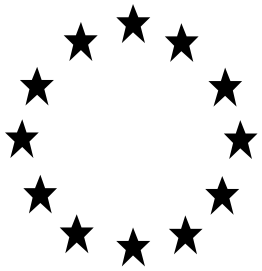
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



recozit Mottenpapier

Product type(s) 18

Transfluthrin

Case Number in R4BP: [BC-VS020288-11]
Asset number in R4BP: [CH-0013883-0000]
IUCLID Dossier UUID: [IUC5-575e0567-2ea4-41b2-9278-0c4b478d9e70]

Evaluating Competent Authority: Switzerland

Date: June 2021

Overview of applications

Table 1 - Overview regarding all applications that lead to modifications in the PAR.

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment)
NA-MIC	CH	BC-HA056040-73		Minor change (Amendment of storage stability)
NA-ADC	CH	BC-PB042041-67	09/10/2018	Administrative change (addition of trade name)

Changes of the original PAR (Date: April 2020) are highlighted in yellow (points 2.2.2, 2.2.5.8 and 3.8).

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1 CONCLUSION

Based on the evaluation in this report, in accordance with the Regulation (EU) 528/2012, it is concluded that "recozit Mottenpapier" with the active substance transfluthrin (12.95% w/w in the slurry formulation, i.e. the biocidal product without paper carrier according to CA-Nov16-Doc.4.3 – Final – Carrier based products) is sufficiently effective against the common clothes moth (*Tineola bisselliella*). It has no unacceptable effects on human health and the environment, provided the product is used according the provisions of this authorization. Therefore, the Swiss CA proposes the authorization of the biocidal product "recozit Mottenpapier" as an insecticide against the common clothes moth (*Tineola bisselliella*).

The carrier-based biocidal product "recozit Mottenpapier" is a ready-to-use moth paper. The slurry formulation, i.e. the biocidal product without paper carrier, contains the active substance transfluthrin at a concentration of 12.95% (w/w). Rosin (CAS 8050-09-7) has been identified as a substance of concern. For detailed information on the composition please refer to confidential Annex 3.8.

The product is classified according to Regulation (EC) No 1272/2008 as "Skin Irrit. 2", "Skin sens. 1", and "Aquatic Acute 1" and "Aquatic Chronic 1". Detailed information on classification and labelling is provided in chapter 2.1.3.

The authorized uses include the use in wardrobes/closets as well as in drawers and chests. Dosage is 1 strip (150 mm x 825mm) for 1 m^3 wardrobe/closet. The authorized uses are summarized in chapter 2.1.4.

The general directions for use of the product are summarized in chapter 2.1.5. In particular the product has to be replaced every four months, if treatment is still necessary. Time to produce the effect is ≤ 3 weeks for larvae and ≤ 1 week for adult common clothes moth.

Physical, chemical and technical properties
Physical, chemical and technical properties are summarized in chapter 2.2.2. In particular, the stability of the product was shown in an accelerated storage stability study, with an ambient temperature stability study currently ongoing.

Physical hazards and respective characteristics
Physical hazards and respective characteristics are given in chapter 2.2.3. The biocidal product does not possess any explosive, flammable or oxidizing properties, and does not require classification for self-heating or self-reactivity.

Methods for detection and identification
A GC-FID method is available for the determination of the active substance in the biocidal product and was validated according to the EU guidance with respect to linearity, precision (repeatability), accuracy, and specificity.
The methods described in the CAR of the active substance can be used for the determination of the active substance in soil, water and air. Methods are not required for monitoring residues in animal and human body fluids and tissues or food and feeding stuff of plant or animal origin.

Efficacy against target organisms
The product proved to be sufficiently effective (≥ 90% of mortality) against both adult and larvae stages of the common clothes moth (*Tineola bisselliella)* for up to four months (with a time to effect from start of treatment of ≤ 1 week for adult moths and ≤ 3 weeks for larvae).

The following labelling instructions are required:
Replace once every four months, for as long as necessary.
Time to produce the effect (mortality ≥ 90%) after start of treatment:
Common clothes moth (adults): ≤ 1 week
Common clothes moth (larvae): ≤ 3 weeks

Risk assessment for human health
No studies were submitted and for all human health endpoints, classification of the "recozit Mottenpapier" was addressed using available data on the individual components of the slurry formulation, i.e. the biocidal product without paper carrier. According to this data, the product "recozit Mottenpapier" is classified for human health hazard as skin irrit.2 and skin sens.1.
Human health risk assessment has been carried out for non-professional use according to the intended uses. For details on exposure assessment please refer to chapter 2.2.6.2 and Annex 3.3.
According to the performed risk assessment it is unlikely that the intended uses may lead to an unacceptable risk for the non-professional user (primary exposure) as well as bystanders (secondary exposure including infants as worst case). Furthermore, local effects resulting from possible skin sensitisation and skin irritation were qualitatively assessed and considered to be sufficiently controlled.

Risk assessment for the environment
In view of the proposed uses, significant exposure of the environment via air is not expected. Under the refined exposure scenario, no unacceptable risk from transfluthrin or its major metabolites was identified for the STP, surface water organisms and sediment dwelling organisms (PEC/PNEC <1). A small risk (PEC/PNEC = 1.15) was found for transfluthrin in soil. This risk coefficient, however, is expected to fall well below 1 when considering degradation in the soil compartment. Such an assumption is justified by indicative results from a dissipation study in soil (which is not yet formally validated to be used in risk assessment) and from degradation in sediment. In countries, where the use of effluent sludge as an agricultural fertilizer is prohibited (such as in Switzerland) the emission pathway from sludge to agricultural soil and groundwater is not relevant. Furthermore, no unacceptable risk to soil organisms was identified from the major metabolites of transfluthrin, and no unacceptable risk to groundwater was identified from transfluthrin nor from its major metabolites (PEC/PNEC <1). Primary poisoning is considered as not relevant, and secondary poisoning is not expected. More details are given in chapter 2.2.8.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	**Country (if relevant)**
recozit Mottenpapier	Switzerland, Austria, Germany

Note: "recozit Moth paper" is an alternative name for the product trade name. "Mottenpapier" and "Moth paper" are used interchangeably throughout the dossier for "recozit Mottenpapier". "Mottenpapier" is the German translation for "Moth paper".

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Reckhaus AG
	Address	Strahlholz 13 CH-9056 Gais Switzerland
Authorisation number	CH—2018-ZL-0001	
Date of the authorisation	14.08.2018	
Expiry date of the authorisation	13.08.2028	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Reckhaus GmbH & Co KG
Address of manufacturer	Industriestr. 53 33689 Bielefeld Germany
Location of manufacturing sites	Same as above

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

Active substance	Transfluthrin
Name of manufacturer	Bayer CropScience
Address of manufacturer	Alfred-Nobel-Straße 50 40789 Monheim am Rhein Germany
Location of manufacturing sites	Same as above

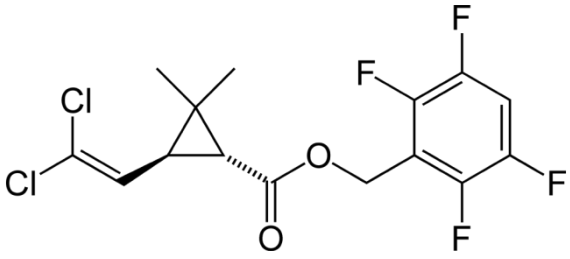
2.1.2 Product composition and formulation

NB: the full composition of the product according to Annex III Title 1 is provided in the confidential Annex 3.8.

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 trans-2-(2,2-dichlorovinyl)-3,3-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% min
Structural formula	

* The EC no. refers 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

Not applicable.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Transfluthrin	2,3,5,6-tetrafluorobenzyl trans-2-(2,2-dichlorovinyl)-3,3-dimethylcyclopropane-carboxylate	Active substance	118712-89-3	405-060-5	12.95*
Co-formulants					87.05**

* Percentage in the slurry formulation, i.e. the biocidal product without paper carrier. Refer to the confidential Annex 3.8 for details on the composition.
** Refer to the confidential Annex 3.8 for details on the co-formulants.

2.1.2.4 Information on technical equivalence

The active substance contained in the product is from the same source as the active substance listed in the Union list of approved active substances under Regulation No. 528/2012. The Applicant sources the active substance from the sole notifier for transfluthrin.

2.1.2.5 Information on the substance(s) of concern

Rosin (CAS 8050-09-7) [redacted] is a substance of concern. For more details please refer to the confidential annex 3.8 and the safety data sheet.

2.1.2.6 Type of formulation

VP Vapour releasing product

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Skin irrit.2 Skin sens.1 Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H315: Causes skin irritation H317: May cause an allergic skin reaction H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	Warning
Hazard statements	H315: Causes skin irritation H317: May cause an allergic skin reaction* H410: Very toxic to aquatic life with long lasting effects
Precautionary state-ments	P102: Keep out of reach of children P264: Wash hands thoroughly after handling P302 + P352: IF ON SKIN: Wash with plenty of water. P333 + P313: If skin irritation or a rash occurs: Get medical advice/attention. P273: Avoid release to the environment P501: Dispose of contents/container in accordance with national regulation. Contact your local council for details.
Pictogram	 GHS09  GHS07

P statement P391: 'collect spillage' was triggered by the classification, however it has been removed as it is considered redundant for this type of product.
P statement P261: "Avoid breathing dust/fume/gas/mist/vapours/spray" was triggered by H317 classification. It has been removed as the component (Rosin) that triggers H317 classification is bound within the product and is not released during the product's intended use in any physical state (dust/fume/gas/mist/vapours/spray).
P statement P280: "Wear protective gloves/protective clothing/eye protection/face protection" was triggered by both H317 and H315 classification. It has been removed, as product design allows handling of the product with no contact to treated areas (see corresponding risk mitigation measures). Please see also the local risk assessment for skin sensitization and skin irritation.
* The substances rosin and cobalt carboxylate are both classified as H317 Skin sensitization category 1. According to their concentration in the biocidal product (slurry formulation), they must be indicated on the product label.

2.1.4 Authorized use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Use in wardrobes/closets

Product Type	Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Indoor insecticide for general public (non-professional use). For the protection of fabrics in wardrobes/closets. The product protects woollens, clothes and fur coats.
Target organism (including development stage)	*Tineola bisselliella*: Common clothes moth Adults and larvae
Field of use	Indoor
Application method(s)	Open system: Diffusion
Application rate(s) and frequency	12.95% w/w (in the slurry formulation, i.e. the biocidal product without paper carrier), 0.03374 g Transfluthrin/strip (96.5% purity) 1 strip (150 mm x 825 mm) per m^3 (10 pieces of paper per strip) Replace once every four months, for as long as necessary
Category(ies) of users	General public (non-professional use)
Pack sizes and packaging material	Two strips (each 150 mm x 825 mm) are supplied in a plastic packet (95 mm x 205 mm x 2 mm = 38.95 cm^3). The plastic packaging is a multilayer foil. Secondary packaging: 22 packages in a carton. Size 210 mm x 97 mm x 105 mm

An overview of the paper and packaging dimensions is given in Annex 3.7

Table 2. Use # 2 – Use in other clothes storage compartments (drawers, chests, suitcases, and clothes bags)

Product Type	Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Indoor insecticide for general public (non-professional use). For the protection of fabrics in clothes storage compartments such as drawers, suitcases, chests, clothes bags. The product protects woollens, clothes and fur coats.
Target organism (including development stage)	*Tineola bisselliella*: Common clothes moth Adults and larvae
Field of use	Indoor
Application method(s)	Open system: Diffusion
Application rate(s) and frequency	12.95% w/w (in the slurry formulation, i.e. the biocidal product without paper carrier), 0.03374 g Transfluthrin/strip (96.5% purity) Use 1 piece of paper (150 mm x 82.5 mm) per drawer, chest, clothes bag or suitcase (placing paper inside). Replace once every four months, for as long as necessary.

Category(ies) of users	General public (non-professional use)
Pack sizes and packaging material	Two strips (each 150 mm x 825 mm, 10 pieces of paper per strip) are supplied in a plastic packet (95 mm x 205 mm x 2 mm = 38.95 cm^3). The plastic packaging is a multilayer foil. Secondary packaging: 22 packages in a carton. Size 210 mm x 97 mm x 105 mm

An overview of the paper and packaging dimensions is given in Annex 3.7

2.1.4.2 Use-specific instructions for use

Use # 1 – Use in wardrobes/closets

Use 1 strip (150 mm x 825 mm) per m^3.
Ensure that the unfolded strip of "recozit Mottenpapier" is placed in a way in the wardrobe/closet that the active substance can spread between all the clothes (place above clothes rail/hanger or stick on back board).

Use # 2 – Use in other clothes storage compartments (drawers, chests, suitcases, and clothes bags)

Use 1 piece of paper (150 x 82.5 mm) per drawer, chest, clothes bag or suitcase (placing paper inside).

2.1.4.3 Use-specific risk mitigation measures

Use only as directed.
Use only in positions inaccessible to children and animals.
When placing the paper, only touch the edges and untreated parts of paper so contact with the treated areas is avoided.
Do not eat or drink when handling the product.
To prevent contamination of food, do not use in kitchens or other food storage or preparation areas.
Avoid contact with skin and eyes.
Do not allow product to get into surface water, drains and ground water.

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

Likely direct or indirect effects:
No adverse effects expected when used as directed.

First aid instructions:
Refer to 2.1.5.3

Emergency measures to protect the environment:
Refer to 2.1.5.3

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

Refer to 2.1.5.4

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

Refer to 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

Replace once every four months, for as long as necessary. Treated wardrobes, drawers, chests, and other clothes storage compartments should be kept closed as much as possible so that vapour levels are maintained to provide maximum effectiveness.

2.1.5.2 Risk mitigation measures

Refer to 2.1.4.3

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

Likely direct or indirect effects: Very toxic to aquatic life with long lasting effects. First aid instructions: Following skin contact: After contact with skin, wash immediately with soap and plenty of water. Seek medical attention if irritation occurs. Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice. After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Seek medical attention if problems persist. After swallowing: Rinse mouth immediately and drink plenty of water. Seek medical treatment if symptoms persist. Treat symptomatically. Emergency measures to protect the environment: Environmental precautions: Do not allow to penetrate into soil, waterbodies or drains. If necessary notify appropriate authorities. Methods and material for containment and cleaning up: Take up mechanically, placing in appropriate containers for disposal. Final cleaning.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of contents/container in accordance with national regulation. Contact your local council for details.

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

Requirements for storerooms and containers: Keep container tightly closed and dry. Keep in a cool place. Protect from light and heat. Keep away from food, drink and animal feeding stuffs. Keep out of reach of children.

Product is expected to be stable under normal conditions for 4 years.

2.1.6 Other information

Efficacy: Time to produce the effect (mortality ≥ 90%) after start of treatment: Clothes moth (adults): ≤ 1 week Clothes moth (larvae): ≤ 3 weeks Application codes: Not applicable

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)
Plastic packet in a multilayer foil	95 mm x 205 mm x 2 mm; 38.95 cm^3	Plastic	Plastic wrapper	Non-professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Please refer to the reference list in Annex 3.1 for a list of studies submitted on the product in support of this application. In addition, a reference list is included in Annex 3.2 for new data generated on the active substance since the assessment report for transfluthrin was issued, and for which the Applicant has submitted a letter of access. These new studies, however, cannot be taken into consideration by the eCA as part of the risk assessment until they are reviewed and approved by the Biocidal Product Committee and its working groups. They will be cited here for purposes of information.

2.1.8.2 Access to documentation

The Applicant has submitted a letter of access to the data available on the active substance, transfluthrin dated 6th October 2015. The letter of access outlines the data that the competent authority Switzerland has access to.

2.2 Assessment of the biocidal product

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

Table 1. Intended use # 1 – Use in wardrobes/closets

Product Type	Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Indoor insecticide for general public (non-professional use). For the protection of fabrics in wardrobes/closets. The product protects woollens, clothes and fur coats.
Target organism (including development stage)	*Tineola bisselliella*: Common clothes moth Adults and larvae
Field of use	Indoor
Application method(s)	Open system: Diffusion
Application rate(s) and frequency	12.95% w/w (in the slurry formulation, i.e. the biocidal product without paper carrier), 0.03374 g Transfluthrin/strip (96.5% purity) 1 strip (150 mm x 825 mm) per m^3 (10 pieces of paper per strip)

	Replace once every four months, for as long as necessary
Category(ies) of users	General public (non-professional use)
Pack sizes and packaging material	Two strips (each 150 mm x 825 mm, 10 pieces of paper per strip) are supplied in a plastic packet (95 mm x 205 mm x 2 mm = 38.95 cm^3). The plastic packaging is a multilayer foil. Secondary packaging: 22 packages in a carton. Size 210 mm x 97 mm x 105 mm

An overview of the paper and packaging dimensions is given in Annex 3.7

Table 2. Intended use # 2 – Use in other clothes storage compartments (drawers, suitcases, chests, and cloth bags)

Product Type	Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Indoor insecticide for general public (non-professional use). For the protection of fabrics in clothes storage compartments such as drawers, suitcases, chests, clothes bags. The product protects woollens, clothes and fur coats.
Target organism (including development stage)	*Tineola bisselliella*: Common cloth moth Adults and larvae
Field of use	Indoor
Application method(s)	Open system: Diffusion
Application rate(s) and frequency	12.95% w/w (in the slurry formulation, i.e. the biocidal product without paper carrier), 0.03374 g Transfluthrin/strip (96.5% purity) Use 1 piece of paper (150 x 82.5 mm) per drawer, chest, clothes bag or suitcase (placing paper inside). Replace once every four months, for as long as necessary.
Category(ies) of users	General public (non-professional use)
Pack sizes and packaging material	Two strips (each 150 mm x 825 mm, 10 pieces of paper per strip of paper) are supplied in a plastic packet (95 mm x 205 mm x 2 mm = 38.95 cm^3). The plastic packaging is a multilayer foil. Secondary packaging: 22 packages in a carton. Size 210 mm x 97 mm x 105 mm

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Content of active substance in biocidal product (% w/w, with and without paper carrier, see footnotes 1 and 2, respectively)	Results	Reference IUCLID section
Physical state at 20 °C and 101.3 kPa[1]	Visual	0.233	Solid	Anon, 2015 (3.1-01)
Physical state at 35°C[2]	ADR-guideline 94/55/EG, appendix A part 2.3.4 and TRbF 003	12.95	Liquid	Ahrens, 2017a (3.1-01)
Colour at 20 °C and 101.3 kPa[1]	Visual	0.233	White/yellow	Anon, 2015 (3.1-01)
Odour at 20 °C and 101.3 kPa[1]	Visual	0.233	Paper-like odour.	Anon, 2015 (3.1-01)
Acidity / alkalinity[1]	CIPAC MT 75.3	0.233	pH 9.6	Anon, 2015 (3.2)
Relative density / bulk density[1]	EU A.3	0.233	1.279 g/cm^3	Anon, 2015 (3.3)
Storage stability test – **Evaporation study**[1]	-	0.233	[redacted]	Manka, S. 2016 (3.4.1-01)
Storage stability test – **accelerated storage**[1]	-	-	[redacted]	Manka, S, 2016 (3.4.1.1-01)

1 Biocidal product as it is supplied to the user, i.e. including the paper carrier. Note that, according to CA Document CA-Nov16-Doc.4.3, the biocidal product is a "Type A" product, and stability tests as well as tests required for the exposure assessment should be carried out with the product as it is supplied to the user.

2 Biocidal product without paper carrier (slurry formulation). Note that, according to CA Document CA-Nov16-Doc.4.3, the biocidal product is a "Type A" biocidal product, and for classification and labelling the carrier is not included as part of the biocidal product composition.

