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

**RISK ASSESSMENT OF A BIOCIDAL FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the eCA)



**Night & Day™ Family**

Product type PT 18

Transfluthrin

Case Number in R4BP: BC-TH020224-49

Evaluating Competent Authority: The Netherlands

Date: October 2020

Table of Contents

[1 CONCLUSION 4](#_Toc59197938)

[2 ASSESSMENT REPORT 6](#_Toc59197939)

[2.1 Summary of the product assessment 6](#_Toc59197940)

[2.1.1 Administrative information 6](#_Toc59197941)

[2.1.1.1 Identifier of the product / product family 6](#_Toc59197942)

[2.1.1.2 Authorisation holder 8](#_Toc59197943)

[2.1.1.3 Manufacturer(s) of the products of the family 9](#_Toc59197944)

[2.1.1.4 Manufacturer(s) of the active substance(s) 9](#_Toc59197945)

[2.1.2 Product (family) composition and formulation 10](#_Toc59197946)

[2.1.2.1 Identity of the active substance 10](#_Toc59197947)

[2.1.2.2 Candidate(s) for substitution 10](#_Toc59197948)

[2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product 11](#_Toc59197949)

[2.1.2.4 Qualitative and quantitative information on the composition of the biocidal product family 11](#_Toc59197950)

[2.1.2.5 Information on technical equivalence 12](#_Toc59197951)

[2.1.2.6 Information on the substance(s) of concern 12](#_Toc59197952)

[2.1.2.7 Endocrine disruption assessment 12](#_Toc59197953)

[2.1.2.8 Type of formulation 12](#_Toc59197954)

[2.1.3 Hazard and precautionary statements 12](#_Toc59197955)

[2.1.4 Authorised use(s) 14](#_Toc59197956)

[2.1.4.1 Use description 14](#_Toc59197957)

[2.1.4.2 Use-specific instructions for use 1 15](#_Toc59197958)

[2.1.4.3 Use-specific risk mitigation measures 16](#_Toc59197959)

[2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 16](#_Toc59197960)

[2.1.4.5 Where specific to the use, the instructions for safe disposal of the product and its packaging 16](#_Toc59197961)

[2.1.4.6 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 17](#_Toc59197962)

[2.1.4.7 Use description 17](#_Toc59197963)

[2.1.4.8 Use-specific instructions for use 2 18](#_Toc59197964)

[2.1.4.9 Use-specific risk mitigation measures 20](#_Toc59197965)

[2.1.4.10 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 21](#_Toc59197966)

[2.1.4.11 Where specific to the use, the instructions for safe disposal of the product and its packaging 21](#_Toc59197967)

[2.1.4.12 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 21](#_Toc59197968)

[2.1.5 General directions for use 22](#_Toc59197969)

[2.1.5.1 Instructions for use 22](#_Toc59197970)

[2.1.5.2 Risk mitigation measures 22](#_Toc59197971)

[2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 23](#_Toc59197972)

[2.1.5.4 Instructions for safe disposal of the product and its packaging 23](#_Toc59197973)

[2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage 23](#_Toc59197974)

[2.1.6 Other information 24](#_Toc59197975)

[2.1.7 Packaging of the biocidal product 24](#_Toc59197976)

[2.1.8 Documentation 25](#_Toc59197977)

[2.1.8.1 Data submitted in relation to product application 25](#_Toc59197978)

[2.1.8.2 Access to documentation 25](#_Toc59197979)

[2.2 Assessment of the biocidal product (family) 26](#_Toc59197980)

[2.2.1 Intended use(s) as applied for by the applicant 26](#_Toc59197981)

[2.2.2 Physical, chemical and technical properties 27](#_Toc59197982)

[2.2.3 Physical hazards and respective characteristics 35](#_Toc59197983)

[2.2.4 Methods for detection and identification 39](#_Toc59197984)

[2.2.5 Efficacy against target organisms 42](#_Toc59197985)

[2.2.5.1 Function and Field of Use 42](#_Toc59197986)

[2.2.5.2 Organisms to be controlled and products, organisms or objects to be protected 42](#_Toc59197987)

[2.2.5.3 Effects on target organisms, including unacceptable suffering 42](#_Toc59197988)

[2.2.5.4 Mode of action, including time delay 42](#_Toc59197989)

[2.2.5.5 Efficacy data 43](#_Toc59197990)

[Reports list Night&Day by the project name Obewan and Night&Day Trio by project name Leia. The composition of the tested substances are identical to the product to be authorized. 43](#_Toc59197991)

[2.2.5.6 Occurrence of resistance and resistance management 58](#_Toc59197992)

[2.2.5.7 Known limitations 58](#_Toc59197993)

[2.2.5.8 Evaluation of the label claims 58](#_Toc59197994)

[2.2.5.9 Relevant information if the product is intended to be authorised for use with other biocidal product(s) 62](#_Toc59197995)

[2.2.6 Risk assessment for human health 63](#_Toc59197996)

[2.2.6.1 Assessment of effects on Human Health 63](#_Toc59197997)

[2.2.6.2 Exposure assessment 71](#_Toc59197998)

[**2.2.7 Risk assessment for animal health** 92](#_Toc59197999)

[2.2.8 Risk assessment for the environment 93](#_Toc59198000)

[2.2.8.1 Effects assessment on the environment 93](#_Toc59198001)

[2.2.8.2 Exposure assessment 108](#_Toc59198002)

[2.2.8.3 Risk characterisation 118](#_Toc59198003)

[2.2.9 Measures to protect man, animals and the environment 124](#_Toc59198004)

[2.2.10 Assessment of a combination of biocidal products 124](#_Toc59198005)

[2.2.11 Comparative assessment 124](#_Toc59198006)

[3 Annexes 125](#_Toc59198007)

[3.1 List of studies for the biocidal product (family) 126](#_Toc59198008)

[3.2 Output tables from exposure assessment tools 131](#_Toc59198009)

[3.3 New information on the active substance 134](#_Toc59198010)

[3.4 Residue behaviour 135](#_Toc59198011)

[3.5 Summaries of the efficacy studies (B.5.10.1-xx) 135](#_Toc59198012)

[3.6 QSAR estimates and PNEC calculation for metabolites 136](#_Toc59198013)

[3.7 PEARL output (env RA) 142](#_Toc59198014)

[3.8 Confidential annex 143](#_Toc59198015)

[3.9 References 143](#_Toc59198016)

# CONCLUSION

The vapour releasing product family Night & Day™ containing 13.4 % transfluthrin. It can be used by the general public (non-professional) one or three heating settings (use # 4.1 and 4.2).

The product is not meant to be co-applied with other substances or products.

The family Night & Day™ is a vapour releasing product. The product family consists of a single formulation used in two electrical heating devices: Night & Day™ and Night & Day™ Trio. The formulation used in the devices consists of transfluthrin absorbed in an inert carrier matrix. The inert matrix is heated by an electrical heater unit which causes the transfluthrin to evaporate in a controlled manner.

Night & Day™ Trio has three heating settings and Night & Day™ a single heating setting. The setting for Night & Day™ is equivalent to the “middle” setting on Night & Day™ Trio, hence Night & Day™ has the same evaporation rate as the “middle” setting on Night & Day™ Trio

The product was stored in the commercial packaging and found to be stable over 48 months at ambient temperature, 6 months at 40°C and 2 weeks at 54°C. The silver foil excludes light from the sandcore during storage.

The efficacy and duration claim for the Night&Day device is equivalent to the Night&Day Trio device at the ‘medium’ setting and the experimentally measured value from CEMR-3150 states the Transfluthrin release rate for Raid Night&Day to be 1.0247mg/h.

Efficacy of the products to be authorized was tested in simulated-use tests with Aedes aegypti, Aedes albopictus, Anopheles gambiae, Culex quinquefasciatus, Musca domestica and Lasius niger. Efficacy was demonstrated for fresh product as well as for product in the middle and at the end of the lifespan. Furthermore, efficacy was demonstrated at the low and high release settings for Night&Day Trio.

As the use of Transfluthrin will be indoors only for small scale, localised use as a domestic insecticide (amateur, ready-to-use household product), no significant direct exposure of outdoor environmental compartments will occur.

It is considered that the ecotoxicological information on the active substance Transfluthrin, and the data provided on the components of the product, are sufficient to assess any potential risk to the environment from use of the product. A study using the formulated product is therefore not considered necessary nor an appropriate use of animals.

The environmental risk assessment for the products ‘Night & Day™ ’ and ‘Night & Day™ Trio’ 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. Both products are the same with the exception that ‘Night & Day™ Trio’ has an adjustable setting. The duration of use was taken as 160 hours, reflecting the maximum duration of use associated with ‘Night & Day™ Trio’ on ‘High’ setting. This is a worst-case value, which means that the risk assessment also covers use of Night & Day™ Trio.

Two different estimates of emission to wastewater were calculated: One assuming ESD default values; and one taking account of a refinement that better reflects the actual exposure potential associated with the use of the product.

Using conservative estimates of partitioning in STP (SimpleTreat 4.0 with 3.1 settings in-line with WG agreements), the default calculations indicated a potential risk for the water and sediment compartments when the 10% refinement was not included.

Application of refinement based on increased understanding of potential for removal by cleaning reduces the PEC/PNEC values in water for both parent and metabolites to acceptable levels.

All PEC/PNEC values for the terrestrial environment were <1, both for the parent transfluthrin and all relevant metabolites, demonstrating that unacceptable risk would not be expected for this compartment.

Predicted concentrations in groundwater were below < 0.1 μg/L for the active substance and all metabolites. For the metabolites, a 2nd tier exposure assessment (PEARL) was required.

An assessment of secondary poisoning potential also demonstrated that no unacceptable risk via the food chain would be expected.

Therefore, it is concluded that the use of the products ‘Night & Day™’ and ‘Night & Day™ Trio’ in accordance with label instructions will not result in unacceptable risk to the environment.

# ASSESSMENT REPORT

## Summary of the product assessment

### Administrative information

#### Identifier of the product / product family

| **Identifier[[1]](#footnote-1)** | **Country (if relevant)** | **Registration Number** |
| --- | --- | --- |
| Night & Day™ | Netherlands |  |
| Night & Day™ Trio | Netherlands |  |
| Raid® Night & Day™ | Netherlands |  |
| Raid® Night & Day™ Trio | Netherlands |  |
| Raid® Night&Day™ Trio Insekten-Stecker | Austria |  |
| Raid® Night&Day™ Trio Insekten-Stecker Nachfüller | Austria |  |
| Baygon® Diffuseur de Concentré Actif | Belgium | Current registration number 5611/B |
| Baygon® Geconcentreerd Actief Verspreider | Belgium | Current registration number 5611/B |
| Raid® Ден и Нощ  Трио срещу комари, мухи и мравки | Bulgaria | Current registration number 1189-1 |
| Raid® Ден и Нощ срещу комари, мухи и мравки | Bulgaria | Current registration number 1189-1 |
| RAID® ELEKTIRČNI APARATIĆ NIGHT & DAY™ - PROTIV MUHA I KOMARACA | Croatia | UP/I-543-04/09-05/522  Ur. broj: 534-08-01-4/5-10-2 |
| RAID® ELEKTIRČNI APARATIĆ NIGHT & DAY™ - PROTIV MUHA I KOMARACA Punjenje | Croatia | UP/I-543-04/09-05/522  Ur. broj: 534-08-01-4/5-10-2 |
| RAID NIGHT &  DAY | Cyprus | Current registration number B356 |
| RAID NIGHT & DAY TRIO | Cyprus |  |
| RAID ΝΥΧΤΑ & ΜΕΡΑ | Cyprus |  |
| BAYGON NIGHT & DAY | Cyprus |  |
| BAYGON ΝΥΧΤΑ & ΜΕΡΑ | Cyprus |  |
| BAYGON NIGHT & DAY TRIO | Cyprus |  |
| Raid® proti komárům a mouchám pro den i noc odpařovač | Czech Republic | Current registration number REG-33.7.1-26.9.06/40180 |
| Raid® proti komárům a mouchám pro den i noc náhradní náplň | Czech Republic | Current registration number REG-33.7.1-26.9.06/40180 |
| Raid® noc & den trio-odpařovač | Czech Republic | Current registration number MZDR 56043/2011/SOZ |
| Raid® noc & den trio-náplň | Czech Republic | Current registration number MZDR 56043/2011/SOZ |
| RAID® Night & Day™ - Diffuseur Anti-Moustiques, Mouches et Fourmis (Diffuseur+Recharge / Recharge) | France | INVENTORY NUMBER: 26322 / INRS AR N°120174 |
| RAID Night & Day - Diffuseur Anti-Moustiques, Moustiques tigres et Mouches (Diffuseur+Recharge / Recharge) | France | INVENTORY NUMBER: 26322 / INRS AR N°120174 |
| RAID® Night & Day™ Trio - Diffuseur Anti-Moustiques, Moustiques Tigres, Mouches et Fourmis (Diffuseur+Recharge / Recharge) | France | INVENTORY NUMBER: 31633 / AR N°17451 |
| Raid® Night&Day™ Trio Insekten-Stecker | Germany | Current notification number N-51719 |
| Raid® Night&Day™ Trio Insekten-Stecker Nachfüller | Germany | Current notification number N-51720 |
| RAID NIGHT & DAY | Greece | Current registration number ΤΠ18-0006 |
| RAID NIGHT & DAY TRIO | Greece |  |
| RAID ΝΥΧΤΑ & ΜΕΡΑ | Greece |  |
| BAYGON NIGHT & DAY | Greece |  |
| BAYGON ΝΥΧΤΑ & ΜΕΡΑ | Greece |  |
| BAYGON NIGHT & DAY TRIO | Greece |  |
| Raid® 240 oras szunyog es legyirto Korong | Hungary | Current registration number OTH-1147-4-2009 |
| Raid® Night & Day™ | Italy | Current registration number 19247 |
| Raid® Night & Day™ Trio | Italy | Current registration number 19758 |
| Baygon® Diffuseur de Concentré Actif | Luxembourg | Current notification number 21/12/L-000 |
| Raid® Night & Day™ przeciw muchom, komarom i mrówkom - elektrofumigator owadobójczy z wymiennym wkładem | Poland | Current registration number 3036/06 |
| Raid® Night & Day™ przeciw muchom, komarom i mrówkom -wymienny wkład do elektrofumigatora owadobójczego | Poland | Current registration number 3037/06 |
| Raid® Night & Day™ Trio - elektrofumigator owadobójczy z wymiennym wkładem | Poland | Current registration number 4545/11 |
| Raid® Night & Day™ Trio - wymienny wkład do elektrofumigatora owadobójczego | Poland | Current registration number 5050/12 |
| Raid® Night & Day™ Eléctrico | Portugal | Current registration number 1514S |
| RAID® NIGHT & DAY™ BAZA | Romania | Current registration number 1707BIO/18/12.24 |
| Raid® Night & DayTM aparat împotriva ţânţarilor, muştelor şi furnicilor |
| RAID® NIGHT & DAY™ REZERVA | Romania | Current registration number 1708BIO/18/12.24 |
| Raid® Night & DayTM rezervă pentru aparat împotriva ţânţarilor, muştelor şi furnicilor |
| RAID® NIGHT & DAY™ TRIO REZERVA | Romania | Current registration number 2346BIO/18/12.24 |
| Raid® Night & DayTM Trio aparat împotriva ţânţarilor comuni, ţânţarilor tigru, muştelor şi furnicilor |
| Raid® Night & DayTM Trio rezervă pentru aparat împotriva ţânţarilor comuni, ţânţarilor tigru, muştelor şi furnicilor |
| Raid® proti komárom a muchám pre deň i noc odparovač | Slovakia | Current registration number bio/1050/D/06/CCHLP |
| Raid® proti komárom a muchám pre deň i noc náhradná náplň | Slovakia | Current registration number bio/1050/D/06/CCHLP |
| RAID® NOC & DEŇ TRIO-odparovač / RAID® NOC & DEŇ TRIO-náplň | Slovakia | Current registration number bio/1320/D/11/5/CCHLP |
| Raid® Night & Day™ Mosquitos Comunes y Tigre | Spain | Current registration number 11-30-00037 |
| Raid® Night & Day™ Moscas, Mosquitos y Hormigas | Spain | Current registration number 12-30-04374 |
| Raid® Night & DAY™ | Slovenia |  |
| Raid® Night & Day™ Trio | Slovenia |  |
| Raid® NIGHT & DAY™ Trio | United Kingdom | Current registration number HSE 9534 |

#### 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** |  | |
| **Expiry date of the authorisation** |  | |

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

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

|  |  |
| --- | --- |
| **Active substance** | Transfluthrin |
| **Name of manufacturer** | Bayer SAS |
| **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, 2nd phase  GIDC, Vapi 396 195, Gujarat  India |

### Product (family) composition and formulation

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% |
| **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. refers to the correct isomer.*

#### Candidate(s) 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

| **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, or,  2,3,5,6-tetrafluorobenzyl (1R)-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate | Active substance | 118712-89-3 | 405-060-5 | 13.4\*  (technical)  12.9 (pure) |
| Refer to the confidential annex 3.6 for details of the co-formulants | | | | | |
| \*equivalent to 300 mg of pure transfluthrin per device, range (255-345 mg per device, ±15%). Minimum purity of Transfluthrin is 96.5%. | | | | | |

The product family consists of a single formulation used in two electrical heating devices: **Night & Day™** and **Night & Day™ Trio**. The formulation used in the devices consists of transfluthrin absorbed in an inert carrier matrix. The inert matrix is heated by an electrical heater unit which causes the transfluthrin to evaporate in a controlled manner.

Night & Day™ Trio has **three** heating settings and Night & Day™ a **single** heating setting. The setting for Night & Day™ is equivalent to the “middle” setting on Night & Day™ Trio, hence Night & Day™ has the same evaporation rate as the “middle” setting on Night & Day™ Trio.

There are product configurations which are considered to be within a single product family:

* Night & Day™ + 1 refill
* Night & Day™ Trio + 1 refill
* Refill pack (contains two refills) – these can be used in either device.

The product also contains a small use-up cue which indicates the level of insecticide remaining in the device. The use-up cue is fully enclosed in a plastic sheath and is separated from the active/carrier component. Refer to the Confidential Annex 3.6 for details of the co-formulants.

#### Information on technical equivalence

Letter of Supply (Article 95)

The used manufacturing source of the active substance is the reference source evaluated in the CAR.

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

No substances of concern are present.

#### Endocrine disruption assessment

Although Night & Day contains only the active substance in an inert sandcore unit to which direct contact cannot take place, an endocrine disruption assessment is carried out for the co-formulants. None of the co-formulants triggered an alert for ED property. More detailed information is available in the confidential annex of the PAR.

#### Type of formulation

|  |
| --- |
| VP – vapour releasing product.  Transfluthrin is released from an inert base by a plug-in electrical heater. |

### Hazard and precautionary statements

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

| **Classification** | | |
| --- | --- | --- |
| Hazard category | Skin Irritant. 2  Aquatic Acute 1  Aquatic Chronic 1 | |
| Hazard statement | H315: Causes skin irritation.  H410: Very toxic to aquatic life with long lasting effects.  EUH208: Contains methenamine. May cause an allergic reaction. | |
|  | | |
| **Labelling** | | |
| Hazard Pictogram | exclam1 |  |
| GHS07: exclamation mark | GHS09: environment |
| Signal words | Warning | |
| Hazard statements | H315: Causes skin irritation.  H410: Very toxic to aquatic life with long lasting effects.  EUH208: Contains methenamine. May cause an allergic reaction. | |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand.  P102: Keep out of reach of children.  P264: Wash hands thoroughly after handling.  P501: Dispose of contents/container in accordance with local/regional/national/international regulation. | |
| Note | P103, P302+P352 and P332+P313 are considered not necessary since these are signed as optional in the CLP Guidance on Labelling and Packaging. P280 is considered as not necessary since use of PPE (including gloves) is not a realistic option for non-professional users, in addition direct dermal contact is not foreseen. P321 is not required as no specific treatment is available. P362+P364 is removed because contamination of clothing is unlikely. | |

Transfluthrin is listed in Annex VI of regulation 1272/2008. The classification of the product, however, is based on the acute oral toxicity endpoint (583 mg/kg) listed in the Transfluthrin Assessment Report (2014).

### Authorised use(s)

#### Use description

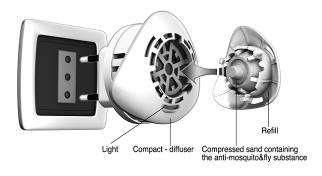
Use # 1 – One heating setting

|  |  |  |
| --- | --- | --- |
| **Product Type** | PT18: Insecticides, acaricides and products to control other arthropods | |
| **Where relevant, an exact description of the authorised use** | Insecticide | |
|  | **Scientific name:** | Muscidae |
|  | **Common name:** | Flies |
|  | **Development stage:** | Adults |
|  |  |  |
|  |  |  |
|  |  |  |
|  | **Scientific name:** | Culicidae |
|  | **Common name:** | Mosquitoes |
|  | **Development stage:** | Adults |
| **Field of use** | Indoor | |
| **Application method(s)** | Electrically heated vaporiser with one heating setting. | |
| **Application rate(s) and frequency** | One unit will last for 240 hours in a room up to 20 m3  (for 10 days if used 24 h/day). | |
| **Category(ies) of users** | General public (non-professional) | |
| **Pack sizes and packaging material** | Solid fibreboard unit box containing:  - Night & Day™ + 1 refill  or  - two refills  Night & Day™ is an unfilled diffuser unit.  Assembly for a unit - PP - 4.75 g  Metalized pouch - Metalized (aluminium) PP and PET - 106 x 106 mm (containing 1 refill)  1 refill is a sandcore in assembly for diffuser unit. | |

#### Use-specific instructions for use 1

**One heating setting - Raid® NIGHT&DAYTM**

**For night and day usage (24 hrs a day) for 240 hours**





Compressed sand containing the

anti-mosquito and fly substance

|  |  |
| --- | --- |
| ico_UI-03bn10gg | 1) To assemble the product:   * Tear open the silver pouch and extract the refill holding it via the triangular plastic shell. * Insert refill in the refill slot on the diffuser   and twist it clockwise to lock. |
| ico_UI-04bn | 2) To prepare the use up indicator that tells you when the product has finished:   * hold the tab and peel off the silver coloured foil from the top of the refill exposing the blue liquid use-up indicator. * The liquid will evaporate during use only when the diffuser is plugged in. * It is time to replace the refill when the liquid in the indicator has dried up. |
|  | 3) To activate the product and start anti-mosquito/flyprotection plug it into a 230V electrical outlet.   * Any orientation of the plug is acceptable. * A red light tells you that the product is working. * For optimal efficacy, activate the device 1 hour in advance for mosquitoes and 1.5 hours in advance for flies. |
| cal_10gg | 4) Use it night and day for 24 hours a day.   * One refill lasts 10 days (if used 24 hours a day). * After 10 days the indicator will tell you it is time to replace the refill to renew anti-mosquito/fly protection. Use only RAID Night&Day refills in the diffuser. * To deactivate the product at any time, simply unplug the diffuser from the power outlet. * For use in rooms up to 20 m3. * High ventilation and use of air conditioning may reduce product efficacy. * For optimal efficacy the windows should be closed during use of this product |

#### Use-specific risk mitigation measures

|  |
| --- |
| See general directions for use |

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

|  |
| --- |
| See general directions for use |

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

|  |
| --- |
| See general directions for use |

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

|  |
| --- |
| See general directions for use |

#### Use description

Use # 2 – Three heating settings

|  |  |  |
| --- | --- | --- |
| **Product Type** | PT18: Insecticides, acaricides and products to control other arthropods | |
| **Where relevant, an exact description of the authorised use** | Insecticide | |
|  | **Scientific name:** | Muscidae |
|  | **Common name:** | Flies |
|  | **Development stage:** | Adults |
|  |  |  |
|  |  |  |
|  |  |  |
|  | **Scientific name:** | Culicidae |
|  | **Common name:** | Mosquitoes |
|  | **Development stage:** | Adults |
| **Field of use** | Indoor | |
| **Application method(s)** | Electrically heated vaporiser with three heating settings. | |
| **Application rate(s) and frequency** | One unit will last for ~   * 320 hours on low setting for small rooms up to 16m3 * 240 hours on medium setting for medium size rooms up to20m3 and * 160 hours on high setting, suitable for large rooms up to30m3 | |
| **Category(ies) of users** | General public (non-professional) | |
| **Pack sizes and packaging material** | Solid fibreboard unit box containing:  - Night & Day™ + 1 refill  or  - Night & Day™ Trio + 1 refill  or  - two refills  Night & Day™ and Night & Day™ Trio are unfilled diffuser units.  Assembly for a unit - PP - 4.75 g  Metalized pouch - Metalized (aluminium) PP and PET - 106 x 106 mm (containing 1 refill)  1 refill is a sandcore in assembly for diffuser unit. | |

#### 

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Use-specific instructions for use 2 **Three heating settings - Raid® NIGHT&DAYTM Trio**  **For night and day usage (24 hrs a day) for up to 320 hours.**   |  |  | | --- | --- | | ico_UI-03bn10gg | 1) To assemble product:   * Tear open the silver pouch and extract the refill holding it via triangular plastic shell. * Insert refill in the refill slot on the diffuser and twist it clockwise to lock. | | ico_UI-04bn | 2) To prepare the use up indicator that tells you when the product has finished :   * hold the tab and peel off the silver coloured foil from the top of the refill exposing the blue liquid use-up indicator. * The liquid will evaporate during use only when the diffuser is plugged in. * It is time to replace the refill when the liquid in the indicator has dried up. | |  | 3) To activate the product and start anti-mosquito/fly protection plug it into a 230V electrical outlet.   * Any orientation of plug is acceptable. * A red light tells you that the product is working. * For optimal efficacy, activate the device 1 hour in advance for mosquitoes and 1.5 hours in advance for flies. | | cal_10gg  No light = off  1 light = low       - 16m3 rooms  2 light = medium - 20m3 rooms  3 light = high     - 30m3 rooms | 4) Use it night and day for 24 hours a day:   * One unit lasts 10 days on medium setting (if used 24 hours a day * The indicator will tell you it is time to replace the refill to renew anti-mosquito/fly protection. Use only RAID Night&Day refills in the diffuser.   To deactivate the product at any time, simply unplug the diffuser from the power outlet.  Press the button to change from “low” to “medium” to “high” to “off”.    OR  Press the button to change from “low” to “medium” to “high”.  Refill will last for ~   * 320 hours on low setting for small rooms up to16m3 * 240 hours on medium setting for medium size rooms up to20m3 and * 160 hours on high setting, suitable for large rooms up to30m3 * High ventilation and use of air conditioning may reduce product efficacy. * For optimal efficacy the windows should be closed during use of this product | |

