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

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

(submitted by the eCA)



**Moth Gel Family**

(Moth Gel Lavender/Moth Gel Cedar)

Product type 18

Transfluthrin

Case Number in R4BP: BC-PJ020494-38

Evaluating Competent Authority: The Netherlands

Date: 29 October 2021

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# CONCLUSION

**Analytical methods and Physical Chemical Properties conclusion**

Moth gel family comprises of two meta SPC: Lavender (purple gel) and Cedar (orange gel). Transfluthrin is the active substance of the products in this family. A shelf-life of 4 years is supported at ambient temperatures in a PET blister coated with a permeable PE-PP membrane, covered by aluminium foil. The product should be stored at room temperature. No classification with respect to physical hazards is required for both Moth Gel Lavender and Moth Gel Cedar.

**Data gap for renewal:**

* A corrosion to metals study should be provided addressing both uniform and localised corrosion. The test method should be conforming the test method as described in the UN-MTC.
* The specificity of the GC-FID method should be addressed for meta SPC 2: moth gel Cedar.

**Efficacy conclusion**

Based on the provided tests efficacy of the products of the Moth Gel family against *Tineola bisselliella* adults and larvae was sufficiently demonstrated in drawers for up to 12 weeks against adults and up to 4 weeks against larvae.

Allow 2 weeks for maximum effect.

**Conclusions Human Health**

Based on the human health risk assessment, no adverse health effects are expected after use of Moth Gel Family in accordance to the intended use.

**Conclusions Environment**

The risk assessment for the environment was performed for the scenario Consumer use of insecticide diffuser product, for transfluthrin, its metabolites and a number of SoCs. The risk assessment demonstrated that risks for the environment are acceptable for the intended use of Moth Gel Family as vapour releasing products indoors for consumers.

# 2 ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product / product family

| **Identifier[[1]](#footnote-1)** | **Country (if relevant)** |
| --- | --- |
| Moth Gel Family  Raid Moth Gel Lavender  Raid Moth Gel Cedar  Baygon Moth Gel Lavender  Baygon Moth Gel Cedar | The Netherlands (eCA) |
| Raid® Motten-Gel Lavendel-Duft  Raid® Motten-Gel Zedern-Duft | Austria |
| РАЙД СРЕЩУ МОЛЦИ-ГЕЛ ЛАВАНДУЛА,  1211-1/13.01.2012 Г.  РАЙД СРЕЩУ МОЛЦИ ГЕЛ КЕДЪР, 1212-1/13.01.2012 Г. | Bulgaria |
| Raid® Tarme protiv moljaca, miris Lavanda  Raid® Tarme protiv moljaca, miris Cedar | Croatia |
| RAID GEL /  BAYGON GEL | Cyprus |
| Raid® proti molům gel Levandule  Biolit Plus® M gel levandule  Raid® proti molům gel Cedr  Biolit Plus® M gel cedr | Czech Republic |
| Raid® Kointorjunta | Finland |
| RAID® Gel Anti-Mites - Senteur Lavande  RAID® Gel Anti-Mites - Senteur Bois de Cèdre | France |
| Raid® Motten-Gel Lavendel-Duft  Raid® Motten-Gel Zedern-Duft | Germany |
| RAID GEL /  BAYGON GEL | Greece |
| Raid® molyirtó gél Levendula illattal  Raid® molyirto gel Cedrus illattal | Hungary |
| Raid® Tarme Gel | Italy |
| Raid® zawieszki przeciw molom  w żelu o zapachu lawendowym  Raid® zawieszki przeciw molom  w żelu o zapachu cedrowym | Poland |
| Raid® Anti Traças Lavanda Fresca  Raid® Anti Traças Cedro | Portugal |
| RAID® ANTI-MOLII GEL LAVANDĂ  RAID® ANTI-MOLII GEL CEDRU | Romania |
| Raid® proti moliam gél Levanduľa  Biolit Plus® M gél levanduľa  Raid® proti moliam gél Céder  Biolit Plus® M gél céder | Slovakia |
| Raid® Tarme Gel Lavanda  Raid® Tarme Gel Cedro | Slovenia |
| Polil Raid® Gel Lavanda | Spain |

Other names used in internal unpublished studies are:

NEVAR LPT =Moth Gel Lavender

Raid® Moth Proofer (fragrance Eagle) = Moth Gel Lavender

Raid® Moth Proofer (fragrance Cedar) = Moth Gel CedarRadec =Moth Gel Cedar

Cedar ABX =Moth Gel Cedar

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | SC Johnson Europe Sàrl |
| **Address** | Z.A. la Piece 8, 1180, Rolle, Switzerland |
| **Authorisation number** |  | |
| **Date of the authorisation** | 5 November 2021 | |
| **Expiry date of the authorisation** | 5 November 2031 | |

#### Manufacturer of the product/ product family

|  |  |
| --- | --- |
| **Name of manufacturer** | SC Johnson Europe Sàrl |
| **Address of manufacturer** | Z.A. la Piece 8, 1180, Rolle, Switzerland |
| **Location of manufacturing sites** | Zobele Holding S.p.A.  Via Fersina, 4,  38123 Trento,  Italy |

|  |  |
| --- | --- |
| **Name of manufacturer** | SC Johnson Europe Sàrl |
| **Address of manufacturer** | Z.A. la Piece 8, 1180, Rolle, Switzerland |
| **Location of manufacturing sites** | IGO Srl, Via Palazzo, 46, 24061 Albano S.A. Italy |

|  |  |
| --- | --- |
| **Name of manufacturer** | SC Johnson Europe Sàrl |
| **Address of manufacturer** | Z.A. la Piece 8, 1180, Rolle, Switzerland |
| **Location of manufacturing sites** | Packaging Imolese S.p.A, Via F.Turati, 22 40026,Imola Italy. |

#### Manufacturer of the active substance

|  |  |
| --- | --- |
| **Active substance** | Transfluthrin |
| **Name of manufacturer** | BAYER SAS  (formerly BAYER Environmental Science) |
| **Address of manufacturer** | 16 rue Jean-Marie Leclair, CS 90106, 69266 Lyon Cedex 09, France |
| **Location of manufacturing sites** | Bayer Vapi Private Limited  Plot No 306/3, II Phase, GIDC  Vapi 396 195  Gujarat  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** | 2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2- dimethylcyclopropanecarboxylate, or,  2,3,5,6-tetrafluorobenzyl (1R)-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate |
| **EC number** | 405-060-5 \* |
| **CAS number** | 118712-89-3 \* |
| **Index number in Annex VI of CLP** | 607-223-00-8 |
| **Minimum purity / content** | 96.5% (1R, trans isomer) |
| **Structural formula** |  |

*\* The EU index no. and ELINCS no. refer to the 1R,trans and 1S,trans configurations, which is not in agreement with the definition of transfluthrin, which is exclusively the 1R,trans isomer. The CAS registry no. does refer to the correct isomer.*

#### Candidate for substitution

Transfluthrin is not a candidate for substitution.

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

Not applicable.

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

**Level 1 composition (family)**

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Transfluthrin | 2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 118712-89-3 | 405-060-5 | 0.16 TC  (Pure active: 0.15%) |
|  | p-menthan-8-yl acetate | Non-active ingredient | 58985-18-5 | 261-543-9 | 20 - 33 |
|  | 3,5,5-trimethylhexyl acetate | Non-active ingredient | 58430-94-7 | 261-245-9 | 6.5 - 13 |
|  | linalool | Non-active ingredient | 78-70-6, 126-91-0 | 201-134-4 | 6.5 - 13 |
|  | Linalyl acetate | Non-active ingredient | 115-95-7 | 204-116-4 | 1.26 - 13 |
|  | Cineole | Non-active ingredient | 470-82-6 | 207-431-5 | 0.072 – 6.5 |
|  | p-menth-1-en-8-ol | Non-active ingredient | 98-55-5 | 202-680-6 | 0 - 1.68 |
|  | p-menth-1-en-4-ol | Non-active ingredient | 562-74-3 | 209-235-5 | 0 - 2.0 |
|  | Pentyl salicylate | Non-active ingredient | 2050-08-0/87-20-7 | 218-080-2, 201-730-4 | 0 – 0.65 |
|  | 2-methylundecanal | Non-active ingredient | 110-41-8 | 203-765-0 | 0 – 0.65 |
|  | Precyclemone b | Non-active ingredient | 52475-86-2 | - | 0 – 0.65 |
|  | Diphenyl ether | Non-active ingredient | 101-84-8 | 202-981-2 | 0.098 – 0.65 |
|  | Alpha-cedrene | Non-active ingredient | 469-61-4 | 207-418-4 | 0 - 0.06 |
|  | 3,7-dimethylocta-1,3,6-triene | Non-active ingredient | 13877-91-3 | 237-641-2 | 0 – 0.65 |

**Level 2 composition (meta-SPC 1: Lavender)**

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Transfluthrin | 2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 118712-89-3 | 405-060-5 | 0.16 TC  (Pure active: 0.15%) |
|  | p-menthan-8-yl acetate | Non-active ingredient | 58985-18-5 | 261-543-9 | 20 - 33 |
|  | 3,5,5-trimethylhexyl acetate | Non-active ingredient | 58430-94-7 | 261-245-9 | 6.5 - 13 |
|  | linalool | Non-active ingredient | 78-70-6, 126-91-0 | 201-134-4 | 6.5 - 13 |
|  | Linalyl acetate | Non-active ingredient | 115-95-7 | 204-116-4 | 6.5 - 13 |
|  | Cineole | Non-active ingredient | 470-82-6 | 207-431-5 | 0.65 - 6.5 |
|  | p-menth-1-en-4-ol | Non-active ingredient | 562-74-3 | 209-235-5 | 0.65 – 2.0 |
|  | 2-methylundecanal | Non-active ingredient | 110-41-8 | 203-765-0 | 0.16 – 0.65 |
|  | 1-methyl-4-(4-methyl-3-pentenyl) cyclohex-3-ene-1-carbaldehyde | Non-active ingredient | 52475-86-2 | - | 0.16 – 0.65 |
|  | Diphenyl ether | Non-active ingredient | 101-84-8 | 202-981-2 | 0.16 – 0.65 |
|  | 3,7-dimethylocta-1,3,6-triene | Non-active ingredient | 13877-91-3 | 237-641-2 | 0.16 – 0.65 |

**Level 2 composition (meta-SPC 2: Cedar)**

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (%)** |
| --- | --- | --- | --- | --- | --- |
| Transfluthrin | 2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 118712-89-3 | 405-060-5 | 0.16 TC  (Pure active: 0.15%) |
|  | p-menthan-8-yl acetate | Non-active ingredient | 58985-18-5 | 261-543-9 | 27.3 |
|  | 3,5,5-trimethylhexyl acetate | Non-active ingredient | 58430-94-7 | 261-245-9 | 11.2 |
|  | linalool | Non-active ingredient | 78-70-6, 126-91-0 | 201-134-4 | 9.22 |
|  | Linalyl acetate | Non-active ingredient | 115-95-7 | 204-116-4 | 1.26 |
|  | Cineole | Non-active ingredient | 470-82-6 | 207-431-5 | 0.072 |
|  | p-menth-1-en-8-ol | Non-active ingredient | 98-55-5 | 202-680-6 | 1.68 |
|  | Pentyl salicylate | Non-active ingredient | 2050-08-0, 87-20-7 | 218-080-2, 201-730-4 | 0.65 |
|  | Diphenyl ether | Non-active ingredient | 101-84-8 | 202-981-2 | 0.098 |
|  | Alpha-cedrene | Non-active ingredient | 469-61-4 | 207-418-4 | 0.06 |

The Moth Gel Family contains two formulations in two Meta SPCs with differing dyes and fragrances, but same active substance content and identical uses

#### . Information on technical equivalence

The active substance source is a reference source.

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

The following substances of concern were identified:

* p-menthan-8-yl acetate
* 3,5,5-trimethylhexyl acetate
* linalool
* Linalyl acetate
* Cineole
* p-menth-1-en-8-ol
* p-menth-1-en-4-ol
* Pentyl salicylate
* 2-methylundecanal
* Precyclemone b
* Diphenyl ether
* Alpha-cedrene
* 3,7-dimethylocta-1,3,6-triene

Substances of Concern were identified for human health and the environment. However, as the identified substances were adding to the classification, in line with guidance on SoCs, either risk management is covered by the assigned P-statements or a qualitative or quantitative assessment was sufficient. Based on the evaluation, no risk for the identified SoCs was concluded. For further details see sections 1.2.8.1 and 1.2.10.1 on substances of concern.

#### Information on endocrine disrupting properties

For the active substance transfluthrin no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. The Assessment Reports for transfluthrin (2014) state that this active substance is not be considered as having endocrine disrupting properties. The potential ED properties of the co-formulants were assessed (see confidential annex for more information) and for none of the components an ED alert was identified.

In conclusion, based on available information, Moth Gel Family is not considered to have ED properties.

#### Type of formulation

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

### Hazard and precautionary statements[[2]](#footnote-2)

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

**Moth Gel Family**

| **Classification** | | |
| --- | --- | --- |
| Hazard category | Skin Irrit. 2  Skin Sens. 1  Eye Irrit. 2  Aquatic Acute 1, Aquatic Chronic 1 | |
| Hazard statement | H315: Causes skin irritation.  H317: May cause an allergic skin reaction.  H319: Causes serious eye irritation.  H400: Very toxic to aquatic life.  H410: Very toxic to aquatic life with long lasting effects.  EUH066: Repeated exposure may cause skin dryness or cracking. | |
|  | | |
| **Labelling** | | |
|  |  | |
| Hazard Pictogram |  |  |
| GHS07 exclamation mark | GHS09: environment |
| Signal words | Warning | |
| Hazard statements | H315: Causes skin irritation.  H317: May cause an allergic skin reaction  H319: Causes serious eye irritation.  H410: Very toxic to aquatic life with long lasting effects. | |
| Precautionary statements | P101 If medical advice is needed, have product container or label at hand.  P102 Keep out of reach of children.  P103 Read label before use.  P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  P337 + P313 If eye irritation persists: Get medical advice/ attention.  P273 Avoid release to the environment  P391 Collect spillage  P501 Dispose of contents /container in accordance with local regulations.  P264 Wash hands thoroughly after handling | |
|  | | |
| Note | EUH066 is triggered by a solvent in the liquid formulation, however, is not included in the label as classified with H315 and therefore does not need to be included (section 1.2.4 of Annex II of CLP)  Linalool, linalyl acetate and p-menthan-8-yl acetate need to be declared based on the assigned H-statements according to Art 18(3) CLP.)  All p-statements triggered by H-statements were assigned, with some exemptions:   * H317 classification triggers P280: gloves. The phrase 'P280: Wear protective gloves' will not be present on the label because dermal exposure will not occur under normal conditions of use. For more information see local risk assessment, section 2.2.6.3. * P332 was omitted because P333 is given on the label. * P321 was not assigned because it is recommended only in exceptional cases where specific treatment is known and required. * P261 was not assigned because the product contains a gel hampering exposure to dust/ fume/ gas/ mist/spray. * P362+364: Take off immediately all contaminated clothing and wash it before reuse is triggered by H317 classification. This sentence is not assigned, because the perfume present in the gel and dislodging from the gel and transferring to the clothes is considered to be low as direct contact of the gel with the clothes is not likely. | |

### Authorised use(s)

#### Use description

Table 1. Insecticide Use – General public (non-professional)

|  |  |
| --- | --- |
| **Product Type** | Product type 18: Insecticides, acaricides and products to control other arthropods |
| **Where relevant, an exact description of the authorised use** | Insecticide |
| **Target organism (including development stage)** | **Scientific name**  *Tineola bisselliella*  **Common name**  Clothes moth  **Development stage**  Adults, Larvae |
| **Field of use** | Indoors  Insecticide for use in drawers |
| **Application method(s)** | Open system: diffusion  Passive diffusion from cartridge |
| **Application rate(s) and frequency** | Use 2 units per drawer measuring 0.018 m3 (that is equal to 18 dm3 or 18 litres)  Product is effective up to 12 weeks against adult moths and up to 4 weeks against larvae. Allow 2 weeks for maximum effect. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | Blister, Plastic pack (PET)  Blister is sealed with a permeable plastic (PE-PP) membrane.  Multi packs or standard packs with two or more cartridges/blister packs (PET). The membrane is covered with a polyester coated Aluminium foil, which can be removed to activate the product |

#### Use-specific instructions for use[[3]](#footnote-3)

|  |
| --- |
| See section 1.1.5.1 |

#### Use-specific risk mitigation measures

|  |
| --- |
| See section 1.1.5.2 |

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

|  |
| --- |
| See section 1.1.5.3 |

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

|  |
| --- |
| See section 1.1.5.4 |

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

|  |
| --- |
| See section 1.1.5.5 |

### General directions for use

#### Instructions for use[[4]](#footnote-4)

|  |
| --- |
| **Use directions:**  Only for use in drawers.  Comply with the instructions for use. Adapt the number of units according to the volume of the treated drawer. Inform the registration holder if the treatment is ineffective.  Keep drawers closed for optimal efficacy. Allow 2 weeks for maximum effect. Wash hands thoroughly after handling.  DUO PACK ONLY    Separate the units. Open backing card of unit without removing it completely.  Remove aluminium foil completely. Avoid making contact with the gel membrane.  Fold the backing card, ensuring it does not cover the gel membrane.  Place 2 units in a drawer (0.018 m3).  MULTIPACK ONLY  Remove aluminium foil completely. Avoid making contact with the gel membrane.  Place 2 units in a drawer (0.018 m3). |
|  |

#### Risk mitigation measures

|  |
| --- |
| Avoid direct contact of the permeable membrane with clothes, fabrics and plastics.  Use only as directed  Do not use near food, drink, and animal feeding stuffs.  Use only in positions inaccessible to children and animals, in particular cats.  No application in rooms, where fish tanks and terrariums are present |

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

|  |
| --- |
| **Likely direct or indirect effects**  No adverse effects expected when used as directed.  Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.  **Description of first aid measures:**  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.  IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.  IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.  **Most important symptoms and effects, both acute and delayed**  Eyes: No adverse effects expected when used as directed.  Skin effect: No adverse effects expected when used as directed.  Inhalation: No adverse effects expected when used as directed.  Ingestion: No adverse effects expected when used as directed.  **Emergency measures to protect the environment**  None proposed. |

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

|  |
| --- |
| Dispose of contents /container 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

|  |
| --- |
| Do not store near food, drink, and animal feeding stuffs. Store at room temperature (store below 40°C). Keep out of reach of children and non-target animals/pets.  The products have a shelf life of 4 years in the packaging (PET blister coated with a permeable plastic (PE-PP) membrane, covered by polyester coated aluminium foil). |

### Other information

|  |
| --- |
|  |

#### Use description

Table 1. Insecticide Use – General public (non-professional)

|  |  |
| --- | --- |
| **Product Type** | Product type 18: Insecticides, acaricides and products to control other arthropods |
| **Where relevant, an exact description of the authorised use** | Insecticide |
| **Target organism (including development stage)** | **Scientific name**  *Tineola bisselliella*  **Common name**  Clothes moth  **Development stage**  Adults, Larvae |
| **Field of use** | Indoors  Insecticide for use in drawers |
| **Application method(s)** | Open system: diffusion  Passive diffusion from cartridge |
| **Application rate(s) and frequency** | Use 2 units per drawer measuring 0.018 m3 (that is equal to 18 dm3 or 18 litres)  Product is effective up to 12 weeks against adult moths and up to 4 weeks against larvae. Allow 2 weeks for maximum effect. |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | Blister, Plastic pack (PET)  Blister is sealed with a permeable plastic (PE-PP) membrane.  The membrane is covered with a polyester coated Aluminium foil, which can be removed to activate the product. Multi packs or standard packs with two or more cartridges/blister packs (PET). |

#### Use-specific instructions for use[[5]](#footnote-5)

|  |
| --- |
| See section 1.1.7.1 |

#### Use-specific risk mitigation measures

|  |
| --- |
| See section 1.1.7.2 |

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

|  |
| --- |
| See section 1.1.7.3 |

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

|  |
| --- |
| See section 1.1.7.4 |

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

|  |
| --- |
| See section 1.1.5.5 |

### General directions for use

#### Instructions for use[[6]](#footnote-6)

|  |
| --- |
| **Use directions:**  Only for use in drawers.  Comply with the instructions for use. Adapt the number of units according to the volume of the treated drawer. Inform the registration holder if the treatment is ineffective.  Keep drawers closed for optimal efficacy. Allow 2 weeks for maximum effect. Wash hands thoroughly after handling.  DUO PACK ONLY    Separate the units. Open backing card of unit without removing it completely.  Remove aluminium foil completely. Avoid making contact with the gel membrane.  Fold the backing card, ensuring it does not cover the gel membrane.  Place 2 units in a drawer (0.018 m3).  MULTIPACK ONLY  Remove aluminium foil completely. Avoid making contact with the gel membrane.  Place 2 units in a drawer (0.018 m3). |
|  |

#### Risk mitigation measures

|  |
| --- |
| Avoid direct contact of the permeable membrane with clothes, fabrics and plastics.  Use only as directed  Do not use near food, drink, and animal feeding stuffs.  Use only in positions inaccessible to children and animals, in particular cats.  No application in rooms, where fish tanks and terrariums are present. |

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

|  |
| --- |
| **Likely direct or indirect effects**  No adverse effects expected when used as directed.  Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.  **Description of first aid measures:**  IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.  IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call a POISON CENTRE or a doctor.  IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation occurs: Get medical advice.  IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor.  **Most important symptoms and effects, both acute and delayed**  Eyes: No adverse effects expected when used as directed.  Skin effect: No adverse effects expected when used as directed.  Inhalation: No adverse effects expected when used as directed.  Ingestion: No adverse effects expected when used as directed.  **Emergency measures to protect the environment**  None proposed. |

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

|  |
| --- |
| Dispose of contents /container 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

|  |
| --- |
| Do not store near food, drink, and animal feeding stuffs. Store at room temperature (not above 40°C). Keep out of reach of children and non-target animals/pets.  The products have a shelf life of 4 years in the packaging (PET blister coated with a permeable plastic (PE-PP) membrane, covered by polyester coated aluminium foil). |

### Other information

|  |
| --- |
|  |

### Packaging of the biocidal product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Peelable membrane with Cardboard backing  Outer packaging:  Solid fibre box with tuck-in closure. | Moth Gel Lavender  Height: 52mm  Width: 35mm  Thickness: 3.0mm  Content of gel: **3.0g**  Moth Gel Cedar  Height: 52mm  Width: 35mm  Thickness: 3mm. Content of gel 3.0g. | Blister, Plastic pack (PET).  Blister is sealed with a permeable plastic (PE-PP) membrane  The membrane is covered with a polyester coated Aluminium foil, which can be removed to activate the product.     Packs are sold as Multi packs or standard packs with two or more cartridges/blister packs. | Polyester coated Aluminium Foil | non-professional | Yes |

**eCA remark:** The packaging has a double function, a blister packaging for storage and, when opened, a cartridge in which the product can be safely placed at the desired location.



### Documentation

#### Data submitted in relation to product application

Product

Please refer to the reference list contained in Annex 3.1.

Active Substance

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

#### Access to documentation

The applicant is the data holder of the product data. For a letter of Access to the active substance data, please refer to IUCLID Section 13.

## Assessment of the biocidal product (family)

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

The uses below are the ones applied for by the applicant, without any changes by the e-CA. These uses are assessed in the following chapters.

Table 2. Insecticide Use – Consumer

|  |  |
| --- | --- |
| **Product Type** | EU BPD Product type 18: Insecticides, acaricides and products to control other arthropods |
| **Where relevant, an exact description of the authorised use** | Insecticide |
| **Target organism (including development stage)** | **Scientific name**  *Tineola bisselliella*  **Common name**  other: Clothes moth  **Development stage**  Adults  Larvae |
| **Field of use** | Indoors |
| **Application method(s)** | Place the suitable number of units in wardrobe hanger, drawer or any even surface. |
| **Application rate(s) and frequency** | 2 units in closets measuring 0.5m3 will last for one season. |
| **Category(ies) of users** | Non-professionals / consumers |
| **Pack sizes and packaging material** | Please see the relevant section. |

#### Use-specific instructions for use[[7]](#footnote-7)

|  |
| --- |
| Duo PACK ONLY   1. Separate the two units. 2. Open backing card of unit without removing it completely. 3. Remove aluminum foil completely. 4. Place the suitable number of units in wardrobe hanger, drawer or any even surface.   MULTIPACK ONLY  Remove aluminum foil completely. When used inside closets, use its convenient holder or place it on a flat surface.  Kills moths for one season (3 months).  Kills moths in 14 days.  Keep drawers and closets closed for maximum effectiveness. |

#### Use-specific risk mitigation measures

|  |
| --- |
| Avoid direct contact of the permeable membrane with clothes, fabrics and plastics. |

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

|  |
| --- |
| **Likely direct or indirect effects:**  No adverse effects expected when used as directed.  Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.  **Description of first aid measures:**  Moth Gel Lavender  Inhalation: No special requirements  Skin contact: Rinse with plenty of water. Get medical attention if irritation develops and persists.  Eye contact: Rinse with plenty of water. Get medical attention if irritation develops and persists.  Ingestion: If symptoms persist, call a physician.  Moth Gel Cedar  Inhalation: No special requirements  Skin contact: Take off all contaminated clothing immediately. Wash off with soap and plenty of water. Get medical attention if irritation develops and persists.  Wash contaminated clothing before re-use.  Eye contact: Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  Ingestion: If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label. Rinse mouth with water.  **Most important symptoms and effects, both acute and delayed**  Eyes: No adverse effects expected when used as directed.  Skin effect: No adverse effects expected when used as directed.  Inhalation: No adverse effects expected when used as directed.  Ingestion: No adverse effects expected when used as directed.  **Emergency measures to protect the environment**  Do not flush into surface water or sanitary sewer system. |

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

|  |
| --- |
| Disposal should be in accordance with local, state or national legislation. |

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

|  |
| --- |
| **Conditions for safe storage, including any incompatibilities:**  Do not use near food, drink, and animal feeding stuffs. Use only in positions inaccessible to children and animals, particularly cats.  The products have a predicted shelf life of 2 years |

### General directions for use

#### Instructions for use[[8]](#footnote-8)

|  |
| --- |
| Refer to Section 2.1.4.2 |

#### Risk mitigation measures

|  |
| --- |
| Refer to Section 2.1.4.3 |

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

|  |
| --- |
| Refer to Section 2.1.4.4 |

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

|  |
| --- |
| Refer to Section 2.1.4.5 |

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

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| --- |
| Refer to Section 2.1.4.6 |

### Other information

|  |
| --- |
| Application codes:-  I.3.12.1 Tineidae  II.1.5 Adults  III.1.2 Inhalation  III.1.3 Contact  III.2.1 Kill effect  III.2.2 Knock-Down Effect  III.4.1 Acute/short acting toxins  IV.1 indoor use  IV.1.1.2 potential for contamination outdoors - no  IV.1.2.2. potential for contamination of food - no  IV 1.3.2 To be used in /at: Households / private areas  V.1 non-professional user / consumer  VII.3 Material protection (e.g. historical buildings, technical objects)/  VI.9 Other method of application (specify) - Vaporiser  VIII.5.1.1 ready-for-use  VIII.5.2 Gel |

