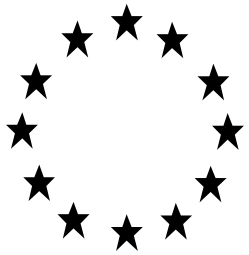
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by eCA)



Transfluthrin Liquid Electric

Product type 18

Transfluthrin

Case Number in R4BP: BC-CH021598-44

Evaluating Competent Authority: Netherlands

Date: 22 October 2020

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1 CONCLUSION

Transfluthrin Liquid Electric is a liquid vaporiser for use indoor by non-professional users against mosquitoes and flies. The product is suited for use against flies in rooms up to 20 m^3 and for use against mosquitoes in rooms up to 30 m^3. Transfluthrin Liquid Electric is intended to be used for 8 or 12 hours at night (for mosquitoes) or during the day (for flies).

Transfluthrin Liquid Electric is a clear colourless liquid with a citrus like odor. A shelf-life of 4 years is supported for the LV formulation in PET.

Based on the high amount of H304 classified components the product is classified with aspiration hazard (H304). The product does not require any physical hazards classification.

For human health, the exposure to transfluthrin was calculated when Transfluthrin Liquid Electric is used on the high setting after 12 and 24 hours use. Based on the risk assessments for human health, adverse effects are not anticipated following consumer use of Transfluthrin Liquid Electric for the 12 hour scenario. Moreover, adverse effects are not anticipated following consumer use of Transfluthrin Liquid Electric for the 24 hour scenario. It should be noted that 24 hour exposure is a highly conservative scenario as an infant of this age would spend time in other rooms in the home (whilst being watched by their care-giver) or outside the home.

For the environment, the assessment was performed assuming 12 and 24 hour use. It is concluded that the use of Transfluthrin Liquid Electric in accordance with label instructions will not result in an 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

Identifier[1]	**Country (if relevant)**
Transfluthrin Liquid Electric Raid Transfluthrin Liquid Electric Baygon Transfluthrin Liquid Electric	The Netherlands (eCA)
Baygon® Genius Protector	Belgium
Байгон електрическо устройство с течност Байгон пълнител за електрическо устройство	Bulgaria
Raid® Citronella,tekućina za električni aparatić	Croatia
Raid® elektrický tekutý s vůní citronelly / Raid® elektrický tekutý s vůní citronelly náplň Biolit Plus® elektrický odpařovač s vůní citronelly Biolit Plus® náplň do el. odpařovače s vůní citronelly	Czech Republic
Kärbse ja sääse fumigaator Biolit Plus Kärbse ja sääse fumigaatori Biolit Plus täitevedelik	Estonia
RAID® 45 NUITS Diffuseur électrique liquide anti-moustiques - Senteur Citronnelle (Refill)	France
Pyrel® 45 Nuits Diffuseur Electrique Liquide Anti-Moustiques – Parfumé à l'huile essentielle de Citronelle	France
BAYGON GENIUS PROTECTOR	Greece
BAYGON GENIUS PROTECTOR	Cyprus
Raid® szúnyogirtó folyadék citronella illattal	Hungary
Raid® Liquido Elettrico	Italy
BAYGON® GENIUS PROTECTOR	Luxembourg
Raid® elektrofumigator z płynem owadobójczym przeciw komarom o zapachu citronelli. Raid® wymienny wkład do elektrofumigatora owadobójczego przeciw komarom o zapachu citronelli.	Poland
BAYGON® GENIUS PROTECTOR – Aparat cu rezerva lichida BAYGON® GENIUS PROTECTOR – Rezerva lichida	Romania
Raid® elektrický tekutý s vôňou citronelly Raid® elektrický tekutý s vôňou citronelly náplň Biolit Plus® elektrický odparovač s vôňou citronelly Biolit Plus® náplň do el. odparovače s vôňou citronelly	Slovakia
Raid® Liquido Elettrico Fragranza alla Citronella	Slovenia

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

Identifier[1]	**Country (if relevant)**
Raid® Electrico Liquido Fragancia Citronella	Spain
Raid® Líquido Eléctrico Melgas & Mosquitos	Portugal
BAYGON® GENIUS PROTECTOR	Portugal

The product is also known as EDIE, Baygon TG2, Baygon Trevi Green 2, Trevi Green, Raid Liquid Electric and Raid LE in unpublished study reports.

For clarity the product consists of a heating device and inserts, which are also sold separately as refills.

Figure 1: Photograph of a Liquid Electric device and refill

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 of the product

Name of manufacturer	SC Johnson Europe Sàrl
Address of manufacturer	Z.A. la Piece 8 1180 Rolle Switzerland
Location of manufacturing sites	ZOBELE BULGARIA EOOD Rakovski Municipality Industrial Zone 2 4142 Striama District Plovdiv BG Bulgaria
Location of manufacturing sites	COSTER AEROSOL VALF SANAYİ AŞ Atatürk Bulv. 7. Cad. Gebze/Kocaeli (İzmit) Turkey
Location of manufacturing sites	S.C. Johnson Polska sp. z o.o. ul Kasprzaka 6a, 66-400 Gorzow Wlkp, Poland

2.1.1.4 Manufacturer of the active substance

Active substance	Transfluthrin
Name of manufacturer	Bayer SAS, Environmental Science Division
Address of manufacturer	16 rue Jean-Marie Leclair, CS 90106, 69266 Lyon Cedex 09, France
Location of manufacturing sites	Bayer Vapi Private Limited Plot No 306/3, II Phase, GIDC Vapi 396 195 Gujarat India

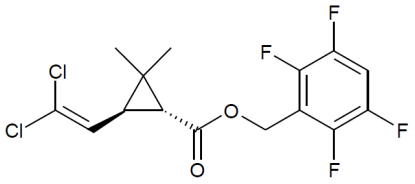
2.1.2 Product composition and formulation

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

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

Yes ☐
No ☒

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 for substitution

Transfluthrin is not a candidate for substitution.

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

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[2]	405-060-5	0.91 (0.*88** pure active)
BHT	2,6-di-tert-butyl-p-cresol	Non-active substance	128-37-0	204-881-4	1%
Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics		Non-active substance		920-114-2	94.59%
Refer to the confidential annex 3.6 for details of the co-formulants					

*0.79-0.97% w/w specification range.

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

Not applicable

2.1.2.5 Information on technical equivalence

Not applicable. The active substance source corresponds to the reference source.

2.1.2.6 Information on the substance(s) of concern

Please see section "Qualitative and quantitative information on the composition of the biocidal product" and the confidential annex for further details.

2 *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.*

As a result of screening no need for ED assessment was identified for any of the co-formulants. See chapter 2.2.6.1 for human health aspect and 2.2.8.1 for environment aspect for further details.

2.1.2.7 Type of formulation

LV - Liquid vaporizer

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	Aspiration Tox. 1 Aquatic Acute 1 Aquatic Chronic 1	
Hazard statement	H304: May be fatal if swallowed and enters airways. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.	
Labelling		
Hazard Pictogram		
	GHS08: Health hazard	GHS09: Environment
Signal words	Danger	
Hazard statements	H304: May be fatal if swallowed and enters airways. H410: Very toxic to aquatic life with long lasting effects.	
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P264: Wash hands thoroughly after handling. P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician. P331: Do NOT induce vomiting. P405: Store locked up. P273: Avoid release to the environment. P501: Dispose of contents/container to … [… in accordance with local/regional/national/international regulation]	
Note	**EUH208: Contains** citronella oil (consisting of citronellal, geraniol, citronellol and limonene). May produce an allergic reaction. EUH066 Repeated exposure may cause skin dryness or cracking. Based on the assigned classification, the following substances need to be declared on the label in accordance with Art 18(3) of the CLP: • Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics (H304)	

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Non-professional – insecticide liquid vaporiser

<table>
<tr><td>Product Type</td><td>Product type 18: Insecticides, acaricides and products to control other arthropods</td></tr>
<tr><td>Where relevant, an exact description of the authorised use</td><td>Insecticide</td></tr>
<tr><td>Target organism (including development stage)</td><td>Scientific name: Culicidae:
Common name: Mosquitoes
Development stage: adults

Scientific name: Muscidae
Common name: Flies
Development stage: adults</td></tr>
<tr><td>Field of use</td><td>Indoor</td></tr>
<tr><td>Application method(s)</td><td>Liquid vaporiser</td></tr>
<tr><td>Application rate(s) and frequency</td><td>Transfluthrin Liquid Electric is intended to be used for 8 or 12 hours at night (for mosquitoes) or during the day (for flies). Each refill (depending upon the size) will last 30, 40 or 45 nights (for mosquitoes) or days (for flies) when used for 8 hours per (night)/(day) or 20, 25 or 30 nights/days when used for 12 hours per night or day. One vaporiser is suited for ventilated rooms of up to 20 m^3 for flies and 30m^3 for mosquitoes.</td></tr>
<tr><td>Category(ies) of users</td><td>General public (non-professional)</td></tr>
<tr><td>Pack sizes and packaging material</td><td>The bottle is made of PET and the cap made of PP Homo-polymer. The refill bottle has a screw fit cap fitted with a child resistant closure, and the bottle/ device are enclosed in a solid fibreboard carton with a tuck flap closure.
The packsizes and volume on the label are indicated below. The packsize is 42 ml.
<table>
<tr><td></td><td>CLAIM/Based on 8hr /night usage</td><td>Volume stated on the label</td></tr>
<tr><td>Base Holder</td><td>Up to 30N</td><td>21ml</td></tr>
<tr><td>Base Holder</td><td>Up to 45 nights</td><td>31ml</td></tr>
<tr><td>Dual Holder</td><td>Up to 30 Nights</td><td>21ml</td></tr>
<tr><td>Dual Holder</td><td>Up to 45 nights</td><td>31ml</td></tr>
<tr><td>Advanced Holder</td><td>Up to 40N</td><td>33ml</td></tr>
<tr><td>Refill</td><td>Up to 30N</td><td>21ml</td></tr>
<tr><td>Refill</td><td>Up to 45N</td><td>31ml</td></tr>
</table>
</td></tr>
</table>

2.1.4.2 Use-specific instructions for use

See general directions for use

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

2.1.5 General directions for use

2.1.5.1 Instructions for use

	CLAIM/Based on 8hr /night or day usage	Volume stated on the label
BASE HLDER	Up to 30 nights/days	21ml
BASE HLDER	Up to 45 nights/days	31ml
Dual	Up to 30 nights/days	21ml
Dual Holder	Up to 45 nights/days	31ml
Advanced Holder	Up to 40nights/days	33ml
Refill	Up to 30 nights/days	21ml
Refill	Up to 45 nights/days	31ml

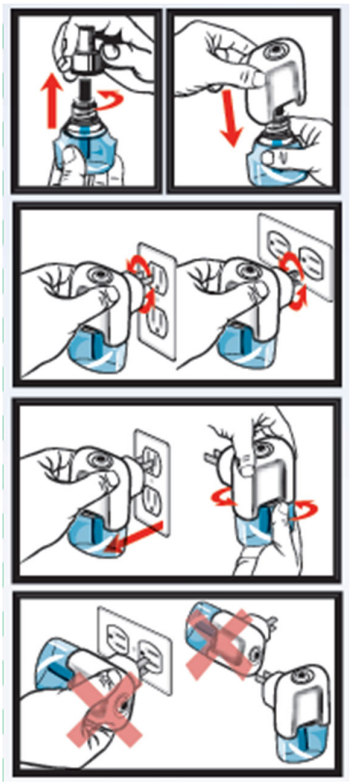
	CLAIM/Based on 12hr /night or day usage	Volume stated on the label
Base Holder	Up to 20 nights/days	21ml
Base Holder	Up to 30 nights/days	31ml
Dual Holder	Up to 20 nights/days	21ml
Dual Holder	Up to 30 nights/days	31ml
Advanced Holder	Up to 25 nights/days	33ml
Refill	Up to 20 nights/days	21ml
Refill	Up to 30 nights/days	31ml

The product consists of a liquid insecticide formulation in a bottle, designed to fit a heater unit. The formulation is drawn up by the heated wick and evaporates at a suitable rate to provide an adequate level of protection against mosquitoes and Flies.

Liquid electric is a liquid that has been developed to eliminate and kill mosquitoes and flies effectively for up to 30, 40 or 45 nights/days (8 hours per night or day and depending on the refil size) or 20, 25 or 30 nights/days (12 hours per night of day and depending on the refill size) in a ventilated room.

There are 3 types of heater which can use the same liquid formula refills:
-Base with only one evaporation rate and function mode
-Dual or Adjustable which is similar to the Base heater but the consumer can choose the level of protection as they can slide the power to a low setting or high setting.
-Advanced heater that turns itself On and Off automatically because the heater has a programmable timer that remembers the consumer settings. This type also has three intensity settings low, medium and high.

Directions for Use – BASE:



Ensure voltage is 230V/local country voltage.

Refill change instructions

Squeeze and turn to remove the cap from the liquid refill and screw/push the bottle into the heating unit until secure. Avoid touching wick.
Rotate plug to keep bottle in a vertical position.

Plug heater into a power outlet to start anti-mosquito efficacy; a light signals that the product is powered.
To stop the device from working just unplug it.

For optimal efficacy, activate the device 1 hour in advance.
When the refill is used up, unplug the heater before changing the refill.

<u>Directions for use</u> - Dual

Refill change instructions
Squeeze and turn to remove the cap from the liquid refill. Screw the bottle into the heating unit until secure. Avoid touching the wick.

Adjust the heater plug to fit the socket's direction, ensure liquid bottle keeps upright.
Connect to power 230V); indicator light will be lit when connected.
Please adjust the **'PowerSlider' / 'PowerControl'** according to your mosquito/flies protection needs.
"-" Turn 'down' / Left means the **regular** insecticide releasing
"+" Turn 'up' / Right means the **maximum** insecticide releasing
Do not lay the heater on its side.
Use in ventilated places.
To stop the device from working just unplug it.
Unplug the heater after use. There is no need to separate the liquid refill from the heater. When the refill is used up, unplug the heater before changing the refill.

Directions for use- EDIE ADVANCED:

Refill change instructions
1. Squeeze and turn to remove the cap from the liquid refill. Avoid touching wick.
2. Screw the bottle into the heating unit until secure. Adjust the heater plug to fit the socket's direction, ensure liquid bottle is kept upright.
3. Do not lay the heater on its side.

Use in ventilated places.

To stop the heater from working, just unplug it or push the Intensity level button until no LED is on.

Programming instructions
This heater has two setting controls : Time setting and Intensity setting.
Time setting is on the right (slider) and Intensity setting is on the left.

To set the hours of protection
Choose the hours of protection (8 or 12 hrs) moving the right slider to the desired position. Plug in the heater at the time of night you want it to start working and the heater will be programmed. It will begin to work automatically at that very same time and duration, day after day. Important: the 8 or 12 hours will start from the moment the heater is plugged into the wall.

Time setting	Hours product will work	Hours product will turn Off	Example of setting
8 hours	8 continuous hours	16 continuous hours	Product is plugged in at 5 PM. Will work until 1 AM next morning Will turn OFF from 1 AM to 5 PM.

			Will turn ON *automatically* at 5 PM again. Will run same schedule every day.
12 hours	12 continuous hours	12 continuous hours	Product is plugged at 9 PM. Will work until 9 AM next morning Will turn OFF from 9 AM to 9 PM. Will turn ON *automatically* at 9 PM again. Will run under same schedule every day.

To reset the hours, unplug the heater, set the time and plug it in again. Time will start counting again.

When set in [Continuous] setting the heater will continue to be On until it gets unplugged.

To set the intensity modes
You can choose from 3 different intensity modes of protection: Low, Medium, High. To select, push the left button, a different LED light will be light up for each setting

Intensity mode	LED	When to use it:
Low	Left LED	limited mosquito/fly occurence. This setting quickly eliminates mosquitoes and automatically returns to a Low setting. It works at maximum for 1 hour and then goes to basic level.
Medium	Central LED	In case of mosquito/fly occurence along the night/day. For high protection at the beginning which eventually goes down during the night. It adjusts automatically throughout the night. Works at maximum level for 4 hours, goes to intermediate level for 3 hours and then goes to basic level.
High	Right LED	For use in case of continuous intense mosquito/fly occurrence.This setting works continuously at maximum level

These intensity modes will last according to the time selected on the Time setting.
You can also turn the heater OFF by pressing a fourth time (No LEDs On) the Intensity button.

In case of electricity outage, Liquid Electric Advanced will default to Low intensity level.

TO ENSURE BEST EFFICACY [This will be included on all the heaters (Base heater, dual heater and Advanced Heater) +refil (This is called the starter pack) and also on the refill only pack]

Please use (Raid), (Baygon), (Biolit) and (Pyrel) liquid refill together with the same branded liquid heater , because appliances from different brands may generate different heater temperatures.
When used for the first time, please pre-heat up for one hour.
Place the liquid heater in the wind direction toward the sleeper.

2.1.5.2 Risk mitigation measures

Keep out of reach of children

Do not use in a confined area.
Retain the outer carton for full use and safety instructions.
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.
Store away from food, beverages and pet food. Do not use in kitchens.
Unplug when the bottle is empty, replace the bottle only when device is unplugged.
Do not touch the wick

[All products sold with the electrical diffuser device will be labelled in accordance with EN Standard 60335 (most up-to-date amendments). Currently this text is:

IMPORTANT SAFETY INSTRUCTIONS: This appliance can be used by children aged from 8 years and above and persons with reduced physical, sensory or mental capabilities or lack of experience and knowledge if they have been given supervision or instruction concerning use of the appliance in a safe way and understand the hazards involved. Children shall not play with the appliance. Cleaning and user maintenance shall not be made by children without supervision. For safe use, plug only into properly functioning wall outlets where device is ventilated and cannot contact bed covering or other material. Do not immerse in water. www.scjproducts.info

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

Inhalation:Get medical attention immediately.

Skin contact: Rinse with plenty of water. Get medical attention if irritation develops and persists.

Eye contact: Rinse with plenty of water. Get medical attention if irritation develops and persists.

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

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

Wash hands thoroughly after handling.

IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician.
Do NOT induce vomiting.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Do not discharge the biocidal product nor spills and residues containing the product into the sewage system or the environment.

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements

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

Shelf-life of 4 years. Protect from direct sunlight. Do not store above 40°C.

2.1.6 Other information

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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)
Bottle	Bottle size is 42ml but the fill level will vary depending	PET	Screw fit, PET	Non-professional	Yes
Cap		PP Homo-polymer	Screw fit	Non-professional	Yes

Unit carton	on the number of nights and the label should include the fill level.	Solid fibreboard	Tuck flap carton	Non-professional	Not applicable

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 within the Transfluthrin Assessment Report (2014).

2.1.8.2 Access to documentation

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

2.2 Assessment of the biocidal product

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

Table 2. Use # 1 – Non-professionals (general public)

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:** Culicidae: *Aedes aegypti* **Common name:** other: Yellow fever mosquito **Development stage:** adults (females) **Scientific name:** Culicidae: *Aedes albopictus* **Common name:** other: Tiger mosquito **Development stage:** adults (females) **Scientific name:** Culicidae: *Culex quinquefasciatus* **Common name:** other: Southern house mosquito **Development stage:** adults (females) **Scientific name:** Culicidae: *Anopheles stephensi* **Common name:** other: Anopheles mosquitoes **Development stage:** adults (females) **Scientific name:** Muscidae: *Musca domestica*

	Common name: house fly **Development stage:** adults (mixed sexes)
Field of use	Indoors
Application method(s)	Liquid vaporiser
Application rate(s) and frequency	Transfluthrin Liquid Electric is intended to be used for 8 or 12 hours at night (for mosquitoes) or during the day (for flies) and each refill depending upon the size will last (30), (40), (45) ,(nights for mosquitoes) /(days for flies) when used for 8hours per (night)/(day). One vaporiser is suited for rooms of up to 20 m^3 for flies and 48m^3 for mosquitoes.
Category(ies) of users	General public (Non-professional)
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

eCA remark: The following test items are the same product but different trade names: Baygon TG2, Transfluthrin Liquid Electric and Trevi Green.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	Transfluthrin Liquid electric refill with 0.88% Transfluthrin Batch number 496Dfield	Liquid	[redacted]
Colour at 20 °C and 101.3 kPa	Visual	Transfluthrin Liquid electric refill with 0.88% Transfluthrin Batch number 496D1	Clear colourless	[redacted]
Odour at 20 °C and 101.3 kPa	Smell	Transfluthrin Liquid electric refill with 0.88% Transfluthrin Batch number 496D1	citronella/citrus like odor	[redacted]
Acidity / alkalinity	-		The product is not an aqueous based formulation and is not intended to be diluted with water. This test is therefore not required.	-
Relative density / bulk density	OECD Method 109	Transfluthrin Liquid electric refill with 0.88% Transfluthrin	0.8107 at 20°C.	[redacted]
Storage stability test – **accelerated storage**	EPA OPPTS 830.6317 (Storage Stability) Analytical method: GC-FID	Transfluthrin Liquid electric refill with 0.88% Transfluthrin	12 months storage at 40°C in a PET bottle. Initial amount of transfluthrin: 0.881%w/w After 2 months at 40°C: 0.882%w/w increase: 0.1%w/w After 6 months at 40°C: 0.874%w/w Decrease: 0.8%w/w	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			After 9 months at 40°C: 0.868%w/w Decrease: 1.5%w/w After 12 months at 40°C: 0.870%w/w Decrease: 1.25%w/w The formulation was observed to be a clear, colorless liquid with a citronella/citrus like odor (before and after storage). No pack/product interaction or corrosion of the packaging was observed during storage. The amount of transfluthrin present in the product after 12 months storage at 40°C was found to be stable.	
eCA remark: Based on CIPAC MT 46.2 (accelerated storage procedure) a provisional shelf-life of 2 years is supported in PET.				
Storage stability test – **long term storage at ambient temperature**	EPA OPPTS 830.6317 (Storage Stability) Analytical method: GC-FID	Transfluthrin Liquid electric refill with 0.88% Transfluthrin Batch number: 496D1	48 months storage at 25°C in a PET bottle. Initial amount of transfluthrin: 0.884%w/w pH(1% dispersion): 6.0 After 3 months at 25°C: 0.877%w/w increase: 0.8%w/w pH(1% dispersion): 5.9 After 6 months at 25°C: 0.873%w/w Decrease: 1.25%w/w	[redacted] (2019)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			pH(1% dispersion): 6.0 After 9 months at 25°C: 0.875%w/w Decrease:1.1 %w/w pH(1% dispersion): 5.8 After 12 months at 25°C: 0.864%w/w Decrease: 2.3%w/w pH(1% dispersion): 5.9 After 18 months at 25°C: 0.872%w/w Decrease: 1.4%w/w pH(1% dispersion): 5.7 After 24 months at 25°C: 0.865%w/w Decrease: 2.1%w/w pH(1% dispersion): 5.8 After 36 months at 25°C: 0.878%w/w Decrease: 0.73%w/w pH(1% dispersion): 5.8 After 48 months at 25°C: 0.874%w/w Decrease: 1.1%w/w pH(1% dispersion): 5.7 The formulation was observed to be a clear, colorless liquid with a citronella/citrus like odor (before and after storage). No pack/product interaction or corrosion of the packaging was	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			observed during storage. The amount of transfluthrin present in the product after 48 months storage at 25°C was found to be stable. A shelf-life of 4 years in PET at 25°C is supported.	
eCA remark: the provided pH values are the result of a 1% dispersion and not a 1% solution. The study report mentions that the product was found not to be miscible with water and therefore the product was dispersed by means of CIPAC method 75.3. eCA remark: The formulation type LV requires that the vaporization rate and the minimum effective period are addressed. The information regarding these matters can be found in the efficacy section: *2.2.5.8 Evaluation of the label claims*. eCA remark: the substances of concern BHT and Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics do not need to be determined in the shelf-life studies since both substances of concern are not part of an equilibrium or the result of a degradation product of a non-stabile substance.				
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Transfluthrin Liquid electric refill with 0.88% Transfluthrin	No separation was observed following storage at 0°C for 7 days. The product is considered to be stable at 0°C for 7 days.	[redacted] (2015a)
Effects on content of the active substance and technical characteristics of the biocidal product – **light**	EPA OPPTS 830.6313 (Storage Stability)		Please see attached photodegradation statement.	N/A
eCA remark: No study results could be found on the effects of light on the product. Therefore, the sentence "protect from direct sunlight" will be stated on the label.				
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	EPA OPPTS 830.6313 (Storage Stability)	Transfluthrin Liquid electric refill with 0.88% Transfluthrin	Product is stable for 12 months at 40°C. Product is stable for 48 months at 25 °C.	[redacted] (2019) Please refer accelerated and long term ambient

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				storage stability. [redacted] [redacted] Is the accelerated storage stability.
eCA remark: Transfluthrin liquid electric is very hydrophobic. The eCA agrees that humidity is therefore not likely to affect the stability of the product. Regarding the temperature: the label will include the sentence "Do not store above 40°C."				
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	EPA OPPTS 830.6313 (Storage Stability)	Transfluthrin Liquid electric refill with 0.88% Transfluthrin	Interim report: No product/pack interactions and no corrosion was observed in the test items. Test on-going	[redacted] (2016a). Please refer to ambient ad accaelerated storage stability. [redacted] [redacted] Is the accelerated storage stability.
Wettability	-	-	Not relevant. The product is a liquid vaporiser and will therefore not be mixed with water.	-
Suspensibility, spontaneity and dispersion stability	-	-	Not relevant. The product is a liquid vaporiser and will therefore not be mixed with water.	-
Wet sieve analysis and dry sieve test	-	-	Not relevant. The product is a liquid vaporiser. This data requirement is only valid for wettable powders, suspension concentrates, water dispersible granules, aqueous capsule suspensions, dispersible concentrates, suspo-emulsions, water soluble granules and water soluble powders.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not relevant. The product is a liquid vaporiser. This data requirement is only valid for emulsifiable products.	-
Disintegration time	-	-	Not relevant. The product is a liquid vaporiser. This data requirement is only relevant to water dispersible solids.	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not relevant. The product is a liquid vaporiser. This data requirement is only valid for powders and granules. As the product is not sprayed, the MMAD of droplets is also not necessary.	-
Persistent foaming	-	-	Not relevant. The product is a liquid vaporiser. This data requirement is only valid for products that are applied in water.	-
Flowability/Pourability/Dustability	-	-	Not relevant. The product is a liquid vaporiser. Flowability and Dustability are only valid for granular materials. Pourability is only valid for suspension concentrates, capsule suspensions or suspo-emulsions.	-
Burning rate — smoke generators	-	-	Not relevant. The product is a liquid vaporiser. The product will not generate smoke.	-
Burning completeness — smoke generators	-	-	Not relevant. The product is a liquid vaporiser. The product will not generate smoke.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Composition of smoke — smoke generators	-	-	Not relevant. The product is a liquid vaporiser. The product will not generate smoke.	-
Spraying pattern — aerosols	-	-	Not relevant. The product is a liquid vaporiser. The product is not an aerosol.	-
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 applicable for this type of product.	-
Surface tension	OECD Guideline 115 (Surface Tension of Aqueous Solutions)	Transfluthrin Liquid electric refill with 0.88% Transfluthrin	27.8 mN/m at 20°C	[redacted] (2015a) [redacted]
Viscosity	OECD Test Guideline 114 (Viscosity of Liquids)	Transfluthrin Liquid electric refill with 0.88% Transfluthrin	The mean result at 20°C was 12.4 mPa.s and the mean result at 40°C was 5.8 mPa.s. The test material displayed Newtonian flow behaviour. **Dynamic Viscosity Equivalence:** Dynamic Viscosity (η) = 12.4 mPa s = 0.0124 Pa s = 0.0124 kg m^{-1} s^{-1} **Density Equivalence:** Density (p) = 0.8107 g/ml = 0.8107 g/cm^3 = 810.7 kg m^{-3} **Kinematic Viscosity Calculation:**	[redacted] (2015a) [redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Kinematic viscosity (v) = η/p = (0.0124 kg m^{-1} s^{-1}) / (810.7 kg m^{-3}) = 1.53 x 10^{-5} m^2 s^{-1} = 15.3 mm^2 s^{-1} **Conclusion:** As demonstrated in the calculations above, Trevi Green, test substance 15436R171, has a 20 °C kinematic viscosity of 15.3 mm^2 s^{-1}. **References:** OECD 114 (2012), Guideline for the Testing of Chemicals, Viscosity of Liquids.	
eCA remark: Based on the high amount of H304 classified components and a kinematic viscosity below 20.5 mm^2/s the product is classified with aspiration hazard (H304).				

Conclusion on the physical, chemical and technical properties of the product
Transfluthrin Liquid Electric is a clear colourless liquid with a citrus like odor. The results for the physical and chemical tests for the Baygon TG2 (Liquid Electric-Trevi Green) formulation were indicative of a light petroleum distillate based formulation. The product has a density of 0.8107 g/cm^3 (20°C), a surface tension of 27.8 mN/m (20°C) and a viscosity of 12.4 mPa.s at 20°C and 5.8 mPa.s at 40°C. The viscosity analysis revealed the test item exhibited Newtonian behaviour. Based on the high amount of H304 classified components and a kinematic viscosity below 20.5 mm^2/s the product is classified with aspiration hazard (H304). A shelf-life of 4 years is supported in PET at ambient temperatures. .

