Application type	refMS/ eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
NA-APP	*NL*	BC-TH020224-49	04.12.2020	Initial assessment	
NA-MIC	*NL*	BC-TH070738-20	04.02.2022	*Removal of text in PAR 2.1.5.2 and section 5.2 of the SPC*	See addendum '20220204_NL-0016419-0000_Addendum'

Changes/additions to the original evaluation are highlighted in yellow.

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

Date: January 2022

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1 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.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier[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 NYXTA & MEPA	Cyprus	
BAYGON NIGHT & DAY	Cyprus	
BAYGON NYXTA & MEPA	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,	France	INVENTORY NUMBER: 26322 / INRS AR N°120174

1 Please fill in here the identifying product name from R4BP.

Identifier[1]	Country (if relevant)	Registration Number
Mouches et Fourmis (Diffuseur+Recharge / Recharge)		
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 NYXTA & MEPA	Greece	
BAYGON NIGHT & DAY	Greece	
BAYGON NYXTA & MEPA	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

Identifier[1]	Country (if relevant)	Registration Number
Raid® Night & Day™ aparat împotriva ţânţarilor, muştelor şi furnicilor		
RAID® NIGHT & DAY™ REZERVA	Romania	Current registration number 1708BIO/18/12.24
Raid® Night & Day™ rezervă pentru aparat împotriva ţânţarilor, muştelor şi furnicilor		
RAID® NIGHT & DAY™ TRIO REZERVA	Romania	Current registration number 2346BIO/18/12.24
Raid® Night & Day™ Trio aparat împotriva ţânţarilor comuni, ţânţarilor tigru, muştelor şi furnicilor		
Raid® Night & Day™ 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

2.1.1.2 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		

2.1.1.3 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

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

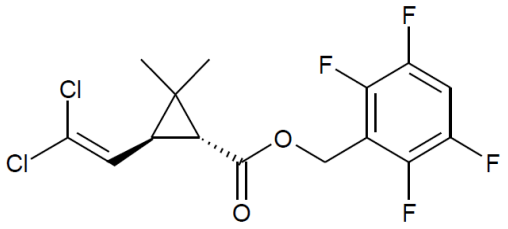
Active substance	Transfluthrin
Name of manufacturer	Bayer SAS
Address of manufacturer	16 rue Jean-Marie Leclair CS 90106 69266 Lyon (Cedex 09) France
Location of manufacturing sites	Bayer Vapi Private Limited Plot No. 306/3, 2nd phase GIDC, Vapi 396 195, Gujarat India

2.1.2 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 ☒

2.1.2.1 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.*

2.1.2.2 Candidate(s) for substitution

Transfluthrin is not a candidate for substitution.

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

Not applicable.

2.1.2.4 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.

2.1.2.5 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.

2.1.2.6 Information on the substance(s) of concern

No substances of concern are present.

2.1.2.7 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.

2.1.2.8 Type of formulation

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

2.1.3 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		
	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).

2.1.4 Authorised use(s)

2.1.4.1 Use description

Use # 1 – One heating setting

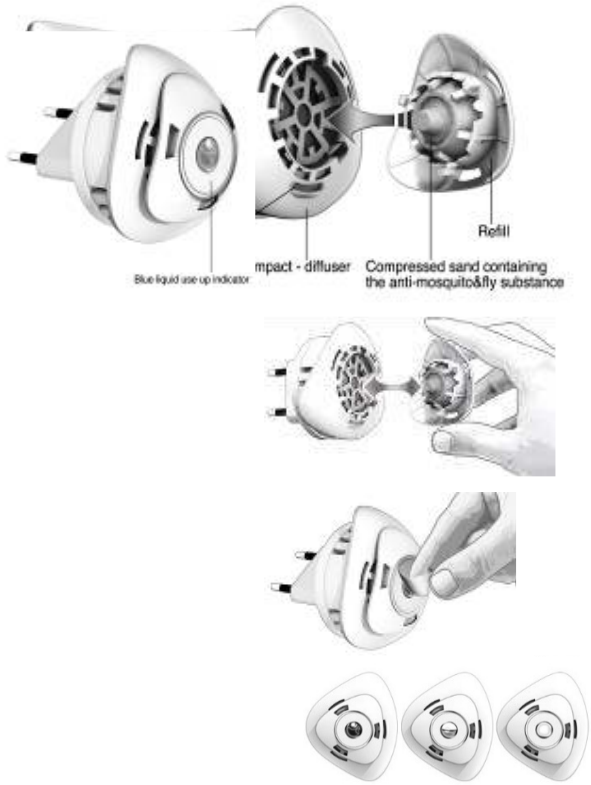
Product Type	PT18: Insecticides, acaricides and products to control other arthropods	
Where relevant, an exact description of the authorised use	Insecticide	
	Scientific name: **Common name:** **Development stage:**	Muscidae Flies Adults
	Scientific name: **Common name:** **Development stage:**	Culicidae Mosquitoes 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 m^3 (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.

2.1.4.2 Use-specific instructions for use 1

One heating setting - Raid® NIGHT&DAY™

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



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.

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 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.

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 m^3.
- High ventilation and use of air conditioning may reduce product efficacy.
- For optimal efficacy the windows should be closed during use of this product

2.1.4.3 Use-specific risk mitigation measures

See general directions for use

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

See general directions for use

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

See general directions for use

2.1.4.6 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

2.1.4.7 Use description

Use # 2 – Three heating settings

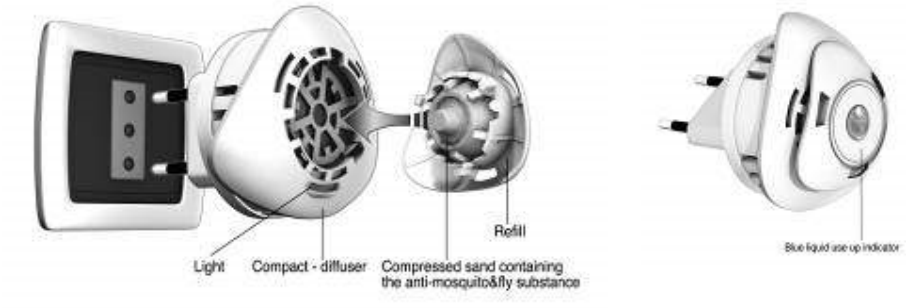
Product Type	PT18: Insecticides, acaricides and products to control other arthropods	
Where relevant, an exact description of the authorised use	Insecticide	
	Scientific name: **Common name:** **Development stage:**	Muscidae Flies Adults
	Scientific name: **Common name:** **Development stage:**	Culicidae Mosquitoes 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 16m^3 • 240 hours on medium setting for medium size rooms up to20m^3 and • 160 hours on high setting, suitable for large rooms up to30m^3	

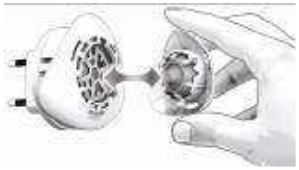
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Solid fibreboard unit box containing: - Night & Day™ + 1 refill or - Night & Day™ Trio + 1 refill or - two refills Night & Day™ and Night & Day™ Trio are unfilled diffuser units. Assembly for a unit - PP - 4.75 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.

2.1.4.8 Use-specific instructions for use 2

Three heating settings - Raid® NIGHT&DAY™ Trio

For night and day usage (24 hrs a day) for up to 320 hours.





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.

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.

No light = off
1 light = low - 16m^3 rooms
2 light = medium - 20m^3 rooms
3 light = high - 30m^3 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 to16m^3
- 240 hours on medium setting for medium size rooms up to20m^3 and
- 160 hours on high setting, suitable for large rooms up to30m^3

- High ventilation and use of air conditioning may reduce product efficacy.

- For optimal efficacy the windows should be closed during use of this product

2.1.4.9 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.

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

See general directions for use

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

See general directions for use

2.1.4.12 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

2.1.5 General directions for use

2.1.5.1 Instructions for use

See the use specific instructions for use

2.1.5.2 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]~~

2.1.5.3 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.

