabolites (DCVA and PBA) are summarised in the following table.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values for the scenario 1** | | | | | | |  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 6.00E-04 | 5.77E-05 | 3.38E-02 | 5.86E-03 | 7.98E-03 | | DCVA | - | 1.93E-05 | 9.42E-05 | 4.16E-04 | 8.91E-02 | | PBA | - | 9.10E-06 | 1.45E-05 | 5.75E-05 | 1.23E-02 |   Scenario 2: Emission during the construction step with horizontal application of the product in urban area (releases to STP only)  The concentrations in the different environmental compartments following releases to the STP for the active substance (permethrin) and metabolites (DCVA and PBA) are summarised in the following table.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values for the scenario 2** | | | | | | |  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** | | [mg.L-1l] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 6.04E-03 | 5.81E-04 | 3.40E-01 | 5.90E-02 | 8.03E-02 | | DCVA | - | 1.94E-04 | 9.48E-04 | 4.18E-03 | **8.97E-01** | | PBA | - | 9.15E-05 | 1.46E-04 | 5.78E-04 | **1.24E-01** |   Scenario 3: Emission during the construction step with vertical application of the product in rural area (releases to soil only)  Predicted concentrations of permethrin and metabolites in soil were calculated considering the volume of the receiving soil compartment adjacent to the TERMIFILM (Vsoil). According to ESD PT8, a volume of the receiving soil compartment around the house of 13 m3 is taking into account as the vertical film is located during the installation above the ground at the periphery of the building.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Input parameters for calculating the PECsoil in scenario 3** | | | | | | **Parameter** | **Symbol** | **Value** | **Unit** | **Remarks** | | **INPUTS** | | | | | | Local emission to adjacent soil | Esoil,leach | 4.35 | [g.d-1.house] | - | | Volume of the soil | Vsoil | 13 | [m3] | Default value - ESD PT8 | | Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | - |   The results for the active substance (permethrin) and metabolites (DCVA and PBA) are summarised in the following table.   |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC values for the scenario 3** | | | |  | **PECsoil** | **PECGW** | | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 1.97E-01 | **0.414** | | DCVA | 1.19E-02 | **3.45** | | PBA | 1.62E-02 | **20.7** |   Scenario 4: Emission during the construction step with horizontal application of the product in rural area (releases to soil only)  Predicted concentrations of permethrin and metabolites in soil were calculated considering the volume of the receiving soil compartment underneath the TERMIFILM (Vsoil). The film is applied on prepared bedding sand or directly on the soil underneath the house. Therefore, the volume of the receiving soil compartment corresponds to (131.25 m × 0.5 m) is 65.6 m3.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Input parameters for calculating the PECsoil in scenario 4** | | | | | | **Parameter** | **Symbol** | **Value** | **Unit** | **Remarks** | | **INPUTS** | | | | | | Local emission to adjacent soil | Esoil,leach | 4.38E+01 | [g.d-1.house] | - | | Volume of the soil | Vsoil | 65.6 | [m3] | - | | Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | - |   The results for the active substance (permethrin) and metabolites (DCVA and PBA) are summarised in the following table.   |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC values for the scenario 4** | | | |  | **PECsoil** | **PECGW** | | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 3.93E-01 | **0.826** | | DCVA | 2.37E-02 | **6.88** | | PBA | 3.22E-02 | **41.3** |   Scenario 5: Emission during the service life with vertical application of the product (releases to soil only)  Predicted concentrations of permethrin and metabolites in soil were calculated from the local emission considering the volume of the receiving soil compartment adjacent to the TERMIFILM (Vsoil). Leaching of the active substance was assumed to occur vertically and horizontally to a distance of 0.5 m from the barrier, in accordance with the ESD for PT18 (OECD, 2008).  The height of the TERMIFILM material applied around the perimeter of the house is 1 m. Therefore, the typical depth of the receiving soil compartment is 1.5 m. The volume of the receiving soil compartment was calculated by subtracting the volume of the foundations to the depth of the receiving compartment (17.5 m × 7.5 m × 1.5 m) from that of the receiving soil compartment together with the foundations (18.5 m × 8.5 m × 1.5 m), resulting in value for Vsoil of 39m3.  According to the ESD for PT8, a steady-state concentration in soil is calculated, assuming continuous release over time, and considering that no emission to soil is assumed for the installation/construction step as 100% of the applied permethrin is considered emitted during the service-life (although the leaching study demonstrates no emission of permethrin for the long-term period).   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Input parameters for calculating the PECsoil in scenario 5** | | | | | | **Parameter** | **Symbol** | **Value** | **Unit** | **Remarks** | | **INPUTS** | | | | | | Local emission to adjacent soil - permethrin | Esoil,leach | 6.62 | [mg.d-1.house-1] | - | | Local emission to adjacent soil - DCVA | Esoil,leach | 0.4 | [mg.d-1.house-1] | - | | Local emission to adjacent soil - PBA | Esoil,leach | 0.544 | [mg.d-1.house-1] | - | | Volume of the soil | Vsoil | 39 | [m3] | - | | Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | - | | Degradation rate in soil of permethrin | kpermethrin | 6.54E-03 | [d-1] |  | | Degradation rate in soil of DCVA | kDCVA | 3.96E-03 | [d-1] |  | | Degradation rate in soil of PBA | kPBA | 2.77E-01 | [d-1] |  | | Assessment time | time | 10950 | [d-1] |  |   The results for the active substance (permethrin) and metabolites (DCVA and PBA) are summarised in the following table.   |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC values for the scenario 5** | | | |  | **PECsoil steady-state** | **PECGW** | | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 1.53E-02 | 0.032 | | DCVA | 1.52E-03 | **0.442** | | PBA | 2.96E-05 | 0.038 |   Scenario 6: Emission during the service life with horizontal application of the product (releases to soil only)  Predicted concentrations of permethrin in soil were calculated from the local emission considering the volume of the receiving soil compartment adjacent to the TERMIFILM (*Vsoil*). Leaching of the active substance was assumed to occur vertically and horizontally to a distance of 0.5 m from the barrier, in accordance with the ESD for PT18 (OECD, 2008).The volume of the receiving soil compartment was therefore calculated as 65.625 m3 (131.25 m2 × 0.5 m).  According to the ESD for PT8, as explained for the scenario 5, a steady-state concentration in soil is calculated, assuming continuous release over time, and considering that no emission to soil is assumed for the installation/construction step. So, 100 % release to soil over the life span of the product.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Input parameters for calculating the PECsoil in scenario 6** | | | | | | **Parameter** | **Symbol** | **Value** | **Unit** | **Remarks** | | **INPUTS** | | | | | | Local emission to adjacent soil - permethrin | Esoil,leach | 17.4 | [mg.d-1.house-1] | - | | Local emission to adjacent soil - DCVA | Esoil,leach | 1.05 | [mg.d-1.house-1] | - | | Local emission to adjacent soil - PBA | Esoil,leach | 1.43 | [mg.d-1.house-1] | - | | Volume of the soil | Vsoil | 65.6 | [m3] | - | | Bulk density of wet soil | RHOsoil | 1700 | [kg.m-3] | - | | Degradation rate in soil of permethrin | kpermethrin | 6.54E-03 | [d-1] |  | | Degradation rate in soil of DCVA | kDCVA | 3.96E-03 | [d-1] |  | | Degradation rate in soil of PBA | kPBA | 2.77E-01 | [d-1] |  | | Assessment time | time | 10950 | [d-1] |  |   The results for the active substance (permethrin) and metabolites (DCVA and PBA) are summarised in the following table.   |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC values for the scenario 6** | | | |  | **PECsoil steady-state** | **PECGW** | | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 2.38E-02 | 0.050 | | DCVA | 2.37E-03 | **0.689** | | PBA | 4.61E-05 | 0.059 | |

