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

DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the eCA)

Moth Active Paper

Product type 18

Transfluthrin

Case Number in R4BP: [BC-FY021377-15]

Evaluating Competent Authority: The Netherlands

Date: 2 July 2021

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1 CONCLUSION

Analytical methods and Physical Chemical Properties conclusion
Moth active paper is a vapour releasing (VP) product comprising of a liquid and a carrier component. The active substance is transfluthrin. A shelf-life of 4 years is supported at ambient temperatures in PET/LDPE.
No classification with respect to physical hazards is required for Moth Active Paper.

Efficacy conclusion
Moth Active Paper in wardrobes is effective against adult cloth moths (*Tineola bisselliella*) for up to 12 weeks after product placement and against larvae from 2 weeks up to 12 weeks after product placement. Protection of clothes in wardrobes is substantiated from 2 weeks up to 12 weeks after product placement.

Moth Active Paper in drawers is effective against adult cloth moths for up to 12 weeks after product placement and against larvae from 2 weeks up to 12 weeks after placement of the product. Protection of clothes in drawers is substantiated from 8 weeks up to 12 weeks after product placement.

Reduction of wool damage, although not full protection of wool, can be claimed from 2 up to 12 weeks.

Conclusions Human Health
Based on the human health risk assessment, no adverse health effects are expected after use of Moth Active Paper in accordance to the intended use.

Conclusions environment
The risk assessment for the environment was performed for the scenario Consumer use of insecticide diffuser product, for transfluthrin, its metabolites and a SoC. This assessment demonstrated that risks for the environment are acceptable for the intended use of Moth Active Paper as vapour releasing product indoors for consumers.

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)**
Moth Active Paper	The Netherlands (eCA)
Raid® Mottenschutz-Papier	Austria
Raid® Ленти срещу молци Raid® ленти против молци	Bulgaria
Raid® Aktivni Mirisni Listići	Croatia
RAID 4 SEASONS	Cyprus
Raid® proti molům aktivní závěs čerstvé květy	Czech Republic
RAID® Papier Anti-Mites	France
Raid® Mottenschutz-Papier	Germany
RAID 4 SEASONS	Greece
Raid® Active molyirtó lap friss virág illattal	Hungary
Raid® Foglietti Antitarme	Italy
Raid® – aktywne zawieszki na mole	Poland
Raid® Papel Anti-Traças	Portugal
RAID® Moth Pa per	Republic of Ireland
Raid® Active Paper	Romania
Raid® proti moliam aktívny záves čerstvé kvety	Slovakia
Raid® Foglietti Antitarme Fresco profumo Fiorito	Slovenia
Polil Raid® Tiras Activas	Spain

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

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	NL-0018843-0000	
Date of the authorisation	02 July 2021	
Expiry date of the authorisation	02 July 2031	

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	IGO s.r.l. Via Palazzo 46, 24061 Albano Sant' Alessandro (BG) Italy

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

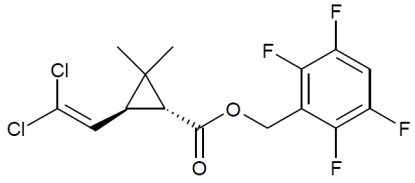
2.1.2 Product composition and formulation

The full composition of the product according to Annex III Title 1 is 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. does refer to the correct isomer.*

2.1.2.2 Candidate(s) for substitution

Transfluthrin is not a candidate for substitution

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product[2]

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[3]	405-060-5	2.31%* (TGAI) (2.23%w/w pure active)
	2,6-dimehtyloct-7-en-2-ol	Non-active ingredient	18479-58-8	242-362-4	30.3%
	tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	Non-active ingredient	63500-71-0	405-040-6	7.58%
	Tetrahydrolinalyl acetate	Non-active ingredient	20780-48-7	244-033-0	2.27%
	1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one	Non-active ingredient	54464-57-2	259-174-3	2.27%
	tetrahydrolinalool	Non-active ingredient	78-69-3	201-133-9	2.27%
	Geranyl acetate	Non-active ingredient	105-87-3	203-341-5	2.27%
	4-tert-butylcyclohexyl acetate	Non-active ingredient	32210-23-4	250-954-9	2.27%
Refer to the confidential annex for details of the co-formulants					

* Excluding carrier. Equivalent to 6.7 (TC) mg per unit.

2 Please delete as appropriate.

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

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

The active substance source is a reference source.

2.1.2.6 Information on the substance(s) of concern

Substances of Concern where identified for human health and the environment. However, as the identified substances where adding to the classification, in line with guidance on SoCs, either risk management is covered by the assighed P-statements or a qualitative or quantitative assessment was sufficient. Based on the evaluation, no risk for the identified SoCs was concluded. For further details see sections 2.2.6.1 and 2.2.8.1 on substances of concern.

2.1.2.6 Information on endocrine disrupting properties

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

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

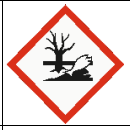
2.1.2.7 Type of formulation

VP Vapour releasing product

2.1.3 Hazard and precautionary statements[4]

Classification and labelling of the product according to the Regulation (EC) 1272/2008

[4] For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Classification*	
Hazard category	Asp. Tox. 1 Skin Irrit. 2 Eye Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H304: May be fatal if swallowed and enters airways. H315: Causes skin irritation. H319: Causes serious eye irritation. H317: May cause an allergic skin reaction. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects. EUH066: Repeated exposure may cause skin dryness or cracking.
Labelling	
Hazard Pictogram	 GHS07: Exclamation  GHS09: Environment
Signal words	Warning
Hazard statements	H315: Causes skin irritation. H319: Causes serious eye irritation. H317: May cause an allergic skin reaction. 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. P273: Avoid release to the environment P302+P352: IF ON SKIN: Wash with plenty of water/… P333+P313: If skin irritation or rash occurs: Get medical advice/attention. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention. P264: Wash hands thoroughly after handling. P391: Collect spillage. P501: Dispose of contents/container to … [… in accordance with local/regional/national/international regulation]

Note	H304 classification is triggered by a solvent in the liquid formulation, however, is not included in the label as the product is a ready-to-use product in solid form. EUH066 is triggered by a solvent in the liquid formulation, however, is not included in the label as classified with H315 and therefore does not need to be included (section 1.2.4 of Annex II of CLP) Substances: 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one, Geranyl acetate, 4-tert-butylcyclohexyl acetateneed to be declared based on the assigned H-statements according to Art 18(3) CLP.) P261: Avoid breathing dust/fume/gas/mist/vapours/spray was not assigned, although triggered by H317 classification, because the product is a ready-to-use paper sheet hampering exposure to dust/ fume/ gas/ mist/spray. H317 classification triggers P280: gloves. However, based on the product included and the intended use, this is considered not necessary. For more information see local risk assessment, section 2.2.6.3. CLP indicates that this P-statement is highly recommended only in exceptional cases where specific treatment is known and required. No specific treatment is known, therefore P321 is not assigned. "P332+P313: If skin irritation occurs: Get medical advice/attention." is not assigned as covered by "P333+P313: If skin irritation or rash occurs: Get medical advice/attention." P362+364: Take off immediately all contaminated clothing and wash it before reuse is triggered by H317 classification. This sentence is not assigned, because the perfume present in the paper and dislodging from the paper and transferring to the clothes is considered to be low as direct contact of the paper with the clothes is not likely.

* The product is considered as an article with intended release and consequently the product is classified based on the liquid solution. The inert matrix only serves as a method of delivery.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Consumer Use of Vapour releasing product (VP) Indoors

Product Type	Product type 18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide

Target organism (including development stage)	**Scientific name** *Tineola bisselliella* **Common name** other: Webbing Clothes moth **Development stages** Adults, Larvae
Field of use	Indoor
Application method(s)	Open system: diffusion Vapourising mat (passive diffuser)
Application rate(s) and frequency	Dosage: Wardrobes - 12 unit per 0.5 m^3 space. Drawers – 1 unit per 0.018 m^3 space. Reduces webbing cloth moth (*Tineola bisselliella*) damage to clothes in wardrobes and drawers for up to 12 weeks. Allow 2 weeks for maximum effect.
Category(ies) of users	General Public (non-professional)
Pack sizes and packaging material	Pack Sizes: 2, 4, 6, 8, 10, or 12 units per pouch. Unit = ½ of full paper Small pouch size: (110 mm x 83 mm x 3 mm) Volume – 27.4 cm^3 Medium pouch size: (110 mm x 83 mm x 9 mm) Volume – 82.17 cm^3 Packaging material: Pouch (primary packaging) into Box or envelope Pouch: Plastic composite (Polyethylene Terephthalate, Low Density Polyethylene, Ethylene vinyl alcohol) Unit box/envelope: Solid fiberboard Box size: 157 mm x 96 mm x 23 mm, Volume 346.7 cm^3 Envelope size: 185 mm x 109 mm x 12 mm, Volume – 242.0 cm^3.

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

The product is a transfluthrin vapour-releasing mat (passive diffuser). Following removal of the product from the package, for optimum protection against clothes-moths, use 1-36 units for drawers and wardrobes, place one unit per drawer, hang 12 units in a single door wardrobe and 36 units in a double door wardrobe. Adapt the number of units according to the volume of the treated wardrobe or drawer. Dosage: 1 unit per 0.018m^3 (12 units or 6 full paper sheets per 0.5 m^3) space. Wash hands thoroughly after handling. The whole content of the package should be used up immediately after opening. The users should report to the authorization holder if the treatment is ineffective.

2.1.5.2 Risk mitigation measures

Keep away from naked flames. Use only as directed. Do not use near food, drink and animal feedingstuffs Use only in positions inaccessible to children and animals, particularly cats. When present in drawer or closet, avoid touching the paper sheets.

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

<u>Likely direct or indirect effects</u>	
No adverse effects expected when used as directed.	
Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.	
<u>Description of first aid measures:</u>	
Skin contact	Wash off with soap and plenty of water. Get medical attention if irritation develops and persists.
Eye contact	Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing.

	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Ingestion	If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label. Rinse mouth with water.

Most important symptoms and effects, both acute and delayed:

Eyes	No adverse effects expected when used as directed.
Skin effect	May cause allergic skin reaction. No adverse effects expected when used as directed.
Inhalation	May cause allergic respiratory reaction. No adverse effects expected when used as directed.
Ingestion	May cause irritation to mouth, throat and stomach. May cause abdominal discomfort. No adverse effects expected when used as directed.

Emergency measures to protect the environment:

Environmental precautions	-

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of unused product, its packaging and all other waste, in accordance with local regulations

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

Do not store near food, drink and animal feedingstuff.
Store at room temperature. No decomposition if stored and applied as directed.
Protect from direct sunlight.
Keep out of reach of children and non-target animals/pets
The product has a shelf-life of 4 (four) years.

2.1.6 Other information

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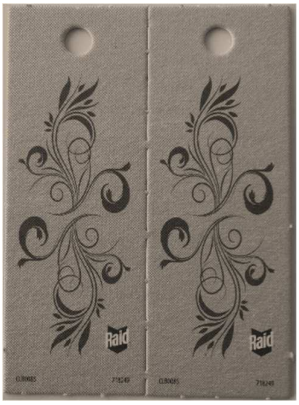
2.1.7 Packaging of the biocidal product

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)
Pouch (primary packaging)	2, 4, 6, 8, 10, or 12 units per pouch (unit means ½ of full paper) Small pouch size: (110 mm x 83 mm x 3 mm) Volume – 27.4 cm^3 Medium pouch size: (110 mm x 83 mm x 9 mm) Volume - 82.17 cm^3	Plastic composite (*Polyethylene Terephthalate, Low Density Polyethylene, Ethylene vinyl alcohol)*	Heat sealed	Non-professional	Yes
Unit box	Box size: (157 mm x 96 mm x 23 mm) Volume 346.7 cm^3 Envelope size: 185mm x 109 mm x 12mm Volume – 242.0 cm^3.	Solid fiberboard	tuck-in	Non-professional	Yes

Photos:

			
Unit box	Pouch	Full paper	Unit

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 AR.

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 as applied for by the applicant

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

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

Table 2. Use # 1 – Consumer Use of Vapour releasing product (VP) Indoors

Product Type	Product type 18: Insecticides, acaricides and products to control other arthropods

Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	**Scientific name** *Tineola bisselliella* **Common name** other: Clothes moth **Development stages** Adults, Larvae
Field of use	Protects clothes against Webbing cloth moth (*Tineola bisselliella*) damage for up to 3 months, without staining delicate fabrics such as silk and cashmere.
Application method(s)	Vapourising mat (passive diffuser)
Application rate(s) and frequency	Dosage: four units per 1 m^3 space. Product is effective up to 3 months.
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

The product is a ready-to-use liquid formulation with a carrier component. The paper carrier is a Type A carrier matrix, see carrier guidance (CA-Nov16-Doc.4.3). Following the accelerated storage of the product, Moth Active Paper was considered to be stable for 4 years under the test parameters. The long term storage stability study at ambient temperature, demonstrated both active and formulation stability, and packaging compatibility. The long term stability was conducted on Autan 4Seasons Anti-Moth, and has been bridged to Moth Active Paper.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	Baseline 7.36 mg; Pure Nominal 0.27%	Liquid formulation on a solid carrier	[redacted]
Colour at 20 °C and 101.3 kPa	Visual	Baseline 7.36 mg; Pure Nominal 0.27%	Dependent upon the colour of the paper. (yellow/brown/green)	[redacted]
Odour at 20 °C and 101.3 kPa	Smell	Baseline 7.36 mg; Pure Nominal 0.27%	Characteristic perfume odour	[redacted]
Acidity / alkalinity	-	-	Product is not an aqueous based formulation and is not intended to be diluted	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			with water. This test is therefore not relevant.	
eCA remark: The liquid product used to impregnate the carrier is neither aqueous nor miscible with water and an acidity/alkalinity determination will therefore not result in a meaningful value.				
Relative density / bulk density	EC44 0/2008 Annex Method A.3	2.227% pure active, Nominal active 2.27% (tested on the liquid intermediate)	Density at 20°C was found to be 0.9189 g/cm^3 for the liquid intermidate	[redacted]
Storage stability test – **accelerated storage**	CIPAC MT 46.3 (storage stability) Analytical method: GC-FID	Baseline 7.36 mg; Pure Nominal 0.27%	An accelerated (3 months at 40°C) storage stability study was performed for Moth Active Paper in air-tight bag made of plastic film PET, thickness of 12 microns and LDPE thickness of 35 micron plus 5 micron barrier layer of EVOH. The active substance is determined by GC-FID. **Active substance content** <u>Initial amount</u> Transfluthrin: 7.36 mg <u>After (40°C):</u> <u>1 month:</u> 7.42 mg Transfluthrin <u>3 months:</u> 7.54 mg Transfluthrin There is 2.4% increase of Transfluthrin level compared to the initial amount. **Conclusion** The amount of Transfluthrin in Moth Active Paper after 3 months at 40°C was found to be stable. A provisional shelf-life of 2 years can be assigned (see long term storage data for 4 years shelf-life).	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
eCA remark: the accelerated storage stability study is not completely in agreement with CIPAC MT 46.3. No data is available after 8 weeks at 40°C and the complete study continues till 12 months. The long term storage stability study, however, shows that a shelf-life of 4 years is supported at ambient temperature. The eCA is therefore of the opinion that the (accelerated) storage stability study at 40°C can be used to show that the product is stable intermittently up to 40°C. eCA remark: the provided amount of transfluthrin, 0.27%w/w (7.36 mg), corresponds to a mass balance that includes the carrier. The specification for the product including the carrier correspond to 0.26%w/w transfluthrin (pure active). The specification for the product without the carrier corresponds to 2.2%w/w transfluthrin (pure active).				
Determination of evaporation kinetics and physico-chemical properties of Herald before and after storage for 8 weeks at 40°C	CIPAC 46.3 (Accelerated storage procedure)	Baseline 6.59 mg; Pure Nominal 0.27%.	The weight loss after storage for 8 weeks at 40°C was not more than 3.76%. The weight loss after evaporation for over 13 weeks was not more than 7.48% for the non-stored samples. The weight loss after evaporation for over 13 weeks was not more than 7.94% for the stored samples.	[redacted]
Storage stability test – **long term storage at ambient temperature**	GC-FID	Baseline 7.36 mg; Pure Nominal 0.27%	A long term storage stability study was performed at 20°C for 4 years and at 25 °C (60%RH) for 4 years. The active substance is determined by GC-FID. **Active substance content** Initial amount Transfluthrin: 7.36 mg (0.27%w/w) After (20°C) 3 months: 7.23 mg Transfluthrin 6 months: 7.25 mg Transfluthrin 12 months: 7.26 mg Transfluthrin 24 months: 6.91 mg Transfluthrin 36 months: 7.32 mg Transfluthrin	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			48 months: 7.20 mg Transfluthrin (2.2 %w/w decrease) After (25°C 60%RH) 3 months: 7.48 mg Transfluthrin 6 months: 7.56 mg Transfluthrin 12 months: 7.21 mg Transfluthrin 24 months: 7.11 mg Transfluthrin 36 months: 7.73 mg Transfluthrin 48 months: 7.18 mg Transfluthrin (2.4 %w/w decrease) **Packaging** The Moth Active Paper was tested in an air-tight bag made of PET and LDPE. **Conclusion** Moth Active Paper is considered to be stable at 20°C and 25°C for 4 years. A shelf-life of 4 years can be assigned in PET/LDPE.	
eCA remark: The long term storage stability study was performed with the product "Autan 4 Seasons Anti-Moth". This product is identical to the Moth Active Paper formulation except for the type of paper that was used. No differences are expected between the use of the product "Moth Active Paper" and "Autan 4 Seasons Anti-Moth". eCA remark: the provided amount of transfluthrin, 0.27%w/w (7.36 mg), corresponds to a mass balance that includes the carrier. The specification for the product including the carrier correspond to 0.26%w/w transfluthrin (pure active). The specification for the product without the carrier correspond to 2.2%w/w transfluthrin (pure active).				
Storage stability test – **low temperature stability test for liquids**	CIPAC MT-39.3	-	The product is sold as a carrier impregnated with liquid. It will not separate or create precipitation par the CIPAC MT-39.3 guidelines upon storage at	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			0°C. The product will never be sold as the liquid. Hence no low temperature stability testing is required.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	BPR guidance Vol.1 Parts A+B+C May 2018 section 3.6.4.2	Baseline 7.36 mg; Pure Nominal 0.27%	During the storage stability studies the samples were stored in the commercial packaging which excludes light and moisture, and were found to be stable when stored as intended. No further testing is therefore considered to be necessary. Please refer to sections above for tests investigating the effect of temperature on storage stability.	[redacted]
eCA remark: Nevertheless, the applicant added the sentence "protect from direct sunlight" to the label.				
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**		Baseline 7.36 mg; Pure Nominal 0.27% for Mo2977 and Baseline 6.59 mg; pure nominal 0.27% for Mo5228	Please see the section on evaporation kinetics and the long term storage stability. There is no observed effect of temperature or humidity. The label will include the following sentence: Store at room temperature	[redacted]
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**		Baseline 7.36 mg; Pure Nominal 0.27%	There is no storage related changes in the physical appearance and packaging after storage for 48 months at 20°C or 25°C at 60%RH	[redacted]
Wettability	-	-	Not relevant. Moth active paper is not a solid that will be dispersed in water.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Suspensibility, spontaneity and dispersion stability	-	-	Not relevant. Moth Active Paper will not be mixed with water.	-
Wet sieve analysis and dry sieve test	-	-	Not relevant. Moth Active Paper is a vapourising mat. 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 powder.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Not relevant. Moth Active Paper will not be mixed with water. This data requirement is only valid for emulsifiable products.	-
Disintegration time	-	-	Not relevant. This data requirement is only relevant to water dispersible solids.	-
Particle size distribution, content of dust/fines, attrition, friability	-	-	Not relevant. This data requirement is only valid for powders and granules.	-
Persistent foaming	-	-	Not relevant. This data requirement is only valid for products that are applied in water.	-
Flowability/Pourability/Dustability	-	-	Not relevant. 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 will not generate smoke.	-
Burning completeness — smoke generators	-	-	Not relevant. 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 will not generate smoke.	-
Spraying pattern — aerosols	-	-	Not relevant. The product is not an aerosol.	-
Physical compatibility	-	-	Not relevant. Moth Active Paper is not intended to be used with other biocidal products.	-
Chemical compatibility	-	-	Not relevant. Moth Active Paper 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	EC440/2008 Method A.5	2.227% pure active, nominal active 2.27% (tested on the liquid intermediate)	Surface tension for the liquid intermediate was measured to be 29.5 mN/m (corrected)	[redacted]
eCA remark: The surface tension is only relevant for liquid formulations. Since Moth Active Paper is a liquid in combination with a carrier, the surface tension has no meaning and is therefore irrelevant.				
Viscosity	OECD 114, MT192	2.227% pure active, nominal active 2.27% (tested on the liquid intermediate)	Dynamic viscosity at 20 °C Shear rates **20 s^{-1}** : 6.39 mPa.s **40 s^{-1}** : 7.54 mPa.s **60 s^{-1}** : 7.89 mPa.s **80 s^{-1}** : 8.14 mPa.s **100 s^{-1}** : 8.26 mPa.s Dynamic viscosity at 40°C Shear rates **20 s^{-1}** : 2.51 mPa.s **40 s^{-1}** : 3.32 mPa.s **60 s^{-1}** : 3.60 mPa.s **80 s^{-1}** : 3.72 mPa.s **100 s^{-1}** : 3.78 mPa.s Kinematic Viscosity at 40 °C Kinematic Viscosity for Moth Gel Lavender 40°C: **20 s^{-1}** : 2.78 cSt **40 s^{-1}** : 3.68 cSt	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			60 s^{-1} : 3.99 cSt **80 s^{-1}** : 4.12 cSt **100 s^{-1}** : 4.19 cSt eCA remark: 1 cSt corresponds to 1 mm^2/s.	
eCA remark: Any classification labelling based on the liquid formulation is not relevant for this product since product is immersed in paper and therefore not likely to cause an aspiration hazard. The product is not able to form a puddle in the mouth which is a criterion to consider the product for classification as an aspiration hazard.				