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	-	-	None of the components of the product are known to be explosive. Experience in the use	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			of the product does not indicate that the product is explosive.	
eCA remark: According to appendix 6 of the UN MTC, explosive properties may be induced by certain functional groups. None of those are present, with the exception of unsatured C-C moieties. The active substance contains a double bond, but is known not to be explosive based on the data within the substance dossier. The product also contains perfumes, which may contain unsaturated C-C moieties, but naturally occurring terpenes are non-explosive. Therefore, the eCA considers that the product does not need to be considered for classification as explosive.				
Flammable gases	-	-	Not applicable to a liquid product.	-
Flammable aerosols	-	-	Not applicable to a liquid product.	-
Oxidising gases	-	-	Not applicable to a liquid product.	-
Gases under pressure	-	-	Not applicable to a liquid product.	-
Flammable liquids	A.9	Transfluthrin Liquid electric refill with 0.88% transfluthrin.	Flashpoint: 122.0°C (not classified)	[redacted] (2015a) [redacted]
Flammable solids	-	-	Not applicable to a liquid product.	-
Self-reactive substances and mixtures	-	-	None of the components of the product are classified as self-reacting substances. Experience in the use of the product does not indicate that the product will self-react.	-
eCA remark: The product is not explosive. In addition, in appendix 6 of the UN MTC, table A6.3, additional functional groups are mentioned that may induce self-reactive behaviour. These functional groups are not present with the product. Therefore, the product does not need to be considered for classification as self-reactive.				
Pyrophoric liquids	-	-	None of the components of the product are classified as pyrophoric. Experience in the use of the product does not indicate that the	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			product will be pyrophoric.	
Pyrophoric solids	-	-	Not applicable to a liquid product.	-
Self-heating substances and mixtures	-	-	None of the components of the product are known to be self-heating. Experience in the use of the product does not indicate that the product is self-heating.	-
eCA remark: The product is a liquid and is not adhered to a large surface. Therefore, this hazard class does not apply.				
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.	-
eCA remark: The active substance is known not to be reactive to water, based on the data in the active substance dossier. Although there is no formal evidence for the other components, the perfumes and the matrix of the product are not expected to be able to react to water, nor release flammable gases.				
Oxidising liquids	-	-	Following a review of the components of the product it can be concluded that the product will not be oxidizing. All oxygen, fluorine and chlorine atoms are bonded only to carbon or hydrogen (see appendix 6 of the UN MTC).	-
Oxidising solids	-	-	Not applicable to a liquid product.	-
Organic peroxides	-	-	Following a review of the components of the product it can be	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			concluded that the product does not contain any organic peroxides.	
Corrosive to metals	-	-	This formula contains no acid, no base, no complexing agent and it's pH neutral (this formula contains no water as result 1% solution was used to determine pH for 36 months stability testing). The active content in this product was stable and never degraded below 2.3% at any testing interval. The 2.3% is within the allowed analytical variation. However, the active contains halogens but they are bound with carbon atoms. Based on the stability result there is no appreciable degradation to conclude that these halogens will be available to cause corrosion. The product is sold in plastic primary packaging which is suitable for this active (transfluthrin).	-
eCA remark: Transfluthrin Liquid Electric contains no acid, no base, no complexing agent, pH is not relevant since no water is present. However, the active substance transfluthrin contains halogens, Cl and F, although bound to carbon only and not in their free form in which they may be corrosive. Since the amount of active substance is only 0.88%w/w the eCA has agreed with a waiver for corrosiveness to metals study.				
Auto-ignition temperatures of products (liquids and gases)	A15	Transfluthrin Liquid electric refill with 0.88% Transfluthrin	Auto-ignition temperature is 211°C	[redacted] (2015) (2016)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Relative self-ignition temperature for solids	-	-	Not applicable to a liquid product.	
Dust explosion hazard	-	-	Not applicable to a liquid product.	-

Conclusion on the physical hazards and respective characteristics of the product
Following a review of the components of the product it can be concluded that the product is not explosive, flammable or oxidising. The product does not require classification under Regulation (EC) No 1272/2008 for physical 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		
Transfluthrin Liquid Electric Active substance: Transfluthrin (0.88% purity)	GC-FID, internal standard (Dipentyl phthalate) The product is dissolved in acetone together with the internal standard prior to analysis by GC.	80% (0.50%w/w), 100% (0.87%w/w) and 120% (1.25%w/w) of nominal content ; 3 replicates per fortification level	0.5988 - 2.3950 mg/mL (corresponding to 0.37 – 1.50 %w/w in the test item); r^2 = 0.9998 n: 7 Slope: 2.604 Intercept: 0.005	No interferences Analyte identity was confirmed by retention time match with analytical standards and by mass spectra data.	80% of nominal concentration – 120% of nominal concentration At 80% 100.97-101.37 At 100% 101.29 – 101.59 At 120% 99.86 – 100.72	Overall 101.01	System precision/RSD (n=6):0.38 Horwitz criterion: 2.73	N/A	[redacted] (2015) [redacted]
Transfluthrin Liquid Electric Active substance: Transfluthrin (0.88% purity)	GC-FID, internal standard (dibutyl phthalate) The product is dissolved in acetone together with the	80% (0.45%w/w), 100% (0.85%w/w) and 120% (1.12%w/w) of nominal content ; 3 replicates per fortification level	0.6117 mg/mL to 1.7990 mg/mL (corresponding to 0.38-1.12%w/w in the test item); r^2 = 0.9999 n: 6 Slope: 4.5751 Intercept: 0.0634	No interferences Analyte identity was confirmed by retention time match with analytical standards and by mass	80% of nominal concentration – 120% of nominal concentration At 80% 100.73-101.05 At 100%	Overall 100.14	System precision/RSD (n=6):0.28 Horwitz criterion: 2.76	N/A	[redacted] (2015d) [redacted]

	internal standard prior to analysis by GC.			spectra data.	99.66 – 99.72 At 120% 99.45 – 100.23				

N/A = Not Applicable

eCA remark: No analytical method for the SoC *BHT* and *Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics* are provided. This is considered acceptable since both *BHT* and *Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics* are not part of an equilibrium and the amount is therefore not likely to increase due to a shift in the equilibrium. Neither are both of the SoC a degradation product of a non-stabile substance.

Conclusion on the methods for detection and identification of the product
Two methods of analysis, both employing GC-FID are provided for the determination of the active substance in the product. Both methods were fully validated in accordance with SANCO/3030/99 rev. 4 11/07/00. An analytical method for the SoC *BHT* and *Hydrocarbons, C14-C19, isoalkanes, cyclics, <2% aromatics* is not considered necessary since the amount is not expected to increase. 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 are followed (store away from food, beverages and pet food and do not use in kitchens.).

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Transfluthrin liquid electric vaporiser consists of a liquid insecticide (PT18) formulation in a bottle, designed to fit a heater unit. The formulation is drawn up by the heated wick and evaporates at a suitable rate to provide an adequate level of protection against mosquitoes and house flies. Transfluthrin Liquid electric is a liquid that has been developed to eliminate mosquitoes and house flies effectively for up to 30, 40 or 45 nights/days (8 hours per night or day and depending on the refill size) or 20, 25 or 30 nights/days (12 hours per night of day and depending on the refill size) in a ventilated room.

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

The product is intended to control mosquitoes and house flies that may be a nuisance to humans and/or pets.

Products/Organisms to be protected: humans and pets

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, contained in the product refill has a broad spectrum of activity, affecting the insects 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 knockdown and death of the insect.

2.2.5.5 Efficacy data

The product consists of liquid insecticide formulation in a bottle, designed to fit a heater unit. The formulation is drawn up by the heated wick and evaporates at a suitable rate to provide an adequate level of protection against mosquitoes and house flies.

There are 3 types of heater which can use the same liquid formula refills:

- EDIE Base with only one evaporation rate and function mode.
- EDIE Advanced heater which can turn itself On and Off automatically as the heater has a programmable timer.There are also three levels of intensity settings.
- EDIE Dual or Adjustable which is similar to the Advanced heater with the exception that the consumer can choose the level of protection by altering the intensity to a low or high setting.

In each of the studies the product tested is exactly of the same composition as for which authorisation is requested.

Rationale for Exclusion of Lab Bench Tests

S.C. Johnson currently evaluates many insect control products using various test methods. As part of these product evaluations, rigorous test parameters are maintained as part of the methodologies used, while also trying to incorporate as close to real world consumer conditions as possible. Labs Bench Tests, such as the Cone Test Method, were not performed because they do not apply to this use of this product. The Cone Method is to be used when insects will be coming into contact with the product substrate (i.e. – bed nets). These Liquid Electric (LE) products are more in keeping with that of a heater driven device.

In the case of the LE efficacy test methods, the LE products were tested for claims purposes. The LE products were tested in large ($20m^3$) chambers against various species of insects (e.g. - *Aedes aegypti*, *Aedes albopictus*, *Anopheles stephensi*, *Culex quinquefasciatus* and *Musca domestica*). The insects were tested as caged and/or free-flying. While some tests were performed with Air Exchange (AE), most were performed in static mode (0 AE). Tests were performed on the LE products at Fresh Life & End life in order to show continued efficacy with the product throughout its life. For adjustable devices, the LE devices were tested at High & Low Settings of the devices. 24-hour Mortality data was generated for the tests as required for claims. The products were tested for a night's usage (8 hours). KT Values were calculated for all the tests and are in the reports in the dossier. The complete results are in the efficacy reports in the dossier.

Given the assurance that these products were tested with rigor and in simulated typical consumer room-sized ($20m^3$) chambers, it can be concluded that the efficacy studies for Liquid Electric mosquito claims accurately represent their performance. The applicant respectfully requests that the rationale and justification of the method followed be allowed to substantiate the effectiveness of this product as claimed.

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

<table>
<tr><th>Field of use</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>PT18</td><td>0.88% (w/w) transfluthrin

Vaporiser type: EDIE Liquid Base</td><td>House fly (Musca domestica) Laboratory cultured F58WT strain (treated) DDT resistant wild strain</td><td>Simulated use test

Environmental conditions:
Temperature 27 ± 4°C
Humidity: 50 ±10%
Artificial lighting

Replicates:
Three replicates per test substance variable are conducted daily along with four"no-treatment" control to monitor background counts and the potential for chamber contamination.

Number of houseflies (of mixed sex) tested per replicate: 50.

Chamber size/KD (knockdown) cage size:20m^3 chamber / KD cages were 240mL containers with aluminium mesh screens on two opposite sides.

Air-exchange rate: 2.5 exchanges per hour

The test substance was placed on the floor in the centre of the chamber and plugged in to a power source. The insects were release at the same time as the test substance was plugged in the power source.

At 5, 10, 15, 20, 25, 30, 40, 50, 60, 75, 90, 105, 120, 150, 180, 210, 240, 300, 360, and 480 minutes, the number of house flies knocked down was observed and recorded. After 24 hours, from test start, the number of dead house flies are counted.</td><td>Table : KT Values of free flying, house flies in 20 m^3 chambers in an 8-hour test using the liquid electric EDIE base and an air exchange rate of 2.5 per hour (50 m^3/h).

<table>
<tr><th></th><th colspan="2">Time to knockdown % of house flies (minutes)</th><th></th></tr>
<tr><th>Vaporiser / Age of Refill / Release Rate</th><th>KT$_{50}$</th><th>KT$_{80}$</th><th>24 hr. Mortality</th></tr>
<tr><td>EDIE Base / Fresh (40-48h) / (39.4 mg/hr.)</td><td>49.7</td><td>67.9</td><td>100</td></tr>
<tr><td>Control</td><td>n/a</td><td>n/a</td><td>1.5</td></tr>
</table>
Note: Numbers presented in table are estimates generated by linear interpolation of the mean % knockdown measured at 5,10,15,20,25,30,40, 50,60,75,90,105,120,150,180,210,240,300, 360 and 480 minutes.</td><td>[redacted] (2013)</td></tr>
</table>

<table>
<tr>
<td>PT18</td>
<td>0.88% (w/w) transfluthrin

Vaporiser type: EDIE Liquid Advanced</td>
<td>Yellow fever mosquito , (Aedes aegypti) Laboratory cultured</td>
<td>Simulated use test

Environmental conditions:
Temperature 27 ± 4°C
Humidity: 50 ±10%
Artificial lighting

Replicates:
Three replicates per test substance variable are conducted daily along with four"no-treatment" control to monitor background counts and the potential for chamber contamination.

Number of female mosquitoes tested per replicate: 10 mosquitoes per KD (knockdown) cages; 2 cages per replicate.

Chamber size/KD cage size: 20m^3 chamber / KD cages were 240mL containers with aluminium mesh screens on two opposite sides. Mosquito knockdown containers are placed in clamps secured to a pole. One knockdown cage, per species, is placed on each side of the chamber.

Air exchange rate: 0 exchanges per hour.

A fan (17.8cm) is placed facing the front of the chamber at ca. 45 degrees upward, and turned on at low speed to aid the mixing of air in the chamber.

The insects were placed in the chamber seconds before plugging in the test substance. The heater is plugged in and placed on the floor in the centre of the chamber to initiate the test.

At 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 180, 240, 360 and 480 minutes, the number of mosquitoes knocked down is counted and recorded. The test is concluded at 8 hours.</td>
<td>Table: KT Values of Caged, Female Mosquitoes in 20 m^3 Chambers in an 8-Hour Test
<table>
<tr><td></td><td colspan="5">Time to knockdown % of mosquitoes (minutes)
Treatment: 3 replicates; Control: 4 replicates</td></tr>
<tr><td>Age of Refill / Release Rate</td><td>KT$_{50}$</td><td>KT$_{80}$</td><td>KT$_{95}$</td><td>KT$_{100}$</td><td>24 hr. Mortality</td></tr>
<tr><td colspan="6">EDIE Advanced Liquid Electric - Low Setting</td></tr>
<tr><td>Fresh (24-32h) / (70.0 mg/hr)</td><td>25.7</td><td>29.1</td><td>35.7</td><td>40.0</td><td>100</td></tr>
<tr><td>End-life (144-152h) / (58.8 mg/hr)</td><td>25.0</td><td>28.1</td><td>29.7</td><td>50.0</td><td>100</td></tr>
<tr><td>Control - Fan Only</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>10</td></tr>
<tr><td colspan="6">EDIE Advanced Liquid Electric - High Setting</td></tr>
<tr><td>Fresh (24-32h) / (97.6 mg/hr)</td><td>25.1</td><td>28.1</td><td>29.7</td><td>50.0</td><td>100</td></tr>
<tr><td>End-life (120-128h) / (66.3 mg/hr)</td><td>25.3</td><td>28.7</td><td>34.0</td><td>40.0</td><td>100</td></tr>
<tr><td>Control - Fan Only</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>10</td></tr>
</table>
Note: Numbers presented in the table are estimates generated by linear interpolation of the mean % knockdown measured at 5, 10, 15, 20, 25, 30, 40, 50, 60, 75, 90, 105, 120, 150, 180, 210, 240, 300, 360, and 480 minutes.</td>
<td>[redacted](2015a)</td>
</tr>
</table>

<table>
<tr>
<td>PT18</td>
<td>0.88% (w/w) transfluthrin

Vaporiser type: EDIE Liquid Advanced</td>
<td>Tiger mosquitoes (Aedes albopictus) Laboratory cultured</td>
<td>Simulated use test

Environmental conditions:
Temperature 27 ± 4°C
Humidity: 50 ±10%
Artificial lighting

Replicates:
Three replicates per test substance variable are conducted daily along with four"no-treatment" control to monitor background counts and the potential for chamber contamination.

Number of female mosquitoes tested per replicate: 10 mosquitoes per KD (knockdown) cages; 2 cages per replicate.

Chamber size/KD cage size: 20m^3 chamber / KD cages were 240mL containers with aluminium mesh screens on two opposite sides. Mosquito knockdown containers are placed in clamps secured to a pole. One knockdown cage, per species, is placed on each side of the chamber.

Air exchange rate: 0 exchanges per hour.

A fan (17.8cm) is placed facing the front of the chamber at ca. 45 degrees upward, and turned on at low speed to aid the mixing of air in the chamber.

The insects were placed in the chamber seconds before plugging in the test substance. The heater is plugged in and placed on the floor in the centre of the chamber to initiate the test.

At 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 180, 240, 360 and 480 minutes, the number of mosquitoes knocked down is counted and recorded. The test is concluded at 8 hours.</td>
<td>Table: KT Values of Caged, Female Mosquitoes in 20 m^3 Chambers in an 8-Hour Test

<table>
<tr><th></th><th colspan="4">Time to knockdown % of mosquitoes (minutes)
Treatment: 3 replicates; Control: 4 replicates</th><th></th></tr>
<tr><th>Age of Refill / Release Rate</th><th>KT$_{50}$</th><th>KT$_{80}$</th><th>KT$_{95}$</th><th>KT$_{100}$</th><th>24 hr. Mortality</th></tr>
<tr><td colspan="6">EDIE Advanced Liquid Electric - Low Setting</td></tr>
<tr><td>Fresh (24-32h) / (70.0 mg/hr)</td><td>24.4</td><td>27.8</td><td>29.4</td><td>30.0</td><td>100</td></tr>
<tr><td>End-life (144-152h) / (58.8 mg/hr)</td><td>18.6</td><td>25.2</td><td>28.8</td><td>30.0</td><td>100</td></tr>
<tr><td>Control - Fan Only</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>13</td></tr>
<tr><td colspan="6">EDIE Advanced Liquid Electric - High Setting</td></tr>
<tr><td>Fresh (24-32h) / (97.6 mg/hr)</td><td>24.7</td><td>27.9</td><td>29.5</td><td>30.0</td><td>100</td></tr>
<tr><td>End-life (120-128h) / (66.3 mg/hr)</td><td>21.2</td><td>26,7</td><td>29.4</td><td>40.0</td><td>100</td></tr>
<tr><td>Control - Fan Only</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>13</td></tr>
</table>
Note: Numbers presented in the table are estimates generated by linear interpolation of the mean % knockdown measured at 5, 10, 15, 20, 25, 30, 40, 50, 60, 75, 90, 105, 120, 150, 180, 210, 240, 300, 360, and 480 minutes.</td>
<td>[redacted] (2015f)</td>
</tr>
</table>

PT18	0.88% (w/w) Transfluthrin Vaporiser type: EDIE Liquid Advanced	Southern house mosquito (*Culex quinquefasciatus*) Laboratory cultured	Simulated use test Environmental conditions: Temperature 27 ± 4°C Humidity: 50 ±10% Artificial lighting Replicates: Three replicates per test substance variable are conducted daily along with four"no-treatment" control to monitor background counts and the potential for chamber contamination. Number of female mosquitoes tested per replicate: 10 mosquitoes per KD (knockdown) cages; 2 cages per replicate. Chamber size/KD cage size: 20m^3 chamber / KD cages were 240mL containers with aluminium mesh screens on two opposite sides. Mosquito knockdown containers are placed in clamps secured to a pole. One knockdown cage, per species, is placed on each side of the chamber. Air exchange rate: 0 exchanges per hour. A fan (17.8cm) is placed facing the front of the chamber at *ca.* 45 degrees upward, and turned on at low speed to aid the mixing of air in the chamber. The insects were placed in the chamber seconds before plugging in the test substance. The heater is plugged in and placed on the floor in the centre of the chamber to initiate the test. At 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 180, 240, 360 and 480 minutes, the number of mosquitoes knocked down is counted and recorded. The test is concluded at 8 hours.	**Table:** KT Values of Caged, Female Mosquitoes in 20 m^3 Chambers in an 8-Hour Test Time to knockdown % of mosquitoes (minutes) Treatment: 3 replicates; Control: 4 replicates **Age of Refill / Release Rate** | **KT_{50}** | **KT_{80}** | **KT_{95}** | **KT_{100}** | **24 hr. Mortality** **EDIE Advanced Liquid Electric - Low Setting** **Fresh (24-32h) / (70.0 mg/hr)** | 36.8 | 48.0 | 57.8 | 70.0 | 100 **End-life (144-152h) / (58.8 mg/hr)** | 37.3 | 46.4 | 56.7 | 80.0 | 100 **Control - Fan Only** | n/a | n/a | n/a | n/a | 13 **EDIE Advanced Liquid Electric - High Setting** **Fresh (24-32h) / (97.6 mg/hr)** | 39.6 | 48.5 | 57.5 | 70.0 | 100 **End-life (120-128h) / (66.3 mg/hr)** | 43.2 | 49.6 | 64.0 | 70.0 | 100 **Control - Fan Only** | n/a | n/a | n/a | n/a | 13 Note: Numbers presented in the table are estimates generated by linear interpolation of the mean % knockdown measured at 5, 10, 15, 20, 25, 30, 40, 50, 60, 75, 90, 105, 120, 150, 180, 210, 240, 300, 360, and 480 minutes.	[redacted] (2015g)

PT18	0.88% (w/w) Transfluthrin Vaporiser type: EDIE Liquid Advanced	House fly (*Musca domestica*) Laboratory cultured F58WT strain (treated) DDT resistant wild strain	Simulated use test Environmental conditions: Temperature 27 ± 4°C Humidity: 50 ±10% Artificial lighting Replicates: Three replicates per test substance variable are conducted daily along with four"no-treatment" control to monitor background counts and the potential for chamber contamination. Number of mixed sexed houseflies tested per replicate: 10 houseflies per KD (knockdown) cages; 10 cages per chamber. Chamber size/KD cage size: 20m^3 chamber / KD cages were 240mL containers with aluminium mesh screens on two opposite sides. Mosquito knockdown containers are placed in clamps secured to a pole. One knockdown cage, per species, is placed on each side of the chamber. Air exchange rate: 0 exchanges per hour. A fan (17.8cm) is placed facing the front of the chamber at *ca.* 45 degrees upward, and turned on at low speed to aid the mixing of air in the chamber. The insects were placed in the chamber seconds before plugging in the test substance. The heater is plugged in and placed on the floor in the centre of the chamber to initiate the test. At 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 180, 240, 360 and 480 minutes, the number of mosquitoes knocked down is counted and recorded. The test is concluded at 8 hours.	**Table:** KT Values of Caged, Mixed sex house flies in 20 m^3 Chambers in an 8-Hour Test Time to knockdown % of the house flies (minutes) Treatment: 3 replicates; Control: 4 replicates **Age of Refill / Release Rate** | **KT_{50}** | **KT_{80}** | **KT_{95}** | **KT_{100}** | **24 hr. Mortality** **EDIE Advanced Liquid Electric - Low Setting** **Fresh (24-32h) / (70.0 mg/hr)** | 52.6 | 64.0 | 80.0 | 120.0 | 98 **End-life (144-152h) / (58.8 mg/hr)** | 40.7 | 54.0 | 67.5 | 110.0 | 100 **Control - Fan Only** | n/a | n/a | n/a | n/a | 0 **EDIE Advanced Liquid Electric - High Setting** **Fresh (24-32h) / (97.6 mg/hr)** | 47.1 | 57.3 | 75 | 100.0 | 100 **End-life (120-128h) / (66.3 mg/hr)** | 48.5 | 60.0 | 80.0 | 90.0 | 100 **Control - Fan Only** | n/a | n/a | n/a | n/a | 0 Note: Numbers presented in the table are estimates generated by linear interpolation of the mean % knockdown measured at 5, 10, 15, 20, 25, 30, 40, 50, 60, 75, 90, 105, 120, 150, 180, 210, 240, 300, 360, and 480 minutes.	[redacted] (2015h)

PT18	0.88% (w/w) Transfluthrin Vaporiser type: EDIE Liquid Dual or Adjustable	Yellow fever mosquito , (*Aedes aegypti*) Laboratory cultured	Simulated use test Environmental conditions: Temperature 27 ± 4°C Humidity: 50 ±10% Artificial lighting Replicates: Three replicates per test substance variable are conducted daily along with four"no-treatment" control to monitor background counts and the potential for chamber contamination. Number of female mosquitoes tested per replicate: 10 mosquitoes per KD (knockdown) cages; 2 cages per replicate. Chamber size/KD cage size: 20m^3 chamber / KD cages were 240mL containers with aluminium mesh screens on two opposite sides. Mosquito knockdown containers are placed in clamps secured to a pole. One knockdown cage, per species, is placed on each side of the chamber. Air exchange rate: 0 exchanges per hour. A fan (17.8cm) is placed facing the front of the chamber at *ca.* 45 degrees upward, and turned on at low speed to aid the mixing of air in the chamber. The insects were placed in the chamber seconds before plugging in the test substance. The heater is plugged in and placed on the floor in the centre of the chamber to initiate the test. At 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 180, 240, 360 and 480 minutes, the number of mosquitoes knocked down is counted and recorded. The test is concluded at 8 hours.	**Table:** KT Values of Caged, female mosquitoes in 20 m^3 Chambers in an 8-Hour Test Time to knockdown % of the mosquitoes (minutes) Treatment: 3 replicates; Control: 4 replicates **Age of Refill / Release Rate** | **KT_{50}** | **KT_{80}** | **KT_{95}** | **KT_{100}** | **24 hr. Mortality** **EDIE Dual or Adjustable Liquid Electric - Low Setting** **Fresh (24-32h) / (72.7 mg/hr)** | 24.7 | 28.4 | 32.5 | 40.0 | 100 **End-life (232-240h) (52.1 mg/hr)** | 25.3 | 28.4 | 30.0 | 50.0 | 100 **Control - Fan Only** | n/a | n/a | n/a | n/a | 4 **EDIE Dual or Adjustable Liquid Electric - High Setting** **Fresh (24-32h) /(79.5 mg/hr)** | 25.0 | 28.3 | 30 | 40.0 | 100 **End-life (216 -224h) /(66.0 mg/hr)** | 25.0 | 28.1 | 29.7 | 40.0 | 100 **Control - Fan Only** | n/a | n/a | n/a | n/a | 4 Note: Numbers presented in the table are estimates generated by linear interpolation of the mean % knockdown measured at 5, 10, 15, 20, 25, 30, 40, 50, 60, 75, 90, 105, 120, 150, 180, 210, 240, 300, 360, and 480 minutes.	[redacted] (2015e)

PT18	0.88% (w/w) Transfluthrin Vaporiser type: EDIE Liquid Dual or Adjustable	Tiger mosquito (*Aedes albopictus*) Laboratory cultured	Simulated use test Environmental conditions: Temperature 27 ± 4°C Humidity: 50 ±10% Artificial lighting Replicates: Three replicates per test substance variable are conducted daily along with four"no-treatment" control to monitor background counts and the potential for chamber contamination. Number of female mosquitoes tested per replicate: 10 mosquitoes per KD (knockdown) cages; 2 cages per replicate. Chamber size/KD cage size: 20m^3 chamber / KD cages were 240mL containers with aluminium mesh screens on two opposite sides. Mosquito knockdown containers are placed in clamps secured to a pole. One knockdown cage, per species, is placed on each side of the chamber. Air exchange rate: 0 exchanges per hour. A fan (17.8cm) is placed facing the front of the chamber at *ca.* 45 degrees upward, and turned on at low speed to aid the mixing of air in the chamber. The insects were placed in the chamber seconds before plugging in the test substance. The heater is plugged in and placed on the floor in the centre of the chamber to initiate the test. At 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 180, 240, 360 and 480 minutes, the number of mosquitoes knocked down is counted and recorded. The test is concluded at 8 hours.	**Table:** KT Values of Caged, Female Mosquitoes in 20 m^3 Chambers in an 8-Hour Test Time to knockdown % of the mosquitoes (minutes) Treatment: 3 replicates; Control: 4 replicates **Age of Refill / Release Rate** | **KT_{50}** | **KT_{80}** | **KT_{95}** | **KT_{100}** | **24 hr. Mortality** **EDIE Dual or Adjustable Liquid Electric - Low Setting** **Fresh (24-32h) / (72.7 mg/hr)** | 15.2 | 18.3 | 19.8 | 30.0 | 100 **End-life (232-240h) (52.1 mg/hr)** | 20.0 | 26.2 | 29.3 | 40.0 | 100 **Control - Fan Only** | n/a | n/a | n/a | n/a | 11 **EDIE Dual or Adjustable Liquid Electric - High Setting** **Fresh (24-32h) /(79.5 mg/hr)** | 23.2 | 27.3 | 29.3 | 30.0 | 100 **End-life (216 -224h) /(66.0 mg/hr)** | 21.9 | 26.8 | 29.2 | 30.0 | 100 **Control - Fan Only** | n/a | n/a | n/a | n/a | 11 Note: Numbers presented in the table are estimates generated by linear interpolation of the mean % knockdown measured at 5, 10, 15, 20, 25, 30, 40, 50, 60, 75, 90, 105, 120, 150, 180, 210, 240, 300, 360, and 480 minutes.	[redacted] (2015b)

<table>
<tr>
<td>PT18</td>
<td>0.88% (w/w) Transfluthrin

Vaporiser type: EDIE Liquid Dual or Adjustable</td>
<td>Southern house mosquito (Culex quinquefasciatus) Laboratory cultured</td>
<td>Simulated use test

Environmental conditions:
Temperature 27 ± 4°C
Humidity: 50 ±10%
Artificial lighting

Replicates:
Three replicates per test substance variable are conducted daily along with four"no-treatment" control to monitor background counts and the potential for chamber contamination.

Number of female mosquitoes tested per replicate: 10 mosquitoes per KD (knockdown) cages; 2 cages per replicate.

Chamber size/KD cage size: 20m^3 chamber / KD cages were 240mL containers with aluminium mesh screens on two opposite sides. Mosquito knockdown containers are placed in clamps secured to a pole. One knockdown cage, per species, is placed on each side of the chamber.

Air exchange rate: 0 exchanges per hour.

A fan (17.8cm) is placed facing the front of the chamber at ca. 45 degrees upward, and turned on at low speed to aid the mixing of air in the chamber.

The insects were placed in the chamber seconds before plugging in the test substance. The heater is plugged in and placed on the floor in the centre of the chamber to initiate the test.

At 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 180, 240, 360 and 480 minutes, the number of mosquitoes knocked down is counted and recorded. The test is concluded at 8 hours.</td>
<td>Table: KT Values of Caged, Female Mosquitoes in 20 m^3 Chambers in 8-Hours Test
<table>
<tr><th></th><th colspan="4">Time to knockdown % of the mosquitoes (minutes)
Treatment: 3 replicates; Control: 4 replicates</th><th></th></tr>
<tr><th>Age of Refill / Release Rate</th><th>KT$_{50}$</th><th>KT$_{80}$</th><th>KT$_{95}$</th><th>KT$_{100}$</th><th>24 hr. Mortality</th></tr>
<tr><td colspan="6">EDIE Dual or Adjustable Liquid Electric - Low Setting</td></tr>
<tr><td>Fresh (24-32h) / (72.7 mg/hr)</td><td>36.5</td><td>47.7</td><td>62.9</td><td>80.0</td><td>100</td></tr>
<tr><td>End-life (232-240h) (52.1 mg/hr)</td><td>42.2</td><td>58.0</td><td>75.0</td><td>80.0</td><td>100</td></tr>
<tr><td>Control - Fan Only</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>0</td></tr>
<tr><td colspan="6">EDIE Dual or Adjustable Liquid Electric - High Setting</td></tr>
<tr><td>Fresh (24-32h) /(79.5 mg/hr)</td><td>39.5</td><td>49.4</td><td>63.3</td><td>90.0</td><td>100</td></tr>
<tr><td>End-life (216 -224h) /(66.0 mg/hr)</td><td>48.1</td><td>57.4</td><td>65.7</td><td>70.0</td><td>100</td></tr>
<tr><td>Control - Fan Only</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>0</td></tr>
</table>
Note: Numbers presented in the table are estimates generated by linear interpolation of the mean % knockdown measured at 5, 10, 15, 20, 25, 30, 40, 50, 60, 75, 90, 105, 120, 150, 180, 210, 240, 300, 360, and 480 minutes.</td>
<td>[redacted] (2015c)</td>
</tr>
</table>

<table>
<tr>
<td>PT18</td>
<td>0.88% (w/w) Transfluthrin

Vaporiser type: EDIE Liquid Dual or Adjustable</td>
<td>House fly (Musca domestica) Laboratory cultured F58WT strain (treated) DDT resistant wild strain</td>
<td>Simulated use test

Environmental conditions:
Temperature 27 ± 4°C
Humidity: 50 ±10%
Artificial lighting

Replicates:
Three replicates per test substance variable are conducted daily along with four"no-treatment" control to monitor background counts and the potential for chamber contamination.

Number of female mosquitoes tested per replicate: 10 mosquitoes per KD (knockdown) cages; 2 cages per chambers.