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| **Infobox 21** **- FR CA position:**  ***High-tier assessment for groundwater for scenario 1 to 6***  During the construction step and the service life of TERMIFILM, the groundwater compartment presents PEC values > 0.1 µg/L for permethrin and/or its metabolites DCVA and PBA. These values indicate a potential risk to groundwater. A more realistic, higher-tier assessment of the potential for groundwater contamination associated with soil applications of permethrin has also been carried out using the simulation model FOCUS-PEARL 4.4.4.  The leaching potential of permethrin and its metabolites were 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.  It is necessary to calculate an effective permethrin application rate per hectare. The total daily loading rate of permethrin in soil from a single treated house is calculated in considering a worst case approach where the product is applied around the external perimeter (use 1) and underneath (use 2) a building:  The assessment assumes a default value of 16 houses build and treated with TERMIFILM per hectare (Nhouse). The corresponding application rate of permethrin to land can be calculated using the following equation:  As explained in the **Infobox 11 - FR CA position:**, based on the semi-field data on TERMIFILM, after few weeks of weathering exposure, 339.3 mg of permethrin leached out 1 m2 for the horizontal application and 93.5 mg for the vertical application. These values are used to set the first application rate event for one house newly constructed, knowing that 16 houses are considered by hectare including only one newly constructed per year (arbitrary set in January). Calculated parameters are presented in the following table.   |  |  |  |  | | --- | --- | --- | --- | | **Parameters used to determine inputs data in FOCUS PEARL for the installation phase** | | | | | **Symbol** | **Value** | **Unit** | **Remarks** | | AREA barrier vertical | 50 | [m2.house-1] | Input | | AREA barrier horizontal | 131.25 | [m2.house-1] | Input | | Qleach time barrier vertical | 339.3 | [mg.m-2] | Measured | | Qleach time barrier horizontal | 93.5 | [mg.m-2] | Measured | | Esoil, leach barrier vertical | 4.68E+03 | [mg.house-1] | Output | | Esoil, leach barrier horizontal | 4.45E+04 | [mg.house-1] | Output | | Esoil, leach total | 4.92E+04 | [mg.house-1] | Output | | Nhouse (installation phase) | 1 | [house.ha-1] | Default | | Emission days | 1 | [d.year-1] | Default | | Nb application per year | 1 | - | Default | | Appl rate for a newly constructed house | 4.92E-02 | [kg.ha-1] | Output |   As detailed in the **Infobox 11 - FR CA position:**, the average values of 9.55E-06 and 6.06E-05 mg/m2/day for vertical and horizontal device respectively are used to set the rate events for one house during its service-life, knowing that 16 houses are considered by hectare including only one newly constructed per year. Calculated parameters are presented in the following table   |  |  |  |  | | --- | --- | --- | --- | | **Parameters used to determine inputs data in FOCUS PEARL for the service life** | | | | | **Symbol** | **Value** | **Unit** | **Remarks** | | AREA barrier vertical | 50 | [m2.house-1] | Input | | AREA barrier horizontal | 131.25 | [m2.house-1] | Input | | Qleach time barrier vertical | 9.55E-06 | [mg.d-1.m-2] | Measured | | Qleach time barrier horizontal | 6.06E-05 | [mg.d-1.m-2] | Measured | | Esoil, leach barrier vertical | 4.78E-04 | [mg.d-1.house-1] | Output | | Esoil, leach barrier horizontal | 7.96E-03 | [mg.d-1.house-1] | Output | | Esoil, leach total | 8.44E-03 | [mg.d-1.house-1] | Output | | Nhouse | 16 | [house.ha-1] | Default | | Emission days | 365 | [d.year-1] | Default | | Nb application per year | 10 | - | Default | | Appl rate for 16 houses (1 ha) | 4.92E-06 | [kg.ha-1] | Output |   Ten applications of permethrin were modelled each year during the simulation period (30 years). The first application rate is of 4.92E-02 kg a.s.ha-1 (considering leaching for one new house and 15 houses for which service-life is relevant), and the next application rate for the nine other dates is of 4.92E-06 kg 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 FOCUS PEARL 4.4.4** | | | **Parameter** | **Value** | | Scenario | | | Location | All 9 EU scenario | | Crop Calendar | GRASS (alfalfa) | | Repeat interval for application events | 1 year | | Deposition | No deposition | | Freundlich exponent | 1 | | Coefficient for uptake for plant | 0 | | Molar activation energy | 54 kJ.mol-1 | | Substances | | | Name | Permethrin | | Parent | Yes | | 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 at 01-Jan (kg/ha) | **4.92E-02** | | Dosage at the nine other date (kg/ha) | **4.92E-06** |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Overview of result from FOCUS PEARL** | | | | | | **Result-text** | **Permethrin** | **DCVA** | **PBA** | **Location** | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.032978 | 0 | CHATEAUDUN | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.057668 | 0 | HAMBURG | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.037996 | 0 | JOKIOINEN | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.03685 | 0 | KREMSMUENSTER | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.049679 | 0 | OKEHAMPTON | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.041298 | 0 | PIACENZA | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.030192 | 0 | PORTO | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.011306 | 0 | SEVILLA | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.019098 | 0 | THIVA |   Conclusion: All PECGW values for permethrin and its metabolites were below the trigger value of 0.1 μg.L-1, indicating safe use for permethrin and its metabolites DCVA and PBA.  The FOCUS modelling covers all the scenarios (construction and service-life) for the use of TERMIFILM, as well as a potential cumulative application of films in vertical and horizontal positions. |

***Primary and secondary poisoning***

Primary poisoning

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| **Infobox 22 - FR CA position:**  Not relevant |

Secondary poisoning

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 23 - FR CA position:**  The active substance permethrin has a log Kow > 3 (log Kow = 4.67) and a BCF > 100 (mean BCF in fish = 570 L.kg-1, BMF = 1 and BCF in earthworm = 15108 L.kg-1). According to the scenario secondary poisoning may occur via the aquatic food chain and/or 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.  The results for each scenario are summarised in the following tables.   |  |  |  | | --- | --- | --- | | **Summary table on estimated theoretical exposition for the permethrin** | | | |  | **PEC in fish** | **PEC in earthworm** | | [mg.kg wet fish-1] | [mg.kg wet earthworm-1] | | Scenario 1 (construction vertical urban) | 1.64E-02 | 5.44E-02 | | Scenario 2 (construction horizontal urban) | 1.65E-01 | 5.48E-01 | | Scenario 3 (construction vertical rural) | - | 2.82 | | Scenario 4 (construction horizontal rural) | - | 5.62 | | Scenario 5 (service-life vertical) | - | 2.19E-01 | | Scenario 6 (service-life horizontal) | - | 3.41E-01 | |