2.1.5.4 Instructions for safe disposal of the product and its packaging

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

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

This product has a shelf-life of 4 years

2.1.6 Other information

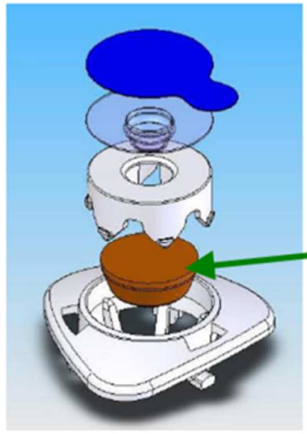
The product contains 300 mg pure transfluthrin per unit.

2.1.7 Packaging of the biocidal product

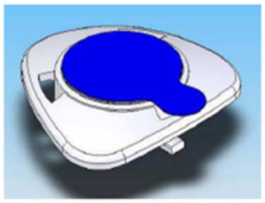
Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Assembly for sandcore unit	4.75g	Polypropylene	snap in	non-professional	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.



(Fig. 3) Disassembled Refill



(Fig. 4) Fully Assembled Refill

(Fig. 5) Pouch

this is the sandcore with the active ingredient

2.1.8 Documentation

2.1.8.1 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.

2.1.8.2 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.

2.2 Assessment of the biocidal product (family)

2.2.1 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 m^3 room for 10 days if used 24 hrs/day (Night & Day™). In the case of Night & Day Trio™, one unit will treat 30 m^3 on high rate (160 hrs) or a 16 m^3 room on low rate (320 hrs).	
Category(ies) of users	Non-professionals/consumers	

2.2.2 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	[redacted], (2010)
Colour at 20 °C and 101.3 kPa	Visual	13.4%	Yellowish brown	[redacted], (2010)
Odour at 20 °C and 101.3 kPa	-	-	Odourless	[redacted], (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	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			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	[redacted], (2010)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			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.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
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.	[redacted], (2010)
Storage stability test – **low temperature stability test for liquids**	-	-	Not applicable to a solid.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
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.	[redacted], (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.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
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	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			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.

2.2.3 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.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			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.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
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	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			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.

2.2.4 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	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	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 %	N/A	[redacted] (2006)

		unit in the used test item).	2.40 – 5.61 mg/ml with a correlation coefficient (r) = 0.9997 and the linearity equation being y = 0.0039x + 0.0044				Horwitz value: 1.80%		

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 175°C increasing to 250°C at 5°C/min. No temperature holds are used at the beginning or end of the experimental run. Injector (split) and detector temperatures are 200°C and 300°C, 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).

2.2.5 Efficacy against target organisms

2.2.5.1 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 m^3 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.

2.2.5.2 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.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Knockdown and mortality.

2.2.5.4 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.

2.2.5.5 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)

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method
Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td>Insecticide against moquitoes, indoors.</td><td>Obewan Unit with 240/720 Hour Refill at 230V as a heatable sandcore.</td><td>Southern House Mosquito, (Culex quinquefasciatus) Females, 14-18 days, laboratory cultured</td><td>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.</td><td>Table: Knockdown Time Values of free-flying Culex quinquefasciatus (14-18 day old adult females) in a standard 20m³ chamber (4 replicates)
<table><tr><th></th><th></th><th colspan="3">Time to knockdown % of the mosquitoes (minutes)</th></tr><tr><th></th><th>Age</th><th>KT50</th><th>KT80</th><th>KT95</th></tr><tr><td rowspan="2">Culex quinquefasciatus</td><td>Fresh 0 hours</td><td>20.7</td><td>34.5</td><td>65.0</td></tr><tr><td>End-life 238 hours</td><td>21.7</td><td>35.0</td><td>55.0</td></tr></table>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).</td><td>[redacted] (2008a)</td></tr>
<tr><td>Insecticide against moquitoes, indoors.</td><td>Obewan Unit with 240/720 Hour Refill at 230V as a heatable sandcore.</td><td>Yellow fever mosquito (Aedes aegypti)
Females 13-17days, laboratory cultured</td><td>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</td><td>Table: KT Values of free-flying Aedes aegypti (13-17 day old adult females) in a standard 20m³ chamber (4 replicates).
<table><tr><th></th><th></th><th colspan="3">Time to knockdown % of the mosquitoes (minutes)</th></tr><tr><th></th><th>Age</th><th>KT50</th><th>KT80</th><th>KT95</th></tr><tr><td>Aedes aegypti</td><td>Fresh 0 hours</td><td>17.1</td><td>21.3</td><td>30.0</td></tr></table>Note: These samples were tested as fresh for this species.

Untreated control knockdown: 0.5% (30 mins); 1.5% (60 mins).</td><td>[redacted] (2008b)</td></tr>
</table>

<table>
<tr><th colspan="6">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method
Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>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.</td><td></td><td></td></tr>
<tr><td>Insecticide against moquitoes indoors.</td><td>Obewan Unit with 240/720 Hour Refill at 230V as a heatable sandcore.</td><td>Indo-Pakistan malaria mosquito
(Anopheles stephensi)
Females, 16-20 days, laboratory cultured</td><td>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.</td><td>Table: Values of free-flying Anopheles stephensi (16-20 days) old adult females) in a standard 20m³ chamber (4 replicates).
<table><tr><td></td><td></td><td colspan="3">Time to knockdown % of the mosquitoes (minutes)</td></tr><tr><td></td><td>Age</td><td>KT₅₀</td><td>KT₈₀</td><td>KT₉₅</td></tr><tr><td>Anopheles stephensi</td><td>Fresh 0 hours</td><td>20.4</td><td>33.9</td><td>57.5</td></tr></table>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).</td><td>[redacted] (2008c)</td></tr>
<tr><td>Insecticide against moquitoes indoors.</td><td>Obewan Unit with 240/720 Hour Refill at 230V as a heatable sandcore.</td><td>Tiger mosquito (Aedes albopictus)
Females, 15±2 days, laboratory cultured</td><td>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</td><td>Table: Values of free-flying Aedes albopictus (15 day±2days) old adult females) in a standard 20m³ chamber (4 replicates).
<table><tr><td></td><td></td><td colspan="3">Time to knockdown % of the mosquitoes (minutes)</td></tr><tr><td></td><td>Age</td><td>KT₅₀</td><td>KT₈₀</td><td>KT₉₅</td></tr><tr><td>Aedes albopictus</td><td>Fresh 0 hours</td><td>17.3</td><td>20.1</td><td>30.0</td></tr></table>Note: These samples were only be tested as fresh for this species.

Untreated control knockdown: 0% (30 mins -120 mins).</td><td>[redacted] (2008d)</td></tr>
</table>

<table>
<tr><th colspan="6">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method
Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>concentration: 1.366 mg/hour (fresh sample) in 20m³ room, equivalent to 0.0683 mg/hr/m³.</td><td></td><td></td></tr>
<tr><td>Insecticide against flies indoors.</td><td>Obewan Unit with 240/720 Hour Refill at 230V as a heatable sandcore.</td><td>House fly (Musca domestica)
1-6 days old mixed sex adults, DDT resistant strain laboratory cultured</td><td>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.</td><td>Table: Values of free-flying Musca domestica (1-6 days old adults mixed sexes) in a standard 20m³ chamber (4 replicates).
<table><tr><th></th><th></th><th colspan="3">Time to knockdown % of the house flies (minutes)</th></tr><tr><th></th><th>Age</th><th>KT50</th><th>KT80</th><th>KT95</th></tr><tr><td>Musca domestica</td><td>Fresh
0 hours</td><td>35.4</td><td>46.3</td><td>63.3</td></tr></table>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 ([redacted] 2006c).
Untreated control knockdown: 0% (30 mins-120 mins).</td><td>[redacted] (2008e)</td></tr>
<tr><td>Insecticide against moquitoes indoors.</td><td>Obewan Unit with 30 night (240h) Refill at 230V as a heatable sandcore</td><td>Southern House Mosquito, (Culex quinquefasciatus) Females, 16±2 days, laboratory cultured</td><td>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.</td><td>Table: KT Values of free-flying Culex quinquefasciatus in a standard 20m³ chamber (4 replicates)
<table><tr><th></th><th></th><th colspan="3">Time to knockdown % of the mosquitoes (minutes)</th></tr><tr><th></th><th>Age</th><th>KT50</th><th>KT80</th><th>KT95</th></tr><tr><td rowspan="3">Culex quinquefasciatus</td><td>Fresh
0 hours</td><td>25.0</td><td>40.0</td><td>60.0</td></tr><tr><td>Mid-life
120hours</td><td>18.0</td><td>26.0</td><td>35.0</td></tr><tr><td>End-life
240 hours</td><td>24.0</td><td>41.0</td><td>73.3</td></tr></table>Note: Numbers represented in table are estimates generated by linear interpolation of the mean % knockdown.</td><td>[redacted] (2006a)</td></tr>
</table>