Chamber size/KD cage size: 20m^3 chamber / KD cages were 240mL containers with aluminium mesh screens on two opposite sides. Mosquito knockdown containers are placed in clamps secured to a pole. One knockdown cage, per species, is placed on each side of the chamber.

Air exchange rate: 0 exchanges per hour.

A fan (17.8cm) is placed facing the front of the chamber at ca. 45 degrees upward, and turned on at low speed to aid the mixing of air in the chamber.

The insects were placed in the chamber seconds before plugging in the test substance. The heater is plugged in and placed on the floor in the centre of the chamber to initiate the test.

At 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 180, 240, 360 and 480 minutes, the number of mosquitoes knocked down is counted and recorded. The test is concluded at 8 hours.</td>
<td>Table: KT Values of Caged, Mixed sex house flies in 20 m^3 Chambers in an 8-Hour Test
<table>
<tr><td></td><td colspan="5">Time to knockdown % of the house flies (minutes)
Treatment: 3 replicates; Control : 4 replicates</td></tr>
<tr><td>Age of Refill / Release Rate</td><td>KT$_{50}$</td><td>KT$_{80}$</td><td>KT$_{95}$</td><td>KT$_{100}$</td><td>24 hr. Mortality</td></tr>
<tr><td colspan="6">EDIE Dual or Adjustable Liquid Electric - Low Setting</td></tr>
<tr><td>Fresh (24-32h) / (72.7 mg/hr)</td><td>43.8</td><td>62.2</td><td>85.0</td><td>180.0</td><td>98</td></tr>
<tr><td>End-life (232-240h) (52.1 mg/hr)</td><td>48.0</td><td>62.5</td><td>86.7</td><td>180.0</td><td>100</td></tr>
<tr><td>Control - Fan Only</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>0</td></tr>
<tr><td colspan="6">EDIE Dual or Adjustable Liquid Electric - High Setting</td></tr>
<tr><td>Fresh (24-32h) /(79.5 mg/hr)</td><td>44.4</td><td>53.0</td><td>66.7</td><td>90.0</td><td>100</td></tr>
<tr><td>End-life (216 -224h) /(66.0 mg/hr)</td><td>51.4</td><td>59.5</td><td>80.0</td><td>90.0</td><td>100</td></tr>
<tr><td>Control - Fan Only</td><td>n/a</td><td>n/a</td><td>n/a</td><td>n/a</td><td>0</td></tr>
</table>
Note: Numbers presented in the table are estimates generated by linear interpolation of the mean % knockdown measured at 5, 10, 15, 20, 25, 30, 40, 50, 60, 75, 90, 105, 120, 150, 180, 210, 240, 300, 360, and 480 minutes.</td>
<td>[redacted] (2015d)</td>
</tr>
</table>

<table>
<tr>
<td>PT18</td>
<td>0.88% (w/w) Transfluthrin

Vaporiser type: EDIE Liquid Base</td>
<td>Aedes aegypti, Culex quinquefasciatus, Anopheles stephensi and Aedes albopictus Laboratory cultured</td>
<td>Simulated use test

Environmental conditions:
Temperature 27 ± 4°C
Humidity: 50 ±10%
Artificial lighting

Replicates: 4 replicates of Test Substance and 4 replicates of Untreated Control

No. of mosquitoes per replicate:10 females per cage; 20 cages per chamber. Five adjustable poles were placed in the chamber at each location. The locations were in all four corners and in the centre of the chamber. At each location, there were clamps at 0.91 and 1.83 meters from the floor upon which to hang two sets of each mosquito species (4 species) at each location and at the different heights.

Air-exchange rate: 0 exchanges per hour, No fan.

The insects were placed into the chamber, then the Test Substance was plugged into an outlet, on the floor against one side of the wall in a 20m^2 footprint chamber (48.6m^3 volume). The product was tested, at fresh (40 hrs) aged and efficacy was determined using caged mosquitoes by observing knockdown periodically through an eight hour test (every 10 minutes through 120 minutes, and then hourly until 8 hrs.) and then observing and recording 24 hour mosquito mortality.</td>
<td>Table 1: KT Values (Time in Minutes) -Time to Knockdown (50%, 80%, 90% and 95%) of the Mosquitoes Using Test Substance 0.88% Transfluthrin (Europe) Liquid Electric (refill aged for 40 Hours) using Edie Base Vaporiser.
<table>
<tr><th>KT Value</th><th>Aedes aegypti</th><th>Culex quinquefasciatus</th><th>Anopheles stephensi</th><th>Aedes albopictus</th></tr>
<tr><td>KT_{50}</td><td>56.7</td><td>88.6</td><td>51.8</td><td>56.8</td></tr>
<tr><td>KT_{80}</td><td>98.0</td><td>160.1</td><td>88.4</td><td>86.9</td></tr>
<tr><td>KT_{90}</td><td>113.8</td><td>200.5</td><td>106.0</td><td>98.1</td></tr>
<tr><td>KT_{95}</td><td>120.4</td><td>220.8</td><td>117.1</td><td>115.7</td></tr>
<tr><td>24 hr. Mortality</td><td>100%</td><td>100%</td><td>100%</td><td>100%</td></tr>
</table>
Note: Numbers presented in the table are estimates generated by linear interpolation of the mean % knockdown measured at 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, 110, 120, 180, 240, 300, 360, 420, and 480 minutes.

Table 2: Percentage Knockdown & 24 hr. mortality (Time in Minutes) of the Mosquitoes Using Control Test Substance.
<table>
<tr><th>Species</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>Aedes aegypti</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Culex quinquefasciatus</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Anopheles stephensi</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Aedes albopictus</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
</table>
<table>
<tr><th>Species</th><th>100</th><th>110</th><th>120</th><th>240</th><th>300</th><th>360</th><th>420</th><th>480</th><th>24 hrs. Mortality</th></tr>
<tr><td>Aedes aegypti</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Culex quinquefasciatus</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Anopheles stephensi</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
<tr><td>Aedes albopictus</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>1</td></tr>
</table>
</td>
<td>[redacted] (2015)</td>
</tr>
</table>

<table>
<tr>
<td>PT18</td>
<td>SCJ Raid Liquid Electric : 0.88% (w/w) Transfluthrin

Vaporiser type: EDIE Dual Heater Liquid Electric</td>
<td>Aedes aegypti, Culex quinquefasciatus</td>
<td>Simulated use test

Environmental conditions:
Temperature 27 ± 5°C
Humidity: 50 ±20%
Artificial lighting

Replicates: 2 replicates of Test Substance per Air-exchange rate.

No. of mosquitoes per replicate:10 females per species per cage; 4 cages per chamber per replicate (16 cages total).

Chamber size/KD cage size: 30m^3 chamber / KD cages were 240mL containers with aluminium mesh screens on two opposite sides of the room. Mosquito knockdown containers are placed in clamps secured to a pole. At both locations, there were clamps at 0.91 and 1.83 meters from the floor upon which to hang two sets of each mosquito species at the different heights.

Air-exchange rate: 0 and 2,5

The insects were placed in the chamber seconds before plugging in the test substance. The heater is plugged in and placed on the floor in the centre of the chamber to initiate the test.

At 5, 10, 15, 20,25, 30, 40, 50, 60, 75, 90, 105, 120, 180, 240, 300, 360, 420 and 480 minutes, the number of mosquitoes knocked down is counted and recorded. After 8 hours the air in the test chamber is purged from the product. After 24 hours mosquito mortality is recorded.
The product was tested, at fresh (40 hrs aged).</td>
<td>Table1: KT values (Time in minutes) – Time to Knockdown (50, 80 and 90%) of the Mosquitoes Using Test Sunstance SCJ Liquid Electric, using Edie Dual Heater on Low in 30m3 chamber with 2.5 & O Air Exchange.

<table>
<tr><th>KT Value</th><th>Aedes aegypti, 2.5 AE</th><th>Aedes aegypti, 0 AE</th><th>Culex quinquefasciatus, 2.5 AE</th><th>Culex quinquefasciatus, 0 AE</th></tr>
<tr><td>KT$_{50}$</td><td>35.4</td><td>39.5</td><td>74.4</td><td>82.8</td></tr>
<tr><td>KT$_{80}$</td><td>41.8</td><td>46.1</td><td>93.8</td><td>103.1</td></tr>
<tr><td>KT$_{90}$</td><td>45.9</td><td>48.3</td><td>100.4</td><td>115.6</td></tr>
<tr><td>24 hr. Mortality</td><td>100%</td><td>100%</td><td>100%</td><td>100%</td></tr>
</table>
Note: Numbers presented in the table are estimates generated by linear interpolation of the mean % knockdown measured at 5, 10, 15, 20,25, 30, 40, 50, 60, 75, 90, 105, 120, 180, 240, 300, 360, 420 and 480 minutes.

Controls were conducted for 120 minutes. During those 120 minutes 0% knockdown or mortality occurred for both mosquito species.</td>
<td>[redacted] (2019)</td>
</tr>
</table>

Conclusion on the efficacy of the product
Transfluthrin Liquid Electric can be used against mosquitoes and flies. The efficacy of EDIE Base, EDIE Advanced heater and EDIE Dual or Adjustable was demonstrated in the submitted simulated-use tests against Muscidae (shown on *Musca domestica*) and Mosquitoes (shown on *Culex quinquefascia, Aedes aegypti, Aedes albopictus , and Anopheles stephensi*). Evaluation of efficacy data demonstrate that the formula refill and the different heaters meet the requirements from the Technical Notes of Guidance for product Type 18 - CA-Dec12-Doc.6.2.a_Final – and support all the product label claims. See section 2.2.5.8 for a more detailed evaluation of the label claims.

2.2.5.6 Occurrence of resistance and resistance management

No resistance to Transfluthrin Liquid Electric products has been reported for the target species. Therefore no resistance management measures are required.

2.2.5.7 Known limitations

No efficacy limitations have been found if the product is used according to the use instructions.

2.2.5.8 Evaluation of the label claims

Label instructions and claims:

EDIE Base (Mosquito & Fly)

Transfluthrin Liquid Electric protects a room of up to 20m^3 for flies and up to 30 m^3 for mosquitoes for up to 240 hours or 360h (depending on the size of the refill).

The level of the liquid can be easily observed: when the bottle is finished, insert a new refill for another 240 hours or 360hours of protection.

For optimal efficacy against mosquitoes and flies, activate the device 1 hour in advance. Product is efficacious in ventilated rooms.

EDIE Dual holder (Mosquito & Fly)

Transfluthrin Liquid Electric protects a room of up to 20m^3 for flies and up to 30 m^3 for mosquitoes for up to 240 hours or 360 hours (depending on the size of the refill and the used intensity setting).

Up to 45 nights/days (used for 8 hours) of continuous protection (360 hours) when used on low setting with Dual Holder for mosquitoes and flies.

Up to 30 nights/days (used for 8 hours) of continuous protection (240 hours) when used on high setting with Dual Holder for mosquitoes and flies

For optimal efficacy, activate the device 1 hour in advance.
Product is efficacious in ventilated rooms.

EDIE Advanced holder (Mosquito & Fly)
Transfluthrin Liquid Electric protects a room of up to 20m^3 for flies and up to 30 m^3 for mosquitoes for up to 320 hours.

There are three levels of protection: Low, Medium and High.
Up to 40 nights/days (used for 8 hours) of continuous protection (320 hours) when used on low setting with Advanced Holder for mosquitoes and flies.

For optimal efficacy, activate the device 1 hour in advance.
Product is efficacious in ventilated rooms.

House Flies (Musca domestica):

Against house flies 1 simulated use test was provided.

A study performed using the EDIE Base ([redacted] (2013)) demonstrated that in a 20 m^3 chamber, employing a "cold" treatment test start, and using a consumer-simulated air exchange rate of 2.5 room exchanges per hour, the test substance can provide 100% knockdown for House flies (*Musca domestica*) by 2 hours and 100% mortality by 24-hour with simulated open windows. Although the study performed was only conducted during the initial product service life, a study conducted to investigate the evaporation rate (IUCLID Section 3.5: Vaporization Rate, [redacted] (2015a)) showed that EDIE Base has a stable release rate during all of the product service life ((average 0.43 g/cycle of 8 hours = 0.47 mg Transfluthrin/h), see Graph E1).

From this study in conjunction with the study performed by [redacted] (2015) it is possible to conclude that the devices will be effective against flies in rooms up to 20m^3 and during all of the claimed duration 240h (30 nights x 8h) with windows open

Mosquitoes:

Against mosquitoes 10 simulated use tests were provided.

All trials submitted demonstrate efficacy of the three devices tested; EDIE Base, EDIE Advanced heater and EDIE Dual (Adjustable).

-4 Studies reported by [redacted] (2015a, f, g and h) demonstrated efficacy of the global 0.88% transfluthrin liquid electric formula using the EDIE Advanced Heater (Liquid Electric Advanced) at low (58.8-70.0 mg/hr) and high (66.3-97.6mg/hr) settings, employing a "cold" treatment test start, in a 20m^3 room size against standard European mosquitoes (*Aedes aegypti*, *Aedes albopictus* and *Culex quinquefasciatus*) and Common house flies (*Musca domestica*). Protection of up to 144-152 h at low setting was demonstrated.

These tests achieved an average mosquito knockdown (KT_{80}: 26.5-47.2 min / KT_{95}: 29.1-57.3 min using low setting and KT_{80}: 27.3-49.05 min / KT_{95}: 29.5-60.8 min using high setting) and house fly knockdown (KT_{80}: 59.0 min / KT_{95}: 73.8 min using low setting and

KT_{80}: 58.7 min / KT_{95}:77.5 min using high setting). These data demonstrate the efficacy against mosquitoes and house flies in a 20 m^3 room.

-4 Studies reported by [redacted] (2015b, c, d and e) demonstrated efficacy of the global 0.88% transfluthrin liquid electric formula using the EDIE Dual (Adjustable) Heater (Liquid Electric Adjustable) at low (52.1-72.7 mg/hr) and high (66.0-79.5 mg/hr) settings, employing a "cold" treatment test start, in a 20m^3 room size against the standard European mosquitoes (*Aedes aegypti*, *Aedes albopictus* and *Culex quinquefasciatus*) and Common house flies (*Musca domestica*). Protection of up to 232-240 h was demonstrated.

These tests achieved an average mosquito knockdown (KT_{80}: 22.3-52.9 min / KT_{95}: 24.6-69.0 min using low setting and KT_{80}: 27.1-53.4 min / KT95: 29.3-64.5 min using high setting) and a fast house fly knockdown (KT_{80}: 63.7 min / KT_{95}: 85.9 min using low setting and KT_{80}: 56.3 min / KT_{95}:73.4 min using high setting). These data demonstrate the efficacy against mosquitoes and house flies in a 20m^3 room.

A study performed using the EDIE Base ([redacted] (2015)) demonstrated that in an unventilated (0 air-exchange rate)20 m^2 chamber (equivalent to 48.6m^3 volume) the test substance can provide 100% knockdown in 4 hours for four species of mosquitoes (*Aedes aegypti, Culex quinquefasciatus, Anopheles stephensi* and *Aedes albopictus*) and 100% mortality after 24 hours. The study was performed using a refill that had been aged 40 hours.

A study performed using the EDIE Dual heater ([redacted] 2019) demonstrated that in a ventilated (2.5 air-exchange rate) 30m^3 chamber the test substance can provide 100% knockdown within 3 hours for two species of mosquitoes (*Aedes aegypti & Culex quinquefasciatus)* and 100% mortality after 24 hours. The study was performed using a refill that had been aged 40 hours.

From this study in conjunction with the study performed by [redacted] (2015) it is possible to conclude that the devices will be effective against mosquitoes in rooms that are 48.6m^3 if the windows are closed and 30m^3 with the windows open.

All the simulated use tests were performed with light and not in dark conditions. Most mosquitoes are more active during nighttime and the light regime could influence the behaviour of the mosquitoes. However, the eCA considers the conducted test with light conditions representative for the efficacy of the product as in this test set-up the behaviour of the mosquitoes placed in the chamber will not influence whether the substance in the air will kill them or not.

Efficacy during the whole lifetime of the product:

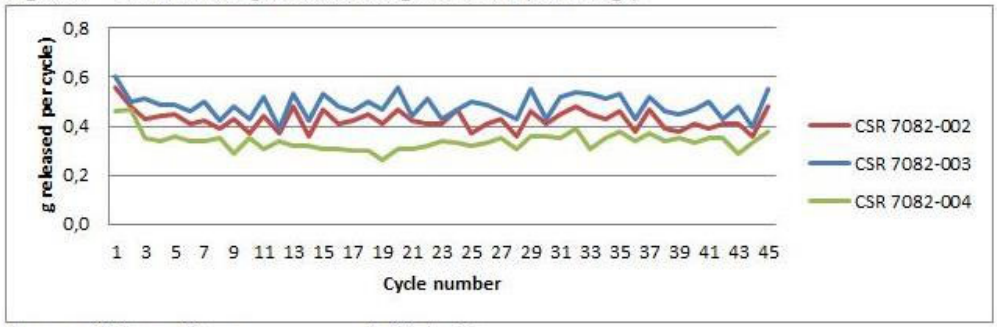
Although the test reports were not conducted during all the durations claimed (EDIE Dual (Adjustable), 45 nights-360 h and EDIE Advanced Heater 40 nights-320 h) , the release rate is considered stable for 45 nights. This is based on the results from the evaporation rate study ([redacted] (2015) presented in IUCLID Section 3.5) and below in the PAR.

From the graphs (Graph E1, E2 and E3) it can be concluded that the different heaters (EDIE Base, EDIE Adjustable and EDIE Advance Heater at low and high setting) have a stable release rate and the duration of use for the refill only depends upon the size of the refill. As

a consequence, if the release rate is stable, efficacy is stable and will be assured during the lifetime of the refill.

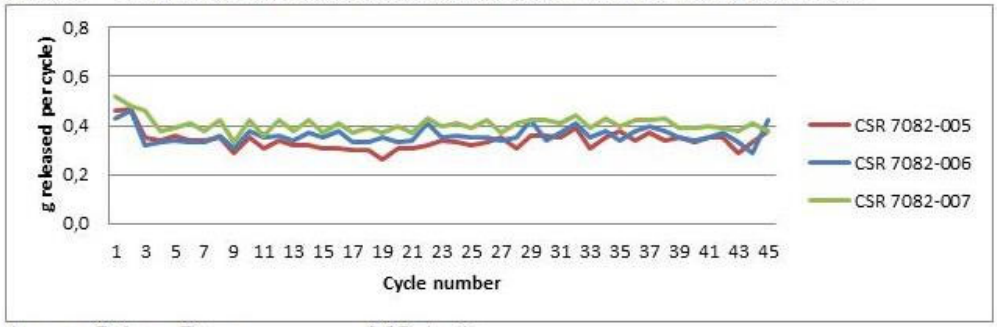
Test substance number: 15436R171
Document Number: CEMR-7082
Study Number: CEMS-7082

Figure 7 Release rate per heater using Base units (no storage)



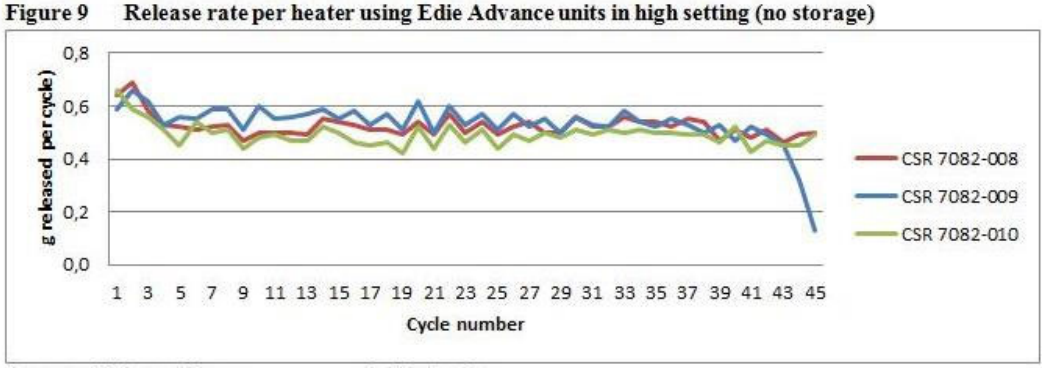
Average Release Rate = 0.43g/cycle

Figure 8 Release rate per heater using Edie Advance units in low setting (no storage)



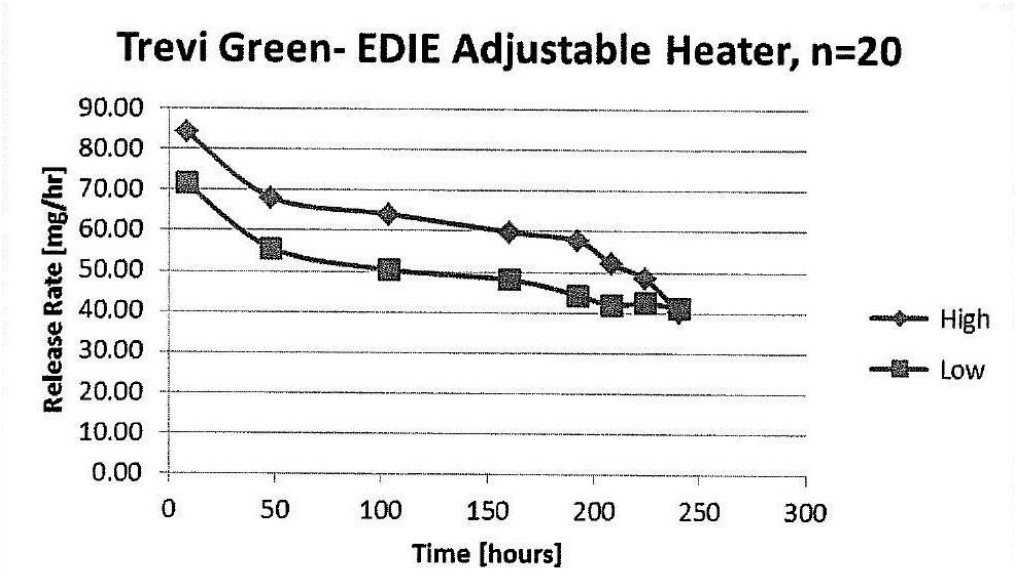
Average Release Rate = 0.37g/cycle

Figure 9 Release rate per heater using Edie Advance units in high setting (no storage)

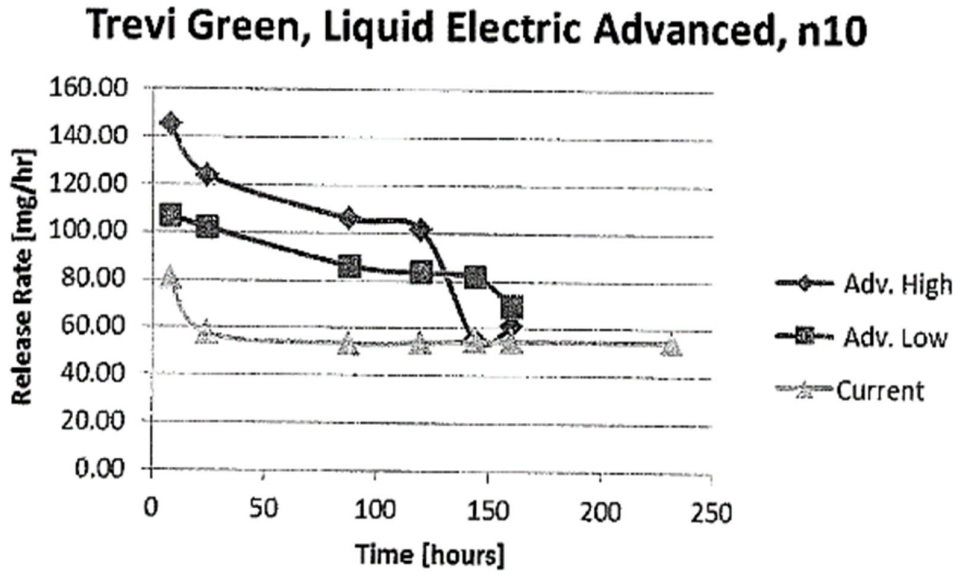


Average Release Rate = 0.52g/cycle

Graph E1: Release rate (g/cycle of 8h) per heater EDIE Base and EDIE Advanced Heater (low and high setting) [redacted], 2015a Physical/chemical testing study on Trevi Green test items [redacted])



Graph E2: Release rate (mg/h) per heater EDIE Adjustable (low and high setting) from ([redacted] (year unknown)



Graph E3: Release rate (mg/h) per heater EDIE Advanced (low and high setting) and EDIE Base (Current) from ([redacted] (year unknown))

The different variants of the Liquid Electric product (Base, Dual (Adjustable) and Advance) are summarized in the table below. In each case, the range of emission rates and associated duration of protection (assuming 8 hours use per day) are listed. It should be noted that for each variant different fill levels are available (small = 21 mL; Large = 31 ml). In addition, for the Advance variant a 'starter pack' is also available, with fill level 33 mL.

Heater	Fill level (mL)	Weight of fill (g)	Mass of transfluthrin (g)	Rate	Emission rate (mg formula/hr)[3]	Use duration (hrs per day)	Total Duration (hrs)
Base	21 mL	16.4	0.14432	[-]	55mg/hr	8hrs/day	240 hrs (30 Nights)
Base	31 mL	25.2	0.22176	[-]	55mg/hr	8hrs/day	360 hrs (45 nights)
Adjustable (Dual)	21 mL	16.4	0.14432	Low	55mg/hr	8hrs/day	240 hrs (30 Nights)
				High	65mg/hr	8hrs/day	224 hrs (28 Nights)
Adjustable (Dual)	31 mL	25.2	0.22176	Low	55mg/hr	8hrs/day	360hrs (45 nights)
				High	65mg/hr	8hrs/day	320hrs (40nights)
Advance	21 mL	16.4	0.14432	Low	80mg/hr	8hrs/day	160 hrs (20Nights)
				High	110 mg/hr	8hrs/day	128hrs (16 Nights)
Advance	31 mL	25.2	0.22176	Low	80mg/hr	8hrs/day	240hrs (30nights)
				High	110 mg/hr	8hrs/day	192hrs (24 nights)
Advance (starter pack)	33 mL	26.8	0.2358	Low	80mg/hr	8hrs/day	320 hrs (40nights)
				High	110 mg/hr	8hrs/day	224hrs (28 nights)

The EDIE Dual or Adjustable heater has an emanation rate after 100 hours of approximately 0.44 mg Transfluthrin/h at the low setting and 0.57 mg Transfluthrin/h at high setting ([redacted] (year unknown)).

Although release rates in Graph E3 are higher than in Graphs E1 and E2, it demonstrates that release rates of EDIE Advanced at low and high settings are higher than EDIE Base, and therefore require a reduced duration statement vs EDIE Base. This data also supports bridging EDIE Base efficacy data for ventilated rooms to EDIE Advance at the low and high settings.

[3] Derived from [redacted] (year unknown).

Efficacy of the different release rates of the heaters:

The following table shows the relationship between release rate (mg Transfluthrin/m^3) and efficacy from low evaporation rate (EDIE Adjustable at the Low setting) to higher evaporation rate (EDIE Adjustable heater at the high release rate). Although there are no empirical data for the EDIE base device (except for a study assessing the effect of open window and house flies) it is possible to bridge the efficacy data for mosquitoes to the EDIE Base device, from the low level of the Adjustable device where we make the same duration claims as the base device.

EDIE device	**Data from Graph E2 and E3**		**Efficacy against *Culex quinquefasciatus* ([redacted] (2015g)) in 20m³ room**		**Efficacy against *Musca domestica* ([redacted] (2015h)) in 20m³ room**	
	g formula /h	**mg Transfluthrin /h**	**KT_{80}**	**KT_{95}**	**KT_{80}**	**KT_{95}**
Adjustable Low setting	0.050	0.44	Fresh (24h):48.0 m Final (144h): 46.4m	Fresh (24h):57.8m Final (144h): 56.7m	Fresh (24h):64.0 m Final (144h): 54.0m	Fresh (24h): 80.0 m Final (144h): 67.5 m
Base	0.054	0.47	No data but can be bridged due to the release rate	No data but can be bridged due to the release rate	Data with open windows	Data with open windows
Adjustable High setting	0.065	0.57	Fresh (24h): 48.5m Final (144h): 49.6m	Fresh (24h):57.5 m Final (144h):64.0 m	Fresh (24h):57.3m Final (144h):60.0m	Fresh (24h): 75.0m Final (144h): 80.0 m

EDIE device	**Data from Graph E2 and E3**		**Efficacy against *Aedes aegypti* ([redacted] (2015a)) in a 20m³ room**		**Efficacy against *Aedes albopictus* ([redacted] (2015f)) in a 20m³ room**	
	g formula/h	**mg Transfluthrin/h**	**KT_{80}**	**KT_{95}**	**KT_{80}**	**KT_{95}**
Adjustable Low setting	0.050	0.44	Fresh (24h): 29.1m Final (144h): 28.1m	Fresh (24h): 35.7m Final (144h): 29.7m	Fresh(24h): 27.8 m Final (144h): 25.2 m	Fresh (24h): 29.4m Final (144h): 28.8m
Base	0.054	0.47	No data but can be bridged due to the release rate	No data but can be bridged due to the release rate	No data but can be bridged due to the release rate	No data but can be bridged due to the release rate
Adjustable High setting	0.065	0.57	Fresh (24h): 28.1 m Final (144h): 28.7 m	Fresh (24h): 29.7m Final (144h): 24.0m	Fresh (24h):27.9 m Final (144h): 26.7m	Fresh (24h): 29.5m Final (144h):29.4 m

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.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

A skin irritation study has been performed using a similar formulation to Transfluthrin Liquid Electric (Baygon Genius) with the exception that it contains a different fragrance and solvent composition (please refer to the confidential bridging letter entitled, "Bridging letter Trevi and Hydrogenius" contained within IUCLID Section 13).

The results from this study are considered to be valid for the assessment of the formulation and a separate assessment has also been performed based upon the calculation method for mixtures defined in Regulation (EC) No 1272/2008.

