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)



VITOMIT BOULES ANTI-MITES

Product type 18

Transfluthrin

Case Number in R4BP: BC-VR020904-15

Evaluating Competent Authority: France

Date: March 2018

Updated: February 2021

Table of Contents

[Table of Contents 2](#_Toc65140558)

[*1* CONCLUSION 5](#_Toc65140559)

[*2* ASSESSMENT REPORT 7](#_Toc65140560)

[2.1 Summary of the product assessment 7](#_Toc65140561)

[2.1.1 Administrative information 7](#_Toc65140562)

[**2.1.1.1** Identifier of the product 7](#_Toc65140563)

[**2.1.1.2** Authorisation holder 7](#_Toc65140564)

[**2.1.1.3** Manufacturer(s) of the products 7](#_Toc65140565)

[**2.1.1.4** Manufacturer(s) of the active substance(s) 7](#_Toc65140566)

[2.1.2 Product composition and formulation 8](#_Toc65140567)

[**2.1.2.1** Identity of the active substance 8](#_Toc65140568)

[2.1.2.2 Candidate(s) for substitution 8](#_Toc65140569)

[**2.1.2.3** Qualitative and quantitative information on the composition of the biocidal product 9](#_Toc65140570)

[2.1.2.4 Information on technical equivalence 9](#_Toc65140571)

[2.1.2.5 Information on the substance(s) of concern 9](#_Toc65140572)

[2.1.2.6 Type of formulation 9](#_Toc65140573)

[2.1.3 Hazard and precautionary statements 9](#_Toc65140574)

[2.1.4 Authorised use(s) 10](#_Toc65140575)

[2.1.4.1 Use description 10](#_Toc65140576)

[2.1.4.2 Use-specific instructions for use 10](#_Toc65140577)

[2.1.4.3 Use-specific risk mitigation measures 10](#_Toc65140578)

[2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 11](#_Toc65140579)

[2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging 11](#_Toc65140580)

[2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 11](#_Toc65140581)

[2.1.5 General directions for use 11](#_Toc65140582)

[2.1.5.1 Instructions for use 11](#_Toc65140583)

[2.1.5.2 Risk mitigation measures 11](#_Toc65140584)

[2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 11](#_Toc65140585)

[2.1.5.4 Instructions for safe disposal of the product and its packaging 11](#_Toc65140586)

[2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage 12](#_Toc65140587)

[2.1.6 Other information 12](#_Toc65140588)

[2.1.7 Packaging of the biocidal product 12](#_Toc65140589)

[2.1.8 Documentation 12](#_Toc65140590)

[2.1.8.1 Data submitted in relation to product application 12](#_Toc65140591)

[2.1.8.2 Access to documentation 13](#_Toc65140592)

[2.2 Assessment of the biocidal product 13](#_Toc65140593)

[2.2.1 Intended use(s) as applied for by the applicant 13](#_Toc65140594)

[2.2.2 Physical, chemical and technical properties 14](#_Toc65140595)

[2.2.3 Physical hazards and respective characteristics 20](#_Toc65140596)

[2.2.4 Methods for detection and identification 25](#_Toc65140597)

[2.2.5 Efficacy against target organisms 26](#_Toc65140598)

[2.2.5.1 Function and field of use 26](#_Toc65140599)

[2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected 26](#_Toc65140600)

[2.2.5.3 Effects on target organisms, including unacceptable suffering 27](#_Toc65140601)

[2.2.5.4 Mode of action, including time delay 27](#_Toc65140602)

[2.2.5.5 Efficacy data 27](#_Toc65140603)

[2.2.5.6 Occurrence of resistance and resistance management 30](#_Toc65140604)

[2.2.5.7 Known limitations 30](#_Toc65140605)

[2.2.5.8 Evaluation of the label claims 30](#_Toc65140606)

[2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s) 30](#_Toc65140607)

[2.2.6 Risk assessment for human health 31](#_Toc65140608)

[**2.2.6.1** Assessment of effects on Human Health 31](#_Toc65140609)

[2.2.6.2 Exposure assessment 36](#_Toc65140610)

[2.2.6.3 Risk characterisation for human health 45](#_Toc65140611)

[2.2.7 Risk assessment for animal health 48](#_Toc65140612)

[2.2.8 Risk assessment for the environment 48](#_Toc65140613)

[2.2.8.1 Effects assessment on the environment 48](#_Toc65140614)

[PNEC surface water for transfluthrin 49](#_Toc65140615)

[PNEC sediment for transfluthrin 49](#_Toc65140616)

[PNEC soil for transfluthrin 50](#_Toc65140617)

[2.2.8.2 Exposure assessment 55](#_Toc65140618)

[**2.2.8.3** Risk characterisation 63](#_Toc65140619)

[2.2.9 Conclusion 66](#_Toc65140620)

[2.2.10 Measures to protect man, animals and the environment 67](#_Toc65140621)

[2.2.11 Assessment of a combination of biocidal products 68](#_Toc65140622)

[2.2.12 Comparative assessment 68](#_Toc65140623)

[*3* Annexes 69](#_Toc65140624)

[3.1 List of studies for the biocidal product 69](#_Toc65140625)

[3.2 Output tables from exposure assessment tools 70](#_Toc65140626)

[3.3 New information on the active substance 70](#_Toc65140627)

[3.4 Residue behaviour 70](#_Toc65140628)

[3.5 Summaries of the efficacy studies (B.5.10.1-xx) 70](#_Toc65140629)

[3.6 Confidential annex 70](#_Toc65140630)

[3.7 Other 70](#_Toc65140631)

**Note to the reader**

This PAR has been updated with the post-authorisation data provided by the applicant and is based on the PAR of the first authorisation.

In this consolidated PAR, the assessments related to the post authorisation data of the product are at the end of the concerned section and are highlighted in grey.

The SPC (in the first section of the PAR) corresponds to the currently authorised uses in France.

**History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | *FR* | *BC-VR020904-15* | 04.04.2018 | Initial assessment |
| 2021 | Post authorisation data assessment |

# CONCLUSION

The product VITOMIT BOULES ANTI-MITES is to be used as insecticide against cloth moths, carpet beetlesand house dust mites.

Tablets of product should be placed in closets or drawers by non-professional users.

* *Physico-chemical properties*

The product VITOMIT BOULES ANTI-MITES is a tablet (TB) formulation. The appearance of the product is a white round tablet with a characteristic odour.

An accelerated storage study 2weeks at 54°C is provided. The stability data indicate a shelf life of at least 2 years when stored in PET+PP packaging. Nevertheless, a long term storage study at ambient temperature should be provided to confirm the stability of product. The product is neither flammable nor auto-flammable. It has no explosive and no oxidizing properties.

The analytical method is fully validated for the determination of the active substance transfluthrin in the product.

* **Post-authorisation 2021**

Long-term storage stability study shows that after 4 years at ambient temperature, the product VITOMIT BOULES ANTI-MITES remains stable. Consequently, the shelf life of the product is maintained at 2 years.

* *Efficacy assessment*

In accordance with the submitted test and the requirements of the TNsG on product evaluation for PT18/19[[1]](#footnote-1), the product VITOMIT BOULES ANTI-MITESis efficient against cloth moths *Tineola bisselliella* and carpet beetles *Anthrenus verbasci* (adults, larvae and eggs) and house dust mites *Dermatophagoides pteronyssinus* (adults and nymphs)at the application rate of 10 tablets (62 g of product) for 0.5 m3 and up to 4 months.

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

* *Risk assessment for human health*

The risk for non-professional users is acceptable during application of the product. The risk for adult and children is acceptable during secondary exposure.

* *Risk for consumers via residues*

For indoor uses by non-professional in closets and drawers, no specific residue data were submitted in the context of this dossier.

No direct or indirect contamination of food is expected. Nevertheless, to avoid any contamination, the following precautionary statements are proposed:

“Avoid direct or indirect contact with food, feed and drinks”

* *Risk assessment for environment*

The environmental risk assessment for VITOMIT BOULES ANTI-MITES is performed according to the ‘Diffuser’ scenario provided in the Emission Scenario Document for “insecticides, acaricides and products to control other arthropods for household and professional users”, (OECD, 2008). The same approach was adopted for a similar product in the Transfluthrin Assessment Report (2014) and updated with the recent discussions in WGIV2017.

PEC/PNEC values are calculated for all relevant exposed compartments for both the active substance and relevant metabolites considering the last conclusions of the technical meeting WGIV2017 including new PNECs for the active substance and harmonized parameters in the environmental exposure assessment.

For STP, surface water, sediment, soil and secondary poisoning, the calculated PEC/PNEC values for the active substance are below 1.

The risk assessment leads to acceptable risks in the STP and water for both metabolites TFB-OH and TFB-COOH, and in soil and groundwater for the last one.

Groundwater concentrations are below the threshold value of 0.1 µg/L for the active substance and relevant metabolites.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| VITOMIT BOULES ANTI-MITES | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Relevi S.p.A |
| **Address** | Via Postumia 146040 Rodigo (Mantova)Italy |
| **Authorisation number** | **FR-2018-0013** |
| **Date of the authorisation** | **04/04/2018** |
| **Expiry date of the authorisation** | **03/04/2028** |

#### Manufacturer(s) of the products

|  |  |
| --- | --- |
| **Name of manufacturer** | Relevi S.p.A |
| **Address of manufacturer** | Via Postumia 146040 Rodigo (Mantova)Italy |
| **Location of manufacturing sites** | Via Postumia 146040 Rodigo (Mantova)Italy |

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

|  |  |
| --- | --- |
| **Active substance** | Transfluthrin |
| **Name of manufacturer** | Bayer SAS Environmental Science |
| **Address of manufacturer** | 16 rue Jean-Marie LeclairCS 9010669266 Lyon Cedex 09France |
| **Location of manufacturing sites** | Bayer Vapi Private Limited (Formerly Bilag Industries Pvt. Ltd.) Plot No.306/3 Phase II G.I.D.C.Vapi 396195 GujaratIndia |

### 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 [x]

#### Identity of the active substance

|  |
| --- |
| **Main constituent(s)** |
| **ISO name** | Transfluthrin |
| **IUPAC or EC name** | 2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)- 2,2-dimethylcyclopropanecarboxylate or,2,3,5,6-tetrafluorobenzyl (1R)- trans-3-(2,2-dichlorovinyl)-2,2- dimethylcyclopropanecarboxylate |
| **EC number** | 405-060-5 |
| **CAS number** | 118712-89-3 |
| **Index number in Annex VI of CLP** | 607-223-00-8 |
| **Minimum purity / content** | 965 g/kg |
| **Structural formula** | Afficher l'image d'origine |

#### Candidate(s) for substitution

Not relevant

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

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Transfluthrin pure | (2,3,5,6-Tétrafluorophényl)acétate de (1S,3R)-3-(2,2-dichlorovinyl)-2,2-diméthylcyclopropyle | Active substance | 118712-89-3 | 405-060-5 | 0.03 |

#### Information on technical equivalence

Not relevant

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

There is no substance of concern in the biocidal product.