### Physical, chemical and technical properties

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at *20 °C and 101.3 kPa* | Visual  (BPR 3.1.2) | For Moth Gel Lavender: 0.153% Transfluthrin  For Moth Gel Cedar: 0.166% Transfluthrin. | **Moth Gel Lavender**  Purple gel  **Moth Gel Cedar**  Orange gel | For Moth Gel Lavender: GLP Study number: Mo4952  xxxx (2019) For Moth Gel Cedar: GLP Study number: Mo5139 |
| Colour at 20 °C and 101.3 kPa | Visual (BPR 3.1.3) | For Moth Gel Lavender 0.153% Transfluthrin  For Moth Gel Cedar: 0.166% Transfluthrin | **Moth Gel Lavender**  Clear Purple  **Moth Gel Cedar**  Clear transparent Orange  The results above are at baseline. The data were collected at 21±1° C. | For Moth Gel Lavender GLP Study number: Mo4952  xxxx (2019)  For Moth Gel Cedar: GLP Study number: Mo5139  (xxxx (2019)) |
| Odour at 20 °C and 101.3 kPa | Smell  (BPR 3.1.4) | For Moth Gel Lavender: 0.152% Transfluthrin  For Moth Gel Cedar: 0.166% Transfluthrin | **Moth Gel Lavender and Cedar**  Strong perfumed | For Moth Lavender: GLP Study number: Mo4952  xxxx (2019)  For Moth Gel Cedar: GLP Study number: Mo5139  (xxxx (2019)) |
| Acidity / alkalinity | CIPAC MT75.3 | For Moth Gel Lavender: 0.152% Transfluthrin  For Moth Gel Cedar: 0.166% Transfluthrin | **Moth Gel Lavender**  pH (1%w/v solution) 6.6 (22°C)  **For Moth Gel Cedar**  pH (1%w/v solution) 4.8. (22°C)  As per BPR guidelines 528/2012 The test is not applicable when the pH of the biocidal product or its dispersion in water (1 %) is within the pH range 4-10 | For Moth Gel Lavender: GLP Study number: Mo4952  xxxx (2019)  For Moth Gel Cedar: GLP Study number: Mo5139  (xxxx (2019)) |
| Relative density / bulk density | Council Regulation (EC) No 440/2008  method\_A.3  OECD guideline 109 | For Moth Gel Lavender: 0.157% Transfluthrin  For Moth Gel Cedar: 0.154% Transfluthrin | **For Moth Gel Lavender** 0.8904 g/cm3 at 20°C.  **For Moth Gel Cedar**  0.8990g/mL at 20°C. | For Moth Gel Lavender: GLP Study number: Mo6565  (xxxx (2019))  For Moth Gel Cedar: GLP Study number: Mo6566  (xxxx (2019)) |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 | For Moth Gel Lavender: 0.152% Transfluthrin  For Moth Gel Cedar: 0.166% Transfluthrin | **For Moth Gel Lavender:** An accelerated storage stability study was performed at 40°C for 8 weeks in the commercial packaging (The packaging is made from Recycled PET, Oriented Polyester, Polyethylene Extrudate, Coated Aluminum Foil, Polypropylene, PE-PP Peelable Membranes.)  **Appearance**  initial: Clear purple transparent gel. Strong perfumed odor.  after 8 weeks:  Clear purple transparent gel. Strong perfumed odor.  **Stability of the packaging**  initial:  no corrosion visible and no leakage observed  after 8 weeks:  no corrosion visible and no leakage observed  **Weight loss:**  The weight loss of the samples was no more that 2.28%.  **pH(1% dilution)**  initial value (from the accelerated storage samples):  pH 6.6 (average of two samples)  after 8 weeks (from the accelerated storage samples):  pH 6.1 (average of two samples)  **Active substance content**  Initial amount Transfluthrin: 0.152%w/w (average of 3 test items with RSD 0.37%)  After 8 weeks  Transfluthrin: 0.155%w/w (average of 3 test items with RSD 0.833%)  That is an increase of 1.97% in transfluthrin.  **conclusion**  The amount of transfluthrin in the product after 8 weeks at 40°C was found to be stable.  **Moth Gel Cedar**  An accelerated storage stability study was performed at 40°C for 8 weeks in the commercial packaging (The packaging is made from Recycled PET, Oriented Polyester, Polyethylene Extrudate, Coated Aluminum Foil, Polypropylene, PE-PP Peelable Membranes.)  **Appearance**  initial:Clear orange transparent gel. Strong perfumed odor.  after 8 weeks:  Clear orange transparent gel. Strong perfumed odor.  **Stability of the packaging**  initial:  no corrosion visible and no leakage observed  after 8 weeks:  no corrosion visible and no leakage observed  **Weight loss:**  The weight loss of the samples was no more that 2.28%.  **pH (1% dilution)**  initial value (from the accelerated storage samples):  pH 4.8 (average of two samples)  after 8 weeks (from the accelerated storage samples):  pH 4.9 (average of two samples)  **Active substance content**  Initial amount Transfluthrin:0.166 %w/w (average of 3 test items with RSD 2.06%)  After 8 weeks  Transfluthrin: 0.161%w/w (average of 3 test items with RSD 0.86%)  That is a decrease of 3.01% in transfluthrin.  **conclusion**  The amount of transfluthrin in the product after 8 weeks at 40°C was found to be stable. | For Moth Gel Lavender: Mo4956  (xxxx (2015))  For Moth Gel Cedar: GLP Study number: Mo 5140  (xxxx (2015)) |
| Storage stability test – **long term storage at ambient temperature** | No guideline.  Storage at 20°C for 48 months in Brach & Moll climatic chambre. | For Moth Gel Lavender: 0.152% Transfluthrin | **For Moth Gel Lavender**  **Appearance:**  Initial: Clear purple transparent gel. Strong perfumed odor.  After 48 months:  Clear purple transparent gel. Strong perfumed odor.  **Stability of the packaging:**  Initial:  no corrosion visible and no leakage observed  After 48 Months:  no corrosion visible and no leakage observed  **Weight loss:** The weight loss for the product was no more than 0.92% after 48 months of storage.  **pH (1% dilution):** initial value (ambient):  pH 6.6 (average of two samples)  after 48 months 5.6(ambient):  pH (average of two samples)  **Active substance content:**  Initial amount Transfluthrin: 0.152%w/w (average of 3 test items with RSD 0.37%)  After 48 months  Transfluthrin: 0.153%w/w (average of 3 test items with RSD 0.07%)  That is an increase of 0.66% in transfluthrin.  **conclusion**  The amount of transfluthrin in the product after 48 months at ambient temperature was found to be stable. Therefore, a shelf life of 4 years can be assigned to this product in the commercial packaging (PET blister coated with a permeable plastic (PE-PP) membrane, covered by polyester coated aluminium foil).  **For Moth Gel Cedar:**  **Appearance:**  Initial: Clear orange transparent gel. Strong perfumed odor.  After 48 months:  Clear orange transparent gel. Strong perfumed odor.  **Stability of the packaging:**  Initial:  no corrosion visible and no leakage observed  After 48 Months:  no corrosion visible and no leakage observed  **Weight loss:** The maximum weight loss for any individual test item was 0.54% weight loss.  **pH (1% dilution):** initial value (ambient):  pH 4.8 (average of two samples)  after 48 months (ambient):  pH 4.5  (average of two samples)  **Active substance content:**  Initial amount Transfluthrin: 0.166%w/w (average of 3 test items with RSD 2.06%)  After 48 months  Transfluthrin: 0.162%w/w (average of 3 test items with RSD 0.27%)  That is a decrease of 2.4% in transfluthrin.  **conclusion**  The amount of transfluthrin in the product after 48 months at ambient temperature was found to be stable. Therefore, a shelf life of 4 years can be assigned to this product in the commercial packaging (PET blister coated with a permeable plastic (PE-PP) membrane, covered by aluminium foil). | For Moth Gel Lavender: GLP Study number: Mo4952  xxxx (2019)  For Moth Gel Cedar: GLP Study number: Mo5139  (xxxx (2019)) |
| Storage stability test – **low temperature stability test for liquids** | CIPAC MT 39.3 | For Moth Gel Lavender: 0.152% Transfluthrin  For Moth Gel Lavender 0.166% Transfluthrin | **Moth Gel Lavender for 1 week at 0oC**  Clear purple transparent gel with neither precipitation nor phase separation  **Moth Gel Cedar for 1 week at 0oC.**  Before and after storage the gel remained clear orange in colour and homogeneous. Air bubbles were observed at the start and at the end of the test. | For Moth Gel Lavender: GLP Study number: Mo4952  xxxx (2019)  For Moth Gel Cedar Mo5139.  (Rodriguez, R. xxxx (2019)) |
| Effects on content of the active substance and technical characteristics of the biocidal product – **light** | - | - | During the storage stability studies the samples were stored in the commercial packaging and were found to be stable when stored as intended. The packaging was designed to limit moisture and light exposure. No further testing is therefore considered to be necessary. | For Moth Gel Lavender: GLP Study number: Mo4952  xxxx (2015a)  For Moth Gel Cedar: GLP Study number: Mo5139  (xxxx (2019)) |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** |  | For Moth Gel Lavender: 0.152% Transfluthrin | During the storage stability studies the samples were stored in the commercial packaging which excludes moisture and were found to be stable when stored as intended.  The test item possessed the ability to distribute its active substance when opened and then hung up. On average about 13% of the starting amount of transfluthrin evaporated off whereas the maximum weight loss was 40% at 23-28 oC, relative humidity 42 – 73%. | For Moth Gel Lavender: GLP Study number: Mo4952  xxxx (2015a)  For Lavender Evaporation study Mo4951  (xxxx  (2014)) |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** |  | For Moth Gel Lavender: 0.152% Transfluthrin | The packaging material did not change, after 8 weeks at 40 oC and during 4 years at ambient temperature. | For Moth Gel Lavender: GLP Study number: Mo4952(Ambient study)  xxxx (2015a)  For moth gel lavender Mo4956 (Accelerated study)  (xxxx (2015)) |
| Wettability | - | - | Not relevant. Moth Gel products are gel vapourisers and will not be mixed with water. | - |
| Suspensibility, spontaneity and dispersion stability | - | - | Not relevant. Moth Gel products are gel vapourising products and will not be mixed with water. | - |
| Wet sieve analysis and dry sieve test | - | - | Not relevant. Moth Gel products are gel vapourising products. This data requirement is only valid for wettable powders, suspension concentrates, water dispersible granules, aqueous capsule suspensions, dispersible concentrates, suspo-emulsions, water soluble granules and water-soluble powders. | - |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant. Moth Gel products are gel vapourising products. This data requirement is only valid for emulsifiable products. | - |
| Disintegration time | - | - | Not relevant. Moth Gel products are gel vapourising products. This data requirement is only relevant to water dispersible solids. | - |
| Particle size distribution, content of dust/fines, attrition, friability | - | - | Not relevant. Moth Gel products are gel vapourising products. This data requirement is only valid for powders and granules. | - |
| Persistent foaming | - | - | Not relevant. Moth Gel products are gel vapourising products. This data requirement is only valid for products that are applied in water. | - |
| Flowability/Pourability/Dustability | - | - | Not relevant. Moth Gel products are gel vapourising products. Flowability and Dustability are only valid for granular materials. Pourability is only valid for suspension concentrates, capsule suspensions or suspo-emulsions. | - |
| Burning rate — smoke generators | - | - | Not relevant. Moth Gel products are gel vapourising products. The products will not generate smoke. | - |
| Burning completeness — smoke generators | - | - | Not relevant. Moth Gel products are gel vapourising products. The products will not generate smoke. | - |
| Composition of smoke — smoke generators | - | - | Not relevant. Moth Gel products are gel vapourising products. The product will not generate smoke. | - |
| Spraying pattern — aerosols | - | - | Not relevant. Moth Gel products are gel vapourising products. The products are not aerosols. | - |
| Physical compatibility | - | - | Moth Gel is not intended to be used with other biocidal products. | - |
| Chemical compatibility | - | - | Moth Gel products are not intended to be used with other biocidal products. | - |
| Degree of dissolution and dilution stability | - | - | Not applicable for these types of product. | - |
| Surface tension | EC 440/2008  A.5 | For moth gel lavender 0.157% w/w transfluthrin  For moth gel Cedar 0.154% w/w transfluthrin | For moth gel lavender  neat formulation: 29.2±0.16 mN/m  For moth gel Cedar neat formulation: 31.4±0.18 mN/m | For Moth Gel Lavender: GLP Study number: Mo6565  (xxxx (2019))  For Moth Gel Cedar: GLP Study number: Mo6566  (xxxx (2019)) |
| Viscosity | CIPAC MT192 (Viscosity of Liquids by rotational viscometry) | For moth gel lavender 0.157% w/w transfluthrin  For moth gel Cedar 0.154% w/w transfluthrin | For Moth gel lavender dynamic viscosity at 20°C (neat formulation):  Shear rates  **20 s-1** : 461 mPa.s  **40 s-1** : 244 mPa.s  **60 s-1** : 171 mPa.s  **80 s-1** : 135 mPa.s  **100 s-1** : 114 mPa.s  Kinematic Viscosity for Moth Gel Lavender 20°C (neat formulation):  **20 s-1** : 518 cSt  **40 s-1** : 274 cSt  **60 s-1** : 192 cSt  **80 s-1** : 152 cSt  **100 s-1** : 128 cSt  For Moth gel lavender dynamic viscosity at 40°C (neat formulation):  Shear rates  **20 s-1** : 242 mPa.s  **40 s-1** : 176 mPa.s  **60 s-1** : 121 mPa.s  **80 s-1** : 94 mPa.s  **100 s-1** : 78 mPa.s  Kinematic Viscosity for Moth Gel Lavender 40°C (neat formulation):  **20 s-1** : 277 cSt  **40 s-1** : 201 cSt  **60 s-1** : 138 cSt  **80 s-1** : 107 cSt  **100 s-1** : 89 cSt  For Moth gel Cedar dynamic viscosity at 20°C (neat formulation):  Shear rates  **20 s-1** : 1038 mPa.s  **40 s-1** : 553 mPa.s  **60 s-1** : 387 mPa.s  **80 s-1** : 303 mPa.s  **100 s-1** : 252 mPa.s  Kinematic Viscosity for Moth Gel Cedar 20°C (neat formulation):  **20 s-1** : 1155 cSt  **40 s-1** : 615 cSt  **60 s-1** : 430 cSt  **80 s-1** : 337 cSt  **100 s-1** : 280 cSt  For Moth gel Cedar dynamic viscosity at 40°C (neat formulation):  Shear rates  **20 s-1** : 808 mPa.s  **40 s-1** : 430 mPa.s  **60 s-1** : 294 mPa.s  **80 s-1** : 226 mPa.s  **100 s-1** : 185 mPa.s  Kinematic Viscosity for Moth Gel Cedar 40°C (neat formulation):  **20 s-1** : 915 cSt  **40 s-1** : 487 cSt  **60 s-1** : 333 cSt  **80 s-1** : 256 cSt  **100 s-1** : 209 cSt | For Moth Gel Lavender: GLP Study number: Mo6565  (xxxx (2019))  For Moth Gel Cedar: GLP Study number: Mo6566  (xxxx (2019)) |
| eCA remark: The kinematic viscosity (40°C) for moth gel lavendar corresponds to 89 – 277 mm2/s. The kinematic viscosity (40°C) for moth gel Cedar corresponds to 209 – 915 mm2/s. Neither the moth gel Lavendar (meta SPC 1) nor the moth gel Cedar (meta SPC 2) requires H304 classification based on kinematic viscosity data at 40°C. | | | | |

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| **Conclusion on the physical, chemical, and technical properties of the product** |
| Moth gel Lavender is a purple gel and moth gel cedar is an orange gel. The ambient storage stability data supports the claimed shelf life of 4 years in the commercial packaging (PET blister coated with a permeable plastic (PE-PP) membrane, covered by aluminium foil). The accelerated storage stability study (8 weeks at 40°C) shows that the product can be stored intermittently up to 40°C. The low temperature storage stability study shows that the product is stable at low temperatures. In addition, the following parameters were also measured, for moth gel lavender and cedar: pH, surface tension, viscosity and Kinematic viscosity. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | - | - | None of the components of the Moth Gel products are known to be explosive. Experience in the use of these products do not indicate that the products are explosive. | - |
| eCA remark: According to appendix 6 of the UN MTC, explosive properties may be induced by certain chemical groups. None of those are present, with the exception of unsaturated C-C moieties which might be present in the perfume component. Naturally occurring terpenes, however, are non-explosive. Therefore, the eCA considers that the product does not need to be considered for classification as explosive. | | | | |
| Flammable gases | - | - | Not applicable for these types of product. | - |
| Flammable aerosols | - | - | Not applicable for these types of product. | - |
| Oxidising gases | - | - | Not applicable for these types of product. | - |
| Gases under pressure | - | - | Not applicable for these types of product. | - |
| Flammable liquids | EC 440/2008 A.9. Flash Point  ASTM D 93 (procedure B) | For moth gel lavender 0.157%w.w transfluthrin | Moth Gel Lavender  Flash point: 84.5oC  Moth Gel Cedar  Flash point: 70.5 oC  The moth gel products Lavender and Cedar are not considered flammable liquids. | For Moth Gel Lavender: GLP Study number: Mo6565  ( xxxx (2019))  For Moth Gel Cedar: GLP Study number: Mo5147  ( xxxx (2015)) |
| Flammable solids | - | - | Not applicable for these types of product. | - |
| Self-reactive substances and mixtures | - | - | None of the components of the Moth Gel products are classified as self-reacting substances. Experience in the use of these products do not indicate that the products will self-react. | - |
| **eCA remark:** According to appendix 6 of the UN MTC, self reactive properties may be induced by certain chemical groups of which none are present in the formulation. Therefore, the eCA considers that the products within the biocidal product family do not need to be considered for classification as self reactive. | | | | |
| Pyrophoric liquids | - | - | None of the components of the Moth Gel products are classified as pyrophoric. Experience in the use of these products do not indicate that the products will be pyrophoric. | - |
| Pyrophoric solids | - | - | The product is not a solid. | - |
| Self-heating substances and mixtures | - | - | None of the components of the Moth Gel products are known to be self-heating. Experience in the use of the Moth Gel products do not indicate that the products are self-heating. | - |
| **eCA remark:** Self heating is only associated with solids or liquids adsorbed to a large surface. Given the fact that the formulation of the products is a gel, the surfaces of the products are not large enough to react with air in such a way that self-heating is induced. Therefore, the eCA considers that the product does not need to be considered for classification as self-heating. | | | | |
| Substances and mixtures which in contact with water emit flammable gases | - | - | None of the components the Moth Gel products are known to emit flammable gases when in contact with water. Experience in the use of these products do not indicate that the products will emit flammable gas when in contact with water. | - |
| Oxidising liquids | - | - | Following a review of the components of the Moth Gel products it can be concluded that the products will not be oxidizing. All oxygen, fluorine and chlorine atoms are bonded only to carbon or hydrogen. | - |
| Oxidising solids | - | - | Not applicable as the product is not a solid. | - |
| Organic peroxides | - | - | Following a review of the components of the Moth Gel products it can be concluded that the products do not contain any organic peroxides. | - |
| Corrosive to metals | UN C.1 | For moth gel lavender 0.157%  For moth gel Cedar 0.154% w/w transfluthrin | Corrosiveness to metals was performed at 55 ± 5°C for a test duration of 28 days.  For moth gel Lavender:  Weight loss for aluminium plate <0.1% for non-immersed, partly immersed and fully immersed.  Weight loss for steel plate <0.1% for non-immersed, partly immersed and fully immersed.  For moth gel Cedar:  Weight loss for aluminium plate <0.1% for non-immersed, partly immersed and fully immersed.  Weight loss for steel plate <0.1% for non-immersed, partly immersed and fully immersed. | For Moth Gel Lavender: GLP Study number: Mo6565  ( xxxx (2019))  For Moth Gel Cedar: GLP Study number: Mo6566  ( xxxx (2019)) |
| **eCA remark:** the corrosiveness to metals study does not address localized corrosion. Based on the fact that no significant weight loss was observed for both steel and aluminium plates at all types of immersion (no immersion, partly immersed and fully immersed) the eCA expects that localized corrosion is not significant. Nevertheless, localized corrosion should be addressed for the renewal.  **Data gap for renewal**  A corrosion to metals study should be provided addressing both uniform and localised corrosion. The test method should conform the test method as described in the UN-MTC. | | | | |
| Auto-ignition temperatures of products (liquids and gases) | EC440/2008 A.15 | For moth gel lavender 0.157% w/w transfluthrin  For moth gel Cedar 0.154% w/w transfluthrin | For moth gel lavender Autoignition temperature is 275°C  For moth gel cedar Autoignition temperature is 270°C | For Moth Gel Lavender: GLP Study number: Mo6565  ( xxxx (2019))  For Moth Gel Cedar: GLP Study number: Mo6566  ( xxxx (2019)) |
| Relative self-ignition temperature for solids | - | - | Not applicable as the product is not a solid. | - |
| Relative self-ignition temperature for solids | - | - | Not applicable as the product is not a solid. | - |
| Dust explosion hazard | - | - | Not applicable for a gel. | - |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| Following a review of the components of the Moth Gel products it can be concluded that the products are not explosive, self-reactive or oxidising. Moth gel lavender is not corrosive to metals. Flashpoint of Moth Gel Lavender is  84.5°C. Flashpoint of Moth gel Cedar is 70.5°C. The auto-ignition temperature for Moth Gel Lavender is 275°C and for Moth Gel Cedar 270°C. No classification with respect for physical hazards is required for both Moth Gel Lavender and Moth Gel Cedar.  **Data gap for renewal**  A corrosion to metals study should be provided addressing both uniform and localised corrosion. The test method should conform the test method as described in the UN-MTC. |

### Methods for detection and identification

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Analytical methods for the analysis of the product as such including the active substance, impurities and residues** | | | | | | | | | |
| **Analyte (type of analyte e.g. active substance)** | **Analytical method** | **Fortification range / Number of measurements** | **Linearity** | **Specificity** | **Recovery rate (%)** | | | **Limit of quantification (LOQ) or other limits** | **Reference** |
| Range | Mean | RSD |
| **For Moth gel Lavender**  Active substance:  Transfluthrin  (Purity 98.5%) | GC-FID  With internal standard dipentyl phthalate  Recovery was determined using spiked placebo samples at 70, 100 and 130%fortification level.  .  Sample preparation: 2 g of sample was dissolved in acetone (100 mL total). | **For Moth gel Lavender**  Fortification level:  70%  100%  130%;  3 replicates  **Method Precision**  Mean value transfluthrin (n=6): 0.152  RSD = 1.83%  These results meet the acceptance criterion RSD < 3.57 | **For Moth gel Lavender**  Transfluthrin: 0.01518 to 0.0440 mg/mL  (n=6)  Y = 0.7378X+0.00034  r=1.000 | **For Moth gel Lavender**  No interferences present at >3% at the retention times thereby demonstrating the specificity of the method. | **For Moth gel Lavender**  70%: 100.6-102% (n=3)  100%: 100.4-100.8 (n=3)  130%: 99.3-100.8 (n=3) | **For Moth gel Lavender**  100.7 (n=9) | **For Moth gel Lavender**  0.7 | N/A | **For Moth gel Lavender**  xxxx (2014)  Mo4964 |

N/A = Not applicable

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| One method of analysis, employing GC-FID, is provided for the determination of the active substance in the product. The method was fully validated in accordance with SANCO/3030/99 rev. 4 11/07/00.  For linearity 6 samples were used, to create a linearity curve with r= 1. This meets the requirement of r>0.99. Linearity was determined within a range of 0.01518 to 0.0440mg/ml (50-150% of the expected sample concentration).  For precision the % RSD was 1.83 and it meets the requirements of the Horwitz equation which is <3.57%.  For Specificity there was no interference from other substance >3% of total peak area.  The mean recovery was 100.7%, which is within the range of 95-105%.  **eCA remark regarding Substance of concern:** Since the substances of concern are not to be expected to change in concentration upon storage, the eCA is of the opinion that no analytical methods for Substances of Concern are required.  **eCA remark regarding chiral methods:** Since isomerisation of the 1R trans into another isomer is not feasible, we do not consider it relevant to use a chiral method simply to confirm that the active substance is available as the correct isomer. Moreover, the active substance has a minimum purity of 96.5% 1R trans isomer which is confirmed by a chiral HPLC-UV method (refer to AR). Isomerization can be excluded and hence a chiral method is not justified.  **eCA remark regarding specificity of Moth gel Cedar:** We consider the provided GC-FID method fit for purpose. However, interference cannot be excluded entirely. Therefore, the specificity of the GC-FID method should still be addressed for meta SPC 2: moth gel Cedar. This is considered a data gap for renewal.  **Data gap for renewal:**  The specificity of the GC-FID method should be addressed for meta SPC 2: moth gel Cedar.    Methods of analysis for the determination of Transfluthrin residues in soil, water, air and body fluids and tissues have previously been evaluated at EU level and accepted for inclusion to Annex I of Directive 98/8/EC. Methods for monitoring residues in food/feed of plant and animal origin are not necessary, asthe intended uses will not result in significant residues when the label instructions are followed (Do not use near food, drink, and animal feeding stuffs.). |

### Efficacy against target organisms

The products in the Moth Gel Familiy are insecticides (PT18) based on the active substance transfluthrin. The ready-to-use packs containing the product are used for the control of the clothes moth (*Tineola bisselliella*) in drawers by non-professional users.

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

The organism to be controlled is the clothes moth (*Tineola bisselliella).* The objective of the product is to protect clothing from damage by the larval stage of the target organism.

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

Exposure to the product leads to knockdown and mortality in the target organism. Animal welfare is not evaluated for invertebrates.