Conclusion on the physical, chemical and technical properties of the product
Moth Active Paper is a vapour releasing product (VP): liquid formulation with a carrier component. Based on the measured parameters relevant to this product we found there is no impact of temperature and humidity on the active substance content and the appearance and packaging of the product. The ambient storage stability data supports the claimed shelf-life of 4 years at 20°C and 25°C in PET/LDPE. The product should be stored below 40°C.

2.2.3 Physical hazards and respective characteristics

eCA remark: The amount of transluthrin corresponds to 2.2%w/w when not taking the mass of the carrier into account. When including the mass of the carrier the amount of transfluthrin corresponds to 0.27%w/w.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	-	-	None of the components of the product, Moth Active Paper, are known to be explosive. Experience in the use 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 chemical groups. None of those are present with the exception of unsaturated C-C moieties which might be present in the perfume component. Naturally occurring terpenes, however, are non-explosive. Therefore, the eCA considers that the product does not need to be considered for classification as explosive.				
Flammable gases	-	-	Not applicable to a solid product.	-
Flammable aerosols	-	-	Not applicable to a solid product.	-
Oxidising gases	-	-	Not applicable to a solid product.	-
Gases under pressure	-	-	Not applicable to a solid product.	-
Flammable liquids/flash point	EC440/2008 Method A.9	2.227% pure active, nominal active 2.27% (tested on the liquid intermediate)	The flash point is determined to be 85.5 ^{0}C The product is not considered to be flammable.	[redacted]
Flammable solids	EU Method A.10 (Flammability (Solids)	7.25 mg pure active, nominal active 0.27%	Not applicable per CA-Nov16-Doc.4.3	[redacted]
eCA remark: The applicant provided data for the product including carrier. However, as data for CLP classification are only required for the impregnating liquid according to CA-Nov16-Doc.4.3., the results for the impregnated paper are redundant and are therefore not summarized here.				
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.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
eCA remark: According to appendix 6 of the UN MTC, self-reactive properties may be induced by certain chemical groups. None of those groups are present. Therefore, the eCA considers that the product does not need to be considered for classification as self-reactive.				
Pyrophoric liquids	-	-	Experience in the use of the product does not indicate that the liquid is pyrophoric.	-
Pyrophoric solids	-	-	Not relevant as the impregnating mixture is a liquid.	-
Self-heating substances and mixtures	-	-	Not relevant as the impregnating mixture is a liquid.	-
Substances and mixtures which in contact with water emit flammable gases	-	-	None of the components of the product are known to emit flammable gases when in contact with water. Experience in the use of the product does not indicate that the product will emit flammable gas when in contact with water. The product is also not expected to be in contact with water during use.	-
Oxidising liquids	-	-	Following a review of the components of Moth Active Paper it can be concluded that the product will not be oxidizing. All oxygen, fluorine and chlorine atoms are bonded only to carbon or hydrogen.	-
Oxidising solids	-	-	Not relevant as the impregnating mixture is a liquid.	-
Organic peroxides	-	-	Following a review of the components of Moth Active Paper it can be concluded that the product does not contain any organic peroxides.	-
Corrosive to metals	EC1272/2008	2.227% pure active, nominal active 2.27% (tested on the	Corrosiveness to metals study was performed for 28 day at 55°C:	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		liquid intermediate)	Weight loss for aluminium plate <0.1% for non-immersed, partly immersed and fully immersed. Weight loss for steel plate <0.1% for non-immersed, partly immersed and fully immersed. Test results for uniform corrosion: negative Test results for localized corrosion: negative Not corrosive for aluminium and steel	
Auto-ignition temperatures of products (liquids and gases)	(EC) No 440/2008 A.15	2.227% pure active, nominal active 2.27% (tested on the liquid intermediate)	The autoignition temperature for liquid intermediate was 240°C	[redacted]
Relative self-ignition temperature for solids	EU Method A.16 (Relative Self-Ignition Temperatur e for Solids)		No self-ignition temperature was observed up to the maximum test temperature of 404 °C in the sense of the consolidated version of Council Directive 67/548/EEC Annex V, Method A.16. The test item is not considered to have a self-ignition temperature according to Regulation (EC) No 1272/2008.	[redacted]
eCA remark: The self-ignition temperature is not relevant as the impregnating mixture is a liquid and already covered by the auto-ignition temperature.				
Dust explosion hazard	-	-	Not relevant as the impregnating mixture is a liquid.	-

Conclusion on the physical hazards and respective characteristics of the product

Following a review of the components of Moth Active Paper it can be concluded that the product is not explosive, self-reactive, oxidising or an organic peroxide.

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		
Moth Active Paper Active substance: Transfluthrin	GC-FID, internal standard (dipentylphthalate) The paper mats were cut into pieces and extracted with 2-propanol together with ascorbic acid and the internal standard.	70% (0.0523 mg/mL), 100% (0.0747 mg/mL) and 130% (0.0971 mg/mL); 3 replicates per fortification level (duplicate injections) (Blank paper mats were spiked with transfluthrin standard and the regular extraction procedure was performed.)	0.024 to 1.21 mg/mL; r^2 = 0.9999 n: 6 slope: 4.8701 intercept: 0.0121	No interferences No chromatographic detector response was generated in the area of the expected analyte peaks. The identity of the analyte was confirmed by a retention time match with a standard.	70% of nominal concentration – 130% of nominal concentration At 70% 98-99% At 100% 100% At 130% 101-103%	Overall 100	RSD at 70% (n=3): 0.6% RSD at 100% (n=3): 0.0% RSD at 130% (n=3): 1.1% System precision/RSD (n=12): 1.59% Horwitz criterion: 2.37%	N/A	[redacted]

Conclusion on the methods for detection and identificationof the product
A method of analysis employing GC-FID is provided for the determination of the active substance in the product. The method is fully validated in accordance with SANCO/3030/99 rev. 4 11/07/00. 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 (Do not store near food, drink and animal feedingstuff).

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Insecticide (Product Type 18) based on the active substance transfluthrin.
The ready-to-use product consists of a transfluthrin vapour releasing mat that protects clothes against Webbing cloth moth (*Tineola bisselliella*) damage for up to 12 weeks.

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

Organisms to be controlled: webbing Clothes Moth (*Tineola Bisselliella*).
Lifestages to be controlled: Adult Moth and Larvae.
Products/Organisms to be protected: Textile / Fabrics.

2.2.5.3 Effects on target organisms, including unacceptable suffering

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

2.2.5.4 Mode of action, including time delay

The active substance in Moth Active Paper (Transfluthrin) has a broad spectrum of activity, affecting insect presynaptic voltage gate sodium channels in nerve membranes, resulting in rapid knockdown. It disrupts the transmission of nerve impulses at the nicotinic acetylcholine receptor leading to death of the pest.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)					
Function and Field of use envisaged	**Test substance**	**Test organism**	**Test method / Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**

PT18 Moth Active Paper	Test Substance Name: RAID Moth active Paper SKU 665943 with 0.27 % Transfluthrin (0.27 g / 100 g) Application rates: In 0.5 m³ cabinets: 6 full papers (6 x 80 mm x 110 mm per cabinet	Webbing cloth moth, (*Tineola bisseliella*) Laboratory cultured	**SUMMARY OF TEST METHOD** Execution of Method BPD BioG B 940-01 (modified) Test of moth products for insecticidal effect in 0.5 m³ cabinets. The product is placed on the rod, hanging in the centre of the cabinet, without coming into contact with any surfaces of the cabinet. On the rod a hanger with cloths is placed. The cloth material is not coming into contact with the test product. The cloths consist of black lamb's wool material (100 % wool). The product and the cloths remain in the cabinet for the complete testing period. As a control, cabinets containing no product and clean cloth are used. Test insect exposure: The clothes moths are exposed to the product at different exposure points. Therefore, the adult Clothes moths (20 Clothes moths per replicate) are positioned inside the cabinets in a plastic vial with wire gauze cover and a piece of cut out fabric (each 5 x 5 cm in size) on the bottom. The larvae of clothes moth (20 larvae per replicate) are placed on pieces of cut out fabric inside the larvae test boxes, each 5 x 5 cm in size. The plastic vial with the adults and the test boxes for larvae of the Clothes moth are positioned on the shelf of each single cabinet underneath the product. Test start: Each test object is hung from the centre of the rod. On both sides of the test product, the black woolen cloth is hung without coming into contact with the product. The cloths and the products remain in the cabinets for the duration of the testing period. The exposure points are 0, 2, 4, 6, 8, 10 and 12 weeks after the introduction of the product into the cabinet. At the relevant exposure points, the adult and larvae Clothes moths are placed on pieces of fabric from the hanging cloth (each 5 x 5 cm in size). As a control, cabinets not containing any products are used. Evaluation: At each test point the cabinets are opened first after 24 hours and then after 2, 3, 5, 7, 10 and 14 days for examining the insects.	Table 1: **Bioefficacy of RAID Moth Active Paper SKU 665943, tested with 6 full papers in 0.5 m³ cabinets, against Clothes moths, *Tineola bisselliella*, adults** Study: BIO2019-073 temperature: 24 – 25°C Method N°: Bio B 940-01 (modified) mean of 5 replicates rel. humidity: 50 – 70 % See table below Note: all means rounded to integers	[redacted]

Product	Test day	% mortality of clothes moth (adults) in cabinets at test points: 0 weeks	2 weeks	4 weeks	6 weeks	8 weeks	10 weeks	12 weeks
RAID Moth Active Paper SKU 665943 0.27 % (m/m) Transfluthrin	1	100	100	100	100	100	100	100
	2	100	100	100	100	100	100	100
	3	100	100	100	100	100	100	100
	5	100	100	100	100	100	100	100
	7	100	100	100	100	100	100	100
	10	100	100	100	100	100	100	100
	14	100	100	100	100	100	100	100
	Total number of moth	20	20	20	20	20	20	20
	Number of eggs after 1d	10	>30	>30	>25	>29	14	>15
	Number of larvae after 14d	>18	0	0	0	0	0	0
	Grub of hatched larvae	yes	no	no	no	no	no	no

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

The adult Clothes moths are evaluated to determine the mortality rate (on demand the Clothes moth are evaluated for the number of eggs laid, hatched larvae are counted, hatched larvae are evaluated for grub, means black colour intestinal of larvae corresponds to feeding.)

The Clothes moth larvae are evaluated for the mortality rate. Also, the material is assessed for surface damage and holes.

The temperature and relative humidity is given in the tables.

The cabinets are opened daily for 10 seconds.

5 replicates are made (untreated control: 5).

Table 2: **Untreated controls of adult Clothes moths, *Tineola bisselliella*, tested in 0.5 m³ cabinets**

Study: BIO2019-073 temperature: 24 – 25°C

Method N°: Bio B 940-01 (modified) mean of 5 replicates rel. humidity: 50 – 70 %

Product	Test day	% mortality of clothes moth (adults) in cabinets at test points: 0 weeks	2 weeks	4 weeks	6 weeks	8 weeks	10 weeks	12 weeks
Untreated control	1	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0
	3	0	0	0	0	0	1	3
	5	15	15	16	14	15	17	18
	7	21	19	22	24	24	22	25
	10	26	29	31	30	32	30	34
	14	40	37	40	41	39	37	38
	Total number of moth	20	20	20	20	20	20	20
	Number of eggs after 1d	>25	>30	>30	>30	>30	>30	>30
	Number of larvae after 14d	>30	>30	>30	>30	>30	>30	>30
	Grub of hatched larvae	Yes	yes	yes	yes	yes	yes	yes

Note: all means rounded to integers

Table 3: **Bioefficacy of RAID Moth Active Paper, tested with 6 full papers in 0.5 m³ cabinets, against Clothes moths, *Tineola bisselliella*, larvae**

Study: BIO2019-073 temperature: 24 – 25°C

Method N°: Bio B 940-01 (modified) mean of 5 replicates rel. humidity: 50 – 70%

Product	Test day	% mortality of clothes moth (larvae) in cabinets at test points: 0 weeks	2 weeks	4 weeks	6 weeks	8 weeks	10 weeks	12 weeks
RAID Moth Active Paper SKU 665943 0.27 % (m/m) Transfluthrin	1	0	13	81	68	96	100	100
	2	1	38	100	76	96	100	100
	3	6	80	100	93	96	100	100
	5	13	97	100	100	100	100	100
	7	15	98	100	100	100	100	100
	10	16	100	100	100	100	100	100
	14	26	100	100	100	100	100	100
	Total number of larvae	20	20	20	20	20	20	20
	Wool damage	yes	no	no	no	no	no	no
	Grub	yes	no	no	no	no	no	no

Note: all means rounded to integers

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

Table 4: **Untreated controls of Clothes moth larvae, *Tineola bisselliella*, tested in 0.5 m³ cabinets**

Study: BIO2019-073 temperature: 24 – 25°C

Method N°: Bio B 940-01 (modified) mean of 5 replicates rel. humidity: 50 – 70%

Product	Test day	% mortality of clothes moth (larvae) in cabinets at test points: 0 weeks	2 weeks	4 weeks	6 weeks	8 weeks	10 weeks	12 weeks
Untreated control	1	0	0	0	0	0	0	0
	2	0	0	0	0	0	1	0
	3	0	0	0	0	0	1	0
	5	0	0	0	2	3	1	0
	7	0	0	0	3	3	2	2
	10	1	1	3	3	7	7	5
	14	1	5	4	10	10	10	5
	Total number of larvae	20	20	20	20	20	20	20
	Wool damage	yes	yes	yes	yes	yes	yes	yes
	Grub	yes	yes	yes	yes	yes	yes	yes

Note: all means rounded to integers; n.t. = not tested

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

PT18 Moth Active Paper

Test Substance Name:

RAID Moth active Paper SKU 665943 with 0.27 % Transfluthrin (0.27 g / 100 g)

Application rates:

In 0.018 m³ drawers: 1/2 full papers per drawer (i.e. 1 x 40 mm x 110 mm)Beer Mat

0.27% (w/w) transfluthrin

6.7 mg per mat

Webbing Cloth moth, (*Tineola bisseliella*) Laboratory cultured

SUMMARY OF TEST METHOD

Execution of Method BPD BioG B 940-01 (modified)

Test of moth products for insecticidal effect in 0.018 m³ drawers.

