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

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

(submitted by the evaluating Competent Authority)



Yanco Transfluthrin Product Family

Product type18

Transfluthrin

Case Number in R4BP: BC-CQ065244-33

Evaluating Competent Authority: FR CA

Date: 19/09/2022

Table of Contents

[History of the dossier 4](#_Toc114500112)

[1 CONCLUSION 5](#_Toc114500113)

[1.1.1 Usage area 5](#_Toc114500114)

[1.1.2 Pest and application rate 5](#_Toc114500115)

[1.1.3 Active substance details 5](#_Toc114500116)

[1.1.4 Comparative assessment and authorisation 6](#_Toc114500117)

[1.2 NECESSARY ISSUES ACCOUNTED FOR IN THE PRODUCT LABEL 6](#_Toc114500118)

[1.3 REQUIREMENT FOR FURTHER INFORMATION 7](#_Toc114500119)

[Introduction of the application 7](#_Toc114500120)

[Summary and overall conclusion of the assessment 7](#_Toc114500121)

[Introduction of the application 8](#_Toc114500122)

[Summary and overall conclusion of the assessment 8](#_Toc114500123)

[Brief summary of the point of disagreement: 9](#_Toc114500124)

[*2* ASSESSMENT REPORT 9](#_Toc114500125)

[Part I - First information level 9](#_Toc114500126)

[2.1 Summary of the product assessment 9](#_Toc114500127)

[2.1.1 Administrative information 9](#_Toc114500128)

[2.1.2 Product family composition and formulation 11](#_Toc114500129)

[VP - Vapour releasing product 12](#_Toc114500130)

[2.1.3 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 3 13](#_Toc114500131)

[2.1.4 Authorised use(s) of the META SPC 3 13](#_Toc114500132)

[*\*Natureflex is confirmed as a bioplastic film (reconstituted cellulose laminated by barrier plastic film)* 14](#_Toc114500133)

[2.1.5 General directions for use of the meta SPC 3 15](#_Toc114500134)

[2.1.6 Other information 15](#_Toc114500135)

[PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3 16](#_Toc114500136)

[2.1.7 Trade name(s), authorisation number and specific composition of each individual product 16](#_Toc114500137)

[Part II - Second information level - meta SPC 4 16](#_Toc114500138)

[2.1.8 Meta SPC 4 administrative information 16](#_Toc114500139)

[2.1.9 Meta SPC 4 composition 17](#_Toc114500140)

[VP – Vapour releasing product 17](#_Toc114500141)

[2.1.10 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 4 17](#_Toc114500142)

[2.1.11 Authorised use(s) of the META SPC 4 18](#_Toc114500143)

[*\*Natureflex is confirmed as a bioplastic film (reconstituted cellulose laminated by barrier plastic film)* 19](#_Toc114500144)

[2.1.12 General directions for use of the meta SPC 4 19](#_Toc114500145)

[2.1.13 Other information 20](#_Toc114500146)

[PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4 20](#_Toc114500147)

[2.1.14 Trade name(s), authorisation number and specific composition of each individual product 20](#_Toc114500148)

[2.1.31. Packaging of the biocidal product 21](#_Toc114500149)

[2.1.32. Documentation 23](#_Toc114500150)

[2 Assessment of the biocidal product (family) 23](#_Toc114500151)

[2.1 Physical, chemical and technical properties 23](#_Toc114500152)

[2.1.1 Physical hazards and respective characteristics 29](#_Toc114500153)

[2.1.2 Methods for detection and identification 30](#_Toc114500154)

[2.1.3 Analytical methods for the monitoring of residues (soil, water, air, body fluids and tissues and food) 33](#_Toc114500155)

[2.2 Efficacy against target organisms 36](#_Toc114500156)

[2.2.1 Function and field of use 36](#_Toc114500157)

[2.2.2 Organisms to be controlled and products, organisms or objects to be protected 36](#_Toc114500158)

[2.2.3 Effects on target organisms, including unacceptable suffering 36](#_Toc114500159)

[2.2.4 Mode of action, including time delay 37](#_Toc114500160)

[2.2.5 Efficacy data 39](#_Toc114500161)

[2.2.6 Occurrence of resistance and resistance management 52](#_Toc114500162)

[2.2.7 Known limitations 57](#_Toc114500163)

[2.2.8 Evaluation of the label claims 57](#_Toc114500164)

[2.2.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s) 57](#_Toc114500165)

[2.3 Risk assessment for human health 57](#_Toc114500166)

[2.3.1 Assessment of effects on Human Health 57](#_Toc114500167)

[2.3.2 Exposure assessment 64](#_Toc114500168)

[2.3.3 Risk characterisation for human health 86](#_Toc114500169)

[2.4 Risk assessment for the environment 92](#_Toc114500170)

[2.4.1 Effects assessment on the environment 93](#_Toc114500171)

[2.4.2 Exposure assessment 94](#_Toc114500172)

[2.4.3 Risk characterisation 116](#_Toc114500173)

[2.4.4 Measures to protect man, animals and the environment 122](#_Toc114500174)

[3. Annexes 124](#_Toc114500175)

[3.1. List of studies for the biocidal product (family) 124](#_Toc114500176)

[3.2. Output tables from exposure assessment tools 128](#_Toc114500177)

[3.3. New information on the active substance 142](#_Toc114500178)

[3.4. Residue behaviour 142](#_Toc114500179)

[3.5. Summaries of the efficacy studies 142](#_Toc114500180)

**Note to the reader**

This consolidated PAR for the minor change application of the YANCO TRANSLUTHRIN PRODUCT FAMILY product authorisation is based on the PAR of the initial assessment by the United-Kingdom Competent Authority, in which all necessary addenda have been included.

The SPC (in section 2.1 of the PAR) corresponds to the authorised uses in the frame of this minor application (2021) in France.

In the following assessment report of this consolidated PAR, each section contains the initial assessment and the subsequent successive assessments (minor change, major change, post-authorisation data…). The amendement related to the referral to CG in 2022 are highlighted in grey.

History of the dossier

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **Ref MS** | **Case number in the ref MS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | UK | BC-GF020541-64 | 26/03/2019 | Initial assessment |
| NA-MIC | FR | BC-LD058496-36 | 17/02/2021 | National application for minor change :   * Addition of packagings to the Meta SPC 3 * Administrative changes: addition of trade names * Post-authorisation data |
| NA-MIC | FR | BC-CQ065244-33 | 30/09/2021 | National application for minor change :   * Addition of packagings |
| NA | FR | NA | tbd | Referral to CG (BE as iCMS) and outcome to CG of the 28/06/2022 : amendement of the SPC : Meta-SPCs 1 and 2 has been removed from the SPC. |

# CONCLUSION

* **FIRST AUTHORISATION - UK – 2018**

It is concluded after evaluation, that sufficient data have been provided to verify the outcome and conclusions, and permit authorisation of the biocidal product subject to the following conditions:

### Usage area

|  |  |
| --- | --- |
| User | Usage area |
| Non-professional | Yanco Transfluthrin Family is an an insecticide for non-professional indoor use. It is supplied as impregnated paper strips for use against cloth moths and mosquitoes and as a paper sheet installed in a clothes hanger shaped plastic cartridge, for use against moths in contained areas. |

### Pest and application rate

This product family is authorised for use against mosquitoes, and cloth moths. It is supplied as an impregnated paper, or as impregnated paper encased in plastic cartridges (moth hangers).

The application rate for impregnated paper for use against mosquitoes in rooms: Use one Sheet (0.08 × 0.0625 m) per 10m2 of floor area (0.45% transfluthrin). Do not exceed the use of 2 sheets per house on the same day (2 sheets will provide protection for a single room of an average size of 22m2).

The application rate for impregnated paper (moth paper) for use against moths in contained areas such as drawers cupboards and wardrobes is: Three double sheets (0.16 × 0.0625 m) per 0.5 m3 of cupboard space (0.45% transfluthrin). - Use once every three months.

The application rate for moth hangers (moth paper - sheet installed inside a rectangular plastic cartridge) for use against moths in contained areas such as drawers, cupboards and wardrobes: The sheet in the cartridge represents three single sheets. One hanger (containing three single sheets of 0.08 x 0.0625 m) per 0.25m3 cupboard space (0.45% transfluthrin). Use once every three months.

### Active substance details

The concentration of the active substance transfluthrin in the biocidal product is 0.34 - 0.56w/w (technical). The source is Bayer SAS, and the minimum purity is 96.5% w/w.

### Comparative assessment and authorisation

Transfluthrin is not considered to be a candidate for substitution or exclusion in accordance with Articles 10 and 5 respectively of the BPR (EU) Regulation 528/2012. Therefore this product family has not been subject to a comparative assessment and the product can be authorised for a maximum of 10 years.

## NECESSARY ISSUES ACCOUNTED FOR IN THE PRODUCT LABEL

For mSPC1 and 2:

Avoid breathing fumes.

Remove domestic animals during use.

Seal fish tank prior to treatment.

Do not exceed the use of 2 sheets per house on the same day (2 sheets will provide protection for a single room of average size : 22 m2)

To prevent contamination of food, do not use in kitchens or other food storage or preparation areas

For mSPC 3 and 4:

Keep animals away from treated wardrobes and textiles.

Avoid any direct or indirect exposure via food.

For all mSPC:

Read label before use

Wash hands thoroughly after handling.

In case of contact with eyes: rinse cautiously with water for several minutes. Remove contact lenses if applicable and they can be easily removed. Continue rinsing. If eye irritation persists: consult a doctor.

In case of contact with skin: wash thoroughly with soap and water.

If irritation or rash occurs: Seek medical attention if an allergic reaction/irritation develops, persists or worsens

If swallowed, consult a doctor or nearest, anti-poison centre immediately and show product label. UK medical professionals should contact the National Poisons Information Service (www.npis.org) for further advice.

Do not allow to get into surface water, drains and ground water.

Do not use directly on or near food, feed or drinks, or on or near surfaces or utensils likely to be in direct contact with food, feed, drinks and animals

Harmful to aquatic organisms, may cause long-term adverse effects to the aquatic environment.

Methods and materials for containment and cleaning up:

Use mechanical handling equipment. Clean contaminated floors and objects thoroughly, observing environmental regulations. Keep in suitable, closed containers for disposal.

Dispose of contents to a household waste recycling centre as hazardous waste except for empty containers which can be disposed of by recycling.Contact your local council for details.

Contaminated packaging: Not completely emptied packaging should be disposed of as hazardous waste.

Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place.

Store in a place accessible by authorized persons only.

Keep away from direct sunlight.

Keep away from food, drink and animal feeding stuffs.

Product is expected to be stable under normal conditions.

Shelf life of 24 months

## REQUIREMENT FOR FURTHER INFORMATION

N/A

* **MINOR CHANGE – FR CA (2020)**

**Introduction of the application**

France, as e-CA, received an application from Yanco Insecticide Solutions Ireland Limited for a minor change of authorisation for the biocidal product family YANCO TRANSLUTHRIN PRODUCT FAMILY.

The biocidal products from the YANCO TRANSFLUTHRIN PRODUCT FAMILY are product types 18 containing 0.47% of transfluthrin. The product family is divided into 4 META SPCs. The biocidal products are impregnated sheets intended to be used to fight against clothing mites and mosquitoes.

The minor change request concerns the addition of packagings in the META RCP 3 and addition of trade names.

Post-Authorization data required during the initial assessment performed by UK and submitted by the applicant has also been evaluated in the frame of this minor change.

**Summary and overall conclusion of the assessment**

**Physico-chemical properties and analytical methods**

The change consists of the addition of a new size for the primary packaging (sachet with a size of 100mm x 160mm) and a new packaging (secondary packaging which is a kraftboard carton and a tertiary packaging which is a carton (corrugated board), only for meta SPC3). The new packagings have no impact on the previous assessment.

The physico-chemical properties of the biocidal product family YANCO TRANSFLUTHRIN PRODUCT FAMILY described in the first authorisation remain acceptable in the conditions of use detailed in the SPC. No additional assessment is needed.

The analytical methods remain acceptable. A new validation with a chiral column was provided to demonstrate the specificity to 1R-transfluthrin.

**Overall conclusion**

The conformity to the uniform principles, as defined in the Regulation (EU) n°528/2012, for the biocidal product family YANCO TRANSFLUTHRIN PRODUCT FAMILY in the frame of the minor change has been demonstrated.

* **MINOR CHANGE – FR CA (2021)**

**Introduction of the application**

France, as e-CA, received an application from Yanco Insecticide Solutions Ireland Limited for a minor change of authorisation for the biocidal product family YANCO TRANSLUTHRIN PRODUCT FAMILY.

The biocidal products from the YANCO TRANSFLUTHRIN PRODUCT FAMILY are product types 18 containing 0.47% of transfluthrin. The product family is divided into 4 META SPCs. The biocidal products are impregnated sheets intended to be used to fight against clothing mites and mosquitoes.

The minor change request concerns the addition of a new packaging material.

Note for the renewal: burning completeness (point 3.5.10 of the BPR) and composition of smoke (point 3.6.5.11 of the BPR) are missing and should be provided at the renewal of the biocidal product.

**Summary and overall conclusion of the assessment**

**Physico-chemical properties and analytical methods**

The minor change consists in the addition of a new packaging material for sachet (PP/aluminium/PET). The change concerns primary packaging sachets for all meta-SPCs.

The stability for this film type was submitted in the frame of the initial authorization for the approval of Natureflex NK23. Stability in sachet made of PP/aluminium/PET has then already been addressed during the first assessment. eCA considers that this new material is compatible with the product and can be authorised.

The physico-chemical properties of the biocidal product family YANCO TRANSFLUTHRIN PRODUCT FAMILY described in the first authorisation remain acceptable in the conditions of use detailed in the SPC. No additional assessment is needed.

The analytical methods remain acceptable.

**Overall conclusion**

The conformity to the uniform principles, as defined in the Regulation (EU) n°528/2012, for the biocidal product family YANCO TRANSFLUTHRIN PRODUCT FAMILY in the frame of the minor change has been demonstrated.

**After referral to CG-52 (june 2022) : article 48**

YANCO TRANSFLUTHRIN PRODUCT FAMILY was autorised in France on 12/06/2019 via mutual recognition in parallel from the UK. After Brexit, FR-CA has become the Reference Member State for this case.

An application for authorisation via mutual recognition in sequence was then submitted in Belgium. During the mutual recognition process Belgium notified its disagreement to the Coordination Group (CG) in accordance with Article 35(2) of the Regulation (EU) No 528/2012 (BPR).

**Brief summary of the point of disagreement:**

Products from meta-SPCs 1 and 2 are paper sheet products intended to be burned, i.e., smoke generators. Thus, information on “burning completeness” and “composition of smoke” should have been provided, as both properties are part of the core data set for biocidal products and are mandatory to ensure a comprehensive picture of physico-chemical properties of the products of meta-SPCs 1 and 2.

The referral was discussed at CG 52 of June 2022 and the Members of the CG agreed by consensus on 28 June 2022 that:

Meta-SPCs 1 and 2 will be removed from the SPC and the authorised uses of the PAR, since the physico-chemical properties of the product and, consequently, the risks to human health cannot be evaluated in the absence of these data. The product family meets the condition for granting an authorisation for Meta-SPCs 3 and 4 in accordance with Article 19(1)(d) of the BPR.

# ASSESSMENT REPORT

**Part I - First information level**

## Summary of the product assessment

### Administrative information

#### Identifier of the product family

| **Identifier[[1]](#footnote-1)** | **Country (if relevant)** |
| --- | --- |
| Yanco Transfluthrin Product Family |  |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Yanco Insecticide Solutions Ireland Limited |
| **Address** | 1 Estuary Commerce Park  Liverpool  L24 8RQ |
| **Authorisation number** | **FR-2019-0064** | |
| **Date of the authorisation** | **12/06/2019** | |
| **Expiry date of the authorisation** | **26/03/2029** | |

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

|  |  |
| --- | --- |
| **Name of manufacturer** | Yanco Limited |
| **Address of manufacturer** | 1 Estuary Banks, Estuary Commerce Park  L24 8RQ, Liverpool, United Kingdom |
| **Location of manufacturing sites** | 1 Estuary Banks, Estuary Commerce Park  L24 8RQ, Liverpool, United Kingdom |
| AGRECOL SP. Z O.O.,  MESZNARY 2,  98-400 WIERUSZÓW,  POLAND |

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

|  |  |
| --- | --- |
| **Active substance** | Transfluthrin |
| **Name of manufacturer** | Bayer SAS Bayer Environmental Science |
| **Address of manufacturer** | 16 rue Jean-Marie Leclair, CP 106, 69266 Lyon Cedex 09 France |
| **Location of manufacturing sites** | Bayer Vapi Private Limited (Formerly, Bilag Industries Pvt. Ltd.)  II Phase, GIDC,  Vapi-396195,  Gujarat State, India |

### Product family composition and formulation

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

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

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | Transfluthrin |
| **IUPAC or EC name** | (1R,3S)-3-(2,2-Dichlorovinyl)-2,2-dimethyl-1-cyclopropanecarboxylic acid (2,3,5,6-tetrafluorophenyl)methyl ester |
| **EC number** | 405-060-5 |
| **CAS number** | 118712-89-3 |
| **Index number in Annex VI of CLP** | 607-223-00-8 |
| **Minimum purity / content** | 96.5 % min. |
| **tructural formula** | image |

#### Candidate(s) for substitution

The biocidal product family Yanco Transfluthrin Family contains the active substances transfluthrin.

This active substance is not a candidate for substitution.

#### Qualitative and quantitative information on the composition of the biocidal product family2

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Transfluthrin | (1*R*,3*S*)-3-(2,2-Dichlorovinyl)-2,2-dimethyl-1-cyclopropanecarboxylic acid (2,3,5,6-tetrafluorophenyl)methyl ester | Active substance | 118712-89-3 | 405-060-5 | 0.466 (without carrier : 3.66) | 0.466  (without carrier : 3.7) |
| 4-tert-butylcyclohexyl acetate | 4-tert-butylcyclohexyl acetate | Formulant | 32210-23-4 | 250-954-9 | 0.08  (without carrier : 0.63) | 0.08  (without carrier : 0.63 |
| Linalool | 3,7-dimethylocta-1,6-dien-3-ol | Formulant | 201-134-4 | 78-70-6 | 0.16 (without carrier : 1.26) | 0.16 (without carrier : 1.26) |

#### Information on technical equivalence

The notified source of transfluthrin (Bayer S.A.S.) is the same as that considered for BPR inclusion.

Bayer S.A.S. owns the transfluthrin dossier and has provided the applicant (Yanco Ltd.) with a letter of access to these data and therefore no further consideration is required.

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

Please see the confidential annex of this PAR for further details (section 4.6).

#### Type of formulation

|  |
| --- |
| VP- Vapour releasing product |

**Part II - Second information level - meta SPC 3**

### Meta SPC 3 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 3 |
| --- | --- |

#### Suffix to the authorisation number

| 3 |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 18 |
| --- | --- |

### Meta SPC 3 composition

#### Qualitative and quantitative information on the composition of the meta SPC 3

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Transfluthrin | (1*R*,3*S*)-3-(2,2-Dichlorovinyl)-2,2-dimethyl-1-cyclopropanecarboxylic acid (2,3,5,6-tetrafluorophenyl)methyl ester | Technical Active substance | 118712-89-3 | 405-060-5 | 0.466 (without carrier : 3.7) | 0.466  (without carrier : 3.7) |
| 4-tert-butylcyclohexyl acetate | 4-tert-butylcyclohexyl acetate | Co-formulant | 32210-23-4 | 250-954-9 | 0.08  (without carrier : 0.63) | 0.08  (without carrier : 0,63) |
| Linalool | 3,7-dimethylocta-1,6-dien-3-ol | Co-formulant | 201-134-4 | 78-70-6 | 0.16 (without carrier : 1.26) | 0.16(without carrier : 1.26) |

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

|  |
| --- |
| VP - Vapour releasing product |

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

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

| **Classification** | |
| --- | --- |
| Hazard category | Skin sensitisation Category 1  Acute Category 1  Chronic Category 1 |
| Hazard statement | H317 May cause an allergic skin reaction  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H317 May cause an allergic skin reaction  H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P102: Keep out of reach of children  P261: Avoid breathing vapours.  P273: Avoid release to the environment  P391: Collect spillage  P501: Dispose of contents/container to a household waste recycling centre as hazardous waste except for empty containers which can be disposed of by recycling. Contact your local council for details. |
|  | |
| Note |  |

### Authorised use(s) of the META SPC 3

#### Use description

Table 1. Use # 1 – Non-professional use against Moths – Indoors – Moth Paper

|  |  |
| --- | --- |
| **Product Type** | PT 18: Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Cloth Moth (*Tineidae sp.*)  Adults |
| **Field of use** | Indoor Use |
| **Application method(s)** | Open system: evaporation |
| **Application rate(s) and frequency** | Three double sheets (0.16 × 0.0625 m) will protect a volume of 0.5 m3 of cupboard space.  Use once every three months. |
| **Category(ies) of users** | Non-professional |
| **Pack sizes and packaging material** | Sachet - Natureflex NK23\* or PET/ALU/PP - 85mm x 120mm  or 100mm x 160mm  *\*Natureflex is confirmed as a bioplastic film (reconstituted cellulose laminated by barrier plastic film)*  Booklets containing a maximum of 18 single sheets are supplied in sachets.  **Secondary packaging:**  **Option 1:** Packing cartons 350 x252 x 90 mm  Carton material:corrugated Board  Number of units per carton: 160 sachets (each containing one 18 sheet booklet)  **Option 2:**  Printed carton (300x200x65mm)  Carton material: Kraftboard  **Secondary/Tertiary packaging:** Packing cartons containing printed cartons described above and/or individual sachets  Carton Material: corrugated board  Number of units per carton: range of 6 to 48 printed cartons or up to 480 individual sachets |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

|  |
| --- |
| - |

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

#### Instructions for use

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

#### Risk mitigation measures

|  |
| --- |
| * Wash hands thoroughly after handling. * Avoid any direct or indirect exposure via food. * Remove domestic animals during use. |

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

|  |
| --- |
| * In case of contact with eyes: rinse cautiously with water for several minutes. Remove contact lenses if applicable and they can be easily removed. Continue rinsing. If eye irritation persists: consult a doctor. * In case of contact with skin: wash thoroughly with soap and water. * If irritation or rash occurs: Seek medical attention if an allergic reaction/irritation develops, persists or worsens * If swallowed, consult a doctor or nearest, anti-poison centre immediately and show product label * If the infestation persists contact a professional pest control operators |

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

|  |
| --- |
| * Dispose of unused product, its packaging and all other waste (X), in accordance with local regulations. * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains |

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

|  |
| --- |
| * Keep away from direct sunlight. * Shelf life of 24 months |

### Other information

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

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | ECOMIT  PYREL Papier Anti-Mites  PYREL Papier Anti-Mites Fraîcheur Lavande  AVIRO MOTH KILLER PAPER BOOKLET  AVIRO MOTH KILLER PAPER | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Transfluthrin | (1R,3S)-3-(2,2-Dichlorovinyl)-2,2-dimethyl-1-cyclopropanecarboxylic acid (2,3,5,6-tetrafluorophenyl)methyl ester | Technical active substance | 118712-89-3 | 405-060-5 | 0.466 (without carrier : 3.7) |
| 4-tert-butylcyclohexyl acetate | 4-tert-butylcyclohexyl acetate | Formulant | 32210-23-4 | 250-954-9 | 0.08  (without carrier : 0.63) |
| Linalool | 3,7-dimethylocta-1,6-dien-3-ol | Formulant | 201-134-4 | 78-70-6 | 0.16 (without carrier : 1.26) |

**Part II - Second information level - meta SPC 4**

### Meta SPC 4 administrative information

#### Meta SPC identifier

| **Identification** | META SPC 4 |
| --- | --- |

#### Suffix to the authorisation number

| 4 |  |
| --- | --- |

#### Product type(s)

| **Product type(s)** | 18 |
| --- | --- |

### Meta SPC 4 composition

#### Qualitative and quantitative information on the composition of the meta SPC 4

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Transfluthrin | (1R,3S)-3-(2,2-Dichlorovinyl)-2,2-dimethyl-1-cyclopropanecarboxylic acid (2,3,5,6-tetrafluorophenyl)methyl ester | Technical active substance | 118712-89-3 | 405-060-5 | 0.466 (without carrier : 3.7) | 0.466 (without carrier : 3.7) |
| 4-tert-butylcyclohexyl | 4-tert-butylcyclohexyl acetate | Formulant | 32210-23-4 | 250-954-9 | 0.08 (without carrier : 0.63) | 0.08 (without carrier : 0.63) |
| Linalool | 3,7-dimethylocta-1,6-dien-3-ol |  | 201-134-4 | 78-70-6 | 0.16 (without carrier : 1.26) | 0.16 (without carrier : 1.26) |

#### Type(s) of formulation of the meta SPC 4

|  |
| --- |
| VP – Vapour releasing product |

### Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 4

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

| **Classification** | |
| --- | --- |
| Hazard category | Skin sensitisation Category 1  Acute Category 1  Chronic Category 1 |
| Hazard statement | H317 May cause an allergic skin reaction  H400: Very toxic to aquatic life  H410: Very toxic to aquatic life with long lasting effects |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H317 May cause an allergic skin reaction  H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P102: Keep out of reach of children  P261: Avoid breathing vapours.  P273: Avoid release to the environment  P391: Collect spillage  P501: Dispose of contents/container to a household waste recycling centre as hazardous waste except for empty containers which can be disposed of by recycling. Contact your local council for details. |
|  | |
| Note |  |

