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

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

(submitted by the evaluating Competent Authority)



TERMIFILM FLEX

Product type 18

Permethrin

Case Number in R4BP: BC-FQ023997-15

Evaluating Competent Authority: BE

Date: 20/04/2028

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# Conclusion

BE considers that the product TERMIFILM FLEX, formulated by BERKEM DEVELOPPEMENT, with the active substance permethrin concentrated at 1.6 % w/w may be authorized as insecticide (PT18). Termifilm flex is an innovative film to be placed during construction of building in the basement in order to form a barrier against termite. The conclusions of each assessment are summarized below.

The biocidal product TERMIFILM FLEX is a light green plastic sheet (mesh). At ambient temperature the product has a long term stability of 2 years and is stable under cold and accelerated storage conditions. The product should be protected from direct exposition to light. Physical and chemical compatibility with other products is not relevant. No classification related to physico-chemical risks is necessary.

The product TERMIFILM FLEX is considered effective when used as an internal perimeter lining to protect the building against subterranean termites; Coptotermes gestroi and Reticulitermes flavipes (ex santonensis)). Please note that a long term field study, and data on perforation of the test and control subjects will be reassessed 4, 6, 8 and 10 years after the tests was started. The placementof the film must be carried out at the interface of the foundation and the structure of the building.

Normal use of TERMIFILM FLEX product by professionals is considered to present acceptable risk for 2 workers managing one private house per day, if they wear gloves.

According to the evaluation performed, no unacceptable risk has been identified for the environment.

# Assessment Report

## Summary of the product assessment

### Administrative information

#### Identifier of the product / product family

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| TERMIFILM FLEX | Belgium |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | BERKEM DEVELOPPEMENT |
| **Address** | Marais Ouest, F-24680, Gardonne, FR |
| **Authorisation number** | BE2018-0008 | |
| **Date of the authorisation** | 20/04/2018 | |
| **Expiry date of the authorisation** | 20/04/2028 | |

#### Manufacturer(s) of the product

|  |  |
| --- | --- |
| **Name of manufacturer** | ADKALIS |
| **Address of manufacturer** | Marais Ouest F-24680 Gardonne FR |
| **Location of manufacturing sites** | Marais Ouest F-24680 Gardonne FR |

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

|  |  |
| --- | --- |
| **Active substance** | Permethrin |
| **Name of manufacturer** | LANXESS Deutschland GmbH |
| **Address of manufacturer** | Kennedyplatz 1 D-50569 Köln Germany |
| **Location of manufacturing sites** | Bayer Vapi Private Limited, Vapi – 396 195, Gujarat, 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)-cis,trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate  or  3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate |
| **EC number** | 258-067-9 |
| **CAS number** | 52645-53-1 |
| **Index number in Annex VI of CLP** | 613-058-00-2 |
| **Minimum purity / content** | ≥93% w/w sum of all permethrin isomers  Cis:trans permethrin % ratio = 22-28:72-78 cis:trans.  1Rcis permethrin content = 5.0 – 10.0% w/w.  1Scis permethrin content = 15.0 – 20.0% w/w.  1Rtrans permethrin content = 45.0 – 55.0% w/w.  1Strans permethrin content = 17.0 – 27.0% w/w. |
| **Structural formula** |  |

#### Candidate(s) for substitution

Permethrin (various isomer mixtures) is not a PBT candidate nor are its individual constituent isomers.

Permethrin is considered to fulfill the T criteria, but does not fulfill the B criteria. However, permethrin could also be considered as potentially persistent based on a constituent of permethrin (the cis isomer) and therefore fulfill the P criteria.

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Permethrin | (3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate | Active substance | 52645-53-1 | 258-067-9 | Technical content: 1.6 |
| Pure content: 1.5 |
| For the full composition, please see the confidential Annex | | | | | |

#### Information on technical equivalence

Not relevant

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

Not applicable since there is no substance of concern.

#### Type of formulation

|  |
| --- |
| XX Others: polyester fiber impregnated with PVC  (Polyester fiber with a fine mesh coated with a PVC resins containing 1,6% w/w active substance.) |

### Hazard and precautionary statements

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

| **Classification** | |
| --- | --- |
| Hazard category | Skin Sens cat.1  Aquatic Acute cat. 1  Aquatic Chronic cat. 1 |
| Hazard statement | H317  H400 (M= 100)  H410 (M= 10000) |
|  | |
| **Labelling** | |
| Pictograms | GHS07  GHS09 |
| Signal words | Warning |
| Hazard statements | May cause an allergic skin reaction  Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P280 **Wear protective clothing**  P302 + P352 **IF ON SKIN: Wash with plenty of soap and water**  P333 + P313 **If skin irritation or rash occurs: Get medical advice/attention**  P273 **Avoid release to the environment**  P391 **Collect spillage**  P501 **Dispose contents/container in accordance with all local, national and international regulations** |

### Authorised use(s)

#### Use description

|  |  |
| --- | --- |
| **Table 1. Use # 1 – preventive protection of new building against termites** | |
| **Product Type** | PT18: insecticide |
| **Where relevant, an exact description of the authorised use** | Chemical-physical barrier when used as an internal perimeter lining for the preventive protection of new building against termites. |
| **Target organism (including development stage)** | Termites : *Coptotermes gestroi, Reticulitermes flavipes (ex santonensis)* |
| **Field of use** | Protection of new construction |
| **Application method(s)** | TERMIFILM FLEX is unrolled through the slot done in the cardboard and cut according to the area to be protected. |
| **Application rate(s) and frequency** | Applied during the construction of the new building. The product is a ready-to-use film containing 1.6% (w/w) of permethrin, which corresponds to 3.8 g/m². |
| **Category(ies) of users** | Professional users |
| **Pack sizes and packaging material** | Roller, Polyester impregnated with PVC, 10cm x 50m  Roller, Polyester impregnated with PVC, 15cm x 50m  Roller, Polyester impregnated with PVC, 20cm x 50m |

#### Use-specific instructions for use

|  |
| --- |
| Always read the label and product information before use.  TERMIFILM FLEX is unrolled through the slot done in the cardboard and cut according to the area to be protected.  TERMIFILM FLEX is active against Coptotermes gestroi *and* Reticulitermes flavipes (ex santonensis))*.* |

#### Use-specific risk mitigation measures

|  |
| --- |
| Handling:  Good standards of hygiene should be maintained every time.  Avoid contact with skin, eyes and clothes.  Do not eat, drink, and smoke while working.  Use of the required PPE : gloves. |

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

|  |
| --- |
| First aid in general:  Move the affected person into fresh air. Keep warm and at rest. In case of suspected poisoning, you must immediately call a doctor. Tell the doctor that no specific antidote is known, a symptomatic treatment is necessary. NEVER give anything by the mouth to an unconscious person.  General safety and hygiene measures:  Observe the precautions generally taken with chemicals.  In case of contact with eyes:  Wash thoroughly with soft, clean water during 15 minutes holding the eyelids open.  Regardless of the initial state, refer the patient to an ophthalmologist and show him the label.  In case of skin contact:  In case of allergic reaction, seek a medical advice.  Remove contaminated clothing and shoes and wash thoroughly contaminated body parts and hair with soap and water. Destroy or thoroughly clean the soiled clothes and shoes before each re-use.  In case of swallowing:  If the swallowed quantity is small (no more than one mouthful), rinse the mouth with water and consult a doctor.  Remain at rest. Do not induce vomiting.  Consult a doctor and show him the label.  In case of accidentally swallowing, call a doctor to judge the necessity for monitoring and for a subsequent treatment in hospital. Show the label.  Emergency measures to protect the environment:  If the product contaminates waterways, lakes, rivers of drains, alert the competent authorities in accordance with regulatory procedures into force.  Do not discharge the product into drains or into the environment. Prevent entry into waters or soil.  Place containers or drums for disposal of waste recovered in accordance with applicable regulations. |

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

|  |
| --- |
| The product residue, packaging and any other waste related to the treatment should be considered as hazardous waste under the full responsibility of the holder of that waste and treated in specialized center. |

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

|  |
| --- |
| Storage:  Keep the original container hermetically closed and in a dry place, away from light and moisture.  Store in standard conditions of temperature (frost-free).  Ensure adequate ventilation of the storage area.  Avoid any direct or indirect contact with food, drink and animal feeding stuffs.  Store on tight area or retention area.  Shelf-life of the product under normal conditions of storage: 2 years. |

### General directions for use

#### Instructions for use

|  |
| --- |
| Please refer to 2.1.4.2 |

#### Risk mitigation measures

|  |
| --- |
| Please refer to 2.1.4.3 |

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

|  |
| --- |
| Please refer to 2.1.4.4 |

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

|  |
| --- |
| Please refer to 2.1.4.5 |

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

|  |
| --- |
| Please refer to 2.1.4.6 |

### Other information

|  |
| --- |
| - |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Roller, in a cardboard box | 10 cm x 50m  (thikness 0.45 mm) | Polyester impregnated with PVC | - | professional | Y |
| Roller, in a cardboard box | 15 cm x 50m  (thikness 0.45 mm) | Polyester impregnated with PVC | - | professional | Y |
| Roller, in a cardboard box | 20 cm x 50m  (thikness 0.45 mm) | Polyester impregnated with PVC | - | professional | Y |

### Documentation

#### Data submitted in relation to product application

The whole list of data submitted by the applicant is included in the annex.

#### Access to documentation

The applicant has submitted one Letter of Acces, granting access to BE eCA to the data on the active substance permethrin from Lanxess Deutschland GmbH.