<table>
<tr><th colspan="5">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method
Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td>Insecticide against moquitoes indoors.</td><td>Obewan Unit with 30 night (240h) Refill at 230V as a heatable sandcore.</td><td>Tiger mosquito (Aedes albopictus)
Females, 16±2 days, laboratory cultured</td><td>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.</td><td>Table: KT Values of free-flying Aedes albopictus in a standard 20m³ chamber (4 replicates)
<table><tr><th></th><th></th><th colspan="3">Time to knockdown % of the mosquitoes (minutes)</th></tr><tr><th></th><th>Age</th><th>KT50</th><th>KT80</th><th>KT95</th></tr><tr><td>Aedes albopictus</td><td>Fresh
0 hours</td><td>19.0</td><td>24.0</td><td>34.0</td></tr></table>These samples were only be tested as fresh for this species because aged sample testing was conducted against Culex quinquefasciatus ([redacted] 2006a) which is known to be the most robust of our species.</td><td>[redacted] (2006b)</td></tr>
<tr><td>Insecticide against flies indoors.</td><td>Obewan Unit with 30 night (240h) Refill at 230V as a heatable sandcore.</td><td>House fly (Musca domestica)
3-6 days old adult mixed sexes, laboratory cultured</td><td>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.</td><td>Table: KT Values of free-flying Musca domestica in a standard 20m³ chamber (4 replicates)
<table><tr><th></th><th></th><th colspan="3">Time to knockdown % of the mosquitoes (minutes)</th></tr><tr><th></th><th>Age</th><th>KT50</th><th>KT80</th><th>KT95</th></tr><tr><td rowspan="3">Musca domestica</td><td>Fresh
0 hours</td><td>15.0</td><td>20.0</td><td>29.6</td></tr><tr><td>Mid-life
120hours</td><td>29.0</td><td>40.0</td><td>54.3</td></tr><tr><td>End-life
240 hours</td><td>54.0</td><td>78.0</td><td>>120.0</td></tr></table>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.</td><td>[redacted] (2006c)</td></tr>
</table>

<table>
<tr><th colspan="6">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method
Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td>Insecticide against moquitoes indoors.</td><td>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.</td><td>Southern House Mosquito, (Culex quinquefasciatus) Females, 16±2 days, laboratory cultured</td><td>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.</td><td>Table: Mean % Knockdown of free-flying Culex quinquefasciatus (14-18 day old adult females) in a standard 20m³ chamber (4 replicates) using fresh samples
<table>
<tr><th></th><th></th><th colspan="3">Time to knockdown % of the mosquitoes (minutes)</th></tr>
<tr><th></th><th>Age</th><th>KT_{50}</th><th>KT_{80}</th><th>KT_{95}</th></tr>
<tr><td rowspan="2">Culex quinquefasciatus</td><td>Obewan Unit with 30 Night Refill @ 230V (13.43% transfluthrin)</td><td>10.0</td><td>16.0</td><td>24.0</td></tr>
<tr><td>European Electric Mat @ 230V (3.64% Pynamin Forte)</td><td>18.0</td><td>40.0</td><td>61.0</td></tr>
</table>
Untreated control knockdown: 0% (30 mins-90 mins); 1% (120 mins).</td><td>[redacted] (2007)</td></tr>
</table>

Experimental data on the efficacy of the biocidal product against target organism(s)

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method
Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr><td>Insecticide against ants indoors.</td><td>Obewan Unit with 10 days (240h) Refill at 230V as a heatable sandcore.</td><td>Garden Black ant (Lasius niger)
Workers, laboratory cultured.</td><td>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.</td><td>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).
<table>
<tr><th></th><th>Age</th><th>% of knockdown at 4 hours</th><th></th><th>% Mortality at 24hours</th><th></th></tr>
<tr><th></th><th></th><th>treatment</th><th>Untreated controls</th><th>treatment</th><th>Untreated controls</th></tr>
<tr><td rowspan="4">Lasius niger</td><td>Fresh 0-1 days</td><td>100.0</td><td>0</td><td>100.0</td><td>3</td></tr>
<tr><td>Mid-life 4-5 days</td><td>100.0</td><td>0</td><td>100.0</td><td>1</td></tr>
<tr><td>End-life 9-10 days</td><td>100.0</td><td>1</td><td>100.0</td><td>3</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
</table></td><td>[redacted] (2010a)</td></tr>
<tr><td>Insecticide against moquitoes indoors.</td><td>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).</td><td>Yellow fever mosquito (Aedes aegypti)
Females, laboratory cultured</td><td>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</td><td>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.
<table>
<tr><th></th><th>KT₅₀ (min)</th><th>KT₉₅ (min)</th><th>KT₁₀₀ (min)</th></tr>
<tr><td>Fresh product (day 0, 0 - 2 hours)</td><td>25.2</td><td>42.0</td><td>50.0</td></tr>
<tr><td>Product mid-life (day 3, 48 - 50 hours)</td><td>11.4</td><td>35.4</td><td>40.0</td></tr>
<tr><td>Product end life (day 6, 120 - 122 hours)</td><td>18.0</td><td>42.0</td><td>50.0</td></tr>
</table>
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.
<table>
<tr><th></th><th>KT₅₀ (min)</th><th>KT₉₅ (min)</th><th>KT₁₀₀ (min)</th></tr>
</table></td><td>[redacted] (2010b)
Amendment [redacted] (2015a)</td></tr>
</table>

			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).	**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.				

<table>
<tr><th colspan="6">Experimental data on the efficacy of the biocidal product against target organism(s)</th></tr>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method
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<tr><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Insecticide against moquitoes indoors.</td><td>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).</td><td>Southern House Mosquito, (Culex quinquefasciatus) Females, laboratory cultured</td><td>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.</td><td>Table 1: Efficacy of Raid Night & Day™ , operated with 205 volt (Leia low setting), in 16 m³ rooms against free flying Culex quinquefasciatus, females.
<table>
<tr><th></th><th>KT₅₀ (min)</th><th>KT₉₅ (min)</th><th>KT₁₀₀ (min)</th></tr>
<tr><td>Fresh product (day 0, 0 - 2 hours)</td><td>34.2</td><td>66.0</td><td>80.0</td></tr>
<tr><td>Product mid life (day 3, 48 - 50 hours)</td><td>23.4</td><td>51.6</td><td>60.0</td></tr>
<tr><td>Product end life (day 6, 120 - 122 hours)</td><td>18.0</td><td>54.0</td><td>100.0</td></tr>
</table>
Table 2: Efficacy of Raid Night & Day™ , operated with 225 volt (Leia high setting), in 30 m³ rooms against free flying, Culex quinquefasciatus, females.
<table>
<tr><th></th><th>KT₅₀ (min)</th><th>KT₉₅ (min)</th><th>KT₁₀₀ (min)</th></tr>
<tr><td>Fresh product (day 0, 0 - 2 hours)</td><td>15.6</td><td>35.4</td><td>60.0</td></tr>
<tr><td>Product mid life (day 7, 144 - 146 hours)</td><td>18.0</td><td>60.0</td><td>70.0</td></tr>
<tr><td>Product end life (day 13, 288 - 290 hours)</td><td>18.0</td><td>54.0</td><td>90.0</td></tr>
</table>
For all untreated controls, knockdown was 0% during the whole testing period.</td><td>[redacted] (2010c)
Amendment [redacted] (2015b)</td></tr>
</table>