### Authorised use(s) of the META SPC 4

#### Use description

Table 1. Use # 1 – Non professional use against Moths – Indoors – Moth Paper Hanger

|  |  |
| --- | --- |
| **Product Type** | PT 18: Insecticides, acaricides and products to control other arthropods (Pest control) |
| **Where relevant, an exact description of the authorised use** |  |
| **Target organism (including development stage)** | Cloth Moth (*Tineidae sp.*)  Adults |
| **Field of use** | Indoor |
| **Application method(s)** | Open system: evaporation |
| **Application rate(s) and frequency** | One hanger (containing three single sheets of 0.08 × 0.0625 m treated area) per 0.25m3 cupboard space.  Use once every three months. |
| **Category(ies) of users** | Non-professional |
| **Pack sizes and packaging material** | Hangers individually wrapped in plastic sachets  Sachet : Natureflex NK23\* or PET/ALU/PP – 105 x 165mm  Sachet : Natureflex NK23\* or PET/ALU/PP – 110 x 160mm  *\*Natureflex is confirmed as a bioplastic film (reconstituted cellulose laminated by barrier plastic film)*  Minor change 2021:  **Secondary packaging:**  Printed carton containing 1-10 individually wrapped hanger units  Carton material: Kraftboard  **Secondary/Tertiary packaging:**  Packing cartons 170 x 180 x 180mm  Carton Material: corrugated board  Number of units per carton: range of 24 to 48 individual hangers |

##### Use-specific instructions for use

|  |
| --- |
|  |

##### Use-specific risk mitigation measures

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |
| --- |
|  |

### General directions for use of the meta SPC 4

#### Instructions for use

|  |
| --- |
| * Always read the label or leaflet before use and respect all the instructions provided. * Hang one unit on the rail of a wardrobe to protect up to 0.25 m3 or inside of the wardrobe door. * Place one hanger in each drawer or laundry bag. |

#### Risk mitigation measures

|  |
| --- |
| * Wash hands thoroughly after handling. * Keep animals away from treated wardrobes and textiles. * Avoid any direct or indirect exposure via food. |

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

|  |
| --- |
| * In case of contact with eyes: rinse cautiously with water for several minutes. Remove contact lenses if applicable and they can be easily removed. Continue rinsing. If eye irritation persists: consult a doctor. * In case of contact with skin: wash thoroughly with soap and water. * If irritation or rash occurs: Seek medical attention if an allergic reaction/irritation develops, persists or worsens * If swallowed, consult a doctor or nearest, anti-poison centre immediately and show product label. UK medical professionals should contact the National Poisons Information |

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

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains * Dispose of unused product, its packaging and all other waste (X), in accordance with local regulations. |

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

|  |
| --- |
| * Keep away from direct sunlight. * Shelf life of 24 months |

### Other information

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

**PART III - THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4**

### Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | CROCHETS ANTI-MITES  AVIRO MOTH KILLER PAPER HANGER | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| Transfluthrin | (1R,3S)-3-(2,2-Dichlorovinyl)-2,2-dimethyl-1-cyclopropanecarboxylic acid (2,3,5,6-tetrafluorophenyl)methyl ester | Technical active substance | 118712-89-3 | 405-060-5 | 0.466 (without carrier : 3.7) |
| 4-tert-butylcyclohexyl acetate | 4-tert-butylcyclohexyl acetate | Formulant | 32210-23-4 | 250-954-9 | 0.08  (without carrier : 0,63) |
| Linalool | 3,7-dimethylocta-1,6-dien-3-ol | Formulant | 201-134-4 | 78-70-6 | 0.16(without carrier : 1.26) |

### 2.1.31. 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 | 100 x 160  105 x 165 or  85 x 120 mm | Natureflex NK23  (*bioplastic film*) | N/A | Non-professional | Yes. Long term storage stability data showed the insecticide paper products are stable in PET/PP foil lined packaging. These data can be extrapolated to the Natureflex NK23 packaging. |
| Plastic hanger† | - | Polypropylene | N/A | Non-professional | Yes. Long term storage stability data shown the insecticide paper products are stable in PET/PP packaging. |

The moth paper hanger products are stored and used as a sheet of impregnated paper contained within a polypropylene plastic hanger. Each individual hanger is then wrapped within a plastic wrap made from the same film as the paper booklets, Natureflex NK23. The storage stability trials were performed in a PET 12 / 25 MET CPP flexible film (PET/PP). This stability report has been submitted and evaluated as part of the dossier. This film is based on a metallised printed PET layer, laminated on both sides with CPP (Cast Polypropylene). Therefore, the internal layer of this film is polypropylene – which is the layer in direct contact with the papers. The results from these storage stability studies showed no adverse interactions between the insecticide paper and PET/PP packaging. In addition to this, as the paper product is dry by its nature, there is negligible risk of the active being transferred into the plastic hanger.

* **MINOR CHANGE 2020 – FR CA**

New packagings have been proposed for meta SPC 3:

* New size for sachets (100x160mm, already authorized for other meta SPC)
* New secondary packaging (kraftboard) and tertiary packaging (corrugated board)

These changes are detailed for Meta SPC 3 in the SPC above.

* **MINOR CHANGE 2021 – FR CA**

The minor change consists in the addition of a new packaging material for sachet (PP/aluminium/PET). The change concerns primary packaging sachets for all meta-SPCs. The stability for this film type was submitted in the frame of the initial authorization for the approval of Natureflex . Stability in sachet made of PP/aluminium/PET has then already been addressed during the first assessment. eCA considers that this new material is compatible with the product and can be authorised.

### Documentation

#### 2.1.32.1. Data submitted in relation to product application

#### 

#### Please see annex 3.1

#### 2.1.32.2. Access to documentation

*-*

# Assessment of the biocidal product (family)

## Physical, chemical and technical properties

| **Property** | **Guideline and Method** | **Purity of the test substance (% w/w)** | **Results** | **Reference** | **UK CA comments** |
| --- | --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual assessment | Transfluthrin XX 0.45E  lavender scented insecticide paper | Paper sheet | Manka, S., 2014, report number Mo4376 | Acceptable. |
| Colour at 20 °C and 101.3 kPa | Visual assessment | Transfluthrin XX 0.45E  lavender scented insecticide paper | Rose/white-rose | Manka, S., 2014, report number Mo4376 | Acceptable. |
| Odour at 20 °C and 101.3 kPa | Olfactory assessment | Transfluthrin XX 0.45E  lavender scented insecticide paper | Perfumed with slight solvent odour | Manka, S., 2014, report number Mo4376 | Acceptable. |
| pH | CIPAC MT 75.3 | Transfluthrin XX 0.45E  lavender scented insecticide paper | 1% dilution of the test item = 9.8 | Manka, S., 2014, report number Mo4376 | Acceptable, as pH is within 4 – 10 acidity or alkalinity are not required. |
| Acidity / alkalinity | - | - | - | - | Not required, pH within the range 4 – 10. |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  Validated GC-FID method MV035  Visual assessment  CIPAC MT 75.3  Weight assessment  Visual assessment after burning  CIPAC MT 30.5  Visual assessment | Transfluthrin XX 0.45E  lavender scented insecticide paper | After 2 weeks at 54 °C or 8 weeks at 40 °C in PET/PP-foil.  Active substance content  Initial: 0.48 % w/w  After 2 weeks: 0.47 % w/w  After 8 weeks: 0.46 % w/w  Appearance  Initial: Rose/white-rose paper sheet, perfumed with a slight solvent odour.  After 2 weeks: Rose/white-rose paper sheet, perfumed with a slight solvent odour but less fresh than start.  After 8 weeks: Rose/white-rose paper sheet, perfumed with a slight solvent odour.  pH value (1% dilution)  Initial: 9.8  After 2 weeks: 9.7  After 8 weeks: 9.7  Weight change (average)  After 2 weeks: -2.7 %  After 8 weeks: -1.37 %  Burning rate and behaviour  Initial: 0.27 cm2/s, small amount of not burned paper.  After 2 weeks: 0.32, small amount of not burned paper.  After 8 weeks:0.33 cm2/s, small amount of not burned paper.  Water content  Initial: 5.76 %  After 2 weeks: 5.53 %  After 8 weeks: 3.85 %  Packaging  Test items remained in sound condition, sealed and without leakages. No significant changes in the packaging dimensions were noted after either 2 or 8 weeks. | Manka, S., 2014, report number Mo4376 | Acceptable, no significant decrease in transfluthrin content after accelerated storage.  Acceptable, no significant change in product appearance or odour.  Acceptable, no significant change in the pH of a 1% dilution of the product.  Acceptable, no significant weight loss of the product after accelerated storage.  Acceptable, burn rates and behaviour remain constant after accelerated storage.  Acceptable, no significant change in water content after accelerated storage for 2 weeks. A decrease of almost 2 % was noted after 8 weeks however this is likely to be a temperature effect.  Acceptable, however not strictly necessary after accelerated storage. |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  IMSP LAP014, equivalent to Validated GC-FID method MV035  Visual assessment | Insecticide paper (batch Y3SL082/15) | After 2 weeks at 54 °C in Natureflex NK23 composite material.  Active substance content  Initial: 0.53 % w/w  After: 0.54 % w/w  Burning time  Initial: 2’58”  After: 3’04” | Latham, A., 2016, | Acceptable, no significant decrease in transfluthrin content after accelerated storage in Natureflex NK23 composite packaging.  Acceptable, no significant change in burning time after accelerated storage. |
| Storage stability test – **long term storage at ambient temperature** | Validated GC-FID method MV035  Visual assessment  CIPAC MT 75.3  Weight assessment  Visual assessment after burning  CIPAC MT 30.5  Visual assessment | Transfluthrin XX 0.45E  lavender scented insecticide paper | After 24 months at 20 °C in PET/PP-foil packaging.  Active substance content  Initial: 0.48 % w/w  After: 0.46 % w/w  Appearance  Initial: Rose/white-rose paper sheet, perfumed with a slight solvent odour.  After: Rose/white-rose paper sheet, perfumed with a slight solvent odour.  pH value (1% dilution)  Initial: 9.8  After: 9.7  Weight change (average)  +1.3 %  Burning rate and behaviour  Initial: 0.27 cm2/s, small amount of not burned paper.  After: 0.24 cm2/s, small amount of not burned paper.  Water content  Initial: 5.76 %  After: 5.18 %  Packaging  Test items remained in sound condition, sealed and without leakages. No changes in the packaging dimensions were noted. | Manka, S., 2014, report number Mo4376 | Acceptable, no significant decrease in transfluthrin content after storage for 2 years.  Acceptable, no change in product appearance or odour.  Acceptable, no significant change in the pH of a 1 % dilution.  Acceptable, no significant change in product weight after storage for 2 years.  Acceptable, no significant change in burning rate or burning behaviour. However, burning completeness (point 3.5.10 of the BPR) and composition of smoke (point 3.6.5.11 of the BPR) are missing and should be provided at the renewal of the biocidal product.  Acceptable, slight decrease in water content is noted but this is not of concern, as no other properties have significantly changed, specifically burning rate/behaviour and active substance content.  Acceptable, the PET/PP-foil packaging remained intact after storage for 2 years and no changes to the packaging dimensions were noted. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Case | - | Not applicable as the products are packed and stored in foil lined PET sachets therefore are not exposed to light. | IUCLID dossier, section 3.4.2 | Acceptable. |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | - | - | The product is not expected to be exposed to adverse temperatures or humid conditions. See storage stability above, product is stable for 2 weeks at 54 °C. |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | Transfluthrin XX 0.45E  lavender scented insecticide paper | No adverse effects noted between the product and the commercial foil lined PET packaging after 2 years of storage. | - | Acceptable, see storage stability data above. It is possible to extrapolate these data to the Natureflex NK23 packaging.  See section 2.1.7 ‘Packaging of the biocidal product’ for further details. |
| Physical compatibility | - | All members of the product family | - | - | The products are not designed to be used in conjunction with any other product. No claims of compatibility are made on the label. |
| Chemical compatibility | - | All members of the product family | - | - | The products are not designed to be used in conjunction with any other product. No claims of compatibility are made on the label. |
| **Other studies:** |  |  |  |  |  |
| Evaporation characteristics | In house method | Insecticide paper | Test to determine transfluthrin content after the paper sheets have been stored out of the packaging.  Initial: 0.52 % w/w  After 12 weeks: 0.44 % w/w | Anon, 2014 (IUCLID dossier, section 3.5.13) | Acceptable but not strictly required. |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| The physical, chemical and technical properties of the lavender insecticide paper are acceptable for a vapour releasing formulation. The product tested is a suitable representation of all 4 products in the biocidal product family, covering all four meta SPCs. Therefore the data provided are sufficient to support the BPF requested (details in confidential annex of this PAR).  The accelerated and long term storage data are acceptable for the insecticide paper products in PET/PP-foil packaging. Most significantly the transfluthrin content does not decrease and the packaging remains intact. Accelerated storage data (active substance content and burning time) are acceptable for the insecticide paper products in Natureflex NK23 composite packaging. As the biocidal products are solid, extrapolation between these two similar packaging types is acceptable. Therefore a 2 year shelf life in the Natureflex NK23 composite packaging is supported.   * **Minor Change (2021)**   The minor change consists in the addition of a new packaging material for sachet (PP/aluminium/PET). The change concerns primary packaging sachets for all meta-SPCs. The stability for this film type was submitted in the frame of the initial authorization for the approval of Natureflex . Stability in sachet made of PP/aluminium/PET has then already been addressed during the first assessment. eCA considers that this new material is compatible with the product and can be authorised.  Note: burning completeness (point 3.5.10 of the BPR) and composition of smoke (point 3.6.5.11 of the BPR) are missing and should be provided at the renewal of the biocidal product. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** | **UK CA comments** |
| --- | --- | --- | --- | --- | --- |
| Explosives | EC method A.14 | Insecticide paper | The test item has no explosive properties as defined by the EC Regulation No. 440/2008, method A.14 and EPA Product Properties Test Guideline OPPTS 830.6316. | Dornhagen, J., 2012, report number 20120094.03 | Acceptable, insecticide paper will not be classified as explosive (meta SPC 1 extrapolated to meta SPC 2).  This can be extrapolated to the moth paper products (meta SPC 3 and 4) as they are chemically comparable. |
| Flammable solids | EC method A.10 | Insecticide paper | The test item is not a highly flammable solid in the sense of the EC Regulation No. 440/2008, method A.10. | Dornhagen, J., 2012, report number 20120094.01 | Acceptable, insecticide paper will not be classified as flammable (meta SPC 1 extrapolated to meta SPC 2).  This can be extrapolated to the moth paper products (meta SPC 3 and 4) as they are chemically comparable. |
| Oxidising solids | EC method A.17 | Insecticide paper | The test item had no oxidizing properties in the sense of the EC Regulation No. 440/2008, method A.17. | Dornhagen, J., 2012, report number 20120094.05 | Acceptable, insecticide paper was tested using EC A17 and was found to be classified as oxidising (meta SPC 1 extrapolated to meta SPC 2)  This can be extrapolated to the moth paper products (meta SPC 3 and 4) as they are chemically comparable. |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The insecticide paper products in the BPF are not oxidising, flammable or explosive, therefore a non-classification of the BPF is acceptable from a chemistry perspective. |

### Methods for detection and identification

Analytical methods for the active and impurities in the technical material

The source of the active substance is the same as that considered for BPR inclusion, therefore methods of analysis for the active substance and impurities have already been considered. No further consideration is required from a chemistry perspective.

Analytical methods for the active substance in the biocidal product

Insecticide paper (meta SPCs 1,2, 3 and 4)

The method for determining the transfluthrin content in the insecticide paper is a GC-FID method with an internal standard. The following instrument conditions were noted:

|  |  |
| --- | --- |
| Column: | Rtx®-20, Corssbond® 80% dimethyl 20% diphenyl polysiloxane, 30 m x 0.32 mm, film thickness 0.25 µm |
| Insert liner: | CarboFrit inlet liner |
|  |  |
| Temperature: | Injector: 240 °C  Detector: 350 °C |
| Oven: | Initial temp.: 150 °C  Initial time: 2 minutes   |  |  |  |  | | --- | --- | --- | --- | | Ramps | Rate (°C/min) | Final temp. (°C) | Final time (min) | | 1 | 10 | 290 | 3 | |
| Carrier gas: | Nitrogen at approx. 4 mL/min |
| Split ratio: | 6:1 |
| Injection volume: | 1 µL |
| Run time: | 19 min |
| Retention times: | Transfluthrin: 8.0 min  Dipentylphthalate (internal standard): 10.6 min |

Samples are prepared for analysis by cutting the test sample in small pieces and transferring 2 g of this into a 100 mL volumetric flask. To this 60 mL acetone and 5 mL of internal standard solution (dipentylphthalate 15 mg/mL) were added and the transfluthrin extracted in an ultrasonic bath for at least 90 minutes. Once the sample is at room temperature it was made up to the mark with acetone. This gives a resulting sample concentration of 20 mg/mL and therefore a nominal transfluthrin concentration of 0.09 mg/mL. The following points were noted:

* The extraction time depend on the performance of the ultrasonic bath.
* Solutions will be filtered before analysis where necessary.
* The standard preparation is given as an example, other weights and dilutions are possible as long as the final concentration remains the same.
* Adjustments should be made for samples of significantly different concentrations concerning both weights for standards and test solutions. The linear range should be taken into consideration.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | |
| **Matrix** | **Analyte** | **LOQ** | **Recovery fortification level (mg/mL)** | **Recoveries % (mean)** | **Repeatability % RSD (n)** | **Linearity** | **Specificity** | **Reference** |
| Insect-icide paper | Transfluthrin | 0.063 mg/mL  (equivalent to 0.32% active in the product) | 0.063  (0.32%)  0.090  (0.45%)  0.117  (0.6%) | 99.7, 99.8, 99.9 (99.8)  100.5, 100.8, 101.0 (100.8)  97.4, 97.8, 98.4 (97.9) | % RSD = 1.14 % (6x2) for a mean content of 0.47 % w/w  Acceptable Horwitz %RSD = 3.0 | 0.054 – 0.144 mg/mL, equivalent to 60 – 160 % nominal content.  n = 6x3  R2 = > 0.999 | Spectra of the blank, standard solutions and test solution were provided showing no interference. | Manka, S., 2012, report number MV035  Manka, S., 2012, report number Mo4375 |

### Analytical methods for the monitoring of residues (soil, water, air, body fluids and tissues and food)

Methods of analysis for the determination of transfluthrin residues in soil, water and air have previously been evaluated at EU level. Methods for body fluids and tissues are not required as the active substance is not considered toxic. Method for detection in food/feed of plant and animal origin are not required due to lack of exposure via the intended uses. Therefore, concerning product authorisation no further consideration is required from a chemistry perspective.

|  |
| --- |
| **Conclusion on the methods for detection and identificationof the product** |
| The analytical method, MV035, for the detection of transfluthrin in insecticide paper is acceptable and considered fit for the intended purpose, this covers meta SPCs 1, 2, 3 and 4, however evidence is required that the method is capable of separating the R-transflurin from its isomers.  Data Gap – Evidence (chromatograms) is required that the method of analysis for the determination of R-Transfluthrin in the product is specific i.e is capable of separate it from its other isomers.  The monitoring methods for soil, water and air have previously been evaluated and accepted at EU level. The monitoring methods for animal/human body fluids and tissues and food/feeding stuff are not relevant to the biocidal product family. |

* **Post autorisation data -November 2020 (FR CA)**

A new validation of the CIPAC method has been provided (S. Manka, 2020, report Mo6869, Biogenius).

The method MV035 is based on CIPAC 741/TC/M/3.2 (gas chromatography with flame ionization detection).

Reference item: 1R-Transfluthrin, 98.1%, batch PNLO000157

Principle: samples are cut into small pieces, dissolved into acetone and extracted at least 90 min in an ultrasonic bath. Samples are then filled up to the calibration mark with acetone and shaken well. An aliquot of the solution was filtered through a syringe filter before being injected in duplicate.





The column Hydrodex R-beta 6-TBDM from supplier Macherey & Nagel is a chiral column. So it will separate all isomers of transfluthrin.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | |
| **Matrix** | **Analyte** | **LOQ** | **Recovery fortification level (mg/mL)** | **Recoveries % (mean)** | **Repeatability % RSD (n)** | **Linearity** | **Specificity** | **Reference** |
| Insect-icide paper (bonodor papel insecticida, batch Y3LL127/20, 0.45% 1R-transfluthrin) | 1R-Transfluthrin | Not applicable | At 0.45%w/w a.i in reconstituted product (eq to 0.09 mg/mL of a.i in measuring solution) | 96.5, 97.9, 97.2% (mean= 97.2% with a RSD of 0.8%) | % RSD = 0.75 % (n=6) for a mean content of 0.427 % w/w (eq to 0.09mg/mL of a.i in measuring solution)  RSDr=3.02%  Acceptable Horwitz %RSD =  Hr=0.25 | Not assessed in this study | Spectra of the blank, standard solutions of 1R-transfluthrin, placebo (87.4% paper and 12.6% imprenated solution) and test item were provided showing no interference. | Manka, S., 2020, report Mo6869 |

eCA: the method is considered validated. Data on linearity were not submitted. However, this criteria was already demonstrated in the previous study. The adapted method involves a chiral column and will allow to separate isomers of transfluthrin. In the chromatograms of test item (and standard), only one peak is found and is related to 1R-transfluthrin. The other isomers (impurities in technical active ingredient) are not found, and this may be explained by low contents in measuring solution (the active substance is present at 0.45%w/w in test item and 0.09mg/mL in measuring solution). eCa considers that the new data provided are sufficient for the determination of the isomer 1R-transflurthrin in technical material.

## Efficacy against target organisms

### Function and field of use

Yanco transfluthrin product family is a product family consisting of 4 insecticide products (PT 18). These are: Insecticide Paper with Lavender fragrance; Insecticide Paper with Spice fragrance; Moth Paper – presented as individually dispensable paper sheets; Moth Paper – presented as a paper sheet installed in a plastic cartridge (clothes hanger shaped).

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

Insecticide Paper with Lavender fragrance and Insecticide Paper with Spice fragrance are both for use against mosquitoes. The other 2 products are for use against textile-attacking moths.

### Effects on target organisms, including unacceptable suffering

Insecticide Paper with Lavender fragrance and Insecticide Paper with Spice fragrance are both cellulose (paper) based products for use in domestic premises. Each product contains 0.45 % transfluthrin and the formulations are virtually identical (please see confidential annex of this PAR).

In each product, the active substance is impregnated into the paper and is released into the air upon ignition and subsequent combustion of the paper sheet. The products are applied at a rate of 1 sheet (2.4 mg transfluthrin) 10 m-2 floor area.

The Moth Paper (individual sheets) and Moth Paper (sheet in cartridge) products have the same formulation as Insecticide Paper with Lavender fragrance, and are for use in cupboards and wardrobes in domestic premises.

Moth Paper (individual sheets) is applied at a rate of 3 double sheets (4.8 mg transfluthrin per double sheet i.e. 14.4 mg transfluthrin in total) 0.5 m-3 of cupboard space, and should be replaced 3 months after introduction into the cupboard/wardrobe.

Moth Paper (sheet in cartridge) is applied at a rate of 3 single sheets (2.4 mg transfluthrin per single sheet i.e. 7.2 mg transfluthrin in total) 0.25 m-3 of cupboard space, and should be replaced 3 months after introduction into the cupboard/wardrobe.

The proposed label claims for the products are:

Insecticide Paper with Lavender fragrance and Insecticide Paper with Spice fragrance

* ‘Paper insecticide giving fast kill and protection against mosquitoes’.
* ‘Effective against mosquitoes that may carry parasites’.

Moth Paper (individual sheets) and Moth Paper (sheet in cartridge)

* ‘Lavender fragrance paper insecticide for amateur use indoors giving protection against cloth moths, larvae and eggs.’
* ‘Protection from cloth moths *Tineola bisselliella*.’

### Mode of action, including time delay

The applicant has provided the following statement describing the mode of action of the active substance.

*Transfluthrin is a synthetic pyrethroid which acts on harmful organisms by contact, inhalation and ingestion. It expresses a fast-acting strong knock-down effect against flying insects, such as mosquitoes and flies, and material pests, such as moths.*

*Pyrethroids impair ion transport through the membrane of nerve axons, causing muscular paralysis in the insect; death seems to follow a nervous system impairment that occurs a few minutes after pesticide absorption (Reigart & Roberts, 1992).*

*The primary site of activity of transfluthrin is the voltage sensitive sodium channel in nerve membrane. Transfluthrin prolongs the opening of the sodium channels (i.e. the channels directly responsible for generating nerve action potentials) leading to neuronal hyperexcitability.*

*According to the IRAC Mode of Action Classification Scheme (version 8.1, issued April 2016)3Transfluthrin is classed as a Sodium channel modulator sub group 3A.*

*The behavioural and physiological manifestations are an initial period of sensory hyperexcitation leading successively to loss of coordination, ataxia, prostration, convulsions and finally death.*

*In comparison to traditional pyrethroids, transfluthrin has two major advantages:*

*1. Comparatively high volatility enables ambient temperature diffusion (passive emanation) and formulation of passive insect control products including moths.*

*2. Good heat stability of transfluthrin in conjunction with high volatility enables highly effective usage in smoke products (paper for example) at lower active inclusions.*

The UK CA considers the applicant’s statement on mode of action to be acceptable.