## Assessment of the biocidal product (family)

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

|  |  |
| --- | --- |
| **Table 1. Use # 1 – Preventive protection of new building against termites** | |
| **Product Type** | PT18 – Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** | - |
| **Target organism (including development stage)** | Reticulitermes sp. (adults)  Coptotermes (adults) |
| **Field of use** | Antitermite preventive protection before construction |
| **Application method(s)** | - |
| **Application rate(s) and frequency** | 38 m²/day – 100% |
| **Category(ies) of users** | professional |
| **Pack sizes and packaging material** | Roller, Polyester impregnated with PVC , 10cm x50 m  Roller, Polyester impregnated with PVC , 15cm x50 m  Roller, Polyester impregnated with PVC , 20 cm x 50 m |

### Physical, chemical and technical properties

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Organoleptic observation | TERMIFILM FLEX | Polyester fiber impregnated with a PVC solution. | For more details, please see the confidential version of the PAR |
| Colour at 20 °C and 101.3 kPa | Organoleptic observation | TERMIFILM FLEX | Light green plastic sheet (mesh) | For more details, please see the confidential version of the PAR |
| Odour at 20 °C and 101.3 kPa | Organoleptic observation | TERMIFILM FLEX | The impregnation solution has no specific odour | For more details, please see the confidential version of the PAR |
| Acidity / alkalinity | Waived | - | - | The product is a treated article in solid form |
| Relative density / bulk density | Calculated on basis of support density and impregnation liquid density (treated article) | TERMIFILM FLEX | For more details, please see the confidential version of the PAR | For more details, please see the confidential version of the PAR |
| Storage stability test – **accelerated storage** | CIPAC MT46.3 (54°C, 2 weeks) | TERMIFILM FLEX  For more details, please see the confidential version of the PAR | For more details, please see the confidential version of the PAR | For more details, please see the confidential version of the PAR |
| Storage stability test – **long term storage at ambient temperature** | Ambient temperature, 2 years  HPLC/UV | TERMIFILM FLEX  For more details, please see the confidential version of the PAR | For more details, please see the confidential version of the PAR | For more details, please see the confidential version of the PAR |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3  0°C 1 week | TERMIFILM FLEX  For more details, please see the confidential version of the PAR | For more details, please see the confidential version of the PAR | For more details, please see the confidential version of the PAR |
| Effects on content of the active substance and technical characteristics of the biocidal product - **ligh**t | - | - | - | Avoid exposure of the product to sunlight. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | Waived | - | - | For temperature effect, please see the storage stability studies  Humidity is not likely to have any impact on the stability of the formulation. |
| Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material | Waived | - | - | The product is a treated article, and is not likely to interact with container material |
| Wettability | Waived | - | - | The biocidal product is not intended to be dispersed in water |
| Suspensibility, spontaneity and dispersion stability | Waived | - | - | The biocidal product is not intended to be suspended in water |
| Wet sieve analysis and dry sieve test | Waived | - | - | The biocidal product is not intended to be suspended in water |
| Emulsifiability, re-emulsifiability and emulsion stability | Waived | - | - | The biocidal product is not liquid |
| Disintegration time | Waived | - | - | The biocidal product is not a tablet |
| Particle size distribution, content of dust/fines, attrition, friability | Waived | - | - | The biocidal product is neither a powder nor granules |
| Persistent foaming | Waived | - | - | The biocidal product is not intended to be applied in water |
| Flowability/Pourability/Dustability | Waived | - | - | The biocidal product is neither a powder nor granules |
| Burning rate — smoke generators | Waived | - | - | The biocidal product is not a smoke generator |
| Burning completeness — smoke generators | Waived | - | - | The biocidal product is not a smoke generator |
| Composition of smoke — smoke generators | Waived | - | - | The biocidal product is not a smoke generator |
| Spraying pattern — aerosols | Waived | - | - | The biocidal product is not an aerosol |
| Physical compatibility | Waived | - | - | Study scientifically unjustified since the product does not require mixing with other products. |
| Chemical compatibility | Waived | - | - | Study scientifically unjustified since the product does not require mixing with other products. |
| Degree of dissolution and dilution stability | Waived | - | - | The product is not intended to be diluted or dissolved |
| Surface tension | Waived | - | - | The product is a treated article in solid form |
| Viscosity | Waived | - | - | The product is a treated article in solid form |

|  |
| --- |
| Conclusion on the physical, chemical and technical properties of the product |
| TERMIFILM FLEX is a light green plastic sheet (mesh). Long term stability was proven over a period of 2 years; accelerated storage stability at 54°C during 2 weeks is stable; and low temperature stability at 0°C during 1 week also does not result in changes of content, colour or changes of pattern. Advice to avoid exposure to sunlight is given and humidity is not likely to have any impact on the stability of the formulation. The impregnated product does not require mixing with other products and as it is a solid other phys chem properties are not relevant. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | Waived | - | - | - TERMIFILM FLEX doesn’t contain any components that have explosive properties and furthermore there are no structural indications of explosivity.  - TERMIFILM FLEX is thermally stable and not liable to undergo a strongly exothermic decomposition even without participation of oxygen (air).  - TERMIFILM FLEX is not likely to undergo exothermic reaction.  - There are no chemical groups present in TERMIFILM FLEX associated with explosive or self- reactive properties. |
| Flammable gases | Waived | - | - | The product is not gaseous |
| Flammable aerosols | Waived | - | - | The product is not an aerosol |
| Oxidising gases | Waived | - | - | The product is not gaseous |
| Gases under pressure | Waived | - | - | The product is not gaseous |
| Flammable liquids | Waived | - | - | The product is not liquid |
| Flammable solids | Waived | - | - | - TERMIFILM FLEX doesn’t contain any components that have flammable properties |
| Self-reactive substances and mixtures | Waived | - | - | - TERMIFILM FLEX doesn’t contain any components that have explosive properties and furthermore there are no structural indications of explosivity.  - TERMIFILM FLEX is thermally stable and not liable to undergo a strongly exothermic decomposition even without participation of oxygen (air).  - TERMIFILM FLEX is not likely to undergo exothermic reaction.  - There are no chemical groups present in TERMIFILM FLEX associated with explosive or self- reactive properties. |
| Pyrophoric liquids | Waived | - | - | The product is not liquid |
| Pyrophoric solids | Waived | - |  | - TERMIFILM FLEX doesn’t contain any components that ignite spontaneously on coming into contact with air at normal temperatures explosive properties.  - The substances contained in TERMIFILM FLEX are known to be stable at room temperature for prolonged periods of time (days). |
| Self-heating substances and mixtures | Waived | - | - | - TERMIFILM FLEX doesn’t contain any components that by reaction with air and without energy supply, is liable to self-heat  - It doesn’t contain any components that ignite when they are contained in large amounts (kilograms) and after long periods of time (hours or days).  - There are no chemical groups present associated with self-heating.  - The substances contained in TERMIFILM FLEX are known to be stable at room temperature for prolonged periods of time (days). |
| Substances and mixtures which in contact with water emit flammable gases | Waived | - | - | - The chemical structure of the components does not contain metals or metalloids  - Experience in production or handling shows that TERMIFILM FLEX does not react with water |
| Oxidising liquids | Waived | - | - | The product is not liquid |
| Oxidising solids | Waived | - | - | - TERMIFILM FLEX doesn’t contain any components that have oxidising properties |
| Organic peroxides | Waived | - | - | - The formulation doesn’t contain any component with the bivalent -O-O- structure  - Components contained in the formulation may not be considered derivatives of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. |
| Corrosive to metals | Waived | - | - | - The formulation doesn’t contain any component classified as H290 (May be corrosive to metals)  - The formulation doesn’t contain any component which by chemical action will materially damage, or even destroy, metals. |
| Auto-ignition temperatures of products (liquids and gases) | Waived | - | - | The product is neither liquid nor gaseous |
| Relative self-ignition temperature for solids | Waived | - | - | - The substances contained in TERMIFILM FLEX are known to be stable at room temperature for prolonged periods of time (days). |
| Dust explosion hazard | Waived | - | - | The product is sold treated article |

|  |
| --- |
| Conclusion on the physical hazards and respective characteristics of the product |
| TERMIFILM FLEX doesn’t contain any physical hazard.  TERMIFILM FLEX doesn’t contain any components that have explosive properties and furthermore there are no structural indications of explosivity. It is thermally stable and not liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). It is not likely to undergo exothermic reaction. There are no chemical groups present associated with explosive or self- reactive properties. TERMIFILM FLEX doesn’t contain any components that ignite spontaneously on coming into contact with air at normal temperatures explosive properties. TERMIFILM FLEX doesn’t contain any components that by reaction with air and without energy supply, is liable to self-heat It doesn’t contain any components that ignite when they are contained in large amounts (kilograms) and after long periods of time (hours or days). There are no chemical groups present associated with self-heating. The chemical structure of the components does not contain metals or metalloids. Experience in production or handling shows that TERMIFILM FLEX does not react with water  The formulation doesn’t contain any component with the bivalent -O-O- structure. Components contained in the formulation may not be considered derivatives of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The formulation doesn’t contain any component classified as H290 (May be corrosive to metals). The formulation doesn’t contain any component which by chemical action will materially damage, or even destroy, metals.  The substances are finally known to be stable at room temperature for prolonged periods of time (days). |

### Methods for detection and identification

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **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 (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| Permethrin | For more details, please see the confidential version of the PAR | For more details, please see the confidential version of the PAR | For more details, please see the confidential version of the PAR | For more details, please see the confidential version of the PAR | For more details, please see the confidential version of the PAR | | | For more details, please see the confidential version of the PAR | For more details, please see the confidential version of the PAR |

Analytical methods for monitoring, for detection in soil, in air, in water, in animal and human body fluids and tissues and residues in food and feeding stuff are described and defined in the CAR of active substance.

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The applicant has submitted one validation methods for permethrin detection.  The content in active substance permethrin is determined in the product using a validated GC/MS method. The identity of the analyse is confirmed by comparison of the m/z. The standard regression is linear and the method is repeatable. For more details, please see the confidential version of the PAR. |

### Efficacy against target organisms

#### Function and field of use

MG03: pest control

PT18: Insecticides, acaricides and products to control other arthropods

Termifilm Flex is a ready-to-use product containing 1.6 % of permethrin (w/w) (m-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (CAS 52645-53-1)), which corresponds to 3.8 g/m² (weight of the film: 0.24 kg/m²).