#### Use-specific risk mitigation measures

|  |
| --- |
| Please take care that the device is used in the correct setting depending on the size of the room based on potential risks for human health. |

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

|  |
| --- |
| See general directions for use |

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

|  |
| --- |
| See general directions for use |

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

|  |
| --- |
| See general directions for use |

### General directions for use

#### Instructions for use

|  |
| --- |
| See the use specific instructions for use |

#### Risk mitigation measures

|  |
| --- |
| Tactile Warning of Danger (EN/ISO 11683)  Application should be done in accordance with the instructions for use regarding room size, do not use in a confined area.  If skin contact with refill should occur, wash immediately with soap and water.  Do not allow materials of any kind to cover the device while it is in use.  Do not touch device with metal instruments or wet hands.  Remove or cover terrariums, aquariums and animal cages before application.  Turn off aquarium air-filter during use.  Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals. Do not use in kitchens.  Do not store near food, drink and animal feedingstuff.  Contains transfluthrin (pyrethroids), may be lethal to cats. Prevent cats from coming into contact with the treated area.  Keep out of reach of children and pets  IMPORTANT SAFETY INSTRUCTIONS: Instructions to avoid the hazards of fire, toxicity, electric shock, or injury. PLEASE READ  BEFORE USING AND SAVE THESE IMPORTANT SAFETY INSTRUCTIONS. WARNING: when using electrical appliances, basic  precautions should always be followed including the following: CAUTION: to reduce risk of injury and prevent play, children shall  not use product. Close supervision is necessary when a product is used near children 8 years and above or persons with special  needs. For safe use, plug only into properly functioning wall outlets where device is ventilated and cannot contact bed covering or  other material. Do not use with extension cords or multi-plugs. Do not immerse in water. Do not insert anything into outlet above it.  Use only (Brand Name) refills in (Brand Name) holders. These instructions are available at [website] |

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

|  |
| --- |
| Transfluthrin may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.  **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.  . Eye contact: Rinse with plenty of water.  Get medical attention if irritation develops and persists. Ingestion: Do NOT induce vomiting.  Rinse mouth with water.  Get medical attention immediately.  Never give anything by mouth to an unconscious person.  If medical advice is needed, have product container or label at hand  In case of incident, call a poison centre *[insert national phone number]*  **Emergency measures to protect the environment**  Do not flush into surface water or sanitary sewer system. |

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

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

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

|  |
| --- |
| This product has a shelf-life of 4 years |

### Other information

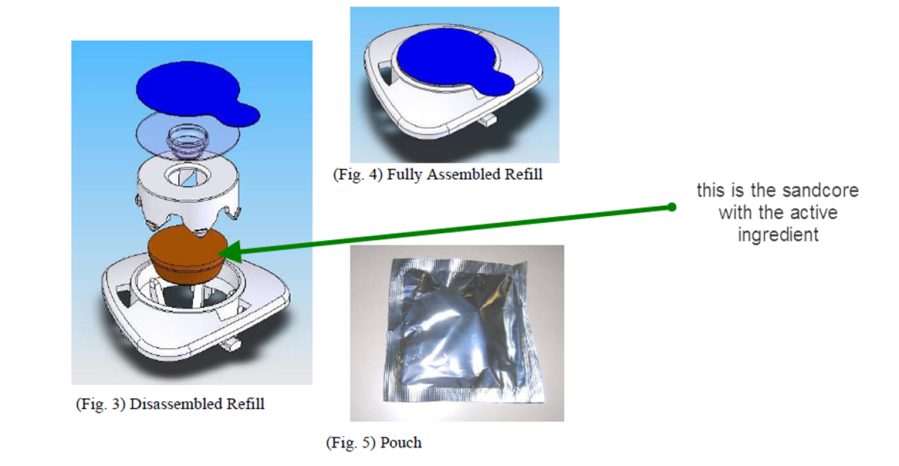
|  |
| --- |
| The product contains 300 mg pure transfluthrin per unit. |

### 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)** |
| Assembly for sandcore unit | 4.75g | Polypropylene | snap in | non-professional | Yes |
| Unit box | Night & Day™ + 1 refill  Or  Night & Day™ Trio + 1 refill | Solid Fibreboard | Tuck-in | non-professional | Yes |
| Unit box for Refill | 2 refills | Solid Fibreboard | Tuck-in | non-professional | Yes |
| Metalized Pouch | 1 refill,  106mm x 106mm | Metalized (aluminium) PP and PET | Heat sealed | non-professional | Yes |

There are three product configurations which are considered to be within a single product family:

* Night & Day™ + 1 refill
* Night & Day™ Trio + 1 refill
* Refill pack (contains two refills) – these can be used in either device.



### 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 in the original Transfluthrin Assessment report.

#### Access to documentation

The applicant is the owner 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.

See 2.1.4 for the authorised uses, after assessment of the dossier.

Table 1. Intended use # 1 – 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:** | *Culex quinquefasciatus* |
| **Common name:** | Southern House Mosquito |
| **Development stage:** | Adults |
|  | **Scientific name:** | *Aedes aegypti* |
|  | **Common name:** | Yellow Fever Mosquito |
|  | **Development stage:** | Adults |
|  | **Scientific name:** | *Anopheles stephensi* |
|  | **Common name:** | Indo-Pakistan malaria mosquito |
|  | **Development stage:** | Adults |
|  | **Scientific name:** | *Aedes albopictus* |
|  | **Common name:** | Tiger Mosquito |
|  | **Development stage:** | Adults |
|  | **Scientific name:** | *Musca domestica* |
|  | **Common name:** | House Fly |
|  | **Development stage:** | Adults |
|  | **Scientific name:** | *Lasisus niger* |
|  | **Common name:** | Garden Black Ant |
|  | **Development stage:** | Adults |
|  | **Scientific name:** | *Anopheles gambiae* |
|  | **Common name:** | African malaria mosquito |
|  | **Development stage:** | Adults |
| **Field of use** | Indoors | |
| **Application method(s)** | Electrically heated vaporiser. | |
| **Application rate(s) and frequency** | One unit will treat a 20 m3 room for 10 days if used 24 hrs/day (Night & DayTM). In the case of Night & Day TrioTM, one unit will treat 30 m3 on high rate (160 hrs) or a 16 m3 room on low rate (320 hrs). | |
| **Category(ies) of users** | Non-professionals/consumers | |

### Physical, chemical and technical properties

The product is sold as a device together with the sandcore refill in metalized pouch or as refills only. The product was considered as type C according to the carrier guidance (CA-Nov16-Doc.4.3 – Final). Therefore, the concentration of the active substance (13.4% w/w) in the product is based on the composition of the biocidal mixture including the sandcore. The data in the table below concern the sandcore refill.

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Physical state at 20 °C and 101.3 kPa | Visual | 13.4% | Solid | xxxx, (2010) |
| Colour at 20 °C and 101.3 kPa | Visual | 13.4% | Yellowish brown | xxxx, (2010) |
| Odour at 20 °C and 101.3 kPa | - | - | Odourless | Xxxx, (2010) |
| Acidity / alkalinity | - | - | This data requirement is only relevant to aqueous liquid products or products that are applied dispersed in water. | - |
| Relative density / bulk density | - | - | This data requirement is only relevant to liquid products or products that are supplied as powders or granules. Not applicable for pre-shaped solid devices. | - |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3 | 13.4% | No significant changes were seen following storage tests for two weeks at 54°C, and 40°C at 6 months.  **Test result summary** - 2 weeks at 54°C in silver foil pouch (made of metalized PET and PP).  **Appearance**  Before:  brown/yellowish brown sandcore plug  After:  Sandcore somewhat browner at the top  **Packaging**  Before: heat sealed silver foil pouch (made of metalized PET and PP)  After: unchanged  **Weight**  Before:  5.617-5.769 g (n=30)  After:  Weight change -0.05-0.24 g (n=30)  **Active substance content**  Before:  305.00-332.79 mg (n=5)  After:  312,69-333.37 mg (n=3)  Mean 3.17% w/w increase  Within the specification range of 285-345 mg per sandcore plug range.  **Test result summary** - 6 months at 40°C in silver foil pouch (made of metalized PET and PP).  **Appearance**  Before:  brown/yellowish brown sandcore plug  After:  Sandcore somewhat browner at the top  **Packaging**  Before: heat sealed silver foil pouch (made of metalized PET and PP)  After: unchanged  **Weight**  Before:  5.637-5.708 g (n=26)  After:  Weight change -0.035-0.053 g (n=26)  **Active substance content**  Before:  305.00-332.79 mg (n=5)  After:  312.16-318.68 mg (n=3)  Mean 0.61% w/w increase  Within the specification range of 285-345 mg per sandcore plug range. | xxxx, (2010) |
| Storage stability test – **long term storage at ambient temperature** | According to TNsG | 13.4% | No significant changes were seen following storage for 48 months at ambient temperature.  **Test result summary**  **Appearance**  Before:  brown/yellowish brown sandcore plug  After:  There was some white residue on the surface of the sandcore.  **Packaging**  Before: heat sealed silver foil pouch (made of metalized PET and PP)  After: unchanged  **Weight**  Before:  5.628-5.705 g (n=24)  After:  Weight change (n=24): -0.000-0.035 g  **Active substance content**  Before:  305.00-302.79 mg (n=5)  After:  315.93-324.35 mg (n=3)  Mean 2.11% w/w increase  Within the specification range of 255-345 mg per sandcore plug range. | xxxx, (2010) |
| Storage stability test – **low temperature stability test for liquids** | - | - | Not applicable to a solid. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | - | 13.4% | The product was stored in the commercial packaging and found to be stable over 48 months at ambient temperature, 6 months at 40°C and 2 weeks at 54°C. The silver foil excludes light from the sandcore during storage. | xxxx, (2010) |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | See long- and short-term stability tests. | - |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | See long- and short-term stability tests. | - |
| Wettability | - | - | Not relevant. The product consists of the insecticide, transfluthrin, which is absorbed by a sand-core matrix which acts as a carrier material. The sandcore will not be mixed with water. | - |
| Suspensibility, spontaneity and dispersion stability | - | - | Not relevant. The product consists of the insecticide, transfluthrin, which is absorbed by a sand-core matrix which acts as a carrier material. The sandcore will not be mixed with water. | - |
| Wet sieve analysis and dry sieve test | - | - | Not relevant. The product consists of the insecticide, transfluthrin, which is absorbed by a sand-core matrix which acts as a carrier material. The sandcore will not be mixed with water. | - |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | Not relevant. The product consists of the insecticide, transfluthrin, which is absorbed by a sand-core matrix which acts as a carrier material. The sandcore will not be mixed with water. | - |
| Disintegration time | - | - | Not relevant. The product consists of the insecticide, transfluthrin, which is absorbed by a sand-core matrix which acts as a carrier material. The sandcore will not be mixed with water. | - |
| Particle size distribution, content of dust/fines, attrition, friability | - | - | This product is not a granule or powder product. | - |
| Persistent foaming | - | - | Not relevant. The product consists of the insecticide, transfluthrin, which is absorbed by a sand-core matrix which acts as a carrier material. The sandcore will not be mixed with water. | - |
| Flowability/Pourability/Dustability | - | - | Not relevant. The product consists of the insecticide, transfluthrin, which is absorbed by a sand-core matrix which acts as a carrier material. The product is not a granule or powder product that will be applied through application equipment that will subject the granules to pressure and heat. | - |
| Burning rate — smoke generators | - | - | Not relevant. The product consists of the insecticide, transfluthrin, which is absorbed by a sand-core matrix which acts as a carrier material. The product is not intended to generate smoke. | - |
| Burning completeness — smoke generators | - | - | Not relevant. The product consists of the insecticide, transfluthrin, which is absorbed by a sand-core matrix which acts as a carrier material. The sandcore product is not intended to generate smoke. | - |
| Composition of smoke — smoke generators | - | - | The sand-core matrix is not intended to burn and therefore, not intended to generate smoke.  The sand-core is heated causing the active material, transfluthrin, to evaporate in a controlled manner. | - |
| Spraying pattern — aerosols | - | - | Not relevant. The product consists of the insecticide, transfluthrin, which is absorbed by a sand-core matrix which acts as a carrier material. This is not relevant as the product is not an aerosol or trigger spray product. | - |
| Physical compatibility | - | - | The product is not intended to be used with other biocidal products. | - |
| Chemical compatibility | - | - | The product is not intended to be used with other biocidal products. | - |
| Degree of dissolution and dilution stability | - | - | Not relevant. The product consists of the insecticide, transfluthrin, which is absorbed by a sand-core matrix which acts as a carrier material. The sandcore will not be mixed with water. | - |
| Surface tension | - | - | Not relevant to a solid, which is not diluted before use. | - |
| Viscosity | - | - | Not relevant to a solid. | - |

|  |
| --- |
| **Conclusion on the physical, chemical and technical properties of the product** |
| Data supports a shelf life of 4 years. This sand-core product is a solid, odourless material that is yellowish-brown in colour. With storage, the sand-core material will appear slightly darker brown in color. The appearance of the sandcore plugs changed slightly over the storage time at all temperature conditions with some colour darkening and the appearance of white residue on the surface. |

### Physical hazards and respective characteristics

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **Reference** |
| --- | --- | --- | --- | --- |
| Explosives | - | - | The product does not contain any potentially explosive compounds: the carrier nor the active substance are classified and based on the information available, the functional groups relating to explosive properties, as defined in appendix 6 of the UN manual of tests and criteria, do not seem to be present in the formulation. The product does not need to be classified as an explosive in the sense of Regulation (EC) 1272/2008. | - |
| Flammable gases | - | - | Not applicable to a solid. | - |
| Flammable aerosols | - | - | Not applicable to a solid. | - |
| Oxidising gases | - | - | Not applicable to a solid. | - |
| Gases under pressure | - | - | Not applicable to a solid. | - |
| Flammable liquids | - | - | Not applicable to a solid. | - |
| Flammable solids | - | - | There are no components in the formulation which are classified as flammable. The formulation is, therefore, not classified as flammable. | - |
| Self-reactive substances and mixtures | - | - | None of the components of the product are classified as self-reacting substances. Experience in the use of the product does not indicate that the product will self-react | - |
| Pyrophoric liquids | - | - | Not applicable to a solid | - |
| Pyrophoric solids | - | - | Experience in use does not indicate that the product is spontaneously flammable in air. | - |
| Self-heating substances and mixtures | - | - | Substances or mixtures with a low melting point (< 160 °C) should not be considered for classification in this class since the melting process is endothermic and the substance-air surface is drastically reduced. The melting point of the product absorbed on the carrier is much lower than 160°C. | - |
| Substances and mixtures which in contact with water emit flammable gases | - | - | None of the components of the product are known to emit flammable gases when in contact with water. Experience in the use of the product does not indicate that the product will emit flammable gas when in contact with water. The product is also not expected to be in contact with water during use. | - |
| Oxidising liquids | - | - | Not applicable to a solid. | - |
| Oxidising solids | - | - | The product does not contain any potentially oxidising compounds. The active substance nor the carrier are classified and based on the information available, the functional groups relating to oxidising properties, as defined in appendix 6 of the UN manual of tests and criteria, do not seem to be present in the formulation. The product does not need to be classified as oxidising in the sense of Regulation (EC) 1272/2008. | - |
| Organic peroxides | - | - | The product does not contain any organic peroxides. | - |
| Corrosive to metals | - | - | No test method available. UN Test C.1 as described in Section 37.4 of the UN-MTC is only applicable for liquids and solids that may become liquid during transport. The product Night&Day is not expected to become fluid during transport. | - |
| Auto-ignition temperatures of products (liquids and gases) | - | - | Not applicable to a solid. | - |
| Relative self-ignition temperature for solids | - | - | The recommended test method for determination of relative self-ignition temperature according to Guidance on the BPR: Volume I Parts A+B+C, Version 2.0 May 2018, is UN Test N.4, as described in Section 33.3.1.6 of the UN-MTC. Section 33.3.1.6.3 indicates that this procedure is applicable only to powders and granules.  The auto-ignition temperature of transfluthrin is 415°C. The carrier is considered not to have an auto ignition temperature of any concern. | - |
| Dust explosion hazard | - | - | The product is a sandcore plug and therefore there should be no dust present. | - |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product is not classified under Regulation (EC) no 1272/2008 as for physical or chemical hazards. |

### 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 |
| Active substance | GC-FID | 240 mg pure active/core, 300 mg pure active/core,  360 mg pure active/core  3 replicates of each concentration  The accuracy of the method was determined at three levels approximately equivalent to 73, 91 and 109% of the nominal active ingredient content for pure transfluthrin (which was 331 mg per unit in the used test item). | The linearity was determined by the analysis of solutions containing transfluthrin which were intected in duplicate into the GC system over the following ranges: 240 to 561 mg on sandcore plug.  The method is linear in the concentration range 2.40 – 5.61 mg/ml with a correlation coefficient (r) = 0.9997 and the linearity equation being y = 0.0039x + 0.0044 | No interferences corresponding to the transfluthrin or the internal standard were seen. | See table below for mean recovery % at each concentration | 240 mg – 99.7%  300 mg – 99.7%  360 mg – 99.4% | 240 mg - % RSD = 0.12%  300 mg - % RSD = 0.59%  360 mg – % RSD = 0.10%  Precision (n=5, mean active substance content 13.91% w/w): RSD=1.65%  Horwitz value: 1.80% | N/A | xxxx (2006) |

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| A method of analysis employing GC-FID is provided for the determination of the active substance in the product. The method is fully validated in accordance with SANCO/3030/99 rev. 4 11/07/00.  **Analytical Method Summary**  The test substance, a porous sandcore plug material containing approximately 300 mg of transfluthrin, is placed into a 125 mL round bottom flask with 50 mL of acetone and refluxed for 30 minutes then allowed to cool.  The reflux condenser is rinsed with 25 mL of acetone and collected in the round bottom flask.  To the flask is added 5 mL of a 4.0% dipentyl phthalate solution as the internal standard.  Another 20 mL of acetone is added to bring the volume to 100 mL, creating a sample solution with a transfluthrin concentration of approximately 3 mg/mL.  The sample solution is placed into a sample vial and injected onto a gas chromatograph fitted with a 0.32 mm ID x 30 m, 0.25 micron thick DB-1 (or equivalent) stationary phase and a flame ionization detector. Helium is used as the carrier gas with an initial oven temperature of 175oC increasing to 250oC at 5oC/min. No temperature holds are used at the beginning or end of the experimental run. Injector (split) and detector temperatures are 200oC and 300oC, respectively. A helium flow rate of 2.4 mL/min and a 45:1 injector split ratio are recommended, but these values can be adjusted as needed to optimize chromatographic separation and analyte sensitivity for the specific gas chromatographic system being used to conduct the analysis.  Validation of analytical method ARTM-W-211855 yielded a linear response with a correlation coefficient of 0.9997 over the range of 2.40 to 5.61 mg/mL, equivalent to 240 to 561 mg transfluthrin on the sandcore plug.  Method specificity was confirmed by the lack of interference and response of blank sandcore plugs, solvents and internal standard at the retention time of the analyte.  Accuracy was addressed by analyzing three fortified blank sandcore plugs at each of three transfluthrin fortification levels of 240 mg, 300 mg and 360 mg.  Recoveries ranged from 99.4% to 99.7% with a range of % RSD values of 0.10 to 0.59%.  **Conclusion**  Analytical method ARTM-W-211855 for the determination of transfluthrin in porous sandcore plug material was fully validated in accordance with the criteria and guidance in SANCO/3030/99 rev. 4 11/7/00 for test method linearity, accuracy and specificity.  Therefore, method ARTM-W-211855 is suitable for use to quantitatively measure transfluthrin in porous sandcore plug materials.  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, as the intended uses will not result in significant residues when the label instructions is followed (store away from food, beverages and pet food). |

### 

### Efficacy against target organisms

#### Function and Field of Use

The product consists of an insecticide (product type 18) impregnated inert carrier matrix (sand-core) within a plastic housing/chassis. The heat required to evaporate the insecticide from the matrix is supplied by an appropriate electrical heater unit.

The Night&Day device has a fixed evaporation rate whereas Night&Day Trio device has three settings giving three release rates suitable for different sized rooms (low, medium and high settings for 16, 20 and 30 m3 rooms, respectively).

|  |  |  |  |
| --- | --- | --- | --- |
| **Night & Day™ Trio Setting Selector** | **Low** | **Medium** | **High** |
| **Release Rate Target**  **(Measured Released Rate)** | 0.937mg/h  (0.931mg/h) | 1.25mg/h  (1.296 mg/h) | 1.875mg/h  (1.827mg/h) |

The efficacy and duration claim for the Night&Day device is equivalent to the Night&Day Trio device at the ‘medium’ setting and the experimentally measured value from CEMR-3150 states the Transfluthrin release rate for Raid Night&Day to be 1.0247mg/h.

For indication of usage of the product, the use-up cue liquid evaporates from the use-up cue through the membrane cover once the silver foil has been removed. There is no contact between the indicator liquid and the active ingredient (Transfluthrin) located in the inert carrier matrix.

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

The intended organisms to be controlled are mosquitoes (Culicidae), flies (Muscidae) and ants (Formicidae).

Humans are protected from nuisance insects.

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

Knockdown and mortality.

#### Mode of action, including time delay

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

Efficacy of the product starts after 10 minutes. For an optimal efficacy (>90% of the target insects are knockdown or dead) the diffuser should be switched on 1 to 1.5 hours before entering the room.

#### Efficacy data

#### Reports list Night&Day by the project name Obewan and Night&Day Trio by project name Leia. The composition of the tested substances are identical to the product to be authorized.