The testing drawer have a size of 0.018 m³ (depth 0.4 m x width 0.3 m x height 0.15 m). The product is laid in each drawer in the centre.

Test insect exposure: The Clothes moth adults are exposed to a cloth in plastic dishes (diameter = 9.5 cm, height = 7.5 cm) and sealed with gauze lids. The larvae of the moths are placed to a cloth in Clothes moth larvae test boxes. The insects are set up next to the product.

Test start: Each test product is laid in the centre of the drawer. On both sides of the test product, the black woolen cloth is laid without coming into contact with the product. The cloths and the products remain in the drawer for the duration of the testing period. The exposition points are 0, 2, 4, 6, 8, 10 and 12 weeks after the introduction of the product into the drawer. At the relevant exposition points, the adult Clothes moths are placed on pieces of fabric from the laying cloth (each 5 x 5 cm in size) in plastic dishes. Also, the larvae are placed on pieces of fabric from the laying cloth (each 5 x 5 cm in size), but in larvae test boxes. The plastic dishes and the larvae test boxes are positioned in the drawer containing fabric and the test products. As a control, drawers without product are used.

Evaluation: At each exposition point, the drawers are opened first after 24 hours and then after 2, 3, 5, 7, 10 and 14 days for examining the insects.

The adult Clothes moths are evaluated to determine the mortality rate (on demand the Clothes moth are evaluated for the number of eggs laid, hatched larvae are counted, hatched larvae are evaluated for

Table 1: **Bioefficacy of RAID Moth Active Paper SKU 665943, tested with 1/2 full papers in 0.018 m³ drawers, against Clothes moths, *Tineola bisselliella*, adults**

Study: BIO2019-073 temperature: 24 – 25°C

Method N°: Bio B 940-01 (modified) mean of 5 replicates rel. humidity: 50 – 70 %

Product	Test day	% mortality of clothes moth (adults) in cabinets at test points: 0 weeks	2 weeks	4 weeks	6 weeks	8 weeks	10 weeks	12 weeks
RAID Moth Active Paper SKU 665943 0.27 % (m/m) Transfluthrin	1	100	54	100	100	100	100	100
	2	100	86	100	100	100	100	100
	3	100	94	100	100	100	100	100
	5	100	100	100	100	100	100	100
	7	100	100	100	100	100	100	100
	10	100	100	100	100	100	100	100
	14	100	100	100	100	100	100	100
	Total number of moth	20	20	20	20	20	20	20
	Number of eggs after 1d	0	>24	>30	>24	9	16	>14
	Number of larvae after 14d	0	>30	>15	>26	0	0	0
	Grub of hatched larvae	no	yes	yes	yes	no	no	no

Note: all means rounded to integers; n.t. = not tested

[redacted]

grub, means black colour intestinal of larvae corresponds to feeding.)

The Clothes moth larvae are evaluated for the mortality rate. Also, the material is assessed for surface damage and holes.

The temperature and relative humidity are monitored and recorded.

The drawers are opened daily for 5 seconds.

5 replicates are done (untreated control: 5).

Table 2: **Untreated controls of adult Clothes moths, *Tineola bisselliella*, tested in 0.018 m³ drawers**

Study: BIO2019-073 temperature: 24 – 25°C

Method N°: Bio B 940-01 (modified) mean of 5 replicates rel. humidity: 50 –70 %

Product	Test day	% mortality of clothes moth (adults) in cabinets at test points: 0 weeks	2 weeks	4 weeks	6 weeks	8 weeks	10 weeks	12 weeks
Untreated control	1	0	0	0	0	0	0	0
	2	0	0	0	0	0	0	0
	3	0	0	0	0	0	1	3
	5	12	15	16	14	15	17	18
	7	18	19	22	24	24	22	25
	10	27	29	31	30	32	30	34
	14	36	37	40	41	39	37	38
	Total number of moth	20	20	20	20	20	20	20
	Number of eggs after 1d	>25	>30	>30	>30	>30	>30	>30
	Number of larvae after 14d	>30	>30	>30	>30	>30	>30	>30
	Grub of hatched larvae	yes	yes	yes	yes	yes	yes	yes

Note: all means rounded to integers; n.t. = not tested

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

Table 3: **Bioefficacy of RAID Moth Active Paper, tested with 1/2 full papers in 0.018 m³ drawers, against Clothes moths, *Tineola bisselliella*, larvae**

Study: BIO2019-073 temperature: 24 – 25°C

Method N°: Bio B 940-01 (modified) mean of 5 replicates rel. humidity: 50 –70 %

Product	Test day	% mortality of clothes moth (larvae) in cabinets at test points: 0 weeks	2 weeks	4 weeks	6 weeks	8 weeks	10 weeks	12 weeks
RAID Moth Active Paper SKU 665943 0.27 % (m/m) Transfluthrin	1	0	3	45	42	91	100	100
	2	0	8	83	63	94	100	100
	3	1	8	96	84	94	100	100
	5	4	84	100	100	100	100	100
	7	8	88	100	100	100	100	100
	10	12	93	100	100	100	100	100
	14	38	96	100	100	100	100	100
	Total number of larvae	20	20	20	20	20	20	20
	Wool damage	yes	yes	no	no	no	no	no
	Grub	yes	yes	no	no	no	no	no

Note: all means rounded to integers; n.t. = not tested

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

Table 4: **Untreated controls of Clothes moth larvae, *Tineola bisselliella*, tested in 0.018 m³ drawers**

Study: BIO2019-073 temperature: 24 – 25°C

Method N°: Bio B 940-01 (modified) mean of 5 replicates rel. humidity: 50 – 70 %

Product	Test day	% mortality of clothes moth (larvae) in cabinets at test points: 0 weeks	2 weeks	4 weeks	6 weeks	8 weeks	10 weeks	12 weeks
Untreated control	1	0	0	0	0	0	0	0
	2	0	0	0	0	0	1	0
	3	0	0	0	0	0	1	0
	5	0	0	0	2	3	1	0
	7	0	0	0	3	3	2	2
	10	1	1	3	3	7	7	5
	14	1	5	4	10	10	13	5
	Total number of larvae	20	20	20	20	20	20	20
	Wool damage	yes	yes	yes	yes	yes	yes	yes
	Grub	yes	yes	yes	yes	yes	yes	yes

Note: all means rounded to integers; n.t. = not tested

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

PT18 Moth Active Paper

Test Substance Name:RAID Moth active Paper SKU 665943 with 0.27 % Transfluthrin (0.27 g / 100 g)

Application rates:In glass jars: 1/2 full papers per glass jar (i.e. 1 x 40 mm x 110 mm)

Webbing cCloth moth, (*Tineola bisseliella*) Laboratory cultured

SUMMARY OF TEST METHOD

Execution of Method BPD BioG B 940-01 (modified)
Test of moth products for insecticidal effect in glass jars.
The testing jars have a volume of 350 ml (diameter: 9.5 cm, height: 5.5 cm). Test jars contain activated product, a piece of woollen cloth and test insects. Test jars are closed with a glass lid.
Test insect exposure: The Clothes moth adults are exposed to woollen cloth inside, next to the activated product. The larvae of the moths are also exposed to a cloth inside glass jars next to the activated product.
Test start: Glass jars with product, woollen cloth and insects are closed with a glass lid. The products remain inside the glass jars for the duration of the testing period.
The exposition points are 0, 2, 4, 8 and 12 weeks after the introduction of the product into the glass jars. At the relevant exposition points, the adult Clothes moths are placed on pieces of woollen cloth into the glass jars. As a control, glass jars not containing any products, but only untreated woollen cloth are used.
Evaluation: At each test point the insects inside the glass jars are evaluated first after 24 hours and then after 2, 3, 5, 7, 10 and 14 days. Examination is done through the glass or if needed jars are opened.
The adult Clothes moths are evaluated to determine the mortality rate (on demand the Clothes moth are evaluated for the number of eggs laid, hatched larvae are counted, hatched larvae are evaluated for grub, means black colour intestinal of larvae corresponds to feeding.)
The Clothes moth larvae are evaluated for the mortality rate. Also, the material is assessed for surface damage and holes.
The temperature and relative humidity are monitored and recorded.
No regular aeration during test is performed.
5 replicates are done (untreated control: 5).

Table 1: **Bioefficacy of RAID Moth Active Paper SKU 665943, tested with 1/2 full papers in glass jars, against Clothes moths, *Tineola bisselliella*, adults**

Study: BIO2019-073 temperature: 24 – 25°C

Method N°: Bio B 940-01 (modified) **mean of 5 replicates** rel. humidity: 50 – 68 %

Product	Test day	% mortality of clothes moth (adults) in cabinets at test points: 0 weeks	2 weeks	4 weeks	8 weeks	12 weeks
RAID Moth Active Paper SKU 665943 0.27 % (m/m) Transfluthrin	1	100	100	100	100	100
	2	100	100	100	100	100
	3	100	100	100	100	100
	5	100	100	100	100	100
	7	100	100	100	100	100
	10	100	100	100	100	100
	14	100	100	100	100	100
	Total number of moth	20	20	20	20	20
	Number of eggs after 1d	2	0	0	0	0
	Number of larvae after 14d	0	0	0	0	0
	Grub of hatched larvae	no	no	no	no	no

Note: all means rounded to integers; n.t. = not tested

[redacted]

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

Table 2: **Untreated controls of adult Clothes moths, *Tineola bisselliella*, tested in glass jars**

Study: BIO2019-073 temperature: 24 – 25°C

Method N°: Bio B 940-01 (modified) **mean of 5 replicates** rel. humidity: 50 – 68 %

Product	Test day	% mortality of clothes moth (adults) in cabinets at test points: 0 weeks	2 weeks	4 weeks	8 weeks	12 weeks
Untreated control	1	0	0	0	0	0
	2	0	0	0	0	0
	3	0	0	0	0	11
	5	13	11	12	15	19
	7	22	18	26	25	23
	10	28	28	32	33	29
	14	39	38	41	37	37
	Total number of moth	20	20	20	20	20
	Number of eggs after 1d	19	>30	>30	>30	0
	Number of larvae after 14d	>30	>30	>30	>30	>30
	Grub of hatched larvae	yes	yes	yes	yes	yes

Note: all means rounded to integers; n.t. = not tested

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

Table 3: **Bioefficacy of RAID Moth Active Paper, tested with 1/2 full papers in glass jars, against Clothes moths, *Tineola bisselliella*, larvae**

Study: BIO2019-073 temperature: 24 – 25°C

Method N°: Bio B 940-01 (modified) **mean of 5 replicates** rel. humidity: 50 – 68 %

Product	Test day	% mortality of clothes moth (larvae) in cabinets at test points: 0 weeks	2 weeks	4 weeks	8 weeks	12 weeks
RAID Moth Active Paper SKU 665943 0.27 % (m/m) Transfluthrin	1	100	100	100	100	100
	2	100	100	100	100	100
	3	100	100	100	100	100
	5	100	100	100	100	100
	7	100	100	100	100	100
	10	100	100	100	100	100
	14	100	100	100	100	100
	Total number of larvae	20	20	20	20	20
	Wool damage	no	no	no	no	no
	Grub	no	no	no	no	no

Note: all means rounded to integers; n.t. = not tested

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

Table 4: **Untreated controls of Clothes moths larvae, *Tineola bisselliella*, tested in glass jars**

Study: BIO2019-073 temperature: 24 – 25°C
Method N°: Bio B 940-01 (modified) **mean of 5 replicates** rel. humidity: 50 – 68 %

Product	Test day	% mortality of clothes moth (larvae) in cabinets at test points: 0 weeks	2 weeks	4 weeks	8 weeks	12 weeks
Untreated control	1	0	0	0	0	0
	2	1	0	0	0	0
	3	1	0	0	1	0
	5	3	2	3	2	1
	7	3	2	3	2	1
	10	3	2	8	8	1
	14	5	9	13	10	2
	Total number of larvae	20	20	20	20	20
	Wool damage	yes	yes	yes	yes	yes
	Grub	yes	yes	yes	yes	yes

Note: all means rounded to integers; n.t. = not tested

Conclusion on the efficacy of the product
To demonstrate efficacy of Moth Active Paper against cloth moths (*Tineola bisselliella)* two simulated use tests and one laboratory test were provided. For an evaluation of the label claims, see section 2.2.5.8.

2.2.5.6 Occurrence of resistance and resistance management

No resistance has been observed to-date for the active substance in the product to be authorized (Transfluthrin).

2.2.5.7 Known limitations

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

2.2.5.8 Evaluation of the label claims

Label claims and instructions:

Kills adult moths and their larvae in your wardrobes and drawers for up to 12 weeks at a dosage of 12 units or 6 full paper in wardrobes per 0.5 m^3 and 1 unit in drawers per 0.018 m^3. Allow 2 weeks for maximum effect.

Reduces damage to your wool wardrobe/woollen garments.

Effectiveness:

Simulated use test BIO2019-073/BIO114b-19 was provided to demonstrate efficacy of Moth Active Paper against adult and larval cloth moths (*Tineola bisselliella*) in wardrobes. In this test 6 full papers (12 units) of the product were placed in a 0.5 m^3 wardrobe. In the test with adults mortality was 100% after 1 day up to 12 weeks after placement of the product. At t=0 weeks after placement of the product laid eggs did hatch and 14 days later living larvae and grub were observed. 2-12 weeks after product placement eggs were still laid but living larvae or grub were not observed after 14 days. The control test with adults showed around 20% mortality after 5-7 days and living larvae and grub at all time points from 0 to 12 weeks. In the test with larvae, mortality was only 26% after 14 days at t=0 weeks. At 2-12 weeks after product placement the larval mortality was >90% within 1-5 days. Wool damage and grub was only observed after exposure at t=0 weeks. Control mortality in the larval test was max 10% after 14 days and wool damage and grub were observed in all cases. Efficacy of the product was sufficiently demonstrated in this test against adult moths for up to 12 weeks after placement of the product and against larvae from 2 weeks up to 12 weeks after placement of the product. Based on these test results protection of clothes could be claimed from 2 to 12 weeks after product placement.

Simulated use test BIO2019-073 / BIO115b-19 was provided to demonstrate efficacy of Moth Active Paper against adult and larval cloth moths (*Tineola bisselliella*) in drawers. In this test ½ full paper (1 unit) of the product was placed in a 0.018 m^3 drawer. In the test with adults mortality was 100% after 1 day up to 12 weeks after placement of the product except for 2 weeks after placement when 90% mortality was obtained after 3 days and 100% after 5 days. At t=0 weeks no eggs were laid. From 2 to 12 weeks after placement of the product eggs were laid and for t=2, 4 and 6 weeks living larvae and grub were observed 14 days later. The control test with adults showed around 20% mortality after 5-7 days and living larvae and grub at all time points from 0 to 12 weeks. In the test with larvae, mortality was only 38% after 14 days at t=0 weeks. At 2 weeks after product placement the larval mortality was >90% within 10 days and at t=4-12 weeks >90% mortality was obtained

within 5 days. Wool damage and grub was observed after exposure at t=0 and 2 weeks. Control mortality in the larval test was max 13% after 14 days and wool damage and grub were observed in all cases. Efficacy of the product was sufficiently demonstrated in this test against adult moths for up to 12 weeks after placement of the product and for larvae from 2 weeks up to 12 weeks after placement of the product. Furthermore, based on the test results protection of clothes could be claimed from 8 to 12 weeks after product placement.

Laboratory test BIO2019-073 / BIO116b-19 was provided to demonstrate efficacy of Moth Active Paper against adult and larval cloth moths (*Tineola bisselliella*) in glass jars. In this test ½ full paper (1 unit) of the product was placed in a 350 ml glass jar. In the test with adults mortality was 100% after 1 day up to 12 weeks after placement of the product. Only at t=0 weeks a few eggs were laid which did not result in living larvae 14 days later. The control test with adults showed around 20% mortality after 5-7 days and living larvae and grub at all time points from 0 to 12 weeks. In the test with larvae, mortality was 100% after 1 day up to 12 weeks after placement of the product and no wool damage or grub was observed. Control mortality in the larval test was max 13% after 14 days and wool damage and grub were observed in all cases. Efficacy of the product was sufficiently demonstrated in this test against adult moths and larvae for up to 12 weeks after placement of the product.

Conclusion: efficacy of Moth Active Paper in 0.5 m³ wardrobes (6 full papers/12 units per wardrobe) is substantiated against adult cloth moths (*Tineola bisselliella*) for up to 12 weeks after product placement and against larvae from 2 weeks up to 12 weeks after product placement. Protection of clothes in wardrobes is substantiated from 2 weeks up to 12 weeks after product placement. Efficacy in 0.018 m³ drawers (½ full paper/1 unit per drawer) is substantiated against adult cloth moths for up to 12 weeks after product placement and against larvae from 2 weeks up to 12 weeks after placement of the product. Protection of clothes in drawers is substantiated from 8 weeks up to 12 weeks after product placement. Based on the results we can conclude that reduction of wool damage, though not full protection, can be claimed from 2 up to 12 weeks.

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

Moth Active paper is not intended to be used in combination with other biocidal products.