#### Type of formulation

|  |
| --- |
| Tablet (TB) |

### Hazard and precautionary statements

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

| **Classification** |
| --- |
| Hazard category | Aquatic Acute 1Aquatic Chronic 1 |
| Hazard statement | H400: Very toxic to aquatic life.H410: Very toxic to aquatic life with long lasting effects. |
|  |
| **Labelling** |
|  |  |
| Signal words | Warning |
| Hazard statements | H410: Very toxic to aquatic life with long lasting effects. |
| Precautionary statements | P273: Avoid release to the environmentP391: Collect spillageP501: Dispose of contents/container in accordance with local/regional/national/international regulation. |
|  |
| Note | **-** |

|  |
| --- |
| **Box 1- FR CA position:****Specific note from FR-CA about the product classification:**The classification presented above is in accordance with the applicant proposal. However, FR CA would like to underline that this classification takes into account a new data set for the active substance which were not submitted for this product authorization dossier. If the data set from the CAR (Transfluthrin (CAS n°:118712-89-3), RMS NL, 2014.) is used for the classification, the product is classified H400-H412. Thus according to the Guidance on the Application of the CLP Criteria Version 4.1 – June 2015, the labelling is H410. |

### Authorised use(s)

#### Use description

Table 1. Use # 1 – Insecticide (Anti moth, carpet beetles and mites) for domestic use

|  |  |
| --- | --- |
| **Product Type** | TP 18 |
| **Where relevant, an exact description of the authorised use** | Insecticide (Anti moth, carpet beetles and mites) for domestic use |
| **Target organism (including development stage)** | * Cloth moths : *Tineola bisselliella*
* carpet beetles : *Anthrenus verbasci* (adults, larvae and eggs)
* House dust mites : *Dermatophagoides pteronyssinus* (adults and nymphs)
 |
| **Field of use** | Indoor use : in cabinets and drawers |
| **Application method(s)** | Passive vaporiser |
| **Application rate(s) and frequency** | 10 tablets/0.5 m3The product remains efficacious up to 4 months. |
| **Category(ies) of users** | Non-professional users |
| **Pack sizes and packaging material** | Sachet of 275g (PET+PP)  |

#### Use-specific instructions for use[[2]](#footnote-2)

|  |
| --- |
| - |

#### Use-specific risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

###

### General directions for use

#### Instructions for use[[3]](#footnote-3)

|  |
| --- |
| * In cabinet: place the tablets on the base of the cabinet or between the leaders to protect. For drawers: place the tablets on the side of the tray.
* Always read the label or leaflet before use and respect follow all the instructions provided.
* The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.
 |

#### Risk mitigation measures

|  |
| --- |
| * Avoid direct or indirect contact with food, feed and drinks
 |

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

|  |
| --- |
|  |

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

|  |
| --- |
| * Remove the entire unused product after the end of treatment for its disposal.
* Dispose of unused product, its packaging and all other waste in accordance with local regulations.
* Do not discharge unused product, into a water course, into the sink, on the ground or down the drain and into the environment.
 |

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

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

### Other information

|  |
| --- |
| * The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA)
 |

### 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)** |
| Sachet | 275g | PET+PP | / | non-professional | Not demonstrated |

The product is composed by a dual layer sachet (PET+PP) which contains the unpackaged tablets.

Characteristics of the product

|  |  |  |  |
| --- | --- | --- | --- |
| **Sachet** | **Number of tablets per sachet** | **Weight of one tablet (g)** | **mass of active substance in one tablet (mg)** |
| 275g | 44 | 6.2 | 1.86mg of active substance in one tablet |

### Documentation

#### Data submitted in relation to product application

**Identity, physico-chemical and analytical method data**

Physico-chemical properties studies and analytical methods on the biocidal product VITOMIT BOULES ANTI-MITES were provided by Relevi S.p.A.

**Efficacy data**

Simulated use test with the product VITOMIT BOULES ANTI-MITES (0.03 % w/w transfluthrin), at opening, 2 months and 4 months after opening, according to CEB 135 bis*[[4]](#footnote-4)* method modified performed on cloth moths Tineola bisselliella, carpet beetles Anthrenus verbasci and house dust mites Dermatophagoides pteronyssinus.

**Toxicology and Ecotoxicology data**

* Product

Please refer to the reference list contained in Annex 3.1.

* Active Substance

Please refer to Annex 3.3 for a list of additional studies, supplied by the Active Substance data holder, not contained within the Transfluthrin Assessment Report.

**Residue data**

No specific residue data were submitted in the context of this dossier. The product VITOMIT BOULES ANTI-MITES is intended to be applied by non-professional users in closets and drawers. VITOMIT BOULES ANTI-MITES will not get in contact with food, feed and drink. Residue in food, feed and drink are not expected.

#### Access to documentation

Relevi S.p.A has access to data on the active substance Transfluthrin with a Letter of Access of Bayer SAS, one applicant of the active substance Transfluthrin.

## Assessment of the biocidal product

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

Table 1. Intended use # 1 – Insecticide for domestic uses

|  |  |
| --- | --- |
| Product Type(s) | PT18 |
| Where relevant, an exact description of the authorised use | Insecticide (Anti moth and mites) for domestic use |
| Target organism (including development stage) | Cloth moth *Tineola bisselliella*, carpet beetles *Anthrenus verbasci* and house dust mite *Dermatophagoides pteronyssinus* |
| Field of use | Indoor use |
| Application method(s) | For cabinet: Place the tablets on the base of the cabinet or between the leaders to protect. For drawers: place the tablets on the side of the tray. |
| Application rate(s) and frequency | 10 pieces in 0.5 m3Replace the product after 4 months, ie after one season. |
| Category(ies) of user(s) | Non-professional users |
| Pack sizes and packaging material | Packaging: plastic sachet containing 44 tablets. |

### Physical, chemical and technical properties

The biocidal product is not the same as the one assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC. The composition of the product is confidential and is presented in a confidential annex.

The product contains 0.0311% of technical active substance and 0.03% of pure active substance (purity: 96.5%).

The product does not contain PT6 preservative.

The product is not diluted for use.

Hydrocarbon and H304 co-formulant content: None.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| Physical state at 20 °C and 101.3 kPa | Visual inspection of product | Biocide tablet with transfluthrin at 0.05%Batch: 5H2002 | white round tabletodour: lavender | Acceptable  | A.Meluso 2016S-2015-03516AM |
| Colour at 20 °C and 101.3 kPa |
| Odour at 20 °C and 101.3 kPa |
| Acidity / alkalinitypH (1%w/v) | CIPAC MT 75.3 | Biocide tablet with transfluthrin at 0.05%Batch: 5H2002 | pH (1%%w/v) : 8.07 at 20°C | Acceptable  | A.Meluso 2016S-2015-03516AM |
| Relative density / bulk density | */* | / | No data provided. | Acceptable.Not relevant for a TB formulation | */* |
| Storage stability test – accelerated storage | CIPAC method MT 46.3 | Naked tablets@0.03%Batch 12240/17B |

|  |  |  |
| --- | --- | --- |
|  | initial | After 2W at 54°C |
| Appareance | White tablets | White friable tablets |
| Appareance of packaging | Packaging : PET+adhesive+PP | No variation of initial (no leackage, no ballooning, no deformation, no paneling) |
| Content of active substance (method 2010/147Ami-1-MdP-Rev 1 -valdated)  | 0.026% | 0.027% |

 | Acceptable |  Belussi.C2017 |
| Storage stability test – long term storage at ambient temperature | / | / | No data provided. | No stability study has been provided by the notifier to demonstrate the stability of the product. Data required | / |
|  | Long term storage study has been provided in post-authorisation.Please refer to the paragraph below |  |
| Storage stability test – low temperature stability test for liquids | / | / | / | Not relevant as the product is a solid | / |
| Effects on content of the active substance and technical characteristics of the biocidal product - light | Statement | / | The active substances contained in the products does not absorb wavelengths greater than 290 nm. | Acceptable | / |
| Effects on content of the active substance and technical characteristics of the biocidal product – temperature and humidity | / | / | No data provided. | No data provided | /  |
| Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material | / | / | No data provided. | No data provided | */* |
| Wettability | / | / | / | Not relevant as the product is a solid | / |
| Suspensibility, spontaneity and dispersion stability | / | / | / | Not relevant as the product is a solid | / |
| dry sieve test | CIPAC MT 59.1 | Biocide tablet with transfluthrin at 0.05%Batch: 5H2002 | Dry sieve test : 0.0% on 45µm0.04% on 150µm | Acceptable  | A.Meluso 2016S-2015-03516AM |
| Emulsifiability, re-emulsifiability and emulsion stability | / | / | / | Not relevant as the product is a solid | / |
| Disintegration time | */* | */* | */* | Not relevant considering the use of the product  | */* |
| Particle size distribution, content of dust/fines, attrition, friability | / | / | / | Not relevant for a TB formulation | / |
| Persistent foaming | / | / | / | Not relevant as the product is a solid | / |
| Flowability/Pourability/Dustability | / | / | / | Not relevant for a TB formulation | / |
| Burning rate — smoke generators | / | / | / | Not relevant as the product is a solid | / |
| Burning completeness — smoke generators | / | / | / | Not relevant as the product is a solid | / |
| Composition of smoke — smoke generators | / | / | / | Not relevant as the product is a solid. | / |
| Spraying pattern — aerosols | / | / | / | Not relevant as the product is a solid | / |
| Physical compatibility | */* | / | The product is provided to be used alone, not in combination with other biocides. | Acceptable | / |
| Chemical compatibility | */* | / | The product is provided to be used alone, not in combination with other biocides. | Acceptable | / |
| Degree of dissolution and dilution stability | / | / | / | The product is a Tablet, is not a liquid formulation. The test is not applicable.Acceptable. | / |
| Surface tension | / | / | The product is a Tablet, is not a liquid formulation. The test is not applicable | Acceptable | / |
| Viscosity | / | / | The product is a Tablet, is not a liquid formulation. The test is not applicable. | Acceptable | / |

* **Post-authorization data provided on January 2021 (4 years storage stability):**

|  |  |  |  |
| --- | --- | --- | --- |
| Guideline and method | Results | Reference | Comment |
| Technical monograph N°.17For AS content:Method 2010/147 Ami-1-MdP-Rev.1 (already validated) |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | T0 | T6 | T12 | T18 | T24 | T36 | T48 |
| Appearance of test item | White tablets | No change | White tablets partially shattered | White tablets partially shattered | White tablets partially shattered | White tablets partially shattered | White tablets partially shattered |
| Appearance of the packaging | Transparent sachet (PET (12 micron) + adhesive + PP (50 micron) | No variation from initial | No variation from initial | No variation from initial | No variation from initial | No variation from initial | No variation from initial |
| Weight loss % | - | 3.57% | 2.29% | 3.69% | 2.19% | 4.46% | 6.54% |
| Content of AS transfluthrin (%w/w) | 0.0293% w/w | 0.0286% w/w | 0.0276% w/w | 0.0273% w/w | 0.0288% w/w | 0.0283% w/w | 0.0286% w/w |
| variation | - | 97.6% of T0 | 94.2% of T0 | 93.2% of T0 | 98.3% of T0 | 96.6% of T0 | 97.6% of T0 |

 | Study N° 2016/342 AM | Acceptable.Product is stable for 4 years in PET+adhesive+PP |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The product VITOMIT BOULES ANTI-MITES is a tablet (TB) formulation. The appearance of the product is a white round tablet with a characteristic odour. An accelerated storage study 2weeks at 54°C is provided. The stability data indicate a shelf life of at least 2 years when stored in PET+PP packaging. Nevertheless, a long term storage study at ambient temperature should be provided to confirm the stability of product.Storage of the product: 2 years* **Post-authorisation 2021**