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Function and Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method**  **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide against moquitoes, indoors. | Obewan Unit with 240/720 Hour Refill at 230V as a heatable sandcore. | Southern House Mosquito, (*Culex quinquefasciatus*) Females, 14-18 days, laboratory cultured | Approximately 50 adult female mosquitoes were released into a standard 20m3 test chamber. The heater unit was placed on the floor in the centre of the chamber. The units, with the sandcore were weighed prior to, and immediately after use. Product samples used were ‘fresh’ samples (0 hours use) and ‘end-of-life’ samples (238 hours use). A cold system start was used for each treatment/test period. The chamber exhaust was turned off and no fan was placed inside the chamber. Once the mosquitoes were acclimatised (introduced into the chamber 1 hour before the test) the unit was turned on and left running for 120 minutes. At the end of the tested period, the room was vacuumed to enable a count of those insects knocked down during the test. Any remaining free-flying insects were then knocked down and vacuumed up separately, to accurately assess the number of insects entering the chamber. After insect removal, the chamber exhaust was used to purge the chamber. Visual assessment of knockdown (KD) was made at 5 minute intervals for the duration of the test. Mean transfluthrin concentration: 1.36 mg/hour (fresh sample); 1.02mg/hr (end of life sample). Mean: 1.19 mg/hr in 20m³ room) equivalent to 0.0595 mg/hr/m³. | **Table:** Knockdown Time Values of free-flying *Culex quinquefasciatus* (14-18 day old adult females) in a standard 20m³ chamber (4 replicates)   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | Time to knockdown % of the mosquitoes (minutes) | | | |  | **Age** | **KT50** | **KT80** | **KT95** | | *Culex quinquefasciatus* | **Fresh**  **0 hours** | 20.7 | 34.5 | 65.0 | | **End-life**  **238 hours** | 21.7 | 35.0 | 55.0 |   Note: Numbers represented in table are estimates generated by linear interpolation of the mean % knockdown.  Untreated control knockdown: 0% (30 mins); 0.25% (60 mins); 0% (90 and 120 mins). | xxxx (2008a) |
| Insecticide against moquitoes, indoors. | Obewan Unit with 240/720 Hour Refill at 230V as a heatable sandcore. | Yellow fever mosquito (*Aedes aegypti*)  Females 13-17days, laboratory cultured | Approximately 50 adult female mosquitoes were released into a standard 20m3 test chamber. The heater unit was placed on the floor in the centre of the chamber. The unit, with the sandcore were weighed prior to, and immediately after use. Product samples used were ‘fresh’ samples (0 hours use). A cold system start was used for each treatment/test period. The chamber exhaust was turned off and no fan was placed inside the chamber. Once the mosquitoes were acclimatised (introduced into the chamber 1 hour before the test) the unit was turned on and left running for 120 minutes. At the end of the tested period, the room was vacuumed to enable a count of those insects knocked down during the test. Any remaining free-flying insects were then knocked down and vacuumed up separately, to accurately assess the number of insects entering the chamber. After insect removal, the chamber exhaust was used to purge the chamber. Visual assessment of knockdown (KD) was made at 5 minute intervals for the duration of the test (assessments were discontinued after 50 minutes as 100% knockdown had occurred for 10 minutes prior to that assessment). Mean transfluthrin concentration: 1.39 mg/hour (fresh sample) in 20m³ room, equivalent to 0.0695 mg/hr/m³. | **Table:** KT Values of free-flying *Aedes aegypti* (13-17 day old adult females) in a standard 20m³ chamber (4 replicates).   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | Time to knockdown % of the mosquitoes (minutes) | | | |  | **Age** | **KT50** | **KT80** | **KT95** | | *Aedes aegypti* | **Fresh**  **0 hours** | 17.1 | 21.3 | 30.0 |   Note: These samples were tested as fresh for this species.  Untreated control knockdown: 0.5% (30 mins); 1.5% (60 mins). | xxxx (2008b) |
| Insecticide against moquitoes indoors. | Obewan Unit with 240/720 Hour Refill at 230V as a heatable sandcore. | Indo-Pakistan malaria mosquito  *(Anopheles stephensi)*  Females, 16-20 days, laboratory cultured | Approximately 50 adult female mosquitoes were released into a standard 20m3 test chamber. The heater unit was placed on the floor in the centre of the chamber. The unit, with the sandcore were weighed prior to, and immediately after use. Product samples used were ‘fresh’ samples (0 hours use). A cold system start was used for each treatment/test period. The chamber exhaust was turned off and no fan was placed inside the chamber. Once the mosquitoes were acclimatised (introduced into the chamber 1 hour before the test) the unit was turned on and left running for 120 minutes. At the end of the tested period, the room was vacuumed to enable a count of those insects knocked down during the test. Any remaining free-flying insects were then knocked down and vacuumed up separately, to accurately assess the number of insects entering the chamber. After insect removal, the chamber exhaust was used to purge the chamber. Visual assessment of knockdown (KD) was made at 5 minute intervals for the duration of the test. Mean transfluthrin concentration: 1.14 mg/hour (fresh sample) in 20m³ room, equivalent to 0.057 mg/hr/m³. | **Table:** Values of free-flying *Anopheles stephensi* (16-20 days) old adult females) in a standard 20m³ chamber (4 replicates).   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | Time to knockdown % of the mosquitoes (minutes) | | | |  | **Age** | **KT50** | **KT80** | **KT95** | | *Anopheles stephensi* | **Fresh**  **0 hours** | 20.4 | 33.9 | 57.5 |   Note: These samples were only be tested as fresh for this species.  Untreated control knockdown: 0.5% (30 mins); 3.25% (60 mins); 11.1% (90 mins). | xxxx (2008c) |
| Insecticide against moquitoes indoors. | Obewan Unit with 240/720 Hour Refill at 230V as a heatable sandcore. | Tiger mosquito (*Aedes albopictus*)  Females, 15±2 days, laboratory cultured | Approximately 50 adult female mosquitoes were released into a standard 20m3 test chamber. The heater unit was placed on the floor in the centre of the chamber. The unit, with the sandcore were weighed prior to, and immediately after use. Product samples used were ‘fresh’ samples (0 hours use). A cold system start was used for each treatment/test period. The chamber exhaust was turned off and no fan was placed inside the chamber. Once the mosquitoes were acclimatised (introduced into the chamber 1 hour before the test) the unit was turned on and left running for 120 minutes. At the end of the tested period, the room was vacuumed to enable a count of those insects knocked down during the test. Any remaining free-flying insects were then knocked down and vacuumed up separately, to accurately assess the number of insects entering the chamber. After insect removal, the chamber exhaust was used to purge the chamber. Visual assessment of knockdown (KD) was made at 5 minute intervals for the duration of the test. Mean transfluthrin concentration: 1.366 mg/hour (fresh sample) in 20m³ room, equivalent to 0.0683 mg/hr/m³. | **Table:** Values of free-flying *Aedes albopictus* (15 day±2days) old adult females) in a standard 20m³ chamber (4 replicates).   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | Time to knockdown % of the mosquitoes (minutes) | | | |  | **Age** | **KT50** | **KT80** | **KT95** | | *Aedes albopictus* | **Fresh**  **0 hours** | 17.3 | 20.1 | 30.0 |   Note: These samples were only be tested as fresh for this species.  Untreated control knockdown: 0% (30 mins -120 mins). | xxxx (2008d) |
| Insecticide against flies indoors. | Obewan Unit with 240/720 Hour Refill at 230V as a heatable sandcore. | House fly (*Musca domestica*)  1-6 days old mixed sex adults, DDT resistant strain laboratory cultured | Approximately 50 adult house flies were released into a standard 20m3 test chamber. The heater unit was placed on the floor in the centre of the chamber. The unit, with the sandcore were weighed prior to, and immediately after use. Product samples used were ‘fresh’ samples (0 hours use). A cold system start was used for each treatment/test period. The chamber exhaust was turned off and no fan was placed inside the chamber. Once the flies were acclimatised (introduced into the chamber 1 hour before the test) the unit was turned on and left running for 120 minutes. At the end of the tested period, the room was vacuumed to enable a count of those insects knocked down during the test. Any remaining free-flying insects were then knocked down and vacuumed up separately, to accurately assess the number of insects entering the chamber. After insect removal, the chamber exhaust was used to purge the chamber. Visual assessment of knockdown (KD) was made at 5 minute intervals for the duration of the test. Mean transfluthrin concentration: 1.366 mg/hour (fresh sample) in 20m³ room, equivalent to 0.0683 mg/hr/m³. | **Table:** Values of free-flying *Musca domestica* (1-6 days old adults mixed sexes) in a standard 20m³ chamber (4 replicates).   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | Time to knockdown % of the house flies (minutes) | | | |  | **Age** | **KT50** | **KT80** | **KT95** | | *Musca domestica* | **Fresh**  **0 hours** | 35.4 | 46.3 | 63.3 |   Note: These samples were only being tested as fresh for this species because aged sample testing was conducted in a previous non-GLP work request (xxxx 2006c).  Untreated control knockdown: 0% (30 mins-120 mins). | xxxx (2008e) |
| Insecticide against moquitoes indoors. | Obewan Unit with 30 night (240h) Refill at 230V as a heatable sandcore | Southern House Mosquito, (*Culex quinquefasciatus*) Females, 16±2 days, laboratory cultured | Approximately 50 mosquitoes were released into a standard 20m3 test chamber. The heater unit was placed on the floor in the centre of the chamber. The refill was weighed prior to, and immediately after use. Product samples used were ‘fresh’ samples (0 hours use), ‘mid-life’ samples (120 hours use) and ‘end-of-life’ samples (240 hours use). A cold system start was used for each treatment/test period. The chamber exhaust was turned off and no fan was placed inside the chamber. Once the mosquitoes were acclimatised (introduced into the chamber 1 hour before the test) the unit was turned on and left running for 120 minutes (2 hours). At the end of the tested period, the room was vacuumed to enable a count of those insects knocked down during the test. Any remaining free-flying insects were then knocked down and vacuumed up separately, to accurately assess the number of insects entering the chamber. After insect removal, the chamber exhaust was used to purge the chamber. Visual assessment of knockdown (KD) was made at 5 minute intervals for the duration of the test. Mean transfluthrin concentration: 1.095 mg/hour (fresh sample); 0.954 mg/hr (mid-life sample); 0.913 mg/hr (end of life sample). Mean: 0.987 mg/hr in 20m³ room) equivalent to 0.0494 mg/hr/m³. | **Table:** KT Values of free-flying *Culex quinquefasciatus* in a standard 20m³ chamber (4 replicates)   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | Time to knockdown % of the mosquitoes (minutes) | | | |  | **Age** | **KT50** | **KT80** | **KT95** | | *Culex quinquefasciatus* | **Fresh**  **0 hours** | 25.0 | 40.0 | 60.0 | | **Mid-life 120hours** | 18.0 | 26.0 | 35.0 | | **End-life**  **240 hours** | 24.0 | 41.0 | 73.3 |   Note: Numbers represented in table are estimates generated by linear interpolation of the mean % knockdown. | xxxx (2006a) |
| Insecticide against moquitoes indoors. | Obewan Unit with 30 night (240h) Refill at 230V as a heatable sandcore. | Tiger mosquito (*Aedes albopictus*)  Females, 16±2 days, laboratory cultured | Approximately 50 mosquitoes were released into a standard 20m3 test chamber. The heater unit was placed on the floor in the centre of the chamber. The refill was weighed prior to, and immediately after use. Product samples used were ‘fresh’ samples (0 hours use). A cold system start was used for each treatment/test period. The chamber exhaust was turned off and no fan was placed inside the chamber. Once the mosquitoes were acclimatised (introduced into the chamber 1 hour before the test) the unit was turned on and left running for 120 minutes (2 hours). At the end of the tested period, the room was vacuumed to enable a count of those insects knocked down during the test. Any remaining free-flying insects were then knocked down and vacuumed up separately, to accurately assess the number of insects entering the chamber. After insect removal, the chamber exhaust was used to purge the chamber. Visual assessment of knockdown (KD) was made at 5 minute intervals for the duration of the test. Mean transfluthrin concentration: 1.481 mg/hour (fresh sample) in 20m³ room, equivalent to 0.074 mg/hr/m³. | **Table:** KT Values of free-flying *Aedes albopictus* in a standard 20m³ chamber (4 replicates)   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | Time to knockdown % of the mosquitoes (minutes) | | | |  | **Age** | **KT50** | **KT80** | **KT95** | | *Aedes albopictus* | **Fresh**  **0 hours** | 19.0 | 24.0 | 34.0 |   These samples were only be tested as fresh for this species because aged sample testing was conducted against Culex quinquefasciatus (xxxx 2006a) which is known to be the most robust of our species. | xxxx (2006b) |
| Insecticide against flies indoors. | Obewan Unit with 30 night (240h) Refill at 230V as a heatable sandcore. | House fly (*Musca domestica*)  3-6 days old adult mixed sexes, laboratory cultured | Approximately 50 house flies were released into a standard 20m3 test chamber. The heater unit was placed on the floor in the centre of the chamber. The refill was weighed prior to, and immediately after use. Product samples used were ‘fresh’ samples (0 hours use), ‘mid-life’ samples (120 hours use) and ‘end-of-life’ samples (240 hours use). A cold system start was used for each treatment/test period. The chamber exhaust was turned off and no fan was placed inside the chamber. Once the flies were acclimatised (introduced into the chamber 1 hour before the test) the unit was turned on and left running for 120 minutes (2 hours). At the end of the tested period, the room was vacuumed to enable a count of those insects knocked down during the test. Any remaining free-flying insects were then knocked down and vacuumed up separately, to accurately assess the number of insects entering the chamber. After insect removal, the chamber exhaust was used to purge the chamber. Visual assessment of knockdown (KD) was made at 5 minute intervals for the duration of the test. Mean transfluthrin concentration: 1.166 mg/hr (end of life sample) in 20m³ room, equivalent to 0.0583 mg/hr/m³. | **Table:** KT Values of free-flying *Musca domestica* in a standard 20m³ chamber (4 replicates)   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | Time to knockdown % of the mosquitoes (minutes) | | | |  | **Age** | **KT50** | **KT80** | **KT95** | | *Musca domestica* | **Fresh**  **0 hours** | 15.0 | 20.0 | 29.6 | | **Mid-life 120hours** | 29.0 | 40.0 | 54.3 | | **End-life**  **240 hours** | 54.0 | 78.0 | >120.0 |   Note: Numbers represented in table are estimates generated by linear interpolation of the mean % knockdown.  More than 90% knockdown was achieved 80 minutes after switching-on of the unit, for the whole in-use life (240 hours) of the product. | xxxx (2006c) |
| Insecticide against moquitoes indoors. | Obewan Unit with 30 night (240h) Refill at 230V as a heatable sandcore and  European Electric Mat (containing 3.64% Pynamin Forte) @ 230V as a heated cardboard mat. | Southern House Mosquito, (*Culex quinquefasciatus*) Females, 16±2 days, laboratory cultured | Two 20 m3 chambers were used to evaluate the submitted samples in a free-flying knockdown efficacy test using 50 adult, free-flying mosquitoes. The heater was placed approximately 45cm off the floor in the centre of the chamber. Weights were taken immediately before and after each test period to determine 2-hour weight losses for each evaluation. Product samples used were ‘fresh’ samples (0 hours use). Contamination checks (no treatment) were conducted to monitor for potential residual contamination within the chamber. The chamber exhaust was turned off (and blast gate closed) for each evaluation. No fan was placed inside the chamber. Four replicates per treatment were conducted. Following each evaluation, the total number of mosquitoes in the chamber was determined by entering the chamber to take a physical count while vacuuming the mosquitoes for removal from the chamber. Mosquitoes that remained up were first knocked down to be included in the total count. The chambers were washed down with hot water after each test period. The chambers were then allowed to purge between each evaluation. In the event of contamination evidence the chambers were re-washed and vented then another contamination check was run. Knockdown counts were taken at 5-minute intervals for each 120 minute evaluation. Note: Tests were terminated before the 120 minute period when 2 consecutive 100% knockdown counts occurred to avoid contamination of the chambers (unit and test substance continued to run in the chamber after vents were opened to achieve 2 hour weight loss). A cold system start was used for each treatment. Mean transfluthrin concentration: 0.967 mg/hour (fresh sample) in 20m³ room, equivalent to 0.0484 mg/hr/m³. | **Table:** Mean % Knockdown of free-flying *Culex quinquefasciatus* (14-18 day old adult females) in a standard 20m³ chamber (4 replicates) using fresh samples   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  |  | Time to knockdown % of the mosquitoes (minutes) | | | |  | **Age** | **KT50** | **KT80** | **KT95** | | *Culex quinquefasciatus* | **Obewan Unit with 30 Night Refill @ 230V (13.43% transfluthrin)** | 10.0 | 16.0 | 24.0 | | **European Electric Mat @ 230V (3.64% Pynamin Forte)** | 18.0 | 40.0 | 61.0 |   Untreated control knockdown: 0% (30 mins-90 mins); 1% (120 mins). | xxxx (2007) |
| Insecticide against ants indoors. | Obewan Unit with 10 days (240h) Refill at 230V as a heatable sandcore. | Garden Black ant (*Lasius nige*r)  Workers, laboratory cultured. | The tests were done in 20 m3 test rooms (all windows closed) at three various test points: fresh product (day 0), product midlife (day 4) and product end life (day 9). The diffuser (operating for the complete duration of test of 10 days) was placed in the centre of the room in a height of 30 cm. The heated vaporizer provides a heated plume that reaches the floor level for ant efficacy (as demonstrated by the studies; this was taken into account when designing experiment and location of the ants) when it is circulated throughout the room by convection or diffusion.  The ants kept in glass petri dishes (diameter 15cm with a height of 1.8cm, provided with pieces of apples and sugar water swabs, without any shelter) on various positions (4) equally distributed on the bottom of the room. Ants were exposed at the beginning of each test point for 24 hours. Three replicates were used for the test treatment and 1 replicate for the untreated control. | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | **Age** | **% of knockdown at 4 hours** | | **% Mortality at 24hours** | | |  |  | **treatment** | **Untreated controls** | **treatment** | **Untreated controls** | | *Lasius niger* | **Fresh**  **0-1 days** | 100.0 | 0 | 100.0 | 3 | | **Mid-life**  **4-5 days** | 100.0 | 0 | 100.0 | 1 | | **End-life**  **9-10 days** | 100.0 | 1 | 100.0 | 3 | |  |  |  |  |  |   **Table:** Efficacy of Raid Night & Day™ in 20 m3 rooms against Black ants*, Lasius niger* with an End-life product (at 0, 4 and 9 days). Ants were exposed on 4 positions per test room in glass Petri dishes (mean of 3 replicates (rooms). | xxxx (2010a) |
| Insecticide against moquitoes indoors. | Obewan Unit operating at different voltages that lead to different temperatures and therefore to different release rates of active (205v = Leia low setting, 225v= Leia high setting). | Yellow fever mosquito (*Aedes aegypti*)  Females, laboratory cultured | For a period of 13 days (290 hours) tests were done against mosquitoes in 16 m³ test rooms with systems operated with a voltage of 205 volt (low release) and for a period of 6 days (122 hours) in 30 m³ test rooms with systems operated with a voltage of 225 volt (high release). Assessments were done at three test points: fresh product (day 0 [0 - 2 hours]; 205 volt and 225 volt), product mid-life (day 7 [144 - 146 hours] for systems operated with 205 volt and day 3 [48 - 50 hours] for systems operated with 225 volt) and product end life (day 13 [288 - 290 hours] for systems operated with 205 volt and day 6 [120 - 122 hours] for systems operated with 225 volt). The diffuser (operating for the complete duration of test) was placed in the centre of the room in a height of 50 cm. Fifty female mosquitoes were exposed into the room free flying. One hour later the relevant vaporizer system was positioned in the test room.  The operating time was 2 hours inside the test rooms. Knockdown evaluation was done every 10 minutes up to 2 hours. Three replicates were used for the test treatment and 1 replicate for the untreated control.  Release rate of transfluthrin from the device at 205volts: 1.75 mg/hour (2 hours); 1.15 mg/hour (146 hours); 0.93 mg/hour (290 hours).  Release rate of transfluthrin from the device at 225 volts: 1.95 mg/hour (2 hours); 3.21 mg/hour (50 hours); 2.07 mg/hour (122 hours). | **Table 1:** Efficacy of Raid Night & Day™ , operated with 205 volt (Leia low release), in 16 m³ rooms against free flying Yellow fever mosquitoes, *Aedes aegypti*, females.   |  |  |  |  | | --- | --- | --- | --- | |  | **KT50 (min)** | **KT95 (min)** | **KT100**  **(min)** | | **Fresh product (day 0, 0 - 2 hours)** | 25.2 | 42.0 | 50.0 | | **Product mid-life (day 3, 48 - 50 hours)** | 11.4 | 35.4 | 40.0 | | **Product end life (day 6, 120 - 122 hours)** | 18.0 | 42.0 | 50.0 |   **Table 2:** Efficacy of Raid Night & Day™ , operated with 225 volt (Leia high release), in 30 m³ rooms against free flying Yellow fever mosquitoes, *Aedes aegypti*, females.   |  |  |  |  | | --- | --- | --- | --- | |  | **KT50 (min)** | **KT95 (min)** | **KT100**  **(min)** | | **Fresh product (day 0 , 0 - 2 hours)** | 24.0 | 41.4 | 50.0 | | **Product mid-life (day 7, 144 - 146 hours)** | 22.8 | 51.0 | 60.0 | | **Product end life (day 13, 288 - 290 hours)** | 18.0 | 30.0 | 50.0 |   For all untreated controls, knockdown was 0% during the whole testing period. | xxxx (2010b)  Amendment xxxx (2015a) |
| Insecticide against moquitoes indoors. | Obewan Unit operating at different voltages that lead to different temperatures and therefore to different release rates of active (205v = Leia low setting, 225v= Leia high setting). | Southern House Mosquito, (*Culex quinquefasciatus*) Females, laboratory cultured | For a period of 13 days (290 hours) tests were done against mosquitoes in 16 m³ test rooms with systems operated with a voltage of 205 volt (low release) and for a period of 6 days (122 hours) in 30 m³ test rooms with systems operated with a voltage of 225 volt (high release). Assessments were done at three test points: fresh product (day 0 [0 - 2 hours]; 205 volt and 225 volt), product mid-life (day 7 [144 - 146 hours] for systems operated with 205 volt and day 3 [48 - 50 hours] for systems operated with 225 volt) and product end life (day 13 [288 - 290 hours] for systems operated with 205 volt and day 6 [120 - 122 hours] for systems operated with 225 volt). The diffuser (operating for the complete duration of test) was placed in the centre of the room in a height of 50 cm. Fifty female mosquitoes were exposed into the room free flying. One hour later the relevant vaporizer system was positioned in the test room.  The operating time was 2 hours inside the test rooms. Knockdown evaluation was done every 10 minutes up to 2 hours. Three replicates were used for the test treatment and 1 replicate for the untreated control. | **Table 1:** Efficacy of Raid Night & Day™ , operated with 205 volt (Leia low setting), in 16 m³ rooms against free flying *Culex quinquefasciatus*, females.   |  |  |  |  | | --- | --- | --- | --- | |  | **KT50 (min)** | **KT95 (min)** | **KT100**  **(min)** | | **Fresh product**  **(day 0, 0 - 2 hours)** | 34.2 | 66.0 | 80.0 | | **Product mid life**  **(day 3, 48 - 50 hours)** | 23.4 | 51.6 | 60.0 | | **Product end life**  **(day 6, 120 - 122 hours)** | 18.0 | 54.0 | 100.0 |   **Table 2:** Efficacy of Raid Night & Day™ , operated with 225 volt (Leia high setting), in 30 m³ rooms against free flying, *Culex quinquefasciatus*, females.   |  |  |  |  | | --- | --- | --- | --- | |  | **KT50 (min)** | **KT95 (min)** | **KT100**  **(min)** | | **Fresh product**  **(day 0, 0 - 2 hours)** | 15.6 | 35.4 | 60.0 | | **Product mid life**  **(day 7, 144 - 146 hours)** | 18.0 | 60.0 | 70.0 | | **Product end life**  **(day 13, 288 - 290 hours)** | 18.0 | 54.0 | 90.0 |   For all untreated controls, knockdown was 0% during the whole testing period. | xxxx (2010c)  Amendment xxxx (2015b) |
| Insecticide against moquitoes indoors. | Obewan Unit operating at different voltages that lead to different temperatures and therefore to different release rates of active (205v = Leia low setting, 225v= Leia high setting). | African malaria mosquito*, (Anopheles gambiae)*  Females, laboratory cultured | For a period of 13 days (290 hours) tests were done against mosquitoes in 16 m³ test rooms with systems operated with a voltage of 205 volt (low release) and for a period of 6 days (122 hours) in 30 m³ test rooms with systems operated with a voltage of 225 volt (high release). Assessments were done at three test points: fresh product (day 0 [0 - 2 hours]; 205 volt and 225 volt), product mid-life (day 7 [144 - 146 hours] for systems operated with 205 volt and day 3 [48 - 50 hours] for systems operated with 225 volt) and product end life (day 13 [288 - 290 hours] for systems operated with 205 volt and day 6 [120 - 122 hours] for systems operated with 225 volt). The diffuser (operating for the complete duration of test) was placed in the centre of the room in a height of 50 cm. Fifty female mosquitoes were exposed into the room free flying. One hour later the relevant vaporizer system was positioned in the test room.  The operating time was 2 hours inside the test rooms. Knockdown evaluation was done every 10 minutes up to 2 hours. Three replicates were used for the test treatment and 1 replicate for the untreated control. | **Table 1:** Efficacy of Raid Night & Day™ , operated with 205 volt (Leia low setting), in 16 m³ rooms against free flying *Anopheles gambiae*, females.   |  |  |  |  | | --- | --- | --- | --- | |  | **KT50 (min)** | **KT95 (min)** | **KT100**  **(min)** | | **Fresh product**  **(day 0, 0 - 2 hours)** | 20.4 | 55.8 | 60 | | **Product mid life**  **(day 3, 48 - 50 hours)** | 22.2 | 45.6 | 60 | | **Product end life**  **(day 6, 120 - 122 hours)** | 42.6 | 68.4 | 80 |   **Table 2:** Efficacy of Raid Night & Day™ , operated with 225 volt (Leia high setting), in 30 m³ rooms against free flying *Anopheles gambiae* females.   |  |  |  |  | | --- | --- | --- | --- | |  | **KT50 (min)** | **KT95 (min)** | **KT100**  **(min)** | | **Fresh product**  **(day 0, 0 - 2 hours)** | 21 | 36.6 | 70 | | **Product mid life**  **(day 7, 144 - 146 hours)** | 22.2 | 36.6 | 60 | | **Product end life**  **(day 13, 288 - 290 hours)** | 24 | 54 | 70 |   For all untreated controls, knockdown was 0% during the whole testing period. | xxxx (2010a)  Amendment xxxx (2015c) |
| Insecticide against moquitoes indoors. | Obewan Unit operating at different voltages that lead to different temperatures and therefore to different release rates of active (205v = Leia low setting, 225v= Leia high setting). | Tiger mosquito (*Aedes albopictus*)  Females, laboratory cultured | For a period of 13 days (290 hours) tests were done against mosquitoes in 16 m³ test rooms with systems operated with a voltage of 205 volt (low release) and for a period of 6 days (122 hours) in 30 m³ test rooms with systems operated with a voltage of 225 volt (high release). Assessments were done at three test points: fresh product (day 0 [0 - 2 hours]; 205 volt and 225 volt), product mid-life (day 7 [144 - 146 hours] for systems operated with 205 volt and day 3 [48 - 50 hours] for systems operated with 225 volt) and product end life (day 13 [288 - 290 hours] for systems operated with 205 volt and day 6 [120 - 122 hours] for systems operated with 225 volt). The diffuser (operating for the complete duration of test) was placed in the centre of the room in a height of 50 cm. Fifty female mosquitoes were exposed into the room free flying. One hour later the relevant vaporizer system was positioned in the test room.  The operating time was 2 hours inside the test rooms. Knockdown evaluation was done every 10 minutes up to 2 hours. Three replicates were used for the test treatment and 1 replicate for the untreated control. | **Table 1:** Efficacy of Raid Night & Day™ , operated with 205 volt (Leia low setting), in 16 m³ rooms against free flying tiger mosquito, *Aedes albopictus*, females.   |  |  |  |  | | --- | --- | --- | --- | |  | **KT50 (min)** | **KT95 (min)** | **KT100**  **(min)** | | **Fresh product**  **(day 0, 0 - 2 hours)** | 17.4 | 32.4 | 50 | | **Product mid life**  **(day 3, 48 - 50 hours)** | 10.8 | 21 | 60 | | **Product end life**  **(day 6, 120 - 122 hours)** | 18 | 24 | 40 |   **Table 2:** Efficacy of Raid Night & Day™ , operated with 225 volt (Leia high setting), in 30 m³ rooms against free flying Tiger mosquitoes, *Aedes albopictus*, females.   |  |  |  |  | | --- | --- | --- | --- | |  | **KT50 (min)** | **KT95 (min)** | **KT100**  **(min)** | | **Fresh product**  **(day 0, 0 - 2 hours)** | 14.4 | 29.4 | 50 | | **Product mid life**  **(day 7, 144 - 146 hours)** | 12 | 36 | 50 | | **Product end life**  **(day 13, 288 - 290 hours)** | 18 | 42 | 50 |   For all untreated controls, knockdown was max 2% during the whole testing period. | xxxx (2010b)  Amendment xxxx (2015d) |
| Insecticide against flies indoors. | Obewan Unit operating at different voltages that lead to different temperatures and therefore to different release rates of active (205v = Leia low setting, 225v= Leia high setting). | House fly (*Musca domestica*)  adult mixed sexes, laboratory cultured | For a period of 13 days (290 hours) tests were done against House flies in 16 m³ test rooms with systems operated with a voltage of 205 volt (low release) and for a period of 6 days (122 hours) in 30 m³ test rooms with systems operated with a voltage of 225 volt (high release). The tests were done in test rooms (all windows closed) at three various test points: fresh product (day 0 [0 - 2 hours]; 205 volt and 225 volt), product mid-life (day 7 [144 - 146 hours] for systems operated with 205 volt and day 3 [48 - 50 hours] for systems operated with 225 volt) and product end life (day 13 [288 - 290 hours] for systems operated with 205 volt and day 6 [120 - 122 hours] for systems operated with 225 volt). The diffuser (operating for the complete duration of test) was placed in the centre of the room in a height of 50 cm.  50 flies (mixed sex) were exposed into the room free flying. One hour later the relevant vaporizer system was positioned in the test room.  The operating time was 2 hours inside the test rooms. Evaluation for knock down was done every 10 minutes up to 2 hours. The rooms were entered for evaluation. Three replicates were used for the test treatment and 1 replicate for the untreated control. | **Table 1:** Efficacy of Raid Night & Day™ , operated with 205 volt (Leia low setting), in 16 m³ rooms against free flying house flies, *Musca domestica*, mixed sex.   |  |  |  |  | | --- | --- | --- | --- | |  | **KT50 (min)** | **KT95 (min)** | **KT100**  **(min)** | | **Fresh product**  **(day 0, 0 - 2 hours)** | 37.8 | 58.8 | 70 | | **Product mid life**  **(day 3, 48 - 50 hours)** | 20.4 | 42 | 90 | | **Product end life**  **(day 6, 120 - 122 hours)** | 24 | 42 | 90 |   **Table 2:** Efficacy of Raid Night & Day™ , operated with 225 volt (Leia high setting), in 30 m³ rooms against free flying house flies, *Musca domestica*, mixed sex.   |  |  |  |  | | --- | --- | --- | --- | |  | **KT50 (min)** | **KT95 (min)** | **KT100**  **(min)** | | **Fresh product**  **(day 0, 0 - 2 hours)** | 28.2 | 63.6 | 70 | | **Product mid life**  **(day 7, 144 - 146 hours)** | 30 | 78 | 80 | | **Product end life**  **(day 13, 288 - 290 hours)** | 30 | 66 | 90 |   For all untreated controls, knockdown was 0% during the whole testing period. | xxxx (2010d)  Amendment xxxx  (2015e) |
| Insecticide against ants indoors. | Obewan Unit operating at different voltages that lead to different temperatures and therefore to different release rates of active (205v = Leia low setting, 225v= Leia high setting). | Garden Black ant (*Lasius nige*r)  Workers, laboratory cultured. | For a period of 13 days (312 hours) tests were done against Black ants in 16 m³ test rooms with systems operated with a voltage of 205 volt (low release) and for a period of 6 days (144 hours) in 30 m³ test rooms with systems operated with a voltage of 225 volt (high release). The tests were done in test rooms (all windows closed) at three various test points: fresh product (day 0 [0 - 24 hours]; 205 volt and 225 volt), product mid-life (day 7 [144 - 168 hours] for systems operated with 205 volt and day 3 [48 - 72 hours] for systems operated with 225 volt) and product end life (day 13 [288 - 312 hours] for systems operated with 205 volt and day 6 [120 - 144 hours] for systems operated with 225 volt). The diffuser (operating for the complete duration of test) was placed in the centre of the room in a height of 50 cm. The heated vaporizer provides a heated plume that reaches the floor level for ant efficacy (as demonstrated by the studies; this was taken into account when designing experiment and location of the ants) when it is circulated throughout the room by convection or diffusion.  Four Petri dishes with 20 ants each were equally distributed on the bottom. Fresh product was started simultaneously with exposure of ants, with mid-life products and end life products systems were used inside test rooms 24 hours before exposure of ants.  The products operated continuously. Evaluation was done every 4 hours. The rooms are entered for evaluation. During the test the ants are provided with a piece of apple and a swab with sugar water. Three replicates were used for the test treatment and 1 replicate for the untreated control. | **Table 1:** Efficacy of Raid Night & Day™ , operated with 205 volt (Leia low setting), in 16 m³ rooms against workers of Garden Black ant (*Lasius nige*r).   |  |  |  | | --- | --- | --- | |  | **KT50 (hours)** | **KT95 (hours)** | | **Fresh product**  **(day 0, 0 - 24 hours)** | 7.00 | 9.22 | | **Product mid life**  **(day 7, 144 - 168 hours)** | 3.80 | 3.97 | | **Product end life**  **(day 13, 288 – 312 hours)** | 4.66 | 7.20 |   **Table 2:** untreated controls (% knockdown, time in hours)   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **4 hours** | **8 hours** | **12 hours** | **24 hours** | | **Fresh product**  **(day 0, 0 - 24 hours)** | 0 | 0 | 0 | 0 | | **Product mid life**  **(day 7, 144 - 146 hours)** | 0 | 0 | N/A | 0 | | **Product end life**  **(day 13, 288 - 290 hours)** | 0 | 1 | 1 | 3 |   **Table 3:** Efficacy of Raid Night & Day™ , operated with 225 volt (Leia high setting), in 30 m³ rooms against workers of Garden Black ant (*Lasius niger*).   |  |  |  | | --- | --- | --- | |  | **KT50 (hours)** | **KT95 (hours)** | | **Fresh product**  **(day 0, 0 - 24 hours)** | 6.23 | 8.47 | | **Product mid life**  **(day 3, 48 - 72 hours)** | 3.88 | 4.05 | | **Product end life**  **(day 6, 120 - 144 hours)** | 5.97 | 10.68 |     For all untreated controls, knockdown was 0% during the whole testing period. | xxxx (2010e)  Amendment xxxx (2015f) |