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	This ready-to-use moth paper product should be classified according to Regulation (EC) No 1272/2008 as skin irritation category 2; H315: Causes skin irritation.
Justification for the value/conclusion	During manufacturing, this ready-to-use product has a liquid formulation dried onto a paper carrier. The end-product consumer will never interact with the liquid formulation; however, according to the carrier guidance for biocidal products (CA-Nov16-Doc.4.3-Final) carrier components, such as paper, "…should not be considered as a part of the composition of the biocidal product.". Therefore, the liquid formulation will be considered for classification derivation. Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for skin irritation/corrosion hazards by calculation. In accordance with section 3.2.3.3.1 of the Regulation, it is assumed that the 'relevant ingredients' of a mixture are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a presumption (e.g., in the case of corrosive ingredients) that an ingredient present at a concentration of less than 1% can still be relevant for classifying the mixture for skin irritation/corrosion. Table 3.2.3 contains the generic concentration limits to be used to determine if a mixture is considered to be an irritant or corrosive to the skin. Details of the product composition are presented in the confidential annex. The total concentration of ingredients with a category 2 classification exceeds the 10% concentration limit value given in Table 3.2.3 of Section 3.2.3 pf the Regulation. As such, this product requires classification as a skin irritant category 2. As the calculation method is considered adequate to determine the classification, a study is therefore not required, nor considered an appropriate use of animals.

Classification of the product according to CLP	Skin irritation category 2; H315: Causes skin irritation. And

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	This ready-to-use moth paper product should be classified according to Regulation (EC) No 1272/2008 as eye irritation category 2; H319: Causes serious eye irritation.
Justification for the value/conclusion	During manufacturing, this ready-to-use product has a liquid formulation dried onto a paper carrier. The end-product consumer will never interact with the liquid formulation; however, according to the carrier guidance for biocidal products (CA-Nov16-Doc.4.3-Final) carrier components, such as paper, "…should not be considered as a part of the composition of the biocidal product.". Therefore, the liquid formulation will be considered for classification derivation. Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for eye irritation/serious eye damage by calculation. In accordance with section 3.3.3.3.1 of the Regulation, it is assumed that the 'relevant ingredients' of a mixture are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a presumption (e.g., in the case of corrosive ingredients) that an ingredient present at a concentration of less than 1% can still be relevant for classifying the mixture for eye irritation/corrosion. Details of the product composition are presented in the confidential annex. Using the equations outlined in Table 3.3.3 of Section 3.3.3 of the Regulation, the total concentration of ingredients with the requisite classification for eye and skin irritation exceeds the 10% generic concentration limit value. As such, this product requires classification as an eye irritant category 2. As the calculation method is considered adequate to determine the classification, a study is therefore not required, nor considered an appropriate use of animals.

Classification of the product according to CLP	Eye irritation category 2; H319: Causes serious eye irritation.

Respiratory tract irritation

Endpoint not required.

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

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	This ready-to-use moth paper product should be classified according to Regulation (EC) No 1272/2008 for skin sensitisation category 1; H317: May cause an allergic skin reaction.
Justification for the value/conclusion	During manufacturing, this ready-to-use product has a liquid formulation dried onto a paper carrier. The end-product consumer will never interact with the liquid formulation; however, according to the carrier guidance for biocidal products (CA-Nov16-Doc.4.3-Final) carrier components, such as paper, "…should not be considered as a part of the composition of the biocidal product.". Therefore, the liquid formulation will be considered for classification derivation. Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for skin sensitisation by calculation. In accordance with Section 3.4.3.3.1 of the Regulation, classification of a product for sensitizing effects is necessary if it contains at least one ingredient that has been classified for skin sensitization and is present at or above the appropriate generic concentration limits noted in Table 3.4.5 or is present at of above the concentration limit for sensitized individuals presented in Table 3.4.6.

	Details of the product composition are presented in the confidential annex. The total concentration of ingredients with the requisite classification for skin sensitization exceeds the generic concentration limit values. As such, this product requires classification as a skin sensitizer category 1 As the calculation method is considered adequate to determine the classification, a study is therefore not required, nor considered an appropriate use of animals.
Classification of the product according to CLP	Skin sensitisation category 1; H317: May cause an allergic skin reaction.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	This ready-to-use moth paper 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. In accordance with Section 3.4.3.3.1 of the Regulation, classification of a product for sensitizing effects is necessary if it contains at least one ingredient that has been classified for respiratory sensitization and is present at or above the appropriate generic concentration limits noted in Table 3.4.5 or is present at or above the concentration limit for sensitized individuals presented in Table 3.4.6 Details of the product composition are presented in the confidential annex. As the calculation method is considered adequate to determine the classification, a study is therefore not required, nor considered an appropriate use of animals.
Classification of the product according to CLP	Not classified

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	This ready-to-use moth paper does not require classification for acute oral toxicity according to Regulation (EC) No 1272/2008. The liquid formulation could theoretically trigger H304; however, this is not relevant as the finished product is a solid.
Justification for the selected value	Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for acute oral toxicity by calculation. In accordance with Section 3.1.3 of the Regulation, the acute toxicity estimate (ATE) of ingredients are calculated and compared to Table 3.1.1 to derive the category of toxicity. Details of the product composition are presented in the confidential annex. As the classification method is considered adequate to determine the classification, a study is not required, nor considered an appropriate use of animals. Aspiration Hazard H304 The solvent used in the liquid formulation, EXXSOL™ D140 (EC No. 919-029-3), is classified by oral exposure as "H304; May be fatal if swallowed and enters airways". This relates to aspiration hazard, where classification is required for substances which are hydrocarbons and have a kinematic viscosity of 20.5 mm²/s or less, measured at 40 °C. In accordance with section 3.10.3.3.1.1 of the Regulation, mixtures which contain ≥10% of a substance or substances classified in Category 1, and have a kinematic viscosity of 20.5 mm²/s or less, measured at 40 °C, shall be classified in Category 1. Aspirational hazard is not applicable since the ready-to-use product is in solid form.
Classification of the product according to CLP	Not classified

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	This ready-to-use moth paper does not require classification for acute inhalation toxicity according to Regulation (EC) No 1272/2008.
Justification for the selected value	Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified for acute inhalation toxicity by calculation. In accordance with Section 3.1.3 of the Regulation, the acute toxicity estimate (ATE) of ingredients are calculated and compared to Table 3.1.1 to derive the category of toxicity. Details of the product composition are presented in the confidential annex. As the calculation method is considered adequate to determine the classification, a study is therefore not required, nor considered an appropriate use of animals.
Classification of the product according to CLP	Not classified

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	This ready-to-use moth paper 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. In accordance with Section 3.1.3 of the Regulation, the acute toxicity estimate (ATE) for ingredients is calculated and compared to Table 3.1.1 to derive the category of toxicity. Details of the product composition are presented in the confidential annex. As the calculation method is considered adequate to determine the classification, a study is therefore not required, nor considered an appropriate use of animals.
Classification of the product according to CLP	Not classified

Information on dermal absorption

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

The EU guidance (Guidance Document on Dermal Absorption EFSA Journal 2017;15(6):4873) on the assessment of dermal penetration states that in the absence of data, a 70% dermal penetration factor should be assumed for a dilution which has an active substance concentration of ≤5%. However, this assumption may be modified to a lower default value of 10% based on expert judgement if sufficient data is provided to justify this figure. A consideration of the available data for transfluthrin and pyrethroids in general is made below to justify a default value of 10%.

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

A number of factors are described which, combined, fulfil a requirement for "Expert judgement" and permit selection of a 10% default value for dermal penetration:
- Physico-chemical properties approach values where assumption of 10% default absorption is suggested in guidance.
- Data from other comparable pyrethroids suggests a dermal penetration value as low as 3 % in humans, would remain a protective overestimate.
- Human skin appears particularly refractory to pyrethroid absorption.

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

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Transfluthrin
Value(s)	10%
Justification for the selected value(s)	Please refer to section above.

NL CA 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)

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

As this product is classified for skin irritation category 2 (H315), skin sensitization category 1 (H317), and eye irritation category 2 (H319), criteria (a) noted above is fulfilled as such an additional evaluation is needed. Please refer to the confidential annex for additional details of the chemicals which are driving the various classifications.

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

Substances classified as skin sensitization (H317) fall into band B for which a qualitative exposure and risk assessment should be performed to determine whether P-statements normally associated with concerned H statements are sufficient or whether other risk mitigation measures should be applied.

There are no chemicals present in the formula which fulfil the SOC criteria, (c), (d) and (e).

Substances that add to the classification of Moth Active Paper and therefore idenfied as SoCs are included in the table below:

Moth Active Paper					
Substance	**Substance Classification**	**Conc. in the liquid formulation (without carrier)**	**Product classification triggered by SoC**	**SoC Band**	**Associate Evaluation/risk management**

		(% w/w)			
2,6-dimehtyloct-7-en-2-ol	Skin Cat. 2:H315 Eye Cat. 2: H319	30.3%	Eye Cat. 2:H319	A	P-statements
tetrahydro-2-isobutyl-4-methylpyran-4-ol, mixed isomers (cis and trans)	Eye Cat. 2: H319	7.58 %	Eye Cat. 2: H319	A	P-statements
Tetrahydrolinalyl acetate	Skin Cat. 2:H315	2.27%	Skin Cat. 2:H315	A	P-statements
1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one	Skin Cat. 2:H315 Skin Sens. Cat. 1:H317	2.27%	Skin Cat. 2:H315 Skin Sens. Cat. 1:H317	A&B	QRA & P-statements
tetrahydrolinalool	Skin Cat. 2: H315 Eye Cat. 2: H319	2.27%	Skin Cat. 2: H315 Eye Cat. 2: H319	A	P-statements
Geranyl acetate	Skin Cat. 2: H315 Skin Sens. Cat. 1:H317	2.27%	Skin Cat. 2: H315 Skin Sens. Cat. 1:H317	A&B	QRA & P-statements
4-tert-butylcyclohexyl acetate	Skin Sens. Cat. 1:H317	2.27%	Skin Sens. Cat. 1:H317	B	QRA

Available toxicological data relating to a mixture

Not applicable

Other

No data are required for the following endpoints:-

- Food and feedstuffs as the biocidal product will not be in contact with feedstuffs. This is included as a condition of storage in the SPC: "Do not store near food, drink and animal feedingstuff".
- *The effects of Industrial processing or domestic preparation are not relevant as the product is Ready to Use.*

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

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

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

> a) It shows an adverse effect in [an intact organism or its progeny]/[non-target organisms], which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences
> b) It has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system
> c) the adverse effect is a consequence of the endocrine mode of action

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

Remark NL CA:

For the active substance transfluthrin no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. The Assessment Reports for transfluthrin (2014) state that this active substance is not be

considered as having endocrine disrupting properties. The potential ED properties of the co-formulants were assessed (see confidential annex for more information) and for none of the components an ED alert was identiefied.

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

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	Yes	No	No	No	No
Oral	No	No	No	No	No	No	No

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1. Dermal exposure	Application	This product is used in closets and drawers to protect clothes from moths. The preloaded ready-to-use moth papers, already containing the transfluthrin, come joined in pairs *via* a perforated edge, that is two halves which come as a full paper. To use the papers, the consumer can tear along the perforated edge to achieve the required efficacious dose, noted below. The moth paper can be placed over a hanger using the pre-cut hole. The label instructions state that six full moth papers should be used in a 0.5 m^3 space, for up to 3 months. Dermal exposure was determined for product application (handling and placing moth paper in the closet). This type of exposure will only occur once, when the product is placed in the closet. Given the brief application time and the low vapor pressure of Transfluthrin (9×10^{-4} Pa; defined as non-volatile by RIVM documentation), an inhalation exposure is considered negligible as an appreciable transfluthrin air concentration will not have been reached.	Non- Professional
2. Inhalation exposure	Post Application	The product works as the active substance is passively released as a vapour at room temperature into the closet/drawer space. Therefore, when the consumer removes clothing from the closet/drawer, the vapour that has volatilized can be inhaled for a brief period of time. The active substance in the moth paper evaporates due to passive air flow at room temperature.	Non- Professional & General public

Industrial exposure

Not applicable

Professional exposure

Not applicable, the product is intended for non-professional use only.

Non-professional exposure

Scenario 1: Application

Description of Scenario 1

The label instruction directs the consumer to place 12 units equivalent to six full ready-to-use moth papers in a 0.5 m^3 space and replace after 3 months (full papers having not been cut and are still joined by the perforated edge). For the purposes of exposure assessment, a 'standard closet' of 1.5 m^3 was assumed, in line with the RIVM pest control fact sheet (RIVM, 2006). Therefore, 18 full papers would be used in a standard closet of 1.5 m^3.

This scenario covers the interaction between the consumer and the moth paper during application. As instructed, the preloaded moth papers, already containing transfluthrin, come ready-to-use. To use the papers, the consumer can tear along the perforated edge to achieve the required efficacious dose, noted above. The moth paper can be placed over a hanger using the pre-cut hole.

The parameters used in the calculation are shown below.

	Parameters	Value
Tier 1	Frequency of use	90 days (RIVM, 2006)
	Amount of active substance	12.5 mg transfluthrin/paper Weight of single paper = 4.62 g Transfluthrin content = 0.27% 0.27% x 4.62=12.5mg transfluthrin = 225 mg transfluthrin/18 papers
	Surface area of one paper	176 cm^2 Dimensions of full paper: 110x80 mm 110x80 = 8800 mm^2 or 88 cm^2 88 cm^2 per side x 2 sides= 176 cm^2
	Dermal transfer	18% (ECHA, 2013)
	Dermal Absorption	70% (see remark included for dermal absorption above)
	Default adult body weight	60 kg (HEADhoc No. 14, 2017)
	Surface area of a few finger tips[1]	10 cm^2 (Transfluthrin Assessment Report, 2014 – DocIIB p26)

Calculations for Scenario

To calculate the amount of active available for dermal transfer it is conservatively assumed that all the transfluthrin is evenly distributed on the outer surface of the paper and thus is available for dermal contact.

12.5 mg transfluthrin/ (176 cm^2)
= 6.75 mg/ 89.6 cm^2
= 0.071 mg/cm^2 of paper

The consumer then handles the moth paper using a few fingertips:
0.071 mg/cm^2 x 10 cm^2
= 0.71 mg

Allowing for 18% dermal transfer:
0.71 mg x 18%
= 0.128 mg

Internal dermal exposure for a 60kg adult for one moth paper is:
(0.128 mg x 70% dermal abs) / 60 kg
=1.49 $x10^{-3}$ mg/kg/day

The label states that 18 papers should be used per closet, therefore the consumer would be exposed to 2.68 x 10^{-2} mg/kg/day (Based on 1.49 $x10^{-3}$ mg/kg x 18 papers).

NL CA remark: the provided amount of transfluthrin, 0.27%w/w (7.36 mg), corresponds to a mass balance that includes the carrier and is considered the technical content. The specification for the product including the carrier correspond to 0.26%w/w transfluthrin (pure active).

Scenario 2: Post Application

Description of Scenario 2		
The label instructions advise the consumer to place 12 units equivalent to 6 moth papers in a 0.5 m^3 area, and replace after 3 months. Therefore 18 papers would be used in a standard closet of 1.5 m^3 (RIVM 2006). During use, the active substance is passively released from the paper to kill moths and their larvae. This scenario assumes a consumer spends five minutes per day inhaling the vapour in the closet whilst they are choosing clothes. Only adult inhalation exposure was determined as it is unlikely that young children will remove clothing from the closet (Transfluthrin Assessment Report, 2014).		
	Parameters	Value
Tier 1	Model	ConsExpo Web (Exposure to Vapour) Model, Constant rate
	Frequency of Use	90 days (RIVM, 2006)
	Emission Duration	90 days (It was assumed that all the active was released in 90 days)
	Exposure Duration	5 minutes / day (RIVM, 2006)
	Emission Rate	12.5 mg transfluthrin/ paper Weight of single paper = 4.62 g Transfluthrin content = 0.27% 0.27%x4.62=12.5mg transfluthrin/paper = 225 mg transfluthrin/ 18 papers = 225 mg transfluthrin/ 90 days This is based on the assumption that all of the active substance is released over the 90 day period not on evaporation rate data.
	Room Volume	1.5 m^3 (RIVM, 2006)
	Ventilation Rate	0.3 hr^{-1} (RIVM, 2006)
	Inhalation absorption	100%
	Default Adult Body Weight	60 kg (HEADhoc No. 14, 2017)
	Inhalation Rate	1.25 m^3/hour (HEADhoc No. 14, 2017, Short term exposure value)

Calculations for Scenario

Moth Active Paper	
Active substance	Transfluthrin (CAS 118712-89-3) 0.27% w/w
Molecular weight of active substance	371 g/mol (Transfluthrin Assessment Report, 2014)
Vapour pressure of active substance	9 x 10^{-4} Pa at 20°C (Transfluthrin Assessment Report, 2014)

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

2.9 x 10^{-3} mg/m^3 x 5 min x 0.0208 m^3/min x 100% abs/60 kg = 5.03 x 10^{-6} mg/kg/day

Further information and considerations on scenario 2
The mean event air concentration has been calculated to be 2.9 x 10^{-3} mg/m^3.

Summary table: external and systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake/inhalation external exposure**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake/inhalation external exposure**
Scenario 1 Dermal exposure	1/ No PPE required	N/A	2.68 x 10^{-2} mg/ kg/ day	N/A	2.68 x 10^{-2} mg/kg/day
Scenario 2 Inhalation exposure	1/ No PPE required	5.03 x 10^{-6} mg/kg/day	N/A	N/A	5.03 x 10^{-6} mg/kg/day
	1/ No PPE required	2.9 x 10^{-3} mg/m^3	N/A	N/A	2.9 x 10^{-3} mg/m^3

Combined scenarios

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

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 1 and 2. Adult primary and secondary exposure to Moth Active Paper	1/ No PPE required	5.03×10^{-6} mg/kg bw/day	2.68×10^{-2} mg/kg bw	N/A	2.68×10^{-2} mg/kg bw

Exposure of the general public

It is possible that an adult places theMoth Active Paper into the closet in a room that is occupied by somebody else who is subsequently secondary exposed to transfluthrin when opening the closet. The exposure is considered the same as for the person placing the paper into a closet and is subsequently exposed (see scenario 2: post application, non-professional exposure). Therefore, for the exposure assessment for the exposure of the general public, be referred to scenario 2: post application, non-professional exposure.

