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

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT (FAMILY) FOR NATIONAL AUTHORISATION APPLICATIONS**



[TRITHOR S]

Product type [18]

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

Case Number in R4BP: [BC-RQ023975-09]

Evaluating Competent Authority: [FR]

Date: [10/09/2018]

**Table of Contents**

[1 CONCLUSION 4](#_Toc497231117)

[2 ASSESSMENT REPORT 6](#_Toc497231118)

[2.1 Summary of the product assessment 6](#_Toc497231119)

[2.1.1 Administrative Information 6](#_Toc497231120)

[**2.1.1.1** Identifier of the product 6](#_Toc497231121)

[**2.1.1.2** Authorisation holder 6](#_Toc497231122)

[**2.1.1.3** Manufacturer of the products 6](#_Toc497231123)

[**2.1.1.4** Manufacturer of the active substance 6](#_Toc497231124)

[2.1.2 Product composition and formulation 7](#_Toc497231125)

[**2.1.2.1** Identity of the active substance 7](#_Toc497231126)

[**2.1.2.2** Candidate(s) for substitution 7](#_Toc497231127)

[**2.1.2.3** Qualitative and quantitative information on the composition of the biocidal product 7](#_Toc497231128)

[**2.1.2.4** Information on technical equivalence 8](#_Toc497231129)

[**2.1.2.5** Information on the substance(s) of concern 8](#_Toc497231130)

[**2.1.2.6** Type of formulation 8](#_Toc497231131)

[2.1.3 Hazard and precautionary statements 8](#_Toc497231132)

[2.1.4 Authorised use(s) 9](#_Toc497231133)

[**2.1.4.1** Use description 9](#_Toc497231134)

[**2.1.4.2** Use-specific instructions for use 10](#_Toc497231135)

[**2.1.4.3** Use-specific risk mitigation measures 10](#_Toc497231136)

[**2.1.4.4** Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 10](#_Toc497231137)

[**2.1.4.5** Where specific to the use, the instructions for safe disposal of the product and its packaging 10](#_Toc497231138)

[**2.1.4.6** Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 10](#_Toc497231139)

[2.1.5 General directions for use 10](#_Toc497231140)

[**2.1.5.1** Instructions for use 10](#_Toc497231141)

[**2.1.5.2** Risk mitigation measures 10](#_Toc497231142)

[**2.1.5.3** Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 11](#_Toc497231143)

[**2.1.5.4** Instructions for safe disposal of the product and its packaging 11](#_Toc497231144)

[**2.1.5.5** Conditions of storage and shelf-life of the product under normal conditions of storage 11](#_Toc497231145)

[2.1.6 Other information 11](#_Toc497231146)

[2.1.7 Packaging of the biocidal product 11](#_Toc497231147)

[2.1.8 Documentation 12](#_Toc497231148)

[**2.1.8.1** Data submitted in relation to product application 12](#_Toc497231149)

[**2.1.8.2** Access to documentation 14](#_Toc497231150)

[2.2 Assessment of the biocidal product 15](#_Toc497231151)

[2.2.1 Intended use(s) as applied for by the applicant 15](#_Toc497231152)

[2.2.2 Physical, chemical and technical properties 16](#_Toc497231153)

[2.2.3 Physical hazards and respective characteristics 23](#_Toc497231154)

[2.2.4 Methods for detection and identification 25](#_Toc497231155)

[2.2.5 Efficacy against target organisms 27](#_Toc497231156)

[**2.2.5.1** Function and field of use 27](#_Toc497231157)

[**2.2.5.2** Organisms to be controlled and products, organisms or objects to be protected 27](#_Toc497231158)

[**2.2.5.3** Effects on target organisms, including unacceptable suffering 27](#_Toc497231159)

[**2.2.5.4** Mode of action, including time delay 28](#_Toc497231160)

[**2.2.5.5** Efficacy data 29](#_Toc497231161)

[**2.2.5.6** Occurrence of resistance and resistance management 35](#_Toc497231162)

[**2.2.5.7** Known limitations 35](#_Toc497231163)

[**2.2.5.8** Evaluation of the label claims 35](#_Toc497231164)

[**2.2.6** Risk assessment for human health 36](#_Toc497231165)

[**2.2.6.1** Assessment of effects on Human Health 36](#_Toc497231166)

[**2.2.6.2** Exposure assessment 38](#_Toc497231167)

[**2.2.6.3** Risk characterisation for human health 46](#_Toc497231168)

[2.2.7 Risk assessment for animal health 48](#_Toc497231169)

[2.2.8 Risk assessment for the environment 48](#_Toc497231170)

[**2.2.8.1** Effects assessment on the environment 48](#_Toc497231171)

[**2.2.8.2** Exposure assessment 52](#_Toc497231172)

[**2.2.8.3** Risk characterisation 80](#_Toc497231173)

[2.2.9 Comparative assessment 96](#_Toc497231175)

[3 Annexes 96](#_Toc497231176)

[3.1 List of studies for the biocidal product 96](#_Toc497231177)

[3.2 Output tables from exposure assessment tools 101](#_Toc497231178)

[3.3 New information on the active substance 101](#_Toc497231179)

[3.4 Residue behaviour 101](#_Toc497231180)

[3.5 Summaries of the efficacy studies (B.5.10.1-xx) 101](#_Toc497231181)

[3.6 Confidential annex 101](#_Toc497231182)

# Note to the reader

This consolidated PAR for the product authorisation ofr THRITHOR S is based on the PAR of the first authorisation, in which post-authorisation data assessment have been included.

**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-RQ023975-09 | 20/04/2018 | First authorisation |
| NA | *FR* | NA | NA | Post-authorisation data (recevived on the 02/07/2018) |

# CONCLUSION

The biocidal product TRITHOR S is a physico-chemical barrier in the form of film composed by 3 layers:

* an inferior layer: medium-density polyethylene film of 50 microns ,
* an middle layer: non woven polyester impregnated with a permethrin solution of a thickness of 1.20 mm +/- 20%,
* an upper layer: medium-density polyethylene film of 100 microns.

This product is designed to prevent termites to attack buildings.

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

The biocidal product TRITHOR S™ is a physico-chemical barrier.

The appearance of the product is a solid and white film. It is not explosive and has no oxidising properties. The product is not flammable.

Regarding the stability of the product, the following management measure should be added:

- Store away from light.

- Do not store at temperatures above 40°C.

~~To update the dossier, final results of the on-going stability storage study should be provided in post-authorisation within one year~~.

The stability data indicate the product TRITHIOR S is stable after 12 months storage in its commercial packaging.

Regarding the method of analysis, an analytical method is provided for the determination of permethrine in the product TRITHOR S.

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.

**Conclusion on Efficacy**

French competent authorities consider that the efficacy of the product TRITHOR S, used as physico-chemical barrier (peripheral application) to protect building is demonstrated against subterranean termites (*Reticulitermes spp., Coptotermes spp., Heterotermes spp.* and tree termites *(Nasutitermes spp*.). Efficacy is demonstrated against European and tropical species of termites.

**Conclusion on risk assessment for human health**

For peripheral aplication, the risk for human health is considered acceptable for professionals users taking into account the wear of gloves when manipulating the product.

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

**Conclusion on risk for consumers via residues**

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

- Avoid any direct or indirect contact with food and feed.

**Conclusion on risk assessment for the environment**

* Construction step:

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

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

* Service life

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

# ASSESSMENT REPORT

## **Summary of the product assessment**

### Administrative Information

#### Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| TRITHOR S |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | ENSYSTEX EUROPE |
| **Address** | 16 avenue de la forêt  33 320 EYSINES  France |
| **Authorisation number** |  | |
| **Date of the authorisation** |  | |
| **Expiry date of the authorisation** |  | |

#### Manufacturer of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | BAMBERGER Kaliko Textile Finishing |
| **Address of manufacturer** | Kronacher Str. 59, 96052, Bamberg, Germany |
| **Location of manufacturing sites** | Kronacher Str. 59, 96052, Bamberg, Germany |

#### Manufacturer of the active substance

|  |  |
| --- | --- |
| **Active substance** | Permethrin |
| **Name of manufacturer** | TAGROS |
| **Address of manufacturer** | Tagros Chemicals India Limited,  "Jhaver Centre", IV Floor,  Rajha Annamalai Building,  No. 72, Marshalls Road,  Egmore,  Chennai - 600 008,  India |
| **Location of manufacturing sites** | Tagros Chemicals India Limited A4/1&2,  SIPCOT Industrial Complex,  Kudikadu, Cuddalore,  Tamil Nadu,  India. |

### Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | 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** | ≥93.0% 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 TRITHOR S 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)** |
| --- | --- | --- | --- | --- | --- | --- |
| Permathrin (technical)  Permethrin  (Pure) | 3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2- dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 52645-53-1 | 258-067-9 | 0.59\*  0.55 | 2.15\*\*    2 |

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

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

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

The active substance provider is TAGROS. They did supported the active substance dossier.

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

TRITHOR S doesn’t contain any substance of concern.

#### Type of formulation

|  |
| --- |
| XX: other (Film) |

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Skin sens. 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/fume/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/ Plenty of soap.  P321: Specific treatment (see ... on this label)  P333+P313: If skin irritation or rash occurs, get medical advice/attention  P362 + P364: Take off contaminated clothing and wash it before reuse  P391: Collect spillage  P501: Dispose of contents/container to ... |
|  | |
| Note | **-** |

### Authorised use(s)

#### Use description

Table 1. Use # 1 –**Preventive treatment - peripheral application**

|  |  |
| --- | --- |
| **Product Type** | PT 18: Insecticides, acaricides and products to control others arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | The product TRITHOR S is 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.)*  Tree termites *(Nasutitermes spp*.)  Workers, soldiers, nymphs |
| **Field of use** | Preventive treatment, during the construction |
| **Application method(s)** | TRITHOR S is used between building layers an internal perimeter lining, with subsequent coverage by a layer of concrete. |
| **Application rate(s) and frequency** | Ready-to-use product containing 0.55 % permethrin.  One application, during the construction of the building.  Before or after pouring of the slab. |
| **Category(ies) of users** | Professionals |
| **Pack sizes and packaging material** | Paper bags containing:   * 5 MDPE rolls of 100 mm of width \* 50 m of length, * 5 MDPE rolls of 150 mm of width \* 50 m of length, * 4 MDPE rolls of 200 mm of width \* 50 m of length, * 4 MDPE rolls of 250 mm of width \* 50 m of length, * 2 MDPE rolls of 300 mm of width \* 50 m of length. * 2 MDPE rolls of 500 mm of width \* 50 m of length. |

#### Use-specific instructions for use

|  |
| --- |
| - |

#### Use-specific risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

### General directions for use

#### Instructions for use

|  |
| --- |
| 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. |

#### Risk mitigation measures

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

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

|  |
| --- |
| * Skin contact: Remove contaminated clothing and shoes. 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 product: 1 year. * Do not store at temperature above 40°C. * Store away from light. |

### 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. |

### Packaging of the biocidal product

Rolls are stored in paper bags.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of packaging** | **Width (mm)** | **Length (m)** | **Number of rolls in a pack** | **Intended user (e.g. professional, non-professional)** |
| Roll | 100 | 50 | 5 | Professional |
| Roll | 150 | 50 | 5 | Professional |
| Roll | 200 | 50 | 4 | Professional |
| Roll | 250 | 50 | 4 | Professional |
| Roll | 300 | 50 | 2 | Professional |
| Roll | 500 | 50 | 2 | Professional |

TRITHOR S™ is a film composed by 3 layers:

* an inferior layer: medium-density polyethylene film of 50 microns ,
* an middle layer: non woven polyester impregnated with a permethrin solution,
* an upper layer: medium-density polyethylene film of 100 microns .



Binder 1: see confidential data

Binder2: see confidential data

### Documentation

#### Data submitted in relation to product application

**Identity, physicochemical and analytical method data**

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

***Efficacy data:***

* ***Laboratory tests:***
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550[[1]](#footnote-1), with the product TRITHOR S (2 g/m² permethrin), without ageing, on termites (*Reticulitermes flavipes)*;
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product TRITHOR S (2 g/m² permethrin), without ageing, on termites (*Coptotermes gestroi)*;
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product TRITHOR S (2 g/m² permethrin), after artificial ageing (leaching) according to the protocol XP ENV 1250-2[[2]](#footnote-2), on termites (*Reticulitermes flavipes)*;
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product TRITHOR S (2 g/m² permethrin), after artificial ageing (leaching) according to the protocol XP ENV 1250-2, on termites (*Coptotermes gestroi)*;
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product TRITHOR S (2 g/m² permethrin), in alkaline condition (alkaline contact) according to the protocol CTBA BIO-E-007[[3]](#footnote-3), on termites (*Reticulitermes flavipes)*;
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product TRITHOR S (2 g/m² permethrin), in alkaline condition (alkaline contact) according to the protocol CTBA BIO-E-007, on termites (*Coptotermes gestroi)*;
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product TRITHOR S (2 g/m² permethrin), after natural weathering (UV – vertical (3 months) according to the protocol CTBA BIO-E-016[[4]](#footnote-4), on termites (*Reticulitermes flavipes);*
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product TRITHOR S (2 g/m² permethrin), after natural weathering (UV – vertical (3 months) according to the protocol CTBA BIO-E-016, on termites (*Coptotermes gestroi);*
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product TRITHOR S (2 g/m² permethrin), after natural weathering (UV - horizontal) according to the protocol CTBA BIO-E-016, on termites (*Reticulitermes flavipes)*;
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product TRITHOR S (2 g/m² permethrin), after natural weathering (UV - horizontal) according to the protocol CTBA BIO-E-016, on termites (*Coptotermes gestroi)*;
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product TRITHOR S (2 g/m² permethrin), after exposure to liquid chemical according to the protocol EN 1847[[5]](#footnote-5), on termites (*Reticulitermes flavipes)*;
* A laboratory efficacy study conducted according to the experimental standard XP X 41-550, with the product TRITHOR S (1.8 g/m² permethrin), after natural weathering (UV - horizontal) according to the protocol CTBA BIO-E-016, on termites (*Reticulitermes flavipes)*;
* ***Field tests :***
* A field efficacy study, with the product TRITHOR S (2 g/m² permethrin), performed in France (Oleron island), according to the methodology CTBA BIO-E-008[[6]](#footnote-6), with a 1 year exposure to termites (*Reticulitermes flavipes)*;
* A field efficacy study, with the product TRITHOR S (2 g/m² permethrin), performed in France (Guyane), according to the methodology CTBA BIO-E-008, with a 1 year exposure to termites (*Heterotermes tenuis, Coptotermes testaceus and Nasutitermes spp.)*;

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

No study was provided.

#### Access to documentation

A letter of access is submitted by LIMARU NV/TAGROS for the active substance full dossier concerning permethrin technical.