Long-term storage study shows that after 4 years at ambient temperature in PET+adhesive+PP packaging, the product remains stable.Consequently, the shelf life of the product is kept at 2 years. Shelf life can only be increased in the frame of a minor change application. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Statement | */* | The product is not classified as explosive according to Annex I of Dir. 67/548/CEE and Reg. 1272/2008/CE. | Acceptable  | / |
| Flammable gases | */* | */* | */* | Not relevant as the product is a solid | */* |
| Flammable aerosols | */* | */* | */* | Not relevant as the product is a not an aerosol | */* |
| Oxidising gases | / | / | / | Not relevant as the product is a solid | */* |
| Gases under pressure | */* | */* | */* | Not relevant as the product is not a gas under pressure | */* |
| Flammable liquids | */* | */* | */* | Not relevant as the product is a solid |  |
| Flammable solids | EU Method A.10 | Biocide tablet with transfluthrin at 0.05%Batch: 161214 | In the preliminary test, the test strip was obtained piling a first layer of tablets in the mould and then piling a second layer over the first one but slightly shifted, in order to ensure the contact between the sample tablets. The test flame was applied for over two minutes. The testes sample did not ignite: only a few embers were observed on the part directly hit by flame. The tested sample slowly blackened and few bubbles were observed. According to test method A.10 the sample labelled as Biocide tablet with transfluthrin at 0.05% is not readly flammable. | Acceptable  | A. Mazzei 2015, report: 201502001 |
| Self-reactive substances and mixtures | Statement | VITOMIT BOULES ANTI-MITES | According to the CLP Reg, self-reactive substance or mixtures are thermally unstable liquid or solid substances or mixtures liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). There are no chemical groups present in the molecule associated with explosive or self-reactive properties. For this reason, the study was waived.  | Acceptable  | / |
| Pyrophoric liquids | */* | */* | */* | Not relevant as the product is a solid | / |
| Pyrophoric solids | Statement | VITOMIT BOULES ANTI-MITES | According to section 2.10 of Annex I to the CLP Regulation the test was not performed. In fact the experience in manufacture and handling shows that is known to be stable at room temperature for prolonged periods of time. | Acceptable  | / |
| Self-heating substances and mixtures | Statement | VITOMIT BOULES ANTI-MITES | according to the CLP Regulation, a self-heating substance or mixture is a liquid or solid substance or mixture, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat; this substance or mixture differs from a pyrophoric liquid or solid in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days). The experience in manufacture and handling shows that the product is stable at room temperature for prolonged periods of time, and it does not react in contact with air. For this reason, the study was not performed. | Acceptable  | / |
| Substances and mixtures which in contact with water emit flammable gases | Statement | VITOMIT BOULES ANTI-MITES | According to the CLP Regulation, substances or mixtures which, in contact with water, emit flammable gases means solid or liquid substances or mixtures which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities. The product has not these characteristics, moreover the contact with water is not foreseen, in normal condition of use; the product consists in anti-mites tablets to be put into drawers or wardrobes. For these reasons, the study was not performed.  | Acceptable  | / |
| Oxidising liquids | / | / | / | Not relevant as the product is a solid | */* |
| Oxidising solids | Statement | / | The formulation doesn't show any oxidizing properties according to Annex I of Dir. 67/548/CEE and Reg. 1272/2008/CE. | Acceptable  | / |
| Organic peroxides | Statement | VITOMIT BOULES ANTI-MITES | In the formulation there are not co-formulants that are peroxides. The study is scientifically unjustified  | Acceptable  | / |
| Corrosive to metals | Statement | VITOMIT BOULES ANTI-MITES | The product is intended to be used in drawers/wardrobes; in normal condition of use, the contact with metal surfaces is not foreseen. For this reason the study was not performed.  | Acceptable  | / |
| Auto-ignition temperatures of products (liquids and gases) | */* | */* | */* | Not relevant as the product is a solid | */* |
| Relative self-ignition temperature for solids | EU Method A.16 | Biocide tablet with transfluthrin at 0.05%Batch: 161214 | The temperature-time curves show that there are no exothermic effects up to 400°C.  | Acceptable | A. Mazzei 2015, report: 201502001 |
| Dust explosion hazard | Statement | VITOMIT BOULES ANTI-MITES | According to "Guidance on the Biocidal Products Regulation Volume I: Identity/physico-chemical properties/analytical methodology – Part A: Information Requirements Version 1.1 November 2014", a dust explosion hazard is applicable to all powders and products containing, or able to produce, dust that can either ignite or explode when exposed to an ignition source when dispersed in air (relevant for particulates up to 1 mm in diameter). A relative self-ignition temperature for solids study was conducted, showing the product does not auto-ignited up to 400°C. For these reasons, the study was not performed.  | Acceptable  | / |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is neither flammable nor auto-flammable. It has no explosive and no oxidizing properties.  |

### Methods for detection and identification

Report: Validation of a GC method for the identification and quantification of the active ingredient transfluthrin in the test product PALL

Report no 2010/147/AM

Principle of the method:

The samples to be analysed were dissolved in acetone and were investigated by capillary column and by GC-FID technique.

The validation of this method was considered in compliance with SANCO/3030/99 rev.4.

Validation data:

|  |  |
| --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:* Solvent blank (acetone)
* Formulation blank
* Reference item of the active substance.

No interference was found: no peak appears in the solvent blank and in the formulation blank, one peak is observed at the same retention time for the reference item and test item. |
| Linearity | Linearity was studied by carrying out five concentrations between 0.02% to 0.06%. Calibration curve has been provided with a R2 higher than 0.99. |
| Compound | Linearity % |
| Active substance | Y = 0.0221x-0.0028R2 = 0.9999n=5 |
| Precision | Repeatability was evaluated by analyzing six test item solutions.  |
| Compound | Repeatability (RSD) |
| Active substance | RSD = 4.2% |
| Accuracy | Accuracy was determined by analysis of 3 reconstituted samples. The accuracy results are expressed as the recovery rate.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Fortification level % | Recovery rate | Mean recovery rate % | RSD (%) | n |
| 0.02 | 99.5 to 99.8 | 99.7 | 0.1 | 3 |
| 0.03 | 99.1 to 100.6 | 100.3 | 0.7 | 3 |
| 0.04 | 99.7 to 99.9 | 99.8 | 0.1 | 3 |
| 0.05 | 100.2 to 100.3 | 100.2 | 0.04 | 3 |
| 0.06 | 99.6 to 99.7 | 99.6 | 0.04 | 3 |

 |

The analytical method is fully validated for the determination of the active substance transfluthrin in the product.

Analytical methods for transfluthrin residues in soil, air, water (drinking water) and sediment are available in Assessment Report of transfluthrin. The applicant Relevi S.p.A has a Letter of Access from BAYER for these data.

As the active substance transfluthrin is not classified Toxic or Very Toxic, an analytical method for the determination of transfluthrin residue in human body fluids and tissues is unnecessary.

As the product VITOMIT BOULES ANTI-MITES is not intended to be used with surface in contact with food/feed of plant and animal origin, analytical method for the determination of transfluthrin residue in food/feed of plant and animal origin is unnecessary.

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The analytical method is fully validated for the determination of the active substance transfluthrin in the product.  |
| **Methods for monitoring of residues of active substance** |
| Analytical methods were provided at EU level for the determination of active substance residue in soil, water and air with respectively LOQ = 0.005mg/kg, 0.05µg/L and 0.5µg/m3.Active substance is not a toxic (T) nor very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required.The product is not intended to be used on surface in contact with food/feed of plant and animal origin, analytical method for the determination of active substance in food/feed of plant and animal origin is not required. |

### Efficacy against target organisms

#### Function and field of use

MG 03: Pest Control.

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

VITOMIT BOULES ANTI-MITES consists of tablets containing 0.03 % w/w of Transfluthrin, which evaporates at a suitable rate to provide an adequate level of protection.

The product is intended to be used indoor.

The continuous action of tablets has been developed to eliminate cloth moth *Tineola bisselliella*, carpet beetles *Anthrenus verbasci* and house dust mite *Dermatophagoides pteronyssinus* effectively for up to 4 months.

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

According to the uses claimed by the applicant, the product VITOMIT BOULES ANTI-MITESis intended to be used to control cloth moths *Tineola bisselliella* and carpet beetles *Anthrenus verbasci* (adults, larvae and eggs), and house dust mites *Dermatophagoides pteronyssinus* (adults and nymphs) indoor.

The products, organisms or objects to be protected are human health.

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

As described in the CAR, Transfluthrin is a synthetic pyrethroid which acts on harmful organisms by contact and ingestion. It expresses a strong knock-down effect, followed by mortality of insects.

#### Mode of action, including time delay

The active substance, Transfluthrin, is a broad spectrum insecticide which affects insect’s presynaptic voltage gate sodium channels in nerve membranes resulting in rapid knockdown. The active substance disrupts the transmission of nerve impulses at the nicotinic acetylcholine receptor leading to death of the pest.

#### Efficacy data

The applicant has submitted one simulated use test which is compliant with the requirements and criteria described in the section 11.2.2.2 for textile-attacking insects and in the section 8.2.2 for mites of TNsG on product evaluation for PT 18.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** |  |
| --- | --- |
| **Function and field of use envisaged** | **Test substance** | **Test organism** | **Test method / Test system / concentrations applied / exposure time**  | **Test results: effects** | **Reference** | **R.I** |
| Insecticide/AcaricideIndoor | TABLETS (0.03 % w/w of transfluthrin) = VITOMIT BOULES Anti-mites(1 tablet = 6.2 g) | Cloth moth(*Tineola bisselliella*)Carpet beetles(*Anthrenus verbasci*)House dust mite(*Dermatophagoides pteronyssinus*) | To assess the insecticide efficacy of evaporating product for use in volumes, a bioassay is carried out in a volume of 0.5 m3 simulating a wardrobe to protect from clothes moths, carpet beetles and house dust mites in simulated-use conditions.Tests were carried out against adult and larvae of cloth moths and carpet beetles60 adults/replicate30 larvae/replicate10 eggs of only cloth moths were tested/ replicate For house dust mites 200 adults and nymphs were tested. 5 replicates for each development stage were testedOnly 30 adults + 10 larvae x 5 replicates were monitored as untreated controls (difficulty to breed these insects)Bioassays and storage conditions: 22 +/- 2°C; 65+/- 5% RH; photoperiod 16h dark /8h light 700 luxThe same procedure and conditions for the samples of 2 and 4 months aged after opening.Pieces of wool were exposed to larvae of cloth moths and carpet beetles in the testing volume to check if there was any damage. Untreated controls were carried out with the same procedure and conditions.Application rate: 10 tablets (62 g)/0.5 m3 | **Table 1. Time of exposure to100 % of Knockdown or kill effect**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| TABLETS | 10 in 0.5 m3 | Targets\*\* | Developement stage | KT100\* opening | KT100+2 months | KT100+4 months |
| CM | Adults | 1h | 1h | 4h |
| CM | Larvae | 2h | 2h | 24h |
| CM | Eggs\*\*\* | Complete | Complete | Complete |
| CB | Adults | 1h | 1h | 24h |
| CB | Larvae | 2h | 2h | 24h |
| HDM | Adults + nymphs | 2h | 2h | 24h |

\*KT100 = Killing time 100 = time of exposure to 100 % of knockdown or kill effect\*\*CM = cloth moths CB = carpet beetle HDM = house dust mite\*\*\* For eggs, the mention ”complete” means there was no further developement after exposure**Table 2. Mean of % of mortality of untreated control after 24 h of exposure**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| TABLETS | 10 in 0.5 m3 | Targets | Developement stage | % M opening | %M+2 months | %M+4 months |
| CM | Adults | 2 | 0.7 | 2.7 |
| CM | Larvae | 0 | 0 | 0 |
| CB | Adults | 0 | 0 | 0 |
| CB | Larvae | 4 | 2 | 2 |
| HDM | Adults + nymphs | 2.5 | 1.9 | 1.5 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Table 3. Wool damages caused by larvae of cloth moths and carpet beetles (ISO 3998-1977 standard)\*\*\*\***TABLETS | Targets  | Opening | +2 months | +4 months |
| CM | 1A | 1A | 1A |
| CB | 1A | 1A | 1A |
| Untreated control | CM | 4D | 4D | 4D |
| CB | 4D | 4D | 4D |

\*\*\*\*The damages caused by insects were assessed according to the ISO 3998-1977 standard tables below:

|  |
| --- |
| Cropping |
| 1 | No detectable damage |
| 2 | Very slight visible cropping |
| 3 | Moderate cropping |
| 4 | Very heavy cropping |

|  |
| --- |
| Holes |
| A | No detectable damage |
| B | Yern or fibers partially severed |
| C | A few small holes; yarn or fibers severed |
| D | Several large holes |

**Conclusion**: According to the conditions of the test, the results show that at the application rate of 10 tablets (62 g of product) in a volume of 0.5 m3, the product provides a complete and fast killing efficacy against cloth moths *Tineola bisselliella* and carpet beetles *Anthrenus verbasci* (adults, larvae and eggs), and against house dust mites *Dermatophagoides pteronyssinus* (adults and nymphs).The larvae of cloths moths and carpet beetles were killed without damaging the wool parts. The efficacy remains complete 4 months after opening. | Serrano. BReport N° 1870a/1214 | 2 |

Regarding the claimed use “Anti moth and mites” (cloth moths *Tineola bisselliella*), carpet beetles *Anthrenus verbasci* and against house dust mites *Dermatophagoides pteronyssinus*)for domestic use, submitted efficacy data are compliant with the requirements of the TNsG PT 18. The results of simulated use test fulfilled the criteria of the TNsG PT 18

* for mites and moths (mortality ≥ 90 % for adults and larvae) and
* complete elimination of eggs for moths up to 4 months.

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| In accordance with the submitted test and the requirements of the TNsG on product evaluation for PT18 (2012), the product VITOMIT BOULES ANTI-MITES is efficient against cloth moths *Tineola bisselliella* and carpet beetles *Anthrenus verbasci* (adults, larvae and eggs), and against house dust mites *Dermatophagoides pteronyssinus* (adults and nymphs) at application rate of 10 tablets (62 g of product) in a volume of 0.5 m3 up to 4 months. |

#### Occurrence of resistance and resistance management

No reduction in efficacy was reported in the literature for such applications indicating that no development of resistance for the target species has occurred until now.

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

#### Known limitations

No efficacy limitations have been found if the product is used following the label use instructions.