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 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. **Fresh product (day 0, 0 - 2 hours)**: KT_{50} 20.4 min; KT_{95} 55.8 min; KT_{100} 60 min **Product mid life (day 3, 48 - 50 hours)**: KT_{50} 22.2 min; KT_{95} 45.6 min; KT_{100} 60 min **Product end life (day 6, 120 - 122 hours)**: KT_{50} 42.6 min; KT_{95} 68.4 min; KT_{100} 80 min **Table 2:** Efficacy of Raid Night & Day™ , operated with 225 volt (Leia high setting), in 30 m³ rooms against free flying *Anopheles gambiae* females. **Fresh product (day 0, 0 - 2 hours)**: KT_{50} 21 min; KT_{95} 36.6 min; KT_{100} 70 min **Product mid life (day 7, 144 - 146 hours)**: KT_{50} 22.2 min; KT_{95} 36.6 min; KT_{100} 60 min **Product end life (day 13, 288 - 290 hours)**: KT_{50} 24 min; KT_{95} 54 min; KT_{100} 70 min For all untreated controls, knockdown was 0% during the whole testing period.	[redacted] (2010a) Amendment [redacted] (2015c)

Experimental data on the efficacy of the biocidal product against target organism(s)

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<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method
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<td>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).</td>
<td>Tiger mosquito (Aedes albopictus)
Females, laboratory cultured</td>
<td>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.</td>
<td>
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.
<table>
<tr><th></th><th>KT₅₀ (min)</th><th>KT₉₅ (min)</th><th>KT₁₀₀ (min)</th></tr>
<tr><td>Fresh product (day 0, 0 - 2 hours)</td><td>17.4</td><td>32.4</td><td>50</td></tr>
<tr><td>Product mid life (day 3, 48 - 50 hours)</td><td>10.8</td><td>21</td><td>60</td></tr>
<tr><td>Product end life (day 6, 120 - 122 hours)</td><td>18</td><td>24</td><td>40</td></tr>
</table>
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.
<table>
<tr><th></th><th>KT₅₀ (min)</th><th>KT₉₅ (min)</th><th>KT₁₀₀ (min)</th></tr>
<tr><td>Fresh product (day 0, 0 - 2 hours)</td><td>14.4</td><td>29.4</td><td>50</td></tr>
<tr><td>Product mid life (day 7, 144 - 146 hours)</td><td>12</td><td>36</td><td>50</td></tr>
<tr><td>Product end life (day 13, 288 - 290 hours)</td><td>18</td><td>42</td><td>50</td></tr>
</table>
For all untreated controls, knockdown was max 2% during the whole testing period.
</td>
<td>[redacted] (2010b)
Amendment [redacted] (2015d)</td>
</tr>
</table>

Experimental data on the efficacy of the biocidal product against target organism(s)

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method
Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr>
<td>Insecticide against flies indoors.</td>
<td>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).</td>
<td>House fly (Musca domestica)
adult mixed sexes, laboratory cultured</td>
<td>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.</td>
<td>
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.
<table>
<tr><th></th><th>KT₅₀ (min)</th><th>KT₉₅ (min)</th><th>KT₁₀₀ (min)</th></tr>
<tr><td>Fresh product (day 0, 0 - 2 hours)</td><td>37.8</td><td>58.8</td><td>70</td></tr>
<tr><td>Product mid life (day 3, 48 - 50 hours)</td><td>20.4</td><td>42</td><td>90</td></tr>
<tr><td>Product end life (day 6, 120 - 122 hours)</td><td>24</td><td>42</td><td>90</td></tr>
</table>
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.
<table>
<tr><th></th><th>KT₅₀ (min)</th><th>KT₉₅ (min)</th><th>KT₁₀₀ (min)</th></tr>
<tr><td>Fresh product (day 0, 0 - 2 hours)</td><td>28.2</td><td>63.6</td><td>70</td></tr>
<tr><td>Product mid life (day 7, 144 - 146 hours)</td><td>30</td><td>78</td><td>80</td></tr>
<tr><td>Product end life (day 13, 288 - 290 hours)</td><td>30</td><td>66</td><td>90</td></tr>
</table>
For all untreated controls, knockdown was 0% during the whole testing period.
</td>
<td>[redacted] (2010d)
Amendment [redacted] (2015e)</td>
</tr>
</table>

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 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 niger*) 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 niger*). **Fresh product (day 0, 0 - 24 hours)**: KT_{50} 7.00 hours; KT_{95} 9.22 hours **Product mid life (day 7, 144 - 168 hours)**: KT_{50} 3.80 hours; KT_{95} 3.97 hours **Product end life (day 13, 288 – 312 hours)**: KT_{50} 4.66 hours; KT_{95} 7.20 hours **Table 2:** untreated controls (% knockdown, time in hours) **Fresh product (day 0, 0 - 24 hours)**: 4 hours 0; 8 hours 0; 12 hours 0; 24 hours 0 **Product mid life (day 7, 144 - 146 hours)**: 4 hours 0; 8 hours 0; 12 hours N/A; 24 hours 0 **Product end life (day 13, 288 - 290 hours)**: 4 hours 0; 8 hours 1; 12 hours 1; 24 hours 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*). **Fresh product (day 0, 0 - 24 hours)**: KT_{50} 6.23 hours; KT_{95} 8.47 hours **Product mid life (day 3, 48 - 72 hours)**: KT_{50} 3.88 hours; KT_{95} 4.05 hours **Product end life (day 6, 120 - 144 hours)**: KT_{50} 5.97 hours; KT_{95} 10.68 hours For all untreated controls, knockdown was 0% during the whole testing period.	[redacted] (2010e) Amendment [redacted] (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).	**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 **Mean % Knockdown** **Mosquito Species** / **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** / **100 m** / **110 m** / **120 m** / **180 m** / **240 m** / **360 m** / **480 m** / **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	[redacted] (2014a)

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
			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.	% 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	

Experimental data on the efficacy of the biocidal product against target organism(s)

<table>
<tr><th>Function and Field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method
Test system / concentrations applied / exposure time</th><th>Test results: effects</th><th>Reference</th></tr>
<tr>
<td>Insecticide against flies indoors.</td>
<td>Obewan unit with 240/720 Hour Refill at 230V as a heatable sandcore.</td>
<td>House flies (Musca domestica)
Mixed sex 12-13days, laboratory cultured</td>
<td>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.</td>
<td>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.
<table>
<tr><th></th><th colspan="9">Time in minutes</th></tr>
<tr><th></th><th>10</th><th>20</th><th>30</th><th>40</th><th>50</th><th>60</th><th>70</th><th>80</th><th>90</th></tr>
<tr><td>Musca domestica</td><td>4.3</td><td>10.1</td><td>17.2</td><td>52.7</td><td>78.4</td><td>89.0</td><td>94.4</td><td>99.0</td><td>100.0</td></tr>
<tr><th></th><th colspan="9">Time in minutes</th></tr>
<tr><th></th><th>100</th><th>110</th><th>120</th><th>180</th><th>240</th><th>360</th><th>480</th><th colspan="2">24h mortality</th></tr>
<tr><td>Musca domestica</td><td>99.0</td><td>100.0</td><td>98.5</td><td>100.0</td><td>100.0</td><td>100.0</td><td>100.0</td><td colspan="2">99.5%</td></tr>
</table>
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.
<table>
<tr><th>Test substance</th><th>Rep 1</th><th>Rep 2</th><th>Rep 3</th><th>Rep 4</th><th>Mean</th><th>Std Dev</th></tr>
<tr><td>Electric Heater Refill - Fresh</td><td>23.8</td><td>25.7</td><td>29.7</td><td>29.8</td><td>27.25</td><td>2.99</td></tr>
</table>
For all untreated controls, knockdown was 0% during the whole testing period.</td>
<td>[redacted] (2016)</td>
</tr>
</table>

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.

2.2.5.6 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.

2.2.5.7 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.