| **Experimental data on the efficacy of the biocidal product against target organism(s)** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Function and Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method**  **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| Insecticide against moquitoes indoors. | Obewan unit with 240/720 Hour Refill at 230V as a heatable sandcore. | *Aedes aegypti, Aedes albopictus, Anopheles stephensi* and *Culex quinquefasciatus* Females, 14-25 days, laboratory cultured | Hidden Mosquito Method: Female mosquitoes (*Aedes aegypti, Aedes albopictus, Anopheles stephensi* and *Culex quinquefasciatus*) aged between 14 and 25 days, were set up 1 day prior to test. Approximately 10 of each species of mosquito were released through a small hole, into each of the plastic KD test cages. A paper clip was taped to the outside of the cages to be used for under the table test so they could hang under the table. Approximately 20 of each species of mosquito were released into each of the stainless steel-framed KD cages used behind curtain barriers. Dental wick (or culture tube containing 10% sugar water solution stopped with dental wick - for the stainless steel-framed KD cages) was placed in the hole as soon as the insects were released.  Following mosquito set-up, the plastic KD containers were placed in a holding tray containing 10% sugar water solution outside the chamber and the stainless steel-framed KD cages (with 10% sugar-water in culture tubes) were placed in the chambers at a height of 5 feet (1.52 meters) measured at centre of cage from the floor. Stainless steel-framed KD cages were placed in the chamber to check for the potential for chamber contamination prior to each test start. (Note: No chamber contamination was present in this study). All KD cages were checked for overnight control mortality prior to test start. Zero control mortality was observed prior to each test start. Four replicates of the test substance were conducted, with knockdown counts taken at 10 minute intervals through 120 minutes then at 3 hours and 4 hours and every 2 hours thereafter through 8 hours for mosquitoes located behind curtain barriers. Each count was taken at ± approximately one minute around designated time. Knockdown counts for mosquitoes located under covered tables occurred at the end of the 8 hours of sample exposure. Knockdown counts for mosquitoes located in the comers were taken at the end of the 8 hours of sample exposure to chamber. Mortality counts were taken at 24±6 hours post treatment. Untreated controls were conducted by placing stainless steel-framed KD cages of mosquitoes in the chamber overnight prior to test initiation to determine overnight mortality and potential for chamber contamination (Zero control mortality and no chamber contamination were present in this study).  Chamber exhausts remained off.  The device was placed and started near the floor in the centre of the chamber and orientated as though plugged (at 230V) into a wall. Product samples used were ‘fresh’ samples (0 hours use).  Once the test started, the number of mosquitoes knocked down in stainless steel-framed KD cages located behind curtains were counted and recorded. Data was taken at 10-minute intervals through 120 minutes then at 180 minutes, at 4 hours, 6 hours, and 8 hours. Each count was taken ± approximately 1 minute  around the designated time. The number of mosquitoes knocked down in KD cages located under covered tables and in cages located in the comers were counted and recorded. Data was taken at the end of 8 hours. Each count was taken ± approximately 1minute around the designated time.  The level of 24-hour mortality in all the KD cages was assessed (counted and recorded) the following day. These counts were made 24±6 hours from test initiation: 1.19 mg/hr in 20m³ room) equivalent to 0.0595 mg/hr/m³. | **Table 1:** Hidden Mosquito behind Curtain Barrier Test- Various mosquito species Test Substance: Electric Heater Refill (300mg Transfluthrin on Sandcore). Mean % Knockdown and Mortality behind Curtain Panels In 20m3 chambers with NO fan. Time in Minutes   |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Mosquito Species** | **Mean % Knockdown** | | | | | | | | | | **10m** | **20m** | **30m** | **40m** | **50m** | **60m** | **70m** | **80m** | **90m** | | ***Culex quinquefasciatus*** | 0 | 0 | 0 | 0 | 2 | **7** | **11** | **19** | **36** | | ***Aedes albopictus*** | 0 | 9 | 23 | 70 | 93 | **100** | **100** | **100** | **100** | | ***Aedes aegyti*** | 0 | 1 | 33 | 89 | 98 | **98** | **98** | **100** | **100** | | ***Anopheles stephensi*** | 0 | 8 | 38 | 56 | 71 | **88** | **90** | **94** | **95** |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Mosquito Species** | **100m** | **110m** | **120m** | **180m** | **240m** | **360m** | **480m** | **24 h Mortality** | | ***Culex quinquefasciatus*** | 34 | 50 | 66 | 98 | 100 | 100 | 100 | 100 | | ***Aedes albopictus*** | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | | ***Aedes aegyti*** | 100 | 100 | 100 | 100 | 100 | 100 | 100 | 100 | | ***Anopheles stephensi*** | 98 | 100 | 100 | 100 | 100 | 100 | 100 | 100 |   Note: 20 adult females per test container *I* one test container per species, per replicate *I* four replicates  **Table 2:** Hidden Mosquito under the Table Test - Various mosquito species Test Substance: Obewan Electric Heater Refill (300mg Transfluthrin on Sandcore). Mean % Knockdown and Mortality under Tables in 20m³ chamber with NO fan time in Minutes   |  |  |  | | --- | --- | --- | | **Mosquito Species** | **% knockdown at 480m** | **24 h Mortality** | | ***Culex quinquefasciatus*** | 100 | 100 | | ***Aedes albopictus*** | 100 | 100 | | ***Aedes aegyti*** | 100 | 100 | | ***Anopheles stephensi*** | 100 | 100 |   Note: 10 adult females per test container *I* two test containers per species, per replicate *I* four replicates.  **Table 3:** Hidden Mosquito under the Table Test - Various mosquito species Test Substance: Electric Heater Refill (300mg Transfluthrin on Sandcore). Mean % knockdown and mortality in the corners in 20 m³ chamber with NO fan time in Minutes   |  |  |  | | --- | --- | --- | | **Mosquito Species** | **% knockdown at 480m** | **% 24 h Mortality** | | ***Culex quinquefasciatus*** | 100 | 100 | | ***Aedes albopictus*** | 100 | 100 | | ***Aedes aegyti*** | 100 | 100 | | ***Anopheles stephensi*** | 100 | 100 |   Note: 10 adult females per test container *I* two test containers per species, per replicate *I* four replicates.  **Table 4:** Pre-control checks in closed 20m³ chambers for mosquitoes behind open curtains only. % mortality after 16 hours   |  |  |  | | --- | --- | --- | | **Mosquito Species** | **Chamber #** | **% mortality 16 h** | | ***Culex quinquefasciatus*** | East | 0 | | ***Aedes albopictus*** | East | 0 | | ***Aedes aegyti*** | West | 0 | | ***Anopheles stephensi*** | West | 0 | | xxxx (2014a) |
| Insecticide against flies indoors. | Obewan unit with 240/720 Hour Refill at 230V as a heatable sandcore. | House flies (*Musca domestica*)  Mixed sex 12-13days, laboratory cultured | An Electric Heater Refill (300mg Transfluthrin) was placed and started in a 20m³ chamber. According to the label claim of 8 hours of usage per night, the device was turned on upon placement and removed after 8 hours. Product samples used were ‘fresh’ samples (0 hours use).  Housefly set-up (1 day prior to test):  a. Anesthetize Houseflies from the rearing test cage.  b. Release approximately 50 of mixed sex Houseflies through the small hole, into each of the plastic KD test cages.  c. Seal the hole with dental wick as soon as the insects are released into the cage.  3. Following Housefly set-up, the plastic KD containers were placed in a holding tray containing 10% sugar water solution outside the chamber. Contamination checks for the potential for chamber contamination prior to each test start. (Note: No chamber contamination was present in this study).  4. Release free flying Houseflies into the chamber through exhaust port.  Houseflies were released into the chambers and knockdown counts were recorded at 10 minute intervals for the initial 2 hours, then at 3 and 4 hours and then every 2 hours up to 8 hours. Knockdown observations were made at the end of the 8th hour. All flies were removed from the test chamber and held for 24-hour mortality observations. | **Table 1:** Free Flying Housefly (*Musca domestica*). Test Test Substance: Electric Heater Refill (300mg Transfluthrin on Sandcore). Mean % knockdown and mortality in 20m³ chamber with no fan.   |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  | **Time in minutes** | | | | | | | | | | | | **10** | **20** | **30** | **40** | **50** | **60** | **70** | | **80** | | **90** | | *Musca domestica* | 4.3 | 10.1 | 17.2 | 52.7 | 78.4 | 89.0 | 94.4 | | 99.0 | | 100.0 | |  | **Time in minutes** | | | | | | | | | | | | **100** | **110** | **120** | **180** | **240** | **360** | | **480** | | **24h mortality** | | | *Musca domestica* | 99.0 | 100.0 | 98.5 | 100.0 | 100.0 | 100.0 | | 100.0 | | 99.5% | |   **Table 2:** Weight Loss (mg) Data. 8-Hour Weight Loss (mg) of Electric Heater Refill (300mg Transfluthrin on Sandcore) using heater in 20 m3 Chamber.   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **Test substance** | **Rep 1** | **Rep 2** | **Rep 3** | **Rep 4** | **Mean** | **Std Dev** | | **Electric Heater Refill - Fresh** | 23.8 | 25.7 | 29.7 | 29.8 | 27.25 | 2.99 |   For all untreated controls, knockdown was 0% during the whole testing period. | xxxx (2016) |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| Efficacy of the products to be authorized was tested in simulated-use tests with *Aedes aegypti*, *Aedes albopictus*, *Anopheles stephensi*, *Anopheles gambiae, Culex quinquefasciatus and Musca domestica.*This is suffient to authorise a claim against mosquitoes and flies. Efficacy was demonstrated for fresh product as well as for product in the middle and at the end of the lifespan. Furthermore, efficacy was demonstrated at the low and high release settings for Night&Day Trio.  Although simulated use tests were provided with *Lasius niger*, sufficient efficacy against this target species was not shown.  For a complete evaluation of the label claims, please refer to section 2.2.5.8. |

#### Occurrence of resistance and resistance management

No resistance to transfluthrin has been reported for the target species. Due to the scale of the proposed uses (indoor, household use) the proportion of the target population treated is small and selection pressure for the development of resistance in the EU is consequently considered to be low. Therefore no resistance management measures are required.

#### Known limitations

Do not use in ventilated rooms (e.g. airconditioned rooms or rooms with open windows) as this may reduce product efficacy. Insects hidden behind curtains may require more time to kill.

#### Evaluation of the label claims

The product is claimed to be effective :

* Against mosquitoes and tropical mosquitoes;
* Against house flies;
* Against ants.

Night & Day and Night & Day trio is claimed to be effective against mosquitoes, tropical mosquitoes, flies and ants by vaporizing transfluthrin absorbed in an inert carrier matrix. The inert matrix is heated by an electrical heater unit which causes the transfluthrin to evaporate in a controlled manner.

Use1:

* Refill will last for ~240 hours to be used for medium size rooms approx 20m3

Use 2:

Refill will last for ~

* 320 hours on low setting for small rooms approx 16m3
* 240 hours on medium setting for medium size rooms approx 20m3 and
* 160 hours on high setting, suitable for large rooms, 30m3

*Evaluation of the label claims*

Use 1 corresponds with the medium setting in use 2. Therefore the two uses are combined in this evaluation section.

Duration:

* 320 hours on low setting for small rooms (≤16m³)
* 240 hours on medium setting for medium size rooms (≤20m³)
* 160 hours on high setting, suitable for large rooms (≤30m³)

For optimal efficacy, activate the device 1 hour in advance for mosquitoes and 1.5 hours in advance for flies.

Efficacy against mosquitoes

Efficacy against Southern House Mosquito (*Culex quinquefasciatus)* was tested in:

* A simulated use test at the medium setting where efficacy (KT95) was demonstrated for the fresh product (0 hours) in a 20m³ room after 65 minutes and for the end-of-life product (238 hours) after 55 minutes (xxxx 2008a)
* A simulated use test at the medium setting where efficacy (KT95) was demonstrated for the fresh product (0 hours) in a 20m³ room after 60 minutes, for the mid-life product (120 hours) after 35 minutes and for the end-of-life product (240 hours) after 73.3 minutes. This study is considered invalid as no untreated control data were present (xxxx 2006a).
* A simulated use test at the medium setting where efficacy (KT95) was demonstrated for the fresh product (0 hours) in a 20m³ room after 24 minutes (xxxx 2007)
* A simulated use test at the low setting and the high setting where efficacy (KT95) was demonstrated at the low setting in a 16m³ room for the fresh product (0-2 hours) after 66 minutes, for the mid-life product (48-50 hours) after 51.6 minutes and for the end-of-life product (120-122 hours) after 54 minutes. At the high setting efficacy was demonstrated in a 30m³ room for the fresh product (0-2 hours) after 35.4 minutes, for the mid-life product (144-146 hours) after 60 minutes and for the end-of-life product (288-290 hours) after 54 minutes (xxxx 2010c)
* A simulated use test at the medium setting where efficacy (KT90) was demonstrated for the fresh product (0 hours) in a 20m³ room for mosquitoes behind curtain barriers after 180 minutes and for mosquitoes under tables and in the corners after 480 minutes (checked for the first time) (xxxx 2014a)

Efficacy against Yellow fever mosquito (*Aedes aegypti)* was tested in:

* A simulated use test at the medium setting where efficacy (KT95) was demonstrated for the fresh product (0 hours) in a 20m³ room after 30 minutes (xxxx 2008b)
* A simulated use test at the low setting and the high setting where efficacy (KT95) was demonstrated at the low setting in a 16m³ room for the fresh product (0-2 hours) after 42 minutes, for the mid-life product (48-50 hours) after 35.4 minutes and for the end-of-life product (120-122 hours) after 42 minutes. At the high setting efficacy was demonstrated in a 30m³ room for the fresh product (0-2 hours) after 41.4 minutes, for the mid-life product (144-146 hours) after 51 minutes and for the end-of-life product (288-290 hours) after 30 minutes (xxxx 2010b)
* A simulated use test at the medium setting where efficacy (KT90) was demonstrated for the fresh product (0 hours) in a 20m³ room for mosquitoes behind curtain barriers after 50 minutes and for mosquitoes under tables and in the corners after 480 minutes (checked for the first time) (xxxx 2014a)

Efficacy against Tiger mosquitoe (*Aedes albopictus)* was tested in:

* A simulated use test at the medium setting where efficacy (KT95) was demonstrated for the fresh product (0 hours) in a 20m³ room after 30 minutes (xxxx 2008d)
* A simulated use test at the medium setting where efficacy (KT95) was demonstrated for the fresh product (0 hours) in a 20m³ room after 34 minutes. This study is considered invalid as no untreated control data were present (xxxx 2006b).
* A simulated use test at the low setting and the high setting where efficacy (KT95) was demonstrated at the low setting in a 16m³ room for the fresh product (0-2 hours) after 32.4 minutes, for the mid-life product (48-50 hours) after 21 minutes and for the end-of-life product (120-122 hours) after 24 minutes. At the high setting efficacy was demonstrated in a 30m³ room for the fresh product (0-2 hours) after 29.4 minutes, for the mid-life product (144-146 hours) after 36 minutes and for the end-of-life product (288-290 hours) after 42 minutes (xxxx 2010b)
* A simulated use test at the medium setting where efficacy (KT90) was demonstrated for the fresh product (0 hours) in a 20m³ room for mosquitoes behind curtain barriers after 50 minutes and for mosquitoes under tables and in the corners after 480 minutes (checked for the first time) (xxxx 2014a)

Efficacy against Indo-Pakistan malaria mosquito (*Anopheles stephensi)* was tested in:

* A simulated use test at the medium setting where efficacy (KT95) was demonstrated for the fresh product (0 hours) in a 20m³ room after 57.5 minutes (xxxx 2008c)
* A simulated use test at the medium setting where efficacy (KT90) was demonstrated for the fresh product (0 hours) in a 20m³ room for mosquitoes behind curtain barriers after 70 minutes and for mosquitoes under tables and in the corners after 480 minutes (checked for the first time) (xxxx 2014a)

Efficacy against African malaria mosquito (*Anopheles gambiae)* was tested in:

* A simulated use test at the low setting and the high setting where efficacy (KT95) was demonstrated at the low setting in a 16m³ room for the fresh product (0-2 hours) after 55.8 minutes, for the mid-life product (48-50 hours) after 45.6 minutes and for the end-of-life product (120-122 hours) after 68.4 minutes. At the high setting efficacy was demonstrated in a 30m³ room for the fresh product (0-2 hours) after 36.6 minutes, for the mid-life product (144-146 hours) after 36.6 minutes and for the end-of-life product (288-290 hours) after 54 minutes (xxxx 2010a)

No laboratory tests were provided against mosquitoes. However, we consider the simulated use tests worst case compared to laboratory tests and these simulated use tests convincingly demonstrate efficacy against mosquitoes.

Most simulated use studies only provide information about knockdown and not about mortality. However, in none of the studies provided any of the mosquitoes which were knockdown became active again. In combination with the simulated use data which did show mortality (with fresh product at medium setting) and in combination with knockdown data, we consider it possible to bridge these studies and find the knockdown data sufficient to demonstrate efficacy.

Therefore, the results of the studies above demonstrate efficacy of this product against mosquitoes, shown on *Culex spp., Aedes spp.* and *Anopheles spp*. For optimal efficacy against all mosquitoes, activate the device 1 hour in advance and keep the windows closed during use of this product.

Efficacy against flies

Efficacy against *Musca domestica* was tested in:

* A simulated use test at the medium setting where efficacy (KT95) was demonstrated for the fresh product (0 hours) in a 20m³ room after 63.3 minutes (xxxx 2008e)
* A simulated use test at the medium setting where efficacy (KT95) was demonstrated for the fresh product (0 hours) in a 20m³ room after 29.6 minutes, for the mid-life product (120 hours) after 54.3 minutes and for the end-of-life prduct (240 hours) >120 minutes. More than 90% knockdown was achieved 80 minutes after switching-on of the unit, for the whole in-use life (240 hours) of the product. This study is considered invalid as no untreated control data were present (xxxx 2006c).
* A simulated use test at the low setting and the high setting where efficacy (KT95) was demonstrated at the low setting in a 16m³ room for the fresh product (0-2 hours) after 58.8 minutes, for the mid-life product (48-50 hours) after 42 minutes and for the end-of-life product (120-122 hours) after 42 minutes. At the high setting efficacy was demonstrated in a 30m³ room for the fresh product (0-2 hours) after 63.6 minutes, for the mid-life product (144-146 hours) after 78 minutes and for the end-of-life product (288-290 hours) after 66 minutes (xxxx 2010d)
* A simulated use test at the medium setting where efficacy (KT90) was demonstrated for the fresh product (0 hours) in a 20m³ room after 70 minutes (xxxx 2016)

No laboratory tests were provided against flies. However, we consider the simulated use tests worst case compared to laboratory tests and these simulated use tests convincingly demonstrate efficacy against flies.

Most simulated use studies only provide information about knockdown and not about mortality. However, in none of the studies provided any of the flies which were knockdown became active again. In combination with the simulated use data which did show mortality (with fresh product at medium setting) and in combination with knockdown data, we consider it possible to bridge these studies and find the knockdown data sufficient to demonstrate efficacy.

Therefore,the results of the studies above demonstrate efficacy of this product against flies, shown on *Musca domestica*. For optimal efficacy against flies, activate the device 1.5 hours in advance and keep the windows closed during use of this product

Efficacy against ants

Efficacy against *Lasius niger* was tested in:

* A simulated use test at the medium setting where efficacy (KT100) was demonstrated in a 20m³ room for the fresh product (0-1 days), for the mid-life product (4-5 days) and for the end-of-life product (9-10 days) after 4 hours (xxxx 2010a)
* A simulated use test at the low setting and the high setting where efficacy (KT95) was demonstrated at the low setting in a 16m³ room for the fresh product (0-24 hours) after 9.22 hours, for the mid-life product (144-168 hours) after 3.97 hours and for the end-of-life product (288-312 hours) after 7.20 hours. At the high setting efficacy was demonstrated in a 30m³ room for the fresh product (0-2 hours) after 8.47 hours, for the mid-life product (48-72 hours) after 4.05 hours and for the end-of-life product (120-144 hours) after 10.68 hours (xxxx 2010e)

No laboratory tests were provided against ants and the simulated use tests demonstrates efficacy after 4 hours or more. Therefore, no authorization can be granted for this target organism as most ants will leave the room in less than 4 hours, especially since transfluthrin, a synthethic pyrethroid, is also known as a repellent active substance and ants are in particular sensitive for this repellent effect.

In conclusion, the data submitted fully supports the label claims against mosquitoes and flies for the products Night & Day™ and Night & Day™ Trio. The claim against ants is not supported.

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

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

### Risk assessment for human health

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

The product was considered as type C according to the carrier guidance (CA-Nov16-Doc.4.3 – Final). Therefore, the concentration of the active substance (13.4% w/w) in the product is based on the composition of the biocidal mixture including the sandcore.