Property	Guideline and Method	Content of active substance in biocidal product (% w/w, with and without paper carrier, see footnotes 1 and 2, respectively)	Results	Reference IUCLID section
Storage stability test – **long term storage at ambient temperature**[1]	CIPAC MT75.3	-	[redacted]	Manka, S, 2019; BioGenius GmbH, study no. Mo5336

Property	Guideline and Method	Content of active substance in biocidal product (% w/w, with and without paper carrier, see footnotes 1 and 2, respectively)	Results	Reference IUCLID section
			[redacted]	

Property	Guideline and Method	Content of active substance in biocidal product (% w/w, with and without paper carrier, see footnotes 1 and 2, respectively)	Results	Reference IUCLID section
			[redacted]	
Storage stability test – **low temperature stability test for liquids**[1]	WAIVER: A low temperature stability study is not required since the biocidal product as it is supplied to the user (i.e. impregnated on a paper carrier) is not a liquid. In addition, the product usage states store at room temperature, therefore, it should not be stored at temperatures less than 20 °C.			
Effects on content of the active substance and technical characteristics of the biocidal product - **light**[1]	WAIVER: The biocidal product as it is supplied to the user is packaged, folded, and wrapped in a film. In addition, in use the product is placed in wardrobes/closets and other clothes storage compartments with no exposure to light.			
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**[1]	-	-	[redacted]	Manka, S, 2019; BioGenius GmbH, study no. Mo5336
Effects on content of the active substance and technical char-	-	-	[redacted]	Manka, S, 2019; BioGenius GmbH,

Property	Guideline and Method	Content of active substance in biocidal product (% w/w, with and without paper carrier, see footnotes 1 and 2, respectively)	Results	Reference IUCLID section
acteristics of the biocidal product - **reactivity towards container material**[1]			[redacted]	study no. Mo5336
Wettability[1]	WAIVER: the biocidal product as it is supplied to the user is a solid preparation which is not designed to be dispersed in water.			
Suspensibility, spontaneity and dispersion stability[1]				
Wet sieve analysis and dry sieve test[1]				
Emulsifiability, re-emulsifiability and emulsion stability[1]				
Disintegration time[1]				
Particle size distribution, content of dust/fines, attrition, friability[1]	WAIVER: the biocidal product as it is supplied to the user is neither a powder nor a granulate and no exposure to aerosols, fine particles or droplets is to be expected.			
Persistent foaming[1]	WAIVER: the biocidal product as it is supplied to the user is a solid preparation which is not designed to be applied in water for use.			
Flowability/Pourability/Dustability[1]	WAIVER: Not required since the biocidal product as it is supplied to the user is not a granular formulation, suspension concentrate, capsule suspension, suspoemulsion or powder.			
Burning rate — smoke generators[1]	WAIVER: Not applicable since the biocidal product as it is supplied to the user is not intended for use with smoke generators.			
Burning completeness — smoke generators[1]				
Composition of smoke — smoke generators[1]				

Property	Guideline and Method	Content of active substance in biocidal product (% w/w, with and without paper carrier, see footnotes 1 and 2, respectively)	Results	Reference IUCLID section
Spraying pattern — aerosols[1]	WAIVER: Not applicable since the biocidal product as it is supplied to the user is not an aerosol.			
Physical compatibility[1]	WAIVER: The biocidal product, „recozit Mottenpapier, as it is supplied to the user is not intended to be used in conjunction with other biocidal products.			
Chemical compatibility[1]				
Degree of dissolution and dilution stability[1]	WAIVER: Not applicable since the biocidal product as it is supplied to the user is not intended for dissolving.			
Surface tension[1]	WAIVER: The biocidal product as it is supplied to the user is not designed to be dispersed in water so testing is not required.			
Viscosity[1]	WAIVER: The biocidal product as it is supplied to the user is a solid preparation			
Other studies: Evaporation kinetics over 24 weeks[1]	-	-	[redacted]	Manka, S, 2016

Conclusion on the physical, chemical and technical properties of the product
The biocidal product as it is supplied to the user is a white/yellow paper with a paper-like odour. The density of the biocidal product is 1.279 g/cm^3. An accelerated storage stability study showed no appreciable changes in the appearance (physical state, colour, and odour), packaging stability, pH value and density of the test item following storage for 8 weeks at 40 °C. An ambient temperature stability study provided results up to 48 months. After 36 months, the biocidal product is stable under the conditions of the test. After 48 months, the transfluthrin content in the paper falls to 88% of its initial value due to migration to the packaging material. This decrease in active substance content is slightly higher than the 10%-limit stipulated in point 3.4.2 of the Guidance on the BPR Volume I. Nevertheless, given that migration to the packaging material does not affect the risk assessment and that the product efficacy remains acceptable with a transfluthrin content of 88% (see chapter 2.2.5.8 of this PAR), the biocidal product is considered to be stable after 48 months under the conditions of the test.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% w/w, with and without paper carrier, see footnotes 1 and 2, respectively)	Results	Reference
Explosives[2]	EU Method A14	N/A	Not explosive	Albaya and Curl, 2015a[3] (4.1-01)
Flammable gases[2]	WAIVER: Not applicable since the biocidal product without paper carrier (i.e. the slurry formulation) is not a gas.			
Flammable aerosols[2]	WAIVER: Not applicable since the biocidal product without paper carrier (i.e. the slurry formulation)is not an aerosol			
Oxidising gases[2]	WAIVER: Not applicable since the biocidal product without paper carrier (i.e. the slurry formulation) is not a gas.			
Gases under pressure[2]				
Flammable liquids[2]	EU Method A9	12.95	Flash point of 108°C, non-flammable liquid.	Ahrens, 2017b (4.6-01)
Flammable solids[2]	WAIVER: The biocidal product without paper carrier (i.e. the slurry formulation)) is not a solid.			
Self-reactive substances and mixtures[2]	United Nations Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria. (UN RTDG, MTC)	N/A	Following theoretical assessment, the biocidal product does not require classification as a self-reactive material.	Albaya and Curl, 2015b (4.8-01)[3]
Pyrophoric liquids[2]	WAIVER: None of the components of the biocidal product without paper carrier (i.e. the slurry formulation) are classified as a physical hazard under CLP regulation EC No 1272/2008.			
Pyrophoric solids[2]	WAIVER: The biocidal product without paper carrier (i.e. the slurry formulation)) is not a solid.			
Self-heating substances and mixtures[2]	WAIVER: The biocidal product without paper carrier (i.e. the slurry formulation)) is a liquid, for which the test for self-heating is technically not feasible, according to the Guidance on the Application of the CLP Criteria - Version 5.0 – July 2017, p. 181.			
Substances and mixtures which in contact with water emit flammable gases[2]	WAIVER: The biocidal product without paper carrier (i.e. the slurry formulation) is not designed to have contact with water, or to emit flammable gases if placed in contact with water.			

[3] The study (theoretical expert statement) has been carried out based on the biocidal product as it is supplied to the user. Nevertheless, the conclusions of this study are considered valid also for the biocidal product without paper carrier (i.e. the slurry formulation).

Property	Guideline and Method	Purity of the test substance (% w/w, with and without paper carrier, see footnotes 1 and 2, respectively)	Results	Reference
Oxidizing liquids[2]	EU A.17	N/A	No oxidizing properties.	Albaya and Curl, 2015d (4.14-01)[3]
Oxidizing solids[2]	WAIVER: Not applicable. The biocidal product without paper carrier (i.e. the slurry formulation) is not a solid.			
Organic peroxides[2]	WAIVER: In accordance with Section 2.15 of the CLP regulation EC No 1272/2008, the biocidal product without paper carrier (i.e. the slurry formulation) does not contain any components which contain the bivalent -O-O- structure and may be considered to be derivatives of hydrogen peroxide. A study on the biocidal product without paper carrier (i.e. the slurry formulation) is therefore considered unjustified as by theoretical assessment it can be stated that the product is not a peroxide.			
Corrosive to metals[2]	Theoretical assessment	N/A	Not considered corrosive to metals.	Albaya and Curl, 2015e (4.16-01)[3]
Auto-ignition temperatures of products (liquids and gases)[2]	WAIVER: A test has been submitted on the biocidal product as it is supplied to the user (including the paper carrier), using EU Method A.16 (see below). The fact that no self-ignition temperature was observed up to a maximum test temperature of 404°C indicates that the product contains no components with low auto-ignition points. Further, the biocidal product without paper carrier (i.e. the slurry formulation) is classified as non-flammable by determination of its flash point. Therefore, auto-ignition of the slurry is considered irrelevant at normal usage conditions.			
Relative self-ignition temperature for solids[1]	EU Method A.16	0.233	No self-ignition temperature was observed up to a maximum test temperature of 404 °C.	Ahrens, 2015 (14.17.2-01)
Dust explosion hazard[2]	WAIVER: The biocidal product without paper carrier (i.e. the slurry formulation) is not a dust, powder or granular material.			

Conclusion on the physical hazards and respective characteristics of the product
The biocidal product without paper carrier (i.e. the slurry formulation) does not possess any explosive, flammable or oxidizing properties. From theoretical assessment, it does not require classification for self-heating or self-reactivity.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance	GC-FID	Fortification Level: 70-130% (n=3 per level)	Range 0.04318-0.1152 mg/mL r>0.99	There was no interference from other substances at a level of 3% or greater in the control samples.	99.2-101.4	100	0.7	N/A	Manka, S, 2015 (5.1-01)

Analytical methods for monitoring									
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		
Not required. The methods or information available in the Assessment Report for the active substance can be used since the nature of the formulations will not affect methods to detect the active substance in the relevant matrices.									

Analytical methods for soil									
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		
Not required. The methods or information available in the Assessment Report for the active substance can be used since the nature of the formulations will not affect methods to detect the active substance in soil.									

Analytical methods for air									
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		
Not required. The methods or information available in the Assessment Report for the active substance can be used since the nature of the formulations will not affect methods to detect the active substance in air.									

Analytical methods for water									
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		
Not required. The methods or information available in the Assessment Report for the active substance can be used since the nature of the formulations will not affect methods to detect the active substance in water.									

Analytical methods for animal and human body fluids and tissues									
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		
Not required. The information available in the Assessment Report for the active substance states that methods to detect the active substance and residues for animal and human body fluids and tissues are not required.									

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
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		
Not required. The information available in the Assessment Report for the active substance states that methods to detect the active substance and residues in food and feeding stuffs are not required. Under normal conditions of use for this product, direct contact with food or feedstuffs of plant or animal origin will not occur.									

Conclusion on the methods for detection and identification of the product
A GC-FID method is available for the determination of the active substance in the biocidal product and was successfully validated according to the EU guidance with respect to linearity, precision (repeatability), accuracy, and specificity. The methods described in the CAR of the active substance can be used for the determination of the active substance in soil, water and air since the nature of the formulations will not affect methods to detect the active substance in these matrices. Methods are not required for monitoring residues in animal and human body fluids and tissues or food and feeding stuff of plant or animal origin.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

The product contains transfluthrin and is intended for use as an insecticide by non-professional users.

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

The product is a paper impregnated with transfluthrin used for the protection of fabrics in wardrobes/closets and other clothes storage compartments (chests, suitcase, drawers, and clothes bags). The product protects woollens, clothes and fur coats. The target organisms are the larvae and adults of the common clothes moth (*Tineola bisselliella*).

2.2.5.3 Effects on target organisms, including unacceptable suffering

The product is an insecticide that acts on contact or through ingestion and results in paralysis and death of the target organism.

2.2.5.4 Mode of action, including time delay

The product contains transfluthrin which belongs to the pyrethroid insecticides. This class of insecticides are sodium channel modulators that are fast acting on contact or ingestion resulting in paralysis and death of the target organism. In this respect there is no time delay for the onset of effects.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
The product is an insecticide	The envisaged field of use is the protection of fabrics in wardrobes/closets, and other clothes storage compartments (such as drawers, chests, suitcases, and clothes bags)	Transfluthrin impregnated paper (0.233g/100g paper)	Adults and larvae of the common clothes moth, *Tineola bisselliella*	Simulated Use Test: Organisms were exposed to a space of volume 0.5 m^3 into which the test product had been placed.	[redacted]	[redacted]	Gundalai, 2015 (6.7-01)

Conclusion on the efficacy of the product
The available data have shown that the product effectively reduces populations of both adult and larvae stages of the common clothes moth *Tineola bisselliella*, with an effect of greater than 90% being recorded for both stages of development. The product protects the space for up to and including 4 months (time to a mortality of ≥ 90% from start of treatment was ≤ 1 week for adults and ≤ 3 weeks for larvae). Mortality of larvae at the 6 months' time point was lower than 90% so that the efficacy claim for 6 months was not accepted, although the mortality of adults after 6 months was still 100%.

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2.2.5.6 Occurrence of resistance and resistance management

According to the Assessment Report (13 March 2014) approving the active substance, there are no known resistance issues with the target organism (*Tineola bisselliella*).
The approval Regulation 407/2014 for transfluthrin includes no specific conditions relating to resistance or resistance management for product authorization and further information are therefore not considered necessary.

2.2.5.7 Known limitations

No known limitations have been found – neither in the active substance Assessment Report nor in the product specific efficacy studies.

2.2.5.8 Evaluation of the label claims

The Swiss competent authority assessed that the product "recozit Mottenpapier" has shown sufficient efficacy for the following uses:

1) Use in wardrobes/closets: indoor insecticide for general public (non-professional use). For the protection of fabrics in wardrobes/closets.
   Application rate: 1 strip (150 mm x 825 mm) per m^3 (10 pieces of paper per strip)

2) Use in other clothes storage compartments (drawers, suitcases, chests, and cloth bags): indoor insecticide for general public (non-professional use). For the protection of fabrics in clothes storage compartments such as drawers, suitcases, chests, clothes bags.
   Application rate: 1 piece of paper (150 x 82.5 mm) per drawer, chest, clothes bag or suitcase.

The product protects woollens, clothes and fur coats against the following organisms:
Tineola bisselliella: Common clothes moth: Adults and larvae

The product has shown to be efficient for up to 4 month. The time to a sufficient efficacy from start of treatment is ≤ 1 week for adults and ≤ 3 weeks for larvae.

The product was subjected to a simulated use test[4] (6.7-01 described in 2.2.5.5) against development stages (adults and larvae) of the target organism *Tineola bisselliella*. *T. bisselliella* (the common clothes moth) is a known causative organism of damage to natural fibre fabrics. The simulated use trial made use of a cabinet of 0.5 m^3 volume. This was chosen as representative of the spaces envisaged to be protected by the product – wardrobes/closets and other clothes storage compartments such as chests, suitcases, and clothes bags. The product demonstrated rapid control of adult moths and acceptable control of larvae. In both cases control was greater than 90% mortality within an acceptable time period (time to effect from start of treatment was ≤ 1 week for adult moths and ≤ 3 weeks for larvae). This effect was observed throughout the trial including the 4 months' time point. At the 6 months' time point, the efficacy was below

[4] The submission of either a simulated-use test or a field trial is prerequisite for the authorization of insecticides against textile-attacking insects (see EU document „Transitional Guidance on Efficacy Assessment for Product Type 18, Insecticide, Acaricides & other Biocidal Products against Arthropods and Product Type 19, Repellents & Attractants"). The submitted test was accepted as simulated-use test, even though the element of simulating clothes in the wardrobe/closets was not properly represented. Since there is no guidance available for the efficacy assessment of moth papers, and in the CAR details of the test protocol are not completely disclosed, the eCA has accepted the test to prove efficacy of the product.

90% for larvae so that the claim for 6 month efficacy was not accepted, although the mortality of adults after 6 months was still 100%.

In the simulated use test, efficacy was achieved including daily opening of the closet doors (10 seconds). However, as efficacy is likely to be reduced in treated areas when doors/drawers are opened very often or remain open for long periods of time, the instructions for use should state that treated wardrobes/closets and drawers should be kept closed as much as possible so that active substance vapour levels are maintained and result in given effectiveness.

Active substance content after 4 years of storage decreased to 88% of the original content. Efficacy of the aged product was not tested, however, based on the given evaporation and efficacy data and extrapolation between fresh and aged product, the eCA concludes that efficacy of the aged product will be comparable to the fresh product. The extrapolation of the volatility data to the efficacy data from the fresh product to the aged is based on the following reasoning:

First, the evaporation test and the efficacy test were conducted under very similar conditions: the volume of the cabinets were the same and both were opened for 10 sec per day in both studies to simulate the use of the cabinets. The only difference in the set up were the two rather small strips of cloth which were present in the efficacy study, but not in the evaporation study. Second, evaporation data was generated after 2, 4, and 6 month and efficacy data was generated after day 0, week 1, and after 2, 4 and 6 month. Thus, the study set ups are sufficiently similar to deduce from the evaporation test of the fresh product, how much active substance was still remaining in the product in the efficacy test of the fresh product at time points 2, 4 and 6 month. Further, from the evaporation data it can be concluded that the evaporation rate of the aged product will not significantly differ from the fresh product, as it is shown that the evaporation rate is constant also with decreasing a.s. content in the product up to 24 weeks (please see evaporation rate graph in Annex 3.8). An 88% a.s. concentration corresponds approximately to 4.7 weeks of use according to the evaporation study. As the evaporation rate will be constant for the following 16 weeks (constant rate until week 24), it can be assumed that the evaporation rate of the aged product will also be constant during the claimed residual efficacy of 16 weeks. In consequence, the same and sufficient amount of a.s./time will evaporate and deposit on surfaces (such as walls and clothes). While the product's efficacy was not above the required 90% mark for larvae after 6 months, it still reached 87%. Given the constant evaporation rate, one could therefore add the 4.7 weeks of extrapolated evaporation time to the guideline compliant 4 month time point. At 4 months, for larvae, the product is 100% efficacious and at 6 months 87%. Therefore, the eCA expects the efficacy to be above 90% after the theoretical 4 months + 4.7 weeks.

Thus, the above stated label claims remain unchanged.

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

Not applicable

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on human health

According to the BPR guidance, no testing on the product is necessary if valid data on each of the components in the mixture is available and considered sufficient to allow classification of the mixture. Therefore, for all human health endpoints, classification of the "recozit Mottenpapier" is addressed using available data on the individual components of the biocidal product[5] .No synergistic effects between any of the components are expected.

2.2.6.1.1 Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Irritating to the skin
Justification for the value/conclusion	Transfluthrin is a skin irritant and is classified as H315 skin irritant Category 2 according to CLP Regulation (EC) No 1272/2008 and is present in the biocidal product without paper carrier (slurry formulation) at 12.95 %[6] None of the other ingredients of "recozit Mottenpapier" are classified for skin corrosion / irritation. The concentration of transfluthrin is above the generic concentration limit for the classification of the product as a skin irritant i.e. it is above 10% of the composition of the product (Table 3.2.3, Regulation (EC) No 1272/2008 of the European parliament and of the council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006). Therefore, the biocidal product "recozit Mottenpapier" meets the criteria for classification as a skin irritant according to CLP Regulation 1272/2008/EC.
Classification of the product according to CLP and DSD	The product is classified as H315, skin irritant category 2.

2.2.6.1.2 Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating
Justification for the value/conclusion	None of the components of "recozit Mottenpapier" are classified as irritating to the eyes according to CLP Regulation (EC) No 1272/2008. Therefore, "recozit Mottenpapier" does not meet the

[5] Biocidal product without paper carrier (slurry formulation). Note that, according to CA Document CA-Nov16-Doc.4.3, the biocidal product is a "Type A" biocidal product, and for classification and labelling the carrier is not included as part of the biocidal product composition.

[6] For information on the composition of the slurry, please refer to confidential Annex 3.8.1 and the corresponding safety data sheet.

	criteria for classification as an eye irritant according to CLP Regulation 1272/2008/EC.
Classification of the product according to CLP and DSD	Not classified

2.2.6.1.3 Respiratory tract irritation

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating.
Justification for the value/conclusion	None of the components of "recozit Mottenpapier" are classified as irritating to the respiratory tract according to CLP Regulation (EC) No 1272/2008. Therefore, "recozit Mottenpapier" does not meet the criteria for classification as a respiratory irritant according to CLP Regulation 1272/2008/EC.
Classification of the product according to CLP and DSD	Not classified

2.2.6.1.4 Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Skin sensitizing.
Justification for the value/conclusion	"recozit Mottenpapier" contains two components which are classified for skin sensitization according to CLP Regulation 1272/2008/EC: Cobalt carboxylate ([redacted]) and rosin ([redacted]) are both classified as: H317 Skin sensitization Category 1. Of the two components, rosin exceeds the generic concentration for the classification of the biocidal product as a skin sensitizer i.e. the content of rosin is above 1% of the composition of the biocidal product without paper carrier (slurry formulation)[7] (Table 3.4.5, Regulation (EC) No 1272/2008 of the European parliament and of the council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006). Therefore, "recozit Mottenpapier" does meet the criteria for classification as a skin sensitizer according to CLP Regulation 1272/2008/EC. According to CLP Regulation 1272/2008/EC the label on the packaging of mixtures classified as sensitising containing other substance(s) classified as sensitising (in addition to the one that leads to the classification of the mixture) and present in a concentration

[7] For information on the composition of the slurry formulation, please refer to confidential Annex 3.8.1.

	equal to or greater than that specified in Table 3.4.6 of Annex I shall bear the name(s) of that/those substance(s) on the label. As cobalt carboxylate is present in the biocidal product without paper carrier (slurry formulation) at a concentration greater than specified in Table 3.4.6 of Annex I (0.1%), cobalt carboxylate must also be on the product label.
Classification of the product according to CLP and DSD	The product is classified as H317, skin sensitizer category 1.

2.2.6.1.5 Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitization	
Value/conclusion	Not sensitizing.
Justification for the value/conclusion	None of the components of "recozit Mottenpapier" are classified for respiratory sensitization according to CLP Regulation (EC) No 1272/2008. Therefore, "recozit Mottenpapier" does not meet the criteria for classification as a respiratory sensitizer according to CLP Regulation 1272/2008/EC.
Classification of the product according to CLP and DSD	Not classified.

2.2.6.1.6 Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value/conclusion	Not acutely toxic by the oral route.
Justification for the selected value	"recozit Mottenpapier" contains one component which is classified for acute oral toxicity according to CLP Regulation 1272/2998/EC: Cobalt carboxylate ([redacted]) is classified as: H302 Acute oral toxicity Category 4. Cobalt carboxylate does not exceed the generic concentration limit for the classification of the biocidal product for acute oral toxicity i.e. it is below 1% of the composition of the biocidal product without paper carrier (slurry formulation)[8] (Table 1.1, Regulation (EC) No 1272/2008 of the European parliament and of the council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006)). None of the other ingredients are classified for oral acute toxicity. Therefore, "recozit Mottenpapier" does not meet the criteria for classification for acute oral toxicity according to CLP Regulation 1272/2008/EC.

[8] For information on the composition of the slurry formulation, please refer to confidential Annex 3.8.1.

Classification of the product according to CLP and DSD	Not classified.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not acutely toxic by the inhalation route.
Justification for the selected value	None of the components of "recozit Mottenpapier" are classified for acute inhalation toxicity. Therefore, "recozit Mottenpapier" does not meet the criteria for classification for acute dermal toxicity according to CLP Regulation 1272/2008/EC.
Classification of the product according to CLP and DSD	Not classified.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acutely toxic by the dermal route.
Justification for the selected value	None of the components of "recozit Mottenpapier" are classified for acute dermal toxicity. "recozit Mottenpapier" does not therefore meet the criteria for classification for acute dermal toxicity according to CLP Regulation 1272/2008/EC.
Classification of the product according to CLP and DSD	Not classified.