2.2.5.8 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 20m^3

Use 2:
Refill will last for ~

- 320 hours on low setting for small rooms approx 16m^3
- 240 hours on medium setting for medium size rooms approx 20m^3 and
- 160 hours on high setting, suitable for large rooms, 30m^3

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 ([redacted] 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 ([redacted] 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 ([redacted] 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 ([redacted] 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) ([redacted] 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 ([redacted] 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 ([redacted] 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) ([redacted] 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 ([redacted] 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 ([redacted] 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 ([redacted] 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) ([redacted] 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 ([redacted] 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) ([redacted] 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 ([redacted] 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 ([redacted] 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 ([redacted] 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 ([redacted] 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 ([redacted] 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 ([redacted] 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 ([redacted] 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.

2.2.5.9 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.

2.2.6 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.

2.2.6.1 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 P_{ow} (lipid solubility) –1 < > 4 are accepted to have a dermal penetration rate of 10% or less. Transfluthrin has MW 371 and log P_{ow} 5.4; values which (in common with most pyrethroids) are close to the MW criterion and well beyond the P_{ow} 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/16m^3 room = 0.094mg/m^3

The Scientific committee on Occupational exposure limits has established a 8h TWA of 50 ppm (192 mg/m^3) 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]

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:

[2] SUBSTANCE EVALUATION REPORT Toluene, eMS Finland, 12 november 2013 https://echa.europa.eu/documents/10162/03167071-aa36-4bc3-9a08-00475f9a16d1

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.

2.2.6.2 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

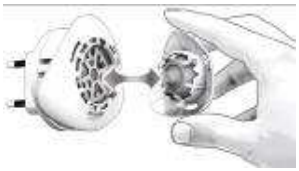
Non-professional exposure
See exposure assessment

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 m^3 room, which would represent a small bedroom.

The different emission rates from Night & Day™ Trio are 0.058, 0.065, 0.063 mg/hr/m^3 for the low, medium and high setting, respectively (See Table in section 2.2.5.1, expressed per m^3). 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 16m^3 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).



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 m^3 (RIVM, 2006b)
	Ventilation Rate	1 hr^{-1} (RIVM, 2006b)
	Toddler Body Weight	10 kg (HEAd hoc recommendation 142017)
	Toddler Inhalation Rate	8 m^3 / day (HEAd hoc recommendation 172017)
	Adult Body Weight	60 kg (HEAd hoc recommendation 142017)
	Adult Inhalation Rate	16 m^3/ 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/m^3 x 16m^3)/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 ([redacted] 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 32.3m^3. 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/m^3 at 8 hours, when the devices were switched off. The peak air concentration of 4.9 µg/m^3 was used to calculate systemic inhalation exposure for an toddler and adult in a small bedroom. The air concentration was scaled to a 16 m^3 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 m^3	0.35/hour
ConsExpo small bedroom (RIVM, 2006b)	16 m^3	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 16m^3 bedroom = (0.0049 mg/m^3 from Vesin x 2.02)/2.86

= 0.00346 mg/m^3

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 m^3/24 hour day, with a bodyweight of 10kg. For adults, the equivalent value is 16 m^3/24 hour day, with an accompanying bodyweight of 60kg.

Toddler: (0.00346 mg/m^3 x 8m^3/day) / 10 kg = 0.00277 mg/kg/day

Adult: (0.00346 mg/m^3 x 16 m^3/day) / 60 kg = 0.000923 mg/kg/day

Scenario 1, Tier 2b exposure refinements, based on [redacted] 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/m^3 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/m^3. 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 ([redacted] 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 [redacted] 2016 was 0.0137 mg/m^3. The air concentration was scaled to one device in a 16 m^3 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)
[redacted] (2016)	52.1 m^3	0.5/hour
ConsExpo small bedroom (RIVM, 2006b)	16 m^3	1/hour

The table above shows that the experimental chamber used by [redacted] 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 16m^3 bedroom = (0.0137 mg/m^3 from [redacted] /2 devices x 3.26)/2

= 0.0112 mg/m^3

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

Systemic inhalation exposure based on [redacted] 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 m^3/24 hour day, with a bodyweight of 10kg. For adults, the equivalent value is 16 m^3/24 hour day, with an accompanying bodyweight of 60kg.

Toddler: (0.0112 mg/m^3 x 8m^3/day) / 10 kg = 0.00896 mg/kg/day

Adult: (0.0112 mg/m^3 x 16 m^3/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 [redacted] 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: [redacted]).

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 [redacted], 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 m^2 Based on 16 m^3 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 m^2/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 m^2/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 m^2
= 1.94 mg active/m^2

Dislodgeable fraction is 8%, so:
= 1.94 mg active/m^2 x 8% = 0.1555 mg active/m^2

The transfer coefficient is 0.20m^2/hour (see above)

Dermal Exposure:
= (1 hr/day x 0.20 m^2/hour x 0.1555 mg active/m^2 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 m^2/hour x 0.1555 mg/m^2) 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:

$$C_{sat} = (VP * CF1 * MW * CF2 * CF3) / (R*T)$$

Where:

Csat	=	Saturation concentration (mg/m^3);
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 (10^3 mg/g); and
CF3	=	Conversion factor (10^3 L/m^3).

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	**C_{sat}**	**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:

$$EvapT = 10^{[7.3698 - 0.9546 * \log_{10}(C_{sat})]}$$

Where:

EvapT = Evaporation time (sec)

C_{sat} = Saturation concentration (0.136 mg/m^3, calculated previously)

Table 3.6.2.2. Evaporation Time		
Parameter	**Definition**	**Value**
Saturable concentration	C_{sat}	0.136
Evaporation Time	**EvapT**	**1.57 x 10^8**

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 10^8
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:

$$E = \frac{IR * M}{ACH * V} * [1 - (\frac{(ACH * e^{-k*ET}) - (k * e^{-ACH*ET})}{ACH - k})]$$

Where:

E = Exposure (mg/day)
IR = Inhalation Rate (m^3/hr)
M = Mass of a.i. applied, determined from product label (mg)
V = Volume of room (m^3)
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**	**$Dose_{infant}$**	**$Dose_{adult}$**
First order decay rate	K	5.27×10^{-5}	5.27×10^{-5}
Inhalation rate (m^3/hr)	IR	8/24=0.33	16/24=0.667
Mass of a.i. applied (mg)	M	31.1	31.1
Volume of room (m^3)	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	4.18×10^{-5}	3.1×10^{-4}	3.1×10^{-4}	6.64×10^{-4}
Scenario 2. Post application, adult.	1 / No PPE	2.16×10^{-5}	N/A	N/A	2.16×10^{-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) + 4.18×10^{-5} (indirect)	3.1×10^{-4} (indirect)	3.1×10^{-4} (indirect)	0.00962
Scenario 1+2, adult	0.00299 (direct) + 2.16×10^{-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):

$AEC_{acute, inhalation}$
In a 13-week inhalation study, with an exposure duration of 6 h/day, the NOAEC for neurotoxicity was 46.7 mg/m^3 (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/m^3 and the default assessment factor of 100, an $AEC_{acute, inhalation}$ of 0.5 mg/m^3 is derived.

$AEL_{chronic, systemic}$
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 $AEL_{chronic}$ of 1/ 100= 0.01 mg/kg/day is established.

Reference	Study	NOAEC/NOAEL	AF	Correction for absorption	AEC/AEL Value
$AEC_{short-term}$ (inhalation)	13-week rat	46.7 mg/m^3	100	None	0.5 mg/m^3
$AEL_{medium/ long-term}$ (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 [redacted], 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	2.16×10^{-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/m^3) 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 16m^3, 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/m^3, 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/m^3 / 7.2 = 0.0156 mg/m^3

Air concentration was expressed as a percentage of the acute inhalation AEC for transfluthrin (0.5 mg/m^3):

(0.0156 mg/m^3 ÷ 0.5 mg/m^3) x 100 = 3.12%

For systemic exposure via inhalation:

Toddler: 0.0156 mg/m^3 x 8m^3/day x 1/10 kg = 0.0124 mg/kg/day

Adult: 0.0156 mg/m^3 x 16 m^3/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.