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

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

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | According to Regulation (EC) No 1272/2008 the product requires classification for skin irritation as Skin Irrit. 2; H315. |
| 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. 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.  The product contains Transfluthrin that is classified for skin irritation (Skin Irrit. 2; H315), and is present at ≥10% and, therefore, the product requires classification according to Regulation (EC) No 1272/2008 as Skin Irrit. 2; H315.  The carrier contains two components that are classified for corrosion and the calculation method is considered adequate to determine the classification. However, these components do not drive the classification (unlike Transfluthrin).  It should also be noted that there is no direct dermal contact with the formulation as the refill is held by the plastic shell during assembly, so skin irritation is unlikely to occur. |
| Classification of the product according to CLP | Skin Irrit. 2; H315. |

***Eye irritation***

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

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | The product does not require classification for eye irritation according to Regulation (EC) No 1272/2008. |
| 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 by calculation. 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/serious eye damage.  Details of the product composition are presented in Confidential Annex 3.6. The product does not contain any substances which are classified as for eye irritation and does not therefore require classification.  The carrier contains two components that are classified for corrosion and the calculation method is considered adequate to determine the classification. The concentration of these components is lower than the relevant concentration limit, therefore no classification is warranted.  It should also be noted that there is no direct contact with the formulation as the refill is held by the plastic shell during assembly therefore subsequent ocular contact is not anticipated. |
| Classification of the product according to CLP | Not classified. |

***Respiratory tract irritation***

There are no standard tests for this endpoint and testing is not required under the BPR. Predicted air concentrations from consumer use are well below the AEC set for TFN. Local irritation effects are not anticipated during product use.

***Skin sensitisation***

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

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | The product does not require classification for skin sensitisation according to Regulation (EC) No 1272/2008. |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for skin sensitisation by calculation. Section 3.4.3 of the Regulation states that classification of a product for sensitising effects is necessary if it contains at least one ingredient has been classified as a skin sensitizer and is present at or above the appropriate generic concentration limit as shown in Table 3.4.5 or is present at or above the concentration limit for sensitised individuals presented in Table 3.4.6.  The carrier contains two components that are classified for skin sensitisation and the calculation method is considered adequate to determine the classification. The concentration of these components is lower than the relevant concentration limit, therefore no classification is warranted.  It should also be noted that there is no direct dermal contact with the formulation as the refill is held by the plastic shell during assembly. Dermal contact is required for sensitisation to occur; therefore adverse effects are not anticipated. |
| Classification of the product according to CLP | Not classified. |

***Respiratory sensitisation (ADS)***

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

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | The product does not require classification for respiratory sensitisation according to Regulation (EC) No 1272/2008. |
| Justification for the value/conclusion | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for respiratory sensitisation by calculation. Section 3.4.3 of the Regulation states that classification of a product for sensitising effects is necessary if it contains at least one ingredient that has been classified as a respiratory sensitizer and is present at or above the appropriate generic concentration limit shown in Table 3.4.5.  Details of the product composition are presented in Confidential Annex 3.6. There is one components of the product classified for respiratory sensitisation according to the MSDS; however according to the harmonised classification this classification is not longer warranted. Therefore, the product does not require classification for respiratory sensitisation. |
| lassification of the product according to CLP | Not classified. |

***Acute toxicity***

*Acute toxicity by oral route*

No *in-vivo* or human data are available.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | The product is not classified for acute oral toxicity according to Regulation (EC) No 1272/2008. |
| Justification for the selected value | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for acute oral toxicity by calculation. 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 Confidential Annex 3.6. The product contains no substances classified for acute oral toxicity. Transfluthrin has an oral LD50 of 583 mg/kg bw (Transfluthrin Assessment Report). The ATE calculation with this LD50 value results in an ATE > 2000 mg/kg for the product. It is therefore not necessary to classify this product for acute oral toxicity. |
| Classification of the product according to CLP | Not classified |

*Acute toxicity by inhalation*

No *in-vivo* or human data are available.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | The product does not require classification for acute inhalation toxicity according to Regulation (EC) No 1272/2008. |
| Justification for the selected value | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for acute inhalation toxicity by calculation. 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 Confidential Annex 3.6. The product contains no substances classified for acute inhalation toxicity. It is therefore not necessary to classify this product for acute inhalation toxicity. |
| Classification of the product according to CLP | Not classified. |

*Acute toxicity by dermal route*

No *in-vivo* or human data are available.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | The product does not require classification for acute dermal toxicity according to Regulation (EC) No 1272/2008. |
| Justification for the selected value | Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for acute dermal toxicity by calculation. The acute toxicity estimate (ATE) for the mixture is calculated and compared to Table 3.1.1 to derive the category of toxicity.    Details of the product composition are presented in Confidential Annex 3.6 Section 2. The product contains no substances classified for acute dermal toxicity. No classification is therefore proposed for acute dermal toxicity. |
| Classification of the product according to CLP | Not classified. |

***Information on dermal absorption***

No dermal absorption study is performed with Night & Day, but reference to the dermal absorption value of the active substance is made. Dermal absorption on the active substance is summarised and reported within the active substance dossier submitted for Annex I inclusion (Document IIA, Section 3.1).

A value of 10% was derived in the active substance evaluation based the physical-chemical values of transfluthrin and the comparison with other pyrethoids in several formulations. Chemicals fulfilling both criteria of molecular weight (MW) >500 and log Pow (lipid solubility) –1 < > 4 are accepted to have a dermal penetration rate of 10% or less. Transfluthrin has MW 371 and log Pow 5.4; values which (in common with most pyrethroids) are close to the MW criterion and well beyond the Pow criterion.

Dermal absorption studies with pyrethroids in vivo or in vitro suggest that the actual dermal absorption value might be significantly less than 10%. Therefore, using 10% for dermal absorption would provide a protective overestimate.

As this conclusion integrates the physical-chemical properties as well as knowledge on several other pyrethoids tested in several different formulations, a dermal absorption value of 10% will be carried forward to perform the risk assessment of Night & Day. In the case for Night & Day, dermal exposure is only expected in the scenario for an toddler crawling on a floor containing deposited residues.

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

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

Toluene is a substance for which occupational exposure limit (OEL) is set, and should therefore be considered as a Substance of Concern (SoC) regarding human health when present in the formulation as a co-formulant. For Night & Day, toluene is present in the Transfluthrin raw material at 0.5% and in the formula at 0.3495%, when the carrier is excluded. Toluene is thus not present as a co-formulant in the formulation. However, ECHA states that specific substances (e.g. other active substances and those on the REACH candidate list) should be considered SoCs if they are present in the biocidal product at a concentration ≥ 0.1% (European Commission, 2014). Therefore, the same approach was used for toluene as for a SoC and a human health risk assessment (Tier 1) was conducted.

As a worst-case approach, the air concentration of toluene was calculated assuming that all the toluene in one sandcore was immediately released into a small bedroom with no ventilation. The air concentration of toluene was calculated to be:

1.5mg (300mg transfluthrin per unit x 0.5% toluene).

For a small bedroom, the air concentration of toluene would be:

1.5mg/16m3 room = 0.094mg/m3

The Scientific committee on Occupational exposure limits has established a 8h TWA of 50 ppm (192 mg/m3 ) and also has ‘skin’ notation. The consumer exposure calculations were all lower than the respective OEL, indicating there is no concern for human health.

Regarding dermal exposure the Finnish CA in the substance evaluation report under REACH concludes that for toluene vapours the dermal route is not considered to be very important, but liquid toluene can be absorbed through the skin. As use of this product

concerns the exposure to toluene vapours, the dermal route is not further considered.[[2]](#footnote-2)

***Endocrine disruption activity of non-active substances***

According to the ED (endocrine disruptor) criteria with respect to humans established in the Commission Delegated Regulation (EU) 2017/2100, 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 product was not tested for potential endocrine disruption properties. Night and Day contains the active substance transflutrin in a sandcore matrix. The co-formulants in the sandcore matrix are screened for possible ED properties (see confidential annex).

To examine if any of the other co-formulants contained in the product may possess ED properties, a screening was performed by examining the co-formulants are

* Classified as CMR or PBT;
  + Identified as ED in the DG Santé’s Impact Assessment study on Screening of available evidence on chemical substances for the identification of endocrine disruptors;
  + Identified as ED in the EU list of potential endocrine disruptors; or
  + Listed in CoRAP linked to ED concerns.

None of the co-formulants triggered an alert for ED property. See assessment included in the confidential annex.

Subsequently, it was examined if there are any concerns for adverse effect to meet the criteria a) as described above using ECHA REACH database. Furthermore, US databases EDSP21 and ToxCast were checked. This examination did not result in alerts, and therefore no further ED assessment was required.

Also see confidential annex 3.6.1

**Available toxicological data relating to a mixture**

Not applicable

**Other**

The Night & Day™ Family contains two formulations with identical compositions: Night & Day™ and Night & Day™ Trio. They contain an insecticide absorbed in an inert matrix which acts as a carrier material. The temperature required to evaporate the insecticide from the inert matrix is generated by an appropriate electric heater unit. As Night & Day contains only the active substance in an inert sandcore unit, no endocrine disruption assessment needs to be carried out for the co-formulants.

The product also contains a small use-up cue which indicates the level of insecticide remaining in the device. The use-up cue is fully enclosed in a plastic sheath and is separated from the active/carrier component. For indication of usage of the product, the use-up cue liquid evaporates from the use-up cue through the membrane cover once the silver foil has been removed. There is no contact between the indicator liquid and the active ingredient (Transfluthrin) located in the inert carrier matrix.

Since the cue up liquid evaporates in order to indicate the level of remaining active substance, an exposure to the cue up liquid itself could be possible. The use-up cue has a volume of 0.12 ml and slowly evaporates over time to be an indicator for replacing the Night&Day unit. One refill last for 10day, so over time 0.012 ml will be evaporate in 24h in a room of 16m3. In the highest setting one refill last for 160 hours (6.7 days). The highest setting is only to used in room >30m3. The exposure to the use-up cue liquid can thus be considered as negligible.

#### 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 | Yes | No | No | Yes | No |
| Dermal | No | No | No | No | No | Yes | No |
| Oral | No | No | No | No | No | Yes | No |

**List of scenarios**

| **Summary table: scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Scenario** | **Primary or secondary exposure**  **Description of scenario** | **Exposed group** |
| 1. | During Application | Night & Day™ and Night & Day™ Trio are designed to be used against mosquitos and other insects. When the product is in use, the active ingredient forms a vapour, which can be inhaled.  For Scenario 1, it was conservatively assumed that a toddler and adult spent 24 hours in a small bedroom inhaling the vapour, without leaving the room. | Non- Professionals |
| 2. | Post-Application | Following the use of the product, active substance in the air can settle on the ground leaving residues for further exposure.  For Scenario 2, dermal exposure was estimated for an toddler crawling on a floor containing residues. Oral exposure from hand-to-mouth contact was also estimated for the toddler.  Active substance that has settled onto surfaces can also become revolatilised into the air for potential inhalation. Exposure was also determined for a toddler and adult via this route. | General Public |

**Industrial exposure**

Not applicable

**Professional exposure**Not applicable

**Non-professional exposure**

See exposure assessment

| **Description of Scenario 1: Direct Inhalation** |
| --- |
| The product Night & Day™ has one fixed emission rate, whereas Night & Day™ Trio has three emission rates (low, medium and high) that the consumer can select for rooms of different sizes. The consumer is advised to use the low setting for a 16 m3 room, which would represent a small bedroom.  The different emission rates from Night & Day™ Trio are 0.058, 0.065, 0.063 mg/hr/m3 for the low, medium and high setting, respectively (See Table in section 2.2.5.1, expressed per m3). The fixed release rate for Night & Day™ is equivalent to the Night & Day Trio device at the 'medium' setting and is the most conservative value to be used for the exposure estimation. Consequently, the exposure calculations in Scenarios 1 and 2 are based on the use of Night & Day™ in a small 16m3 bedroom.  To use Night & Day™, the consumer is instructed to hold the refill via the triangular plastic shell, insert into the diffuser and twist to lock. Neat active is present on the small sandcore unit embedded in the plastic shell (see first picture below). The consumer then needs to peel back the foil to reveal the use-up indicator and plug into an electrical outlet (see second and third pictures below).  ico_UI-03bn10gg    ico_UI-04bn    The active is then released into the air to kill insects. Tier 1 calculations were conducted using the ConsExpo Vapour model (Constant rate). Tier 2 calculations were based on experimental data. |

| **Tier 1** | **Parameters** | **Value** |
| --- | --- | --- |
|  | Model | ConsExpo Vapour model, Constant rate. |
| Frequency of Use | 150 days/year  The product will be used mainly during the months when mosquitos are present (RIVM, 2006a). However, exposure on the day of use was estimated. |
| Emission Duration | 24 hours (1 day) |
| Emission Rate | 1.296 mg active/hour (measured data)  Therefore 31.1 mg/24 hours. |
| Room Volume | 16 m3 (RIVM, 2006b) |
| Ventilation Rate | 1 hr-1 (RIVM, 2006b) |
| Toddler Body Weight | 10 kg (HEAd hoc recommendation 142017) |
| Toddler Inhalation Rate | 8 m3 / day (HEAd hoc recommendation 172017) |
| Adult Body Weight | 60 kg (HEAd hoc recommendation 142017) |
| Adult Inhalation Rate | 16 m3/ day (HEAd hoc recommendation 142017) |

**Calculations for Scenario 1**

Once plugged into mains electricity, the device becomes heated and releases the active as a vapour. Unlike liquid electrics (electrical evaporators), the emitted vapour does not result in significant droplet formation. This has been confirmed experimentally where it has been shown the active remains in the vapour phase, and the airborne particulate phase is negligible using particle size detection in the range of 11.1 to 1083.3 nm (Vesin *et al*. 2013a, Vesin *et al*. 2013b). Therefore, it was not considered necessary to determine oral uptake from the non-respirable fraction, as seen with the ConsExpo Spray model.

Air concentration for toddler exposure were calculated using the Vapour model (Constant rate) in ConsExpo Web (see output table of Consexpo in Annex 3.2):

Systemic exposure via the inhalation route was 0.0621 mg/kg bw/day for toddlers.

Adult systemic exposure was calculated to be:

(0.0776 mg/m3 x 16m3)/60 kg = 0.0207 mg/kg bw/day

As this results into a risk a tier2 exposure estimation was performed. Tier 2a based on Vesin *et al* 2013a, b and Tier 2b based on data from the applicant (xxxx 2016).

**Scenario 1, Tier 2a exposure refinements**

***Air concentration of transfluthrin, based on Vesin et al 2013 a, b***

The concentration of transfluthrin in the air following the application of the device has also been measured experimentally in a non-GLP study (Vesin *et al*. 2013b) and the results compared to ConsExpo 4.0 (Vesin *et al*. 2013a). The authors used the same Raid Night & Day device for this experiment, referred to as 'Raid Electric Fly & Mosquito protector' or 'Raid' in the publications. In the experimental study, air concentrations of transfluthrin were determined in an unfurnished test chamber of 32.3m3. Two experiments were run with 'Raid Electric Fly & Mosquito protector', using an air exchange rate of 0.14 or 0.35 ACH. The experiment with the higher air concentration of 0.35 ACH ('Experiment A') has been evaluated as this is closer to the default air exchange of 1 ACH. Temperature and relative humidity were measured at 26.3 (±1.2 s.d.)°C and 39.3 (±2.1 s.d.)% RH, respectively. To enhance monitoring sensitivity, 5 vapourisers were used (but the results were corrected for 1 unit). These were mounted in the centre of the room, 1 m above floor level, and at a distance of approximately 2m from the sampling line. The vapourisers were applied for 8 hours to represent typical sleep duration (although the study was run during the day time). A High Sensitivity Proton-Transfer-reaction Mass Spectrometer (HS-PTR-MS) was used to measured concentration of transfluthrin in the air, and a Scanning Mobility Particle Sizer (SMPS) device used to detect particles. Air concentration of transfluthrin was determined before, during and after product application. Vapourisers were weighed before and after product application to determine the quantity of Transfluthrin emitted during the experimental phase. The study was replicated twice.

In experiment A, Vesin (2013b) measured a peak air concentration of 4.9 µg/m3 at 8 hours, when the devices were switched off. The peak air concentration of 4.9 µg/m3 was used to calculate systemic inhalation exposure for an toddler and adult in a small bedroom. The air concentration was scaled to a 16 m3 room with an AER of 1/hour (according to table 10 of the General Fact Sheet, Consexpo, RIVM) to represent a small bedroom:

|  |  |  |
| --- | --- | --- |
| Data source | Room size | Ventilation rate (AER) |
| Vesin *et al.* (2013) | 32.3 m3 | 0.35/hour |
| ConsExpo small bedroom (RIVM, 2006b) | 16 m3 | 1/hour |

The table above shows that the experimental chamber used by Vesin is 2.02-fold larger than the room volume of a ConsExpo small bedroom; however, the ventilation rate in the ConsExpo small bedroom is 2.86-fold higher than the experimental chamber. Therefore the air concentration in the small bedroom will be approximately 2.02-fold higher due to size differences, but 2.86-fold lower due to the difference in ventilation rates:

Air concentration in 16m3 bedroom = (0.0049 mg/m3 from Vesin x 2.02)/2.86 = 0.00346 mg/m3

This air concentration was used to calculate systemic inhalation exposure for toddlers and adults on the day of exposure.

***Systemic inhalation exposure based on Vesin et al.***

Based on the defaults in HeAdhoc recommendation 14 (2017)the exposure for toddlers is considered as worst case for inhalation exposure. The long-term inhalation rate is reported for toddlers as 8 m3/24 hour day, with a bodyweight of 10kg. For adults, the equivalent value is 16 m3/24 hour day, with an accompanying bodyweight of 60kg.

Toddler: (0.00346 mg/m3 x 8m3/day) / 10 kg = 0.00277 mg/kg/day

Adult: (0.00346 mg/m3 x 16 m3/day) / 60 kg = 0.000923 mg/kg/day

**Scenario 1, Tier 2b exposure refinements, based on xxxx 2016**

In the experiment by Vesin *et al* (2013a,b) the Raid Night & Day devices were run for 8 hours before being switched off. It is unclear if the steady state air concentration had been reached by this time point and if the reported peak air concentration of 4.9 µg/m3 would be representative of steady state. The authors used the Consexpo 4.0 Vapour model (constant rate) to predict a steady state air concentration of 5.4 µg/m3. However, this scenario used emission rate data derived from the weight loss of the refills (experiment A, table 3, Vesin *et al* 2013b), rather than chemical analysis of the refills before and after use. Calculated emission rates by Vesin were significantly different from those measured by SC Johnson.

SC Johnson conducted another air concentration for Raid Night & Day, addressing the limitations above (xxxx 2016). Details of the experiment can be found in Confidential Annex 3.8.2. The results and exposure calculations are presented below.

The average air concentration reported by xxxx 2016 was 0.0137 mg/m3. The air concentration was scaled to one device in a 16 m3 room with an AER of 1/hour (according to table 10 of the General Fact Sheet, Consexpo, RIVM):

|  |  |  |
| --- | --- | --- |
| Data source | Room size | Ventilation rate (AER) |
| xxxx (2016) | 52.1 m3 | 0.5/hour |
| ConsExpo small bedroom (RIVM, 2006b) | 16 m3 | 1/hour |

The table above shows that the experimental chamber used by xxxx is 3.26-fold larger than the room volume of a ConsExpo small bedroom; however, the ventilation rate in the ConsExpo small bedroom is 2.00-fold higher than the experimental chamber. Therefore the air concentration in the small bedroom will be approximately 3.26-fold higher due to size differences, but 2-fold lower due to the difference in ventilation rates:

Air concentration in 16m3 bedroom = (0.0137 mg/m3 from xxxx /2 devices x 3.26)/2 = 0.0112 mg/m3

This air concentration was used to calculate systemic inhalation exposure for toddlers and adults on the day of exposure.

***Systemic inhalation exposure based on*** xxxx ***2016***

Based on the defaults in HeAdhoc recommendation 14 (2017) the exposure for toddlers is considered as worst case for inhalation exposure. The long-term inhalation rate is reported for toddlers as 8 m3/24 hour day, with a bodyweight of 10kg. For adults, the equivalent value is 16 m3/24 hour day, with an accompanying bodyweight of 60kg.

Toddler: (0.0112 mg/m3 x 8m3/day) / 10 kg = 0.00896 mg/kg/day

Adult: (0.0112 mg/m3 x 16 m3/day) / 60 kg = 0.00299 mg/kg/day

In the test of Vesin (tier 2a) it was not clear whether a steady state was reached, although the measured value was near the modelled value. It was obtained from public literature and GLP status was unknown. The xxxx study used for tier2b was conducted under GLP conditions with the product itself. In both studies room size and ventilation rate differed from a small bedroom size. In the calculation a surrogate value was used scaling to the standard value of room size and ventilation rate assuming a linear relationship. Therefore NL decided to present both tiers in the table below (Tier 2a: Vesin et al.;

Tier 2b: xxxx).

| **Summary table: Direct exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg/day)** | **Estimated dermal uptake**  **(mg/kg/day)** | **Estimated oral uptake**  **(mg/kg/day)** | **Estimated total uptake**  **(mg/kg/day)** |
| Scenario 1. Application, Toddler | 1/ No PPE | 0.0621 | N/A | N/A | 0.0621 |
| Scenario 1. Application, adult | 1/ No PPE | 0.0207 | N/A | N/A | 0.0207 |
| Scenario 1. Application, Toddler | 2a/ No PPE | 0.00277 | N/A | N/A | 0.00277 |
| Scenario 1. Application, adult | 2a/ No PPE | 0.000923 | N/A | N/A | 0.000923 |
| Scenario 1. Application, Toddler | 2b/ No PPE | 0.00896 | N/A | N/A | 0.00896 |
| Scenario 1. Application, adult | 2b/ No PPE | 0.00299 | N/A | N/A | 0.00299 |

Tier1 is based on Consexpo constant rate

Tier 2a is based on Vesin 2013a, b

Tier 2b is based on xxxx, 2016

Combined scenarios

Not applicable.

**Exposure of the general public**

Scenario 2

| **Description of Scenario: Post-application** | | |
| --- | --- | --- |
| Following the use of Night & Day™, significant droplet formation and gravitational settling is not anticipated. However, in order to be conservative, toddler dermal and oral exposure from contact with deposited residues were estimated.  Toddler dermal exposure could occur from crawling on the floor, and oral exposure could occur from hand- to-mouth contact and ingestion of residues. Dermal and oral exposure was calculated using the RIVM guidance for post-application exposure for electrical evaporators (RIVM, 2006a).  Active that has settled onto surfaces can evaporate into the air and become available for inhalation. Therefore, inhalation exposure from revolatilised residues was also determined, based on the conservative assumption of 100% deposition. Exposure for this scenario was determined for a toddler and adult. | | |
|  | Parameters | Value |
| Tier 1 | Amount of formula emitted | 31.1 mg active |
| Deposition | 10% (Applicant data, see Section 3.8.3) |
| Surface Area of floor | 6.4 m2  Based on 16 m3 room with a height of 2.5 m (RIVM, 2006b) |
| Dislodgeable Fraction | 0.08 (US EPA Residential SOPs 2012) |
| Oral Absorption | 100% |
| Dermal Absorption | 10% |
| Crawling Time | 1 hr/day (RIVM, 2006a) |
| Transfer coefficient | 0.2 m2/hr  (HEAdHoc Recommendation 12) |
|  | Toddler Body Weight | 10 kg (HEEG, 2013) |

**Calculations for Scenario 2**

***Deposition and dislodgeable fraction from floor***

A deposition value of 10% was used for the fraction of active substance emitted to floor (based on Emission Scenario Document for PT18, p96).

A certain fraction of the active becomes dislodged as an toddler moves on the floor. RIVM assumes a default dislodgeable amount of 30% for all actives (RIVM, 2006a) which was also used in the assessment report of transfluthrin. However, the more recent US EPA Residential SOPs (2012) contain measured data for a number of actives transferred from both carpets and hard surfaces. The following text is taken directly from the SOP (Page 7-32)

“The values for fraction of residue transferred from carpets and hard surfaces are based on information provided from two sources, which examine transferability of a variety of chemicals from both surfaces.

1) Beamer et. al (2009): performed an extensive analysis of numerous transfer efficiency studies which covered various methods (including the cloth roller, drag sled, PUF roller, and bare hand press), surfaces (hard surfaces/sheet vinyl and carpets) and various chemicals (chlorpyrifos, Pyrethrin and piperonyl butoxide (PBO)). Sources included: Camann, 1996; Fortune, 1997; Krieger, 2000; Ross, 1991; Clothier,2000.

2) Non-Dietary Exposure Task Force (NDETF): examined transferability for bare handpresses on carpets and vinyl/hard surfaces for deltamethrin, permethrin, PBO and Pyrethrin.

Complete datasets (using data from all available sources) were compiled for five chemicals: Pyrethrin, permethrin, piperonyl butoxide (PBO), chlorpyrifos and deltamethrin. These datasets were analyzed and the results are provided in Table 7-8 and Table 7-9, for carpets and hard surfaces, respectively. For the chemicals in Table 7-8 and Table 7-9, that have chemical specific data available, the arithmetic means should be used in post-application dermal exposure assessments. For chemicals not included in those tables, chemical-specific data are preferred, but if not available, a screening level value is recommended based on the available data. For chemicals that do not have chemical-specific data available, the recommended screening level point estimates for use in post-application dermal exposure assessments are 0.06 for carpets and 0.08 for hard surfaces.”

In the absence of chemical-specific data, a point estimate of 0.08 was used for transfluthrin for the exposure assessment. Hard surface data were favoured over carpet data because the values were higher and therefore more conservative.

The BHHEM documents presents values for transfer efficiency for different type of surfaces, the dislodgeable amount ranges from 1% to 60%. In the US residential SOP (2012) a large number of datasets were evaluated by the US EPA. From these datasets a screening level point estimate was derived, specifically for hard surface and carpets. This data is considered sufficiently valid and appropriate for this application. However, the values using a dislogeable amount of 20% for dried fluid on cotton, knitwear, plastic and wood as described in the BHHEM (based on a report from Fogh et al. 1999) are presented in line with other assessments in the risk characterisation section.

***Transfer coefficient***

The transfer coefficient for an infant (HEAdHoc Recommendation 12) is 0.2 m2/hour. For other children > 12 months the worst-case value of TC for infants is applicable.

***Post-application dermal and oral exposure***

Amount of transfluthrin emitted over 24 hours = 31.1 mg

Every day in the season (5 month) the vaporizer is used. It is assumed that the residues are removed from the floor once a week (as a result of walking, vacuuming etc). Due to accumulation the average amount on the floor during these 7 days is 4 times as high as the amount on the first day of use (RIVM, 2006a). The average amount of transfluthrin emitted during the week is:

31.1 mg x 4 = 124.4 mg.