2.2.6.1.7 Information on dermal absorption

No data for dermal absorption of transfluthrin are available as no dermal absorption study of the active substance was performed (refer to EU Assessment Report for Transfluthrin PT18, March 2014). In the assessment report, the RMS (the Netherlands) considered for transfluthrin a value of 10% dermal absorption. The default value of 10% was defined based on transfluthrin having a MW of 375 g/mol and a log P_{ow} of 5.4 (thus being close to the MW criterion and beyond the P_{ow} criterion for setting the 10% default value) and based on a comparison to other pyrethroids. Dermal absorption in comparison with other pyrethroids are summarized and reported within the active substance dossier submitted for Annex I inclusion. Refer to Document IIA, Section 3.1. In the assessment report, the reference products were evaluated with a dermal absorption value of 10%, but the RMS indicated that dermal absorption should be re-evaluated at product authorization.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Transfluthrin
Value(s)	10%
Justification for the selected value(s)	The dermal absorption of transfluthrin is assumed to be 10%, on the basis of a MW of 371 g/mol and log Pow of 5.4, and data from other pyrethroids in other formulations (according to EU Assessment Report for Transfluthrin PT18, March 2014). This default value is considered to be conservative and was used in the Assessment Report of transfluthrin for all the representative products. As "recozit Mottenpapier" has a similar formulation type as the moth paper reference product in the assessment report of transfluthrin, it is considered a reasonable approach to use the same dermal absorption value.

Data waiving	
Information requirement	IUCLID Section 8.6
Justification	Data waiving: The biocidal product, "recozit Mottenpapier", is a product containing a paper carrier. "recozit Mottenpapier" contains transfluthrin in the slurry at a concentration of 12.95%. The concentration of transfluthrin on the treated area of the paper carrier is 0.335%. According to the EU Assessment Report for Transfluthrin PT18 (March 2014) the dermal absorption of transfluthrin is considered to be 10% on the basis of a molecular weight of 371 g/mol and a log Pow of 5.4, and data from other pyrethroids in other formulations. Since "recozit Mottenpapier" is a paper-based biocidal product in which the active substance and other components are bound within the composition of the paper, dermal contact giving rise to significant dermal absorption is unlikely. „recozit Mottenpapier" is considered to have a similar formulation type (paper-based product with impregnated active substance) as the moth paper reference product in the assessment report for which a dermal absorption of 10% was assumed.

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

The product "recozit Mottenpapier" contains rosin (CAS 8050-09-7, EC 232-475-7), a substance of concern (SoC). According to CLP Regulation (EC) No. 1272/2008, rosin is classified as "Skin Sensitizer Category 1" with the hazard statement H317: May cause an allergic skin reaction.
For the composition, please refer to the confidential Annex 3.8 and the corresponding safety data sheet.

2.2.6.1.9 Available toxicological data relating to a mixture

"recozit Mottenpapier" meets the criteria to be classified as skin irritant and skin sensitizer. However, no toxicological data related to a mixture have been submitted.

2.2.6.1.10 Other

Food and feeding stuffs
The biocidal product "recozit Mottenpapier" is not intended for use in direct contact with food or feeding stuffs. The product is a paper-based insecticide which will be used by consumers in indoor living spaces and in furniture. Under normal conditions of use, direct contact with food or feedstuffs will not occur and, therefore, residue studies are not required. As an additional measure the sentence "Keep away from food, drink and animal feeding stuffs." was added to the general directions of use (conditions of storage).

Effects of industrial processing and / or domestic preparation
The biocidal product, "recozit Mottenpapier", is not intended for use in direct contact with food or feeding stuffs. The product is a paper-based insecticide which will be used by consumers in indoor living spaces and in furniture. The effects of industrial processing or domestic preparation are not relevant as the product is ready-to-use. Therefore, under normal conditions of use, direct contact with food or feedstuffs will not occur and studies to investigate the effects of processing are not required.

Other tests related to exposure to humans

The toxicity of the active substance, transfluthrin, has been characterized in a comprehensive set of studies and the substance has been approved for use in biocidal products according to PT 18 (insecticides). The biocidal product "recozit Mottenpapier" is classified as H317 and H315according to Directive 1999/45/EEC or Regulation (EC) No. 1272/2008. However, the likelihood of exposure to its components is low since these are bound in the composition of the paper. Exposure under normal foreseeable conditions of use is predicted to be negligible. There are no concerns relating to the proposed use of the product and no additional studies are required.

2.2.6.2 Exposure assessment

According to the document CA-Nov16-Doc.4.3 – Final – Carrier based products exposure assessment should be carried out with the product as it is supplied to the user. "recozit Mottenpapier" (containing the active substance Transfluthrin at a concentration of 0.335% w/w (biocidal product including the treated part of the paper carrier) is an evaporating insecticide product. It is a ready-to-use household insecticide product that is designed to be used by non-professionals (e.g. consumers) who may obtain the product from a retailer. It can be used for the control of the common clothes moth (*Tineola bisselliella*, larvae and adults). The product is intended to protect fabrics in wardrobes/closets and other clothes storage compartments (such as chests, suitcases, drawers and clothes bags). The product is composed primarily of paper to which the active substance and two other non-active ingredients have been added.

In line with the TNsG on Human Exposure to Biocidal Products (2007), an exposure assessment for human health has been carried out on "recozit Mottenpapier" containing transfluthrin based on a tiered approach. In the first instance, for each exposure scenario, a Tier 1 assessment reflecting worst-case assumptions (e.g. task duration) has been carried out. If the risk to human health following exposure to transfluthrin is considered to be acceptable following comparison of the predicted systemic dose with the appropriate NOAEL/NOAEC from animal studies, then no further refinement of the exposure scenario will be carried out. If an unacceptable risk is identified for a particular exposure scenario, then a further refinement of the exposure/risk assessment will be carried out using additional parameters.
For risk assessment purposes, a dermal absorption value of 10% has been used. According to the Competent Authority Assessment Report for Transfluthrin (March 2014), the dermal absorption of transfluthrin is considered to be 10% on the basis of a molecular weight of 371.2 g/mol, a log Pow of 5.4 and data from other pyrethroids in other formulations. "recozit Mottenpapier" is a paper-based product that is very similar to the representative moth paper product in the assessment report of transfluthrin for which a dermal absorption of 10% was assumed. In line with the considerations made in the Assessment Report of transfluthrin, a dermal absorption of 10% is assumed for risk assessment purposes and is considered to be conservative for this type of product.
The primary routes of exposure to transfluthrin when using "recozit Mottenpapier" are the dermal and inhalation routes. Exposure via the oral route during normal use is not envisaged. However, the eCA considers that separate secondary scenarios such as seepage from treated wardrobe/closet into a room, wearing clothing from a treated wardrobe/closet and mouthing of clothing from a treated wardrobe/closet by toddlers and infants might be relevant during normal use. These scenarios are not part of the risk assessment since the outcome of the assessments are negligible. However, they are presented for completeness in Annex 3.3.2.

The exposure scenarios for human exposure are labelled as H1 to H2 (in order to distinguish them from the environmental exposure scenarios E1 and E2 in the relevant sections of the PAR).

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in the 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	N/A	N/A	Yes	N/A	N/A	Yes	No
Dermal	N/A	N/A	Yes	N/A	N/A	Yes	No
Oral	N/A	N/A	No	N/A	N/A	No	No

2.2.6.2.1 List of scenarios

The considered human exposure scenarios (H1 to H2) are listed in the table below:

Summary table: scenarios			
Scenario number Path of exposure	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
H1.Dermal and inhalation exposure	Mixing and loading	Primary exposure. Tearing and placing the paper in a wardrobe/closet.	Non-professionals
H2.Inhalation exposure	Application	Secondary exposure. Using a wardrobe/closet containing "recozit Mottenpapier".	Non-professionals

"recozit Mottenpapier" is a ready-to-use household insecticide product that is designed to be used by non-professionals (e.g. consumers). It can be used for the control of the common clothes moth. The product is intended to protect fabrics in wardrobes/closets, and other clothes storage compartments (such as drawers, chests, suitcases, and clothes bags). "recozit Mottenpapier" contains transfluthrin as the active substance (0.335% w/w including the treated part of the paper carrier).

To use the product, the paper should be removed from the packaging and torn to size depending on the size of the enclosed space where it will be placed (e.g. wardrobe/closet or drawer). Two strips of "recozit Mottenpapier" (each 150 mm x 825 mm) are provided in each packet and each strip can be divided into 10 pieces of paper (each 150 mm x 82.5 mm). Each strip (150 mm x 825 mm) will provide protection for 1 m^3 volume. One piece of paper (150 mm x 82.5 mm) would provide protection for a smaller area such as a drawer or clothes bag. When using the strip in a wardrobe/closet, it should be placed unfolded in a manner so that the active substance can spread between all the clothes. The "recozit Mottenpapier" (strip or individual pieces of paper) could therefore be placed above the clothes on a rail or hanger or stuck on the back board of the cupboard. If using the "recozit Mottenpapier" for a large wardrobe/closet, then multiple strips (each 150 mm x 825 mm) should be used. The product should be replaced once every four months, for as long as necessary.

During the intended use of the product, the potential for exposure to transfluthrin will occur primarily during mixing and loading activities. Since there should be no direct handling of the paper during its use, exposure during the application of the product is expected to be incidental, but has nevertheless been considered.

These uses are described in more detail in the "Non-professional exposure" section.

The eCA considers that separate secondary scenarios such as seepage from treated wardrobe/closet into a room, wearing clothing from a treated wardrobe/closet, and mouthing of clothing from a treated wardrobe/closet by toddlers and infants might be relevant during normal use. These scenarios are not part of the risk assessment since the outcome of the assessments is negligible. However, they are presented for completion in Annex 3.3.2.

2.2.6.2.2 Industrial exposure

No industrial applications have been applied for.

2.2.6.2.3 Professional exposure

No professional applications have been applied for.

2.2.6.2.4 Non-professional exposure

Scenario H1: Mixing and loading – tearing and placing the paper

Non-professionals (consumers) may be exposed to transfluthrin when removing the "recozit Mottenpapier" product from its packaging, tearing the paper to size and placing it at the required location (e.g. in a wardrobe/closet or chest of drawers). This 'mixing and loading' activity would typically take place three times a year, as the product would need replacing every four months.

Exposures in consumers have been assessed using ConsExpo 4.1 and the guidance provided in the RIVM Pest Control Products Fact Sheet and RIVM General Fact Sheet. The RIVM Pest Control Factsheet contains default data for insecticide products which involve evaporation from strips and cassettes (p.49). The active substance transfluthrin is within the slurry which is applied on a paper carrier and evaporates from the treated area of the paper during application.

According to the RIVM Pest Control Products Fact Sheet p. 53, the inhalation exposure is calculated using the 'Evaporation model', specifically for evaporation from a constant surface, compound in pure form. The surface is corrected for the weight fraction of the active substance because the model is ideal for liquids whereas paper is a solid matrix. In order to apply the model, it is assumed that only the active substance is present (the model does not take into account that the active substance is caught in a solid matrix). The evaporating surface is adapted to the percentage of active substance in the matrix (RIVM Pest Control Products Fact Sheet p. 50). Using this model will overestimate the exposure; hence this can be regarded as a conservative estimate. The weight fraction of the compound for the inhalation exposure is set to 1, as the release area is adjusted to account for the percentage of active substance in the paper (RIVM Pest Control Products Fact Sheet p. 50).

The amount of product that the consumer would be exposed to by inhalation is calculated as follows: Each pack of "recozit Mottenpapier" contains 2 strips which are each 15 cm x 82.5 cm = 1237.5 cm^2 in size each. Each strip consists of a treated and an untreated portion. The treated area of each

strip is 11 x 77.5 cm = 852.5 cm^2, which is equal to 68.9% of the total strip area. Only the treated portion of the strip will be considered in the exposure assessment. The weight of one untreated strip is 14.23 g. The weight of the portion of the strip which will be treated is determined as: 14.23 g x (68.9/100) = 9.803 g. [redacted]

The percentage of the active substance in the product, 0.335% w/w (including the treated part of the paper carrier) has been determined as follows. [redacted]. All of the active substance is applied only on the treated portion of the paper. Thus, the percentage of active substance in the treated area of the paper is: ([redacted] 0.335%. This percentage of the active substance has been used to calculate exposure.

The release area of the "recozit Mottenpapier" has been calculated according to the method described in the RIVM Pest Control Products Fact Sheet p. 51: The total treated area of the paper being handled is: 852.5 cm^2 x 2 = 1705 cm^2. This is adjusted for the percentage of active substance in the paper: 1705 x (0.335/100) = 5.71175 cm^2.

The RIVM Pest Control Products Fact Sheet p. 53 advises that the default exposure duration and application duration are both set at 10 minutes. The room volume is assumed to be the area around the consumers breathing zone at 1 m^3 and the ventilation rate is 0.6 air exchanges per hour; the default rate for a standard ventilated room (RIVM Pest Control Products Fact Sheet p53). The temperature is assumed to be 20^0C i.e. standard room temperature.

The dermal exposure is calculated using the constant rate model for direct dermal contact with the product. The contact rate is 1 mg/min and the release duration is 10 minutes as advised by RIVM Pest Control Products Fact Sheet p53. The exposed area was taken to be the area of the hands for adults, which is 0.082 m^2 according to the HEEG Opinion 17. For the dermal exposure, the above calculated weight fraction of the compound in the paper was used (0.335% w/w).
The active substance is transfluthrin, which has a molecular weight of 371.2 g/mol and a vapour pressure of 9 x 10^{-4} Pa at 20^0C. The mass transfer rate is calculated using the default Langmuir method as advised in RIVM Pest Control Products Fact Sheet p53, as 1.9 x 10^3 m/min.

To model inhalation exposure from "recozit Mottenpapier" the evaporation model, in evaporation release mode was used in ConsExpo 4.1. This is the recommended model in the RIVM Pest Control Products fact sheet for this type of product (chapter 3: Evaporation strips and cassettes). This model describes the release of a compound from the surface of a product by evaporation. Evaporation is driven by several factors: the difference in vapour pressure between the room air and the saturated vapour concentration of the compound, the surface area of the product and the mass transfer rate. The mass transfer rate is a measure of how fast the substance is removed from the product surface and depends upon the rate of diffusion of the substance through the air and the rate of air movement.

[9] An overview of the paper and package dimensions and weights is given in Annex 3.7

[10] See confidential Annex 3.8 for composition of slurry and product

As recommended in the RIVM Pest Control Products fact sheet, Langmuir's method was used to calculate the mass transfer rate. This method of determining the rate of evaporation does not include any limiting processes and assumes that the rate of diffusion is infinitely fast. This method therefore gives an overestimation of the evaporation rate and can be thought of as a worst case.

In summary Langmuir's method was used to calculate the evaporation rate in accordance with the RIVM Pest Control Products fact sheet. This will overestimate the evaporation rate and therefore the exposure. This is a worst case but the exposure was still found to be an acceptable level for human health.

Tier 1 assumes no PPE is used (consumers would not be expected to wear gloves or any other type of protective clothing or equipment when handling the paper product). Exposure is assessed for an adult with body weight 60 kg and inhalation rate 1.25 m^3/h (Biocides Human Health Exposure Methodology / HEEG opinion 17 endorsed at TM II 2013). A default inhalation absorption value of 100% was used and the dermal absorption of transfluthrin was taken as 10%.

Description of Scenario H1: Mixing and loading – tearing and placing the paper		
"recozit Mottenpapier" is designed for non-professional use, indoors. The "recozit Mottenpapier" product is removed from its packaging, the strip is then torn to individual pieces of paper and placed at the required location (such as in a wardrobe/closet or drawers). This task takes place three times a year, every four months. The duration of exposure is 10 minutes and exposure is expected to be via the dermal and inhalation routes. The concentration of active substance within the treated part of the paper has been calculated as 0.355%. A default of 100% for inhalation absorption and 10% dermal absorption was used. Exposures have been calculated in ConsExpo 4.1 using the evaporation model for inhalation and the constant rate model for dermal exposure.		
	Parameters	Value
Tier 1	Temperature	20^0C
	Molecular weight of transfluthrin	371.2 g/mol
	Vapour pressure of transfluthrin	9×10^{-4} Pa at 20^0C
	Mass transfer rate	1.9×10^3 m/min, determined by Langmuir method
	Exposure duration, application duration and release duration	10 min
	Product amount (see calculation above)	[redacted]
	Room volume	1 m^3, assumed to be breathing zone
	Ventilation rate	0.6 exchanges per hour
	Release area (see calculation above)	5.71175 cm^2
	Inhalation uptake	100%
	Area exposed dermally	0.082 m^2
	Contact rate	1 mg/min
	Dermal uptake	10%
	Bodyweight (Adult only)	60 kg
	Inhalation rate (Adult only)	1.25 m^3/h

Calculations for Scenario H1: Mixing and loading – tearing and placing the paper

Summary table: systemic exposure from inhalation in non-professionals		
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake / exposure**
Mixing and loading – tearing and placing the paper: inhalation exposure	Tier 1: no PPE	0.12 mg/m^3

Summary table: systemic exposure from dermal exposure in non-professionals					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Mixing and loading – tearing and placing the paper: dermal exposure	Tier 1: no PPE	NA	5.6 x 10^{-5} mg a.s./kg bw/day	NA	5.6 x 10^{-5} mg a.s./kg bw/day

Further information and considerations on scenario H1

Further information is not required.

Scenario H2: Application – using a wardrobe or cupboard containing "recozit Mottenpapier"

There is no direct handling of the "recozit Mottenpapier" product during the application phase. Once the product has been placed, it will not be handled again until it is replaced. Therefore, exposures in consumer users are not possible. Exposures may, however, arise in members of the public (e.g. adults and children) during the application phase, for example when they are using wardrobes/closets or drawers where the products have been placed. While these exposures are indirect and secondary, they have been considered as relevant to the application phase (in line with the default approach in the RIVM for products in a sealed space, application phase).

Exposures in consumers have been assessed using ConsExpo 4.1 and the guidance provided in the RIVM Pest Control Products Fact Sheet and RIVM General Fact Sheet, respectively. The wardrobe was used as a worst-case scenario and was based on the approach for the use of pest control products in a sealed area provided in the RIVM Pest Control Factsheet p.50, Section 3. The approach assumes exposure will occur shortly when opening a wardrobe/closet, drawer or other clothes storage compartments. As a worst-case assumption, it is assumed that the consumer will have their nose in the wardrobe/closet. The guidance indicates that there is no better approach available for this type of assessment. A wardrobe/closet would require use of a greater amount of product than smaller closed spaces, such as drawers, and other clothes storage compartments, and was considered a reasonable worst-case. It is assumed that the wardrobe/closet is opened every day to obtain

clothes, such that the exposure frequency is expected to be 365 times per year for adults (RIVM pest control products fact sheet p53), but is likely to be much less frequent for younger children.

According to the RIVM Pest Control Products Fact Sheet p. 53, the inhalation exposure is calculated using the evaporation model, specifically for evaporation from a constant surface, compound in pure form. The surface is corrected for the weight fraction of the active substance because the model is ideally for liquids whereas paper is a solid matrix. In order to apply the model, it is assumed that only the active substance is present (the model does not take into account that the active substance is caught in a solid matrix). The evaporating surface is adapted to the percentage of active substance in the matrix (RIVM Pest Control Products Fact Sheet p50). Using this model will overestimate the exposure; hence this can be regarded as a conservative estimate. The weight fraction of the compound for the inhalation exposure is set to 1, as the release area is adjusted to account for the percentage of active substance in the paper (RIVM Pest Control Products Fact Sheet p. 50).

The amount of product that the member of the public would be exposed to by inhalation is calculated as follows:
Each strip of "recozit Mottenpapier" has a treated area of 852.5 cm^2 weighing [redacted] (see calculation in mixing and loading activity). The wardrobe is assumed to be 1.5 m^3 in volume (RIVM Pest Control Products Fact sheet p. 53). Since one strip should be used for a volume of 1 m^3, therefore, 1.5 strips would be used in the wardrobe/closet: 1.5 x [redacted] product.

As discussed previously, all the active substance is in the treated portion of the paper. The percentage of active substance used in the exposure assessment is therefore 0.335% w/w.

The release area of the "recozit Mottenpapier" has been calculated according to the method described in RIVM Pest Control Products Fact Sheet p. 51:
The surface area of the treated paper in the wardrobe is 852.5 cm^2 x 1.5 = 1278.75 cm^2. This is adjusted for the percentage of active substance in the treated area: 1278.75 cm^2 x (0.335/100) = 4.284 cm^2.

The RIVM Pest Control Products Fact Sheet p. 53 advises that the default exposure duration and application duration is 5 minutes. The room volume is assumed to be the volume of the wardrobe/closet at 1.5 m^3 and the ventilation rate is 0.3 air exchanges per hour (RIVM Pest Control Products Fact Sheet p. 53). The temperature is assumed to be 20^0C as standard room temperature.

The active substance is transfluthrin which has a molecular weight of 371.2 g/mol and a vapour pressure of 9 x 10^{-4} Pa at 20^0C. The mass transfer rate is calculated using the default Langmuir method as advised in RIVM pest control products fact sheet p53, as 1.9 x 10^3 m/min.