The product is intended to be used preventively, as an internal perimeter lining creating a physico-chemical barrier against termites, by professional only. It consist of a flexible polyester containing the active substance coated with a polyvinyl chloride.

The placement must be carried out at the interface of the foundation and the structure of the building.

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

The target species to be controlled are some species of termites (*Reticulitermes flavipes and Coptotermes gestroi*)*.* The aim of the use is to avoid the damages caused by termites activity in building.

Rmk: In Europe, the 6 principal problematic species reported are part of the genus *Reticulitermes.* In Reunion, the reported damages are caused mainly by *Coptotermes gestroi.*

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

The target organisms ingest a small amount of the permethrin contained in the product, which once ingested lead to death.

#### Mode of action, including time delay

The mode of action of permethrin is described in the CAR. « 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.

#### Efficacy data

To support the claim, 10 studies were submitted to prove the efficacy of the product against the target organisms.

1. A Field test (**perforation of the film)** performed on the product TERMIFILM FLEX on ***Coptotermes gestroi***.

For more details, please see the confidential version of the PAR.

**Conclusion**: **test validated**

The test method (perforation of the film) used to perform the efficacy test is conform to the requirements mentioned in the document TNsG-Eff-PT 18 & 19.

According to this field test, the results obtained on the product TERMIFILM FLEX seem to show a good protection against Coptotermes gestroi.

1. A Laboratory test (**perforation of the film**) performed on the product TERMIFILM FLEX on ***Coptotermes gestroi*** on ***Coptotermes gestroi***

For more details, please see the confidential version of the PAR.

**Conclusion: test validated**

The test method (perforation of the film) used to perform the efficacy test is conform to the requirements mentioned in the document TNsG-Eff-PT 18 & 19.

According to this laboratory test, the results obtained on the product TERMIFILM FLEX seem to show a good protection against Coptotermes gestroi.

1. A Laboratory test (**perforation of the film after effect of alkalinity**) performed on the product TERMIFILM FLEX on ***Coptotermes gestroi***

For more details, please see the confidential version of the PAR.

**Conclusion: test validated**

The test method (perforation of the film after effect of alkalinity ) used to perform the efficacy test is conform to the requirements mentioned in the document TNsG-Eff-PT 18 & 19.

According to this laboratory test, the results obtained on the product TERMIFILM FLEX seem to show a good protection against Coptotermes gestroi after effect of alkalinity.

1. A Laboratory test (**perforation of the film after effect of immersion**) performed on the product TERMIFILM FLEX on ***Coptotermes gestroi***

For more details, please see the confidential version of the PAR.

**Conclusion: test validated**

The test method (perforation of the film after effect of water) used to perform the efficacy test is conform to the requirements mentioned in the document TNsG-Eff-PT 18 & 19.

According to this laboratory test, the results obtained on the product TERMIFILM FLEX seem to show a good protection against Coptotermes gestroi after effect of water.

1. A Laboratory test (**perforation of the film after effect of natural light**) performed on the product TERMIFILM FLEX on ***Coptotermes gestroi***

For more details, please see the confidential version of the PAR.

**Conclusion: test validated**

The test method (perforation of the film after effect of the natural light) used to perform the efficacy test is conform to the requirements mentioned in the document TNsG-Eff-PT 18 & 19.

According to this laboratory test, the results obtained on the product TERMIFILM FLEX seem to show a good protection against Coptotermes gestroi after effect of natural light.

1. A Laboratory test (**perforation of the film after effect of alkalinity**) performed on the product TERMIFILM FLEX on ***Reticulitermes flavipes (ex santonensis*)**

For more details, please see the confidential version of the PAR.

**Conclusion: test validated**

The test method (perforation of the film after effect of alkalinity) used to perform the efficacy test is conform to the requirements mentioned in the document TNsG-Eff-PT 18 & 19.

According to this laboratory test, the results obtained on the product TERMIFILM FLEX seem to show a good protection against Reticulitermes flavipes.

1. A field test performed on the product TERMIFILM FLEX *on* ***Reticulitermes flavipes (ex santonensis)***

For more details, please see the confidential version of the PAR.

**Conclusion: test validated**

The test method (perforation of the film) used to perform the efficacy test is conform to the requirements mentioned in the document TNsG-Eff-PT 18 & 19.

According to this field test, the results obtained on the product TERMIFILM FLEX seem to show a good protection against Reticulitermes flavipesafter effect of alkalinity.

1. A Laboratory test (**perforation of the film**) performed on the product TERMIFILM FLEX on ***Reticulitermes flavipes (ex santonensis)***

For more details, please see the confidential version of the PAR.

**Conclusion: test validated**

The test method (perforation of the film) used to perform the efficacy test is conform to the requirements mentioned in the document TNsG-Eff-PT 18 & 19.

According to this laboratory test, the results obtained on the product TERMIFILM FLEX seem to show a good protection against Reticulitermes flavipes.

1. A Laboratory test (**perforation of the film after effect of natural light**) performed on the product TERMIFILM FLEX on ***Reticulitermes flavipes (ex santonensis)***

For more details, please see the confidential version of the PAR.

**Conclusion: test validated**

The test method (perforation of the film) used to perform the efficacy test is conform to the requirements mentioned in the document TNsG-Eff-PT 18 & 19.

According to this laboratory test, the results obtained on the product TERMIFILM FLEX seem to show a good protection against Reticulitermes flavipes.

1. A Laboratory test (**perforation of the film after effect of immersion**) on **Reticulitermes flavipes (ex santonensis)**

For more details, please see the confidential version of the PAR.

**Conclusion: Test validated**

The test method (perforation of the film after effect of water) used to perform the efficacy test is conform to the requirements mentioned in the document TNsG-Eff-PT 18 & 19.

According to this laboratory test, the results obtained on the product TERMIFILM FLEX seem to show a good protection against Reticulitermes flavipes after effect of water.

The experimental data are summarized in the table below.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **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** |
| *PT18*  *Insecticide* | *Film ready-to-use*  *Barrier against termites*  *professional user* | *TERMIFILM FLEX*  *Active substance: Permethrin: 4 g/m²* | **Termites**  *Coptotermes gestroi* | Field test | *Installation of test devices for evaluating effectiveness in the natural environment* | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR. |
| *PT18*  *Insecticide* | *Film ready-to-use*  *Barrier against termites*  *professional user* | *TERMIFILM FLEX*  *Active substance: Permethrin: 4 g/m²* | **Termites**  *Coptotermes gestroi* | Laboratory test | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR.  *78 %* | For more details, please see the confidential version of the PAR. |
| *PT18*  *Insecticide* | *Film ready-to-use*  *Barrier against termites*  *professional user* | *TERMIFILM FLEX*  *Active substance: Permethrin: 4 g/m²* | **Termites**  *Coptotermes gestroi* | Laboratory test after effect of alkalinity | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR. |
| *PT18*  *Insecticide* | *Film ready-to-use*  *Barrier against termites*  *professional user* | *TERMIFILM FLEX*  *Active substance: Permethrin: 4 g/m²* | **Termites**  *Coptotermes gestroi* | Laboratory test after effect of immersion | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR. |
| *PT18*  *Insecticide* | *Film ready-to-use*  *Barrier against termites*  *professional user* | *TERMIFILM FLEX*  *Active substance: Permethrin: 4 g/m²* | **Termites**  *Coptotermes gestroi* | Laboratory test after effect of natural light. | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR. |
| *PT18*  *Insecticide* | *Film ready-to-use*  *Barrier against termites*  *professional user* | *TERMIFILM FLEX*  *Active substance: Permethrin: 4 g/m²* | **Termites**  *Reticulitermes flavipes (ex santonensis)* | Laboratory test after effect of alkalinity | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR. |
| *PT18*  *Insecticide* | *Film ready-to-use*  *Barrier against termites*  *professional user* | *TERMIFILM FLEX*  *Active substance: Permethrin: 4 g/m²* | **Termites**  *Reticulitermes flavipes (ex santonensis)* | Field test | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR. |
| *PT18*  *Insecticide* | *Film ready-to-use*  *Barrier against termites*  *professional user* | *Active substance: Permethrin: 4 g/m²* | *Reticulitermes flavipes (ex santonensis)* | Laboratory test | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR. |
| *PT18*  *Insecticide* | *Film ready-to-use*  *Barrier against termites*  *professional user* | *TERMIFILM FLEX*  *Active substance: Permethrin: 4 g/m²* | **Termites**  *Reticulitermes flavipes (ex santonensis)* | Laboratory test | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR. |
| *PT18*  *Insecticide* | *Film ready-to-use*  *Barrier against termites*  *professional user* | *Grille*  *Active substance: Permethrin: 4 g/m²* | **Termites**  *Reticulitermes flavipes (ex santonensis)* | Laboratory test after effect of immersion | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR. | For more details, please see the confidential version of the PAR.  reliability:1 |

On the basis of 10 studies submitted, the product Termifilm Flex applied at the interface between the foundation and the structure of the building seems to provide a good protection against termites (*Coptotermes gestroi, Reticulitermes flavipes (ex santonensis)).*

The claim of the product mentions a protection against Coptotermes gestroi, Reticulitermes flavipes (ex santonensis), the target organisms were tested as required in the TNsG.