## Assessment of the biocidal product

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

Table 1. Intended use # 1 – Preventive treatment against termites, as an impregnated film

|  |  |
| --- | --- |
| Product Type(s) | 18 |
| Where relevant, an exact description of the authorised use | Preventive treatment against termites |
| Target organism (including development stage) | *Coptotermes gestroi, Reticulitermes flavipes, Heterotermes*  *tenuis + Coptotermes testaceus + Nasutitermes sp.*  (all adult stage) |
| Field of use | Preventive treatment, during the construction |
| Application method(s) | Impregnated film |
| Application rate(s) and frequency | 2 g/m²  Once at the beginning of the construction of the building. |
| Category(ies) of user(s) | Professionals |
| Pack sizes and packaging material | THITHOR S™ is a film composed by 3 layers: a Polyethylene terephthalate (PET) film of 50 microns (inferior layer), a non woven material impregnated with a permethrin solution and a PET film of 100 microns (upper layer).  2, 4 or 5 rolls in a pack: rolls of 100, 150, 200, 250, 300, 500 mm of width and 50 m of length. |

### 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)** |
| TRITHOR S | 0.55 | 0.59\* | 2.0 | 2.15\*\* |

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

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

The biocidal product TRITHOR S™ is a physico-chemical barrier. Physico-chemical properties 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 | - | - | Solid | - |
| Colour at 20 °C and 101.3 kPa | - | - | White | - |
| Odour at 20 °C and 101.3 kPa | - | - | Not applicable | - |
| Acidity / alkalinity | - | - | Not applicable | - |
| Relative density / bulk density | - | - | The density of the product TRITHOR (g/m²) is not available and should be provided. | - |
| Storage stability test – **accelerated storage** | NF X 41-580-10  Method HPLC-UV **validated** report No 402/13/1097F/ab/f-e | - | Storage for 8 weeks at 40°C in an inert and closed packaging (glass flask with PTFE cap)   |  |  |  | | --- | --- | --- | |  | AI content | No samples | | Initial | 2.29 g/m2 | n=6 | | After storage | 2.70g/m2 | n=2 |   Deviation from the initial content +17.9 %  Significant change (>10%) in permethrin content after storage.  **eCa conclusion:**  The standard deviation of the method for the determination of permethrine indicates that the content of permethrine reported in the table above is RSD:17.4%.  In fact, initialy, the content of permethrine (2.29g/m2) corresponds to the mean value of 6 analysis. After storage, the content of permethrine (2.70g/m2) corresponds to the mean value of only 2 analysis. Significant change (>10%) in permethrin content after storage is explained so by the variability of the measurment of the method (the value 2.7g/m2 is included in the analysis of permethrine before storage).  eCA considers that the formulation is stable after storage.  The following management measure should be added: Do not store at temperature above 40°C. | REPORT No  402/13/1097F/c/f-e |
| Storage stability test – **long term storage at ambient temperature** | - | - | **A shelf life study in commercial packaging is ongoing (study plan no 16/1285F/a, 02/2017).**  **No complementary data is provided.**  **Study should be provided in post-authorisation** | - |
| Storage stability test – **long term storage at ambient temperature** | - | Batch FA207186 | Complementary data provided in post-authorisation (07/2018)  Certificate of analysis (initial, after 6 months and 12months) have been provided. Raw data are reported below:  Note: Raw data in Certificate of analysis come from GLP study   |  |  |  |  | | --- | --- | --- | --- | |  | Initial | After 6months storage | After 12 months storage | | Appareance | Film, a yellow face and a black face with a white polyester layer at center | | | | Packaging | - | No potential signs of degradation (no discoloration and no deformation) | | | Content of active substance (method provided in the REPORT No 402/13/1097F/ab/f-e) –method validated | 2.44g/m² | 2.31g/m² | 2.55g/m² | | LEGAY Stephane 2017  Certificat of analysis n°COA-402/16/1285F/1/a/T0 ; COA-402/16/1285F/1/a/T6M; COA-402/16/1285F/1/a/T12M-e |
| Storage stability test – **low temperature stability test for liquids** | NF X 41-580-3  Method **not validated** for AI content extracted from report No 402/13/1097F/ab/f-e |  | Storage for 16 hours at -10°C in an inert and closed packaging (glass flask with PTFE cap)   |  |  |  | | --- | --- | --- | |  | AI content | No samples | | Initial | 2.29 g/m2 | n=6 | | After storage | 2.33g/m2 | n=2 |   Deviation from the initial content +1.75 %  Acceptable. As the product is stable at -10°C, it is expected to be stable at 0°C. | REPORT No  402/13/1058F/ab/f-e |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | - | A justification was required to demonstrate that the light has no effect on the stability of the product. No justification was provided.  **In consequence, the following management measure should be added: Store away from light.** | - |
| 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 8 weeks at 40°C.  The individual commercial packaging (roll packaged in LDPE) is sealed. With this closure system, the packaging is leak-tight. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | See the storage stability test: : no change in appearance and permethrin content when stored in glass flask  The long term storage study at ambient temperature in its commercial packaging is still on-going | - |
| 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 required | - |
| Chemical compatibility | - | - | Not required | - |
| 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 TRITHOR S is a solid chemical-physical barrier containing 0.55%w/w permethrin (technical AS).  An accelerated storage study has been provided and considered as acceptable.  The product TRITHOR S is considered as stable.  It should be indicate in the label:  - Do not store at temperature above 40°C.  - Stored away from light.  Post-authorisation data -2018:  The long terme stability study indicates that the product is stable during 12 months. The shelf life of the product is 12 months. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | - | - | Based on content and chemical structure, it was concluded that the formulation was not explosive. | - |
| Flammable gases | - | - | Not applicable | - |
| Flammable aerosols | - | - | Not applicable | - |
| Oxidising gases |  |  | Not applicable | - |
| Gases under pressure | - | - | Not applicable | - |
| Flammable liquids | - | - | Not applicable | - |
| Flammable solids | - | - | TRITHOR S contains no compound supposed to impact flammability. | - |
| Self-reactive substances and mixtures | - | - | TRITHOR S contains no compound supposed to impact flammability. | - |
| Pyrophoric liquids | - | - | Not applicable. | - |
| Pyrophoric solids | - | - | TRITHOR S contains no compound supposed to impact flammability | - |
| Self-heating substances and mixtures | - | - | Not applicable. | - |
| Substances and mixtures which in contact with water emit flammable gases | - | - | TRITHOR S contains no compound supposed to impact flammability. | - |
| Oxidising liquids | - | - | Not applicable. | - |
| Oxidising solids | - | - |  | - |
| Organic peroxides | - | - | Not applicable. | - |
| Corrosive to metals | - | - | Not required as the product has not a low or high pH value | - |
| Auto-ignition temperatures of products (liquids and gases) | - | - | Not applicable. | - |
| Relative self-ignition temperature for solids | - | - | TRITHOR S contains no compound supposed to impact flammability. | - |
| Dust explosion hazard | - | - | Not applicable | - |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product has not explosive properties, nor oxidising properties. It is not highly flammable and not auto-flammable at ambient temperature. |

### Methods for detection and identification

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Precision** | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| *permethrin* | HPLC-UV (210 nm) after extraction by ASE with acetonitrile  (100 bar and 100°C) | 6 samples made with spiked matrix (filter paper) at the target value (22.6 mg/L)As no matrix without AI is available, the validation criterion which has been defined is precision by spiking 6 times **a filter paper** to the “target value”. | 20 – 30 mg/L  (n=5) | Any interference | 94.84 – 98.57 | 97.2 | 1.39 | Quantitative analysis of permethrin  RSD=17.4%  (n=6)  Note: **the precision is performed with the formulation.** Considering the RSD=17.4%, the method is not acceptable (RSD<20%) | NA | REPORT No 402/13/1097F/ab/f-e |
| *Permethrin*  Method to determine permethrin in fabrics treated with “Sanitized AM 23-24” | HPLC-UV (210 nm)  Column: Purospher Star columns: RP18 endcapped  Solvent: 8/2 (acetonitrile/water) | Spiking at 0.7581 mg/L (n=2)  Spiking at 0.3209 mg/L (n=2) | *Permetrhin trans*  Range: 0.05 -0.87mg/L (n=5, r>0.99)  *Permethrin cis*  Range: 0.02-0.38mg/L (n=5, r>0.99) | Chromatograms of blank formulation and of standards solution are provided.  Chromatogram of formulation is not provided.  The specifity of the method is not demonstrated  Note: In the standards chromatogram, regarding the ratio of isomers is calculed by comparaison of surface of each permethrin. The peak@7permethrin is permethrin *trans* and peak@6permetrin is permethrin *cis* | 100.1-100.4 (n=2)  100.0-100.7 (n=2) | 100.3  100.3 | -  - | RSD<5% (n=3x6)  RSD<5% (n=3x6) | 0.027 mg/L (estimated based on the signal-to-noise ratio)  0.008 mg/L  (estimated based on the signal-to-noise ratio) | Study number STZ39 -2016 Schlegl.P |

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| **Analytical methods for monitoring** |
| Analytical methods on environmental and biological matrix are the same as those for the active substance. These methods are covered by the Letter of Access granted by Tagros to ENSYSTEX Europe. |

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| **Conclusion on the methods for detection and identification of the product** |
| *REPORT No 402/13/1097F/ab/f-e:* The analytical method for the determination of permethrin in the product TRITHOR S is validated. Validation data (specificity, accuracy) are performed in the matrix paper filter (No matrix was supplied by the sponsor). Precision of the method is performed in the test item. The method is suitable for the determination of permethrin in the formulation.  *Study number STZ39:* The analytical method for the determination of permethrin in the product TRITHOR S is not fully validated. The specificity of the method is not demonstrated (chromatogram of formulation is missing). Moreover the method is not considered as a chiral method for the determination of 4 stereoisomers of the active substance. |

### 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 TRITHOR S is a ready to use physico-chemical barrier. It is a film composed by 3 layers: a polyethylene film of 50 microns (inferior layer), an impregnated non woven material, and a polyethylene film of 100 microns (upper layer).

The product is designed for the preventive protection of buildings against termites

The impregnation process leads to an amount of 2 g permethrin per m² of product which represents a concentration in the product of 0.55 % of permethrin w/w.

The product is applied in peripheral application, the perifilm can be applied before or after pouring of the slab.

One application takes place during the building construction.

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

According to the uses claimed by the applicant, the product TRITHOR S is used between building layers as internal barrier enclosed as an internal perimeter lining, with subsequent coverage by a layer of concrete. The product is intended to prevent the attack of subterranean termites (*Reticulitermes spp., Coptotermes spp., Heterotermes spp.)* and tree termites *(Nasutitermes spp*.)

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

The development stages claimed are larvae, nymphs and adults.

#### Mode of action, including time delay

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

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

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

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

#### Efficacy data

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **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, acaricides and products to control other arthropods  Preventive anti-termites barrier | TRITHOR S  2 g a.i./m² permethrin | Subterranean termites  (*Reticulitermes flavipes*) | Efficacy according to XP X 41-550 (lab test) | According to the methodology | All the devices (control and test) are made in quadruplicate.  For the control, all the survival rates are higher than 50 % (69.2 %) and all the bait woods are ranked with a quotation of 4.  In the test devices, all the bait woods are protected (quotation 0) | Paulmier et al. 2013  401/12/174F/1/a  6.7-01  IC2 |
| Insecticide, acaricides and products to control other arthropods  Preventive anti-termites barrier | TRITHOR S  2 g a.i./m² permethrin | Subterranean termites  (*Coptotermes gestroi*) | Efficacy according to XP X 41-550(lab test) | According to the methodology | All the devices (control and test) are made in quadruplicate.  For the control, all the survival rates are higher than 50 % (63.4 %) and all the bait woods are ranked with a quotation of 4.  In the test devices, all the bait woods are protected (quotation 0) | Paviel et al. 2014  03-14a  6.7-02  IC1 |
| Insecticide, acaricides and products to control other arthropods  Preventive anti-termites barrier | TRITHOR S  2 g a.i./m² permethrin | Subterranean termites  (*Reticulitermes flavipes*) | Efficacy according to XP X 41-550 after ageing according to WP ENV 1250-2 (effect of water) (lab test) | According to the methodology | All the devices (control and test) are made in quadruplicate.  Prior the test according to XP X41-550, the product has been aged following the methodology of the ENV 1250-2 method for 4 days.  For the control, all the survival rates are higher than 50 % (76.3 %) and all the bait woods are ranked with a quotation of 4.  In the test devices, all the bait woods are protected (quotation 0) | Paulmier et al. 2014  401/12/174F/2/n  6.7-03  IC1 |
| Insecticide, acaricides and products to control other arthropods  Preventive anti-termites barrier | TRITHOR S  2 g a.i./m² permethrin | Subterranean termites  (*Coptotermes gestroi*) | Efficacy according to XP X 41-550 after ageing according to WP ENV 1250-2 (effect of water) (lab test) | According to the methodology | All the devices (control and test) are made in quadruplicate.  Prior the test according to XP X41-550, the product has been aged following the methodology of the ENV 1250-2 method for 4 days.  For the control, all the survival rates are higher than 50 % (56.6 %) and all the bait woods are ranked with a quotation of 4.  In the test devices, all the bait woods are protected (quotation 0) | Paviel et al. 2014  12-14a  6.7-04  IC1 |
| Insecticide, acaricides and products to control other arthropods  Preventive anti-termites barrier | TRITHOR S  2 g a.i./m² permethrin | Subterranean termites  (*Reticulitermes flavipes*) | Efficacy according to XP X 41-550 after ageing according to CTBA BIO-E-007 v2 (effect of alkalinity) (lab test) | According to the methodology | All the devices (control and test) are made in quadruplicate.  Prior the test according to XP X41-550, the product has been aged following the methodology of the CTBA-BIO-E-007-v2 method  For the control, all the survival rates are higher than 50 % (70.2 %) and all the bait woods are ranked with a quotation of 4.  In the test devices, all the bait woods are protected (quotation 0) | Paulmier et al. 2013  401/12/174F/1/c  6.7-05  IC2 |
| Insecticide, acaricides and products to control other arthropods  Preventive anti-termites barrier | TRITHOR S  2 g a.i./m² permethrin | Subterranean termites  (*Coptotermes gestroi*) | Efficacy according to XP X 41-550 after ageing according to CTBA BIO-E-007 v2 (effect of alkalinity)  (lab test) | According to the methodology | All the devices (control and test) are made in quadruplicate.  Prior the test according to XP X41-550, the product has been aged following the methodology of the CTBA-BIO-E-007-v2 method  For the control, all the survival rates are higher than 50 % (59.8 %) and all the bait woods are ranked with a quotation of 4.  In the test devices, all the bait woods are protected (quotation 0) | Paviel 2014  12-14b  6.7-06  IC2 |
| Insecticide, acaricides and products to control other arthropods  Preventive anti-termites barrier | TRITHOR S  2 g a.i./m² permethrin | Subterranean termites  (*Reticulitermes flavipes*) | Efficacy according to XP X 41-550 after ageing according to CTBA BIO-E-016 (effect of the natural light) (lab test) | According to the methodology | All the devices (control and test) are made in quadruplicate.  For the control, all the survival rates are higher than 50 % (69.3 %) and all the bait woods are ranked with a quotation of 4.  In vertical position (105 days) for ageing, all the bait woods are protected (quotation 0) and the tested product is not penetrated. | Paulmier 2015  401/12/174F/3/f  6.7-07  IC1 |
| Insecticide, acaricides and products to control other arthropods  Preventive anti-termites barrier | TRITHOR S  2 g a.i./m² permethrin | Subterranean termites  (*Reticulitermes flavipes*) | Efficacy according to XP X 41-550 after ageing according to CTBA BIO-E-016 (effect of the natural light) (lab test) | According to the methodology | All the devices (control and test) are made in quadruplicate.  For the control, all the survival rates are higher than 50 % (79.3 %) and all the bait woods are ranked with a quotation of 4.  In horizontal position (26 days) for ageing, all the bait woods are protected (quotation 0) | Paulmier 2014  401/12/174F/3/e  6.7-08  IC2 |
| Insecticide, acaricides and products to control other arthropods  Preventive anti-termites barrier | TRITHOR S  2 g a.i./m² permethrin | Subterranean termites  (*Coptotermes gestroi*) | Efficacy according to XP X 41-550 after ageing according to EN EN 1847 adapted (effect of alkalinity by immersion in sulfuric acid 5 to 6%)(lab test) | According to the methodology | All the devices (control and test) are made in quadruplicate.  Prior the test according to XP X41-550, the product has been aged following the methodology of the adapted method EN 1847  For the control, all the survival rates are higher than 50 % (68.5 %) and all the bait woods are ranked with a quotation of 4.  In the test devices, all the bait woods are protected (quotation 0) | Paulmier et al 2013  401/12/174F/1/d  6.7-15  IC2 |
| Insecticide, acaricides and products to control other arthropods  Preventive anti-termites barrier | TRITHOR S  2 g a.i./m² permethrin | Subterranean termites  (*Reticulitermes flavipes*) | Efficacy according to XP X 41-550 after ageing according to CTBA BIO-E-016 (effect of the natural light) (lab test) | According to the methodology | All the devices (control and test) are made in quadruplicate.  For the control, all the survival rates are higher than 50 % (64.9 %) and all the bait woods are ranked with a quotation of 4 except one where the development of fungi killed the termites. This deviation is allowed in the standard.  In horizontal position (the duration of exposure is not mentioned) for ageing, all the bait woods are protected (quotation 0) | Thevenon 2014  14-09/X41-550  6.7-16  IC2 |
| Insecticide, acaricides and products to control other arthropods  Preventive anti-termites barrier | TRITHOR S  2 g a.i./m² permethrin | Subterranean termites  (*Coptotermes gestroi*) | Efficacy according to XP X 41-550 after ageing according to CTBA BIO-E-016 (effect of the natural light) (lab test) | According to the methodology | All the devices (control and test) are made in quadruplicate.  For the control, all the survival rates are higher than 50 % (63.4 %) and all the bait woods are ranked with a quotation of 4.  In horizontal position (17 days) for ageing, all the bait woods are protected (quotation 0) | Paviel 2014  03-14b-EH  6.7-09  IC1 |
| Insecticide, acaricides and products to control other arthropods  Preventive anti-termites barrier | TRITHOR S  2 g a.i./m² permethrin | Subterranean termites  (*Coptotermes gestroi*) | Efficacy according to XP X 41-550 after ageing according to CTBA BIO-E-016 (effect of the natural light) (lab test) | According to the methodology | All the devices (control and test) are made in quadruplicate.  For the control, all the survival rates are higher than 50 % (59.2 %) and all the bait wood are ranked with a quotation of 4.  In vertical position (102 days) for ageing, all the bait woods are protected (quotation 0) and the tested product is not penetrated. | Paviel 2014  03-14b-EV  6.7-10  IC1 |
| Insecticide, acaricides and products to control other arthropods  Preventive anti-termites barrier | TRITHOR S  2 g a.i./m² permethrin | Subterranean termites  (*Reticulitermes flavipes*) | Efficacy according to CTBA-BIO-E-008/4 (field test) | According to the methodology | 10 devices compared to 5 other devices used as control. The test device and the control devices are installed side by side very closed to assess the termite activity.  Some test devices are adapted to simulate the construction condition met in the field (cable outlet, pipes…)  🡪Installation stage | Paulmier 2014  401/12/174F/3/g  6.7-11  IC1 |
| Insecticide, acaricides and products to control other arthropods  Preventive anti-termites barrier | TRITHOR S  2 g a.i./m² permethrin | Subterranean termites  (*Reticulitermes flavipes*) | Efficacy according to CTBA-BIO-E-008/4  (field test) | According to the methodology | 1 year report related to the installation study 401/12/174F/3/g  10 devices compared to 5 other devices used as control. The test device and the control devices are installed side by side very closed to assess the termite activity.  Some test devices are adapted to simulate the construction condition met in the field (cable outlet, pipes…)  After one year of the test, the activity of termites is noted in and outside the test control (4/5). The methodology is validated.  After one year of exposure, 100 % of protection of the product is observed (the bait woods in the test devices remained untouched and the product remained unpenetrated). | Paulmier 2015  401/12/174F/3/h  6.7-12  IC1 |
| Insecticide, acaricides and products to control other arthropods  Preventive anti-termites barrier | TRITHOR S  2 g a.i./m² permethrin | Subterranean termites  (*Heterotermes tenuis,*  *Coptotermes testaceus,*  *Tree termites*  *Nasutitermes spp)* | Efficacy according to CTBA-BIO-E-008/4(field test) | According to the methodology | 10 devices compared to 5 other devices used as control. The test device and the control devices are installed side by side very closed to assess the termite activity.  Some test devices are adapted to simulate the construction condition met in the field (cable outlet, pipes…)  🡪Installation stage | Paulmier et al. 2014  401/12/174F/2/o  6.7-13  IC2 |
| Insecticide, acaricides and products to control other arthropods  Preventive anti-termites barrier | TRITHOR S  2 g a.i./m² permethrin | Subterranean termites  (*Heterotermes tenuis,*  *Coptotermes testaceus,*  *Tree termites*  *Nasutitermes spp)* | Efficacy according to CTBA-BIO-E-008/4 (field test) | According to the methodology | 1 year report related to the installation study 401/12/174/F/2/o  10 devices compared to 5 other devices used as control. The test device and the control devices are installed side by side very closed to assess the termite activity.  Some test devices are adapted to simulate the construction condition met in the field (cable outlet, pipes…)  After one year of the test, the activity of termites is noted in and outside the test control (5/5). The methodology is validated.  After one year of exposure, 100 % of protection of the product is observed (the bait woods in the test devices remained untouched and the product remained unpenetrated). | Paulmier et al. 2015  401/12/174F/3/p  6.7-14  IC2 |