Assuming 10% of this deposits onto the floor of the bedroom  
= (124.4mg x 10%)/6.4 m2

= 1.94 mg active/m2

Dislodgeable fraction is 8%, so:  
= 1.94 mg active/m2 x 8% = 0.1555 mg active/m2

The transfer coefficient is 0.20m2/hour (see above)

Dermal Exposure:

= (1 hr/day x 0.20 m2/hour x 0.1555 mg active/m2 x 10% dermal abs)/ 10 kg

= 3.1x 10-4 mg/kg/day

For toddlers, oral uptake is also possible through 'mouthing' of surfaces such as hands, which may contain residues of the active substance. To estimate oral exposure, it is assumed that oral exposure equates to 10% of the external dermal dose.

Oral Exposure:

= (1 hr/day x 0.20 m2/hour x 0.1555 mg/m2)x 10%/ 10 kg

= 3.1 x 10-4 mg/kg/day

***Post application inhalation-evaporation from surfaces***

Evaporation of transfluthrin from surfaces will be small due to its low vapour pressure of 9x10-4 Pa at 20°C (Transfluthrin Assessment Report, 2014). RIVM provides the following criteria for defining the volatility of pest control actives: “Volatile is defined as compounds with vapour pressure > 0.1 Pa, non-volatile < 0.01 Pa and slightly volatile between 0.01and 0.1 Pa” (RIVM, 2006a). This would put transfluthrin into the category of non-volatile and therefore post-application inhalation exposure is likely to be minimal.

In accordance with HEEG Opinion 13 (Assessment of Inhalation Exposure of Volatilised Biocide Active Substance), post-application inhalation exposure was calculated. The US EPA Residential SOPs (2012) provide equations for determining post-application inhalation exposure from the emission of pesticide vapours from a treated surface (see full reference below).

In order to calculate inhalation exposure to pesticide vapours following application, the saturable air concentration must first be determined as shown below:

Calculation:

Csat= (VP \* CF1 \* MW \* CF2 \* CF3) / (R\*T)

Where:

Csat = Saturation concentration (mg/m3);

VP = Vapour pressure (mm Hg);

MW = Molecular weight (g/mol);

R = Gas constant = 0.0821 L-atm/mol-K;

T = Temperature of the air (296 K);

CF1 = Conversion factor (atm/760 mm Hg);

CF2 = Conversion factor (103 mg/g); and

CF3 = Conversion factor (103 L/m3).

Vapour pressure and molecular weight were taken from the Transfluthrin Assessment Report (2014)

|  |  |  |
| --- | --- | --- |
| **Table 3.6.2.1. Saturable Air Concentration** | | |
| **Parameter** | **Definition** | **Value** |
| Vapor pressure | VP | 6.75 x 10-6 mmHg |
| Conversion factor | CF1 | 0.001315789 |
| Molecular weight | MW | 371.2 |
| Conversion factor | CF2 | 1000 |
| Conversion factor | CF3 | 1000 |
| Gas constant | R | 0.0821 |
| Temperature of the air | T | 296 |
| **Saturable concentration** | **Csat** | **0.136** |

The saturable air concentration can then be used to determine the evaporation time (EvapT) for transfluthrin using the calculation below. The results are reported in Table 3.6.2.2 below.

Calculation:

EvapT = 10[7.3698 – 0.9546 \* log10 (Csat)]

Where:

EvapT = Evaporation time (sec)

Csat = Saturation concentration (0.136 mg/m3, calculated previously)

|  |  |  |
| --- | --- | --- |
| **Table 3.6.2.2. Evaporation Time** | | |
| **Parameter** | **Definition** | **Value** |
| Saturable concentration | Csat | 0.136 |
| **Evaporation Time** | **EvapT** | **1.57 x 108** |

Evaporation time is then used to calculate the first order decay rate (k) as summarised in Table 3.6.2.3.

Calculation:

k = [(ln(10) \* CF1) / EvapT]

Where:

k = First order decay rate (1/hr)

CF1 = Conversion factor (sec/hr)

EvapT = Evaporation time (sec)

|  |  |  |
| --- | --- | --- |
| **Table 3.6.2.3. Decay Rate** | | |
| **Parameter** | **Definition** | **Value** |
| Conversion Factor | CF1 | 3600 |
| Evaporation Time | EvapT | 1.57 x 108 |
| **First order decay rate** | **K** | **5.27 x 10-5** |

The first order decay rate is an integral part of estimating post-application exposure as shown below and in Table 3.6.2.4.

The mass of active applied was calculated using information from the label:

300 mg of active is released over 10 days, when the unit is run continuously. Based on measurements 1.296 mg active/hour is released, which corresponds to 31.1 g/day.

Calculation:



Where:

E = Exposure (mg/day)

IR = Inhalation Rate (m3/hr)

M = Mass of a.i. applied, determined from product label (mg)

V = Volume of room (m3)

ACH = Air exchanges per hour (1/hr)

k = First order decay rate (1/hr)

ET = Exposure Time (hr)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Table 3.6.2.4. Post application inhalation exposure** | | | | |
| **Parameter** | **Definition** | **Doseinfant** | **Doseadult** |
| First order decay rate | K | 5.27 x 10-5 | 5.27 x 10-5 |
| Inhalation rate (m3/hr) | IR | 8/24=0.33 | 16/24=0.667 |
| Mass of a.i. applied (mg) | M | 31.1 | 31.1 |
| Volume of room (m3) | V | 16 | 16 |
| Air changes per hour | ACH | 1 | 1 |
| Exposure Time (hrs) | ET | 24 | 24 |
| Absorption factor | AF | 1 | 1 |
| Body weight (kg) | BW | 10 | 60 |
| **Dose (mg/kg/day)** | **D** | ***4.18 x 10-5*** | ***2.16 x 10-5*** |

Post-application dermal, oral and inhalation exposure for toddlers and adults is summarised in the table below.

| **Summary table: Post application exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake**  **(mg/kg/day)** | **Estimated dermal uptake**  **(mg/kg/day)** | **Estimated oral uptake**  **(mg/kg/day)** | **Estimated total uptake**  **(mg/kg/day)** |
| Scenario 2. Post application, toddler | 1 / No PPE | 4.18 x 10-5 | 3.1 x 10-4 | 3.1 x 10-4 | 6.64 x 10-4 |
| Scenario 2. Post application, adult. | 1 / No PPE | 2.16 x 10-5 | N/A | N/A | 2.16 x 10-5 |

Combined scenarios

| **Summary table: Combined systemic exposure from non-professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Scenarios combined** | **Estimated inhalation uptake**  **(mg/kg/day)** | **Estimated dermal uptake**  **(mg/kg/day)** | **Estimated oral uptake**  **(mg/kg/day)** | **Estimated total uptake**  **(mg/kg/day)** |
| Scenario 1+2, toddler | 0.00896 (direct) +  4.18 x 10-5  (indirect) | 3.1 x 10-4  (indirect) | 3.1x 10-4 (indirect) | 0.00962 |
| Scenario 1+2, adult | 0.00299 (direct) +  2.16 x 10-5  (indirect) | N/A | N/A | 0.00301 |

**Monitoring data**

Not applicable

**Dietary exposure**

Not applicable

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

Not applicable**Risk characterisation for human health**

**Reference values to be used in risk characterisation**

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

**AECacute, inhalation**

In a 13-week inhalation study, with an exposure duration of 6 h/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 AECacute, inhalation of 0.5 mg/m3 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.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEC/NOAEL** | **AF** | **Correction for absorption** | **AEC/AEL Value** |
| AECshort-term (inhalation) | 13-week rat | 46.7 mg/m3 | 100 | None | 0.5 mg/m3 |
| AELmedium/ long-term (systemic) | 2-year dietary rat | 1 mg/kg/day | 100 | None | 0.01 mg/kg/day |

As ADI and ARfD the following values were set:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL** | **AF** | **Reference Value** |
| ARfD | Dev. Study rappit | 15 mg/kg/bw | 100 | 0.15 mg/kg/day |
| ADI | 2-year dietary rat | 1 mg/kg/day | 100 | 0.01 mg/kg/day |

**Maximum residue limits or equivalent**

Not applicable

**Risk for industrial users**

Not applicable

**Risk for professional users**

Not applicable

**Risk for non-professional users**

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

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **NOAEC**  mg/m3 | **AEC**  mg/m3 | **Estimated air concentration**  mg/m3 | **Estimated air concentration/ AEC**  **(%)** | **Acceptable**  **(yes/no)** |
| Inhalation exposure- Air concentration | 1 | 47.7 | 0.5 | 0.0112 | 2.2 | Yes |

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg/day** | **AEL**  **mg/kg/day** | **Estimated uptake**  **mg/kg/day** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| 1- Application, Toddler | 1 | 1 | 0.01 | 0.0621 | 621 | No |
| 1- Application, Adult | 1 | 1 | 0.01 | 0.0207 | 207 | No |
| Scenario 1. Application, Toddler | 2a | 1 | 0.01 | 0.00277 | 27.7 | Yes |
| Scenario 1. Application, adult | 2a | 1 | 0.01 | 0.000923 | 9.2 | Yes |
| Scenario 1. Application, Toddler | 2b | 1 | 0.01 | 0.00896 | 89.6 | Yes |
| Scenario 1. Application, adult | 2b | 1 | 0.01 | 0.00299 | 29.9 | Yes |

Tier1 is based on Consexpo constant rate

Tier 2a is based on Vesin 2013a, b

Tier 2b is based on xxxx, 2016

**Combined scenarios**

See the next section on the risk for the general public

**Risk for the general public**

**Systemic effects**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **Systemic NOAEL**  **mg/kg/day** | **AEL**  **mg/kg/day** | **Estimated uptake**  **mg/kg/day** | **Estimated uptake/ AEL**  **(%)** | **Acceptable**  **(yes/no)** |
| Scenario 2. Post application, toddler | 1 | 1 | 0.01 | 0.00062 | 6.2% | Yes |
| Scenario 2. Post application, adult. | 1 | 1 | 0.01 | 2.16 x 10-5 | <1% | Yes |

**Combined scenarios**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Scenarios combined** | **Tier** | **Systemic NOAEL**  **mg/kg/d** | **AEL**  **mg/kg/d** | **Estimated uptake**  **mg/kg/d** | **Estimated uptake/ AEL (%)** | **Acceptable**  **(yes/no)** |
| Scenarios 1+2, toddler | 1 | 1 | 0.01 | 0.00962 | 96.2 | Yes |
| Scenarios 1+2, adult | 1 | 1 | 0.01 | 0.00301 | 30.1 | Yes |

**Considerations on dislogeable fraction**

A dislodgeable amount of 8% is used in the risk assessment. The choice for the US EPA Residential SOP is explained in the PAR on p79. However, below combined exposure for toddlers using a dislogeable amount of 20% (dry hand) and 30 % (wet hand) for dried fluid on cotton, knitwear, plastic and wood as described in the BHHEM is presented (see for calculation 3.2 output tales).

**Scenarios 1+2, toddler**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Tier** | **Systemic NOAEL**  **mg/kg/d** | **AEL**  **mg/kg/d** | **Estimated uptake**  **mg/kg/d** | **Estimated uptake/ AEL (%)** | **Acceptable**  **(yes/no)** |
| 20% / 24 h | 1 | 1 | 0.01 | 0.0106 | 106 | Yes (see below) |
| 30% / 24h | 1 | 1 | 0.01 | 0.0113 | 113 | Yes (see below) |
| 20% / 18 h | 1 | 1 | 0.01 | 0.0083 | 83 | Yes |
| 30% / 18h | 1 | 1 | 0.01 | 0.0091 | 91 | Yes |

Exposure primarily results from the direct contact to transfluthrin via air when the device is turned on (i.e. 89.6% of the AEL for a 24 h exposure). The AEL is slightly exceeded taken into account a dislodgeable amount of 20% or 30% to determine the total exposure during a period of 24h. It was conservatively assumed that a toddler spent 24 hours in a small bedroom inhaling the vapour, without leaving the room. As being in the same room for more than 18h for a toddler is considered an exceptional case, calculations were refined using 18h and resulted in values below the AEL. Furthermore, the calculations are also conservative as decrease in a.s. content over time due to reaction, degradation or ventilation is not taken into account and accumulation over time on sequential days is included (as described in Pest Control Fact sheet).

Thus, even when considering a higher dislodgeable value, no risk is expected.

**Additional Misuse Scenario**

At the request of the eCA, the risk was also evaluated if the consumer misused Night&Day Trio by running the device at the highest rate in a small bedroom, against the use directions. A calculation was conducted to demonstrate that exposure was still acceptable even if the product was misused by the consumer. Air concentration was estimated for the above scenario.

Product emission rate and room size for exposure calculation:

The target emission rate for Night&Day Trio on the highest setting is 1.875 mg/hour (worst case compared to measured data of 1.827 mg/m3) for the active (see sections 2.2.5.1 and 2.2.5.8). Therefore in 24 hours, 45mg of active would be released. Therefore, it was conservatively assumed that the high rate (1.875 mg active/hour) was used in a small bedroom of 16m3, with a ventilation rate of 1h-1. Air concentration was modelled using the ConsExpo Vapour model (constant rate):

Product: Raid Trio Misuse scenario

Compound

Compound name : Transfluthrin

CAS number :

molecular weight 371 g/mol

vapour pressure 0.0009 Pascal

KOW linear

General Exposure Data

exposure frequency 1/year

body weight kilogram

Inhalation model: Exposure to vapour : constant rate

weight fraction compound 1 fraction

exposure duration 24 hour

room volume 16 m3

ventilation rate 1 1/hr

applied amount 45 milligram

release duration 24 hour

Uptake model: Fraction

Output

Inhalation (point estimates)

inhalation mean event concentration : 0.112 mg/m3

The mean event air concentration was 0.112 mg/m3, when the ConsExpo vapour model was used. Experimental data indicate that for sandcore technology such as Raid Night & Day, the ConsExpo vapour model (Constant rate) will overestimate air concentration by 7.2-fold (see section 3.8.2). Therefore, the actual air concentration would be:

0.112 mg/m3 / 7.2 = 0.0156 mg/m3

Air concentration was expressed as a percentage of the acute inhalation AEC for transfluthrin (0.5 mg/m3):

(0.0156 mg/m3 ÷ 0.5 mg/m3) x 100 = 3.12%

For systemic exposure via inhalation:

Toddler: 0.0156 mg/m3 x 8m3/day x 1/10 kg = 0.0124 mg/kg/day

Adult: 0.0156 mg/m3 x 16 m3/day x 1/60 kg = 0.0042 mg/kg/day

For the toddler the AEL is exceeded: 0.0124 / 0.01 = 124%

Conclusion:

The calculations above demonstrate that if Night&Day Trio is misused by the consumer and run on the highest setting in a small room, the exposure estimate is still acceptable and well below the acute AEC for Transfluthrin.

Based on the calculation above adverse effects due to systemic exposure for the toddler cannot be excluded. It should be noted, however, that in the risk assessment an exposure time of 24h is taken into account, which is a very conservative approach. Furthermore, the exposure due to post-application needs to be added. As the amount emitted per square meter is worst case for the small room, the estimated risk for post-application of 8.2% as calculated above can be used. The total risk is than estimated to be 124 + 6.2 = 130.2% when staying in the room for 24h including post-application via dermal exposure. When a recalculation is made with the exposure time, a toddler should stay more than 18 hours in the treated room in order to reach the AEL.

It is considered that being in the same room for more than 18h for a toddler is an exceptional case. Furthermore, in the calculations worst case assumptions are made, e.g. accumulation on the floor in the post-application exposure without degradation or ventilation.To minimise the change of misuse of using the device in a wrong setting, the instruction for use must be clearly indicate that Night&Day Trio must be used in the correct setting. A RMM is therefore included in section 2.1.4.2: ‘Please take care that the device is used in the correct setting depending on the size of the room based on potential risks for human health’.

Based on above considerations, adverse health effects for the toddler due to transfluthrin exposure as a result of the use of Night&Day Trio are not expected.

**Local effects**

Transfluthrin contributes to the classification of the product as a skin irritant, under Regulation (EU) No 1272/2008 CLP. In accordance with CLP, the product will carry the appropriate P phrases as set out in the regulation to protect the consumer. In addition, there will be no direct dermal contact with the active under normal conditions of use (see description of product assembly in scenario 1).

With regard to secondary exposure skin irritation is not to be expected in the amount that are deposited over time, so no local risk assessment is performed.

**Conclusion**

Based on the risk assessments above, adverse effects are not anticipated following consumer use of Night & Day™ and Night & Day™ Trio. All routes of exposure combined resulted in exposure estimates below the relevant AEL for different age groups. Even in a worst-case situation of misuse (highest setting in a small room), adverse effect from the use of Night&Day and Night&Day Trio are not expected.

**Risk for consumers via residues in food**

Night & Day™ and Night & Day™ Trio may be used in places, in which potentially exposure to food could occur. To prevent possible exposure to food the following RMM are included:

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

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

Not applicable

**2.2.7 Risk assessment for animal health**

A quantitative risk assessment for Night & Day™ and Night & Day™ Trio for pets is not considered necessary as the assessment performed for humans will cover companion animals too. However, particular cats may be sensitive to pyrethroids, therefore the following RMMs is included:

* Contains transfluthrin (pyrethroids), may be lethal to cats. Prevent cats from coming into contact with the treated area.

### Risk assessment for the environment

#### Effects assessment on the environment

***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 – Amended List of Endpoints (BPC-24, 2018) |
| *Fathead minnow (pimephales promelas)* | Transfluthrin | Chronic | NOEC | 0.399 µg/L | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| *Oncorhynchus mykiss* | TFB-COOH[[3]](#footnote-3) | Acute | LC50 | >100 mg/L | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| *Invertebrates* | | | | | |
| *Daphnia magna* | Transfluthrin | Acute | EC50 | 1.2 µg/L | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| *Daphnia magna* | Transfluthrin | Chronic | NOEC | 17.5 ng/L | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| *Daphnia magna* | TFB-COOH | Acute | EC50 | >100 mg/L | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| *Algae (growth inhibition)* | | | | | |
| *Scenedesmus subspicatus* | Transfluthrin | Acute | ErC50 | >100 µg/L | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| Chronic | NOErC | 50 μg/L |
| *Pseudokirchneriella subcapitata* | TFB-COOH | Acute | 96h ErC50 | >100 mg/L | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| Chronic | NOErC | 3.056 mg/L |
| *Sediment organisms* | | | | | |
| *Chironomus riparius* | Transfluthrin | Chronic emergence rate | NOEC | 0.164 mg/kg dw sed | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| *Lumbriculus* | Transfluthrin | Chronic | NOEC | 2.21 mg/kg dw sed | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| *Mircoorganisms* | | | | | |
| Respiration activated sludge | Transfluthrin | Acute | NOEC | 57 μg/L (water solubility) | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| EC50 | >10000 mg/L |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 (trans-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 21 day 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  Regarding metabolites, an additional study was provided (and agreed at WGIII-2018 and by the BPC at meeting no. 24 (2018); please refer to the studies in the fate section below), which demonstrated formation of the metabolite 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH). In addition, formation of the metabolite trans-DCVA was also expected. Hence, for soil, TFB-COOH and trans-DCVA are considered as the environmentally relevant metabolites. In the case of the metabolite 2,3,5,6-Tetrafluorobenzoic acid (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 2,3,5,6-Tetrafluorobenzyl alcohol (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 (trans-DCVA; also named permethric acid). Considering the incomplete data set QSAR (Epiwin) calculations based on baseline toxicity were performed resulting in an 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. It should be noted that the baseline QSAR might not be representative for this type of molecule, but it is accepted for now. Accordingly, a PNECaquatic of 0.0064 mg/L was determined for trans-DCVA, by applying an assessment factor of 1000. | | | |
|  | | | | | |
|  |  | |  |  |  |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment - Aquatic Sediment Toxicity** | |
| Value/conclusion | PNECsediment for Transfluthrin: PNEC for sediment organisms: 1.64 μg/kg dw sed (equivalent to 0.36 µg/kg ww 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 ecotoxicity 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 the in the chironomus study the test organisms were fed with fresh food, thus theoretically limiting the exposure to the test substance. Therefore, according to the conclusion in the Environment Working Group Meeting IV 2017 (ECHA, 2017a) the PNEC sediment value is 1.64E-03 mg/kg dw.  It should be noted that this PNEC value does not take account of differences organic carbon content between test conditions and those assumed in the EU Vol IV part B&C (v.2.0; 2017) for PEC calculation.  In the case of the metabolites 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH) and 2,3,5,6-Tetrafluorobenzyl alcohol (TFB-OH) and permethric acid (DCVA), the risk assessment for sediment is covered by that for water, as defined in the Transfluthrin Assessment Report (2014). |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table for terrestrial toxicity data** | | | | | | |
| Species | Substance | Timescale | End point | Results | Endpoint (normalised to organic matter at 3.4%) | Reference |
| Earthworms | Transfluthrin | Acute | LC50 | 184 mg/kg dw soil (10% OM) | 62.6 mg/kg dw soil | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| Earthworms | Transfluthrin | Chronic | NOEC | 10 mg/kg dw soil (10% OM) | 3.4 mg/kg dw soil | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| *Collembola (folsomia candida)* | Transfluthrin | Reproduction | NOEC | 18 mg/kg dw soil (5% OM) | 12.24 mg/kg dw soil | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| Nitrogen mineralisation | Transfluthrin | Chronic | NOEC | 5.24 mg/kg dw soil (3.4% OM) | 5.24 mg/kg dw soil | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| Non-target plants | Transfluthrin | Seedling | EC50 | 210.4 mg/kg dw soil |  | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| NOEC | 50 mg/kg dw soil |  |

1All effect concentrations from terrestrial plants and terrestrial organisms should be converted to the standard organic matter content, according to infobox 9 of the Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C (version 2, 2017)

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Terrestrial Toxicity Data** | |
| Value/conclusion | PNECsoil for Transfluthrin: 0.10mg/kg dw soil (equivalent to 0.088 mg/kg ww soil)  PNECsoil for 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH): 0.012 mg/kg ww soil  PNECsoil for trans-DCVA and : 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 effect), on collembolan (reproduction study) and micro-organisms (Nitrogen effects), as well as a non-target plant study.  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); please refer to the studies in the fate section below), which demonstrated formation of the metabolite 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH). In addition, formation of the metabolite trans-DCVA was 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 (xxxx, 2018).  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 (EPIwin derived values) (parameters estimated using EPIsuite; please refer to Annex 3.2). |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **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 (2014), 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 and metabolites***

The following PNEC values have been derived from data on the active substance and metabolites and also from studies performed on the active substance which were completed subsequent to the issue of the Transfluthrin Assessment Report (2014), as documented in th Amended List of Endpoints (BPC-24, 2018). In addition, for the DCVA metabolites, QSAR data was used by eCA (please refer to Annex 3.7 for EPIWIN results). During the product authorisation process of products with transfluthrin additional data have been submitted as refinement. These data have been evaluated and agreed upon at different WG meetings in the period of 2016 to 2018 and at the BPC meeting no. 24 (2018), resulting in harmonised PNEC values for the aquatic and terrestrial environment.

|  |  |  |
| --- | --- | --- |
| **Summary table for PNECs used in Risk Assessment** | | |
| **Parameters** | **Concentration** | **Notes** |
| Transfluthrin | | |
| PNECSTP | 57 µg/l | As specified in Transfluthrin Assessment Report (2014) |
| PNECwater | 1.75 ng/L | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| PNECsediment | 1.64 µg/kg dw sediment 0.36µg/kg ww sediment | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| PNECsoil | 0.1 mg/kg dw soil  0.088 mg/kg ww soil | Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018) |
| PNECoral, mammals | 6.67 mg/kg feed | As specified in Transfluthrin Assessment Report (2014) |
| Metabolites | | |
| 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 | Transfluthrin Assessment Report – Amended List of Endpoints, BPC-24, 2018 |
| trans-DCVA  cis-CH2OH-trans-DCVA | | |
| PNECwater | 0.0064 mg/L | Based on QSAR data. Please refer to section 3.8 for details |
| PNECsoil | 0.0128mg/kg ww soil |

As it is not clear if or to what extent the metabolite TFB-COOH is formed in the STP (please refer to the study on biodegradation in sewage sludge in the fate section and section 2.2.8.2 on the metabolites below) and in view of the chemical structure similarity with TFB-OH and the comparable physico-chemical characteristics (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 3.2) 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.

***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 product composition 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.

Taking account of the concentration of Transfluthrin in the biocidal product, the minimum environmental classification of the product can be calculated as follows:

Acute Environmental Classification of Product:

Acute 1 x M ≥25% = Acute 1

(13.4% x 1000) = 13400 including sandcore carrier

Chronic Environmental Classification of Product:

Chronic 1 x M ≥ 25% + chronic 1

(13.4% x 1000) = 13400 including sandcore carrier

Therefore, the environmental classification according to CLP-Regulation (EC) No 1272/2008 is Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410)*.*

As the use of Transfluthrin will be indoors only for small scale, localised use as a domestic insecticide (amateur, ready-to-use household product), no significant direct exposure of outdoor environmental compartments will occur.

It is considered that the ecotoxicological information on the active substance, Transfluthrin (presented in detail in the active substance dossier Doc. IIIA, section 7, with the addition of the BPC-24, 2018 results)), and the data provided on the components of the product are sufficient to assess any potential risk to the environment from use of the product. A study using the formulated product is therefore not considered necessary or an appropriate use of animals.

***Further Ecotoxicological studies***

No data are available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | - |
| Justification | All information on the ecotoxicology of the product can be extrapolated from the information on the active substance and co-formulants. Ecotoxicity data for the active substance are summarised in the section above. No additional testing with the product is therefore considered necessary |

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

No data are available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | - |
| Justification | This is not a core data requirement.  The biocidal product is not anticipated to have any effect on non-target organisms (flora and fauna), as the application is indoors only.  Information concerning the potential for the product to cause adverse effects on non-target organisms (flora and fauna) can be extrapolated from information on the active substance (Document IIIA7.5.1.3). |

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

No data are available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | - |
| Justification | The product is 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***

No data are available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | - |
| Justification | The product is 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)***

No data are available.