### Efficacy data

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | |
| **Function and field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method /**  **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide for the control of mosquitoes | Insecticide Paper with Spice fragrance | *Aedes aegypti*  *A. albopictus*  *Culex quinquefasciatus*  *Anopheles gambiae* | Simulated use test conducted in two 20 m3 stainless steel test chambers (3 m long x 2.49 m wide x 2.69 m high, thus floor area 7.47 m2).  6 replicate tests per species (3 replicates per chamber). For each chamber, in replicate 1, a wire cage (1 mm mesh) containing 20 mosquitoes was suspended from the ceiling at a height of 1.8 m and 0.45 m from one of the walls. In the second replicate, a different cage, containing a new batch of insects, was suspended at 1.8 m and 0.45 m from one of the other walls. This procedure was repeated for the third replicate, where the cage was positioned 0.45 m from a third wall. The position of the cage was therefore different in each replicate.  In each replicate, the product (1 paper) was placed on the floor in the middle of the test chamber and activated. The paper burned for approximately 2 minutes 30 seconds. A 20 cm diameter fan was placed in one corner facing the room and rotated right/left/right, etc. during the entire test period.  In each replicate, the extent of knockdown was determined at 3, 10, 30 and 60 minutes after exposure to the product. After 60 minutes, the cage was removed and the insects provided with sugar water swabs. The extent of mortality was then determined after 24 hours.  The above procedure was repeated in separate tests in which the insects were exposed 0.5, 1, 2, 3, 4, 5, 6 or 7 hours post-activation of the product.  Each replicate was accompanied by an untreated control using the same procedure, but without the product.  The tests were conducted at a temperature of 24oC and 68 – 73 % relative humidity. | *C. quinquefasciatus*   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Time after activation (hours)** | **Mean % knockdown after**  **(minutes)** | | | | **Mean**  **24 hour mortality** | | **3** | **10** | **30** | **60** | | **0** | 20 | 100 | 100 | 100 | 100 | | **0.5** | 66 | 100 | 100 | 100 | 100 | | **1** | 27 | 96 | 100 | 100 | 100 | | **2** | 37 | 91 | 100 | 100 | 100 | | **3** | 23 | 92 | 100 | 100 | 100 | | **4** | 19 | 78 | 100 | 100 | 100 | | **5** | 18 | 74 | 100 | 100 | 100 | | **6** | 16 | 75 | 100 | 100 | 100 | | **7** | 17 | 65 | 100 | 100 | 100 |   Untreated control: Zero % knockdown after 1 hour and mean mortalities of 2 - 3 % after 24 hours.  *A. aegypti*   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Time after activation (hours)** | **Mean % knockdown after**  **(minutes)** | | | | **Mean**  **24 hour mortality** | | **3** | **10** | **30** | **60** | | **0** | 37 | 100 | 100 | 100 | 100 | | **0.5** | 95 | 100 | 100 | 100 | 100 | | **1** | 44 | 100 | 100 | 100 | 100 | | **2** | 40 | 100 | 100 | 100 | 100 | | **3** | 43 | 100 | 100 | 100 | 100 | | **4** | 38 | 100 | 100 | 100 | 100 | | **5** | 23 | 100 | 100 | 100 | 100 | | **6** | 27 | 100 | 100 | 100 | 100 | | **7** | 30 | 100 | 100 | 100 | 100 |   Untreated control: Zero % knockdown after 1 hour and mean mortalities of 3 - 5 % after 24 hours.  *A. albopictus*   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Time after activation (hours)** | **Mean % knockdown after**  **(minutes)** | | | | **Mean**  **24 hour mortality** | | **3** | **10** | **30** | **60** | | **0** | 54 | 100 | 100 | 100 | 100 | | **0.5** | 97 | 100 | 100 | 100 | 100 | | **1** | 48 | 100 | 100 | 100 | 100 | | **2** | 52 | 100 | 100 | 100 | 100 | | **3** | 50 | 100 | 100 | 100 | 100 | | **4** | 45 | 100 | 100 | 100 | 100 | | **5** | 47 | 100 | 100 | 100 | 100 | | **6** | 47 | 100 | 100 | 100 | 100 | | **7** | 42 | 100 | 100 | 100 | 100 |   Untreated control: Mean knockdowns of 0 – 2 % after 1 hour and mean mortalities of 3 - 5 % after 24 hours.  *A. gambiae*   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Time after activation (hours)** | **Mean % knockdown after**  **(minutes)** | | | | **Mean**  **24 hour mortality** | | **3** | **10** | **30** | **60** | | **0** | 22 | 100 | 100 | 100 | 100 | | **0.5** | 57 | 100 | 100 | 100 | 100 | | **1** | 37 | 96 | 100 | 100 | 100 | | **2** | 38 | 91 | 100 | 100 | 100 | | **3** | 37 | 92 | 100 | 100 | 100 | | **4** | 26 | 78 | 100 | 100 | 100 | | **5** | 25 | 74 | 100 | 100 | 100 | | **6** | 14 | 75 | 100 | 100 | 100 | | **7** | 22 | 65 | 100 | 100 | 100 |   Untreated control: Mean knockdown of 2 % after 1 hour and mean mortality of 3 % after 24 hours. | Radecki, C., (2014). |
|  | Insecticide Paper with Lavender Fragrance | *Aedes aegypti*  *A. albopictus*  *Culex quinquefasciatus*  *Anopheles gambiae* | Simulated use test conducted in 25 m3 test chambers, each with a floor area of 10 m2.  3 replicate tests per species. In each replicate, 3 wire cages, each containing 20 mosquitoes, were suspended from the ceiling at a height of 1.8 m and each with minimum 45 cm distance from the relevant walls.  In each replicate, 1 paper was placed in a glass dish on the floor in the middle of the test chamber, and activated. The paper burned for 2 minutes 51 seconds.  In each replicate, the extent of knockdown was determined at 3, 10, 30 and 60 minutes after exposure to the product. After 60 minutes, the cages were removed and the insects provided with cellulose swabs soaked in 10 % sugar solution. The extent of mortality was then determined after 24 hours.  Each replicate was accompanied by an untreated control using the same procedure, but without the product.  The tests were conducted at a temperature of 21-24oC and 39 – 64 % relative humidity. | *C. quinquefasciatus*   |  |  | | --- | --- | | **Time after activation (minutes)** | **Mean percentage knockdown** | | **3** | 67 | | **10** | 100 | | **30** | 100 | | **60** | 100 |   Mean 24 hour mortality – 100 %.  Untreated controls: Mean of 0 % knockdown after 60 minutes and mean of 0 % mortality after 24 hours.  *A. aegypti*   |  |  | | --- | --- | | **Time after activation (minutes)** | **Mean percentage knockdown** | | **3** | 88 | | **10** | 100 | | **30** | 100 | | **60** | 100 |   Mean 24 hour mortality – 100 %.  Untreated controls: Mean of 0 % knockdown after 60 minutes and mean of 2 % mortality after 24 hours.  *A. albopictus*   |  |  | | --- | --- | | **Time after activation (minutes)** | **Mean percentage knockdown** | | **3** | 93 | | **10** | 100 | | **30** | 100 | | **60** | 100 |   Mean 24 hour mortality – 100 %.  Untreated controls: Mean of 0 % knockdown after 60 minutes and mean of 0 % mortality after 24 hours.  *A. gambiae*   |  |  | | --- | --- | | **Time after activation (minutes)** | **Mean percentage knockdown** | | **3** | 85 | | **10** | 100 | | **30** | 100 | | **60** | 100 |   Mean 24 hour mortality – 100 %.  Untreated control: Mean of 0 % knockdown after 60 minutes and mean of 2 % mortality after 24 hours. | Kalla, K, (2019). |
| Insecticide for the control of moths | Insecticide Paper with Lavender fragrance | *Tineola bisselliella*  adults. | Simulated use tests conducted in 0.5 m3 chambers.  In each test, the product was hung from a rod that was fastened 30 mm from under the ceiling of the chamber and was attached parallel to the opening and in the centre of the chamber. The product consisted of 3 double sheets, giving a total of 15 mg active substance. Two pieces of cloth, each made of 100 % lamb’s wool, were suspended from a bar either side of, but not in contact with, the product. The test insects (20 in total) were contained in a plastic container and were placed on pieces of cloth (5cm x 5 cm) within the container. The container was placed inside the chamber and the product activated. The chamber was then opened after 24 hours and opened again after 2, 3, 5, 7, 10 and 14 days. At each time point, the extent of insect mortality was determined, together with the number of eggs laid and the number of hatched larvae. Any larvae that had hatched were also evaluated for grub i.e. a check was made to determine the colour of the larvae’s intestines, as a black intestine is considered indicative of the larvae having fed on the black lamb’s wool.  The above procedure was repeated twice i.e. a total of 3 replicates were conducted. The above procedure was also conducted without the product i.e. as untreated controls (3 replicates).  The above procedure was repeated (3 replicates), using fresh batches of 20 insects, at 2, 6 and 12 weeks post-activation of the product, to assess the residual efficacy of the product.  The tests were conducted at a temperature of 23 – 26oC and 60 – 70 % relative humidity.  During the tests, the chambers were opened once per day for a period of 10 seconds, to simulate the typical use of a closet. | Treatment   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Test days** | **Mean % *T. bisselliella* mortality after weeks** | | | | | 0 | 2 | 6 | 12 | | **1** | 0 | 100 | 100 | 100 | | **2** | 26.7 | 100 | 100 | 100 | | **3** | 38.3 | 100 | 100 | 100 | | **5** | 80 | 100 | 100 | 100 | | **7** | 80 | 100 | 100 | 100 | | **10** | 95 | 100 | 100 | 100 | | **14** | 100 | 100 | 100 | 100 | | **Mean no. of eggs laid**  **after 1 day** | > 30 | > 22 | 8.3 | 12 | | **Mean no. of larvae**  **hatched after**  **14 days** | > 30 | 0 | 0 | 0 | | **Mortality of larvae hatched after**  **14 days** | No | N/A | N/A | N/A | | **Grub** | Yes | N | N | N |   N/A = Not applicable(as no larvae had hatched).  Untreated controls   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Test days** | **Mean % *T. bisselliella* mortality after weeks** | | | | | 0 | 2 | 6 | 12 | | **1** | 0 | 0 | 0 | 0 | | **2** | 0 | 0 | 0 | 0 | | **3** | 0 | 0 | 0 | 0 | | **5** | 11.7 | 11.7 | 11.7 | 8.3 | | **7** | 16.7 | 20 | 16.7 | 16.7 | | **10** | 31.7 | 30 | 31.7 | 21.7 | | **14** | 43.3 | 40 | 43.3 | 30 | | **Mean no. of eggs laid**  **after 1 day** | > 30 | > 30 | > 30 | > 30 | | **Mean no. of larvae**  **hatched after**  **14 days** | > 30 | > 30 | > 30 | > 30 | | **Mortality of larvae hatched after**  **14 days** | No | No | No | No | | **Grub** | Yes | Yes | Yes | Yes | | Lüpkes, K.H., (2016). |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| Insecticide Paper with Lavender fragrance and Insecticide Paper with Spice fragrance  For product authorisation, the efficacy of insecticide products is governed by the ‘Technical Notes for Guidance on Product Evaluation – Product Type 18 – Insecticides, Acaricides And Products To Control Other Arthropods’ (TNsG).  Under the TNsG, for vapouriser products for use against mosquitoes in domestic premises, the data requirements are as follows.  Simulated use data showing > 80 % knockdown and > 90 % 24-hour mortality of *Culex* spp.  The UK CA considers the methodology used in the Radecki, (2014) tests, and the test species, to be acceptable, and considers them as complying with the TNsG.  The results for *C. quinquefasciatus* showed that the test product produced > 80 % knockdown within 10 minutes up to 3 hours post-activation, within 30 minutes up to 7 hours post-activation, and 100 % mortality after 24 hours up to 7 hours post-activation. Based on the TNsG, the results demonstrated the efficacy of the product against *C. quinquefasciatus*.  The results for *A. aegypti* and *A. albopictus* showed that the product produced > 80 % knockdown within 10 minutes and 100 % mortality after 24 hours, up to 7 hours post-activation. Those for *A. gambiae* showed > 80 % knockdown within 10 minutes up to 3 hours post-activation, within 30 minutes up to 7 hours post-activation, and 100 % mortality after 24 hours up to 7 hours post-activation.  Based on the TNsG, the results for *C. quinquefasciatus* demonstrated the efficacy of the product against mosquitoes. Those for the other test species provided further evidence of the product’s efficacy against mosquitoes.  The applicant has stated to the UK CA that the test product was Insecticide Paper with Spice fragrance. As stated earlier, apart from the fragrance, the product Insecticide Paper with Lavender fragrance has an identical formulation to the test product (please see confidential annex of this PAR). Therefore, as the UK CA doesn’t consider the fragrance as having a negative impact on efficacy, the UK CA considers the data as supporting the efficacy of both the mosquito Insecticide Paper products.  As stated earlier, the application rate for both mosquito paper products is 1 paper per 10 m-2 floor area. The study report states that the test chamber was 3 m long x 2.49 m wide. This gives a floor area of 7.47 m2. Although this is a smaller floor area than that requested for treatment with 1 paper, the difference in the floor areas is equivalent to a difference in floor dimensions of approximately 1 m length or width. The UK CA considers this difference to be minimal, and can therefore accept the data as demonstrating the efficacy of the mosquito paper products when applied at the requested application rate of 1 paper 10 m-2.  The UK CA considers the methodology used in the Kalla, (2019) tests, and the test species, to be acceptable, and considers them as complying with the TNsG.  The results for all 4 test species showed 100 % knockdown after 10 minutes, and 100 % mortality after 24 hours.  The UK CA considers the results as demonstrating the efficacy of the product against mosquitoes when used in a 25 m3 room and with a floor area of 10 m2.  The mosquito paper products both include the claim that they provide ‘fast kill’ of mosquitoes. In support of this claim, the applicant has provided the following reasoned case.  *‘The study included four mosquito species (Aedes aegypti, Culex quiquefasciatus, Aedes albopictus, Anopheles gambiae). The housefly Musca domestica was also tested as were other species, but are not reviewed here.*  *60 subjects were introduced at hourly intervals and left in place for one hour, whilst assessing knockdown at interim intervals. Mortality was assessed after 24 hours.*  *The data shows complete knockdown across all mosquito species within the ten-minute application period as defined within the instructions of use for the paper fumer.*  *Where subjects were knocked down, there was no subsequent recovery, and mortality was complete at 24 hours.*  *Subjects of all four species present during and after 30 minutes of application showed 100% knockdown after 10 minutes exposure and 100% mortality after 24 hours.*  *Three mosquito species (Aedes aegypti, Aedes albopictus, Anopheles gambiae) continued to show 100% knockdown after 10 minutes exposure, with 100% mortality, even when introduced up to 7 hours after application.*  *One mosquito species (Culex quiquefasciatus) continued to be show extremely high levels of knockdown > 90% after 10 minutes exposure when introduced up to 3 hours after application. A reduction in knockdown efficacy was observed from 4 hours onwards at the 10 minute exposure interval. However, even this species still gave 100% knockdown after 30 minutes exposure and 100% mortality after 24 hours.*  *It should also be noted that there was clear evidence of continued efficacy (both knockdown and mortality) against subjects introduced at subsequent time intervals.’*  The UK CA agrees that the results showed very high levels of knockdown within 10 minutes of exposure, and considers it reasonable that non-professional users will consider this level of performance as representing quick knockdown. The UK CA therefore considers this to be acceptable to justify a claim that the product produces fast knockdown. The UK CA accepts the applicant’s reasoned case, and thus considers the claim for fast kill to be acceptable.  Moth Paper (individual sheets) and Moth Paper (sheet in cartridge)  Under the TNsG, for vapouriser products for use against textile-attacking moths, the data requirements are as follows.   * At the end of an exposure period (e.g. 1 week), > 90 % mortality of *Tineola bisselliella* or *T. pellionella* L. adults or larvae (or both adults and larvae, depending on the efficacy claim).   As stated earlier, the formulation of the test product - Insecticide Paper with Lavender fragrance – is identical to that of these two moth paper products. The test product is therefore acceptable in support of these products.  The UK CA considers the methodology used in the Lüpkes, (2016) tests, and the test species, to be acceptable, and considers them as complying with the TNsG.  The results showed that the product produced > 90 % adult mortality after 10 days for freshly activated product (week 0), and 100 % adult mortality after 14 days up to and including week 12.  Eggs continued to be laid (in decreasing numbers) within 1 day up to and including week 12.  The data for the initial post-activation period showed that > 30 larvae had hatched after 14 days, and the results also showed that these larvae had fed on the wool. The data from week 2 onwards showed that no larvae had hatched after 14 days, and thus no new feeding on the wool occurred.  In the untreated controls, although the adult mortalities were, for the most part, > 10 % after 5 – 14 days, the results showed that eggs had been laid after 1 day, live larvae had hatched after 14 days, and there was evidence of larval feeding on the wool. The untreated control results therefore showed that the wool was not protected and thus the UK CA considers the control results to be acceptable.  The study report indicates that the test product - Insecticide Paper with Lavender fragrance - contained a total of 15 mg active substance. The applicant has, however, clarified that the transfluthrin technical grade material used in the test product has a nominal active content of 96.5 %, and that this equates to a total of 14.475 mg active substance. The UK CA can accept this as being an equivalent amount to that stated earlier for Moth Paper (individual sheets) i.e. 3 double sheets, each containing 4.8 mg active substance = 14.4 mg total active substance.  On the basis of the acceptability criterion set out in the TNsG, the UK CA considers the results for adults as complying with this criterion, and thus considers the results as demonstrating the efficacy of Moth Paper (individual sheets) against adult *T. bisselliella* for up to 12 weeks after application at the requested application rate of 3 double sheets 0.5 m-3 volume.  The formulation of Moth Paper (sheet in cartridge) is identical to that of Moth Paper (individual sheets). In addition, although the application rate is 3 single sheets (7.2 mg total active substance) 0.25 m-3, the UK CA considers this to be equivalent to the rate used in the study i.e. 3 double sheets (14.4 mg total active substance) 0.5 m-3. The UK CA therefore considers the results as supporting the efficacy of the Moth Paper (sheet in cartridge) product against adult *T. bisselliella* at the requested application rate of 3 single sheets (7.2 mg total active substance) 0.25 m-3.  As the results showed that eggs continued to be laid up to and including 12 weeks post application, the label claim that the products give protection against eggs, is not supported.  Given the larval results for the initial post-activation period, this indicates that the wool was not protected. The study report appears to acknowledge this in the conclusion, where it is stated that ‘A claim of fabric protection might be possible’. Given these larval results, the UK CA considers that the label claim that the products give protection against larvae, is not supported.  Summary  Insecticide Paper with Lavender fragrance and Insecticide Paper with Spice Fragrance  The data supports the efficacy of the above products against *A. aegypti*, *A. albopictus*, *A. gambiae* and *C. quinquefasciatus* when applied at the requested application rate of 1 sheet 10 m-2 floor area.  The label claims supported by the data are:   * ‘Paper insecticide giving fast kill and protection against mosquitoes’. * ‘Effective against mosquitoes that may carry parasites’.   Moth Paper (individual sheets) and Moth Paper (sheet in cartridge)  The data supports the efficacy of the above products against *T. bisselliella* adults when applied at the requested application rates of 3 double sheets 0.5 m-3 volume  (Moth Paper – individual sheets) and 3 single sheets 0.25 m-3 volume (Moth Paper – sheet in cartridge).  The data does not support the efficacy of the above products against *T. bisselliella* eggs. For this reason, the proposed label claim that the product gives protection against eggs, is not supported.  The label claims supported by the data are:   * ‘Lavender fragrance paper insecticide for amateur use indoors giving protection againstt adult cloth moths.’ * ‘Protection from adult cloth moths Tineola bisselliella.’ |

### Occurrence of resistance and resistance management

The applicant has provided the following statement on resistance and resistance management.

***Development of Resistance to Transfluthrin***

*No known resistance in the target species (mosquitoes or food moth) has been observed to-date for the active Transfluthrin.*

*Transfluthrin is a pyrethroid insecticide 1. Some resistance to pyrethroids has been found to varying degrees, depending on the pest species and location 2. In Europe the main problems have occurred in some areas with pests of agricultural significance 3. Laboratory tests on resistant strains have shown, for Myzus persicae, a resistance factor of 200 (to control the resistant strain requires 200 times the dose required to control a sensitive strain).*

*A review by the WHO of Vector Resistance to Pesticides4 identified no reports of resistance to synthetic pyrethroids in mosquitoes and other sucking insects in Europe. However, resistance among some species of flies and cockroach populations was more evident. Resistance to synthetic pyrethroids among European agricultural pest species, where insecticide use is more intensive, may be more widespread 5.*

*Cross-resistance of pest species to the group of synthetic pyrethroids is to be anticipated due to a common mode of action 6, and instances of cross-resistance (or multiple resistance) between pyrethroids and organochlorine insecticides have been reported 7.*

***Efficacy of Transfluthrin Active Against Resistant Strains***

*Several mechanisms exist that potentially lead to insecticide resistance – including metabolic P450 monooxygenase/enzyme mechanism of the Anopheles funestus FUMOZ-R strain and target site knockdown resistance (kdr) mutation prevalent in Aedes sp. and Anopheles gambiae RSP-H strain 3,9,11.*

*Evidence is emerging that compounds that comprise a polyfluorobenzyl moiety, such as Transfluthrin, continue to exhibit efficacy against resistant mosquitoes in the presence of these mechanisms. Recent studies indicate Transfluthrin remains effective against multiple mechanisms of resistance 8,9,10,11.*

*In this manner the likelihood of natural selection of resistance is potentially reduced, as the active remains more efficacious against resistant species.*

***Paper Performance to Mitigate Occurrence of Resistance***

*The presented efficacy studies performed on the products show that when used in accordance with instructions for use and correct dosage, total knockdown and mortality is achieved well within the defined period of use before re-entry. In this way we anticipate that the likelihood of resistance occurring through selective mortality is limited.*

*The instructions for use on mosquito paper state that treated areas (including windows and doors) should be closed during usage to maximise the performance against target species, and ensure effective knockdown and mortality. This action is inherent within the moth control usage.*

*The moth control product has been found to work effectively at all stages of life cycle, and therefore likelihood of resistance is considered low when used in accordance with instruction for use.*

***Management strategies***

*Resistance is well known to be a potential problem, and therefore strategies to avoid resistance are normal practice. For example, the use of alternating sequences, mixtures and avoidance of frequent repeated use are standard.*

*The principles of strategies for preventing and managing the development of resistance are similar for transfluthrin as for other synthetic pyrethroids. General advice is available from the International Resistance Action Committee (IRAC) 2,3, and complemented by published opinions on pyrethroid insecticides from the Biocidal Product Committee (BPC) 12,13.*

*IRAC recommends the following general strategies be incorporated into a resistance mitigation strategy*

*Where possible, application treatments should be recommended to be combined with non-chemical measures.*

*Products should always be used in accordance with label recommendations.*

*Applications should always be made against the most susceptible stages in the pest life cycle.*

*Where an extended period of control is required, treatments should be alternated with products with different modes of action.*

*Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refugia can contribute to the risk of re-infestation.*

*In cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing the same class of chemistry should cease.*

***Specific measures***

*Yanco has in place an effective system for monitoring customer complaints. Should complaints surrounding lack of effectiveness be reported these will be thoroughly investigated and should any concerns over resistance found these will be reported to the relevant authorities.*

*We work closely with our active supplier Bayer, who are co-developers of the paper products. Bayer are very active with respect to insecticide resistance. Any data or findings with regards to resistance from Bayer will be included into our ongoing regulatory and technical assessments.*

*The proposed frame labels state that product(s) clearly define the floor area or volumes to be treated. Yanco is happy to propose that these are extended to include the phrase similar to “Always use the product in full accordance with the instructions for use and the recommended dosages. Avoid using at lower or higher concentrations than those specified”.*

*Should the HSE require, in order to ensure reporting of potential resistance, Yanco are happy to consider incorporating additional phrases similar to those specified in recent BPC opinions: “In the case of reduced efficacy the user is advised to contact a professional pest control operator”.*

*Both uses of products are considered to be very seasonal, and therefore it is considered highly likely that natural “breaks” in usage will be foreseen across the year, thereby mitigating the potential for resistance for different species. It is foreseen that the majority of usage against mosquito species will fall within Late Spring/Summer, moth usage tends to fall within Autumn/Winter season as garments are stored.*

***References***

|  |  |  |  |
| --- | --- | --- | --- |
| *1* | *Naumann, K.* | *1990* | *Synthetic pyrethroid insecticides: structures and properties. Springer Verlag, Date: 01.10.1990, published* |
| *2* | *Anon.* | *1987* | *Insecticide/acaricide resistance: survey and recommendations by industry.*  *FRAC/IRAC Newsletter, December 1987.* |
| *3* | *Anon.* | *2007* | *Resistance Management for Sustainable Agriculture and Improved Public Health. Insecticide Resistance Action Committee (IRAC International), April 2007.* |
| *4* | *Anon.* | *1992* | *Vector Resistance to Pesticides. Fifteenth Report of the WHO Expert Committee on Vector Biology and Control, TRS 818, 1992.* |
| *5* | *Anon.* | *2000* | *Guidelines for preventing and managing insecticide resistance in the peach-potato aphid, Myzus persicae. Insecticide Resistance Action Group, February 2000.* |
| *6* | *Staetz* | *2004* | *Insecticide Mode of Action Classification: A Key to Insecticide Resistance Management (v.3.3.2). Insecticide Resistance Action Committee (IRAC International), 2004.* |
| *7* | *Brogdon & McAllister* | *1998* | *Insecticide Resistance and Vector Control*  *Emerging Infectious Diseases; Vol. 4 No. 4, December 1998.* |
| *8* | *Tan & McCaffrey* | *2007* | *Efficacy of various pyrethroid structures against a highly metabolically resistant isogenic strain of Helicoverpa armigera (Lepidoptera: Noctuidae) from China. Pest Manag Sci. 2007;63: 960–968 [ doi: 10.1002/ps.1419]* |
| *9* | *Horstmann, Sonneck, Velten & Werner* | *2012* | *Use of a compound comprising a polyfluorobenzyl moiety against insecticide-resistant pests. Bayer Cropscience AG. Publication number WO2014079928 A1. Publication date May 30, 2014. Filing date Nov 21, 2013. Priority date Nov 23, 2012* |
| *10* | *Horstmann* | *2013* | *New findings on the resistance breaking potential of Transfluthrin. Bayer CropScience AG, R&D, Environmental Science, Germany.*  *http://www.relcov.org/wp-content/uploads/2015/01/Evaluacion-de-Transfluthrin.pdf* |
| *11* | *Horstmann & Sonneck* | *2016* | *Contact Bioassays with Phenoxybenzyl and Tetrafluorobenzyl Pyrethroids against Target-Site and Metabolic Resistant Mosquitoes. PLoS One. 2016; 11(3):e0149738. Epub 2016 Mar 1. https://www.ncbi.nlm.nih.gov/pubmed/26930058* |
| *12* | *Anon.* | *2014* | *Biocidal Products Committee (BPC), Opinion on the application for approval of the active substance Permethrin Product Type 18. ECHA/BPC/004/2014. April 2014.* |
| *13* | *Anon.* | *2016* | *Biocidal Products Committee (BPC), Opinion on the application for approval of the active substance Cyfluthrin Product Type 18. ECHA/BPC/090/2016. February 2016.* |
|  | *Reigart & Roberts,* | *1999* | *Recognition and management of pesticide poisonings. Washington, DC: US Environmental Protection Agency, Office of Prevention, Pesticides, and Toxic Substances (March). Fifth Edition.* |

The UK CA considers the applicant’s statement on resistance and resistance management to be acceptable. The UK CA also considers acceptable the inclusion of the proposed additional label phrases referred to under ‘Specific measures’.