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| **Conclusion on the efficacy of the product** |
| French competent authorities (FR CA) considered that in accordance with the submitted tests and the requirements of the TNsG on PT18, the efficacy of the product TRITHOR S, used as physico-chemical barrier (peripheral application) to protect building is demonstrated against subterranean termites (*Reticulitermes spp., Coptotermes spp., Heterotermes spp.* and tree termites *(Nasutitermes spp*.).  The application rates validated are the following:  The concentration of active substance in the product is 2 g permethrin / m². One application of the product takes place during the building construction. |

#### Occurrence of resistance and resistance management

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

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

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

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

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

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

#### Known limitations

*None*

#### Evaluation of the label claims

French competent authorities (FR CA) assessed data presented in the dossier that allow the demonstration of the efficacy of the product TRITHOR S against termites (*Reticulitermes spp., Coptotermes spp., Heterotermes spp. and Nasutitermes spp*.) for the use claimed by the applicant.

The application rate validated is the following:

The product is used between building layers as internal barrier as an internal perimeter lining, with subsequent coverage by a layer of concrete. The product TRITHOR S contains 2 g/m² permethrin.

* + 1. **Risk assessment for human health**

TRITHOR S™ is a physico-chemical barrier in order to prevent termites invasion buildings. The article is designed to prevent termites to attack buildings. In order to perform such task, the non-woven material is impregnated with the active substance permethrin (PT18).

The impregnation process leads to a claim of a 2.15 g/m2 of Permethrin in the product which represents a dilution of the premix to a level of 0.55 % of permethrin (w/w) or 0.59% considering technical concentration.

The product is intended to be applied by professional users.

* + - 1. Assessment of effects on Human Health

No animal study or human data is available for TRITHOR S.

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

***Skin corrosion and irritation***

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

***Eye irritation***

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

***Respiratory tract irritation***

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

***Skin sensitization***

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Skin Sensitizer |
| Justification for the value/conclusion | The material taken into account for skin sensitization is the impregnating liquid present at a concentration of 1.4% w/ww in the non woven material.  The content of a.s classified H317 is higher than 1% (general concentration limit), leading to a classification of the products as skin sensitizer. |
| Classification of the product according to CLP | Skin Sens 1 - H317: May cause an allergic skin reaction. |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Skin sensitization |
| Justification | No study has been performed on TRITHOR S.  Regarding the content of a.s and co-formulants, and according to the classification rules laid down in the CLP regulation, a classification Skin Sens 1 – H317 is required for the product. |

***Respiratory sensitization (ADS)***

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

***Acute toxicity***

*Acute toxicity by oral route*

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

*Acute toxicity by inhalation*

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

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Dermal acute toxicity |

***Information on dermal absorption***

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

***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, TRITHOR S does not contain any substance of concern.

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

All the components are only classified for acute toxicity and synergistic effects between any of the components are not expected regarding their toxicological profiles.

* + - 1. Exposure assessment

The product TRITHOR S is a physico-chemical barrier in order to prevent termites invasion buildings.

That system is set during the construction of the buildings. TRITHOR S system consists of the establishment of a multilayer membrane on the constructions areas that constitute a potential access to the buildings for subterranean termites. These access areas include the joints between masonry materials, the passage areas of ducts and pipes in the ground-mount interface.

TRITHOR S is a film composed by 3 layers:

* a Polyethylene terephthalate (MDPE) film of 50 microns (inferior layer)
* a non-woven material impregnated with a permethrin solution (thickness of 1.20 mm +/- 20% which leads to a maximum thickness of 1.44 mm in a worst case point of view)
* a MDPE film of 100 microns (upper layer).

According to the intended uses of the product TRITHOR S (application of multilayer film on the house ground by professionals), primary exposure is intended for professionals via inhalation and dermal routes. Secondary exposure is not intended.

**Figure 2, 3 and 4: examples of application of TRITHOR S**

The product is sold in strips of different widths from 100 to 500 mm. The operator may need to cut in the fibrous layer to adapt it. The fibrous layer sandwiched betwen the two MDPE membranes is impregnated with the active substance permethrin (2.15 g/m2).

Dermal exposure is expected with the membranes and with the open edges of the fibrous layer.

Due to the very low vapour pressure of permethrin (2.55 x 10-6 Pa; 20ºC; and the specific composition of TRITHOR S (i.e. impregnated fibrous layer sandwiched between two plastic membranes) the risk for inhalation exposure to permethrin is considered to be negligible. Hence, concerning primary exposure the dermal route (i.e. potential contact with the treated fibre during placing of product family TRITHOR S) is regarded to be the main route of exposure.

There is no standard scenario and models in the TNsGs 2002 or 2007. Consequently, two scenarios were developed: one for the contact with the open edges and another 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 | Yes | No | No | No | No | No | No |
| Dermal | Yes | Yes | No | No | No | No | No |
| Oral | No | No | No | No | No | No | No |

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| 1.Application | a) dermal contact with membrane | The film is deposit on the foundations of building.  During application of the product, the professional will have multiple contacts with membranes. Assessing the total surface to which the professional is exposed during use is very uncertain. A reverse scenario is thus developed. | Professionals |
|  | b) dermal contact with open edges | The film is deposit on the foundations of building.  During application of the product, the professional will have multiple contacts with the open edges when applicating the product on the house ground surface. | Professionals |

***Industrial exposure***

Not applicable.

***Professional exposure***

*Scenario [1a] Application – Dermal contact with membrane*

| **Description of Scenario [1a]** |
| --- |
| The product TRITHOR S is a physico-chemical barrier in order to prevent termites invasion buildings. During application of the pre-cut treated film in the foundations of the house, the professional will have multiple contacts with membranes.  Regarding the use, the design of the film and the layer of PE and the volatility of permethrin, exposure via inhalation route (and oral route) is considered as negligible.  Only the dermal exposure via hand manipulation of the film will be assessed.  The contact area is limited to the hands, it is noted that the PE layers will not be considered (permeation value of 1). This situation is highly unrealistic as the PE layers avoid any contact between the treated film and the operator gloves. However a value of dislodgeable residue will be considered.  No data on active substance migration from the fibrous layer to the membrane is available. Consequently, a very worst case approach is used considering the same concentration in the membrane as in the fibrous layer (0.2 mg/cm2).  Non-woven material thickness is considered to reach a minimum of 1 mm (1.20 mm +/- 20%). And polymer thickness is 100 µm and 50 µm. As a worst case only the thickness of the textile is taken into account.  Then 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.  So surface concentration can be calculated as follow: a.s concentration on material    = (0.215 mg a.s./cm2/1 mm) \* 0.1 mm  = 0.0215 mg/cm2  A default value of 3% is used for transfer coefficients from membrane to skin is used *(Biocides Human Health Exposure Methodology).* This approach is very conservative as substance will far less dislodgeable in membrane than in fibrous layer or in carpet.  Further assumptions taken into account to assess dermal exposure are summarised in the Table 5 here below.  It should be noted that the product is classified as skin sensitizer, the wearing of gloves if required. |

**Calculations for Scenario [1a]**

Figure 5: Contact with membrane - exposure results

|  |  |  |
| --- | --- | --- |
| Parameters1 | Tier 1 Without PPE | Tier 2 with gloves |
| Impregnation concentration a.s. (mg/cm2) | 0.215 | 0.215 |
| Fibrous layer thickness (mm) | 1 | 1 |
| Relevant depth for transfer (mm) | 0.1 | 0.1 |
| Surface loading (mg/cm2) | 0.0215 | 0.0215 |
| Transfer coefficient fibrous layer/skin | 3% | 3% |
| Dislodgeable active substance (mg/cm2) | 6.00E-04 | 6.00E-04 |
| Gloves penetration factor | 100% | 5% |
| Internal exposure |  |  |
| AEL long term (mg/kg) | 0.05 | 0.05 |
| Body weight (kg) | 60 | 60 |
| Internal acceptable exposure a.s. (mg) | 3 | 3 |
| External exposure |  |  |
| Dermal absorption | 3% | 3% |
| Acceptable potential exposure (mg) | 100 | 2000 |
| Acceptable surface (m2) | 15.5 | 310 |

| **Summary table: estimated exposure from professional uses** | | |
| --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Maximum acceptable contact surface (m2)** |
| Scenario [1a] | Without PPE | 15.5 |
| With gloves | 310 |

*Scenario [1b] Application – Dermal contact with open edges*

| **Description of Scenario [1b]** |
| --- |
| The product TRITHOR S is a physico-chemical barrier in order to prevent termites invasion buildings. During application of the pre-cut treated film in the foundations of the house, the professional will have multiple contacts with membranes.  The professional  Applying the product TRITHOR S is likely to be in contact with the open edges (uncoated with PET).  To assess dermal exposure applying TRITHOR S in a conservative approach the house ground surface can be assumed to be approximately 130 m2 (= 7.5 m x 17.5 m) corresponding to approximately 50 m of TRITHOR S to be placed (7.5 m x 2 + 17.5 x 2)[[7]](#footnote-7).  Based on this approach the operator potentially could come into contact with of approximately 100 m length of open edges. Considering the thickness of the fabric (1.20 mm +/- 20% or 1.4 mm in a worst case approach), the surface of the open edges is calculated to be 1400 cm2 (= 10000 cm x 0.14 cm). For a direct contact with textile, it can be assumed that up to a depth of 1 mm residues of the treated fibre are relevant for transfer to the skin.  So surface loading can be calculated as follow:  = (0.215 mg a.s./cm2 ÷ 0.14 cm) \* 0.1 cm  = 0.15 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).*  Further assumptions taken into account to assess dermal exposure are summarised in the Table 6 here below. |

**Calculations for Scenario [1b]**

Figure 6: Contact with open edges - exposure results

| Parameters | Tier 1 without PPE | Tier 2 with gloves |
| --- | --- | --- |
| Impregnation concentration a.s (mg/cm2) | 0.215 | 0.215 |
| Fibrous layer thickness (cm) | 1.4 | 1.4 |
| Relevant depth for transfer (cm) | 0.1 | 0.1 |
| Surface loading a.s. (mg/cm2) | 0.15 | 0.15 |
| Length of open edges for contacts (m) | 100 | 100 |
| Contact surface (cm2) | 1400 | 1400 |
| Transfer coefficient fibrous layer/skin (%) | 3 | 3 |
| Dislodgeable active substance (mg/cm2) | 4.61E-04 | 4.61E-04 |
| Dermal exposure | | |
| Potential dermal load (mg) | 6 | 6 |
| Gloves penetration factor | 100% | 5% |
| Actual dermal load (mg) | 6 | 0.3 |
| Dermal absorption (%) | 3 | 3 |
| Internal exposure | | |
| Body weight (kg) | 60 | 60 |
| Systemic exposure (mg/kg/d) | 3.2E-03 | 1.6E-04 |
| AEL long term (mg/kg/d | 0.05 | 0.05 |
| % AEL | 6.0 | 0.3 |

| **Summary table: estimated exposure from professional uses** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated oral uptake (mg/kg/d)** | **Estimated inhalation uptake (mg/kg/d)** | **Estimated dermal uptake (mg/kg/d)** | **Estimated total uptake (mg/kg/d)** | **% AEL** |
| Scenario [1b] | Without PPE | Negligible | Negligible | 3.2E-03 | 3.2E-03 | 6.5 |
| With gloves | Negligible | Negligible | 1.6E-04 | 1.6E-04 | 0.3 |

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

*Combined scenarios*

Not applicable

***Non-professional exposure***

Not applicable

***Exposure of the general public***

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

***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”*.

TRITHOR S™ is a physico-chemical barrier against termites used by professional only, once at the beginning of the construction of new building. 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.

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.

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

Not applicable

***Aggregated exposure***

Not applicable

* + - 1. Risk characterisation for human health

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** (**mg/kg bw/day)** | **AF1** | **Correction for oral absorption** | **Value (mg/kg bw/d)** |
| AELshort-term | 2 year rat study (oral) | NOAEL=50 | 100 | none | 0.5 |
| AELmedium-term | dog 12 month study | NOAEL = 5 | 100 | none | 0.05 |
| AELlong-term | 12-month dog study | NOAEL = 5 | 100 | none | 0.05 |
| 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 (m2)** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL (%)** | **Acceptable**  **(yes/no)** |
| Scenario 1a: Application, dermal contact with membrane | Tier 1 without PPE | 15.5 | Not applicable | 100 | **No** |
| Tier 2 with gloves | 310 | Not applicable | 100 | yes |
| Scenario 1b: Application, dermal contact with open edges | Tier 1 without PPE | Not applicable | 3.2E-03 | 6.5 | yes |
| Tier 2 with gloves | Not applicable | 1.6E-04 | 0.3 | Yes |

**Conclusion**

Considering the wear of gloves, a maximum contact surface of 310 m2 has been calculated. Exposure to the open edges of the product is very limited.