### Risk characterisation

***Atmosphere***

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| **Infobox 24 - FR CA position:**  Significant exposure of the environment via air is not expected whatever the considered use (external perimeter or underneath building).  According to the CAR, volatilization of permethrin is considered to be negligible based on the vapour pressure (2.155 × 10-6 Pa at 20°C) and Henry constant (4.5 × 10-2 Pa.m3.mole-1). Permethrin would not be transported over large distances in the atmosphere in gaseous phase.  Conclusion:Emissions and PECs in air are considered as negligible. It can be concluded that the use of the product TERMIFILM will not pose a significant risk to the atmospheric compartment. |

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

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 25 - FR CA position:**   |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC/PNEC values for permethrin** | | **Conclusion** | |  | **PEC/PNECSTP** | | Scenario 1 (construction vertical urban) | 1.21E-01 | Acceptable | | Scenario 2 (construction horizontal urban) | **1.22** | Unacceptable |   No ecotoxicological data are available to set a PNEC value for the metabolites for the STP compartment.  Conclusion:  During the construction step,the risk characterisation ratio is below 1 for the use 1 (vertical application) of TERMIFILM . For the use 2 (horizontal application) of the product, the risk characterisation is above 1. Consequently during the construction step, the risk for the STP is acceptable for the use 1 and not acceptable for the use 2. |

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| **Phase** | **Scenario** | **Active substance** | **PECSTP [mg/L]** | **PNECSTP [mg/L]** |  |  |
| **Single private house assessment** | | | | | | |
| Implementation | Horizontal application | Permethrin | 7,2E-08 | 4,95E-03 | 1,45E-05 | **2,9E-05** |
| DCVA | 2,8E-07 | 127,6 | 2,2E-09 |
| PBA | 1,3E-07 | 16,91 | 7,7E-09 |
| Vertical application | Permethrin | 7,2E-08 | 4,95E-03 | 1,45E-05 |
| DCVA | 2,8E-07 | 127,6 | 2,2E-09 |
| PBA | 1,3E-07 | 16,91 | 7,7E-09 |
| Service life | Horizontal application | Permethrin | 7E-08 | 4,95E-03 | 1,41E-05 | **2,8E-05** |
| DCVA | 2,7E-07 | 127,6 | 2,1E-09 |
| PBA | 1,3E-07 | 16,91 | 7,7E-09 |
| Vertical application | Permethrin | 7E-08 | 4,95E-03 | 1,41E-05 |
| DCVA | 2,7E-07 | 127,6 | 2,1E-09 |
| PBA | 1,3E-07 | 16,91 | 7,7E-09 |

Cumulative assessment: The number of private houses connected to STP is supposed to be 4.000. We consider, as a worst case, that 50% of the households have been protected with TERMIFILM , so 2.000 households.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Phase** | **Scenario** | **Active substance** | **PECSTP [mg/L]** | **PNECSTP [mg/L]** |  |  |
| **Cumulative private house assessment** | | | | | | |
| Implementation | Horizontal application | Permethrin | 1,44E-04 | 4,95E-03 | 2,9E-02 | **5,8E-02** |
| DCVA | 5,6E-04 | 127,6 | 4,4E-06 |
| PBA | 2,6E-04 | 16,91 | 1,5E-05 |
| Vertical application | Permethrin | 1,44E-04 | 4,95E-03 | 2,9E-02 |
| DCVA | 5,6E-04 | 127,6 | 4,4E-06 |
| PBA | 2,6E-04 | 16,91 | 1,5E-05 |
| Service life | Horizontal application | Permethrin | 1,4E-04 | 4,95E-03 | 2,8E-02 | **5,6E-02** |
| DCVA | 5,4E-04 | 127,6 | 4,2E-06 |
| PBA | 2,6E-04 | 16,91 | 1,5E-05 |
| Vertical application | Permethrin | 1,4E-04 | 4,95E-03 | 2,8E-02 |
| DCVA | 5,4E-04 | 127,6 | 4,2E-06 |
| PBA | 2,6E-04 | 16,91 | 1,5E-05 |

***Aquatic compartment***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **Infobox 26 - FR CA position:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Summary table on calculated PEC/PNEC values** | | | | **Conclusion** | |  |  | **PEC/PNECwater** | **PEC/PNECsed** | | Scenario 1 (construction vertical urban) | Permethrin | **123.8** | **155.9** | Unacceptable | | DCVA | 1.29E-03 | 7.85E-03 | Acceptable | | PBA | 9.10E-04 | 1.62E-03 | Acceptable | | Scenario 2 (construction horizontal urban) | Permethrin | **1235** | **1568** | Unacceptable | | DCVA | 1.29E-02 | 7.90E-02 | Acceptable | | PBA | 9.15E-03 | 1.63E-02 | Acceptable |   Conclusion:  During the construction step, the risk characterisation ratios for permethrin in water and sediment compartments are above 1 for the use 1 (vertical application) and 2 (horizontal application) of the product TERMIFILM. The risk characterisation ratios for metabolites are below 1.  The risks related to the use of TERMIFILM during the construction step are not acceptable for the aquatic compartment when releases are directed to an STP.  Risk mitigation measures are necessary to limit the emission to STP during the installation phase of the TERMIFILM product. |

For this evaluation, it has been assumed that the first compartment impacted by the emission of active ingredient is soil and in a second phase, according to the mobility of soil of the active ingredient, a part of the emission in the soil is able to migrate into the surface water compartment.

*Elocalsurfacewater,time= Esoil,leach,time [kg.d-1] X FKoc*

FKoc is the fraction of active ingredient leaching to deeper soil layers,depending on the Koc

* Koc < 500 ⇨ FKoc = 1
* Koc = 500 – 2000 ⇨ FKoc = 0,5
* Koc = 2000 – 5000 ⇨ FKoc = 0,1
* Koc > 5000 ⇨ FKoc = 0

Permethrine : Koc = 26930 ⇨ FKoc = 0

DCVA : Koc = 93 ⇨ FKoc = 1

PBA : Koc = 141 ⇨ FKoc = 1

*Clocalsurfacewater,time= Elocalsurfacewater,time / FLOW surfacewater,time*

The OECD ESD does not give a default value of FLOW*surfacewater*. This can be assumed to be a small creek with a flow of 0.3 m3/s.

*Clocalsurfacewater= Elocalsurfacewater,time x 106 / (86400x0.3x103) = Elocalsurfacewater,time X 0,04 [mg/L]*

*= Esoil,leach,time X FKoc X 0,04 [mg/L]*

NB : For permethrin we have considered that the degradation of permethrin in soil will result in 2 main metabolites to obtain :