#### 

### Known limitations

There are no known limitations to consider for Yanco Transfluthrin product family.

#### 

### Evaluation of the label claims

The UK CA considers the following label claims to be acceptable.

Insecticide Paper with Lavender fragrance and Insecticide Paper with Spice fragrance

* ‘Paper insecticide giving fast kill and protection against mosquitoes’.
* ‘Effective against mosquitoes that may carry parasites’.

Moth Paper (individual sheets) and Moth Paper (sheet in cartridge)

* ‘Lavender fragrance paper insecticide for amateur use indoors giving protection against adult cloth moths’.
* ‘Protection from adult cloth moths Tineola bisselliella.’

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

None

## Risk assessment for human health

Transfluthrin XX 0.45E W is an impregnated insecticide paper. It is intended for use indoors by non-professional users to control mosquitoes, and cloth moths. The formulation contains the active ingredient transfluthrin (0.47% (calculated including the carrier[[2]](#footnote-2))). Please see the confidential annex of this PAR for full details of the formulation.

### Assessment of effects on Human Health

***Skin corrosion and irritation***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table of animal studies on skin corrosion /irritation** | | | | | |
| **Method, Guideline,**  **GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance, Vehicle, Dose levels,  Duration of exposure** | **Results**  *Average score**(24, 48, 72h)/*  *observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological*  *findings* | **Remarks** *(e.g. major deviations)* | **Reference** |
| *In vivo* dermal irritation study in rabbits  OECD404  GLP compliant  Reliability 1 | Rabbit, New Zealand White  3 male | Transfluthrin XX 0.45% w/w impregnated paper  Test item cut to 2.5 x 2.5 cm (approx 6 cm2) under semi-occlusive dressing.  Exposure duration: 4 hours  Observations at 1, 24, 48 and 72 hours post exposure | Scores for erythema and oedema were 0 at all time points in all rabbits | - | Gerbeix, 2012 |

Transfluthrin XX 0.45% was tested for skin irritancy in rabbits in accordance with OECD guideline 404. The rabbits were exposed for 4 hours to a 6 cm2 piece of the test substance under a semi-occlusive dressing after which the exposed area was washed with water. The rabbits were monitored at 1, 24, 48 and 72 hours for clinical signs and irritation. No cutaneous reactions were observed during the study. Based on these results, Transfluthrin XX 0.45%w/w is not considered to be a skin irritant in the rabbit and does not require classification according to Regulation (EC) 1272/2008.

No human data available.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Not irritating to the skin |
| Justification for the value/conclusion | Based on the results from the skin irritation study with Transfluthrin XX 0.45% w/w. |
| Classification of the product according to CLP | Transfluthrin XX 0.45%w/w does not required classification for skin irritation |

***Eye irritation***

No data on eye irritation has been presented. Classification of the product is addressed using available data on the individual ingredients of the formulation. It should be noted that the carrier of the biocidal product has not been included as part of the product composition when considering the classification and labelling in accordance with the Guidance on carriers-based biocidal products (CG-17-2016-05 AP 13.3)

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Transfluthrin XX 0.45% E W is not irritating to the eye (cat 2). |
| Justification for the value/conclusion | Based on the data evaluated during the EU review of the active substance transfluthrin is not corrosive or irritating to the eye. When the classification of the co-formulants is considered two ingredients in Transfluthrin XX 0.45 E W contain components classified for eye irritation. Applying the formula 10x Cat 1 + cat 2 (as set out in Regulation (EC) 1272/2008) gives a value for eye irritant components <10%. This is less than the generic cut-off value for classification as a category 2 eye irritant. Therefore Transfluthrin XX 0.45% E W is considered not to have the potential to cause eye irritation. For further details please see the confidential annex of this PAR. |
| Classification of the product according to CLP | Not classified |

***Respiratory tract irritation***

No data on respiratory tract irritation with the formulation has been presented. Classification of the product is addressed using available data on the individual ingredients of the formulation. It should be noted that the carrier of the biocidal product has not been included as part of the product composition when considering the classification and labelling in accordance with the Guidance on carriers-based biocidal products (CG-17-2016-05 AP 13.3)

|  |  |
| --- | --- |
| **Conclusion used in the Risk Assessment – Respiratory tract irritation** | |
| Justification for the conclusion | Transfluthrin is not classified for respiratory tract irritation. Similarly, according to the submitted MSDSs none of the co‑formulants are classified for this endpoint. On this basis no classification for respiratory tract irritation is proposed for Transfluthrin XX 0.45% E W. In addition, the applicant has also provided summary information on a study in which mice were exposed to smoke generated with a prototype version of the lavender paper formulation. No signs of respiratory irritation were reported at exposures of up to 40x the normal used conditions. For further details please see the confidential annex of this PAR. |
| Classification of the product according to CLP | Transfluthrin XX 0.45% E W is not irritating to the respiratory tract. |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table of animal studies on skin corrosion /irritation** | | | | | |
| **Method, Guideline,**  **GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance, Vehicle, Dose levels,  Duration of exposure** | **Results**  *Average score**(24, 48, 72h)/*  *observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological*  *findings* | **Remarks** *(e.g. major deviations)* | **Reference** |
| No details provided | Mouse  5 male | Transfluthrin (XX 0.2 containing 1 mg transfluthrin/0.5 g paper (0.20 % w/w)]  1, 3, and 10 papers/chamber  1, 3, and 10 papers/chamber  Duration: 1 hour | No mortality up to the maximum tested concentration. Non-specific effects: reduced motility at the high dose level. No clinical signs at post-exposure and no findings at necropsy. |  | Pauluhn, 2007 |

The potential of a prototype version of the paper formulation to induce respiratory sensory irritation has previously been evaluated in the mouse (Pauluhn, 2007). In this study groups of 5 male mice were exposed to the smoke generated from the prototype formulation [Transfluthrin (XX 0.2 containing 1 mg transfluthrin/0.5 g paper (0.20 % w/w)] over a time period of 1 hour. The exposure chamber (volume 2.3 m³, 1 air exchange/hour) was 'loaded' with 1, 3, and 10 papers/chamber, respectively. These load rates were equivalent to approximately 4, 13, and 40 times normal use conditions of the formulation Transfluthrin XX 0.45 E W Lavender scent (Company code UVP 80521944) (1 paper per room floor area of 10 m², air volume approximately 25 m³). No mortality was observed up to the maximum tested concentration. Minimal non-specific effects consisting of reduced motility was reported in animals treated at the high dose level. However no clinical signs were observed at the subsequent post-exposure day. No findings were observed at necropsy. The absence of mortality and specific treatment-related findings in animals treated up to dose levels that were approximately 40 times normal use conditions of the formulation Transfluthrin XX 0.45E W Lavender scent (Company code UVP 80521944), shows that the smoke liberated by this formulation can be considered not to be associated with any reasonable inhalation risk to humans.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | IUCLID Section 8.5.2 |
| Justification | These data also confirm that a new acute inhalation study is unlikely to provide any additional useful scientific information and in the interest of animal welfare, is considered not to be warranted or justified. |

***Skin sensitisation***

No data on skin sensitisation has been presented. Classification of the product is addressed using available data on the individual ingredients of the formulation. It should be noted that the carrier of the biocidal product has not been included as part of the product composition when considering the classification and labelling in accordance with the Guidance on carriers-based biocidal products (CG-17-2016-05 AP 13.3)

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Skin sensitisation Category 1 |
| Justification for the value/conclusion | Based on the data evaluated during the EU review of the active substance, tranfluthrin is not classified as a skin sensitiser. Classification of the co-formulants is taken from the submitted MSDSs.  The products contain either linalool or 4-tert-butylcyclohexyl acetate (skin sens 1B) (both classified as skin sens 1B) that are present in excess of the trigger for the classification for skin sensitisation.  Both of these non-active co-formulates contain additional skin sensitisers below the level for classification, but at levels triggering EUH208. See confidential annex of this PAR for futher details. |
| Classification of the product according to CLP | Skin sensitisation category 1 (H317) |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Skin sensitisation (IUCLID Section 8.3) |
| Justification | The applicant has submitted a waiver for skin sensitisation, on the basis that the study is not technically feasible (expert statement (Wason & Renault-Billault, 2012)). Classification of the product is adequately addressed using data on the individual ingredients in accordance with Regulation (EC) No 1272/2008.  The waiver is agreed. |

***Respiratory sensitization (ADS)***

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not a respiratory sensitiser |
| Justification for the value/conclusion | There is no study to address respiratory sensitisation. The active substance is not classified for respiratory sensitisation, nor according to the sumbitted MSDSs are any of the co-formulants. Therefore based on the available information for the active substances and co-formulants no classification for this endpoint is proposed. For further details please see the confidential annex of this PAR. |
| Classification of the product according to CLP | No classification proposed |

***Acute toxicity***

No data have been presented. Classification of the product is addressed using available data on the individual ingredients of the formulation. It should be noted that the carrier of the biocidal product has not be included as part of the product composition when considering the classification and labelling in accordance with the Guidance on carriers-based biocidal products (CG-17-2016-05 AP 13.3).

*Acute toxicity by oral route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | Not acutely toxic via the oral route |
| Justification for the selected value | No acute oral toxicity study is available with Transfluthrin XX 0.45% E W. Classification is based on the inherent toxicity of the active substance and the co-formulants. Based on the data evaluated during the EU review of transfluthrin and the submitted MSDSs for the co-formulants, and applying the calculation method in accordance with Regulation (EC) 1272/2008, a calculated ATE of >2000 mg/kg bw is achieved. Therefore Transfluthrin XX 0.45% does not require classification for acute toxicity via the oral route. For further details please see the confidential annex of this PAR. |
| Classification of the product according to CLP | No classification proposed |

*Acute toxicity by inhalation*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not acutely toxic via the inhalation route |
| Justification for the selected value | No acute inhalation toxicity study is available with Transfluthrin XX 0.45% E W. Classification is based on the inherent toxicity of the active substance and the co-formulants. Based on the data evaluated during the EU review of transfluthrin and the submitted MSDSs for the co-formulants, and applying the calculation method in accordance with Regulation (EC) 1272/2008 a calculated ATE of >5 mg/l is achieved. Therefore Transfluthrin XX 0.45% does not require classification for acute toxicity via the inhalation route. For further details please see the confidential annex of this PAR. |
| Classification of the product according to CLP | No classification proposed |

*Acute toxicity by dermal route*

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not acutely toxic via the dermal route |
| Justification for the selected value | No acute toxicity studies are available with the formulation. Classification is based on the inherent toxicity of the active substance and the co-formulants. Based on the data evaluated during the EU review of transfluthrin and the submitted MSDSs for the co-formulants, neither the active substance nor any of the co-formulants are classified as acutely toxic via the dermal route. Therefore Transfluthrin XX 0.45% E W does not require classification for acute toxicity via the dermal route. No classification proposed. For further details please see the confidential annex of this PAR. |
| Classification of the product according to CLP | No classification proposed |

***Information on dermal absorption***

|  |  |
| --- | --- |
|  | |
| **Value(s) used in the Risk Assessment – Dermal absorption[[3]](#footnote-3)** | | |
| Substance | Transfluthrin | |
| Value(s) | 10% | |
| Justification for the selected value(s) | No dermal absorption data has been submitted for this product. A default value of 10% from the Transfluthrin CAR is applied for risk assessment.  The agreed dermal absorption value from the Transfluthrin CAR is based on the molecular weight of 371 and log Pow of 5.4 and values from other pyrethroids. While the EFSA guidance requires that both criteria of molecular weight (MW) >500 and log Pow –1 < > 4 should be met, the CAR considered that the values for Transfluthrin were close to the MW criterion and well beyond the Pow criterion suggesting dermal penetration substantially less than 10%. Furthermore, evaluations of several pyrethroids and several formulations were reported to have concluded that a default assumption of 10% absorption was appropriate. Therefore a default value of 10% is consistent with that of other pyrethroids. | |

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

No data is available however two substances of concern have been identified as Skin sensitisation category 1 (H317), these are:

* 4-tert-butylcyclohexyl acetate and;
* Linalool

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

None

***Other***

None

#### 

### Exposure assessment

Yanco Transfluthrin Product Family consist of four individual insecticide products each containing 0.45% w/w transfluthrin as active substance. The products are ready-to-use by non-professionals in indoors situations. The active substance is impregnated onto inert support mediums necessary for the function of the product. An overview of the products in the family is provided below.

|  |  |  |
| --- | --- | --- |
| **Intended uses of the product family** | | |
| **Product category** | **Use** | **Application rate** |
| Insecticide paper | The impregnated paper is combusted to allow vapours to be released in the treatment area | 1 sheet/10 m2 |
| Moth paper | The impregnated paper releases vapour by evaporation in contained areas e.g. cupboard | 3 double sheets/0.5 m3 |
| Moth paper hangers | The impregnated paper is contained within a plastic hanger. Vapour is released by evaporation in contained areas e.g. cupboard | 1 hanger/0.25 m3 |

**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 | Yes | Yes | N/a |
| Dermal | N/A | N/A | Yes | N/A | Yes | Yes | N/a |
| Oral | N/A | N/A | No | N/A | Yes | Yes | N/a |

***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. | Handling/preparing insecticide paper | Primary exposure: A non-professional user prepares the paper for application e.g. tearing from booklet | Non-professional |
| 2. | Ignition of insecticide paper | Primary exposure: A non-professional user ignites the paper and departs the room | Non-professional |
| 3. | Handling/preparing moth paper | Primary exposure: A non-professional user prepares the paper for application e.g. tearing from booklet | Non-professional |
| 4. | Handling/preparing moth paper hangers | Primary exposure: A non-professional user prepares and hang the paper hanger in the desired location | Non-professional |
| 5. | Application of moth paper/moth hangers | Secondary (acute) exposure: A non-professional/bystander use of/access to areas where the product is placed e.g. opening of wardrobe | Non-professional and bystander |
| 6. | Application of moth paper hanger | Secondary (chronic) exposure: A non-professional/bystander exposure during application of moth paper | Non-professional and bystander |
| 7. | Post-application (re-entry) insecticide paper (combusted) | Secondary exposure: A non-professional/bystander re-entry in to the treated area | Non-professional and bystander |

***Non-professional exposure***

*Scenario 1: Primary exposure during handling and preparation of impregnated insecticide paper*

Primary exposure to biocidal products occurs to the individual who directly uses/applies the product. The product is an impregnated paper containing 0.45% w/w transfluthrin used as an insecticide for flying insects by non-professional users in indoor situations. The product label advises that application is achieved by ignition and subsequent combustion of the paper sheet where the user should then leave the room immediately and not re-enter within the next 10 minutes. One sheet of impregnated paper (8 x 6.25 cm) contains 2.4 mg of transfluthrin and the maximum application rate is one sheet per 10 m2 room floor area per day. The product is supplied in booklet form contained within a sachet. Each booklet contains a maximum of 18 sheets.

Primary exposure for a non-professional user occurs during the handling and preparation of the impregnated paper e.g. tearing a sheet from the booklet and positioning paper in the desired location. Primary exposure via skin contact and via inhalation is considered in this scenario.

| **Description of Scenario 1** | | |
| --- | --- | --- |
| Adult non-professional user handling impregnated paper and prepare/position a sheet of paper in a desired location. ConsExpo 4.1 and the default parameters in the Pest Control Products Fact Sheet[[4]](#footnote-4) for mixing and loading products in sealed areas have been used to predict inhalation exposure resultant from evaporation of impregnated paper sheets and dermal exposure (constant rate model). It is assumed that this task will take no longer than 10 minutes. | | |
|  | Parameter | Value |
| Tier 1 | Body weight | 60 kg |
| Molecular weight | 371.2 g/mol |
| Vapour pressure | 9x10-4 Pa at 20 °C |
| Inhalation rate | 1.25 m3/hour |
| Inhalation absorption | 100% |
| Transfluthrin content in insecticide paper | 0.45% w/w |
| Exposure duration | 10 min |
| Product amount handled | 9.6 g |
| Release area | 4.05 cm2 |
| Room volume | 1 m3 |
| Ventilation rate | 0.6 per hour |
| Mass transfer rate | Langmuir model |
| Molecular weight matrix\* | 14.7 g/mol |
| Contact rate | 1 mg/min |
| Release duration | 10 min |
| Dermal penetration | 10% |
| \*Molecular weight matrix calculated in accordance with RIVM 320104004 Consumer Exposure and Uptake Models Program Manual (p.41). | | |

**Tier 1 assessment**

It is assumed that no clothing or gloves are worn and that a non-professional user would be handling/preparing the product for 10 minutes per day.

Inhalation exposure via evaporation from impregnated paper occurs when the user takes the booklet containing a maximum of 18 paper sheets out of one sachet. For the worst-case scenario, it is assumed that the user is exposed to the total surface area of each paper sheet in the booklet. Given that one sheet has a size of 8 x 6.25 cm = 50 cm2, the total surface area of 18 paper sheets is 50 cm2 x 18 = 900 cm2. Thus a non-professional user would be exposed to a release area of 900 x 0.45% w/w transfluthrin i.e. 4.05 cm2.

Considering one sheet contains 2.4 mg transfluthrin then theoretically a booklet contains 43.2 mg transfluthrin (equivalent to 9.6 g product).

Dermal exposure

Dermal contact at constant rate (1 mg/min) is assumed in the ConsExpo model.

**Calculations for Scenario 1**

| **Summary table: systemic exposure from non-professional uses** | | | |
| --- | --- | --- | --- |
| **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/day)** | **Estimated dermal uptake**  **(mg/kg bw/day)** | **Estimated total uptake**  **(mg/kg bw/day)** |
| 1 (no PPE) | 7.36x10-8 | 7.50x10-5 | 7.51x10-5 |

Scenario 2: Primary exposure during ignition of insecticide paper

Dermal and inhalation exposure to airborne residues occurs when the user ignites the insecticide paper and sequentially exits the treatment room.

Inhalation exposure

Considering that the default value[[5]](#footnote-5) for the area of a living room is 22 m2 (volume 58 m3), it is reasonable to assume that inhalation exposure during the departure of the room will be no longer than that expected for the preparation of the paper considered in scenario 1 (10 mins). As a worst-case scenario, it is assumed that the room is fully saturated with the active substance and no ventilation during application. This assumption is considered to be highly conservative given that the release of airborne residues to the target air concentration will not immediately fully saturate the air in the room (i.e. there will be a delay between ignition of the paper and generation of airborne residues and diffusion through the air space), and the user will ignite the paper sequentially moving towards the open door of the room.

The amount of active in the room is calculated as follows:

RC = AR ÷ V

Where

RC = Residues concentration in the room (mg/m3)

AR = application rate (mg)

V = volume of room (m3)

RC = 7.2 (mg) ÷ 58 (m3)

= 0.124 mg/m3

Considering the inhalation rate of an adult is 1.25 m3/hr and an exposure duration of 10 mins, inhalation exposure to transfluthrin is calculated as follows:

I = RC x IR x D x Iabs

Where

SI = systemic inhalation exposure (mg/kg bw/day)

RC = Residues concentration in the room (mg/m3)

IR = inhalation rate (m3/hr)

D = exposure duration (hr)

Iabs = inhalation absorption (%)

I = 0.124 mg/m3 x 1.25 m3/hr x (10/60 min) x 100%

= 0.0258 mg/day

= 0.00043 mg/kg bw/day

Dermal exposure

Dermal exposure occurs when the user is departing the treatment room walking through airborne residues. In the absence of any specific exposure models for this scenario, TNsG Fogging Model 34 is used as the best-fit surrogate data for dermal exposure during fogging at mid-level. The potential dermal exposure (75th percentile) value is 0.79 mg/min, thus for a 10 min exposure duration (worst-case time for the user to depart the treatment room), dermal exposure is calculated as follows:

DE =0.79 mg/min x 10 min x 0.45% w/w transfluthrin x 10%

= 0.00356 mg/day

= 0.000059 mg/kg bw/day

It should be noted the conservatism of the dermal exposure estimate since the calculation uses potential dermal exposure values which does not consider the protection from clothing.

**Calculations for Scenario 2**

| **Summary table: systemic exposure from non-professional uses** | | | |
| --- | --- | --- | --- |
| **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/day)** | **Estimated dermal uptake**  **(mg/kg bw/day)** | **Estimated total uptake**  **(mg/kg bw/day)** |
| 1 (no PPE) | 4.3x10-4 | 5.9x10-5 | 4.9x10-4 |

*Scenario 3: Primary exposure during handling and preparation of impregnated moth paper*

Primary exposure to biocidal products occurs to the individual who directly uses/applies the product. The product is an impregnated paper containing 0.45% w/w transfluthrin used as an insecticide for common clothes moths. The product is intended to be used by non-professionals to protect fabrics in wardrobes, cupboards or draws. The product is supplied in booklet form where the user tears out the required number of double sheets for the area they wish to treat. The product label informs that 3 double sheets will cover a volume of 0.5 m3 enclosed space and the product can be replaced every 3 months. The applicant informs that one single paper sheet of size 8 x 6.25 cm weights 0.49 g, thus one double sheet weights 0.98 g and is 16 x 6.25 cm. Each booklet supplied in a sachet contains a maximum of 18 single sheets.

Primary exposure for a non-professional user occurs during the handling and preparation of the impregnated paper e.g. tearing a sheet from the booklet and positioning paper in the desired location. Primary exposure via skin contact and via inhalation is considered in this scenario.

| **Description of Scenario 3** | | |
| --- | --- | --- |
| Non-professional user handling impregnated paper and prepare/position sheet of paper in a desired location. ConsExpo 4.1 and the default parameters in the Pest Control Products Fact Sheet2 for mixing and loading products in sealed areas have been used to predict inhalation exposure resultant from evaporation of impregnated paper sheets and dermal exposure via constant rate. It is assumed that this task will take no longer than 10 minutes. | | |
|  | Parameters | Value |
| Tier 1 | Body weight | 60 kg |
| Molecular weight | 371.2 g/mol |
| Vapour pressure | 9x10-4 Pa at 20 °C |
| Inhalation rate | 1.25 m3/hour |
| Inhalation absorption | 100% |
| Transfluthrin content in moth paper | 0.45% w/w |
| Exposure duration | 10 min |
| Release area | 4.05 cm2 |
| Product amount handled | 8.82 g |
| Room volume | 1 m3 |
| Ventilation rate | 0.6 per hour |
| Mass transfer rate | Langmuir model |
| Contact rate | 1 mg/min |
| Release duration | 10 min |
| Dermal absorption | 10% |
| Molecular weight matrix\* | 14.7 g/mol |
| \*Molecular weight matrix calculated in accordance with RIVM 320104004 Consumer Exposure and Uptake Models Program Manual (p.41). | | |

**Tier 1 assessment**

It is assumed that no clothing or gloves are worn and that a non-professional user would be handling/preparing the product for 10 minutes per day.

Inhalation exposure

Inhalation exposure via evaporation from impregnated paper occurs when the user takes the booklet containing a maximum of 18 paper sheets out of one sachet. For the worst-case scenario, it is assumed that the user is exposed to the total surface area of each paper sheet in the booklet i.e. 18 sheets. Given that one single sheet has a size of 8 x 6.25 cm = 50 cm2, the total surface area of 18 paper sheets is 50 cm2 x 18 = 900 cm2. Thus a non-professional user would be exposed to a release area of 900 x 0.45% w/w transfluthrin i.e. 4.05 cm2. As one sheet weights 0.49 g, 18 sheets weights 8.82 g.

Dermal exposure

Dermal contact at constant rate (1 mg/min) is assumed in the ConsExpo model.

**Calculations for Scenario 3**

| **Summary table: systemic exposure from non-professional uses** | | | |
| --- | --- | --- | --- |
| **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg bw/day)** | **Estimated dermal uptake**  **(mg/kg bw/day)** | **Estimated total uptake**  **(mg/kg bw/day)** |
| 1 (no PPE) | 7.36x10-8 | 7.50x10-5 | 7.51x10-5 |

| **Summary table: acute exposure from non-professional uses** | | |
| --- | --- | --- |
| **Tier/PPE** | **Estimated inhalation uptake**  **(mg/m3)** | **Estimated dermal uptake**  **(mg/kg bw/day)** |
| 1 (no PPE) | 1.47x10-7 | 7.5x10-4 |

*Scenario 4: Primary exposure during handling and preparation of moth paper hanger*

Paper moth hangers are packaged individually in sealed sachets. Each moth hanger containing 3 sheets of moth paper can be used to cover an area of 0.25 cm3. As such 6 hangers will be required for a wardrobe with a volume of 1.5 cm3, which is equivalent to 18 singles sheets or 9 double sheets of moth paper. Therefore non-professional exposure during handling and preparing moth hangers is within the risk envelope of the exposure assessed for a non-professional user during handling and preparing moth paper.