#### Evaluation of the label claims

French competent authorities (FR CA) assessed that the product VITOMIT BOULES ANTI-MITES has shown a sufficient efficacy, for the following use claimed:

10 tablets (62 g of product) in a volume of 0.5 m3 against cloth moths *Tineola bisselliella* and carpet beetles *Anthrenus verbasci* (adults, larvae and eggs) and against house dust mites *Dermatophagoides pteronyssinus* (adults and nymphs) as an indoor treatment for non-professionals.

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

* In cabinet, place the tablets on the base of the cabinet or between the leaders to protect. For drawers: place the tablets on the side of the tray.
* Always read the label or leaflet before use and respect follow all the instructions provided.

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

The product VITOMIT BOULES ANTI-MITES is not intended to be used with an other biocidal product.

### Risk assessment for human health

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

No study performed with the product VITOMIT BOULES ANTI-MITES has been provided.

However, two skin corrosion studies performed with a product presenting a formulation comparable to the formulation of VITOMIT BOULES ANTI-MITES have been submitted. In this tested formulation, the content of active substance is 0.05% whereas for the product VITOMIT BOULES ANTI-MITES the content of a.s. is 0.03%. Consequently, it has been used as a worst-case for the assessment of the product VITOMIT BOULES ANTI-MITES.

|  |
| --- |
| **Summary table of in vitro studies on skin corrosion/irritation** |
| **Method,Guideline,****GLP status, Reliability** | **Test substance, Doses** | **Relevant information about the study** | **Results** | **Remarks** *(e.g. major deviations)* | **Reference** |
| OECD Guideline 431 (*In Vitro* Skin Corrosion: Human Skin Model Test)Reliability of 1GLP compliance | Transfluthrin, 0.05% | The tested sample containgin 0,05%. The composition of the tested product is identical to VITOMIT BOULES ANTI-MITES except for the active substance concentration (worst-case) | Negative | No deviation | B.Fiore, 2015*In vitro* SKIN CORROSION ON “BIOCIDE TABLETS WITH TRANSFLUTHRIN @ 0.05%” |
| OECD Guideline 439 (*In Vitro* Skin Irritation: Reconstructed Human Epidermis Test methodReliability of 1GLP compliance | B.Fiore,2015IN VITRO SKIN IRRITATION ON “BIOCIDE TABLETS WITH TRANSFLUTHRIN @ 0.05%”: RECONSTRUCTED HUMAN EPIDERMIS (RHE) TEST METHOD, |

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** |
| Value/conclusion | The tested product is not irritating and not corrosive to skin either. |
| Justification for the value/conclusion | According to the scores in the skin irritation study and to the percentage of viability after 3 minutes (100%) and after 1 hour (84.41%) in the corrosion study. |
| Classification of the product according to CLP  | No classification for skin corrosion and irritation of the biocidal product VITOMIT BOULES ANTI-MITES is required. |

***Eye irritation***

No *in vivo/in vitro* eye irritation test has been performed with VITOMIT BOULES ANTI-MITES and no human data are available.

The eye irritation potential of the biocidal product is therefore assessed by calculation considering the content of substances classified as eye irritant.

The biocidal product contains one formulant classified for eye irritation (H318 category 1) but at a concentration below the threshold value for classification. Therefore, no classification is required.

|  |
| --- |
| **Conclusion used in Risk Assessment – Eye irritation**  |
| Value/conclusion | Not classified as an eye irritant product. |
| Justification for the value/conclusion | By the calculation method, the content of substance classified for eye irritation is lower than the cut-off value of 3%. |
| Classification of the product according to CLP  | Not classified according to Regulation (EC) No 1272/2008 (CLP).  |

***Respiratory tract irritation***

No *in vivo/in vitro* respiratory tract irritation test has been performed with VITOMIT BOULES ANTI-MITES and no human data are available.

The respiratory tract irritation potential of the biocidal product is therefore assessed by calculation considering the content of substances classified as irritant for the respiratory tract.

The biocidal product does not contain substance classified for respiratory tract irritation (H335 category 3). Therefore, no classification is required.

|  |
| --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** |
| Justification for the conclusion | The product does not contain any substance classified for the irritation of the respiratory tract. |
| Classification of the product according to CLP  | Not classified as an irritant product for respiratory tract according to the Regulation (EC) No 1272/2008 (CLP).  |

***Skin sensitization***

No *in vivo*/*in vitro* skin sensitization test has been performed with VITOMIT BOULES ANTI-MITES and no human data are available.

The skin sensitization potential of the biocidal product is therefore assessed by calculation considering the content of substances classified as skin sensitizers.

VITOMIT BOULES ANTI-MITES contains only one substance classified for skin sensitization (H317 category 1) at content (0.65%), which is lower than the threshold value of 1%. Therefore, no classification for skin sensitization is required. Moreover, the concentration of each sensitizing formulant is lower than the threshold value for EUH 208 mention elicitation (0.1% for Skin Sens. 1 B). Therefore, no EUH 208 mention is required for the product.

|  |
| --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** |
| Value/conclusion | Not a skin sensitizer. |
| Justification for the value/conclusion | By calculation method, the content of substance classified for skin sensitization is lower than the threshold value of 1% from Regulation (EC) 1272/2008. Each formulant classified for skin senzitisation is lower than the threshold value of 0.1 % triggering the EUH 208 mention for Skin Sens. 1B. |
| Classification of the product according to CLP  | No classification for skin sensitization. |

***Respiratory sensitization (ADS)***

No *in vivo*/*in vitro* respiratory sensitization test has been performed with VITOMIT BOULES ANTI-MITES and no human data are available.

The respiratory sensitization potential of the biocidal product is therefore assessed by calculation considering the content of substances classified as respiratory sensitizers.

The biocidal product does not contain any substance classified for respiratory sensitization (H334). Therefore, no classification is required.

|  |
| --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** |
| Value/conclusion | Not classified |
| Justification for the value/conclusion | There is no component classified for respiratory sensitization.  |
| Classification of the product according to CLP  | The product does not require classification for respiratory sensitization according to Regulation (EC) No 1272/2008 (CLP). |

***Acute toxicity***

*Acute toxicity by oral route*

An acute toxicity study by oral route was performed with a formulation considered comparable to VITOMIT BOULES ANTI-MITES. However, this study is incomplete as only one test dose of 300 mg/kg has been assessed.

According to the OECD Guideline N°420, when no case of mortality is observed during the study with the dose of 300 mg/kg (case C in the annex 3), an additional test with 2000 mg/kg must be performed, unless this dose level caused death in the sighting study.

Given that no sighting study has been carried out and that neither mortality nor toxicity have been observed in the main study with 300 mg/kg, this study is considered only as indicative. Moreover no human data are available.

Therefore a classification by the calculation method is applied for acute oral toxicity.

Regarding the content of active substance and co-formulants, no classification for acute oral toxicity is required for VITOMIT BOULES ANTI-MITES.

| **Summary table of animal studies on acute oral toxicity** |
| --- |
| **Method Guideline****GLP status, Reliability**  | **Species,Strain,Sex,No/group** | **Test substance****Dose levelsType of administration** *(gavage, in diet, other)* | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **ValueLD50** | **Remarks** *(e.g. major deviations)* | **Reference**  |
| Guideline N°420Reliability 3 | 5 female rats Sprague-Dawley | 300 mg/kg | No case of mortality Nothing abdormal was detected. | 300 mg/kg bw < LD50 < 2000 mg/kg bw | The study is incomplete | Acute oral toxicity – fixed dose method – on ”Biocide tablets with transfluthrin @0.05% |

|  |
| --- |
| **Value used in the Risk Assessment – Acute oral toxicity** |
| Value | No classification for acute oral toxicity of the biocidal product. |
| Justification for the selected value | The classification was established by the calculation method in the absence of a complete study. |
| Classification of the product according to CLP  | No classification is required according to Regulation (EC) No 1272/2008 (CLP).  |

*Acute toxicity by inhalation*

No test has been performed for the acute toxicity by inhalation for VITOMIT BOULES ANTI-MITES and no human data are available.

Therefore, the acute inhalation toxicity potential of the biocidal product is assessed by calculation considering the content of substances classified for acute inhalation toxicity.

The biocidal product contains only one substance classified for inhalation toxicity at a really low concentration. Therefore, no classification is required.

|  |
| --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** |
| Value | No data |
| Justification for the selected value | A classification by calculation method was performed. According to the content of substance classified for acute inhalation toxicity, no classification is required for VITOMIT BOULES ANTI-MITES. |
| Classification of the product according to CLP  | No classification required for acute inhalation toxicity of VITOMIT BOULES ANTI-MITES according to Regulation (EC) 1272/2008. |

*Acute toxicity by dermal route*

No test has been performed for the assessment of acute toxicity by dermal route of VITOMIT BOULES ANTI-MITES and no human data are available.

Therefore, the acute dermal toxicity potential of the biocidal product is assessed by calculation considering the content of substances classified for acute dermal toxicity.

The biocidal product contains three substances classified for dermal toxicity but at extremely low concentration and do not induce a classification of the product.

|  |
| --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** |
| Value | No data |
| Justification for the selected value | By the calculation method, no classification is required for acute dermal toxicity. |
| Classification of the product according to CLP  | According to Regulation (EC) 1272/2008, no classification is required for acute dermal toxicity of VITOMIT BOULES ANTI-MITES. |

***Information on dermal absorption***

No dermal absorption study has been performed with VITOMIT BOULES ANTI-MITES.

Therefore, default values should be applied according to the EU guidance (Guidance Document on Dermal Absorption EFSA Journal 2012; 10(4):2665).

In this guidance, a default value of 10% is proposed for an active substance with a Log Pow > 4 and a MW > 500 g/mol.

The proposed dermal absorption value of **10%** has been approved in the Assessment Report of Transfluthrin following a comparison between severals pyrethrinoids presenting the same profil (Log Pow > 4 and MW < 500 g/mol).

The dermal absorption value of 10% is used for the risk assessment.

|  |
| --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** |
| Substance | Transfluthrin |
| Value(s)\* | 10% |
| Justification for the selected value(s) | See above |

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

There are no substances of concern in the biocidal product VITOMIT BOULES ANTI-MITES.

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

No toxicological data for the mixture are available.

#### Exposure assessment

**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 | n.a | Yes | n.a | n.a | Yes | No |
| Dermal | n.a | n.a | Yes | n.a | n.a | Yes | No |
| Oral | n.a | n.a | no | n.a | n.a | Yes  | No  |

***List of scenarios***

| **Summary table: scenarios** |
| --- |
| **Scenario number** | **Scenario**(e.g. mixing/ loading) | **Primary or secondary exposure** **Description of scenario** | **Exposed group**(e.g. professionals, non-professionals, bystanders) |
| 1.Application | Inhalation and dermal exposure during the opening and the installation of the 10 tablets in the closet. | **Primary exposure, inhalation**VITOMIT BOULES ANTI-MITES is a ready to use product (tablets in bulk in a plastic sachet). Amateurs have to open the sachet and deposit the tablets in the closet. During these short operations, the non-professional user is exposed to vapours of the biocidal product. **Primary exposure, dermal contact**The application of the biocidal product in the closet requires a dermal contact. Knowing that each tablet is not packed in a plastic film, direct contact with the product occurs.  | Non-professionals, adults |
| Non-professionals, adults |
| 2.Opening of the closet | Inhalation exposure to vapour during the evaporation of the product in the closet and dermal exposure in case of contact. | **Secondary exposure**After application, non-professional users are likely to open the closet during the day and to touch one tablet.Therefore, each opening of the closet by adults or toddlers leads to an exposure to vapours of the biocidal product, and each tablet touched leads to a dermal exposure.The dermal exposure being covered by the primary exposure for adults, dermal exposure for toddlers is estimated for contact to only one tablet. | General public (adults and toddlers) |
| 3.Ingestion of one tablet | Ingestion of biocidal by a toddler | **Secondary exposure, ingestion**Ingestion of one tablet by toddlers may occur. A reverse scenario has been performed to estimate the maximum amount of biocidal product a toddler can ingest to reach the acute oral AEL. | General public (toddlers) |

***Industrial exposure***

Not applicable.

No industrial exposure is foreseen. VITOMIT BOULES ANTI-MITES is an insecticide product used by non-professionals.

***Professional exposure***

Not applicable.

No professional exposure is foreseen. VITOMIT BOULES ANTI-MITES is an insecticide product used by non-professionals.

***Non-professional exposure***

VITOMIT BOULES ANTI-MITES is a ready to use product (tablets in bulk in a plastic sachet). Amateur users have to open the sachet and deposit the tablets in the closet. During these short operations, the non-professional user is exposed to vapours of the biocidal product and to the product via dermal route during the manipulation of the tablets.