Monitoring data

Not Relevant

Dietary exposure

Not Relevant

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

Production and formulation is addressed under other EU legislation (e.g. Directive 98/24/EC) and not repeated under Regulation 528/2012 (this principle was agreed at Biocides Technical Meeting TMI06).
As the product is applied directly from the container and this is disposed of once empty, there is no cleaning operation to consider.

Aggregated exposure

Not Relevant

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1. Dermal exposure	Non-professional, adult	Tier 1, No PPE	2.68×10^{-2} mg/kg/day
2. Inhalation exposure	Non-professional & general public, adult	Tier 1, No PPE	5.03×10^{-6} mg/kg/day
2. Inhalation exposure	Non-professional & general public, adult	Tier 1, No PPE	2.9×10^{-3} mg/m^3

Combined scenarios

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 1 and 2. Adult primary and secondary exposure to Moth Active Paper	1/ No PPE required	5.03×10^{-6} mg/kg bw/day	2.68×10^{-2} mg/kg bw	N/A	2.68×10^{-2} mg/kg bw

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 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, 10% absorption)	3-week rabbit	1000 mg/kg/day	100	None	1 mg/kg/day
AELchronic (systemic)	2-year dietary rat	1 mg/kg/day	100	None	0.01 mg/kg/day

ADI (if residues in food or feed)	2-year dietary rat	1 mg/kg/day	100	none	Although there are no residues in food or feed expected an ADI of 0.01 mg/kg bw/day is used in the statement of negligible exposure (Doc IIB 3.1.4)
ARfD (acute reference dose)	Dev. study,rabbit	15 mg/kg/day	100	None	Although there are no residues in food or feed expected an ARfD of 0.15 mg/kg bw/day is used in the statement of negligible exposure (Doc IIB 3.1.4)

Risk for industrial users
Not Relevant

Risk for professional users
Not Relevant

Risk for non-professional users

Systemic effects

Task/ Scenario	Tier	NOAEL or NOAEC	AEL or AEC	Estimated uptake	Estimated uptake/ AEL or AEC (%)	Acceptable (yes/no)
1- Dermal exposure	1	1000 mg/kg	1 mg/kg/day	2.68×10^{-2} mg/kg/day	3	Yes
2- Inhalation exposure	1	1 mg/kg/day	0.01 mg/kg	5.03×10^{-6} mg/kg/day	<1	Yes
2- Inhalation exposure	1	46.7 mg/m^3	0.5 mg/m^3	2.9×10^{-3} mg/m^3	1	Yes

Combined scenarios

Task/ Scenario	Tier	NOAEL	AEL	Estimated uptake	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1 and 2 - Adult primary and secondary exposure to Moth Active Paper	1	1000 mg/kg & 1 mg/kg/day	1 mg/kg/day & 0.01 mg/kg	2.68×10^{-2} mg/kg/day & 5.03×10^{-6} mg/kg/day	3 + <1 = 3	Yes

Local effects

The formulation is classified as a skin sensitiser, driven by 1-(Octahydro-Tetramethyl-2-Naphthyl)Ethan-1-one (CAS No 54464-57-2). The quantitative risk assessment below shows that induction of dermal sensitisation is not anticipated after the use of this product. The quantitative risk assessment approach for dermal sensitisation is well established and currently endorsed in the REACH Technical Guidance (Api *et al*., 2008, ECHA 2012). Historically, the methodology has been used for fragrances and preservatives in a variety of consumer products including cosmetics and household cleaners (Basketter *et al.,* 2008, Basketter *et al.,* 2010, Basketter *et al.,* 2015, Corea *et al.,* 2006).

Acceptable Exposure Level (AEL):
The derivation of the AEL first requires the estimation of a threshold for the induction of sensitisation, the No Expected Skin Sensitisation Induction Level (NESIL), taking into account the sensitising potency of the chemical of concern (Api *et al*., 2008). Suitable thresholds can be identified from experimental data such as the EC3 from a Local Lymph Node Assay (LLNA) which is the concentration required to induce a threshold positive response (stimulation index equal to 3) (ECHA, 2012).

A LLNA for 1-(Octahydro-Tetramethyl-2-Naphthyl)Ethan-1-one produced an EC3 of 6.07% (Chapdelaine J.M. (2015), the equivalent of 1517 µg/cm^2 (6.07% x conversion factor of 250).

The threshold (NESIL) is then extrapolated to the consumer exposure scenario by dividing by 3 Sensitisation Assessment Factors (SAFs) to account for human variability, matrix differences, and use considerations (Api *et al.,* 2008, Corea *et al.,* 2006, Felter *et al.,* 2002). A value between 1 and 10 is selected for each SAF based on the exposed population, the product and its use characteristics. The threshold is then divided by the product of these uncertainty factors to derive the AEL:

AEL = NESIL / SAF

The AEL was calculated as follows:

EC3 for 1-(Octahydro-Tetramethyl-2-Naphthyl)Ethan-1-one = 1517 µg/cm^2

Sensitisation Assessment Factors selected:
Inter-individual variability: 10 (the highest value possible)
Formula differences: 10 (nothing to enhance skin penetration but formula classed as irritant)
Use considerations: 1 (finger tips only, brief and infrequent exposure)
Overall SAF = 100 (from 10 x 10 x 1)

AEL = NESIL/SAF = 1517 µg/cm^2 / 100 = 15.17 µg/cm^2

Consumer Exposure Level (CEL):
Consumer exposure was calculated by adapting the previous equation for dermal exposure to transfluthrin.

Level of 1-(Octahydro-Tetramethyl-2-Naphthyl)Ethan-1-one in the paper = 1.89%

Percentage of transfluthrin in the formula (excluding paper) = 2.27%

Equivalent weight of transfluthrin = 12.5 mg transfluthrin per full paper.

So if 2.27% is equivalent to 12.75 mg transfluthrin, then 1.89% would be approximately 10.4 mg of the fragrance component.

Therefore it was assumed there was 10.4 mg of 1-(Octahydro-Tetramethyl-2-Naphthyl)Ethan-1-one per full paper.

Using the approach outlined in the REACH Consumer exposure model, ECETOC TRA v.3.1, which has been endorsed by ECHA for consumer exposure assessment under REACH, a thickness layer of 0.001cm has been specifically assigned to printed papers (REACH Article Category 8, AC8: Paper articles).

The moth paper is 1mm in thickness (depth) when measured. This is equivalent to one hundred layers, each equivalent to 0.01mm or 0.001cm thickness, using the ECETOC TRA model. If each layer contains a proportional amount of fragrance material, this would be equivalent to 0.104 mg fragrance component per layer, assuming even distribution. All the fragrance in the layer would then be available for dermal exposure, taking dermal transfer (18%) and surface area (88 cm^2) into account:

Dermal exposure = 0.104 mg/88cm^2 x 18% dermal transfer = 0.000213 mg/cm^2
= 0.213 µg/cm^2

According to the label instructions 18 papers should be placed in a standard closet, therefore consumer exposure is:

Consumer Exposure Level (CEL) = 0.213 µg/cm^2 x 18 papers = 3.83 µg/cm^2

Risk characterisation:

The Acceptable Exposure Level was divided by the Consumer Exposure Level to determine the Margin of Safety (AEL/CEL = MOS):

MOS = AEL/CEL = 15.17 µg/cm^2 / 3.83 µg/cm^2 = 3.96

This assessment results in margin of safety greater than 1, indicating exposure is below the acceptable threshold and therefore the risk of inducing sensitisation to 1-(Octahydro-Tetramethyl-2-Naphthyl)Ethan-1-one is low.

It should be noted that although an EC3 value from a LLNA was used for the risk assessment above, the RIFM database (RIFM 2015) also cites 8 human studies (Human Repeat Insult Patch Tests) conducted between 1973 and 2004, in which none of the subjects exhibited positive responses when 1-(Octahydro-Tetramethyl-2-Naphthyl)Ethan-1-one was tested from 2.5 to 40%.

Also, frequency and duration of exposure are important factors influencing the likelihood of inducing dermal sensitisation (Kimber *et al*., 2008). There are several conservative assumptions in the current assessment; one of these is that exposure is calculated for the day the product is used whereas, in reality, exposure only occurs once every 3 months. Consequently, dermal contact will be infrequent and short in duration, unlike other consumer products such as cosmetics and cleaning products for which the sensitisation QRA approach is used. Also, it was assumed the consumer did not wash their hands after handling the paper and that all transferred residues remained on the skin. This is in contrast to the use instructions, which advise the consumer to wash their hands after application. Consequently, dermal exposure to the fragrance component would be significantly lower than the value calculated above.

NL CA remark: The included qualitative risk assessment only includes one of the co-formulants, i.e. 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthyl)ethan-1-one that is responsible for H317 classification, whereas this does not include the other 3 co-formulants: Geranyl acetate, 4-tert-butylcyclohexyl acetate. Furthermore, the LLNA study referred to, Chapdelaine J.M. (2015), was not included in the provided IUCLID dossier. Therefore, we consider the assessment as included not sufficient. Additionally, it is noted that no guidance is available for a quantitative assessment in the context of biocidal assessments.

All four substances mentioned that trigger H317 classifciation are part of the included fragrance component. H317 classification triggers the use of gloves. However, considering that the classification is based on the liquid that impregnates the carrier, the concentration in the final product, which includes the paper, reduces the concentration of the sensitising substances 10-fold, to a concentration that would trigger EUH208 instead of H317. According to the intended use 1-36 units are placed in drawers or wardrobes, exposing only the finger tips to the sheets. The product is efficacious for 12 weeks. Therefore, even if multiple drawers/closets are treated in a home, the exposure is considered infrequent. Furthermore, even if more closets are treated, not at the same day, the exposure is considered infrequent. Additionally, in the intended use it is included that hands need to be washed thoroughly after handling. Considering this, the exposure is considered acceptable without the use of gloves.

Conclusion

The risk assessment for the active Transfluthrin shows that consumer exposure is well within the acceptable levels for the use of Moth Active Paper. Both routes of exposure, i.e. dermal and inhalation, result in an estimated uptake of less than 1% of the relevant AEL.

In addition, the quantitative sensitisation risk assessment for the substances that thrigger H317 classification indicates that the likelihood of inducing sensitisation following skin contact is expected to result in a low level of risk from consumers using the product as directed. Additionally, the risk of local effects is adequately mitigated with the use of appropriate hazard and precautionary phrasing on the product label.

Risk for the general public
Not Relevant

NL CA remark: People entering a room in which Moth Active Paper is used, could be indirectly exposed via inhalation to transfluthrin. However, the indirect exposure is much lower than the exposure assessed for the non-professional user. It is assumed that an adult (60 kg) is exposed every day to this concentration during 5 minutes. Although longer exposure times could be possible. Closets/wardrobes are not airtight and are often sited in occupied rooms (e.g. bedrooms). Persons occupying the rooms could be exposed by inhalation to transfluthrin permeating out of the closets through doors gaps. Bedrooms can be occupied (e.g. little children or by people who are ill/invalid) for 24 hours per day for considerable periods. Although considering the estimated internal chronic exposure 3% of the AEL and the dilution effect (factor 10) of using 16m^3 as bed room (closet is set at 1.5m^3) and approximately 300 times more exposure time per day (from 5 minutes to 24 hours) the exposure will not result in exceedance of the AEL. It should be noted that the assumptions are in practise very worst case, as the active substance is not highly volatile and does not included any air changes in the room.

In addition to the secondary inhalatory exposure, people might be exposed secondary via the dermal route via transfer from textiles being present in treated closets. However, it is to be expected that handling textile from a treated closet results in a lower dermal exposure compared to touching the paper directly during application. Transflutrin is present in the paper and dislodging from the paper and transferring to the clothes is considered to be low as direct contact of the paper with the clothes is not likely. A risk assessment for the general public touching textiles containing transflutrin was therefore not considered necessary.

As safe use was concluded for the unprotected user (see risk for non-professional user), this conclusion also applies to indirect exposure. Therefore, no adverse health effects are expected by indirect exposure to transfluthrin as a result of the application of Moth Active Paper.

Risk for consumers via residues in food
Not Relevant

2.2.7 Risk assessment for animal health

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

NL CA remark: The product is to be used inside closets and therefore repeated animal exposure is not considered an exposure scenario. Furthermore, in the general risk mitigiation measures the following sentence is included: "Use only in positions inaccessible to children

and animals, particularly cats" and "Do not use near food, drink and animal feedingstuffs". Furthermore, under storage conditions the following sentence is included: "Do not store near food, drink and animal feedingstuff".

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

Information relating to the ecotoxicity of the active substance

The endpoints used for PNEC derivation, as agreed at WG IV 2017 and reported at the BPC 24 (25th of April 2018). This concerns an update from the AR (2014) endpoints and PNECs. Additional studies were provided to RMS NL in 2015.

Summary table for aquatic toxicity data				
Species	Substance	Timescale	End point	Results
Fish				
Oncorhynchus mykiss	Transfluthrin	Acute	LC_{50}	0.7 µg/L
Fathead minnow (pimephales promelas)	Transfluthrin	Chronic	NOEC	0.399 µg/L
Oncorhynchus mykiss	TFB-COOH[1]	Acute	LC_{50}	>100 mg/L
Invertebrates				
Daphnia magna	Transfluthrin	Acute	EC_{50}	1.4 µg/L
Daphnia magna	Transfluthrin	Chronic	NOEC	0.0175 µg/L
Daphnia magna	TFB-COOH	Acute	EC_{50}	>100 mg/L
Daphnia magna	Trans-DCVA[2]	Acute	EC_{50}	6.42 mg/L
Algae				
Scenedesmus subspicatus	Transfluthrin	Acute	E_rC_{50}	>100 µg/L
		Chronic	NOE_rC	50 µg/L
Pseudokirchneriella subcapitata	TFB-COOH	Acute	96h E_rC_{50}	>100 mg/L
		Chronic	NOE_rC	3.05 mg/L
Sediment organisms				
Chironomus riparius	Transfluthrin	Chronic emergence rate	NOEC	0.164 mg/kg dw sed
			EC_{10}	0.302 mg/kg dw sed
Lumbriculus variegatus	Transfluthrin	Chronic	NOEC	2.21 mg/kg dw sed
			EC_{10}	1.77 mg/kg dw sed
Microorganisms (STP)				
Respiration activated sludge	Transfluthrin	Acute	NOEC	57 µg/L
			EC_{50}	>10000 mg/L

[1] 2,3,5,6-Tetrafluorobenzyl acid (TFB-COOH)

[2] 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid (trans-DCVA, also named permethric acid)

Conclusion used in Risk Assessment – STP Microorganisms	
Value/conclusion	$PNEC_{STP}$ for transfluthrin: 0.057 mg/L
Justification for the value/conclusion	As discussed in the Assessment Report for transfluthrin, the test was performed at concentrations ranging from 100 to 10000 mg/L, whereas the water solubility of transfluthrin is 0.057 mg/L. Therefore, it is not possible to draw a definitive conclusion as to whether the absence of effects is due to the fact that transfluthrin is indeed not toxic to bacteria or is caused by the absence of exposure. 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.

Conclusion used in Risk Assessment - Aquatic Toxicity

Value/conclusion	$PNEC_{aquatic}$ for Transfluthrin: 1.75 ng/L $PNEC_{aquatic}$ for 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH): >0.1 mg/L $PNEC_{aquatic}$ 2,3,5,6-Tetrafluorobenzyl alcohol (TFB-OH): >0.1 mg/L $PNEC_{aquatic}$ 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid (trans-DCVA; also named permethric acid): 0.0064 mg/L
Justification for the value/conclusion	During the BPD review of transfluthrin, only studies on acute toxicity to aquatic organisms were available. Accordingly, a $PNEC_{aquatic}$ of 0.7 ng/L was determined on the basis of the lowest acute LC_{50} of 0.7 µg/L for fish (*Oncorhynchus mykiss*) with an assessment factor of 1000 (Transfluthrin Assessment Report, 2014). However, further chronic studies (reproduction toxicity study on daphnia and ELS test with fish) have subsequently been conducted with transfluthrin. The lowest chronic endpoint is a NOEC 17.5 ng/L reported for a 21 day flow-through daphnia reproduction study. Since chronic studies covering three trophic levels are available, it is appropriate to apply an assessment factor of 10 to this endpoint. Accordingly , the revised $PNEC_{aquatic}$ for transfluthrin is proposed to be 1.75 ng/L As discussed in the Assessment Report for transfluthrin, the environmentally relevant metabolites in the aquatic compartment are 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH), 2,3,5,6-Tetrafluorobenzyl alcohol (TFB-OH), as well as 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid (trans-DCVA). An additional study was provided (and agreed at WGIII-2018 and BPC 24 (2018); please refer to the studies in the fate section below), in which also two metabolites of trans-DCVA were identified; cis-OH-DCVA and trans-OH-DCVA.In the case of the metabolite TFB-COOH, two acute toxicity studies were available during the BPR review (fish and daphnia), both with 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 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 an acute LC50 for daphnia of 25 mg/l was reported for 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid (trans-DCVA; also named permethric acid). Considering the incomplete data set, QSAR (Epiwin) calculations based on baseline toxicity were performed resulting in an fish 96 hr LC50 of 9.97 mg/L, a Daphnia 48 hr LC50 of 6.420 mg/L and a green algae EC50 of 8.101 mg/L. Accordingly, a PNECaquatic of 0.0064 mg/L was determined for trans-DCVA, by applying an assessment factor of 1000. For the metabolites cis-OH-DCVA and trans-OH-DCVA, no ecotoxicity data are available.