***Exposure of the general public***

*Scenario 5: Secondary (acute) exposure during the use of/access to areas containing moth paper/moth hanger e.g. opening wardrobe*

Secondary exposure occurs during application when bystander (e.g. adult and children) access areas where the moth paper has been used e.g. opening of wardrobe. It is assumed that moth control products are used all year round and in everyday wardrobes. As a realistic worst-case, it is assumed that exposure will be no longer than 5 minutes when opening the wardrobe. ConsExpo 4.1 and the default parameters in the Pest Control Products Fact Sheet2 have been used to predict inhalation exposure.

| **Description of Scenario 5** | | |
| --- | --- | --- |
| General public (acute) exposure during the application of moth paper when access into areas where the product has been used occurs e.g. opening of wardrobe. ConsExpo 4.1 and the default parameters in the Pest Control Products Fact Sheet2 have been used to predict inhalation exposure via evaporation from constant surface. | | |
|  | Parameters1 | Value |
| Tier 1 | Adult body weight | 60 kg |
| Child body weight | 23.9 kg |
| Adult inhalation rate | 1.25 m3/hr |
| Child inhalation rate | 1.32 m3/hr |
| Frequency | 365 per year |
| Transfluthrin content in moth paper | 0.45% w/w |
| Exposure duration | 5 mins |
| Product amount (3 double sheets) | 8.82 g |
| Room volume | 1.5 m3 |
| Ventilation rate | 0.3 per hour |
| Release area (3 double sheets) | 4.05 cm2 |
| Application duration | 5 mins |
| Mass transfer rate | Langmuir model |
| Molecular weight matrix\* | 14.7 g/mol |
| \*Molecular weight matrix calculated in accordance with RIVM 320104004 Consumer Exposure and Uptake Models Program Manual (p.41). | | |

Tier 1 assessment

The applicant informs that one double sheet has a size of 16 x 6.25 cm = 100 cm2 and weights 0.93 g. The product label informs that 3 double sheets treats 0.5 m3, then 9 double sheets is required to treat a volume of 1.5 m3. Therefore the amount of product applied is 0.98 g x 9 sheets and the release area is 900 cm2 x 0.45% transfluthrin.

**Calculations for Scenario 5**

| **Summary table: systemic exposure of members of the public** | |
| --- | --- |
| **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/day)** |
| 1 (adult no PPE) | 2.74x10-8 |
| 1 (child no PPE) | 7.26x10-8 |

| **Summary table: acute exposure of members of the public** | |
| --- | --- |
| **Tier/PPE** | **Estimated inhalation uptake (mg/m3)** |
| 1 (adult no PPE) | 5.48x10-8 |
| 1 (child no PPE) | 5.48x10-8 |

**Futher information and consideration for scenario 5**

Although general public users may be exposed to transfluthrin via transfer from textiles contained in treated draws/wardrobes, it is not envisaged that higher dermal exposure would result considering the transfer from paper (the product) to textiles would be lower than from direct handling of the product during application. Therefore further consideration of general public exposure to contaminated textiles is not required.

Remark post Mutual Recognition’s comment :

The exposure of the toddler that is in contact with treated clothes has not been assessed specifically.

No such standard scenario exists in the guidance for human exposure.

The corresponding systemic exposure of the toddler can be assessed with very worst case parameters that are not necessarily realistic ones.

* The maximum of concentration of Transfluthrin on the surface of the product sheet is 0.048 mg/cm2 (i.e., 2.4 mg Transfluthrin / 8 x 6.25 cm2).
* The transfer from a dried liquid on a paper surface to clothes by direct contact can be estimated to be far below the transfer coefficient of 8 – 18% for transfer of dried fluid from various types of surface to hands (BHEEM), as hands might be a bit moist or fatty, whereas in contrast clothes are dry.
* So taking into account a coefficient transfer of 8%, there would be maximum of 0,00384 mg/cm2 transferred on the clothes.

The systemic dermal exposure for the toddler can be estimated as follows:

Systemic dermal exposure = concentration a.s. on surface x body surface x body surface covered by clothing x dislodgeable amount x dermal absorption / body weight

= 0.00384 mg/cm2 x 4800 cm2 x 80% x 9% x 10% / 10 kg = 0.013 mg/kg bw/day

which is equivalent to the chronic AEL.

Importantly, this estimation does not take into account neither evaporation nor the realistic adhesion or the real transfer factors for the materials. To be noted also that the bioavailability of the active substance is likely reduced as it is impregnated into the carrier component.

Considering all these uncertainties and in absence of more realistic values, these estimated values are considered to be gross overestimations.

*Scenario 6: Secondary (chronic) exposure during application of moth paper/moth paper hanger*

General public may be exposed to transfluthrin during application of moth paper in wardrobes. Since wardrobes are not airtight and are often sited in occupied rooms e.g. bedrooms, persons occupying the room could be exposure to transfluthrin permeating out of the wardrobes through door gaps.

| **Description of Scenario 6** | | |
| --- | --- | --- |
| Adults and children may be exposed to transfluthrin when volatilised residues permeating out of non-airtight spaces e.g. wardrobes. As a worst-case scenario, exposure duration of 24 hours is assumed for occupied rooms. ConsExpo 4.1 and the default parameters in the Pest Control Products Fact Sheet have been used to predict inhalation exposure via evaporation from constant surface. | | |
|  | Parameters1 | Value |
| Tier 1 | Adult body weight | 60 kg |
| Child body weight | 23.9 kg |
| Toddler body weight | 10 kg |
| Infant body weight | 8 kg |
| Adult inhalation rate | 16 m3/day |
| Child inhalation rate | 12 m3/day |
| Toddler inhalation rate | 8 m3/day |
| Infant inhalation rate | 5.4 m3/day |
| Molecular weight of transfluthrin | 371 g/mol |
| Frequency | 365 per year |
| Transfluthrin content in moth paper | 0.45% w/w |
| Exposure duration | 24 hours |
| Product amount | 8.82 g |
| Room volume (unspecified) | 20 m3 |
| Ventilation rate (unspecified) | 0.6 per hour |
| Release area | 4.05 cm2 |
| Emission duration | 24 hours |
| Molecular weight matrix\* | 14.7 g/mol |
| \*Molecular weight matrix calculated in accordance with RIVM 320104004 Consumer Exposure and Uptake Models Program Manual (p.41). | | |

Tier 1 assessment

The applicant informs that one double sheet has a size of 16 x 6.25 cm = 100 cm2 and weights 0.93 g. The product label informs that 3 double sheets treats 0.5 m3, then 9 double sheets are required to treat a volume of 1.5 m3. Therefore the amount of product applied is 0.98 g x 9 sheets and the release area is 900 cm2 x 0.45% transfluthrin.

Considering transfluthrin moth paper can be used for wardrobes or cupboards which can be sited in any rooms, the default parameters in the Pest Control Products Fact Sheet for an unspecified room has been used.

**Calculations for scenario 6**

| **Summary table: systemic exposure of members of the public** | |
| --- | --- |
| **Tier/PPE** | **Estimated inhalation uptake (mg/kg bw/day)** |
| 1 (adult no PPE) | 5.15x10-6 |
| 1 (child no PPE) | 9.69x10-6 |
| 1 (toddler no PPE) | 1.54x10-5 |
| 1 (infant no PPE) | 1.30x10-5 |

**Futher information and consideration for scenario 6**

Although general public users may be exposed to transfluthrin via transfer from textiles contained in treated draws/wardrobes, it is not envisaged that higher dermal exposure would result considering the transfer from paper (the product) to textiles would be lower than from direct handling of the product during application. Therefore further consideration of general public exposure to contaminated textiles is not required.

*Scenario 7: Secondary exposure during re-entry into areas treated with insecticide paper*

Secondary exposure occurs when bystander (e.g. adult and child) re-enters into the room after treatment of insecticide paper through combustion. The product label advises the user to then leave the room immediately after and not to re-enter within the next 10 minutes. Secondary exposure via inhalation of volatilised residues and dermal exposure to surfaces with residue deposits (e.g. carpet) are considered in this scenario.

Dermal exposure

Dermal exposure to airborne residues during re-entry into treated room is calculated using TNsG Fogging Model 3[[6]](#footnote-6) as the best-fit surrogate data for dermal exposure during fogging at mid-level. The potential dermal exposure (75th percentile) value is 0.79 mg/min. Considering the systemic AEL is 0.01 mg/kg bw/day and dermal penetration of 10%, a user would have to be dermally exposed to 6 mg of airborne transfluthrin to exceed AEL. Thus, 6 (mg) / 0.79 (mg/min) x 0.45% w/w transfluthrin = 1688 mins (equivalent to 28 hours) to exceed the systemic AEL.

It should be noted the conservatism of the dermal exposure estimate since the calculation uses potential dermal exposure values which does not consider the protection from clothing.

Inhalation exposure

Tier 1 assessment

As a worst-case scenario, it is assumed the room is fully saturated with the active substance, occupied 24 hours per day and no ventilation in the room. HEEG Opinion 13[[7]](#footnote-7) considers the worst-case scenario on the basis a person is exposed to 100% saturated vapour concentration of the active substance for 24 hours a day. An approach for a Tier 1 screening tool in order to determine whether inhalation exposure can be neglected or should be included into the risk assessment is advised. The following screen test is based on the inhalation exposure for a toddler whom represents the worst-case:

*Let mw and vp denote the molecular weight (in g/mol) and the vapour pressure (in Pa).*

*For toddler (based on an inhalation rate of 8 m3/24 hr and bw of 10 kg) and using an AEL*

*in mg a.s./kg bw/d, if*

**

*then risk from inhalation exposure for the toddler is negligible, otherwise inhalation exposure should be included in the risk assessment.*

Thus, to determine whether inhalation exposure can be neglected for this product;

0.328 x 371.2 g/mol x 0.0009 Pa

0.01 mg/kg bw/day is greater than 1.

Therefore inhalation exposure cannot be excluded.

According to HEEG Opinion 13, the saturated vapour concentration is calculated as follows:



SVC = 0.41 x 371.2 (g/mol) x 0.0009 (pa)

= 0.137 mg/m3

Taking into consideration the inhalation rate for adult, toddler and infant is 16 m3/24h, 8 m3/24h and 5.4 m3/24h respectively, systemic inhalation exposure is summarised below.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Adult | Toddler | Infant |
| SVC (mg/m3) | 0.137 | 0.137 | 0.137 |
| Inhalation rate (m3/24 hours occupancy) | 16 | 8 | 5.4 |
| Body weight (kg) | 60 | 10 | 8 |
| Amount of a.s. inhaled over 24 hours (mg) | 2.192 | 1.096 | 0.740 |
| Systemic exposure (mg/kg bw/d) | 0.0365 | 0.1096 | 0.092 |

Tier 2 assessment

ConsExpo exposure to vapour (constant rate) model from the RIVM (p.37) Consumer Exposure and Uptake Models Program Manual[[8]](#footnote-8) has been used to calculation inhalation exposure.

| **Description of Scenario 7** | | |
| --- | --- | --- |
| Adult and toddler exposure to vapour when occupying treated room for 24 hours per day after room is treated with insecticide paper. ConsExpo constant rate model and the default parameters from RIVM General Fact Sheet3 have been used in the calculations. It is assumed that the emission duration is 10 min which is the worst-case assumption of the time it takes for the insecticide paper to burn. | | |
|  | Parameters | Value |
| Tier 2 (inhalation) | Molecular weight | 371 g/mol |
| Vapour pressure | 0.0009 Pa |
| Product amount applied (3 sheets) | 1.6 g (equivalent to 7.2 mg a.s) |
| Transfluthrin content in insecticide paper | 0.45% w/w transfluthrin |
| Adult body weight | 60 kg |
| Toddler body weight | 10 kg |
| Infant body weight | 8 kg |
| Volume of living room | 58 m3 |
| Ventilation rate of living room | 0.5 per hour |
| Exposure duration | 24 hours |
| Emission duration | 10 mins |
| Adult inhalation rate | 16 m3/day |
| Toddler inhalation rate | 8 m3/day |
| Infant inhalation rate | 5.4 m3/day |
| Inhalation absorption | 100% |

Dermal and oral exposure

Airborne residues of transfluthrin may deposit on the floor and other materials present in the treated room. Re-entry of children (toddler) into treated areas may lead to dermal and oral (hand-to-mouth) exposure to transfluthrin when crawling/playing on the floor. ConsExpo 4.1 and the default parameters in the Pest Control Factsheet for the ‘rubbing off’ model and the ‘constant rate’ model have been used to calculate dermal and oral exposure respectively.

| **Description of Scenario 7** | | |
| --- | --- | --- |
| Children (toddler) re-entry exposure to transfluthrin when crawling/playing in treated areas where airborne residues may have deposited e.g. floor. Exposure via dermal and oral (hand-to-mouth) route has been estimated using ConsExpo 4.1 and the default parameters in the pest control factsheet. | | |
|  | Parameters1 | Value |
| Tier 1 (dermal and oral) | Infant body weight | 8 kg |
| Toddler body weight | 10 kg |
| Transfluthrin content in insecticide paper | 0.45% w/w |
| Transfer coefficient | 0.6 m2/hr |
| Dislodgeable amount (calculated) | 21.81 mg/m2 |
| Contact time | 60 min |
| Rubbed surface | 7 m2 |
| Ingestion rate (calculated) | 0.02181 mg/min |
| Exposure time | 60 min |
| Dermal penetration | 10% |

Tier 1 assessment

Dermal exposure

For the worst-case scenario, 100% deposition of airborne residue on to the floor is assumed. Considering that the default value for the area of a living room is 22 m2 and the maximum application rate of insecticide paper is 1 sheet (2.4 mg transfluthrin) per 10 m2, the dislodgeable amount of active on the floor is (2.4 mg x 3 sheets) / 22 m2 = 0.327 mg a.s/m2 (equivalent to 72.7 mg product/m2). ConsExpo Pest Control Product factsheet2 (p.28) informs that, of the amount on the floor surface 30% is dislodgeable. Therefore the dislodgeable amount is 72.7 mg product/m2 x 30% = 21.81 mg product/m2.

Oral exposure

According to the RIVM pest control products factsheet2 (p.34), the constant rate model should be used to assess oral exposure. The ingestion rate is calculated on the basis that 10% of the dermal exposure is ingested as hand-to-mouth contact (p.28).

Dislodgeable amount (mg product/m2) x Transfer coefficient (m2/hr) x Contact time (hr) x % Ingested

21.81 (mg product/m2) x 0.6 (m2/hr) x 1hr x 10%

= 1.309 mg

= 0.02181 mg/min

This assessment is considered conservative as the amount of residue deposition on the floor is assumed to be 100% and does not consider the loss of airborne residues resulting from the inhalation route which is based on 100% saturated vapour concentration i.e. it is unlikely that there would be 100% deposition of airborne residues and 100% saturated vapour of transfluthrin in the room.

**Calculations for Scenario 7**

| **Summary table: systemic exposure of members of the public** | | | | |
| --- | --- | --- | --- | --- |
|  | **Estimated inhalation uptake (tier 1)**  **(mg/kg bw/day)** | **Estimated dermal uptake**  **(mg/kg bw/day)** | **Estimated oral uptake**  **(mg/kg bw/day)** | **Estimated total uptake**  **(mg/kg bw/day)** |
| Adult | 0.0365 | N/A | N/A | 0.0365 |
| Toddler | 0.1096 | 0.000588 | 0.000588 | 0.1108 |
| Infant | 0.092 | 0.000736 | 0.000736 | 0.0935 |

| **Summary table: systemic exposure of members of the public** | | | | |
| --- | --- | --- | --- | --- |
|  | **Estimated inhalation uptake (tier 2)**  **(mg/kg bw/day)** | **Estimated dermal uptake**  **(mg/kg bw/day)** | **Estimated oral uptake**  **(mg/kg bw/day)** | **Estimated total uptake**  **(mg/kg bw/day)** |
| Adult | 0.00276 | N/A | N/A | 0.00276 |
| Toddler | 0.00828 | 0.000588 | 0.000588 | 0.00945 |
| Infant | 0.00698 | 0.000736 | 0.000736 | 0.00845 |

***Summary of exposure assessment***

Transfluthrin insecticide paper

| **Summary table: systemic exposure from non-professional use** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group (e.g. professionals, non-professionals, bystanders)** | **Tier** | **Estimated systemic exposure**  **(mg/kg bw/day)** |
| 1. | Primary exposure for non-professional user preparing and handling insecticide paper | 1 | 7.51x10-5 |
| 2. | Primary exposure of non-professional user during ignition of insecticide paper | 1 | 4.9x10-4 |
| 7. | Secondary exposure of non-professional/bystander re-entry into treated area | 1 | 0.0365 |
| 2 | 0.00276 |
| Secondary exposure of bystander (toddler) re-entry into treated area | 1 | 0.1108 |
| 2 | 0.00945 |
| Secondary exposure of bystander (infant) re-entry into treated area | 1 | 0.0935 |
| 2 | 0.00845 |

Combined scenarios

| **Summary table: combined systemic exposure from non-professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation uptake (mg/kg bw/day)** | **Estimated dermal uptake**  **(mg/kg bw/day)** | **Estimated oral uptake (mg/kg bw/day)** | **Estimated total uptake (mg/kg bw/day)** |
| Scenarios 1, 2 and 7 (tier 2) Adult primary and secondary exposure to insecticide paper | (7.36x10-8 + 4.3x10-4 + 0.00276) = 3.19x10-3 | 7.5x10-5+ 5.9x10-5 =1.34x10-4 | N/A | 3.32x10-3 |

Transfluthrin moth paper/moth paper hanger

| **Summary table: systemic exposure from non-professional use** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group (e.g. professionals, non-professionals, bystanders)** | **Tier** | **Estimated systemic exposure**  **(mg/kg bw/day)** |
| 3. | Primary exposure for non-professional user preparing and handling moth paper | 1 | 7.51x10-5 |
| 5. | Secondary (acute) exposure of adult during the use of/access to areas containing moth paper e.g. opening wardrobe | 1 | 2.74x10-8 |
| Secondary (acute) exposure of child during the use of/access to areas containing moth paper e.g. opening wardrobe | 1 | 7.26x10-8 |
| 6. | Secondary (chronic) exposure of adult during the application of moth paper | 1 | 5.15x10-6 |
| Secondary (chronic) exposure of child during the application of moth paper | 1 | 9.69x10-6 |
| Secondary (chronic) exposure of toddler during the application of moth paper | 1 | 1.54x10-5 |
| Secondary (chronic) exposure of infant during the application of moth paper | 1 | 1.30x10-5 |

| **Summary table: acute exposure from non-professional use** | | |
| --- | --- | --- |
| **Scenario number** | **Exposed group (e.g. professionals, non-professionals, bystanders)** | **Estimated acute inhalation exposure (mg/m3)** |
| 5. | Secondary (acute) exposure of adult during the use of/access to areas containing moth paper e.g. opening wardrobe | 5.48x10-8 |
| Secondary (acute) exposure of child during the use of/access to areas containing moth paper e.g. opening wardrobe | 5.48x10-8 |

Combined scenarios

| **Summary table: combined systemic exposure from non-professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation uptake (mg/kg bw/day)** | **Estimated dermal uptake**  **(mg/kg bw/day)** | **Estimated oral uptake (mg/kg bw/day)** | **Estimated total uptake (mg/kg bw/day)** |
| Scenarios 3, 5 and 6 Adult primary and secondary exposure to moth paper | 7.36x10-8 + 2.74x10-8 +5.15x10-6 = 5.25x10-6 | 7.50x10-5 | N/A | 8.02x10-5 |
| Scenario 5 and 6 (child secondary exposure to moth paper) | 7.26x10-8 + 9.69x10-6 = | N/A | N/A | 9.77x10-6 |

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

The modelling of exposures and subsequent risk characterisation during production and formulation of Yanco Transfluthrin Product Family is addressed under EU legislation (e.g. Directive 98/24/EC) and is not repeated under EU Biocides Regulation 528/2012 (agreed at Biocides Technical Meeting TMI06). The UK has not considered exposure from production of the biocidal product further.

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

The following risk mitigation measures is required to prevent indirect exposure via food, drinking water or livestock:

“To prevent contamination of food, do not use in kitchens or other food storage or preparation areas.”

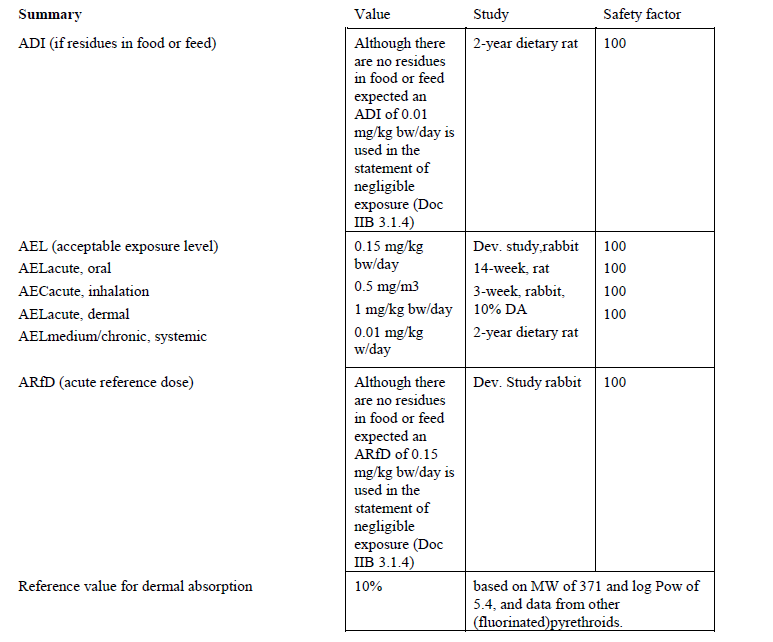
“Keep away from food, drink and pets”

### Risk characterisation for human health

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF1** | **Correction for oral absorption** | **Value** |
| AELacute(oral) | Developmental toxicity study in rabbits | 15 mg/kg bw/d | 100 | None | 0.15 mg/kg bw/d |
| AELacute(inhalation) | 14-week inhalation study in rats | 50 mg/m3 | 100 | None Default 100% inhalation absorption | 0.5 mg/m3 |
| AELacute(dermal) | 3-week dermal study in rabbits | 100 mg/kg bw/d | 100 | 10% dermal absorption | 1 mg/kg bw/d |
| AELmedium-term/chronic(systemic)- | 2-year dietary study in rats | 1 mg/kg bw/d | 100 | None | 0.01 mg/kg bw/d |
| ARfD | Developmental toxicity study in rabbits | 15 mg/kg bw/d | 100 | None | 0.15 mg/kg bw/d |
| ADI | 2-year dietary study in rats | 1 mg/kg bw/d | 100 | None | 0.01 mg/kg bw/d |

1 See CAR for derivation of assessment factors.



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

Transfluthrin insecticide paper

In considering the label informs that transfluthrin insecticide paper can be used daily, the long-term AEL of 0.01 mg/kg bw/day is considered the most relevant endpoint for the expected frequency of use.

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| 1. Primary exposure for non-professional user preparing and handling insecticide paper | 1 | 0.01 | 7.51x10-5 | 0.75% | Y |
| 2. Primary exposure of non-professional user during ignition of insecticide paper | 1 | 0.01 | 4.9x10-4 | 5% | Y |
| 7. Secondary exposure of non-professional/bystander re-entry into treated area | 2 | 0.01 | 0.00276 | 28% | Y |

**Combined scenarios**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenarios 1, 2 and 7 (tier 2)  Adult primary and secondary exposure to insecticide paper | 0.01 | 3.32x10-3 | 33% | Y |

**Conclusion**

The primary exposure scenarios considered above are predicted to result in acceptable levels of systemic exposure to transfluthrin.

Classification

The insecticide and moth paper products containing transfluthrin impregnated onto inert support mediums are classified for skin sensitisation category 1 (H317). According to the BPR Guidance[[9]](#footnote-9), this classification is a medium hazard for non-professional users, however considering the frequency of use (e.g. moth paper applied once every 3 months) and duration of potential exposure (e.g. <10 mins when handling and preparing insecticide/moth paper), the risk of exposure is likely to be low.

It should be noted that these products are considered to be “carrier-based biocidal products”[[10]](#footnote-10), (*Type A: Biocidal products in which the carrier component fulfils the function of a simple carrier matrix, allowing for an easier handling, application or delivery of the biocidal mixture/substance (“carrier-based biocidal products”). Normally the carrier would consist of one or more material(s) having undergone a form-giving process (plastics, tissues, cellulose or paper). Examples include (window) stickers, (gas generating) strips or disinfecting wipes (even if they could have a collateral cleaning function)*; Type C: Biocidal products in a specific type of packaging (container) that is not removed before use (i.e. to prevent contact with users). Examples include hangers containing a biocidal liquid in an internal compartment (Anti-moth biocidal mixture closed in a plastic device/crochet/hanger) or prefilled bait stations or (pressurized) cartridges.), such that the classification is determined based on only the biocidal mixture/substance used in the product i.e. excluding the carrier component in the composition of the biocidal product. However, the exposure to non-professional users occurs when handling the biocidal product i.e. biocidal mixture/substance and the carrier. Therefore since the carrier component (paper) is impregnated from a form-giving process to allow for easier handling and application of the biocidial formulation, the product design further reduces and eliminates exposure to the user.

According to CA-Sept 13-Doc 6.2.a. , the consequence of the classification for skin sensitization (H317) would normally lead to non-authorisation for non-professional users as the only possible method to reduce non-professional exposure would be wearing PPE. However it shoud be noted that this guidance is not relevant for this product since the product demonstrates reduced exposure as a result of the product design (e.g. the bioavailability of free sensitiser substance is reduced as it is impregnated into the carrier component (paper)) such that the wearing of PPE would not be necessary as RMM for the safe use by non-professionals.

On the basis of the above and in accordance with the CA-Nov16-Doc.4.3 Guidance[[11]](#footnote-11), the P statement P280 is not required in the SPC or on the product label.