*Scenario [1]: Inhalation exposure during the opening and the installation of the 10 tablets in the closet + dermal exposure during the application of the tablets.*

| **Description of Scenario [1] Application, inhalation route** |
| --- |
| The model ”Exposure to vapour – Evaporation constant rate” from ConsExpo Web was used to estimate the concentration in the air during the manipulation of the tablets (opening and installation the tablets in the closet). The default parameters used to estimate the mean concentration in the air are from the Pest Control Fact Sheet of Consexpo. Then, a calculation is performed in order to estimate the exposure of the amateur user. The characteristics of one tablet are : * Weight: 6.2 g
* Diameter: 24 mm
* Height: 12 mm
* Surface: 18.864 mm²

Therefore, the release mode is constant evaporation from an area of 180.864 cm² considering the use of 10 tablets for 0.5 m3 of closet. As a worst case it is considered that the user is directly exposed to the concentration in the closet without dilution in the volume of the room.An emission and an exposure of 10 minutes of non-professional users are considered.The following parameters were used in ConsExpo Web to estimate the mean air concentration: |
|  | **Parameters1** | **Value** | **Unit** | **Reference** |
| **Tier 1** | Exposure model | Exposure to vapour - Evaporation | ConsExpo Web |
| Exposure duration | 10 | min |  |
| Weight fraction substance | 0.0311 | % |  |
| Product amount(considering 10 tablets) | 62 | g |  |
| Room volume | 0.5 | m3 |  |
| Ventilation rate (opened doors) | 0.6 | Per hour | Fact sheet of ConsExpo |
| Inhalation rate | 1.25 | m3/hour | HEEG Opinion 17 on default human factor values |
| Application temperature | 20 | °C |  |
| Vapour pressure of the active substance | 9x10-4 | Pa |  |
| Molecular weight of the active substance | 371  | g/mol |  |
| Mass transfer coefficient | 10.9 | m/hour |  |
| Release area mode | Constant | - |  |
| Release area | 180.864 | cm² |  |
| Emission duration | 10 | min |  |
| Product in pure form | No | - |  |
| Molecular weight matrix | 246 | g/mol |  |
|  | Absorption model | Fixed fraction |  |  |
|  | Absorption fraction | 100 | % |  |
|  | Mean air concentration after 10min emission | 8.8 x 10-7 | mg/m3 | ConsExpo Web modelisation |

1 Include e.g. generic parameters and protection/penetration rates for PPE if relevant. Use footnotes for references and justifications.

| **Description of Scenario [1] Application, Dermal route** |
| --- |
| This scenario estimates dermal exposure of non-professional users manipulating 10 tablets in order to put them into the closet. The user is in contact with a surface layer of 0.1 mm from the tablets. The calculations were performed with the following parameters : |
|  | **Parameters1** | **Value** | **Unit** | **Reference** |
| **Tier 1** | Exposure model | No model was used |  |
| Exposure duration | 10 | min |  |
| Weight fraction substance | 0.0311 | % |  |
| Product amount | 62 | g |  |
| Room volume | 0.5 | m3 |  |
| Application temperature | 20 | °C |  |
| Vapour pressure of the active substance | 9x10-4 | Pa |  |
| Molecular weight of the active substance | 371  | g/mol |  |
| Emission duration | 10 | min |  |
| Dermal absorption | 10 | % |  |
| Number of plaquets manipulated | 10 | - |  |
| Adult weight | 60 | kg |  |
| AEL acute dermal route used in risk assessment | 1 | mg/kg bw/d | AR of the active substance |
| **Characteristics of one tablet** |
| Diameter (D) | 24 | mm |  |
| Radius (r) | 12 | mm |  |
| Height (H) | 12 | mm |  |
| Mass  | 6.2 | g |  |
| Surface | 1808.64 | mm² |  |
| Thick surface layer of the tablet in contact with the skin | 0.1 | mm | HEEG Opinion 16 and expert judgement |

**Calculations for Scenario [1] inhalation and dermal routes**

| **Summary table: systemic exposure from non-professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [1] inhalation and dermal routes | 1 / No PPE | 3.06x10-9 mg/kg bw/d | 1.07x10-6 mg/kg bw/d | - | 1.07x10-6 mg/kg bw/d |

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

*Combined scenarios*

Not relevant

***Exposure of the general public***

*Scenario [2] Opening of the closet – Secondary exposure*

| **Description of Scenario [2] Opening of the closet – Secondary exposure** |
| --- |
| After application of the tablets into the closet, the general public is likely to open the closet and touch tablets. This scenario is for adults and toddlers.The assessment for the inhalation route is performed by first calculating the concentration in the air of substance after 24h with closed door (ventilation rate 0.3 per hour). As for scenario 1, the exposure model Exposure to Vapour from ConsExpo Web was used.As a very worst case, it was considered that adults and toddlers will be exposed to the estimated concentration in the air during 24h.For the dermal exposure of an adult, it is considered that this scenario is covered by the primary exposure during depositing 10 tablets from the sachet into the closet. For toddler, the same approach is applied but with only one tablet. The following parameters were used for the **inhalation route (adult):** |
|  | **Parameters1** | **Value** | **Unit** | **Reference** |
| **Tier 1** | Exposure model | Exposure to vapour – Evaporation |  | ConsExpo Web |
| Exposure duration | 24 hours |  |  |
| Weight fraction substance | 0.0311 | % | Assessment Report Transfluthrin |
| Product amount | 62 | g |  |
| Room volume | 0.5 | m3 |  |
| Ventilation rate (closed doors) | 0.3 | per hour | Fact sheet of ConsExpo |
| Adult inhalation rate  | 16 | m3/24hr | HEEG Opinion 17 on default human factor values |
| Application temperature | 20 | °C |  |
| Vapour pressure of the active substance | 0.0009 | Pa |  |
| Molecular weight of the active substance | 371 | g/mol |  |
| Mass transfer coefficient  | 10.9 | m/hr |  |
| Release aera mode | Constant |  |  |
| Release area | 180.864  | cm² | 10 tablets |
| Emission duration | 24  | hours |  |
| Product in pure form | No |  |  |
| Molecular weight matrix | 246 | g/mol |  |
| Absorption model | Fixed fraction | - |  |
| Absorption fraction | 100 | % |  |
| Adult weight | 60 | kg |  |
| AEL medium long-term used in risk assessment | 0.01 | mg.kg bw/d |  |
| Mean air concentration after 10min emission | 1.6 x 10-5 | mg/m3 | ConsExpo Web modelisation |

**Inhalation toddler:**

For the estimation of inhalation uptake of a toddler, only the following parameters differ from the previous ones fixed for an adult:

|  | **Parameters1** | **Value** | **Unit** | **Reference** |
| --- | --- | --- | --- | --- |
| Tier 1 | Inhalation rate | 8 | m3/24hr | HEEG Opinion 17 on default human factor values |
| Toddler weight | 10 | kg | HEEG Opinion 17 on default human factor values |

**Dermal route:**

For the dermal route, it is considered that the estimation dose calculated for the primary exposure covers the estimated dermal uptake of the secondary exposure for an adult, considering that in this scenario 2, few tablets will be touched whereas in the scenario 1, 10 tablets are taken into account.

For the toddler, a calculation was performed with the same approach considering that only one tablet is handled.

**Calculations for Scenario [2] Opening of the closet – Secondary exposure**

| **Summary table: systemic exposure from non-professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario [2]Adult | Tier 1 / No PPE | 4.27x10-6 mg/kg bw/d | 1.07x10-6 mg/kg bw/d | - | 5.34x10-6 mg/kg bw/d |
| Scenario [2]Toddler | Tier 1 / No PPE | 1.12x10-5 mg/kg bw/d | 6.41x10-7 mg/kg bw/d |  | 1.18x10-5 mg/kg bw/d |

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

Not relevant

*Scenario [3] Ingestion exposure, toddler*

| **Description of Scenario [3] Accidental Ingestion exposure, toddler** |
| --- |
| Ingestion of one tablet by toddlers may occur. A reverse scenario has been performed to estimate the maximum amount of biocidal product a toddler can ingest to reach the acute oral AEL. The biocidal product contains a bittering agent, the ingestion is considered limited, the toddler will not ingest a complete tablet or more than one.The following formula was used:

|  |
| --- |
| *(AEL x Body weight)/(content of active substance x oral absorption)* |

 |
|  | **Parameters1** | **Value** | **Unit** | **Reference** |
| **Tier 1** | Exposure model | Reverse scenario, exposure by ingesting |  |  |
| Product amount/tablet | 6200 | mg |  |
| Weight fraction substance | 0.0311 | % | Assessment Report of Transfluthrin |
| Body weight (toddler) | 10 | kg | HEEG Opinion 17 on default human factor values |
| Oral absorption | 100 | % | Assessment Report of Transfluthrin |
| AEL acute oral used in risk assessment | 0.15 | mg.kg bw/d | Assessment Report of Transfluthrin |

**Calculations for Scenario [3]** **Accidental Ingestion exposure, toddler**

| **Summary table: systemic exposure from non-professional uses** |
| --- |
| **Exposure scenario** | **Tier/PPE** | **Maximum acceptable oral product uptake** |
| Scenario [3] | Tier 1 / No PPE | 4823 mg/day |

It is estimated with a reverse scenario that a toddler has to ingest 4823 mg of product to reach the acute oral AEL, equivalent to 78% of one tablet (6200mg).

***Monitoring data***

None

***Aggregated exposure***

Not relevant

***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.Application, inhalation  | Non-professional users, adults | Tier 1 / No PPE | 3.06x10-9 mg/kg bw/d |
| 1.Application, dermal  | 1.07x10-6 mg/kg bw/d |
| 2. Opening of the closet – Secondary exposure | General public, adults and toddlers | Tier 1 / No PPE | Adult : 5.34x10-6 mg/kg bw/dToddler : 1.18x10-5 mg/kg bw/d |
| 3. Ingestion exposure, toddler | General public, toddlersReverse scenario | Tier 1 / No PPE | 4823 mg product /day |

***Dietary exposure***

The product VITOMIT BOULES ANTI-MITES is intended for indoor application uses by non-professional in closets and drawers. No specific residue data were submitted in the context of this dossier.

As regards to the intended use of the product VITOMIT BOULES ANTI-MITES in closets and drawers, no direct or indirect contamination of food is expected.

Nevertheless to avoid any contamination, the following precautionary statement should be indicated on the labels:

“Avoid direct or indirect contact with food, feed and drinks”.

*List of scenarios*

Not relevant.

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

Not relevant.

*Estimating Livestock Exposure to Active Substances used in Biocidal Products*

Not relevant.

*Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)*

Not relevant.

*Estimating transfer of biocidal active substances into foods as a result of non-professional use*

Not relevant.

#### Risk characterisation for human health

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference**  | **Study** | **NOAEL (LOAEL)** | **AF** | **Correction for oral absorption** | **Value** |
| AELacute oral | developmental toxicity study, rabbit | 15 mg/kg bw/day | 100 | No correction for oral absorption | 0.15 mg/kg bw |
| AEL acute dermal | 3 week dermal toxicity study, rabbit | 1000 mg/kg bw/day | 100 | No correction for oral absorption | 1 mg/kg bw |
| AEL acute inhalation | 13-week inhalation study, rat | 46.7 mg/m3 equivalent to 17 mg/kg bw/day | 100 | No correction for oral absorption | 0.5 mg/m3 corresponding to 0.17 mg/kg bw/d with FS of 100 |
| AEL medium-term | 2-year dietary study in rat | 20 ppm equal to 1 mg/kg | 100 | No correction for oral absorption | 0.01 mg/kg bw |
| AEL long-term |
| ARfD | Developpment study, rabbit | 15 mg/kg | 100 | No | 0.15 |
| ADI | 2-year dietary study in rat | 1 mg/kg | 100 | No | 0.01 |

* **Maximum residue limits or equivalent**

Not relevant.

***Risk for industrial users***

Not applicable

***Risk for professional users***

Not applicable

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

Primary exposure of adult non-professional users was estimated by inhalation and dermal routes for the following tasks:

* opening of the sachet of VITOMIT BOULES ANTI-MITES;
* deposit of 10 tablets into the closet.