To model inhalation exposure from "recozit Mottenpapier" the evaporation model, in evaporation release mode was used in ConsExpo 4.1. This is the recommended model in the RIVM Pest Control Products fact sheet for this type of product (chapter 3: Evaporation strips and cassettes). This model describes the release of a compound from the surface of a product by evaporation. Evaporation is driven by several factors: The difference in vapour pressure between the room air and the saturated vapour concentration of the compound, the surface area of the product and the mass transfer rate. The mass transfer rate is a measure of how fast the substance is removed from the product surface and depends upon the rate of diffusion of the substance through the air and the rate of air movement.

As recommended in the RIVM Pest Control Products fact sheet, Langmuir's method was used to calculate the mass transfer rate. This method of determining the rate of evaporation does not include any limiting processes and assumes that the rate of diffusion is infinitely fast. This method therefore gives an overestimation of the evaporation rate and can be thought of as a worst case.

In summary Langmuir's method was used to calculate the evaporation rate in accordance with the RIVM Pest Control Products fact sheet. This will overestimate the evaporation rate and therefore the exposure. This is a worst case but the exposure was still found to be an acceptable level for human health.

Exposure is assessed for the following members of the public: adult (body weight 60 kg, inhalation rate 1.25 m^3/h), child (bodyweight 23.9 kg, inhalation rate 1.32 m^3/h), toddler (body weight 10 kg, inhalation rate 1.26 m^3/h) and infants (body weight 8 kg, inhalation rate 0.84 m^3/h) which may be carried during use of the wardrobe/closet (Biocides Human Health Exposure Methodology 6 / HEEG opinion 17 endorsed at TM II 2013). The default inhalation absorption value of 100% was used. It is not expected that dermal exposure would occur during normal use of the product.

Description of Scenario H2: Application phase – using a wardrobe/closet containing "recozit Mottenpapier"		
"recozit Mottenpapier" is designed for non-professional use, indoors. There is no direct handling of the product during the application phase. Exposures will occur when people use wardrobes/closets or drawers where the product has been placed, this is expected to occur 365 times per year. Duration of exposure is 5 minutes and exposure is only expected to be via the inhalation route. The concentration of active within the treated part of the paper has been calculated at 0.335%. A default of 100% for inhalation absorption has been used. Exposures have been calculated in ConsExpo 4.1 using the evaporation model for inhalation exposure only.		
	Parameters	Value
Tier 1	Temperature	20^0C
	Molecular weight of transfluthrin	371.2 g/mol
	Vapour pressure of transfluthrin	9×10^{-4} Pa at 20^0C
	Mass transfer rate	1.9×10^3 m/min, determined by Langmuir method
	Exposure duration and application duration	5 min
	Product amount (see calculation above)	[redacted]
	Room volume	1.5 m^3, assumed size of wardrobe/closet.
	Ventilation rate	0.3 exchanges per hour
	Release area (see calculation above)	4.284 cm^2
	Inhalation uptake	100%
	Bodyweight (Adult)	60 kg
	Bodyweight (Child)	23.9 kg
	Bodyweight (Toddler)	10 kg
	Bodyweight (infant)	8 kg
	Inhalation rate (Adult)	1.25 m^3/h
	Inhalation rate (Child)	1.32 m^3/h
	Inhalation rate (Toddler)	1.26 m^3/h
	Inhalation rate (infant)	0.84 m^3/h

Calculations for Scenario: Application – using a wardrobe/closet containing "recozit Mottenpapier"

Summary table: chronic systemic exposure from inhalation, non-professional use					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Application: using a wardrobe/closet containing "recozit Mottenpapier": Adult	No PPE	1.6×10^{-4} mg a.s./kg bw/day	NA	NA	1.6×10^{-4} mg a.s./kg bw/day
Application: using a wardrobe/closet containing "recozit Mottenpapier": Child	No PPE	4.0×10^{-4} mg a.s./kg bw/day	NA	NA	4.0×10^{-4} mg a.s./kg bw/day
Application: using a wardrobe/closet containing "recozit Mottenpapier": Toddler	No PPE	9.5×10^{-4} mg a.s./kg bw/day	NA	NA	9.5×10^{-4} mg a.s./kg bw/day
Application: using a wardrobe/closet containing "recozit Mottenpapier": Infant	No PPE	7.9×10^{-4} mg a.s./kg bw/day	NA	NA	7.9×10^{-4} mg a.s./kg bw/day

Further information and considerations on scenario H2

Further information is not required.

2.2.6.2.5 Combined scenarios

Not relevant for the above described exposure scenarios. However, combined scenarios have been presented for completeness in Annex 3.3.2 for the separate secondary scenarios which the eCA considered to be potentially relevant during normal use.

2.2.6.2.6 Exposure of the general public

Indirect exposures have been assumed to be the same as for the application phase of the biocidal product. Users are considered to be members of the public, who open/close wardrobes/closets etc. where the biocidal product has been placed. Further calculations are therefore not needed.

2.2.6.2.7 Monitoring data

Not relevant.

2.2.6.2.8 Dietary exposure

Dietary exposure is not foreseen under normal use of the product.

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

Not relevant.

2.2.6.2.10 Aggregated exposure

Not relevant.

2.2.6.2.11 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 / exposure**
H1a.	Non-professionals, inhalation exposure	Tier 1, no PPE	0.12 mg/m^3
H1b.	Non-professionals, dermal exposure	Tier 1, no PPE	5.6 x 10^{-5} mg/kg bw/day
H2a.	Non-professionals, inhalation exposure, adult	Tier 1, no PPE	1.6 x 10^{-4} mg/kg bw/day
H2b.	Non-professionals, inhalation exposure, child	Tier 1, no PPE	4.0 x 10^{-4} mg/kg bw/day
H2c.	Non-professionals, inhalation exposure, toddler	Tier 1, no PPE	9.5 x 10^{-4} mg/kg bw/day
H2d.	Non-professionals, inhalation exposure, infant	Tier 1, no PPE	7.9 x 10^{-4} mg/kg bw/day

Scenario H1 refers to the mixing and loading phase: Tearing and placing "recozit Mottenpapier" in a wardrobe/closet. This scenario is only performed by adults and is assessed for inhalation and dermal exposure separately, these are identified as H1a for inhalation and H1b for dermal exposure. Scenario H2 refers to the application phase: Using a wardrobe/closet containing "recozit Mottenpapier". During this task "recozit Mottenpapier" is not handled directly and only inhalation exposure has been assessed. Since exposure is possible in different populations, it has been assessed for adults, children, toddlers, and infants identified as scenarios H2a, H2b, H2c, and H2d respectively.

2.2.6.3 Risk characterization for human health

This section addresses the risk characterization for human health associated with the uses of "recozit Mottenpapier" containing transfluthrin as the active substance. "recozit Mottenpapier" is an evaporating insecticide product used against the common clothes moth and is designed to be used indoors, for example to be hung in a wardrobe/closet. The product is composed primarily of paper to which the active substance and two other non-active ingredients have been added. The end product is essentially a dried / printed paper. The product is designed for the protection of fabric in wardrobes/closets, and other clothes storage compartments (such as chests, suitcases, drawers and clothes bags) with the control of all development stages of the common clothes moth. "recozit Mottenpapier" is for use by non-professionals (i.e. consumers).

"recozit Mottenpapier" contains transfluthrin at a concentration of 0.335% w/w (including the treated part of the paper carrier) and is intended for use as a biocidal product in product type (PT) 18 insecticides.

2.2.6.3.1 Reference values to be used in Risk Characterization

Reference	Study	NOAEL (LOAEL)	AF*	Correction for oral absorption	Value
$AEC_{short\text{-}term\ (inhalation)}$	Assessment report, 13th March 2014 No/ 528/2012.	46.7 mg/m³ **	100	NA	0.5 mg/m³
$AEL_{short\text{-}term\ (dermal)}$		1000 mg/kg bw/d	100	NA	1 mg/kg bw/d ***
$AEL_{long\text{-}term\ (systemic)}$		1 mg/kg bw/d	100	NA	0.01 mg/kg bw/d

* A default AF value of 100 has been used to account for inter- and intraspecies differences.

** NOAEC

*** corrected for 10% dermal absorption

The critical endpoints and acceptable exposure levels for transfluthrin for uses according to PT 18 are reported in the Assessment Report (Evaluation of Active Substances), 13th March 2014 (Rapporteur Member State: Netherlands) prepared according to Regulation EU) No/ 528/2012 concerning the making available on the market and use of biocidal products.
The following acceptable exposure levels (AELs) have been derived for transfluthrin and are presented in the Assessment Report:

An $AEC_{short\text{-}term\ (inhalation)}$ value of 0.5 mg/m³ has been derived based on a NOAEC for neurotoxicity of 46.7 mg/m³ (equivalent to 17 mg/kg bw/day) and the application of a default assessment of 100 to account for inter- and intraspecies differences.

An $AEL_{short\text{-}term\ (dermal)}$ value of 1 mg/kg bw (corrected for 10% dermal absorption) has been derived for systemic toxicity based on a NOAEL of 1000 mg/kg bw/day from a 3 week rabbit dermal study and the application of a default assessment of 100 to account for inter- and intraspecies differences. This AEL value is considered to be adequately protective towards local effects.

An $AEL_{long\text{-}term\ (systemic)}$ value of 0.01 mg/kg bw/day has been derived based on a NOAEL if 1 mg/kg bw/day from 2 year dietary study in rats and the application of a default assessment of 100 to account for inter- and intraspecies differences. This AEL value is considered to be adequately protective towards local effects.
The approach taken to the risk characterization for "recozit Mottenpapier" follows the tiered approach adopted for the exposure assessment presented.

The comparison of the exposure and the toxicity is typically represented by the Acceptable Exposure Level (AEL) approach for systemic toxicity. The Acceptable Exposure Concentration (AEC) approach is used to assess local toxicity.

In the AEL concept the exposure estimates should be compared with the AEL (where the AEL is determined as the NOAEL for the critical effect (in mg/kg bw/day) / an Assessment Factor (AF)). In this approach, safe uses are shown when the ratio of exposure: AEL is <1.

2.2.6.3.2 Maximum residue limits or equivalent

Not relevant.

2.2.6.3.3 Specific reference value for groundwater

The calculated PEC_{grw} is below the general limit of 0.1 µg/L for organic pesticides in all cases and a risk is not expected.

2.2.6.3.4 Risk for industrial users

Not relevant. No industrial applications have been applied for.

2.2.6.3.5 Risk for professional users

Not relevant. No professional applications have been applied for.

2.2.6.3.6 Risk for non-professional users

Non-professionals (consumers) may be exposed to transfluthrin when using "recozit Mottenpapier" to control the common clothes moth in the home. The product would be removed from the packaging and torn to size depending on the wardrobe/closet to be protected. The paper should be placed unfolded in a wardrobe/closet in a manner that allows the active substance to spread between all the clothes; either placing it above the clothes on a rail / hanger or sticking it to the back board of the wardrobe/closet. During use, residents of the house would be exposed to transfluthrin when the wardrobe/closet is opened to retrieve items of clothing.

The following tasks have been identified for non-professionals using "recozit Mottenpapier":

Mixing and loading: Tearing and hanging the paper

The primary routes of exposure associated with the mixing and loading task are the dermal and inhalation routes. The paper would be replaced in the wardrobe/closet every 4 months. This is considered to be a **short-term exposure scenario**.

Application: Using a wardrobe/closet containing "recozit Mottenpapier"

The primary route of exposure for the application task is the inhalation route. Consumers would be expected to open the wardrobe/closet once a day for 365 days / year. This is considered to be a **long-term exposure scenario**.

Ingestion of the product is not expected during normal use.

Systemic effects

Task	Scenario	Tier	Systemic NOAEL[1]	AEL[1]	Estimated uptake / exposure	Estimated uptake/ AEL (%)	Acceptable (yes/ no)
Tearing and placing the paper in a wardrobe/ closet	H1a. Inhalation exposure	1	46.7 mg/m^3 (NOAEC)	0.5 mg/m^3 (AEC)	0.12 mg/m^3	24	Yes
	H1b. Dermal exposure	1	1000 mg/kg bw/d	1 mg/kg bw/d	5.6 x 10^{-5} mg/kg bw/d	5.6 x 10^{-3}	Yes
Using a wardrobe/ closet containing "recozit Mottenpapier"	H2a. inhalation exposure, adult	1	1 mg/kg bw/d	0.01 mg/kg bw/d	1.6 x 10^{-4} mg/kg bw/d	1.6	Yes
	H2b. Inhalation exposure, child	1	1 mg/kg bw/d	0.01 mg/kg bw/d	4.0 x 10^{-4} mg/kg bw/d	4.0	Yes
	H2c. Inhalation exposure, toddler	1	1 mg/kg bw/d	0.01 mg/kg bw/d	9.5 x 10^{-4} mg/kg bw/d	9.5	Yes
	H2d. Inhalation exposure, infant	1	1 mg/kg bw/d	0.01 mg/kg bw/d	7.9 x 10^{-4} mg/kg bw/d	7.9	Yes

[1]Scenario H1a uses a NOAEC in mg/m^3 and an AEC in mg/m^3. All other scenarios use a NOAEL and AEL in the units described.

Systemic exposures to transfluthrin in non-professionals when tearing and hanging "recozit Mottenpapier" and using a wardrobe/closet containing "recozit Mottenpapier" were determined using ConsExpo 4.1, the RIVM Pest Control Products fact sheet, the RIVM General fact sheet and the HEEG opinion. This approach is discussed in detail earlier. A tiered approach was used. The results of the risk assessment for systemic effects, taking into account a dermal absorption value of 10% are shown in the table above.

Combined scenarios

Not relevant.

Local effects

The slurry formulation of the "recozit Mottenpapier" is classified as H315 and H317 due to the active substance transfluthrin and the component rosin, respectively.
According to the guidance on the BPR, Volume III Human Health, Assessment + Evaluation (Parts B+C) a risk characterization for local effects is triggered when the biocidal product is classified for local effects.

For transfluthrin, the AEL $_{\text{acute dermal}}$ in the CAR is considered to be also adequately protective with respect to local effects. Thus, as the dermal systemic risk assessment for mixing and loading phase is acceptable (see above), the eCA considers the local effects to be covered by this risk assessment. This conclusion is further supported by low likelihood of exposure through product design with clear indication of treated and untreated parts and the RMM "When placing the paper, only touch the edges and untreated parts of paper so contact with the treated areas is avoided".

For rosin, no dermal AEC is derived and thus, a qualitative local risk assessment is performed.

Qualitative local risk characterisation for dermal sensitisation:
The slurry of "recozit Mottenpapier" is classified as H317, skin sensitizer, due to rosin which occurs at a concentration of ≥ 1%[11]. In view of the physical form of the final product, "recozit Mottenpapier" is considered to be in the medium hazard category for local effects. Exposure could happen during mixing and loading. Normally, a product labelled with H317 would trigger H280 "Wear protective gloves". However, due to the product design with slurry-free handling zones[12], no or negligible exposure during handling of the product without gloves is expected.
In summary, due to the low frequency (3 times/year), short exposure duration (10 min) and low likelihood of exposure (product design), the risk for skin sensitization by "recozit Mottenpapier" is considered negligible. In order to ascertain that only the treatment free part of the paper is touched, the sentence "When placing the paper, only touch the edges and untreated parts of paper so contact with the treated areas is avoided" is included in the RMM. In addition, the untreated and treated part of the paper are labelled accordingly.

In conclusion, the risk for local effects through the use of the product is considered to be acceptable.

Conclusion

Based on the predicted exposures and risk characterization for health effects, tasks involving the use of "recozit Mottenpapier" containing transfluthrin are not considered to pose an unacceptable risk to human health. A human health risk from acute local effects is not expected if appropriate labelling is available. The label should state "When placing the paper, only touch the edges and untreated parts of paper so contact with the treated areas is avoided".

2.2.6.3.7 Risk for the general public

Secondary indirect exposure has been considered to be the same as for the application phase (users are considered to be members of the public who open/close wardrobes/closets etc. where the product has been placed).

2.2.6.3.8 Risk for consumers via residues in food

Not relevant.

11 For information on the composition of the slurry, please refer to confidential Annex 3.8.1 and the corresponding SDS.

12 For information on the dimensions of the treated and non-treated parts of the "recozit Mottenpapier", please refer to Annex 3.7

2.2.6.3.9 Risk characterization from combined exposure to several active substances or substances of concern within a biocidal product

Not relevant.

2.2.7 Risk assessment for animal health

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

2.2.8 Risk assessment for the environment

The proposed use of "recozit Mottenpapier" is for indoor use for non-professional users. It is not applied directly on, in, or near to water surfaces due to its proposed use pattern and label recommendations.

Other than the active substance, none of the components of the biocidal product are considered relevant to the aquatic or terrestrial compartment, and they are not expected to affect the overall fate (degradation or mobility) or toxicity profile of transfluthrin in the environment. Therefore no additional studies using the formulated product were carried out.

The risk assessment therefore covers the active substance transfluthrin and the two major metabolites TFB-COOH and TFB-OH included in the list of endpoints (appendix 1, chapter 4 of the Assessment Report on transfluthrin). A further metabolite, DCVA (permethric acid, also termed dichlorochrysantemic acid, CAS 55701-05-8) is referred to in the Assessment Report as a probable metabolite, but for which no further environmental studies were submitted. According to the CAR on cyfluthrin (for which DCVA has been detected as a metabolite), DCVA is considered to be persistent in freshwater-sediment systems. However, its aquatic toxicity is by orders of magnitude lower than that of transfluthrin.

2.2.8.1 Effects assessment on the environment

2.2.8.1.1 Aquatic compartment

In the assessment report from 2014, acute toxicity data for transfluthrin were available at three trophic levels (fish, daphnia and algae), along with an activated sludge respiration inhibition test. Chronic data were available for algae only. Data were also available for the effects of the metabolite TFB-COOH on fish and daphnia. On the second metabolite, TFB-OH, no studies have been submitted.

In 2015, additional studies have been carried out on the active substance, including chronic toxicity data on fish, daphnia and sediment organisms. These additional studies require the review and validation by the Biocidal Products Committee (BPC) and its working groups before they can be used by the eCA in risk assessment for this product. Here, the endpoints from the additional studies are summarized for informative purposes only, along with the endpoints from the 2014 assessment report.

Key endpoints obtained from aquatic organism studies (Assessment Report on Transfluthrin, 2014)

Species	Substance	Time Scale	Endpoint	Result	Reference within Assessment Report 2014
Fish					
Oncorhynchus mykiss	transfluthrin	acute	LC_{50}	0.7 µg/L	Grau (1988)
Oncorhynchus mykiss	TFB-COOH	acute	LC_{50}	> 100 mg/L	Nieden (2005)
Invertebrates					
Daphnia magna	transfluthrin	acute	EC_{50}	1.2 µg/L	Bruns (2001)
Daphnia magna	TFB-COOH	acute	EC_{50}	> 100 mg/L	Dorgerloh (2005)
Algae					
Scenedesmus subspicatus	transfluthrin	acute	E_rC_{50}	> 100 µg/L	Heimbach (1987)
Scenedesmus subspicatus	transfluthrin	chronic	NOE_rC	50 µg/L	Bruns (2001)
STP					
Respiration activated sludge	transfluthrin	acute	NOEC EC_{50}	57 µg/L (water solubility) >10,000 mg/L	Krohn (1995)

Further endpoints obtained from additional aquatic organism studies (not yet validated by the BPC, for information purposes only)

Species	Substance	Time Scale	Endpoint	Result	Reference
Fish					
Pimephales promelas	transfluthrin	chronic	NOEC	≥0.399 µg/L	Matlock, D., Moore, S. (2015). Early Life Toxicity of Transfluthrin Technical to the Fathead Minnow (Pimephales promelas) Under Flow-Through Conditions. SynTech Research Laboratory, USA. Report No: M-522816-01-1. GLP. Unpublished

Species	Substance	Time Scale	Endpoint	Result	Reference
Invertebrates					
Daphnia magna	transfluthrin	chronic	NOEC	17.5 ng a.i./L	Matlock, D., Moore, S. (2015). Chronic Toxicity of Transfluthrin Technical to Daphnia magna Under Flow-Through Conditions. SynTech Research Laboratory, USA. Report No: M-522462-01-1. GLP. Unpublished.
Algae					
Pseudokirchneriella subcapitata	TFB-COOH	acute	EC_{50}	> 50 mg/L	Matlock, D. and Moore, S. (2015) Toxicity of Transfluthrin-Tetrafluorobenzoic acid to the Green Algae Pseudokirchneriella subcapitata During a 96 Hour Exposure. SynTech Research Laboratory, USA. Report No: EBTBN007. GLP. Unpublished.
Sediment organisms					
Chironomus riparius	transfluthrin	chronic**	NOEC	0.164 mg/kg dwt sed	Kuhl, K. (2015). Chironomus riparius 28-day chronic toxicity test with transfluthrin (tech.) in a water-sediment system using spiked sediment. Report No: M-508598-01-1. GLP. Unpublished.
			EC_{10}	0.302 mg/kg dwt sed	
Lumbriculus	transfluthrin	chronic	NOEC	2.21 mg/kg dwt sed	Egeler, P. (2015). A study on the chronic toxicity to the sediment dweller Lumbriculus variegates.

Species	Substance	Time Scale	Endpoint	Result	Reference
					ECT Oekotox-ikologie GmbH, Germany. Report No: M-529774-01-1. GLP. Un-published.