For more details, please see the confidential version of the PAR.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| In the field test Report N° 15-02 / Inspection September 2015, no perforation was observed in test samples, nor in the control samples. In field tests, termites cannot be forced into the devices, as there are many wood subjects present that can serve as an alternative to the bait. Please note that this is a long term study, and data on perforation of the test and control subjects will be reassessed 4, 6, 8 and 10 years after the tests was started.  Since all tests required were performed and the norms used are equivalent at the norms mentioned in the TNsG and taking into account the experience of the CTBA for this kind of application and the localization claimed, the product is considered effective to protect the building against subterranean termites; Coptotermes gestroi and Reticulitermes flavipes (ex santonensis)). The placement must be carried out at the interface of the foundation and the structure of the building. |

#### Occurrence of resistance and resistance management

Resistance to Permethrin has been documented in wide varieties of insects. These species include pear psylla (Preem D.J. et al -J.Econ.Entomol.83:2159-2163, 1990), fall army worm (Smith, J.E. Pest Biochem, Physiol. 39:84-91, 1991), German cockroach (Atkinson, T.H.et al - J.Econ.Entomol. 84:1247-1250, 1991), spotted tentiform leafminer (Marshall, D.B. and D.J. Pree. Can.Ent. 118:1123-1130, 1986), diamondback moth (Tabashnik, B.E., N.J. Cushing, and M.W. Johnson. Econ.Entomol. 80:1091-1099), house fly (Shen, J and F.W.Plapp. J.Econ.Entomol.83:1689-1697, 1990), Stable fly (Cilek, J.E and G.I. Greena, J.Econ.entomol. 87:275-279, 1994), headlice (Rupes, V. et al. Cent.Eur.J.Public Health, 3:30-32, 1995) (Mumcuoglu, K.Y.et al, med.Vet.Entomol 9:427-432, 447, 1995), (Burgess, I.F. et al, Brit.Med.J. 311 (7007):752 1995), tobacco budworm (Wolfenbarger, A. and J.vargas-Camplis. Resist.Pest Manage.9:39-42, 1997).

The level of resistance is less than tenfold in some of the species but high levels of resistance have been observed in cockroaches (45-fold) (Atkinson, T.H.et al - J.Econ.Entomol. 84:1247-1250, 1991), lice (up to 385 fold) (Rupes, V. et al. Cent.Eur.J.Public Health, 3:30-32, 1995), and budworm (1400 fold) (Wolfenbarger, A. and J.vargas-Camplis. Resist.Pest Manage.9:39-42, 1997).

Resistance to permethrin has been documented in a wide variety of organisms. In the Colorado potato beetle, it is suggested that resistance is due to low levels of Permethrin hydrolysis. In the fungus gnat, resistance to Permethrin is attributed to changes in monooxidase activity in the resistant population. In H. virescens, altered functioning of the Na+ channels, and a subsequent elevation of the action potential threshold is thought to cause the resistance. Resistance to pyrethroids has developed rapidly (among head lice) since Permethrin was introduced in 1991.

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. Cross-resistance to pyrethroids and the susceptibility to carbaryl suggested that a common site of pyrethroid action exists.

Application of Permethrin synergists such as Piperonyl butoxide (PBO) or Triphenyl phosphate (TPP) to Permethrin resistant head lice suggests that monooxygenases (cytochrome P-450s) and the esterase enzyme systems were responsible for some pyrethroid resistance. A lack of synergism of D-phenothrin resistance by Piperonyl butoxide suggests that a non-oxidative mechanism, such as nerve insensitivity is also present in resistant lice.

It is extremely important to generate a pest management strategy in order to combat the onset of resistance. Assumptions of such a plan include the absence of cross-resistance and lack of similarity in biochemical mechanisms in head lice. The use of synergists for the inhibition of detoxifying enzymes represent not only an alternative to improve control, but a tool for elucidating resistance mechanisms.

The principles of strategies for managing the development of resistance are similar for Permethrin as they are for other synthetic pyrethroids:

• where possible, application treatments should be recommended to be combined with non-chemical measures

• products should always be used in accordance with label recommendations

• complete elimination of insect pests should be attempted in infested areas

• applications should always be made against the most susceptible stages in the pest life cycle

• where an extended period of control is required, treatments should be alternated with products with different modes of action

• levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance.

Because of the anticipated low level of selection pressure from the proposed uses, no specific strategy for management of the development of resistance is required.

#### Known limitations

No undesirable or unintended side effects have been observed in any of the tests performed.

#### Evaluation of the label claims

The applicant has to indicate that the product is adapted for application in Europe and on Reunion Island. Efficacy demonstrated against subterranean termites (*Coptotermes gestroi* and *Reticulitermes flavipes* (ex santonensis)).

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

Not applicable.

### Risk assessment for human health

#### Assessment of effects on Human Health

No human health studies were submitted for this product. There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Studies with the biocidal product are scientifically not justified.

##### Skin corrosion and irritation

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Biocidal product not classified for skin corrosion and irritation according to (EU) nr. 1272/2008 |
| Justification for the value/conclusion | Neither the active ingredient nor one of the other relevant ingredients of the biocidal product are classified with respect to skin corrosion and irritiation. Thus, Termifilm Flex has no potential for an  skin corrossion hazard and no classification with respect to skin corrosion is required.  No human data are available for skin corrosion and irritation. |
| Classification of the product according to CLP and DSD | none |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified |
| Justification | Since the skin corrosion of Termifilm Flex can be assessed on the basis of the properties of the ingredients, the performance of an skin corrosion study with the biocidal product is scientifically not justified. See IUCLID data point 8.1.1 Endpoint study record  There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. |

##### Eye Irritation

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Biocidal product not classified eye irritation according to (EU) nr. 1272/2008 | |
| Justification for the value/conclusion | Neither the active ingredient nor one of the other relevant ingredients of the biocidal product are classified with respect to eye irritiation. Thus, Termifilm Flex has no potential for an eye irritation hazard and no classification with respect to eye irritation is required.  No human data are available for eye irritation. | |
| Classification of the product according to CLP and DSD | none | |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Study scientifically unjustified |
| Justification | Since the eye irritation of Termifilm Flex can be assessed on the basis of the properties of the ingredients, the performance of an eye irritation study with the biocidal product is scientifically not justified. See IUCLID data point 8.1.2 Endpoint study record  There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. |

##### Respiratory tract irritation

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | Neither the active ingredient nor one of the other relevant ingredients of the biocidal product are classified with respect to respiratory tract irritation. Termifilm Flex does not pose a respiratory tract irritation hazard.  No human data are available |
| Classification of the product according to CLP and DSD | none |

##### Skin sensitization

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Skin sens cat 1 |
| Justification for the value/conclusion | The mixture is classified as a skin sensitiser because the mixture contains an ingredient classified as a skin sensitiser with a concentration present equal or above the appropriate generic concentration limit. |
| Classification of the product according to CLP and DSD | Skin sens cat 1  H317  GHS07, warning |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | study scientifically not necessary |
| Justification | Since the skin sensitization of Termifilm Flex can be assessed on the basis of the properties of the ingredients, the performance of a study with the biocidal product is scientifically not justified.  There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. |

##### Respiratory sensitization (ADS)

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory sensitization** | |
| Justification for the conclusion | Neither the active ingredient nor one of the other relevant ingredients of the biocidal product are classified with respect to respiratory sensitization. Termifilm Flex does not pose a respiratory sensitization hazard.  No human data are available |
| Classification of the product according to CLP and DSD | none |

##### Acute toxicity

###### Acute toxicity by oral route

|  |  |  |
| --- | --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | | |
| Value/conclusion | No acute oral toxicity |
| Justification for the value/conclusion | As the mixture itself has not been tested to determine its acute toxicity and as there is no data on similar mixtures to adequately characterize the hazards of the mixture, the classification of the mixture has to be done by using the bridging rules. |
| Classification of the product according to CLP and DSD | / |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | study scientifically not necessary |
| Justification | Since the acute oral toxicity of Termifilm Flex can be assessed on the basis of the properties of the ingredients, the performance of a study with the biocidal product is scientifically not justified.  There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. |

###### Acute toxicity by inhalation

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value/conclusion | No acute inhalation toxicity |
| Justification for the value/conclusion | As the mixture itself has not been tested to determine its acute toxicity and as there is no data on similar mixtures to adequately characterize the hazards of the mixture, the classification of the mixture has to be done by using the bridging rules. |
| Classification of the product according to CLP and DSD | / |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | study scientifically not necessary |
| Justification | Since the acute toxicity of Termifilm Flex can be assessed on the basis of the properties of the ingredients, the performance of a study with the biocidal product is scientifically not justified.  There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. |

###### Acute toxicity by dermal route

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value/conclusion | No acute dermal toxicity |
| Justification for the value/conclusion | As the mixture itself has not been tested to determine its acute toxicity and as there is no data on similar mixtures to adequately characterize the hazards of the mixture, the classification of the mixture has to be done by using the bridging rules. |
| Classification of the product according to CLP and DSD | / |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | study scientifically not necessary |
| Justification | Since the acute toxicity of Termifilm Flex can be assessed on the basis of the properties of the ingredients, the performance of a study with the biocidal product is scientifically not justified.  There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. |

##### Information on dermal absorption

No dermal absorption studies with the biocidal product have been performed.

The BE CA proposes a default dermal absorption of 10%. That value will be used in the risk assessment of the product TERMIFILM FLEX.

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | Permethrin |
| Value(s) | 10% |

For more information, please refer to the confidential annex.

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

Not applicable

##### Available toxicological data relating to a mixture

Not applicable

#### Exposure assessment

TERMIFILM FLEX is a treated article impregnated with solution of permethrin. Final concentration of permethrin in the product is 1.6% w/w (corresponding to 3.8 g/m²).

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

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

##### List of scenarios

Process description:

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

TERMIFLM FLEX is a polyester fibre with a fine mesh coated with a PVC resins containing 1,6% w/w.

The colour of TERMIFILM FLEX is green.

For more details, please see the confidential version of the PAR.

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| 1. | Adult handling | Primary exposure | professionals |

No secondary exposure since the product will be below a concrete slab and/or buried. According to the method of application, during its service life it will not be accessible to people.