Conclusion used in Risk Assessment - Aquatic Sediment Toxicity	
Value/conclusion	$PNEC_{sediment}$ for transfluthrin: 0.36 µg/kg ww sediment (equivalent to 1.64 µg/kg dw sediment)
Justification for the value/conclusion	During the BPD review of transfluthrin, no specific studies concerning potential toxicity to sediment dwelling organisms were available. As a result, the $PNEC_{sediment}$ was derived on the basis of the available aquatic ecotoxicity data using the equilibrium partitioning method (EPM). In order to take account of uncertainty applying the EPM to substance with Log Kow>5, an additional safety factor was applied. Further chronic studies have subsequently been conducted with Transfluthrin. An OECD 225 study with *Lumbriculus variegatus* reported a NOEC 2.21 mg/kg dw sediment. However, an OECD 218 study with *Chironomus riparius* showed relatively greater sensitivity. A statistically significant difference was calculated for the highest test concentration with emergence, i.e. 0.352 mg a.s./kg dw sediment, compared to the pooled controls, resulting in a NOEC of 0.164 mg a.s./kg dw sed. Since chronic studies covering two trophic levels are available, it is appropriate to apply an assessment factor of 50 to the NOEC reported for chironomid. A further AF of 2 is added because in the chironomus study the test organisms were fed with fresh food, thus theoretically limiting the exposure to the test substance via sediment/particle ingestion. Therefore, according to the conclusion in the Environment Working Group Meeting IV 2017 (ECHA, 2017a) the PNEC sediment value is 1.64 µg/kg dw. In the case of the metabolites TFB-COOH, TFB-OH and trans-DCVA, the risk assessment for sediment is covered by that for water, as defined in the Transfluthrin Assessment Report (2014).

Summary table for terrestrial toxicity data				
Species	Substance	Timescale	End point	Endpoint*
Earthworms (*Eisenia fetida*)	Transfluthrin	Acute	LC_{50}	184 mg/kg dw soil (10% OM)
Earthworms (*Eisenia fetida*)	Transfluthrin	Chronic	NOEC	10 mg/kg dw soil (10% OM)
Collembola *(folsomia candida)*	Transfluthrin	Reproduction	NOEC	18 mg/kg dw soil (5% OM)
Soil microorganisms (Nitrogen mineralisation)	Transfluthrin	Chronic	EC_{10}	5.24 mg/kg dw soil (3.4% OM)
Non-target terrestrial plants	Transfluthrin	Seedling emergence and growth	NOEC	50 mg/kg dw soil (2% OC)

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

predominantly driven by its log Kow, and that organisms (except earthworm) are exposed predominantly via pore water.

Conclusion used in Risk Assessment – Terrestrial Toxicity Data	
Value/conclusion	$PNEC_{soil}$ for Transfluthrin: 0.088 mg/kg ww soil (equivalent to 0.1 mg/kg dw soil) $PNEC_{soil}$ for 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH): 0.012 mg/kg ww soil $PNEC_{soil}$ for trans-DCVA: 0.0128 mg/kg ww soil.
Justification for the value/conclusion	During the BPD review of transfluthrin, only the earthworm acute study was available for terrestrial organisms, therefore the $PNEC_{soil}$ 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), collembolan (reproduction), micro-organisms (nitrogen transformation) and non-target plants (seedling emergence and growth). Following discussion at Environment Working Group Meeting IV 2017, it was agreed that the $PNEC_{soil}$ should be based on the endpoint for nitrogen mineralization of 5.24 mg/kg dw standard soil. Since chronic studies covering at least two trophic levels are currently available, an assessment factor of 50 is applied to this endpoint, giving a PNEC value of 0.10 mg/kg dw (0.088 mg/kg ww). Regarding metabolites, an additional study was provided (and agreed at WGIII-2018 and by the BPC at meeting no. 24 (2018); please refer to the studies in the fate section below), which demonstrated formation of the metabolite 2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH). In addition, formation of the metabolite trans-DCVA was also expected. Hence, for soil, TFB-COOH and trans-DCVA are considered as the environmentally relevant metabolites. In the case of the metabolites TFB-COOH and trans-DCVA no data have been generated on terrestrial organisms. Therefore, the Equilibrium Partitioning Method is used to derive the PNECsoil based on the PNECaquatic. Concerning TFB-COOH taking account of the PNECaquatic of > 0.1 mg/L, water solubility of 6110 mg/L, vapour pressure of 0.44 Pa and an assumed worst case Koc of 0 L/kg, the PNECsoil was calculated to be 0.012 mg/kg ww. For trans-DCVA the PNECsoil was calculated to be 0.0128 mg/kg ww; based on the water solubility of 127.6 mg/L, vapour pressure of 2.60 Pa and a log Koc of 2.025 (parameters estimated using EPIsuite; please refer to Annex 3.2).

Summary table for Secondary Poisoning *via* the Food Chain

Species	Substance		End point	Results	Reference
Rat	Transfluthrin	Oral Diet	NOEC 2-generation	200 mg/kg feed	Transfluthrin Assessment Report (2014)

Conclusion used in Risk Assessment – Secondary Poisoning *via* the Food Chain	
Value/conclusion	$PNEC_{oral,\ mammals}$ for transfluthrin: 6.67 mg/kg feed
Justification for the value/conclusion	The $PNEC_{oral}$ for secondary poisoning of mammals is derived by applying an assessment factor of 30 to the chronic NOEC of 200 mg/kg feed, resulting in a $PNEC_{oral,mammal}$ of 6.67 mg/kg feed. As stated in the Transfluthrin Assessment Report, only acute data were available. 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 used in the risk assessment have been derived from data on the active substance and also from studies performed on the active substance which were completed subsequent to the issue of the Transfluthrin Assessment Report (2014). During the product authorisation process of products with transfluthrin additional data have been submitted as refinement. These data have been evaluated and agreed upon at different WG meetings in the period of 2016 to 2018 and at the BPC meeting no. 24 (2018), resulting in harmonised PNEC values for the aquatic and terrestrial environment.

Summary table for PNECs used in Risk Assessment	
Parameters	**Concentration**
Transfluthrin	
$PNEC_{STP}$	0.057 mg/L
$PNEC_{water}$	1.75 ng/L
$PNEC_{sediment}$	0.36 µg/kg ww sediment
$PNEC_{soil}$	0.088 mg/kg ww soil
$PNEC_{oral,\ mammals}$	6.67 mg/kg feed
2,3,5,6-Tetrafluorobenzoic acid (TFB-COOH)	
$PNEC_{soil}$	0.012 mg/kg ww soil
3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid (trans-DCVA; also named permethric acid)	
$PNEC_{water}$	0.0064 mg/L
$PNEC_{soil}$	0.0128 mg/kg ww soil

In view of the chemical structure similarity and the comparable physico-chemical characteristics of TFB-OH and TFB-COOH (as also discussed in the Assessment Report for transfluthrin (2014)), the risk of TFB-OH for the aquatic compartment is covered by the risk assessment for TFB-COOH. Hence, the $PNEC_{water}$ for TFB-OH is not included.
Regarding the metabolites of trans-DCVA, cis-OH-DCVA and trans-OH-DCVA, no ecotoxicity data are available. QSAR data (please refer to Annex 3.2) indicate that these metabolites are much less toxic than trans-DCVA (with L/EC50 values from 90 mg/L; more than times

higher than values estimated for trans-DCVA). Therefore, no PNEC values are included here and the risk for these metabolites is covered by the risk assessment for trans-DCVA.

Air compartment

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

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

In accordance with the Guidance on the BPR: Volume IV. Part A Chapter III: Requirements for Biocidal Products 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). Under Regulation (EC) No 1272/2008, in the absence of data, preparations may be classified by calculation based on toxicity data for the product components.

Both the liquid product used to impregnate the carrier as well as the end-product (with carrier) were included for classification. Details of the products 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.

For example, taking the concentration of Transfluthrin in the liquid product into account, the minimum environmental classification of the product can be calculated as follows:

Acute Environmental Classification of the liquid product:
Acute 1 x M ≥25% = Acute 1

(2.31 x 1000) = 2310

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

(2.31 x 1000) = 2310

Taking into account also the co-formulants relevant for the environment, the environmental classification of both the liquid product and the end-product, according to CLP-Regulation (EC) No 1272/2008 is Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).

Further Ecotoxicological studies

In line with the Guidance on BPR (Vol IV, ENV Parts B+C) Section 8, a substance of concern was identified for the product. This substance should be included in the risk assessment and below the endpoints for the substance used in the risk assessment are presented.

Soc	Species	Test	Result	Remarks	Reference
Tetrahydrolinalyl acetate [CAS 20780-48-7]	Fish	96 hr acute	LC_{50} = 0.225 mg/L	GLP, K2, based on read across substance tetrahydrolinalool	REACH Registered Substances database[1]
	Fish	-	NOEC = 0.025 mg/L	ECOSAR v2.0	
	Daphnid	48 hr acute	LC_{50} 0.09 mg/L Based on mean measured concentration	GLP, K2	
	Daphnid	-	NOEC = 0.29 mg/L	ECOSAR v2.0	
	Green Algae	72 hr acute	ErL_{50} > 0.09 mg/L NOErL = 0.09 mg/L Based on mean measured concentration	GLP, K2	
	activated sludge	28 d chronic	NOEC = 101 mg/L	GLP, K2. Based on toxicity control data	

[1] https://echa.europa.eu/nl/registration-dossier/-/registered-dossier/25046

Summary of PNEC values for substance of concern

Summary table for PNECs used in Risk Assessment		
Parameters	**Concentration**	**Notes**
Tetrahydrolinalyl acetate [CAS 20780-48-7]		
$PNEC_{STP}$	10.1 mg/L	AF = 10
$PNEC_{water}$	0.0025 mg/L	AF = 10
$PNEC_{sediment}$	0.003 mg/kg sediment ww	The PNECsed is derived from the PNECaquatic using the equilibrium partitioning method (EPM), with an additional assessment factor of 10 as a consequence of the log Pow >5. Koc = 432.4 L/kg at 20°C
$PNEC_{soil}$	0.002 mg/kg soil ww	The PNECsoil is derived from the PNECaquatic using the equilibrium partitioning method (EPM), with an additional assessment factor of 10 as a consequence of the log Pow >5. Koc = 432.4 L/kg at 20°C

Screening for endocrine disrupting potential

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders). It means that ED hazard assessment should be included in the PAR.
For the active substance an ED assessment is not required, because for active substances which have been approved, the EU assessment in the assessment report should be followed. However, a screening for co-formulants contained in the product should be performed. As also discussed in Section 2.2.6.1 and in the confidential Annex, a screening for endocrine disruption potential was performed for the product.

In addition to the databases included in the screening as discussed in Section 2.2.6.1 and in the confidential annex, the eCA NL also consulted the following databases which are more specific regarding the environment:
• Identified as ED by the United Nations Environment (July 2017) Programme(http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y and https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)
•List of endocrine disrupting chemicals, by Danish Centre on endocrine disrupters (http://cend.dk/files/DK_ED-list-final_2018.pdf)
•Strategic Programs on Environmental Endocrine Disruptors '98 (SPEED '98), by the Government of Japan, Ministry of the Environment (https://www.env.go.jp/en/chemi/ed/speed98/sp98t3.html).

None of the co-formulants included in Moth Active Paper were identified as having ED potential. Therefore ED potency of co-formulants was not examined further.

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

No data are available.

Data waiving	
Information requirement	-
Justification	This is not a core data requirement. The biocidal product is not anticipated to have any effect on non-target organisms (flora and fauna), as the application is indoors only. Information concerning the potential for the product to cause adverse effects on non-target organisms (flora and fauna) can be extrapolated from information on the active substance (Document IIIA, TNG Section IIIA7.4.3.5).

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

No data are available.

Data waiving

Information requirement	-
Justification	The product is not in the form of a bait or granules and therefore this endpoint does not apply.

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

No data are available.

Data waiving	
Information requirement	-
Justification	The product is not in the form of a bait or granules and therefore this endpoint does not apply.

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

No data are available.

Data waiving	
Information requirement	-
Justification	The biocidal product is intended to be used indoors and will not, therefore, have an effect on a large proportion of a specific habitat. No further scientific investigation is therefore considered necessary.

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

The product is for indoor use, in wardrobes and drawers. When the floor around the wardrobes/drawers are wet-cleaned, emission may occur via the STP to the aquatic environment and soil (application of sewage sludge). As the product is applied in wardrobes and drawers emission to outdoor air is considered to be negligible.

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

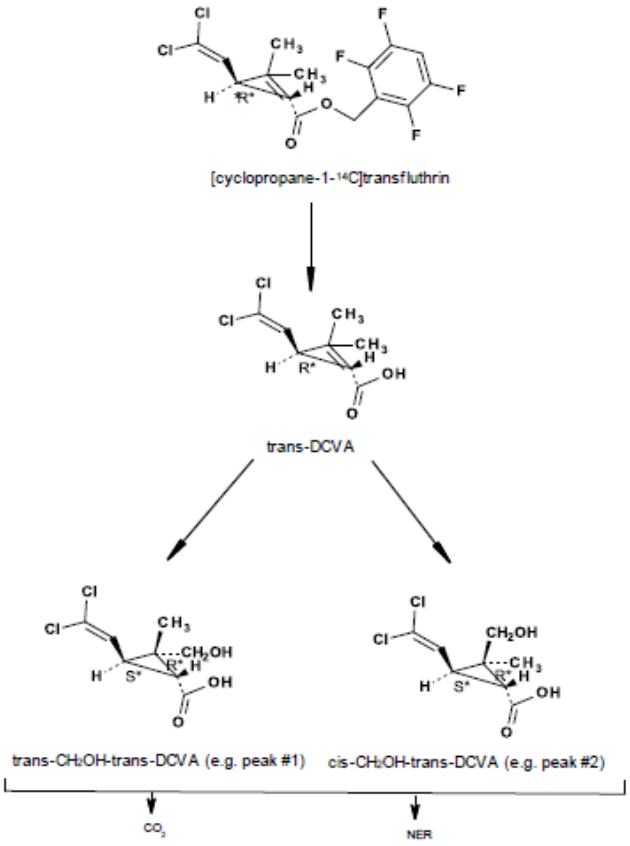
After finalization of Assessment Report for transfluthrin (2014) the applicant provided additional data, including new studies on aerobic degradation of transfluthrin in soil and on biodegradation in active sewage sludge. These studies have been evaluated by eCA NL and agreed at WGIII-2018 and by the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

Biodegradation in active sewage sludge
Aerobic degradation of transfluthrin in sewage sludge was investigated in sludge from a sewage treatment plant (Monheim, Germany) that mainly receives domestic waste water. The test was performed according to OECD 314 B. Transfluthrin underwent both primary and ultimate biodegradation over the course of the 8-day study. Mass balance of the biotic sludge system ranged from 96.8 to 99.5 of the applied radioactivity (% AR). Ultimate

biodegradation (conversion to CO2) occurred at 21.3% AR. Three degradation products were identified with the following maximum occurrences:

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

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



Trans-DCVA may be regarded as transient and trans-OH-DCVA (also named trans-CH_2OH-trans-DCVA) degrades rapidly as well. Cis-OH-DCVA (also named cis-CH_2OH-trans-DCVA) is however persistent in sewage sludge. TFB-OH (also named NAK 4452) and TFB-COOH (also named NAK 4723) must be regarded as persistent with a formation fraction of one as one mole transfluthrin produces one mole of these metabolites, as these metabolites were not addressed in the study. The DT_{50} values and formation fractions are summarised below.

Degradation of transfluthrin in activated sludge

Substance	Matrix	Method	Condition	Duration [d]	DT_{50} [d]	Formation fraction	Model	Reference
transfluthrin	Acticated sludge		146 µg/L	8	0.284	-	FOMC	[redacted]

Substance	Matrix	Method	Condition	Duration [d]	DT_{50} [d]	Formation fraction	Model	Reference
trans-DCVA		OECD 314B	21.7±0.8°C		0.897	0.968	SFO	
cis-OH-DCVA[1]					>10000	0.619	SFO	
trans-OH-DCVA[2]					0.341	0.267	SFO	
TFB-OH[3]					>10000	1	-	
TFB-COOH[4]					>10000	1	-	

[1] also named trans-CH_2OH-trans-DCVA
[2] also named cis-CH_2OH-trans-DCVA
[3] Also called NAK 4452
[4] Also called NAK 4723

Biodegradation in soil
Degradation of transfluthrin was studied in four different German soils under laboratory aerobic conditions in the dark at 20±2°C according to OECD 307. The test substance was radiolabeled at the methyl-group of the tetrafluorophenyl-moiety of the molecule.
The applied concentration (45 µg/kg soil dry weight) due to analytical reasons multiple times higher than the estimated concentration in soil resulting from the intended biocidal uses. The test was performed in static systems consisting of Erlenmeyer flasks each containing 50 g soil (dry weight equivalents) and equipped with traps (permeable for oxygen) for the collection of carbon dioxide and volatile organic compounds. Duplicate samples were processed and analysed 0, 0.25, 1, 2, 3, 7 and 14 days after treatment (DAT).