** emergence rate

PNEC derivation for aquatic organisms

Transfluthrin

In the assessment report, a **$PNEC_{water}$ of 0.7 ng/L** (*Oncorhynchus mykiss*, LC_{50} 0.7 µg/L, AF of 1000) had been suggested, based on the then available studies.

Once the new studies get approved by the BPC, the lowest relevant endpoint for aquatic organisms would be that of the *Daphnia magna* study, with a 21 day NOEC of 17.5 ng a.i./L. As chronic and acute data will then be available for 3 trophic levels, a lower assessment factor can be applied in accordance with the Guidance on the Biocidal Products Regulation, Volume IV Environment, Part B.

Metabolite TFB-COOH

Two acute studies are available from the assessment report for TFB-COOH (fish and daphnia) with LC_{50}/EC_{50} values greater than 100 mg/L. An assessment factor of 1000 was applied to the lowest endpoint. This gives a standard tier **$PNEC_{water}$ of >0.1 mg/L.**

Metabolite TFB-OH

No ecotoxicity data are available for TFB-OH, but in view of the chemical structure similarity with TFB-COOH and the comparable physico-chemical characteristics, it is proposed that TFB-OH also has a **$PNEC_{water}$ of >0.1 mg/L**.

PNEC derivation for sediment dwelling organisms

In the assessment report, a **$PNEC_{sediment}$ of 0.76 µg/kg wwt sed** had been derived from $PNEC_{water}$ via equilibrium partitioning. An additional assessment factor of 10 will be applied to the corresponding PEC/PNEC ratio as a consequence of the log Pow of transfluthrin >5.

PNEC derivation for sewage organisms

The three-hour EC_{50} of transfluthrin to the respiration of activated sludge was 57 µg/L (water solubility). An assessment factor of 10 was applied in accordance with the Guidance on the Biocidal Products Regulation, Volume IV Environment, Part B. This gives a standard tier **$PNEC_{stp}$ of 5.7 µg/L**.

2.2.8.1.2 Atmosphere

In view of the proposed uses significant exposure of the environment via air is not expected. As such an assessment of effects in air is not considered to be needed.

2.2.8.1.3 Terrestrial compartment

In the assessment report from 2014, acute toxicity data for transfluthrin was available for earthworms.

In 2014 and 2015, three additional studies have been carried out on the active substance, including chronic toxicity data on earthworms and collembolans, as well as a nitrogen mineralization test. These additional studies require still the review and validation by the Biocidal Products Committee (BPC) and its working groups before they can be used by the eCA in risk assessment. Here, the endpoints from the additional studies are summarized for informative purposes only, along with the endpoints from the 2014 assessment report.

The key endpoints obtained from terrestrial organism studies (Assessment Report on Transfluthrin, 2014)

Species	Substance	Time Scale	Endpoint	Result	Reference within Assessment Report 2014
Earthworms	transfluthrin	acute	LC_{50}	184 mg/kg dwt soil (10% OM). Correction to standard OM content: 62.6 mg/kg dwt	Heimbach, 1991

Further endpoints obtained from additional terrestrial organism studies (not yet validated by the BPC, for information purposes only)

Species	Substance	Time Scale	Endpoint	Result	Reference
Earthworms, *Eisenia fetida*	transfluthrin	chronic	NOEC	10 mg/kg dwt soil (10% OM). Correction to standard OM content: 3.4 mg/kg dwt soil	Friedrich, S. (2014). Sublethal toxicity to the earthworm Eisenia fetida in artificial soil. BioChem agrar GmbH, Germany. Report No: M-503247-01-1. GLP. Unpublished.
Nitrogen mineralization	transfluthrin	chronic	EC_{10} (stimulation)	12 mg/kg dwt soil (1.47% OC). Correction to standard OM content: 16.33 mg/kg dwt soil	Schultz, L. (2014). Effects on the activity of soil microflora (Nitrogen transformation test). BioChem agrar GmbH, Germany. Report No: M-500036-01-1. GLP. Unpublished.
Collembolan, *Folsomia candida*	transfluthrin	chronic	NOEC	18 mg/kg soil dwt	Friedrich, S. (2014) Effects on the reproduction of the collembolan Folsomia candida. BioChem agrar GmbH, Germany. Report No: M-504775-01-1. GLP. Unpublished.
Terrestrial plants					ongoing

PNEC derivation for soil

Transfluthrin

In the assessment report, because of the limited data, a **$PNEC_{soil}$ of 6.17 x 10^{-4} mg/kg wwt** was derived using equilibrium partitioning (based on the $PNEC_{water}$). The reasoning for this was that the available acute data for earthworms does not represent properly the more sensitive non-target insects (transfluthrin is known to have a specific mode of action against insects). An additional assessment factor of 10 will be applied to the corresponding PEC/PNEC ratio as a consequence of the log Pow of transfluthrin >5.

Metabolite TFB-COOH

No data has been generated on terrestrial organisms. Therefore, the equilibrium partitioning method was used to derive the $PNEC_{soil}$ for the metabolite TFB-COOH based on the $PNEC_{water}$. This resulted in a **$PNEC_{soil}$ of 0. 19 mg/kg wwt.** An additional assessment factor of 10 will be applied to the corresponding PEC/PNEC ratio as a consequence of the log Pow of transfluthrin >5 and in the absence of information on the Pow of metabolites.

2.2.8.1.4 Secondary Poisoning

In the following, the risk of secondary poisoning for birds and mammals is assessed.

In the absence of short-term or long-term dietary toxicity data for birds, a $PNEC_{oral,\ bird}$ cannot be derived. However, for the $PNEC_{oral,\ bird}$ to fall below the $PEC_{oral,\ bird}$, the NOEC should be lower than the $PEC_{oral,\ bird}$ x 30. With the calculated concentrations of 3.36 x 10^{-5} mg/kg in fish, and 3.77 x 10^{-4} mg/kg in worms (see Section 2.2.8.2), NOEC should become <0.001 mg/kg feed in case of fish and <0.011 mg/kg feed in case of earthworms. Following a similar reasoning for short-term tests, the LC_{50} should be lower than the $PEC_{oral,\ bird}$ x 3000, or <0.1 mg/kg feed and 1.1 mg/kg feed in case of fish and earthworms, respectively.

In view of the absence of acute toxicity in a non-dietary test to birds at doses up to 1890 mg/kg bw (equivalent to approximately 10,000 – 20,000 mg/kg feed in the amount of one daily intake), it is not expected that chronic toxicity levels as low as 0.01 mg/kg feed, or short-term toxicity levels as low as 1.1 mg/kg feed will be reached.

Furthermore, there are several reasons to assume that the calculated PECs in water and soil (and therefore the concentrations in fish and earthworms) may be worst-case estimates. In view of this, a risk of secondary poisoning of birds is not expected. From the viewpoint of animal welfare, it is not considered justified to require further studies on birds (Assessment report, 2014).

The $PNEC_{oral,mammal}$ for secondary poisoning of mammals is derived by applying an assessment factor of 30 to the chronic NOEC of 200 mg/kg feed (from long-term toxicity tests), resulting in a $PNEC_{oral,mammal}$ of 6.7 mg/kg feed.

2.2.8.1.5 Further studies and data

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

Other than the active substance, none of the components of the biocidal product are considered relevant to the aquatic or terrestrial compartment, and they are not expected to affect the overall fate (degradation or mobility) or toxicity profile of transfluthrin in the environment. Therefore no further information is required for classification of the product.

Classification was derived in accordance with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

The classification of "recozit Mottenpapier" is based on the LC_{50} of Transfluthrin of 0.7 µg/L, an M-factor of 1000, and the concentration of 12.95% Transfluthrin in the slurry formulation of "recozit Mottenpapier", i.e. the biocidal product without paper carrier:

Aquatic Acute 1; H400 Very toxic to aquatic life.
Aquatic Chronic 1; H410 Very toxic to aquatic life with long lasting effects

Further Ecotoxicological studies

No further data is required. Sufficient data exists on both the active substance and its metabolites, therefore, it is not considered scientifically justified to carry out additional eco-toxicity studies using the formulated product.

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

No further data is required. Sufficient data exists on both the active substance and its metabolites, therefore, it is not considered scientifically justified to carry out additional eco-toxicity studies using the formulated product.

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

No further data is required. Sufficient data exists on both the active substance and its metabolites, therefore, it is not considered scientifically justified to carry out additional eco-toxicity studies using the formulated product.

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

No further data is required. Sufficient data exists on both the active substance and its metabolites, therefore, it is not considered scientifically justified to carry out additional eco-toxicity studies using the formulated product.

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

No further data is required. Sufficient data exists on both the active substance and its metabolites, therefore, it is not considered scientifically justified to carry out additional eco-toxicity studies using the formulated product.

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

"recozit Mottenpapier" is a ready-to-use household insecticide product that is designed to be used by non-professionals (e.g. consumers). It is used for the control of the common clothes moth (*Tineola bisselliella,* larvae and adults). The product is intended to protect fabrics in wardrobes/closets and other storage compartments (such as chests, suitcases, drawers and clothes bags). "recozit Mottenpapier" contains transfluthrin as the active substance.

As the active substance in the product is intended to volatilize, in a worst case 100% of the transfluthrin goes to air. In a more realistic case, however, only a fraction of the applied transfluthrin will volatilize during the recommended time of usage of 4 months, as it has been shown in a study on evaporation kinetics (see Section 2.2.2). The remainder is expected to be incinerated or disposed of as hazardous waste.

Some of the volatilized transfluthrin may be absorbed to clothing and carpets which are in close proximity to the paper strips. Clothing and carpets may then be subject to washing or cleaning which would lead to down the drain emissions. In addition to this, the transfluthrin which volatilizes from the paper strips may settle to hard floors, which are then subject to wet cleaning.

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

The fate and behaviour of the active substance is not expected to be altered by the co-formulants in the product. The product as it is supplied to the user is a moth paper from which the active substance is expected to volatilize in pure form and as such will only reach the environment as pure transfluthrin. As such, the data submitted for the active substance is considered sufficient to cover all endpoints for environmental fate and behaviour. As single further study on fate and behaviour of the product, a study on evaporation kinetics of transfluthrin from moth paper has been conducted. No further product specific studies are required.

Leaching behaviour (ADS)

Leaching behaviour is not relevant for this product type as the product is an insecticide and is not intended for incorporation into treated articles.

Testing for distribution and dissipation in soil (ADS)

No product specific data has been generated as the co-formulants in the product are not expected to influence the fate and behaviour of transfluthrin in the environment.

Distribution in Soil

An OECD 121 HPLC-method study conducted with the active substance has found that transfluthrin has a log Koc of 4.7.

Dissipation in Soil

Since the original active substance submission for transfluthrin a new study has been conducted with [methylene-^{14}C] transfluthrin in order to investigate the degradation in four soils. In all four soils the DT_{50} was found to be between 0.8 and 1.0 days. Mineralization was up to 78.3% of AR at day 14. This new study requires still the review and validation by the Biocidal Products Committee

(BPC) and its working groups before it can be used in risk assessment. Here, the endpoint is presented for information purposes only.

Summary table on further studies on fate and behaviour in the environment

Method, Guideline, GLP status, Reliability	Compartment	pH	Temp [°C]	Initial TS concentration, C_0[mol/l]	Half-life, DT_{50} [d]	Remarks	Reference
OECD 308, GLP, Klimisch 1	Soil	Not available	Not available	Not available	1.0 day	The study will be submitted separately by the data owner.	Hein, E-M, Junge, T. (2015). [methylene-14C]transfluthrin: Aerobic Degradation/Metabolism in Four Soils. Report No: M-534156-01-1. GLP. Unpublished

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

The fate and behaviour of the active substance are not expected to be altered by the co-formulants in the product. Therefore the available studies for transfluthrin have been used to cover all information requirements here.

Distribution in Water and Sediment

An OECD 121 HPLC-method study conducted with the active substance has found that transfluthrin has a log Koc of 4.7.

Dissipation in Water and Sediment

Transfluthrin is not readily biodegradable. In water/sediment systems the dissipation of transfluthrin from the water phase is dominated by sorption. The average system DT_{50} has been found to be 11.1 days, with a DT_{50} for sediment of 14.1 days. The metabolites in NAK 4452 (2,3,5,6-tetrafluorobenzyl alcohol; TFB-OH) and NAK 4723 (2,3,5,6-tetrafluorobenzoix acid; TFB-COOH) were detected in water at > 10% at maximum levels of 38 and 59% respectively. In sediment the same metabolites were detected at 2.9% and 26% respectively.

The system DT_{50} of metabolite TFB-OH was estimated to be <14 days. The system DT_{50} of TFB-COOH could not be obtained as the number of data points were too few, however, the degradation rate of TFB-COOH is expected to be low.

Conclusion used in Risk Assessment –distribution and dissipation in water and sediment

Value/conclusion	The DT_{50} for water-sediment systems is 11.1 days and the DT_{50} for sediment is 14.1 days.
Justification for the value/conclusion	The values are taken from the CAR for transfluthrin. As none of the co-formulants are expected to influence the environmental fate and behaviour of transfluthrin, it is considered appropriate to use these values.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	Fate and behaviour in air
Justification	As exposure to air is expected to be minimal and very localized, studies on fate and behaviour in air are not 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)

Data waiving	
Information requirement	Overspray study
Justification	No further data is available. The product is an indoor use moth paper. As such, there is no risk from the product being sprayed near surface waters and further information on this is not required.

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)

Data waiving	
Information requirement	Overspray study
Justification	No further data is available. The product is an indoor use moth paper. As such, there is no risk from the product being sprayed near surface waters and further information on this is not required.

2.2.8.2 Exposure assessment

2.2.8.2.1 General information

Assessed PT	PT 18
Assessed scenarios	Scenario E1: Indoor, diffusers, 10% to STP (realistic worst case according to ESD); Scenario E2: Indoor, diffusers,

	3.8% to STP (realistic worst case, including information from the evaporation kinetics study).
ESD(s) used	Emission Scenario Document for Product Type 18: Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses.
Approach	The approach used to estimate exposure is based on actual consumption data in conjunction with information from the PT18 ESD and the EU TGD part II. This approach was preferred given that the use of actual consumption data seemed more reliable and resulted in a more conservative emission estimate in comparison to using a simultaneity factor. Nevertheless, the calculation based on simultaneity factors is presented in Annex 3.3.2.1 for comparison and transparency.
Distribution in the environment	Calculated in EUSES 2.1.2 based on EU TGD 2003 equations.
Groundwater simulation	Standard tier groundwater calculations were performed in EUSES 2.1.
Confidential Annexes	NO
Life cycle steps assessed	Scenario: Production No Formulation No Use Yes Service life No
Remarks	Exposure calculations were based on known levels of consumption in Switzerland.

2.2.8.2.2 Emission estimation: indoor use of diffusers

"recozit Mottenpapier", as it is supplied to the user, is a ready-to-use household insecticide product that is designed to be used by non-professionals (e.g. consumers). It is used for the control of the common clothes moth (*Tineola bisselliella,* larvae and adults). The product is intended to protect fabrics in wardrobes/closets and other clothes storage compartments (such as chests, suitcases, drawers and clothes bags). "recozit Mottenpapier" contains transfluthrin as the active substance. "recozit Mottenpapier" is sold in a pack with 2 strips per pack. Each strip weighs 14.5g with 0.03374g of transfluthrin per strip.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenarios E1 and E2: Indoor use of diffusers			
Application rate of biocidal product	1	strip/m^3	Each strip (150 x 825 mm) of the product is intended to provide protection for 1 m^3 for 4 months

Weight of each strip (= 10 pieces of paper)	14.5	g	Information from Applicant.
Quantity of active substance per strip	0.03374	g/strip	[redacted]
Number of strips sold in Switzerland annually with the original instruction for use to replace the product after 6 month	[redacted]	[redacted]	[redacted]
Expected number of strips sold in Switzerland annually with the adapted instruction for use to replace the product after 4 month	[redacted]	[redacted]	[redacted]

Calculations:

The following calculation of the emission estimate is based on market data provided by the Applicant. With this, eCA deviates from the default method of using simultaneity factors as described in the ESD of PT18. This is in agreement with the conclusion of the 5th meeting of the Task Force on Biocides that the simultaneity factors have to be considered as "general information until more relevant data are available to take into account the specificity of the different OECD member countries." Nevertheless, the calculation based on simultaneity factors is presented in Annex 3.3.2.1 for comparison and transparency.

Originally, the Applicant recommended the product to be replaced once every 6 months. This replacement interval has been reduced to 4 months during the evaluation by eCA, given that in recent efficacy studies the product failed to reach the target of 90% mortality within the 14 day exposure period (see Section 2.2.5.5). To reflect this adapted instruction for use, the sales number provided by the Applicant was augmented by 50% for calculating the emission scenario, reflecting a replacement of the product three times per year instead of two times per year.

In total, it is therefore expected that [redacted] of "recozit Mottenpapier" will be sold in Switzerland each year. This number is thought to [redacted] Thus, the Swiss consumption of moth paper constitutes a worst case scenario in terms of emissions and will hence be used for this risk assessment.

[redacted] the whole country of Switzerland and the assessment considers the use in a standard sized small town, this figure has been scaled to consider how much of the product will be used in a single town. The PT18 ESD assumes that a total of 4,000 houses are attached to a single standard STP with a 10,000 inhabitant capacity (Emission Scenario Document for Insecticides, Acaricides and Products to Control Other Arthropods for Household and Professional Uses (2008), p39). The total number of households in

Switzerland is estimated to be 3,540,000 (Swiss Federal Statistical Office, 2013)[13]. Based on this information, a standard sized town will have [redacted] in the country. It can reasonably be assumed that this is approximately representative of the rest of Europe, where market penetration is likely to be similar. Therefore, the number of "recozit Mottenpapier" strips used annually in a single, standard sized town is calculated with:

[redacted]

As previously discussed, each "recozit Mottenpapier" strip contains 0.03374 g of transfluthrin. Consequently, the total amount of transfluthrin used in a town of 10,000 inhabitants per year is:

[redacted]

The emission pathway for such a product is difficult to characterize. Each paper is effective for 4 months. Some of the applied transfluthrin may be absorbed to clothing and carpets which are in close proximity to the "recozit Mottenpapier" strips. Clothing and carpets may then be subject to washing or cleaning which would lead to down the drain emissions. In addition to this, the transfluthrin which volatilizes from the strips may settle to hard floors, which are then subject to wet cleaning.

A realistic worst case scenario *E1* has been calculated, assuming that 100% of the applied transfluthrin will volatilize, and that 10% of this amount will be directed down the drain to the STP. These assumptions reflect the realistic worst case scenario provided in the *Emission Scenario Document (ESD) for insecticides, acaricides and products to control other arthropods for household and professional uses*.

Furthermore, a refined scenario *E2* has been calculated, considering the results of the evaporation kinetics study, in particular that during 4 months (16 weeks) of exposure time only 38% of the applied transfluthrin is actually released from the moth paper via evaporation.[14] From this amount, again 10% will be directed down the drain to the STP (i.e. 3.8% of the overall applied active substance). 62% of the overall applied active substance will remain on the moth paper, which is expected to be incinerated or disposed of as hazardous waste. The total daily emission to both the STP and air are summarized in the table below.

Resulting local emission to relevant environmental compartments		
Scenario	**Compartment**	**Local emission (E_{local} compartment) [kg/d]**
E1	STP	1.253×10^{-5}
	Air	1.253×10^{-4}
E2	STP	4.763×10^{-6}
	Air	1.253×10^{-4}

13 http://www.bfs.admin.ch/bfs/portal/en/index/themen/01/04/blank/key/01/05.html

14 The eCA found the evaporation kinetics study to be consistent with the efficacy study: While the volatilization rate of transfluthrin decreases over time, there is also a reduction in killing efficacy towards the end of the 6 month exposure time. Therefore, eCA considers the evaporation kinetics study sufficiently robust to use its results for the refined emission scenario.

The Applicant pointed out that small amounts of transfluthrin may partition to clothes and fabrics that have been in close proximity to the product, but that they are unlikely to remain there through wearing time until the clothes are washed. This finding was based on a moderately high Henrys Law constant and consequent volatilization at the human body temperature of 37°C. Therefore, no emissions to the STP via washing are expected.

Further, the Applicant suggested that the estimates of releases to the STP based on emission scenarios from the ESD are overly conservative in the case of moth paper. The reason provided for this argument was that the ESD considers wet cleaning as a pathway for entry into the STP, whereas moth paper is intended to be used in rooms which are typically carpeted and where wet cleaning does not usually occur. To further support this, the manual of technical agreements (MOTA, version 6 2013, decision from Technical Meeting I 2010) was cited that states that only kitchen and bathrooms are wet cleaned (this decision is now also included in the Technical Agreements for Biocides, version June 2016, Section 2.4.15 paragraph ENV 88).

Whereas eCA accepts the former argument of negligible emissions to STP via washing, eCA considers the estimates of emissions to STP via wet cleaning as appropriate. This opinion is based on recent evidence that non-carpet floors are increasingly common in European houses, and that only 24% of all households have carpet installed (http://globalflooringalliance.com/news_2011_archives.html), and wet cleaning is therefore a probable emission pathway to the STP.

There will be no emission during preparation because the products do not require any preparation by domestic users. Similarly, there will be no application emissions as the products are simply placed in situ and, once used up, go to incineration or hazardous waste treatment without end of life emissions.