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 404/ EC Guideline B.4.	Rabbit, Himalayan, 3 males	0.5 ml, 4 h exposure	Not irritating (0 at all timepoints)	None	[redacted] (1997a)

No human data are available.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The product does not require classification for skin irritation according to Regulation (EC) No 1272/2008.
Justification for the value/conclusion	The result from the study ([redacted] (1997)) performed using a similar formulation to Transfluthrin Liquid Electric (Baygon Genius) with the exception that it contains a different fragrance and solvent composition (please refer to the confidential bridging letter entitled, "Bridging letter Trevi and Hydrogenius" contained within IUCLID Section 13), concludes that the product should not be classified as a skin irritant. The difference in solvent composition is considered to be the most relevant difference. Although there is a relatively large difference in concentrations of these solvents, they are structurally closely related. Moreover, the main solvent used in Baygon Genius (the formulation used for the skin irritation

	study) shows a higer level of skin irritation in rabbits compared to the main solvent in Transfluthrin Liquid Electric and a study performed with Bayon genius is therefore considered to be worst case and bridging is therefore acceptable. In addition to the difference in solvent composition, the change in formulation includes a new fragrance material. Citronella oil was added to the product at 1%. Citronella oil is classified as a skin irritant and therefore the calculation was conducted as instructed under Regulation (EC) No 1272/2008. 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. There are two substances in the product (Transfluthrin and Citronella Oil) that are classified for skin irritation (Skin Irrit. 2; H315), however, when summed the ingredients are not ≥10% and, therefore, do not require classification. The product does not, therefore, require classification for skin irritation according to Regulation (EC) No 1272/2008. The calculation method is considered adequate to determine the classification. An additional study assessing skin irritation with Transfluthrin Liquid Electric is not required, nor considered an appropriate use of animals. A study ([redacted] (1997)) on a similar product containing the active substance, Transfluthrin, concluded that the product is not irritating to skin which is in line with the calculation performed according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Not classified

Eye irritation

An eye irritation study has been performed using a similar formulation to Transfluthrin Liquid Electric (Baygon Genius) with the exception that it contains a different fragrance and solvent composition (please refer to the confidential bridging letter entitled, "Bridging letter Trevi and Hydrogenius" contained within IUCLID Section 13).

The classification of product is based on the calculation method for mixtures defined in Regulation (EC) No 1272/2008 and is supported by the results from this study.

Summary table of in vitro studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
EU Method B.5 (Acute Toxicity: Eye Irritation / Corrosion) OECD Guideline 405 (Acute Eye Irritation / Corrosion), GLP, Reliability 2	Baygon Genius (0.88% transfluthrin), 0.1 mL/ animal	3♀ Himalayan rabbits; single dose administered into the conjunctival sac of the right eye and the lid gently held together for *ca* 1s. Rabbits were kept in restrainers for 8h.	All scores were 0 at 1h, 24h, 48h and 72h. Not irritating to eyes	None	[redacted] (1997b)

No 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	The result from the study ([redacted] (1997b)) performed using a similar formulation to Transfluthrin Liquid Electric (Baygon Genius) with the exception that it contains a different fragrance and solvent composition (please refer to the confidential bridging letter entitled, "Bridging letter Trevi and Hydrogenius" contained within IUCLID Section 13), concludes that the product should not be classified as an eye irritant. The difference in solvent composition is considered to be the most relevant difference. Although there is a relatively large difference in concentrations of these solvents, they are structurally closely related. However, the main solvent used in Baygon Genius (the formulation used for the skin irritation study) does not show eye irritation in rabbits whereas the main solvent in Transfluthrin Liquid Electric did show slight irritation in rabbits. Although the respective solvent does not have an harmonised classification for eye irritation, the study performed with Bayon Genius might represent an underestimation of eye irritation compared to Translfluthrin Liquid Electric and the eye irritation study with Bayon genius is therefore considered to present supplemental information. In addition to the difference in solvent composition, the change in formulation includes a new fragrance material. Citronella oil was added to the product at 1%. Citronella oil is classified as an eye irritant and therefore the calculation was conducted as instructed under Regulation (EC) No 1272/2008. 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 in the confidential annex. One of the co-formulants (Citronella oil) is classified as Eye Dam. 1; H318, however, when using the calculation method to assess the mixture components, in the absence of any study data generated using the mixture, as the substance which is classified as H318 is <1%, the product does not require classification. The calculation method in combination with the bridged study is considered adequate to determine the classification. An additional study assessing eye irritation with Transfluthrin Liquid Electric is not required, nor considered an appropriate use of animals. A study ([redacted] (1997b)) on a similar product containing the active substance, Transfluthrin, concluded that the product is not irritating to eyes.
Classification of the product according to CLP	Not classified

Respiratory tract irritation

Endpoint not required.

Skin sensitization

A Modified Buehler Design Sensitisation Study was performed.

A separate assessment has also been performed based upon the calculation method for mixtures defined in Regulation (EC) No 1272/2008.

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
Modified Buehler Design OECD Guideline 406; EPA OPPTS 870.2600; EU Method B.6; JMAFF Agchem Test Guidelines, 12 Nohsan No. 8147, Skin Sensitization (2-1-6) GLP, Reliability 1	Guinea pig; Hartley-derived albino; 10 ♀ and 10 ♂	Baygon TG2 (0.88% transfluthrin); mineral oil USP; dose 0.3 ml; Induction: 100%; Challenge (test and control groups): 75%; Re-challenge (test and control groups): 25 and 50%; exposure *ca* 6h, dermal exposure using an occlusive patch.	1/20 test animals at 24h 1/10 challenge controls at 24h Not Sensitising	Please see below*	[redacted] (2004)

* Following rechallenge with 25% w/w Baygon TG2 in mineral oil, USP, dermal reactions in the test and rechallenge control animals were scores of O. Group mean dermal scores were noted to be the same in the test animals as compared with the rechallenge control animals.

Following rechallenge with 50% w/w Baygon TG2 in mineral oil, USP, dermal reactions in the test and rechallenge control animals were limited to scores of 0 (No reaction) to ± (Slight patchy erythema). Group mean dermal scores were noted to be similar in the test animals as compared with the rechallenge control animals.

No data are available on humans.

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	Following challenge with 75 % w/w test substance in mineral oil, USP, dermal scores of 1 were noted in 1/20 test animals and 1/10 challenge control animals at the 24 hour scoring interval. These scores were reduced to ± - Slight patchy erythema at the 48 hours reading. Dermal reactions in the remaining test and challenge control animals at 24 and 48 hours were limited to scores of 0 - No reaction to ± - Slight patchy erythema. Group mean dermal scores

	were noted to be similar in the test animals as compared with the challenge control animals. Following re-challenge with 25% test substance in mineral oil, USP, dermal reactions in the test and re-challenge control animals were scores of 0 for all animals at 24 and 48 hours. Group mean dermal scores were noted to be the same in the test animals as compared with the re-challenge control animals. Following re-challenge with 50 % w/w test substance in mineral oil, USP, dermal reactions in the test and re-challenge control animals at 24 and 48 hours were limited to scores of 0 - No reaction to ± - Slight patchy erythema. Group mean dermal scores were noted to be similar in the test animals as compared with the re-challenge control animals. Based on the results of the study, the test substance is not considered to be a contact sensitizer in guinea pigs. The level of three of the components of Citronella Oil present in Transfluthrin Liquid Electric (≥0.1% and <1%) do, however, require the use of special labelling in accordance with Regulation (EC) No 1272/2008, Section 3.4.3, Note 1, to protect already sensitised individuals. The product packaging should contain the phrase **"Contains Citronella Oil. May produce an allergic reaction"**. The calculation method is consistent with the result from the study report ([redacted] 2004).
Classification of the product according to CLP	Not classified, however, the product packaging should contain the phrase **"Contains Citronella Oil. May produce an allergic reaction"**.

Respiratory sensitization (ADS)

No data are available on humans.

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 has been classified as a respiratory sensitizer and is present at or above the appropriate generic concentration limit as shown in Table 3.4.5 and for individuals who are already sensitised to the substance or mixture refer to Table 3.4.6. Details of the product composition are presented in the confidential annex. There are no components of the product classified for respiratory sensitisation. The product does not therefore require

	classification for respiratory sensitisation. A study is not required, nor considered an appropriate use of animals.
Classification of the product according to CLP	Not classified

Acute toxicity

Acute toxicity by oral route

Acute toxicity studies have been performed using a similar formulation to Transfluthrin Liquid Electric (Baygon Genius) with the exception that it contains a different fragrance (please refer to the confidential bridging letter entitled, "Bridging letter Trevi and Hydrogenius" contained within IUCLID Section 13).

The results from these studies are considered to be valid for the assessment of the formulation and a separate assessment has also been performed based upon the calculation method for mixtures defined in Regulation (EC) No 1272/2008.

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels Type of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method), GLP, Reliability 2	Rat; Hsd Cpb: WU; 3 ♀ and 3 ♂	2000 mg/kg bw single exposure	At the dose of 2000 mg/kg bw diarrhoea was observed in all three male rats and in one female rat. Diarrhoea was observed only 4-5 hours after administration. Soft faeces are known to be caused by oral administration of the vehicle (polyethylene glycol 400) alone, therefore, this effect was not considered to be test substance related.	> 2500 mg/kg bw	None	[redacted] (1997)

No human data are available.

Value used in the Risk Assessment – Acute oral toxicity	
Value	> 2500 mg/kg bw According to Regulation (EC) No 1272/2008 the product does not require classification for acute oral toxicity by ingestion but is

	classified for aspiration toxicity as Category 1, H304: May be fatal if swallowed and enters airways.
Justification for the selected value	The result from the study ([redacted] (1997)) performed using a similar formulation to Transfluthrin Liquid Electric (Baygon Genius) with the exception that it contains a different fragrance and solvent composition (please refer to the confidential bridging letter entitled, "Bridging letter Trevi and Hydrogenius" contained within IUCLID Section 13), concludes that the product should not be classified by oral ingestion. The difference in solvent composition is considered to be the most relevant difference. Although there is a relatively large difference in concentrations of these solvents, they are structurally closely related. Although, the main solvent used in Baygon Genius (the formulation used for the skin irritation study) shows a lower level of acute oral toxicity in rat compared to the main solvent in Transfluthrin Liquid Electric, both LD50 values are relatively high and do not require classification for acute oral toxicity. There are no substances which are classified for acute oral toxicity present in Transfluthrin Liquid Electric that were not present in the formulation tested. It is therefore considered that an additional study is not required, nor an appropriate use of animals. <u>Aspiration Hazard</u> Two substances contained in Transfluthrin Liquid Electric (Isopar M and Isopar V) are, however, classified as Aspiration toxicant: Category 1, H304: May be fatal if swallowed and enters airways. This relates to a mixture which contains a total of 10% or more of a substance or substances classified in Category 1, and has a kinematic viscosity of 20.5 mm^2/s or less measured at 40°C. Transfluthrin Liquid Electric contains classified co-formulants which constitute significantly more than 10% of the mixture and thus Transfluthrin Liquid Electric should be classified as Category 1, H304: May be fatal if swallowed and enters airways.
Classification of the product according to CLP	The product is classified as Category 1, H304: May be fatal if swallowed and enters airways according to Regulation (EC) No 1272/2008.

Acute toxicity by inhalation

Summary table of animal studies on acute inhalation toxicity						
Method, Guideline, GLP status , Reliability	**Species, Strain, Sex, No/group**	**Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD) Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LC50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD Guideline 403 (Acute Inhalation Toxicity) Acute Toxic Class Method, GLP, Reliability 2	SPF bred Wistar rats, strain Hsd Cpb:WU (SPF). 5 ♀ and 5 ♂	Airborne total mass and the active ingredient transfluthrin concentration were 174 and 0.44 mg/m^3 air, respectively. Particle size: Group 2 MMAD = 5.37um, Group 3 MMAD = 1.50um, Group 4 MMAD = 1.62um. Nose only exposure.	The animals showed a transient piloerection after exposure. No effect on body temperature or body weights was observed.	LC50 of the product under the condition of use is >> 174 mg/ m^3 air or >> 2.8 devices/ m^3 air	None	[redacted] (1998)

No 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	The result from the study ([redacted] (1998)) performed using a similar formulation to Transfluthrin Liquid Electric (Baygon Genius) with the exception that it contains a different fragrance and solvent composition (please refer to the confidential bridging letter entitled, "Bridging letter Trevi and Hydrogenius" contained within IUCLID Section 13), concludes that the product should not be classified as the effects observed were due to the kerosene and not the active substance. It was concluded that the product is not acutely toxic by inhalation ([redacted] (1998). Based on the bridging statement provided, the difference in solvent composition is considered to be the most relevant difference. Although there is a relatively large difference in concentrations of these solvents,

	they are structurally closely related. However, based on the bridging statement provided no LC50 value is provided and therefore is is difficult to determine whether the new formulation is expected to result in a comparable outcome with regard to acute inhalation toxicity, especially considering the large difference in concerntration of the respective solvents in the old and new formulation. Therefore, bridging cannot be accepted and the study was not used for classification of Transfluthrin Liquid Electric. Due to the change in formulation, the calculation method for determining classification has also been used. Under Regulation (EC) No 1272/2008, 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 in the confidential annex. Transfluthrin Liquid Electric contains no substances classified for acute inhalation toxicity. It is, therefore, not necessary to classify this product and an additional study is not required, nor considered an appropriate use of animals.
Classification of the product according to CLP	Not classified

Acute toxicity by dermal route

No in vitro, animal 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 in the confidential annex. Transfluthrin Liquid Electric contains no substances classified for acute dermal toxicity. No classification is therefore proposed for acute dermal toxicity. A study is not required, nor considered an appropriate use of animals.
Classification of the product according to CLP	Not classified

Information on dermal absorption

No dermal absorption study is performed with Transfluthrin Liquid Electric, but reference to the dermal absorption value of the active substance is made. Dermal absorption on the active substance are summarised and reported within the active substance dossier submitted for Annex I inclusion. Refer to Document IIA, Section 3.1.

A value of 10% was derived in the active substance evaluation based on expert judgement taking into account 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 Transfluthrin Liquid Electric. In the case for Transfluthrin Liquid Electric dermal exposure is only expected in the scenario for an infant 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)	Please refer to section above.		

eCA remark: The applicant considers the value of 10% for dermal absorption applicable based on a number of factors. In the assessment report of transfluthrin a value of 10% for dermal absorption is included, based on MW of 371 and log Pow of 5.4, and data from other (fluorinated)pyrethroids. Although the 10% for dermal absorption is indeed included in the EFSA Guidance on dermal absorption (2012) applicable to this PAR, the 10% for dermal absorption based on physical chemical properties is no longer included in the updated EFSA guidance from 2017. More importantly, in the EFSA guidance from 2012 it is noted that a default value of 10% can be used in cases where log Pow < -1 or > 4 and MW > 500. However, transflutrin has a log Pow of 5.4, which fulfils the criteria, and a MW of 371 which is below the limit value of 500. A dermal absorption value of 10% may thus not be applied according to the EFSA guidance (2012). In the CAR of transfluthrin it was concluded that although the MW is below 500, it is close to the MW criterion and read across was made to other pyrethroids which also do not fulfil the MW criterion but for which the available data suggest a dermal absorption below the default value of 10%. However, many EU discussions on dermal absorption of pyrthroids on recent product authorisations have taken place. From these discussions it can be concluded that dermal absorption is considered product specific and only referring to other pyrethroids without extensive argumentation for read across is not acceptable for product authorisation. In conclusion, we consider the argumentation to lower the default dermal absorption value to 10% not sufficient.
Subsequently, a standard default value for dermal absorption needs to be used for the risk assessment. Therefore, a 70% dermal absorption value should be used for an active substance concentration of ≤5% of an organic based formaulation (EFSA guidance 2017).

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

This product is classified as an aspiration hazard due to the high concentration of hydrocarbon solvents (CAS No. 64742-46-7, 64742-47-8 and 8000-29-1) coupled with the low kinematic viscosity (7.8 mm^2/s). In accordance with CLP the product label will carry the appropriate P phrases set out in the regulation to protect the consumer; the label will also carry a tactile warning of danger to alert visually impaired consumers. Finally, the product is fitted with child resistant packaging to prevent accidental ingestion by toddlers and young children.

Available toxicological data relating to a mixture

Refer to Section 2.2.6.1 for data on the product.

Other

No data are required for the following endpoints:

- Food and feedstuffs: as the biocidal product will not be in contact with feedstuffs. The material safety data sheet advises: "Store away from food, beverages and pet food" and "Do not use in kitchens.".
- The effects of Industrial processing or domestic preparation: as the product is Ready to Use.

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

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting (ED) properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders). Hence, as requested by the evaluating Member State Competent Authority (The Netherlands), a screen for indications of ED potential has been performed for Transluthrin Liquid Electric.
According to the EU Commission's guidance note on 'The Implementation of scientific criteria for the determination of endocrine-disrupting properties in the content of biocidal product authorisation (CA-March18-Doc.7.3.b-final, paragraph 23) the detailed evaluation of a non-active substance (co-formulant) per the ECHA/EFSA guidance should only occur where there are indications of ED properties based on the existing knowledge and the available scientific information. An agreed screening process for a co-formulant to identify indications of endocrine disrupting (ED) in substances has not been established. Therefore, a screening approach was developed utilizing existing evidence according to the ECHA/EFSA guidance (http://www.efsa.europa.eu/en/press/news/180607), which adapted the WHO definition, that a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

a) It shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development,

reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences

b) It has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system
c) the adverse effect is a consequence of the endocrine mode of action

The indicating ED screen overview for the co-formulants in Transfluthrin Liquid Electric is summarised in confidential Annex 3.6. All co-formulants identified from the safety data sheets for all ingredients and the finished product were included in the screen.

From the screening 1 co-formulant triggered an alert for ED properties 2,6-Di-tert-butyl-4-methylphenol.

Regarding co-formulant 2,6-Di-tert-butyl-4-methylphenol a concern has been raised by a member state to include this substance in the CoRAP (Community rolling action plan) list due to its ED potency. No further ED assessment was considered necessary for this PAR because the discussion should be coordinated at the EU level. The ED assessment for this co-formulant should await the outcome of the discussions at EU level.

More information about the ED screening of the co-formulants including identity of the co-formulant and ED assessment are found in Confidential Annex 3.6.

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

Exposure was calculated for 2 of the heating devices:

- Adjustable (Dual) heater on the high setting (65 mg formula/hr) after 12 and 24 hours use.

- Advanced heater on the high setting (110 mg formula/hr) after 12 and 24 hours use.

For the base heating device no calculations were made since the emission rate is lower compared to the adjustable and advanced heater and is thus considered covered by the risk assessment for these devices.

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.a.	During Application	This product is designed to be used in bedrooms during the night to protect against mosquitos, during which the active can be inhaled. For scenario 1a, an inhalation exposure assessment was carried out for an infant and adult sleeping for 8-12 hours in a small bedroom. Oral exposure from the non-respirable fraction was also quantified.	Non-Professionals
1.b.	During Application	This product is designed to be used in bedrooms during the night to protect against mosquitos, during which the active can be inhaled. It was assumed that the user forgot to switch the device off/unplug the device.	Non-Professionals
2.a.	Post-Application	Following the use of the product, active in the air can settle on the ground leaving residues for further exposure. For scenario 2, dermal exposure was estimated for an infant crawling on a floor containing residues. Oral exposure from hand-to-mouth contact was also estimated for the infant. Active that has settled onto surfaces can also become revolatilised into the air for potential inhalation. Exposure was determined for an infant and adult.	General Public
2.b.	Post-Application	Following the use of the product, active in the air can settle on the ground leaving residues for further exposure. It was assumed that the user forgot to switch the device off/unplug the device. For scenario 2, dermal exposure was estimated for an infant crawling on a floor containing residues. Oral exposure from hand-to-mouth contact was also estimated for the infant. Active that has settled onto surfaces can also become revolatilised into the air for potential inhalation. Exposure was determined for an infant and adult.	General Public

Industrial exposure
Not applicable

Professional exposure
Not applicable

Non-professional exposure for Adjustable (Dual) heater on high setting

Scenario 1.a.

Description of Scenario 1.a.: Direct Inhalation		
The liquid electric product is used at night to protect the sleeper against mosquitos. To use this product, the device is plugged into mains electricity, becomes heated and releases the formula as a vapour. As the vapour comes into contact with cool air in the room, it condenses to form droplets that can then be inhaled by the sleeping individual. Inhalation exposure was determined for infants and adults sleeping in a small bedroom for 12 hours, using the Spray model as described by RIVM for electrical evaporators (RIVM, 2006). Exposure was modelled for the use of Transfluthrin Liquid Electric Adjustable (Dual) heating unit on the high setting.		
	Parameters	Value
Tier 1	Model	ConsExpo 4.1 Spray Model (RIVM, 2006)
	Frequency of Use	150 days/year representing use throughout the whole season (RIVM, 2006)
	Emission Duration	12 hours (RIVM, 2006)
	Emission Rate	0.065 g formula/hour, equal to 0.57 mg transfluthrin/ h = 0.78 g formulafor 12 hours exposure ([redacted], 2015)
	Room Volume	16 m^3 (RIVM, 2006)
	Ventilation Rate	1 hr^{-1} (RIVM, 2006)
	Airborne fraction	1 (RIVM, 2006)
	Density non volatile	1.5 g/cm3 (RIVM, 2006)
	Inhalation cut off diameter	15 µm (RIVM 2006)
	Aerosol diameter distribution type	Log-normal (RIVM, 2006)
	Median diameter (CV)	8 µm (0.3 µm) (RIVM, 2006)
	Default Infant Body Weight	8 kg (HEEG, 2013)
	Default Infant Inhalation Rate	5.4 m^3/day = 0.225 m^3/hour (HEAd hoc recommendation no. 14)
	Default Adult Body Weight	60 kg (HEEG, 2013)
	Default Adult Inhalation Rate	16 m^3/ day = 0.667 m^3/hour (HEAd hoc recommendation no. 14)

Calculations for Scenario 1.a.

Transfluthrin Liquid Electric

Active substance	Transfluthrin (CAS 118712-89-3) 0.88% w/w
Molecular weight of active substance	371 g/mol (Transfluthrinn Assessment Report, 2014)
Vapour pressure of active substance	9 x 10^{-4} Pa at 20ºC (Transfluthrinn Assessment Report, 2014)

The mean event air concentration from ConsExpo was approximately 0.0078 mg/m^3 (see below). This was used to calculate systemic inhalation exposure for the two age groups on the day of exposure:

Infant: 0.0078 mg/m^3 x 12 hours x 0.225 m^3/ hour x 1/8 kg = 0.0026 mg/kg bw/day

Adult: 0.0078 mg/m^3 x 12 hours x 0.667 m^3/hour x 1/60 kg = 0.00104 mg/kg bw/day

Summary table: Direct exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake (non-respirable)**	**Estimated total uptake**
Scenario 1a. Application, infant	1/ No PPE	0.0026 mg/kg bw/day	N/A	1.1 x 10^{-5} mg/kg bw/day	0.0026 mg/kg bw/day
Scenario 1a. Application, adult	1/ No PPE	0.00104 mg/kg bw/day	N/A	4. 2 x 10^{-6} mg/kg bw/day	0.0014 mg/kg bw/day

Further information and considerations on scenario
The mean event concentration has been calculated as 0.0078 mg/m^3. This was used to calculate direct systemic exposure via inhalation.

Combined scenarios
Not applicable.

Exposure of the general public for Adjustable (Dual) heater on high setting

Scenario 2.a.

Description of Scenario: Post-application		
Following the use of Transfluthrin Liquid Electric at night, it was assumed that residues of transfluthrin deposited onto the floor resulting in infant exposure. Dermal exposure would occur from crawling on the floor and oral exposure from hand to mouth contact, resulting in ingestion of residues. Dermal and oral exposure were calculated using the RIVM guidance for Electrical evaporators (RIVM, 2006). Inhalation exposure from revolatilised residues was also determined. Active that has settled onto surfaces can evaporate into the air and become available for inhalation. Exposure for this scenario was determined for an infant and adult. Exposure was modelled for the use of Transfluthrin Liquid Electric Adjustable (Dual) heating unit on the high setting.		
	Parameters	Value
Tier 1	Model	ConsExpo webversion, Rubbing off
	Amount of formula emitted	780 mg formula, equal to 6.86 mg transfluthrin/ day (based on 65 mg formula/hour x 12 hours)
	Deposition	10% (ESD 2008)
	Amount of active	0.88%
	Surface Area of floor	7 m^2
	Dislodgeable Fraction	8%
	Oral Absorption	100%
	Dermal Absorption	70% (see Dermal absorption waiver)
	Crawling Time	1 hr/day (RIVM, 2006)
	Area covered when crawling (transfer coefficient)	0.2 m^2/hr (HEAdHoc Recommendation no.12)

Note eCA: the applicant provided a refinement of the deposition value. However, the study was not considered acceptable (see evaluation in the environmental section). The value of 25% as used in the assessment report of transfluthrin which was accepted by the member states during the peer review of transfluthrin was considered too worst case since this value was for a mosquito coil that forms solid particulates when burned while for the current application a liquid electric device is considered. Therefore, the harmonised value of 10% fraction emitted to floor (default for 'general diffusers' in ESD 2008) was used for calculations (see also section 3.6.3). The dislodgeable amount of 30% which was used in the assessment report of transfluthrin was also considered worst case taking into account

that a relatively lower value of 8% was recently reported by the US EPA (2012) compared to the value used in the assessment report of transfluthrin.

Dermal exposure

It is assumed that 10% of the transfluthrin which is released from the vaporiser deposits on the floor (ESD 2008).The total amount of transfluthrin which is released is 6.86 mg / day; 10% of this amount deposits on 7 m^2 (area of bedroom floor), this means 6.86 x 0.10 / 7 = 0.098 mg a.s./ m^2.
It is assumed that 8% of this quantity is dislodgeable (US EPA Residential SOPs). 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 (default ConsExpo 4.1; Bremmer et al., 2006). The average dislodgeable amount during the week is:
0.098 mg a.s./m^2 x 0.08 x 4-fold accumulation = 0.0314 mg a.s./ m^2.

Dermal Exposure:
= (1 hr/day x 0.2 m^2/hour x 0.0314 mg active/m^2 x 70% dermal abs)/ 8 kg
= 5.50 x 10^{-4} mg/kg bw/day

Based on the calculations made using ConsExpo:
External dermal exposure = 7.85 x 10^{-4} mg a.s./kg/day
Internal dermal exposure = 5.50 x 10^{-4} mg a.s./kg bw/day.

Oral exposure

For infants, 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 0.2 m^2/hour x 0.0314 mg/m^2) x 10%/ 8 kg
= 7.85 x 10^{-5} mg/kg bw/day

Air concentration of active following revolatilisation

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, 2006). This would put transfluthrin into the category of non-volatile and therefore post-application inhalation exposure is likely to be minimal. Therefore, this exposure route was not taken into account.

Calculations for Scenario 2.a. for Adjustable (Dual) heater on high setting

See confidential annex 3.6.2 for explanation of dislodgeable fraction.

Summary table: Post application exposure from non-professional uses					
Exposure scenario	**Tier/PPE**		**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 2.a. Post application, infant.	1 / No PPE		5.50×10^{-4} mg/kg/day	7.85×10^{-5} mg/kg/day	0.000628 mg/kg/day
Scenario 2.a. Post application, adult.	1 / No PPE		N/A	N/A	N/A

Combined scenarios (1a + 2a)

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.a.+2.a., infant	0.0026 (direct)	5.50×10^{-4} (indirect)	1.1×10^{-5} (direct) + 7.85×10^{-5} (indirect)	0.0032
Scenario 1.a.+2.a., adult	0.00104 (direct)	N/A	4.2×10^{-6} (direct)	0.00104

Scenario 1.b. for Adjustable (Dual) heater on high setting

Description of Scenario 1.b.: Direct Inhalation		
The liquid electric product is used at night to protect the sleeper against mosquitos. To use this product, the device is plugged into electricity, becomes heated and releases the formula as a vapour. As the vapour comes into contact with cool air in the room, it condenses to form droplets that can then be inhaled by the sleeping individual. It was assumed that the user forgot to switch the device off/unplug the device. Inhalation exposure was determined for infants sleeping in a small bedroom for 24 hours, as a conservative worst case scenario. Exposure was modelled for the use of Transfluthrin Liquid Electric Adjustable (Dual) heating unit on the high setting.		
	Parameters	Value
Tier 1	Model	ConsExpo 4.1 Spray Model (RIVM, 2006)
	Frequency of Use	150 days/year (RIVM, 2006)
	Emission Duration (Spray duration)	24 hours
	Emission Rate	0.065 g formula/hour = 1.08 mg formula/min = 1.56 g formulafor 24 hours exposure
	Room Volume	16 m^3 (RIVM, 2006)
	Ventilation Rate	1 hr^{-1} (RIVM, 2006)
	Airborne fraction	1 (RIVM, 2006)
	Density non volatile	1.5 g/cm3 (RIVM, 2006)
	Inhalation cut off diameter	15 µm (RIVM 2006)
	Aerosol diameter distribution type	Log-normal (RIVM, 2006)
	Median diameter (CV)	8 µm (0.3 µm) (RIVM, 2006)
	Exposure duration	24 hours (RIVM, 2006)
	Default Infant Body Weight	8 kg (HEAd hoc recommendation no. 14)
	Default Infant Inhalation Rate	5.4 m^3/day = 0.225 m^3/hour (HEEG, 2013)
	Default Adult Body Weight	60 kg (HEEG, 2013)
	Default Adult Inhalation Rate	16 m^3/ day = 0.667 m^3/hour (HEAd hoc recommendation no. 14)

Calculations for Scenario 1.b.

Transfluthrin Liquid Electric

Active substance	Transfluthrin (CAS 118712-89-3) 0.88% w/w
Molecular weight of active substance	371 g/mol (Transfluthrin Assessment Report, 2014)
Vapour pressure of active substance	9 x 10^{-4} Pa at 20ºC (Transfluthrin Assessment Report, 2014)

The mean event air concentration from ConsExpo was approximately 0.0079 mg/m^3 (see ConsExpo reports below). This was used to calculate systemic inhalation exposure for the two age groups on the day of exposure:

Infant: 0.0079 mg/m^3 x 24 hours x 0.225 m^3/ hour x 1/8 kg = 0.00533 mg/kg bw/day

Adult: 0.0079 mg/m^3 x 24 hours x 0.667 m^3/hour x 1/60 kg = 0.0021 mg/kg bw/day

Summary table: Direct exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake (non-respirable)**	**Estimated total uptake**
Scenario 1b. Application, infant	1/ No PPE	0.00533 mg/kg bw/day	N/A	2.1 x 10^{-5} mg/kg bw/day	0.00535 mg/kg bw/day
Scenario 1b. Application, adult	1/ No PPE	0.0021 mg/kg bw/day	N/A	8.4 x 10^{-6} mg/kg bw/day	0.0021 mg/kg bw/day

Further information and considerations on scenario
The mean event concentration has been calculated as 0.0079 mg/m^3. This was used to calculate direct systemic exposure via inhalation.