Permethrin = 73,7%

DCVA = 11,3%

PBA = 15%

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Phase** | **Scenario** | **Active substance** | **PECwater [mg/L]** | **PNECwater [mg/L]** |  |  |
| **Tier 1** | | | | | | |
| Implementation | Horizontal application | Permethrin | 5.2E-06 | 4,7E-07 | 10,6 | **21** |
| DCVA | 2E-05 | 1,5E-02 | 1,3E-03 |
| PBA | 9.6E-06 | 1E-02 | 9,6E-04 |
| Vertical application | Permethrin | 5.2E-06 | 4,7E-07 | 10,6 |
| DCVA | 2E-05 | 1,5E-02 | 1,3E-03 |
| PBA | 9.6E-06 | 1E-02 | 9,6E-04 |
| **Tier 2** | | | | | | |
| Implementation | Horizontal application | Permethrin | 2.2E-06 | 4,7E-07 | 4,7 | **6** |
| DCVA | 8.7E-06 | 1,5E-02 | 6E-04 |
| PBA | 4.1E-06 | 1E-02 | 4.1E-04 |
| Vertical application | Permethrin | 6,4E-07 | 4,7E-07 | 1,36 |
| DCVA | 2.5E-06 | 1,5E-02 | 1,6E-04 |
| PBA | 1.2E-06 | 1E-02 | 1,1E-04 |
| **Tier 3** | | | | | | |
| Implementation | Horizontal application | Permethrin | 4.5E-08 | 4,7E-07 | 9,6E-02 | **0,12** |
| DCVA | 1.7E-07 | 1,5E-02 | 1,1E-05 |
| PBA | 0,8E-07 | 1E-02 | 0,8E-05 |
| Vertical application | Permethrin | 1,3E-08 | 4,7E-07 | 2.8E-02 |
| DCVA | 5E-08 | 1,5E-02 | 3,3E-06 |
| PBA | 2.4E-08 | 1E-02 | 2,4E-06 |
| **Service life – Tier 1** | | | | | | |
| Service life | House | Permethrin | 3,4E-10 | 4,7E-07 | 7E-04 | **7E-04** |
| DCVA | 1,3E-09 | 1,5E-02 | 8,6E-08 |
| PBA | 6,3E-10 | 1E-02 | 6,3E-07 |

***Terrestrial compartment***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 27 - FR CA position:**   |  |  |  |  | | --- | --- | --- | --- | | **Summary table on calculated PEC/PNEC soil values** | | | **Conclusion** | |  |  | **PEC/PNECsoil** |  | | Scenario 1  (construction vertical urban) | Permethrin | 6.69E-02 | Acceptable | | DCVA | 9.04E-05 | Acceptable | | PBA | 3.99E-05 | Acceptable | | Scenario 2  (construction horizontal urban) | Permethrin | 6.73E-01 | Acceptable | | DCVA | 9.09E-04 | Acceptable | | PBA | 4.02E-04 | Acceptable | | Scenario 3  (construction vertical rural) | Permethrin | **2.25** | Unacceptable | | DCVA | 2.58E-03 | Acceptable | | PBA | 1.12E-02 | Acceptable | | Scenario 4  (construction horizontal rural) | Permethrin | **4.48** | Unacceptable | | DCVA | 5.15E-03 | Acceptable | | PBA | 2.24E-02 | Acceptable | | Scenario 5  (service-life vertical) | Permethrin | 1.74E-01 | Acceptable | | DCVA | 3.31E-04 | Acceptable | | PBA | 2.05E-05 | Acceptable | | Scenario 6  (service-life horizontal) | Permethrin | 2.72E-01 | Acceptable | | DCVA | 5.16E-04 | Acceptable | | PBA | 3.20E-05 | Acceptable |   Conclusion:  During the construction step,the risk characterisation ratios are below 1 for permethrin and its metabolites in soil for the use 1 (vertical application) and 2 (horizontal application) in urban area (when releases are directed to the STP), but risks are deemed unacceptable for permethrin in rural area (when releases are directed to the adjacent soil).  During the service life, the risk characterisation ratios for permethrin and its metabolites are below 1.  The risks for the terrestrial compartment related to the use of TERMIFILM during the construction step are not acceptable for the soil compartment when releases are directed to the adjacent soil. For the exposure of soil during the service life of the product, the risks are acceptable. |

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| --- | --- | --- | --- | --- | --- | --- |
| **Phase** | **Scenario** | **Active substance** | **PECSoil [mg/L]** | **PNECSoil [mg/L]** |  |  |
| **Tier 1** | | | | | | |
| Implementation | Horizontal application | Permethrin | 5.3E-06 | 8,76E-02 | 0,6E-04 | **1,2E-04** |
| DCVA | 4.4E-07 | 4,6 | 0,96E-07 |
| PBA | 5.9E-07 | 1,44 | 4,1E-07 |
| Vertical application | Permethrin | 5.3E-06 | 8,76E-02 | 0,6E-04 |
| DCVA | 4.4E-07 | 4,6 | 0,96E-07 |
| PBA | 5.9E-07 | 1,44 | 4,1E-07 |
| **Tier 2** | | | | | | |
| Implementation | Horizontal application | Permethrin | 5.9E-07 | 8,76E-02 | 0,7E-05 | **0,9E-05** |
| DCVA | 4,8E-08 | 4,6 | 1E-08 |
| PBA | 6.6E-08 | 1,44 | 4,6E-08 |
| Vertical application | Permethrin | 1.6E-07 | 8,76E-02 | 1,8E-06 |
| DCVA | 1.3E-08 | 4,6 | 0,3E-08 |
| PBA | 1.8E-08 | 1,44 | 1,3E-08 |
| **Tier 3** | | | | | | |
| Implementation | Horizontal application | Permethrin | 5.9E-07 | 8,76E-02 | 0,7E-05 | **0,9E-05** |
| DCVA | 4,8E-08 | 4,6 | 1E-08 |
| PBA | 6.6E-08 | 1,44 | 4,6E-08 |
| Vertical application | Permethrin | 1.6E-07 | 8,76E-02 | 1,8E-06 |
| DCVA | 1.3E-08 | 4,6 | 0,3E-08 |
| PBA | 1.8E-08 | 1,44 | 1,3E-08 |
| **Service life – Tier 1** | | | | | | |
| Service life | House | Permethrin | 7.4E-07 | 8,76E-02 | 8,4E-05 | **8,4E-05** |
| DCVA | 6E-08 | 4,6 | 1,3E-08 |
| PBA | 8.2E-08 | 1,44 | 5,7E-08 |

***Groundwater***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 28 - FR CA position:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Summary table on calculated PEC groundwater (µg/L)**  **Comparison with the limit value of 0.1 µg/L.** | | | **Conclusion** | | | **Tier 1** | **Tier 2** | | Scenario 1  (construction vertical urban) | Permethrin | 7.98E-03 | Acceptable | **Acceptable for all locations with FOCUS PEARL 4.4.4 (scenario covering installation of films and service-life as well as the cumulative use in vertical and horizontal positions)** | | DCVA | 8.91E-02 | Acceptable | | PBA | 1.23E-02 | Acceptable | | Scenario 2  (construction horizontal urban) | Permethrin | 8.03E-02 | Acceptable | | DCVA | **0.897 (>0.1)** | **Unacceptable** | | PBA | **0.124 (>0.1)** | **Unacceptable** | | Scenario 3  (construction vertical rural) | Permethrin | **0.414 (>0.1)** | **Unacceptable** | | DCVA | **3.45 (>0.1)** | **Unacceptable** | | PBA | **20.7 (>0.1)** | **Unacceptable** | | Scenario 4  (construction horizontal rural) | Permethrin | **0.826 (>0.1)** | **Unacceptable** | | DCVA | **6.88 (>0.1)** | **Unacceptable** | | PBA | **41.3 (>0.1)** | **Unacceptable** | | Scenario 5  (service-life vertical) | Permethrin | 0.032 | Acceptable | | DCVA | **0.442 (>0.1)** | **Unacceptable** | | PBA | 0.037 | Acceptable | | Scenario 6  (service-life horizontal) | Permethrin | 0.050 | Acceptable | | DCVA | **0.689 (>0.1)** | **Unacceptable** | | PBA | 0.059 | Acceptable |   Conclusion:  According to the results of FOCUS-PEARL model (presented in **Infobox 21 - FR CA position:**), concentrations in groundwater for permethrin, DCVA and PBA are below the limit value of 0.1µg/L in all considered scenarios. |