2.2.8.2.3 Fate and distribution in exposed environmental compartments

The following emission pathways into environmental compartments were considered for risk assessment and modelling of environmental exposure, together with the input parameters from the Assessment Report (2014). The emission pathway to soil and groundwater has been calculated according to the standard methodology implemented in the EUSES 2.1.2 model, although in Switzerland the use of effluent sludge as an agricultural fertilizer has been prohibited since 1 October 2006[15], and therefore the emission pathway from sludge to agricultural soil and ground water does not occur at all.

Identification of relevant receiving compartments based on the exposure pathway, all scenarios									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
	+	+			+	+	(+)	(+)	

The brackets indicate an emission pathway that does not occur in countries where the use of effluent sludge as an agricultural fertilizer is prohibited.

15 https://www.bafu.admin.ch/bafu/en/home/topics/waste/guide-to-waste-a-z/biodegradable-waste/types-of-waste/effluent-sludge.html

Input parameters for all scenarios (only set values) for calculating the fate and distribution of transfluthrin in the environment			
Input	Value	Unit	Remarks
Molecular weight	371.2	g/mol	Assessment report page 6
Melting point	32	°C	Assessment report page 7
Boiling point	242	°C	Assessment report page 7
Vapour pressure (at 25°C)	2 $x10^{-3}$	Pa	Assessment report page 7
Water solubility (at 20°C)	0.057	mg/L	Assessment report page 7
Log Octanol/water partition coefficient	5.94	Log 10	Assessment report page 40
Organic carbon/water partition coefficient (Koc)	50118	L/kg	Assessment report page 21
Henry's Law Constant (at 20°C)	5.86	$Pa/m^3/mol$	Assessment report page 7
Bioconcentration factor for fish	1783	L/kg wwt	Assessment report page 21
Bioconcentration factor for earthworms	10452	L/kg wwt	Assessment report page 21
Biodegradability	Not readily biodegradable		Assessment report page 21
DT_{50} for biodegradation in surface water	7	d (at 20ºC)	Assessment report page 20
DT_{50} for biodegradation in sediment	14.1	d (at 20ºC)	Assessment report page 20
DT_{50} for degradation in soil	1 x 10^6	d (at 12°C)	Based on result of ready biodegradability test

Input parameters (only set values) for calculating the fate and distribution of TFB-OH in the environment			
Input	Value	Unit	Remarks
Molecular weight	180	g/mol	Calculated from molecular formula
Organic carbon/water partition coefficient (Koc)	1995	L/kg	Competent Authority Report, Document IIA, page 42
Biodegradability	Not readily biodegradable		Worst case assumption

Input parameters (only set values) for calculating the fate and distribution of TFB-COOH in the environment			
Input	Value	Unit	Remarks
Molecular weight	194	g/mol	Calculated from molecular formula
Organic carbon/water partition coefficient (Koc)	100	L/kg	Competent Authority Report, Document IIA, page 42
Biodegradability	Not readily biodegradable		Worst case assumption

Calculated fate and distribution of transfluthrin in the STP		
Compartment	Percentage [%]	Remarks
Air	0.851	Calculated by SimpleTreat module of EUSES
Water	19.2	Calculated by SimpleTreat module of EUSES
Sludge	79.9	Calculated by SimpleTreat module of EUSES
Degraded in STP	0	Calculated by SimpleTreat module of EUSES

Since the original active substance submission for transfluthrin, a study with [methylene-^{14}C] transfluthrin has been conducted in order to investigate the degradation in four soils. This additional study requires still the review and validation by the Biocidal Products Committee (BPC) and its working groups before it can be used in risk assessment. Here, the endpoint is presented for information purposes only.

Further input parameters for calculating the fate and distribution in the environment (not yet validated by the BPC, for information purposes only)			
Input	Value	Unit	Remarks
DT_{50} for degradation in soil	1	d (at 20ºC)	The study will be submitted separately by the data owner. Measured DT_{50} values in four soils ranged from 0.8 to 1.0 days. A value of 1.0 days has been used here as a worst case.

2.2.8.2.4 Calculated PEC values

Based on the inputs listed above, the following PECs are derived for the emission scenarios E1 and E2. A report on EUSES inputs/outputs for emission scenario E2 is included in Annex 3.3.2.2.

Summary table on calculated PEC values for transfluthrin						
Scenario	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]	[mg/m^3]
E1	1.20×10^{-6}	1.12×10^{-7}	1.22×10^{-4}	1.85×10^{-4}	2.09×10^{-4}	3.48×10^{-8}
E2	4.57×10^{-7}	4.25×10^{-8}	$4.64 \cdot 10^{-5}$	7.11×10^{-5}	8.04×10^{-5}	3.48×10^{-8}

The PECs for the major metabolites were calculated from the PECs for transfluthrin multiplied by the relevant formation fraction and a correction for molecular weight. The PECs for the major metabolites are presented in the table below.

Summary table on calculated PEC values for major metabolites						
Metabolite/ Scenario	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]	[mg/m^3]
TFB-OH						
E1	0	2.06×10^{-8}	1.72×10^{-6}	3.44×10^{-5}	3.85×10^{-5}	N/A
E2	0	7.84×10^{-9}	6.52×10^{-7}	$1.32 \cdot 10^{-5}$	$1.48 \cdot 10^{-5}$	N/A
TFB-COOH						
E1	0	3.45×10^{-8}	1.66×10^{-5}	$5.75 \cdot 10^{-5}$	$6.44 \cdot 10^{-5}$	N/A
E2	0	1.31×10^{-8}	6.30×10^{-6}	$2.21 \cdot 10^{-5}$	$2.48 \cdot 10^{-5}$	N/A

Primary and secondary poisoning

Primary poisoning

Primary poisoning in not expected to be relevant given the use pattern and low emission of this product to the environment.

Secondary poisoning

The concentrations for secondary poisoning are presented in the table below.

Summary table on concentrations for secondary poisoning by transfluthrin		
Scenario	**Concentration in fish**	**Concentration in earthworms**
	[mg/kg_{wwt}]	[mg/kg_{wwt}]
E1	9.96×10^{-5}	9.90×10^{-4}
E2	3.79×10^{-5}	3.81×10^{-4}

2.2.8.3 Risk characterization

2.2.8.3.1 Atmosphere

Conclusion:

In view of the proposed uses significant exposure of the environment via air is not expected.

2.2.8.3.2 Sewage treatment plant (STP)

PEC/PNEC values in the STP for transfluthrin	
Scenario	**$PEC/PNEC_{STP}$**
E1	2.11×10^{-4}
E2	8.02×10^{-5}

Conclusion:

No unacceptable risk from transfluthrin to the STP was identified (PEC/PNEC <1).

2.2.8.3.3 Aquatic compartment

PEC/PNEC values in the aquatic compartment for transfluthrin		
Scenario	**$PEC/PNEC_{water}$**	**$PEC/PNEC_{sed}$**
E1	1.60×10^{-1}	1.60
E2	6.08×10^{-2}	6.08×10^{-1}

PEC/PNEC values in the aquatic compartment for major metabolites		
Metabolite / Scenario	**$PEC/PNEC_{water}$**	**$PEC/PNEC_{sed}$**
TFB-OH		
E1	2.06×10^{-7}	N/A
E2	7.84×10^{-8}	N/A

PEC/PNEC values in the aquatic compartment for major metabolites		
Metabolite / Scenario	**PEC/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**
TFB-COOH		
E1	3.45 x 10^{-7}	N/A
E2	1.31 x 10^{-7}	N/A

Conclusion:

No unacceptable risk from transfluthrin to surface water organisms was identified nor from its major metabolites (PEC/PNEC <1). A risk (PEC/PNEC = 1.60) from transfluthrin to sediment dwelling organisms was identified under the worst case scenario, but no unacceptable risk was found under the refined scenario.

2.2.8.3.4 Terrestrial compartment including ground water

PEC/PNEC values in the terrestrial compartment for transfluthrin		
Scenario	**PEC/PNEC$_{soil}$**	**PEC/PNEC$_{groundwater}$**
E1	2.98	2.09 x 10^{-3}
E2	1.15	8.04 x 10^{-4}

PEC/PNEC values in the terrestrial compartment for major metabolites		
Metabolite / Scenario	**PEC/PNEC$_{soil}$**	**PEC/PNEC$_{groundwater}$**
TFB-OH		
E1	N/A	3.85 x 10^{-4}
E2	N/A	1.48 x 10^{-4}
TFB-COOH		
E1	4.79 x 10^{-3}	6.44 x 10^{-4}
E2	1.84 x 10^{-3}	2.48 x 10^{-4}

Conclusions:

A risk from transfluthrin to soil organisms was identified under both scenarios. The risk under the refined scenario can be considered to be small, with a PEC/PNEC ratio of 1.15. This ratio is expected to fall well below 1 when considering degradation in the soil compartment. Although the additional study on dissipation in soil (Hein, E-M, Junge, T. (2015), see table in Section 2.2.8.1.5) is not yet validated to be used in risk assessment, its indicative results as well as the results on degradation in sediment show that degradation in soil is likely to occur. Moreover, in Switzerland the use of

effluent sludge as an agricultural fertilizer has been prohibited since 2006[16], and therefore the emission pathway from sludge to agricultural soil and groundwater does not occur at all.

No unacceptable risk to soil organisms was identified from TFB-COOH. No unacceptable risk to groundwater was identified from transfluthrin nor from its major metabolites (PEC/PNEC <1).

2.2.8.3.5 Primary and secondary poisoning

Primary poisoning

Not relevant.

Secondary poisoning

Conclusion:

No long- or short-term dietary toxicity for birds has been provided. However, for the $PNEC_{oral,\ bird}$ to fall below the PEC, the NOEC should be lower than the $PEC_{oral,\ bird}$ x 30, and should thus be <0.001 mg/kg feed in case of fish and <0.01 mg/kg feed in case of earthworms. Following a similar reasoning for short-term tests, the LC_{50} should be <0.1 and 1.0 mg/kg feed, respectively (<$PEC_{oral,\ bird}$ x 3000). In view of the absence of acute toxicity to birds at doses up to 1890 mg/kg bw, it is not expected that chronic toxicity levels as low as 0.01 mg/kg feed will be reached.

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

Requirements for storerooms and containers: Keep container tightly closed and dry. Keep in a cool place. Protect from light and heat. Keep away from food, drink and animal feeding stuffs. Keep out of reach of children.
Product is expected to be stable under normal conditions for 2 years.

Recommended methods and precautions concerning handling and transport

Precautions for safe handling:
Use only as directed.
Avoid contact with skin and eyes.
When placing the paper, only touch the edges and untreated parts of paper so contact with the treated areas is avoided.
Do not eat or drink when handling the product.
To prevent contamination of food, do not use in kitchens or other food storage or preparation areas.
Use only in positions inaccessible to children and animals.
Do not allow product to get into surface water, drains and ground water.

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

Suitable extinguishing media: Water fog, foam, extinguishing powder, carbon dioxide

16 https://www.bafu.admin.ch/bafu/en/home/topics/waste/guide-to-waste-a-z/biodegradable-waste/types-of-waste/effluent-sludge.html

Special protective equipment for firefighters: Wear a self-contained breathing apparatus and chemical protective clothing. Do not allow fire water to penetrate into surface or ground water.
Although the active substance contains fluorine, the biocidal product as it is supplied to the user contains only 0.233% active substance. It is considered that although hydrogen fluoride is a potential pyrolysis product, the proportion that is likely to be present in combustion gases would be minor. The rest of the product is mostly composed of paper with [redacted]. The combustion and pyrolysis gases are expected to contain the products of combustion of cellulose and lignin based materials: Typically, these combustion products are mostly oxides of carbon and hydrogen, but other pyrolysis products would be generated on a smaller scale. For example; aromatic derivatives, acroleins, aldehydes and other partially pyrolysed organic species. With reference to substances identified in ISO 19701:2013, it is unlikely that the pyrolysis/combustion products would contain cyanides, oxides or other compounds of sulphur, ammonia, or compounds of antimony, arsenic or phosphorus. It is reasonable to assume that in the case of an accidental fire that no special precautions need to be taken over and above those that would normally be employed by firefighters tackling a household fire.

Particulars of likely direct or indirect adverse effects

Very toxic to aquatic life with long lasting effects

First aid instructions, antidotes

Following skin contact: After contact with skin, wash immediately with soap and plenty of water. Seek medical attention if irritation occurs.
After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Seek medical attention if problems persist.
After swallowing: Rinse mouth immediately and drink plenty of water. Seek medical treatment if symptoms persist.Never give anything by mouth to an unconscious person.
Treat symptomatically.

Emergency measures to protect environment in case of accident

Environmental precautions: Do not allow to penetrate into soil, waterbodies or drains. If necessary notify appropriate authorities.
Methods and material for containment and cleaning up: Take up mechanically, placing in appropriate containers for disposal. Final cleaning.

Control measures of repellents or poison included in the biocidal product, to prevent action against non-target organisms.

The area of use is a closed environment. It excludes the possibility of action on non-target organisms. The product is targeted at cloths moth only and this is the only organism likely to be present in the areas of intended use.

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

Possibility of reuse or recycling

Non-contaminated carton packages (secondary packaging) may be recycled.

Possibility of neutralization of effects

Effects are based on the insecticidal properties of Transfluthrin. Transfluthrin is evaporated during use, there aren't any actions that would neutralize the effects other than the product should be disposed of in accordance with national regulation.

Conditions for controlled discharge including leachate qualities on disposal
Not applicable, as product is expected to be incinerated or disposed of in accordance with national regulation.

Conditions for controlled incineration
Not applicable, incineration is not permitted.

Instructions for safe disposal of the biocidal product and its packaging for different groups of users (relevant for biocidal products only)
Dispose of contents/container in accordance with national regulation. Contact your local council for details.

2.2.10 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorized for the use with other biocidal products.

Not applicable

2.2.11 Comparative assessment

Not applicable

3 ANNEXES

3.1 List of studies for the biocidal product

IUCLID Section No / Reference No	Author(s)	Year	Title Source Report No GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
3.1-01	Anon	2015	Certificate of Analysis (CoA) Biogenius GmbH Study No. Mo5336	Y	Reckhaus
3.4.1-01	Manka, S.	2015	Determination of Content of Active during Product Use of Moth Paper Biogenius GmbH Report No: Mo5286 GLP, unpublished	Y	Reckhaus
3.4.1-02	Manka, S.	2019	Determination of Physico-Chemical Properties and Storage Stability Tests for Moth Paper – 48 Months Interim Report Biogenius GmbH Study Plan No: Mo5336 GLP, unpublished	Y	Reckhaus
4.1-01	Albaya, J. and Curl, M.G.	2015a	Expert Statement on the Explosive Properties of Mothpaper Report no. TSGE_18-022-05_Mothpaper_Exp Not GLP, unpublished	Y	Reckhaus
4.8-01	Albaya, J. and Curl, M.G.	2015b	Expert Statement on the Self-Reactivity of Mothpaper TSGE_18-022-05_Mothpaper_SR Not GLP, unpublished	Y	Reckhaus
4.11-01	Albaya, J. and Curl, M.G.	2015c	Expert Statement on Self-Heating for Mothpaper Formulation TSGE_18-022-05_Mothpaper_SH Not GLP, unpublished	Y	Reckhaus
4.14-01	Albaya, J. and Curl, M.G.	2015d	Expert Statement on the Oxidizing Properties of Mothpaper Report no. TSGE_18-022-05_Mothpaper_Ox Not GLP, unpublished	Y	Reckhaus
IUCLID Section No / Reference No	**Author(s)**	**Year**	**Title Source Report No GLP (where relevant) / (Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
4.16-01	Albaya, J. and Curl, M.G.	2015e	Expert Statement on "Corrosive to Metals" for Mothpaper Formulation TSGE_18-022-05_Mothpaper_CTM	Y	Reckhaus
4.17.2	Ahrens, A.	2015	Auto-flammability (Solids-Determination of Relative Self-Ignition Temperature) A.16 Report No. 20150345.01 GLP, unpublished	Y	Reckhaus

5.1-01	Manka, S.	2015	Validation of Method MV122: REC: GC-Determination of 1R-trans Transfluthrin in Moth Paper Biogenius GmbH Report No: Mo5282 GLP, unpublished Amendment No.1 to Final report Validation of Method MV122: REC: GC-Determination of 1R-trans Transfluthrin in Moth Paper	Y	Reckhaus
6.7	Gundalai, E.	2016	Simulated-use test: Efficacy test against adult and larvae of clothes moths, *Tineola bisselliella* with a Moth Paper. Biogenius GmbH Report No: Mo5278 GLP, unpublished	Y	Reckhaus

3.2 List of new studies generated on the active substance (access provided by a LoA)

Author(s)	Section No. / Reference No.	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes / No)	Owner
Hein, E-M., Junge, T.	7.2.2.1/01	2015	[methylene-14C]transfluthrin: Aerobic Degradation / Metabolism in Four Soils Bayer CropScience unpublished report No: eNsa-15-0550 Bayer CropScience Report No: M-534156-01-1 GLP. Unpublished	Y	Bayer Crop-Science
Reinken, G.; Alt, F.; Heruth, D.	7.2.2.1/02	2015	Transfluthrin (BFT) soil kinetics for modelling - Kinetic evaluation of the degradation of transfluthrin and its metabolite NAK4723 under aerobic laboratory soil conditions Report EnSa-15-0752 Bayer CropScience Report N°: M-534584-01-1 Not GLP - Unpublished	Y	Bayer Crop-Science
Matlock, D., Moore, S.	7.4.1.3	2015	Toxicity of Transfluthrin-Tetrafluorobenzoic acid to the Green Algae Pseudokirchneriella subcapitata During a 96 Hour Exposure SynTech Research Laboratory, USA Bayer CropScience unpublished report No: EBTBN007 Bayer CropScience Report No: M-528046-01-1 GLP. Unpublished	Y	Bayer Crop-Science
Matlock, D., Moore, S.	7.4.3.1	2015	Early Life Stage Toxicity of Transfluthrin Technical to the Fathead minnow (Pimephales promelas) Under Flow-Through Conditions. SynTech Research Laboratory, USA Bayer CropScience unpublished report No: EBTBL007 Bayer CropScience Report No: M-522816-01-1 GLP. Unpublished	Y	Bayer Crop-Science
Matlock, D., Moore, S.	7.4.3.4	2015	Chronic Toxicity of Transfluthrin Technical to Daphnia magna Under Flow-Through Conditions SynTech Research Laboratory, USA Bayer CropScience unpublished report No: EBTBL006 Bayer CropScience Report No: M-522462-01-1 GLP. Unpublished.	Y	Bayer Crop-Science

Author(s)	Section No. / Reference No.	Year	Title Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes / No)	Owner
Kuhl, K.	7.4.3.5.1/01	2015	Chironomus riparius 28-day chronic toxicity test with transfluthrin (tech.) in a water-sediment system using spiked sediment. Bayer CropScience unpublished report No: EBTBL005 Bayer CropScience Report No: M-508598-01-1 GLP. Unpublished.	Y	Bayer Crop-Science
Egeler, P	7.4.3.5.1/02	2015	A study on the chronic toxicity to the sediment dweller Lumbriculus variegatus. ECT Oekotoxikologie GmbH, Germany Bayer CropScience Report No: M-529774-01-1 GLP. Unpublished.	Y	Bayer Crop-Science
Schultz, L.	7.5.1.1	2014	Transfluthrin a.s. (BCS-AW53131): Effects on the activity of soil microflora (Nitrogen transformation test). BioChem agrar GmbH, Germany Bayer CropScience unpublished report No: EBTBL004 Bayer CropScience Report No: M-500036-01-1 GLP. Unpublished	Y	Bayer Crop-Science
Study on-going	7.5.1.3.		Transfluthrin a.s. Effects on the seedling emergence and growth of five species of non-target terrestrial plants (Tier 2). Bayer CropScience, Germany. Study ID.. SE15/030 GLP. Unpublished Study on-going	Y	Bayer Crop-Science
Friedrich, S.	7.5.2.1	2014	Transfluthrin a.s. (BCS-AW53131): Sublethal toxicity to the earthworm Eisenia fetida in artificial soil BioChem agrar GmbH, Germany Bayer CropScience unpublished report No: EBTBL008 Bayer CropScience Report No: M-503247-01-1 GLP. Unpublished.	Y	Bayer Crop-Science
Friedrich, S.	7.5.2.1	2014	Transfluthrin a.s.: Effects on the reproduction of the collembolan Folsomia candida BioChem agrar GmbH, Germany Bayer CropScience unpublished report No: EBTBL002 Bayer CropScience Report No: M-504775-01-1 GLP. Unpublished.	Y	Bayer Crop-Science

3.3 Output tables and calculations for exposure assessment

3.3.1 Exposure assessment for human health

3.3.1.1 Non-professional exposure output report from ConsExpo 4.1

ConsExpo 4.1 report

Report date: 23/09/2015

Compound

Compound name:	Transfluthrin	
CAS number :	118712-89-3	
molecular weight	3.71E2	g/mol
vapour pressure	0.0009	Pascal
KOW		linear

Populations

Adults

body weight	60	kilogram

Children

body weight	24	kilogram

Toddlers

body weight	10	kilogram

Products

"recozit Mottenpapier"

weight fraction compound	0.335	%

Details for scenario: Adults, "recozit Mottenpapier": Adults mixing & loading "recozit Mottenpapier"

Inhalation model: Exposure to vapour: evaporation

weight fraction compound	0.335		%
exposure duration	10	minute	
room volume	1	m3	
ventilation rate	0.6	1/hr	
applied amount	20.1	gram	
release area	5.71	cm2	
application duration	10	minute	
mass transfer rate	1.94E3	m/min	

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	1.25	m3/hour

Dermal model: Direct dermal contact with product: constant rate

weight fraction compound	0.335		%
exposed area	0.082	m2	
contact rate	1	mg/min	
release duration	10	minute	

Uptake model: fraction

uptake fraction	10	%	

Details for scenario: Adults, "recozit Mottenpapier": Adults Application "recozit Mottenpapier"

Inhalation model: Exposure to vapour: evaporation

weight fraction compound	0.335		fraction
exposure duration	5	minute	
room volume	1.5	m3	
ventilation rate	0.3	1/hr	
applied amount	15	gram	
release area	4.28	cm2	
application duration	5	minute	
mass transfer rate	1.9E3	m/min	

Uptake model: Fraction

uptake fraction	1	fraction	
inhalation rate	1.3	m3/hour	

Details for scenario: Children, "recozit Mottenpapier": Child Application "recozit Mottenpapier"

Inhalation model: Exposure to vapour: evaporation

weight fraction compound	0.335		fraction
exposure duration	5	minute	
room volume	1.5	m3	
ventilation rate	0.3	1/hr	
applied amount	15	gram	
release area	4.28		cm2
application duration	5	minute	
mass transfer rate	1.9E3	m/min	

Uptake model: Fraction

uptake fraction	1	fraction	
inhalation rate	1.3	m3/hour	

Details for scenario: Toddlers, "recozit Mottenpapier": Toddler Application "recozit Mottenpapier"

Inhalation model: Exposure to vapour: evaporation

weight fraction compound	0.335		fraction
exposure duration	5	minute	
room volume	1.5	m3	
ventilation rate	0.3	1/hr	
applied amount	15	gram	
release area	4.54		cm2
application duration	5	minute	
mass transfer rate	1.9E3	m/min	

Uptake model: Fraction

uptake fraction	1	fraction	
inhalation rate	1.3	m3/hour	

Details for scenario: Infants, "recozit Mottenpapier": Infant Application "recozit Mottenpapier"

Inhalation model: Exposure to vapour: evaporation

weight fraction compound	0.335		fraction
exposure duration	5	minute	
room volume	1.5	m3	
ventilation rate	0.3	1/hr	
applied amount	15	gram	
release area	4.28		cm2
application duration	5	minute	
mass transfer rate	1.9E3	m/min	

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	0.84	m3/hour

3.3.1.2 Calculations of additional secondary exposure scenarios that eCA considered potentially relevant

Summary table: scenarios			
Scenario number Path of exposure	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
H3. Inhalation exposure	Application	Secondary exposure. Seepage from treated wardrobe/closet	Non-professionals
H4. Dermal exposure	Application	Secondary exposure Wearing clothing from a treated wardrobe/closet	Non-professionals
H5. Oral exposure	Application	Secondary exposure Mouthing of clothing from a treated wardrobe/closet by toddlers	Non-professionals

Scenario H3: Application – Seepage from treated wardrobe/closet into room

An additional secondary inhalation exposure might be relevant during the application phase through seepage from treated wardrobes/closets, drawers, etc. into a room. This scenario has also been mentioned in the ConsExpo factsheet on pest control products.