The risk is therefore considered acceptable.

For peripheral application, the % AEL is lower than 100 % without and with gloves.

However, regarding the classification of the product as skin sensitizer, gloves have to be worn during the application of the product.

***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 direct contact with food and feed.

### Risk assessment for animal health

Not applicable.

### Risk assessment for the environment

|  |
| --- |
| 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.** |

Permethrin is assessed together with two environmentally relevant metabolites, 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane) carboxylate (DCVA) and 3-phenoxybenzoic acid (PBA).

DCVA and PBA were recovered in soil and in water-sediment system during investigation of degradation of permethrin (Assessment Report[[8]](#footnote-8)).

* + - 1. 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 | 4.70E-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 | |

Ecotoxicity and E-fate data are related to the active substance permethrin. ENSYSTEX Europe has been granted a Letter of Access for the data on Permethrin of TAGROS. That LoA is attached in the iuclid dossier. However in order to facilitate the risk assessment, PNEC values have been summarised in the following table. These PNECs have been derived regarding the List of Endpoint in the Assessment Report of Permethrin5.

Table 3: Overview of Predicted no effect concentration (PNECs) for permethrin based on AR of Permethrin.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Compartment | Lowest enpoint | AF | PNEC | Test/species |
| *Permethrin* | | | | |
| Aquatic | NOEC: 4.7E-06 mg /L | 10 | 4.7E-04 µg/L | *Daphnia magna* |
| Sediment |  |  | 2.17E-04 mg/kg wwt |  |
| STP |  |  | 4.95E-03 mg/L |  |
| Soil | > 0.099 mg/kg soil dwt | 100 | 0.0876 mg/kg wwt | Soil micro-organisms |
| Birds | NOEC: ≥ 500 mg/kg food | 30 | 16.7 mg/kg food | *Colinus virginianus* |
| Mammals | NOEC: 3600 mg/kg food | 30 | 120 mg/kg food | Rat |
| *DCVA* | | | | |
| Aquatic | LC50 14.7 mg/L | 1000 | 0.015 mg/L | Fish |
| Sediment | Equilibrium partitioning Ksusp 4.24 | 1 | 0.055 mg/kg wwt |  |
| Soil | 526 mg/kg dwt | 100 | 4.6 mg/kg wwt | *Hypoaspis aculeifer* |
| *PBA* | | | | |
| Aquatic | LC50 >10 mg/L | 1000 | 0.01 mg/L | Algae |
| Sediment | Equilibrium partitioning Ksusp 4.86 | 1 | 0.042 mg/kg wwt |  |
| Soil | 526 mg/kg dwt | 300 | 1.44 mg/kg wwt | Extrapolated[[9]](#footnote-9) |

***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***

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 2 - FR CA position:**  The biocide product TRITHOR S has the same classification than the active substance (permethrin).   |  |  | | --- | --- | | **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): NOEC 4.7E-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 TRITHOR S** | | | Value/conclusion | Aquatic Acute Cat 1; H400  Aquatic Chronic Cat 1; H410 | |

***Further Ecotoxicological studies***

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

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

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

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

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

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

|  |
| --- |
| **Infobox 9 - FR CA position:**  No data is available. |

***Leaching behaviour (ADS)***

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

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

|  |
| --- |
| **Infobox 11 - FR CA position:**  No data is available. |

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

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

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

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

***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)***

|  |
| --- |
| **Infobox 14 - FR CA position:**  No 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)***

|  |
| --- |
| **Infobox 15 - FR CA position:**  Not relevant. |

Exposure assessment

TRITHOR S™ is a physico-chemical barrier in order to prevent invasion of termites in buildings. It is installed where termites may potentially pass, between the construction frame to be protected and the soil. It consists of a geotextile blanket impregnated with permethrin of 1450 µm laminated top and bottom by polyethylene films of 50 and 100 µm thick, respectively.

Concentration of active substance in the barrier is of 2 g/m².

Field of applications:

TRITHOR S™ is intended to be installed in new buildings such as individual houses, multi-residential buildings, tertiary and public buildings.

The implementation of the process is realised by companies certified by Ensystex outside seismic areas, with climatic conditions above -30°C and in absence of rainy event.

Article laying:

In case of installation in a new individual house, the treated article used is a 10 cm wide and 50 m length roll. It arrives packed into the construction site and it is unrolled and cut along the construction perimeter by a qualified technician.

The treated article is nailed to the slab perimeter before the wall construction at a minimal distance of 20 cm from the ground (see Figure 1 to Figure 3).

The duration of the installation of TRITHOR S™ is of half an hour to one hour depending on the construction. The period between the end if the TRITHOR S™ laying and the start of the wall construction is of 24 hours. In case of unexpected climatic event (freeze or rainy event), the treated article may stay uncovered during a few days.

Constructions occurs all year long.

Fractions of treated articles not used for the construction are kept in order to be used at the next construction site.



Figure 1: Laying of TRITHOR S™ during the construction of an individual house (Source ENSYSTEX Europe)



Location of the wall to be built

TRITHOR S 10 cm width

Figure 2: Laying of TRITHOR S™ during the construction of an individual house (Source ENSYSTEX Europe)



Figure 3: TRITHOR S™ partially covered by the wall and to be covered by the door thresholds (Source ENSYSTEX Europe)

In case of secondary and tertiary buildings constructions, the used material is 15 cm width and 50 m length rolls. It arrives packed into the construction site. After walls and roof construction steps are over, the treated article is unrolled and layered on the inside perimeter of the construction The article is installed folded in angle and spiked against the walls and the floor (concrete slab or compacted sand).

Duration for the installation of TRITHOR S™ is estimated of 20 to 30 minutes per roll.

The article is protected against climatic events during all the construction period as it is installed after the completion of the roof.



Figure 4 Laying of TRITHOR S™ before casting the slab (Source ENSYSTEX Europe)

In all cases, there is no cleaning nor washing steps of the article.

At the end of constructions, the treated article is completely covered by the different building components and is no more into contact with the open air.

French market division:

10% of the annual production of TRITHOR S™ is dedicated to individual houses construction, 20% of the production is dedicated to multi-residential building and the major part of the production is dedicated to the secondary/tertiary buildings (70%).

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| **Infobox 16 - FR CA position:**  **General information**   |  |  | | --- | --- | | Assessed PT | PT 18 | | Assessed scenarios | TRITHOR S is a chemical-physical barrier for the preventive protection of new building against infestations by termites. TRITHOR S is a geotextile layer sandwiched between two plastic membranes (MDPE). The film is composed of an upper layer of 100 µm of polyethylene (not impregnated), an intermediate layer of geotextile impregnated with the insecticidal active substance, permethrin (2.15 g/m2), and a lower layer of 50 µm of polyethylene (not impregnated). Thus, in the TRITHOR S product permethrin is only distributed in the geotextile layer in the film.  The application of TRITHOR S may only be carried out by professional (building activity). The film is placed mainly on the internal perimeter of the house during its construction (horizontally on 50 cm, which corresponds to the largest packaging of the product), to establishing a barrier to prevent any entrance of the termites inside the building. | | 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 into the environment can take place from the following steps:   * Construction step   A time-interval of 2 weeks can be considered between the TRITHOR S installation and the slab pouring. During this interval, a short-term exposure of the environment by rainfall events is considered as relevant. Two separate theoretical environments can be considered, depending on whether emissions directed either to adjacent soil (here below called “rural area”), or to a sewage treatment plant (STP) (here below called “urban area”), 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. 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, as a very worst case situation as the product is not supposed to be in contact with the environment, but enclosed in the building matrix.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Step | Area | Environmental compartments (Service life step) | | | | | | Air | STP | Soil | Surface water | Groundwater | | Service-life | Rural | - | - | ++ | - | + |   To conclude, 3 scenarios are submitted for the environmental risk assessment:  - Scenario 1: During the construction step in urban area.  - Scenario 2: During the construction step in rural area.  - Scenario 3: During the service life of the product. | | Remarks |  | |

This Environmental exposure assessment doesn’t take into account formulations and production steps.

**Emission scenario**

Two steps in which releases may occur are identified. Emissions of substance may occur during application/laying step over the building/houses constructions when the article is in contact with the free air, and during the treated article service-life

The article exposition to the environment is specifically significant when considering the case of an individual house construction. Indeed, in this case neither the walls nor the roof are built when the article is layered, leading to a potential exposition to climatic events pending the walls construction.Emissions are also expected to occur over building lifetime due to eventual water infiltrations and variation of humidity in the slab and in other buiding material sealing the treated article.

The scenarios used to assess the environmental exposition of Permethrin due to the laying TRITHOR S™ during constructions and service-life of TRITHOR S™ are based on the case of individual houses.

For the assessment, the entire annual production of TRITHOR S™ is considered to be dedicated to individual house constructions.

**General information**

The emission scenarios were created in order to realise a reasonable worst-case exposure assessment of Permethrin and its relevant metabolites at a local scale. These scenarios are based on data from different sources:

* Ensystex
* French national institute Insee “Institut national de la statistique et des études économiques”
* ESD PT10: “Emission scenario document for biocides used as masonry preservatives.” [[10]](#footnote-10) (product type 10)
* ESD PT9: “Emission scenario document for biocides used as preservatives in the textile processing industry.” [[11]](#footnote-11)

In product laying scenarios, TRITHOR S™ is exposed to a rainy event occurring right after its installation in a site construction of an individual house while the treated article is not yet covered by walls nor roof.

|  |  |
| --- | --- |
| Assessed PT | PT 18 |
| Assessed scenarios | Scenario 1: Treatment of a house in a city  Scenario 2: Treatment of a house in a countryside  Scenario 3: Service-life (house) |
| ESD(s) used | “Emission scenario document for biocides used as masonry preservatives.”(product type 10), November 2002  “Emission scenario document for biocides used as preservatives in the textile processing industry.”, May 2001 |
| Approach | Average consumption |
| Distribution in the environment | Scenario 1: Calculated based on TGD 2003 |
| Groundwater simulation | None |
| Confidential Annexes | *Yes* |
| Life cycle steps assessed | Production: No Formulation: No Use: Yes Service life: Yes |
| Remarks | Scenarios were created based on different existing ESDs. |

***Emissions during house construction (scenario 1 and 2)***

The route of exposure considered during construction is the leaching of Permethrin from the treated article by rainfall leading to emissions to soil.

Scenarios 1 and 2 are based on the model house described in ESD PT10 and already proposed in OECD (2002). Dimensions are presented in the figure below:

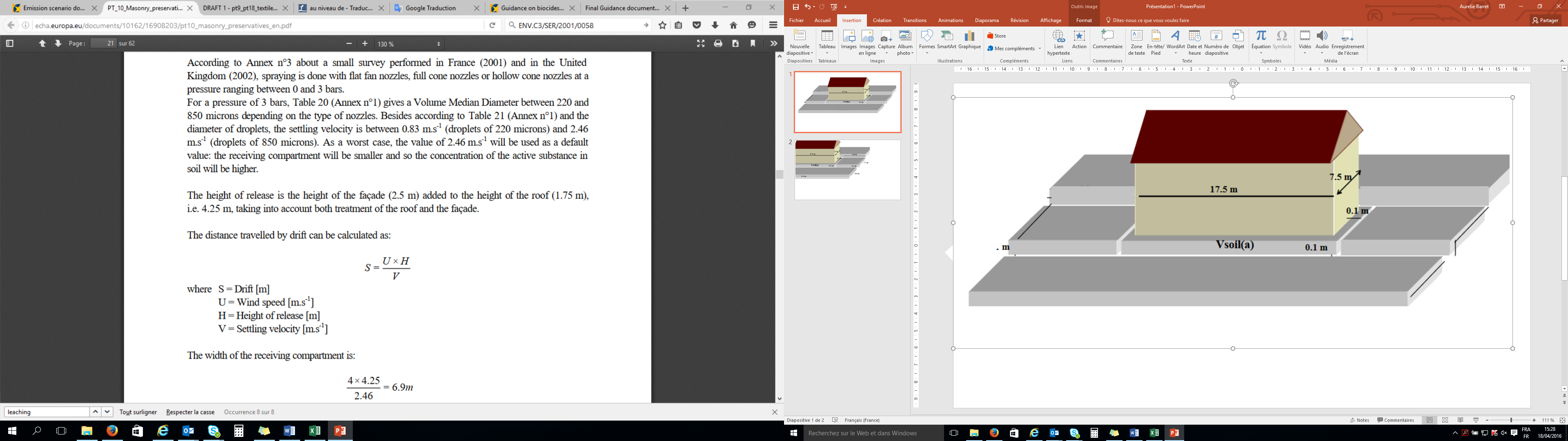
Figure 5: Dimensions of the model houses and of the receiving soil (a)

Figure 5 shows the dimensions of the model house and receiving adjacent soil according to ESD for PT10.

For the following exposure assessment, dimensions of the receiving soil adjacent to the house are updated in accordance with the Technical Agreement for Biocide[[12]](#footnote-12) recommendations regarding soil depth to be considered. In order to harmonise the procedure with all product types, a soil depth of 50 cm is used for the assessment.

Taking into account informations provided by the model house from PT10 and TAB recommendations, the volume of soil receiving the leaching fluid (Vsoil(a)) iis estimated at 2.5 m3.

According to ESD PT10, two settings have to be considered when assessing treatment of houses. A building to be treated can be located either in the countryside or within a city. If it is located within a city, the losses are likely to fall upon paved ground and washed with rain to the sewer system. In a more rural setting, the losses are more likely to end up on unpaved soil.

The local concentration of the active substance in soil is only calculated for a treated surface located in the countryside (scenario 2).

Releases to water are collected by the storm water system (scenario 1). A common collection system for waste water and storm water is considered by default in this scenario. The local concentration in surface water, in sediment and in agricultural soil are then calculated according to the general methods described in the Guidance in BPR[[13]](#footnote-13).

A tiered approach is used to estimate emissions of Permethrin due to the laying of TRITHOR S™ in construction sites of individual houses:

* At Tier 1a level, worst case assumption where 100% of the active substance is assumed to leach during the rainy event.
* At Tier 1b level, the treated article is assumed to release 30%[[14]](#footnote-14) of active substance during the rainy event.

At Tier 2 level, permethrin is considered to be released from edges of the article only, where the impregnated layer isn’t covered by polyethylene films.

In lower Tier, Permethrin is assumed to be released by 100% of the impregnated layer area. At Tier 2, 1.44% of the impregnated layer is assumed to release active substance, corresponding to the actual fraction of impregnated layer not covered by films.

Calculations to determine the fraction used for Tier 2 simulations are available in Annexe 3.2.

Final concentrations in environmental compartments are estimated for the active substance Permethrin and its metabolites PBA and DCVA.

Assessment of these metabolites are performed in accordance with the methodology presented in the Assessment Report of Permethrin5. In order to estimate potential water and sediment exposure to the major metabolites due to losses to wastewater compartment according to scenario 1, it is assumed that metabolites are formed at the point of emission (from Clocaleff and diluted by the default factor of 10) at a quantity equivalent to 100 % of the parent adjusted to take into account differences in the molar masses of the compounds.

Similarly, soil exposure to metabolites due to sludge application (scenario 2) is estimated on the worst-case assumption that the metabolite is formed in the sludge at a quantity equivalent to 100% of the parent (adjusted to take into account differences in the molar masses of the compounds). The concentrations arising in soil after 10 successive yearly applications of sludge is then calculated.

***Emissions during service-life (Scenario 3)***

Emissions if permethrin during service-life was also estimated based on the existing model house from ESD PT10 (Scenario 3). The same receiving soil volume as for emissions during laying step is used.

The route of exposure considered during service-life is the leaching of active substance due to variations of humidity in soil and/or water infiltrations in slab under the treated article over the whole building lifetime.