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| 1. application inhalation | 1 | 17 | 0.17 | 3.06x10-9 | 1.80x10-6 | Yes |
| 1. application, dermal | 1 | 1000 | 1 | 1.07x10-6 | 1.07x10-4 | Yes |

**Combined scenarios**

Not relevant

**Local effects**

None

**Conclusion**

There is no unacceptable risk for non-professional users during the opening and the installation of the biocidal product into the treated closet.

***Risk for the general public***

Secondary exposure of general public (adult and toddler) was estimated by inhalation, dermal and oral routes for the following tasks:

* inhalation exposure during the opening of the closet (scenario 2);
* dermal exposure during handling of tablet (see primary exposure by dermal route for adults and calculation for toddlers);
* oral exposure for a toddler (scenario 3).

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| 2. Opening of the closet, secondary exposureAdult  | 1 | 1 | 0.01 | 5.34x10-6 | 0.0534 | Yes |
| 2. Opening of the closet, secondary exposure Toddler | 1 | 1 | 0.01 | 1.18x10-5 | 0.118 | Yes |

**Scenario 3: Ingestion exposure, toddler**

It is considered by the reverse scenario that a toddler has to ingest 4823 mg of product to reach the acute oral AEL, equivalent to 78% of one tablet (6200mg). The product contains a bittering agent, the situation is considered unrealistic and therefore the risk is deemed acceptable.

**Combined scenarios**

It is considered in this situation that the non-professional user opens the sachet containing the tablets, deposits 10 pellets into the closet and then, during the same day, opens the cupboard.

Therefore, a combined exposure is estimated route by route of short term exposure for an adult only, considering that a toddler will not be in contact with the biocidal product for the installation.

| **Summary table: combined systemic exposure from non-professional uses** |
| --- |
| **Scenarios combined** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenarios [1+2] inhalation route of exposureTier 1 | 3.06x10-9 + 4.27x10-6 mg/kg bw/d | - | - | 4.27x10-6 mg/kg bw/d |
| Scenarios [1+2] dermal route of exposureTier 1 | - | 1.07x10-6 + 1.07x10-6 mg/kg bw/d | - | 2.14x10-6mg/kg bw/d |

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/****Scenario** | **Tier** | **Systemic NOAEL****mg/kg bw/d** | **AEL****mg/kg bw/d** | **Estimated uptake****mg/kg bw/d** | **Estimated uptake/ AEL** **(%)** | **Acceptable****(yes/no)** |
| Scenarios [1+2] inhalation route of exposure | 1 | 17 | 0.17 | 4.27x10-6 | 2.51x10-3 | Yes |
| Scenarios [1+2] dermal route of exposure | 1 | 1000 | 1 | 2.14x10-6 | 2.14x10-4 | Yes |

**Local effects**

Not applicable

**Conclusion**

There is no unacceptable risk for general public (adult and toddler) during the opening of the treated closet.

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

The product is intended to be applied in closets and drawers. It does not come in direct contact with food and feedstuffs. Based on the intended uses and the proposed risk mitigation measure, the exposure to residues is unlikely. Regarding consumer health protection, there are no objections against the intended uses.

Nevertheless to avoid any contamination, the following precautionary statement should be indicated on the labels:

“Avoid direct or indirect contact with food, feed and drinks”.

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

Not relevant

### Risk assessment for animal health

As no guidance is currently available to assess the risk for animal health, the eCA did not perform risk assessment.

### Risk assessment for the environment

#### Effects assessment on the environment

|  |
| --- |
| **Box 2- FR CA position:**Please notice that the risk assessment for the environment (section 2.2.9) is reported as provided by the applicant. The FR CA position is presented in **green evaluation boxes.** |

For the environmental scenario Euses 2.1.2 was used. The proposed scenario for the insecticide

PT18 takes is consideration the application phase, because the product is a ready-to-use formulation and, according to the guidelines (ENV/JM/MONO (2008)14), no emissions are foreseen in the preparation phase (mixing and loading).

Using the ecotoxicity endpoints (PNEC values) identified in the Assessment Report of the active substance we calculate the environmental exposure.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 3 - FR CA position: PNECs summary**New data to refine the PNEC values for aquatic and terrestrial compartments were provided by the applicant at the product authorisation stage. These data were assessed at the European level and used in the FR-CA risk assessment according to the conclusion of the ENV WG-IV 2017 meeting.*PNEC surface water for transfluthrin*The lowest endpoints of transfluthrin for aquatic species based on information from the assessment report of transfluthrin and new studies submitted by the applicant are summarized below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Species** | **Substance** | **Time-scale** | **Endpoint** | **Toxicity** |
| **Aquatic organisms** |
| Fish |
| *Onchorhynchus mykiss* | Transfluthrin | Acute | LC50 | 0.7 µg/L |
| *Pimephales promelas* (new data) | Transfluthrin | Chronic, ELS | NOEC | 0.399 µg/L |
| Invertebrates |
| *Daphnia magna* | Transfluthrin | Acute | EC50 | 1.4 µg/L (geometric mean of 1.2 and 1.7 µg/L) |
| *Daphnia magna*(new data) | Transfluthrin | Chronic | NOEC | **0.0175 µg/L** |
| Algae |
| *Scenedesmus subspicatus* | Transfluthrin | Acute | ErC50 | > 100 µg/L |
| *Scenedesmus subspicatus* | Transfluthrin | Chronic | NOErC | 1. g/L
 |

Considering the new data on long term toxicity for fish and invertebrates submitted by the active substance transfluthrin producer, the new PNEC value for surface water, validated at the ENV WG-IV 2017 meeting , is 1.75 ng/L using an assessment factor of 10 and *daphnia magna* NOEC of 0.0175 µg/L.🡪 **PNECwater = 1.75E-06 mg a.i./L***PNEC sediment for transfluthrin*The lowest endpoints of transfluthrin for sediment species based on information from the assessment report of transfluthrin and new studies submitted by the applicant are summarized below:

|  |
| --- |
| **Sediment organisms** |
| *Chironomus riparius*(new data) | Transfluthrin | Chronic  | NOEC | **0.164 mg/kg dw sed** |
| *Lumbriculus variegatus*(new data) | Transfluthrin | Chronic | NOEC | 2.21 mg/kg dw sed |

Two trophic levels with valid NOEC from long-term toxicity tests (*Chironomus* and *Lumbriculus*) are now available. The lowest endpoint is the NOEC of the chironomus test. An assessment factor of 100 for the PNEC sediment derivation was stated during the ENV WG-IV 2017 meeting. Indeed, an extra AF of 2 is added to the one that should be used according to the dataset (AF of 50) because in the chironomus study the test organisms were fed with freshfood, thus limiting the exposure to the strongly adsorbing test substance. According to the ENV WG-IV 2017conclusion, the PNEC sediment value is:🡪 **PNECsediment = 1.64E-03 mg a.i./kg dw***PNEC soil for transfluthrin*The lowest endpoints of transfluthrin for soil species based on information from the assessment report of transfluthrin and new studies submitted by the applicant are summarized below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Organisms** | **Substance** | **Time-scale** | **Endpoint** | **Toxicity\*** |
| **Earthworms** |
| Earthworms | transfluthrin | Acute | LC50 | 184 mg/kg dw  |
| Earthworms(new data) | transfluthrin | Chronic | NOEC | 10 mg/kg dw  |
| **Non-target arthropods** |
| *Collembola (Folsomia candida)*(new data) | transfluthrin | Chronic | NOEC | 18 mg/kg dw standard soil |
| **Soil micro-organisms** |
| Soil micro-organisms(new data) | transfluthrin | Chronic | NOEC | **5.24** mg/kg dw standard soil |
| **Non target plants** |
| Non-target plants(new data) | transfluthrin | Acute/Chronic  | EC50NOEC | 210.4 mg/kg standard dw soil50 mg/kg dw standard soil |

The ENV WG-IV 2017agreed to use the NOEC from microorganism study of 5.24 mg/kg dw applying an AF of 50. The new PNEC is 0.1 mg/kg dw.🡪 **PNECsoil= 0.1mg a.i./kg dw**🡪 **PNECsoil= 8.8E-02mg a.i./kg ww (eq 82b)**The PNEC values used by FR CA for the environmental risk assessment are summarized below:

|  |
| --- |
| **Summary table for PNECs used in Risk Assessment** |
| **Parameters** | **Concentration** | **Notes** |
| **Transfluthrin** |
| PNECSTP | 100 mg/L | As specified in Transfluthrin Assessment Report (2014) |
| PNECwater | 1.75 ng/L  | According to the conclusion of the technical meeting WGIV2017\_ENV. |
| PNECsediment | 1.64 E-03 mg a.i./kg dw | According to the conclusion of the technical meeting WGIV2017\_ENV. |
| PNECsoil | 8.80E-02 mg a.i./kg ww | According to the conclusion of the technical meeting WGIV2017\_ENV. |
| PNECoral, mammals | 0.33 mg.kg bw/d | As specified in Transfluthrin Assessment Report (2014) |
| PNECoral, birds | Not available | As specified in Transfluthrin Assessment Report (2014) |
| **2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH)-NAK47231** |
| PNECwater | >0.1 mg/L | As specified in Transfluthrin Assessment Report (2014) |
| PNECsoil | 0.012 mg/kg ww soil | Calculated using EPM (TFL-PAI-Version 9, 2015)In the case of the metabolite 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH) no data has been generated on terrestrial organisms. Therefore, the Equilibrium Partitioning Method (eq 72 in guidance on BPR Volume IV Environment, Assessment & Evaluation-Parts B+C) is used to derive the PNECsoil based on the PNECaquatic. Taking account of the The PNECaquatic of > 0.1 mg/L, water solubility of 6110 mg/L, vapour pressure of 0.44 Pa and an assumed worst case Koc of 0, the PNECsoil was calculated to be 0.012 mg/kg ww |
| **2,3,5,6-Tetrafluorobenzyl alcohol (TFB-OH)** |
| PNECwater | >0.1 mg/L | As specified in Transfluthrin Assessment Report (2014) |

 |

**Information relating to the environmental fate of the active substance**

Insecticides applied indoor will generally not reach directly the environmental compartments. Therefore, indoor receiving materials will be considered as “intermediate compartments”. But As a matter of fact most surfaces will be cleaned. The cleaning step will therefore lead to releases either to wastes or to waste water. Therefore the sewage treatment plants (STP) is considered as one of the main “receiving compartment” where insecticides will be released through wet cleaning events. Then, the “final” environmental compartment will logically be the surface water, the groundwater (through STP), the soil (from sludge application) and the outdoor air.

In the case of diffuser formulations, that have to be put into wardrobes or in drawers, the cleaning events result in emissions to wastes: 100% of the surfaces are cleaned by vacuum/broom and the products are disposable. All the releases are directed to solid wastes during cleaning including those emitted by the applicator. Exposure to aquatic (surface, groundwater, STP) and to soil compartments is expected to be negligible due to the use of the product.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 4- FR CA position:**Regarding the aquatic compartment, FR CA agrees with the applicant version.Regarding the soil compartment, in the CAR of transfluthrin, no experimental data are available for the biodegradation of the active substance. A new soil degradation study has been submitted during the product authorisation level. Nevertheless, these data were not used by the applicant and the FRCA for the PEC calculations for this product and therefore, not presented hereFor details about the metabolite PEC calculations please see box 22..**E-fate parameters taken into account for the environmental exposure assessment of transfluthin:**

| **Parameter** | **Value** | **Unit** | **Note** |
| --- | --- | --- | --- |
| Scenario | 18 Insecticides | - |  |
| Additional information | 18.2.6 Indoor diffusers | - | Only houses considered, number of applications in large buildings set to 0 |
| Molecular weight | 371.2 | g/mol |  |
| Vapour pressure | 9 x 10-4 | Pa | 20 °C |
| Water solubility | 0.057 | mg/L | 20 °C |
| log Pow | >5 |  | Indicative value not used in the PECwater and soil calculations |
| Koc | 50 119 | L/kg | based on log Koc from HPLC measurement pH 6 |
| Degradation | not biodegradable | - | No degradation considered in the risk assessment. DT50 in soil set to 1.00E+06 days. |
| Emission days per year | 365 | d | Whole year use according to intended uses |
| Fraction emission after STP in air (FSTP, air) | 0.85 | % | Simple Treat v 3.1 calculation, as specified in Transfluthrin Assessment Report (2014) and by the applicant |
| Fraction emission after STP in water (FSTP, water) | 19.2 | % | Simple Treat v 3.1 calculation, as specified in Transfluthrin Assessment Report (2014) and by the applicant |
| Fraction emission after STP in sludge (FSTP, sludge) | 79.9 | % | Simple Treat v 3.1 calculation, as specified in Transfluthrin Assessment Report (2014) and by the applicant |
| Fraction degradated in STP | 0 | % | Simple Treat v 3.1 calculation, as specified in Transfluthrin Assessment Report (2014) and by the applicant |

 |
|  |

***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***

|  |
| --- |
| **Box 5- FR CA position:** Please refer to section 2.1.3. |

***Further Ecotoxicological studies***

|  |
| --- |
| **Box 6- FR CA position:**A substance classified as “Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment” is used in the biocidal product as bittering agent. Nevertheless at the concentration used for the formulation of VITOMIT BOULES ANTI-MITES, the substance does not contribute to the classification of the biocidal product. No other substance used in the biocidal product is classified for the environment.Therefore, FR CA considered that the effects of transfluthrin outweigh those of the non-active components of the product and that the effects assessment for the product VITOMIT BOULES ANTI-MITES can be extrapolated from the effects assessment of the active substance transfluthrin. FR CA agrees that no further study is needed. |