2.2.8 Risk assessment for the environment

2.2.8.1 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	LC_{50}	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]	Acute	LC_{50}	>100 mg/L	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
Invertebrates					
Daphnia magna	Transfluthrin	Acute	EC_{50}	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	EC_{50}	>100 mg/L	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
Algae (growth inhibition)					
Scenedesmus subspicatus	Transfluthrin	Acute	E_rC_{50}	>100 µg/L	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
		Chronic	NOE_rC	50 µg/L	
Pseudokirchneriella subcapitata	TFB-COOH	Acute	96h E_rC_{50}	>100 mg/L	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
		Chronic	NOE_rC	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					
	Transfluthrin	Acute	NOEC	57 µg/L (water solubility)	

[3] 2,3,5,6-Tetrafluorobenzyl acid (TFB-COOH)

Summary table for aquatic toxicity data					
Respiration activated sludge			EC_{50}	>10000 mg/L	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)

Conclusion used in Risk Assessment – STP Microorganisms	
Value/conclusion	$PNEC_{STP}$ 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 $PNEC_{STP}$ for Transfluthrin of 0.057 mg/L.

Conclusion used in Risk Assessment - Aquatic Toxicity	
Value/conclusion	$PNEC_{aquatic}$ for Transfluthrin: 1.75 ng/L $PNEC_{aquatic}$ for 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH): >0.1 mg/L $PNEC_{aquatic}$ 2,3,5,6-Tetrafluorobenzyl alcohol (TFB-OH) : >0.1 mg/L $PNEC_{aquatic}$ 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 $PNEC_{aquatic}$ of 0.7 ng/L was determined on the lowest acute LC_{50} 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 $PNEC_{aquatic}$ 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 LC_{50}/EC_{50} greater than 100 mg/L. Accordingly, a $PNEC_{aquatic}$ 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 EC_{50} 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 $PNEC_{aquatic}$ 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 $PNEC_{aquatic}$ 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	$PNEC_{sediment}$ 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 $PNEC_{sediment}$ 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	LC_{50}	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		

[1]All 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	$PNEC_{soil}$ for Transfluthrin: 0.10 mg/kg dw soil (equivalent to 0.088 mg/kg ww soil) $PNEC_{soil}$ for 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH): 0.012 mg/kg ww soil $PNEC_{soil}$ 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 $PNEC_{soil}$ of 6.17E-04 mg/kg ww soil was derived from the $PNEC_{aquatic}$ 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 $PNEC_{soil}$ 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 $PNEC_{soil}$ based on the $PNEC_{aquatic}$. Concerning TFB-COOH taking account of the $PNEC_{aquatic}$ 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 $PNEC_{soil}$ was calculated to be 0.012 mg/kg ww ([redacted], 2018). For trans-DCVA the $PNEC_{soil}$ 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	$PNEC_{oral,\ mammals}$ for Transfluthrin: 6.67 mg/kg feed
Justification for the value/conclusion	The $PNEC_{oral}$ 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 $PNEC_{oral,mammal}$ 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 $PEC/PNEC_{oral,bird}$ 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		
$PNEC_{STP}$	57 µg/l	As specified in Transfluthrin Assessment Report (2014)
$PNEC_{water}$	1.75 ng/L	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
$PNEC_{sediment}$	1.64 µg/kg dw sediment 0.36µg/kg ww sediment	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
$PNEC_{soil}$	0.1 mg/kg dw soil 0.088 mg/kg ww soil	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
$PNEC_{oral,\ mammals}$	6.67 mg/kg feed	As specified in Transfluthrin Assessment Report (2014)
Metabolites		
2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH)		
$PNEC_{water}$	>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-CH_2OH-trans-DCVA		
$PNEC_{water}$	0.0064 mg/L	Based on QSAR data. Please refer to section 3.8 for details
$PNEC_{soil}$	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 $PNEC_{water}$ 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 LC_{50} 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[+]	Yes[+]	Yes[+]	Yes[+]	Yes[++]	Not relevant[(+)]	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 ([redacted], 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 CO_2. 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 ([redacted], 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:

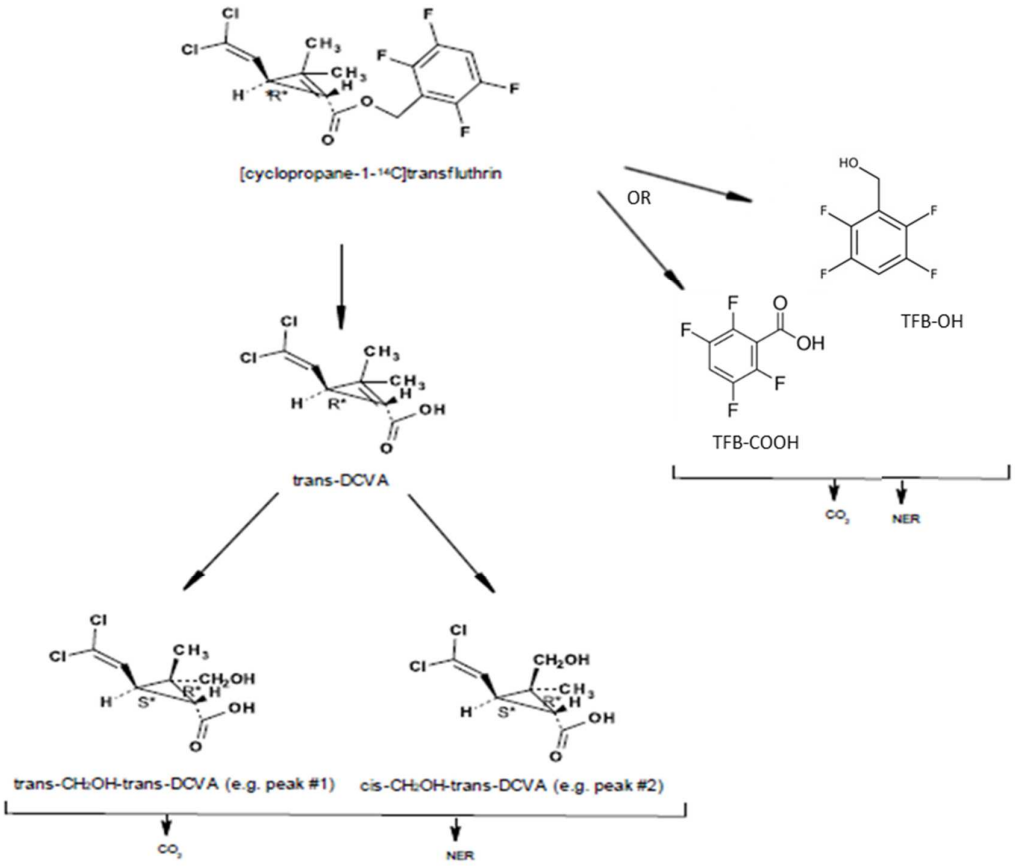
Pathway:

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

[++] Compartment primarily exposed (STP)

[(+)]Compartment potentially exposed

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 (12°C) 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 $DT_{50,water}$ was < 7 days. The average $DT_{50,system}$ was 11.1 days, the $DT_{50,sediment}$ 14.1 days at 20°C ([redacted], 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 ([redacted], 2018).

The DT_{50},system of metabolite TFB-OH was estimated to be < 14 days. A reliable estimate of the DT_{50}, 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-^{14}C] Transfluthrin was observed resulting in DT_{50} between 0.8 to 1.0 days in four soils tested. Mineralization (CO_2) 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 (12°C).

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.