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

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

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

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

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

	Model	χ2	$DT_{50\text{-modelling}}$ (20°C)	$DT_{50\text{-modelling}}$ (12°C)	ff
Laacher Hof (LH)					
Parent	FOMC	3.98	1.93	3.66	
NAK 4723[1]	SFO	13.8	1.93	3.66	0.6231
Whole model		7.68			
Dollendorf II (DD)					
Parent	FOMC	4.38	1.29	2.45	
NAK 4723[1]	SFO	10.5	1.79	3.40	0.6130
Whole model		7.17			
Höfchen					
Parent	DFOP	0.87	18.3	34.71	
NAK 4723[1]	SFO	10.1	1.6	3.03	0.7512
Whole model		6.03			
Wurmwiese (WW)					
Parent	FOMC	6.46	1.28	2.4	
NAK 4723[1]	SFO	16.1	1.53	2.9	0.4886
Whole model		10.0			
DT50 for PEC (geometric mean)			Parent: 2.76 NAK 4723: 1.71	Parent: 5.17 NAK 4723: 3.23	
f. f. for PEC (arithmetic mean)					**0.6190**

[1] Alternative name is TFB-COOH

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

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

Leaching behaviour (ADS)

Data waiving

Information requirement	-
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.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1: 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	Scenario 1: 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. Technical Agreements for Biocides Environment (ENV). Version 2.1, December 2019. European Chemicals Agency, Helsinki, Finland.
Groundwater simulation	Not relevant
Confidential Annexes	YES: In the confidential Annex 3.6 business confidential information concerning composition of the product is included

Life cycle steps assessed	Scenario 1: 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

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks (S/D/O/P)**
Scenario: Consumer use of insecticide diffuser product			
Quantity of product contained in the device/diffuser (Q_{prod})	4.62	g	S; this is the weight per full paper (which consist of two units)
Number. of diffusers per wardrobe ($N_{diffusers}$)	18	[-]	Based on efficacy data 6 full papers (12 units) are required to treat 0.5m^3. According to TAB ENV each wardrobe has a volume of 1.5m^3. Therefore, as a worst case 18 papers per wardrobe were assessed.
Number of wardrobes per household	2.5		D (TAB; ENV 150)
Fraction of active substance in product (F_{AI})	0.0027	[-]	S
Maximal duration of use of the device/diffuser (T_{max})	2160	h	S - The product is intended for continual use and provides protection for 3 months (90 days)
Duration of use per day (Tday)	24	h.d^{-1}	P (Default for Passive diffuser selected)
Fraction emitted to floor during application ($F_{application,floor}$)	0.1	[-]	D (TAB; ENV150)
Cleaning efficacy (F_{CE})	1	[-]	D (TAB; ENV150)
Fraction of total surface area which is cleaned	0.3	[-]	D (TAB; ENV 148)
Number of emission days ($T_{emission}$)	365	d	S - Transfluthrin Assessment Report (2014)[5]

[1] S= set, D = default, O = output

Calculations for consumer use of insecticide diffuser product

Application step

Emission to air

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

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

Emission to Floor

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

Active substance				
Variable/Parameter	**Symbol**	**Unit**	**Value**	**S/D/O/P[1]** Error! Bookmark not defined.
Input				
Quantity of product contained in the device/diffuser	Q_{prod}	g	4.62	S
No. of diffusers per wardrobe	$N_{diffusers}$	-	18	S
Number of wardrobes per household	$N_{dwellers}$	-	2.5	D
Fraction of active substance in product	F_{AI}	[-]	0.0027	S
Maximal duration of use of the device/diffuser	T_{max}	h	2160	S
Duration of use per day (passive)	T_{day}	$h.d^{-1}$	24	D
Fraction emitted to floor during application	$F_{application,floor}$	[-]	0.1	D
Output				
Emission to floor during the application step	$E_{application,floor}$	$kg.d^{-1}$	6.24E-07	O

[1] S= set, D = default, O = output

Substance of concern				
Variable/Parameter	**Symbol**	**Unit**	**Value**	**S/D/O/P[1]**
Input				
Quantity of product contained in the device/diffuser	Q_{prod}	g	4.62	S
No. of diffusers per wardrobe	$N_{diffusers}$	-	18	S
Number of wardrobes per household	$N_{dwellers}$	-	2.5	D
Fraction of SoC in product	F_{soc}	[-]	0.0045	S
Maximal duration of use of the device/diffuser	T_{max}	h	2160	S
Duration of use per day (passive)	T_{day}	$h.d^{-1}$	24	D
Fraction emitted to floor during application	$F_{application,floor}$	[-]	0.1	D (Default – diffusers)
Output				
Emission to floor during the application step	$E_{application,floor}$	$kg.d^{-1}$	1.04E-06	O

[1] S= set, D = default, O = output

Cleaning step

Emission to Wastewater

As stated by the Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses (OECD, 2008) emission to the environment is mainly due to residues deposited onto floor which will be wet cleaned. There is no emission during the preparation step and the device can be disposed to solid waste. It is assumed that 100% of the active ingredient is emitted from the diffuser during the lifecycle (application step) of the product. An amount of the product may diffuse within the wardrobe and each time the wardrobe is opened, a fraction of this diffused product may fall on the floor of the room. It is assumed that 30% of the floor is wet-cleaned (in line with the TAB (ENV 148)) and that cleaning efficiency of the floor is 100% (F_{CE} = 1; in line with the TAB (ENV 150)), with subsequent emission to wastewater.

Thus, the emission from floor/treated surface is calculated using equation 36 in the ESD and the following parameters:

Variable/Parameter	**Symbol**	**Unit**	**Value**	**S/D/O/P[1]**
Input				
Emission to floor during the application step	$E_{application,floor}$	$kg.d^{-1}$	6.24E-07	O
Fraction emitted to wastewater during the cleaning step (Fraction of total surface area which is wet-cleaned)	F_{ww}	-	0.3	D
Cleaning efficiency	F_{CE}	-	1	D
Output				
Emission from floor to wastewater during the cleaning step	$E_{treated,ww}$	$kg.d^{-1}$	1.87E-07	O

[1] S= set, D = default, O = output

Substance of concern				
Variable/Parameter	**Symbol**	**Unit**	**Value**	**S/D/O/P[1]**
Input				
Emission to floor during the application step	$E_{application,floor}$	$kg.d^{-1}$	1.04E-06	O
Fraction emitted to wastewater during the cleaning step ((Fraction of total surface area which is wet-cleaned)	F_{ww}	-	0.3	D
Cleaning efficiency	F_{CE}	-	1	D
Output				
Emission from floor to wastewater during the cleaning step	$E_{treated,ww}$	$kg.d^{-1}$	3.12E-07	O

[1] S= set, D = default, O = output

The calculated emission rates to wastewater, expressed in $kg.d^{-1}$, can be used further in exposure assessment as input values in Simpletreat 4.0. The OECD Emission Scenario Document (OECD, 2008) 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 in line with the TAB (ENV 150) is 0.055. The resulting estimates of emission to wastewater at the catchment scale are summarised in the following table.

Resulting local emission to relevant environmental compartments – Active substance			
Substance	**Compartment**	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Transfluthrin	STP	4.13E-05	Default $F_{simultaneity}$ is applied

Resulting local emission to relevant environmental compartments – Substance of concern			
Substance	**Compartment**	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Tetrahydrolinalyl acetate	STP	6.89E-05	Default $F_{simultaneity}$ is applied

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway							
Scenario	Fresh-water*	Freshwater sediment*	STP	Air	Soil	Ground-water	Secondary poisoning
Consumer use of insecticide vapour releasing product	Yes[+]	Yes	Yes[++]	Yes[(Q)]	Yes[+]	Yes[+]	Yes[+]

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

* Emission to the marine environment is not expected

Active substance

Input parameters (only set values) for calculating the fate and distribution in the environment*			
Input	**Value**	**Unit**	**Remarks**
Transfluthrin			
Molecular weight	371.2	g/mol	
Melting point	32	°C	
Vapour pressure (at 20 °C)	9.00E-04	Pa	
Water solubility (at 20 °C)	0.057	mg/l	
Henry's law constant (at 20 °C)	5.86	$Pa.m^3.mol^{-1}$	
Log Octanol/water partition coefficient (log Kow)	5.94	Log 10	
Organic carbon/water partition coefficient (Koc)	50119	l/kg	
Biodegradability	Not readily biodegradable		
DT_{50} for biodegradation in active sludge	0.50 0.284	d (at 15ºC) d (at 21.7ºC)	New OECD 314B study (Hellpointner & Kasel, 2017)
DT_{50} for biodegradation in aquatic compartment	1E+06	d (at 12ºC)	Default value for not readily biodegradable substances
DT_{50} for degradation in soil	5.17	d (at 12ºC)	Updated LoEP transfluthrin (2017)
DT_{50} for degradation in air	2.4	d	
Bioconcentration factor (BCF), fish	1783	L/kg	
Bioconcentration factor (BCF), earthworms	10452	L/kg	

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

(+)Compartment potentially exposed

Fate and distribution within the STP was estimated using the SimpleTreat 4.0 which implements a concentration of suspended solids in effluent value of 0.03 $kg.m^{-3}$ in accordance with the TAB, and applying the data from the new OECD 314B study.

Calculated fate and distribution in the STP: Transfluthrin	
Compartment	Distribution (%)
Air	0.2
Water	1.31
Sludge	59.9
Degraded in STP	38.6

Metabolites

Metabolites in STP and subsequent aquatic environment

As discussed in Section 2.2.8.1, an OECD 314B study on biodegradation in activated sludge of the active substance transfluthrin was conducted.
In the study, three metabolites were found; trans-DCVA, cis-OH-DCVA and trans-OH-DCVA. As also stated above in Section 2.2.8.1, the metabolites cis-OH-DCVA and trans-OH-DCVA are expected to be much less toxic than trans-DCVA. Therefore, no calculations are included here and the risk assessment for these metabolites is covered by the risk assessment for trans-DCVA. The metabolites TFB-OH and TFB-COOH (see AR transfluthrin) that are formed from the benzene moiety were not included in the Hellpointner study, because this section of the molecule was not labelled. Either of these metabolites may be formed in the STP and both were identified as environmentally relevant metabolites in water/sediment systems (please refer to Assessment Report for transfluthrin). In view of the chemical structure similarity and the comparable physico-chemical characteristics of TFB-OH and TFB-COOH (as also discussed in the Assessment Report for transfluthrin (2014)), the risk to TFB-OH is covered by the risk assessment for TFB-COOH.

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

$$Elocal_{water\_TP} = Elocal_{water\_Parent} * F_{STP\ degraded} * f_{ij} * \frac{Mass_{molar_{TP}}}{Mass_{molar_{Parent}}}$$

Symbol	Description	Unit
$Elocal_{water\_TP}$	local emission rate of transformation product	[kg d^{-1}]
$Elocal_{water\_Parent}$	local emission rate of parent substance	[kg d^{-1}]
$F_{STP,\ degraded}$	fraction of parent substance degraded in STP	[-]
f_{ij}	formation fraction of transformation product	[-]
$Mass_{molarTP}$	molecular mass of transformation product	[g mol^{-1}]
$Mass_{molarParent}$	molecular mass of parent substance	[g mol^{-1}]

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

The emission rate for the metabolites was derived from the parent's emission (41.3 mg/d) according to aforementioned equation. Concentrations were calculated by applying a volume of 2000 m^3/d. These concentrations were corrected for sorption to suspended matter in line with the BPR GD (ENV B+C; equation 48), to obtain the PECsurface water values.

Metabolites in soil

The study on degradation in soil (please refer to Section 2.2.8.1) indicates that the metabolite TFB-COOH is formed in soil. In addition, it is expected that trans-DCVA is also

formed, as also discussed in the Assessment Report for cyfluthrin (2018). The PEC values of the metabolites in soil were calculated in line with the AHEE document on 'Exposure assessment of metabolites in the terrestrial compartment' (2019), using concentration of parent in sludge as well as formation fraction and ratio of molecular weights.

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

	Input parameters (only set values) for calculating the fate and distribution of metabolites in the aquatic and soil compartment				
	Molecular weight	**Molweight ratio**	**Formation fraction STP***	**Csludge**	**Remarks**
	g/mol	g/g	mol/mol	mg/kg wwt	
Transfluthrin	371.2	-	-	4.82	
trans-DCVA	208.1	0.56	0.9678	2.61	f.f. from transfluthrin
TFB-COOH	194.08	0.52	1	2.51	f.f. from transfluthrin

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

	Input parameters for calculating the fate and distribution of metabolites in groundwater						
	Koc[1]	**Kp_{soil}**	**VP[2]**	**Sol**	**K_{soil_water}[3]**	**DT50 (12°)**	**Remarks**
	L/kg	L/kg	Pa	mg/L	-		
trans-DCVA	106	2.12	2.6	127.6	3.38	174.8	
TFB-COOH	10.71	0.214	8.45	2114	0.521	3.66	

[1] QSAR estimates from Kow method

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

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

Substances of Concern

Input parameters (only set values) for calculating the fate and distribution in the environment*			
Input	**Value**	**Unit**	**Remarks**
Tetrahydrolinalyl acetate			
Molecular weight	200.318	g/mol	
Vapour pressure (at 20 °C)	19.23	Pa	
Water solubility (at 20 °C)	1.58	mg/L	
Log Octanol/water partition coefficient	5.6	Log 10	
Organic carbon/water partition coefficient (Koc)	432.4	L/kg	Calculated with QSAR
Biodegradability	inherently biodegradable, fulfilling		

	specific criteria		
DT_{50} for degradation in soil	3000	d (at 12ºC)	Default value for inherenly biodegradable substances and estimated Kp soil of > 100, ≤ 1000 based on the log Kow of 5.6

* Parameters from REACH Registered Substances database: https://echa.europa.eu/nl/registration-dossier/-/registered-dossier/25046

Calculated fate and distribution in the STP: Tetrahydrolinalyl acetate		
Compartment	Percentage (%)	Remarks
Air	53.89	-
Water	4.24	-
Sludge	36.90	-
Degraded in STP	4.96	-

Calculated PEC values

Summary table on calculated PEC values (active substance)					
	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]
Transfluthrin	2.41E-07	2.24E-08	2.45E-05	4.47E-05	1.23E-05

	Summary table on calculated PEC values (metabolites)			
	PEC_{STP}	PEC_{water}[1]	PEC_{soil}	PEC_{GW}
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[µg/L]
trans-DCVA	n.a.	4.32E-07	2.96E-05	1.39E-02
TFB-COOH	n.a.	4.17E-07	2.34E-05	1.31E-02

n.a. not applicable
[1] No PNEC sediment is available for metabolites. Hence, the risk assessment for water also covers the risk for sediment

Summary table on calculated PEC values (Substance of concern)					
	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]
Tetrahydrolinalyl acetate	1.46E-06	1.44E-07	2.69E-05	1.30E-04	8.43E-04

Primary and secondary poisoning

Primary poisoning

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

Secondary poisoning

The log Kow of transfluthrin is 5.94 and BCF values for fish and earthworms are 1783 L/kg and 10452 L/kg, respectively. These data indicate high potential for bioacumulation and assessment of secondary poisoning is required. The metabolites TFB-OH and TFB-COOH have log Kow values below the trigger value of 3. The log Kow for the metabolite trans-DCVA is 3.376. As no additional data on toxicity are available for the metabolites and bioaccumulation potential for the parent is expected to be higher than for the metabolites, the risk assessment for transflutrin also covers the risks for the metabolites. The SoC has log Kow of 5.04 and a Koc of 3439. Hence, bioaccumulation potential is high. However, EPIsuite demonstrates that BCF = 41.61 L/kg wwt, which indicates that bioaccumulation is low (BCF <100 L/kg). As toxicity data are lacking, no assessment can be performed.

Regarding transfluthrin, the predicted environmental concentration 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. $PEC_{oral,\ predator}$ 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.

Summary table on estimated theoretical exposition (ETE)		
	$PEC_{oral,\ predator}$ (freshwater)	**$PEC_{oral,\ predator}$ (terrestrial)**
	[mg/kg_{ww}]	**[mg/kg_{ww}]**
Transfluthrin	2.00E-05	6.00E-05

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.

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

The estimated half-life of the SoC in air is 1.9 days, which is below the trigger value of 2 days, which is used as cut-off value to identify chemicals that could be of potential concern for long range transport through the atmosphere. Although the vapour pressure (19.23 Pa) indicates a high volatility, the high Koc indicates that the substance has a tendency to bind to particles. Therefore the long-range transport in air is expected to be rather limited. Moreover, the SoC is not listed by the FOCUS air groups as causing ozone depletion and considering the relative small total amounts used and the volume of the atmospheric compartment, possible abiotic effects of the SoC on the atmosphere are expected to be negligible.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values (Active substance)	
	PEC/PNEC$_{STP}$
Transfluthrin	<0.001

Summary table on calculated PEC/PNEC values (SoC)	
	PEC/PNEC$_{STP}$
Tetrahydrolinalyl acetate	<0.001

Conclusion: The assessments for active substance and SoC result in PEC/PNEC values < 1. Therefore the proposed use of the product Moth Active Paper is expected to result in an acceptable risk to microorganisms in the STP.

Aquatic compartment

Summary table on calculated PEC/PNEC values (Active Substance)		
	PEC/ PNEC$_{water}$	**PEC/ PNEC$_{sed}$**
Transfluthrin	0.013	0.068

Summary table on calculated PEC/PNEC values (Metabolites)	
	PEC/ PNEC$_{water}$[1]
trans-DCVA	<0.001
TFB-COOH	<0.001

[1] Risk assessment for the metabolites also covers the risk for sediment

Summary table on calculated PEC/PNEC values (SoC)		
	PEC/ PNEC$_{water}$	**PEC/ PNEC$_{sed}$**
Tetrahydrolinalyl acetate	< 0.001	0.009

Conclusion: The assessments for active substance, metabolites and SoC result in PEC/PNEC values < 1 for the water compartment and sediment compartment.

As a result it can be concluded that use of the product will not result in unacceptable risk to the aquatic compartment.

Exposure of the marine environment is not considered to be a route of exposure.

Terrestrial compartment

Summary table on calculated PEC/PNEC values (Active substance)	
	$PEC/PNEC_{Soil}$
Transfluthrin	0.001

Summary table on calculated PEC/PNEC values (Metabolites)	
	$PEC/PNEC_{Soil}$
trans-DCVA	0.002
TFB-COOH	0.002

Summary table on calculated PEC/PNEC values (SoC)	
	$PEC/PNEC_{Soil}$
Tetrahydrolinalyl acetate	0.065

Conclusion: Conclusion: In all cases, PEC/PNEC values are < 1 for the active substance, metabolites and SoC. As a result, it can be concluded that the risk to the terrestrial compartment of use of the product is acceptable.

Groundwater

As shown in Section 2.2.8.2, all predicted concentrations in groundwater are below the threshold of 0.1 µg/L for active substance, metabolites and SoC. Hence, no further calculations are required and the risk for groundwater is acceptable.

Primary and secondary poisoning

Primary poisoning

Not relevant for this product.

Secondary poisoning

Summary table on secondary poisoning		
Scenario	**Food chain**	**$PEC/PNEC_{mammals}$**
Transfluthrin	Aquatic	<0.001
	Terrestrial	<0.001

Conclusion: Using the concentration in fish and worms and the $PNEC_{oral,mammal}$ of 6.67 mg/kg_{ww} feed, the $PEC/PNEC_{oral,mammal}$ is < 1 and the risk is acceptable.