***Risk for the general public***

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| 7. Secondary exposure of bystander (toddler) re-entry into treated area | 2 | 0.01 | 0.00945 | 95% | Y |
| 7. Secondary exposure of bystander (infant) re-entry into treated area | 2 | 0.01 | 0.00845 | 85% | Y |

**Conclusion**

The secondary exposure scenarios considered above are predicted to result in acceptable levels of systemic exposure to transfluthrin for bystanders.

Transfluthrin moth paper/moth paper hanger

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

As the label informs that transfluthrin moth paper/hanger can be used once every 3 month, the medium/long-term AEL of 0.01 mg/kg bw/day is considered the most relevant endpoint for the expected frequency of use.

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| 3. Primary exposure for non-professional user preparing and handling moth paper | 1 | 0.01 | 7.51x10-5 | 0.75% | Y |
| 5. Secondary (acute) exposure of adult during the use of/access to areas containing moth paper e.g. opening wardrobe | 1 | 0.01 | 2.74x10-8 | <1% | Y |
| 6. Secondary (chronic) exposure of adult during the application of moth paper | 1 | 0.01 | 5.15x10-6 | <1% | Y |

**Combined scenarios**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenarios 3, 5 and 6 Adult primary and secondary exposure to moth paper | 0.01 | 8.02x10-5 | 0.8% | Y |

**Conclusion**

The primary exposure scenarios considered above are predicted to result in acceptable levels of systemic exposure to transfluthrin.

***Risk for the general public***

**Systemic effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| 5. Secondary (acute) exposure of child during the use of/access to areas containing moth paper e.g. opening wardrobe | 1 | 0.01 | 7.26x10-8 | <1% | Y |
| 6. Secondary (chronic) exposure of child during the application of moth paper | 1 | 0.01 | 9.69x10-6 | 0.1% | Y |
| 6. Secondary (chronic) exposure of toddler during the application of moth paper | 1 | 0.01 | 1.54x10-5 | 0.2% | Y |
| 6. Secondary (chronic) exposure of infant during the application of moth paper | 1 | 0.01 | 1.30x10-5 | 0.1% | Y |

**Acute effects**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL acute (inhalation)**  **mg/m3** | **Estimated uptake**  **mg/m3** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| 5. Secondary (acute) exposure of adult during the use of/access to areas containing moth paper e.g. opening wardrobe | 1 | 0.5 | 5.48x10-8 | <1% | Y |
| 5. Secondary (acute) exposure of child during the use of/access to areas containing moth paper e.g. opening wardrobe | 1 | 0.5 | 5.48x10-8 | <1% | Y |

**Combined scenarios**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario 5 and 6  Child secondary exposure to moth paper | 0.01 | 9.77x10-6 | 0.1% | Y |

**Conclusion**

The secondary exposure scenarios considered above are predicted to result in acceptable levels of systemic exposure to transfluthrin.

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

The modelling of exposures and subsequent risk characterisation during production and formulation of Yanco Transfluthrin Product Family is addressed under EU legislation (e.g. Directive 98/24/EC) and is not repeated under EU Biocides Regulation 528/2012 (agreed at Biocides Technical Meeting TMI06). The UK has not considered exposure from production of the biocidal product further.

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

The following risk mitigation measures is required to prevent indirect exposure via food, drinking water or livestock:

“To prevent contamination of food, do not use in kitchens or other food storage or preparation areas.”

“keep away from food, drink and pets”

## Risk assessment for the environment

The biocidal product family consists of “Insecticide Paper Spice”, “Insecticide Paper Lavender”, and “Moth Paper Lavender”.

The product family is intended for indoor use by non-professional users, for the control of nuisance and biting insects (e.g. mosquitoes) or to protect fabrics (e.g. garments stored in confined spaces such as wardrobes and drawers) from damage by moths and their larvae. The products contain a single active substance: transfluthrin, coated on an inert paper or card support matrix. The products contain no other substance(s) of concern for the environment. The treatment is effected by passive fumigation, following volatilisation of the active substance into the confined atmosphere of the treated space.

No direct application of the product family in the outdoor environment is foreseen and neither the inert support matrices or any other co-formulants of the products are expected to modify the known behaviour of transfluthrin in the environment or its effects on non-target organisms. The consequences of any indirect entry of transfluthrin into the environment following use of the product family may therefore be predicted adequately from the existing information available for the technical active substance. Accordingly, tests of the fate and behaviour of any product(s) representative of the family in the environment are inappropriate and unnecessary and have not been performed. The environmental risk assessment for the product family is therefore based entirely and adequately on endpoints for transfluthrin a.s.

Losses to environment are expected to occur predominantly via wet cleaning of contaminated surfaces from deposition, with subsequent discharge of wastewater to drains and local STP.

The ecotoxicological endpoints relied upon in the following environmental risk assessment are taken from the transfluthrin CAR and Assessment report of 2014and updated with the conclusions of WGIV2017 ENV 6-6 where updated PNECs for some compartments were agreed.

### Effects assessment on the environment

The product contains only one active substance and no substances of concern. Therefore all toxicity data can be obtained from the CAR. The PNECs are summarised below:

PNECs transfluthrin

PNECaquatic = 1.75 ng/L / 0.00175 µg/L

Sediment ~~–~~ 1.64 µg/kg dw

PNECstp = 100 mg/L

PNECsoil = 0.1 mg/kg dw

PNECoral,mammal = 6.7 mg/kg feed

The experimentally derived BCF for fish is 1783 L/kg ww, based on Total Radioactive Residues in whole fish.

According to the Assessment Report for transfluthirn:

As a worst-case estimate, the NOEC for respiration of activated sludge is set to the water solubility of 0.057 mg/L. Applying an assessment factor of 1 to this value, leads to a PNECstp for transfluthrin of 0.057 mg/L. In line with discussions held at the TMII08 for Flocoumafen a PNECstp based on the reported endpoint of EC50 > 10,000 mg/L is included additionally. Application of an assessment factor of 100 leads to a PNECstp for transfluthrin of 100 mg/L.

Therefore both PNECs will be considered.

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

No additional data required.

***Further Ecotoxicological studies***

Additional ecotoxicological studies have been submitted for this product family. These new studies have been submitted to the RMS for transfluthrin (The Netherlands) with the Evaluating Competent Authority (Ctgb) assessing them EU wide. These studies were considered and revised PNECs agreed at WGIV2017\_ENV\_6-6 and have been used in this assessment.

**Summary table - Further ecotoxicological studies**

No data is available.

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

No additional data are required.

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

No additional data are required.

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

Data are not required.

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

Data are not required.

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

Please refer to section Fate and distribution in exposed environmental compartments in Section 2.2.6.2

### Exposure assessment

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

The product family is intended for indoor use only. The treatment occurs by fumigation following the volatilisation of transfluthrin from an inert support matrix. Neither the support matrix nor any of the co-formulants are expected to modify the environmental fate (degradation or mobility) or ecotoxicity profile of transfluthrin in the environment, and the potential effects following use of the products may adequately be extrapolated from existing data available for the active substance.

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)

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT18 |
| Assessed scenarios | Scenario 1: Indoor, diffusers representing of “Insecticide Paper Spice”, “Insecticide Paper Lavender”.  Scenario 2: Indoor diffusers representing “Moth Paper Lavender” (individual sheets) and Moth Paper (sheet in cartridge) for use over 3 months inside wardrobes, drawers, cupboards, laundry bags and suitcases. |
| ESD(s) used | Emission Scenario Document for Product Type 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses, July 2008. |
| Approach | Scenario 1: Consumption based on the combustion of paper impregnated with a.s.  Scenario 2: Consumption based on the passive volatilisation of an indoor diffuser. |
| Distribution in the environment | Calculated based on ECHA Guidance on Environmental Risk Assessment (ERA) Volume IV Environment- Part B Risk Assessment (version 1 2015). |
| Groundwater simulation | Scenario 1: No higher tier groundwater simulation performed  Scenario 2: No higher tier groundwater simulation performed |
| Confidential Annexes | No |
| Life cycle steps assessed | Production: No covered under AR.  Formulation No covered under AR.  Use: Yes consumption based approach used  Service life: No the packaging material and inert matrix will be disposed of as municipal waste and EU waste legislation will apply. |
| Remarks | For Scenario 2 the use emission will take place over 3 month periods, but the emission rate to the local compartment (STP) is calculated as an average quantity per day. |

***Emission estimation***

**Scenario 1**

“Insecticide Paper Spice” and “Insecticide Paper Lavender” are ready-to-use domestic household insecticide for non-professionals for use against mosquitoes. The product is intended to be used indoors. “Insecticide Paper Spice” and “Insecticide Paper Lavender” contain the active substance transfluthrin. The risk assessment covers both “Insecticide Paper Spice” and “Insecticide Paper Lavender” as the only reported difference between products is related to their scent. The insecticide paper is sold as a booklet containing 18 pages. Each sheet contains 0.0024 g of transfluthrin. The a.s. is applied to the room by igniting the paper sheet, blowing out the flame, and leaving the room. Assuming that a standard room is treated (of 22 m2) then two sheets per room will be required. Emissions have been calculated assuming that a maximum of one room per day is treated in a domestic dwelling.

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario 1: Insecticides, indoor diffusers representing “Insecticide Paper Spice” and “Insecticide Paper Lavender” | | | |
| Application rate of biocidal product | 2 | sheets in one room | 1 sheet per 10m2 and assuming a surface area of a room as 22m2 (EU Technical Guidance Note on human exposure) |
| Concentration of active substance in the product | 0.0024 g of transfluthrin per sheet | g/sheet | Information from product manufacturer |
| Diffuser type | Passive | - | - |
| Maximum duration of use of the diffuser | 24 | hr | - |
| Number of applications per day, house | 1 | per day | comprising 2 sheets |
| Number of application per day, larger buildings | 0 | per day | The product is designed specifically for domestic household use. The number of applications in larger buildings (industrial, commercial, public; ESD, 2008) is therefore set to zero. |

However, this scenario represents an extreme worst case (Tier 1) assessment in that all active substance which has deposited to surfaces within a room (10 % of total a.s. held on 2 sheets) is then completely removed by wet cleaning : the model effectively assumes removal from all 22 m2 of surface within a typical room. Discussions at ENV WG and an expert PT 18 sub-group (during 2017- 2018) have concluded that wet cleaning can be expected to remove a.s. only from a reduced area and in this case, that area could be assumed to be 6.5 m2 of the total (22 m2).

**Scenario 2**

“Moth Paper Lavender” and “Moth Paper Lavender in a hanger” are domestic ready-to-use household insecticides for non-professional use against clothes moths, larvae and eggs. The product is intended to be used indoors to protect fabrics in cupboards, drawers, wardrobes, laundry bags and suitcases. Both contain the active substance transfluthrin, as outlined below:

| **Input parameters for calculating the local emission** | | | |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario 2: Insecticides, Indoor diffusers representing “Moth Paper Lavender” | | | |
| Concentration of active substance in the product and application rate of biocidal product | 0.0048 g | a.s./double sheet | Booklet of paper sheets containing 0.0048 g a.s./double sheet (18 sheets per booklet).  3 double sheets are intended to provide protection in 0.5 m3 for 3 months. |
| Scenario: Insecticides, Indoor diffusers representing “Moth Paper Lavender” in a hanger | | | |
| Concentration of active substance in the product and application rate of biocidal product | 0.0072 g | a.s./cassette | 3 single “Moth Paper Lavender” sheets inside a plastic hanger. Each single sheet contains 0.0024 g a.s./sheet, therefore, 0.0072  g a.s./cassette (sold as 10 cassettes per pack).  1 cassette is intended to provide protection in 0.25m3 for 3 months. |

It has been assumed that all wardrobes within a dwelling are treated simultaneously with replacement every three months. The fraction emitted to the air during application is assumed to be 0.9 and the fraction emitted to the floor (and therefore subject to wet cleaning and the emission pathway to the STP) is assumed to be 0.1 (ESD, 2008). The fraction emitted to wastewater from cleaning of a treated surface is assumed to be 1 with a cleaning efficiency of 100 % (ESD, 2008).

Following the TAB (v2 2018) ENV it is agreed that the default number of wardrobes per household are 2.5, with an associated volume of 1.5 m3. This gives a maximum volume of 3.75 m3 that could be protected at any one time by this product.

Therefore the total mass of transfluthrin emitted to STP per household per product is:

“Moth Paper Lavender”

0.048 g transfluthrin per double sheet to treat 0.5 m2 giving a total of 0.0048 g x 3 / m3 x 2 x 3.75 m3 = 108 mg per household

“Moth Paper Lavender” in a hanger

0.024 g transfluthrin per single sheet to treat 0.25 m2 giving a total of 0.0024 g x 3 / m3 x 4 x 3.75 m3 = 108 mg per household

Hence the emission to the environment is the same for either product.

**Emissions calculations**

For the indoor use of 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. It is then assumed that cleaning of the floor will result in emissions to waste water. The daily emission to 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 general calculation for emissions to the floor during application of diffuser products is as follows (ESD, Section 3.4.6.2, p. 96):

Eapplication,floor = Qprod x FAI x Tday/ Tmax x Fapplication,floor x 10-3

Where;

Eapplication,floor = Emission to the floor [kg/ d]

Qprod = Quantity of product in the diffuser [g]

FAI = Fraction of active in the product [-]

Tday = Duration of use per day [h] which is 24 hours for passive diffusers

Tmax = Maximal duration of use of the diffuser [h]

Fapplication,floor = Fraction emitted to the floor, default 0.1 [-]

For the products under consideration, the quantity of active per sheet are given, so Qprod x FAI is replaced by Qactive. In a similar fashion a calculation for the amount of active released into the air is made using the following equation;

Eapplication,air = Qactive x (Tday/ Tmax) x Fapplication,air x 10-3 (31)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | **Nomenclature** | **Scenario 1**  **Tier 1** | **Scenario 1**  **Tier 2** | **Scenario 2** | **Units** |
| Quantity of active per application |  | 0.0024 | 0.0024 | 0.0072 | g |
| Number |  | 2 | 2 | 10 |  |
| Total active per day | Qactive | 0.0048 | 0.0048 | 0.0108 | g day-1 |
| Maximal duration of use | Tmax | 1 | 1 | 90 | days |
| Duration per day | Tday | 24 | 24 | 2160 | hours day-1 |
| Fraction emitted to air | Fapplication,air | 0.9 | 0.9 | 0.9 | default |
| Emission to air | Eapplication,air | 4.32E-06 | 4.32E-06 | 1.08E-06 | kg day-1 |
| Fraction emitted to floor | Fapplication,floor | 0.1 | 0.1 | 0.1 | default |
| Emissions to floor | Eapplication,floor | 4.80E-07 | 4.80E-07 | 1.20E-07 | kg day-1 |

**Emission to outdoor air**

It is defined in the ESD for PT 18 that the fraction of active emitted to the air from this use is 90 %- which gives the following emission to air per house.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | **Nomenclature** | **Scenario 1**  **Tier 1** | **Scenario 1**  **Tier 2** | **Scenario 2** | **Units** |
| Fraction emitted to air | Fapplication,air | 0.9 | 0.9 | 0.9 | default |
| Emission to air | Eapplication,air | 4.32E-06 | 4.32E-06 | 1.08E-06 | kg day-1 |

However the ESD also states that an instant dilution takes place as active is released outside of a building into the wider environment and the level of active emitted via this route is expected to be irrelevant.

**Emission to Wastewater**

During the cleaning step two cases are considered:

* Cleaning events result only in emissions to wastes : 100 % of the surfaces are cleaned by vacuum/ broom
* Cleaning events result only in emissions to wastewater: 100 % of the surfaces are washable

If it is assumed that all cleaning of contaminated surfaces is performed by vacuum cleaner/ broom then emissions to STP will be zero. However if the worst case is assumed i.e. that all cleaning is undertaken with water then Fww = 1 and all releases are directed to waste water as follows (ESD, Section 3.5, p. 101);

Etreated,ww = Eapplication,floor x Fww x FCE

Etreated,ww = Emission from the floor/treated to waste water [kg/d]

Eapplication,floor = Emission to the floor [kg/d]

Fww = Fraction emitted to waste water, default 1 [-]

FCE = Cleaning efficiency, default 1 (see ESD Table 3.3-8, p. 64)

Decisions at EU level conclude that wet cleaning cannot be avoided, such that as a “very” worst case assumption:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Parameter** | **Nomenclature** | **Scenario 1** | **Scenario 1**  **Tier 2** | **Scenario 2** | **Units** |
| Emissions to floor during application step | Eapplication,floor | 4.80E-07 | 4.80E-07 | 1.20E-07 | kg d-1 |
| Fraction emitted to waste water during cleaning | Fww | 1 | 1 | 1 |  |
| Cleaning efficiency | FCE | 1 | 1 | 1 |  |
| Emission from floor/treated surfaces during cleaning | Etreated,ww (same as Eww for diffuser application) | 4.80E-07 | 4.80E-07 | 1.20E-07 | kg d-1 |

The PT18 ESD assumes that a total of 4,000 dwellings are attached to a single standard STP with a 10,000 inhabitant capacity (ESD, 2008; p39). As the product is designed for domestic use, the use in larger buildings (industrial, commercial and public (ESD, 2008) is not considered relevant and can be discounted from the assessment. A simultaneity factor of 5.52 % is used (ESD, 2008; p39) to reflect a daily usage, therefore the local emission to wastewater during an episode is;

Mass of transfluthrin per household x number of houses per STP x simultaneity factor

| **Resulting local emission to relevant environmental compartments** | | | |
| --- | --- | --- | --- |
|  | **Scenario 1: use of 2 sheets in one room** | | **Scenario 2: treatment of 3.75 m3 storage space** |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Local emission (Elocalcompartment) [kg/d] Tier 2** | **Local emission (Elocalcompartment) [kg/d]** |
| Water | 1.06E-04 | 3.13E-05 | 2.65E-05 |

In the case of scenario 1, this represents an extreme worst case (Tier 1) assessment in that all active substance which has deposited to surfaces within a room (10% of total a.s. held on 2 sheets) is then completely removed by wet cleaning : the model effectively assumes pick-up of every particle of a.s. from all 22 m2 of surface within a typical room. Discussions at ENV WG and an expert PT 18 sub-group (during 2017-2018) have concluded that wet cleaning can be expected to remove a.s. only from a reduced area and in this case, that area could be assumed to be 6.5 m2 of the total (22 m2).

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| Input | Value | Unit | Remarks |
| Molecular weight | 371.2 | g/mol |  |
| Melting point | 32 | °C |  |
| Boiling point | 242 | °C |  |
| Vapour pressure (at 20 °C) | 9.0E-04 | Pa |  |
| Water solubility (at 20 °C) | 0.057 | mg/l |  |
| Log Octanol/water partition coefficient Kow | 5.94 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 50119 | l/kg |  |
| Henry’s Law Constant (at 20°C) | 5.86 | Pa/m3/mol |  |
| Ready Biodegradability | No | - |  |
| Bioconcentration factor for fish | 1783 | l/kg wwt | Measured value |

|  |  |  |
| --- | --- | --- |
| **Calculated fate and distribution in the STP (AR values)** | | |
| Compartment | Percentage [%] | Remarks |
| Scenario 1 |
| Air | 0.851 |  |
| Water | 19.2 |  |
| Sludge | 79.9 |  |
| Degraded in STP | 0 |  |

**Calculation of Aquatic PECs**

The concentration in the untreated wastewater Clocalinf can be calculated from the local emission to wastewater and the influent flow to the STP using the following;



Where EFFLUENTstp = 2000000 l/d (the effluent discharge rate of the STP)

Typically, the PECSTP can be considered as being either the Clocalinf or Clocaleff value, representing either the concentration of compound in untreated wastewater or the concentration of compound in STP effluent. In situations where release of a chemical into drains is intermittent, the use of Clocalinf is more appropriate for PECSTP but the alternative is true in the case of daily release (Clocaleff should be used to represent PECSTP). However, releases are likely to be continuous if discharges to drains can occur from cleaning events so the PEC should be based upon the value for Clocaleff.



Where;

Fstpwater = fraction emission directed to water by STP (0.192 according to the Transfluthrin AR)

|  |  |  |
| --- | --- | --- |
| **Scenario** | **Clocalinf**  **(mg l-1)** | **PECSTP**  **(Clocaleff)**  **(mg.l-1)** |
| Scenario 1 (tier 1) | 5.30E-05 | 1.02E-05 |
| Scenario 1 (tier 2) | 1.57E-05 | 3.01E-06 |
| Scenario 2 | 1.32E-05 | 2.54E-06 |

These PECSTP values for transfluthrin have been used to assess the risk to sewage micro-organisms.

No consideration of metabolite risk to STP has been performed as degradation of transfluthrin during transit is expected to be zero.

The proposed use pattern of Yanco Transfluthrin family products does not allow for direct exposure to surface waters, only the potential for indirect exposure via discharges to the local STP. The local concentration arising from the indirect emission to a watercourse via the STP during the proposed use of this product was calculated to take into account dilution and removal to suspended sediments (ECHA guidance on ERA equation 45) as follows:



Where:

Clocalwater = local concentration in surface water during emission episode (mg l-1) so **= PECsurface water**

Clocaleff = concentration of substance in the STP effluent (and represent calculated PECSTP values)

Kpsusp = solids-water partitioning coefficient of suspended matter (5012 l kg-1; calculated using ECHA guidance FOCsus x Koc = 0.1 x 50119)

SUSPwater = concentration of suspended matter in the river (default: 15 mg l-1)

DILUTION = dilution factor (default: 10)

Based upon the proposed pattern of Yanco transfluthrin family products, emissions to surface waters are predicted as follows;

|  |  |  |
| --- | --- | --- |
| **Emissions to surface waters from indoor use** | | |
| **Scenario** | **Clocaleff**  **(mg l-1)** | **PECsurface water**  **(mg.l-1)** |
| Scenario 1 (tier 1) | 1.02E-05 | 9.46E-07 |
| Scenario 1 (tier 2) | 3.01E-06 | 2.80E-07 |
| Scenario 2 | 2.54E-06 | 2.37E-07 |

PECsurface water values for major metabolites have also been calculated taking into account the maximum amount formed in water from the water/ sediment study, adjusted for the molecular weight difference following the approach taken in the transfluthrin AR. This approach is appropriate in this case because the SimpleTreat 3.1 calculations assume zero degradation in the STP.

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculation of PECsurface water (mg.l-1) for metabolites** | | | |
| **Compound** | **Transfluthrin** | **TFB-OH** | **TFB-COOH** |
| Maximum formation (%) | 100 | 38 | 59 |
| Molecular weight | 371.2 | 180.1 | 194.08 |
| **Scenario** |  |  |  |
| Scenario 1 | 9.46E-07 | 1.74E-07 | 2.92E-07 |
| Scenario 1 (tier 2) | 2.80E-07 | 5.15E-08 | 8.62E-08 |
| Scenario 2 | 2.37E-07 | 4.36E-08 | 7.30E-08 |

As both metabolites are present at a lower level than transfluthrin and are of lower (eco) toxicity- the risk posed by the metabolites can be considered to be covered by the parent transfluthrin. Hence no PEC/ PNEC ratios have been calculated for the two metabolites.

**PECsediment**

The concentration of active in bulk sediment can be derived from the corresponding water body concentration, assuming thermodynamic partitioning equilibrium:

Where:

RHOsusp = bulk density of wet suspended matter (1150 kg/ m3)

PEClocalwater = local concentration in surface water

Ksusp-water = 1254

|  |  |  |
| --- | --- | --- |
| **Scenario** | **PECsurface water**  **(mg.l-1)** | **PECsediment (mg.kg-1 wwt)** |
| Scenario 1 (tier 1) | 9.46E-07 | 1.03E-03 |
| Scenario 1 (tier 2) | 2.80E-07 | 3.05E-04 |
| Scenario 2 | 2.37E-07 | 2.58E-04 |

As no PNECsediment were available for the metabolites PECsed values were not calculated and it was assumed that any risks to the sediment compartment would be covered by the parent (similar to aquatic risks).

**PECair**

As stated in the ESD for PT 18 for the outdoor use of diffuser insecticides;

*‘The fraction emitted to air is not expected to have an action of environmental relevance on the air concentration, due to air instant dilution. ‘*

So following the approach taken in the transfluthrin AR PECair has not been calculated.

**PEC in soil (including groundwater)**

The concentration of active substance in dry sewage sludge can be calculated using equations (36 and 37) taken from the ECHA guidance on ERA plus default parameters presented in the same guidance document;



where:

SLUDGERATE = 0.66 x SUSPCONCinf x EFFLUENTstp + SURPLUSsludge x CAPACITYstp

and: EFFLUENTstp = CAPACITYstp x WASTEWinhab

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application of sewage sludge parameters for transfluthrin reaching STP** | | | | |
| **Parameters** | **Nomenclature** | **Value** | **Unit** | **S/D/O/R\*** |
| Concentration of suspended matter in STP influent | SUSPCONCinf | 0.45 | kg/m3 | D |
| Effluent discharge rate of STP | EFFLUENTstp | 2000 | m3 /d | D |
| Surplus sludge per inhabitant equivalent | SURPLUSsludge | 0.019 | kg/d /eq | D |
| Capacity of STP | CAPACITYstp | 10,000 | eq | D |
| Sewage flow per inhabitant | WASTEWinhab | 200 | l/d /eq | D |
| Rate of sewage sludge production | SLUDGERATE | 790 | kg/ d | O |
| Local emission rate to water during treatment episode | Elocalwater |  | kg /d | O |
| Fraction of emission directed to sludge by STP  (SimpleTreat) | Fstpsludge | 0.799 |  | S |
| Concentration in dry sewage sludge | Csludge |  | mg/kgdwt | O |
| \*S=Set, D=Default, O=Output, R=Refinement |  |  |  |  |

Based upon the relevant physicochemical properties of transfluthrin, SimpleTreat predicts 79.9 % adsorption onto sewage sludge, with only the minority of transfluthrin expected to be discharged to surface water. As a result, the calculated Csludge values resulting from the different uses of transfluthrin have been determined as;

|  |  |  |
| --- | --- | --- |
| **Emissions of Transfluthrin in sewage sludge** | | |
| **Scenario** | **Elocalwater**  **(kg.d-1)** | **Csludge**  **(mg.kg-1 dwt)** |
| Scenario 1 (tier 1) | 1.06E-04 | 1.07E-01 |
| Scenario 1 (tier 2) | 3.13E-05 | 3.17E-02 |
| Scenario 2 | 2.65E-05 | 2.68E-02 |

Therefore, small releases of active substance to agricultural land can be predicted following the discharge of wastewater via drains to a local STP after domestic and commercial wet cleaning. Where sewage sludge is applied to agricultural soil, an application rate of 5000 kg.ha-1 per year has been assumed (based on typical application rates across the EU) whilst the rate for grassland is assumed to be lower at 1000 kg.ha-1.yr-1 - these applications are considered to occur once per year. As transfluthrin does not appear to be readily biodegradable, there is potential for accumulation of the compound when sewage sludge is applied over consecutive years (as a realistic worst case, it is generally assumed that sludge is applied annually for 10 years).