##### Industrial exposure

Not applicable

##### Professional exposure

###### Scenario [1]: Primary exposure by application of Termifilm flex by professionals

| **Description of Scenario [1]** | | |
| --- | --- | --- |
| Mainly hands and body will be able to be in contact with the film during manipulation of TERMIFILM FLEX  Adult Handling Treated Timber – Acute Exposure. TNsG Part 3, (2002) p. 50 | | |
|  | Parameters | Value |
| Tier 1 | weight fraction of a.s. in product1  **Wf** | 3.8 g/m² |
| Hands surface contact2  **H** | 820 cm² |
| Lower legs surface contact2  **L** | 2132 cm2 |
| Number of contacts per day3 | 100 |
| Dermal absorption | 10% |
| Transfer coefficient (Termifilm Flex to hands)4  **Tf** | 0.49% |
| Tier 2 | Gloves | 10% |

1producer data

2HEEG opinion 17 – Default Human factor values for use in exposure assesments for biocidal products

3CAR permethrin PT8

4 For more details, please see the confidential version of the PAR.

Calculations for scenario [1]

Total exposure = Wf \* (H+L) \* 100 \* dermal absorption \*Tf \* mitigation gloves

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table: estimated exposure from industrial uses** | | | | | |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [1] | 1/ no PPE | n.a. | 0.255 mg/kg bw /day | n.a. | 0.255 mg/kg bw /day |
| Scenario [1] | 2/gloves | n.a. | 0.0255 mg/kg bw /day | n.a. | 0.0255 mg/kg bw /day |

###### Scenario [2]: Primary exposure by application of Termifilm flex by professionals: reverse scenario

| **Description of Scenario [2]** | | |
| --- | --- | --- |
| Mainly hands and body will be able to be in contact with the film during manipulation of TERMIFILM FLEX  Reverse scenario | | |
|  | Parameters | Value |
| Tier 1 | weight fraction of a.s. in product1  **Wf** | 3.8 g/m² |
| Hands surface contact2  **H** | 820 cm² |
| Dermal absorption | 10% |
| Transfer coefficient (Termifilm Flex to hands)4  **Tf** | 0.49% |
| Tier 2 | Gloves | 10% |

1producer data

2HEEG opinion 17 – Default Human factor values for use in exposure assessments for biocidal products

4 For more details, please see the confidential version of the PAR.

Calculations for scenario [2]

|  |  |
| --- | --- |
| AEL (short term) | 0.5 mg/kg bw/day |
| AEL (long term) | 0.05 mg/kg bw/day |

|  |  |  |
| --- | --- | --- |
| **Summary table: estimated exposure from industrial uses** | | |
| **Exposure scenario** | **Tier/PPE** | **Max. volume of m² product handling per day** |
| Scenario [2] | 1/ no PPE | 16.1 m²/day (short term) |
| Scenario [2] | 2/ gloves | 161 m²/day (short term) |
| Scenario [2] | 1/ no PPE | 1.6 m²/day (long term) |
| Scenario [2] | 2/ gloves | 16 m²/day (long term) |

##### Non-professional exposure

Not applicable

##### Exposure of the general public

Not applicable

##### Monitoring data

Not applicable

##### Dietary exposure

Not applicable

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

Not applicable

##### Aggregated exposure

Not applicable

##### Summary of exposure assessment

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake** |
| 1. | Professionals | TIER 1/no PPE | 0.255 mg/kg bw /day |
| 1. | Professionals | TIER 2/PPE (gloves) | 0.0255 mg/kg bw /day |
| 2. | Professionals | TIER 1/no PPE | 1.6 m²/day (reversed scenario) |
| 2. | Professionals | TIER 2/PPE (gloves) | 16 m²/day (reversed scenario) |

#### Risk characterisation for human health

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Reference** | **Study** | **AF** | **Value** |
| AELshort-term | Rat 2 year oral study (acute effect)  Bayer (Ishmael and Litchfield, 1988) | 100 | 0.5 mg/kg bw/day |
| AELmedium-term | 12-month dog study.  Bayer (Kalinowski et al, 1982 ) | 100 | 0.05 mg/kg bw/day |
| AELlong-term | 12-month dog study.  Bayer (Kalinowski et al, 1982 ) | 100 | 0.05 mg/kg bw/day |

##### Risk for industrial users

Not applicable

##### Risk for professional users

###### Systemic effects

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL** | **Acceptable**  **(yes/no)** |
| 1. | TIER 1/no PPE | 0.05 | 0.255 | 510 | no |
| 1. | TIER 2/PPE (gloves) | 0.05 | 0.0255 | 51 | Yes |

| **Exposure scenario** | **Tier/PPE** | **Max. volume of m² product handling per day** | **Acceptable**  **(yes/no)** |
| --- | --- | --- | --- |
| Scenario [2] | 1/ no PPE | 1.6 m²/day | yes |
| Scenario [2] | 2/ gloves | 16 m²/day | yes |

###### Conclusion

For scenario 1, tier 2 (with gloves) the estimated uptake is higher than the AEL. For this scenario it was considered 100 contacts per day (analogue CAR).

According to the reverse scenario 2 (frequent application) a maximum of 16 m² (tier 2) product/day can be applied by a worker (with gloves). This is close to the information of the applicant which states 19 m2 per day per worker.

The risk is thus acceptable for 2 workers managing one private house per day (38 m2), if they wear gloves.

##### Risk for non-professional users

Not applicable

##### Risk for the general public

Not applicable

##### Risk for consumers via residues in food

Not applicable

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

Not applicable

### Risk assessment for animal health

Not applicable

### Risk assessment for the environment

TERMIFILM FLEX is a permethrin- base product which differs from the product submitted in the PT 18 CAR for permethrin. Compared with the CAR a leaching study has been provided in support of the product authorisation.

All other data on the effects or on the environmental fate of the active are identical to those provided in the CAR.

#### Effects assessment on the environment

##### Environmental fate and behavior of the active substance

**Aquatic compartment including STP and sediment**

Permethrin was observed to be hydrolytically stable between pH 3.0/4.0 to 7.6/7 at 25/50°C respectively. Only at pH 9.0/9.6 was permethrin observed to hydrolyse, with DT50 values for cis- and trans-permethrin estimated at 35 days and 42 days, respectively (at pH 9.6 and 25°C). Permethrin is not readily biodegradable according to OECD 301B (CO2 evolution method)/US EPA OPPTS 835.3110 and OECD 301 F (oxygen consumption). Permethrin is strongly adsorbed to soil (Mean Kf oc 73,442 L/kg (n= 10)).

Permethrin (46:54 and 53:47 cis:trans) was observed to degrade in aerobic water/sediments systems, with whole-system DT50 values of cis- and trans-permethrin calculated at 63.7 days and 27.3 days, respectively at 25°C (equivalent to corresponding values at 12 °C of 180.2 days and 77.2 days).

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

Maximum observed levels of DCVA, PBA and PB alcohol in the water compartment were 62.6 %AR, 28.8%AR and 38.2 %AR respectively. DCVA and PBA were also major metabolites in the sediment compartment (21.7 % and 16.4 % respectively).

Permethrin was observed to degrade more slowly under anaerobic conditions, with whole-system DT50 values of cis- and trans-permethrin calculated at 179.4 days and 114.5 days, respectively (equivalent to corresponding values at 12 °C of 507.6 days and 323.9 days). Cis- and trans-permethrin appeared to be rather immobile in the sediment, remaining in the upper portion (0-5 cm). DT50 values determined for the cis- and trans-permethrin isomers in the sediment phase ranged from 118 to 256 days and 18 to 62 days, respectively.

Direct photolysis of permethrin (49:51 cis:trans) indicated slow degradation of the test material resulting in a DT50 value of 118 days with 12 hr sunlight per day under outdoor conditions at latitude of 50°N and the fall season.

**Atmosphere**

Volatilization of permethrin is considered to be negligible based on the vapour pressure (2.155 x 10-6 Pa at 20°C, 25:75 cis:trans) and Henry constant (4.6 x 10-3 - > 4.5 x 10-2 Pa m3 mol-1). Permethrin volatilisation loss from a soil surface over 24 hours to the atmosphere was calculated to be 0.73% assuming a temperature of 25 °C. Permethrin is rapidly degraded and would not be transported over large distances in the atmosphere in gaseous phase.

**Terrestrial compartment**

Degradation of permethrin was investigated under aerobic conditions in several soils. The range of reliable SFO DT50s ranged from 77 d to ~141 d at 12°C. The corresponding geomean DT50 was 106d. The cis isomer degraded more slowly than the trans isomer based on the cis:trans ratio at the time of application changing from 40:60 to 50:50 by day 30 and 78:22 by day 365. It can be expected that a DT50 value of 106 days is conservative enough to represent the degradation in soil at 12oC of permethrin samples containing a cis:trans ratio of 25:75.

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

Permethrin was observed to be relatively stable when exposed to photolysing conditions in soil. A DT50 of 200 d was estimated. No transformation product greater than 10 %AR was observed.

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

##### Effect assessment of the active substance

All the data refer to the chapter Effects assessment are from Doc IIA as well as from Doc IIB for the active substances Permethrin.

There has not been submitted any new data regarding the active substance. The PNEC values have been taken from the Assessment Report for PT8.

The PNEC values used in the risk assessment are the following:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on PNEC values for active substance** | | | | |
| **Active substance** | **PNECwater**  **(mg.l-1)** | **PNECsediment**  **(mg.kg-1wwt)** | **PNECsoil**  **(mg.kg-1wwt)** | **PNECSTP**  **(mg.l-1)** |
| **Permethrin** | 4.7E-07 | 2.17E-04 | 8.76E-02 | 4.95E-03 |

##### 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

No other constituent apart from the active substance has an influence on the environmental classification and labelling of the product.