#### Mode of action, including time delay

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

Amount of content: **3.0g**

#### 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** | **Test method / Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide | Raid Moth Gel ‘Lavender’ 0.153 % transfluthrin) | Clothes moth, (*Tineola bisselliella*)  Adult + larvae clothes moths  Laboratory cultured | Simulated-use test  Dose: 2 cartridge / 0.018 m3 drawer.  The testing drawers have a size of 0.018 m3 (depth 0.4 m x width 0.3 m x height 0.15 m).  Each test object is laid in the centre of the drawer. On both sides of the test product, the black woolen cloth is laid without coming into contact with the product. The cloths and the products remain in the drawer for the duration of the testing period. The exposition points are 0, 2, 4, 6, 8, 10 and 12 weeks after the introduction of the product into the drawer. At the relevant exposition points, the adult clothes moths are placed on pieces of fabric from the laying cloth (each 5 x 5 cm in size) in plastic dishes. Also the larvae are placed on pieces of fabric from the laying cloth (each 5 x 5 cm in size), but in larvae test boxes. The plastic dishes and the larvae test boxes are positioned in the drawer containing fabric and the test products. As a control, cabinets not containing any products are used.  **Evaluation**: At each exposition point, the drawers are opened first after 24 hours and then after 2, 3, 5, 7, 10 and 14 days for examining the insects.  The adult clothes moths are evaluated in order to determine efficacy, number of eggs laid in one (1) day, and number of larvae hatched after 14 days  The clothes moths larvae are evaluated for efficacy and visible wool damage  The temperature and relative humidity is monitored and recorded  The drawers are opened daily for 5 seconds.  Number of test animals per replicate: 20  Number of replicates: 5 | **Table 1:**    Note: all means rounded to integers  **Table 2:**    Note: all means rounded to integers | Test report: Biology\_055b-17  xxxx (2017) |
|  |  |  |  | Table 3    All replicates did show some fabric damage |  |
|  |  |  |  | Table 4: |  |
| Insecticide | Radec, equal to Raid Moth Gel Cedar (0.15 % transfluthrin) | Clothes moth, (*Tineola bisselliella*)  Adult + larvae clothes moths  Laboratory cultured | Laboratory test  Tests were conducted against Clothes moths, adults and larvae in glass jars. The glass jars have a volume of 350 ml (diameter: 9.5 cm, height: 5.5 cm).  Glass jars with 1 unit of the product, woollen cloth and insects were closed with a glass lid. The product remains inside the glass jars for the duration of the testing period. The exposition points were 0, 2, 4, 8 and 12 weeks after the introduction of the product into the glass jars. At the relevant exposition points, the adult and larvae Clothes moths were placed on pieces of woollen cloth into the glass jars. As a control, glass jars not containing any products but only untreated woollen cloth were used.  At each test point the insects inside the glass jars were evaluated first after 24 hours and then after 2, 3, 5, 7, 10 and 14 days. |  | Test report: Biology\_117a-19  xxxx (2019) |
| Insecticide | Nevar LPT, equal to Raid Moth Gel Lavender (0.15 % transfluthrin) | Clothes moth, (*Tineola bisselliella*)  Adult + larvae clothes moths  Laboratory cultured | Laboratory test  Tests were conducted against Clothes moths, adults and larvae in glass jars. The glass jars have a volume of 350 ml (diameter: 9.5 cm, height: 5.5 cm).  Glass jars with 1 unit of the product, woollen cloth and insects were closed with a glass lid. The product remains inside the glass jars for the duration of the testing period. The exposition points were 0, 2, 4, 8 and 12 weeks after the introduction of the product into the glass jars. At the relevant exposition points, the adult and larvae Clothes moths were placed on pieces of woollen cloth into the glass jars. As a control, glass jars not containing any products but only untreated woollen cloth were used.  At each test point the insects inside the glass jars were evaluated first after 24 hours and then after 2, 3, 5, 7, 10 and 14 days. |  | Test report: Biology\_144a-19  xxxx (2019) |
| Insecticide | Raid Moth proofer (fragrance Eagle)  = equal to Moth Gel Lavender | Clothes moth, (*Tineola bisselliella*)  Adult Laboratory cultured | Simulated-use test  Dose: 2 blisters / 0.5 m3 cabinet (0.58 m x 0.46 m x 1.90 m)  5 replicates for treatment and control.  The testing cabinets are divided by a shelf leaving a gap of 180 mm in order to permit an air exchange between the halves. A bar on which the hangers can hang is fastened 30 mm under the top of the cabinets in the centre parallel to the opening. Each test object should be hung in the centre of the rod. On one side of the test object a hanger with cloths to be placed without the material coming into contact with the test object. The cloths are black loden material (100% wool). As a controlling measurement a cabinet not containing any product is used.  The clothes moths are exposed to a cloth in glass dishes with rings and gauze lids (diameter= 9.5 cm, height= 17 cm).  The test insects are placed on pieces of cut out cloth, each 5x5 cm in size, at week 1, 2, 4, 8 and 12. The insects are introduced to the cabinets containing a cloth and the product and are placed on the shelf in the cabinets. The cloth and the product remain in the cabinet and later on the insects are freshly introduced at the times shown in the tables. Mortality is checked at day 1,2,3,4,5,6,7,10 and 14.  The cabinets are opened daily for 10 seconds.  Environmental conditions:25-26O C, humidity 57-68% | Table 1: Bioefficacy of Moth Gel Lavender, two blisters per 0.5m³ cabinet against clothes moths (Tineola bisselliella), adults (mean of 3 replicates):   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **% of dead clothes moth (adults) in 0,5m³ cabinets after** | | | | | | | **Day** | **Week 1** | **Week 2** | **Week 4** | **Week 8** | **Week 12** | | **1** | 52 | 52 | 47 | 30 | 70 | | **2** | 83 | 83 | 72 | 60 | 97 | | **3** | 83 | 83 | 83 | 95 | 100 | | **4** | 88 | 88 | 92 | 100 | 100 | | **5** | 90 | 90 | 98 | 100 | 100 | | **6** | 93 | 93 | 98 | 100 | 100 | | **7** | 95\* | 95\* | 100 | 100 | 100 |   \*100% at 14 days  Table 2: Controls in 0.5m³ cabinet against clothes moths (Tineola bisselliella), adults (mean of 3 replicates):   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **% of dead clothes moth (adults) in 0,5m³ cabinets after** | | | | | | | **Day** | **Week 1** | **Week 2** | **Week 4** | **Week 8** | **Week 12** | | **1** | 2 | 0 | 0 | 3 | 3 | | **2** | 7 | 13 | 0 | 5 | 8 | | **3** | 30 | 13 | 10 | 18 | 25 | | **4** | 33 | 20 | 20 | 33 | 33 | | **5** | 42 | 23 | 27 | 43 | 38 | | **6** | 48 | 35 | 40 | 63 | 65 | | **7** | 63 | 48 | 57 | 68 | 77 |   Raid moth proofer (fragrance Eagle) showed 100% mortality at all test times during 12 weeks evaluation of the product. Speed to 100% mortality increased during evaluation with 100% mortality achieved within 3 days at the 12 weeks test. | Test report:  BIO25b-10  xxxx 2010a |
| Insecticide | Raid Moth proofer (fragrance Cedar)  = equal to Moth Gel Cedar | Clothes moth, (*Tineola bisselliella*)  Adult Laboratory cultured | Simulated-use test  Dose: 2 blisters / 0.5 m3 cabinet (0.58 m x 0.46 m x 1.90 m)  The testing cabinets are divided by a shelf leaving a gap of 180 mm in order to permit an air exchange between the halves. A bar on which the hangers can hang is fastened 30 mm under the top of the cabinets in the centre parallel to the opening. Each test object should be hung in the centre of the rod. On one side of the test object a hanger with cloths to be placed without the material coming into contact with the test object. The cloths are black loden material (100% wool). As a controlling measurement a cabinet not containing any product is used.  The clothes moths are exposed to a cloth in glass dishes with rings and gauze lids (diameter= 9.5 cm, height= 17 cm).  The test insects are placed on pieces of cut out cloth, each 5x5 cm in size, at week 1, 2, 4, 8 and 12. The insects are introduced to the cabinets containing a cloth and the product and are placed on the shelf in the cabinets. The cloth and the product remain in the cabinet and later on the insects are freshly introduced at the times shown in the tables. Mortality is checked at day 1,2,3,4,5,6,7,10 and 14.  Environmental conditions:23-25O C, humidity 63-70% | Bioefficacy of Moth Gel Cedar, two blisters per 0.5m³ cabinet against clothes moths (Tineola bisselliella), adults (mean of 3 replicates)   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **% of dead clothes moth (adults) in 0,5m³ cabinets after** | | | | | | | **Day** | **Week 1** | **Week 2** | **Week 4** | **Week 8** | **Week 12** | | **1** | 20 | 10 | 85 | 27 | 100 | | **2** | 47 | 27 | 97 | 72 | 100 | | **3** | 75 | 42 | 100 | 85 | 100 | | **4** | 80 | 58 | 100 | 95 | 100 | | **5** | 82 | 72 | not tested | not tested | not tested | | **6** | 90 | 75 | 100 | 98 | 100 | | **7** | 93\* | 87\*\* | 100 | 100 | 100 |   \*100% at 14 days, with one exception at week 1 (with one of the three cabinets only 95% mortality after 14 days was reached)  \*\*100% at 14 days   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **% of dead clothes moth (adults) in 0,5m³ cabinets after** | | | | | | | **Day** | **Week 1** | **Week 2** | **Week 4** | **Week 8** | **Week 12** | | **1** | 0 | 8 | 0 | 0 | 5 | | **2** | 10 | 12 | 17 | 5 | 8 | | **3** | 15 | 18 | 23 | 15 | 18 | | **4** | 27 | 25 | 33 | 18 | 22 | | **5** | 52 | 33 | not tested | not tested | not tested | | **6** | 63 | 57 | 55 | 30 | 42 | | **7** | 67 | 63 | 75 | 37 | 60 |   Raid moth proofer (fragrance Cedar) showed 100% mortality at all test times during 12 weeks evaluation of the product, with one exception in week 1 (with one of three cabinets only 95% mortality after 14 days was reached). Speed to 100% mortality increased during evaluation with 100% mortality achieved within 1 day at the 12 weeks test. | Test report:  BIO097-10  xxxx 2010b |
| Insecticide | Nevar LPT, equal to Raid Moth Gel Lavender (0.15 % transfluthrin) | Clothes moth, (*Tineola bisselliella*)  Adult  Laboratory cultured | Simulated-use test  Dose: 1 blisters / 0.5 m3 cabinet (0.58 m x 0.46 m x 1.90 m)  5 replicates for treatment and control.  The testing cabinets are divided by a shelf leaving a gap of 180 mm in order to permit an air exchange between the halves. A bar on which the hangers can hang is fastened 30 mm under the top of the cabinets in the centre parallel to the opening. Each test object should be hung in the centre of the rod. On one side of the test object a hanger with cloths to be placed without the material coming into contact with the test object. The cloths are black loden material (100% wool). As a controlling measurement a cabinet not containing any product is used.  The clothes moths are exposed to a cloth in glass dishes with rings and gauze lids (diameter= 9.5 cm, height= 17 cm).  The test insects are placed on pieces of cut out cloth, each 5x5 cm in size, at week 1, 2, 4, 8 and 12. The insects are introduced to the cabinets containing a cloth and the product and are placed on the shelf in the cabinets. The cloth and the product remain in the cabinet and later on the insects are freshly introduced at the times shown in the tables. Mortality is checked at day 1,2,3,4,5,7,8,10 and 14.  The cabinets are opened daily for 10 seconds.  Environmental conditions:25-26O C, humidity 57-65% | Table 1: Bioefficacy of Moth Gel Lavender (Nevar LPT), one blister per 0.5m³ cabinet against clothes moths (Tineola bisselliella), adults (mean of 5 replicates):   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **% of dead clothes moth (adults) in 0,5m³ cabinets after** | | | | | | | | **Day** | **Week 0** | **Week 1** | **Week 2** | **Week 4** | **Week 8** | **Week 12** | | **1** | 1 | 2 | 2 | 13 | 26 | 17 | | **2** | 17 | 13 | 21 | 44 | 39 | 34 | | **3** | 34 | 22 | 26 | 84 | 60 | 48 | | **5** | 66 | 37 | 54 | 87 | 88 | 77 | | **7** | 77 | 75 | 82 | 90 | 95 | 96 | | **10** | 89 | 88 | 92 | 96 | 100 | 100 | | **14** | 99 | 99 | 99 | 100 | 100 | 100 |   Table 2: Controls in 0.5m³ cabinet against clothes moths (Tineola bisselliella), adults (mean of 5 replicates):   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **% of dead clothes moth (adults) in 0,5m³ cabinets after** | | | | | | | | **Day** | **Week 0** | **Week 1** | **Week 2** | **Week 4** | **Week 8** | **Week 12** | | **1** | 0 | 0 | 0 | 0 | 0 | 0 | | **2** | 0 | 0 | 0 | 0 | 0 | 0 | | **3** | 0 | 0 | 0 | 0 | 1 | 0 | | **5** | 0 | 7 | 7 | 8 | 9 | 9 | | **7** | 5 | 17 | 15 | 18 | 16 | 21 | | **10** | 16 | 19 | 20 | 34 | 29 | 34 | | **14** | 37 | 30 | 27 | 38 | 38 | 43 |   For test weeks 0-12, the mean % mortality achieved after 14 days was consistently 99-100%. | Test report:  BIO103-14  xxxx 2015a |
| Insecticide | Cedar ABX, equal to Raid Moth Gel Cedar (0.15 % transfluthrin) | Clothes moth, (*Tineola bisselliella*)  Adult  Laboratory cultured | Simulated-use test  Dose: 2 blisters / 0.5 m3 cabinet (0.58 m x 0.46 m x 1.90 m)  5 replicates for treatment and control.  The testing cabinets are divided by a shelf leaving a gap of 180 mm in order to permit an air exchange between the halves. A bar on which the hangers can hang is fastened 30 mm under the top of the cabinets in the centre parallel to the opening. Each test object should be hung in the centre of the rod. On one side of the test object a hanger with cloths to be placed without the material coming into contact with the test object. The cloths are black loden material (100% wool). As a controlling measurement a cabinet not containing any product is used.  The clothes moths are exposed to a cloth in glass dishes with rings and gauze lids (diameter= 9.5 cm, height= 17 cm).  The test insects are placed on pieces of cut out cloth, each 5x5 cm in size, at week 1, 2, 4, 8 and 12. The insects are introduced to the cabinets containing a cloth and the product and are placed on the shelf in the cabinets. The cloth and the product remain in the cabinet and later on the insects are freshly introduced at the times shown in the tables. Mortality is checked at day 1,2,3,4,5,7,10 and 14.  The cabinets are opened daily for 10 seconds.  Environmental conditions:23-26O C, humidity 60-70% | Table 1: Bioefficacy of Moth Gel Cedar (Cedar ABX), 2 cartridges per 0.5m³ cabinet against clothes moths (Tineola bisselliella), adults (mean of 5 replicates):   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **% of dead clothes moth (adults) in 0,5m³ cabinets after** | | | | | | | | **Day** | **Week 0** | **Week 1** | **Week 2** | **Week 4** | **Week 8** | **Week 12** | | 1 | 0 | 7 | 48 | 46 | 43 | 58 | | 2 | 8 | 35 | 66 | 62 | 62 | 79 | | 3 | 30 | 48 | 77 | 74 | 76 | 84 | | 5 | 58 | 68 | 89 | 85 | 91 | 87 | | 7 | 70 | 74 | 98 | 88 | 93 | 91 | | 10 | 89 | 77 | 100 | 96 | 93 | 94 | | 14 | 94 | 91 | 100 | 98 | 96 | 95 |   Table 2: Controls in 0.5m³ cabinet against clothes moths (Tineola bisselliella), adults (mean of 5 replicates):   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **% of dead clothes moth (adults) in 0,5m³ cabinets after** | | | | | | | | **Day** | **Week 0** | **Week 1** | **Week 2** | **Week 4** | **Week 8** | **Week 12** | | 1 | 0 | 0 | 0 | 0 | 0 | 0 | | 2 | 0 | 0 | 0 | 0 | 0 | 0 | | 3 | 0 | 2 | 3 | 3 | 1 | 0 | | 5 | 7 | 4 | 5 | 7 | 8 | 6 | | 7 | 13 | 13 | 11 | 15 | 17 | 16 | | 10 | 20 | 23 | 16 | 27 | 16 | 22 | | 14 | 28 | 32 | 31 | 32 | 32 | 32 |   For test weeks 0-12, the mean % mortality achieved after 14 days was consistently more than 90 %. | Test report:  BIO043-15  xxxx 2015b |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| Two laboratory tests and 5 simulated use tests were provided to demonstrate efficacy of the products in the Moth Gel family against clothes moths (*Tineola bisselliella)*. For an evaluation of the label claims, see section 1.2.7.7 |

#### Occurrence of resistance and resistance management

No known resistance has been observed to-date for this active substance (transfluthrin).

#### Known limitations

No efficacy limitations have been found if the products are used following the use instructions.

#### Evaluation of the label claims

Moth Gel Family contains 2 Meta SPCs:

Meta SPC-1: Moth Gel Lavender

Meta SPC-2: Moth Gel Cedar

*Label claims & instructions*

The label claims for both Meta SPCs in Moth Gel Family are as follows:

**With a dose of 2 units per 0.018 m3)**

Kills all adult moths in 2 days with a residual efficacy of 12 weeks

Kills larvae in 2 weeks with a residual efficacy of 4 weeks

Allow 2 weeks for maximum effect.

*Support of the label claims*

Two laboratory tests and five simulated use tests have been provided to demonstrate efficacy of the products in the Moth Gel family against the cloth moth *Tineola bisselliella.*Tests have been conducted with both products. .

**Meta SPC-1: Moth Gel Lavender**

Laboratory test:

-In test 144a-19 (xxxx (2019)) the efficacy of 1 unit of Moth Gel Lavender against *Tineola bisselliella* adults and larvae in 350 ml glass jars was demonstrated for adults (100% mortality after 1 day) and larvae (100% mortality after 5 days) for up to 12 weeks after opening. Control mortality for adults after 1 day was 0% and for larvae after 5 days was max 3%. As such, although the control mortality was >10 % at a later time, the mortality effect of the product reached 100% before the control mortality became too high.

The quantity used in this study is very much higher in the glas jar compared to the dosage of 2 units per drawer, Therefore, the eCA considers this laboratory test to show the innate efficacy of the product only. However,as the simulated use test below is worst-case compared to this laboratory test it can be used to authorise this product.

Simulated use tests:

-In test 055b-17 (xxxx (2017)), presented in the first 4 rows of the efficacy table, the efficacy of 2 units of Moth Gel Lavender against *Tineola bisselliella* adults and larvae in 0.018 m3 drawers was demonstrated for adults (>90% mortality after 1 day, 100% after 2 days for up to 12 weeks after opening) and larvae (>90% mortality after 14 days 0-4 weeks after opening, 59-83% mortality after 14 days 6-12 weeks after opening). While the table in the efficacy table mentions ‘knockdown/mortality’ the raw data tables in the test report mention % dead cloth moths, it was therefore concluded that the data presented here represent mortality and not knockdown. Control mortality for adults after 2 days was max 2% and for larvae after 14 days was max 8%. Almost all eggs that were laid during the test did not develop into living larvae 14 days later while in the control test many larvae were found after 14 days. In the larval test fabric damage was observed in all replicates. Efficacy of the product was sufficiently demonstrated in this test for adults up to 12 weeks after opening and for larvae up to 4 weeks after opening of the product. A period of 2 weeks is recommended for maximum effect.

-In test BIO025-10 (xxxx 2010a), the efficacy of 2 units of Moth Gel Lavender against *Tineola bisselliella* adults in 0.5 m3 cabinets was demonstrated for adults (>90% mortality 5 days after placing moths in the cabinet with the product, 100% after 14 days for up to 12 weeks after opening). However, control mortality for adults was >10% after 2 or 3 days for all treatment groups. Therefore, the results of this test are only used as supporting data.

In test BIO103-14 (xxxx 2015a), the efficacy of 1 unit of Moth Gel Lavender against *Tineola bisselliella* adults in 0.5 m3 cabinets was demonstrated for adults (>90% mortality 14 days after placing moths in the cabinet with the product, for up to 12 weeks after opening). However, control mortality for adults was >10% after 7-10 days for all treatment groups. Therefore, the results of this test are only used as supporting data.

Conclusion: based on the provided tests, efficacy of the product of Meta SPC 1 of the Moth Gel family against *Tineola bisselliella* adults and larvae was sufficiently demonstrated with a dosage of 2 units per drawer (0.018m3). While larval mortality was lower than the required 90% after more than 4 weeks this is unlikely to present a major issue as egg hatching\larval development is severely repressed during the whole claimed effective period. Use in cabinets (0.5 m3) was not supported as control mortality of was too high.

**Meta SPC-2: Moth Gel Cedar**

Laboratory test:

In test 117a-19 (xxxx (2019)) the efficacy of 1 unit of Moth Gel Cedar against *Tineola bisselliella* adults and larvae in 350 ml glass jars was demonstrated for adults (100% mortality after 1 day) and larvae (100% mortality after 5 days) for up to 12 weeks after opening. Control mortality for adults after 1 day was 0% and for larvae after 5 days was max 3%. As such, although the control mortality was >10 % at a later time, the mortality effect of the product reached 100% before the control mortality became too high.

The quantity used in this study is very much higher in the glas jar compared to the dosage of 2 units per drawer, Therefore, the eCA considers this laboratory test to show the innate efficacy of the product only. However, as the simulated use test below is worst-case compared to this laboratory test it can be used to authorise this product.

Simulated use tests:

-In test 055b-17 (xxxx (2017)), presented in the first 4 rows of the efficacy table, the efficacy of 2 units of Moth Gel Lavender against *Tineola bisselliella* adults and larvae in 0.018 m3 drawers was demonstrated for adults (>90% mortality after 1 day, 100% after 2 days for up to 12 weeks after opening) and larvae (>90% mortality after 14 days 0-4 weeks after opening, 59-83% mortality after 14 days 6-12 weeks after opening). While the table in the efficacy table mentions ‘knockdown/mortality’ the raw data tables in the test report mention % dead cloth moths, it was therefore concluded that the data presented here represent mortality and not knockdown. Control mortality for adults after 2 days was max 2% and for larvae after 14 days was max 8%. Almost all eggs that were laid during the test did not develop into living larvae 14 days later while in the control test many larvae were found after 14 days. In the larval test fabric damage was observed in all replicates. Efficacy of the product was sufficiently demonstrated in this test for adults up to 12 weeks after opening and for larvae up to 4 weeks after opening of the product. A period of 2 weeks is recommended for maximum effect.

This test was conducted with Moth Gel lavender which is a Meta SPC-1 product. However, as the active subtance concentration of both Meta SPC-1 and Meta SPC-2 are identical, read across was considered acceptable.

-In test BIO097-10 (xxxx 2010b), the efficacy of 2 units of Moth Gel Cedar against *Tineola bisselliella* adults in 0.5 m3 cabinets was demonstrated for adults (>90% mortality 6 days after placing moths in the cabinet with the product, 100% after 14 days for up to 12 weeks after opening). However, control mortality for adults was >10% after 2 or 3 days for all treatment groups. Therefore, the results of this test are only used as supporting data.

In test BIO043-015 (xxxx 2015b), the efficacy of 2 units of Moth Gel Cedar against *Tineola bisselliella* adults in 0.5 m3 cabinets was demonstrated for adults (>90% mortality 14 days after placing moths in the cabinet with the product, for up to 12 weeks after opening). However, control mortality for adults was >10% after 7 days for all treatment groups. Therefore, the results of this test are only used as supporting data.

Conclusion: Based on the provided tests efficacy of the product of the Moth Gel family in Meta SPC-2 against *Tineola bisselliella* adults and larvae was sufficiently demonstrated with a dosage of 2 units per drawer (0.018m3). While larval mortality was lower than the required 90% after more than 4 weeks this is unlikely to present a major issue as egg hatching\larval development is severely repressed during the whole claimed effective period. Although the simulated use test in drawers was only conducted with Moth Gel Lavender (which is not part of Meta SPC-1) read across is considered acceptable due to the similar mortality results which are found in the simulated use tests in cabinets with the products Moth Gel Lavender and Moth Gel Cedar. Use in cabinets (0.5 m3) was not supported by these tests as the control mortality was too high.

### Risk assessment for human health

The product is not identical to the representative product included in the Annex I inclusion dossier for Transfluthrin.

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

No *in vitro*, *in vivo* or human data are available.

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| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | The Lavender and Cedar variant of this product family require classification for skin irritation according to Regulation (EC) No 1272/2008 and amendment No. 286/2011; H315: Causes skin irritation. |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for skin irritation/corrosion hazards by calculation. In accordance with Section 3.2.3.3.1 of the Regulation, it is assumed that the ‘relevant ingredients’ of a mixture are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a presumption (e.g., in the case of corrosive ingredients) that an ingredient present at a concentration of less than 1 % can still be relevant for classifying the mixture for skin irritation/corrosion. Under Section 3.2.3 of the regulation, Table 3.2.3 contains the generic concentration limits to be used to determine if a mixture is considered to be an irritant or corrosive to the skin.  **Moth Gel Lavender**  Several fragrance components (linalyl acetate, linalool, 3,5,5-trimethylhexyl acetate and p-menth-1-en-4-ol) are classified as category 2 skin irritants and are present in the product at 6.5-13% and 6.5-13%, 6.5-13% and 0.65-2.0% respectively. In sum the total contribution of category 2 skin irritants exceeds the 10% generic threshold limit; therefore, resulting in category 2 skin irritant classification.  **Moth Gel Cedar**  Several fragrance components (3,5,5-trimethylhexyl acetate, linalool, p-menth-1-en-8-ol, and linalyl acetate) are classified as category 2 skin irritants and are present in the product at 11.18%, 9.22%, 1.68% and 1.26%, respectively. In sum the total contribution of category 2 skin irritants exceeds the 10% generic concentration limit; therefore, resulting in category 2 skin irritant classification.  As the calculation method is considered adequate to determine the classification, a study is therefore not required, nor considered an appropriate use of animals |
| Classification of the product according to CLP | Skin Irritant Category 2; H315 (Lavender and Cedar variant): Causes skin irritation. |

***Eye Irritation***

No *in vitro*, *in vivo*, or human data are available.

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| --- | --- |
| **Conclusion used in Risk Assessment – Eye Irritation** | |
| Value/conclusion | The Lavender and Cedar variant of this product family require classification for eye irritation according to Regulation (EC) No 1272/2008 and amendment No. 286/2011; H319: Causes serious eye irritaqtion. |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for eye irritation/serious eye damage hazards by calculation. In accordance with Section 3.3.3.3.1 of the Regulation, it is assumed that the ‘relevant ingredients’ of a mixture are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a presumption (e.g. in the case of corrosive ingredients) that an ingredient present at a concentration of less than 1 % is still relevant for classifying the mixture for eye irritation/corrosion. Under Section 3.3.3 of the regulation, Table 3.3.3 contains the generic concentration limits to be used to determine if a mixture is considered to be an irritant or corrosive to the eye.  **Moth Gel Lavender**  Several fragrance components (p-menthan-8-yl acetate, linalyl acetate, and linalool) are classified as category 2 eye irritants and are present in the product at 20-33%, 6.5-13%, and6.5-13%, respectively. In sum the total contribution of category 2 eye irritants exceeds the 10% generic concentration limit; thertefore, resulting in category 2 eye irritant classification.  **Moth Gel Cedar**  Several fragrance components (p-menthan-8-yl acetate, linalool, p-menth-1-en-8-ol, and linalyl acetate) are classified as category 2 eye irritants and are present in the product at 27.3%, 9.22%, 1.68% and 1.26%, respectively. In sum the total contribution of category 2 eye irritants exceeds the 10% generic concentration limit; therefore, resulting in category 2 eye irritant classification.  As the calculation method is considered adequate to determine the classification, a study is therefore not required, nor considered an appropriate use of animals. |
| Classification of the product according to CLP | Eye Irritant Category 2; H319 (Lavender and Cedar variant): Causes serious eye irritation. |

***Respiratory tract irritation***

Endpoint not required.

NL CA remark: Considering irritating properties on the respiratory tract is required. However, based on the information on the active substance, Tranfluthrin is not classified for this endpoint (i.e. H335), based on the harmonised classification, the EU LoEP and the provided MSDS. Furthermore, none of the co-formulants are classified for this endpoint. Additionally, the product is not classified for corrosive properties and therefore it is also not necessary to classify additionally for effects on the respiratory tract. Therefore, it can be concluded that Moth Gel Family does not need to be classified for respiratory tract irritation.

***Skin sensitization***

No *in vitro*, *in vivo* or human data are available.

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| --- | --- |
| **Conclusion used in Risk Assessment – Skin Sensitization** | |
| Value/conclusion | The Lavender and Cedar variant of this product family require classification for skin sensitization according to Regulation (EC) No 1272/2008 and amendment No. 286/2011; H317: May cause an allergic skin reaction. |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for skin sensitization by calculation. In accordance with Section 3.4.3.3.1 of the Regulation, classification of a product for sensitizing effects is necessary if it contains at least one ingredient that has been classified for skin sensitization and is present at or above the appropriate generic concentration limits noted in Table 3.4.5 or is present at or above the concentration limit for sensitized individuals presented in Table 3.4.6.  **Moth Gel Lavender**  Several fragrance components (p-menthan-8-yl acetate, linalyl acetate, linalool, and cineole) are classified for skin sensitization and are present in the formula at 20-33%, 6.5-13%, 6.5-13%, and 0.65-6.5%, respectively. As such, these values exceed the 1% generic concentration limit, resulting in a category 1B skin sensitization classification.  **Moth Gel Cedar**  Several fragrance components (p-menthan-8-yl acetate, linalool, and linalyl acetate) are classified for skin sensitization and are present in the product at 27.3%, 9.22%, and 1.25%. As such, these values exceed the 1% generic concentration limit, resulting in a category 1B skin sensitization classification.  As the calculation method is considered adequate to determine the classification, a study is therefore not required, nor considered an appropriate use of animals. |
| Classification of the product according to CLP | Skin Sensitization Category 1B; H317 (Lavender and Cedar variant): May cause an allergic skin reaction. |

**Respiratory sensitization**

No *in vitro*, *in vivo* or human data are available.

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| --- | --- |
| **Conclusion used in Risk Assessment – Respiratory Sensitization** | |
| Value/conclusion | The Lavender and Cedar variant of this product family do not require classification for respiratory sensitization according to Regulation (EC) No 1272/2008 and amendment No. 286/2011. |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for respiratory sensitization by calculation. In accordance with Section 3.4.3.3.1 of the Regulation, classification of a product for sensitizing effects is necessary if it contains at least one ingredient that has been classified for skin sensitization and is present at or above the appropriate generic concentration limits noted in Table 3.4.5 or is present at or above the concentration limit for sensitized individuals presented in Table 3.4.6.  Details of the product composition are presented in the Confidential Annex.  As the calculation method is considered adequate to determine the classification, a study is therefore not required, nor considered an appropriate use of animals. |
| Classification of the product according to CLP | Not classified |

**Acute Toxicity**

*Acute toxicity by oral route*

No *in vitro*, *in vivo* or human data are available.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Acute Oral Toxicity** | |
| Value/conclusion | The Lavender and Cedar variant of this product family do not require classification for acute oral toxicity according to Regulation (EC) No 1272/2008 and amendment No. 286/2011. |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for acute oral toxicity by calculation. In accordance with Section 3.1.3 of the Regulation, the acute toxicity estimate (ATE) of ingredients are calculated and compared to Table 3.1.1 to derive the category of toxicity.  **Moth Gel Lavender**  ATEmix: 5882 mg/kg bw.  Details of the product composition and the supporting calculations are presented in the Confidential Annex.  As the calculation method is considered adequate to determine the classification, a study is therefore not required, nor considered an appropriate use of animals.  Additionally, these products do not need to be classified as an aspiration hazard due to the physiochemical properties and section 3.10 of the Regulation. |
| Classification of the product according to CLP | Not classified |

*Acute toxicity by inhalation route*

No *in vitro*, *in vivo* or human data are available.

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| --- | --- |
| **Conclusion used in Risk Assessment – Acute Inhalation Toxicity** | |
| Value/conclusion | The Lavender and Cedar variant of this product family do not require classification for acute inhalation toxicity according to Regulation (EC) No 1272/2008 and amendment No. 286/2011. |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for acute inhalation toxicity by calculation. In accordance with Section 3.1.3 of the Regulation, the acute toxicity estimate (ATE) of ingredients are calculated and compared to Table 3.1.1 to derive the category of toxicity.  **Moth Gel Lavender**  ATEmix: 169 mg/L.  Details of the product composition and the supporting calculations are presented in the Confidential Annex.  As the calculation method is considered adequate to determine the classification, a study is therefore not required, nor considered an appropriate use of animals. |
| Classification of the product according to CLP | Not classified |

*Acute toxicity by dermal route*

No *in vitro*, *in vivo* or human data are available.

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| --- | --- |
| **Conclusion used in Risk Assessment – Acute Dermal Toxicity** | |
| Value/conclusion | The Lavender and Cedar variant of this product family do not require classification for acute dermal toxicity according to Regulation (EC) No 1272/2008 and amendment No. 286/2011. |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for acute inhalation toxicity by calculation. In accordance with Section 3.1.3 of the Regulation, the acute toxicity estimate (ATE) of ingredients are calculated and compared to Table 3.1.1 to derive the category of toxicity.  Details of the product composition are presented in the Confidential Annex.  As the calculation method is considered adequate to determine the classification, a study is therefore not required, nor considered an appropriate use of animals. |
| Classification of the product according to CLP | Not classified |

***Information on dermal absorption***

Dermal absorption studies on the active substance are summarized and reported within the active substance dossier submitted for Annex I inclusion.  Refer to Document IIA, Section 3.1.

The EU guidance (Guidance Document on Dermal Absorption EFSA Journal 2012;10(4):2665) on the assessment of dermal penetration states that in the absence of data, a 75 % dermal penetration factor should be assumed for a concentrate which has an active substance concentration of ≤5%.  However, this assumption may be modified to a lower default value of 10% based on expert judgement, if sufficient data is provided to justify this figure.  A consideration of the available data for transfluthrin and pyrethroids in general is made below to justify a default value of 10 %.

The following conclusion was reached in the course of the data evaluation:-

A number of factors are described which, combined, fulfil a requirement for “Expert judgement” and permit selection of a 10% default value for dermal penetration:

- Physico-chemical properties approach values where assumption of 10% default absorption is suggested in guidance.

- Data from other comparable pyrethroids suggests a dermal penetration value as low as 3 % in humans, would remain a protective overestimate.

- Human skin appears particularly refractory to pyrethroid absorption.