Scenario 2.b.for Adjustable (Dual) heater on high setting

Description of Scenario: Post-application		
Following the use of Transfluthrin Liquid Electric at night, it was assumed that residues of transfluthrin deposited onto the floor resulting in infant exposure. It was assumed that the user forgot to switch the device off/unplug the device. Dermal exposure would occur from crawling on the floor and oral exposure from hand to mouth contact, resulting in ingestion of residues. Dermal and oral exposure were calculated using the RIVM guidance for Electrical evaporators (RIVM, 2006). Exposure was modelled for the use of Transfluthrin Liquid Electric Adjustable (Dual) heating unit on the high setting.		
	Parameters	Value
Tier 1	Amount of formula emitted	1560 mg formula (based on 65 mg formula/hour x 24 hours) = 13.73 mg ai
	Deposition	10%
	Amount of active	0.88%
	Surface Area of floor	7 m^2
	Dislodgeable Fraction	8%
	Oral Absorption	100%
	Dermal Absorption	70%
	Crawling Time	1 hr/day (RIVM, 2006)
	Area covered when crawling	0.2 m^2/hr (Ad hoc Working Group on Human Exposure, Recommendation 12)

Note eCA: the applicant provided a refinement of the deposition value. However, the study was not considered acceptable (see evaluation in the environmental section). The value of 25% as used in the assessment report of transfluthrin which was accepted by the member states during the peer review of transfluthrin was considered too worst case since this value was for a mosquito coil that forms solid particulates when burned while for the current applicantion a liquid electric device is considered. Therefore, the harmonised value of 10% fraction emitted to floor (default for 'general diffusers' in ESD 2008) was used for calculations (see also section 3.6.3). The dislodgable amount of 30% which was used in the assessment report of transfluthrin was also considered worst case taking into account that a relatively lower value of 8% was recently reported by the US EPA (2012) compared to the value used in the assessment report of transfluthrin.

Dermal exposure

It is assumed that 10% of the transfluthrin which is released from the vaporiser deposits on the floor (ESD 2008).The total amount of transfluthrin which is released is 13.73 mg/day; 10% of this amount deposits on 7 m^2 (area of bedroom floor), this means 13.73 x 0.10 / 7 = 0.196 mg a.s./ m^2.
It is assumed that 8% of this quantity is dislodgeable (US EPA Residential SOPs). 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 (default ConsExpo 4.1; Bremmer et al., 2006). The average dislodgeable amount during the week is:
0.196 mg a.s./m^2 x 0.08 x 4-fold accumulation = 0.0628 mg a.s./ m^2.

Dermal Exposure:
= (1 hr/day x 0.2 m^2/hour x 0.0628 mg active/m^2 x 70% dermal abs)/ 8 kg
= 1.10 x 10^{-3} mg/kg bw/day

Based on the calculations made using ConsExpo:
External dermal exposure = 1.57 x 10^{-3} mg a.s./kg/day
Internal dermal exposure = 1.10 x 10^{-3} mg a.s./kg/day.

Oral exposure

For infants, 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 0.2 m^2/hour x 0.0628 mg/m^2) x 10%/ 8 kg
= 1.57 x 10^{-4} mg/kg/day

Inhalation following revolatilisation

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, 2006). This would put transfluthrin into the category of non-volatile and therefore post-application inhalation exposure is likely to be minimal.
Considering this and that it is assumed that the electric device is not switched off and therefore continuously generates transfluthrin vapour, only the direct exposure to transfluthrin was determined (scenario 1b).

Calculations for Scenario 2.b. for Adjustable (Dual) heater on high setting

See confidential annex 3.6.2 for explanation of dislodgeable fraction and revolatilisation.

Summary table: Post application exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 2b. Post application, infant.	1 / No PPE	Not determined	1.10×10^{-3} mg/kg/day	1.57×10^{-4} mg/kg/day	1.26×10^{-3} mg/kg/day
Scenario 2b. Post application, adult.	1 / No PPE	Not determined	N/A	N/A	Not determined

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.b.+2.b., infant	0.00533 (direct)	1.10×10^{-3} (indirect)	2.1×10^{-5} (direct) + 1.57×10^{-4} (indirect)	0.00660
Scenario 1.b.+2.b., adult	0.0021 (direct)	N/A	8.2×10^{-6} (direct)	0.0021

Monitoring data
Not applicable

Dietary exposure
Not applicable

Exposure associated with production, formulation and disposal of the biocidal product
Not applicable

Non-professional exposure for Advanced heater on high setting

Scenario 1.a.

Description of Scenario 1.a.: Direct Inhalation		
The liquid electric product is used at night to protect the sleeper against mosquitos. To use this product, the device is plugged into mains electricity, becomes heated and releases the formula as a vapour. As the vapour comes into contact with cool air in the room, it condenses to form droplets that can then be inhaled by the sleeping individual. Inhalation exposure was determined for infants and adults sleeping in a small bedroom for 12 hours, using the Spray model as described by RIVM for electrical evaporators (RIVM, 2006). Exposure was modelled for the use of Transfluthrin Liquid Electric Advanced heating unit on the high setting. This device had the highest emission rate of the liquid electric variants and would therefore be protective for all the product variants and settings.		
	Parameters	Value
Tier 1	Model	ConsExpo 4.1 Spray Model (RIVM, 2006)
	Frequency of Use	150 days/year representing use throughout the whole season (RIVM, 2006)
	Emission Duration	12 hours (RIVM, 2006)
	Emission Rate	110 mg formula/hour, equal to 0.97 mg transfluthrin/ h = 1.32 g formula for 12 hours exposure (see section 2.2.3)
	Room Volume	16 m^3 (RIVM, 2006)
	Ventilation Rate	1 hr^{-1} (RIVM, 2006)
	Airborne fraction	1 (RIVM, 2006)
	Density non volatile	1.5 g/cm3 (RIVM, 2006)
	Inhalation cut off diameter	15 µm (RIVM 2006)
	Aerosol diameter distribution type	Log-normal (RIVM, 2006)
	Median diameter (CV)	8 µm (0.3 µm) (RIVM, 2006)
	Default Infant Body Weight	8 kg (HEEG, 2013)
	Default Infant Inhalation Rate	5.4 m^3/day = 0.225 m^3/hour (HEEG, 2013)
	Default Adult Body Weight	60 kg (HEEG, 2013)
	Default Adult Inhalation Rate	16 m^3/ day = 0.667 m^3/hour (HEEG, 2013)

Calculations for Scenario 1.a. for Advanced heater on high setting

Transfluthrin Liquid Electric	
Active substance	Transfluthrin (CAS 118712-89-3) 0.88% w/w
Molecular weight of active substance	371 g/mol (Transfluthrinn Assessment Report, 2014)
Vapour pressure of active substance	9 x 10^{-4} Pa at 20ºC (Transfluthrinn Assessment Report, 2014)

The mean event air concentration from ConsExpo was approximately 0.013 mg/m^3 (see below). This was used to calculate systemic inhalation exposure for the two age groups on the day of exposure:

Infant: 0.013 mg/m^3 x 12 hours x 0.225 m^3/ hour x 1/8 kg = 0.0044 mg/kg/day

Adult: 0.013 mg/m^3 x 12 hours x 0.667 m^3/hour x 1/60 kg = 0.0017 mg/kg/day

Summary table: Direct exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake (non-respirable)**	**Estimated total uptake**
Scenario 1a. Application, infant	1/ No PPE	0.0044 mg/kg	N/A	1.8 x 10^{-5} mg/kg	0.0044 mg/kg
Scenario 1a. Application, adult	1/ No PPE	0.0017 mg/kg	N/A	7.0 x 10^{-6} mg/kg	0.0017 mg/kg

Further information and considerations on scenario
The mean event concentration has been calculated as 0.013 mg/m^3. This was used to calculate direct systemic exposure via inhalation.

Combined scenarios
Not applicable.

Exposure of the general public- for Advanced heater on high setting

Scenario 2.a.

Description of Scenario: Post-application		
Following the use of Transfluthrin Liquid Electric at night, it was assumed that residues of transfluthrin deposited onto the floor resulting in infant exposure. Dermal exposure would occur from crawling on the floor and oral exposure from hand to mouth contact, resulting in ingestion of residues. Dermal and oral exposure were calculated using the RIVM guidance for Electrical evaporators (RIVM, 2006). Inhalation exposure from revolatilised residues was also determined. Active that has settled onto surfaces can evaporate into the air and become available for inhalation. Exposure for this scenario was determined for an infant and adult. Exposure was modelled for the use of Transfluthrin Liquid Electric Advanced heating unit on the high setting. This device had the highest emission rate of the liquid electric variants and would therefore be protective for all the product variants and settings.		
	Parameters	Value
Tier 1	Amount of formula emitted	1320 mg formula, equal to 11.62 mg transfluthrin/ day (based on 110 mg formula/hour x 12 hours)
	Deposition	10% (ESD 2008)
	Amount of active	0.88%
	Surface Area of floor	7 m^2
	Dislodgeable Fraction	8%
	Oral Absorption	100%
	Dermal Absorption	70% (see Dermal absorption waiver)
	Crawling Time	1 hr/day (RIVM, 2006)
	Area covered when crawling (transfer coefficient)	0.2 m^2/hr (HEAdHoc Recommendation no.12)

Dermal exposure

It is assumed that 10% of the transfluthrin which is released from the vaporiser deposits on the floor (ESD 2008).The total amount of transfluthrin which is released is 11.62 mg/ day; 10% of this amount deposits on 7 m^2 (area of bedroom floor), this means 11.62 x 0.10 / 7 = 0.166 mg a.s./ m^2.

It is assumed that 8% of this quantity is dislodgeable (US EPA Residential SOPs). 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 (default ConsExpo 4.1; Bremmer et al., 2006). The average dislodgeable amount during the week is:
0.166 mg a.s./m^2 x 0.08 x 4-fold accumulation = 0.0531 mg a.s./ m^2

Dermal Exposure:
= (1 hr/day x 0.2 m^2/hour x 0.0531 mg active/m^2 x 70% dermal abs)/ 8 kg
= 9.29 x 10^{-4} mg/kg bw/day

Based on the calculations made using ConsExpo:
External dermal exposure = 1.33 x 10^{-3} mg a.s./kg/day
Internal dermal exposure = 9.29 x 10^{-4} mg a.s./kg bw/day.

Oral exposure

For infants, 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 0.2 m^2/hour x 0.0531 mg/m^2) x 10%/ 8 kg
= 1.33 x 10^{-4} mg/kg bw/day

Calculations for Scenario 2.a. for Advanced heater on high setting

See confidential annex 3.6.2 for explanation of dislodgeable fraction.

Summary table: Post application exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (revolatilisation)**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 2.a. Post application, infant.	1 / No PPE	not calculated	9.29×10^{-4} mg/kg/day	1.33×10^{-4} mg/kg/day	0.001062 mg/kg/day
Scenario 2.a. Post application, adult.	1 / No PPE	not calculated	N/A	N/A	N/A

Combined scenarios (1a + 2a)

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.a.+2.a., infant	0.0044 (direct)	9.29×10^{-4} (indirect)	1.8×10^{-5} (direct) + 1.33×10^{-4} (indirect)	0.0055
Scenario 1.a.+2.a., adult	0.0017 (direct)	N/A	7.0×10^{-6} (direct)	0.0017

Scenario 1.b. for Advanced heater on high setting

Description of Scenario 1.b.: Direct Inhalation		
The liquid electric product is used at night to protect the sleeper against mosquitos. To use this product, the device is plugged into mains electricity, becomes heated and releases the formula as a vapour. As the vapour comes into contact with cool air in the room, it condenses to form droplets that can then be inhaled by the sleeping individual. It was assumed that the user forgot to switch the device off/unplug the device. Inhalation exposure was determined for infants sleeping in a small bedroom for 24 hours, as a conservative worst case scenario. Exposure was modelled for the use of Transfluthrin Liquid Electric Advanced heating unit on the high setting. This device had the highest emission rate of the liquid electric variants and would therefore be protective for all the product variants and settings.		
	Parameters	Value
Tier 1	Model	ConsExpo 4.1 Spray Model (RIVM, 2006)
	Frequency of Use	150 days/year (RIVM, 2006)
	Emission Duration (Spray duration)	24 hours
	Emission Rate	110 mg formula/hour = 1.83 mg formula/min
	Room Volume	16 m^3 (RIVM, 2006)
	Ventilation Rate	1 hr^{-1} (RIVM, 2006)
	Exposure duration	24 hours (RIVM, 2006)
	Default Infant Body Weight	8 kg (HEEG, 2013)
	Default Infant Inhalation Rate	5.4 m^3/day = 0.225 m^3/hour (HEEG, 2013)
	Default Adult Body Weight	60 kg (HEEG, 2013)
	Default Adult Inhalation Rate	16 m^3/ day = 0.667 m^3/hour (HEEG, 2013)

Calculations for Scenario 1.b.

Transfluthrin Liquid Electric	
Active substance	Transfluthrin (CAS 118712-89-3) 0.88% w/w
Molecular weight of active substance	371 g/mol (Transfluthrin Assessment Report, 2014)
Vapour pressure of active substance	9 x 10^{-4} Pa at 20ºC (Transfluthrin Assessment Report, 2014)

The mean event air concentration from ConsExpo was approximately 0.013 mg/m^3 (see ConsExpo reports below). This was used to calculate systemic inhalation exposure for the two age groups on the day of exposure:

Infant: 0.013 mg/m^3 x 24 hours x 0.225 m^3/ hour x 1/8 kg = 0.0089 mg/kg/day

Adult: 0.013 mg/m^3 x 24 hours x 0.667 m^3/hour x 1/60 kg = 0.00337 mg/kg/day

Summary table: Direct exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake (non-respirable)**	**Estimated total uptake**
Scenario 1b. Application, infant	1/ No PPE	0.0089 mg/kg	N/A	3.6 x 10^{-5} mg/kg	0.0089 mg/kg
Scenario 1b. Application, adult	1/ No PPE	0.0035 mg/kg	N/A	1.4 x 10^{-5} mg/kg	0.0035 mg/kg

Further information and considerations on scenario
The mean event concentration has been calculated as 0.013 mg/m^3. This was used to calculate direct systemic exposure via inhalation.

Scenario 2.b. for Advanced heater on high setting

Description of Scenario: Post-application		
Following the use of Transfluthrin Liquid Electric at night, it was assumed that residues of transfluthrin deposited onto the floor resulting in infant exposure. It was assumed that the user forgot to switch the device off/unplug the device. Dermal exposure would occur from crawling on the floor and oral exposure from hand to mouth contact, resulting in ingestion of residues. Dermal and oral exposure were calculated using the RIVM guidance for Electrical evaporators (RIVM, 2006). Exposure was modelled for the use of Transfluthrin Liquid Electric Advanced heating unit on the high setting. This device had the highest emission rate of the liquid electric variants and would therefore be protective for all the product variants and settings.		
	Parameters	Value
Tier 1	Amount of formula emitted	2640 mg formula (based on 110 mg formula/hour x 24 hours) = 23.23 mg ai
	Deposition	10%
	Amount of active	0.88%
	Surface Area of floor	7 m^2
	Dislodgeable Fraction	8%
	Oral Absorption	100%
	Dermal Absorption	70%
	Crawling Time	1 hr/day (RIVM, 2006)
	Area covered when crawling	0.2 m^2/hr (Ad hoc Working Group on Human Exposure, Recommendation 12)

Dermal exposure

It is assumed that 10% of the transfluthrin which is released from the vaporiser deposits on the floor (ESD 2008).The total amount of transfluthrin which is released is 23.23 mg/day; 10% of this amount deposits on 7 m^2 (area of bedroom floor), this means 23.23 x 0.10 / 7 = 0.332 mg a.s./ m^2.
It is assumed that 8% of this quantity is dislodgeable (US EPA Residential SOPs). 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 (default ConsExpo 4.1; Bremmer et al., 2006). The average dislodgeable amount during the week is:
0.332 mg a.s./m^2 x 0.08 x 4-fold accumulation = 0.106 mg a.s./ m^2.

Dermal Exposure:

= (1 hr/day x 0.2 m^2/hour x 0.106 mg active/m^2 x 70% dermal abs)/ 8 kg
= 1.9 x 10^{-3} mg/kg bw/day

Based on the calculations made using ConsExpo:
External dermal exposure = 2.7 x 10^{-3} mg a.s./kg/day
Internal dermal exposure = 1.9 x 10^{-3} mg a.s./kg bw/day.

Oral exposure

For infants, 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 0.2 m^2/hour x 0.106 mg/m^2) x 10%/ 8 kg
= 2.7 x 10^{-4} mg/kg bw/day

Calculations for Scenario 2.b. for Advanced heater on high setting

See confidential annex 3.6.2 for explanation of dislodgeable fraction and revolatilisation.

Summary table: Post application exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 2b. Post application, infant.	1 / No PPE	Not calculated	1.9 x 10^{-3} mg/kg/day	2.7 x 10^{-4} mg/kg/day	2.1 x 10^{-3} mg/kg/day
Scenario 2b. Post application, adult.	1 / No PPE	Not calculated	N/A	N/A	N/A

Combined scenarios (1b + 2b)

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.b.+2.b., infant	0.0089 (direct)	1.9×10^{-3} (indirect)	3.6×10^{-5} (direct) + 2.7×10^{-4} (indirect)	0.0111
Scenario 1.b.+2.b., adult	0.0035 (direct)	N/A	1.4×10^{-5} (direct)	0.0035

Monitoring data
Not applicable

Dietary exposure
Not applicable

Exposure associated with production, formulation and disposal of the biocidal product
Not applicable

2.2.6.3 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 PT18 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.

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

$AEL_{chronic, systemic}$
The NOAEL of 20 ppm was observed in a 2-year dietary study in rats, equivalent 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.

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

Reference values to be used in Risk Characterisation

Reference	Study	NOAEC/NOAEL	AF	Correction for absorption	AEC/AEL Value
AEC acute (inhalation)	13-week rat	46.7 mg/m^3	100	None	0.5 mg/m^3
AEL acute (dermal, external)	3-week rabbit	1000 mg/kg/day	100	None	10 mg/kg/day
AELchronic (systemic)	2-year dietary rat	1 mg/kg/day	100	None	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- 12 hour scenario- Adjustable (Dual) heater

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg/d	AEL mg/kg/d	Estimated uptake mg/kg/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1a- Application, Infant	1	1	0.01	0.00260 mg/kg	26	Yes
1a- Application, Adult	1	1	0.01	0.0014 mg/kg	14	Yes

Combined scenarios
Not Applicable

Risk for the general public- 12 hour scenario- Adjustable (Dual) heater

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg/d	AEL mg/kg/d	Estimated uptake mg/kg/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
2a- Post application, infant.	1	1	0.01	0.000628	6	Yes
2a- Post application, adult.	1	1	0.01	N/A	N/A	Yes

Combined 12 hour scenarios- *Adjustable (Dual) heater*

Scenarios combined	Tier	Systemic NOAEL mg/kg/d	AEL mg/kg/d	Estimated uptake mg/kg/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios 1a+2a, infant	1	1	0.01	0.0032	32	Yes
Scenarios 1a+2a, adult	1	1	0.01	0.00104	10	Yes

Local effects
Not applicable

Conclusion for 12 hour scenario- *Adjustable (Dual) heater*

Based on the risk assessments above, adverse effects are not anticipated following consumer use of Transfluthrin Liquid Electric for the 12 hour scenario. All routes of exposure result in exposure estimates of < 30% of the relevant AEL.

Risk for non-professional users- 24 hour scenario- Adjustable (Dual) heater

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg/d	AEL mg/kg/d	Estimated uptake mg/kg/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1b- Application, Infant	1	1	0.01	0.00535 mg/kg	54	Yes
1b- Application, Adult	1	1	0.01	0.0021 mg/kg	21	Yes

Combined scenarios
Not Applicable

Risk for the general public- 24 hour scenario- Adjustable (Dual) heater

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg/d	AEL mg/kg/d	Estimated uptake mg/kg/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
2b- Post application, infant.	1	1	0.01	1.26×10^{-3}	13	Yes
2b- Post application, adult.	1	1	0.01	Not determined	Not applicable	Yes

Combined 24 hour scenarios- *Adjustable (Dual) heater*

Scenarios combined	Tier	Systemic NOAEL mg/kg/d	AEL mg/kg/d	Estimated uptake mg/kg/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios 1b+2b, infant	1	1	0.01	0.00660	66	Yes
Scenarios 1b+2b, adult	1	1	0.01	0.0021	21	Yes

Local effects
Not applicable

Conclusion for 24 hour scenario- *Adjustable (Dual) heater*

Based on the risk assessments above, adverse effects are not anticipated following consumer use of Transfluthrin Liquid Electric for the 24 hour scenario. All routes of exposure result in exposure estimates of < 60% of the relevant AEL. It should be noted that 24 hour exposure is a highly conservative scenario as an infant of this age would spend time in other rooms in the home (whilst being watched by their care-giver) or outside the home.

Risk for consumers via residues in food
Not applicable

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product
Not applicable

Risk for non-professional users- 12 hour scenario- Advanced heater

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg/d	AEL mg/kg/d	Estimated uptake mg/kg/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1a- Application, Infant	1	1	0.01	0.0044 mg/kg	44	Yes
1a- Application, Adult	1	1	0.01	0.0017 mg/kg	17	Yes

Combined scenarios
Not Applicable

Risk for the general public- 12 hour scenario- Advanced heater

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg/d	AEL mg/kg/d	Estimated uptake mg/kg/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
2a- Post application, infant.	1	1	0.01	0.0.001062	11	Yes
2a- Post application, adult.	1	1	0.01	Not calculated	N/A	N/A

Combined 12 hour scenarios- *Advanced heater*

Scenarios combined	Tier	Systemic NOAEL mg/kg/d	AEL mg/kg/d	Estimated uptake mg/kg/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios 1a+2a, infant	1	1	0.01	0.00	55	Yes
Scenarios 1a+2a, adult	1	1	0.01	0.0017	17	Yes

Local effects
Not applicable

Conclusion for 12 hour scenario- *Advanced heater*

Based on the risk assessments above, adverse effects are not anticipated following consumer use of Transfluthrin Liquid Electric for the 12 hour scenario. All routes of exposure result in exposure estimates of < 50% of the relevant AEL.

Risk for non-professional users- 24 hour scenario- Advanced heater

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg/d	AEL mg/kg/d	Estimated uptake mg/kg/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1b- Application, Infant	1	1	0.01	0.0089 mg/kg	89	Yes
1b- Application, Adult	1	1	0.01	0.0035 mg/kg	35	Yes

Combined scenarios
Not Applicable

Risk for the general public- 24 hour scenario- Advanced heater

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg/d	AEL mg/kg/d	Estimated uptake mg/kg/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
2b- Post application, infant.	1	1	0.01	2.1×10^{-3}	21	Yes
2b- Post application, adult.	1	1	0.01	Not determined	Not applicable	Yes

Combined 24 hour scenarios- *Advanced heater*

Scenarios combined	Tier	Systemic NOAEL mg/kg/d	AEL mg/kg/d	Estimated uptake mg/kg/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios 1b+2b, infant	1	1	0.01	0.0111	111	Yes*
Scenarios 1b+2b, adult	1	1	0.01	0.0035	35	Yes

* see conclusion below

Local effects
Not applicable

Conclusion for 24 hour scenario- - *Advanced heater*

Based on the risk assessments above, adverse effects are not anticipated following consumer use of Transfluthrin Liquid Electric for the 24 hour scenario when adults are concerned.
However, considering the combined 24h scenario for the advanced heater (direct and indirect exposure), this would result in 111% of the AEL and thus a slight exceedance of the AEL for infants. Nevertheless, it should be noted that 24 hour exposure is a highly conservative scenario for the following reasons:

- Calculations are made for the advanced heater at high level setting for a period of 24 h. However, this is considered a worst case approach since the advanced heater turns itself On and Off automatically because the heater has a programmable timer that remembers the consumer settings. This type also has three intensity settings low, medium and high. Calculations were made for the high use setting.
- It was conservatively assumed that an infant spents 24 hours in a small bedroom inhaling the vapour, without leaving the room. It is considered that being in the

same room for more than 18h for an infant is an exceptional case. An infant of this age would spend time in other rooms in the home as well (whilst being watched by their care-giver) or outside the home. Please note that in case the apparatus is left on during 24 h but that an infant spends 18 h per day in that particular room, the combined direct and indirect exposure of an infant does not result in an exceedance of the AEL (i.e. 87% AEL).

- Furthermore, in the calculations for post-application worst case assumptions are made, e.g. accumulation on the floor (dermal and oral exposure to the amount deposited in 7 sequential days resulting in a 4-fold accumulation) in the post-application exposure without a decrease in a.s. content due to reaction, degradation or ventilation.
- The use of a 70% absorption value is considered as a worst case approach in the absence of product specific data.

Thus, even when considering a default dermal absorption value of 70% and although the AEL is slightly exceeded (111% of the AEL), no risk is expected for infants.

Risk for consumers via residues in food

Not applicable

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 Transfluthrin Liquid Electric for pets is not considered necessary as the assessment performed for humans will cover companion animals as well. For infants the exposure assessment made results in an exposure value below the AEL. The assessment made is considered worst case considering that the device is turned on for a period of 24 hours and that a child is present in the respective room for the entire 24 hours and also crawls on the floor during an hour. These worst case assumptions are considered to sufficiently cover the exposure to pets, e.g. cats who are not likely to be present in a bedroom for 24 hours. Please note that the exposure mainly comes from direct exposure during application, e.g. being present in a room where the device is used.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

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

The new ecotox endpoints for transfluthrin and metabolite TFB-COOH and the DT50 soil for transfluthrin and metabolite NAK 4723 (2,3,5,6-tetrafluorobenzoic acid, BCS-AA52185) are included in the amended LoEP for transfluthrin PT18 containing the data submitted after active substance approval agreed by the BPC at meeting no. 24 (2018).

Information relating to the ecotoxicity of the active substance

Summary table for aquatic toxicity data					
Species	**Substance**	**Timescale**	**Endpoint**	**Results**	**Reference**
Fish					
Oncorhynchus mykiss	Transfluthrin	Acute	LC_{50}	0.7 µg/L	Transfluthrin Assessment Report (NL, 2014)
Pimephales promelas	Transfluthrin	Chronic	NOEC	0.399 µg/L	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
Oncorhynchus mykiss	TFB-COOH	Acute	LC_{50}	>100 mg/L	Transfluthrin Assessment Report (NL, 2014)
Invertebrates					
Daphnia magna	Transfluthrin	Acute	EC_{50}	1.4 µg/L (geomean of 1.2 and 1.7 µg/L)	Transfluthrin Assessment Report (NL, 2014)
Daphnia magna	Transfluthrin	Chronic	NOEC	0.0175 µg/L	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
Daphnia magna	TFB-COOH	Acute	EC_{50}	>100 mg/L	Transfluthrin Assessment Report (NL, 2014)
Algae (growth inhibition)					
Scenedesmus subspicatus	Transfluthrin	Acute	E_rC_{50}	>100 µg/L	Transfluthrin Assessment Report (NL, 2014)
		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	3.05 mg/L	
Sediment organisms					
Chironomus riparius	Transfluthrin	Chronic emergence rate	NOEC	0.164 mg/kg dw sed	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
Lumbriculus	Transfluthrin	Chronic	NOEC	2.21 mg/kg dw sed	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
Mircoorganisms					
Respiration activated sludge	Transfluthrin	Acute	NOEC	57 µg/L (water sol.)	Transfluthrin Assessment Report (NL, 2014)
			EC_{50}	>10000 mg/L	

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. A PNECstp based on the reported endpoint of EC50 > 10,000 mg/L is included additionally. Application of an assessment factor of 100 leads to a PNECstp for transfluthrin of 100 mg/L. The lowest $PNEC_{STP}$ of 0.057 mg/L will be used in the risk assessment. • *The applicant notes that it is considered highly unlikely that metabolites will represent an issue to STP microorganisms as there was no inhibition in the OECD 314 B study.* No activated sludge toxicity data are available for metabolites identified in the OECD 314 B test. No assessment of the toxicity of the test substance towards the bacteria (no toxicity test, containing both the test substance and a reference compound), was included in the experiment. Nevertheless the eCA considers the risk assessment for the STP of the active substance sufficient for covering also the metabolites.

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 (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 of 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 ths endpoint. Accordingly , the revised $PNEC_{aquatic}$ for transfluthrin is proposed to be 1.75 ng/L. 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 3-(2,2-dichlorovinyl)-2,2-dimethylcyclo-propane carboxylic acid (DCVA; also named permethric acid) an acute LC50 for daphnia of 25 mg/l was reported. 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, by applying an assessment factor of 1000. For the metabolites cis-OH-DCVA and trans-OH-DCVA, no ecotoxicity data are available.

Conclusion used in Risk Assessment - Aquatic Sediment Toxicity	
Value/conclusion	$PNEC_{sediment}$ for Transfluthrin: 1.64 µg/kg dw sediment (equivalent to 0.36 µg/kg ww sediment)
Justification for the value/conclusion	During the BPD review of Transfluthrin, no specific studies concerning potential toxicity to sediment dwelling organisms were available. As a result, the PNECsediment was derived on the basis of the available aquatic ecotoxicty data using the equilibrium partitioning method (EPM). In order to take account of uncertainty applying the EPM to substance with Log Kow>5, an additional safety factor was applied. Further chronic studies have subsequently been conducted with transfluthrin. An OECD 225 study with *Lumbriculus* 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 used test organisms were fed with fresh food, thus theoretically limiting the exposure to the test substance. In accordance with the conclusions in the Environment Working Group Meeting IV 2017 (ECHA, 2017a) the PNEC sediment value is set at 1.64E-03 mg/kg dw (equivalent to 0.36 µg/kg ww). 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 (NL, 2014)

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 (standard soil with 3.4 % OM)	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
Nitrogen mineralisation	Transfluthrin	Chronic	EC_{10}	3.8 mg/kg dw soil (1.47% OM)	5.24 mg/kg dw soil (standard soil with 3.4 % OM)	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
Non-target plants	Transfluthrin	Seedling emergence and growth	EC_{50} NOEC	75.73 mg/kg dw soil 18 mg/kg dw soil (0.72% OC)	210.4 mg/kg dw soil 50 mg/kg dw soil (standard soil with 2% OC)	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)

* endpoint was disregarded at WG in this case.

Conclusion used in Risk Assessment – Terrestrial Toxicity Data	
Value/conclusion	$PNEC_{soil}$ for transfluthrin: 0.1 mg/kg dw (equivalent to 0.088 mg/kg ww) $PNEC_{soil}$ for 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH): 0.012 mg/kg ww $PNEC_{soil}$ 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 PNECaquatic using the Equilibrium Partitioning Method (EPM). Since the approval decision, additional studies have been conducted on earthworm (sub-lethal effects), on collembolan (reproduction) and micro-organisms (nitrogen transformation) and non-target plants (seedling emergence andgrowth). 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). In the case of the metabolite 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH) no data has been generated on terrestrial organisms. Therefore, the Equilibrium Partitioning Method is used to derive the $PNEC_{soil}$ based on the $PNEC_{aquatic}$. Taking account of the 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 (Blondaz, 2018). For 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).

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 the Transfluthrin Assessment Report, 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 and metabolites 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)..