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | - |
| Justification | The biocidal product is 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 product is designed to be used in indoor domestic situations to provide control of flying insects, including mosquitoes. To achieve this, the liquid in the product is heated to vapourise the active substance (transfluthrin). Condensation can theoretically lead to deposition of a fraction of emitted active substance onto indoor floor surfaces. The Emission Scenario Document (PT18) for insecticides, acaricides and products to control other arthropods for household and professional uses (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. For substances emitted to wastewater, depending upon fate characteristics, subsequent exposure can occur to air, STP, water and sediment or soil and groundwater via application of sewage sludge to agricultural land.

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
|  | Yes[[4]](#footnote-4)+ | Yes+ | Yes+ | Yes+ | Yes[[5]](#footnote-5)++ | Not relevant[[6]](#footnote-6)(+) | Yes+ | Yes+ | Not relevant |

+ Compartment secondarily exposed (surface water from STP discharge, agricultural soil from sludge application, groundwater further to soil exposure)

++ Compartment primarily exposed (soil, STP)

(+) Compartment potentially exposed

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

**STP**

For this product, a new OECD 314B study (xxxx, 2017) was submitted by the applicant. eCA NL evaluated this study and asked for commenting from other member states via e-consultation. After the comments were received by eCA, the evaluation was finalised by a dedicated ad hoc expert group. This results in a new agreed endpoint for the degradation rate of transfluthrin, as well as the identification of major metabolites that are formed in the STP, including their endpoints. These endpoints include degradation rates (in STP), formation fractions, max observed %’s and data on ultimate degradation to CO2. Parallel to this product dossier, this data will be included in the AR and LoEP for transfluthrin. At the time of writing (August 2019), it is expected that the OECD 314B endpoints will be noted by the BPC of December 2019.

The study investigated the rate of degradation of transfluthrin in an activated sludge system at room temperature (mean temperature 21.7°C). The results of this study were evaluated according to FOCUS Kinetics (xxxx, 2018)6, with two kinetic models (SFO and FOMC) fitted to the data using the CAKE software to determine the best fit model. As SFO did not result in a visually nor statistically acceptable fit, FOMC was selected as the appropriate kinetic model, resulting in an acceptable fit of the data. However, since SimpleTreat cannot directly simulate biphasic degradation, it is necessary to derive a pseudo-SFO DT50 from the FOMC fit for use in the model. Provided at least 90% of the test item is degraded during the study period, FOCUS recommends that this pseudo-SFO DT50 should be derived by dividing the FOMC DT90 value by 3.32. This value can be used to calculate a refined estimate of fate of transfluthrin in a wastewater treatment plant.

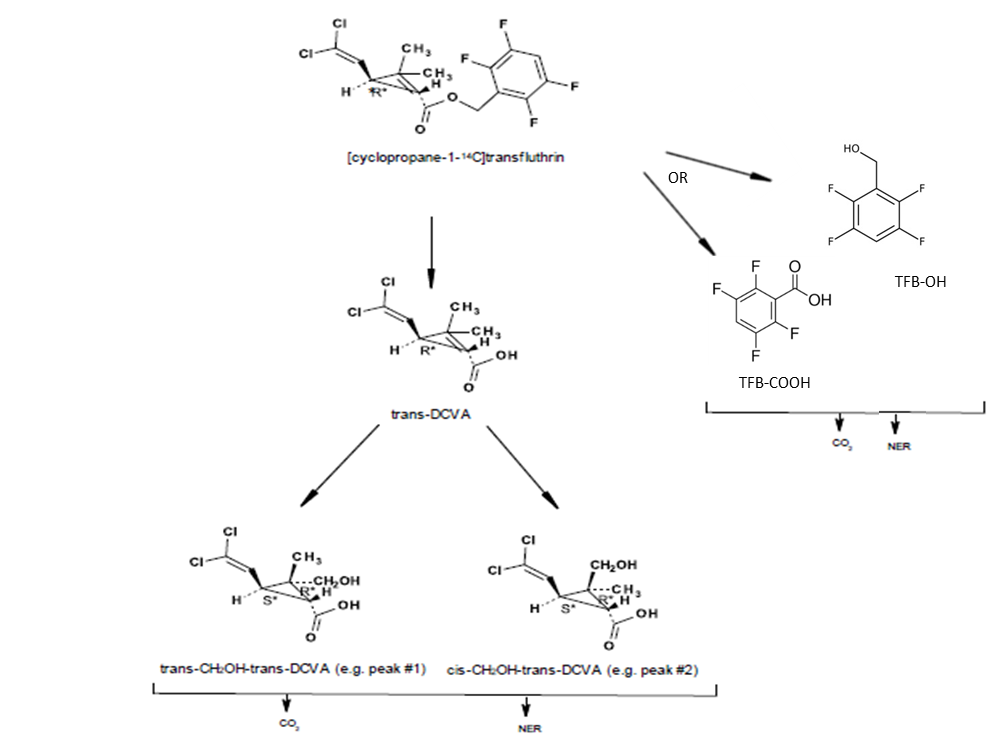
The study results are as follows:

Pathway:

The study describes a pathway that includes transfluthrin > trans-DCVA > trans-OH-DCVA & cis-OH-DCVA (degradation of the phenyl moiety). The benzene moiety was unlabeled and was therefore not included in the analysis.

However, the degradation of this moiety most likely results in TFB-COOH (2,3,5,6-tetrafluorobenzoic acid; NAK 4723) and/or TFB-OH (2,3,5,6-tetrafluorobenzyl alcohol; NAK 4452 (info available in CAR).

When all information is put together, the following pathway can be drawn:



The study was discussed at WGIII 2018 and DT50 (12oC) values of 174.4 days and 3.66 days for trans-DCVA and TFB-COOH were agreed, respectively.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment** | |
| Cleaning efficiency for transfluthrin:) | Bespoke experiments were conducted to investigate the potential emission of active substance from a range of representative flooring surfaces following standardised wet cleaning methods. Full details of these studies can be found in the Confidential Annex. These will be addressed qualitatively in the risk assessment. |

**Aquatic Compartment**

In natural water/sediment systems, the dissipation of Transfluthrin from the water phase was dominated by sorption, the DT50,water was < 7 days. The average DT50,system was 11.1 days, the DT50,sediment 14.1 days at 20°C (xxxx, 2018).

Metabolites 2,3,5,6-tetrafluorobenzyl alcohol (TFB-OH) and 2,3,5,6-tetrafluorobenzoic acid (TFB-COOH) were detected in amounts > 10 % of AR in the water phase with maximum levels being 38 and 59% of AR, respectively. The same metabolites were found in sediment, maximum level was 2.9% of AR for TFB-OH and 26% of AR for TFB- COOH (xxxx, 2018).

The DT50,system of metabolite TFB-OH was estimated to be < 14 days. A reliable estimate of the DT50, system of metabolite TFB-COOH could not be obtained. Analytical results obtained in the water/sediment system indicate that metabolite TFB-COOH has a low degradation rate and is persistent in a water/sediment system.

**Soil Compartment**

In an aerobic soil biodegradation study, fast degradation of [methylene-14C] Transfluthrin was observed resulting in DT50 between 0.8 to 1.0 days in four soils tested. Mineralization (CO2) accounted for up to 78.3% of AR at 14 days after treatment. Only one major degradation product 2,3,5,6-tetrafluorobenzoic acid (TFB-COOH) was identified and accounted for up to 36.5% of AR (WG IV final minutes, 2017). The DT50 for TFB-COOH was calculated to be 3.23 d (12oC).

Due to the low water solubility and high log Pow of Transfluthrin, the sorption to soil could not be determined in a batch equilibrium experiment. As specified in the Transfluthrin Assessment Report (2014), a log Koc of 4.7 (Koc = 50119 L/kg) obtained at pH 6 using the HPLC-method according to OECD 121, is used in the environmental risk assessment.

|  |  |
| --- | --- |
| **Summary table on further studies on fate and behaviour in the environment** | |
| Refinement A | See Confidential Annex 3.6.3 Risk assessment for the environment – Confidential Fate & Effects assessment |
| Refinement B | See Confidential Annex 3.6.3 Risk assessment for the environment – Confidential Fate & Effects assessment |

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment** | |
| Value/conclusion | See Confidential Annex 3.6.3 Risk assessment for the environment – Confidential Fate & Effects assessment |
| Justification for the value/conclusion | See Confidential Annex 3.6.3 Risk assessment for the environment – Confidential Fate & Effects assessment |

***Leaching behaviour (ADS)***

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | - |
| Justification | A leaching test is not required for this type of product. |

***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 product 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 product will not be sprayed. Not relevant.

#### Exposure assessment

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 18 |
| Assessed scenarios | Consumer use of insecticide diffuser product |
| 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.  Revised Emission Scenario Document for Product Type 14  Rodenticides, ECHA, August 2018 (*groundwater only*)  TAB version 2.1 Release date: 17 December 2019 agreement ENV 148 Diffusers in indoor treatment |
| Approach | Consumption-based approach, taking account of product-specific dose rate |
| 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 |
| Groundwater simulation | Tier 1 (pore water AHEE guidance Exposure assessment of metabolites in the terrestrial compartment Aug. 2019) and Tier 2 (FOCUS PEARL 4.4.4.) |
| Confidential Annexes | YES: In the confidential Annex 1 to Part B the business confidential information concerning refinement of the environmental assessment are provided. |
| Life cycle steps assessed | Production: No  Formulation: No  Use: Yes  Service life: No |
| Remarks | The product is sold in a ready to use form; therefore the mixing/loading step identified in the Emission Scenario Document (OECD, 2008) is not relevant for this product. There is no differentiation between use and service life, so separate assessments are not required for these steps. |

***Emission estimation***

**Scenario 1** is made in line with ENV 148 using the following approach:

Because efficacy data is not available the default number of diffusers in a house used is 2. This value was deduced by assuming one diffuser per bedroom and two bedrooms per house. However this value should be used regardless of the place in the house where the treatment takes place. Resulting emission scenario: two diffusers in a house of 130 m² are considered; in this house 30% of the surface area (i.e. 38.5 m²) are wet cleaned (Fwet cleaned = 0.3).

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario:Consumer use of insecticide diffuser product | | | |
| Quantity of active substance contained in the device/diffuser (QAI ) | 0.3 | g | S |
| Number of diffusers | 2 | - | D |
| Maximal duration of use of the device/diffuser (Tmax) | 160 | h | S – This is a worst-case value, reflecting the maximum duration of use associated with Raid Night & Day™ Trio on ‘High’ setting. The ‘medium’ setting gives 240 hours, (which is the same as Raid Night & Day™). The ‘Low’ setting gives 320 hours – Product Label, Section 2.1.4.2 |
| Duration of use per day (Tday) | 24 | h.d-1 | S – Product Label, Section 2.1.4.2 |
| Number of emission days (Temission) | 152 | d | S – Reflecting seasonality of use, as specified in Transfluthrin Assessment Report (2014)[[7]](#footnote-7) |

Calculations for Scenario 1

*Emission to air*

The Emission Scenario Document (OECD, 2008) states that during the application, 90% of the insecticide applied may remain airborne. The emission to air from is calculated as follows:

** PT18 ESD, eq.31

Where:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Variable/Parameter** | **Symbol** | **Unit** | **Value** | **S/D/O/P** |
| Input | | | | |
| Quantity of active substance contained in the device/diffuser | QAI | g | 0.3 | S |
| Number of difusers | *Ndif* | - | 2 | ENV148 | |
| Maximal duration of use of the device/diffuser | Tmax | h | 160 | S – This is a worst-case value, reflecting the maximum duration of use associated with Raid Night & Day™ Trio on ‘High’ setting. The ‘medium’ setting gives 240 hours, (which is the same as Raid Night & Day™). The ‘Low’ setting gives 320 hours – Product Label, Section 2.1.4.2 |
| Duration of use per day (Electric) | Tday | h.d-1 | 24 | S – Product Label, Section 2.1.4.2 |
| Fraction emitted to air during application | Fapplication, air | - | 0.9 | D |
|  | | | | |
| Emission to air during the use of the device/diffuser | Eapplication,air | Kg.d-1 | 8.1E-05 | O |

*Emission to Floor*

The Emission Scenario Document (OECD, 2008) notes that a fraction of insecticides deposited on the floor in indoor situations may be removed as a result of cleaning. The quantity of active substance deposited on the floor is calculated as follows:

PT18 ESD, eq.32 modified

Where:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Variable/Parameter*** | ***Symbol*** | ***Unit*** | ***Value*** | ***S/D/O/P*** |
| Input | | | | |
| Quantity of active substance contained in the device/diffuser | *QAI* | g | 0.3 | S |
| Number of difusers | *Ndif* | - | 2 | ENV148 |
| Maximal duration of use of the device/diffuser | *Tmax* | h | 160 | S – This is a worst-case value, reflecting the maximum duration of use associated with Raid Night & Day™ Trio on ‘High’ setting. The ‘medium’ setting gives 240 hours, (which is the same as Raid Night & Day™). The ‘Low’ setting gives 320 hours – Product Label, Section 2.1.4.2 |
| Duration of use per day (electric) | *Tday* | h.d-1 | 24 | S – Product Label, Section 2.1.4.2 |
| 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 | 9E-06 | O |

\*: Inline with TAB version 2.1 agreement ENV148:

*Emission to Solid Waste*

The Emission Scenario Document (OECD, 2008) notes that a fraction of insecticides deposited on the floor in indoor situations may theoretically be removed as a result of cleaning. Where cleaning is carried out using dry methods, this could result in a potential emission to solid waste.

The potential emission to solid waste depends upon the fraction of the insecticide that may be exposed to dry cleaning. It is assumed that 100% of the active ingredient is emitted from the diffuser during the lifecycle of the product. It is assumed that the entire portion of deposited insecticide exposed to cleaning is removed (cleaning efficiency = 100%). Thus, the emission from floor/treated surface is calculated as follows:

ESD, eq.34 (modified)

Where:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Variable/Parameter*** | ***Symbol*** | ***Unit*** | ***Value*** | ***S/D/O/P*** |
| *Input* | | | | |
| Emission to floor during the application step | Eapplication,floor | kg.d-1 | 2.7E-06 | O (Default) |
| Fraction of the treated surface that is cleaned | Fcleaned | - | 0.3 | D |
| Fraction emitted to solid waste during the cleaning step | Fw | - | 1 | D |
| Cleaning Efficacy | Fce | - | 1 | P |
| *Output* | | | | |
| Emission from floor/treated to solid waste during the cleaning step | Etreated,w | kg.d-1 | 2.7E-06 | O (Default) |

*Emission to Wastewater*

The Emission Scenario Document (PT18) for insecticides, acaricides and products to control other arthropods for household and professional uses 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

Thus, the emission from floor/treated surface is calculated as follows:

ESD, eq.36 (modified)

Where:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Variable/Parameter*** | ***Symbol*** | ***Unit*** | ***Value*** | ***S/D/O/P*** |
| *Input* | | | | |
| Emission to floor during the application step | Eapplication,floor | kg.d-1 | 2.7E-06 | O (Default - diffusers) |
| Fraction emitted to wastewater during the cleaning step | Fww | - | 1 | D |
| Cleaning efficacy | Fce | - | 1 | P (Default) |
| *Output* | | | | |
| Emission from floor/treated to wastewater during the cleaning step | Etreated,ww | kg.d-1 | 2.7E-06 | O (Default) |

A refined assessment has also been conducted, taking account of measured data concerning the potential for emission of residues from representative flooring surfaces following cleaning (see confidential Annex 3.6) Following review of the data at WG IV 2017 and CG discussions it was agreed that the results of these measured data will be handled qualitatively as refinement in the risk assessment.

The calculated emission rates to wastewater, expressed in kg.d-1, can be used further in exposure assessment as input values for the environmental risk assessment. The OECD Emission Scenario Document (ESD) for insecticides, acaricides and products to control other arthropods for household and professional uses 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). In-line with Working Group agreements,he default figure of 0.0552 was applied for passive diffuser products.

The resulting estimates of emission to wastewater at the catchment scale are summarised in the following table.

*Elocalstp = Etreated,ww \* 4000 \* 0.0552*

| **Resulting local emission to relevant environmental compartments** | | |
| --- | --- | --- |
| **Compartment** | **Local emission (Elocalcompartment) [kg/d]** | **Remarks** |
| STP | 5.96E-04 | Default (Daily Fsimultaneity and Fce applied) |
| Solid waste | 5.96E-04 | Default |

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

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment | STP | Air | Soil | Ground-water | Other |
| Scenario 1 | Yes[[8]](#footnote-8)+ | Yes+ | Yes[[9]](#footnote-9)++ | Not relevant[[10]](#footnote-10)(+) | Yes+ | Yes+ | Not relevant |

| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| --- | --- | --- | --- |
| **Input** | **Value** | **Unit** | **Remarks** |
| *Transfluthrin* | | | |
| Molecular weight | 371.2 | g/mol | Transfluthrin Assessment Report (NL, 2014) |
| Melting point | 32 | °C | Transfluthrin Assessment Report (NL, 2014) |
| Vapour pressure (at 20 °C) | 9.00E-04 | Pa | Transfluthrin Assessment Report (NL, 2014) |
| Water solubility (at 20 °C) | 0.057 | mg/l | Transfluthrin Assessment Report (NL, 2014) |
| Log Octanol/water partition coefficient | 5.94 | Log 10 | Transfluthrin Assessment Report (NL, 2014) |
| Organic carbon/water partition coefficient (Koc) | 50119 | l/kg | Transfluthrin Assessment Report (NL, 2014) |
| Biodegradability | Not readily biodegradable |  | Transfluthrin Assessment Report (NL, 2014) |
| 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 surface water | 1E+06 | d (at 12ºC) | Default value in EUSES 2.1.2 |
| DT50 for hydrolysis in surface water | 1E+06 | d (at 12ºC) | Default value in EUSES 2.1.2 |
| DT50 for photolysis in surface water | 1E+06 | d | Default value in EUSES 2.1.2 |
| DT50 for degradation in soil | 5.17 | d (at 12ºC) | Transfluthrin Assessment Report – Amended List of Endpoints, BPC-24, 2018 |
| DT50 for degradation in air | n.a. | d or hr |  |
| Bioconcentration factor (BCF) (fish) | 1783 | L/kg | Average of measured values (1704 and 1861 L/kg ww) |
| Bioconcentration factor (BCF) (earthworms) | 10452 | L/kg | Estimated BCF (Transfluthrin Assessment Report, 2014) |

Fate and distribution within the STP was estimated using the SimpleTreat 4.0. In accordance with Minutes of Meetings of the Environmental Working Group of the Biocidal Products Committee (WG-I-2017), the model was also run with a modified parameterisation, assuming values for BOD (Mass of O2-binding material in sewage per day) and SLR (sludge loading rate) as specified in SimpleTreat 4.0, in combination with the value for concentration of suspended solids in effluent as implemented in the 3.1 version.

|  |  |
| --- | --- |
| **Calculated fate and distribution in the STP -Transfluthrin** | |
| Compartment | Percentage [%] |
| Simpletreat 4.0[[11]](#footnote-11) including OECD 314B |
| Air | 0.19 |
| Water | 1.31 |
| Sludge | 59.94 |
| Degraded in STP | 38.56 |
| Total | 100.0 |

**Metabolites**

An OECD 314B study on biodegradation in activated sludge of the active substance Transfluthrin was conducted (xxxx, 2017)[[12]](#footnote-12).

In the study, three metabolites were found, with maximum occurrences of 64.0% (trans-DCVA); 5.8% (trans-CH2OH-trans-DCVA) and 60.4% AR (cis-CH2OH-trans-DCVA). Trans-CH2OH-trans-DCVA is a minor metabolite and is therefore not further included in the RA. The formation fractions have been derived using Cake. See the table below for the relevant parameters for PEC calculations.

The water 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. It is assumed that either of these metabolites are formed after STP degradation of transfluthrin.

For the calculation of the metabolite PECs, it is assumed that the entire fraction of transfluthrin that is degraded in the STP results in the formation of the above mentioned metabolites. Since no information is available on the distribution between water, sediment and sludge, it is assumed that all mass goes to both water (effluent STP) and surplus sludge. No sediment PECs are presented, because both PECs and PNECs are based on equilibrium partitioning, which would result in similar PEC/PNEC ratios for the water and sediment compartment.

This is a worst-case first tier approach. As a second tier, the distribution of the metabolites could be estimated with QSAR, of which the results should then be used to calculate a more realistic distribution of the metabolites between water and sludge.

The above mentioned method results in the following procedure: the PECparent is divided by the effluent fraction (see [distribution](#Distribution)) and multiplied by the degraded fraction (see distribution), and then multiplied with the molar weight ratio and formation fraction, to acquire the PECmetabolite.

Based on the transfluthrin STP parameters (Koc, Henry coefficient, DT50 of 0.5d from OECD 314B (at 15ºC)), the percentage of degradation is 38.56% (see distribution). As mentioned above, based on the degraded fraction of transfluthrin, the primary metabolite PECs are calculated using the concentration of the parent in sludge. This also requires correction for the mol weight ratio of metabolite/parent and the formation fraction.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | | **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 |  |
| Transfluthrin | 371.2 | | - | - | 4.40E-01 |  |
| trans-DCVA | 208.1 | | 0.56 | 0.9678 | 2.39E-01 | f.f. from transfluthrin |
| TFB-COOH | 194.08 | | 0.52 | 1 | 2.30E-01 | 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.

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 section 3.7 for the QSAR estimates.

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

***Calculated PEC values***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values (Active Substance)** | | | | | | |
|  |  | PECSTP | PECwater | PECsed | PECsoil | PECGW (pore water) |
| [mg/L] | [mg/l] | [mg/kgwwt] | [mg/kg wwt] | [μg/l] |
| SimpleTreat 4.0 with 3.1 settings (refined using OECD 314B) | Default Fce=1 | 3.92E-06 | 3.64E-07 | 3.97E-04 | 6.44E-03 | 0.0073 |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values (Metabolites)** | | | | | |  |
| (SimpleTreat 4.0 refined using OECD 314B) | Scenario | PECSTP | PECwater | PECsed | PECsoil | PECGW (pore water) |
| [mg/L] | [mg/l] | [mg/kgwwt] | [mg/kg wwt] | [μg/l] |
| Metabolite trans-DCVA | Default | n.a. | 6.24E-06 | n.r. a | 4.29E-04 | **0.201** |
| Metabolite TFB COOH | Default | 5.58E-06 | 3.38E-04 | **0.189** |

a Not reported because both PEC and PNEC should be calculated with equilibrium partitioning from the water compartment, which would result in the same PEC/PNEC ratio.

***Primary and secondary poisoning***

Primary poisoning

This product is designed for use indoors. The use of the product will not result in primary poisoning of birds and mammals.

Secondary poisoning

The concentration of a contaminant in food (fish) of fish-eating predators (PECoralpredator) is derived from the PEC for surface water, the measured BCF for fish and the biomagnification factor (BMF). Since the log Kow of transfluthrin is 5.4 and a measured BCF for fish of 1783 L/Kg the BMF of 1 is used in the calculation (as reported in Guidance on BPR Vol IV Part B+C (2017), Table 23 “Default BMF values for organic substances”). For the assessment of PECbiota, the PECwater is reduced to 50% according to the Guidance on BPR Vol IV Part B+C (2017) where 50% of the diet comes from a local area and 50% of the diet comes from a regional area is considered. The same 50% approach was used for the PECsoil and PECgw values.

The calculation of PECoralpredator is presented below.

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on estimated theoretical exposition (ETE)** | | | |
|  |  | **PECoral, predator (freshwater)** | **PECoral, predator a (terrestrial)** |
| [mg/wwt] | [mg/kgwwt] |
| Simple Treat 4.0 with 3.1 settings (refined using OECD 314B) | Default | 6.49E-04 | 6.92E-02 |

a Is similar to Cearthworm

Estimates of secondary poisoning *via* the food chain were calculated using EUSES 2.1.2.

#### 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). However, due to its short atmospheric life time, it is not listed as causing ozone depletion. Moreover, 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.

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

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values (Active Substance)** | | |
| **Scenario** | **Refinement** | **PEC/PNECSTP** |
| SimpleTreat 4.0 (refined using OECD 314B) | Default | <0.001 |

Conclusion: The calculated PEC/PNEC values for the sewage treatment plant (STP) are significantly < 1 regardless of refinement.Therefore the proposed use of the product Night & Day™ Trio does not pose a risk to microorganisms in the STP.

For the metabolites, no PEC/PNEC is calculated for the STP compartment, since those metabolites are formed from parent degradation *inside* the STP.

***Aquatic compartment***

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values (Active Substance)** | | | |
| **Scenario** | **Refinement** | **PEC/ PNECwater** | **PEC/ PNECsed** |
| Simple Treat 4.0 with 3.1 settings (refined using OECD 314B) | Default | 0.208 | **1.10** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on calculated PEC/PNEC values (Metabolites)** | | | |
| **Scenario** | **Refinement** | **PEC/ PNECwater** | **PEC / PNECsed** |
| Metabolite trans-DCVA | Default | 0.001 | n.r. a |
| Metabolite TFB COOH | Default | <0.001 |

a PEC/PNECsed are identical to the PEC/PNECwater because both PEC and PNEC sediment is based on equilibrium partitioning

For the cumulative risk assessment the PEC:PNEC ratios of all evaluated substances are added to a single PEC/PNEC value for this compartment.

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values (Metabolites)** | | |
| **Scenario** | **Refinement** | **PEC/PNECsed** |
| All substances combined | Default | **1.10** |

Conclusion: The worst case default assessment for active substance results in PEC/PNEC values > 1 for the sediment compartment using version 4.0 of SimpleTreat modified as per the Minutes of Meetings of the Environmental Working Group of the Biocidal Products Committee (WG-I-2017), including the OECD 314B study results.

Refinement of the fraction emitted to wastewater due to cleaning was discussed at CG August 2020. There it was concluded that data does not support the proposed high reduction of cleaning efficiency (FCE), but justifies a Fce of at least 0.9 reducing PEC/PNEC values to <1 also for sediment.

For the metabolites trans-DCVA and TFB-COOH, all PEC/PNEC values are <1, regardless of refinements.

As a result, taking account of the fate data that is available (refinement concerning potential for removal by cleaning, as well as an OECD 314B study on fate withing wastewater treatment plants), it can be concluded that use of the product will not result in unacceptable risk to the aquatic compartment.