For this scenario, it was assumed that a steady release of transfluthrin occurs (assumption taken from ESD for PT 18) based on the total active substance in the product and the duration of use, 4 months, in the wardrobe/closet.
The amount of Transfluthrin emitted per hour in 1.5 m^3 wardrobe/closet was calculated as follows: Number of strips x mass of transfluthrin per strip (see mixing and loading calculations) / duration of product use / 24 h/d = 1.5 x 0.03374 g / (4*30 d) / 24 h/d = 1.8 x 10^{-5} g

The Consexpo default value of 0.3 h^{-1} for the ventilation of a sealed area (such as a wardrobe/closet) was then used to determine how much transfluthrin might seep out into a bedroom over a 24 h period.
The calculation of the seepage into the bedroom per hour was performed as follows:
Ventilation rate wardrobe/closet x transfluthrin emitted per hour in 1.5 m^3 wardrobe/closet = 0.3 h^{-1} x 1.8 x 10^{-5} g = 5.46 x 10^{-3} mg/h

Further, assuming a continuous seepage per hour into the bedroom and a ventilation rate of 0.6 h^{-1} of the bedroom itself, a post-ventilation steady state concentration of transfluthrin in the bedroom was calculated to assume long-term exposure:

Summary table: Post-ventilation steady state			
Seepage into room (mg/h)	**Initial concentration in 16 m^3** (mg/m^3)	**Concentration in 16 m^3 room after ventilation 0.6 h^{-1}**	**Hour**
0.00546	0.00034125	0.0001365	1
	0.00047775	0.0001911	2
	0.00053235	0.00021294	3
	0.00055419	0.000221676	4
	0.000562926	0.00022517	5
	0.00056642	0.000226568	6
	0.000567818	0.000227127	7
	0.000568377	0.000227351	8
	0.000568601	0.00022744	9
	0.00056869	0.000227476	10
	0.000568726	0.00022749	11
	0.00056874	0.000227496	12
	0.000568746	0.000227498	13
	0.000568748	0.000227499	14
	0.000568749	0.0002275	15
	0.00056875	0.0002275	16
	0.00056875	0.0002275	17
	0.00056875	0.0002275	18
	0.00056875	0.0002275	19
	0.00056875	0.0002275	20
	0.00056875	0.0002275	21

According to the calculations, the worst-case pre-ventilation steady state concentration of transfluthrin is 5.7×10^{-4} mg/m^3.

Description of Scenario H3: Seepage from treated wardrobe/closet		
This approach involves consideration of the amount of transfluthrin that could seep out of a treated wardrobe/closet. The Consexpo default of 0.3 h^{-1} for the ventilation of a sealed area (such as a wardrobe/closet) was used to determine how much transfluthrin might seep into a room over a 24 h period. It is assumed that a steady release of transfluthrin occurs (ESD for PT18) based on total active substance in the product and a use duration of 4 months in a wardrobe/closet. In addition it is assumed that a steady-state post-ventilation concentration is established by using a constant seepage amount per hour and the default standard ventilation rate of a room. The mass of transfluthrin is taken from the calculations from the mixing and loading model. The default of 100% for inhalation absorption is used.		
	Parameters	Value
Tier 1	Mass of Transfluthrin in strip	0.03374 g
	Size wardrobe/closet	1.5 m^3
	Transfluthrin emitted per hour in 1.5 m^3 wardrobe/closet (steady release over 4 mt, 1.5 strips)	1.8 x 10^{-5} g
	Exposure duration	24 h
	Room volume (small size bedroom)	16 m^3,
	Ventilation rate (wardrobe/closet)	0.3 exchanges per hour
	Seepage into room/h	5.46 x 10^{-3} mg/h
	Ventilation rate (bedroom)	0.6 exchanges per hour
	Post-ventilation steady-state concentration (Excel calculation)	5.7 x 10^{-4} mg/m^3.
	Inhalation uptake	100%
	Body weight (Adult)	60 kg
	Inhalation rate (Adult)	16 m^3/d
	Body weight (Child)	23.9 kg
	Inhalation rate (Child)	12 m^3/d
	Body weight (Toddler)	10 kg
	Inhalation rate (Toddler)	8 m^3/d
	Body weight (Infant)	8 kg
	Inhalation rate (Infant)	5.4 m^3/d

Calculations for Scenario H3: Seepage from treated wardrobe/closet into room

Long-term systemic inhalation:

Adult:	(5.7 x 10-4 mg/m^3) x (16 m^3/d) / (60 kg)	=	0.000152 mg/kg bw/d
Child:	(5.7 x 10-4 mg/m^3) x (12 m^3/d) / (23.9 kg)	=	0.000286 mg/kg bw/d
Toddler:	(5.7 x 10-4 mg/m^3) x (8 m^3/d) / (10 kg)	=	0.000456 mg/kg bw/d
Infant:	(5.7 x 10-4 mg/m^3) x (5.4 m^3/d) / (8 kg)	=	0.000384 mg/kg bw/d

Summary table: H3 Seepage from wardrobe/closet into room, long-term systemic exposure from inhalation, non-professionals				
Exposure scenario H3	**Tier/PPE**	**Estimated inhalation uptake**	**AEL long-term**	**AEL (%)**
Seepage from treated wardrobe/closet: inhalation exposure, adult	Tier 1: no PPE	0.000152 mg a.s./kg bw/day	0.01 mg/kg bw	1.5
Seepage from treated wardrobe/closet: inhalation exposure, child	Tier 1: no PPE	0.000286 mg a.s./kg bw/day	0.01 mg/kg bw	2.86
Seepage from treated wardrobe/closet: inhalation exposure, toddler	Tier 1: no PPE	0.000456 mg a.s./kg bw/day	0.01 mg/kg bw	4.56
Seepage from treated wardrobe/closet: inhalation exposure, infant	Tier 1: no PPE	0.000384 mg a.s./kg bw/day	0.01 mg/kg bw	3.8

Scenario H4: Application – Wearing clothing from a treated wardrobe/closet

The wearing of clothing from a treated wardrobe/closet might be a source of dermal exposure. The worst-case scenario would be dermal exposure of infants, although the exposure of toddlers, children and adults should also be quantified to assess total daily systemic exposure due to exposure from different routes (i.e. inhalation and dermal) and tasks/scenarios from use of the product.

It is assumed that transfluthrin is released from the product in a first-order rate process, in a linear manner over the duration of product use of four months. This linear release per day is in line with the OECD ESD for the environment.

From the mixing and loading calculations, it was calculated that each strip contains 0.03374 g or 33.74 mg of transfluthrin which is used to treat 1 m^3. If this amount of transfluthrin is released steadily over 4 months (amount of time strip is in use), the amount of transfluthrin released per day = 33.74 mg/m^3 / 120 days = 0.281167 mg/m^3/day.

For an extreme worst-case calculation it is assumed that all of the transfluthrin which is evaporated daily per m^3 is adsorbed into the piece of clothing that is to be worn on a particular day. This is considered an extreme worst-case scenario since transfluthrin distributes and adsorbs in the entire wardrobe/closet including the wardrobe/closet itself to be effective against the common clothes moth (larvae and adults).

Furthermore, it is conservatively assumed that half of the transfluthrin is adsorbed on the inside of the clothing, since the inside represents half of the total surface area available on any particular piece of clothing.

Of the transfluthrin that has adsorbed onto the inside surface of the clothing, it is assumed that 20% will leach out onto the skin and become available for dermal absorption (20% is taken from the default for leaching from textiles during washing, in the ESD for PT19; this will also cover leaching due to sweat since washing is considered more than simple skin contact with the clothing).

The dermal absorption value from the Assessment Report of 10% is used. It is assumed that entire skin surface is in contact with the clothing.

Description of Scenario H4: Wearing clothing from a treated wardrobe/closet		
This approach considers the potential for dermal exposure when clothing from a treated wardrobe/closet is worn. It is assumed that transfluthrin is released in a first-order rate process and that the daily evaporated transfluthrin adsorbs only onto the items of clothing that are to be worn on a particular day. Furthermore, it is assumed that 50% of the transfluthrin is adsorbed on the inside of the clothing and that 20% of the adsorbed transfluthrin will be leached to become available for dermal absorption.		
	Parameters	Value
Tier 1	Mass of Transfluthrin released per day	0.281167 mg/m^3
	Amount of Transfluthrin on inside of clothing	50%
	Dermal absorption	10%
	Duration of treatment	4 months
	Amount transfluthrin available for dermal absorption	20%
	Body weight (Adult only)	60 kg
	Body weight (Children only)	23.9 kg
	Body weight (Toddler only)	10 kg
	Body weight (Infant only)	8 kg

The worst-case long-term systemic dermal dose is shown below (DA = dermal absorption):

Adult: (((0.281167 mg/m^3 / 2)*0.2)/(60. kg bw)) x 10% DA = 4.49 x 10^{-5} mg/kg bw/d
Child: (((0.281167 mg/m^3 / 2)*0.2)/(23.9 kg bw) x 10% DA = 1.18 x 10^{-4} mg/kg bw/d
Toddler: (((0.281167 mg/ m^3 / 2)*0.2)/(10 kg bw) x 10% DA = 2.91 x 10^{-4} mg/kg bw/d
Infant: (((0.281167 mg/ m^3 / 2)*0.2)/(8 kg bw) x 10% DA = 3.64 x 10^{-4} mg/kg bw/d

Summary table: H4 Wearing clothing from a treated wardrobe/closet, non-professionals				
Exposure scenario H4	**Tier/ PPE**	**Estimated dermal uptake**	**$AEL_{Long-term}$**	**AEL (%)**
Wearing clothing from a treated wardrobe/closet: dermal exposure, Adult	Tier 1/ no PPE	4.69 x 10^{-5} mg/kg bw/d	0.01 mg/kg bw/d	0.47
Wearing clothing from a treated wardrobe/closet: dermal exposure, Child	Tier 1/ no PPE	1.18 x 10^{-4} mg/kg bw/d	0.01 mg/kg bw/d	1.18
Wearing clothing from a treated wardrobe/closet: dermal exposure, Toddler	Tier 1/ no PPE	2.81 x 10^{-4} mg/kg bw/d	0.01 mg/kg bw/d	2.81
Wearing clothing from a treated wardrobe/closet: dermal exposure, Infant	Tier 1/ no PPE	3.51 x 10^{-4} mg/kg bw/d	0.01 mg/kg bw/d	3.51

Scenario H5: Application – Mouthing of clothing from a treated wardrobe/closet by infants and toddlers

Oral exposure through mouthing of clothing from a treated wardrobe/closet is only considered likely for infants and toddlers. In the Consexpo fact sheet on 'Children's toys', mouthing an item of clothing during the day is mentioned as a relevant scenario, however no default area for mouthing is given. Furthermore, in the Consexpo fact sheet a decline in mouthing is shown between 13.5 months and 18 months of age (Table 8). Therefore, for children mouthing is not expected.

In this scenario, it is assumed that all of the transfluthrin released in one day is adsorbed onto 1 item of infant clothing; all the transfluthrin is adsorbed onto the outside of the clothing (see calculation above for mass of Transfluthrin released per day). According to HEEG opinion 17, the surface area of the trunk and arms of an infant is 1533.4 cm^2 + 582.2= 2115.6 cm^2. Therefore, the available concentration of transfluthrin for infants is calculated as:
0.281167 mg / 2115.6 cm^2 = 0.00013 mg/cm^2
This is considered as the worst-case concentration for infants as all transfluthrin that is released during one day is available for mouthing.

According to HEEG opinion 17, the surface area of the trunk and arms of a toddler is 1795.2 cm^2 + 618.6 cm^2= 2413.8 cm^2. Therefore, the available concentration of transfluthrin for toddlers is calculated as:
0.281167 mg / 2413.8 cm^2 = 0.00012 mg/cm^2
This is considered as the worst-case concentration for toddlers as all transfluthrin that is released during one day is available for mouthing.

Since no default area for mouthing is given in the Consexpo fact sheet or in other relevant sources, a reverse reference scenario was performed. It is assumed that 100% of the transfluthrin is removed by mouthing in any particular area of clothing. The maximum area to be mouthed will be calculated and the likelihood of mouthing occurring during the time the clothing is worn, will be assessed.

Description of Scenario H5: Mouthing of clothing from a treated wardrobe/closet by infants and toddlers		
Oral exposure through mouthing of clothing from treated wardrobe/closet is considered for infants and toddlers through a reverse reference scenario. It is assumed in this scenario, that all the transfluthrin which is released in one day is adsorbed onto one item of infant clothing which will be worn on that particular day. Furthermore, it is assumed that transfluthrin is adsorbed onto the outside of the clothing and that 100% of the adsorbed transfluthrin will be leached by mouthing.		
	Parameters	Value
Reverse reference scenario	Available concentration of transfluthrin	0.00013 mg/cm^2
	Amount leached by mouthing	100%
	AEL chronic	0.01 mg/kg bw/d
	Body weight of infant	8 kg
	Body weight of toddler	10 kg

Calculations for infants:

Maximum tolerable amount available for infants via oral route = $AEL_{long\text{-}term}$ x body weight infant 0.01 mg/kg x 8 kg = 0.08 mg

Maximum area of clothing needed to be mouthed by infant = 0.08 mg / 0.00013 mg/cm^2 = 615 cm^2

Calculations for toddlers:

Maximum tolerable amount available for toddlers via oral route = $AEL_{long\text{-}term}$ x body weight toddler 0.01 mg/kg x 10 kg = 0.1 mg

Maximum area of clothing needed to be mouthed by toddler = 0.1 mg / 0.00012 mg/cm^2 = 828.4 cm^2

Summary table: H5 Mouthing of clothing from a treated wardrobe/closet by infants and toddlers		
Exposure scenario H4	**Tier/PPE**	**Maximum area of clothing needed to be mouthed**
Mouthing of clothing from a treated wardrobe/closet: oral exposure, infants	Tier 1: no PPE	615 cm^2
Mouthing of clothing from a treated wardrobe/closet: oral exposure, toddlers	Tier 1: no PPE	828.4 cm^2

Combined secondary exposure

Summary table: Combined secondary exposure assessment				
Exposure route / Exposure scenario	**Infant**	**Toddler**	**Child**	**Adult**
Inhalation: Using wardrobe/closet	7.9×10^{-4} mg/kg bw/d	9.5×10^{-4} mg/kg bw/d	4.0×10^{-4} mg/kg bw/d	1.6×10^{-4} mg/kg bw/d
Inhalation: Seepage from treated wardrobe/closet	3.84×10^{-4} mg/kg bw/d	4.56×10^{-4} mg/kg bw/d	2.86×10^{-4} mg/kg bw/d	1.52×10^{-4} mg/kg bw/d
Dermal: wearing clothing from treated wardrobe/closet	3.51×10^{-4} mg/kg bw/d	2.81×10^{-4} mg/kg bw/d	1.18×10^{-4} mg/kg bw/d	4.69×10^{-5} mg/kg bw/d
Oral: mouthing of clothing	Reverse reference	Reverse reference	NA	NA
Total	1.53×10^{-3} mg/kg bw/d	1.69×10^{-3} mg/kg bw/d	8.04×10^{-4} mg/kg bw/d	3.59×10^{-4} mg/kg bw/d
$AEL_{Long\text{-}term}$	0.01 mg/kg bw/d	0.01 mg/kg bw/d	0.01 mg/kg bw/d	0.01 mg/kg bw/d
AEL (%)	15.3	16.9	8.0	3.6

3.3.2 Environmental exposure calculations

3.3.2.1 Emission estimate based on simultaneity factors

An estimation provided by the Applicant in a pre-submission to the current PAR on the use of "recozit Mottenpapier" indicated that in a household there would be a maximum of [redacted] With a replacement interval of 4 months this results in the use of [redacted] per household.

To obtain the number of sheets used annually in a single, standard sized town, this use is scaled to the number of households that emit to one STP, considering also a simultaneity factor F_{sim}. The simultaneity factor for a product that is used daily [redacted] according to the table on page 39 of the ESD for PT18. Note that "recozit Mottenpapier" is placed once every four months, but its application as a passive diffuser is daily due to the continuous release of the active substance, so the F_{sim} for daily application is appropriate.

$N_{strips\ per\ town}$ =
$N_{strips\ per\ household}$ x $N_{households\ that\ emit\ to\ one\ STP}$ x F_{sim} =
[redacted]

This number is slightly below the value calculated on the basis of market data [redacted] see Section 2.2.8.2.2), and therefore the use of market data as the more conservative approach is justified.

3.3.2.2 Environmental exposure output report from EUSES 2.1.2

The relevant information from the EUSES 2.1.2 output file for the refined emission scenario *E2* has been included here for informational purposes.