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| **FOCUS-PEARL Scenario** | **Active substance** | **PECwater [mg/L]** | **PNECwater  [mg/L]** |  |  |
| **Tier 1** | | | | | |
| Apple-Châteaudun | Permethrin | 4,15E-02 | 5,85E-02 | 7,09E-01 | **4,8E+00** |
| DCVA | 1,6E-01 | 5,77E-02 | 2,77E+00 |
| PBA | 7,6E-02 | 5,86E-02 | 1,30E+00 |
| Potatoes-Châteaudun | Permethrin | 1,62E-02 | 5,85E-02 | 2,77E-01 | **1,9E+00** |
| DCVA | 6,32E-02 | 5,77E-02 | 1,10E+00 |
| PBA | 2,98E-02 | 5,86E-02 | 5,09E-01 |
| Vines-Châteaudun | Permethrin | 4,26E-02 | 5,85E-02 | 7,28E-01 | **4,8E+00** |
| DCVA | 1,6E-01 | 5,77E-02 | 2,77E+00 |
| PBA | 7,8E-02 | 5,86E-02 | 1,33E+00 |
| **Tier 2** | | | | | |
| Apple-Châteaudun | Permethrin | 8,08E-03 | 5,85E-02 | 1,38E-01 | **9,3E-01** |
| DCVA | 3,14E-02 | 5,77E-02 | 5,44E-01 |
| PBA | 1,48E-02 | 5,86E-02 | 2,53E-01 |
| Potatoes-Châteaudun | Permethrin | 3,78E-03 | 5,85E-02 | 6,46E-02 | **4,4E-01** |
| DCVA | 1,47E-02 | 5,77E-02 | 2,55E-01 |
| PBA | 6,94E-03 | 5,86E-02 | 1,18E-01 |
| Vines-Châteaudun | Permethrin | 8,34E-03 | 5,85E-02 | 1,43E-01 | **9,7E-01** |
| DCVA | 3,24E-02 | 5,77E-02 | 5,62E-01 |
| PBA | 1,53E-02 | 5,86E-02 | 2,61E-01 |

***Primary and secondary poisoning***

Primary poisoning

|  |
| --- |
| **Infobox 29 - FR CA position:**  Not relevant |

**Terrestrial compartment**

PNECsoil = 9,17x10-3 mg/kg X 1,3 kg/L = 11,9x10-3 mg/L

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Phase** | **Scenario** | **Active substance** | **PECSoil [mg/L]** | **PNECSoil [mg/L]** |  |  |
| **Tier 1** | | | | | | |
| Implementation | Horizontal application | Permethrin | 5.3E-06 | 11,9E-03 | 0,4E-03 | **1E-03** |
| DCVA | 4.4E-07 | 0,4E-04 |
| PBA | 5.9E-07 | 0,5E-04 |
| Vertical application | Permethrin | 5.3E-06 | 0,4E-03 |
| DCVA | 4.4E-07 | 0,4E-04 |
| PBA | 5.9E-07 | 0,5E-04 |
| **Tier 2** | | | | | | |
| Implementation | Horizontal application | Permethrin | 5.9E-07 | 11,9E-03 | 0,5E-04 | **0,7E-04** |
| DCVA | 4,8E-08 | 0,4E-05 |
| PBA | 6.6E-08 | 0,6E-05 |
| Vertical application | Permethrin | 1.6E-07 | 0,1E-04 |
| DCVA | 1.3E-08 | 0,1E-05 |
| PBA | 1.8E-08 | 0,2E-05 |
| **Tier 3** | | | | | | |
| Implementation | Horizontal application | Permethrin | 5.9E-07 | 11,9E-03 | 0,5E-04 | **0,7E-04** |
| DCVA | 4,8E-08 | 0,4E-05 |
| PBA | 6.6E-08 | 0,6E-05 |
| Vertical application | Permethrin | 1.6E-07 | 0,1E-04 |
| DCVA | 1.3E-08 | 0,1E-05 |
| PBA | 1.8E-08 | 0,2E-05 |
| **Service life – Tier 1** | | | | | | |
| Service life | House | Permethrin | 7.4E-07 | 11,9E-03 | 0,6E-04 | **0,7E-04** |
| DCVA | 6E-08 | 0,5E-05 |
| PBA | 8.2E-08 | 0,7E-05 |

**Freshwater compartment**

PNECwater = 0,0047 µg/L / 10 = 0,47x10-3 µg/L = 4,7x10-7 mg/L

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Phase** | **Scenario** | **Active substance** | **PECwater [mg/L]** | **PNECwater [mg/L]** |  |  |
| **Tier 1** | | | | | | |
| Implementation | Horizontal application | Permethrin | 5.2E-06 | 4,7E-07 | 10 | **140** |
| DCVA | 2E-05 | 40 |
| PBA | 9.6E-06 | 20 |
| Vertical application | Permethrin | 5.2E-06 | 10 |
| DCVA | 2E-05 | 40 |
| PBA | 9.6E-06 | 20 |
| **Tier 2** | | | | | | |
| Implementation | Horizontal application | Permethrin | 2.2E-06 | 4,7E-07 | 5 | **41** |
| DCVA | 8.7E-06 | 18 |
| PBA | 4.1E-06 | 9 |
| Vertical application | Permethrin | 6,4E-07 | 1,4 |
| DCVA | 2.5E-06 | 5 |
| PBA | 1.2E-06 | 2,5 |
| **Tier 3** | | | | | | |
| Implementation | Horizontal application | Permethrin | 4.5E-08 | 4,7E-07 | 0,1 | **0,81** |
| DCVA | 1.7E-07 | 0,36 |
| PBA | 0,8E-07 | 0,17 |
| Vertical application | Permethrin | 1,3E-08 | 0,03 |
| DCVA | 5E-08 | 0,1 |
| PBA | 2.4E-08 | 0,05 |
| **Service life – Tier 1** | | | | | | |
| Service life | House | Permethrin | 3,4E-10 | 4,7E-07 | 7E-04 | **5E-03** |
| DCVA | 1,3E-09 | 3E-03 |
| PBA | 6,3E-10 | 1,3E-03 |

Secondary poisoning

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 30 - FR CA position:**  Birds (PNEC oral bird≥16.7 mg.kg food ) are more sensitive species than mammals (PNEC oral small mammals =120 mg.kg food). Thus, only the most conservative ratio PEC/PNECbirds are presented.  The results for each scenario are summarised in the following table.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Summary table on table on secondary poisoning for permethrin** | | | | | |  | **PECoral predator**  [mg.kg wet fish-1] | **PEC/PNECbirds** | **PEC oral predator**  [mg.kg wet earthworm-1] | **PEC/PNECbirds** | | Scenario 1  (construction vertical urban) | 1.64E-02 | 9.85E-04 | 5.44E-02 | 3.26E-03 | | Scenario 2  (construction horizontal urban) | 1.65E-01 | 9.91E-03 | 5.48E-01 | 3.28E-02 | | Scenario 3  (construction vertical rural) | - | - | 2.82 | 1.69E-01 | | Scenario 4  (construction horizontal rural) | - | - | 5.62 | 3.37E-01 | | Scenario 5  (service-life vertical) | - | - | 2.19E-01 | 1.31E-02 | | Scenario 6  (service-life horizontal) | - | - | 3.41E-01 | 2.04E-02 |   Conclusion:For all assessed scenarios, the RCRs are below 1 for the birds (and small mammals) in the aquatic and/or the terrestrial food chains. Therefore, the risk of secondary poisoning is acceptable when using the products TERMIFILM according to the label recommendations. |