Liberation rate of substance from the treated article over time is expected to be affected by several internal and external parameters. Identified parameters are the modification of physical properties of TRITHOR S™ due to wall pressure, variation of weather conditions (temperature, humidity) and diminution of the active substance concentration in the impregnated layer. Some parameters would lead to an increase of the liberation rate of substance year after year, while others are expected to lead to its decrease.

The resulting variation of liberation rate over time is thus difficult to predict.

In order to simulate releases from the treated article spread over its service-life, several hypothesis are admitted.

* Assessment is performed considering exposure of local soil under the house only. Indeed, exposition is considered possible via leaching of the substance through the building material and/or the treated article directly in contact with soil. Once transferred to the local soil, the substance is unlikely to reach the sewer system.
* As a worst-case consideration, it is assumed that 100% of the substance is released over the entire service-life of the treated article. For metabolites assessment, each metabolite is estimated to be formed at a quantity equivalent to 100% of the parent (adjusted to take into account differences in the molar masses of the compounds)
* The building lifetime, corresponding to the service-life of building material (including TRITHOR S) is assumed to be of a minimum of 50 years[[15]](#footnote-15). The minimum guaranteed efficacy duration of TRITHOR S™ is of 10 years. For the assessment of exposure of soil to permethrin and its major metabolites during service-life of the treated article, its physical integrity is considered to be maintained during the first decade, reducing the releasing period to 40 years.
* The porosity of TRITHOR S™ is assumed to be unchanged during the 40 years of releases. As a result, it is also assumed that the quantity of released substance from the treated article will not increase nor decrease over the considered period.

Accumulation and degradation processes of permethrin, DCVA and PBA in soil during the whole releasing period are taken into account in this assessment.

Concentrations in soil of active substance and its metabolites after 40 years of exposure are estimated following two different assumptions on releases frequeny in order to cover the different possibilities.

In the first place, concentrations are calculated considering two releases of substance a year during 40 years, illustrating ponctuals liberation when weather conditions are the most unfavourable (during spring and autumn). (1)

Concentrations are then calculated considering daily releases of substance during 40 years, illustrating a progressive and constant liberation of substance on a day by day basis. (2)

In both cases, 100% of the substance is considered released from the treated article after 40 years.

Soil exposure to metabolites is estimated on the worst-case assumption that the metabolite is immediately formed in soil at a quantity equivalent to 100% of the parent (adjusted to take into account differences in the molar masses of the compounds).

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 17 - 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 TRITHOR S, 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. |

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water |
| Scenario 1 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| Scenario 2 | No | No | No | No | No | No | Yes | Yes |
| Scenario 3 | No | No | No | No | No | No | Yes | Yes |

Distributions in the environment of permethrin according to Scenario 1 and 3 are calculated with EUSES V2.1.2. Emissions to waste water previously calculated were manually entered as local emission to water at “Local emissions” step of EUSES.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| Input | Value | Unit | Remarks |
| **Permethrin** | | | |
| Molecular weight | 391.29 | g/mol | Assessment Report, 2014[[16]](#footnote-16) |
| Melting point | - | °C |  |
| Boiling point | - | °C |  |
| Vapour pressure (at 20°C) | 2.16E-6 | Pa | Assessment Report, 2014 |
| Water solubility (at 25°C) | 0.18 | mg/l | Assessment Report, 2014 |
| Log Octanol/water partition coefficient | 4.67 | Log 10 | Assessment Report, 2014 |
| Organic carbon/water partition coefficient (Koc) | 26 930 | l/kg | Assessment Report, 2014 |
| Biodegradability | Not Biodegradable |  | Assessment Report, 2014 |
| **DCVA** | | | |
| Molecular weight | 209.066 | g/mol |  |
| Melting point | - | °C |  |
| Boiling point | - | °C |  |
| Vapour pressure (at 20°C) | 0.26 | Pa | QSAR value EPI Suite MpBpwin v1.43 Modified Grain method |
| Water solubility (at 25°C) | 372.19 | mg/l | QSAR value EPI Suite Waternt v1.01 |
| Log Octanol/water partition coefficient | 3.3763 | Log 10 | QSAR value EPI Suite KOWWIN v1.68 |
| Organic carbon/water partition coefficient (Koc) | 93.2 (n=5) | l/kg | Assessment Report, 2014 |
| Biodegradability | Not Biodegradable | - | Default value |
| **PBA** | | | |
| Molecular weight | 214.22 | g/mol |  |
| Melting point | - | °C |  |
| Boiling point | - | °C |  |
| Vapour pressure (at 20°C) | 0.000421 | Pa | QSAR value EPI Suite MpBpwin v1.43 Modified Grain method |
| Water solubility (at 25°C) | 20.53 | mg/l | QSAR value EPI Suite Waternt v1.01 |
| Log Octanol/water partition coefficient | 3.93 | Log 10 | QSAR value EPI Suite KOWWIN v1.68 |
| Organic carbon/water partition coefficient (Koc) | 141.2 | l/kg | Assessment Report, 2014 |
| Biodegradability | Not Biodegradable | - | Default value |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Calculated fate and distribution in the STP** | | | |
| Compartment | Percentage [%] | | | Remarks |
| **Permethrin** | **DCVA** | **PBA** |
| Air | 1.35E-03 | 0.138 | 3.64E-4 | EUSES V2.1.2 |
| Water | 27.6 | 98.7 | 87.5 | EUSES V2.1.2 |
| Sludge | 72.4 | 1.15 | 12.5 | EUSES V2.1.2 |
| Degraded in STP | 0 | 0 | 0 | EUSES V2.1.2 |

***Emission estimation***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 18 - FR CA position:**   1. ***Construction step***   The following scenarios consider that the installation of TRITHOR S 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 TRITHOR S 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 TRITHOR S 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 TRITHOR S 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).  Some 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 2: During the construction step in urban and rural area  As presented by the applicant, TRITHOR S is placed horizontally around the entire internal perimeter, with a strip width of 50 cm. In the environmental assessment, no leaching data are available about TRITHOR S product, however, considering that in the film only the intermediate layer is impregnated of permethrin, the assumption can be made that only the edges of the strip release permethrin in the environmental compartment over a depth of 1 mm. The surface area for a house where leaching occurs (*AREAbarrier*) is calculated in the following table.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **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 | | House surface area where leaching occurs | AREA film | 0.10 | [m2] | House perimeter of 50 m, 2 borders, and 1 mm depth of film is released via the borders. | | Quantity of permethrin in the product applied | Dose | 2.15 | [g.m-2] | - | | **Scenario 1: Emission during the construction step in urban area** | | | | | | **OUTPUT SCENARIO 1** | | | | | | Local emission to waste water | Elocal,ww | 2.15E-04 | [kg.d-1] | - | | **Scenario 2: Emission during the construction step in rural area** | | | | | | **OUTPUT SCENARIO 2** | | | | | | Local emission to adjacent soil | Esoil,leach | 2.15E-04 | [kg.d-1] | - |  1. ***Service life step***   Scenario 3: Emission during the service life of the product  The use of TRITHOR S around the internal 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 TRITHOR S 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.  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). TRITHOR S is placed horizontally around the entire internal perimeter, with a strip width of 50 cm. The total area of TRITHOR S applied to a single house (*AREAbarrier*) is 25 m2. Considering 100% emission over 30 years and a maximum active substance dose rate of 2.15 g.m-2 for TRITHOR S, 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 3   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Input parameters for calculating the local emission in scenario 3** | | | | | | **Parameter** | **Symbol** | **Value** | **Unit** | **Remarks** | | **Scenario 3: Emission during the service life of the product in rural and urban area** | | | | | | **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 | 2.15 | [g.m-2] | - | | Width of the product (max) | Wproduct | 0.5 | [m] | - | | Area of the barrier around the building | AREAbarrier | 25 | [m2] | (Lhouse+ Whouse)\*2\* Wproduct | | Expected product life (30 years) | TIME | 10950 | [d-1] | - | | **OUTPUT** | | | | | | Quantity of permethrin released per m2 over the product lifetime | Qleach | 2150 | [mg.m-2] | Eq. ESD PT8 | | Local emission to adjacent soil per day over the product lifetime | Esoil,leach,time | 4.91 | [mg.d-1.house-1] | Eq. ESD PT8 | |

**Scenario 1 Treatment of a house in a city**

In scenario 1, 100% of the permethrin releases are assumed to reach the sewer system by runoff.

As a first step, the quantity of permethrin released to the sewage system from the treated article for one construction site, during a rainy event was determined.

As a second step, daily releases rate of permethrin due to the use of TRITHOR S™ in a standard town of 10,000 inhabitants (with a standard sewage treatment plant) was calculated.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Laying of TRITHOR S™ on a site construction of an individual house in a city | | | |
| Concentration of active substance in the treated article | 2 | g/m² | Ensystex |
| Fixation degree of active substance in the treated article | Tier 1a: 0% Tier 1b:70%  Tier 2: 1.44% | - | Tier 1a : Default value for Worst-case assumption[[17]](#footnote-17)  Tier 1b: Default value ESD PT9 |
| Thickness of the treated article (Tier 2) | 200 | µm | Ensystex |
| Width of the treated article (Tier 2) | 10 | cm | Ensystex |
| Thickness of the impregnated layer (Tier 2) | 50 | µm | Ensystex |
| Length of the house | 17.5 | m | Default value ESD PT10 (see Figure 3) |
| Width of the house | 7.5 | m | Default value ESD PT10 (see Figure 3) |
| Nb of individual housing starts during a year in France | 202,800 | Year-1 | Mean (n=14, from 2000 to 2013) Insee data[[18]](#footnote-18) |
| French population | 63,218,000 | inhabitants | Mean (n=14, from 2000-2013), Insee data[[19]](#footnote-19) |
| Nb of inhabitant in a standard town | 10,000 | inhabitants | Default value for local assessment 14 |

Calculations for Scenario 1

Calculations for Scenario 1 are provided in Annexe 3.2.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalwaste water) [kg/d]** | **Remarks** |
| **Permethrin** | | |
| STP | Tier 1a: 8.79 E-4 Kg/d  Tier 1b: 2.64 E-4 Kg/d  Tier 2: 1.27E-05 Kg/d | According to scenario 1, waste waters are the receiving compartment. |

**Scenario 2 Treatment of a house in a countryside**

In this scenario the receiving compartment is the local soil adjacent to the house.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Laying of TRITHOR S™ on a site construction of an individual house in a countryside | | | |
| **Scenario parameters** | | | |
| Concentration of active substance in the treated article | 2 | g/m² | Ensystex |
| Volume of receiving soil | 2.5 | m3 | Default value TAB9  2016 (See section 2.2.8.1.2) |
| Fixation degree of active substance in the treated article | Tier 1a: 0% Tier 1b: 70% | - | Tier 1a : Default value for Worst-case assumption14  Tier 1b: Default value ESD PT9 |
| Soil density | 1700 | Kg wet weight/m3 | Default value from TGD10 |
| Thickness of the treated article (Tier 2) | 200 | µm | Ensystex |
| Width of the treated article (Tier 2) | 10 | cm | Ensystex |
| Thickness of the impregnated layer (Tier 2) | 1450 | µm | Ensystex |
| Length of the house | 17.5 | m | Default value ESD PT10 (see Figure 3) |
| Width of the house | 7.5 | m | Default value ESD PT10 (see Figure 3) |
| **Active substance and metabolites parameters** | | | |
| Molar ratio of DCVA/Permethrin | 0.534 | - |  |
| Molar ratio of PBA/Permethrin | 0.547 | - |  |
| Formation fraction of DCVA from permethrin | 100 | % | Default value |
| Formation fraction of PBA from Permethrin | 100 | % | Default value |

Calculations for Scenario 2

Calculations for Scenario 2 are provided in Annexe 3.2 (confidential).

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local concentration in soil (Clocalsoil) [mg/ Kg w.wt]** | **Remarks** |
| **Permethrin** | | |
| Soil | Tier 1a: 2.35 mg/Kg w.wt  Tier 1b: 0.71 mg/Kg w.wt  Tier 2: 1.02E-2mg/Kg w.wt | Adjacent soil |
| **DCVA** | | |
| Soil | Tier 1a: 1.26 mg/Kg w.wt  Tier 1b: 0.38 mg/Kg w.wt  Tier 2: 5.43E-03 mg/Kg w.wt | Adjacent soil |
| **PBA** | | |
| Soil | Tier 1a: 1.29 mg/Kg w.wt  Tier 1b: 0.39 mg/Kg w.wt  Tier 2: 5.57E-03 mg/Kg w.wt | Adjacent soil |

**Scenario 3 Service-life**

In this scenario the receiving compartment is the local soil adjacent to the house.

In order to simulate progressive releases and degradation of permethrin over 40 years in soil, two sets of results are presented.

In a first case, a model simulating a daily and constant release of permethrin over 40 years is used.

In a second case, calculations are performed considering two releases of substance a year during 40 years.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario: Emissions during service-life of TRITHOR S™ in an individual house | | | |
| **Scenario parameters** | | | |
| Concentration of active substance in the treated article | 2 | g/m² | Ensystex |
| Volume of receiving soil | 2.5 | m3 | Default value TAB16  2016 (See section 2.2.8.1.2)Default value ESD PT10 (see Figure 11) |
| Soil density | 1700 | Kg wet weight/m3 | Default value from |
| Width of the treated article (Tier 2) | 10 | cm | Ensystex |
| Length of the house | 17.5 | m | Default value ESD PT10 (see Figure 11) |
| Width of the house | 7.5 | m | Default value ESD PT10 (see Figure 11) |
| Duration of service-life of building materials | 50 | years | Default value (Guideline on life-cycle steps19 ) |
| Period during which the efficacy of TRITHOR S™ is guaranteed | 10 | years | Ensystex |
| Fraction of active substance released from the treated article during service-life | 100 | % | Default value |
| **Active substance and metabolites parameters** | | | |
| Molar ratio of DCVA/Permethrin | 0.534 | - |  |
| Molar ratio of PBA/Permethrin | 0.547 | - |  |
| Formation fraction of DCVA from permethrin | 100 | % | Default value |
| Formation fraction of PBA from Permethrin | 100 | % | Default value |
| Half-life in soil at 12°C of Permethrin | 106 (geomean) | d | Assessment Report, 2014 |
| Half-life in soil at 12°C of Permethrin | 175 (worst-case value) | d | Assessment Report, 2014 |
| Half-life in soil at 12°C of Permethrin | 2.5 (worst-case value) | d | Assessment Report, 2014 |

Calculations for Scenario 3

Calculations for Scenario 3 are provided in Annexe 3.2.