If removal via volatilisation and leaching from topsoil are ignored as being minor processes, so losses would solely be as a result of soil degradation, then the pseudo-first order rate constant k (represented by Kbiosoil) can be derived from the following equation:

|  |  |
| --- | --- |
| Kbiosoil = | ln 2 |
|  | DT50biosoil |

Where DT50biosoil is the half-life for (bio) degradation in aerobic soil (corrected to 12 °C)

As no experimental data are available for the biodegradation of transfluthrin in soil as a conservative estimate it has been assumed that no degradation occurs and a DT50 value of 1000,000 days has been assumed. Using equivalent rate constant k of 6.93E-07 d-1: this would crudely represent the removal rate of transfluthrin from top soil. At the end of each year, a fraction of the initial concentration (Facc) may potentially remain in the top soil layer and this can be determined by use of the equation stating:



Where Facc = fraction accumulation in 1 year

The fraction of initial concentration (Facc) remaining in the top soil layer after one year has therefore been determined as1. In line with guidance presented in the ECHA guidance on ERA (equation 60), the concentration of transfluthrin in soil (represented as Csludge soil 1 (0)) after the first year of manure application can be given as;



Where:

Csludge is the concentration in sludge (in mg kg-1 dwt)

APPLsludge is the sludge application rate (0.1 kg m2 yr-1 for grass for cattle or 0.5 kg m2 yr-1 for terrestrial ecosystems and crops for human consumption (arable)

DEPTHsoil is the mixing depth of soil (0.1 for grass for cattle or 0.2 m for terrestrial ecosystems and crops for human consumption (arable)

RHOsoil is the bulk density (wet) of soil (1700 kg m-3; default)

Csludge soil 1 (0) is the concentration in soil due to sludge application in first year at t = 0

As a realistic worst case it is assumed that sludge application can take place for 10 consecutive years on the same site. This calculation assumes that the contributions from deposition and sludge application occur separately. The concentration due to 10 years of continuous deposition is given by the following equation;

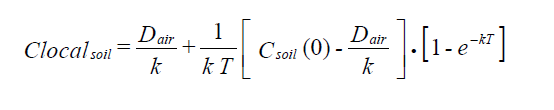


At the end of 10 years the concentration in soil resulting from the sludge application is given by;



|  |  |  |  |
| --- | --- | --- | --- |
| **Concentration following the application of sewage sludge** | | | |
| **Scenario** | **Csludgesoil1 (0)**  **Arable**  **(mg kg-1)** | **Csludgesoil1 (0)**  **Grass**  **(mg kg-1)** | **Csludgesoil1 (0)**  **Local**  **(mg kg-1)** |
| Scenario 1 (tier 1) | 1.58E-04 | 6.31E-05 | 1.58E-04 |
| Scenario 1 (tier 2) | 4.66E-05 | 1.86E-05 | 4.66E-05 |
| Scenario 2 | 3.94E-05 | 1.58E-05 | 3.94E-05 |
| **Scenario** | **Csludgesoil10 (0)**  **Arable**  **(mg kg-1)** | **Csludgesoil10 (0)**  **Grass**  **(mg kg-1)** | **Csludgesoil10 (0)**  **Local**  **(mg kg-1)** |
| Scenario 1 (tier 1) | 1.57E-03 | 6.30E-04 | 1.57E-03 |
| Scenario 1 (tier 2) | 4.65E-04 | 1.86E-04 | 4.65E-04 |
| Scenario 2 | 3.94E-04 | 1.57E-04 | 3.94E-04 |

The PEC for local soil (referred to as Clocalsoil) has been calculated using the following equation taken from the ECHA guidance on ERA (equation 55);



Where

Dair is the aerial deposition flux per kg of soil (in mg.kg-1.d-1) assumed to be 0

T is the averaging time (180 d for arable land and grassland as a representative growing period for crops and 30 days for terrestrial ecosystems)

k is the first order rate constant for removal from top soil (assumption based on insignificant degradation of 6.93E-07 d-1 : lack of experimental data)

Csoil (0) is the initial concentration in soil after sludge application (calculated in mg.kg-1)

Clocalsoil is the average concentration in soil over T days

|  |  |  |  |
| --- | --- | --- | --- |
| **PEClocalsoil values for Transfluthrin in grassland arable land and terrestrial ecosystems applied via sewage sludge to land** | | | |
| **Scenario** | **PEClocalsoil**  **Grassland**  **[mg kg-1 wwt]** | **PEClocalsoil**  **Arable land**  **[mg kg-1 wwt]** | **PEClocalsoil**  **Ecosystem**  **[mg kg-1 wwt]** |
| Scenario 1 (tier 1) | 6.30E-04 | 1.57E-03 | **1.57E-03** |
| Scenario 1 (tier 2) | 1.86E-04 | 4.65E-04 | **4.65E-04** |
| Scenario 2 | 1.57E-04 | 3.94E-04 | **3.94E-04** |

These PECsoil values for transfluthrin have been used to assess the risk to terrestrial organisms.

As no information on the actual level of metabolites formed in soil is available PECsoil values for major metabolites have been calculated taking into account the maximum amount formed in water from the water/ sediment study, adjusted for molecular weight for the different scenarios.

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculation of PECsoil (mg kg-1 wwt)**  **for metabolites** | | | |
| **Compound** | **Transfluthrin** | **TFB-OH** | **TFB-COOH** |
| Maximum formation (%) | 100 | 38 | 59 |
| Molecular weight | 371.2 | 180.1 | 194.08 |
| **Scenario** |  |  |  |
| Scenario 1 (tier 1) | 1.57E-03 | 2. 90E-04 | 4.86E-04 |
| Scenario 1 (tier 2) | 4.65E-04 | 8.58E-05 | 1.44E-04 |
| Scenario 2 | 3.94E-04 | 7.26E-05 | 1.21E-04 |

As the predicted concentrations in soil are lower than those predicted for transfluthrin and the (eco)toxicity of the metabolites is lower, it is considered than any risk to soil will be covered by the risk for transfluthrin and soil PEC/PNEC ratios have not been calculated.

**Groundwater**

The KOC value of 50119 L.kg-1 measured by HPLC demonstrates that transfluthrin will be of restricted mobility in soil and so therefore indirect exposure of groundwater (and even surface waters via run-off from fields) is unlikely. Guidance within the ESD advocates calculating first tier ground water concentration on the basis of porewater predictive modelling according to the method of Montfoort (1999).

Predicted concentrations of transfluthrin in local soil can be used to crudely indicate groundwater levels in line with the following equation presented in the ECHA guidance on ERA (equation 67), but the approach is very simplistic and takes no account of soil characterisation (neglecting consideration of transformation plus dilution in deeper soil layers);

|  |  |
| --- | --- |
| PEClocalsoil, porewater = | PEClocalsoil x RHOsoil |
|  | Ksoil-water x 1000 |

PEClocalsoil, porewater is the predicted environmental concentration in porewater (calculated in mg l-1)

PEClocalsoil is the predicted environmental concentration in soil (presented as mg kgwwt-1 in section 3.3.3.3.2)

RHOsoil is the bulk density of wet soil (default of 1700 kg m-3)

Ksoil-water is the soil-water partitioning co-efficient (calculated as 1504 m3 m-3)

Where;

Ksoil-water = Fairsoil x Kair-water + Fwatersoil + Fsolidsoil x (Kpsoil/ 1000) x RHOsolid

Fairsoil is the fraction of air in soil (default 0.2 m3 m-3)

Kair-water partitioning coefficient (= Henry’s law constant/ (R x Temp) 6.33E-06 / (8.314 x 285) = 2.47E-03

Fwatersoil is the fraction of water in soil (default 0.2 m3 m-3)

Fsolidsoil is the fraction of solids in soil (default 0.6 m3 m-3)

Kpsoil is the solids- water partitioning coefficient in soil (Focsoil x Koc = 0.02 x 50119 = 1002 l kg-1)

RHOsolid is the density of the solid phase (default 2500 kg m-3)

Based upon the presented PECsoil values, and using PEClocalsoil (arable land) and equation 24 from the ECHA guidance on ERA (2013) the following PEClocalsoil, porewater values can be calculated.

|  |  |  |
| --- | --- | --- |
| **Calculation of porewater concentrations of Transfluthrin from application via sewage sludge** | | |
| **Scenario** | **PEClocalsoil arable**  **(mg kg-1 wwt)** | **PEClocalsoil, porewater**  **(µg l-1)** |
| Scenario 1 (tier 1) | 1.57E-03 | 1.78E-03 |
| Scenario 1 (tier 2) | 4.65E-04 | 5.26E-04 |
| Scenario 2 | 3.94E-04 | 4.45E-04 |

Values less than the 0.1 μg l-1 current quality standard set by the EU Drinking Water Directive (98/83/EC) were obtained for the proposed applications of Yanco transfluthrin family products indicating that the risk of contamination to groundwater from the proposed worst case uses of transfluthrin is low.

As the predicted levels of transfluthrin reaching groundwater are at least 10 x below the water directive quality standard, it is likely that levels of metabolites are also likely to be significantly less than 0.1 µg l-1 however for completeness the calculations are presented below;.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **EpiSuite Parameters used to Calculate PEClocalsoil, porewater** | | | | |
| **Metabolite** | **Henry’s Law Constant**  (HENRYWIN v3.20 using the Bond Method) | | **Koc**  (KOCWIN v2.00 using MCI method) | |
| **TFB-OH** | 4.09E-02 | Pa m3/ mol | 154.1 | L/ kg |
| **TFB-COOH** | 2.04E-02 | Pa m3/ mol | 118.9 | L/ kg |

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculation of porewater concentrations from application via sewage sludge PEClocalsoil, porewater (µg l-1)** | | | |
|  | **Transfluthrin** | **TFB-OH** | **TFB-COOH** |
| Scenario 1 (Tier 1) | 1.78E-03 | **0.102** | **0.219** |
| Scenario 1 (Tier 2) | 5.26E-04 | 0.030 | 0.065 |
| Scenario 2 | 4.45E-04 | 0.026 | 0.055 |

Levels above the drinking water trigger level of 0.1 g/ l have been identified for Scenario 1 at the first tier- however acceptable levels are predicted to porewater for Scenario 1 (tier 2) and Scenario 2.

***Calculated PEC values***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] |
| Scenario 1 (tier 1) | 1.02E-05 | 9.46E-07 | 1.03E-03- | 1.57E-03 | 1.78E-03 |
| Scenario 1 (tier 2) | 3.01E-06 | 2.80E-07 | 3.05E-04 | 4.65E-04 | 5.26E-04 |
| Scenario 2 | 2.54E-06 | 2.37E-07 | 2.58E-04 | 3.94E-04 | 4.45E-04 |

Metabolites NAK 4452 (2,3,5,6-tetrafluorobenzyl alcohol; TFB-OH) and NAK 4723 (2,3,5,6-tetraflorobenzoc acid; TFB-COOH) were detected in amounts >10 % of AR in the water phase, maximum levels of 38 and 59 % of AR, respectively. In the sediment phase the same metabolites were of found, maximum level was 2.9 % of AR for TFB-OH and 26 % of AR TFB-COOH >10 % AR.

The PECsurface water of the two metabolites were calculated based on the PECs for the parent multiplied by a formation fraction in the water (using the maximum levels as % of AR) and a correction for the molecular weight, 180.1 g/ mol for TFB-OH and 194.08  g/ mol for TFB-COOH.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | **PECGW** |
| [mg/l] | [mg/l] | [mg/kgwwt] | [mg/kgwwt] | [μg/l] |
| Scenario 1 (tier 1): TFB-OH | - | 1.74E-07 | - | 2.90E-04 | **0.102** |
| Scenario 1 (tier 1): TFB-COOH | - | 2.92E-07 | - | 4.86E-04 | **0.219** |
| Scenario 1 (tier 2): TFB-OH | - | 5.15E-08 | - | 8.58E-05 | 0.030 |
| Scenario 1 (tier 2): TFB-COOH | - | 8.62E-08 | - | 1.44E-04 | 0.026 |
| Scenario 2: TFB-OH | - | 4.36E-08 | - | 7.26E-05 | 0.065 |
| Scenario 2: TFB-COOH | - | 7.30E-08 | - | 1.21E-04 | 0.055 |

***Primary and secondary poisoning***

Primary poisoning

Not relevant

Secondary poisoning

Secondary poisoning concerns toxic effects in organisms at high trophic levels based on ingestion of organisms from lower trophic levels. Measured or predicted concentrations of residues in top predators are compared to no effect concentrations for the predators. The key components of the assessment of secondary poisoning are the assessment of potential bioaccumulation and potential toxicity of the substance following exposure to residues of the active substance.

**Via the consumption of worms from contaminated soil**

As previously described the exposure of soil to transfluthrin could result from the indirect application of sewage sludge to land. The PECsoil value is taken for the local ecosystem, and using the equations previously described, a corresponding porewater concentration can be calculated;

|  |  |
| --- | --- |
| PEClocalsoil, porewater = | PEClocalsoil x RHOsoil |
|  | Ksoil-water x 1000 |

PEClocalsoil, porewater is the predicted environmental concentration in porewater (calculated in mg l-1)

PEClocalsoil is the predicted environmental concentration in soil (presented as mg kgwwt-1)

RHOsoil is the bulk density of wet soil (default of 1700 kg m-3)

Ksoil-water is the soil-water partitioning co-efficient (calculated as 1504 m3 m-3)

According to the ECHA guidance on ERA, when birds and mammals consume worms this includes the gut of the earthworms which may contain substantial amounts of soil. The exposure of these predators (birds and small mammals) may be affected by the amount of active substance in the consumed soil.

The PECoral predator is calculated as PECoral predator = Cearthworm where Cearthworm is the total concentration of the active substance in the worm as a result of bioaccumulation in worm tissues and the adsorption of the active substance to the soil present in the earthworm’s gut. The total concentration in an entire worm can be calculated as the weighted average of the worm’s tissues (through BCF and porewater) and contents of the gut (through soil concentration) using the following equation (82c);

Cearthworm = [(BCFearthworm x Cporewater) + (Csoil x Fgut x CONVsoil)]

[1+(Fgut x CONVsoil)]

Where Csoil = PEClocalsoil (Ecosystem)

Cporewater = PEClocalsoil, porewater

Fgut = 0.1 (ECHA guidance default)

CONVsoil = RHOsoil / (Fsolid x RHOsolid) = 1700 / (0.6 x 2500) = 1.13

BCFearthworm = 10452 (calculated value AR)

And RHOearthworm is taken to be 1 kgwwt. L-1

|  |  |  |  |
| --- | --- | --- | --- |
| **Cearthworm values resulting from the application of sewage sludge** | | | |
| **Scenario** | **Clocalsoil**  **[mg kg-1 wwt]** | **PECporewater**  **(mg l-1)** | **PECoral predator (Cearthworm)**  **(mg kgwetworm-1)** |
| Scenario 1 (tier 1) | 1.57E-03 | 1.78E-06 | **1.69E-02** |
| Scenario 1 (tier 2) | 4.65E-04 | 5.26E-07 | **4.99E-03** |
| Scenario 2 | 3.94E-04 | 4.45E-07 | **4.22E-03** |

These PECoral predator values have then been compared to the PNEC values for birds and mammals.

**Via the aquatic food chain**

Predicted Environmental Concentrations of transfluthrin in surface water resulting from the proposed indoor use have previously been calculated in Section 3.3.3.1.2. According to ECHA guidance on ERA, the simplest way to estimate the potential of a substance to bioaccumulate in aquatic species is by the experimental measure of the Bioconcentration Factor (BCF).

The concentration in fish is given by;

PECoral,predator = PECwater x BCFfish x BMF

Where

PECoral,predator is the Predicted Environmental Concentration in food (in mg kgwet fish -1)

PECwater is the Predicted Environmental Concentration in water (in mg l-1)

BMF is the biomagnification factor in fish taken from the following table (1 for transfluthrin)

**Default BMF values for organic substances**

**(Taken from ECHA guidance on ERA Table 23)**

|  |  |  |
| --- | --- | --- |
| **Log Kow of substance** | **BCFfish** | **BMF** |
| < 4.5 | < 2000 | 1 |
| 4.5 - < 5 | 2000 - 5000 | 2 |
| 5 - 8 | > 5000 | 10 |
| > 8 - 9 | 2000 - 5000 | 3 |
| > 9 | < 2000 | 1 |

The BCFfish can be calculated using equation 74 from the ECHA Guidance on ERA, however a measured average value of 1783 l kg-1 has been described in the transfluthrin AR.

|  |  |  |
| --- | --- | --- |
| **PECoral predator using PECsurface water** | | |
| **Scenario** | **PECsurface water**  **(mg.l-1)** | **PECoral predator**  **(mg kgwet fish-1)** |
| Scenario 1 (tier 1) | 9.46E-07 | **1.69E-03** |
| Scenario 1 (tier 2) | 2.80E-07 | **4.99E-04** |
| Scenario 2 | 2.37E-07 | **4.22E-04** |

As a first tier approach the worst case PECs for local surface water (assuming no degradation at STP) calculated previously have been considered. However this may lead to an overestimation of the risk as fish eating birds and mammals may also forage on fish from sites other than the site of discharge. Also, biodegradation in surface water is not taken into account using this approach.

These values have then been compared to the PNEC values for birds and mammals.

### Risk characterisation

***Atmosphere***

Conclusion:

Following guidance in the ESD, the release to air from a single house has been calculated based on the proposed indoor use of this product and has been found to be very low.

This air concentration is then subject to rapid dilution, as detailed in the ESD for PT 18.

Moreover, as any a.s. reaching the atmosphere is expected to be decomposed with a half-life of 2.4 days, it can be expected that the level of risk to air posed by this product family for both worst case uses (scenarios 1 & 2) will be acceptable.

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

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
|  | **PEC/PNECSTP**  **(using 100 mg/l)** | **PEC/PNECSTP**  **(using 0.057 mg/l)** |
| Scenario 1 (tier 1) | 1.02E-07 | 1.78E-04 |
| Scenario 1 (tier 2) | 3.01E-08 | 5.27E-05 |
| Scenario 2 | 2.54E-08 | 4.46E-05 |

Conclusion:

An acceptable level of risk to biological treatment processes at STP is predicted for the proposed worst case uses (scenarios 1 and 2) of this product family (with PEC/PNECs <1).

***Aquatic compartment***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
|  | **PEC/PNECwater** | **PEC/PNECsediment** |
| Scenario 1 (tier 1) | 0.541 | **2.89** |
| Scenario 1 (tier 2) | 0.160 | 0.855 |
| Scenario 2 | 0.135 | 0.724 |

Based on PNECaquatic of 1.75E-6 mg/l and PNECsediment of 3.57E-4 mg /kg wwt

Conclusion:

A level of risk to the sediment compartment has been predicted for scenario 1, however acceptable uses have been demonstrated for scenario 2 and for scenario 1 to surface water.

It should be noted that scenario 1 (tier 1) represents an extreme worst case approach in that it is assumed that all a.s. deposited on surfaces is removed by wet cleaning and is then discharged to drains. Whilst MS have agreed that wet cleaning cannot be avoided, discussions at ENV WG have concluded that, in reality, only a fraction of the available surface area would be subject to wet cleaning and thus a tier 2 approach assuming pick-up from only 6.5 m2 of the total surface (22 m2) can be applied. As zero degradation occurs at STP, the tier 2 PECsediment would be proportionally lower than that predicted at tier 1 and will therefore give rise to a PEC/PNEC of only 0.775. On that basis, scenario 1 risks posed to sediment by use of 2 product sheets in one room of a house can be considered acceptable at tier 2.

***Terrestrial compartment***

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
|  | **PEC/PNECsoil** |
| Scenario 1 (tier 1) | 0.018 |
| Scenario 1 (tier 2) | 0.005 |
| Scenario 2 | 0.004 |

Based on PNECsoil of 8.82E-2 mg/kg wwt

Conclusion:

An acceptable level of risk to the terrestrial compartment is predicted from both proposed worst case uses (scenarios 1 & 2) of Transfluthrin Family products (PEC/PNEC <1).

***Groundwater***

The calculated PECGW values in both worst case scenarios for transfluthrin, based on a simplistic porewater calculation are all below the regulatory threshold of 0.1 μg/L.

***Metabolites***

Predicted environmental concentration for the two major metabolites TFB-OH and TFB-COOH have been calculated for the relevant compartments of surface water and soil.

As the predicted concentrations in the relevant compartments are lower than those predicted for transfluthrin and the (eco) toxicity of the metabolites is lower, it is considered than any risk will be covered by the risk assessment for transfluthrin and metabolite PEC/PNEC ratios have not been calculated.

***Primary and secondary poisoning***

Primary poisoning

Not relevant

Secondary poisoning

The PNECoral,mammal stated in the Assessment Report (2014) is 6.67 mg a.s./ kg food.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on secondary poisoning** | | | | | |
|  |  | **Consumption of fish** | | **Consumption of worms** | |
| **Scenario** | **PECoral predator**  fish/ earthworm | **PEC/PNECbirds** | **PEC/PNECmammals** | **PEC/PNECbirds** | **PEC/PNECmammals** |
| **Scenario 1 (tier 1)** | 1.69E-03/1.691E-02 | **-** | 2.53E-04 | **-** | 2.53E-03 |
| **Scenario 1 (tier 2)** | 4.99E-04/ 4.99E-03 |  | 7.47E-05 |  | 7.48E-04 |
| **Scenario 2** | 4.22E-04/ 4.22E-03 | **-** | 6.32E-05 | **-** | 6.33E-04 |

Conclusion:

An acceptable level of risk is predicted to the environment from the consumption of fish or earthworms contaminated with transfluthrin for both worst case scenarios (1 & 2).

***Mixture toxicity***

*Screening step*

According to the online EChA C&L Inventory, 1 additional compound within the product formulation has the potential to be classified as a “Substances of Concern” based upon reported entries on existing Material Safety Data Sheets for materials currently in the marketplace.

This relates to denatonium benzoate which is classified as H412 aquatic chronic 3. However as this compound is present at such a low level in the formulation that the overall contribution to the risk of the formulation can be considered negligible.

It is expected that any risks will be driven solely due to the presence of the a.s. transfluthrin.

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

According to publicly available information, transfluthrin is a fast acting insecticide, which has been widely used in household and hygiene products mainly against flying insects (such as mosquitoes and flies), but also against material pests such as moths. Therefore, biocidal use of the a.s. is likely to exceed 10 % of total manufactured tonnage.



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

Conclusion: The biocidal product family consists of “Insecticide Paper Spice”, “Insecticide Paper Lavender” and “Moth Paper Lavender”.

For the aggregated exposure for “Insecticide Paper Spice” and “Insecticide Paper Lavender” and the moth product “Moth Paper Lavender” there is no realistic expectation that these products would be bought and used together. It is most likely that one or the other would be bought. Therefore there is no expectation of aggregated exposure from use of the different products at the same time and location.

For the aggregated exposure of different use scenarios for the same product (i.e. use in wardrobe, use in cupboards, use in laundry), based on the assumptions made in the calculations (i.e. whole pack used at each treatment occasion) the worst-case emission estimates presented take aggregated exposure into account.