Summary table for PNECs used in Risk Assessment		
Parameters	**Concentration**	**Notes**
Transfluthrin		
$PNEC_{STP}$	0.057 mg/L	Transfluthrin Assessment Report (NL, 2014)
$PNEC_{water}$	1.75E-06 mg/L	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
$PNEC_{sediment}$	1.64E-03 mg/kg_{dwt} sediment 3.6E-04 mg/kg_{wwt} sediment	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
$PNEC_{soil}$	0.1 mg/kg_{dwt} soil 0.088 mg/kg_{wwt} soil	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
$PNEC_{oral,\ mammals}$	6.67 mg/kg feed	Transfluthrin Assessment Report (NL, 2014)
Metabolites		
2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH)		
$PNEC_{water}$	>0.1 mg/L	Transfluthrin Assessment Report (NL, 2014)
$PNEC_{soil}$	0.012 mg/kg ww soil	Calculated using EPM
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
$PNEC_{soil}$	0.0128 mg/kg ww soil	

For the metabolites, the $PNEC_{sediment}$ is determined by equilibrium partitioning of the PNECwater. However, because the PECsediment is also determined by equilibrium partitioning from the PECwater, no PECs or PNECs are presented for the sediment compartment.

In view of the chemical structure similarity of TFB-OH and TFB-COOH, and the comparable physico-chemical characteristics (as also discussed in the Assessment Report for

transfluthrin (2014)), the risk of TFB-OH 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 3.8) 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 environmental fate of the active substance

Endpoint	Test conditions	Temperature (°C)	Results	Reference
Transfluthrin				
Hydrolysis	pH5	25	Insignificant degradation	Transfluthrin Assessment Report (NL, 2014)
	pH7	25	Insignificant degradation	
	pH9	25	DT_{50} = 14 days	
Ready biodegradability	-	-	Not readily biodegradable	Transfluthrin Assessment Report (NL, 2014)
Degradation in activated sludge - OECD 314B	-	21.7	DT_{50} = 0.284 days Degradation Kinetics recalculated at ENV WG (full documentation not yet provided)	[redacted] (2017); [redacted] (2018)
DT_{50} Water/sediment system	whole system	20	11.1 days	Transfluthrin Assessment Report (NL, 2014)
	water		<7 days	
	sediment		14.1 days	
DT_{50} Soil	-	12 (normalised from 20)	Laacher Hof: -3.66	Transfluthrin Assessment Report – Amended List of Endpoints (BPC-24, 2018)
			Dollendorf II**:** 2.45	
			Höfchen: 34.71	
			Wurmwiese: 2.4	
			Geomean: 5.17	

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.

Co-formulant 2,6-di-tert-butyl-p-cresol is also classified as Aquatic Acute 1 (M=1) H400 and Aquatic Chronic 1 (M=1) H410 based on a lowest acute IC_{50} of > 0.4 mg/L (algae) and lowest chronic NOEC of 0.316 mg/L (Invertebrates).

Taking the concentration of Transfluthrin (0.88% w/w) and 2,6-di-tert-butyl-p-cresol (1% w/w) in the biocidal product into account, the environmental classification of the product can be calculated as follows:

Acute Environmental Classification of Product:
Acute 1 x M ≥25% = Acute 1

(0.88% x 1000) + (1% x 1) = 881%

Chronic Environmental Classification of Product:
Chronic 1 x M ≥ 25% + chronic 1

(0.88% x 1000) + (1% x 1) = 881%

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

The presence of 2,6-di-tert-butyl-p-cresol alone in the formula would trigger classification for Chronic 3:

(M x 100 x Chronic 1) + (10 x Chronic 2) + Chronic 3 > 25%

(1 x 100 x 1%) = 100%

Therefore, 2,6-di-tert-butyl-p-cresol (BHT) is considered a substance of concern for the environment and an environmental risk assessment is required.

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), 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.

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 Competent Authority Report. 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.

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.

Endocrine disruption activity of non-active substances

According to Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR), an ED hazard assessment of the b.p. needs to be performed. To comply with this information requirement, the co-formulants contained in the b.p. were screened for indications of potential ED properties.

Since the identity of co-formulants is confidential information, details on the ED screening approach of the co-formulants and its results are provided in the confidential Annex.

For the co-formulants the databases as stated the confidential Annex are considered, as well as additional databases relevant for non-target organisms including:

- Identified as ED by the United Nations Environment (July 2017) Programme(http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y and https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)
- UN factsheet (https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)
- Denmark EPA (http://cend.dk/files/DK_ED-list-final_2018.pdf)
- Japan ED database (https://www.env.go.jp/en/chemi/ed/speed98/sp98t3.htm)

Only the co-formulant 2,6-di-tert-butyl-p-cresol triggered a potential alert for ED property. This co-formulant is included in the United Nations Environment Programme and has a potential ED alert in CoRAP. (see Section 2.2.5). As discussed in Section 2.2.5, CA NL considers that the ED assessment should await the outcome of the discussions at EU level. If this co-formulant 2,6-di-tert-butyl-p-cresol is concluded to possess ED potency the authorisation granted for Transfluthrin Liquid Electric needs to be re-evaluated.

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 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	Secondary poisoning
Indoors vapouriser	Yes[+]	Yes[+]	Yes[+]	Yes[+]	Yes[++]	Not relevant[(+)]	Yes[+]	Yes[+]	Yes

[+] 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 other member states for comments via e-consultation. All comments received were discussed in a dedicated ad hoc expert group and the evaluation was finalised. 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)[7], 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 d. This value can be used to calculate a refined estimate of fate of transfluthrin in a wastewater treatment plant.
The study results are as follows:

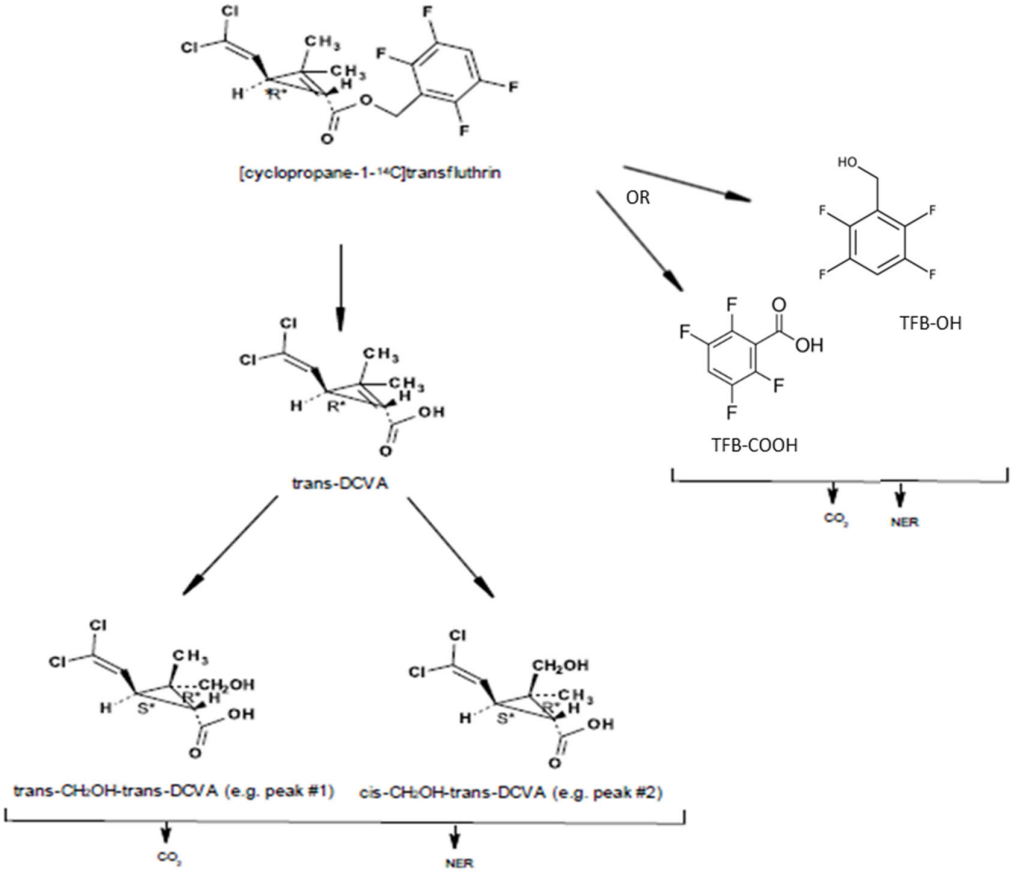
Pathway:
The study describes a pathway that includes transfluthrin > trans-DCVA > trans-OH-DCVA & cis-OH-DCVA (degradation of the phenyl moiety). The benzene moiety was unlabeled and

[+] 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

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:



Name	Max observed %	Formation fraction (Cake results)	DT50 (d) 21.7°C	DT50 for modelling (d) 15°C	Remarks
Transfluthrin	-	-	0.284	0.5	pseudo DT50 (DT90/3.32) from FOMC result
trans-DCVA	64.0	0.9678	0.897	1.5	ff from f_{trans}
trans-OH-DCVA	5.8	0.2609	0.341	0.6	ff from $f_{trans-DCVA}$
cis-OH-DCVA	60.4	0.6192	>10000	>10000	ff from $f_{trans-DCVA}$

According to the metabolite definition in the BPR guidance part B&C volume IV (2017), the metabolites trans-DCVA and cis-OH-DCVA are major metabolites for the STP. Metabolite trans-OH-DCVA is a minor metabolite, because it is only observed once at more than 5%

AR. When a metabolite is considered major in the STP, all subsequent compartments (aquatic and soil) are included in the RA as well, because emission to those compartments is inevitable.

For risk assessment TFB-COOH and TFB-OH should be included. Because both metabolites are similar in their toxicity and formation fraction, it could be sufficient to present only the results of TFB-COOH, because this metabolite has a slightly higher molar weight. For completeness, both metabolites are shown in this risk assessment. Both metabolites can be formed from parent with a theoretical 100% formation (f.f. = 1.0).

Name	Max observed %	Formation fraction (Cake results)	DT50 (d) 21.7°C	DT50 for modelling (d) 15°C	Remarks
TFB-OH	-	1.0	>10000	>10000	ff from f_{trans} worst-case default
TFB-COOH	-	1.0	>10000	>10000	ff from f_{trans} worst-case default

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 soil (ADS)

No further data are required.

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

No further data are required.

Testing for distribution and dissipation in air (ADS)

No further data are required.

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

The biocidal 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.

Information relating to the ecotoxicity of the substance of concern

Summary table for aquatic toxicity data for 2,6-di-tert-butyl-p-cresol (BHT)					
Species	**Guideline**	**Timescale**	**Endpoint**	**Results**	**Reference**
Fish					
Danio rerio	Regulation (EC) No. 440/2008, Annex, C.1	Acute (96h)	LC50	>0.57 mg/L	Supplier MSDS: Vulkanox BHT. v. 2.0
Oryzias latipes	OECD 210	Chronic (42d)	NOEC	0.053 mg/L	Supplier MSDS: Vulkanox BHT. v. 2.0
Invertebrates					
Daphnia magna	OECD 202	Acute (48h)	EC50	0.48 mg/L	Supplier MSDS: Vulkanox BHT. v. 2.0
Daphnia magna	OECD 202	Chronic (21 d)	NOEC	0.023 mg/L	Supplier MSDS: Vulkanox BHT. v. 2.0
Algae (growth inhibition)					
Desmodesmus subspicatus	Regulation (EC) No. 440/2008, Annex, C.3	Acute (72h)	IC50 (growth rate)	>0.4 mg/L	Supplier MSDS: Vulkanox BHT. v. 2.0
Desmodesmus subspicatus	Regulation (EC) No. 440/2008, Annex, C.3	Acute (72h)	NOEC (growth rate)	0.4 mg/L	Supplier MSDS: Vulkanox BHT. v. 2.0
Sediment organisms					
-	-	-	-	-	-
Mircoorganisms					
Tetrahymena pyriformis	-	Acute (24h)	EC50 growth inhibition	1.7 mg/L	ECHA database
Photobacterium phosphoreum	-	Acute (30 min)	EC50 light emission	8.98 mg/L	ECHA database
Pseudomona fluorescens	-	Acute (37 h)	EC50 viable cells	50 mg/L	ECHA database
Respiration activated sludge	OECD 209	Acute (3h)	EC50	>10,000 mg/L	Supplier MSDS: Vulkanox BHT. v. 2.0

Conclusion used in Risk Assessment – STP Microorganisms	
Value/conclusion	$PNEC_{STP}$ for 2,6-di-tert-butyl-p-cresol: 0.17 mg/L
Justification for the value/conclusion	The $PNEC_{STP}$ the endpoint reported in the ECHA database of EC50 1.7 mg/L for growth inhibition of respiration in activated sludge with an assessment factor of 10 applied. Some reservations raise during the commenting period because this endpoint is above solubility and the substance is rather volatile (38% of volatilisation from STP sludge is predicted for this substance). Notwithstanding these reservations the proposed PNEC is accepted considering that significant inhibition was observed in the test and the initial concentration is sufficient to address the toxicity in an STP. The eCA's opinion is that no further factor to correct for volatility is needed. A future more indepth evaluation of the studies and endpoints is, however, recommended.

Conclusion used in Risk Assessment - Aquatic Toxicity	
Value/conclusion	$PNEC_{aquatic}$ for 2,6-di-tert-butyl-p-cresol: 2.3 µg/L
Justification for the value/conclusion	Both acute and chronic studies covering fish, invertebrates and algae have been conducted. The lowest chronic endpoint is a NOEC of 0.023 mg/L reported for a 21-day daphnia reproduction study. Since chronic studies covering three trophic levels are available, it is appropriate to apply an assessment factor of 10 to ths endpoint. Accordingly , the $PNEC_{aquatic}$ for the Substance of Concern 2,6-di-tert-butyl-p-cresol is taken as 2.3 µg/L[4].

[4] It is noted that an alternative PNEC of 0.199 µg/L is reported in the REACH Registered Substance Database. However, this PNEC is based upon an estimated acute toxicity value for fish (with Assessment Factor 1000 applied), so can be disregarded as it is superceded by the more recent chronic studies that were performed on the substance.

Conclusion used in Risk Assessment - Aquatic Sediment Toxicity	
Value/conclusion	$PNEC_{sediment}$ for 2,6-di-tert-butyl-p-cresol: 0.34 mg/kg dry weight sediment (equivalent to 0.0739 mg/kg wet weight sediment) calculated using the Equilibrium Partitioning Method with reported Koc value of 14750 L/kg and an additional safety factor of 10 was applied because of the log Kow >5.
Conclusion used in Risk Assessment - Terrestrial Toxicity	
Value/conclusion	$PNEC_{soil}$ for 2,6-di-tert-butyl-p-cresol: 0.0679 mg/kg dry weight sediment (equivalent to 0.0599 mg/kg wet weight sediment) calculated using the Equilibrium Partitioning Method with reported Koc value of 14750 L/kg and an additional safety factor of 10 was applied, because of the log Kow >5.
Conclusion used in Risk Assessment – Secondary Poisoning *via* the Food Chain	
Value/conclusion	$PNEC_{oral,\ mammals}$ for transfluthrin: 8.33 mg/kg feed
Justification for the value/conclusion	The $PNEC_{oral}$ for secondary poisoning of mammals is derived by applying a conversion factor of 10 and an assessment factor of 30 to the chronic NOAEL of <25 mg/kg bw/d (LOAEL = 25 mg/kg bw/d), resulting in a $PNEC_{oral,mammal}$ of <8.33 mg/kg feed. In the absence of short-term or long-term toxicity data for birds, a $PEC/PNEC_{oral,bird}$ cannot be derived and the risk is based on the PNEC for mammals.

Summary of PNEC values for the Substance of Concern

Summary table for PNECs used in Risk Assessment		
Parameters	**Concentration**	**Notes**
2,6-di-tert-butyl-p-cresol		
$PNEC_{STP}$	0.17 mg/L	Supplier MSDS: Lanxess v. 2.0
$PNEC_{water}$	0.0023 mg/L	Supplier MSDS: Lanxess v. 2.0
$PNEC_{sediment}$	0.34 mg/kg_{dwt} sediment 0.0739 mg/kg_{wwt} sediment	Supplier MSDS: Lanxess v. 2.0
$PNEC_{soil}$	0.0679 mg/kg_{dwt} soil 0.0599 mg/kg_{wwt} soil	Supplier MSDS: Lanxess v. 2.0
$PNEC_{oral,\ mammals}$	<8.33 mg/kg feed	Data available at Ctgb (two-generation study with rats demonstrating effects on weight in offspring and no effects for the parent). As a first tier the AF is set at 30 as default. If the RCR is close to 1 a further assessment is needed.

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.
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) 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 for PT18 (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

The product can be used with three different heater types; Base, Adjustable, and Advanced. The different variants of the different heater types are summarized in the table below. In each case, the range of emission rates and associated duration of protection (assuming 8 hours use per day) are listed. It should be noted that for each variant different refill levels are available (small = 21 mL; Large = 31 mL). In addition, for the Advance variant a 'starter pack' is also available, with fill level 33 mL.

Heater	Fill level (mL)	Weight of fill / quantity of product (g)	Mass of transfluthrin (g)	Use duration (hrs per day)
Base	21 mL	**16.4**	0.14432	8 hrs/day* / 24 hrs/day
Base	31 mL	**25.2**	0.22176	8 hrs/day* / 24 hrs/day
Adjustable (Dual)	21 mL	**16.4**	0.14432	8 hrs/day* / 24 hrs/day
				8 hrs/day* / 24 hrs/day
Adjustable (Dual)	31 mL	**25.2**	0.22176	8 hrs/day* / 24 hrs/day
				8 hrs/day* / 24 hrs/day
Advance	21 mL	**16.4**	0.14432	8 hrs/day* / 12-24 hrs/day
				8 hrs/day* / 12-24 hrs/day
Advance	31 mL	**25.2**	0.22176	8 hrs/day* / 12-24 hrs/day
				8 hrs/day* / 12-24 hrs/day
Advance (starter pack)	33 mL	**26.8**	0.2358	8 hrs/day* / 12-24 hrs/day
				8 hrs/day* / 12-24 hrs/day

* These values are used by the applicant. NL eCA notes that only the Advance heater incorporates a timer, which can be adapted from continuous emission to a emission period of 8 to 12 hours then switches off. The other 2 systems (base and adjustable heater) have to be switched off manually. For these latter systems a 24 h emission is used as a realistic worst case approach.
12 hours period is used as a refinement for the Advance heater system due to the incorporated timer, although the system has the option of continuous emission and the product is for use against flies (active during day time) and mosquitoes (active during night), which may result in a 24 hours use.

Worst-case assessments were performed with both the Adjustable and Advanced heaters. In each case, it was conservatively assumed that the product was used at the highest rate possible (i.e. shortest protection time), which would result in the maximum expected emission per day. The worst case scenario (combinations of fill size and total duration of protection) are highlighted in the above table. It should be noted that the worst case scenarios are not necessarily associated with the largest fill level for each device, but are determined by the ratio between fill level and duration of protection.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Consumer use of insecticide diffuser product			

Quantity of product contained in the device/diffuser (Q_{prod})	25.2	g	S – Weight of refill. This is equivalent to 31 mL
Fraction of active substance in product (F_{AI})	0.0088	[-]	S (The quantitative risk assessment was carried out considering the pure content of active substance in the product. The conclusions of the dossier are the same if it is based on the technical concentration)
Quantity of active substance contained in the device/diffuser (Q_{AI})	0.221	g	S
Fraction of Substance of Concern 2,6-Di-tert-butyl-4-methylphenol CAS 128-37-0 ($F_{SoC)}$	0.01	[-]	S
Quantity of Substance of Concern contained in the device/diffuser (Q_{soc})	0.252	g	S
Maximal duration of use of the device/diffuser (T_{max})	320	h	S – Maximum duration for refill used in Dual (**Adjustable)** heater on High setting
Maximal duration of use of the device/diffuser (T_{max})	192	h	S – Maximum duration for refill used in **Advance** heater on High setting
Duration of use per day (T_{day}) **Adjustable** and **Advance** heater	24	$h.d^{-1}$	S – Worst case assumption
Duration of use per day (T_{day}) **Advance** heater	12	$h.d^{-1}$	S – refinement when using the build-in timer
Number of emission days ($T_{emission}$)	152	d	S - Reflecting seasonality of use, as specified in Transfluthrin Assessment Report (2014)[5]
Number of diffusers per household	2	-	In line with TAB 148 (December 2019)

It is important to note that the environmental risk assessment uses simultaneity to take account of the number of sources in an 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 ($F_{simultaneity}$). The default figure for products used on a daily basis is 0.0552.

Calculations

Application step

[5] $T_{emission}$ required for calculation of secondary poisoining *via* the food chain

Emission to air

The Emission Scenario Document (OECD, 2008) states that during the application, 90% of the insecticide applied may remain airborne. As explained in the ESD for PT18 (2008), the fraction emitted to air during cleaning events is considered to be negligible. Therefore, releases to air are not considered to be significant

Emission to Floor

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

$$E_{application,floor} = Q_{prod} \times F_{AI} \times \frac{T_{day}}{T_{max}} \times F_{application,floor} \times 10^{-3}$$ PT18 ESD, eq.32

Where:

Variable/Parameter	***Symbol***	***Unit***	***Value***	***S/D/O/P***
Active substance				
Input				
Quantity of product contained in the device/diffuser	Q_{prod}	g	25.2	S – Weight of refill. This is equivalent to 31 mL
Fraction of active substance in product	F_{AI}	[-]	0.0088	S (The quantitative risk assessment was carried out considering the pure content of active substance in the product. The conclusions of the dossier are the same if it is based on the technical concentration)
Fraction emitted to floor during application	$F_{application,floor}$	-	0.1	D (Default – diffusers)
Output				
Emission to floor during the application step for **Adjustable** diffuser (T=24h)	$E_{application,floor}$	$kg.d^{-1}$	1.66E-06	O
Emission to floor during the application step for **Advance** diffuser (T=24h)	$E_{application,floor}$	$kg.d^{-1}$	2.77E-06	O
Emission to floor during the application step for **Advance** diffuser refinement (T=12h)	$E_{application,floor}$	$kg.d^{-1}$	1.39E-06	O

Variable/Parameter	***Symbol***	***Unit***	***Value***	***S/D/O/P***
Substance of Concern (2,6-di-tert-butyl-p-cresol)				
Input				
Quantity of product contained in the device/diffuser	Q_{prod}	g	25.2	S (see above)
Fraction of SoC (2,6-di-tert-butyl-p-cresol)	F_{SoC}	[-]	0.01	S

Variable/Parameter	***Symbol***	***Unit***	***Value***	***S/D/O/P***
Fraction emitted to floor during application	$F_{application,floor}$	-	0.1	D
Output				
Emission to floor during the application step for **Adjustable** diffuser (T=24h)	$E_{application,floor}$	$kg.d^{-1}$	1.89E-06	O
Emission to floor during the application step for **Advance** diffuser (T=24h)	$E_{application,floor}$	$kg.d^{-1}$	3.15E-06	O
Emission to floor during the application step for **Advance** diffuser – refinement (T=12h)	$E_{application,floor}$	$kg.d^{-1}$	1.58E-06	O

Cleaning step

Emission to air

As explained in the ESD for PT18 (2008), the fraction emitted to air during cleaning events is considered to be negligible. Therefore, releases to air are not considered to be significant.

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. As emission to solid waste results in negligible exposure of the environment, releases via solid waste are not further included in the risk assessment.

Emission to Wastewater

The Emission Scenario Document (PT18) for insecticides, acaricides and products to control other arthropods for household and professional uses suggests that residues deposited onto floor may potentially be exposed to cleaning. In situations where cleaning is conducted using water, residues may conceptually be emitted to wastewater. In the case of diffusers, the Emission Scenario Document makes some worst case assumptions:

- the entire fraction of deposited residue is exposed to cleaning (Fce = 1)
- cleaning is 100% efficient, neglecting the effect of sorption and degradation
- 30% of the surface area is wet cleaned (in line with TAB 148 (December 2019))

It is noted in the ESD (OECD, 2008) that the F_{CE} values only reflect the fraction of insecticide that is exposed to cleaning and does not take into account the potential degradation and /or sorption onto the different materials exposed. In order to understand the effect of these processes, experiments were conducted to investigate the potential emission of active substance from a range of representative flooring surfaces following standardised wet cleaning methods (please refer to Confidential Annex Section 3.6). These refinement data were discussed at the WG and the CG (August 2020). It was concluded that these data can

be used to justify lowering the Fce slightly. However, as risks are acceptable without the refinement, this is not included in the risk assessment.

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

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

Where:

Variable/Parameter	***Symbol***	***Unit***	***Value***	***S/D/O/P***
Active substance				
Input				
Emission to floor during the application step for **Adjustable** diffuser	$E_{application,floor}$	$kg.d^{-1}$	1.66E-06	O
Emission to floor during the application step for **Advanced** diffuser	$E_{application,floor}$	$kg.d^{-1}$	2.77E-06	O
Emission to floor during the application step for **Advanced** diffuser - refinement	$E_{application,floor}$	$kg.d^{-1}$	1.39E-06	O
Fraction emitted to wastewater during the cleaning step	F_{ww}	-	1	D
Cleaning efficiency	F_{CE}	-	1	P (Default)
Surface area that is wet cleaned	-	-	0.3	
Number of diffusers per household	-	-	2	
Output				
Emission from floor/treated to wastewater during the cleaning step for diffuser:				
Adjustable (T=24h F_{CE}=100%)	$E_{treated,ww}$	$kg.d^{-1}$	9.98E-07	O
Advance (T=24h F_{CE}=100%)	$E_{treated,ww}$	$kg.d^{-1}$	1.66E-06	O
Advance (T=12h F_{CE}=100%)	$E_{treated,ww}$	$kg.d^{-1}$	8.32E-07	O

The calculated emission rates to wastewater, expressed in $kg.d^{-1}$, can be used further in SimpleTreat v. 4.0. 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 ($F_{simultaneity}$). The default figure for products used on a daily basis is 0.0552. The corresponding number of households using the product simultaneously is 221. The resulting estimates of emission to wastewater at the catchment scale are summarised in the following table.

$Elocal_{STP} = E_{treated,ww} * 4000 * 0.0552$

The resulting estimates of emission to wastewater at the catchment scale fpr the active substance and SoC are summarised in the following tables

Resulting local emission to relevant environmental compartments			
Active substance			
Compartment	**Heater**	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	Adjustable	2.20E-04	Default (T=24 h, F_{ce} =100%)
	Advance	3.67E-04	Default (T=24 h, F_{ce} =100%)
	Advance	1.84E-04	Timer refinement (T=12 h, F_{ce} =100%)

Resulting local emission to relevant environmental compartments			
Substance of Concern (2,6-di-tert-butyl-p-cresol)			
Compartment	**Heater**	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	Adjustable	2.50E-04	Default (T=24 h, F_{ce} =100%)
	Advance	4.17E-04	Default (T=24 h, F_{ce} =100%)
	Advance	2.09E-04	Timer refinement (T=12 h, F_{ce} =100%)

Fate and distribution in exposed environmental compartments

Active Substance

Identification of relevant receiving compartments based on the exposure pathway						
Freshwater	Freshwater sediment	STP	Air	Soil	Ground-water	Secondary poisoning
Yes^{+}	Yes^{+}	Yes^{++}	Yes$^{(+)}$	Yes^{+}	Yes^{+}	Yes

$^{+}$ 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

Input parameters for calculating the fate and distribution in the environment (transfluthrin)			
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 degradation in soil	5.17	d (at 12ºC)	Updated LoEP transfluthrin (2017)
DT_{50} for degradation in air	2.4	d	based on 24-hr day and 0.5E6 OH/cm³
Bioconcentration factor (fish)	1783	L/kg	Average of measured values (1704 and 1861 L/kg ww)
Bioconcentration factor (BCF) (earthworms)	10452	L/kg	Estimated BCF (Transfluthrin Assessment Report, 2014)

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

Calculated fate and distribution in the STP -Transfluthrin	
Compartment	Percentage [%]
	Simpletreat 4.0[6] including OECD 314B
Air	0.19
Water	1.31
Sludge	59.94
Degraded in STP	38.56
Total	100.0

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

Metabolites

An OECD 314B study on biodegradation in activated sludge of the active substance Transfluthrin was conducted (Hellpointner and Kasel, 2017)[7].

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 Hellpointner 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. 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 to TFB-OH is covered by the risk assessment for TFB-COOH.

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 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. 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***	**Remarks**
	g/mol	g/g	mol/mol	
Transfluthrin	371.2	-	-	
trans-DCVA	208.1	0.56	0.9678	f.f. from transfluthrin
TFB-COOH	194.08	0.52	1	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.

[7] This study has been submitted directly to Ctgb for evaluation by the Active Substance Supplier

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 3.8 for the QSAR estimates.