Concentrations are presented for (a) two releases a year over 40 years, (b) daily releases over 40 years.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local concentration in soil after 40 years (Clocalsoil) [mg/ Kg w.wt]** | **Remarks** |
| **Permethrin** | | |
| Soil | (a) 4.22E-02  (b) 2.47E-02 | Adjacent soil, after 40 years of emissions |
| **DCVA** | | |
| Soil | (a) 3.05E-02  (b) 2.18E-02 | Adjacent soil, after 40 years of emissions |
| **PBA** | | |
| Soil | (a) 1.61E-02  (b) 3.64E-04 | Adjacent soil, after 40 years of emissions |

***Calculated PEC values***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 19 - FR CA position:**  Scenario 1: Emission during the construction step 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-1] | [mg.L-1] | [mg.kgwwt-1] | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 2.97E-05 | 2.85E-06 | 1.67E-03 | 2.90E-04 | 3.94E-04 | | DCVA | - | 9.54E-07 | 4.66E-06 | 2.05E-05 | 4.41E-03 | | PBA | - | 4.50E-07 | 7.19E-07 | 2.84E-06 | 6.07E-04 |   Scenario 2: Emission during the construction step in rural area.  Predicted concentrations of permethrin and metabolites in soil were calculated considering the volume of the receiving soil compartment adjacent to the TRITHOR S (Vsoil). According to ESD PT8, a volume of the receiving soil compartment around the house of 13 m3 is taking into account as the horizontal film is located above the ground at the periphery of the building.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Input parameters for calculating the PECsoil in scenario 2** | | | | | | **Parameter** | **Symbol** | **Value** | **Unit** | **Remarks** | | **INPUTS** | | | | | | Local emission to adjacent soil | Esoil,leach | 0.215 | [g.house-1] | - | | 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 2** | | | |  | **PECsoil** | **PECGW** | | [mg.kgwwt-1] | [μg.L-1] | | Permethrin | 9.73E-03 | 2.05E-02 | | DVCA | 5.87E-04 | **1.71E-01** | | PBA | 7.99E-04 | **1.02** |   Scenario 3: Emission during the service life of the product in rural or urban area  Predicted concentrations of permethrin in soil were calculated from the local emission considering the volume of the receiving soil compartment adjacent to the TRITHOR S (Vsoil). According to ESD PT8, a volume of the receiving soil compartment around the house of 13 m3 is taking into account as the horizontal film is located above the ground at the periphery of the building.  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.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Input parameters for calculating the PECsoil in scenario 3** | | | | | | **Parameter** | **Symbol** | **Value** | **Unit** | **Remarks** | | **INPUTS** | | | | | | Local emission to adjacent soil | Esoil,leach | 4.91 | [mg.d-1.house-1] | - | | Local emission to adjacent soil - DCVA | Esoil,leach | 0.296 | [mg.d-1.house-1] |  | | Local emission to adjacent soil - PBA | Esoil,leach | 0.403 | [mg.d-1.house-1] |  | | Volume of the soil | Vsoil | 13 | [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 (permethrine) 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 | 3.40E-02 | 7.15E-02 | | DVCA | 3.39E-03 | **9.83E-01** | | PBA | 6.58E-05 | 8.43E-02 | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 20 - FR CA position:**  ***High-tier assessment for groundwater for scenario 2 to 3***  During the construction step and the service life of TRITHOR S, the groundwater compartment present PEC value > 0.1 µg/L for the metabolites of permethrin 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 on a per-hectare basis. The total daily loading rate of permethrin in soil from a single treated house is calculated:  The assessment prosed assumes a default value of 16 houses build per hectare (Nhouse). The corresponding application rate of permethrin to land can be calculated using the following equation:  Calculated parameters are presented in the following table.   |  |  |  |  | | --- | --- | --- | --- | | **Parameters used to determine inputs data in FOCUS PEARL** | | | | | **Symbol** | **Value** | **Unit** | **Remarks** | | AREA barrier | 25 | [m2.house-1] | Calculated | | Qleach time barrier | 2150 | [mg.m-2] | Calculated | | Emission days | 10950 | [d-1] | Default | | Esoil, leach barrier | 4.91 | [mg.d-1.house-1] | Calculated | | Nhouse | 16 | [house.ha-1] | Default | | Emission days | 365 | [d.year-1] | Default | | Nb application per year | 10 | - | Default | | Appl rate for 16 houses per application | 2.86E-03 | [kg.ha-1] | Output |   Ten applications of permethrin were modelled each year during the simulation period (30 years). The application rate is of 2.86E-03 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) | | Irrigation | FOCUS standard irrigation scheme | | Tillage | No tillage | | 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 (checked) | | Transformation scheme editor | | | To substance | DCVA | | Fraction transformed | 0.113 | | To substance | PBA | | Fraction transformed | 0.15 | | Absolute Application | | | Application type | To the soil surface | | Date | 01-Jan | | 06-Feb | | 15-Mar | | 20-Apr | | 27-May | | 02-Jul | | 08-Aug | | 13-Sep | | 20-Oct | | 25-Nov | | Dosage (kg/ha) | 2.86E-03 |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Overview of result from FOCUS PEARL** | | | | | | **Result-text** | **Permethrin** | **DCVA** | **PBA** | **Location** | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.019733 | 0 | CHATEAUDUN | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.034394 | 0 | HAMBURG | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.022363 | 0 | JOKIOINEN | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.021871 | 0 | KREMSMUENSTER | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.029951 | 0 | OKEHAMPTON | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.025859 | 0 | PIACENZA | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.019555 | 0 | PORTO | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.00679 | 0 | SEVILLA | | Concentration closest to the 80th percentile(µg/L) | 0 | 0.012289 | 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 metabolite DCVA and PBA. |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECseawater** | **PECseased** | **PECsoil** | **PECair** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/l] | [mg/kgwwt] | [mg/Kg wwt] | [mg/m3] |
| **Permetrhin** | | | | | | | |
| Scenario 1 Tier 1a | 4.39E-04 | 1.17E-05 | 6.84E-03 | 4.22E-06 | 2.48E-03 | 1.18E-02 | 9.05E-15 |
| Scenario 1 Tier 1b | 1.32E-04 | 3.50E-06 | 2.05E-03 | 1.27E-06 | 7.44E-04 | 3.53E-03 | 2.72E-15 |
| Scenario 1 Tier 2 | 6.45E-06 | 1.71E-07 | 1E-04 | 6.2E-08 | 3.63E-05 | 1.73E-04 | 4.84E-14 |
| **DCVA** | | | | | | | |
| Scenario 1 Tier 1a | - | 6.47E-06 | 1.82E-05 | - | - | 1.48E-03 | 0 |
| Scenario 1 Tier 1b | - | 1.94E-06 | 5.45E-06 | - | - | 4.42E-04 | 0 |
| Scenario 1 Tier 2 | - | 9.51E-08 | 2.67E-07 | - | - | 2.16E-05 | 0 |
| **PBA** | | | | | | | |
| Scenario 1 Tier 1a | - | 6.61E-06 | 1.71E-04 | - | - | 5.71E-03 | 0 |
| Scenario 1 Tier 1b | - | 1.99E-06 | 5.15E-05 | - | - | 1.71E-03 | 0 |
| Scenario 1 Tier 2 | - | 9.72E-08 | 2.52E-06 | - | - | 8.47E-05 | 0 |

***Primary and secondary poisoning***

Primary poisoning

|  |
| --- |
| **Infobox 21 - FR CA position:**  Not relevant. |

Data on the toxicity of Permethrin to birds and mammals are available and are summarised in Assessment Report of Permethrin5 (Doc IIA, Section 4.2). In the terrestrial compartment, permethrin was found to have low avian toxicity but was toxic to bees and may be hazardous to small mammals following acute exposure. It is of low toxicity to terrestrial soil-dwelling organisms, including earthworms, micro-organisms and plants. The soil metabolites DCVA and FPB-acid (analogue for PBA) displayed lower toxicity to soil macro-organisms than the parent active ingredient and thus are not considered to be ecotoxicologically relevant.

Data on the toxicity of Permethrin to aquatic organisms are available and are summarised in Assessment Report of Permethrin5 (Doc IIA, Section 4.2). Permethrin is potentially highly toxic to aquatic organisms, especially invertebrates. The highest risk for environmental toxicity is in the water column immediately after the release incident, because permethrin will bind rapidly to sediment and become less bioavailable to organisms. While permethrin does have a tendency to bioconcentrate based upon its lipophilicity, terrestrial and aquatic organisms have demonstrated the ability to depurate permethrin through excretion. Aquatic metabolites including DCVA and 3-phenoxy benzoic acid (PBA) are far less toxic to aquatic organisms than the parent active ingredient and are not considered to be ecotoxicologically relevant.

As the proposed use will not result in direct exposure of birds and mammals, the risk for the primary poisoning is considered acceptable.

Secondary poisoning

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 22 - 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 table.   |  |  |  | | --- | --- | --- | | **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 | 8.13E-04 | 2.69E-03 | | Scenario 2 | - | 1.39E-01 | | Scenario 3 | - | 4.87E-01 | |

Regarding to the Log P value of Permethrin, secondary poisoning cannot be excluded.

All presented scenarios assume direct or indirect emissions of active substance to soils. Secondary poisoning via terrestrial food chain may occur. Earthworms from these soils could be contaminated and then eated by worm-eating birds or mammals.

The PECoral,predator is calculated based on TGD10 Part.II (equations 80 and 82c), which are:

1) 2)

With,

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameters** | **Value** | **Unit** | **Remarks** |
| PECoralpredator:Predicted Environmental Concentration in food |  | mg.kgwet earthworm-1 |  |
| BCFearthworm: bioconcentration factor for earthworms on wet weight basis | 23.8 | L.kgwet earthworm-1 | Estimated value, Tagros |
| Cearthworm: concentration in earthworm on wet weight basis |  | mg.kgwet earthworm -1 | Estimated value based on TGD10 |
| Cporewater: concentration in porewater |  | mg.L-1 | Estimated With EUSES |
| Csoil: concentration in soil |  | mg.kgwwt-1 | Estimated With EUSES/ ESD |
| CONVsoil: conversion factor for soil concentration wet-dry weight soil | 1.133 | kgwwt.kgdwt-1 | Estimated value based on TGD10 |
| Fsolid: volume fraction of solids in soil | 0.6 | m3.m-3 | Default value from TGD10 |
| Fgut: fraction of gut loading in worm | 0.1 | kgdwt.kgwwt-1 | Default value from TGD10 |
| RHOsoil: bulk density of wet soil | 1700 | kgwwt.m-3 | Default value from TGD10 |
| RHOsolid: density of solid phase | 2500 | kgdwt.m-3 | Default value from TGD10 |

Scenario 1 assumes indirect emission of permethrin to surface water via STP releases. Secondary poisoning via aquatic food chain may occur. Fishes from these waters could be contaminated and then eated by fish-eating predators.

The PECoral,predator is calculated based on TGD10 Part.II (equation 76), which is:

With,

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameters** | **Value** | **Unit** | **Remarks** |
| PECoralpredator:Predicted Environmental Concentration in food |  | mg.kgwet fish-1 |  |
| BCFfish: bioconcentration factor for fish on wet weight basis | 570 | L.kgwet fish-1 | Measured value  (28 day flow-through test in Bluegill sunfish), Bayer/  Sumitomo |
|  |  |  |  |
| PECwater: Predicted Environmental Concentration in wate |  | mg.L-1 | Estimated With EUSES |
| BMF: Biomagnification factor in fish | 22 | - | Default value from TGD10, Table 24 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Soil compartment** | | **PECsoil** | **Cpore water** | **Cearthworm= PEC oral** |
| **mg.kgwwt-1** | **mg.L-1** | **mg.kgwet earthworm -1** |
| **Permethrin** | | | | |
| **Scenario 1: House in a city** | Scenario 1 Tier 1a | 1.18E-2 | 2.47E-05 | 3.36E-01 |
| Scenario 1 Tier 1b | 3.53E-03 | 7.43E-06 | 1.01E-01 |
| Scenario 1 Tier 2 | 1.78E-06 | 3.63E-07 | 4.95E-03 |
| **Scenario 2: House in a countryside** | Scenario 1 Tier 1a | 2.35 | 4.94E-03 | 6.73E+01 |
| Scenario 1 Tier 1b | 0.71 | 1.49E-03 | 2.03E+01 |
| Scenario 1 Tier 2 | 3.56E-04 | 2.15E-05 | 2.92E-01 |
| **Scenario 3: Service-life** | (a) Seasonal basis | 4.22E-02 | 8.88E-05 | 1.21E+00 |
| (b) Daily basis | 2.47E-02 | 5.20E-05 | 7.08E-01 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Surface water compartment** | | **PECsw** | **PEC oral (fish)** |
| **mg.l-1** | **mg.kgwet fish-1** |
| **Scenario 1: House in a city** | Scenario 1 Tier 1a | 1.17E-05 | 1.33E-02 |
| Scenario 1 Tier 1b | 3.50E-06 | 3.99E-03 |
| Scenario 1 Tier 2 | 1.71E-07 | 1.95E-04 |

* + - 1. Risk characterisation

***Atmosphere***

|  |
| --- |
| **Infobox 23 - FR CA position:**  Significant exposure of the environment via air is not expected.  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 TRITHOR S will not pose a significant risk to the atmospheric compartment. |

Volatilization of permethrin is considered to be negligible based on the vapour pressure.

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

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 24 - FR CA position:**   |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC/PNEC values for permethrin** | | **Conclusion** | |  | **PEC/PNECSTP** | | Scenario 1 | 5.99E-03 | Acceptable |   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. Consequently, the risk for the STP is acceptable. |

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
| Scenario 1 | **PEC/PNECSTP** |
| **Permethrin** | |
| Scenario 1 Tier 1a | 8.87E-02 |
| Scenario 1 Tier 1b | 2.67E-02 |
| Scenario 1 Tier 2 | 1.30E-03 |

Conclusion:

Risk assessment for treatment plant is only relevant for Scenario 1, in which emissions of permethrin are directed to waste water. At each level, PNECSTP is superior to the calculated PECSTP. The risk to STP is considered as acceptable from scenario 1.

***Aquatic compartment***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 25 - FR CA position:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Summary table on calculated PEC/PNEC values** | | | | **Conclusion** | |  |  | **PEC/PNECwater** | **PEC/PNECsed** | | Scenario 1 | Permethrin | **6.07** | **7.70** | Non Acceptable | | DCVA | 6.36E-05 | 3.88E-04 | Acceptable | | PBA | 4.50E-05 | 7.99E-05 | Acceptable |   Conclusion:  During the construction step,the risk characterisation ratios for permethrin in water and sediment are above 1. The risk characterisation ratios for metabolites are below 1 in the aquatic compartments.  The risk related to the use of TRITHOR S during the construction step is not acceptable for the aquatic compartment.  Risk mitigation measures are necessary to limit the emission to STP during the installation phase of the TRITHOR S product. These risk mitigation measures should prevent the exposure of the film to the weather during its installation in case of possible rainwater discharge to a water collection system. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECseawater** | **PEC/PNECseased** |
| **Permethrin** | | | | |
| Scenario 1 Tier 1a | **2.49E+01** | **3.15E+01** | - | - |
| Scenario 1 Tier 1b | **7.45** | **9.45** | - | - |
| Scenario 1 Tier 2 | 3.64E-01 | 4.61E-01 | - | - |
| **DCVA** | | | | |
| Scenario 1 Tier 1a | 4.31E-04 | 3.31E-04 | - | - |
| Scenario 1 Tier 1b | 1.29E-04 | 9.91E-05 | - | - |
| Scenario 1 Tier 2 | 6.34E-06 | 4.85E-06 | - | - |
| **PBA** | | | | |
| Scenario 1 Tier 1a | 6.61E-04 | 4.07E-03 | - | - |
| Scenario 1 Tier 1b | 9.72E-06 | 6.00E-05 | - | - |
| Scenario 1 Tier 2 | 5.37E-08 | 3.31E-07 | - | - |

Conclusion:

Risk assessment for surface water is only relevant for Scenario 1, in which the active substance reaches surface water after its passage through the STP. At Tier 1 level, PEC/PNEC ratios > 1. With a refined assessment at Tier 2 level, the risk to the aquatic compartment is considered as acceptable from scenario 1.

***Terrestrial compartment***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 26 - FR CA position:**   |  |  |  |  | | --- | --- | --- | --- | | **Summary table on calculated PEC/PNEC values** | | | **Conclusion** | |  |  | **PEC/PNECsoil** |  | | Scenario 1 | Permethrin | 3.31E-03 | Acceptable | | DCVA | 4.47E-06 | Acceptable | | PBA | 1.97E-06 | Acceptable | | Scenario 2 | Permethrin | 1.11E-01 | Acceptable | | DCVA | 1.28E-04 | Acceptable | | PBA | 5.55E-04 | Acceptable | | Scenario 3 | Permethrin | 3.82E-01 | Acceptable | | DCVA | 7.36E-04 | Acceptable | | PBA | 4.57E-05 | Acceptable |   Conclusion:  During the construction step,the risk characterisation ratios for permethrin and its metabolites in soil compartment are below 1 in rural and urban area.  During the service life, the risk characterisation ratios for permethrin and its metabolites are below 1.  The risk related to the use of TRITHOR S during the construction step and the service life of the product is acceptable for the soil compartment. |

|  |  |  |
| --- | --- | --- |
| **Calculated PEC/PNEC values** | | |
|  | | **PEC/PNECsoil** |
| **Permethrin** | | |
| Scenario 1: House in a city | Scenario 1 Tier 1a | 1.35E-01 |
| Scenario 1 Tier 1b | 4.03E-02 |
| Scenario 1 Tier 2 | 2. 1.97E-03 |
| Scenario 2: House in a countryside | Scenario 2 Tier 1a | **2.68E+01** |
| Scenario 2 Tier 1b | **8.11E+00** |
| Scenario 2 Tier 2 | 1.16E-01 |
| Scenario 3: Service-life | a) Daily basis | 4.28E-01 |
| b) Seasonal basis | 2.82E-01 |
| DCVA | | |
| Scenario 1: House in a city | Scenario 1 Tier 1a | 3.22E-04 |
| Scenario 1 Tier 1b | 9.61E-05 |
| Scenario 1 Tier 2 | 4.70E-06 |
| Scenario 2: House in a countryside | Scenario 2 Tier 1a | 2.74E-01 |
| Scenario 2 Tier 1b | 8.26E-02 |
| Scenario 2 Tier 2 | 1.18E-03 |
| Scenario 3: Service-life | a) Daily basis | 6.63E-03 |
| b) Seasonal basis | 4.74E-03 |
| PBA | | |
| Scenario 1: House in a city | Scenario 1 Tier 1a | 3.97E-03 |
| Scenario 1 Tier 1b | 1.19E-03 |
| Scenario 1 Tier 2 | 3.97E-03 |
| Scenario 2: House in a countryside | Scenario 2 Tier 1a | 8.96E-01 |
| Scenario 2 Tier 1b | 2.71E-01 |
| Scenario 2 Tier 2 | 3.87E-03 |
| Scenario 3: Service-life | a) Daily basis | 1.12E-02 |
| b) Seasonal basis | 2.53E-04 |

Conclusion:

At Tier 1 a) and Tier b) risk assessment, there is an unacceptable risk for the terrestrial compartment considering environmental emissions according to Scenario 2 “House in the countryside”.