Conclusion:

No aggregated exposure is expected from the use of the different products at the same time/location. Aggregated exposure of the same product used in different ways is taken into account in the calculations presented.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| The evaluation of this product family has followed the approach taken in the AR for transfluthrin, where a number of different diffuser products were evaluated. Based on the limited number of exposure routes to the environment being evaluated, the applicant chose to provide only a limited amount of effects data in the supporting package, such thatwas included, so PNECsoil and PNECsediment wereas calculated by EPM. As transfluthrin has a Log Kow > 5, an additional Assessment Factor ofextra x 10 factor was then applied to calculate the risk quotient values for sediment and soil (following guidance in the ECHA Doc IV, part B relating to high Log Kow values). However, further effects data have been submitted by the a.s. manufacturer and assessed at EU level, to set a new PNEC sediment of 3.57E-04 mg/kg wwt and PNEC soil of 8.82E-02 mg/kg wwt based on experimental data - the need for an additional Assessment Factor of 10 to calculated risks has been negated.  Two scenarios have been applied in order to assess likely applications of the product family and each follow latest agreed guidance :  **Scenario 1 : 2 sheets of product in a single room of a house**  It has been assumed for this scenario that one room is treated per house, and based on the applicant application instructions, 2 sheets will be required to treat a room of approximately 22 m2.  When the simultaneity relating to daily use is assumed, the resulting PEC/PNEC ratios indicate acceptable risks to all environmental compartments (with the exception of sediment where an RQ value of 2.89 is predicted and groundwater where a porewater concentration > 0.1 g/ l is predicted for the two metabolites). However, this model represents a worst case (tier 1) approach whereby all of the a.s. being deposited is assumed to be picked up by wet cleaning and discharged to drains. In reality, MS have agreed that the total surface area will not be subject to wet cleaning and therefore tier 2 modelling (where 6.5 m2 of the total 22 m2 area is wet cleaned) give rise to sediment risks <1 and groundwater levels < 0.1 g/ l for a.s. and all metabolites.  As acceptable risks have only been demonstrated at tier 2 level assessment, it would seem appropriate to require labelling instructions such that only 2 treated sheets may be used in the same house on a daily basis.  **Scenario 2 : sheets used to treat the maximum number of wardrobes in a house simultaneously (agreed at 2.5 wardrobes of 1.5 m3 in the TAB)**  The calculation for this scenario has assumed a worst case situation whereby all of the wardrobes are treated simultaneously in one house. Due to the small size of the sheets and limited a.s. content on each sheet, multiple applications would still give rise to acceptable risks in all compartments. Whilst unnecessary over-use of the product type against moths should always be avoided, no restrictions will be required on existing labels of 10 hanger devices or 18 loose sheets.  Note that this scenario 2 assessment covers multiple use of (a) loose sheets or (b)sheets placed within a hanger device.  **Mitigating arguments**  No further mitigating arguments are required for products within this transfluthin family as the majority of use patterns were considered acceptable at tier 1 (worst case) assessment. Small sediment risks and possible risks to groundwater were identified for scenatio 1 (2 loose sheets ignited in one room of a house) but refinement of the wet cleaning model indicated acceptable risks at tier 2 assessment.  **Summary conclusion**  It is expected that the two scenarios used in environmental risk assessment will support meta SP-1, SP-2 and SP-3 being proposed by the applicant for this biocidal product family. Although products may be marketed either as loose sheets or as sheets held within a hanging device, emissions and risk assessment looks specifically at the quantity of a.s. being applied and the levels reaching surfaces following passive diffusion or burning of sheets. Worst case assessments have looked at largest sizes of sheet or situations whereby large numbers of devices could be applied in drawers / cupboards (based on the agreed number of wardrobes per dwelling).  Most risks for both scenarios (1 & 2) are acceptable at tier 1 “worst case” level now that revised PNEC values in soil and sediment can be derived from experimental data and not predictive EPM models. Those that fail at tier 1 are shown to be acceptable at tier 2 when refinements based on more realistic surface area likely to be wet cleaned are applied. However, risks to sediment from ignition of 2 product sheets in one domestic room on a single day (scenario 1) do not allow any margin for increased application rate (such that use in more than one room or more than 2 sheets on the same day cannot be permitted).  Product labelling of the “x” product (combustible sheets assessed under scenario 1) should carry advice to indicate that :  “Do not exceed the use of 2 sheets per house on the same day (2 sheets will provide protection for a single room of average size : 22 m2)”. |

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

For mSPC1 and mSPC2:

Avoid breathing fumes.

Remove domestic animals during use.

Seal fish tank prior to treatment.

Do not exceed the use of 2 sheets per house on the same day (2 sheets will provide protection for a single room of average size : 22 m2)

To prevent contamination of food, do not use in kitchens or other food storage or preparation areas

For mSPC 3 and 4:

Keep animals away from treated wardrobes and textiles.

Avoid any direct or indirect exposure via food.

For all mSPC:

Wash hands thoroughly after handling.

In case of contact with eyes: rinse cautiously with water for several minutes. Remove contact lenses if applicable and they can be easily removed. Continue rinsing. If eye irritation persists: consult a doctor.

In case of contact with skin: wash thoroughly with soap and water.

If irritation or rash occurs: Seek medical attention if an allergic reaction/irritation develops, persists or worsens

If swallowed, consult a doctor or nearest, anti-poison centre immediately and show product label. UK medical professionals should contact the National Poisons Information Service (www.npis.org) for further advice.

Do not allow to get into surface water, drains and ground water.

Do not use directly on or near food, feed or drinks, or on or near surfaces or utensils likely to be in direct contact with food, feed, drinks and animals

Harmful to aquatic organisms, may cause long-term adverse effects to the aquatic environment.

Methods and materials for containment and cleaning up:

Use mechanical handling equipment. Clean contaminated floors and objects thoroughly, observing environmental regulations. Keep in suitable, closed containers for disposal.

Dispose of contents to a household waste recycling centre as hazardous waste except for empty containers which can be disposed of by recycling.Contact your local council for details.

Contaminated packaging: Not completely emptied packaging should be disposed of as hazardous waste.

Store in original container. Keep containers tightly closed in a dry, cool and well-ventilated place.

Store in a place accessible by authorized persons only.

Keep away from direct sunlight.

Keep away from food, drink and animal feeding stuffs.

Product is expected to be stable under normal conditions.

Shelf life of 24 months

# Annexes

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

| **Section No / Reference No** | **Author(s)** | **Year** | **Title Source Report No GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner** |
| --- | --- | --- | --- | --- | --- |
| 3.1-01, 3.2-01, 3.4.1-01, 02 and 03 | Manka, S | 2014 | Determination of Physico-Chemical Properties and Storage Stability Tests for Transfluthrin XX 0.45E  BioGenius GmbH  Report No. Mo4376  GLP  Unpublished | Yes | Bayer |
| 3.5.13 | Anon | 2014 | Packaging trials LT02  Non-GLP  Unpublished | Yes | Yanco |
| 3.5.14 | Lantham A | 2015 | Examination of rate of loss of transfluthrin on Moth hanger  Non-GLP  Unpublished | Yes | Yanco |
| 4.1-01 | Dornhagen J | 2012 | Transfluthrin XX 0,45E Explosive Properties A14  SIEMENS AG  Report No. 2012094.03  GLP  Unpublished | Yes | Bayer |
| 4.2-01 | Dornhagen J | 2012 | Transfluthrin XX 0,45E: Flammability A.10.  SIEMENS AG  Report No. 20120094.01  GLP  Unpublished | Yes | Bayer |
| 4.4-01 | Dornhagen J | 2012 | Transfluthrin XX 0,45E: Oxidising Properties A.17.  SIEMENS AG  Report No. 20120094.05  GLP  Unpublished | Yes | Bayer |
| 4.17.1-01 | Dornhagen J | 2012 | Transfluthrin XX 0,45E: Auto-flammability (Solids –Determination of Relative Self-Ignition Temperature) A.16.  SIEMENS AG  Report No. 20120094.04  GLP  Unpublished | Yes | Bayer |
| 4.17.1-02 | Dornhagen J | 2012 | Transfluthrin XX 0,45E: Pyrophoric Properties of Solids and Liquids A.13.  SIEMENS AG  Report No. 20120094.02  GLP  Unpublished | Yes | Bayer |
| 5.1 | Manka, S. | 2012 | MV035 Determination of Transfluthrin in Paper Coils  BioGenius Report No: MV035  GLP  Unpublished | Yes | Bayer |
| 5.1 | Manka, S. | 2012 | Validation of MV035 - Determination of Transfluthirn in Paper Coils  BioGenius Report No: Mo4375  GLP  Unpublished | Yes | Bayer |
| 5.1 | Manka, S. | 2020 | Re-validation of CIPAC method 741/TC/M/3.2 and MV035 fir the determination of 1R-transfluthrin in Bonodor Papel Insecticida  BioGenius  Report No: Mo6869  GLP  Unpublished | Yes | Bayer |
| 6.7-01/02 | Radecki | 2014 | Efficacy of Rambo Papers against flying and crawling insect species  BioGenius GmbH  Report No: BIO114a-14, Mo4335  Non-GLP (GLP-like)  Unpublished | Yes | Bayer |
| 6.7-03 | Lüpkes, K.-H. | 2008 | Aerosol efficacy of various products against mosquitoes  BioGenius GmbH  Report No: BIO032-08, Mo3579  Non-GLP  Unpublished | Yes | Bayer |
| 6.7-04 | Jung, R. | 2009 | Bio-efficacy of Bayer insecticidal papers against mosquitoes  BioGenius GmbH  Report No: BIO053c-09, Mo3810  Non-GLP  Unpublished | Yes | Bayer |
| 6.7-05 | Dupo, Henry C. | 2008 | Bioefficacy evaluation of YAMO Paper against mosquitoes in simulated use trials under real life conditions in the Philippines  Dupoh BioResearch Centre, Canlubang, Calamba City, Philippines  Report No: BES ID-02943  Non-GLP  Unpublished | Yes | Bayer |
| 6.7-06 | Nentwig, G | 2009 | BES 0527: Three formulations of Yamo paper with fragrances versus standard: efficacy against Culex quinquefasciatus and Anopheles gambiae in rooms of the VVG  Report No: BES 527-09-02  Non-GLP  Unpublished | Yes | Bayer |
| 6.7-07 | Loots, JH and Garbers HV | 2009 | Paper Foggers  SABS Commercial (pty) Ltd SABS Pesticide Trial Section; SANS Method 5807 Report No: 2418/C3087  Non-GLP (GLP-like)  Unpublished | Yes | Bayer |
| 6.7-08 | Lüpkes, K-H | 2014 | Efficacy of Yanco papers against Cloth moths Tineola bisselliella and Bed bugs Cimex lectularius in 0.5m3 cupboards.  BioGenius GmbH, Biology, Bergisch Gladbach, Germany  Report number: BIO010-14, Mo4660  Non-GLP (GLP-like)  Unpublished | Yes | Yanco |
| 8.1.1 | Gerbeix, C. | 2012 | Acute Dermal Irritation Study in Rabbits  Bayer AG, Bayer CropScience, Germany Report No: 38992 TAL  GLP  Unpublished | Yes | Bayer |

## Output tables from exposure assessment tools

**Scenario 1: Primary exposure during handling and preparation of impregnated insecticide paper**

**ConsExpo 4.1 report**

file name:

Report date: 23/01/2017

**Product**

**Compound**

Compound name :

CAS number :

molecular weight 371 g/mol

vapour pressure 0.0009 Pascal

KOW linear

**General Exposure Data**

exposure frequency 365 1/year

body weight 60 kilogram

**Inhalation model: Exposure to vapour : evaporation**

weight fraction compound 0.45 %

exposure duration 10 minute

room volume 1 m3

ventilation rate 0.6 1/hr

applied amount 9.6 gram

release area 4.05 cm2

application duration 10 minute

mol weight matrix 14.7 g/mol

mass transfer rate 1.94E3 m/min

**Uptake model: Fraction**

uptake fraction 100 %

inhalation rate 1.25 m3/hour

**Dermal model: Direct dermal contact with product : constant rate**

weight fraction compound 0.45 %

contact rate 1 mg/min

release duration 10 minute

**Uptake model: fraction**

uptake fraction 10 %

**Output**

**Inhalation (point estimates)**

inhalation mean event concentration : 2.12E-5 mg/m3

inhalation mean concentration on day of exposure: 1.47E-7 mg/m3

inhalation acute (internal) dose : 7.36E-8 mg/kg

**Dermal : point estimates**

dermal load : - mg/cm2

dermal external dose : 0.00075 mg/kg

dermal acute (internal) dose : 7.5E-5 mg/kg

**Integrated (point estimates)**

total external dose: 0.00075 mg/kg

total acute dose (internal): 7.51E-5 mg/kg

**Scenario 3: Primary exposure during handling and preparation of impregnated moth paper**

**ConsExpo 4.1 report**

**Product**

**Compound**

Compound name :

CAS number :

molecular weight 371 g/mol

vapour pressure 0.0009 Pascal

KOW linear

**General Exposure Data**

body weight 60 kilogram

**Inhalation model: Exposure to vapour : evaporation**

weight fraction compound 0.45 %

exposure duration 10 minute

room volume 1 m3

ventilation rate 0.6 1/hr

applied amount 8.82 gram

release area 4.05 cm2

application duration 10 minute

mol weight matrix 14.7 g/mol

mass transfer rate 1.94E3 m/min

**Uptake model: Fraction**

uptake fraction 100 %

inhalation rate 1.25 m3/hour

**Dermal model: Direct dermal contact with product : constant rate**

weight fraction compound 0.45 %

contact rate 1 mg/min

release duration 10 minute

**Uptake model: fraction**

uptake fraction 10 %

**Output**

**Inhalation (point estimates)**

inhalation mean event concentration : 2.12E-5 mg/m3

inhalation mean concentration on day of exposure: 1.47E-7 mg/m3

inhalation acute (internal) dose : 7.36E-8 mg/kg

**Dermal : point estimates**

dermal load : - mg/cm2

dermal external dose : 0.00075 mg/kg

dermal acute (internal) dose : 7.5E-5 mg/kg

**Integrated (point estimates)**

total external dose: 0.00075 mg/kg

total acute dose (internal): 7.51E-5 mg/kg

**Scenario 5: secondary exposure during the use of/access to areas containing moth paper e.g. opening wardrobe (adult, acute exposure)**

**ConsExpo 4.1 report**

**Product**

**Compound**

Compound name :

CAS number :

molecular weight 371 g/mol

vapour pressure 0.0009 Pascal

KOW linear

**General Exposure Data**

exposure frequency 365 1/year

body weight 60 kilogram

**Inhalation model: Exposure to vapour : evaporation**

weight fraction compound 0.45 %

exposure duration 5 minute

room volume 1.5 m3

ventilation rate 0.3 1/hr

applied amount 8.82 gram

release area 4.05 cm2

application duration 5 minute

mol weight matrix 14.7 g/mol

mass transfer rate 1.94E3 m/min

**Uptake model: Fraction**

uptake fraction 100 %

inhalation rate 1.25 m3/hour

**Output**

**Inhalation (point estimates)**

inhalation mean event concentration : 1.58E-5 mg/m3

inhalation mean concentration on day of exposure: 5.48E-8 mg/m3

inhalation acute (internal) dose : 2.74E-8 mg/kg

**Integrated (point estimates)**

total external dose: 2.74E-8 mg/kg

total acute dose (internal): 2.74E-8 mg/kg

**Scenario 5: secondary exposure during the use of/access to areas containing moth paper e.g. opening wardrobe (child, acute exposure)**

**ConsExpo 4.1 report**

**Product**

**Compound**

Compound name :

CAS number :

molecular weight 371 g/mol

vapour pressure 0.0009 Pascal

KOW linear

**General Exposure Data**

exposure frequency 365 1/year

body weight 23.9 kilogram

**Inhalation model: Exposure to vapour : evaporation**

weight fraction compound 0.45 %

exposure duration 5 minute

room volume 1.5 m3

ventilation rate 0.3 1/hr

applied amount 8.82 gram

release area 4.05 cm2

application duration 5 minute

mol weight matrix 14.7 g/mol

mass transfer rate 1.94E3 m/min

**Uptake model: Fraction**

uptake fraction 100 %

inhalation rate 1.32 m3/hour

**Output**

**Inhalation (point estimates)**

inhalation mean event concentration : 1.58E-5 mg/m3

inhalation mean concentration on day of exposure: 5.48E-8 mg/m3

inhalation acute (internal) dose : 7.26E-8 mg/kg

**Integrated (point estimates)**

total external dose: 7.26E-8 mg/kg

total acute dose (internal): 7.26E-8 mg/kg

**Scenario 6: Secondary exposure during application of moth paper (adult, chronic exposure)**

**ConsExpo 4.1 report**

file name:

Report date: 24/01/2017

**Product**

**Compound**

Compound name :

CAS number :

molecular weight 371 g/mol

vapour pressure 0.0009 Pascal

KOW linear

**General Exposure Data**

exposure frequency 365 1/year

body weight 60 kilogram

**Inhalation model: Exposure to vapour : evaporation**

weight fraction compound 0.45 %

exposure duration 24 hour

room volume 20 m3

ventilation rate 0.6 1/hr

applied amount 8.82 gram

release area 4.05 cm2

application duration 24 hour

mol weight matrix 14.7 g/mol

mass transfer rate 1.94E3 m/min

**Uptake model: Fraction**

uptake fraction 100 %

inhalation rate 16 m3/day

**Output**

**Inhalation (point estimates)**

inhalation mean event concentration : 1.93E-5 mg/m3

inhalation mean concentration on day of exposure: 1.93E-5 mg/m3

inhalation acute (internal) dose : 5.15E-6 mg/kg

**Integrated (point estimates)**

total external dose: 5.15E-6 mg/kg

total acute dose (internal): 5.15E-6 mg/kg

**Scenario 6: Secondary exposure during application of moth paper (child, chronic exposure)**

**ConsExpo 4.1 report**

**Product**

**Compound**

Compound name :

CAS number :

molecular weight 371 g/mol

vapour pressure 0.0009 Pascal

KOW linear

**General Exposure Data**

exposure frequency 365 1/year

body weight 23.9 kilogram

**Inhalation model: Exposure to vapour : evaporation**

weight fraction compound 0.45 %

exposure duration 24 hour

room volume 20 m3

ventilation rate 0.6 1/hr

applied amount 8.82 gram

release area 4.05 cm2

application duration 24 hour

mol weight matrix 14.7 g/mol

mass transfer rate 1.94E3 m/min

**Uptake model: Fraction**

uptake fraction 100 %

inhalation rate 12 m3/day

**Output**

**Inhalation (point estimates)**

inhalation mean event concentration : 1.93E-5 mg/m3

inhalation mean concentration on day of exposure: 1.93E-5 mg/m3

inhalation acute (internal) dose : 9.69E-6 mg/kg

**Integrated (point estimates)**

total external dose: 9.69E-6 mg/kg

total acute dose (internal): 9.69E-6 mg/kg

**Scenario 6: Secondary exposure during application of moth paper (toddler, chronic exposure)**

**ConsExpo 4.1 report**

**Product**

**Compound**

Compound name :

CAS number :

molecular weight 371 g/mol

vapour pressure 0.0009 Pascal

KOW linear

**General Exposure Data**

exposure frequency 365 1/year

body weight 10 kilogram

**Inhalation model: Exposure to vapour : evaporation**

weight fraction compound 0.45 %

exposure duration 24 hour

room volume 20 m3

ventilation rate 0.6 1/hr

applied amount 8.82 gram

release area 4.05 cm2

application duration 24 hour

mol weight matrix 14.7 g/mol

mass transfer rate 1.94E3 m/min

**Uptake model: Fraction**

uptake fraction 100 %

inhalation rate 8 m3/day

**Output**

**Inhalation (point estimates)**

inhalation mean event concentration : 1.93E-5 mg/m3

inhalation mean concentration on day of exposure: 1.93E-5 mg/m3

inhalation acute (internal) dose : 1.54E-5 mg/kg

**Integrated (point estimates)**

total external dose: 1.54E-5 mg/kg

total acute dose (internal): 1.54E-5 mg/kg

**Scenario 6: Secondary exposure during application of moth paper (infant, chronic exposure)**

**ConsExpo 4.1 report**

**Product**

**Compound**

Compound name :

CAS number :

molecular weight 371 g/mol

vapour pressure 0.0009 Pascal

KOW linear

**General Exposure Data**

exposure frequency 365 1/year

body weight 8 kilogram

**Inhalation model: Exposure to vapour : evaporation**

weight fraction compound 0.45 %

exposure duration 24 hour

room volume 20 m3

ventilation rate 0.6 1/hr

applied amount 8.82 gram

release area 4.05 cm2

application duration 24 hour

mol weight matrix 14.7 g/mol

mass transfer rate 1.94E3 m/min

**Uptake model: Fraction**

uptake fraction 100 %

inhalation rate 5.4 m3/day

**Output**

**Inhalation (point estimates)**

inhalation mean event concentration : 1.93E-5 mg/m3

inhalation mean concentration on day of exposure: 1.93E-5 mg/m3

inhalation acute (internal) dose : 1.3E-5 mg/kg

**Integrated (point estimates)**

total external dose: 1.3E-5 mg/kg

total acute dose (internal): 1.3E-5 mg/kg

**Scenario 7: Secondary exposure during re-entry into areas treated with insecticide paper (Tier 2, adult)**

**ConsExpo 4.1 report**

**Product**

**Compound**

Compound name :

CAS number :

molecular weight 371 g/mol

vapour pressure 0.0009 Pascal

KOW linear

**General Exposure Data**

exposure frequency 365 1/year

body weight 60 kilogram

**Inhalation model: Exposure to vapour : constant rate**

weight fraction compound 0.45 %

exposure duration 24 hour

room volume 58 m3

ventilation rate 0.5 1/hr

applied amount 1.6 gram

release duration 10 minute

**Uptake model: Fraction**

uptake fraction 100 %

inhalation rate 16 m3/day

**Output**

**Inhalation (point estimates)**

inhalation mean event concentration : 0.0103 mg/m3

inhalation mean concentration on day of exposure: 0.0103 mg/m3

inhalation air concentration year average : 0.0103 mg/m3/day

inhalation acute (internal) dose : 0.00276 mg/kg

inhalation chronic (internal) dose : 0.00276 mg/kg/day

**Integrated (point estimates)**

total external dose: 0.00276 mg/kg

total acute dose (internal): 0.00276 mg/kg

total chronic dose (internal): 0.00276 mg/kg/day

**Scenario 7: Secondary exposure during re-entry into areas treated with insecticide paper (Tier 2, infant)**

**ConsExpo 4.1 report**

**Product**

**Compound**

Compound name :

CAS number :

molecular weight 371 g/mol

vapour pressure 0.0009 Pascal

KOW linear

**General Exposure Data**

exposure frequency 365 1/year

body weight 8 kilogram

**Inhalation model: Exposure to vapour : constant rate**

weight fraction compound 0.45 %

exposure duration 24 hour

room volume 58 m3

ventilation rate 0.5 1/hr

applied amount 1.6 gram

release duration 10 minute

**Uptake model: Fraction**

uptake fraction 100 %

inhalation rate 5.4 m3/day

**Dermal model: Direct dermal contact with product : rubbing off**

weight fraction compound 0.45 %

transfer coefficient 0.6 m2/hr

rubbed surface 7 m2

release duration 60 minute

dislodgeable amount 21.8 mg/m2

**Uptake model: fraction**

uptake fraction 10 %

**Oral model: Oral exposure to product : constant rate**

weight fraction compound 0.45 %

ingestion rate 0.0218 mg/min

exposure time 60 minute

**Uptake model: Fraction**

uptake fraction 100 %

**Output**

**Inhalation (point estimates)**

inhalation mean event concentration : 0.0103 mg/m3

inhalation mean concentration on day of exposure: 0.0103 mg/m3

inhalation acute (internal) dose : 0.00698 mg/kg

**Dermal : point estimates**

dermal load : - mg/cm2

dermal external dose : 0.00736 mg/kg

dermal acute (internal) dose : 0.000736 mg/kg

**Oral : point estimates**

oral external dose : 0.000736 mg/kg

oral acute (internal) dose : 0.000736 mg/kg

**Integrated (point estimates)**

total external dose: 0.0151 mg/kg

total acute dose (internal): 0.00845 mg/kg

**Scenario 7:** **Secondary exposure during re-entry into areas treated with insecticide paper (Tier 2, toddler)**

**ConsExpo 4.1 report**

**Product**

**Compound**

Compound name :

CAS number :

molecular weight 371 g/mol

vapour pressure 0.0009 Pascal

KOW linear

**General Exposure Data**

exposure frequency 365 1/year

body weight 10 kilogram

**Inhalation model: Exposure to vapour : constant rate**

weight fraction compound 0.45 %

exposure duration 24 hour

room volume 58 m3

ventilation rate 0.5 1/hr

applied amount 1.6 gram

release duration 10 minute

**Uptake model: Fraction**

uptake fraction 100 %

inhalation rate 8 m3/day

**Dermal model: Direct dermal contact with product : rubbing off**

weight fraction compound 0.45 %

transfer coefficient 0.6 m2/hr

rubbed surface 7 m2

release duration 60 minute

dislodgeable amount 21.8 mg/m2

**Uptake model: fraction**

uptake fraction 10 %

**Oral model: Oral exposure to product : constant rate**

weight fraction compound 0.45 %

ingestion rate 0.0218 mg/min

exposure time 60 minute

**Uptake model: Fraction**

uptake fraction 100 %

**Output**

**Inhalation (point estimates)**

inhalation mean event concentration : 0.0103 mg/m3

inhalation mean concentration on day of exposure: 0.0103 mg/m3

inhalation acute (internal) dose : 0.00828 mg/kg

**Dermal : point estimates**

dermal load : - mg/cm2

dermal external dose : 0.00589 mg/kg

dermal acute (internal) dose : 0.000589 mg/kg

**Oral : point estimates**

oral external dose : 0.000589 mg/kg

oral acute (internal) dose : 0.000589 mg/kg

**Integrated (point estimates)**

total external dose: 0.0148 mg/kg

total acute dose (internal): 0.00945 mg/kg

## New information on the active substance

No new information has been provided on the active substance Transfluthrin

## Residue behaviour

N/a

## Summaries of the efficacy studies

See Section 3.2.6

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-1)
2. The Guidance on "Handling “carriers” in the authorisation of biocidal product, is currently under discussion. Therefore this assessment will be revised at the renewal step. [↑](#footnote-ref-2)
3. The assessment of the relevance of this dermal absorption default value will be revised at the renewal step, considering the EFSA 2017 guidance. [↑](#footnote-ref-3)
4. RIVM report 320005002/2006 Pest Control Products Fact Sheet [↑](#footnote-ref-4)
5. RIVM report 320104002/2006 General Fact Sheet Limiting conditions and reliability, ventilation, room size, body surface area [↑](#footnote-ref-5)
6. ECHA Biocides Human Health Exposure Methodology (2015, p.331) [↑](#footnote-ref-6)
7. HEEG Opinion 13 (2013) Assessment of inhalation exposure of volatilised biocide active substance [↑](#footnote-ref-7)
8. RIVM report 320104004/2005 Consumer Exposure and Uptake Models Program Manual [↑](#footnote-ref-8)
9. Guidance on BPR: Volume III Parts B+C Version 4.0 December 2017 Volume III Part B+C (Table 26, p. 253) [↑](#footnote-ref-9)
10. CA-Nov16-Doc.4.3 Handling “carriers” in the authorisation of biocidal products [↑](#footnote-ref-10)
11. CA-Sept 13-Doc 6.2.a. Final.Rev1 - Authorisation of biocidal products classified as skin sensitisers requiring PPE for non-professional users [↑](#footnote-ref-11)