**Via the terrestrial food chain**

PECoral,predator = Cearthworm = 0,1Csoil = 0,1PECsoil

According to the assessment report on Permethrin published by Ireland in April 2014,

- PNECoral bird = ≥16.7 mg a.s/kg food

- PNECoral small mammal = 120 mg a.s/kg food

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Phase** | **Scenario** | **Active substance** | **PECoral,predator [mg/Kg]** | **PNECoral bird [mg/Kg]** |  |  |
| **Tier 1** | | | | | | |
| Implementation | Horizontal application | Permethrin | 5.3E-07 | 16,7 | 3E-08 | **7E-08** |
| DCVA | 4.4E-08 | 3E-09 |
| PBA | 5.9E-08 | 4E-09 |
| Vertical application | Permethrin | 5.3E-07 | 3E-08 |
| DCVA | 4.4E-08 | 3E-09 |
| PBA | 5.9E-08 | 4E-09 |
| **Service life – Tier 1** | | | | | | |
| Service life | House | Permethrin | 7.4E-08 | 16,7 | 4E-09 | **5E-09** |
| DCVA | 6E-09 | 4E-10 |
| PBA | 8.2E-09 | 5E-10 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Phase** | **Scenario** | **Active substance** | **PECoral,predator [mg/Kg]** | **PNECoral small mammal [mg/Kg]** |  |  |
| **Tier 1** | | | | | | |
| Implementation | Horizontal application | Permethrin | 5.3E-07 | 120 | 4E-09 | **1E-08** |
| DCVA | 4.4E-08 | 4E-10 |
| PBA | 5.9E-08 | 5E-10 |
| Vertical application | Permethrin | 5.3E-07 | 4E-09 |
| DCVA | 4.4E-08 | 4E-10 |
| PBA | 5.9E-08 | 5E-10 |
| **Service life – Tier 1** | | | | | | |
| Service life | House | Permethrin | 7.4E-08 | 120 | 6E-10 | **7E-10** |
| DCVA | 6E-09 | 5E-11 |
| PBA | 8.2E-09 | 7E-11 |

**Via the freshwater compartment**

PECoral,predator = 5600 X PECwater

According to the assessment report on Permethrin published by Ireland in April 2014,

- PNECoral bird = ≥16.7 mg a.s/kg food

- PNECoral small mammal = 120 mg a.s/kg food

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Phase** | **Scenario** | **Active substance** | **PECoral predator [mg/Kg]** | **PNECoral bird [mg/Kg]** |  |  |
| **Tier 1** | | | | | | |
| Implementation | Horizontal application | Permethrin | 2.9E-02 | 16,7 | 1,7E-03 | **2,3E-02** |
| DCVA | 1,1E-01 | 6,6E-03 |
| PBA | 5.4E-02 | 3,2E-03 |
| Vertical application | Permethrin | 2.9E-02 | 1,7E-03 |
| DCVA | 1,1E-01 | 6,6E-03 |
| PBA | 5.4E-02 | 3,2E-03 |
| **Service life – Tier 1** | | | | | | |
| Service life | House | Permethrin | 1,9E-06 | 16,7 | 1,1E-07 | **5E-06** |
| DCVA | 7,3E-05 | 4,3E-06 |
| PBA | 3,5E-06 | 2,1E-07 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Phase** | **Scenario** | **Active substance** | **PECoral predator [mg/Kg]** | **PNECoral small mammal [mg/Kg]** |  |  |
| **Tier 1** | | | | | | |
| Implementation | Horizontal application | Permethrin | 2.9E-02 | 120 | 2,4E-04 | **3,2E-03** |
| DCVA | 1,1E-01 | 9,1E-04 |
| PBA | 5.4E-02 | 4,5E-04 |
| Vertical application | Permethrin | 2.9E-02 | 2,4E-04 |
| DCVA | 1,1E-01 | 9,1E-04 |
| PBA | 5.4E-02 | 4,5E-04 |
| **Service life – Tier 1** | | | | | | |
| Service life | House | Permethrin | 1,9E-06 | 120 | 1,6E-08 | **7E-07** |
| DCVA | 7,3E-05 | 6E-07 |
| PBA | 3,5E-06 | 2,9E-08 |

***Mixture toxicity***

|  |
| --- |
| **Infobox 31 - FR CA position:**  Not relevant. |

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



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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 32 - FR CA position:**  **Overall conclusion on the risk assessment for the environment of the product**  Scenario [1]: Release during the construction step with vertical application of the product in urban area.  Scenario [2]: Release during the construction step with horizontal application of the product in urban area.  Scenario [3]: Release during the construction step with vertical application of the product in rural area.  Scenario [4]: Release during the construction step with horizontal application of the product in rural area.  Scenario [5]: Release during the service life with vertical application of the product.  Scenario [6]: Release during the service life with horizontal application of the product.   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Step | Scenario | Type of application | STP | Surface water (Via STP) | Sediment (Via STP) | Soil | | Groundwater | | Secondary Poisoning | | Direct Release | Via STP | Direct Release | Via STP | | Construction | [1] Urban (release to STP) | Vertical | Acceptable | **Unacceptable** | **Unacceptable** | - | Acceptable | - | Acceptable | Acceptable | | [2] Urban (release to STP) | Horizontal | **Unacceptable** | **Unacceptable** | **Unacceptable** | - | Acceptable | - | Acceptable | Acceptable | | [3] Rural (release to soil) | Vertical | - | - | - | **Unacceptable** | - | Acceptable | - | Acceptable | | [4] Rural (release to soil) | Horizontal | - | - | - | **Unacceptable** | - | Acceptable | - | Acceptable | | Service life | [5] | Vertical | - | - | - | Acceptable | - | Acceptable | - | Acceptable | | [6] | Horizontal | - | - | - | Acceptable | - | Acceptable | - | Acceptable |   ***Environmental risk assessment***   * Construction step   Following indirect releases to the environment via the STP, all calculated PEC/PNEC ratios were < 1 for soil and groundwater. Thus the risk for these environmental compartments is acceptable. Nevertheless, regarding the exposure of the STP, surface water and sediment, RCR values were > 1 indicating unacceptable risk to these environmental compartments.  Following direct releases to the environment, calculated RCR values were > 1 for the exposure of soil. Thus, the risk for these environmental compartments is unacceptable.  A risk mitigation measure is proposed to prevent the exposure of the aquatic and terrestrial compartments during the construction phase of the building: ***During its application step, do not expose the film to rain***. The application of this risk mitigation measure preventing emissions to the environment would achieve acceptable risks.   * Service life   For the exposure of 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 the summary of product characteristic*

### Assessment of a combination of biocidal products

*Not relevant*

### Comparative assessment

*Permethrin is not a candidate for substitution. As a result, a comparative assessment is not required.*