Current risk assessments for transfluthrin are satisfied by a dermal penetration factor of 10 %.  Given current knowledge, a specific dermal penetration study to refine dermal absorption to a value of 10% or less is therefore not an appropriate use of animals.

|  |  |
| --- | --- |
| **Value(s) used in the Risk Assessment – Dermal absorption** | |
| Substance | Transfluthrin |
| Value(s)\* | 70% |
| Justification for the selected value(s) | SeeeCa remark below. |

eCA remark: The applicant considers the value of 10% for dermal absorption applicable based on a number of factors. In the assessment report of transfluthrin a value of 10% for dermal absorption is included, based on MW of 371 and log Pow of 5.4, and data from other (fluorinated)pyrethroids. Although the 10% for dermal absorption is indeed included in the EFSA Guidance on dermal absorption (2012) applicable to this PAR, the 10% for dermal absorption based on physical chemical properties is no longer included in the updated EFSA guidance from 2017. More importantly, in the EFSA guidance from 2012 it is noted that a default value of 10% can be used in cases where log Pow < -1 or > 4 **and** MW > 500. However, transflutrin has a log Pow of 5.4, which fulfils the criteria, and a MW of 371 which is below the limit value of 500. A dermal absorption value of 10% may thus not be applied according to the EFSA guidance (2012). In the CAR of transfluthrin it was concluded that although the MW is below 500, it is close to the MW criterion and read across was made to other pyrethroids which also do not fulfil the MW criterion but for which the available data suggest a dermal absorption below the default value of 10%. However, many EU discussions on dermal absorption of pyrthroids on recent product authorisations have taken place. From these discussions it can be concluded that dermal absorption is considered product specific and only referring to other pyrethroids without extensive argumentation for read across is not acceptable for product authorisation. In conclusion, we consider the argumentation to lower the default dermal absorption value to 10% not sufficient.

Subsequently, a standard default value for dermal absorption needs to be used for the risk assessment. Therefore, a 70% dermal absorption value should be used for an active substance concentration of ≤5% of an organic based formulation (EFSA guidance 2017).

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

According to Human Health Guidance on the Biocidal Product Regulation ECHA (2017), a chemical is defined as a Substance of Concern (SoC) if it (a) drives the product classification, (b) enhances the effects of the active substance in the product, (c) is on the REACh candidate list at ≥0.1%, (d) substances that have been included in the list (candidate list) established in accordance with the REACH Regulation or (e) has a community workplace exposure limit (SCOEL).

As these products are classified for skin irritation category 2 (H315), skin sensitization (H317), and eye irritation category 2 (H319), criteria (a) noted above is fulfilled as such an additional evaluation is needed.

According to Annex A: Substances of Concern under ECHA (2017), skin and eye irritation classifications (H315 & H319) fall into band A and do not require a full detailed assessment as quantitative dose response information is typically not available. As such, inclusion of appropriate risk mitigation measures, in the form of H-statements and P-statements, is deemed sufficient to address substances of concern driving these hazard classifications. Additionally, any dermal exposure would be minimal and transient (during product placement), and the consumer is advised to wash their hands afterwards so any residues would be removed.

Substances classified as skin sensitization (H317) fall into band B for which a qualitative exposure and risk assessment should be performed to determine whether P-statements normally associated with concerned H statements are sufficient or whether other risk mitigation measures should be applied. However, quantitative risk assessment for H317 has been discussed in recent WG meetings for which it was concluded that there is no guidance for this and will not be available in the near future. Therefore, we cannot include a quantitative risk assessment for the H317 classified product.

The skin sensitization classification is due to the presence of parfums in the product. The product is a gel, separated by a semi-permeable membrane that will be exposed after removal of the silver foil. Perfume will leave the product, however, we cannot quantify the effect of being in the matrix, passing the semi-permeable membrane, subsequent settling on the clothing and then dermal exposure via transfer of the clothing. Although quantification and assessment are not possible, considering that all these steps probably result in reducing the dermal exposure we are not concerned that this would lead to adverse health effects.

There are no chemicals present in the formulas which fulfil the SOC criteria (b), (c) and (d). For the last criteria (e), diphenyl ether is present in both the products and has a SCOEL. Therefore, a quantitative risk assessment was conducted using the 8-hour limit value of 7 mg/m3 (equal to 1 ppm) or 15 minute limit value of 14 mg/m3 which can be found in the confidential annex.

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

Refer to Section 2.2.8 for data on the product.

***Other***

At 18 March 2021 a [RAC Opinion proposing harmonised classification and labelling](https://www.echa.europa.eu/documents/10162/fae3f265-0449-3641-afd9-f7976325fd2a)

[at EU level of transfluthrin (ISO); 2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2- dimethylcyclopropanecarboxylate was adopted](https://www.echa.europa.eu/documents/10162/fae3f265-0449-3641-afd9-f7976325fd2a).

This opinion includes revision of the current classification. Considering the concentration of transfluthrin in the BPF and the revised classification as included in the RAC opinion, the final classification will not be affected.

No data are required for the following endpoints:

* Food and feedstuffs as the biocidal product will not be in contact with feedstuffs. This is included as a risk mitigation measure in the use instructions and the SPC: “Do not use near food, drink and animal feeding stuffs”.
* The effects of industrial processing or domestic preparation are not relevant as the product is Ready-to-Use.

***Screening non-active substance(s) for endocrine disrupting potential***

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting (ED) properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides. Hence, as requested by the evaluating Member State Competent Authority, a screen for indications of ED potential has been performed for these products.

According to the EU Commission’s guidance note on ‘The Implementation of scientific criteria for the determination of endocrine-disrupting properties in the content of biocidal product authorization (CA-March18-Doc.7.3.b-final, paragraph 23) the detailed evaluation of a non-active substance (co-formulant) per the ECHA/EFSA guidance should only occur where there are indications of ED properties based on the existing knowledge and the available scientific information. An agreed screening process for a co-formulant to identify indications of endocrine disrupting (ED) in substances has not been established. Therefore, a screening approach was developed utilizing existing evidence according to the ECHA/EFSA guidance (http://www.efsa.europa.eu/en/press/news/180607), which adapted the WHO definition, that a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

a) It shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences

b) It has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system

c) the adverse effect is a consequence of the endocrine mode of action

The indicating ED screen overview for the co-formulants in Moth Gel Family is summarized in the confidential annex. All co-formulants identified from the safety data sheets for all ingredients and the finished product were included in the screen. None of the co-formulants included in Moth Gels Family were identified as requiring further, detailed evaluation for ED potential.

**Remark NL CA:**

For the active substance transfluthrin no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. The Assessment Reports for transfluthrin (2014) state that this active substance is not be considered as having endocrine disrupting properties. The potential ED properties of the co-formulants were assessed (see confidential annex for more information) and for none of the components an ED alert was identified.

In conclusion, based on available information, Moth Gel Family is not considered to have ED properties.

#### Exposure Assessment

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

| **Summary table: relevant paths of human exposure** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | No | No | No | No | No | Yes | No |
| Dermal | No | No | Yes | No | No | No | No |
| Oral | No | No | No | No | No | No | No |

***List of scenarios***

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g., mixing/ loading) | **Primary or secondary exposure**  **Description of scenario** | **Exposed group**  (e.g., professionals, non-professionals, bystanders) |
| 1. Dermal exposure | Application | This product is used in drawers to protect clothes from moths.  During application of the product, there should be no direct dermal contact with the moth gel so exposure should be minimal. However, a conservative risk assessment has been conducted should skin contact occur.  To use the product, the consumer is directed to remove the silver foil covering one side of the gel contained within a semi-permeable membrane. As noted above, contact should be minimal as the directions for use include the phrase, “Avoid making contact with the gel membrane”. The consumer should then place the product in the desired drawer. Inhalation of the active substance during removal of the silver foil is considered negligible and covered by the inhalation exposure post-application (scenario 2).  The label instructions state that two moth gels should be used in a 0.018 m3 space, the size of a small drawer.  Given the brief application time and the low vapor pressure of Transfluthrin (9 x 10-4 Pa; defined as non-volatile by RIVM documentation), an inhalation exposure is considered negligible as an appreciable transfluthrin air concentration will not have been reached. | Non- Professional |
| 2. Inhalation exposure | Post Application | The product works as the active substance is passively released as a vapour at room temperature into the drawer space. Therefore, when the consumer removes clothing from the drawer, the vapour that has volatized can be inhaled.  The active substance in the moth gel evaporates due to passive air flow at room temperature. The ConsExpo evaporation model (constant rate) is the appropriate model to calculate inhalation exposure. | Non- Professional |

***Industrial exposure***

Not Relevant

***Professional exposure***

Not Relevant

***Non-professional exposure***

*Scenario 1: Application*

| **Description of Scenario 1** | | |
| --- | --- | --- |
| The label instructions direct the consumer to place two moth gels in a 0.018 m3 space and replace after three months. For the purposes of exposure assessment, a drawer the size of 0.018 m3 is assumed and the consumer treats 4 drawers in a dresser. Therefore, 8 moth gels would be used in a dresser.  This scenario covers the potential interaction between the consumer and the moth gel membrane during application. As instructed, the consumer peels off the silver foil on one side to expose the gel contained under a semi-permeable membrane and then places the gel in a drawer. Dermal exposure is unlikely to occur because the gel is housed in a plastic case on three sides which the consumer can hold whilst handling the product. Additionally, once the foil is removed, only one side of the gel is exposed contained by a semi-permeable membrane. However, for the purpose of this assessment, it was conservatively assumed that the consumer made dermal contact with the gel during product assembly.  The parameters used in the calculation are below and the calculated exposure will be compared to the dermal AEL. | | |
|  | Parameters | Value |
| Tier 1 | Frequency of Use | 90 days |
| Amount of Active Substance | 3.0 g of formula per gel  0.0045 g or 4.5 mg Transfluthrin per gel  (3.0 g x 0.15% Transfluthrin = 0.0045 g)  4.5 mg x 8 gels =36 mg |
| Surface Area of gel membrane | 34.2 cm2  Membrane dimensions: 76 mm x 45 mm x 3 mm  76 mm x 45 mm = 3420 mm2 or 34.2 cm2 |
| Dermal Transfer | 18% (ECHA, 2013) |
| Dermal Absorption | 70% (See above) |
| Default Adult Body Weight | 60 kg (HEADhoc Recommendation No. 14) |
| Finger Tip Surface Area | 10 cm2  The default value for a few fingertips is 10cm2 (CAR transfluthrin). |

**Calculations for Scenario**

To calculate the amount of active available for dermal exposure it was conservatively assumed that the transfluthrin is evenly distributed on the entire outer surface of the gel and not evenly distributed throughout the gel.

4.5 mg Transfluthrin / (34.2 cm2)

= 0.132 mg/cm2 of gel

Assuming the consumer touches a single gel with a few fingertips:

0.132 gm/cm2 x 10 cm2

= 1.32 mg

Allowing for 18% dermal transfer:

1.32 mg x 18%

= 0.238 mg

Exposure to the consumer for fingertip contact with a single gel membrane:

(0.238 mg x 70% Dermal Abs) / 60 kg bw

= 2.8 x 10-3 mg/kg bw

While it is unlikely that the consumer will have direct contact with a single gel, given usage directions, the even more conservative scenario considers the consumer repeating that interaction across all 8 gels as part of treating a dresser:

2.8 x 10-3 mg/kg bw x 8 units

= 2.2 x 10-2 mg/kg bw

| **Description of Scenario 2** | | |
| --- | --- | --- |
| The label instructions advise the consumer to place two moth gels in a 0.018 m3 space and replace after three months. For the purposes of exposure assessment, a drawer the size of 0.018 m3 is assumed and the consumer treats 4 drawers in a dresser. Therefore, 8 moth gels would be used in a dresser. During use, the active substance is passively released at room temperature into the drawer space to kill moths.  This scenario assumes a consumer spends five minutes per day inhaling the vapour from the drawer whilst they are choosing clothes. Only adult inhalation exposure was determined as it is unlikely that young children will remove clothing from the drawer (akin to closet scenario noted in CAR transfluthrin). Moreover, the product is labelled with P102: Keep out of reach of children.  The calculated air concentration and systemic exposure were then compared to the AEC/AEL. | | |
|  | Parameters1 | Value |
| Tier 1 | Model | ConsExpo Web - Vapour (evaporation) Model, constant rate. |
| Frequency of Use | 90 days |
| Emission Duration | 90 days |
| Exposure Duration | 5 minutes / day (RIVM, 2006) |
| Emission Rate | 4.5 mg transfluthrin / gel 36 mg transfluthrin / 8 gels  This is based on the assumption that all of the active substance is released over the 90-day period, and not on evaporation rate data. |
| Weight fraction substance | 1  As this assessment is only considering the evaporation of Transfluthrin in the gel. The emission rate has likewise been adjusted to only consider that constituent. |
| Room (Dresser) Volume | 0.072 m3  (0.018 m3 drawer size x 4 drawers/dresser)  As the drawers are unlikely to be sealed from each other, the total air volume of the dresser is considered. |
| Ventilation Rate | 0.3 hr-1 (RIVM, 2006) |
| Default Adult Body Weight | 60 kg (HEADhoc Recommendation No. 14) |
| Inhalation Rate | 1.25 m3/hour or 0.0208 m3/min  (HEADhoc Recommendation No. 14) |

**Calculations for Scenario**

|  |  |
| --- | --- |
| **Moth Gel** | |
| Active substance | Transfluthrin (CAS 118712-89-3) 0.15% w/w |
| Molecular weight of active substance | 371 g/mol (Transfluthrin Assessment Report, 2014) |
| Vapour pressure of active substance | 9 x 10-4 Pa at 20 ºC (Transfluthrin Assessment Report, 2014) |

Using the mean event air concentration from ConsExpo (see output file section 3.2), adult inhalation exposure (on the day of exposure) was calculated to be:

(0.0096 mg/m3 x 5 min x 0.0208 m3/min x 100% Inhalation Abs) / 60 kg bw

= 1.7 x 10-5 mg/kg bw/day

**Further information and considerations on scenario 2**

The mean event air concentration has been calculated to be 9.6 x 10-3 mg/m3.

| **Summary table: external and systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario 1.  Dermal exposure | 1/ No PPE required | N/A | 2.2 x 10-2 mg/kg bw | N/A | 2.2 x 10-2 mg/kg bw |
| Scenario 2.  Inhalation exposure | 1/ No PPE required | 1.7 x 10-5 mg/kg bw/day | N/A | N/A | 1.7 x 10-5 mg/kg bw |
| 1/ No PPE required | 9.6 x 10-3  mg/m3 | N/A | N/A | 9.6 x 10-3  mg/m3 |

*Combined scenarios*

It is possible that an adult is primarily exposed to transfluthrin by placing the Moth Gel into the dressor and is subsequently secondary exposed to transfluthrin when opening the drawer. Therefore, combined exposure of scenario 1 and scenario 2 was assessed.

| **Summary table: external and systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake** | **Estimated oral uptake** | **Estimated total uptake** |
| Scenario 1 and 2.  Adult primary and secondary exposure to Moth Gel | 1/ No PPE required | 1.7 x 10-5 mg/kg bw/day | 2.2 x 10-2 mg/kg bw | N/A | 2.202 x 10-2 mg/kg bw |

***Exposure of the general public***

Not relevant

***Monitoring data***

No relevant data

***Dietary exposure***

Not relevant

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

Production and formulation are addressed under other EU legislation (e.g. Directive 98/24/EC) and not repeated under Regulation 528/2012 (this principle was agreed at Biocides Technical Meeting TMI06).

As the product is applied directly from the container and this is disposed of once empty, there is no cleaning operation to consider.

***Aggregated exposure***

Not Relevant

#### **Risk Characterization for Human Health**

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

The following information had been adapted from section 2.2.1.2 (Critical Endpoints and Acceptable Exposure Levels) of the PT18 Transfluthrin Assessment Report (2014):

**AECacute, inhalation**

In a 13-week inhalation study, with an exposure duration of 6h/day, the NOAEC for neurotoxicity was 46.7 mg/m3 (equivalent to 17 mg/kg/day). This NOAEC is used as a basis for risk assessment for acute inhalation exposure. A default assessment factor of 100 is applied to account for inter- and intraspecies differences. Thus, for inhalation exposure, based on NOAEC of 46.7 mg/m3 and the default assessment factor of 100, an AELacute, inhalation of 0.5 mg/m3 is derived.

**AELacute, dermal**

In a 3-week dermal toxicity study in the rabbit, the NOAEL for systemic effects was 1000 mg/kg/day. This NOAEL is used as a basis for risk assessment for acute dermal exposure. A default assessment factor of 100 is applied to account for inter- and intraspecies differences. Thus, for dermal exposure, based on the NOAEL of 1000 mg/kg/day and the default assessment factor of 100, an external AELacute, dermal of 10 mg/kg/day is derived.

**AELchronic, systemic**

The NOAEL of 20 ppm was observed in a 2-year dietary study in rats, equal to 1.0 mg/kg/day on the basis of glomerulonephrosis, pigment deposition, increased absolute and relative weight of the kidneys at 200 ppm, equal to 9.9 mg/kg/day. A default assessment factor of 100 is applied to account for inter- and intraspecies differences. As the toxicokinetic studies indicate almost complete absorption of radiolabel, no correction for incomplete oral absorption is needed. Based on these considerations an AELchronic of 1/100 = 0.01 mg/kg/day is established.

The AEC/AELs above and the studies from which they were derived are detailed in the table below.

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEC/NOAEL** | **AF** | **Correction for absorption** | **AEC/AEL Value** |
| AEC acute (inhalation) | 13-week rat | 46.7 mg/m3 | 100 | none | 0.5 mg/m3 |
| AEL acute (dermal, 10% absorption) | 3-week rabbit | 1000  mg/kg bw/ day | 100 | none | 1 mg/kg bw/day |
| AEL chronic (systemic) | 2-year dietary rat | 1 mg/kg bw/day | 100 | none | 0.01 mg/kg bw/day |
| ADI (if residues in food or feed) | 2-year dietary rat | 1 mg/kg/day | 100 | none | Although there  are no residues  in food or feed  expected an  ADI of 0.01  mg/kg bw/day is  used in the  statement of  negligible  exposure (Doc  IIB 3.1.4) |
| ARfD (acute reference dose) | Dev. study,rabbit | 15 mg/kg/day | 100 | None | Although there  are no residues  in food or feed  expected an  ARfD of 0.15  mg/kg bw/day is  used in the  statement of  negligible  exposure (Doc  IIB 3.1.4) |

***Risk for industrial users***

Not Relevant

***Risk for professional users***

Not Relevant

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

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **NOAEL/**  **NOAEC** | **AEL or AEC** | **Estimated uptake** | **Estimated uptake/ AEL or AEC**  **(%)** | **Acceptable**  **(yes/no)** |
| 1- Dermal exposure | 1 | 1000  mg/kg bw/day | 1  mg/kg bw/day | 2.2 x 10-2  mg/kg bw | 2.2 | Yes |
| 2- Inhalation exposure | 1 | 1  mg/kg bw/day | 0.01  mg/kg bw/day | 1.7 x 10-5 mg/kg bw | <1 | Yes |
| 46.7  mg/m3 | 0.5  mg/m3 | 9.6 x 10-3  mg/m3 | 1.9 | Yes |

**Combined scenarios**

It is possible that an adult is primarily exposed to transfluthrin by placing the Moth Gel into the dressor and is subsequently secondary exposed to transfluthrin when opening the drawer. Therefore, combined exposure of scenario 1 and scenario 2 was assessed.

| **Summary table: external and systemic exposure from non-professional uses** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier** | **NOAEL/**  **NOAEC** | **AEL or AEC** | **Estimated uptake** | **Estimated uptake/ AEL or AEC**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario 1 and 2.  Dermal exposure | 1/ No PPE required | 1000  mg/kg bw/day | 1  mg/kg bw/day | 2.2 x 10-2  mg/kg bw | 2.2 | Yes |
| Scenario 1 and 2.  Inhalation exposure | 46.7 mg/m3 | 0.5  mg/m3 | 9.6 x 10-3  mg/m3 | 1.9 | Yes |
| sum |  |  |  |  | 4.1 | Yes |

**Local effects**

Both fragrance variants are classified as skin and eye irritants due to the level of components noted in the confidential annex. According to EU guidance on Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorization of Biocidal Products (CA-NOV14-Doc.5.11), a quantitative risk assessment is not warranted for these endpoints as the relevant P-statements associated with these hazard classifications are present on the label and provide a sufficient risk mitigation measure. Additionally, both fragrance variants are classified for skin sensitization (H317), a qualitative risk assessment is provided in the confidential annex to determine the appropriate P-statements needed and provide assurance for safe use by consumers when used as directed.

Both metaSPC on this family require classification as follows according to Regulation 1272/2008/EC:

* Skin sens 1 H317 “May cause an allergic skin reaction”

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Hazard** | | **Exposure** | | | | | | | **Risk** |
| **Hazard category** | **Effect** | **Frequency and duration of potential exposure** | **Who is exposued?** | **Uses** | **Potential exposure route** | **Frequency and duration potetial exposure** | **Potential degree of exposure** | **Relevant RMM** | **Conclusion on risk** |
| High | Skin sens 1 H317 | Less than once per week, and less than few minutes per day. | Non-professional user | To use in drawers where clothes are present. | Dermal exposure will not occur under normal conditions of use. Inhalation exposure is negligible as the product contains a gel hampering exposure to fumes. | Less than a minute per week | Very low, product is contained in a gel inside a plastic package, covered by a semi-permeable membrane. | Wash hands thoroughly after handling.  Read label before use.  Avoid direct contact of the permeable membrane with clothes, fabrics and plastics.  Use only as directed  Do not use near food, drink and animal feedingstuffs.  Use only in positions inaccessible to children and animals, in particular cats.  No application in rooms, where fish tanks and terrariums are present | Acceptable: expected exposure is negligible. |

All substances that trigger H317 classification are part of the included fragrance components. H317 classification triggers the use of gloves. According to the intended use 2 unit are placed in drawers. The packaging is composed of a plastic pack, sealed with a permeable plastic membrane covered with a polyester coated aluminium foil, which can be removed to activate the product. In this way, the dermal exposure is limited to only the fingertips to the plastic membrane when the foil is removed. The product is efficacious for 12 weeks. Therefore, even if multiple drawers/closets are treated in a home, the exposure is considered infrequent. Furthermore, even if more closets are treated, not at the same day, the exposure is considered infrequent. Additionally, in the intended use it is included that hands need to be washed thoroughly after handling. Considering this, the exposure is considered acceptable without the use of gloves.

**Conclusion**

The risk assessment for the active, transfluthrin, shows that consumer exposure is within acceptable levels following the directed use of moth gel. Both routes of exposure, i.e. dermal and inhalation, result in an estimated uptake of approximately 2% or less of the relevant AEL or AEC.

The risk of local effects is adequately mitigated with the use of appropriate hazard and precautionary phrasing on the product label.

***Risk for the general public***

Not Relevant

eCA remark: People entering a room in which Moth Gel Family is used, could be indirectly exposed via inhalation to transfluthrin. However, the indirect exposure is much lower than the exposure assessed for the non-professional user. It is assumed that an adult (60 kg) is exposed every day to this concentration during 5 minutes. Although longer exposure times could be possible. Closets/wardrobes/dressors are not airtight and are often sited in occupied rooms (e.g. bedrooms). Persons occupying the rooms could be exposed by inhalation to transfluthrin permeating out of the dressor through gaps. Bedrooms can be occupied (e.g. little children or by people who are ill/invalid) for 24 hours per day for considerable periods. The concentration included in the closets/wardrobes/dressors is calculated to be 9.6 x 10-3 mg/m3 (see outcome assessment scenario 2) for a 4 drawers/dresser set at 0.072 m3, or 9.6 x 10-3 mg/m3 x 0.072 m3 = 6.9 x 10-4 mg. Considering a 16 m3 bedroom, a worst case concentration can be calculated of 6.9 x 10-4 mg / 16 m3 = 4.3 x 10-5 mg/m3. Considering an infant (worst case compared to adults) inhales 5.3 m3/24-hours and has a bw of 8 kg (HEAdhoc recom. 14), and internal value of = 4.3 x 10-5 mg/m3 x 5.3 m3/24-hours / 8 kg = 2.9 x 10-5 mg/kg bw/d can be derived. Considering the AEL long-term of 0.01 mg/kg bw/d, this results in 0.3% AELlong-term when an infant is considered. It should be noted that this is very worst case, as the calculation does not take into account air change of the room or any other reduction of the active substance during use (i.e. degradation, mechanical removal due to cleaning activities, ect).

In addition to the secondary inhalatory exposure, people might be exposed secondary via the dermal route via transfer from textiles being present in treated dressers. However, it is to be expected that handling textile from a treated dresser results in a lower dermal exposure compared to touching the gel directly. Transflutrin is present in the gel separated by a semi-permeable membrane that will be exposed after removal of the silver foil and dislodging from the gel and transferring to the clothes is considered to be low as direct contact of the gel with the clothes is not likely. In fact, the following sentence is included in the use instructions as a RMM: Avoid direct contact of the permeable membrane with clothes, fabrics and plastics. However, transfluthrin will be present in the air and can settle on the clothes. The concentration included in the closets/wardrobes/dressers is calculated to be 9.6 x 10-3 mg/m3 (see outcome assessment scenario 2) for a 4 drawers/dresser set at 0.072 m3. Although we do not know how this can be translated to a realistic amount on the clothing a very unrealistic worst case assessment for an infant could be performed, in which we consider that the total amount in the air settles on a single clothing item of an infant is 100% systemically available:

9.6 x 10-3 mg/ m3 x 0.072 m3 = 6.9 x 10-4 mg.

6.9 x 10-4 mg/ 8 kg = 8.6 x 10-5 mg/kg bw/d can be derived. Considering the AEL long-term of 0.01 mg/kg bw/d, this results in 0.9% AELlong-term when an infant is considered.

The combined exposure of an infant (worst case compared to an adult) by being present in a room containing treated closets and wearing clothing from that closet results in a combined %AEL long-term of 0.3% + 0.9% = 1.2%.

In conclusion, as safe use was concluded for the unprotected user (see paragraph 6.3.3), this conclusion also applies to indirect exposure. Therefore, when used according to the authorised uses, it can be concluded that no adverse health effects are expected by indirect exposure to transfluthrin as a result of the application of Moth Gel Family.

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

Not Relevant

### Risk assessment for animal health

A quantitative risk assessment for moth gel for pets is not considered necessary as the assessment performed for humans will cover companion animals as well.

As the product is to be used inside drawers and animal exposure is therefore considered very unlikely. According to the general risk mitigation measures, the product should be used only in positions inaccessible to children and animals, in particular cats and should not be applied in rooms, where fish tanks and terrariums are present

### Risk assessment for the environment

#### Effects assessment on the environment

The NL-CA received a data package on the active substance transfluthrin and has agreed to evaluate these studies.

The new ecotox endpoints for transfluthrin and metabolite TFB-COOH are included in the amended LoEP for transfluthrin PT18 containing the data submitted after active substance approval agreed by the BPC at meeting no. 24 (2018).