Exposure of the marine environment is not considered to be a direct route of exposure for the proposed use of this product. No data are provided for marine organisms, so the PNEC would be derived from the PNEC of freshwater, applying an AF of 10. On the other hand, the dilution factor for the marine environment is a factor 10 higher. Consequently, the PEC:PNEC ratios of the marine compartment will be equal to those of the freshwater compartment. An unacceptable risk to the marine environment could be expected.

***Terrestrial compartment***

|  |  |  |
| --- | --- | --- |
| **Summary table calculated PEC/PNEC values (Active Substance)** | | |
|  |  | **PEC/PNECsoil** |
| Simple Treat 4.0 (refined using OECD 314B) | Default | 0.057 |

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values (Metabolites)** | | |
| **Scenario** | **Refinement** | **PEC/PNECsoil** |
| Metabolite trans-DCVA | Default | 0.033 |
| Metabolite TFB COOH | Default | 0.028 |

For the cumulative risk assessment the PEC:PNEC ratios of all evaluated substances are added to a single PEC/PNEC value for this compartment.

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values (Metabolites)** | | |
| **Scenario** | **Refinement** | **PEC/PNECsoil** |
| All substances combined | Default | 0.118 |

Conclusion: In all cases, PEC/PNEC values are < 1 for the active substance and relevant soil metabolites. As a result, it can be concluded that use of the product will not result in unacceptable risk to the terrestrial compartment.

***Groundwater***

The following section is only relevant for member states that use sewer sludge on agricultural soil. eCA NL does not, but nevertheless provides this assessment for fellow member states that do.

No specific limit value is established for transfluthrin under Directive 98/83/EC, and therefore, in accordance with the Transfluthrin Assessment Report (NL, 2014), it has been assumed that the general limit of 0.1 μg/L for organic pesticides applies. In all cases, for the product under consideration predicted concentrations in groundwater are below this threshold (i.e. < 0.1 μg/L) for the active substance. For all the metabolites, the first tier groundwater assessment results in PECs (PECporewater) >0.1 µg/L.

Therefore, a higher tier groundwater assessment was performed, using FOCUS PEARL 4.4.4. All two metabolites are included in the Tier 2 calculations. The procedure for exposure of soil via STP sludge as described in ESD PT 14 (2018) was applied. Please refer to section 4.4.2 of that ESD for the application and crop parameters.

The application rate (expressed in kg/ha) was derived from the Csludge (mg/kg dw), which is equal to the PECsoil\_initial.

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Input parameters for calculating the fate and distribution of metabolites in groundwater Tier 2** | | | | | | | | | |
|  | **Molecular weight** | **vapour pressure1** | **solubility1** | **Koc** | **Kom** | **1/n** | **DT502** | **Molar activation energy** | **Crop uptake** |
|  | g/mol | Pa | mg/L | L/kg | L/kg | - | days | kJ/mol | - |
| trans-DCVA | 208.1 | 2.6 | 127.6 | 106 | 61.48 | 1.0 | 300 | 65.4 | 0.0 |
| TFB-COOH | 194.08 | 8.45 | 2114 | 10.71 | 6.21 | 1.0 | 300 | 65.4 | 0.0 |

1 at 25 °C

2 at 12 °C

The results of Tier 1, the application rates for Tier 2 and the Tier 2 groundwater results are shown in the table below.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table on calculated PECgw values (Metabolites)** | | | | | | |
| (SimpleTreat 4.0 refined using OECD 314B) | | PECGW (pore water, Tier1) | Application rate agricultural soil | Application rate grass | PECGW agricultural soil (PEARL)\* | PECGW grass (PEARL)\* |
| [μg/l] | [kg/ha] | [kg/ha] | [μg/l] | [μg/l] |
| Metabolite trans-DCVA | Default | **0.201** | 1.19E-03 | 2.38E-04 | 0.0462 | 0.0078 |
| Metabolite TFB COOH | Default | **0.189** | 1.15E-03 | 2.23E-04 | <0.001 | <0.001 |

\* The highest value from all scenarios is reported. The other values can be found in the Annex 3.8.

For all the metabolites, the second tier groundwater assessment (PEARL) results in PECs (PECporewater) below 0.1 µg/L. For the parent transfluthrin, no risk was identified in the 1st tier. Concludingly, no groundwater risk is expected.***Primary and secondary poisoning***

Primary poisoning

Not relevant for this product

Secondary poisoning

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table calculated PECoral predator and PEC/PNEC values (Active Substance)** | | | | | |
| **Scenario** |  | **Concentration** | **PECoral predator** **(mg/kg wwt)** | **PEC/PNECmammals** | **PEC/PNECbird** |
| Simple Treat 4.0 (refined using OECD 314B) | Default | Fish | 6.49E-04 | <0.001 | <0.001 |
| Worms | 6.92E-02 | <0.001 | <0.001 |

Conclusion: Using the concentration in fish and worms and the PNECoral,mammal of 6.67 mg/kgwwt feed, the PEC/PNECoral,mammal is < 1 and a risk is not expected.

***Mixture toxicity***

*Screening step*

Screening Step 1: Identification of the concerned environmental compartments

Not relevant. Other than the active substance, the product contains no substances of concern for the environment.

Screening Step 2: Identification of relevant substances

Not relevant. Other than the active substance, the product contains no substances of concern for the environment.

Screening Step 3: Screen on synergistic interactions

There are no known synergists or components declared as synergists present in the product.

|  |  |
| --- | --- |
| **Screening step** | |
|  | Significant exposure of environmental compartments? None expected |
|  | Number of relevant substances >1? None |
|  | Indication for synergistic effects for the product or its constituents in the literature? None |

|  |
| --- |
| **Overall conclusion on the risk assessment for the environment of the product** |
| The environmental risk assessment for the products ‘Night & Day™ ’ and ‘Night & Day™ Trio’ 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). Both products are the same with the exception that ‘Night & Day™ Trio’ has an adjustable setting. The duration of use was taken as 160 hours, reflecting the maximum duration of use associated with ‘Night & Day™ Trio’ on ‘High’ setting. This is a worst-case value, which means that the risk assessment also covers use of Night & Day™ Trio on ‘medium’ (240 hours) and ‘low’ (320 hours) settings. The assessment also covers use of Night & Day™ (240 hours). The duration of use per day was taken as 24 hours.  Two different estimates of emission to wastewater were calculated: One assuming ESD default values; and one taking account of a refinement that better reflects the actual exposure potential associated with the use of the product. This refinement took account of measured data concerning the potential for emission of residues from representative flooring surfaces following cleaning, with a figure of 10% being applied for Cleaning Efficacy (Fce).  Calculations were performed taking account of the results of an OECD 314B study on biodegradation in activated sludge of the active substance Transfluthrin.  Using conservative estimates of partitioning in STP (SimpleTreat 4.0 with 3.1 settings in-line with WG agreements), the default calculations indicated a potential risk for the water and sediment compartments when results from cleaning efficiency studies are not taken into account.  Application of refinement based on increased understanding of potential for removal by cleaning reduces the PEC/PNEC values in water for both parent and metabolites to acceptable levels. This is a product specific decision and should not create a precedent for other cases.  All PEC/PNEC values for the terrestrial environment were <1, both for the parent transfluthrin and all relevant metabolites, demonstrating that unacceptable risk would not be expected for this compartment.  Predicted concentrations in groundwater were below < 0.1 μg/L for the active substance and all metabolites. For the metabolites, a 2nd tier exposure assessment (PEARL) was required.  An assessment of secondary poisoning potential also demonstrated that no unacceptable risk via the food chain would be expected.  Therefore, it is concluded that the use of the products ‘Night & Day™’ and ‘Night & Day™ Trio’ in accordance with label instructions will not result in unacceptable risk to the environment. |

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

See section 2.1.5.2

### Assessment of a combination of biocidal products

Not relevant.

### Comparative assessment

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

# Annexes[[13]](#footnote-13)

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

| **Author** | **Year** | **Title** | **Testing laboratory** | **Report no.** | **Legal entity owner** | **Legal entity study no.** | **Report date** | **GLP** | **Published/ Unpublished** | **Data Protection** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| xxxx | 2010 | Accelerated and Long-Term Storage Stability Study on Porous Sandcore Plug Material | xxxx | CEMR-3149 | S. C. Johnson and Son, Inc | 559 | 2010-11-10 | Yes | Unpublished | Yes |
| xxxx | 2008a | Determining Efficacy of 240/720 Hour Refill Against Mosquitoes (Culex quinquefasciatus) in the Laboratory~ | xxxx | GLP Number: 559E1 | S. C. Johnson and Son, Inc. | WORK REQUEST NUMBERS: 213465 | 2008-04-02 | Yes | Unpublished | Yes |
| xxxx | 2010 | Determination of the Evaporation Kinetics of Obewan | xxxx | Mo4015 | S.C. Johnson & Son, Inc. R, D & E Insect Control 1525 Howe Street Racine WI 53403, USA |  | 2010-10-26 | Yes | Unpublished | Yes |
| xxxx | 2007 | Determine knockdown efficacy of the 30 Night (240 hour) Obewan Delivery System vs the European Electric Mat against mosquitoes (Culex quinquefasciatus) in the laboratory. | xxxx | WORK REQUEST NUMBERS: 213102 | S. C. Johnson and Son, Inc. | WORK REQUEST NUMBERS: 213102 | 2007-01-11 | Yes | Unpublished | Yes |
| xxxx | 2010a | Efficacy of Raid Night & Day™ with different release rates for various volumes of rooms against Malaria mosquitoes Anopheles gambiae. | xxxx | BIO074/10 | S. C. Johnson and Son, Inc. | Mo4001 | 2010-09-08 | Yes | Unpublished | Yes |
| xxxx | 2010 | Determination of the Evaporation Kinetics of Obewan | xxxx | Mo4016 | S.C. Johnson & Son, Inc. R, D & E Insect Control 1525 Howe Street Racine WI 53403, USA |  | 2010-10-26 | Yes | Unpublished | Yes |
| xxxx | 2008 | Determining knockdown efficacy of the Obewan delivery system against mosquitoes (Aedes albopictus) in the laboratory. | xxxx | 213480 | S. C. Johnson and Son, Inc. | WORK REQUEST NUMBERS: 213480 | 2006-07-31 | Yes | Unpublished | Yes |
| xxxx | 2008e | Determining efficacy of 240/720 hour refill delivery system against houseflies (Musca domestica) in the laboratory. | xxxx | GLP Number: 559E5 | S. C. Johnson and Son, Inc. | WORK REQUEST NUMBERS: 213465 | 2008-04-02 | Yes | Unpublished | Yes |
| xxxx | 2006c | Determining knockdown efficacy of the Obewan delivery system against houseflies in the laboratory. | xxxx | WORK REQUEST NUMBERS: 213263 | S. C. Johnson and Son, Inc. | WORK REQUEST NUMBERS: 213263 | 2006-07-31 | Yes | Unpublished | Yes |
| xxxx | 2008d | Determining efficacy of 240/720 hour refill against mosquitoes (Aedes albopictus) in the laboratory. | xxxx | GLP Number: 559E4 | S. C. Johnson and Son, Inc. | WORK REQUEST NUMBERS: 213465 | 2008-04-02 | Yes | Unpublished | Yes |
| xxxx | 2010e | Efficacy of Raid Night & Day™ with different release rates for various volumes of rooms against Black ants Lasius niger | xxxx | BIO080/10 | S. C. Johnson and Son, Inc. | Mo4001a | 2010-09-21 | Yes | Unpublished | Yes |
| xxxx | 2006 | Validation of Analytical Method ARTMW-211855 for Transfluthrin in Porous Sandcore Plug Material | xxxx | CEMR-3148 | SC Johnson and Son, Inc | 559 | 2006-10-19 | Yes | Unpublished | Yes |
| xxxx | 2008c | Determining efficacy of 240/720 hour refill against mosquitoes (Anopheles stephensi) in the laboratory. | xxxx | GLP Number: 559E3 | S. C. Johnson and Son, Inc. | WORK REQUEST NUMBERS: 213465 | 2008-04-02 | Yes | Unpublished | Yes |
| xxxx | 2010b | Efficacy of Raid Night & Day™ with different release rates for various volumes of rooms against Yellow fever mosquitoes Aedes aegypti | xxxx | BIO067a/10 | S. C. Johnson and Son, Inc. | Mo4001 | 2010-08-29 | Yes | Unpublished | Yes |
| xxxx | 2010d | Efficacy of Raid Night & Day™ with different release rates for various volumes of rooms against House flies Musca domestica | xxxx | BIO068a/10 | S. C. Johnson and Son, Inc. | Mo4001 | 2010-08-29 | Yes | Unpublished | Yes |
| xxxx | 2007 | Evaporation Rate Study on Porous Sandcore Plug Material | xxxx | CEMR-3150 | S. C. Johnson and Son, Inc | 559 | 2007-03-12 | Yes | Unpublished | Yes |
| xxxx | 2010b | Efficacy of Raid Night & Day™ with different release rates for various volumes of rooms against Asian tiger mosquitoes Aedes albopictus. | xxxx | BIO075/10 | S. C. Johnson and Son, Inc. | Mo4001 | 2010-09-08 | Yes | Unpublished | Yes |
| xxxx | 2010 | Accelerated and Long-Term Storage Stability Study on Porous Sandcore Plug Material | xxxx | CEMR-3149 | S. C. Johnson & Son Inc. | 559 | 2010-11-01 | Yes | Unpublished | Yes |
| xxxx | 2008b | Determining efficacy of 240/720 hour refill against mosquitoes (Aedes aegypti) in the laboratory. | xxxx | GLP Number: 559E2 | S. C. Johnson and Son, Inc. | WORK REQUEST NUMBERS: 213465 | 2008-04-02 | Yes | Unpublished | Yes |
| xxxx | 2006a | Determining knockdown efficacy of the Obewan delivery system against mosquitoes in the laboratory. | xxxx | WORK REQUEST NUMBERS: 212403 | S. C. Johnson and Son, Inc. | WORK REQUEST NUMBERS: 212403 | 2006-02-28 | Yes | Unpublished | Yes |
| xxxx | 2010a | Efficacy of Raid Night & Day™ against black ants in 20 m3 test rooms. | xxxx | BI0040b/10 | S. C. Johnson and Son, Inc. | Mo3959a | 2007-05-19 | Yes | Unpublished | Yes |
| xxxx | 2010c | Efficacy of Raid Night & Day™ with different release rates for various volumes of rooms against House mosquitoes Culex quinquefasciatus | xxxx | BIO069a/10 | S. C. Johnson and Son, Inc. | Mo4001 | 2010-08-29 | Yes | Unpublished | Yes |

## Output tables from exposure assessment tools

Air concentration and toddler exposure were calculated using the Vapour model (Constant rate) in ConsExpo Web:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Substance** |  |  |  |  |
| Name | Transfluthrin | |  |  |
| CASNumber |  |  |  |  |
| Molecular weight | 371 | g/mol |  |  |
| KOW |  |  |  |  |
| **Product** |  |  |  |  |
| Name | Raid Night & Day- Toddler 24 h exposure | | | |
| Weight fraction substance |  |  |  |  |
| Population |  |  |  |  |
| Name |  |  |  |  |
| Body weight | 10 | kg |  |  |
| Scenario Toddler Inhalation exposure |  | |  |  |
| Frequency | 1 | per day |  |  |
| Description |  |  |  |  |
| Inhalation |  |  |  |  |
| **Exposure model** | **Exposure to vapour - Constant rate** | | | | |
| Exposure duration | 24 | hour |  |  |
| Product in pure form | Yes |  |  |  |
| Product amount | 31.1 | mg |  |  |
| Weight fraction substance | 1 |  |  |  |
| Room volume | 16 | m³ |  |  |
| Ventilation rate | 1 | per hour |  |  |
| Inhalation rate | 8 | m³/day |  |  |
| Emission duration | 24 | hour |  |  |
| Limit concentration to saturated air concentration | Yes |  |  |  |
| Application temperature | 20 | °C |  |  |
| Vapour pressure | 0.0009 | Pa |  |  |
| Molecular weight | 371 | g/mol |  |  |
| Absorption model | Fixed fraction | |  |  |
| Absorption fraction | 1 |  |  |  |
| Dermal |  |  |  |  |
| Exposure model | n.a. |  |  |  |
| Absorption model | n.a. |  |  |  |
| Oral |  |  |  |  |
| Exposure model | n.a. |  |  |  |
| Absorption model | n.a. |  |  |  |
| Results for scenario | Toddler Inhalation exposure | | | |
| Inhalation |  |  |  |  |
| Mean event concentration | 0.0776 | mg/m³ |  |  |
| Peak concentration (TWA 15 min) | 0.081 | mg/m³ |  |  |
| Mean concentration on day of exposure | 0.0776 | mg/m³ |  |  |
| Year average concentration | 0.0776 | mg/m³ |  |  |
| External event dose | 0.0621 | mg/kg bw |  |  |
| External dose on day of exposure | 0.0621 | mg/kg bw |  |  |
| Internal event dose | 0.0621 | mg/kg bw |  |  |
|  |  |  | |  |
|  |  |  | |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  | |  |
|  |  |  | |  |

Please refer to theConfidential Annex 3.6

Calculation combined exposure toddlers, using different disloadgebeal fractions and exposure



## New information on the active substance

Since the approval of Transfluthrin in 2014 the following studies have been

conducted:-

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

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

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

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

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

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

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

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

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

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

## Residue behaviour

Not applicable.

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

Please refer to IUCLID Section 6.7

## QSAR estimates and PNEC calculation 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

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

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)

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)

## PEARL output (env RA)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| SUBSTANCE | DCVA | TFBCO | LOCATION | APPLICATION\_SCHEME |
| DCVA | 0.03191 |  | CHATEAUDUN | agr\_DCVA |
| DCVA | 0.04262 |  | HAMBURG | agr\_DCVA |
| DCVA | 0.03823 |  | KREMSMUENSTER | agr\_DCVA |
| DCVA | 0.04103 |  | OKEHAMPTON | agr\_DCVA |
| DCVA | 0.02647 |  | PIACENZA | agr\_DCVA |
| DCVA | 0.01397 |  | PORTO | agr\_DCVA |
| DCVA | 0.00379 |  | SEVILLA | agr\_DCVA |
| DCVA | 0.02196 |  | THIVA | agr\_DCVA |
| TFBCO |  | 0.00000 | CHATEAUDUN | agr\_TFBCOOH |
| TFBCO |  | 0.00001 | HAMBURG | agr\_TFBCOOH |
| TFBCO |  | 0.00012 | KREMSMUENSTER | agr\_TFBCOOH |
| TFBCO |  | 0.00026 | OKEHAMPTON | agr\_TFBCOOH |
| TFBCO |  | 0.00001 | PIACENZA | agr\_TFBCOOH |
| TFBCO |  | 0.00004 | PORTO | agr\_TFBCOOH |
| TFBCO |  | 0.00000 | SEVILLA | agr\_TFBCOOH |
| TFBCO |  | 0.00000 | THIVA | agr\_TFBCOOH |
| DCVA | 0.00640 |  | CHATEAUDUN | grass\_DCVA |
| DCVA | 0.00727 |  | HAMBURG | grass\_DCVA |
| DCVA | 0.00780 |  | JOKIOINEN | grass\_DCVA |
| DCVA | 0.00594 |  | KREMSMUENSTER | grass\_DCVA |
| DCVA | 0.00704 |  | OKEHAMPTON | grass\_DCVA |
| DCVA | 0.00543 |  | PIACENZA | grass\_DCVA |
| DCVA | 0.00344 |  | PORTO | grass\_DCVA |
| DCVA | 0.00263 |  | SEVILLA | grass\_DCVA |
| DCVA | 0.00318 |  | THIVA | grass\_DCVA |
| TFBCO |  | 0.00000 | CHATEAUDUN | grass\_TFBCOOH |
| TFBCO |  | 0.00000 | HAMBURG | grass\_TFBCOOH |
| TFBCO |  | 0.00000 | JOKIOINEN | grass\_TFBCOOH |
| TFBCO |  | 0.00000 | KREMSMUENSTER | grass\_TFBCOOH |
| TFBCO |  | 0.00002 | OKEHAMPTON | grass\_TFBCOOH |
| TFBCO |  | 0.00001 | PIACENZA | grass\_TFBCOOH |
| TFBCO |  | 0.00000 | PORTO | grass\_TFBCOOH |
| TFBCO |  | 0.00000 | SEVILLA | grass\_TFBCOOH |
| TFBCO |  | 0.00000 | THIVA | grass\_TFBCOOH |

## Confidential annex

Please see separate document for details.

### 

## References

xxxx (2018) Relevant endpoints and PNEC derivation Environment & Ecotoxicity: Transfluthrin CAS No.: 118712-89-3. Unpublished xxxx

CTGB (2015). website (<http://www.ctgb.nl/en/biocidal-products/assessment-framework-biocidal-products/substances-of-concern>), accessed 7th September 2015.

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

ECHA (2008) Guidance on information requirements and chemical safety assessment. Chapter R.10: Characterisation of dose [concentration]-response for environment. May, 2008.

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 (2013). Guidance for Human Health Risk Assessment, Vol.III, Part B, December 2013, v.1, Annex 6, page 315.

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

ECHA (2015) Guidance on the Biocidal Products Regulation. Volume IV Environment - Part B Risk Assessment (active substances). Version 1.0, April 2015

ECHA (2017a) Minutes of Meetings of the Environmental Working Group of the Biocidal Products Committee WG-IV-2017

ECHA (2017b) Minutes of Meetings of the Environmental Working Group of the Biocidal Products Committee WG-I-2017

ECHA Registered Substances Toluene, Toxicological information.001 (http://apps.echa.europa.eu/registered/data/dossiers/DISS-9c7b2ab2-20d7-6aaa-e044-00144f67d249/AGGR-b0c6dbbc-80d9-41c8-9d22-ab9cae3cac89\_DISS-9c7b2ab2-20d7-6aaa-e044-00144f67d249.html#AGGR-b0c6dbbc-80d9-41c8-9d22-ab9cae3cac89), accessed 8th September 2015.

xxxx (2018) Partitioning of Transfluthrin in Sewage Treatment Plants: Derivation of endpoints for use in regulatory environmental risk assessments. Unpublished report xxxx

HEAdhoc recommendation 12 (2016). Default values for indoor Transfer Coefficient

HEAdhoc recommendation 14 (2017). Default human factor values for use in exposure assessments for biocidal products.

HEEG (Human Exposure Expert Group) opinion (2011). Assessment of Inhalation Exposure of Volatilised Biocide Active Substance. Endorsed at TM IV 2011 and amended after TM III 2013 to take into account changed default human factor values.

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

OECD (1998): Report of the OECD Workshop on Statistical Analysis of Aquatic Toxicity Data. Series on Testing and Assessment, No 10. OECD Environment Directorate, Paris

OECD (2004) OECD Guidelines for  the testing of chemicals No. 218: Sediment-water Chironomid Toxicity Test using spiked sediment 218. 13 April 2004

OECD, (2008) 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.

RIVM (2006a). RIVM Pest Control Product Fact Sheets. RIVM Report 320005002/2006.

RIVM (2006b). RIVM General Fact Sheet. RIVM Report 3220104002/2006. Table 16.

xxxx (2016) Determination of Air Concentration. Unpublished report xxxx

Transfluthrin Assessment Report (2014). PT18 Assessment Report. Transfluthrin (insecticides, acaricides and products to control other arthropods). 13th March 2014. RMS: The Netherlands.

U.S. Environmental Protection Agency (EPA). (2011) Exposure Factors Handbook: 2011 Edition. National Center for Environmental Assessment, Washington, DC; EPA/600/R-09/052F. Available from the National Technical Information Service, Springfield, VA, and online at http://www.epa.gov/ncea/efh. See table 6-4 on page 6-24.

U.S. Environmental Protection Agency (1997) Standard Operating Procedures (SOPs) for residential exposure assessments. Contract No. 68-W6-0030, Work Assignment No. 3385. 102.

U.S. Environmental Protection Agency (2012) Standard Operating Procedures for Residential Pesticide Exposure Assessment. October 2012. Section 7.2.2.1 Post-Application Dermal Exposure Algorithm (hard surfaces and carpets), page 7-32.

http://www.epa.gov/pesticides/science/residential-exposure-sop.html

Vesin A, Glorennec P, Le Bot B, Wortham H, Bonvallot N, Quivet E. (2013a) Transfluthrin indoor air concentration and inhalation exposure during application of electric vaporizers. Environ Int. 2013 Oct;60:1-6. doi: 10.1016/j.envint.2013.07.011. Epub 2013 Aug 23.

Vesin, A; Quivet, E; Temime-Roussel, B; Wortham, H. (2013b) Indoor transfluthrin concentration levels during and after the application of electric vaporizers using a Proton-Transfer-Reaction Mass Spectrometer. Atmospheric Environment, 2013, Volume 65, p. 123-128.

1. Please fill in here the identifying product name from R4BP. [↑](#footnote-ref-1)
2. SUBSTANCE EVALUATION REPORT Toluene, eMS Finland, 12 november 2013

   https://echa.europa.eu/documents/10162/03167071-aa36-4bc3-9a08-00475f9a16d1 [↑](#footnote-ref-2)
3. 2,3,5,6-Tetrafluorobenzyl acid (TFB-COOH) [↑](#footnote-ref-3)
4. + Compartment secondarily exposed (surface water from STP discharge, agricultural soil from sludge application, groundwater further to soil exposure) [↑](#footnote-ref-4)
5. ++ Compartment primarily exposed (STP) [↑](#footnote-ref-5)
6. (+)Compartment potentially exposed [↑](#footnote-ref-6)
7. Temission required for calculation of secondary poisoning *via* the food chain in EUSES 2.1.2 [↑](#footnote-ref-7)
8. + Compartment secondarily exposed (surface water from STP discharge, agricultural soil from sludge application, groundwater further to soil exposure) [↑](#footnote-ref-8)
9. ++ Compartment primarily exposed (soil, STP) [↑](#footnote-ref-9)
10. (+)Compartment potentially exposed [↑](#footnote-ref-10)
11. Model parameterisation modified as per Minutes of the meeting of Environmental WG-I-2017 [↑](#footnote-ref-11)
12. This study has been submitted directly to Ctgb for evaluation by the Active Substance Supplier [↑](#footnote-ref-12)
13. When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included. [↑](#footnote-ref-13)