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

|  |
| --- |
| **Box 7- FR CA position:**FR CA agrees that no further study is needed. |

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

|  |
| --- |
| **Box 8- FR CA position:**FR CA agrees that no further study is needed. |

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

|  |
| --- |
| **Box 9- FR CA position:**FR CA agrees that no further study is needed. |

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

|  |
| --- |
| **Box 10- FR CA position:**FR CA agrees that no further study is needed. |

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

Please refer to section 2.2.8.2 Fate and distribution in exposed environmental compartments.

|  |
| --- |
| **Box 11- FR CA position:**FR CA agrees that no further study is needed. |

***Leaching behaviour (ADS)***

|  |
| --- |
| **Box 12- FR CA position:**FR CA agrees that no further study is needed. |

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

|  |
| --- |
| **Box 13- FR CA position:**FR CA agrees that no further study is needed. |

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

|  |
| --- |
| **Box 14- FR CA position:**FR CA agrees that no further study is needed. |

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

|  |
| --- |
| **Box 15- FR CA position:**FR CA agrees that no further study is needed. |

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

|  |
| --- |
| **Box 16- FR CA position:**FR CA agrees that no further study is needed. |

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

|  |
| --- |
| **Box 17- FR CA position:**FR CA agrees that no further study is needed. |

#### Exposure assessment

|  |
| --- |
| **Box 18- FR CA position:**A revised exposure assessment is provided after the applicant’s proposal in Box 19 to 23. |

##### Emission scenario

Since the product is designed for non-professional users, only the private use was considered.

The product is a ready-to-use formulation, no preparation step was considered in the calculation of the Predicted Environmental concentration (PEC).

The product has to be applied into the wardrobe, and we take in consideration the case of indoor emissions.

The emission scenario was built according to EUSES 2.1 as follows:

Physico-chemical properties of transfluthrin:

|  |
| --- |
| **PHYSICO-CHEMICAL PROPERTIES** |
|  | Value | Units | Reference |
| Molecular weight | 371.2 | g/mol | Assessment report of a.s. |
| Melting point | 32 | °C | Assessment report of a.s. |
| Boiling point | 242 | °C | Assessment report of a.s. |
| Vapour pressure at test temperature | 9E-04 | Pa | Assessment report of a.s |
| Temperature at which vapour pressure was measured | 20 | °C | Assessment report of a.s. |
| Vapour pressure at 25 [°C] | 1.27E-03 | Pa | Assessment report of a.s |
| Octanol-water partition coefficient | 5.94 | log10 | Assessment report of a.s. |
| Water solubility at test temperature | 0.057 | mg/l | Assessment report of a.s. |
| Temperature at which solubility was measured | 20 | °C | Assessment report of a.s. |
| Water solubility at 25 [°C] | 0.0611 | mg/l | Assessment report of a.s. |

**Biocidal product scenario input data**

|  |
| --- |
| **BIOCIDE SCENARIO INPUT DATA** |
| Usage/production title | Impregnated tablets |
| Scenario choice for biocides | (18) Insecticides |
| Additional scenario information | (18.2.6) Indoor, diffusers |
| Emission scenario | Local emissions (STP) |
| **RELEASE FRACTIONS AND EMISSION DAYS** |
| Fraction of active ingredient | 0.03 | % |
| Quantity of active contained in the diffuser | 275 | g |
| Diffusser type | Passive |  |
| Duration of use per day | 24 | hr/d |
| Maximum duration of use of the diffuser | 90 | d |
| **APPLICATION** |  |  |
| Number of applications per day, house | 1 | - |
| Quantity of product used per application, house | 0.62 | g |
| Fraction emitted to air during application | 0.9 | - |
| Fraction emitted to the applicator during application | 0 | - |
| Fraction emitted to the floor during application | 0.1 | - |
| Fraction emitted to treated surfaces during application | 0 | - |
| **CLEANING** |  |  |
| Washable or disposable applicators | Disposable | - |
| Fraction emitted to solid waste from applicator | 1 | - |
| Fraction emitted to wastewater from applicator | 0 | - |
| Cleaning method for treated surfaces | Broom, vacuum | - |
| Fraction emitted to solid waste from cleaning treated surfaces | 1 | - |
| Fraction emitted to wastewater from cleaning treated surfaces | 0 | - |
| Cleaning efficiency | 100 | % |

|  |
| --- |
| **Box 19- FR CA position:** The technical guidances used for the environmental risk assessment are: “*Guidance for BPR: volume IV part B risk assessment (active substances) Version 1.0 April 2015*” and “*OECD Series on Emission Scenario Documents No. 18 (2008) – Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses*”. |

***Emission estimation***

**Biocidal product scenario input data**

|  |
| --- |
| **BIOCIDE SCENARIO INPUT DATA** |
| Usage/production title | Impregnated tablets |
| Scenario choice for biocides | (18) Insecticides |
| Additional scenario information | (18.2.6) Indoor, diffusers |
| Emission scenario | Local emissions (STP) |
| **RELEASE FRACTIONS AND EMISSION DAYS** |
| Fraction of active ingredient | 0.03 | % |
| Quantity of active contained in the diffuser | 275 | g |
| Diffusser type | Passive |  |
| Duration of use per day | 24 | hr/d |
| Maximum duration of use of the diffuser | 90 | d |
| **APPLICATION** |  |  |
| Number of applications per day, house | 1 | - |
| Quantity of product used per application, house | 0.62 | g |
| Fraction emitted to air during application | 0.9 | - |
| Fraction emitted to the applicator during application | 0 | - |
| Fraction emitted to the floor during application | 0.1 | - |
| Fraction emitted to treated surfaces during application | 0 | - |
| **CLEANING** |  |  |
| Washable or disposable applicators | Disposable | - |
| Fraction emitted to solid waste from applicator | 1 | - |
| Fraction emitted to wastewater from applicator | 0 | - |
| Cleaning method for treated surfaces | Broom, vacuum | - |
| Fraction emitted to solid waste from cleaning treated surfaces | 1 | - |
| Fraction emitted to wastewater from cleaning treated surfaces | 0 | - |
| Cleaning efficiency | 100 | % |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 20 - FR CA position:**For the indoor use of passive diffusers in general, the ESD considers that the major part of the active substance (90%) will be emitted to air and that the remaining 10% will be emitted to the floor. The product is ready-to-use. It is then assumed that cleaning of the floor will result in emissions to waste water. The daily emission to one STP is then calculated by correction for the number of houses connected to one STP and for the simultaneous use of the product by different households. The risk assessment for VITOMIT BOULES ANTI-MITES is based on the approach of a similar product in the CAR of transfluthrin and on recent discussions in WG ( WGIV2017\_HH and WGIV2017\_ENV).***Number of tablet units per house:***The applicant claimed the use of 10 tablet units per 0.5 m3. Considering wardrobes of 1.5 m3 (CONSEXPO and WGIV2017\_HH), 30 tablet units are used per wardrobe. The weight of one tablet unit is 6.2 g with a transfluthrin concentration of 0.03%.According to the conclusions of WGIV2017\_ENV, 2.5 inhabitants per house (10 000 inhabitants per STP linked to 4 000 houses) and a wardrobe per inhabitant have to be considered for this kind of use. So unlike the applicant, FRCA considered 2.5 wardrobes treated per house.***Emissions towards wastewater:***According to ESD PT18 and the use of VITOMIT BOULES ANTI-MITES, the main releases towards wastewater are from the cleaning of the floor exposed to the biocidal product after application. The parameters used for the emission calculation are presented below:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Parameter*** | ***Symbol*** | ***Value*** | ***Unit*** | ***Source*** |
| Product Name | (-) | VITOMIT BOULES ANTI-MITES | (-) | (-) |
| Active Ingredient | (-) | Transfluthrin | (-) | (-) |
| Product application rate | App | 20 tablets/1 m3 (10 tablets/0.5 m3) | (-) | S – Intended use = 10 tablets for 0.5 m3 |
| Amount of active substance per tablet | Qai/tablet | 1.86 | mgas | S – Total amount of technical active substance included in Vitomit tablet unit |
| Size of standard waredrobe | VOLUMEwaredrobe | 1.5 | m3 | S – WGIV2017 (Consexpo) |
| Number of waredrobe per house | Nbwaredrobe | 2.5 | house-1 | S – WGIV2017\_ENV |
| Quantity of active substance applied per house | Qai/house | 139.5 | mg. house-1 | OutputApp x Qai/tablet x VOLUMEwaredrobe x Nbwaredrobe |
| Duration of use per day | Tday | 24 | h.d-1 | S - The product is intended for continual use and provides protection for 4 months (120 days) |
| Maximal duration of use of the diffuser | Tmax | 2880 | h | S - The product is intended for continual use and provides protection for 4 months (120 days) |
| Fraction emitted to the floor | F application, floor | 0.1 | (-) | D - Default value for diffuser |
| Emission to the floor | E application, floor  | 1.16E-07 | kg.d-1 | Output Qai/house x (Tday/ Tmax) x F application, floor x 10-6 |
| Fraction emitted to the wastewater | Fww | 1 | (-) | D – Default value ESD |
| Cleaning efficiency | Fce | 1 | (-) | D – Default value ESD |
| Surface exposed to the emission of the biocidal product on the floor of the house | Surface treated | 130 | m² | D – Default value TAB |
| Wet cleaning zone of the house leading to a release to the STP | Surface cleaned | 38.5 | m² | D – Default value TAB |
| Emission from the floor to waste water | E floor ww | 3.44E-08 | kg.d-1 | Output E application, floor x Fww x Fce x ( Surface cleaned/ Surface treated) |
| Number of houses per STEP | Nhouses | 4000 | (-) | D – Default value TAB |
| Factor to correct for the simultaneous use of the product | Fsimultaneity | 5.50E-02 | (-) | D – Default value ESD |
| Local Emission by STP during emission episode  | Elocal STP | 7.57E-06 | kg.d-1 | Output E floor ww x Nhouses x Fsimultaneity |

 |

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 21- FR CA position:**The relevant exposed compartments are presented below:

|  | **Fresh-water** | **Freshwater sediment** | **STP** | **Air** | **Soil** | **Ground-water** | **Other** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Indoor use-Passive diffuser | Yes | Yes | Yes | Not relevant | Yes | Yes | Not relevant |

 |

##### Calculated PEC values

From the scenario hypnotized above, based on the indoor application of the product containing transfluthrin, the local PEC values during emission episode were estimated:

**AIR**

Annual average local PEC in air (total) 0 mg.m-3

**WATER, SEDIMENT**

Local PEC in surface water during emission episode (dissolved) 0 mg/l

Annual average local PEC in surface water (dissolved) 0 mg/l

Local PEC in fresh-water sediment during emission episode 0 mg/kg wwt

Local PEC in seawater during emission episode (dissolved) 0 mg/l

Annual average local PEC in seawater (dissolved) 0 mg/l

Local PEC in marine sediment during emission episode 0 mg/kg wwt

**SOIL**

Local PEC in agric. soil (total) averaged over 30 days 0 mg/kg wwt

According to the ESD Guidance, under the proposed conditions of use, the active substance will be emitted in air. But the concentration in air will be not relevant because the instant dilution of transfluthrin. Furthermore, considering the relative small amount used and the volume of the atmospheric compartment, possible abiotic effects of transfluthrin on the atmosphere are expected to be negligible.