DEFAULTS			
DEFAULT IDENTIFICATION			
General name	Standard Euses 2.1		D
Description	According to TGDs		D
CHARACTERISTICS OF COMPARTMENTS			
GENERAL			
Density of solid phase	2.5	[kg.l-1]	D
Density of water phase	1	[kg.l-1]	D
Density of air phase	1.3E-03	[kg.l-1]	D
Environmental temperature	12	[oC]	D
Standard temperature for Vp and Sol	25	[oC]	D
Temperature correction method	Temperature correction for local distribution		D
Constant of Junge equation	0.01	[Pa.m]	D
Surface area of aerosol particles	0.01	[m2.m-3]	D
Gas constant (8.314)	8.314	[Pa.m3.mol-1.K-1]	D
SUSPENDED MATTER			
Volume fraction solids in suspended matter	0.1	[m3.m-3]	D
Volume fraction water in suspended matter	0.9	[m3.m-3]	D
Weight fraction of organic carbon in suspended matter	0.1	[kg.kg-1]	D
Bulk density of suspended matter	1.15E+03	[kgwwt.m-3]	O
Conversion factor wet-dry suspended matter	4.6	[kgwwt.kgdwt-1]	O
SEDIMENT			
Volume fraction solids in sediment	0.2	[m3.m-3]	D
Volume fraction water in sediment	0.8	[m3.m-3]	D
Weight fraction of organic carbon in sediment	0.05	[kg.kg-1]	D

SOIL			
Volume fraction solids in soil	0.6	[m3.m-3]	D
Volume fraction water in soil	0.2	[m3.m-3]	D
Volume fraction air in soil	0.2	[m3.m-3]	D
Weight fraction of organic carbon in soil	0.02	[kg.kg-1]	D
Weight fraction of organic matter in soil	0.034	[kg.kg-1]	O
Bulk density of soil	1.7E+03	[kgwwt.m-3]	O
Conversion factor wet-dry soil	1.13	[kgwwt.kgdwt-1]	O
STP SLUDGE			
Fraction of organic carbon in raw sewage sludge	0.3	[kg.kg-1]	D
Fraction of organic carbon in settled sewage sludge	0.3	[kg.kg-1]	D
Fraction of organic carbon in activated sewage sludge	0.37	[kg.kg-1]	D
Fraction of organic carbon in effluent sewage sludge	0.37	[kg.kg-1]	D
DEGRADATION AND TRANSFORMATION RATES			
Rate constant for abiotic degradation in STP	0	[d-1]	D
Rate constant for abiotic degradation in bulk sediment	0	[d-1] (12[oC])	D
Rate constant for anaerobic biodegradation in sediment	0	[d-1] (12[oC])	D
Fraction of sediment compartment that is aerated	0.1	[m3.m-3]	D
Concentration of OH-radicals in atmosphere	5E+05	[molec.cm-3]	D
Rate constant for abiotic degradation in bulk soil	0	[d-1] (12[oC])	S
RELEASE ESTIMATION			
Fraction of EU production volume for region	100	[%]	D
Fraction of EU tonnage for region (private use)	10	[%]	D
Fraction connected to sewer systems	80	[%]	D
SEWAGE TREATMENT			
GENERAL			
Number of inhabitants feeding one STP	1E+04	[eq]	D
Sewage flow	200	[l.eq-1.d-1]	D
Effluent discharge rate of local STP	2E+06	[l.d-1]	O
Temperature correction for STP degradation	No		D
Temperature of air above aeration tank	15	[oC]	D
Temperature of water in aeration tank	15	[oC]	D
Height of air column above STP	10	[m]	D
Windspeed in the system	3	[m.s-1]	D
RAW SEWAGE			
Mass of O2 binding material per person per day	54	[g.eq-1.d-1]	D
Dry weight solids produced per person per day	0.09	[kg.eq-1.d-1]	D
Density solids in raw sewage	1.5	[kg.l-1]	D
Fraction of organic carbon in raw sewage sludge	0.3	[kg.kg-1]	D
PRIMARY SETTLER			
Depth of primary settler	4	[m]	D
Hydraulic retention time of primary settler	2	[hr]	D
Density suspended and settled solids in primary settler	1.5	[kg.l-1]	D
Fraction of organic carbon in settled sewage sludge	0.3	[kg.kg-1]	D
ACTIVATED SLUDGE TANK			
Depth of aeration tank	3	[m]	D
Density solids of activated sludge	1.3	[kg.l-1]	D
Concentration solids of activated sludge	4	[kg.m-3]	D
Steady state O2 concentration in activated sludge	2E-03	[kg.m-3]	D
Mode of aeration	Surface		D
Aeration rate of bubble aeration	1.31E-05	[m3.s-1.eq-1]	D
Fraction of organic carbon in activated sewage sludge	0.37	[kg.kg-1]	D
Sludge loading rate	0.15	[kg.kg-1.d-1]	D
Hydraulic retention time in aerator (9-box STP)	6.9	[hr]	O
Hydraulic retention time in aerator (6-box STP)	10.8	[hr]	O
Sludge retention time of aeration tank	9.2	[d]	O
SOLIDS-LIQUIDS SEPARATOR			
Depth of solids-liquid separator	3	[m]	D
Density suspended and settled solids in solids-liquid separator	1.3	[kg.l-1]	D
Concentration solids in effluent	30	[mg.l-1]	D
Hydraulic retention time of solids-liquid separator	6	[hr]	D
Fraction of organic carbon in effluent sewage sludge	0.37	[kg.kg-1]	D

LOCAL DISTRIBUTION

AIR AND SURFACE WATER

Concentration in air at source strength 1 [kg.d-1]	2.78E-04	[mg.m-3]	D
Standard deposition flux of aerosol-bound compounds	0.01	[mg.m-2.d-1]	D
Standard deposition flux of gaseous compounds	4E-04	[mg.m-2.d-1]	S
Suspended solids concentration in STP effluent water	15	[mg.l-1]	D
Dilution factor (rivers)	10	[-]	D
Flow rate of the river	1.8E+04	[m3.d-1]	D
Calculate dilution from river flow rate	No		D
Dilution factor (coastal areas)	100	[-]	D

SOIL

Mixing depth of grassland soil	0.1	[m]	D
Dry sludge application rate on agricultural soil	5E+03	[kg.ha-1.yr-1]	D
Dry sludge application rate on grassland	1000	[kg.ha-1.yr-1]	D
Averaging time soil (for terrestrial ecosystem)	30	[d]	D
Averaging time agricultural soil	180	[d]	D
Averaging time grassland	180	[d]	D
PMTC, air side of air-soil interface	1.05E-03	[m.s-1]	O
Soil-air PMTC (air-soil interface)	5.56E-06	[m.s-1]	D
Soil-water film PMTC (air-soil interface)	5.56E-10	[m.s-1]	D
Mixing depth agricultural soil	0.2	[m]	D
Fraction of rain water infiltrating soil	0.25	[-]	D
Average annual precipitation	700	[mm.yr-1]	D

TEMPERATURE

Environmental temperature, regional scale	12	[oC]	D
Environmental temperature, continental scale	12	[oC]	D
Environmental temperature, moderate scale	12	[oC]	D
Environmental temperature, arctic scale	-10	[oC]	D
Environmental temperature, tropic scale	25	[oC]	D
Enthalpy of vaporisation	50	[kJ.mol-1]	D
Enthalpy of solution	10	[kJ.mol-1]	D

MASS TRANSFER

Air-film PMTC (air-water interface)	3.27E-03	[m.s-1]	S
Water-film PMTC (air-water interface)	4.12E-06	[m.s-1]	S
PMTC, air side of air-soil interface	1.05E-03	[m.s-1]	O
PMTC, soil side of air-soil interface	1.91E-11	[m.s-1]	S
Soil-air PMTC (air-soil interface)	5.56E-06	[m.s-1]	D
Soil-water film PMTC (air-soil interface)	5.56E-10	[m.s-1]	D
Water-film PMTC (sediment-water interface)	2.78E-06	[m.s-1]	D
Pore water PMTC (sediment-water interface)	2.78E-08	[m.s-1]	D

AIR

Atmospheric mixing height	1000	[m]	D
Windspeed in the system	3	[m.s-1]	D
Aerosol deposition velocity	1E-03	[m.s-1]	D
Aerosol collection efficiency	2E+05	[-]	D

SEDIMENT

Sediment mixing depth	0.03	[m]	D

SOIL

Fraction of rain water infiltrating soil	0.25	[-]	D
Fraction of rain water running off soil	0.25	[-]	D

DEPTH

Chemical-dependent soil depth	No		D
Mixing depth natural soil	0.05	[m]	D
Mixing depth agricultural soil	0.2	[m]	D
Mixing depth industrial/urban soil	0.05	[m]	D

CHARACTERISTICS OF PLANTS AND WORMS
PLANTS

Volume fraction of water in plant tissue	0.65	[m3.m-3]	D
Volume fraction of lipids in plant tissue	0.01	[m3.m-3]	D
Volume fraction of air in plant tissue	0.3	[m3.m-3]	D
Correction for differences between plant lipids and octanol	0.95	[-]	D
Bulk density of plant tissue (wet weight)	0.7	[kg.l-1]	D
Rate constant for metabolism in plants	0	[d-1]	D
Rate constant for photolysis in plants	0	[d-1]	D
Leaf surface area	5	[m2]	D
Conductance	1E-03	[m.s-1]	D
Shoot volume	2	[l]	D
Rate constant for dilution by growth	0.035	[d-1]	D
Transpiration stream	1	[l.d-1]	D

WORMS

Volume fraction of water inside a worm	0.84	[m3.m-3]	D
Volume fraction of lipids inside a worm	0.012	[m3.m-3]	D
Density of earthworms	1	[kgwwt.l-1]	D
Fraction of gut loading in worm	0.1	[kg.kg-1]	D

SUBSTANCE
SUBSTANCE IDENTIFICATION

General name	Transfluthrin		S

PHYSICO-CHEMICAL PROPERTIES

Molecular weight	371.2	[g.mol-1]	S
Melting point	32	[oC]	S
Boiling point	242	[oC]	S
Vapour pressure at test temperature	2E-03	[Pa]	S
Temperature at which vapour pressure was measured	25	[oC]	D
Vapour pressure at 25 [oC]	2E-03	[Pa]	O
Octanol-water partition coefficient	5.94	[log10]	S
Water solubility at test temperature	0.057	[mg.l-1]	S
Temperature at which solubility was measured	20	[oC]	S
Water solubility at 25 [oC]	0.0611	[mg.l-1]	O

PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS
SOLIDS-WATER

Chemical class for Koc-QSAR	Non-hydrophobics (default QSAR)		S
Organic carbon-water partition coefficient	5.0119E+04	[l.kg-1]	S
Solids-water partition coefficient in soil	1E+03	[l.kg-1]	O
Solids-water partition coefficient in sediment	2.51E+03	[l.kg-1]	O
Solids-water partition coefficient suspended matter	5.01E+03	[l.kg-1]	O
Solids-water partition coefficient in raw sewage sludge	1.5E+04	[l.kg-1]	O
Solids-water partition coefficient in settled sewage sludge	1.5E+04	[l.kg-1]	O
Solids-water partition coefficient in activated sewage sludge	1.85E+04	[l.kg-1]	O
Solids-water partition coefficient in effluent sewage sludge	1.85E+04	[l.kg-1]	O
Soil-water partition coefficient	1.5E+03	[m3.m-3]	O
Suspended matter-water partition coefficient	1.25E+03	[m3.m-3]	O
Sediment-water partition coefficient	1.25E+03	[m3.m-3]	O

AIR-WATER			
Environmental temperature	12	[oC]	D
Water solubility at environmental temperature	0.0508	[mg.l-1]	O
Vapour pressure at environmental temperature	7.97E-04	[Pa]	O
Sub-cooled liquid vapour pressure	1.28E-03	[Pa]	O
Fraction of chemical associated with aerosol particles	0.0723	[-]	O
Henry's law constant at test temperature	5.86	[Pa.m3.mol-1]	S
Temperature at which Henry's law constant was measured	20	[oC]	S
Henry's law constant at 25 [oC]	12.2	[Pa.m3.mol-1]	S
Henry's law constant at environmental temperature	3.7	[Pa.m3.mol-1]	O
Air-water partitioning coefficient	1.56E-03	[m3.m-3]	O
BIOCONCENTRATION FACTORS			
PREDATOR EXPOSURE			
Bioconcentration factor for earthworms	1.05E+04	[l.kgwwt-1]	O
HUMAN AND PREDATOR EXPOSURE			
Bioconcentration factor for fish	1.78E+03	[l.kgwwt-1]	S
QSAR valid for calculation of BCF-Fish	Yes		O
Biomagnification factor in fish	1	[-]	O
Biomagnification factor in predator	1	[-]	O
DEGRADATION AND TRANSFORMATION RATES			
CHARACTARIZATION			
Characterization of biodegradability	Not biodegradable		D
STP			
Degradation calculation method in STP	First order, standard OECD/EU tests		D
Rate constant for biodegradation in STP	0	[d-1]	O
Total rate constant for degradation in STP	0	[d-1]	O
Maximum growth rate of specific microorganisms	2	[d-1]	D
Half saturation concentration	0.5	[g.m-3]	D
WATER/SEDIMENT			
WATER			
Rate constant for hydrolysis in surface water	1E+06	[d] (DT50,12[oC])	O
Rate constant for photolysis in surface water	1E+06	[d] (DT50)	O
Rate constant for biodegradation in surface water	7	[d] (DT50,20[oC])	S
Total rate constant for degradation in bulk surface water	7	[d] (DT50,20[oC])	O
Rate constant for biodegradation in saltwater	1E+40	[d] (DT50,12[oC])	O
Total rate constant for degradation in bulk saltwater	5E+05	[d] (DT50,12[oC])	O
SEDIMENT			
Rate constant for biodegradation in aerated sediment	14.1	[d] (DT50,20[oC])	S
Total rate constant for degradation in bulk sediment	11.1	[d] (DT50,20[oC])	S
AIR			
Specific degradation rate constant with OH-radicals	0	[cm3.molec-1.s-1]	D
Rate constant for degradation in air	2.4	[d] (DT50)	S
SOIL			
Rate constant for biodegradation in bulk soil	1E+06	[d] (DT50,20[oC])	S
Total rate constant for degradation in bulk soil	1E+06	[d] (DT50,20[oC])	O

REMOVAL RATE CONSTANTS SOIL			
Total rate constant for degradation in bulk soil	1E+06	[d] (DT50,20[oC])	O
Rate constant for volatilisation from agricultural soil	8.15E-06	[d-1]	S
Rate constant for leaching from agricultural soil	1.59E-06	[d-1]	O
Total rate constant for removal from agricultural top soil	1.01E-05	[d-1]	O
Rate constant for volatilisation from grassland soil	1.62E-05	[d-1]	O
Rate constant for leaching from grassland soil	3.19E-06	[d-1]	O
Total rate constant for removal from grassland top soil	1.98E-05	[d-1]	O
Rate constant for volatilisation from industrial soil	3.24E-05	[d-1]	O
Rate constant for leaching from industrial soil	6.38E-06	[d-1]	O
Total rate constant for removal from industrial soil	3.92E-05	[d-1]	O
RELEASE ESTIMATION			
CHARACTERIZATION AND TONNAGE			
High Production Volume Chemical	No		D
Production volume of chemical in EU	0	[tonnes.yr-1]	D
Fraction of EU production volume for region	100	[%]	D
Regional production volume of substance	0	[tonnes.yr-1]	O
Continental production volume of substance	0	[tonnes.yr-1]	O
Volume of chemical imported to EU	0	[tonnes.yr-1]	D
Volume of chemical exported from EU	0	[tonnes.yr-1]	D
Tonnage of substance in Europe	0	[tonnes.yr-1]	O
USE PATTERNS			
PRODUCTION STEPS			
OTHER LIFE CYCLE STEPS			
EMISSION INPUT DATA			
Usage/production title			D
LOCAL			
[INDUSTRIAL USE]			
Local emission to air during episode	1.253E-04	[kg.d-1]	S
Emission to air calculated by special scenario	No		O
Local emission to wastewater during episode	4.763E-06	[kg.d-1]	S
Emission to water calculated by special scenario	No		O
Show this step in further calculations	Yes		O
Intermittent release	No		D
DISTRIBUTION			
SEWAGE TREATMENT			
LOCAL			
[INDUSTRIAL USE]			
INPUT AND CONFIGURATION [INDUSTRIAL USE]			
INPUT			
Use or bypass STP (local freshwater assessment)	Use STP		D
Use or bypass STP (local marine assessment)	Bypass STP		D
Local emission to wastewater during episode	4.763E-06	[kg.d-1]	S
Concentration in untreated wastewater	2.38E-06	[mg.l-1]	O
Local emission entering the STP	4.76E-06	[kg.d-1]	O
CONFIGURATION			
Type of local STP	With primary settler (9-box)		D
Number of inhabitants feeding this STP	1E+04	[eq]	O
Effluent discharge rate of this STP	2E+06	[l.d-1]	O
Calculate dilution from river flow rate	No		O
Flow rate of the river	1.8E+04	[m3.d-1]	O
Dilution factor (rivers)	10	[-]	O
Dilution factor (coastal areas)	100	[-]	O
OUTPUT [INDUSTRIAL USE]			
Fraction of emission directed to air by STP	0.851	[%]	O
Fraction of emission directed to water by STP	19.2	[%]	O
Fraction of emission directed to sludge by STP	79.9	[%]	O
Fraction of the emission degraded in STP	0	[%]	O
Total of fractions	100	[%]	O
Local indirect emission to air from STP during episode	4.05E-08	[kg.d-1]	O
Concentration in untreated wastewater	2.38E-06	[mg.l-1]	O
Concentration of chemical (total) in the STP-effluent	4.57E-07	[mg.l-1]	O
Concentration in effluent exceeds solubility	No		O
Concentration in dry sewage sludge	4.82E-03	[mg.kg-1]	O
PEC for micro-organisms in the STP	4.57E-07	[mg.l-1]	O

LOCAL
[INDUSTRIAL USE]
LOCAL CONCENTRATIONS AND DEPOSITIONS [INDUSTRIAL USE]
AIR

Concentration in air during emission episode	2.48E-08	[mg.m-3]	O
Annual average concentration in air, 100 m from point source	2.48E-08	[mg.m-3]	O
Total deposition flux during emission episode	1.37E-07	[mg.m-2.d-1]	O
Annual average total deposition flux	1.37E-08	[mg.m-2.d-1]	O

WATER, SEDIMENT

Concentration in surface water during emission episode (dissolved)	4.25E-08	[mg.l-1]	O
Concentration in surface water exceeds solubility	No		O
Annual average concentration in surface water (dissolved)	4.25E-08	[mg.l-1]	O
Concentration in seawater during emission episode (dissolved)	2.21E-08	[mg.l-1]	O
Annual average concentration in seawater (dissolved)	2.21E-08	[mg.l-1]	O

SOIL, GROUNDWATER

Concentration in agric. soil averaged over 30 days	7.11E-05	[mg.kgwwt-1]	O
Concentration in agric. soil averaged over 180 days	7.11E-05	[mg.kgwwt-1]	O
Concentration in grassland averaged over 180 days	3.03E-05	[mg.kgwwt-1]	O
Fraction of steady-state (agricultural soil)	0.0362	[-]	O
Fraction of steady-state (grassland soil)	0.0696	[-]	O

LOCAL PECS [INDUSTRIAL USE]
AIR

Annual average local PEC in air (total)	3.48E-08	[mg.m-3]	O

WATER, SEDIMENT

Local PEC in surface water during emission episode (dissolved)	4.25E-08	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in surface water (dissolved)	4.25E-08	[mg.l-1]	O
Local PEC in fresh-water sediment during emission episode	4.64E-05	[mg.kgwwt-1]	O
Local PEC in seawater during emission episode (dissolved)	2.21E-08	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in seawater (dissolved)	2.21E-08	[mg.l-1]	O
Local PEC in marine sediment during emission episode	2.42E-05	[mg.kgwwt-1]	O

SOIL, GROUNDWATER

Local PEC in agric. soil (total) averaged over 30 days	7.11E-05	[mg.kgwwt-1]	O
Local PEC in agric. soil (total) averaged over 180 days	7.11E-05	[mg.kgwwt-1]	O
Local PEC in grassland (total) averaged over 180 days	3.03E-05	[mg.kgwwt-1]	O
Local PEC in pore water of agricultural soil	8.04E-08	[mg.l-1]	O
Local PEC in pore water of grassland	3.43E-08	[mg.l-1]	O
Local PEC in groundwater under agricultural soil	8.04E-08	[mg.l-1]	O

EXPOSURE
SECONDARY POISONING
SECONDARY POISONING [INDUSTRIAL USE]

Concentration in fish for secondary poisoning (freshwater)	3.79E-05	[mg.kgwwt-1]	O
Concentration in earthworms from agricultural soil	3.81E-04	[mg.kg-1]	O
Concentration in fish for secondary poisoning (marine)	1.97E-05	[mg.kgwwt-1]	O
Concentration in fish-eating marine top-predators	3.94E-06	[mg.kgwwt-1]	O

3.4 New information on the active substance

Refer to section for 3.2 for a list of new data generated on the active substance

3.5 Residue behaviour

Residues in animal and human body fluids and tissues are not of concern, since transfluthrin is not classified as toxic or highly toxic. Under normal conditions of use, direct contact with food or feedstuffs of plant or animal origin will not occur, therefore residue studies and supporting methods of analysis are not required. Methods for analysis are available in the Assessment Report to detect the active substance in soil, water, air and can be read across to the formulation, since the nature of the formulation will not affect the methods.

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

Efficacy summaries are available in Section 6.7 of the IUCLID dossier.

3.7 Definitions and dimensions of the product "recozit Mottenpapier" as it is supplied to the user

Parameter	Definition	Dimension	Weight
Strip	1 strip contains 10 pieces of paper	150 mm x 825 mm	14.5 g
Piece of paper	10 pieces of paper form a strip*	150 mm x 82.5 mm	1.45 g
Treated area of a strip	Only the centre area of each strip is treated with the mixture of active/[redacted], i.e. the border is kept untreated.	110 mm x 775 mm, i.e. untreated border is 20 mm on each side and 25 mm on top and bottom of strip.	NA
Packaging of product in a plastic packet	Two strips are supplied in a plastic packet. The plastic packaging is a multilayer foil.	95 mm x 205 mm x 2 mm	38 g
Carton as secondary packaging	22 plastic packets in a carton	210 mm x 97 mm x 105 mm	NA

* Design of future product with perforations after each piece of paper.

3.8 Extrapolation evaporation data and efficacy data for aged product

EFF aged product.pdf

3.9 Confidential annex

3.9.1 Product composition

Information is given in the separate confidential document "Final PAR recozit Mottenpapier_CH_2018 confidential annex".

3.9.2 Information on treated area of a strip of recozit Mottenpapier

Information is given in the separate confidential document "Final PAR recozit Mottenpapier_CH_2018 confidential annex".

3.9.3 Efficacy study setup

Information is given in the separate confidential document "Final PAR recozit Mottenpapier_CH_2018 confidential annex".