***Information relating to the ecotoxicity of the active substance***

| **Summary table for aquatic toxicity data** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Species** | **Substance** | **Timescale** | **End point** | **Results** | **Reference** |
| *Fish* | | | | | |
| *Oncorhynchus mykiss* | transfluthrin | Acute | LC50 | 0.7 µg/L | Transfluthrin Assessment Report (2014) |
| *Pimephales promelas* | transfluthrin | Chronic | NOEC | 0.399 µg/L | xxxx (2015a) (Bayer IUCLID - Transfluthrin - Update Environment Section 9.1.6.1) |
| *Oncorhynchus mykiss* | TFB-COOH[[9]](#footnote-9)[\* | Acute | LC50 | >100 mg/L | Transfluthrin Assessment Report (2014) |
| *Invertebrates* | | | | | |
| *Daphnia magna* | transfluthrin | Acute | EC50 | 1.4 µg/L | Transfluthrin Assessment Report (2014) |
| *Daphnia magna* | transfluthrin | Chronic | NOEC | 0.0175 µg/L | xxxx (2015b) (Bayer IUCLID - Transfluthrin - Update Environment Section 9.1.6.2) |
| *Daphnia magna* | TFB-COOH | Acute | EC50 | >100 mg/L | Transfluthrin Assessment Report (2014) |
| *Daphnia magna* | Trans-DCVA\*\* | Acute | EC50 | 6.42 mg/L | Transfluthrin Assessment Report (2014) |
| *Algae (growth inhibition)* | | | | | |
| *Scenedesmus subspicatus* | transfluthrin | Acute | ErC50 | >100 µg/L | Transfluthrin Assessment Report (2014) |
| Chronic | NOErC | 50 μg/L |
| *Pseudokirchneriella subcapitata* | TFB-COOH | Acute | 96h ErC50 | >100 mg/L | xxxx (2015c) (Bayer IUCLID - Transfluthrin - Update Environment Section 9.1.3) |
| Chronic | NOErC | 3.05 mg/L |
| *Sediment organisms* | | | | | |
| *Chironomus riparius* | transfluthrin | Chronic emergence rate | NOEC | 0.164 mg/kg dw sed | xxxx (2015) (Bayer IUCLID - Transfluthrin - Update Environment Section 9.1.9) |
| EC10 | 0.302 mg/kg dw sed |
| *Lumbriculus variegatus* | transfluthrin | Chronic | NOEC | 2.21 mg/kg dw sed | xxxx (2015) (Bayer IUCLID - Transfluthrin - Update Environment Section 9.1.9) |
| EC10 | 1.77 mg/kg dw sed |
| *Microorganisms* | | | | | |
| Respiration activated sludge | transfluthrin | Acute | NOEC | 57 μg/L (water solubility) | Transfluthrin Assessment Report (2014) |
| EC50 | >10000 mg/L |

\* 2,3,5,6-Tetrafluorobenzyl acid (TFB-COOH)

\*\* 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid (DCVA, also named permethric acid)

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – STP Microorganisms** | |
| Value/conclusion | PNECSTP for transfluthrin: 0.057 mg/L |
| Justification for the value/conclusion | As a worst-case estimate, the NOEC for respiration of activated sludge is set to the water solubility of 0.057 mg/L. As stated in the Transfluthrin Assessment Report (2014), application of an assessment factor of 1 to this value, leads to a PNECSTP for transfluthrin of 0.057 mg/L. 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. The lowest PNECSTP of 0.057 mg/L will be used in the risk assessment. |

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| --- | --- | --- | --- | --- | --- |
| **Conclusion used in Risk Assessment - Aquatic Toxicity** | | | | | |
| Value/conclusion | | PNECaquatic for transfluthrin: 1.75 ng/L  PNECaquatic for 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH): >0.1 mg/L  PNECaquatic 2,3,5,6-Tetrafluorobenzyl alcohol (TFB-OH): >0.1 mg/L  PNECaquatic 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid (DCVA; also named permethric acid): 0.0064 mg/L | | | |
| Justification for the value/conclusion | | During the BPD review of transfluthrin, only studies on acute toxicity to aquatic organisms were available. Accordingly, a PNECaquatic of 0.7 ng/L was determined on the lowest acute LC50 of 0.7 μg/L for fish (*Oncorhynchus mykiss*) with an assessment factor of 1000 (Transfluthrin Assessment Report, 2014).  However, further chronic studies (reproduction toxicity study on daphnia and ELS test with fish) have subsequently been conducted with transfluthrin. The lowest chronic endpoint is a NOEC 17.5 ng/L reported for a 21day flow-through daphnia reproduction study. Since chronic studies covering three trophic levels are available, it is appropriate to apply an assessment factor of 10 to this endpoint. Accordingly, the revised PNECaquatic for transfluthrin is proposed to be 1.75 ng/L.  As discussed in the Assessment Report for transfluthrin, the environmentally relevant metabolites in the aquatic compartment are 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH), 2,3,5,6-Tetrafluorobenzyl alcohol (TFB-OH), as well as 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid (trans-DCVA). An additional study was provided (and agreed at WGIII-2018 and BPC 24 (2018); please refer to the studies in the fate section below), in which also two metabolites of trans-DCVA were identified; cis-OH-DCVA and trans-OH-DCVA. In the case of the metabolite TFB-COOH, two acute toxicity studies were available during the BPR review (fish and daphnia), both with LC50/EC50 greater than 100 mg/L. Accordingly, a PNECaquatic of >0.1 mg/L was determined, by applying an assessment factor of 1000. A further algal toxicity study with *Pseudokirchneriella subcapitata* has been conducted. However, since the acute EC50 was greater than 100 mg/L, no change to the existing PNEC aquatic is proposed.  No ecotoxicity data are available for the metabolite TFB-OH but, as defined in the Transfluthrin Assessment Report (2014) a PNECaquatic of >0.1 mg/L is proposed, in view of the chemical structure similarity with TFB-COOH and the comparable physico-chemical characteristics.  In the AR of transfluthrin for DCVA an acute LC50 for daphnia of 25 mg/l was reported for 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid (DCVA; also named permethric acid). Considering the incomplete data set QSAR (Epiwin) calculations based on baseline toxicity were performed resulting in a fish 96 hr LC50 of 9.97 mg/L, a Daphnia 48 hr LC50 of 6.420 mg/L and a green algae EC50 of 8.101 mg/L. Accordingly, a PNECaquatic of 0.0064 mg/L was determined for trans-DCVA, by applying an assessment factor of 1000.  For the metabolites cis-OH-DCVA and trans-OH-DCVA, no ecotoxicity data are available. | | | |
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| **Conclusion used in Risk Assessment - Aquatic Sediment Toxicity** | |
| Value/conclusion | PNECsediment for transfluthrin: 0.36µg/kg ww sediment (equivalent to 1.64µg/kg dw sediment) |
| Justification for the value/conclusion | During the BPD review of transfluthrin, no specific studies concerning potential toxicity to sediment dwelling organisms were available. As a result, the PNECsediment was derived on the basis of the available aquatic ecotoxicty data using the equilibrium partitioning method (EPM). In order to take account of uncertainty applying the EPM to substance with Log Kow>5, an additional safety factor was applied.  Further chronic studies have subsequently been conducted with transfluthrin. An OECD 225 study with *Lumbriculus variegatus* reported a NOEC 2.21 mg/kg dw sediment. However, an OECD 218 study with *Chironomus Riparius* showed relatively greater sensitivity. A statistically significant difference was calculated for the highest test concentration with emergence, i.e. 0.352 mg a.s./kg dw sediment, compared to the pooled controls, resulting in a NOEC of 0.164 mg a.s./kg dw sed.  Since chronic studies covering two trophic levels are available, it is appropriate to apply an assessment factor of 50 to the NOEC reported for chironomid. A further AF of 2 is added because in the chironomus study the test organisms were fed with fresh food, thus theoretically limiting the exposure to the test substance via sediment/particle ingestion. Therefore, according to the conclusion in the Environment Working Group Meeting IV 2017 (ECHA, 2017a) the PNEC sediment value is 1.64 µg/kg dw.  In the case of the metabolites TFB-COOH, TFB-OH and trans-DCVA, the risk assessment for sediment is covered by that for water, as defined in the Transfluthrin Assessment Report (2014). |

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| **Summary table for terrestrial toxicity data** | | | | | | |
| **Species** | **Substance** | **Timescale** | **End point** | | **Endpoint\*** | **Reference** |
| Earthworms (*Eisenia fetida*) | transfluthrin | Acute | LC50 | | 184 mg/kg dw soil (10% OM) | Transfluthrin Assessment Report (2014) |
| Earthworms (*Eisenia fetida*) | transfluthrin | Chronic | NOEC | | 10 mg/kg dw soil (10% OM) | xxxx (2014a) (Bayer IUCLID - Transfluthrin - Update Environment, Section 9.2.2) |
| *Collembola (folsomia candida)* | transfluthrin | Reproduction | NOEC | | 18 mg/kg dw soil (5 % OM) | xxxx (2014b) (Bayer IUCLID - Transfluthrin - Update Environment, Section 9.5) |
| Soil microorganisms (Nitrogen mineralisation) | transfluthrin | Chronic | EC10 | | 5.24 mg/kg dw soil (3.4 % OM) | Xxxx  (2014) (Bayer IUCLID - Transfluthrin - Update Environment, Section 9.2.1) |
| Non-target terrestrial plants | transfluthrin | Seedling emergence and growth | EC50  NOEC | | 50 mg/kg dw soil (2% OC) | xxxx (2015) (Bayer IUCLID - Transfluthrin - Update Environment, Section 9.2.10) |
|  |  |  |  |  |  |  |

\* According to infobox 9 of the Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C (version 1, 2015) all effect concentrations from terrestrial plants and terrestrial microorganisms should normally be converted to the standard organic matter (see Table 5) before choosing one effect value for derivation of PNEC. For non-ionic organic compounds the normalization is considered appropriate assumed that the binding behaviour of the substance in question is predominantly driven by its log Kow, and that organisms (except earthworm) are exposed predominantly via pore water.

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| **Conclusion used in Risk Assessment – Terrestrial Toxicity Data** | |
| Value/conclusion | PNECsoil for transfluthrin: 0.088 mg/kg ww soil (equivalent to 0.1mg/kg dw soil)  PNECsoil for 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH): 0.012 mg/kg ww  PNECsoil for trans-DCVA: 0.0128 mg/kg ww soil. |
| Justification for the value/conclusion | During the BPD review of transfluthrin, only the earthworm acute study was available for terrestrial organisms, therefore the PNECsoil of 6.17E-04 mg/kg ww soil was derived from the PNECaquatic using the Equilibrium Partitioning Method (EPM).  Since the approval decision, additional studies have been conducted on earthworm (sub-lethal effects), collembolan (reproduction), micro-organisms (nitrogen transformation) and non-plants (seedling emergence and growth).  Following discussion at Environment Working Group Meeting IV 2017, it was agreed that the PNECsoil should be based on the endpoint for nitrogen mineralization of 5.24 mg/kg dw standard soil. Since chronic studies covering at least two trophic levels are currently available, an assessment factor of 50 is applied to this endpoint, giving a PNEC value of 0.10 mg/kg dw (0.088 mg/kg ww).  Regarding metabolites, an additional study was provided (and agreed at WGIII-2018 and by the BPC at meeting no. 24 (2018)), which demonstrated formation of the metabolite 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH). In addition, formation of the metabolite DCVA was still also expected. Hence, for soil, TFB-COOH and trans-DCVA are considered as the environmentally relevant metabolites.  In the case of the metabolites 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH) and permethric acid (trans-DCVA) no data have been generated on terrestrial organisms. Therefore, the Equilibrium Partitioning Method is used to derive the PNECsoil based on the PNECaquatic.  Concerning TFB-COOH taking account of the PNECaquatic of > 0.1 mg/L, water solubility of 6110 mg/L, vapour pressure of 0.44 Pa and an assumed worst case Koc of 0 L/kg, the PNECsoil was calculated to be 0.012 mg/kg ww.  For trans-DCVA the PNECsoil was calculated to be 0.0128 mg/kg ww; based on the water solubility of 127.6 mg/L, vapour pressure of 2.60 Pa and a log Koc of 2.025 (parameters estimated using EPIsuite; please refer to Annex 2.3) |

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| --- | --- | --- | --- | --- | --- |
| **Summary table for Secondary Poisoning *via* the Food Chain** | | | | | |
| **Species** | **Substance** |  | **End point** | **Results** | **Reference** |
| Rat | transfluthrin | Oral Diet | NOEC  2-generation | 200 mg/kg feed | Transfluthrin Assessment Report (2014) |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Secondary Poisoning *via* the Food Chain** | |
| Value/conclusion | PNECoral, mammals for transfluthrin: 6.67 mg/kg feed |
| Justification for the value/conclusion | The PNECoral for secondary poisoning of mammals is derived by applying an assessment factor of 30 to the chronic NOEC of 200 mg/kg feed, resulting in a PNECoral,mammal of 6.67 mg/kg feed. As stated in the Transfluthrin Assessment Report, only acute data were available. In the absence of short-term or long-term toxicity data for birds, a PEC/PNECoral,bird cannot be derived. |

***Summary of PNEC values for the active substance***

The following PNEC values have been derived from data on the active substance/metabolites and also from studies performed on the active substance/metabolites which were completed subsequent to the issue of the Transfluthrin Assessment Report (2014). During the product authorisation process of products with transfluthrin ecotoxicity data for aquatic and terrestrial organisms have been submitted as refinement. These data have been evaluated and agreed upon at different WGs in the period of 2016 to 2018 and at the BPC meeting no. 24 (2018), resulting in harmonised updated PNECs for the aquatic and terrestrial environment.

|  |  |  |
| --- | --- | --- |
| **Summary table for PNECs used in Risk Assessment** | | |
| **Parameters** | **Concentration** | **Notes** |
| Transfluthrin | | |
| PNECSTP | 0.057 mg/L | As specified in Transfluthrin Assessment Report (2014) |
| PNECwater | 1.75E-06 mg/L | Taking into account new information on active substance as agreed by the BPC at meeting no. 24 (2018). |
| PNECsediment | 3.6E-04mg/kg ww sediment | Taking into account new information on active substance as agreed by the BPC at meeting no. 24 (2018). |
| PNECsoil | 0.088 mg/kg ww soil | Taking account of new information on active substance as agreed by the BPC at meeting no. 24 (2018). |
| PNECoral, mammals | 6.67 mg/kg feed | As specified in Transfluthrin Assessment Report (2014) |
| 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH) | | |
| PNECwater | >0.1 mg/L | As specified in Transfluthrin Assessment Report (2014) |
| PNECsoil | 0.012 mg/kg ww soil | Calculated using EPM |
| 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid (DCVA; also named permethric acid)\* | | |
| PNECwater | 0.0064 mg/L | As specified in Transfluthrin Assessment Report (2014) |
| PNECsoil | 0.0128 mg/kg ww soil | Calculated using EPM |

In view of the chemical structure similarity and the comparable physico-chemical characteristics of TFB-OH and TFB-COOH (as also discussed in the Assessment Report for transfluthrin (2014)), the risk of TFB-OH for the aquatic compartment is covered by the risk assessment for TFB-COOH. Hence, the PNECwater for TFB-OH is not included.

Regarding the metabolites of trans-DCVA, cis-OH-DCVA and trans-OH-DCVA, no ecotoxicity data are available. QSAR data (please refer to Annex 2.3) indicate that these metabolites are much less toxic than trans-DCVA (with L/EC50 values from 90 mg/L; more than nine times higher than values estimated for trans-DCVA). Therefore, no PNEC values are included here and the risk for these metabolites is covered by the risk assessment for trans-DCVA.

**Air compartment**

The estimated half-life time in air is 2.4 days.

***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***

In accordance with the Guidance on the BPR: Volume IV. Part A Chapter II: Requirements for Active Substances Version 1.1 November 2014 as there are valid data available on each of the components in the mixture and synergistic effects between the components are not expected, classification of the mixture has been made according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

Details of the composition of the meta-SPCs of the Moth Gel Family are presented in the confidential annex 3.6. In the case of the active substance Transfluthrin, the lowest acute aquatic toxicity endpoint is an LC50 of 0.7 μg/L for fish. The lowest chronic aquatic toxicity endpoint is a NOEC of 17.5 ng/L reported for a daphnia reproduction study. In accordance with the guidance on application of the CLP criteria, the classification of transfluthrin is therefore Aquatic Acute 1 (M-factor 1000) H400, Aquatic Chronic 1 (M-factor 1000) H410.

For example, taking the concentration of Transfluthrin into account, the minimum environmental classification of the meta SPCs of the Moth Gel Family can be calculated as follows:

Acute Environmental Classification of Product:

Acute 1 x M ≥25% = Acute 1; (0.15 x 1000) = 150

Chronic Environmental Classification of Product:

Chronic 1 x M ≥ 25% + chronic 1; (0.15 x 1000) = 150

Taking into account also the co-formulants relevant for the environment, the environmental classification of the meta SPCs of the Moth Gel Family according to CLP-Regulation (EC) No 1272/2008 is Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410)*.*

***Further Ecotoxicological studies***

***Information relating to the Ecotoxicity of Substance of Concern***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Product variant** | **SoC** | **Species** | **Test** | **Result** | **Reference** |
| Lavender | 2-methylundecanal [CAS no. 110-41-8/EC no. 203-765-0] | *Oncorhynchus mykiss* | 96 hr acute | LC50 = 0.35 mg/L | REACH Dossier |
| *Daphnia magna* | 48 hr acute | LC50 = 0.21 mg/L |
| *Daphnia magna* | 21 d chronic | NOEC = 33 ug/L |
| *Pseudokirchneriella subcapitata* | 72 hr acute/chronic | EC50 = 0.18 mg/L  NOEC = 0.089 mg/L |
| Microorganisms | Ready biodegradability | NOEC = 100 mg/L |
| Rats | 90 d sub-chronic oral | NOAEL 1046 mg/kg bw/day |
| Lavender | Precyclemone b [CAS no. 52475-86-2 /EC no. 915-712-5] | *Cyprinus carpio* | 96 hr acute | LC50 >1.9 mg/L | REACH Dossier |
| *Daphnia magna* | 48 hr acute | LC50 = 0.15 mg/L |
| *Pseudokirchneriella subcapitata* | 72 hr acute/chronic | EC50 = 1.8 mg/L  EC10 = 0.19 mg/L |
| Microorganisms | No data | No data |
| Lavender/ Cedar | 3,5,5-trimethylhexyl acetate [CAS no. 58430-94-7/EC no. **261-245-9**] | *Pimephales promelas* | 96 hr acute | LC50 = 7.7 mg/L | REACH Dossier |
| *Daphnia magna* | 48 hr acute | EC50 = 5.4 mg/L |
| *Pseudokirchneriella subcapitata* | 72 hr acute/chronic | ErC50 >3.8 mg/L  ErC10 = 0.65 mg/L  NOEC < 0.51 mg/L |
| Microorganisms | Activated sludge | NOEC = 100 mg/L |
| Lavender/ Cedar | Menthanyl acetate [CAS no. 58985-18-5 /EC no. 939-728-7] | *Danio rerio* | 96 hr acute | LC50 = 2.27 mg/L | REACH Dossier |
| *Daphnia magna* | 48 hr acute | EC50 = 4.63 mg/L |
| *Pseudokirchneriella subcapitata* | 72 hr acute/chronic | EC50 = 2.73 mg/L  EC10/NOEC = 0.939 mg/L |
| Microorganisms | Activated sludge | EC50 = 264 mg/L |
| Rats | 63 d acute oral | NOAEL 298.8 mg/kg bw/day |  |
| Cedar | Pentyl salicylate [CAS no. 2050-08-0/87-20-7/EC no. 218-080-2] | *Danio rerio* | 96 hr acute | LC50 = 1.34 mg/L | REACH Dossier |
| *Daphnia magna* | 48 hr acute | LC50 = 0.88 mg/L |
| *Pseudokirchneriella subcapitata* | 72 hr acute/chronic | EC50 = 0.77 mg/L  EC10/NOEC = 0.2 mg/L |
| Microorganisms | Ready biodegradability | EC50 = 100 mg/L |
| Rats | 90 d sub-chronic oral | NOEL 360 mg/kg bw/day |  |
| Cedar | Alpha-cedrene [CAS no. 469-61-4] | Fish | 96 hr acute | LC50 = 0.073 mg/L | Predicted using ECOSAR v. 1.11 |
| Daphnia | 48 hr acute | LC50 = 0.059 mg/L |
| Algae | 96 hr | EC50 = 0.182 mg/L |
| Microorganisms | No data | No data | No data |
| Lavender/ Cedar | Diphenyl ether [CAS no. 101-84-8] | *Oncorhynchus mykiss* | 96 hr acute | LC50 = 4.2 mg/L | REACH Dossier |
| *Daphnia magna* | 48 hr acute | EC50 = 1.96 mg/L |
| *Pseudokirchneriella subcapitata* | 72 hr acute/chronic | ErC50 = 0.455 mg/L  ErC10/NOEC = 0.24 mg/L |
| Microorganisms | Activated sludge | EC50 > 100 mg/L |
| Lavender | 3,7-dimethylocta-1,3,6-triene [CAS no. 13877-91-3] | Fish | No data | No data | REACH Dossier |
| *Daphnia magna* | 48 hr acute | EC50 = 1.47 mg/L |
| *Pseudokirchneriella subcapitata* | 48 hr acute/chronic | EC50 = 0.342 mg/L  ErC10 = 0.274 mg/L |
| Microorganisms | No data | No data |

***Summary of PNEC values for substance of concern***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table for PNECs used in Risk Assessment** | | | |
| **Parameters** | **Concentration** | | **Notes** |
| **2-methylundecanal [CAS no. 110-41-8]** | | | |
| PNECSTP | 10 mg/L | | AF = 10 |
| PNECwater | 6.60E-04 mg/L | | AF = 50 |
| PNECsediment | 5.76E-02 mg/kg ww | | EPM  Koc = 3981 L/kg  Log Pow = 4.9 |
| PNECsoil | 4.64E-02 mg/kg ww | | EPM  Koc =3981 L/kg |
| PNECoral | 116 mg/kg food | | AF =90 |
| **Precyclemone b [CAS no. 52475-86-2]** | | | |
| PNECSTP | n/a | | PNECSTP cannot be derived due to lack of data |
| PNECwater | 1.50E-04 mg/L | | AF = 1000 |
| PNECsediment | 1.08E-02 mg/kg ww | | EPM  Koc = 3280 L/kg  Log Pow = 4.8 |
| PNECsoil | 8.70E-03 mg/kg ww | | EPM  Koc = 3280 L/kg |
| **3,5,5-trimethylhexyl acetate [CAS no. 58430-94-7]** | | | |
| PNECSTP | 10 mg/L | | AF = 10 |
| PNECwater | 7.70E-03 mg/L | | AF = 1000 |
| PNECsediment | 6.29E-01 mg/kg ww | | EPM  Koc = 3724 L/kg  Log Pow = 4.6 |
| PNECsoil | 5.07E-01 mg/kg ww | | EPM  Koc = 3724 L/kg |
| **Menthanyl acetate [CAS no. 58985-18-5]** | | | |
| PNECSTP | 1.7 mg/L | | AF= 10 |
| PNECwater | 2.27E-03 mg/L | | AF = 1000 |
| PNECsediment | 5.52E-02 mg/kg ww | | EPM  Koc = 1081 L/kg  Log Pow = 4.26 |
| PNECsoil | 4.36E-02 mg/kg ww | | EPM  Koc = 1081 L/kg |
| PNECoral | 19.92 mg/kg food | | AF =300 |
| **Pentyl salicylate [CAS no. 2050-08-0/87-20-7]** | | | |
| PNECSTP | | 10 mg/L | AF = 10 |
| PNECwater | | 7.7E-04 mg/L | AF = 1000 |
| PNECsediment | | 8.45E-02 mg/kg ww | EPM  Koc = 5012 L/kg  Log Pow = 4.4 |
| PNECsoil | | 6.82E-02 mg/kg ww | EPM  Koc = 5012 L/kg |
| PNECoral | | 80 mg/kg food | AF =90 |
| **Alpha-cedrene [CAS no. 469-61-4]** | | | |
| PNECSTP | | n/a | PNECSTP cannot be derived due to lack of data |
| PNECwater | | 5.90E-05 mg/L | AF = 1000 |
| PNECsediment | | 1.23E-02 mg/kg ww\* | EPM  Koc = 95719 L/kg  Log Pow = 5.74 |
| PNECsoil | | 9.96E-03 mg/kg ww | EPM  Koc = 95719 L/kg |
| **Diphenyl ether [CAS no. 101-84-8]** | | | |
| PNECSTP | | 10 mg/L | AF = 10 |
| PNECwater | | 0.005 mg/L | AF = 1000 |
| PNECsediment | | 0.22 mg/kg ww | EPM  Koc = 1960 L/kg  Log Pow = 4.21 |
| PNECsoil | | 0.17 mg/kg ww | EPM  Koc = 1960 L/kg |
| **3,7-dimethylocta-1,3,6-triene [CAS no. 13877-91-3]** | | | |
| PNECSTP | | n/a | PNECSTP cannot be derived due to lack of data |
| PNECwater | | 3.42E-04 mg/L | AF = 1000 |
| PNECsediment | | 0.0361 mg/kg ww\* | EPM  Koc = 48560 L/kg (estimated from log Pow with KOCWIN)  Log Pow = 5.4 |
| PNECsoil | | 0.029 mg/kg ww | EPM  Koc = 48560 L/kg (estimated from log Pow with KOCWIN) |

\* Additional safety factor of 10 applied, since substance has a Log Kow >5 and PNECsediment was determined using the Equilibrium Partitioning Method

***Screening for endocrine disrupting potential***

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders). It means that ED hazard assessment should be included in the PAR.

For the active substance an ED assessment is not required, because for active substances which have been approved, the EU assessment in the assessment report should be followed. However, a screening for co-formulants contained in the meta SPCs of the Moth Gel Family should be performed. As also discussed in the confidential Annex, a screening for endocrine disruption potential was performed for the meta SPCs.

In addition to the databases included in the screening as discussed in the confidential annex, the eCA NL also consulted the following databases for more specifically regarding the environment:

• Identified as ED by the United Nations Environment (July 2017) Programme (http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc\_report2.pdf?sequence=1&isAllowed=y and https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc\_report2\_factsheet.pdf?sequence=1&isAllowed=y)

•List of endocrine disrupting chemicals, by Danish Centre on endocrine disrupters (http://cend.dk/files/DK\_ED-list-final\_2018.pdf )

•Strategic Programs on Environmental Endocrine Disruptors '98 (SPEED '98), by the Government of Japan, Ministry of the Environment (https://www.env.go.jp/en/chemi/ed/speed98/sp98t3.html ).

None of the co-formulants included in the meta SPCs of the Moth Gel Family were identified as having ED potential. Therefore, ED potency of co-formulants was not examined further.

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No testing required |
| Justification | This is not a core data requirement and no further data are available. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No testing required |
| Justification | The products of the Moth Gel Family are not in the form of a bait or granules and therefore this endpoint does not apply. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No testing required |
| Justification | The products of the Moth Gel Family are not in the form of a bait or granules and therefore this endpoint does not apply. |

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

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No testing required |
| Justification | The products of the Moth Gel Family are intended to be used indoors and will not, therefore, have an effect on a large proportion of a specific habitat. No further scientific investigation is therefore considered necessary. |

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

The products of the Moth Gel Family are used in indoor domestic situations to protect clothing from moth damage. The products are placed in bedroom drawers and the active substance releases through passive diffusion. A proportion of the products may deposit on floors where it will be subjected to either dry cleaning and released to solid waste or wet cleaning leading to release to STP. Subsequent emission can occur to air, STP, water and sediment, as well as soil and groundwater via application of sewage sludge to agricultural land.

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

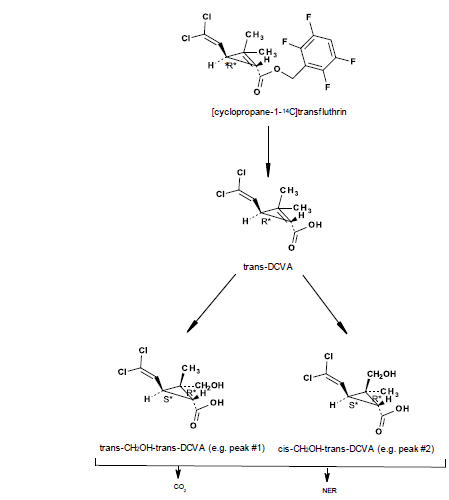
After finalization of Assessment Report for transfluthrin (2014) the applicant provided additional data, including new studies on aerobic degradation of transfluthrin in soil and on biodegradation in the active sewage sludge. These studies have been evaluated by eCA NL and agreed at WGIII-2018 and by the BPC (meeting 24, 2018).

**Biodegradation in active sewage sludge**

Aerobic degradation of transfluthrin in sewage sludge was investigated in sludge from a sewage treatment plant (Monheim, Germany) that mainly receives domestic wastewater. The test was performed according to OECD 314 B. Transfluthrin underwent both primary and ultimate biodegradation over the course of the 8-day study. Mass balance of the biotic sludge system ranged from 96.8 to 99.5 of the applied radioactivity (% AR). Ultimate biodegradation (conversion to CO2) occurred at 21.3% AR. Three degradation products were identified with the following maximum occurrences:

* trans-DCVA with 64.0% AR after 6 hrs;
* trans-OH-DCVA with 5.8% AR after 30 hrs;
* cis-OH-DCVA 60.4% AR at days 6,

The total unidentified residues amounted to a maximum of 3.4% AR, and no single component exceeded 1.5% AR at any sampling interval. As transfluthrin was only labelled at the phenyl-moiety, the fluorinated benzene moiety that results in the metabolite 2,3,4,6-tetrafluorobenzyl alcohol (NAK 4452) and 2,3,5,6-tetrafluorobenzoic acid (TFB-COOH; also called NAK 4723) were not addressed in the study. The proposed pathway is shown below.



Trans-DCVA may be regarded as transient and trans-OH-DCVA (also named trans-CH2OH-trans-DCVA) degrades rapidly as well. Cis-OH-DCVA (also named cis-CH2OH-trans-DCVA) is however persistent in sewage sludge. TFB-OH (also named NAK 4452) and TFB-COOH (also named NAK 4723) must be regarded as persistent with a formation fraction of one as one mole transfluthrin produces one mole of these metabolites, as these metabolites were not addressed in the study. The DT50 values and formation fractions are summarised below.

**Degradation of transfluthrin in activated sludge**

| Substance | Matrix | Method | Condition | Duration  [d] | DT50  [d] | Formation fraction | Model | Reference |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| transfluthrin | Acticated sludge | OECD 314B | 146 µg/L  21.7±0.8°C | 8 | 0.284 | - | FOMC | xxxx, 2017 |
| trans-DCVA | 0.897 | 0.968 | SFO |
| cis-OH-DCVA1 | >10000 | 0.619 | SFO |
| trans-OH-DCVA2 | 0.341 | 0.267 | SFO |
| TFB-OH3 | >10000 | 1 | - |
| TFB-COOH4 |  |  |  |  | >10000 | 1 | - |  |

1 also named trans-CH2OH-trans-DCVA

2 also named cis-CH2OH-trans-DCVA

3 Also called NAK 4452

4 Also called NAK 4723

**Biodegradation in soil**

Degradation of transfluthrin was studied in four different German soils under laboratory aerobic conditions in the dark at 20±2°C according to OECD 307. The test substance was radiolabelled at the methyl-group of the tetrafluorophenyl-moiety of the molecule.

The applied concentration (45 μg/kg soil dry weight) due to analytical reasons multiple times higher than the estimated concentration in soil resulting from the intended biocidal uses. The test was performed in static systems consisting of Erlenmeyer flasks each containing 50 g soil (dry weight equivalents) and equipped with traps (permeable for oxygen) for the collection of carbon dioxide and volatile organic compounds. Duplicate samples were processed and analysed 0, 0.25, 1, 2, 3, 7 and 14 days after treatment (DAT).