The risk is acceptable at Tier 2 with refinements on emissions parameters of Scenario 2.

For scenarios 1 and 3, PNECSoil is superior to all calculated PECSoil. The risk to the terrestrial compartment is considered as acceptable from scenarios 1 and 3.

***Groundwater***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 27 - FR CA position:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Summary table on calculated PEC groundwater (µg/L)**  **Comparison with the limit value of 0.1 µg/L.** | | |  |  | |  | |  | **Tier 1** | **Tier 2** | | Scenario 1 | Permethrin | 3.94E-04 | Acceptable | Acceptable for all locations with FOCUS PEARL 4.4.4 | | DCVA | 4.41E-03 | Acceptable | | PBA | 6.07E-04 | Acceptable | | Scenario 2 | Permethrin | 2.05E-02 | Acceptable | | DCVA | **1.71E-01 (>0.1)** | **Unacceptable** | | PBA | **1.02 (>0.1)** | **Unacceptable** | | Scenario 3 | Permethrin | 7.15E-02 | Acceptable | | DCVA | **9.83E-01 (>0.1)** | **Unacceptable** | | PBA | 8.43E-02 | Acceptable |   Conclusion:  For the construction step in urban area (scenario 1), the concentrations for permethrin and its metabolites in groundwater are lower than the threshold value of 0.1 µg/L. Therefore, the risk for this compartment during the construction step is acceptable when releases are directed to the STP.  For the construction step in rural area (scenario 2), the concentrations of DCVA and PBA exceed the threshold value in groundwater (0.1 µg/L). So, FOCUS-PEARL 4.4.4 was used to refine the risk assessment for the groundwater.  During the service life, the concentrations of permethrin and PBA in groundwater are lower than 0.1 µg/L. However DCVA concentration is higher than 0.1 µg/L. So, a higher-tier assessment of the groundwater contamination has been carried out using the simulation model FOCUS-PEARL 4.4.4.  According to the results of FOCUS-PEARL model (presented in infobox 19), concentrations in groundwater for permethrin, DCVA and PBA are below the limit value of 0.1 µg/L in all scenarios considered. Consequently, the risk associated with the use of the TRITHOR S is acceptable for the groundwater compartment. |

According to the OECD ESD on wood preservatives (Appendix 4, p. 178)[[20]](#footnote-20) for substances with low Kocs or high DT50s in soil there is a concern for groundwater and an assessment must be made.

Therefore, for scenario 2 “House in countryside” and scenario 3 in which emissions are directed to the adgacent soil or to the soil below the treated article, potential environmental emissions of Permethrin and its metabolites to groundwater have been assessed above, based on available guidances.   
Simulations were conducted using two modelling softwares: FOCUS PELMO (v5.5.3) and FOCUS PEARL (4.4.4) and following the FOCUS working group recommendations (FOCUS, 2000[[21]](#footnote-21), 2009[[22]](#footnote-22) and 2011[[23]](#footnote-23)).

As realistic worst-case, an overall vulnerability corresponding to the 90th percentile of predicted concentration in groundwater is defined. This is approximated by combining a 80th percentile value for soil and a 80th percentile value for weather. The softwares and the different scenario properties are described in the FOCUS document (FOCUS, 2000).

Location of the scenarios and the main properties are shown in the table below.



Figure 6: Location of the 9 groundwater scenarios (excerpt from FOCUS, 2009)

Table 1 Properties of the 9 groundwater scenarios

| Location | Mean Annual Temp. (°C) | Annual Rainfall  (mm) | Topsoil | Org. matter  (%) |
| --- | --- | --- | --- | --- |
| Châteaudun | 11.3 | 648 + I\* | Silty clay loam | 2.4 |
| Hamburg | 9.0 | 786 | Sandy loam | 2.6 |
| Jokioinen | 4.1 | 650 | Loamy sand | 7.0 |
| Kremsmünster | 8.6 | 899 | loam/silt loam | 3.6 |
| Okehampton | 10.2 | 1038 | loam | 3.8 |
| Piacenza | 13.2 | 857 + I\* | Loam | 2.2 |
| Porto | 14.8 | 1150+ I\* | loam | 2.5 |
| Sevilla | 17.9 | 493+ I\* | Silt loam | 1.6 |
| Thiva | 16.2 | 500 + I\* | loam | 1.3 |

\* I: Irrigation

Groundwater assessment has been performed for a realistic worst case scenario according to the guidance document “Groundwater exposure assessment for wood preservatives Factors to consider”[[24]](#footnote-24). This worst case scenario is defined by applications of a biocidal product on 35 houses per hectar (based on house density proposed for PT8[[25]](#footnote-25)).

Conditions according to scenario 2 “House in a countryside” and scenario 3 “service-life” are presented below:

|  |  |  |  |
| --- | --- | --- | --- |
| **Conditions** | **Values** | | **Unit** |
| **Scenario 2** | **Scenario 3** |  |
| Surface of treated article used by house | 5 | | m² |
| Concentration of permethrin in the treated article | 2 | | g/m² |
| Release of permethrin per house | Tier 1a : 10  Tier 1b : 3  Tier 2 : 1.51E-3 | 10 | g |
| Number of houses per hectar | 35 | | /hectar |
| Releases period | 10 | 40 | years |

According to the Assessment Report of Permethrin, 3-(2,2-dichorovinyl)-2,2-dimethylcyclopropane carboxylic acid (DCVA) and 3-phenoxybenzoic acid (PBA) are the two relevant soil metabolites of permethrin. These two metabolites are therefore taken into account with permethrin for groundwater risk assessment.

**PECgw considering Scenario 2: Application of TRITHOR S™ during construction of a house in a countryside**

According to the guidance document on factors to consider for groundwater exposure assessment for PT822, the assessment of groundwater contamination due to direct soil exposure is estimated from the leaching taye converted to 10 equal applications per annum.Parameters from the Assessment Report of Permethrin, used for the groundwater assessment following scenario 2 are presented below:

|  |  |  |  |
| --- | --- | --- | --- |
| **Input** | **Permethrin** | **DCVA** | **PBA** |
| Molecular weight (g/mol) | 391.29 |  | 214.22 |
| Vapour pressure (Pa, at 20°C) | 2.155E-6 | 0\* | 0\* |
| Water solubility (mg/L at 25°C) | 0.18 | 1000\* | 1000\* |
| Koc (soil) (L/kg) / Kfoc | 26930 (n=9) | 93.2 (n=5) | 141.2 |
| DT50soil (at 12°C) (d) | 106 | 175 (max: 33.1-175d) | 2.5 (max: 1.7-2.5d) |
| Freundlich exponent (-) | 1.09 | 0.87 | 0.92 |
| Split application rate (kg.ha-1) | Tier 1a :0.035  Tier 1b : 0.0105  Tier 2 : 1.51E-5 | - | - |
| Nb applications (year-1) | 10 | - | - |
| Crop | 0\* | 0\* | 0\* |
| Maximum AR in soil % | - | 11.3 | 15 |

\* Worst case default value

According to the worst case scenario defined previously with 35 houses treated, the application rates in kilograms per hectar taken into account for ground water assessment are about

1. Tier 1a: 35 houses/hectar \* 10g /house : 0.350 Kg/ha
2. Tier 1b: 35 houses/hectar \* 3g /house: 0.105, Kg/ha
3. Tier 2: 35 houses/hectar \* 1.51E-3 g /house : 5.29E-5 Kg/ha

As all houses would not be treated at the same time, in order to weight over time the exposition of Permethrin and its metabolites DCVA and PBA, the single application of permethrin (ex: 0.035Kg/ha) per year is split into 10 applications (about 0.0035 kga.s. /ha) per year.

Chosen dates for split applications are presented below:

|  |  |
| --- | --- |
| **Application** | **Date of split applications** |
| 1st Application | 15/01 |
| 2nd Application | 15/03 |
| 3rd Application | 15/04 |
| 4th Application | 15/05 |
| 5th Application | 15/06 |
| 6th Application | 15/07 |
| 7th Application | 15/08 |
| 8th Application | 15/10 |
| 9th Application | 15/11 |
| 10th Application | 15/12 |

Nine realistic worst-case scenarios have been defined, which collectively represent agricultural use in the EU.

Results for the two FOCUS models are presented in tables below.

Table 2 PECgroundwater PELMO 5.5.4.

| **Scenario** | | **80th Percentile PECGW at 1 m Soil Depth (μg/L)** | | |
| --- | --- | --- | --- | --- |
| **Permethrin** | **DCVA** | **PBA** |
| Tier 1a | Châteaudun | <0.001 | 0.584 | <0.001 |
| Hamburg | <0.001 | 0.762 | <0.001 |
| Jokioinen | <0.001 | 0.563 | <0.001 |
| Kremsmünster | <0.001 | 0.597 | <0.001 |
| Okehamtpon | <0.001 | 0.752 | <0.001 |
| Piacenza | <0.001 | 0.667 | <0.001 |
| Porto | <0.001 | 0.477 | <0.001 |
| Sevilla | <0.001 | 0.249 | <0.001 |
| Thiva | <0.001 | 0.554 | <0.001 |
| Tier 1b | Châteaudun | <0.001 | 0.122 | <0.001 |
| Hamburg | <0.001 | 0.166 | <0.001 |
| Jokioinen | <0.001 | 0.106 | <0.001 |
| Kremsmünster | <0.001 | 0.133 | <0.001 |
| Okehamtpon | <0.001 | 0.174 | <0.001 |
| Piacenza | <0.001 | 0.157 | <0.001 |
| Porto | <0.001 | 0.111 | <0.001 |
| Sevilla | <0.001 | 0.040 | <0.001 |
| Thiva | <0.001 | 0.118 | <0.001 |
| Tier 2 | Châteaudun | <0.001 | <0.001 | <0.001 |
| Hamburg | <0.001 | <0.001 | <0.001 |
| Jokioinen | <0.001 | <0.001 | <0.001 |
| Kremsmünster | <0.001 | <0.001 | <0.001 |
| Okehamtpon | <0.001 | <0.001 | <0.001 |
| Piacenza | <0.001 | <0.001 | <0.001 |
| Porto | <0.001 | <0.001 | <0.001 |
| Sevilla | <0.001 | <0.001 | <0.001 |
| Thiva | <0.001 | <0.001 | <0.001 |

Table 3 PECgroundwater PEARL 4.4.4.

| **Scenario** | | **80th Percentile PECGW at 1 m Soil Depth (μg/L)** | | |
| --- | --- | --- | --- | --- |
| **Permethrin** | **DCVA** | **PBA** |
| Tier 1a | Châteaudun | <0.001 | 0.071 | <0.001 |
| Hamburg | <0.001 | 0.142 | <0.001 |
| Jokioinen | <0.001 | 0.060 | <0.001 |
| Kremsmünster | <0.001 | 0.085 | <0.001 |
| Okehamtpon | <0.001 | 0.134 | <0.001 |
| Piacenza | <0.001 | 0.107 | <0.001 |
| Porto | <0.001 | 0.068 | <0.001 |
| Sevilla | <0.001 | 0.011 | <0.001 |
| Thiva | <0.001 | 0.035 | <0.001 |
| Tier 1b | Châteaudun | <0.001 | 0.010 | <0.001 |
| Hamburg | <0.001 | 0.024 | <0.001 |
| Jokioinen | <0.001 | 0.007 | <0.001 |
| Kremsmünster | <0.001 | 0.014 | <0.001 |
| Okehamtpon | <0.001 | 0.023 | <0.001 |
| Piacenza | <0.001 | 0.019 | <0.001 |
| Porto | <0.001 | 0.011 | <0.001 |
| Sevilla | <0.001 | 0.001 | <0.001 |
| Thiva | <0.001 | 0.005 | <0.001 |

Conclusion:

At Tier 1a level, assuming the reasonable worst case scenario 2, estimated PECgroundwater of permethrin and its metabolite PBA are below the threshold value of 0.1 µg/L for drinking water[[26]](#footnote-26). Metabolite DCVA exceedsthis value with both FOCUS models.

At Tier 1b level, estimated PECgroundwater of metabolite DCVA exceeds the threshold value of 0.1 µg/L level for with FOCUS PELMO model only.

At Tier 2 level, PECgroundwater of permethrin and its metabolites estimated are below the limit of 0.1 µg/L with both FOCUS models.

Risk of contamination of groundwater for permethrin and its metabolites is considered acceptable regarding the use of TRITHOR S™ following the presented conditions of use.

**PECgw considering Scenario 3: Service-life of TRITHOR S™**

Considering a treated house density of 35 per hectar, the application rate in kilograms per hectar and per release assumed for ground water assessment is of 4.375E-3 kg per hectar.

Application rate = 0.125 g/event \* 35 houses/hectar = 4.375E-3 Kg/hectar

Releases of active substance during service-life are assumed to occur at the same time for all houses when weather conditions are the most unfavourable, during spring and autumn.

No calculation for groundwater risk assessment was performed for the service-life scenario as expected frequency and rate of substance liberation are lower than those considered in the previous assessment.

Estimations of groundwater concentrations of permethrin and its metabolites resulting from rainy event during houses construction (Scenario 2) are considered to cover expected concentrations due to the service-life of TRITHOR S™ (scenario 3).

Conclusion:

Risk of contamination of groundwater for permethrin and its metabolites is considered acceptable regarding the service-life of TRITHOR S™ following the presented conditions of use.

***Primary and secondary poisoning***

Primary poisoning

|  |
| --- |
| **Infobox 28 - FR CA position:**  Not relevant. |

As the proposed use will not result in direct exposure of birds and mammals, the risk for the primary poisoning is considered acceptable.

Secondary poisoning

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 29 - 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/PNEC**  **aquatic food chain** | **PEC oral predator**  [mg.kg wet earthworm-1] | **PEC/PNEC terrestrial food chain** | | Scenario 1 | 8.13E-04 | 4.87E-05 | 2.69E-03 | 1.61E-04 | | Scenario 2 | - | - | 1.39E-01 | 8.34E-03 | | Scenario 3 | - | - | 4.87E-01 | 2.91E-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 TRITHOR S according to the label recommendations. |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on secondary poisoning** | | | | |
| **Scenario** | | **Concentration in soil** | **PECoral predator** | **PEC/PNECbirds** |
| **Scenario 1: House in a city** | Scenario 1 Tier 1a | 1.18E-02 | 3.36E-01 | 2.01E-02 |
| Scenario 1 Tier 1b | 3.53E-03 | 1.01E-01 | 6.06E-03 |
| Scenario 1 Tier 2 | 1.73E-04 | 4.95E-03 | 2.96E-04 |
| **Scenario 2: House in a countryside** | Scenario 2 Tier 1a | 2.35 | 6.73E+01 | 4.03E+00 |
| Scenario 2 Tier 1b | 0.71 | 2.03E+01 | 1.22E+00 |
| Scenario 2 Tier 2 | 1.02E-02 | 2.92E-01 | 1.75E-02 |
| **Scenario 3: Service-life** | (a) Seasonal basis | 4.22E-02 | 1.21E+00 | 7.24E-02 |
| (b) Daily basis | 2.47E-02 | 7.08E-01 | 4.24E-02 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on secondary poisoning** | | | | |
| **Scenario** | | **Concentration in water** | **PECoral predator** | **PEC/PNECbirds** |
| **Scenario 1: House in a city** | Scenario 1 Tier 1a | 1.17E-05 | 1.33E-02 | 7.99E-04 |
| Scenario 1 Tier 1b | 3.50E-06 | 3.99E-03 | 3.99E-04 |
| Scenario 1 Tier 2 | 1.71E-07 | 1.95E-04 | 1.17E-05 |

Conclusion:

At tier 1a and 1b level, PEC/PNEC ratios for permethrin are superior to 1 for Scenario 2. At a higher level, with refined emission parameters, PEC/PNEC ratios do not exceed 1 for all considered scenarios, indicating no risk of secondary poisoning via the terrestrial food chain is expected.