2.2.8.2 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 (Q_{AI})	0.3	g	S
Number of diffusers	2	-	D
Maximal duration of use of the device/diffuser (T_{max})	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 (T_{day})	24	$h.d^{-1}$	S – Product Label, Section 2.1.4.2
Number of emission days ($T_{emission}$)	152	d	S – Reflecting seasonality of use, as specified in Transfluthrin Assessment Report (2014)[4]

[4] $T_{emission}$ required for calculation of secondary poisoning *via* the food chain in EUSES 2.1.2

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:

$$E_{application,air} = Q_{prod} \times F_{AI} \times \frac{T_{day}}{T_{max}} \times F_{application,air} \times 10^{-3}$$ PT18 ESD, eq.31

Where:

Variable/Parameter	Symbol	Unit	Value	S/D/O/P
Input				
Quantity of active substance contained in the device/diffuser	Q_{AI}	g	0.3	S
Number of difusers	N_{dif}	-	2	ENV148
Maximal duration of use of the device/diffuser	T_{max}	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)	T_{day}	$h.d^{-1}$	24	S – Product Label, Section 2.1.4.2
Fraction emitted to air during application	$F_{application,\ air}$	-	0.9	D
Emission to air during the use of the device/diffuser	$E_{application,air}$	$Kg.d^{-1}$	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:

$$E_{application,floor} = Q_{prod} \, x \, F_{AI} \, x \, N_{dif} \, x \, \frac{T_{day}}{T_{max}} \, x \, F_{application,floor} \, x \, 10^{-3}$$ 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	Q_{AI}	g	0.3	S
Number of difusers	N_{dif}	-	2	ENV148
Maximal duration of use of the device/diffuser	T_{max}	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)	T_{day}	$h.d^{-1}$	24	S – Product Label, Section 2.1.4.2
Fraction emitted to floor during application	$F_{application,floor}$	-	0.1	D (Default – diffusers)
Output				
Emission to floor during the application step	$E_{application,floor}$	$kg.d^{-1}$	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:

$E_{treated} = E_{application,floor} \; x \; F_{cleaned} \; x \; F_w \; x \; F_{CE}$ ESD, eq.34 (modified)

Where:

Variable/Parameter	***Symbol***	***Unit***	***Value***	***S/D/O/P***
Input				
Emission to floor during the application step	$E_{application,floor}$	$kg.d^{-1}$	2.7E-06	O (Default)
Fraction of the treated surface that is cleaned	$F_{cleaned}$	-	0.3	D
Fraction emitted to solid waste during the cleaning step	F_w	-	1	D
Cleaning Efficacy	F_{ce}	-	1	P
Output				
Emission from floor/treated to solid waste during the cleaning step	$E_{treated,w}$	$kg.d^{-1}$	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 (F_{ce} = 1)
- cleaning is 100% efficient, neglecting the effect of sorption and degradation

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

$E_{treated} = E_{application,floor} \; x \; F_{cleaned} \; x \; F_{ww} \; x \; F_{CE}$ ESD, eq.36 (modified)

Where:

Variable/Parameter	***Symbol***	***Unit***	***Value***	***S/D/O/P***
Input				
Emission to floor during the application step	$E_{application,floor}$	$kg.d^{-1}$	2.7E-06	O (Default - diffusers)
Fraction emitted to wastewater during the cleaning step	F_{ww}	-	1	D
Cleaning efficacy	F_{ce}	-	1	P (Default)
Output				

Emission from floor/treated to wastewater during the cleaning step	$E_{treated,ww}$	$kg.d^{-1}$	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 ($F_{simultaneity}$). 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 ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	5.96E-04	Default (Daily $F_{simultaneity}$ and F_{ce} 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[+]	Yes[+]	Yes[++]	Not relevant[(+)]	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)
DT_{50} for biodegradation in active sludge	0.50 0.284	d (at 15ºC) d (at 21.7ºC)	New OECD 314B study ([redacted], 2017)
DT_{50} for biodegradation in surface water	1E+06	d (at 12ºC)	Default value in EUSES 2.1.2
DT_{50} for hydrolysis in surface water	1E+06	d (at 12ºC)	Default value in EUSES 2.1.2
DT_{50} for photolysis in surface water	1E+06	d	Default value in EUSES 2.1.2
DT_{50} for degradation in soil	5.17	d (at 12ºC)	Transfluthrin Assessment Report – Amended List of Endpoints, BPC-24, 2018
DT_{50} 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)

[+] 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

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[5] 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 ([redacted], 2017)[6].

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 [redacted] 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) and multiplied by the degraded fraction (see

5 Model parameterisation modified as per Minutes of the meeting of Environmental WG-I-2017

6 This study has been submitted directly to Ctgb for evaluation by the Active Substance Supplier

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 $PEC_{porewater}$) is calculated for the metabolites, by using the QSAR Koc values to determine the K_{soil_water}. Please refer to section 3.7 for the QSAR estimates.

	Input parameters for calculating the fate and distribution of metabolites in groundwater						
	Koc[1]	**Kp_{soil}**	**VP[2]**	**Sol**	**K_{soil_water}[3]**	**DT50 (12°)**	**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)						
		PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW} (pore water)
		[mg/L]	[mg/l]	[mg/kg_{wwt}]	[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	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW} (pore water)
		[mg/L]	[mg/l]	[mg/kg_{wwt}]	[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/kg_{wwt}]
Simple Treat 4.0 with 3.1 settings (refined using OECD 314B)	Default	6.49E-04	6.92E-02

[a] Is similar to $C_{earthworm}$

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

2.2.8.3 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**	**$PEC/PNEC_{STP}$**
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/ $PNEC_{water}$**	**PEC/ $PNEC_{sed}$**
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/ $PNEC_{water}$**	**PEC / $PNEC_{sed}$**
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/$PNEC_{sed}$**
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/PNEC$_{soil}$
Simple Treat 4.0 (refined using OECD 314B)	Default	0.057

Summary table on calculated PEC/PNEC values (Metabolites)		
Scenario	**Refinement**	**PEC/PNEC$_{soil}$**
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/PNEC$_{soil}$**
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 ($PEC_{porewater}$) >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 C_{sludge} (mg/kg dw), which is equal to the $PEC_{soil\_initial}$.

Input parameters for calculating the fate and distribution of metabolites in groundwater Tier 2									
	Molecular weight	**vapour pressure[1]**	**solubility[1]**	**Koc**	**Kom**	**1/n**	**DT50[2]**	**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 PEC_{gw} values (Metabolites)						
(SimpleTreat 4.0 refined using OECD 314B)		PEC_{GW} (pore water, Tier1)	Application rate agricultural soil	Application rate grass	PEC_{GW} agricultural soil (PEARL)*	PEC_{GW} 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 ($PEC_{porewater}$) 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**	**$PEC_{oral\ predator}$ (mg/kg $_{wwt}$)**	**$PEC/PNEC_{mammals}$**	**$PEC/PNEC_{bird}$**
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 $PNEC_{oral,mammal}$ of 6.67 mg/kg_{wwt} feed, the $PEC/PNEC_{oral,mammal}$ 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 (F_{ce}).

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.

2.2.9 Measures to protect man, animals and the environment

See section 2.1.5.2

2.2.10 Assessment of a combination of biocidal products

Not relevant.

2.2.11 Comparative assessment

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

3 ANNEXES[7]

[7] When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

3.1 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
[redacted]	2010	Accelerated and Long-Term Storage Stability Study on Porous Sandcore Plug Material	[redacted]	CEMR-3149	S. C. Johnson and Son, Inc	559	2010-11-10	Yes	Unpublished	Yes
[redacted]	2008a	Determining Efficacy of 240/720 Hour Refill Against Mosquitoes (Culex quinquefasciatus) in the Laboratory~	[redacted]	GLP Number: 559E1	S. C. Johnson and Son, Inc.	WORK REQUEST NUMBERS: 213465	2008-04-02	Yes	Unpublished	Yes
[redacted]	2010	Determination of the Evaporation Kinetics of Obewan	[redacted]	Mo4015	S.C. Johnson & Son, Inc. R, D & E Insect Control 1525 Howe Street Racine WI 53403, USA		2010-10-26	Yes	Unpublished	Yes
[redacted]	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.	[redacted]	WORK REQUEST NUMBERS: 213102	S. C. Johnson and Son, Inc.	WORK REQUEST NUMBERS: 213102	2007-01-11	Yes	Unpublished	Yes
[redacted]	2010a	Efficacy of Raid Night & Day™ with different release rates for various volumes of rooms against Malaria mosquitoes Anopheles gambiae.	[redacted]	BIO074/10	S. C. Johnson and Son, Inc.	Mo4001	2010-09-08	Yes	Unpublished	Yes