Mean mass balances were 87.5% applied radioactivity (AR) for soil AX (range from 82.2 to 100.5% AR, abbreviations explained in the table below), 93.7% AR for soil DD (range from 88.2 to 103.4% AR), 91.6% AR for soil HH (range from 85.2 to 102.2% AR) and 88.3% AR for soil WW (range from 82.5 to 102.7% AR). The maximum amount of carbon dioxide was 68.5, 78.3, 72.5 and 72.9% AR at study end (DAT-14) in soil AX, DD, HH and WW, respectively. Formation of volatile organic compounds (VOC) was insignificant as demonstrated by values of ≤ 0.2% AR at all sampling intervals for all soils. The losses of radioactivity observed throughout the study course were investigated by the applicant in additional tests to assure that they were not caused by unknown volatile degradation products. Considering their analysis, and the extensively mineralisation of transfluthrin the applicant concluded that the insufficient mass balances were caused by losses of carbon dioxide during sample processing.

Non-extractable residues (NER) increased from DAT-0 to DAT-7 from 1.1 to 8.9% AR in soil AX, from 2.3 to 12.1% AR in soil DD, from 1.5 to 10.8% AR in soil HH and from 1.2 to 10.0% AR in soil WW. From DAT-7 to DAT-14 NER slightly decreased to 7.6% AR in soil AX, 10.4% AR in soil DD, 8.9% AR in soil HH and 8.6% AR in soil WW.

Besides the formation of carbon dioxide, one degradation product, i.e. NAK 4723 (2,3,5,6-tetrafluorobenzoic acid (TFB-COOH), BCS-AA52185), was identified in all investigated soils and with a maximum occurrence of 36.5% AR at DAT-2 in soil HH.

Recalculation of half-lives and formation fractions (f.f.) using CAKE 3.2 indicate that the visual fit of the degradation curve as well as the distribution of residuals were considered not acceptable for SFO-models in case of the parent. Although 10% of initial was reached in all soils during the study period, FOMC was selected only for the LH soil, whereas for the other three soils visual fit for FOMC was not better than for SFO. Consequently, DFOP was chosen and the modelling endpoint was derived from the slow phase of the degradation curve. In all soils, SFO was applied to model the degradation of NAK 4723.

**Table: Modelling endpoints of transfluthrin and NAK 4723 (also called TFB-COOH) as well as formation fractions**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Model** | **χ2** | **DT50-modelling (20°C)** | **DT50-modelling (12°C)** | **ff** |
| **Laacher Hof (LH)** | | | | | |
| Parent | FOMC | 3.98 | 1.93 | 3.66 |  |
| NAK 47231 | SFO | 13.8 | 1.93 | 3.66 | 0.6231 |
| Whole model |  | 7.68 |  |  |  |
| **Dollendorf II (DD)** | | | | | |
| Parent | FOMC | 4.38 | 1.29 | 2.45 |  |
| NAK 47231 | SFO | 10.5 | 1.79 | 3.40 | 0.6130 |
| Whole model |  | 7.17 |  |  |  |
| **Höfchen** | | | | | |
| Parent | DFOP | 0.87 | 18.3 | 34.71 |  |
| NAK 47231 | SFO | 10.1 | 1.6 | 3.03 | 0.7512 |
| Whole model |  | 6.03 |  |  |  |
| **Wurmwiese (WW)** | | | | | |
| Parent | FOMC | 6.46 | 1.28 | 2.4 |  |
| NAK 47231 | SFO | 16.1 | 1.53 | 2.9 | 0.4886 |
| Whole model |  | 10.0 |  |  |  |
| **DT50 for PEC  (geometric mean)** | Parent: 2.76  NAK 4723: 1.71 | | | Parent: 5.17 NAK 4723: 3.23 |  |
| **f. f. for PEC  (arithmetic mean)** |  | | |  | **0.6190** |

1 Alternative name is TFB-COOH

It has to be acknowledged that the approach taken is not strictly in accordance with the FOCUS kinetics guidance. It is however clearly conservative for parent, with the modelled line over predicting parent throughout the majority of the study duration for all 4 soils. It is accepted that the selection of modelling endpoints for parent and linked metabolites is complex when the parent displays a tendancy to biphasic degradation. The use of conservative parent DT50 values in this case (i.e. FOMC DT90/3.32 for 3 soils and DFOP k2 rate constant for 1 soil) is acceptable in this case because the peer review considered it more important to have a conservative assessment of the parent active substance (rather than to try and more accurately model the metabolites). This is likely to be justifiable in this case because of the greater toxicity of the active substance relative to its metabolites.

Note that the study performed with [methylene-14C]transfluthrin does not provide any information about the degradation of the known metabolite DCVA (3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylic acid), representing the second primary metabolite formed after cleavage of the esterbound. Since DCVA is formed at the same amount as NAK 4723 it should be considered in the groundwater assessment as well. Half-life for DCVA is available from a study submitted for cyfluthrin. In this study, degradation of all four isomers of DCVA was investigated in two soils. For PEC calculation, the worst case DT50 of 174.8 days at 12°C (61.8 days at 20°C) was used.

***Leaching behaviour (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | No testing required |
| Justification | A leaching test is not required for these type of products, as the products are not used outdoors. |

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

No further data are required.

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

No further data are required.

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

No further data are required.

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

The biocidal products will not be sprayed. Not relevant.

***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)***

The biocidal products will not be sprayed. Not relevant.

#### Exposure assessment

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 18 |
| Assessed scenarios | Consumer use of insecticide diffuser products |
| ESD(s) used | OECD Series on Emission Scenario Documents No. 18: Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional users. OECD, Paris. 17th July 2008. |
| Approach | Consumption-based approach, taking account of product-specific dose rate[[10]](#footnote-10) |
| Distribution in the environment | Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Assessment and Evaluation. European Chemicals Agency, Report no. ECHA-17-G-23-EN, Helsinki, Finland, 2017.  Technical Agreements for Biocides Environment (ENV). Version 2.1, December 2019. European Chemicals Agency, Helsinki, Finland. |
| Groundwater simulation | Not relevant |
| Confidential Annexes | YES: In the confidential Annex 3.6 business confidential information concerning composition of the products is included |
| Life cycle steps assessed | Production: No  Formulation: No  Use: Yes  Service life: No |
| Remarks | The products are sold in a ready to use form; therefore, the mixing/loading step identified in the Emission Scenario Document for PT18 (OECD, 2008) is not relevant for these products. There is no differentiation between use and service life, so separate assessments are not required for these steps. |

***Emission estimation***

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks (S/D/O/P)** |
| Scenario:Consumer use of insecticide diffuser products | | | |
| Quantity of product contained in the device/diffuser (Qprod ) | 60 | g | S - The product usage label/directions indicate that for a typical drawer of 0.18m3, 2 sachets of moth gel containing 3 g product each would be required. As a worst case scenario, it is assumed that 2.5 chests of drawers containing 4 drawers each (i.e. 10 drawers) are treated per household based on default number of 2.5 wardrobes per household specified in ENV 150 of the TAB (2019). This equates to a total of 20 moth gel sachets per household with a total weight of 60 g. |
| Fraction of active substance in product (FAI) | 0.0015 | [-] | S |
| Maximal duration of use of the device/diffuser (Tmax) | 2160 | h | S - The products are intended for continual use and provides protection for 3 months (90 days) |
| Duration of use per day (Tday) | 24 | h.d-1 | P (Default for Passive diffuser selected) |
| Fraction emitted to floor during application (Fapplication,floor) | 0.1 | [-] | D (TAB; ENV 150) |
| Cleaning efficacy (FCE) | 1 | [-] | D (TAB; ENV 150) |
| Fraction of total surface area which is cleaned | 0.3 | [-] | D (TAB; ENV 148) |
| Number of emission days (Temission) | 365 | d | S - Transfluthrin Assessment Report (2014) |

S= set, D = default, O = output, P = picklist

Calculations

***Application step***

Emission to air

In line with the relevant TAB scenario for treatment of wardrobes, the emission to the floor is considered to be 10% and 90% of the insecticide in the moth gel may remain airborne. Regarding this airborne fraction of the insecticide, further emission to the environment is not considered.

*Emission to Floor*

The quantity of active substance deposited on the floor is calculated according to the ESD for PT18 (2008) using the following parameters:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable/Parameter** | **Symbol** | **Unit** | **Value** | **S/D/O/P** |
| Input | | | | |
| Quantity of product contained in the device/diffuser | *Qprod* | g | 60 | S |
| Fraction of active substance in product | *FAI* | [-] | 0.0015 | S |
| Maximal duration of use of the device/diffuser | *Tmax* | h | 2160 | S |
| Duration of use per day | *Tday* | h.d-1 | 24 | D |
| Fraction emitted to floor during application | *Fapplication,floor* | [-] | 0.1 | D (Default – diffusers) |
| Output | | | | |
| Emission to floor during the application step | *Eapplication,floor* | kg.d-1 | 1.0E-07 | O |

S= set, D = default, O = output

**Cleaning step**

*Emission to Wastewater*

The Emission Scenario Document (OECD, 2008) suggests that residues deposited onto floor may potentially be exposed to cleaning. In situations where cleaning is conducted using water, residues may conceptually be emitted to wastewater. In the case of diffusers, the Emission Scenario Document makes some worst case assumptions:

* the entire fraction of deposited residue is exposed to cleaning (Fce = 1)
* cleaning is 100% efficient, neglecting the effect of sorption and degradation

According to ENV 148 of the TAB ENV (2019) for PT18 in the case of a house scenario the surface cleaning area is 130 m2 of which 38.5 m2 is subjected to wet cleaning area. A factor of 0.3 (38.5/138 =0.296) was therefore applied to Fww to correct for the wet cleaning zone. Thus, the emission from floor/treated surface is calculated using the following parameters:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable/Parameter** | **Symbol** | **Unit** | **Value** | **S/D/O/P** |
| Input | | | | |
| Emission to floor during the application step | *Eapplication,flo or* | kg.d-1 | 1.0E-07 | O |
| Fraction emitted to wastewater during the cleaning step  (Fraction of total surface area which is wet-cleaned) | *Fww* | - | 0.3 | D |
| Cleaning efficiency | *FCE* | - | 1 | P |
| Output | | | | |
| Emission from floor to wastewater during the cleaning step | *Etreated,ww* | kg.d-1 | 3.0E-08 | O |

D = default, O = output, P = picklist

The calculated emission rates to wastewater, expressed in kg.d-1, can be used further in exposure assessment as input values in SimpleTreat. The Emission Scenario Document PT18 (OECD, 2008) indicates that it is necessary to ‘scale up’ estimated emissions to take account of the potential number of sources within a typical STP catchment of 10,000 inhabitants. This calculation must take account of the number of houses within the catchment, with 4000 households being used as a default for indoor products. The number of houses potentially emitting on any single day is calculated by taking account of the Simultaneity Factor (Fsimultaneity). The default figure for products used on a daily basis in line with the TAB (ENV 150) is 0.0552. The corresponding number of households using the products simultaneously is 221. The resulting estimates of emission to wastewater at the catchment scale are summarised in the following table.

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 6.62E-06 | Default Fsimultaneity applied |

Calculations – Substance of Concern

Application step

*Emission to Floor*

Eight SoCs were identified across metal SPC 1 and meta SPC2. SoCs 3,5,5-trimethylhexyl acetate, diphenyl ether and Menthanyl acetate are present in both meta SPCs. The highest fraction in the product was used for the risk assessment.

The quantity of SoCs deposited on the floor is calculated according to the ESD for PT18 (2008) using the following parameters:

S= set, D = default, O = output

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable/Parameter** | **Symbol** | **Unit** | **Value** | **S/D/O/P[[11]](#footnote-11)** |
| **Input** | | | | |
| Quantity of product contained in the device/diffuser | *Qprod* | g | 60 | S |
| *Fraction of SoC in product* | | | | |
| 2-methylundecanal [CAS no. 110-41-8] | *Fsoc* | [-] | 0.0065 | S |
| 3,5,5-trimethylhexyl acetate [CAS no. 58430-94-7] | 0.13 | S |
| Precyclemone b [CAS no. 52475-86-2] | 0.0065 | S |
| Menthanyl acetate / p-menthan-8-yl acetate [CAS no. 58985-18-5] | 0.33 | S |
| Pentyl salicylate [CAS no. 2050-08-0/87-20-7] | 0.0065 | S |
| Alpha-cedrene [CAS no. 469-61-4] | 0.00060 | S |
| Diphenyl ether [CAS no. 101-84-8] | 0.0065 | S |
| 3,7-dimethylocta-1,3,6-triene [CAS no. 13877-91-3] | 0.0065 | S |
| Maximal duration of use of the device/diffuser | *Tmax* | h | 2160 | S |
| Duration of use per day | *Tday* | h.d-1 | 24 | D |
| Fraction emitted to floor during application | *Fapplication,floor* | [-] | 0.1 | D (Default – diffusers) |
| **Output: Emission to floor during the application step** | | | | |
| 2-methylundecanal [CAS no. 110-41-8] | *Eapplication,floor* | kg.d-1 | 4.33E-07 | O |
| 3,5,5-trimethylhexyl acetate [CAS no. 58430-94-7] | 8.67E-06 | O |
| Precyclemone b [CAS no. 52475-86-2] | 4.33E-07 | O |
| Menthanyl acetate [CAS no. 58985-18-5] | 2.20E-05 | O |
| Pentyl salicylate [CAS no. 2050-08-0/87-20-7] | 4.33E-07 | O |
| Alpha-cedrene [CAS no. 469-61-4] | 4.00E-08 | O |
| Diphenyl ether [CAS no. 101-84-8] | 4.33E-07 | O |
| 3,7-dimethylocta-1,3,6-triene [CAS no. 13877-91-3] | 4.33E-07 | O |

***Cleaning step***

*Emission to Wastewater*

The emission of the SoCs from floor surface is calculated as also discussed for the active substance.

Where:

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Variable/Parameter** | | **Symbol** | | **Unit** | | **Value** | | **S/D/O/P[[12]](#footnote-12)** | |
| Input | | | | | | | | |
| *Emission to floor during the application step* | | | | | | | | |
| 2-methylundecanal [CAS no. 110-41-8] | *Eapplication,floor* | | kg.d-1 | | 4.33E-07 | | S | |
| 3,5,5-trimethylhexyl acetate [CAS no. 58430-94-7] | 8.67E-06 | | S | |
| Precyclemone b [CAS no. 52475-86-2] | 4.33E-07 | | S | |
| Menthanyl acetate [CAS no. 58985-18-5] | 2.20E-05 | | S | |
| Pentyl salicylate [CAS no. 2050-08-0/87-20-7] | 4.33E-07 | | S | |
| Alpha-cedrene [CAS no. 469-61-4] | 4.00E-08 | | S | |
| Diphenyl ether [CAS no. 101-84-8] | 4.33E-07 | | S | |
| 3,7-dimethylocta-1,3,6-triene [CAS no. 13877-91-3] | 4.33E-07 | | S | |
| Fraction emitted to wastewater during the cleaning step | *Fww* | | - | | 0.3 | | D | |
| Cleaning efficiency | *FCE* | | - | | 1 | | P (Default) | |
| Output: Emission from floor/treated to wastewater during the cleaning step | | | | | | | | |
| 2-methylundecanal [CAS no. 110-41-8] | *Etreated,ww* | | kg.d-1 | | 1.30E-07 | | O | |
| 3,5,5-trimethylhexyl acetate [CAS no. 58430-94-7] | 2.60E-06 | | O | |
| Precyclemone b [CAS no. 52475-86-2] | 1.30E-07 | | O | |
| Menthanyl acetate [CAS no. 58985-18-5] | 6.60E-06 | | O | |
| Pentyl salicylate [CAS no. 2050-08-0/87-20-7] | 1.30E-07 | | O | |
| Alpha-cedrene [CAS no. 469-61-4] | 1.20E-08 | | O | |
| Diphenyl ether [CAS no. 101-84-8] | 1.30E-07 | | O | |
| 3,7-dimethylocta-1,3,6-triene [CAS no. 13877-91-3] | 1.30E-07 | | O | |

S= set, D = default, O = output, P = picklist

| **Resulting local emission to relevant environmental compartments** | | | |
| --- | --- | --- | --- |
| **Compartment** | **SoC** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 2-methylundecanal [CAS no. 110-41-8] | 2.87E-05 | Default Fsimultaneity applied |
| 3,5,5-trimethylhexyl acetate [CAS no. 58430-94-7] | 5.74E-04 | Default Fsimultaneity applied |
| Precyclemone b [CAS no. 52475-86-2] | 2.87E-05 | Default Fsimultaneity applied |
| Menthanyl acetate [CAS no. 58985-18-5] | 1.46E-03 | Default Fsimultaneity applied |
| Pentyl salicylate [CAS no. 2050-08-0/87-20-7] | 2.87E-05 | Default Fsimultaneity applied |
| Alpha-cedrene [CAS no. 469-61-4] | 2.65E-06 | Default Fsimultaneity applied |
| Diphenyl ether [CAS no. 101-84-8] | 2.87E-05 | Default Fsimultaneity applied |
| 3,7-dimethylocta-1,3,6-triene [CAS no. 13877-91-3] | 2.87E-05 | Default Fsimultaneity applied |

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

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| Freshwater\* | Freshwater sediment\* | STP | Air | Soil | Ground-water | Secondary poisoning |
| Yes+ | Yes+ | Yes++ | Yes(Q) | Yes+ | Yes+ | Yes+ |

++ Compartment primarily exposed; + Compartment secondarily exposed; (Q) Quantitatively assessed

\* Emission to the marine environment is not expected

*Transfluthrin*

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment: active substance\*** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| *Transfluthrin* | | | |
| Molecular weight | 371.2 | g/mol |  |
| Melting point | 32 | °C |  |
| Vapour pressure (at 20 °C) | 9.00E-04 | Pa |  |
| Water solubility (at 20 °C) | 0.057 | mg/L |  |
| Henry’s law constant (at 20 °C) | 5.86 | Pa.m3.mole-1 |  |
| Log Octanol/water partition coefficient (log Kow) | 5.94 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 50119 | L/kg |  |
| Biodegradability | Not readily biodegradable |  |  |
| DT50 for biodegradation in active sludge | 0.50  0.284 | d (at 15ºC)  d (at 21.7ºC) | New OECD 314B study (xxxx 2017) |
| DT50 for biodegradation in aquatic compartment | 1E+06 | d (at 12ºC) | Default value for not readily biodegradable substances |
| DT50 for degradation in soil | 5.17 | d (at 12ºC) | Updated LoEP transfluthrin (2017) |
| DT50 for degradation in air | 2.4 | d |  |
| Bioconcentration factor (BCF, fish) | 1783 | L/kg |  |
| Bioconcentration factor (BCF, earthworms) | 10452 | L/kg |  |

\* Parameters as presented in Transfluthrin Assessment Report (2014), unless otherwise stated

Fate and distribution within the STP was estimated using SimpleTreat 4.0 which implements a concentration of suspended solids in effluent value of 0.03 kg.m-3 in accordance with ENV 9 of the TAB (2019) and applying the data from the new OECD 314B study.

|  |  |  |
| --- | --- | --- |
| **Calculated fate and distribution in the STP (Transfluthrin)** | | |
| Compartment | Simpletreat 4.0 | Remarks |
| Percentage (%) |
| Air | 0.19 | - |
| Water | 1.31 | - |
| Sludge | 59.9 | - |
| Degraded in STP | 38.6 | - |

*Metabolites*

**Metabolites in STP and subsequent aquatic environment**

As discussed in Section 2.2.8.1, an OECD 314B study on biodegradation in activated sludge of the active substance transfluthrin was conducted.

In the study, three metabolites were found; trans-DCVA, cis-OH-DCVA and trans-OH-DCVA. As also stated above in Section 2.2.8.1, the metabolites cis-OH-DCVA and trans-OH-DCVA are expected to be much less toxic than trans-DCVA. Therefore, no calculations are included here and the risk assessment for these metabolites is covered by the risk assessment for trans-DCVA. The metabolites TFB-OH and TFB-COOH (see AR transfluthrin) that are formed from the benzene moiety were not included in the xxxx study, because this section of the molecule was not labelled. Either of these metabolites may be formed in the STP and both were identified as environmentally relevant metabolites in water/sediment systems (please refer to Assessment Report for transfluthrin). In view of the chemical structure similarity and the comparable physico-chemical characteristics of TFB-OH and TFB-COOH (as also discussed in the Assessment Report for transfluthrin (2014)), the risk to TFB-OH is covered by the risk assessment for TFB-COOH.

For the calculation of the metabolite PEC values in surface water, it is assumed that the entire fraction of transfluthrin that is degraded in the STP (38.6%) results in the formation of the above mentioned metabolites, i.e.:

| **Symbol** | **Description** | **Unit** |
| --- | --- | --- |
| *E*localwater\_TP | local emission rate of transformation product | [kg d-1] |
| *E*localwater\_Parent | local emission rate of parent substance | [kg d-1] |
| FSTP, degraded | fraction of parent substance degraded in STP | [-] |
| *f*ij | formation fraction of transformation product | [-] |
| *Mass*molarTP | molecular mass of transformation product | [g mol-1] |
| *Mass*molarParent | molecular mass of parent substance | [g mol-1] |

Since no information is available on the distribution between water, sediment and sludge, it is assumed that all mass goes to water (effluent STP). No sediment PECs are presented, because both PEC and PNEC values for the metabolites are based on equilibrium partitioning, which would result in similar PEC/PNEC ratios for the water and sediment compartment. Hence, risk assessment for the water compartment also covers the risk for the sediment compartment.

The emission rate for the metabolites was derived from the parent’s emission (6.62 mg/d) according to aforementioned equation. Concentrations were calculated by applying a volume of 2000 m3/d. These concentrations were corrected for sorption to suspended matter in line with the BPR GD (ENV B+C; equation 48), to obtain the PECsurface water values.

**Metabolites in soil**

The study on degradation in soil (please refer to Section 2.2.8.1) indicates that the metabolite TFB-COOH is formed in soil. In addition, it is expected that trans-DCVA is also formed, as also discussed in the Assessment Report for cyfluthrin (2018). The PEC values of the metabolites in soil were calculated in line with the AHEE document on ‘Exposure assessment of metabolites in the terrestrial compartment’ (2019), using concentration of parent in sludge as well as formation fraction and ratio of molecular weights.

The first tier groundwater concentration (based on PECporewater) is calculated for the metabolites, by using the QSAR Koc values to determine the Ksoil\_water. Please refer to Annex 3.4 for the QSAR estimates.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Input parameters (only set values) for calculating the fate and distribution of metabolites in the aquatic and soil compartment** | | | | |
|  | **Molecular weight** | **Molweight ratio** | **Formation fraction STP\*** | **Csludge** | **Remarks** |
|  | g/mol | g/g | mol/mol | mg/kg dwt |  |
| Transfluthrin | 371.2 | - | - | 4.88E-03 |  |
| trans-DCVA | 208.1 | 0.56 | 0.9678 | 2.65E-03 | f.f. from transfluthrin |
| TFB-COOH | 194.08 | 0.52 | 1 | 2.55E-03 | f.f. from transfluthrin |

\* Value of formation fraction (f.f. – derived from Cake modelling) in the STP was used to calculate the PECsw and PECsoil.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Input parameters for calculating the fate and distribution of metabolites in groundwater** | | | | | | |
|  | **Koc1** | **Kp\_soil** | **VP2** | **Sol** | **Ksoil\_water3** | **DT50 (12o)** | **Remarks** |
|  | L/kg | L/kg | Pa | mg/L | - |  |  |
| trans-DCVA | 106 | 2.12 | 2.6 | 127.6 | 3.38 | 174.8 |  |
| TFB-COOH | 10.71 | 0.214 | 8.45 | 2114 | 0.521 | 3.66 |  |

1 QSAR estimates from Kow method

2 Formula 26 in BPR guidance. Vapour pressure and solubility at 25 °C (QSAR estimate from MpBp method)

3 Formula 27 in BPR guidance. RHOsolid = 2.5E3.

*Substances of Concern*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment: Substances of Concern** | | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| *2-methylundecanal [CAS no.* *110-41-8]* | | | |
| Molecular weight | 184.318 | g/mol | EC 203-765-0 REACH Registration Dossier[[13]](#footnote-13) |
| Melting point | -50 | °C | EC 203-765-0 REACH Registration Dossier |
| Vapour pressure (at 20 °C) | 2.4 | Pa | EC 203-765-0 REACH Registration Dossier |
| Water solubility (at 20 °C) | 1.3 | mg/L | EC 203-765-0 REACH Registration Dossier |
| Log Octanol/water partition coefficient | 4.9 | Log 10 | EC 203-765-0 REACH Registration Dossier |
| Organic carbon/water partition coefficient (Koc) | 3981 | L/kg | EC 203-765-0 REACH Registration Dossier, experimental value |
| Biodegradability | Readily biodegradable |  | EC 203-765-0 REACH Registration Dossier |
| *3,5,5-trimethylhexyl acetate [CAS no.* *58430-94-7]* | | | |
| Molecular weight | 186.291 | g/mol | EC 261-245-9 REACH Registration Dossier[[14]](#footnote-14) |
| Melting point | -20 | °C | EC 261-245-9 REACH Registration Dossier |
| Vapour pressure (at 25 °C) | 136 | Pa | EC 261-245-9 REACH Registration Dossier |
| Water solubility (at 20 °C) | 19.1 | mg/L | EC 261-245-9 REACH Registration Dossier |
| Log Octanol/water partition coefficient | 4.6 | Log 10 | EC 261-245-9 REACH Registration Dossier |
| Organic carbon/water partition coefficient (Koc) | 3724 | L/kg | EC 261-245-9 REACH Registration Dossier, calculated value |
| Biodegradability | Readily biodegradable |  | EC 261-245-9 REACH Registration Dossier |
| *Precyclemone b [CAS no.* *52475-86-2]* | | | |
| Molecular weight | 206 | g/mol | EC 915-712-5 REACH Registration Dossier[[15]](#footnote-15) |
| Melting point | -80 | °C | EC 915-712-5 REACH Registration Dossier |
| Vapour pressure (at 25 °C) | 1 | Pa | EC 915-712-5 REACH Registration Dossier |
| Water solubility (at 20 °C) | 3.19 | mg/L | EC 915-712-5 REACH Registration Dossier |
| Log Octanol/water partition coefficient | 4.8 | Log 10 | EC 915-712-5 REACH Registration Dossier |
| Organic carbon/water partition coefficient (Koc) | 3280 | L/kg | Calculated (EUSES 2.1) |
| Biodegradability | inherently biodegradable |  | EC 915-712-5 REACH Registration Dossier |
| *Menthanyl acetate [CAS no.* *58985-18-5]* | | | |
| Molecular weight | 198.3 | g/mol | **EC 939-728-7 REACH Registration dossier**[[16]](#footnote-16) |
| Melting point | -20 | °C | **EC 939-728-7 REACH Registration dossier** |
| Vapour pressure (at 20 °C) | 40 | Pa | **EC 939-728-7 REACH Registration dossier** |
| Water solubility (at 20 °C) | 16.03 | mg/L | **EC 939-728-7 REACH Registration dossier** |
| Log Octanol/water partition coefficient | 4.26 | Log 10 | **EC 939-728-7 REACH Registration dossier** |
| Organic carbon/water partition coefficient (Koc) | 1081 | L/kg | **EC 939-728-7 REACH Registration dossier, calculated value** |
| Biodegradability | Readily biodegradable |  | **EC 939-728-7 REACH Registration dossier** |
| *Pentyl salicylate [CAS no. 2050-08-0/87-20-7]* | | | |
| Molecular weight | 208.254 | g/mol | EC 218-080-2 REACH Registration Dossier[[17]](#footnote-17) |
| Melting point | -11.9 | °C | EC 218-080-2 REACH Registration Dossier |
| Vapour pressure (at 20 °C) | 0.24 | Pa | EC 218-080-2 REACH Registration Dossier |
| Water solubility (at 20 °C) | 5.5 | mg/L | EC 218-080-2 REACH Registration Dossier |
| Log Octanol/water partition coefficient | 4.4 | Log 10 | EC 218-080-2 REACH Registration Dossier |
| Organic carbon/water partition coefficient (Koc) | 5012 | L/kg | EC 218-080-2 REACH Registration Dossier, experimental value |
| Biodegradability | Readily biodegradable |  | EC 218-080-2 REACH Registration Dossier |
| Bioconcentration factor (BCF, fish) | 570 | L/kg | EC 218-080-2 REACH Registration Dossier |
| Bioconcentration factor (BCF, earthworms) | 302 | L/kg | EC 218-080-2 REACH Registration Dossier |
| *alpha-cedrene [CAS no.* *469-61-4]* | | | |
| Molecular weight | 204.36 | g/mol | EPI Suite v. 4.11 |
| Melting point | 47.96 | °C | EPI Suite v. 4.11 |
| Vapour pressure (at 25 °C) | 1.84E-02 | Pa | MPBPVP v. 1.43 |
| Water solubility (at 25 °C) | 0.01504 | mg/L | WSKOW v. 1.41 |
| Log Octanol/water partition coefficient | 5.74 | Log 10 | KOWWIN v. 5.74 |
| Organic carbon/water partition coefficient (Koc) | 95719 | L/kg | KOCWIN v. 2.00 |
| Biodegradability | Readily Biodegradable[[18]](#footnote-18) |  | Jenner et al. (2011) |
| *=Diphenyl ether [CAS no. 101-84-8]* | | | |
| Molecular weight | 170.207 | g/mol | **EC** 202-981-2 **REACH Registration dossier**[[19]](#footnote-19) |
| Melting point | 26.87 | °C | **EC** 202-981-2 **REACH Registration dossier** |
| Vapour pressure (at 25 °C) | 2.7 | Pa | **EC** 202-981-2 **REACH Registration dossier** |
| Water solubility (at 25 °C) | 18 | mg/L | **EC** 202-981-2 **REACH Registration dossier** |
| Log Octanol/water partition coefficient | 4.21 | Log 10 | **EC** 202-981-2 **REACH Registration dossier** |
| Organic carbon/water partition coefficient (Koc) | 1960 | L/kg | **EC** 202-981-2 **REACH Registration dossier, experimental value** |
| Biodegradability | Readily Biodegradable |  | **EC** 202-981-2 **REACH Registration dossier** |
| *3,7-dimethylocta-1,3,6-triene [CAS no. 13877-91-3]* | | | |
| Molecular weight | 136.234 | g/mol | **EC 237-641-2 REACH Registration dossier** |
| Melting point | -20 | °C | **EC 237-641-2 REACH Registration dossier** |
| Vapour pressure (at 25 °C) | 220.7 | Pa | **EC 237-641-2 REACH Registration dossier** |
| Water solubility (at 24 °C) | 14.5 | mg/L | **EC 237-641-2 REACH Registration dossier** |
| Log Octanol/water partition coefficient | 5.4 | Log 10 | **EC 237-641-2 REACH Registration dossier** |
| Organic carbon/water partition coefficient (Koc) | 48560 | L/kg | KOCWIN v. 2.00 |
| Biodegradability | Readily Biodegradable |  | **EC 237-641-2 REACH Registration dossier** |