***Mixture toxicity***

|  |
| --- |
| **Infobox 30 - FR CA position:**  Not relevant. |

Not relevant.

Only one relevant component is identified.

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



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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 31 - FR CA position:**  **Overall conclusion on the risk assessment for the environment of the product**  Scenario [1]: Release during the construction step in urban area.  Scenario [2]: Release during the construction step in rural area.  Scenario [3]: Release during the service life of the product in rural or urban area.   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | Step | Scenario | 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) | Acceptable | **Unacceptable** | **Unacceptable** | - | Acceptable | - | Acceptable | Acceptable | | [2]  Rural (release to soil) | - | - | - | Acceptable | - | Acceptable | - | Acceptable | | Service life | [3] | - | - | - | Acceptable | - | Acceptable | - | Acceptable |   **Conclusion on risk assessment for the environment**   * Construction step:   Following indirect releases to the environment *via* the STP, all calculated RCR values were < 1 for STP, soil and groundwater, indicating an acceptable risk to these environmental compartments. Nevertheless, regarding the exposure of surface water and sediment, RCR values were > 1, indicating unacceptable risk to these environmental compartments. A risk mitigation measure is proposed to prevent the exposure of the aquatic compartment when a release to the STP is foreseen: ***During the application step of the film, if the treated zone is connected to a rainwater collection system or sewer, do not expose the film to rain***. The application of this risk mitigation measure preventing emissions to the STP would achieve acceptable risks.  For the exposure of soil and groundwater, following direct releases to the environment, calculated RCR values were < 1, indicating acceptable risk to these environmental compartments.   * Service life   For the exposure of soil and groundwater, all calculated RCR values were < 1, indicating an acceptable risk to the environmental compartments. |



### Comparative assessment

*Not relevant.*

# Annexes

## List of studies for the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** | **Date of first submission** |
| Stéphane Legay, Elisabeth Raphalen | 2013 | Test on the product Trithor S : stability testing at -10°C in according to NF X 41-580-3  REPORT No  402/13/1058F/ab/f-e | Yes | ENSYSTEX Europe | - |
| Stéphane Legay, Elisabeth Raphalen | 2013 | Test on the products TRITHOR S : stability at 40°C during 8 weeks in according to NF X 41-580-10  REPORT No  402/13/1097F/c/f-e | Yes | ENSYSTEX Europe | - |
| Stéphane Legay, Elisabeth Raphalen | 2013 | Validation of the analytical method for the quantitative analysis of the declared active ingredient (Permethrin)  REPORT No  402/13/1097F/ab/f-e | Yes | ENSYSTEX Europe | - |
| Schlegl.P | 2016 | Release of Permethrin from treated fabrics with Sanitized AM 23-24: Measurement of Migration | Yes | ENSYSTEX Europe | - |
| M-F Thévenon, L. Pignolet | 2014 | Détermination de l’efficacité anti-termites de produits et de matériaux destinés à être utilisés comme barrière Sol et/ou Murs Méthode de laboratoire, Unpublished, Laboratoire de préservation des bois du CIRAD, report 14-09/X41-550, 2014-12-12 | Yes | ENSYSTEX EUROPE, 16 avenue de la Forét, 33 320 EYSINES | 2016-04-22 |
| PAULMIER Ivan | 2015 | TRITHOR S, EFFICACITE ANTI-TERMITE, Essai de terrain - contrôle à 1 an (2/2), unpublished, FCBA, Laboratoire de Biologie de FCBA, report 401/12/174F/3/h, 2015-10-26 | Yes | ENSYSTEX EUROPE, 16 avenue de la Forét, 33 320 EYSINES | 2016-04-22 |
| PAULMIER Ivan | 2014 | TRITHOR S, EFFICACITE ANTI-TERMITE, Essai de terrain Guyane - Contôle à 1 an (2/2), unpublished, FCBA, Laboratoire de Biologie de FCBA, report 401/12/174F/3/p, 2015-12-21 | Yes | ENSYSTEX EUROPE, 16 avenue de la Forét, 33 320 EYSINES | 2016-04-22 |
| PAULMIER Ivan | 2014 | TRITHOR S, EFFICACITE ANTI-TERMITE, Essai de terrain Guyane - Installation (1/2), unpublished, FCBA, Laboratoire de Biologie de FCBA, report 401/12/174F/2/o, 2014-07-23 | Yes | ENSYSTEX EUROPE, 16 avenue de la Forét, 33 320 EYSINES | 2016-04-22 |
| PAULMIER Ivan | 2014 | TRITHOR S, EFFICACITE ANTI-TERMITE, Essai de terrain Oleron - Installation (1/2), unpublished, FCBA, Laboratoire de Biologie de FCBA, report 401/12/174F/3/g, 2014-07-23 | Yes | ENSYSTEX EUROPE, 16 avenue de la Forét, 33 320 EYSINES | 2016-04-22 |
| PAULMIER Ivan | 2014 | TRITHOR S, EFFICACITE ANTI-TERMITE, selon XP X41 -550 après exposition 3 mois au rayonnement solaire en position verticale, unpublished, FCBA, Laboratoire de Biologie de FCBA, report 401/12/174F/3/f | Yes | ENSYSTEX EUROPE, 16 avenue de la Forét, 33 320 EYSINES | 2016-04-22 |
| PAULMIER Ivan | 2014 | TRITHOR S, EFFICACITE ANTI-TERMITE, selon XP X41 -550 après exposition au rayonnement solaire en position horizontale, unpublished, FCBA, Laboratoire de Biologie de FCBA, report 401/12/174F/3/e, 2014-08-26 | Yes | ENSYSTEX EUROPE, 16 avenue de la Forét, 33 320 EYSINES | 2016-04-22 |
| PAULMIER Ivan | 2014 | TRITHOR S, EFFICACITE ANTI-TERMITE, selon XP X41 -550 après exposition en milieu acide, unpublished, FCBA, Laboratoire de Biologie de FCBA, report 401/12/174F/1/d, 2013-07-16 | Yes | ENSYSTEX EUROPE, 16 avenue de la Forét, 33 320 EYSINES | 2016-04-22 |
| PAULMIER Ivan | 2013 | TRITHOR S, EFFICACITE ANTI-TERMITE, selon XP X41 -550 après exposition en milieu alcalin, unpublished, FCBA, Laboratoire de Biologie de FCBA, report 401/12/174F/1/c, 2013-07-16 | Yes | ENSYSTEX EUROPE, 16 avenue de la Forét, 33 320 EYSINES | 2016-04-22 |
| PAULMIER Ivan | 2014 | TRITHOR S, EFFICACITE ANTI-TERMITE, selon XP X41 -550 après XP ENV 1250-2 adaptée, unpublished, FCBA, Laboratoire de Biologie de FCBA, report 401/12/174F/2/n, 2014-02-21 | Yes | ENSYSTEX EUROPE, 16 avenue de la Forét, 33 320 EYSINES | 2016-04-22 |
| PAULMIER Ivan | 2013 | TRITHOR S, EFFICACITE ANTI-TERMITE, selon XP X41 -550 sans vieillissement, unpublished, FCBA, Laboratoire de Biologie de FCBA, report 401/12/174F/1/a, 2013-05-21 | Yes | ENSYSTEX EUROPE, 16 avenue de la Forét, 33 320 EYSINES | 2016-04-22 |
| VUILLEMIN J., PAVIEL F. | 2014 | Vérification de la résistance du film « TRITHOR S» à la pénétration du termite souterrain Coptotermes gestroi à La Réunion après vieillissement par exposition solaire en position Horizontale, unpublished, ORLAT – CHAMBRE de METIERS et de L’ARTISANAT – URMA / Pôle de formation, Rue Comor apoullé – BP 38 – 97 440 Saint-André, report 03-14b-EH, 2014-03-31 | Yes | ENSYSTEX EUROPE, 16 avenue de la Forét, 33 320 EYSINES | 2016-04-22 |
| VUILLEMIN J., PAVIEL F. | 2014 | Vérification de la résistance du film « TRITHOR S» à la pénétration du termite souterrain Coptotermes gestroi à La Réunion après vieillissement par exposition solaire en position verticale, unpublished, ORLAT – CHAMBRE de METIERS et de L’ARTISANAT – URMA / Pôle de formation, Rue Comor apoullé – BP 38 – 97 440 Saint-André, report 03-14b-EV 3/3, 2014-06-23 | Yes | ENSYSTEX EUROPE, 16 avenue de la Forét, 33 320 EYSINES | 2016-04-22 |
| VUILLEMIN J., PAVIEL F. | 2014 | Vérification de la résistance du film « TRITHOR S» à la pénétration du termite souterrain Coptotermes gestroi à La Réunion après vieillissement par immersion (Selon les méthodes FCBA-BIO-E-046-1 puis XP X 41-550-Juin 2009), unpublished, ORLAT – CHAMBRE de METIERS et de L’ARTISANAT – URMA / Pôle de formation, Rue Comor apoullé – BP 38 – 97 440 Saint-André, report 12-14a, 2014-08-05 | Yes | ENSYSTEX EUROPE, 16 avenue de la Forét, 33 320 EYSINES | 2016-04-22 |
| VUILLEMIN J., PAVIEL F. | 2014 | Vérification de la résistance du film « TRITHOR S» à la pénétration du termite souterrain Coptotermes gestroi à La Réunion sans vieillissement (Selon la méthode XP X 41-550 (juin 2009)), unpublished, ORLAT – CHAMBRE de METIERS et de L’ARTISANAT – URMA / Pôle de formation, Rue Comor apoullé – BP 38 – 97 440 Saint-André, report 03-14a, 2014-03-31 | Yes | ENSYSTEX EUROPE, 16 avenue de la Forét, 33 320 EYSINES | 2016-04-22 |
| VUILLEMIN J., PAVIEL F. | 2014 | Évaluation de l'efficacité anti-termites du film « TRITHOR S » en contact avec un milieu alcalin contre le termite souterrain Coptotermes gestroi à La Réunion (Selon la méthode CTBA-BIO-E-007-version 2), unpublished, ORLAT – CHAMBRE de METIERS et de L’ARTISANAT – URMA / Pôle de formation, Rue Comor apoullé – BP 38 – 97 440 Saint-André, report 12-14b, 2014-08-19 | Yes | ENSYSTEX EUROPE, 16 avenue de la Forét, 33 320 EYSINES | 2016-04-22 |
| LEGAY Stephane | 2017 | Certificat of analysis n°COA-402/16/1285F/1/a/T0 ; COA-402/16/1285F/1/a/T6M; COA-402/16/1285F/1/a/T12M-e | Yes | ENSYSTEX EUROPE | 2018.07.02 |

## Output tables from exposure assessment tools



## New information on the active substance

Not relevant.

## Residue behaviour

Not relevant.

## Summaries of the efficacy studies (B.5.10.1-xx)[[27]](#footnote-27)

Not relevant (IUCLID file available).

## Confidential annex

See separate confidential file.

1. 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-1)
2. XP ENV 1250-2: wood preservatives – Methods for measuring losses of active ingredients and other preservative ingredients from treated timber – Part 2: Laboratory method for obtaining samples for analysis to measure losses by leaching into water or synthetic see water. [↑](#footnote-ref-2)
3. CTBA BIO-E-007: CTBA test protocol on wear on an anti-termite barrier by the action of an alkalin environment. [↑](#footnote-ref-3)
4. CTBA BIO-E-016: CTBA test protocol on exposure of anti-termite barrier to sunlight. [↑](#footnote-ref-4)
5. Flexible sheets for waterproofing. Plastics and rubber sheets for roof waterproofing. Methods for exposure to liquid chemicals, including water [↑](#footnote-ref-5)
6. CTBA BIO-E-008: CTBA test methodAssessment of the efficacy of a physico-chemical anti-termite barrier – Field test. [↑](#footnote-ref-6)
7. TGD on environmental risk assessment [↑](#footnote-ref-7)
8. Assessment Report Permethrin Product-Type 18 (Insecticides, acaricides and product to control other arthropods) Rapporteur: Ireland, April 2014 [↑](#footnote-ref-8)
9. <http://www.ctb.agro.nl/ctb_files/140801_08214.PDF> [↑](#footnote-ref-9)
10. INERIS-DRC-02-25582-ECOT-VMi-n°02DR0270, Supplement to the methodology for risk evaluation of biocides Emission scenario document for biocides used as masonry preservatives. (product type 10) (EUBEES) November 2002 [↑](#footnote-ref-10)
11. INERIS-DRC-01-25582-ECOT-CTi/VMi-n°01DR0176, Supplement to the methodology for risk evaluation of biocides Emission scenario document for biocides used as preservatives in the textile processing industry. (Product type 9 & 18) (EUBEES) May 2001 [↑](#footnote-ref-11)
12. Technical Agreement for Biocides, v1.2, ECHA, December 2016 [↑](#footnote-ref-12)
13. Guidance on the Biocidal Products Regulation, Volume IV Environment - Part B Risk Assessment (active substances) V 1.0, April 2015 [↑](#footnote-ref-13)
14. Tier 1b calculations were performed taking into account a degree of fixation of 70% of Permethrin in the treated article. This assumption is based on the default value used to calculate release of active substance in waste water after impregnation process of biocide in textile during finishing step. ESD PT9, Emission scenario document for biocides used as preservatives in the textile industry. May 2001 [↑](#footnote-ref-14)
15. Complementing Guideline for Writing Emission Scenario Documents: The Life-Cycle Step “Service-Life”, OECD Environment, Health and Safety Publications, Series on Emission Dcenario Documents N°19, 2009, p.18 [↑](#footnote-ref-15)
16. Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

    Evaluation of active substances - Assessment Report - Permethrin - Product-Type 18 (Insecticides, acaricides and products to control other arthropods) Rapporteur: Ireland April 2014 [↑](#footnote-ref-16)
17. Guidance on the Biocidal Products Regulation Volume IV Environment - Part B Risk Assessment, V1.0 April 2015 [↑](#footnote-ref-17)
18. http://www.insee.fr/fr/themes/tableau.asp?reg\_id=0&ref\_id=NATTEF11401 [↑](#footnote-ref-18)
19. http://www.insee.fr/fr/themes/tableau.asp?reg\_id=0&ref\_id=NATnon02145 [↑](#footnote-ref-19)
20. Groundwater exposure assessment for wood preservatives Factors to consider [↑](#footnote-ref-20)
21. SANCO/321/2000 rev.2: FOCUS groudwater scenarios in the EU review of active substances. [↑](#footnote-ref-21)
22. FOCUS (2009). Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 1, 604 pp. [↑](#footnote-ref-22)
23. FOCUS (2011). Generic guidance for Tier 1 FOCUS groundwater assessments, Version 2.0, January 2011. [↑](#footnote-ref-23)
24. Groundwater Exposure Assessment for Wood Preservatives (soil studies applicability for mobile and persistant substances and DT50/Koc input values for PELMO/PEARL models), agreed upon at the Technical Meeting on Biocides for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market 13-17 October 2008. [↑](#footnote-ref-24)
25. Endorsed at the 24th meeting of representatives of Members States Competent Authorities for the implementation of Directive 98/8/EC concerning the placing of biocidal products on the market - Groundwater exposure assessment for wood preservatives Factors to consider, ECB 2007. [↑](#footnote-ref-25)
26. Council Directive [98/83/EC](http://eur-lex.europa.eu/legal-content/EN/AUTO/?uri=celex:31998L0083) of 3 November 1998 on the quality of water intended for human consumption [↑](#footnote-ref-26)
27. If an IUCLID file is not available, please indicate here the summaries of the efficacy studies. [↑](#footnote-ref-27)