[redacted]	2010	Determination of the Evaporation Kinetics of Obewan	[redacted]	Mo4016	S.C. Johnson & Son, Inc. R, D & E Insect Control 1525 Howe Street Racine WI 53403, USA		2010-10-26	Yes	Unpublished	Yes
[redacted]	2008	Determining knockdown efficacy of the Obewan delivery system against mosquitoes (Aedes albopictus) in the laboratory.	[redacted]	213480	S. C. Johnson and Son, Inc.	WORK REQUEST NUMBERS: 213480	2006-07-31	Yes	Unpublished	Yes
[redacted]	2008e	Determining efficacy of 240/720 hour refill delivery system against houseflies (Musca domestica) in the laboratory.	[redacted]	GLP Number: 559E5	S. C. Johnson and Son, Inc.	WORK REQUEST NUMBERS: 213465	2008-04-02	Yes	Unpublished	Yes
[redacted]	2006c	Determining knockdown efficacy of the Obewan delivery system against houseflies in the laboratory.	[redacted]	WORK REQUEST NUMBERS: 213263	S. C. Johnson and Son, Inc.	WORK REQUEST NUMBERS: 213263	2006-07-31	Yes	Unpublished	Yes
[redacted]	2008d	Determining efficacy of 240/720 hour refill against mosquitoes (Aedes albopictus) in the laboratory.	[redacted]	GLP Number: 559E4	S. C. Johnson and Son, Inc.	WORK REQUEST NUMBERS: 213465	2008-04-02	Yes	Unpublished	Yes
[redacted]	2010e	Efficacy of Raid Night & Day™ with different release rates for various volumes of rooms against Black ants Lasius niger	[redacted]	BIO080/10	S. C. Johnson and Son, Inc.	Mo4001a	2010-09-21	Yes	Unpublished	Yes
[redacted]	2006	Validation of Analytical Method ARTMW-211855 for Transfluthrin in Porous Sandcore Plug Material	[redacted]	CEMR-3148	SC Johnson and Son, Inc	559	2006-10-19	Yes	Unpublished	Yes

[redacted]	2008c	Determining efficacy of 240/720 hour refill against mosquitoes (Anopheles stephensi) in the laboratory.	[redacted]	GLP Number: 559E3	S. C. Johnson and Son, Inc.	WORK REQUEST NUMBERS: 213465	2008-04-02	Yes	Unpublished	Yes
[redacted]	2010b	Efficacy of Raid Night & Day™ with different release rates for various volumes of rooms against Yellow fever mosquitoes Aedes aegypti	[redacted]	BIO067a /10	S. C. Johnson and Son, Inc.	Mo4001	2010-08-29	Yes	Unpublished	Yes
[redacted]	2010d	Efficacy of Raid Night & Day™ with different release rates for various volumes of rooms against House flies Musca domestica	[redacted]	BIO068a /10	S. C. Johnson and Son, Inc.	Mo4001	2010-08-29	Yes	Unpublished	Yes
[redacted]	2007	Evaporation Rate Study on Porous Sandcore Plug Material	[redacted]	CEMR-3150	S. C. Johnson and Son, Inc	559	2007-03-12	Yes	Unpublished	Yes
[redacted]	2010b	Efficacy of Raid Night & Day™ with different release rates for various volumes of rooms against Asian tiger mosquitoes Aedes albopictus.	[redacted]	BIO075/ 10	S. C. Johnson and Son, Inc.	Mo4001	2010-09-08	Yes	Unpublished	Yes
[redacted]	2010	Accelerated and Long-Term Storage Stability Study on Porous Sandcore Plug Material	[redacted]	CEMR-3149	S. C. Johnson & Son Inc.	559	2010-11-01	Yes	Unpublished	Yes
[redacted]	2008b	Determining efficacy of 240/720 hour refill against mosquitoes (Aedes aegypti) in the laboratory.	[redacted]	GLP Number: 559E2	S. C. Johnson and Son, Inc.	WORK REQUEST NUMBERS: 213465	2008-04-02	Yes	Unpublished	Yes
[redacted]	2006a	Determining knockdown efficacy of the Obewan delivery system against mosquitoes in the laboratory.	[redacted]	WORK REQUEST NUMBERS: 212403	S. C. Johnson and Son, Inc.	WORK REQUEST NUMBERS: 212403	2006-02-28	Yes	Unpublished	Yes

[redacted]	2010a	Efficacy of Raid Night & Day™ against black ants in 20 m3 test rooms.	[redacted]	BI0040b /10	S. C. Johnson and Son, Inc.	Mo3959a	2007-05-19	Yes	Unpublished	Yes
[redacted]	2010c	Efficacy of Raid Night & Day™ with different release rates for various volumes of rooms against House mosquitoes Culex quinquefasciatus	[redacted]	BIO069a /10	S. C. Johnson and Son, Inc.	Mo4001	2010-08-29	Yes	Unpublished	Yes

3.2 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	m^3
Ventilation rate	1	per hour
Inhalation rate	8	m^3/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/m^3

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

	US EPA	BHHEM (20%)	BHHEM (30%)	BHHEM (20%) and 18h	BHHEM (30%) and 18h			
daily emission	31,1	31,1	31,1	31,1	31,1	mg	D	measurements 1.296 mg active/hour = 31.1 g/day.
accumulation factor	4	4	4	4	4		Af	RIVM pest control fact sheet
%deposit onto floor	10,0%	10,0%	10,0%	10,0%	10,0%	%	%deposit	
dislodgeable fraction	0,08	0,2	0,3	0,2	0,3		Df	
floor area	6,4	6,4	6,4	6,4	6,4	m2	A	RIVM general fact sheet
transfer coefficient	0,2	0,2	0,2	0,2	0,2	m2/h	TC	Headhoc recommendation 12
time of exposure	1	1	1	1	1	h	t	HEEG opinion 7
external dermal exposure	3,11E-02	7,78E-02	1,17E-01	7,78E-02	1,17E-01		((D x Af x %deposit x Df) /A)x TC xt))	
dermal absorption	10,0%	10,0%	10,0%	10,0%	10,0%	%	DA	dermal absorption value
internal dermal exposure	3,11E-03	7,78E-03	1,17E-02	7,78E-03	1,17E-02		external Dexp x DA	
bw	10	10	10	10	10	kg		Headhoc recommendation 17
internal dermal exposure per kg bw	3,11E-04	7,78E-04	1,17E-03	7,78E-04	1,17E-03		internal Dexp / bw	
oral exposure	3,11E-03	7,78E-03	1,17E-02	7,78E-03	1,17E-02		10% of external DA	
bw	10	10	10	10	10	kg		Headhoc recommendation 17
oral exposure per kg bw	3,11E-04	7,78E-04	1,17E-03	7,78E-04	1,17E-03		Oral exp / bw	
post-application inhalation	4,18E-05	4,18E-05	4,18E-05	4,18E-05	4,18E-05		see separate calculation in PAR	
total post-application	6,64E-04	1,60E-03	2,37E-03	1,60E-03	2,37E-03		Dermal int per kg bw + Oral per kg bw	
inhalation exposure per kg bw	0,00896	0,00896	0,00896	0,00672	0,00672			
total exposure	**9,62E-03**	1,06E-02	1,13E-02	8,32E-03	**9,09E-03**			
AEL	0,01	0,01	0,01	0,01	0,01			
%AEL inhalation	89,6	89,6	89,6	67,2	67,2			
%AEL post application	6,638	15,968	23,74	15,968	23,74			
% AEL total exposure	**96,2**	**105,6**	**113,3**	**83,2**	**90,9**			

3.3 New information on the active substance

Since the approval of Transfluthrin in 2014 the following studies have been conducted:-

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

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

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

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

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

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

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

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

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

3.4 Residue behaviour

Not applicable.

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

Please refer to IUCLID Section 6.7

3.6 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

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

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

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 $PNEC_{aquatic}$ for DCVA is **0.0064** mg/L.

To determine the $PNEC_{soil}$, 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 $PNEC_{aquatic,}$ the $PNEC_{soil}$ 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

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

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

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)

3.7 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

3.8 Confidential annex

Please see separate document for details.

3.9 References

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