Fate and distribution within the STP was estimated using SimpleTreat 4.0 and the same parameterisation as described above for the active substance.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Calculated fate and distribution in the STP : Substances of Concern** | | | | | | | | |
|  | **2-methylundecanal [CAS no. 110-41-8]** | **3,5,5-trimethylhexyl acetate [CAS no. 58430-94-7]** | **Precyclemone b [CAS no. 52475-86-2]** | **Menthanyl acetate [CAS no. 58985-18-5]** | **Pentyl salicylate [CAS no. 2050-08-0/87-20-7]** | **Alpha-cedrene [CAS no. 469-61-4]** | **Diphenyl ether [CAS no. 101-84-8]** | **3,7-dimethylocta-1,3,6-triene [CAS no. 13877-91-3]** |
| Compartment | Percentage (%) | | | | | | | |
| Air | 20.74 | 34.59 | 18.65 | 28.87 | 1.47 | 11.15 | 3.32 | 31.9 |
| Water | 4.09 | 3.43 | 25.91 | 4.12 | 5.78 | 4.01 | 6.33 | 2.76 |
| Sludge | 23.77 | 17.42 | 23.86 | 12.72 | 27.98 | 39.82 | 14.4 | 32.2 |
| Degraded in STP | 51.40 | 44.56 | 31.59 | 54.29 | 64.77 | 45.02 | 76.0 | 33.1 |

***Calculated PEC values***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values (active substance)** | | | | | |
|  | PECSTP | PECwater | PECsed | PECsoil | PECGW |
| [mg/L] | [mg/L] | [mg/kgwwt] | [mg/kgwwt] | [µg/L] |
| Transfluthrin | 4.35E-08 | 4.05E-09 | 4.41E-06 | 7.18E-06 | 1.98E-06 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values (metabolites)** | | | | |
|  | PECSTP | PECwater\* | PECsoil | PECGW |
| [mg/L] | [mg/L] | [mg/kgwwt] | [µg/L] |
| Trans-DCVA | n.a. | 6.93E-08 | 4.76E-06 | 2.20E-03 |
| TFB-COOH | n.a. | 6.68E-08 | 3.75E-06 | 2.10E-03 |

n.a. not applicable

\* No PNEC sediment is available for metabolites. Hence, the risk assessment for water also covers the risk for sediment

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values (Substances of Concern)** | | | | | |
|  | PECSTP | PECwater | PECsed | PECsoil | PECGW |
| [mg/L] | [mg/L] | [mg/kgwwt] | [mg/kgwwt] | [µg/L] |
| 2-methylundecanal [CAS no. 110-41-8] | 5.87E-07 | 5.83E-08 | 5.09E-06 | 1.24E-05 | 1.27E-04 |
| 3,5,5-trimethylhexyl acetate [CAS no. 58430-94-7] | 9.83E-06 | 9.79E-07 | 5.57E-05 | 1.81E-04 | 2.86E-03 |
| Precyclemone b [CAS no. 52475-86-2] | 3.72E-06 | 3.70E-07 | 2.67E-05 | 1.19E-04 | 2.05E-03 |
| Menthanyl acetate [CAS no. 58985-18-5] | 3.01E-05 | 3.00E-06 | 1.14E-04 | 3.36E-04 | 2.61E-03 |
| Pentyl salicylate [CAS no. 2050-08-0/ 87-20-7] | 8.30E-07 | 8.24E-08 | 9.04E-06 | 1.45E-05 | 1.18E-04 |
| Alpha-cedrene [CAS no. 469-61-4] | 5.31E-08 | 5.24E-09 | 1.15E-06 | 1.91E-06 | 7.72E-06 |
| Diphenyl ether [CAS no. 101-84-8] | 9.08E-07 | 9.06E-08 | 3.93E-06 | 7.48E-06 | 1.55E-04 |
| 3,7-dimethylocta-1,3,6-triene [CAS no. 13877-91-3] | 3.97E-07 | 3.93E-08 | 5.78E-06 | 1.67E-05 | 1.02E-04 |

***Primary and secondary poisoning***

Primary poisoning

The products of the Moth Gel Family are designed for use indoors. The use of the products will not result in primary poisoning of birds and mammals.

Secondary poisoning

The predicted environmental concentration in fish-eating (aquatic) and worm-eating (terrestrial) birds and mammals (PECoral, predator) was calculated according to the Guidance on biocide legislation, Part B+C, volume IV. PECoral, predator for the aquatic environment for transfluthrin was based on a BCF of 1783 L/kg wet fish, a default biomagnification factor (BMF = 1) for compounds with BCF fish < 2000 L/kg wet fish, and the PECwater in the aquatic environment. The PEC for worm-eating birds and mammals was based on a BCF of 10452 L/kg wwt calculated from the active substance’s log Kow, the PECsoil and the equilibrium partitioning-derived concentration in porewater.

All SoCs indicated potential for bioaccumulation with log Kow values >3. However, pentyl salicylate, indicated potential to cause toxic effects if accumulated in higher organisms based on its classification as Acute Toxicity category 4 (oral, H302). Alpha-cedrene and 3,7-dimethylocta-1,3,6-triene indicated potential to cause toxic effects if accumulated in higher organisms based on their classification as presenting an aspiration hazard (H304).

Therefore, in accordance with the Guidance on biocide legislation, Part B+C, volume IV, a secondary poisoning assessment was carried out on pentyl salicylate as only for this SoC PNECoral values could be derived from mammalian toxicology data.

PECoral, predator for the aquatic environment for the SoC was based on a BCF of 570 L/kg wet fish (REACH Registration Dossier), a default biomagnification factor (BMF = 1) for compounds with BCF fish < 2000 L/kg wet fish, and the PECwater in the aquatic environment. The PEC for worm-eating birds and mammals was based on a BCF of 302 L/kg wwt (REACH Registration Dossier) calculated from the active substance’s log Kow, the PECsoil and the equilibrium partitioning-derived concentration in porewater.

|  |  |  |
| --- | --- | --- |
| **Summary table on estimated theoretical exposition (ETE) (active substance)** | | |
| **Scenario** | **PECoral, predator (freshwater)** | **PECoral, predator  (terrestrial)** |
| [mg/kg wet fish] | [mg/kg wet earthworm] |
| Transfluthrin | 3.61E-06 | 9.66E-06 |

|  |  |  |
| --- | --- | --- |
| **Summary table on estimated theoretical exposition (ETE) (substance of concern)** | | |
| **Scenario** | **PECoral, predator (freshwater)** | **PECoral, predator  (terrestrial)** |
| [mg/kg wet fish] | [mg/kg wet earthworm] |
| Pentyl salicylate [CAS no. 2050-08-0/87-20-7] | 2.35E-05 | 1.68E-05 |

#### Risk characterisation

***Atmosphere***

Conclusion: Under the proposed conditions of use, transfluthrin may be emitted to outdoor air, as a result of ventilation in treated rooms. However, according to the ESD, effects on non-target species are expected to be low, even for outdoor uses of insecticides, because of instant dilution and turbulence in air. Exposure of the air compartment is thus limited in time and restricted to local scale. Accordingly, quantitative risk characterisation for biota is not performed for this compartment.

Furthermore, the Transfluthrin Assessment Report (2014) concludes that transfluthrin fulfils the criteria for ozone depletion potential as it contains a halogen substituent (F).

Moreover, the estimated half-life in air is 2.4 days, which is just above the trigger value of 2 days, which is used as cut-off value to identify chemicals that could be of potential concern for long range transport through the atmosphere. However, as discussed in the Assessment Report of transfluthrin (2014) the vapour pressure of transfluthrin indicates low volatility and the high Koc indicates that the substance has a tendency to bind to particles. Therefore, the long-range transport in air is expected to be rather limited. Moreover, transfluthrin is not listed by the FOCUS air groups as causing ozone depletion and considering the relative small total amounts used and the volume of the atmospheric compartment, possible abiotic effects of transfluthrin on the atmosphere are expected to be negligible.

To assess the volatilisation potential of the SoCs a Henry's law constant was calculated with Henrywin. There are no indications that the SoCs contribute to depletion of the ozone layer as the compounds are not listed as ‘controlled substance’ in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. Moreover, AOPwin calculates for the SoCs a half-life of below the trigger of 2 days in air (OH timeframe 24 hrs/day, 0.5×106 OH radicals/cm3), which is used as cut off value to identify chemicals that could be of potential concern for long range transport through the atmosphere. The environmental risk to air is therefore considered acceptable.

|  |  |  |
| --- | --- | --- |
| **Substance of Concern** | **Calculated Henry’s law constant (25 °C)** | **Calculated DT50 in air (OH timeframe 24 hrs/day, 0.5×106 OH radicals/cm3)** |
| 2-methylundecanal [CAS no. 110-41-8] | 298 Pa. m3/mole | 0.43 d |
| 3,5,5-trimethylhexyl acetate [CAS no. 58430-94-7] | 260 Pa. m3/mole | 1.931 d |
| Precyclemone b [CAS no. 52475-86-2] | 97.9 Pa. m3/mole | 0.078 d |
| Menthanyl acetate [CAS no. 58985-18-5] | 100 Pa. m3/mole | 1.259 d |
| Pentyl salicylate [CAS no. 2050-08-0/87-20-7] | 1.43 Pa. m3/mole | 0.950 d |
| Alpha-cedrene [CAS no. 469-61-4] | 19700 Pa. m3/mole | 0.166 d |
| Diphenyl ether [CAS no. 101-84-8] | 28.5 Pa. m3/mole | 1.63 d |
| 3,7-dimethylocta-1,3,6-triene [CAS no. 13877-91-3] | 6670 Pa. m3/mole | 0.019 d |

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

|  |  |
| --- | --- |
|  | **Summary table on calculated PEC/PNEC values: Active substance** |
|  | **PEC/PNECSTP** |
| Transfluthrin | <0.001 |

|  |  |
| --- | --- |
|  | **Summary table on calculated PEC/PNEC values: substances of Concern** |
|  | PEC/PNECstp |
| 2-methylundecanal [CAS no. 110-41-8] | <0.001 |
| 3,5,5-trimethylhexyl acetate [CAS no. 58430-94-7] | <0.001 |
| Precyclemone b [CAS no. 52475-86-2] | n/a |
| Menthanyl acetate [CAS no. 58985-18-5] | <0.001 |
| Pentyl salicylate [CAS no. 2050-08-0/87-20-7] | <0.001 |
| Alpha-cedrene [CAS no. 469-61-4] | n/a |
| Diphenyl ether [CAS no. 101-84-8] | < 0.001 |
| 3,7-dimethylocta-1,3,6-triene [CAS no. 13877-91-3] | n/a |

Conclusion: The calculated PEC/PNEC values for the sewage treatment plant (STP) are significantly < 1 for the (combination of the) active substance and the SoCs. Therefore, the risk to microorganisms in the STP is considered to be acceptable for the proposed use of the products of the Moth Gel Family. For the SoCs for which no PNECstp is available the risks are also expected to be below 1 as the highest PECstp of 3.72E-06 is calculated for the SoC precyclemone b and the PNECstp values for the SoCs are expected to be higher than this PECstp.

***Aquatic compartment***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values (active substance)** | | |
|  | PEC/PNECwater | PEC/PNECsed\* |
| Transfluthrin | 0.002 | 0.012 |

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values (metabolites)** | |
|  | PEC/PNECwater\* |
| Trans-DCVA | <0.001 |
| TFB-COOH | <0.001 |

\* PEC/PNECsed values are identical to the PEC/PNECwater values, because both PEC and PNEC sediment are based on equilibrium partitioning.

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values (Substances of Concern)** | | |
|  | PEC/PNECwater | PEC/PNECsed |
| 2-methylundecanal [CAS no. 110-41-8] | <0.001 | <0.001 |
| 3,5,5-trimethylhexyl acetate [CAS no. 58430-94-7] | <0.001 | <0.001 |
| Precyclemone b [CAS no. 52475-86-2] | 0.002 | 0.002 |
| Menthanyl acetate [CAS no. 58985-18-5] | 0.001 | 0.002 |
| Pentyl salicylate [CAS no. 2050-08-0/87-20-7] | <0.001 | <0.001 |
| Alpha-cedrene [CAS no. 469-61-4] | <0.001 | <0.001 |
| Diphenyl ether [CAS no. 101-84-8] | <0.001 | < 0.001 |
| 3,7-dimethylocta-1,3,6-triene [CAS no. 13877-91-3] | <0.001 | <0.001 |

Conclusion: The assessment for the active substance results in PEC/PNEC values < 1 for the water compartment and sediment compartment.

For the relevant metabolites trans-DCVA and TFB-COOH, the PEC/PNEC values are <1.

For the SoCs, all PEC/PNEC values are also <1.

Therefore it can be concluded that use of the products of the Moth Gel Family will not result in unacceptable risk to the aquatic compartment.

***Terrestrial compartment***

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values (Active substance)** | |
|  | **PEC/PNECsoil** |
| Active substance | <0.001 |

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values (metabolites)** | |
|  | **PEC/PNECsoil** |
| Trans-DCVA | < 0.001 |
| TFB-COOH | < 0.001 |

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values (Substances of Concern)** | |
|  | PEC/PNECsoil |
| 2-methylundecanal [CAS no. 110-41-8] | < 0.001 |
| 3,5,5-trimethylhexyl acetate [CAS no. 58430-94-7] | < 0.001 |
| Precyclemone b [CAS no. 52475-86-2] | 0.014 |
| Menthanyl acetate [CAS no. 58985-18-5] | 0.008 |
| Pentyl salicylate [CAS no. 2050-08-0/87-20-7] | < 0.001 |
| Alpha-cedrene [CAS no. 469-61-4] | < 0.001 |
| Diphenyl ether [CAS no. 101-84-8] | < 0.001 |
| 3,7-dimethylocta-1,3,6-triene [CAS no. 13877-91-3] | <0.001 |

Conclusion: The assessment for the active substance results in PEC/PNEC values < 1 for the terrestrial compartment.

For the relevant metabolites trans-DCVA and TFB-COOH, the PEC/PNEC values are <1.

For the SoCs the PEC/PNEC value are also all <1.

Therefore it can be concluded that use of the products of the Moth Gel Family will not result in unacceptable risk to the terrestrial compartment.

***Groundwater***

As shown in Section 2.2.10.2, all predicted concentrations in groundwater are below the threshold of 0.1 μg/L for active substance, metabolites and SoCs. Hence, no further calculations are required and the risk for groundwater is acceptable.

***Primary and secondary poisoning***

Primary poisoning

Not relevant for these products.

Secondary poisoning

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on secondary poisoning (active substance)** | | | |
| Active substance | **Concentration** | **PECoral predator** **(mg/kg wwt)** | **PEC/PNECmammals** |
| Fish | 3.61E-06 | < 0.001 |
| Earthworms | 9.70E-06 | < 0.001 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on secondary poisoning (substance of concern)** | | | |
| Pentyl salicylate [CAS no. 2050-08-0/87-20-7] | **Concentration** | **PECoral predator** **(mg/kg wwt)** | **PEC/PNECmammals** |
| Fish | 2.35E-05 | < 0.001 |
| Earthworms | 1.68E-05 | <0.001 |

Conclusion: Using the concentration in fish and worms and the PNECoral,mammal of 6.67 mg/kgwwt feed for transfluthrin and the PNECoral,mammal of 80 mg/kgwwt for pentyl salicylate, the PEC/PNECoral,mammal is < 1 for both substances and the risk to fish and earthworm eating mammals is considered to be acceptable.

In the absence of short-term or long-term toxicity data for birds, a PEC/PNECoral,bird cannot be derived for transfluthrin. However, for the PNECoral,bird to fall below the maximum predicted PECoral predator (3.61E-06 mg/kgwwt for fish and 9.66E-06 mg/kgwwt for earthworms), the NOEC should be lower than the PECoral,bird x 30, and should thus be < 1.08E-04 mg/kgwwt feed in case of fish and < 2.90E-04 mg/kgwwt feed in case of earthworms. Following a similar reasoning for short-term tests, the LC50 should be < 1.08E-02 and 2.90E-02 mg/kgwwt feed, respectively (< PECoral,bird x 3000). In view of the absence of acute toxicity to birds at doses up to 1890 mg/kg bw, it is not expected that chronic toxicity levels as estimated above will be reached. In view of this, a risk of secondary poisoning of birds is not expected. This conclusion is consistent with the argumentation presented in the Transfluthrin Assessment Report (2014).

In the absence of short-term or long-term toxicity data for birds, a PEC/PNECoral,bird cannot be derived for the SoC. However, for the PNECoral,bird to fall below the maximum predicted PECoral predator (2.35E-05 mg/kgwwt for fish and 1.68E-05 mg/kgwwt for earthworms), the NOEC should be lower than the PECoral,bird x 30, and should thus be < 7.05E-04 mg/kgwwt feed in case of fish and < 5.03E-04 mg/kgwwt feed in case of earthworms. Following a similar reasoning for short-term tests, the LC50 should be < 7.05E-02 and 5.03E-02 mg/kgwwt feed, respectively (< PECoral,bird x 3000). It is not expected that chronic toxicity levels as estimated above will be reached. In view of this, the risk of secondary poisoning of birds is considered to be acceptable.

***Mixture toxicity***

*Screening step*

Screening Step 1: Identification of the concerned environmental compartments

The conceptual emission pathway to the environment is *via* deposition onto floors and subsequent release to wastewater following washing (wet cleaning). The use of the biocidal products will lead to breakdown of the formula as the liquid is heated and evaporated.

Screening Step 2: Identification of relevant substances

The following substances are regarded as relevant for mixture assessment:

1) Active substances

2) Substances of concern (SoC)

Several co-formulants within the meta SPCs of the Moth Gel Family are present at a concentration that would lead to the products being classified as hazardous to the environment under CLP Regulation.

Please see confidential annex for details of the SoCs identified in Moth Gel family.

Screening Step 3: Synergistic interactions

No indication of synergistic effects have been reported in the literature for any of the identified SoCs.

|  |  |
| --- | --- |
| **Screening step** | |
|  | Significant exposure of environmental compartments? (Y/N) Yes |
|  | Number of relevant substances >1? (Y/N) Yes |
|  | Indication for synergistic effects for the product or its constituents in the literature? (Y/N) No |

Tier 1 Mixture Toxicity Assessment: PEC/PNEC summation

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Substance** | **PEC/PNECwater** | **PEC/PNECsediment** | **PEC/PNECsoil** | **PEC/PNECmammals (via consumption of fish)** | **PEC/PNECmammals((via consumption of earthworms)** |
| Transfluthrin | 0.002 | 0.012 | <0.001 | < 0.001 | < 0.001 |
| Metabolites | <0.001 | - | <0.001 | - | - |
| 2-methylundecanal [CAS no. 110-41-8] | <0.001 | <0.001 | < 0.001 | - | - |
| 3,5,5-trimethylhexyl acetate [CAS no. 58430-94-7] | <0.001 | <0.001 | < 0.001 | - | - |
| Precyclemone b [CAS no. 52475-86-2] | 0.002 | 0.002 | 0.014 | - | - |
| Menthanyl acetate [CAS no. 58985-18-5] | 0.001 | 0.002 | 0.008 | - | - |
| Pentyl salicylate [CAS no. 2050-08-0/87-20-7] | <0.001 | <0.001 | < 0.001 | < 0.001 | < 0.001 |
| Alpha-cedrene [CAS no. 469-61-4] | <0.001 | <0.001 | < 0.001 | - | - |
| Diphenyl ether [CAS no. 101-84-8] | <0.001 | <0.001 | <0.001 | - | - |
| 3,7-dimethylocta-1,3,6-triene [CAS no. 13877-91-3] | <0.001 | <0.001 | < 0.001 | - | - |
| **SUM PEC/PNEC** | 0.012 | 0.022 | 0.03 | 0.002 | 0.002 |

The sum of PEC/PNEC values are < 1 for all environmental compartments indicating no unacceptable risk to the environment is caused by the use of the products of the Moth Gel Family. As the products pass a conservative Tier 1 assessment, no further evaluation of mixture toxicity is required.

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

There is potential overlap in terms of time and space with other PT18 products containing the same active substance used. However, there is relatively large margin of safety in the assessment for this specific family and bearing in mind that there is at present no agreed approach to the assessment of aggregated exposure it is concluded in this case that no further assessment is required.



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

Conclusion

There is unlikely to be any overlap in time and space with other PT classes and therefore no further assessment is required.

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| The environmental risk assessment for Moth Gel was performed according to the ‘Diffuser’ Scenario provided in the Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional users (OECD, 2008). Emission calculations were conducted assuming a default number of emission sources (Fsimultaneity = 5.52. Environmental fate was calculated using SimpleTreat 4.0 incorporating new data on the degradation of transluthrin in STP. PNEC values used in the assessment took account of recently generated data that improve understanding of ecotoxicity profile of transfluthrin.  A quantitative risk assessment was also carried on the relevant metabolites of transfluthrin as well as on SoCs identified in the meta SPCs of products of the Moth Gel Family. In all cases, calculated PEC/PNEC values for the active substance, relevant metabolites and SoCs were <1, indicating that no unacceptable environmental risk is expected to result from the use of the products of the Moth Gel Family.  A mixture assessment was carried out on the products of the Moth Gel Family for the active substance, metabolites and SoCs and the products passed a Tier 1 mixture risk assessment indicating that no unacceptable risk is posed by the products.  Based on harmonised agreements the pure concentration and not the technical concentration of the active substance in the products of the Moth Gel Family was used in the environmental risk assessment. The conclusion of the environmental risk assessment stays the same when the technical concentration would have been used. |

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

**Recommended methods and precautions concerning storage of active substance/biocidal product; shelf-life of biocidal product**

[For the Product Label only]:

(P102)Keep out of the reach of children. (in CLP section as a p phrase)

Do not use near food, drink and animal feedingstuffs.

Shelf life is up to 4 years.

**Recommended methods and precautions concerning handling and transport**

[For the Safety Data Sheet section 8 only]:

Wear personal protective equipment, as detailed below:-

Respiratory protection: In the case of vapour formation use a respirator with an approved filter

Hand protection: Wear suitable gloves.

The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

Before removing gloves clean them with soap and water.

Eye/face protection: Safety glasses

Skin and body protection: Wash contaminated clothing before re-use

|  |
| --- |
| : |

Avoid contact with skin and eyes.

**Recommended methods and precautions concerning fire; in case of fire nature of reaction products, combustion gases etc.**

[For the Safety Data Sheet section 5 only]:

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Particulars of likely direct or indirect adverse effects**

[For the Safety Data Sheet only]:

Most important symptoms and effects, both acute and delayed  
Eyes: Causes serious eye irritation. No adverse effects expected when used as directed.  
Skin effect: May cause an allergic reaction. Causes skin irritation. No adverse effects expected when used as directed.  
Inhalation: No adverse effects expected when used as directed.   
Ingestion: May cause irritation to moth, throat and stomach. May cause abdominal discomfort.

**First aid instructions, antidotes**

[For the Product Label only]:

See P-Phrases in CLP Labelling Section.

[For the Safety Data Sheet only - These measures will not be included in the product label because they are already covered by the CLP labelling]:

Description of first aid measures  
Inhalation: No special requirements.  
Skin contact: Take off all contaminated clothing immediately.Wash off with soap and plenty of water. Get medical attention if irritation develops and persists.Wash contaminated clothing before re-use.

Eye contact: Remove contact lens. Protect unharmed eye. Keep eye wide open while rinsing.In case of contact with eye, rinse immediately with plenty of water and seek medical advice.

Ingestion: If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label.

**Emergency measures to protect environment in case of accident**

[For the Safety Data Sheet only]:

Outside of normal use, avoid release to the environment.

Prevent large amounts of product from entering drains.

Do not flush into surface water or sanitary sewer system.

Prevent further leakage or spillage if safe to do so.

If the product contaminates rivers and lakes or drains inform respective authorities.

Use appropriate containment to avoid environmental contamination

**Control measures of repellents or poison included in the biocidal product, to prevent action against non-target organisms (relevant for biocidal products only)**

Not required for this type of product.

**Possibility of destruction or decontamination following release in or on the following:**

**Air**

There are no measures available to decontaminate the environment. Risk assessments have been conducted in the PAR and show that the risk to the environment is not significant.

**Water, including drinking water**

There are no measures available to decontaminate the environment. Risk assessments have been conducted in the PAR and show that the risk to the environment is not significant.

**Soil**

There are no measures available to decontaminate the environment. Risk assessments have been conducted in the PAR and show that the risk to the environment is not significant.

**Procedures for waste management of active substance/biocidal product, and if appropriate, its packaging:**

**Possibility of reuse or recycling**

None.

**Possibility of neutralisation of effects**

Not applicable

**Conditions for controller discharge including leachate qualities on disposal**

The products should be prevented from entering drains.

**Conditions for controller incineration**

Disposal should be in accordance with local, state or national legislation.

**Instructions for safe disposal of the biocidal product and its packaging for different groups of users (relevant for biocidal products only)**

Disposal should be in accordance with local, state or national legislation. The packaging can be recycled.

**Procedures, if any, for cleaning application equipment (relevant for biocidal products only)**

Not applicable

**Shelf-life of biocidal product**

The data at 40 oC for 8 weeks on the lavender variant supports a shelf life of 2 years and a study at 20 oC for 48 months is completed and 4 years and supports a shelf life of 4 years.

### Assessment of a combination of biocidal products

Not relevant. The biocidal product is not intended to be used in combination with other biocidal products.