Permethrin has a harmonized classification for the environment, which is Aquatic Acute 1 and Aquatic Chronic 1, with an M-factor of 1000. Following this, the product needs to be classified as follows below.

|  |
| --- |
| **Conclusion on the environmental classification and labelling of the product** |
| ***Classification:***  Aquatic Acute cat. 1 (H400) (M=100)  Aquatic Chronic cat. 1 (H410) (M= 10000)  ***Labelling:***  GHS09 Warning H410 |

##### Further Ecotoxicological studies

No additional data submitted

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

No additional data submitted

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

No additional data submitted

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

No additional data submitted

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

No additional data submitted

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

TERMIFILM FLEX is a chemical-physical barrier for the preventive protection of new building against termites, which is supplied in the form of a roll to be placed during construction of building. The product is not intended to be placed in direct contact to soil or to be wetted on a regular basis by rain event. The product in place will be scelled between basements and inner wall and protected from wettering by the external protection of the buildings. However, during the construction of a building, before the building is fully closed and finished, rain event may occurs which leads to emission to the environment. It is also considered that residual moisture during the first week of placing may lead to emission to the environment.

Please refer to Application processes of TERMIFILM FLEX description in Annex 7.

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

*\* Sewages probably not connected during early stage of the construction.*

*\*\*Indirect exposure via leaching of the substance after a rain fall*

*\*\*\*Indirect exposure via leaching of the substance in soil*

**Air:** Emissions can occur to the air by evaporation of the active substance contained in TERMIFILM FLEX. The product TERMIFILM FLEX is a treated article with a primary biocidal function, containing permethrin as an insecticide. Permethrin show very low vapour pressure.

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

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

Emission may occur to surface water by cleaning water from storage place (after impregnation of the film) into facility drain.

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

The emission to sewage treatment plant will be considered for the application phase but is considered not relevant for in service phase.

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

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

The product TERMIFILM FLEX must not be used in direct contact with soil, therefore, no direct soil contamination should be considered.

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

No additional data available

##### Leaching behaviour (ADS)

For more details, please see the confidential version of the PAR.

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

No additional data available

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

No additional data available

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

No additional data available

#### Exposure assessment

In the absence of appropriate scenario, the environmental exposure assessments of the active substance were determined with the Emission Scenario Document (ESD) developed for Product Type 08 (wood preservatives) by OECD: OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Emission Scenario Document for Wood Preservatives.

The emission scenarios estimate the emission of wood preservatives from two stages of their life cycle:

- Application and storage of treated wood prior to shipment;

- Treated wood in service.

For the active substance contained in the treated article TERMIFILM FLEX, Permethrin, the environmental risk assessment has been calculated from laboratory leaching tests used in evaluation of product TERMIFILM FLEX and according to the report of the leaching workshop, Arona, Italy, 13 and 14 June 2005.

##### General information

|  |  |
| --- | --- |
| Assessed PT | PT 18 |
| Assessed scenarios | Scenario 1: Application and storage of treated wood prior to shipment  Scenario 2: Treated wood in service |
| ESD(s) used | OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Emission Scenario Document for Wood Preservatives. |
| Approach | Scenario 1: Average consumption  Scenario 2: Average consumption |
| Distribution in the environment | Calculated based on TGD 2003 |
| Groundwater simulation | *NO* |
| Confidential Annexes | *NO* |
| Life cycle steps assessed | Production: Yes  Formulation/ n.a.  Use: yes  Service life: Yes |
| Remarks | *-* |

##### Emission estimation

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

* Application and storage of treated wood prior to shipment;
* Treated wood in service.

The storage scenario employed in this assessment assumes that the storage area is uncovered and unpaved.

In the case of service life exposure, the following emission scenario have been run for Permethrin : House.

For the emission scenario of service life exposure, calculations of emissions in soil have been done with Permethrin **removal processes in soil taken into account**; according to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Part 3. These scenario have been adapted to take into account the dimension of the film.

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

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

TERMIFILM FLEX is a treated article (polyester fibre with a fine mesh coated with a PVC resins), containing 1,6% w/w or 3,8 g/m² of Permethrin.

**1) Tier 1**

For the emission calculations, as a tier 1, according to the 2nd EU Leaching Workshop, Varese, Italy, June 2013, it was assumed that 50% of active substance has been leached after Time 1 assessment period (considered to be 16 days as a worst case, because after this period TERMIFILM FLEX will be covered by slab and/or soil) and that 100% of active substance has been leached after Time 2 assessment period assumed to be 30 years (10950 days).

**Permethrin leaching behavior**

|  |  |  |  |
| --- | --- | --- | --- |
| Product | Active substance | Assessment period  [days] | Emission rate of permethrin [Kg/m2.day] |
| TERMIFILM FLEX | Permethrin | 16 (Time 1) | 1,2x10-4 |
| 10950 (Time 2) | 3.4x10-7 |

**For Time 1**

Permethrin application rate: 3.8 g/m²

Emission rate: 3,8 g/m²x0,5/16d = 0,12 g/m²/d= 1,2x10-4 kg/m²/d

**For Time 2**

Permethrin application rate: 3.8 g/m²

Emission rate: 3,8 g/m²/10950d = 3.4 x10-4 g/m²/d= 3.4x10-7 kg/m²/d

**2) Tier 2**

According to the document “REVISED EMISSION SCENARIO DOCUMENT FOR WOOD PRESERVATIVES” published by OECD the 27th of September 2013, page 107, Emission fractions (Frunoff, Fkoc) :

- Frunoff: Run-off was only considered with regard to removal of the substance from top soil layers. It is assumed that 10 % of the applied amount is removed by run-off. This is justified by the low mobility of substances used for termite control and the fact that the surface of the perimeter will be covered most likely by gravel or later by plants so that run-off is not a major removal factor.

- FKoc: An additional factor taking into account the mobility of a substance expressed by its Koc. Based on the mobility classes proposed by McCall et al (1981) the following factors have been set:

- Koc > 500 - 2000 (low mobility): 50% of the substance may migrate to adjacent soil

- Koc > 2000 - 5000 (slightly mobile): 10% of the substance may migrate to adjacent soil

- Koc > 5000 (immobile): the substance does not migrate to adjacent soil

According to these data, as a tier 2 evaluation it has been considered that the fraction of rainwater running off the implementation area (i.e. not infiltrating in soil) is equivalent to 0,1 (**Frunoff** ); considering that :

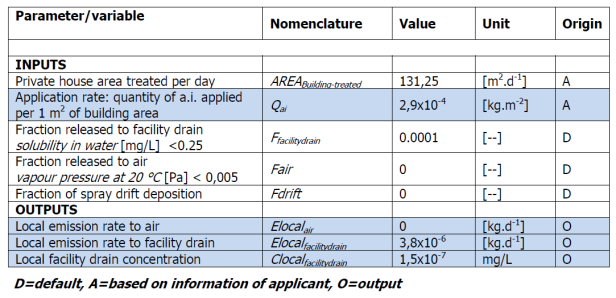
o After a rainfall, the leachate of permethrin will not migrate through the layer of TERMIFILM but will stay on the surface until drying.

o The majority of permethrin leachate will be first bound to the soil.

**Scenario 1 product application**

**Tier 1**

**Implementation phase – STP** Emission scenario for automated spraying – product application



Calculations for Scenario [*1, tier 1, STP*]

Application rate of a.i. (active ingredient) [kg.m-2]: 3.8 g.m-2

Considering 50% of leaching for Time1 and an area treated of 10m² ’((17.5+7.5)\*2 \*0.2= 10)

Qai is equal to 1.9g.m-²

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

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

Elocalair = (17.5+7.5)x2x0.1.9x10-3 x(0+0) = 0 [kg.d-1]

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

Elocalfacilitydrain = AREABuilding-treated x Qai x Ffacilitydrain

Elocalfacilitydrain= (17.5+7.5)x2x0. 1.9x10-3 4x0.0001 = 1.19x10-3 [kg.d-1]

PEC STP :

Considering a Koc of 73442 and a F stp water of 0.276 (simple treat), Pec stp is 1.16x10-4 mg/l

PEC Water = 1.58 E-05 mg/l ( Vol IV B Eq. 23 p 52)

**Implementation phase – Water and Soil Emission** scenario for automated spraying – storage of treated wood prior to shipping)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Value** | **Unit** | **Remarks** |
| **INPUTS** | | | | |
| Area of the perimeter barrier | AREAbarrier | 10 | [m2] | Internal perimeter lining |
| Quantity of permethrin leached after 16 days | Dose | 1.90 | [g.m-2] | 50% of permethrin application rate (3.8 g.m-2) |
| **OUTPUT: Emission during the construction step with perimeter application of the product in urban area** | | | | |
| Local emission to waste water | Elocal,ww | 1.19E-03 | [kg.d-1] | - |
| **OUTPUT: Emission during the construction step with perimeter application of the product in rural area** | | | | |
| Local emission to adjacent soil after 16 days | Esoil,leach | 1.90E-02 | [kg.d-1] | - |

Calculations for Scenario [*1, tier 1, water and soil*]

* Volume of wet soil:

HOUSEcircumference=2x(HOUSElengthxHOUSEwidth)

HOUSEcircumference=2x(17.5+7.5) = 50 m

Vsoil =HOUSEcircumference x DISTANCEhorizontal x DEPTH

Vsoil=50x0.5x0.1= 2.5 m3

Emissions at implementation area :

* Qxleach,time implementation = FLUXimplementation xTIMEimplementation

Qxleach,time implementation = 1,19x10-4x16\*10 = 1,90x10-2 kg

Refer to the working document; guidance document on persistence in soil, European Commission, VI B II.1, 9188/VI/97 rev. 8 of 12 July 2000, page 6.

* kwater=Ln2/DT50water

DT50= 35d

kwater=Ln2/35= 0.0198 d-1

Refer to the working document; guidance document on persistence in soil, European Commission, VI B II.1, 9188/VI/97 rev. 8 of 12 July 2000, page 6.