Input parameters for calculating the fate and distribution of metabolites in groundwater						
	Koc[1]	**$Kp_{\_soil}$**	**Vapour pressure[2]**	**Solubility**	**K_{soil_water}[3]**	**DT50 (12°)**
	L/kg	L/kg	Pa	mg/L	-	
trans-DCVA	106	2.12	2.6	372.2[4]	3.38	174.8
TFB-COOH	10.71	0.21	8.45	2114	0.52	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.
[4] From the Assessment Report of cyfluthrin (2018)

Substance of Concern

Input parameters for calculating the fate and distribution in the environment (Substance of Concern)			
Input	**Value**	**Unit**	**Remarks**
2,6-di-tert-butyl-p-cresol			
Molecular weight	220.35	g/mol	
Melting point	69.8	°C	Supplier MSDS: Vulkanox BHT. v. 2.0
Vapour pressure (at 20 °C)	1	Pa	Supplier MSDS: Vulkanox BHT. v. 2.0
Water solubility (at 25 °C)	0.76	mg/L	Supplier MSDS: Vulkanox BHT. v. 2.0
Log Octanol/water partition coefficient	5.1	Log 10	Supplier MSDS: Vulkanox BHT. v. 2.0
Organic carbon/water partition coefficient (Koc)	14750	L/kg	Supplier MSDS: Vulkanox BHT. v. 2.0
Biodegradability	Not biodegradable		Supplier MSDS: Vulkanox BHT. v. 2.0
Bioconcentration factor (aquatic species)	645.6	L/kg	EPISuite

Calculated fate and distribution in the STP (SoC)		
Compartment	Percentage [%]	Remarks
	SimpleTreat 4.0	
Air	39.1	-
Water	10.8	-
Sludge	50.0	-
Degraded in STP	0	-

Calculated PEC values

Summary table on calculated PEC values (Active Substance)					
Heater	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]
Adjustable (T=24h F_{CE}=100%)	1.45E-06	1.34E-07	1.47E-04	2.39E-04	6.6E-05
Advance (T=24h F_{CE}=100%)	2.41E-06	2.24E-07	2.45E-04	3.98E-04	1.10E-04
Advance (T=12h F_{CE}=100%)	1.21E-06	1.12E-07	1.23E-04	2.00E-04	5.5E-05

Summary table on calculated PEC values (Metabolites)			
Heater	**PEC_{water}[a]**	**PEC_{soil}**	**PEC_{GW} (1st tier)**
	[mg/L]	[mg/kg_{wwt}]	[µg/L]
trans-DCVA			
Adjustable (T=24h F_{CE}=100%)	2.30E-06	1.58E-04	0.07
Advance (T=24h F_{CE}=100%)	3.84E-06	2.64E-04	0.12
Advance (T=12h F_{CE}=100%)	1.93E-06	1.33E-04	0.06
TFB-COOH			
Adjustable (T=24h F_{CE}=100%)	2.22E-06	1.25E-04	0.07
Advance (T=24h F_{CE}=100%)	3.70E-06	2.08E-04	0.12
Advance (T=12h F_{CE}=100%)	1.86E-06	1.05E-04	0.006

[a] The risk assessment for surface water also covers the risk for sediment, because both PEC and PNEC sediment are based on equilibrium partitioning

Heater	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]
2,6-di-tert-butyl-p-cresol					
Adjustable (T=24h FCE=100%)	1.35E-05	1.32E-06	4.26E-04	2.24E-03	8.61E-03
Advance (T=24h FCE=100%)	2.26E-05	2.21E-06	7.10E-04	3.74E-03	1.4E-02
Advance (T=12h FCE=100%)	1.13E-05	1.11E-06	3.56E-04	1.87E-03	7.20E-03

Primary and secondary poisoning

Primary poisoning

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

Secondary poisoning

The predicted environmental concentration of transluthrin in fish-eating (aquatic) and worm-eating (terrestrial) birds and mammals ($PEC_{oral,\ predator}$) was calculated according to the Guidance on biocide legislation, Part B+C, volume IV (ECHA, 2015). $PEC_{oral,\ predator}$ for the aquatic environment was based on a BCF of 1783 L/kg wet fish, a default biomagnification factor (BMF = 1) for compounds with BCF fish < 2000 L/kg wet fish, and the PEC_{water} in the aquatic environment. The PEC for worm-eating birds and mammals was based on a BCF of 10452 L/kg wwt calculated from the active substance's log K_{ow}, the PEC_{soil} and the equilibrium partitioning-derived concentration in porewater.
According to ECHA guidance on BPR – Volume IV Environment – part B + C (2017) the first step in a assessment of secondary poisoning is to consider whether there are indications for bioaccumulation potential. The Substance of Concern (2,6-di-tert-butyl-p-cresol) has a log Kow >4.5, indicating a potential to bioaccumulate. The BCF was estimated to be 645.6 L/kg using EPISuite, however, a study demonstrating a BCF range with a maximum of 2500 L/kg is also available at Ctgb. Hence, as a worst-case, a BMF value of 2 is used in the assessment.

Summary table on estimated theoretical exposition (ETE)		
Heater (refinement)	**$PEC_{oral,\ predator}$ (freshwater)**	**$PEC_{oral,\ predator}$ (terrestrial)**
	[mg/kg $_{wet\ fish}$]	[mg/kg $_{wet\ earthworm}$]
Transfluthrin		
Adjustable (T=24h F_{CE}=100%)	1.19E-04	6.44E-04
Advance (T=24h F_{CE}=100%)	2.00E-04	6.05E-03
Advance (T=12h F_{CE}=100%)	1.08E-04	7.91E-04
2,6-di-tert-butyl-p-cresol		
Adjustable (T=24h FCE=100%)	8.52E-04	2.28E-04
Advance (T=24h FCE=100%)	1.43E-03	3.81E-04
Advance (T=12h FCE=100%)	7.17E-04	1.90E-04

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, quantitive 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)		
Substance	**Heater**	**PEC/PNEC$_{STP}$**
Active substance	Adjustable (T=24h F_{CE}=100%)	<0.001
	Advance (T=24h F_{CE}=100%)	<0.001
	Advance (T=12h F_{CE}=100%)	<0.001

Summary table on calculated PEC/PNEC values (SoC)		
Substance	**Heater**	**PEC/PNEC$_{STP}$**
2,6-di-tert-butyl-p-cresol	Adjustable (T=24h F_{CE}=100%)	<0.001
	Advance (T=24h F_{CE}=100%)	<0.001
	Advance (T=12h F_{CE}=100%)	<0.001

Conclusion: The calculated PEC/PNEC values for both the active substance and substance of concern in the sewage treatment plant (STP) are significantly < 1. Therefore the proposed use of the product Transfluthrin Liquid Electric does not pose a risk to microorganisms in the STP.

Aquatic compartment

Summary table on calculated PEC/PNEC values (Active Substance)			
	Heater	**PEC/ PNEC$_{water}$**	**PEC/ PNEC$_{sed}$**
Active substance	Adjustable (T=24h F_{CE}=100%)	0.077	0.407
	Advance (T=24h F_{CE}=100%)	0.128	0.679
	Advance (T=12h F_{CE}=100%)	0.064	0.341

Summary table on calculated PEC/PNEC values (Metabolites)		
Metabolite	**Heater**	**PEC/ PNEC$_{water}$[a]**
trans-DCVA	Adjustable (T=24h F_{CE}=100%)	<0.001
	Advance (T=24h F_{CE}=100%)	<0.001
	Advance (T=12h F_{CE}=100%)	<0.001
TFB-COOH	Adjustable (T=24h F_{CE}=100%)	<0.001
	Advance (T=24h F_{CE}=100%)	<0.001
	Advance (T=12h F_{CE}=100%)	<0.001

[a] The risk for surface water also covers sediment, because both PEC and PNEC sediment are based on equilibrium partitioning

Summary table on calculated PEC/PNEC values (SoC)			
Substance of Concern	**Heater (refinement)**	**PEC/ $PNEC_{water}$**	**PEC/ $PNEC_{sed}$**
2,6-di-tert-butyl-p-cresol	Adjustable (T=24h F_{CE}=100%)	0.001	0.006
	Advance (T=24h F_{CE}=100%)	<0.001	0.010
	Advance (T=12h F_{CE}=100%)	<0.001	0.005

Conclusion: The default calculations indicate acceptable risk for surface water and sediment compartment for both heaters. All PEC/PNEC values for transfluthrin, its relevant metabolites and the SoC in the relevant compartments were <1.

Exposure of the marine environment is not considered to be a direct route of exposure for the proposed use of this product.

Terrestrial compartment

Calculated PEC/PNEC values (Active Substance)		
	Heater (refinement)	**PEC/$PNEC_{soil}$**
Active substance	Adjustable (T=24h F_{CE}=100%)	0.003
	Advance (T=24h F_{CE}=100%)	0.005
	Advance (T=12h F_{CE}=100%)	0.002

Calculated PEC/PNEC values (Metabolites)		
	Heater (refinement)	**PEC/$PNEC_{soil}$**
trans-DCVA	Adjustable (T=24h F_{CE}=100%)	0.012
	Advance (T=24h F_{CE}=100%)	0.021
	Advance (T=12h F_{CE}=100%)	0.010
TFB-COOH	Adjustable (T=24h F_{CE}=100%)	0.010
	Advance (T=24h F_{CE}=100%)	0.017
	Advance (T=12h F_{CE}=100%)	0.009

Calculated PEC/PNEC values (SoC)		
Substance of Concern	**Heater (refinement)**	**PEC/$PNEC_{soil}$**
2,6-di-tert-butyl-p-cresol	Adjustable (T=24h F_{CE}=100%)	0.037
	Advance (T=24h F_{CE}=100%)	0.062
	Advance (T=12h F_{CE}=100%)	0.031

Conclusion: In all cases, PEC/PNEC values are < 1 for the active substance, substance of concern and relevant soil metabolites. As a result, it can be concluded that use of the product will not result in unacceptable risk for 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 (2014), 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 and substance of concern. Hence, the risk to groundwater is considered acceptable for transfluthrin and the substance of concern.

For the metabolites, the first tier groundwater assessment results in PECs ($PEC_{porewater}$) >0.1 µg/L for the advance heater scenario (24h F_{CE}=100%). Therefore, a higher tier groundwater assessment was performed for the metabolites, using FOCUS PEARL 4.4.4. 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 $PEC_{soil\_initial.}$ The same substance endpoints as for the first tier were used, with the addition of a DT50 of 300 days (default according to Table 6 in BPR guidance) and two default parameters (see table below).

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	54.0	0.0

[1] at 25 °C

[2] at 12 °C

Here results are presented for Tier 2 calculations with PEARL. 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)

	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	0.12	7.10E-04	1.42E-04	0.0254	0.0047
Metabolite TFB COOH	0.12	7.30E-04	1.42E-04	<0.001	<0.001

* The highest value from all PEARL scenarios is reported. Please refer to Annex 3.9 for the results of PEARL calculations for all scenarios.

For the metabolites, the second tier groundwater assessment (PEARL) results in PECs ($PEC_{porewater}$) below 0.1 µg/L. Concludingly, no groundwater risk is expected.

Primary and secondary poisoning

Primary poisoning

Not relevant for this product.
Secondary poisoning

Summary table on secondary poisoning		
Heater (refinement)	Food	**PEC/PNEC**
Transfluthrin		
Adjustable (T=24h F_{CE}=100%)	Fish	<0.001
	Earthworms	<0.001
Advance (T=24h F_{CE}=100%)	Fish	<0.001
	Earthworms	<0.001
Advance (T=12h F_{CE}=100%)	Fish	<0.001
	Earthworms	<0.001
2,6-di-tert-butyl-p-cresol		
Adjustable (T=24h F_{CE}=100%)	Fish	<0.001*
	Earthworms	<0.001*
Advance (T=24h F_{CE}=100%)	Fish	<0.001*
	Earthworms	<0.001*
Advance (T=12h F_{CE}=100%)	Fish	<0.001*
	Earthworms	<0.001*

* Note that the $PNEC_{mammal}$ is a < value. The PEC/PNEC ratio is, however, that low that no adverse effects are expected, even with a lower PNEC.

Conclusion: Using the concentration in fish and worms and the $PNEC_{oral,mammal}$, the $PEC/PNEC_{oral,mammal}$ for transfluthrin and the substance of concern is < 1 and the risk for secondary poisoning is considered to be acceptable.

In the absence of short-term or long-term toxicity data for birds, a $PEC/PNEC_{oral,bird}$ cannot be derived. However, considering the low PECoral values, such low chronic toxicity levels for birds are not expected. Furthermore, there are several reasons to assume that the calculated PECs in water and soil (and therefore the concentrations in fish and earthworms) may be worst-case estimates. In view of this, a risk of secondary poisoning of birds is not expected. This conclusion is consistent with the argumentation presented in the transfluthrin Assessment Report (NL, 2014).

Mixture toxicity

Mixture toxicity was performed by summation of the PEC/PNEC values for the intended use with the maximum emission (advance (T=24h Fce=100%)).

Tier 1. PEC/PNEC summation

Calculated PEC/PNEC values (Mixture)						
Heater (refinement)	**STP**[a]	**Surface water**[b]	**Sediment**[c]	**Soil**[d]	**Ground water**[e]	**Secondary poisoning**[f]

Advance (T=24h F_{CE}=100%)	<0.001	0.131	0.691	0.105	0.066	<0.001

[a] Sum of PEC/PNEC values in STP for active substance (transfluthrin) and Substance of Concern (2,6-di-tert.-butyl-p cresol)

[b] Sum of PEC/PNEC values in surface water for active substance (transfluthrin), metabolites (trans-DCVA and TFB-COOH) and Substance of Concern (2,6-di-tert.-butyl-p cresol)

[c] Sum of PEC/PNEC values in sediment for active substance (transfluthrin), metabolites (trans-DCVA and TFB-COOH – same values as for surface water) and Substance of Concern (2,6-di-tert.-butyl-p cresol)

[d] Sum of PEC/PNEC values in sediment for active substance (transfluthrin), metabolites (trans-DCVA and TFB-COOH) and Substance of Concern (2,6-di-tert.-butyl-p cresol)

[e] Sum of PEC values (ug/l) in groundwater for active substance (transfluthrin), metabolites (trans-DCVA and TFB-COOH – tier 2) and Substance of Concern (2,6-di-tert.-butyl-p cresol)

[d] Sum of PEC/PNEC values for mammals (oral) for active substance (transfluthrin) and Substance of Concern (2,6-di-tert.-butyl-p cresol)

Conclusion: Tier 1 mixture assessment involves the summation of PEC/PNEC values for each relevant substance in order to calculate an PEC/PNEC for the whole product. PEC/PNEC values are <1 for all environmental compartments, indicating an acceptable level of risk for the environment. No further assessment of mixture toxicity is therefore required.

Aggregated exposure (combined for relevant emmission sources)

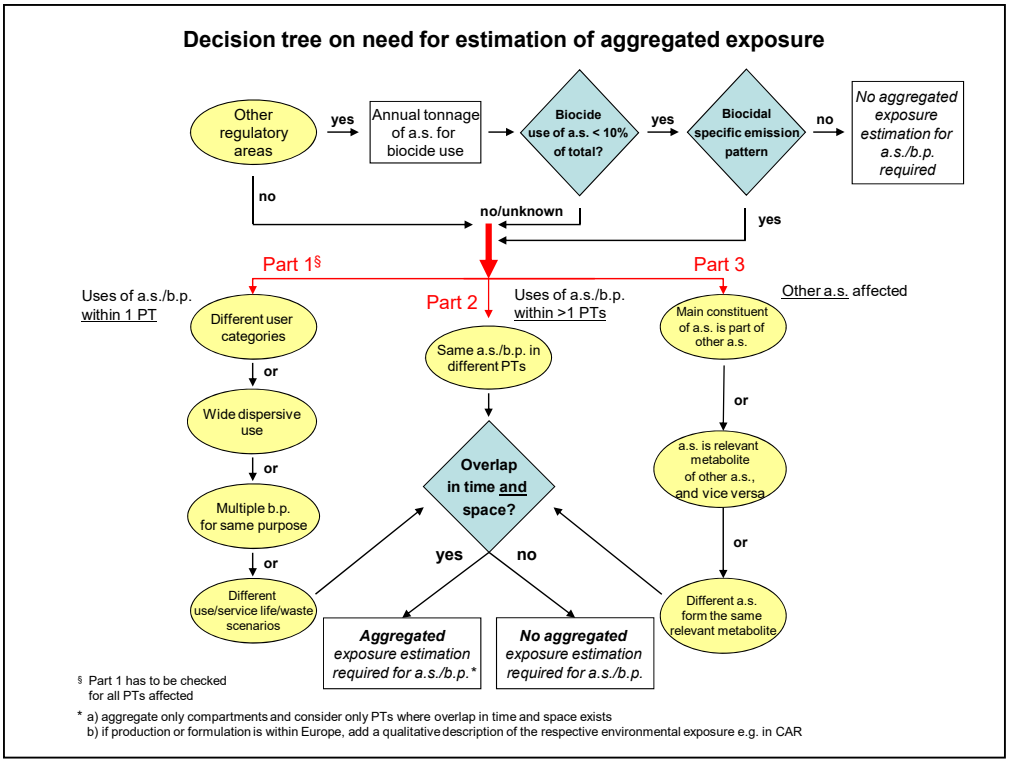


Figure 1: Decision tree on the need for estimation of aggregated exposure

The intended uses for transfluthrin liquid are within one PT and one/similar scenario is assessed. Aggregated exposure is not considered necessary for the product.

Overall conclusion on the risk assessment for the environment of the product

The environmental risk assessment for Transfluthrin Liquid Electric 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).

There are 3 types of heaters which use the liquid formula refills: 'Base', 'Adjustable' (also known as 'dual') and 'Advance'. Estimates of environmental emission were calculated for the 'Adjustable' and 'Advance' heaters. In each case, the total duration of use was taken as the minimum, assuming the product is running on the 'high' setting; 320 hours for the Adjustable heater, and 192 hours for the Advance heater.

Environmental fate in wastewater was calculated according to SimpleTreat 4.0 (parameterised as per Environmental Working Group of the Biocidal Products Committee, WG-I-2017) , taking account of the results of an OECD 314B study on the degradation of the active substance in activated sewage sludge and a refined cleaning efficiency for transfluthrin.

PNEC values used in the assessment took account of recently generated data that improve understanding of ecotoxicity profile of transfluthrin.

PEC/PNEC values were calculated for all relevant potentially exposed compartments for both the active substance, a substance of concern and relevant metabolites of transfluthrin.

The default calculations indicate acceptable risk for the aquatic compartment for both heaters, as all PEC/PNEC < 1 for Adjustable and Advance).

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

In all cases, predicted concentrations in groundwater were below < 0.1 µg/L for the active substance and the substance of concern. For the relevant metabolites tier 2 calculations also demonstrated an acceptable risk for groundwater .

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

Finally, a Tier 1 mixture assessment was performed by summation of PEC/PNEC values for each relevant substance in order to calculate an PEC/PNEC for the whole product. PEC/PNEC values are <1 for all environmental compartments, indicating an acceptable level of risk for the environment.

Therefore, it is concluded that the use of Transfluthrin Liquid Electric 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

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

[For the product label]
Keep out of the reach of children.
Store away from food, beverages and pet food.
Store Locked up (P405)

Recommended methods and precautions concerning handling and transport

[For the Safety Data Sheet only]:

Wear personal protective equipment, as detailed below:
Respiratory protection: In the case of vapour formation use a respirator with an approved filter.
Hand protection: Wear suitable gloves. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Before removing gloves clean them with soap and water.
Eye/face protection: No special requirements.
Skin and body protection: Wash contaminated clothing before re-use.
Other information: When using do not eat, drink or smoke. Wash hands before breaks and at the end of workday.
Avoid contact with skin and eyes.
Smoking, eating and drinking should be prohibited in the application area.
Normal measures for preventive fire protection.

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

[For the Safety Data Sheet only]:

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Special hazards arising from the substance or mixture: In case of fire and/or explosion do not breathe fumes. Exposure to decomposition products may be a hazard to health.
Advice for firefighters: In the event of fire, wear self-contained breathing apparatus. Wear suitable protective clothing and gloves. Refer to current EN or National standard as appropriate.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Special hazards arising from the substance or mixture: In case of fire and/or explosion do not breathe fumes. Exposure to decomposition products may be a hazard to health.
Advice for firefighters: In the event of fire, wear self-contained breathing apparatus. Wear suitable protective clothing and gloves. Refer to current EN or National standard as appropriate.

Particulars of likely direct or indirect adverse effects
No adverse effects expected when used as directed.

First aid instructions, antidotes

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

Description of first aid measures
Inhalation: Get medical attention immediately.
Skin contact: Rinse with plenty of water. Get medical attention if irritation develops and persists.
Eye contact: Rinse with plenty of water. Get medical attention if irritation develops and persists.
Ingestion: If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label.

Most important symptoms and effects, both acute and delayed
Eyes: No adverse effects expected when used as directed.
Skin effect: No adverse effects expected when used as directed.
Inhalation: No adverse effects expected when used as directed. May be fatal if swallowed and enters airways.
Ingestion: Can cause chemical pneumonitis if aspirated into lungs. No adverse effects expected when used as directed. May be fatal if swallowed and enters airways.

Emergency measures to protect environment in case of accident

[For the Safety Data Sheet only - These measures will not be included in the product label because they are not relavent to indoor consumer use]:

Prevent product from entering drains.
Do not flush into surface water or sanitary sewer system.
Prevent further leakage or spillage if safe to do so.
If the product contaminates rivers and lakes or drains inform respective authorities.
Use appropriate containment to avoid environmental contamination.

Control measures of repellents or poison included in the biocidal product, to prevent action against non-target organisms (relevant for biocidal products only)
Not required for this type of product.

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

Air
There are no measures available to decontaminate the environment. Risk assessments have been conducted in the PAR and show that the risk to the environment is acceptable.
Water, including drinking water
There are no measures available to decontaminate the environment. Risk assessments have been conducted in the PAR and show that the risk to the environment is acceptable.
Soil
There are no measures available to decontaminate the environment. Risk assessments have been conducted in the PAR and show that the risk to the environment is acceptable.

Procedures for waste management of active substance/biocidal product, and if appropriate, its packaging:
Possibility of reuse or recycling
The empty packaging can be recycled.
Possibility of neutralisation of effects
Not applicable
Conditions for controller discharge including leachate qualities on disposal
[Not relavant for consumer use product.]
Conditions for controller incineration
Disposal should be in accordance with local, state or national legislation. [Not relevant for consumer use product.]

Instructions for safe disposal of the biocidal product and its packaging for different groups of users (relevant for biocidal products only)
Do not discharge the biocidal product nor spills and residues containing the product into the sewage system or the environment.

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements.
Procedures, if any, for cleaning application equipment (relevant for biocidal products only)
Not applicable

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products which is not the case for Transfluthrin Liquid Electric.

2.2.11 Comparative assessment

Not relevant as Transfluthrin is not included on the list of substances requiring comparative assessment.

3 ANNEXES

3.1 List of studies for the biocidal product

Author	Year	Title	Testing laboratory	Report no.	Legal entity owner	Report date	Endpoint names	GLP	Published/ Unpublished	Data Protection Claimed
[redacted]	No date	Bridging Rationale for Trevi Green Electric formula code 631257/001 to Liquid Electric Adjustable Heater	[redacted]		S.C.Johnson & Son		Bridging document Evaporation rate- Edie Dual or Adjustable, [redacted] _BPR TNsG18	Yes	Unpublished	Yes
[redacted]	1997	Bagon Genius (c.n. Transfluthrin) Study for Acute Oral Toxicity in Rats	[redacted]	PH-26922	S.C.Johnson & Son	1997-12-11	Acute toxicity: oral_ [redacted] (1997)	Yes	Unpublished	Yes
[redacted]	2015a	Physical/chemical testing study on Trevi Green test items	[redacted]	CEMR-7082	S.C.Johnson & Son	2015-06-27	Water content. Apps (2015) Vaporization Rate, Apps (2015) Flammability. Apps (2015) Surface tension. Apps (2015) Viscosity. Apps (2015) Storage stability tests. Low temperature stability. Apps (2015) Relative density (liquids). Apps (2015)	Yes	Unpublished	Yes

Author	Year	Title	Testing laboratory	Report no.	Legal entity owner	Report date	Endpoint names	GLP	Published/ Unpublished	Data Protection Claimed
[redacted]	2015b	Accelerated storage stability study on Trevi Green test items	[redacted]	CEMS-7084	S. C. Johnson & Son Inc., 1525 Howe St., Racine, Wisconsin 53403, USA	2015-10-05	Storage stability tests Accelerated 40C _[redacted] (2015)	Yes	Unpublished	Yes
[redacted]	2015c	Room temperature storage stability study on Trevi Green test items	[redacted]	CEMS-7255	S. C. Johnson & Son Inc., 1525 Howe St., Racine, Wisconsin 53403, USA	2015-10-05	Storage stability tests Ambient_ [redacted] (20015)	Yes	Unpublished	Yes
[redacted]	2015d	Validation of an analytical method for the determination of transfluthrin content in electric heater liquid products	[redacted]	CEMS-7081	S.C.Johnson & Son	2015-06-11	Methods of detection and identification of transfluthrin in liquid products. [redacted] (2015)	Yes	Unpublished	Yes
[redacted]	2015	Validation of an analytical method for the determination of transfluthrin content in electric heater liquid products	[redacted]	CEMS-7256	S.C.Johnson & Son	2015-09-03	Methods of detection and identification of transfluthrin in liquid products. [redacted] (2015)	Yes	Unpublished	Yes
[redacted]	2004	A Dermal Sensitization Study in Guinea Pigs with Baygon TG2 - Modified Buehler Design	[redacted]	RZB00007	S.C.Johnson & Son	2004-05-27	Skin sensitisation_ [redacted] (2004)	Yes	Unpublished	Yes
[redacted]	1997a	Acute skin Irritation Test (Patch Test) of Baygon Genius (Transfluthrin) in Rabbits	[redacted]	R 6918	S.C.Johnson & Son	1997-08-12	Skin irritation / corrosion_ [redacted] (1997)	Yes	Unpublished	Yes

Author	Year	Title	Testing laboratory	Report no.	Legal entity owner	Report date	Endpoint names	GLP	Published/ Unpublished	Data Protection Claimed
[redacted]	1997b	Acute Eye Irritation Study of Baygon Genius (Transfluthrin) By Instillation into the Conjunctival Sac of Rabbits - According to EC Guideline B.5. And OECD Guideline 405	[redacted]	R 6917	SC Johnson	1997-08-14	Eye irritation_[redacted] (1997)	Yes	Unpublished	Yes
[redacted]	1998	BAYGON GENIUS, (H135/036/0185), (Common name of active ingredient: Transfluthrin), Acute Inhalation Toxicity in Rats, According to, OECD-Guideline no. 403 and 92/69/EEC	[redacted]	27576	SC Johnson	1998-06-24	Acute toxicity: inhalation_[redacted] (1998)	Yes	Unpublished	Yes
[redacted]	2004	Physical and Chemical Characteristics of Baygon TG2, Formula Number 15436R171	S[redacted]	15436R171-A2	S.C.Johnson & Son		Appearance (at 20°C and 101.3 kPa).001	Yes	Unpublished	Yes
[redacted]	2015	Determining Efficacy of the 0.88% Transfluthrin Liquid Electric Against Mosquitoes in 20m2 Footprint (48.6m3 volume) Chambers	[redacted]	90017721	S.C.Johnson & Son	2015-09-24	Efficacy data to support these claims ([redacted] 2015)	No	Unpublished	Yes

Author	Year	Title	Testing laboratory	Report no.	Legal entity owner	Report date	Endpoint names	GLP	Published/ Unpublished	Data Protection Claimed
[redacted]	2013	Determining the Knockdown and Mortality Efficacy of 0.88% Transfluthrin in the Trevi Green liquid Electric Formula Against the Common House Fly (Musca domestica) in the Laboratory Using a 2.5 Per Hour Air-Exchange Rate.	[redacted]	WR90014752	S.C.Johnson & Son	2013-05-31	Efficacy data to support these claims (Musca domestica with 2.5h air exchange rate- Edie Base) [redacted] (2013)_BPR TNsG18	No	Unpublished	Yes
[redacted]	2015a	Determining the efficacy of Liquid Electric Advanced (0.88% transfluthin liquid electric refills using the EDIE Advanced heater) against Aedes aegypti mosquitoes in the laboratory	[redacted]	WR90015550	S.C.Johnson & Son	2015-04-27	Efficacy data to support these claims (Aedes aegypti with Edie Advanced) [redacted] (2015a)_BPR TNsG18	No	Unpublished	Yes
[redacted]	2015b	Determining efficacy of Liquid Electric Adjustable (0.88% Transfluthrin liquid electric refills using the EDIE Adjustable heater) against Aedes albopictus mosquitoes in the laboratory.	[redacted]	WR90015550	S.C.Johnson & Son	2015-04-27	Efficacy data to support these claims (Aedes albopictus with Edie Dual or Adjustable) [redacted] (2015b)_BPR TNsG18	No	Unpublished	Yes

Author	Year	Title	Testing laboratory	Report no.	Legal entity owner	Report date	Endpoint names	GLP	Published/ Unpublished	Data Protection Claimed
[redacted]	2015c	Determining efficacy of Liquid Electric Adjustable (0.88% Transfluthrin liquid electric refills using the EDIE Adjustable heater) against Culex quinquefasciatus mosquitoes in the laboratory.	[redacted]	WR90015550	S.C.Johnson & Son	2015-04-27	Efficacy data to support these claims (Culex quinquefasciatus with Edie Dual or Adjustable) [redacted] (2015c)_BPR TNsG18	No	Unpublished	Yes
[redacted]	2015d	Determining efficacy of Liquid Electric Adjustable (0.88% Transfluthrin liquid electric refills using the EDIE Adjustable heater) against Musca domestica in the laboratory.	[redacted]	WR90015550	S.C.Johnson & Son	2015-04-27	Efficacy data to support these claims (Musca domestica Edie Dual or Adjustable) [redacted] (2015d)_BPR TNsG18	No	Unpublished	Yes
[redacted]	2015e	Determining efficacy of Liquid Electric Adjustable (0.88% transfluthrin liquid electric refills using the EDIE Adjustable heater) against Aedes aegypti mosquitoes in the laboratory	[redacted]	WR90015550	S.C.Johnson & Son	2015-04-27	Efficacy data to support these claims (Aedes aegypti with Edie Dual or Adjustable) [redacted] (2015e)_BPR TNsG18	No	Unpublished	Yes
[redacted]	2015f	Determining efficacy of Liquid Electric Advanced (0.88% Transfluthrin liquid electric	[redacted]	WR9001550	S.C.Johnson & Son	2015-04-27	Efficacy data to support these claims (Aedes albopictus with Edie Advanced) [redacted] (2015f)_BPR TNsG18	No	Unpublished	Yes

Author	Year	Title	Testing laboratory	Report no.	Legal entity owner	Report date	Endpoint names	GLP	Published/ Unpublished	Data Protection Claimed
		refills using the EDIE Advanced heater) against Aedes albopictus mosquitoes in the laboratory.								
[redacted]	2015g	Determining efficacy of Liquid Electric Advanced (0.88% Transfluthrin liquid electric refills using the EDIE Advanced heater) against Culex quinquefasciatus mosquitoes in the laboratory.	[redacted]	WR90015550	S.C.Johnson & Son	2015-04-27	Efficacy data to support these claims (Culex quinquefasciatus with Edie Advanced) [redacted] (2015g)_BPR TNsG18	No	Unpublished	Yes
[redacted]	2015h	Determining efficacy of Liquid Electric Advanced (0.88% Transfluthrin liquid electric refills using the EDIE Advanced heater) against Musca domestica in the laboratory.	[redacted]	WR90015550	S.C.Johnson & Son	2015-04-27	Efficacy data to support these claims (Musca domestica Edie Advanced) [redacted] (2015h)_BPR TNsG18	No	Unpublished	Yes

3.2 Output tables from exposure assessment tools

12 Hour Scenarios for Adjustable (Dual) heater

Adult

Scenario *12 hours exposure*

Frequency	150	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	720	minute
Exposure duration	720	minute
Weight fraction substance	0.88	%
Room volume	16	m^3
Room height	2.5	m
Ventilation rate	1	per hour
Inhalation rate	0.667	m^3/hr
Spraying towards person	No	
Mass generation rate	0.00108	g/min
Airborne fraction	1	
Density non volatile	1.5	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	8	µm
Arithmic coefficient of variation	0.3	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	1	

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	1

Results for scenario *12 hours exposure*

☐ Show dose descriptions

Inhalation

Mean event concentration	7.8×10^{-3}	mg/m³
Peak concentration (TWA 15 min)	8.0×10^{-3}	mg/m³
Mean concentration on day of exposure	3.9×10^{-3}	mg/m³
Year average concentration	1.6×10^{-3}	mg/m³
External event dose	1.0×10^{-3}	mg/kg bw
External dose on day of exposure	1.0×10^{-3}	mg/kg bw
Internal event dose	1.0×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.0×10^{-3}	mg/kg bw/day
Internal year average dose	4.3×10^{-4}	mg/kg bw/day

Oral

External event dose	4.2×10^{-6}	mg/kg bw
External dose on day of exposure	4.2×10^{-6}	mg/kg bw
Internal event dose	4.2×10^{-6}	mg/kg bw
Internal dose on day of exposure	4.2×10^{-6}	mg/kg bw/day
Internal year average dose	1.7×10^{-6}	mg/kg bw/day

Integrated

Internal event dose	1.0×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.0×10^{-3}	mg/kg bw/day
Internal year average dose	4.3×10^{-4}	mg/kg bw/day

Infant

Scenario 12 hours exposure

Frequency	150	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	720	minute
Exposure duration	720	minute
Weight fraction substance	0.88	%
Room volume	16	m^3
Room height	2.5	m
Ventilation rate	1	per hour
Inhalation rate	0.225	m^3/hr
Spraying towards person	No	
Mass generation rate	0.00108	g/min
Airborne fraction	1	
Density non volatile	1.5	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	8	µm
Arithmic coefficient of variation	0.3	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	1	

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	1

Results for scenario *12 hours exposure*

☐ Show dose descriptions

Inhalation

Mean event concentration	7.8×10^{-3}	mg/m³
Peak concentration (TWA 15 min)	8.0×10^{-3}	mg/m³
Mean concentration on day of exposure	3.9×10^{-3}	mg/m³
Year average concentration	1.6×10^{-3}	mg/m³
External event dose	2.6×10^{-3}	mg/kg bw
External dose on day of exposure	2.6×10^{-3}	mg/kg bw
Internal event dose	2.6×10^{-3}	mg/kg bw
Internal dose on day of exposure	2.6×10^{-3}	mg/kg bw/day
Internal year average dose	1.1×10^{-3}	mg/kg bw/day

Oral

External event dose	1.1×10^{-5}	mg/kg bw
External dose on day of exposure	1.1×10^{-5}	mg/kg bw
Internal event dose	1.1×10^{-5}	mg/kg bw
Internal dose on day of exposure	1.1×10^{-5}	mg/kg bw/day
Internal year average dose	4.4×10^{-6}	mg/kg bw/day

Integrated

Internal event dose	2.6×10^{-3}	mg/kg bw
Internal dose on day of exposure	2.6×10^{-3}	mg/kg bw/day
Internal year average dose	1.1×10^{-3}	mg/kg bw/day

Infant crawling

Scenario *crawling 12 hours*

Frequency	150	per year
Description		

Inhalation

Exposure model	n.a.
Absorption model	n.a.