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

## List of studies for the biocidal product (family)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author** | **Year** | **Title** | **Owner of data** | **Data protection claimed** | **Essential for the evaluation**  **Yes /No** |
| CSTC | 2015 | Détérmination de la largeur, de la longueur et de la rectitude, de l'épaisseurn de la masse surfacique et de la perte de masse, des propriétés en traction, de la résistance à la déchirure au clou, de la résistance au sisaillement des joints, de la résistance au choc, de la résistance au poinçonnement statique, de l'exposition aux bitumes, de l'étanchéité à l'eau et des propriétés de transmission de la vapeur d'eau, d'une membrane d'étanchéité Termifilm | BERKEM DEVELOPPEMENT | Yes |  |
| CSTC | 2015 | Détermination de l'étanchéité à l'eau d'une membrane d'étanchéité Termifilm | BERKEM DEVELOPPEMENT | Yes |  |
| DEFITRACES | 2016 | Relative Density by Stereopycnometer method on TERMIFILM (Lab2014\_021) | BERKEM DEVELOPPEMENT | Yes |  |
| MPA | 2016 | Stability test (0°C) of biocidal product - TERMIFILM Lab2014\_021 | BERKEM DEVELOPPEMENT | Yes | Y |
| Analytical Laboratory Sarpap & Cecil Industrie | 2015 | TERMIFILM - Antitermite product - Storage stability 2 years | BERKEM DEVELOPPEMENT | Yes | Y |
| MPA | 2016 | Stability test (0°C) of biocidal product - TERMIFILM Lab2014\_021 | BERKEM DEVELOPPEMENT | Yes | Y |
| Analytical Laboratory Sarpap & Cecil Industrie |  | RAPPORT DE VALIDATION ANALYTIQUEPOUR LE CONTRÔLE DE LA PERMETHRINE DANS LETERMIFILM© | BERKEM DEVELOPPEMENT | Yes | Y |
| CTBA | 1995 | Détermination de l'efficacité antitermites | BERKEM DEVELOPPEMENT | Yes |  |
| CTBA | 1996 | Vérification de l'efficacité antitermites des barrières physico-chimiques au contact d'un milieu alcalin | BERKEM DEVELOPPEMENT | Yes |  |
| CIRAD | 1996 | Essai de contact TERMIFILM | BERKEM DEVELOPPEMENT | Yes |  |
| CIRAD | 2005 | Compte rendu d'essai de champ en Guyane | BERKEM DEVELOPPEMENT | Yes |  |
| CSIRO ENTOMOLOGY | 2005 | Evaluation of permethrin-treated TERMIFILM as a barrier against fied colonies of the Australian Mastotermes darwiniensis and the mound building and tree-nesting forms of Coptotermes acinaciformis | BERKEM DEVELOPPEMENT | Yes |  |
| CSIRO ENTOMOLOGY | 2006 | Evaluation of permethrin-treated TERMIFILM as a barrier against fied colonies of the Australian Mastotermes darwiniensis and the mound building and tree-nesting forms of Coptotermes acinaciformis | BERKEM DEVELOPPEMENT | Yes |  |
| CIT | 2005 | Termifilm Algal growth inhibition test | BERKEM DEVELOPPEMENT | Yes |  |
| CIT | 2005 | Termifilm Acute toxicity in Daphnia magna | BERKEM DEVELOPPEMENT | Yes |  |
| CIT | 2005 | Termifilm Acute toxicity in the rainbow trout under static conditions | BERKEM DEVELOPPEMENT | Yes |  |
| BERKEM DEVELOPPEMENT | 2016 | Human Health Risk Assessment for Professional users of TERMIFILM | BERKEM DEVELOPPEMENT | Yes |  |
| EVK France | 1995 | Evaluation of the sensitizing potential of a polyethylene film saturated with insecticide | BERKEM DEVELOPPEMENT | Yes |  |
| BERKEM DEVELOPPEMENT | 2017 | Environmental Risk Assessment of TERMIFILM | BERKEM DEVELOPPEMENT | Yes |  |
| BERKEM DEVELOPPEMENT | 2017 | Groundwater Risk Assessment of TERMIFILM | BERKEM DEVELOPPEMENT | Yes |  |
| Analytical Laboratory Sarpap & Cecil Industrie | 2012 | TERMIFILM Anti-termites product Semi-field leaching test | BERKEM DEVELOPPEMENT | Yes |  |
| Analytical Laboratory Sarpap & Cecil Industrie | 2010 | DOSAGE DE LA PERMETHRINE DANS LES EAUX DE DELAVAGE | BERKEM DEVELOPPEMENT | Yes |  |
| BERKEM DEVELOPPEMENT | 2017 | Human Health Risk Assessment for Professional users of TERMIFILM Additional scenario and monitoring data | BERKEM DEVELOPPEMENT | Yes |  |
| U.S. Environmental Protection Agency | 2012 | Standard Operating Procedures Residential Pesticide Exposure Assessment | U.S. Environmental Protection Agency | No |  |
| Maris Stewart-Parker - RENTOKIL Initial | 2016 | Operator Exposure to Killer Plastic - Trial 2 | BERKEM DEVELOPPEMENT | Yes |  |
| Maris Stewart-Parker - RENTOKIL Initial | 2016 | Method Validation : Permethrin on cotton Gloves | BERKEM DEVELOPPEMENT | Yes |  |
| CTBA | 1996 | Essai de champs: efficacité antitermites | BERKEM DEVELOPPEMENT | Yes |  |
| CTBA | 1997 | Essai de champs: efficacité antitermites | BERKEM DEVELOPPEMENT | Yes |  |
| CTBA | 1998 | Essai de champs: efficacité antitermites | BERKEM DEVELOPPEMENT | Yes |  |
| CTBA | 1999 | Essai de champs: efficacité antitermites | BERKEM DEVELOPPEMENT | Yes |  |
| CTBA | 1995 | Essai de champs: efficacité antitermites | BERKEM DEVELOPPEMENT | Yes |  |
| FCBA | 2010 | Essai de terrain visite de contrôle à 16 ans | BERKEM DEVELOPPEMENT | Yes |  |
| FCBA | 2012 | Essai de terrain visite de contrôle à 18 ans | BERKEM DEVELOPPEMENT | Yes |  |
| FCBA | 2013 | Essai de terrain visite de contrôle à 19 ans | BERKEM DEVELOPPEMENT | Yes |  |
| FCBA | 2014 | Essai de terrain visite de contrôle à 20 ans | BERKEM DEVELOPPEMENT | Yes |  |
| FCBA | 2015 | Essai de terrain visite de contrôle à 21 ans | BERKEM DEVELOPPEMENT | Yes |  |
| FCBA | 2015 | Test de contact du Termifilm à 20 et 21 ans | BERKEM DEVELOPPEMENT | Yes |  |
| CTBA | 2005 | Rapport d'essai d'analyse de matières actives dans un Termifilm | BERKEM DEVELOPPEMENT | Yes |  |
| CTBA | 2003 | Essai de terrain Termifilm : Visite de contrôle | BERKEM DEVELOPPEMENT | Yes |  |
| CTBA | 2005 | Essai de terrain Termifilm : Visite de contrôle | BERKEM DEVELOPPEMENT | Yes |  |
| CIRAD | 1996 | Compte rendu d'essai - 02/07/1996 - Objet : essai de contact Termifilm | BERKEM DEVELOPPEMENT | Yes |  |
| FCBA | 2016 | Essais réalisés par le laboratoire de Biologie de FCBA sur les matériaux destinés à être utilisés comme barrières de protection contre les termites souterrains du genre Reticulitermes | BERKEM DEVELOPPEMENT | Yes |  |