### Comparative assessment

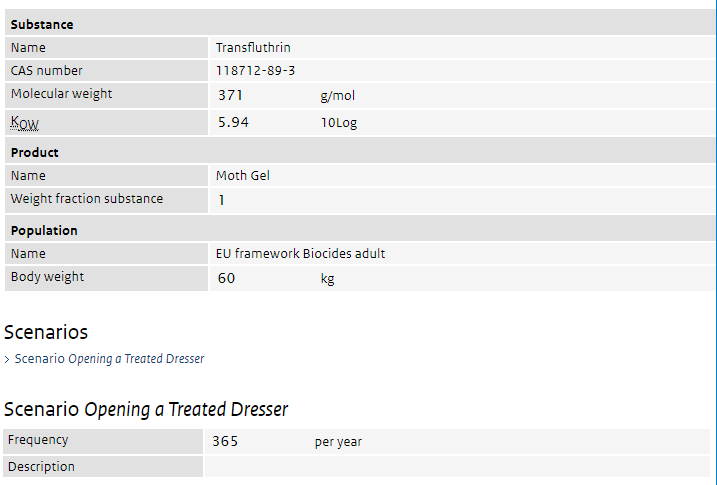
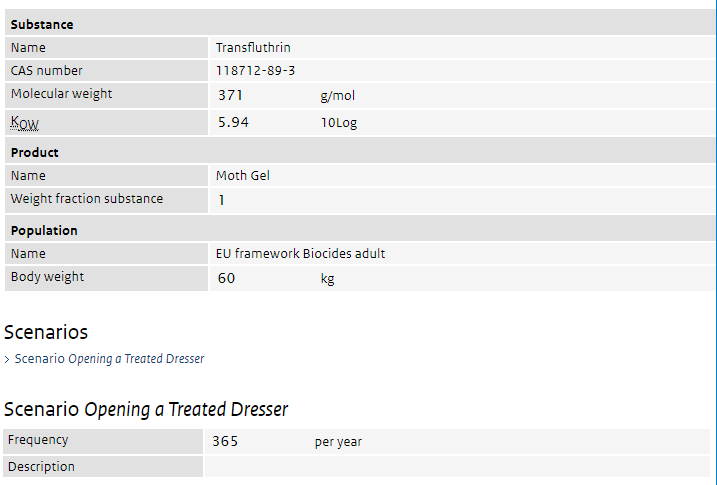
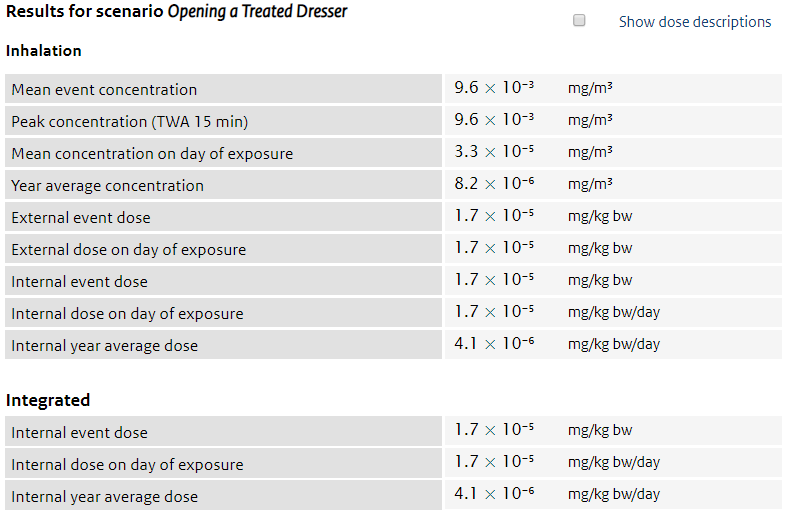
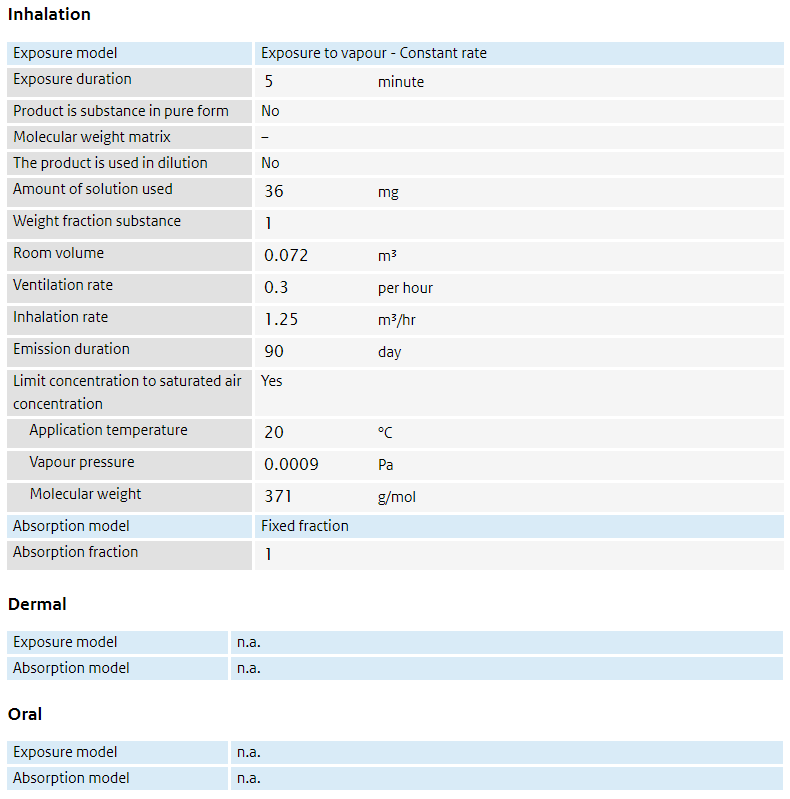
Not relevant. Transfluthrin is not a candidate for substitution. As a result, a comparative assessment is not required.

# Annexes

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

| **Author** | **Year** | **Title** | **Testing laboratory** | **Report no.** | **Legal entity owner** | **Report date** | **Endpoint names** | **GLP** | **Published/**  **Unpublished** | **Data Protection** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| xxxx | 2015a | Efficacy of moth proofer against adults and larvae of clothes moths, Tineola bisselliella, tested in 0.5m³ cabinets | xxxx | BIO103-14 | SC Johnson & Son, Inc | 2015-01-08 | Efficacy data to support these claims, Mo4955 Moth Gel Lavender, (Tineola bisselliella) Gundalai (2015a) | No | Unpublished | Yes |
| xxxx | 2015b | Efficacy of a moth proofer against adults of Clothes moths, Tineola bisselliella tested in 0.5 m³ cabinets | xxxx | BIO043-15 | SC Johnson & Son, Inc | 2015-05-08 | Efficacy data to support these claims, Mo 5137 Moth Gel Cedar, (Tineola bisselliella) Gundalai (2015b) | No | Unpublished | Yes |
| xxxx | 2010a | Efficacy of Raid® Moth Proofer against Clothes moth, adults | xxxx | BIO25b-10 | SC Johnson & Son, Inc | 2010-07-14 | Efficacy data to support these claims, Mo3792 Moth Gel Lavender, (Tineola bisselliella) Jung (2010a) | No | Unpublished | Yes |
| xxxx | 2010b | Efficacy of Raid® Moth Proofer against Clothes moth, adults | xxxx | BIO097-10 | SC Johnson & Son, Inc | 2010-12-15 | Efficacy data to support these claims, Mo3998 Moth Gel Cedar, (Tineola bisselliella) Jung (2010b) | No | Unpublished | Yes |
| xxxx | 2014a | Flash point A.9 of Nevar LPT | xxxx | M04977 | S.C. Johnson & Son, Inc., 1525 Howe St., Racine, Wisconsin 53403, USA | 2014-08-22 | Flash Point\_Mo4977  Moth Gel Lavender | Yes | Unpublished | Yes |
| xxxx | 2014b | Determination of Evaporation Kinetics of Nevar LPT | xxxx | Mo4951 | .C. Johnson & Son, Inc., 1525 Howe St., Racine, Wisconsin 53403, USA | 2014-10-27 | Evaporation Rate \_Mo4951 Moth Gel Lavender | Yes | Unpublished | Yes |
| xxxx | 2014c | Validation of Method "MV101:SCJ: GC-Determination of Transfluthrin in Nevar LPT" | xxxx | Mo4964 | S.C. Johnson & Son, Inc., 1525 Howe St., Racine, Wisconsin 53403, USA | 2014-07-17 | Methods of detection and identification\_Mo4964 Validation of method MV101 Moth Gel Lavender | Yes | Unpublished | Yes |
| xxxx | 2015a | Determination of physico-chemical Properties and Storage Stability Tests for Nevar LPT: 48 months at 20 oC. | xxxx | Mo4952 | S.C. Johnson & Son, Inc., 1525 Howe St., Racine, Wisconsin 53403, USA | 2015-09-15 | Relative density (liquids) and bulk, tap density (solids).001\_Mo4952 Moth Gel Lavender | Yes | Unpublished | Yes |
| xxxx | 2015a | Determination of physico-chemical Properties and Storage Stability Tests for Nevar LPT: 48 months at 20 oC. | xxxx | Mo4952 | S.C. Johnson & Son, Inc., 1525 Howe St., Racine, Wisconsin 53403, USA | 2015-09-15 | Storage stability tests.004\_Mo4952 Moth Gel Lavender 12 month interim report 20 oC  Viscosity | Yes | Unpublished | Yes |
| xxxx | 2015b | Determination of physico-chemical Properties and Storage Stability Tests for Nevar LPT: 12 months at 40 °C | xxxx | Mo4956 | S.C. Johnson & Son, Inc., 1525 Howe St., Racine, Wisconsin 53403, USA | 2015-09-15 | Storage stability tests.002\_Mo4956 Moth Gel Lavender 12 months 40 oC | Yes | Unpublished | Yes |
| xxxx | 2015c | Determination of physico-chemical Properties and Storage Stability Tests for Radec: 12 months at 40 °C | xxxx | Mo5140 | S.C. Johnson & Son, Inc., 1525 Howe St., Racine, Wisconsin 53403, USA | 2015-07-09 | Storage stability tests.001\_Mo5140 Moth Gel Cedar 8 week interim report 40 oC | Yes | Unpublished | Yes |
| xxxx | 2015d | Determination of physico-chemical Properties and Storage Stability Tests for Radec: 48 months at 20 °C | xxxx | Mo5139 | S.C. Johnson & Son, Inc., 1525 Howe St., Racine, Wisconsin 53403, USA | 2015-08-12 | Storage stability tests.003\_Mo5139 Moth Gel Cedar 48 months 20 oC | Yes | Unpublished | Yes |
| xxxx | 2015e | Flash point A.9 of Radec | xxxx | Mo5147 | S.C. Johnson & Son, Inc., 1525 Howe St., Racine, Wisconsin 53403, USA | 2015-08-14 | Flash Point\_ Mo4977 Moth Gel Cedar | Yes | Unpublished | Yes |

## Output tables from exposure assessment tools



## 2.3 QSAR estimates for metabolites

**DCVA**

ECOSAR

Input for SMILES:

Transfluthrin: Fc1c(F)cc(F)c(F)c1C(=O)(O)

DCVA: OC(=O)C2C(C)(C)C2C=C(Cl)Cl

ECOSAR Version 1.11 Results

SMILES : OC(=O)C2C(C)(C)C2C=C(CL)CL

CHEM :

CAS Num:

ChemID1:

MOL FOR: C8 H10 CL2 O2

MOL WT : 209.07

Log Kow: 3.376 (EPISuite Kowwin v1.68 Estimate)

Log Kow: (User Entered)

Log Kow: (PhysProp DB exp value - for comparison only)

Melt Pt: (User Entered for Wat Sol estimate)

Melt Pt: (deg C, PhysProp DB exp value for Wat Sol estimate)

Wat Sol: 127.6 (mg/L, EPISuite WSKowwin v1.43 Estimate)

Wat Sol: (User Entered)

Wat Sol: (PhysProp DB exp value)

--------------------------------------

Values used to Generate ECOSAR Profile

--------------------------------------

Log Kow: 3.376 (EPISuite Kowwin v1.68 Estimate)

Wat Sol: 127.6 (mg/L, EPISuite WSKowwin v1.43 Estimate)

--------------------------------------

ECOSAR v1.11 Class-specific Estimations

--------------------------------------

Vinyl/Allyl Halides-acid

Predicted

ECOSAR Class Organism Duration End Pt mg/L (ppm)

=========================== ================== ======== ====== ==========

--> Acid moeity found: Predicted values multiplied by 10

Vinyl/Allyl Halides-acid : Fish 96-hr LC50 22.759

Vinyl/Allyl Halides-acid : Daphnid 48-hr LC50 20.210

Vinyl/Allyl Halides-acid : Green Algae 96-hr EC50 43.351

Vinyl/Allyl Halides-acid : Fish ChV 3.841

Vinyl/Allyl Halides-acid : Daphnid ChV 0.717

Vinyl/Allyl Halides-acid : Green Algae ChV 17.660 !

Vinyl/Allyl Halides-acid : Fish (SW) 96-hr LC50 12.220

Vinyl/Allyl Halides-acid : Mysid (SW) 96-hr LC50 6.600

Vinyl/Allyl Halides-acid : Earthworm 14-day LC50 2134.007 \*

=========================== ================== ======== ====== ==========

Neutral Organic SAR : Fish 96-hr LC50 9.973

(Baseline Toxicity) : Daphnid 48-hr LC50 6.430

: Green Algae 96-hr EC50 8.101

: Fish ChV 1.133

: Daphnid ChV 0.893

: Green Algae ChV 2.815

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Class Specific LogKow Cut-Offs

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If the log Kow of the chemical is greater than the endpoint specific cut-offs

presented below, then no effects at saturation are expected for those endpoints.

Vinyl/Allyl Halides:

-------------------

Maximum LogKow: 6.0 (Fish 96-hr LC50; Daphnid LC50; Mysid LC50)

Maximum LogKow: 6.4 (Green Algae EC50)

Maximum LogKow: 5.0 (Fish (SW) 96-hr LC50)

Maximum LogKow: 6.0 (Earthworm LC50)

Maximum LogKow: 8.0 (ChV)

Baseline Toxicity SAR Limitations:

---------------------------------

Maximum LogKow: 5.0 (Fish 96-hr LC50; Daphnid LC50)

KOCWIN v2.00 Results

SMILES : OC(=O)C2C(C)(C)C2C=C(Cl)Cl

CHEM :

MOL FOR: C8 H10 CL2 O2

Koc may be sensitive to pH!

Koc Estimate from MCI:

---------------------

First Order Molecular Connectivity Index ........... : 5.370

Non-Corrected Log Koc (0.5213 MCI + 0.60) .......... : 3.3991

Fragment Correction(s):

\* Organic Acid (-CO-OH) ............... : -1.6249

Corrected Log Koc .................................. : 1.7743

Estimated Koc: 59.47 L/kg <===========

Koc Estimate from Log Kow:

-------------------------

Log Kow (Kowwin estimate) ......................... : 3.38

Non-Corrected Log Koc (0.55313 logKow + 0.9251) .... : 2.7947

Fragment Correction(s):

\* Organic Acid (-CO-OH) ............... : -0.7694

Corrected Log Koc .................................. : 2.0253

Estimated Koc: 106 L/kg <===========

|  |
| --- |
| PNEC Results:  Fish 96 hr LC50 of 9.97 mg/L  Daphnia 48 hr LC50 of 6.420 mg/L  Green algae EC50 of 8.101 mg/L  Based on the AF of 1000, the resulting PNECaquatic for DCVA is **0.0064** mg/L.  To determine the PNECsoil, the following parameters were included for equilibrium partitioning:  Water solubility of 127.6 mg/L (QSAR, presented above)  Vapour pressure of 2.60 Pa (at 25 degC, QSAR, MbBp results, not shown here)  log Koc of 2.025 (at 25 degC, QSAR, presented above)  Resulting from this, in combination with the PNECaquatic, the PNECsoil was calculated to be **0.0128** mg/kg ww. |

**cis-CH2OH-trans-DCVA**

SMILES : CC1(C(C1C(=O)O)C=C(CL)CL)CO

CHEM :

CAS Num:

ChemID1:

MOL FOR: C8 H10 CL2 O3

MOL WT : 225.07

Log Kow: 1.911 (EPISuite Kowwin v1.68 Estimate)

Log Kow: (User Entered)

Log Kow: (PhysProp DB exp value - for comparison only)

Melt Pt: (User Entered for Wat Sol estimate)

Melt Pt: (deg C, PhysProp DB exp value for Wat Sol estimate)

Wat Sol: 6059 (mg/L, EPISuite WSKowwin v1.43 Estimate)

Wat Sol: (User Entered)

Wat Sol: (PhysProp DB exp value)

--------------------------------------

Values used to Generate ECOSAR Profile

--------------------------------------

Log Kow: 1.911 (EPISuite Kowwin v1.68 Estimate)

Wat Sol: 6059 (mg/L, EPISuite WSKowwin v1.43 Estimate)

--------------------------------------

ECOSAR v1.11 Class-specific Estimations

--------------------------------------

Vinyl/Allyl Halides-acid

Predicted

ECOSAR Class Organism Duration End Pt mg/L (ppm)

=========================== ================== ======== ====== ==========

--> Acid moeity found: Predicted values multiplied by 10

Vinyl/Allyl Halides-acid : Fish 96-hr LC50 526.519

Vinyl/Allyl Halides-acid : Daphnid 48-hr LC50 422.841

Vinyl/Allyl Halides-acid : Green Algae 96-hr EC50 598.213

Vinyl/Allyl Halides-acid : Fish ChV 239.515

Vinyl/Allyl Halides-acid : Daphnid ChV 2.329

Vinyl/Allyl Halides-acid : Green Algae ChV 125.438 !

Vinyl/Allyl Halides-acid : Fish (SW) 96-hr LC50 374.905

Vinyl/Allyl Halides-acid : Mysid (SW) 96-hr LC50 187.685

Vinyl/Allyl Halides-acid : Earthworm 14-day LC50 2908.102

=========================== ================== ======== ====== ==========

Neutral Organic SAR : Fish 96-hr LC50 222.027

(Baseline Toxicity) : Daphnid 48-hr LC50 125.042

: Green Algae 96-hr EC50 90.050

: Fish ChV 21.494

: Daphnid ChV 11.920

: Green Algae ChV 23.157

Note: \* = asterisk designates: Chemical may not be soluble enough to

measure this predicted effect. If the effect level exceeds the

water solubility by 10X, typically no effects at saturation (NES)

are reported.

NOTE: ! = exclamation designates: The toxicity value was estimated through

application of acute-to-chronic ratios per methods outlined in

the ECOSAR Methodology Document provided in the ECOSAR Help Menu.

------------------------------

Class Specific LogKow Cut-Offs

------------------------------

If the log Kow of the chemical is greater than the endpoint specific cut-offs

presented below, then no effects at saturation are expected for those endpoints.

Vinyl/Allyl Halides:

-------------------

Maximum LogKow: 6.0 (Fish 96-hr LC50; Daphnid LC50; Mysid LC50)

Maximum LogKow: 6.4 (Green Algae EC50)

Maximum LogKow: 5.0 (Fish (SW) 96-hr LC50)

Maximum LogKow: 6.0 (Earthworm LC50)

Maximum LogKow: 8.0 (ChV)

Baseline Toxicity SAR Limitations:

---------------------------------

Maximum LogKow: 5.0 (Fish 96-hr LC50; Daphnid LC50)

Maximum LogKow: 6.4 (Green Algae EC50)

Maximum LogKow: 8.0 (ChV)

**TFB-OH**

SMILES : c1(F)c(F)c(CO)c(F)c(F)c1

CHEM :

MOL FOR: C7 H4 F4 O1

MOL WT : 180.10

--------------------------- KOCWIN v2.00 Results ---------------------------

Koc Estimate from MCI:

---------------------

First Order Molecular Connectivity Index ........... : 5.575

Non-Corrected Log Koc (0.5213 MCI + 0.60) .......... : 3.5058

Fragment Correction(s):

1 Aliphatic Alcohol (-C-OH) ........... : -1.3179

Corrected Log Koc .................................. : 2.1879

Estimated Koc: 154.1 L/kg <===========

Koc Estimate from Log Kow:

-------------------------

Log Kow (Kowwin estimate) ......................... : 1.88

Non-Corrected Log Koc (0.55313 logKow + 0.9251) .... : 1.9650

Fragment Correction(s):

1 Aliphatic Alcohol (-C-OH) ........... : -0.4114

Corrected Log Koc .................................. : 1.5535

Estimated Koc: 35.77 L/kg <===========

Water Sol: 4439 mg/L

SMILES : c1(F)c(F)c(CO)c(F)c(F)c1

CHEM :

MOL FOR: C7 H4 F4 O1

MOL WT : 180.10

---------------------------------- WSKOW v1.42 Results ------------------------

Log Kow (estimated) : 1.88

Log Kow (experimental): not available from database

Log Kow used by Water solubility estimates: 1.88

Equation Used to Make Water Sol estimate:

Log S (mol/L) = 0.796 - 0.854 log Kow - 0.00728 MW + Correction

(used when Melting Point NOT available)

Correction(s): Value

-------------------- -----

Alcohol, aliphatic 0.510

Log Water Solubility (in moles/L) : -1.608

Water Solubility at 25 deg C (mg/L): 4439

Experimental Database Structure Match: no data

SMILES : c1(F)c(F)c(CO)c(F)c(F)c1

CHEM :

MOL FOR: C7 H4 F4 O1

MOL WT : 180.10

------------------------ SUMMARY MPBPWIN v1.43 --------------------

Vapor Pressure Estimations (25 deg C):

(Using BP: 187.16 deg C (estimated))

(MP not used for liquids)

VP: 0.176 mm Hg (Antoine Method)

: 23.5 Pa (Antoine Method)

VP: 0.142 mm Hg (Modified Grain Method)

: 18.9 Pa (Modified Grain Method)

VP: 0.979 mm Hg (Mackay Method)

: 131 Pa (Mackay Method)

Selected VP: 0.159 mm Hg (Mean of Antoine & Grain methods)

: 21.2 Pa (Mean of Antoine & Grain methods)

**TFB-COOH**

Smiles: C1=C(C(=C(C(=C1F)F)C(=O)O)F)F

SMILES : c1c(c(c(c(c1F)F)C(=O)O)F)F

CHEM :

MOL FOR: C7 H2 F4 O2

Koc may be sensitive to pH!

--------------------------- KOCWIN v2.00 Results ---------------------------

Koc Estimate from MCI:

---------------------

First Order Molecular Connectivity Index ........... : 5.947

Non-Corrected Log Koc (0.5213 MCI + 0.60) .......... : 3.7001

Fragment Correction(s):

\* Organic Acid (-CO-OH) ............... : -1.6249

Corrected Log Koc .................................. : 2.0752

Estimated Koc: 118.9 L/kg <===========

Koc Estimate from Log Kow:

-------------------------

Log Kow (Kowwin estimate) ......................... : 1.58

Non-Corrected Log Koc (0.55313 logKow + 0.9251) .... : 1.7990

Fragment Correction(s):

\* Organic Acid (-CO-OH) ............... : -0.7694

Corrected Log Koc .................................. : 1.0297

Estimated Koc: 10.71 L/kg <===========

Water Sol: 2114 mg/L

SMILES : c1c(c(c(c(c1F)F)C(=O)O)F)F

CHEM :

MOL FOR: C7 H2 F4 O2

MOL WT : 194.09

---------------------------------- WSKOW v1.42 Results ------------------------

Log Kow (estimated) : 1.58

Log Kow (experimental): not available from database

Log Kow used by Water solubility estimates: 1.58

Equation Used to Make Water Sol estimate:

Log S (mol/L) = 0.796 - 0.854 log Kow - 0.00728 MW + Correction

(used when Melting Point NOT available)

Correction(s): Value

-------------------- -----

Acid, aromatic 0.000

Log Water Solubility (in moles/L) : -1.963

Water Solubility at 25 deg C (mg/L): 2114

Experimental Database Structure Match:

Name : 2,3,5,6-Tetrafluorobenzoic Acid

CAS Num : 000652-18-6

Exp MP (deg C): 151

Exp BP (deg C): ---

Exp VP (mm Hg): ---

SMILES : c1c(c(c(c(c1F)F)C(=O)O)F)F

CHEM :

MOL FOR: C7 H2 F4 O2

MOL WT : 194.09

------------------------ SUMMARY MPBPWIN v1.43 --------------------

Vapor Pressure Estimations (25 deg C):

(Using BP: 232.98 deg C (estimated))

(Using MP: 151.00 deg C (exp database))

VP: 0.00367 mm Hg (Antoine Method)

: 0.489 Pa (Antoine Method)

VP: 0.0033 mm Hg (Modified Grain Method)

: 0.44 Pa (Modified Grain Method)

VP: 0.00616 mm Hg (Mackay Method)

: 0.821 Pa (Mackay Method)

Selected VP: 0.0033 mm Hg (Modified Grain Method)

: 0.44 Pa (Modified Grain Method)

Subcooled liquid VP: 0.0634 mm Hg (25 deg C, Mod-Grain method)

: 8.45 Pa (25 deg C, Mod-Grain method)

## New information on the active substance

Since the approval of Transfluthrin in 2014 the following studies on fate, behaviour and ecotoxicity have been conducted:

xxxx (2015). A study on the chronic toxicity to the sediment dweller *Lumbriculus variegatus*. xxxx

xxxx (2014a). Transfluthrin a.s. (BCS-AW53131): Sublethal toxicity to the earthworm *Eisenia fetida* in artificial soil xxxx

xxxx (2014b). Transfluthrin a.s.: Effects on the reproduction of the collembolan *Folsomia candida* xxxx

xxxx (2015). [methylene-14C]transfluthrin: Aerobic Degradation / Metabolism in Four Soils. xxxx

xxxx (2017) Transfluthrin: Degradation in activated sludge - OECD Guidelines for Testing Chemicals: 314 B, biodegradation in activated sludge (adopted on October 03, 2008); xxxx

xxxx (2015). *Chironomus riparius* 28-day chronic toxicity test with transfluthrin (tech.) in a water-sediment system using spiked sediment. xxxx

xxxx (2015a). Early Life Stage Toxicity of Transfluthrin Technical to the Fathead minnow (*Pimephales promelas*) Under Flow-Through Conditions. xxxx

xxxx (2015b): Chronic Toxicity of Transfluthrin Technical to *Daphnia magna* Under Flow-Through Conditions. xxxx

xxxx (2015c). Toxicity of Transfluthrin-Tetrafluorobenzoic acid to the Green Algae *Pseudokirchneriella subcapitata* During a 96 Hour Exposure. Xxxx

xxxx (2015). Transfluthrin a.s. Effects on the seedling emergence and growth of five species of non-target terrestrial plants (Tier 2). xxxx

xxxx (2015). Kinetic Evaluation of the Degradation of Transfluthrin and its Metabolite NAK4723 under Aerobic Laboratory Soil Conditions. xxxx

xxxx (2014). Transfluthrin a.s. (BCS-AW53131): Effects on the activity of soil microflora (Nitrogen transformation test), xxxx

## Residue behaviour

The biocidal product will not be in contact with feedstuffs. The material safety data sheet advises: “ Do not use near food, drink and animal feedingstuffs”.

## Summaries of the efficacy studies

Refer to IUCLID section 6.7 and the efficacy data table in the efficacy chapter.

## Confidential annex

Please see separate document.

## References

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CTGB (2013). Doc IIB- Effects and Exposure Assessment- Biocidal Product(s) for Transfluthrin, August 2013. An estimate for a few fingertips (page 26/52) and removal of clothing by adults from treated closet (page 29/52).

European Commission (2014). Note for Discussion with Competent Authorities for Biocidal Products. CA-Nov14-Doc.5.11

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ECHA, (2012). Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health Version: 2.1. November 2012.

ECHA (2014a). European Commission. Note for Discussion with Competent Authorities for Biocidal Products. CA-Nov14-Doc.5.11

ECHA (2014b) Transitional Guidance on mixture toxicity assessment for biocidal products for the environment. ECHA, May 2014

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ECHA (2017) Guidance on the Biocidal Products Regulation. Volume IV Environment - Part B+C: Assessment and Evaluation. Report no. ECHA-17-G-23-EN. 2017

ECHA (2018) Guidance on the Biocidal Products Regulation Volume II Efficacy - Assessment and Evaluation (Parts B+C) Version 3.0 April 2018

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1. [↑](#footnote-ref-1)
2. Moth Gel FamilyPT18

   [↑](#footnote-ref-2)
3. Moth Gel FamilyPT18

   [↑](#footnote-ref-3)
4. [↑](#footnote-ref-4)
5. Moth Gel FamilyPT18

   [↑](#footnote-ref-5)
6. [↑](#footnote-ref-6)
7. iscli/details/121054" https://www.echa.europa.eu/nl/web/guest/information-on-chemicals/cl-inventory-database/-/discli/details/121054). Please provide more information, e.g. in the MSDS of Isopar V, to indicate whether this note is applicable.

   If H350 is indeed needs to be assigned, Isopar V should be regarded as a SoC and an assessment conform the EU guidance on Substances of Concern (CA-Nov14-Doc.5.11) is required. In this guidance the following is indicated with regard to substances classified as H350: *Use of such SoCs to be discouraged; however, if essential and no safer alternatives available, a full risk assessment should be*  [↑](#footnote-ref-7)
8. *conducted against EU IOELVs (when available), DNELs, DMELs, other references values (e.g. AELs and AECs) or in qualitative manner.*

   The Supplier’s 2017 SDS for Isopar V indicates the EC number is 920-114-2, which is not classified as H350. Please see attached SDS and: HYPERLINK "https://www.echa.europa.eu/nl/web/guest/information-on-chemicals/cl-inventory-database/-/discli/details/30379" https://www.echa.europa.eu/nl/web/guest/information-on-chemicals/cl-inventory-database/-/discli/details/30379

   To the applicant (HH2): noted, thank you.

   To the applicant (HH2): Substances that need to be mentioned in accordance to CLP, are i [↑](#footnote-ref-8)
9. [↑](#footnote-ref-9)
10. [↑](#footnote-ref-10)
11. S = Set parameter provided by applicant; D = default value; O = Output value; P = Picklist value [↑](#footnote-ref-11)
12. S = Set parameter provided by applicant; D = default value; O = Output value; P = Picklist value [↑](#footnote-ref-12)
13. <https://www.echa.europa.eu/web/guest/registration-dossier/-/registered-dossier/13317> [↑](#footnote-ref-13)
14. <https://www.echa.europa.eu/web/guest/registration-dossier/-/registered-dossier/13930> [↑](#footnote-ref-14)
15. <https://echa.europa.eu/en/registration-dossier/-/registered-dossier/19748> [↑](#footnote-ref-15)
16. <https://echa.europa.eu/en/registration-dossier/-/registered-dossier/10720> [↑](#footnote-ref-16)
17. <https://www.echa.europa.eu/web/guest/registration-dossier/-/registered-dossier/25677/1> [↑](#footnote-ref-17)
18. Jenner et al. (2011) reported a degradation value of 78% in OECD 301F ready biodegradability test. Whether or not the 10-d window was fulfilled was not specified in the publication. Therefore, for the purpose of this risk assessment it is assumed that the 10-d window was not fulfilled. [↑](#footnote-ref-18)
19. <https://echa.europa.eu/nl/registration-dossier/-/registered-dossier/14971> [↑](#footnote-ref-19)