Dermal

Exposure model	Direct contact - Rubbing off	
Exposed area	7	m^2
Weight fraction substance	1	
Transfer coefficient	0.2	m^2/hr
Dislodgeable amount	0.0314	mg/m^2
Contact time	1	hour
Contacted surface	0.6	m^2
Release duration	–	
Absorption model	Fixed fraction	
Absorption fraction	0.1	

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario *crawling 12 hours*

☐ Show dose descriptions

Dermal

Dermal load	9.0×10^{-8}	mg/cm^2
External event dose	7.9×10^{-4}	mg/kg bw
External dose on day of exposure	7.9×10^{-4}	mg/kg bw
Internal event dose	7.9×10^{-5}	mg/kg bw
Internal dose on day of exposure	7.9×10^{-5}	mg/kg bw/day
Internal year average dose	3.2×10^{-5}	mg/kg bw/day

Integrated

Internal event dose	7.9×10^{-5}	mg/kg bw
Internal dose on day of exposure	7.9×10^{-5}	mg/kg bw/day
Internal year average dose	3.2×10^{-5}	mg/kg bw/day

24 Hour Scenarios for Adjustable (Dual) heater

Adult

Scenario *24 hours exposure*

Frequency	150	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	1440	minute
Exposure duration	1440	minute
Weight fraction substance	0.88	%
Room volume	16	m^3
Room height	2.5	m
Ventilation rate	1	per hour
Inhalation rate	0.667	m^3/hr
Spraying towards person	No	
Mass generation rate	0.00108	g/min
Airborne fraction	1	
Density non volatile	1.5	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	8	µm
Arithmic coefficient of variation	0.3	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	1	

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	1

Results for scenario *24 hours exposure*

☐ Show dose descriptions

Inhalation

Mean event concentration	7.9×10^{-3}	mg/m³
Peak concentration (TWA 15 min)	8.0×10^{-3}	mg/m³
Mean concentration on day of exposure	7.9×10^{-3}	mg/m³
Year average concentration	3.2×10^{-3}	mg/m³
External event dose	2.1×10^{-3}	mg/kg bw
External dose on day of exposure	2.1×10^{-3}	mg/kg bw
Internal event dose	2.1×10^{-3}	mg/kg bw
Internal dose on day of exposure	2.1×10^{-3}	mg/kg bw/day
Internal year average dose	8.7×10^{-4}	mg/kg bw/day

Oral

External event dose	8.4×10^{-6}	mg/kg bw
External dose on day of exposure	8.4×10^{-6}	mg/kg bw
Internal event dose	8.4×10^{-6}	mg/kg bw
Internal dose on day of exposure	8.4×10^{-6}	mg/kg bw/day
Internal year average dose	3.5×10^{-6}	mg/kg bw/day

Integrated

Internal event dose	2.1×10^{-3}	mg/kg bw
Internal dose on day of exposure	2.1×10^{-3}	mg/kg bw/day
Internal year average dose	8.7×10^{-4}	mg/kg bw/day

Infant

Scenario *24 hours exposure*

Frequency	150	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	1440	minute
Exposure duration	1440	minute
Weight fraction substance	0.88	%
Room volume	16	m^3
Room height	2.5	m
Ventilation rate	1	per hour
Inhalation rate	0.225	m^3/hr
Spraying towards person	No	
Mass generation rate	0.00108	g/min
Airborne fraction	1	
Density non volatile	1.5	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	8	µm
Arithmic coefficient of variation	0.3	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	1	

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	1

Results for scenario *24 hours exposure*

☐ Show dose descriptions

Inhalation

Mean event concentration	7.9×10^{-3}	mg/m³
Peak concentration (TWA 15 min)	8.0×10^{-3}	mg/m³
Mean concentration on day of exposure	7.9×10^{-3}	mg/m³
Year average concentration	3.2×10^{-3}	mg/m³
External event dose	5.3×10^{-3}	mg/kg bw
External dose on day of exposure	5.3×10^{-3}	mg/kg bw
Internal event dose	5.3×10^{-3}	mg/kg bw
Internal dose on day of exposure	5.3×10^{-3}	mg/kg bw/day
Internal year average dose	2.2×10^{-3}	mg/kg bw/day

Oral

External event dose	2.1×10^{-5}	mg/kg bw
External dose on day of exposure	2.1×10^{-5}	mg/kg bw
Internal event dose	2.1×10^{-5}	mg/kg bw
Internal dose on day of exposure	2.1×10^{-5}	mg/kg bw/day
Internal year average dose	8.8×10^{-6}	mg/kg bw/day

Integrated

Internal event dose	5.4×10^{-3}	mg/kg bw
Internal dose on day of exposure	5.4×10^{-3}	mg/kg bw/day
Internal year average dose	2.2×10^{-3}	mg/kg bw/day

Infant crawling

Scenario *crawling 24 hours*

Frequency	150	per year
Description		

Inhalation

Exposure model	n.a.
Absorption model	n.a.

Dermal

Exposure model	Direct contact - Rubbing off	
Exposed area	7	m^2
Weight fraction substance	1	
Transfer coefficient	0.2	m^2/hr
Dislodgeable amount	0.0628	mg/m^2
Contact time	1	hour
Contacted surface	0.6	m^2
Release duration	–	
Absorption model	Fixed fraction	
Absorption fraction	0.1	

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario *crawling 24 hours*

☐ Show dose descriptions

Dermal

Dermal load	1.8×10^{-7}	mg/cm^2
External event dose	1.6×10^{-3}	mg/kg bw
External dose on day of exposure	1.6×10^{-3}	mg/kg bw
Internal event dose	1.6×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.6×10^{-4}	mg/kg bw/day
Internal year average dose	6.5×10^{-5}	mg/kg bw/day

Integrated

Internal event dose	1.6×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.6×10^{-4}	mg/kg bw/day
Internal year average dose	6.5×10^{-5}	mg/kg bw/day

12 Hour Scenarios for Advanced heater

Adult

Scenario *12 hours exposure high setting*

Frequency	150	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	720	minute
Exposure duration	720	minute
Weight fraction substance	0.88	%
Room volume	16	m^3
Room height	2.5	m
Ventilation rate	1	per hour
Inhalation rate	0.667	m^3/hr
Spraying towards person	No	
Mass generation rate	0.0018	g/min
Airborne fraction	1	
Density non volatile	1.5	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	8	µm
Arithmic coefficient of variation	0.3	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	1	

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	1

Results for scenario *12 hours exposure high setting*

☐ Show dose descriptions

Inhalation

Mean event concentration	1.3×10^{-2}	mg/m³
Peak concentration (TWA 15 min)	1.3×10^{-2}	mg/m³
Mean concentration on day of exposure	6.5×10^{-3}	mg/m³
Year average concentration	2.7×10^{-3}	mg/m³
External event dose	1.7×10^{-3}	mg/kg bw
External dose on day of exposure	1.7×10^{-3}	mg/kg bw
Internal event dose	1.7×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.7×10^{-3}	mg/kg bw/day
Internal year average dose	7.1×10^{-4}	mg/kg bw/day

Oral

External event dose	7.0×10^{-6}	mg/kg bw
External dose on day of exposure	7.0×10^{-6}	mg/kg bw
Internal event dose	7.0×10^{-6}	mg/kg bw
Internal dose on day of exposure	7.0×10^{-6}	mg/kg bw/day
Internal year average dose	2.9×10^{-6}	mg/kg bw/day

Integrated

Internal event dose	1.7×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.7×10^{-3}	mg/kg bw/day
Internal year average dose	7.2×10^{-4}	mg/kg bw/day

Infant

Scenario *12 hours exposure high setting*

Frequency	150	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	720	minute
Exposure duration	720	minute
Weight fraction substance	0.88	%
Room volume	16	m^3
Room height	2.5	m
Ventilation rate	1	per hour
Inhalation rate	0.225	m^3/hr
Spraying towards person	No	
Mass generation rate	0.0018	g/min
Airborne fraction	1	
Density non volatile	1.5	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	8	µm
Arithmic coefficient of variation	0.3	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	1	

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	1

Results for scenario *12 hours exposure high setting*

☐ Show dose descriptions

Inhalation

Mean event concentration	1.3×10^{-2}	mg/m³
Peak concentration (TWA 15 min)	1.3×10^{-2}	mg/m³
Mean concentration on day of exposure	6.5×10^{-3}	mg/m³
Year average concentration	2.7×10^{-3}	mg/m³
External event dose	4.4×10^{-3}	mg/kg bw
External dose on day of exposure	4.4×10^{-3}	mg/kg bw
Internal event dose	4.4×10^{-3}	mg/kg bw
Internal dose on day of exposure	4.4×10^{-3}	mg/kg bw/day
Internal year average dose	1.8×10^{-3}	mg/kg bw/day

Oral

External event dose	1.8×10^{-5}	mg/kg bw
External dose on day of exposure	1.8×10^{-5}	mg/kg bw
Internal event dose	1.8×10^{-5}	mg/kg bw
Internal dose on day of exposure	1.8×10^{-5}	mg/kg bw/day
Internal year average dose	7.3×10^{-6}	mg/kg bw/day

Integrated

Internal event dose	4.4×10^{-3}	mg/kg bw
Internal dose on day of exposure	4.4×10^{-3}	mg/kg bw/day
Internal year average dose	1.8×10^{-3}	mg/kg bw/day

Infant crawling

Scenario *crawling 12 hours high setting*

Frequency	150	per year
Description		

Inhalation

Exposure model	n.a.
Absorption model	n.a.

Dermal

Exposure model	Direct contact - Rubbing off	
Exposed area	7	m^2
Weight fraction substance	1	
Transfer coefficient	0.2	m^2/hr
Dislodgeable amount	0.0531	mg/m^2
Contact time	1	hour
Contacted surface	0.6	m^2
Release duration	–	
Absorption model	Fixed fraction	
Absorption fraction	0.1	

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario *crawling 12 hours high setting*

☐ Show dose descriptions

Dermal

Dermal load	1.5×10^{-7}	mg/cm^2
External event dose	1.3×10^{-3}	mg/kg bw
External dose on day of exposure	1.3×10^{-3}	mg/kg bw
Internal event dose	1.3×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.3×10^{-4}	mg/kg bw/day
Internal year average dose	5.5×10^{-5}	mg/kg bw/day

Integrated

Internal event dose	1.3×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.3×10^{-4}	mg/kg bw/day
Internal year average dose	5.5×10^{-5}	mg/kg bw/day

24 Hour Scenarios for Advanced heater

Adult

Scenario 24 hours exposure high setting

Frequency	150	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	1440	minute
Exposure duration	1440	minute
Weight fraction substance	0.88	%
Room volume	16	m^3
Room height	2.5	m
Ventilation rate	1	per hour
Inhalation rate	0.667	m^3/hr
Spraying towards person	No	
Mass generation rate	0.0018	g/min
Airborne fraction	1	
Density non volatile	1.5	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	8	µm
Arithmic coefficient of variation	0.3	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	1	

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	1

Results for scenario *24 hours exposure high setting*

☐ Show dose descriptions

Inhalation

Mean event concentration	1.3×10^{-2}	mg/m³
Peak concentration (TWA 15 min)	1.3×10^{-2}	mg/m³
Mean concentration on day of exposure	1.3×10^{-2}	mg/m³
Year average concentration	5.4×10^{-3}	mg/m³
External event dose	3.5×10^{-3}	mg/kg bw
External dose on day of exposure	3.5×10^{-3}	mg/kg bw
Internal event dose	3.5×10^{-3}	mg/kg bw
Internal dose on day of exposure	3.5×10^{-3}	mg/kg bw/day
Internal year average dose	1.4×10^{-3}	mg/kg bw/day

Oral

External event dose	1.4×10^{-5}	mg/kg bw
External dose on day of exposure	1.4×10^{-5}	mg/kg bw
Internal event dose	1.4×10^{-5}	mg/kg bw
Internal dose on day of exposure	1.4×10^{-5}	mg/kg bw/day
Internal year average dose	5.8×10^{-6}	mg/kg bw/day

Integrated

Internal event dose	3.5×10^{-3}	mg/kg bw
Internal dose on day of exposure	3.5×10^{-3}	mg/kg bw/day
Internal year average dose	1.5×10^{-3}	mg/kg bw/day

Infant

Scenario 24 hours exposure high setting

Frequency	150	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	1440	minute
Exposure duration	1440	minute
Weight fraction substance	0.88	%
Room volume	16	m^3
Room height	2.5	m
Ventilation rate	1	per hour
Inhalation rate	0.225	m^3/hr
Spraying towards person	No	
Mass generation rate	0.0018	g/min
Airborne fraction	1	
Density non volatile	1.5	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	8	µm
Arithmic coefficient of variation	0.3	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	1	

Dermal

Exposure model	n.a.
Absorption model	n.a.

Results for scenario *24 hours exposure high setting*

☐ Show dose descriptions

Inhalation

Mean event concentration	1.3×10^{-2}	mg/m³
Peak concentration (TWA 15 min)	1.3×10^{-2}	mg/m³
Mean concentration on day of exposure	1.3×10^{-2}	mg/m³
Year average concentration	5.4×10^{-3}	mg/m³
External event dose	8.9×10^{-3}	mg/kg bw
External dose on day of exposure	8.9×10^{-3}	mg/kg bw
Internal event dose	8.9×10^{-3}	mg/kg bw
Internal dose on day of exposure	8.9×10^{-3}	mg/kg bw/day
Internal year average dose	3.7×10^{-3}	mg/kg bw/day

Oral

External event dose	3.6×10^{-5}	mg/kg bw
External dose on day of exposure	3.6×10^{-5}	mg/kg bw
Internal event dose	3.6×10^{-5}	mg/kg bw
Internal dose on day of exposure	3.6×10^{-5}	mg/kg bw/day
Internal year average dose	1.5×10^{-5}	mg/kg bw/day

Integrated

Internal event dose	8.9×10^{-3}	mg/kg bw
Internal dose on day of exposure	8.9×10^{-3}	mg/kg bw/day
Internal year average dose	3.7×10^{-3}	mg/kg bw/day

Infant crawling

Scenario *crawling 24 hours high setting*

Frequency	150	per year
Description		

Inhalation

Exposure model	n.a.
Absorption model	n.a.

Dermal

Exposure model	Direct contact - Rubbing off	
Exposed area	7	m^2
Weight fraction substance	1	
Transfer coefficient	0.2	m^2/hr
Dislodgeable amount	0.106	mg/m^2
Contact time	1	hour
Contacted surface	0.6	m^2
Release duration	–	
Absorption model	Fixed fraction	
Absorption fraction	0.1	

Oral

Exposure model	n.a.
Absorption model	n.a.

Results for scenario *crawling 24 hours high setting*

☐ Show dose descriptions

Dermal

Dermal load	3.0×10^{-7}	mg/cm^2
External event dose	2.7×10^{-3}	mg/kg bw
External dose on day of exposure	2.7×10^{-3}	mg/kg bw
Internal event dose	2.7×10^{-4}	mg/kg bw
Internal dose on day of exposure	2.7×10^{-4}	mg/kg bw/day
Internal year average dose	1.1×10^{-4}	mg/kg bw/day

Integrated

Internal event dose	2.7×10^{-4}	mg/kg bw
Internal dose on day of exposure	2.7×10^{-4}	mg/kg bw/day
Internal year average dose	1.1×10^{-4}	mg/kg bw/day

3.3 New information on the active substance

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

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

[redacted] (2018) Partitioning of Transfluthrin in Sewage Treatment Plants: Derivation of endpoints for use in regulatory environmental risk assessments. [redacted]

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

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

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

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

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

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

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

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

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

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

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

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 and the efficacy table in section 2.2.3 of this PAR.

3.6 Confidential annex

See separate document.

3.7 References

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[redacted] (2015a) Physical/chemical testing study on Trevi Green test items. [redacted]. S.C. Johnson & Son 2015-07-23

[redacted] (2016) Accelerated storage stability study on Trevi Green test items. [redacted]. S.C. Johnson & Son 2016-11-10

[redacted] (2016a) Room temperature storage study on Trevi Green test items. [redacted]. S.C. Johnson & Son 2016-12-1

[redacted] (No date) Bridging Rationale for Trevi Green Electric formula code 631257/001 to Liquid Electric Adjustable Heater

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

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

ECHA (2015) Guidance on the Biocidal Product Regulation. Volume IV: Environment - Part B+C: Assessment and Evaluation. European Chemicals Agency, Version 1.0, Helsinki, Finland, 2015.

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

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

[redacted] (2018) Partitioning of Transfluthrin in Sewage Treatment Plants: Derivation of endpoints for use in regulatory environmental risk assessments. [redacted]

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

OECD, (2008) OECD Series on Emission Scenario Documents No. 18: Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional users. OECD, Paris. 17th July 2008.

RIVM (2006) Pest Control Fact Sheets. RIVM Report 320005002.

[redacted] (2015) Determining Efficacy of the 0.88% Transfluthrin Liquid Electric Against Mosquitoes in 20m^2 Footprint (48.6m^3 volume) Chambers.

[redacted] (2013) Determining the Knockdown and Mortality Efficacy of 0.88% Transfluthrin in the Trevi Green liquid Electric Formula Against the Common House Fly (Musca domestica) in the Laboratory Using a 2.5 Per Hour Air-Exchange Rate.

[redacted] (2015a) Determining the efficacy of Liquid Electric Advanced (0.88% transfluthin liquid electric refills using the EDIE Advanced heater) against Aedes aegypti mosquitoes in the laboratory.

[redacted] (2015b) Determining efficacy of Liquid Electric Adjustable (0.88% Transfluthrin liquid electric refills using the EDIE Adjustable heater) against Aedes albopictus mosquitoes in the laboratory.

[redacted] (2015c): Determining efficacy of Liquid Electric Adjustable (0.88% Transfluthrin liquid electric refills using the EDIE Adjustable heater) against Culex quinquefasciatus mosquitoes in the laboratory.

[redacted] (2015d): Determining efficacy of Liquid Electric Adjustable (0.88% Transfluthrin liquid electric refills using the EDIE Adjustable heater) against Musca domestica in the laboratory.

[redacted] (2015e): Determining efficacy of Liquid Electric Adjustable (0.88% transfluthrin liquid electric refills using the EDIE Adjustable heater) against Aedes aegypti mosquitoes in the laboratory.

[redacted] (2015f): Determining efficacy of Liquid Electric Advanced (0.88% Transfluthrin liquid electric refills using the EDIE Advanced heater) against Aedes albopictus mosquitoes in the laboratory.

[redacted] (2015g): Determining efficacy of Liquid Electric Advanced (0.88% Transfluthrin liquid electric refills using the EDIE Advanced heater) against Culex quinquefasciatus mosquitoes in the laboratory.

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U.S. Environmental Protection Agency (2012) Standard Operating Procedures for Residential Pesticide Exposure Assessment. October 2012. Section 7.2.2.1 Post-Application Dermal Exposure Algorithm (hard surfaces and carpets), page 7-32. http://www.epa.gov/pesticides/science/residential-exposure-sop.html

3.8 QSAR data 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 *
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)
--> Acid moeity found: Predicted values multiplied by 10				
Vinyl/Allyl Halides-acid	: Fish	96-hr	LC50	526.519
Vinyl/Allyl Halides-acid	: Daphnid	48-hr	LC50	422.841
Vinyl/Allyl Halides-acid	: Green Algae	96-hr	EC50	598.213
Vinyl/Allyl Halides-acid	: Fish		ChV	239.515
Vinyl/Allyl Halides-acid	: Daphnid		ChV	2.329
Vinyl/Allyl Halides-acid	: Green Algae		ChV	125.438 !
Vinyl/Allyl Halides-acid	: Fish (SW)	96-hr	LC50	374.905
Vinyl/Allyl Halides-acid	: Mysid (SW)	96-hr	LC50	187.685
Vinyl/Allyl Halides-acid	: Earthworm	14-day	LC50	2908.102
Neutral Organic SAR	: Fish	96-hr	LC50	222.027
(Baseline Toxicity)	: Daphnid	48-hr	LC50	125.042
	: Green Algae	96-hr	EC50	90.050
	: Fish		ChV	21.494
	: Daphnid		ChV	11.920
	: Green Algae		ChV	23.157

Note: * = asterisk designates: Chemical may not be soluble enough to measure this predicted effect. If the effect level exceeds the water solubility by 10X, typically no effects at saturation (NES) are reported.

NOTE: ! = exclamation designates: The toxicity value was estimated through application of acute-to-chronic ratios per methods outlined in the ECOSAR Methodology Document provided in the ECOSAR Help Menu.

Class Specific LogKow Cut-Offs

If the log Kow of the chemical is greater than the endpoint specific cut-offs presented below, then no effects at saturation are expected for those endpoints.

Vinyl/Allyl Halides:

Maximum LogKow: 6.0 (Fish 96-hr LC50; Daphnid LC50; Mysid LC50)
Maximum LogKow: 6.4 (Green Algae EC50)
Maximum LogKow: 5.0 (Fish (SW) 96-hr LC50)
Maximum LogKow: 6.0 (Earthworm LC50)
Maximum LogKow: 8.0 (ChV)

Baseline Toxicity SAR Limitations:

Maximum LogKow: 5.0 (Fish 96-hr LC50; Daphnid LC50)
Maximum LogKow: 6.4 (Green Algae EC50)
Maximum LogKow: 8.0 (ChV)

TFB-OH
SMILES : c1(F)c(F)c(CO)c(F)c(F)c1
CHEM :
MOL FOR: C7 H4 F4 O1
MOL WT : 180.10
---------- KOCWIN v2.00 Results ----------

Koc Estimate from MCI:

First Order Molecular Connectivity Index ..... : 5.575
Non-Corrected Log Koc (0.5213 MCI + 0.60) ..... : 3.5058
Fragment Correction(s):
1 Aliphatic Alcohol (-C-OH) ..... : -1.3179
Corrected Log Koc ..... : 2.1879

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

Koc Estimate from Log Kow:

Log Kow (Kowwin estimate) ..... : 1.88
Non-Corrected Log Koc (0.55313 logKow + 0.9251) .... : 1.9650
Fragment Correction(s):
1 Aliphatic Alcohol (-C-OH) ..... : -0.4114
Corrected Log Koc ..... : 1.5535

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

Water Sol: 4439 mg/L

SMILES : c1(F)c(F)c(CO)c(F)c(F)c1
CHEM :
MOL FOR: C7 H4 F4 O1
MOL WT : 180.10
---------- WSKOW v1.42 Results ----------
Log Kow (estimated) : 1.88
Log Kow (experimental): not available from database

Log Kow used by Water solubility estimates: 1.88

Equation Used to Make Water Sol estimate:
Log S (mol/L) = 0.796 - 0.854 log Kow - 0.00728 MW + Correction
(used when Melting Point NOT available)

Correction(s):	Value
Alcohol, aliphatic	0.510

Log Water Solubility (in moles/L) : -1.608
Water Solubility at 25 deg C (mg/L): 4439

Experimental Database Structure Match: no data

SMILES : c1(F)c(F)c(CO)c(F)c(F)c1
CHEM :
MOL FOR: C7 H4 F4 O1
MOL WT : 180.10
---------- SUMMARY MPBPWIN v1.43 ----------

Vapor Pressure Estimations (25 deg C):
(Using BP: 187.16 deg C (estimated))
(MP not used for liquids)
VP: 0.176 mm Hg (Antoine Method)
: 23.5 Pa (Antoine Method)
VP: 0.142 mm Hg (Modified Grain Method)
: 18.9 Pa (Modified Grain Method)
VP: 0.979 mm Hg (Mackay Method)
: 131 Pa (Mackay Method)
Selected VP: 0.159 mm Hg (Mean of Antoine & Grain methods)
: 21.2 Pa (Mean of Antoine & Grain methods)

TFB-COOH
Smiles: C1=C(C(=C(C(=C1F)F)C(=O)O)F)F
SMILES : c1c(c(c(c(c1F)F)C(=O)O)F)F
CHEM :
MOL FOR: C7 H2 F4 O2
Koc may be sensitive to pH!
---------- KOCWIN v2.00 Results ----------

Koc Estimate from MCI:

First Order Molecular Connectivity Index ..... : 5.947
Non-Corrected Log Koc (0.5213 MCI + 0.60) ..... : 3.7001
Fragment Correction(s):
* Organic Acid (-CO-OH) ..... : -1.6249
Corrected Log Koc ..... : 2.0752

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

Koc Estimate from Log Kow:

```
      Log Kow  (Kowwin estimate) ..... :  1.58
      Non-Corrected Log Koc (0.55313 logKow + 0.9251)  .... :  1.7990
      Fragment Correction(s):
            *  Organic Acid  (-CO-OH)  .............  : -0.7694
      Corrected Log Koc  ..... :  1.0297

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


            Water Sol: 2114 mg/L

SMILES : c1c(c(c(c(c1F)F)C(=O)O)F)F
CHEM   :
MOL FOR: C7 H2 F4 O2
MOL WT : 194.09
---------------------------------- WSKOW v1.42 Results -----------------------
Log Kow  (estimated)  :  1.58
Log Kow (experimental):  not available from database
Log Kow used by Water solubility estimates:  1.58

Equation Used to Make Water Sol estimate:
  Log S (mol/L) = 0.796 - 0.854 log Kow - 0.00728 MW + Correction
     (used when Melting Point NOT available)

    Correction(s):        Value
    --------------------  -----
     Acid, aromatic        0.000

  Log Water Solubility  (in moles/L) :  -1.963
  Water Solubility at 25 deg C (mg/L):  2114

Experimental Database Structure Match:
  Name     :  2,3,5,6-Tetrafluorobenzoic Acid
  CAS Num  :  000652-18-6
  Exp MP (deg C):  151
  Exp BP (deg C):  ---
  Exp VP (mm Hg):  ---

SMILES : c1c(c(c(c(c1F)F)C(=O)O)F)F
CHEM   :
MOL FOR: C7 H2 F4 O2
MOL WT : 194.09
----------------------- SUMMARY MPBPWIN v1.43 --------------------

Vapor Pressure Estimations (25 deg C):
  (Using BP: 232.98 deg C (estimated))
  (Using MP: 151.00 deg C (exp database))
    VP:  0.00367 mm Hg (Antoine Method)
      :  0.489 Pa  (Antoine Method)
    VP:  0.0033 mm Hg (Modified Grain Method)
      :  0.44 Pa  (Modified Grain Method)
    VP:  0.00616 mm Hg (Mackay Method)
      :  0.821 Pa  (Mackay Method)
  Selected VP:  0.0033 mm Hg (Modified Grain Method)
```

: 0.44 Pa (Modified Grain Method)
Subcooled liquid VP: 0.0634 mm Hg (25 deg C, Mod-Grain method)
: 8.45 Pa (25 deg C, Mod-Grain method)

3.9 PEARL output (ENV)

SUBSTANCE	DCVA	TFBCO	LOCATION	APPLICATION_SCHEME
DCVA	0.01905		CHATEAUDUN	agr_DCVA
DCVA	0.02544		HAMBURG	agr_DCVA
DCVA	0.02282		KREMSMUENSTER	agr_DCVA
DCVA	0.02450		OKEHAMPTON	agr_DCVA
DCVA	0.01580		PIACENZA	agr_DCVA
DCVA	0.00834		PORTO	agr_DCVA
DCVA	0.00226		SEVILLA	agr_DCVA
DCVA	0.01311		THIVA	agr_DCVA
TFBCO		0.00000	CHATEAUDUN	agr_TFBCOOH
TFBCO		0.00001	HAMBURG	agr_TFBCOOH
TFBCO		0.00008	KREMSMUENSTER	agr_TFBCOOH
TFBCO		0.00017	OKEHAMPTON	agr_TFBCOOH
TFBCO		0.00001	PIACENZA	agr_TFBCOOH
TFBCO		0.00003	PORTO	agr_TFBCOOH
TFBCO		0.00000	SEVILLA	agr_TFBCOOH
TFBCO		0.00000	THIVA	agr_TFBCOOH
DCVA	0.00382		CHATEAUDUN	grass_DCVA
DCVA	0.00434		HAMBURG	grass_DCVA
DCVA	0.00466		JOKIOINEN	grass_DCVA
DCVA	0.00355		KREMSMUENSTER	grass_DCVA
DCVA	0.00420		OKEHAMPTON	grass_DCVA
DCVA	0.00324		PIACENZA	grass_DCVA
DCVA	0.00205		PORTO	grass_DCVA
DCVA	0.00157		SEVILLA	grass_DCVA
DCVA	0.00190		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	0.00001	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