During the cleaning step we considered that the emission is only to wastes: 100% of the surfaces are cleaned by vacuum/broom and the products are disposable. All the releases are directed to solid wastes, for this reason the emissions in waste water are considered negligible.

The products are not intended to a direct use to soil, the normal condition of use is the indoor application (in the wardrobe or in the drawer). For this reason the environmental exposure in soil compartment is considered negligible.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 22- FR CA position:**The PECtransfluthrin values for aquatic and terrestrial compartments after release to the STP are summarized below:

|  |
| --- |
| **Summary table on calculated PEC values (active substance)** |
| Scenario | PECSTP | PECwater | PECsed | PECsoil | PECGW |
| [mg/L] | [mg/L] | [mg/kgdwt] | [mg/kgwwt ] | [µg/L] |
| 2.5 wardrobes per house considering the claimed use (10 tablet units/0.5 m3) | 7.27E-07 | 6.76E-08 | 3.39E-04 | 1.11E-04 | 1.25E-04 |

The PECs of the major metabolites were calculated based on the PECs for transfluthrin, multiplied by a formation factor and a correction for the molecular weight (summarized below), according to CAR transfluthrin calculations.

|  |  |  |
| --- | --- | --- |
|  | **Molecular weight (g/mol)** | **Formation fraction in water (%)** |
| Transfluthrin | 371.2 | / |
| TFB-OH | 180.1 | 38 |
| TFB-COOH | 194.08 | 59 |

As a conservative approach, it is considered that degradation takes place only in the STP and not after the STP. Formation fractions in the aquatic compartment are therefore considered. As in the CAR, the exposure assessment of TFB-OH in soil is not relevant.The resulting concentrations are given in the table below.

|  |
| --- |
| **Summary table on calculated PEC values (metabolites)** |
| Scenario | PECSTP | PECwater | PECsoil | PECGW |
| [mg/L] | [mg/L] | [mg/kgwwt ] | [µg/L] |
| Metabolite TFB-OH  | 1.34E-07 | 1.25E-08 | NR\* | NR\* |
| Metabolite TFB-COOH | 2.24E-07 | 2.09E-08 | 3.42E-05 | 3.41E-05 |

\*NR= not relevantCalculation example: PECwater TFB-OH= (PECwater transfluthrin/MWtransfluthrin) xmaximum formation fractionwater, TFB-OH x MW[[5]](#footnote-5) TFB-OH |

##### Primary and secondary poisoning

Birds and mammals may be poisoned through the ingestion of contaminated insects, earthworms

or vegetation resulting from the application of the insecticide. According to the CAR of the active substance, “transfluthrin has a specific mode of action against insects, the confined use and indirect emission to soil are accepted arguments that no further data are required”.

The formulation consists in indoor tablets to be put in the wardrobe or in the drawer, therefore the contamination of insects, earthworms or vegetation is negligible, under the proposed conditions of use.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 23- FR CA position:***Primary poisoning* FR CA agrees with the applicant that primary poisoning is not relevant.*Secondary poisoning*According to FR CA calculations, the PEC oral for predator from aquatic and terrestrial food chains are presented below:***-Via aquatic food:***

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Value for professional uses** | **Unit** |
| PEC in water during emission episode  | PEClocalwater | 6.76E-08 | [kg.d-1] |
| Biocentration factor in fish | BCF | 1783 | [L.kg-1] |
| Biomagnification factor in fish | BMF | 1 | [-] |
| Predicted Environmental Concentration in food (fish) | PECoral, predator | 6.03E-05 | [mg.kg-1] |

-***Via terrestrial food:***

|  |  |  |  |
| --- | --- | --- | --- |
| **Parameter** | **Symbol** | **Value** | **Unit** |
| Bioconcentration factor for earthworm on wet weight basis  | BCF | 1783 | [L.kg-1wet earthworm] |
| Fraction of gut loasing in worm  | Fgut | 0.1 | [kgdwt.kg-1wwt] |
| Conversion factor for soil concentration wet-dry weight soil  | CONVsoil | 1.13 | [kgwwt.kg-1dwt] |
| Predicted environmental concentration in porewater | PEClocalsoil,porewater | 1.25E-07 | [mg.L-1] |
| Predicted environmental concentration in soil | PEClocalsoil | 1.11E-04 | [mg.kg-1wwt] |
| Predicted Environmental Concentration in earthworms  | Cearthworm | 1.19E-03 | [mg.kg-1wwt] |
| Predicted Environmental Concentration in food | PECfood | 5.93E-04 | [mg.kg-1food] |

 |

#### Risk characterisation

Using the ecotoxicity endpoints (PNEC values) identified in the Assessment Report of the active substance we calculate the environmental exposure. PEC/PNEC calculations was carried out in order to assess the environmental risk associated with the use of the product. A PEC/PNEC ratio of 1 indicates no unacceptable risk to the environmental compartment under consideration. A PEC/PNEC ratio > 1 indicates an unacceptable risk.

Laboratory studies conducted on the active substance to assess its toxicity to different compartment are summarized in the a.s. dossier (through the Letter of Access).

The **PNECaquatic is set to 0.7 ng/l, PNECstp is set to 0.057 mg/L and the PNECsoil is 0.063 mg/kg dw** (0.055 mg/kg ww soil) according to the assessment report of the active substance.

**Local PEC/PNEC ratio:**

|  |  |  |
| --- | --- | --- |
| **Exposure scenario** | **PEC** | **PEC/PNEC** |
| Local PEC water during emission episode | 0 mg/l | **0** |
| Local PEC in fresh-water sediment during emission episode | 0 mg/kg wwt | **0** |
| Local PEC in agric. soil (total) averaged over 30 days | 0 mg/kg wwt | **0** |

The PEC/PNEC ratio are smaller than 1, indicate an acceptable risk for the environment under normal conditions of use.

No primary or secondary poisoning are foreseen during the application of the product.

***Atmosphere***

|  |
| --- |
| **Box 24- FR CA position:**According to the claimed uses and the available data, no further assessment is relevant for this compartment. |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Box 25- FR CA position:**The risk characterisation for the STP is summarized below:

|  |  |
| --- | --- |
|  | **Summary table on calculated PEC/PNEC values** |
| **PEC/PNECSTP** |
| Considering the claimed use of 10 tablets/0.5 m3 | 7.27E-09 |

The risk is acceptable for the STP whatever the number of tablets used. |

***Aquatic compartment***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 26- FR CA position:**The risk characterisation for the aquatic compartment is summarized below:

|  |
| --- |
| **Summary table on calculated PEC/PNEC values (active substance)** |
| Scenario | PEC/PNECwater | PEC/PNECsed |
| Considering the claimed use of 10 tablets/0.5 m3 | 3.86E-02 | 2.07E-01 |

|  |
| --- |
| **Summary table on calculated PEC/PNEC values (metabolites)** |
| **Scenario** | **PEC/PNECwater** |
| Metabolite TFB-OH  | 1.25E-07 |
| Metabolite TFB-COOH  | 2.09E-07 |

The risk is acceptable in the aquatic compartment for transfluthrin and its relevant metabolites. |

***Terrestrial compartment and groundwater***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 27- FR CA position:**The risk characterisation for the terrestrial compartment is summarized below:

|  |
| --- |
| **Summary table on calculated PEC values (active substance)** |
| Scenario | PEC/PNECsoil | PECGW |
|  | [µg/L] |
| Considering the claimed use of 10 tablets/0.5 m3 | 1.25E-03 | 1.25E-04 (< 0.1 µg/L) |

|  |
| --- |
| **Summary table on calculated PEC/PNEC values (metabolites)** |
| **Scenario** | **PEC/ PNECsoil** | **PECgroundwater** [µg/L] |
| Metabolite TFB-OH  | NR\* | NR\* |
| Metabolite TFB-COOH  | 2.85E-03 | 3.41E-05 (< 0.1 µg/L) |

 \* Not relevantThe risk is acceptable for the soil compartment. The predicted concentrations in groundwater are lower than the trigger value of 0.1 µg/L for transfluthrin and its relevant metabolites. |

 ***Primary and secondary poisoning***

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 28- FR CA position:**Considering the claimed use of 10 tablets/0.5 m3:

|  |
| --- |
| **Summary table on secondary poisoning** |
| **Scenario** | **Concentration** | **PEC/PNECmammals** |
| Considering the claimed use of 10 tablets/0.5 m3 | Fish | 1.83E-04 |
| Worms | 1.80E-03 |

The risks of secondary poisoning are acceptable for mammals. No PNEC is available for birds. |

***Mixture toxicity***

|  |
| --- |
| **Box 29- FR CA position:**Not relevant according to the product composition. |

### Conclusion

The PEC/PNEC ratio are smaller than 1, indicate an acceptable risk for the environment under normal conditions of use.

No primary or secondary poisoning are foreseen during the application of the product.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Box 30- FR CA position:**

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| The environmental risk assessment for VITOMIT BOULES ANTI-MITES is performed according to the ‘Passive diffuser’ scenario provided in the Emission Scenario Document for “insecticides, acaricides and products to control other arthropods for household and professional users” (OECD, 2008). The same approach was adopted for a similar product in the Transfluthrin Assessment Report (2014) and updated with the recent discussions in WGIV2017. PEC/PNEC values are calculated for all relevant potentially exposed compartments for both the active substance and relevant metabolites considering the last conclusions of the ENV WG-IV 2017 meeting including new PNECs for the active substance and harmonized parameters in the environmental exposure assessment as described in the previous boxes.For STP, surface water, sediment, soil and secondary poisoning, the calculated PEC/PNEC values for the active substance are below 1.The risk assessment leads to acceptable risks in the STP and water for both metabolites TFB-OH and TFB-COOH, and in soil and groundwater for the last one. Groundwater concentrations are below the threshold value of 0.1 µg/L for the active substance and its relevant metabolites. |

 **Summary of the environmental risks:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Type of application / Uses** | **STP** | **Surface water** | **Sediment** | **Soil** | **Ground-****water** | **Secon-dary Poisoning** |
| *Via* STP | *Via* STP | *Via* STP |
| Considering the claimed use of 10 tablets/0.5 m3 | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable | Acceptable |

 |

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

*Please refer to summary of the product assessment and to the relevant sections of the assessment report.*

### Assessment of a combination of biocidal products

Not relevant

### Comparative assessment

Not relevant

# Annexes

## List of studies for the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title.Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** | **Date of first submission** |
| Serrano, B. | 2015 | Simulated-use trial of efficacy of products for the control of clothes moths, carpet beetles and house dust mitesReport No. 1870a/1214GLP nounpublished |  | RELEVI S.p.A | 2013-10-14 |

|  |  |  |
| --- | --- | --- |
| **Author** | **Date** | **Title** |
| A.Meluso | 2016 | Chemical-physical determinations on the test item “Biocide tablets with transfluthrin@0.05%”S-2015-03516AM |
| A. Mazzei | 2015 | Determination of the flammability (solids) and the relative self-ignition temperature for solids on the sample Biocide Tablet with Transfluthrin @0.05%report: 201502001 |
| A.Meluso | 2010 | Validation of a GC method for the identification and quantification of the active ingredient transfluthrin in the test product PALLReport no 2010/147/AM |

* **Post-authorisation 2021**

|  |  |  |
| --- | --- | --- |
| C. Belussi | 2020 | CONTROL OF CRITICAL PARAMETERS UNDER STABILITY CONDITIONSStudy number : 2016/342 AM |

## Output tables from exposure assessment tools

****

## New information on the active substance

|  |
| --- |
| **Box 31- FR CA position:**None available in the updated IUCLID |

## Residue behaviour

For indoor uses by non-professional in closets and drawers, no specific residue data were submitted in the context of this dossier.

No direct or indirect contamination of food is expected. Nevertheless, to avoid any contamination, the following precautionary statements are proposed:

“Avoid direct or indirect contact with food, feed and drinks”

## Summaries of the efficacy studies (B.5.10.1-xx)

Please see IUCLID files

## Confidential annex

Please refer to the confidential annex in an other document.

## Other

Not relevant

1. PT18 and PT 19, Guidance to replace part of appendices to chapter 7 (page 187 to 200) from TNsG on Product Evaluation (2012) [↑](#footnote-ref-1)
2. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-2)
3. Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance. [↑](#footnote-ref-3)
4. CEB 135bis (1996): Laboratory test method to evaluate the efficacy of insecticidal products in premises for the storage, industrial processing and sale of products from animal or plants. [↑](#footnote-ref-4)
5. MW= molecular weight [↑](#footnote-ref-5)