For transfluthrin only acute toxicity data are available (LD50 > 1890 mg/kg bw). In the absence of short-term or long-term toxicity data for birds, a $PEC/PNEC_{oral,bird}$ cannot be derived for transfluthrin. However, for the $PNEC_{oral,bird}$ to fall below the even the maximum predicted $PEC_{oral\ predator}$ (2.00-05 mg/kg_{ww} for fish and 1.20E-04 mg/kg_{ww} for earthworms), the NOEC should be lower than the $PEC_{oral,bird}$ x 30, and should thus be < 6.0E-04 mg/kg_{ww} feed in case of fish and < 3.6E-03 mg/kg_{ww} feed in case of earthworms. In view of the absence of acute toxicity to birds at doses up to 1890 mg/kg bw, it is not expected that chronic toxicity levels as low as estimated above will be reached. In view of this, a risk of secondary poisoning of birds is not expected. This approach is in line with the argumentation presented in the transfluthrin Assessment Report (Transfluthrin Assessment Report, 2014).

As discussed previously, the risk for the metabolites is covered by the risk assessment for the parent. For the SoC, no assessment is performed, as data are lacking.

Mixture toxicity

Screening step

Screening Step 1: Identification of the concerned environmental compartments

The conceptual emission pathway to the environment is *via* deposition onto floors and subsequent release to wastewater following washing (wet cleaning). The use of the biocidal product is expected to lead to breakdown of the formula as the ingredients are volatilized.

Screening Step 2: Identification of relevant substances

The product contains an active substance and a SoC. In the environment metabolites may be performed. For the mixture toxicity, all these substances should be considered.

Screening Step 3: Screen on synergistic interactions
No data with indication of synergistic effects are available for any of the identified SoCs.

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

Tier 1 Mixture Toxicity Assessment: PEC/PNEC summation

Substance	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sediment}$**	**PEC/PNEC$_{soil}$**
Transfluthrin	0.013	0.068	0.001
Metabolites	0.002	-	0.004
Tetrahydrolinalyl acetate	< 0.001	0.009	0.065
SUM PEC/PNEC	0.016	0.077	0.070

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

Aggregated exposure

The application is for one intended use. Hence, aggregated exposure is not relevant.

Overall conclusion on the risk assessment for the environment of the product
The environmental risk assessment for Moth Active Paper was performed according to the 'Diffuser' Scenario provided in the Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional users (OECD, 2008). Emission calculations were conducted assuming a default number of emission sources ($F_{simultaneity}$ = 5.52%).

Environmental fate was calculated incorporating new data on the degradation of transfluthrin in STP. PNEC values used in the assessment took account of recently generated data.

A quantitative risk assessment was also carried out on the relevant metabolites of transfluthrin as well as one substance of concern contained in the product. In all cases, calculated PEC/PNEC values for the active substance, relevant metabolites and SoC were <1, indicating that no unacceptable risk to the environment is expected from the use of the product.

A mixture assessment was carried out on the product for the active substance, metabolites and SoC and the product passed a Tier 1 mixture risk assessment indicating that no unacceptable risk is posed by the intended use of the product.

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

Do not store near food, drink and animal feedingstuffNo decomposition if stored and applied as directed. The product has a predicted shelf-life of 4 (four) years.

Recommended methods and precautions concerning handling and transport

Avoid contact with skin and eyes.Smoking, eating and drinking should be prohibited in the application area.Wear personal protective equipment.Normal measures for preventive fire protection.
Land transport. UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S (transfluthrin), 9, III. Limited quantities derogation may be applicable to this product, please check transport documents.Product not transported as bulk.
Sea transport. UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S (transfluthrin), 9, III. Limited quantities derogation may be applicable to this product, please check transport documents.Product not transported as bulk.
Air transport. UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S (transfluthrin), 9, III. Limited quantities derogation may be applicable to this product, please check transport documents.Product not transported as bulk.

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

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.Further informationCollect contaminated fire extinguishing water separately. This must not be discharged into drains.Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Particulars of likely direct or indirect adverse effects

No adverse effects expected when used as directed.

First aid instructions, antidotes

Inhalation: No special requirements: Skin contact: Wash off with soap and plenty of water. Get medical attention if irritation develops and persists. Wash contaminated clothing before re-use.Eye contact: Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing. In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.Ingestion: If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label. Rinse mouth with water.

Emergency measures to protect environment in case of accident

Environmental precautions: Do not flush into surface water or sanitary sewer system.

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

No repellents or poisons are included.

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 document IIB and show that the risk to the environment is not significant.

Water, including drinking water:

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

Soil:

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

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

Possibility of reuse or recycling

Product: Please recycle empty packaging.

Possibility of neutralisation of effects

Not applicable

Conditions for controlled discharge including leachate qualities on disposal

The product should be prevented from entering drains.

Conditions for controlled incineration

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

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

Product: Disposal should be in accordance with local, state or national legislation.Please recycle empty packaging.

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

Not applicable

2.2.10 Assessment of a combination of biocidal products

Not Relevant.

2.2.11 Comparative assessment

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

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]	2005	Validation of Method MV001 – Determination of transfluthrin in cellulose mats	[redacted]	Mo2978	S.C.Johnson & Son	2005-08-24	Methods of detection and identification (5.1)_ [redacted]	Yes	Unpublished	Yes
[redacted]	2009	48 months at RT, 25°C (60% rel. humidity) and 12 months at 40°C stability study, 4 seasons S/S1 (Formula No.: 661950/001)	[redacted]	Mo 2977	S.C.Johnson & Son	2009-11-09	Storage stability tests (ambient)_ [redacted]	Yes	Unpublished	Yes
[redacted]	2006	Determination of Appearance (physical state. colour and odour} 4 seasons S/S1	[redacted]	Mo3136	S.C.Johnson & Son	2006-03-21	Appearance (at 20°C and 101.3 kPa)_ [redacted]	Yes	Unpublished	Yes
[redacted]	2015	Determination of evaporation kinetics and physico-chemical properties of Herald before and after storage for 8 weeks at 40°C	[redacted]	Mo5228	S.C.Johnson & Son	2015-08-13	Evaporation Kinetics	Yes	Unpublished	Yes
[redacted]	2006	Determination of Physico-Chemical Properties Flammability (Solids) A.10. Auto-Flammability (Solids - Determination Of Relative Self-Ignition Temperature) A.16.	[redacted]	20060078.01	S.C.Johnson & Son	2006-03-13	Flammable solids (4.7)_ [redacted]	Yes	Unpublished	Yes

Author	Year	Title	Testing laboratory	Report no.	Legal entity owner	Report date	Endpoint names	GLP	Published/ Unpublished	Data Protection Claimed
[redacted]	2006	Determination of Physico-Chemical Properties Flammability (Solids) A.10. Auto-Flammability (Solids - Determination of Relative Self-Ignition Temperature) A.16.	[redacted]	20060078.01	S.C.Johnson & Son	2006-03-13	Relative self-ignition temperature for solids (4.17.2)_ [redacted]	Yes	Unpublished	Yes
[redacted]	2019	Efficacy of RAID Active Moth Paper SKU 665943 against adults and larvae of Clothes moths, Tineola bisselliella, tested with 6 full papers in 0.5 m³ cabinets.	[redacted]	BIO114-19	S.C.Johnson & Son	2019-11-13		No	Unpublished	Yes
[redacted]	2019	Efficacy of RAID Active Moth Paper SKU 665943 against adults and larvae of Clothes moths, Tineola bisselliella, tested with 1/2 full paper in 0.018 m³ drawer.	[redacted]	BIO115-19	S.C.Johnson & Son	2019-11-13		No	Unpublished	Yes
[redacted]	2019	Efficacy of RAID Active Moth Paper SKU 665943 against adults and larvae of Clothes moths, Tineola bisselliella, tested with 1/2 full paper in glass jars.	[redacted]	BIO116-19	S.C.Johnson & Son	2019-11-13		No	Unpublished	Yes

3.2 Output tables from exposure assessment tools

ConsExpo Web - Wed Dec 18 2019

Substance		
Name	Transfluthrin	
CAS number	118712-89-3	
Molecular weight	371	g/mol
Kow	5.94	10Log
Product		
Name	Moth Paper	
Weight fraction substance	1	
Population		
Name	EU framework Biocides adult	
Body weight	60	kg

Scenario *Closet_Evaporation*

Frequency	90	per year
Description		

Inhalation

Exposure model	Exposure to vapour - Constant rate	
Exposure duration	5	minute
Product is substance in pure form	No	
Molecular weight matrix	–	
The product is used in dilution	No	
Amount of solution used	225	mg
Weight fraction substance	1	
Room volume	1.5	m^3
Ventilation rate	0.3	per hour
Inhalation rate	1.25	m^3/hr
Emission duration	90	day
Limit concentration to saturated air concentration	Yes	
Application temperature	20	°C
Vapour pressure	0.0009	Pa
Molecular weight	371	g/mol
Absorption model	n.a.	

Results for scenario *Closet_Evaporation*

Show dose descriptions

Inhalation

Mean event concentration	2.9×10^{-3}	mg/m^3
Peak concentration (TWA 15 min)	2.9×10^{-3}	mg/m^3
Mean concentration on day of exposure	10.0×10^{-6}	mg/m^3
Year average concentration	2.5×10^{-6}	mg/m^3
External event dose	5.0×10^{-6}	mg/kg bw
External dose on day of exposure	5.0×10^{-6}	mg/kg bw

QSAR estimates and PNEC calculation for metabolites and SoC

DCVA
ECOSAR

Input for SMILES:
Transfluthrin: Fc1c(F)cc(F)c(F)c1C(=O)(O)
DCVA: OC(=O)C2C(C)(C)C2C=C(Cl)Cl

ECOSAR Version 1.11 Results

SMILES : OC(=O)C2C(C)(C)C2C=C(CL)CL
CHEM :
CAS Num:
ChemID1:
MOL FOR: C8 H10 CL2 O2
MOL WT : 209.07
Log Kow: 3.376 (EPISuite Kowwin v1.68 Estimate)
Log Kow: (User Entered)
Log Kow: (PhysProp DB exp value - for comparison only)
Melt Pt: (User Entered for Wat Sol estimate)
Melt Pt: (deg C, PhysProp DB exp value for Wat Sol estimate)
Wat Sol: 127.6 (mg/L, EPISuite WSKowwin v1.43 Estimate)
Wat Sol: (User Entered)
Wat Sol: (PhysProp DB exp value)

Values used to Generate ECOSAR Profile

Log Kow: 3.376 (EPISuite Kowwin v1.68 Estimate)
Wat Sol: 127.6 (mg/L, EPISuite WSKowwin v1.43 Estimate)

ECOSAR v1.11 Class-specific Estimations

Vinyl/Allyl Halides-acid

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
Vinyl/Allyl Halides-acid	Fish	96-hr	LC50	22.759
Vinyl/Allyl Halides-acid	Daphnid	48-hr	LC50	20.210
Vinyl/Allyl Halides-acid	Green Algae	96-hr	EC50	43.351
Vinyl/Allyl Halides-acid	Fish		ChV	3.841
Vinyl/Allyl Halides-acid	Daphnid		ChV	0.717
Vinyl/Allyl Halides-acid	Green Algae		ChV	17.660 !
Vinyl/Allyl Halides-acid	Fish (SW)	96-hr	LC50	12.220
Vinyl/Allyl Halides-acid	Mysid (SW)	96-hr	LC50	6.600
Vinyl/Allyl Halides-acid	Earthworm	14-day	LC50	2134.007 *

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

```
============================ ================== ========
======  ==========
Neutral Organic SAR       : Fish            96-hr     LC50       9.973
(Baseline Toxicity)       : Daphnid         48-hr     LC50       6.430
                    : Green Algae       96-hr     EC50       8.101
                    : Fish                ChV        1.133
                    : Daphnid               ChV        0.893
                    : Green Algae             ChV        2.815

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

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

Baseline Toxicity SAR Limitations:
---------------------------------
Maximum LogKow: 5.0 (Fish 96-hr LC50; Daphnid LC50)
```

KOCWIN v2.00 Results

```
SMILES : OC(=O)C2C(C)(C)C2C=C(Cl)Cl
CHEM   :
MOL FOR: C8 H10 CL2 O2
            Koc may be sensitive to pH!

  Koc Estimate from MCI:
  --------------------
       First Order Molecular Connectivity Index ..... :  5.370
       Non-Corrected Log Koc (0.5213 MCI + 0.60) ..... :  3.3991
       Fragment Correction(s):
             *   Organic Acid  (-CO-OH) ..............  : -1.6249
       Corrected Log Koc ..................................... :  1.7743

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

  Koc Estimate from Log Kow:
  ------------------------
       Log Kow  (Kowwin estimate) ........................... :  3.38
       Non-Corrected Log Koc (0.55313 logKow + 0.9251)  .... :  2.7947
       Fragment Correction(s):
             *   Organic Acid  (-CO-OH) ..............  : -0.7694
       Corrected Log Koc ..................................... :  2.0253

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

PNEC Results:
Fish 96 hr LC50 of 9.97 mg/L
Daphnia 48 hr LC50 of 6.420 mg/L
Green algae EC50 of 8.101 mg/L

Based on the AF of 1000, the resulting $PNEC_{aquatic}$ for DCVA is **0.0064** mg/L.

To determine the $PNEC_{soil}$, the following parameters were included for equilibrium partitioning:
Water solubility of 127.6 mg/L (QSAR, presented above)
Vapour pressure of 2.60 Pa (at 25 degC, QSAR, MbBp results, not shown here)
log Koc of 2.025 (at 25 degC, QSAR, presented above)
Resulting from this, in combination with the $PNEC_{aquatic,}$ the $PNEC_{soil}$ was calculated to be **0.0128** mg/kg ww.

Cis/trans-CH2OH-trans-DCVA
SMILES : CC1(C(C1C(=O)O)C=C(CL)CL)CO
CHEM :
CAS Num:
ChemID1:
MOL FOR: C8 H10 CL2 O3
MOL WT : 225.07
Log Kow: 1.911 (EPISuite Kowwin v1.68 Estimate)
Log Kow: (User Entered)
Log Kow: (PhysProp DB exp value - for comparison only)
Melt Pt: (User Entered for Wat Sol estimate)
Melt Pt: (deg C, PhysProp DB exp value for Wat Sol estimate)
Wat Sol: 6059 (mg/L, EPISuite WSKowwin v1.43 Estimate)
Wat Sol: (User Entered)
Wat Sol: (PhysProp DB exp value)

Values used to Generate ECOSAR Profile

Log Kow: 1.911 (EPISuite Kowwin v1.68 Estimate)
Wat Sol: 6059 (mg/L, EPISuite WSKowwin v1.43 Estimate)

ECOSAR v1.11 Class-specific Estimations

Vinyl/Allyl Halides-acid

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
Vinyl/Allyl Halides-acid				

--> 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)

3.3 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] (2014a). Transfluthrin a.s. (BCS-AW53131): Sublethal toxicity to the earthworm *Eisenia fetida* in artificial soil [redacted], unpublished report

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

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

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

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

3.4 Residue behaviour

Not relevant

3.5 Summaries of the efficacy studies[6]

Please refer to IUCLID Section 6.7 and the efficacy data table in section 2.2.5.5

6 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

3.6 Confidential annex

See separate document.

3.7 References

Api *et al*., (2008). Dermal Sensitisation Quantitative Risk Assessment (QRA) for fragrance ingredients. Reg. Tox. & Pharm.;52: 3-23.

Basketter *et al*., (2015). Skin sensitisation to fragrance ingredients: is there a role for household cleaning/maintenance products? Eur J Dermatol;25(1): 7-13.

Basketter DA *et al*., (2010). Methyldibromo-glutaronitrile, skin sensitisation and quantitative risk assessment. Cut Ocul Toxicol;29: 4-9.

Basketter *et al*., (2008). Preservatives and Skin Sensitisation Quantitative Risk Assessment. Dermatitis;19: 20-7.

Corea *et al*., (2006). Fragrance allergy: assessing the risk from washed fabrics. Contact Dermatitis;55: 48–53.

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

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

ECETOC (2015) European Centre for Ecotoxicology and Toxicology of Chemicals. Targeted Risk Assessment Tool TRA v3.1 http://www.ecetoc.org/tra (See Defaults tab in Consumer tool for the Thickness Layer for printed papers).

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

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

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

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

Felter *et al*., (2002). A review of the scientific basis for default uncertainty factors for use in quantitative risk assessment of the induction of allergic contact dermatitis. Contact Derm;47: 257-66.

HEEG (Human Exposure Expert Group) opinion (2013). Default human factor values for use in exposure assessments for biocidal products. Endorsed at TM II 2013, EUROPEAN COMMISSION JOINT RESEARCH CENTRE.

Kimber *et al*., (2008). Dose metrics in the acquisition of skin sensitization: Thresholds and importance of dose per unit area. Regulatory Toxicology and Pharmacology;52: 39–45.

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.

RIFM, (2015), Local Lymph Node Assay with 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetreamethyl-2-naphthalenyl)ethanone. OTNE. J.M. Chapdelaine. Unpublished data. Taken from the Research Institute for Fragrance Materials (RIFM) database (http://www.rifm.org/rifm-science-database.php#.Ve3FZt_bKpp), accessed on 27/07/2015

RIVM, (2006). RIVM Pest Control Products Fact Sheets. RIVM Report 320005002/2006.

Struijs J. (2014) SimpleTreat 4.0: a model to predict fate and emission of chemicals in wastewater treatment plants Background report describing the equations. RIVM report 601353005/2014. National Institute for Public Health and the Environment, Bilthoven The Netherlands.

TFL-PAI-Version 9 (2015) Relevant endpoints and PNEC derivation Environment & Ecotoxicity
Substance: Transfluthrin, completed on:2015-10-11

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