## Output tables from exposure assessment tools

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## New information on the active substance

Not applicable

## Residue behaviour

Not applicable

## Summaries of the efficacy studies

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **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  Preventive anti-termites barrier | TERMIFILM  1 % w/w  permethrin | Subterranean termites  (*Reticulitermes santonensis*) | Efficacy according to XP X41-541 (lab test) after alkaline ageing | Film previously worn by exposure to alkalinity  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 | All the devices (control and test) are made in quadruplet.  According to the methodology, the test is considered as valid if the survival rate in the control is higher than 50 % and if all the bait woods are ranked with a quotation of 4.  But in this study, the mean survival rate in the control is only22 % (6, 15, 9, 57)  Supportive data confirmed by efficacy in the field. | Ansard D. and Paulmier I.  BIOTEC/IP/DA – 145/95R/3  IC3 |
| Insecticide  Preventive anti-termites barrier | TERMIFILM  1 % w/w permethrin | Subterranean termites  (*Reticulitermes santonensis*) | Efficacy according to XP X 41-540 (lab test) after ageing according X41-542 (effect of water) | Film previously worn by exposure to alkalinity  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 | All the devices (control and test) are made in quintuple.  For the control, all the survival rates are higher than 50 % (57.7 %) and penetration of 50 mm by the termites is observed.  In the test devices, all the bait woods are protected (quotation 0) | Serment M.-M. 1995  BIOTEC/IP/DA-145/95F  IC2 |
| Insecticide  Preventive anti-termites barrier | TERMIFILM  1 % w/w permethrin | *Coptotermes gestroi* | Efficacy according to XP X 41-550 after ageing according to CTBA BIO-E-016 (effect of the natural light) (lab test)  (vertical 102 days) | 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 % (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. | Vuillemin J 2010  12/09Fb  IC 1 |
| Insecticide  Preventive anti-termites barrier | TERMIFILM  1 % w/w permethrin | *Coptotermes gestroi* | Efficacy according to XP X 41-550 after ageing according to CTBA BIO-E-016 (effect of the natural light) (lab test)  (horizontal 8 weeks) | Film previously worn by exposure to solar radiation (exposed horizontally during 8 weeks, 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 % (63.4 %), 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. | Vuillemin J. and Paviel F. 2014  04-13  IC 1 |
| Insecticide  Preventive anti-termites barrier | TERMIFILM  1 % w/w permethrin | Subterranean termites  (*Reticulitermes santonensis, Reticulitermes lucifugus*)  (Oleron Island, france) | In house method (field: similar to CTBA-BIO-E-008/4)  5 test devices with TERMIFILM  1 control device | Study area: Saint-Trojan-Les Bains  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: 21 years  Replicates: 5 replicates of 2 devices (one with a PVC pipe and one with an electrical conduit).  Controls: 1 | 2 years after the installation, the control device has been colonized by termites that valid the test.  The field test is visited every year since 1994. Most of the time termites are observed in the control device.  19 years after the beginning of the test, one test device has been penetrated by termites and the test wood in the device was attacked. | BIOTEC/AMP - 145.2-5/95R  BIOTEC/AMP - 145.3-5/95R  BIOTEC/AMP - 145.4-5/95R  BIOTEC/AMP - 145.5-5/95R  PC/66/010/03F  PC/66/209/04F  401/10/222F  401/10/222F/c  401/10/222F/d  401/10/222F/e  IC1 |
| Insecticide  Preventive anti-termites barrier | TERMIFILM  1 % w/w permethrin | Subterranean termites  *Coptotermes testaceus*  *Heterotermes tenuis*  Tree termites  *Nasutitermes spp. Cryptotermes spp.*  *(Guyane)* | In house method  Field: concrete slab  3 tests devices with TERMIFILM  1 control device (poplar wood)  1 control device  (tropical wood)  The test is made in duplicate | According to the methodology | 6 months after the beginning of the test, in one control device, the presence of *Coptotermes testaceus* is recorded. The presence of *Heterotermes tenuis* is also recorded after 3.5 years.  All the test devices remained unpenetrated 5.5 years after the beginning of the test | Fouquet D. 2005  Compte rendu essai de champ Guyane (Cirad)  IC1 |
| Insecticide  Preventive anti-termites barrier | TERMIFILM  1 % w/w permethrin | **Darwin (Coolalinga) wet dry tropical. (2 sites)**  *Mastotermes darwiniensis*  *Coptotermes acinaciformis*  *Heterotermes spp.*  **Brisban (humid tropical)**  *Coptotermes acinaciformis*  *Microcerotermes spp.*  *Schedorhinotermes spp.* | Concrete slab  (Cisro) | According to the methodology | **Darwin :**  Site 1: After one year, one of the ten  control device was penetrated by *Mastotermes darwiniensis* and after 6 years all the control devices were penetrated.  Under the test device, the presence of *Mastotermes darwiniensis* , *Heterotermes spp* and *Coptotermes acinaciformis* is noted. After 5.5 years, the test devices remained protected.  Site 2: after 1 year all the control devices were penetrated by *Coptotermes acinaciformis*.  Under the test devices, the presence of *Schedorhinotermes spp.*, *Microcerotermes ssp.* and *Coptotermes acinaciformis* is noted/ After 5.5 years, the test devices remained protected.  **Brisban:**  Some control devices are penetrated 1 year after the beginning of the test and after 2 years, all the controls have been penetrated.  Under the test devices, the presence of *Coptotermes acinaciformis*, *Schedorhinotermes spp*. and *Microcerotermes spp* are noted. After 5.5 years, the test devices remained protected | Termite Group  Report 2005/14  (Cisro)  Termite Group  Report 2006/13  (Cisro)  IC 1 |

## Confidential annex

See the separated confidential annex

## Other

1. Where relevant for the Member State delivering a national authorisation. Insert rows as necessary. [↑](#footnote-ref-1)
2. LDPE : low density polyethylene [↑](#footnote-ref-2)
3. XP X41-541: Wood preservatives – Determination of the protective effectiveness against termites of preservatives treatment product designed for walls, foundations and masonry – Laboratory method. [↑](#footnote-ref-3)
4. XP X41-540 : XP X 41-540: Wood preservatives – Termites – Détermination of anti-termites action for product used in liquid phase for ground treatment (laboratory method). [↑](#footnote-ref-4)
5. XP X41-542 : Wood preservatives – Anti-termites treatment product for floors, walls, foundations and masonry work – Accelerate ageing test of treated materials prior to biological testing – Percolation test. [↑](#footnote-ref-5)
6. 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-6)
7. CTBA BIO-E-016: CTBA test protocol on exposure of anti-termite barrier to sunlight. [↑](#footnote-ref-7)
8. CSIRO n°2005/14 and CSIRO n°2006/13. [↑](#footnote-ref-8)
9. CSIRO: Commonwealth Scientific and Industrial Research Organisation. [↑](#footnote-ref-9)
10. Product TYPE 18 – Insecticides, acarices and products to control other arthropods (2012) [↑](#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)