*Local concentration in soil during the implementation period (rural area)*

* AREATermifilmFlex =

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

AREATermifilmFlex = [( (Lhouse+lhouse) x 2) x lTermfilmFlex ]

= [((17,5+7,5)x2)x0,2]

= 10 m²

* Esoil,leach,time implementation = (AREATermifilmFlex x Qxleach,time implementation)/TIMEimplementation

Esoil,leach,time implementation 16d= 10x1,9x10-3 = 1,9x10-2 [kg.d-1]

Clocalsoil,time implementation = 8.60x10-1 mg. Kg-1

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

|  |  |
| --- | --- |
| **Substance** | **PECsoil [mg.kgwwt-1]** |
| Permethrin | 8.6x10-1 |

Tier II

The results of the leaching study are used to refine for the construction step. The data from the semi-field leaching test show that 0.1299 mg.m-² of permethrin leached out from TERMIFILM-FLEX during the first 8 days. An extrapolation to 16 days can be made with a theoretical quantity of 0.2598 mg.m-2.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Value** | **Unit** | **Remarks** |
| **INPUTS** | | | | |
| Area of the perimeter barrier | AREAbarrier | 10 | [m2] | Internal perimeter lining |
| Quantity of permethrin leached after 16 days | Dose | 0.0002598 | [g.m-2] | Extrapolation from semi-field leaching test |
| **OUTPUT: Emission during the construction step with perimeter application of the product in urban area** | | | | |
| Local emission to waste water | Elocal,ww | 1.62E-07 | [kg.d-1] | - |
| **OUTPUT: Emission during the construction step with perimeter application of the product in rural area** | | | | |
| Local emission to adjacent soil after 16 days | Esoil,leach | 2.60E-06 | [kg.d-1] | - |

Emission to stp (Urban area)

Emission to waste water : (17.5+7.5)x2x 0.2x 0.0002598x10-3 /16= 1.62x10-7

Pec stp : 2.2 x 10-8 mg.l-1

Pec surface water : 2.15E-09 mg.l-1

Emission to soil in rural area:

Emission to soil: (17.5+7.5)x2x 0.2x 0.0002598x 0.001 = 2.6 x10-6

Pec soil : 1.18x10-4 mg.kg-1 wwt

Pnec Soil 0.00876 mg.kg-1 wwt

**Scenario 2 Termifilm Flex in service**

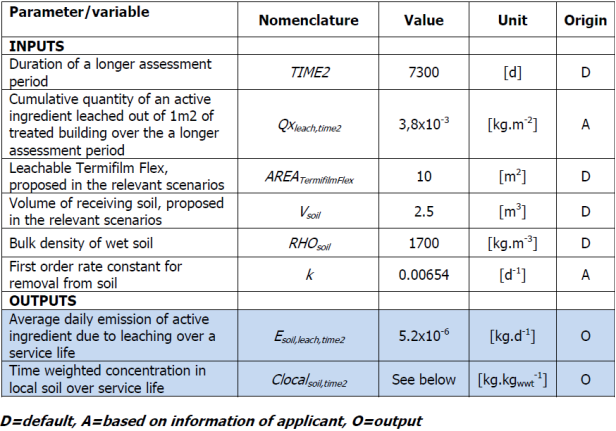
TERMIFILM FLEX is use during the construction of a building. It is placed in the foundation in inner part of the building where is not expected that wettering may occurs. As such, it is considered that not environmental exposure will result from the use of TERMIFILM FLEX in service.

However, emission estimation have been calculated according to the house scenario (PT8)

***House scenario (derived from PT8 model)***

Note from eCA:

The following approach is deviating from the agreed approach (Emission – STP- Simple treat – Concentration in surface water). It has been proposed by the applicant in order to propose and estimation of the emissions. It should be understood that there is currently no agreed emission scenario for this kind of use. According to eCA, during impregnation process and storage it seems very unlikely that the product will be left exposed to wettering. Due to the type of formulation and the relative small volume produce, a reasonable approach is to consider that the treated product will dry in a ventilated area not exposed to wettering. Therefore, no environmentally relevant amount of emission to STP or surface water is to be expected.

***House scenario data*** 

**Calculations Soil and Water :**

* Volume of wet soil

HOUSEcircumference=2x(HOUSElengthxHOUSEwidth)

HOUSEcircumference=2x(17.5+7.5) = 50 m

Vsoil =HOUSEcircumferencexDISTANCEhorizontalxDEPTH

Vsoil=50x0.5x0.5= 12.5 m3 (According to agreed methodology, the depth of the soil should be 0.5m)

AREATermifilmFlex =

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

AREATermifilmFlex = [( (Lhouse+lhouse) x 2) x lTermfilmFlex ]

= [((17,5+7,5)x2)x0,2]

= 10 m²

* Qxleach,time2 = FLUXServiceLifexTIMEServiceLife

Qxleach,time2 = 5,2x10-7x10950 = 5.6x10-3 kg.m-2

* Esoil,leach,time2=( AREATermifilmFlex x Qxleach,time2)/ TIME2

Esoil,leach,time2 = (10x3.8x10-3)/10950 = 3.47x10-6 [kg.d-1]

Termifilm FLEX is used for the construction of the house. Only the releases due to leaching from Termifilm FLEX are taken into consideration and Clocalsoil,applic=0

Derived from “OECD SERIES ON EMISSION SCENARIO DOCUMENTS - Number 2 - Revised Emission Scenario Document for Wood Preservatives” (27 sept 2013) - 3.4.1.2 Time dependent concentrations in soil) :



* Clocalsoil, time2 = 3.47x10-6 /(12.5x1700x0.00654)+(1/(0.00654x10950))x (-3.47x10-6/(12.5x1700x0.00654))x(1-e-10950 x 0.00654)

= 3.68x10-8 [kg.kgwwt-1]

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

Permethrin

Concentration of Permethrin in soil = 3.68x10-8 x 73.7% = 2.78x10-8 [kg.kgwwt-1]

For more details, please see the confidential version of the PAR.

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

|  |  |
| --- | --- |
| **Substance** | **PECsoil [kg.kgwwt-1]** |
| Permethrin | 2.78x10-8 |
| DCVA | 2.2x10-9 |
| PBA | 3.02x10-9 |

*Local concentration in water during the service life period*

*ESTP,time2=( AREATermifilmFlex x Qxleach,time2) / TIME2*

*ESTP,time2=10x3.8x10-3/10950 = 3.47x10-6kg.d-1*

PECSTPtime2 = 5.24x 10-6 mg/l

PECWater*=* 5.04x10-10 mg/l

***Calculated PEC values***

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECseawater** | **PECseased** | **PECsoil** | **PECGW1** | **PECair** |
| [mg/m3] | [mg/l] | [mg/kgwwt] | [mg/l] | [mg/kgwwt] | [kg/kg] | [μg/l] | [mg/m3] |
| Scenario 1; tier I | 1.16x10-4 | 1.58x10-5 | 2.95x 10-11 | / | / | 8.60x10-8 | / | / |
| Scenario 1; tier II | 2.2x10-8 | 2.15x10-9 | / | / | / | 1.18x10-4 | / | / |
| Scenario 2 | 5.24x 10-6 | 5.04x 10-10 | 2.95x10-7 | / | / | 2.78x10-8 | / | / |
| 1 If the PECGW was calculated by using a simulation tool (e.g. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table. | | | | | | | | |

***Primary and secondary poisoning***

Not relevant

#### Risk characterisation

##### Atmosphere

Conclusion:

No risk is foreseen for the air compartment based on the form to which the product is supplied and used.

##### Sewage treatment plant (STP)

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
|  | **PEC/PNECSTP** |
| Scenario 1 | 7.04 x 10-6 |
| Scenario 2 | 1.06x 10-3 |

Conclusion:

No risk has been calculated for the STP compartment following production and use of the product TERMIFILM FLEX

##### Aquatic compartment

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** | **PEC/PNECseawater** | **PEC/PNECseased** |
| Scenario 1, tier I | 33.5 | 1.36x 10-7 | / | / |
| Scenario 1, tier II | 4.58x10-3 | / | / | / |
| Scenario 2 | 1.11x 10-03 | 1.36 x10-3 | / | / |

Conclusion:

Acceptable risks have been identified for the aquatic compartment

##### Terrestrial compartment

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values** | |
|  | **PEC/PNECsoil** |
| Scenario 1, tier I | 9.81 |
| Scenario1, tier II | 1.34x10-3 |
| Scenario 2 | 3.1x10-1 |

Conclusion:

Acceptable risks have been identified for the terrestrial compartment

##### Groundwater

The applicant has provided the following calculation for ground water assessment.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Emission calculation parameters  In the absence of appropriate scenario, exposure assessment of Permethrin from TERMIFILM FLEX has been determined with FOCUS-PEARL software according to OECD SERIES ON EMISSION SCENARIO DOCUMENTS, Number 2, Revised Emission Scenario Document for Wood Preservatives, September 2013, p. 170.  According to Permethrin Assessment Report, Inclusion of active substances in the positive list to Regulation (EU) No 528/2012, Ireland, April 2014, the degradation of Permethrin in soil and in the aquatic systems leads to formation of DCVA (2,2-dimethyl-3-(2,2-dichlorovinyl) cyclopropane carboxylic acid) and PBA (3-phenoxybenzoic acid) as the principal metabolites. In this risk assessment, those metabolites have been taken into account in the following observed levels reported in Permethrin Assessment Report:  DCVA   |  |  |  | | --- | --- | --- | |  | DCVA | PBA | | Maximum observed levels in the soil compartment | 11.3% | 15.0% | | Maximum observed levels in the water compartment | 62.6% | 28.8% |   TERMIFILM FLEX is a treated article (polyester fibre with a fine mesh coated with a PVC resins), containing 1,6% w/w or 3,8 g/m² of Permethrin.  **1) Tier 1**  For Tier 1 groundwater emission calculations, according to the 2nd EU Leaching Workshop, Varese, Italy, June 2013, it was assumed that 100% of active substance has been leached after long time assessment period.  Therefore the application rate of Permethrin introduced in FOCUS-PEARL software for Tier 1 groundwater emission calculation is 3,8 g/m² (38 Kg/ha).  The target depth has been assumed to be 1m (FOCUS-PEARL default value).  **2) Tier** 2  For more details, please see the confidential version of the PAR.  Other Physical and Chemical parameters of Permethrin used in the FOCUS-PEARL groundwater emission calculation from TERMIFILM FLEX are from Permethrin Assessment Report, Inclusion of active substances in the positive list to Regulation (EU) No 528/2012, Ireland, April 2014.  **Groundwater emission scenario**  **Apples-Châteaudun emission scenario**  For Tier 2, the target depth has been assumed to be 4.5m (the maximum realistic depth authorized in FOCUS-PEARL software scenario).  In this risk assessment 3 emission scenarios have been considered on the crop of Apples, Potatoes and Vines in the location of Châteaudun (the location in France available in FOCUS-PEARL among locations where irrigation is possible).  **Result for Tier 1**  The average concentration of Permethrin in groundwater is 1.832 mg/L, according to FOCUS-PEARL report. Refer to ANNEX I.  Due to Permethrin degradation in water leading to DCVA (observed level: 62.6%) and PBA (observed level 28.8%) as principal metabolites, it has been assumed that 8.6% of Permethrin concentration left in water.  Permethrin  Concentration of Permethrin in water = 1.832 x 8.6% = 0.157 [mg/L]  For more details, please see the confidential version of the PAR.  **Summary of estimated local concentration in water from Permethrin:**   |  |  | | --- | --- | | **Substance** | **PECwater [mg/L]** | | Permethrin | 0.157 | | DCVA | 0.613 | | PBA | 0.289 |   **Result for Tier 2**  The average concentration of Permethrin in groundwater is 2.32x10-5 mg/L, according to FOCUS-PEARL report. Refer to ANNEX I.  Due to Permethrin degradation in water leading to DCVA (observed level: 62.6%) and PBA (observed level 28.8%) as principal metabolites, it has been assumed that 8.6% of Permethrin concentration left in water.  Permethrin  Concentration of Permethrin in water = 2.32x10-5 x 8.6% = 2 x10-6 [mg/L]  For more details, please see the confidential version of the PAR.  **Summary of estimated local concentration in water from Permethrin:**   |  |  | | --- | --- | | **Substance** | **PECwater [mg/L]** | | Permethrin | 2 x10-6 | | DCVA | 7.76x 10-6 | | PBA | 3.66 x10-6 |   **Potatoes-Châteaudun emission scenario**  **2.2.2.1. Result for Tier 1**  The average concentration of Permethrin in groundwater is 1.334 mg/L, according to FOCUS-PEARL report. Refer to ANNEX II.  Due to Permethrin degradation in water leading to DCVA (observed level: 62.6%) and PBA (observed level 28.8%) as principal metabolites, it has been assumed that 8.6% of Permethrin concentration left in water.  Permethrin  Concentration of Permethrin in water = 1.334 x 8.6% = 0.115 [mg/L]  For more details, please see the confidential version of the PAR.   |  |  | | --- | --- | | **Summary of estimated local concentration in water from Permethrin: Substance** | **PECwater [mg/L]** | | Permethrin | 0.115 | | DCVA | 0.446 | | PBA | 0.21 |   Result for Tier 2  The average concentration of Permethrin in groundwater is 1.65x10-5 mg/L, according to FOCUS-PEARL report. Refer to ANNEX II.  Due to Permethrin degradation in water leading to DCVA (observed level: 62.6%) and PBA (observed level 28.8%) as principal metabolites, it has been assumed that 8.6% of Permethrin concentration left in water.  Permethrin  Concentration of Permethrin in water = 1.65x10-5 x 8.6% = 1.42 x 10-6 [mg/L]  For more details, please see the confidential version of the PAR.  **Summary of estimated local concentration in water from Permethrin:**   |  |  | | --- | --- | | **Substance** | **PECwater [mg/L]** | | Permethrin | 1.42 x 10-6 | | DCVA | 5.52 x 10-6 | | PBA | 2.60 x 10-6 |   Châteaudun emission scenario  **Result for Tier 1**  The average concentration of Permethrin in groundwater is 2.024 mg/L, according to FOCUS-PEARL report. Refer to ANNEX III.  Due to Permethrin degradation in water leading to DCVA (observed level: 62.6%) and PBA (observed level 28.8%) as principal metabolites, it has been assumed that 8.6% of Permethrin concentration left in water.  Permethrin  Concentration of Permethrin in water = 2.024 x 8.6% = 0.174 [mg/L]  For more details, please see the confidential version of the PAR.   |  |  | | --- | --- | | **Summary of estimated local concentration in water from Permethrin: Substance** | **PECwater [mg/L]** | | Permethrin | 0.174 | | DCVA | 0.677 | | PBA | 0.319 |   Result for Tier 2  The average concentration of Permethrin in groundwater is 2.735x10-5 mg/L, according to FOCUS-PEARL report. Refer to ANNEX III.  Due to Permethrin degradation in water leading to DCVA (observed level: 62.6%) and PBA (observed level 28.8%) as principal metabolites, it has been assumed that 8.6% of Permethrin concentration left in water.  Permethrin  Concentration of Permethrin in water = 2.735x10-5 x 8.6% = 2.35 x 10-6 [mg/L]  For more details, please see the confidential version of the PAR.   |  |  | | --- | --- | | **Summary of estimated local concentration in water from Permethrin: Substance** | **PECwater [mg/L]** | | Permethrin | 2.35 x 10-6 | | DCVA | 9.15 x 10-6 | | PBA | 4.31 x 10-6 |   **RISK CHARACTERISATION**   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **FOCUS-PEARL Scenario** | **Active substance** | | **PECwater [mg/L]** | **PNECwater [mg/L]** | 𝐏𝐄𝐂 𝐏𝐍𝐄𝐂 | | Σ𝐏𝐄𝐂 𝐏𝐍𝐄𝐂 | | **Tier 1** | | | | | | | | | Apple-Châteaudun | Permethrin | | 0,157 | 5,85E-02 | 2,68E+00 | | **1,82E+01** | | DCVA | | 0,613 | | 5,77E-02 | | 1,06E+01 | | | PBA | | 0,289 | | 5,86E-02 | | 4,93E+00 | | | Potatoes-Châteaudun | Permethrin | | 0,115 | 5,85E-02 | 1,97E+00 | | **1,33E+01** | | DCVA | | 0,446 | | 5,77E-02 | | 7,73E+00 | | | PBA | | 0,210 | | 5,86E-02 | | 3,58E+00 | | | Vines-Châteaudun | Permethrin | | 0,174 | 5,85E-02 | 2,97E+00 | | **2,02E+01** | | DCVA | | 0,677 | | 5,77E-02 | | 1,17E+01 | | | PBA | | 0,319 | | 5,86E-02 | | 5,44E+00 | | | **Tier 2** | | | | | | | | | Apple-Châteaudun | Permethrin | | 2,00E-06 | 5,85E-02 | 3,42E-05 | | **2,31E-04** | | DCVA | | 7,76E-06 | | 5,77E-02 | | 1,34E-04 | | | PBA | | 3,66E-06 | | 5,86E-02 | | 6,25E-05 | | | Potatoes-Châteaudun | Permethrin | | 1,42E-06 | 5,85E-02 | 2,43E-05 | | **1,64E-04** | | DCVA | | 5,52E-06 | | 5,77E-02 | | 9,57E-05 | | | PBA | | 2,60E-06 | | 5,86E-02 | | 4,44E-05 | | | Vines-Châteaudun | Permethrin | | 2,35E-06 | 5,85E-02 | 4,02E-05 | | **2,72E-04** | | DCVA | | 9,15E-06 | | 5,77E-02 | | 1,59E-04 | | | PBA | | 4,31E-06 | | 5,86E-02 | | 7,35E-05 | |   PNECwater values used above in risk characterisation are issued from Permethrin Assessment Report, Inclusion of active substances in the positive list to Regulation (EU) No 528/2012, Ireland, April 2014, p. 49. Only the lowest PNECwater values have been used in order to consider the worst case.  Conclusion on ground water assessment:  As reported above in tier 1 the product TERMIFILM FLEX represents unacceptable risk for groundwater as results of ΣPEC PNEC are higher than 1 for the 3 considered FOCUS-PEARL Scenario. Tier 1 assessment is representative of the worst case and doesn’t represent the realistic case of TERMIFILM FLEX application.  The realistic case of TERMIFILM FLEX application is represented by Tier 2 assessment parameters. According to risk characterisation results for Tier 2, there is no unacceptable risk for groundwater as all ΣPEC PNEC are lower than 1.  Therefore, the product TERMIFILM FLEX doesn’t represent unacceptable risk for groundwater compartment according to FOCUS-PEARL software emission scenarios. |

For more details, please see the confidential version of the PAR.

The outcome of the focus scenario should be compared with the trigger value of 0.1µg/l. For Tier 2, all the value are below the trigger value and the risk is acceptable.

##### Primary and secondary poisoning

###### Primary poisoning

Not relevant

###### Secondary poisoning

Not relevant

##### Mixture toxicity

Not relevant

##### Aggregated exposure (combined for relevant emission sources)

Not relevant

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| TERMIFILM FLEX is an innovative film to be placed during construction of building in the basement in order to form a barrier against termite. According to the evaluation performed, no risk has been identified for the environment. |

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

Wearing of PPE (protective gloves and clothes) is mandatory.

For more details, please see relevant sections of the risk assessment.

### Assessment of a combination of biocidal products

Not relevant

### Comparative assessment

Not relevant

# Annexes

## List of studies for the biocidal product

For more details, please see the confidential version of the PAR.

## Output tables from exposure assessment tools

3.2.1 Human exposure

For more details, please see the confidential version of the PAR.

## New information on the active substance

No new data were submitted.

## Residue behaviour

Not relevant.

## Summaries of the efficacy studies

Please refer to the table ***2.2.5.5.1 summary of experimental data.***

## Confidential annex

Please see separate document.

## Other: Application processes of TERMIFILM FLEX and emission scenarios

*Process description*

For more details, please see the confidential version of the PAR.