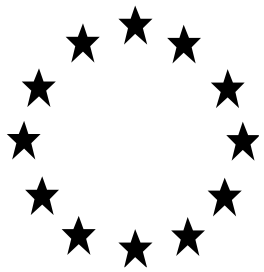
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



VANDAL Mottenhänger

Product type: 18, Insecticide

Active substance name: Transfluthrin

Case Number in R4BP: BC-WJ020446-32

Evaluating Competent Authority: Austria

Date: 18.03.2019

Table of Contents

1 CONCLUSION

The Austrian Competent Authority was responsible for evaluation of the biocidal product VANDAL Mottenhänger.

The ready-to-use product VANDAL Mottenhänger is a combination of the liquid biocidal product which contains 100% (w/w) of the active substance Transfluthrin and the carrier forming the final product. No substances of concern were identified.

The assessment presented in this report has shown the efficacy and no unacceptable risks, if the ready-to-use product, VANDAL Mottenhänger with the active substance Transfluthrin is used as insecticide (product-type 18) for the control of adults and larvae of clothes moths (*Tineola bisselliella*) in wardrobes and drawers according to the directions of use depicted in chapter 2.1.5.1 by non-professional users.

The assessment considered:

- The conclusions and recommendations of the Assessment Report for the approval of the active substance Transfluthrin including the "elements to be taken into account by Member States when authorising products" (The Netherlands, 2014).
- The specific provisions from Inclusion Directive for the active substance Transfluthrin (Regulation (EU) 407/2014).

Approval of the active substance:

The active substance Transfluthrin is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

- In view of the risks for water, sediment and soil compartments, Transfluthrin shall not be used in vaporisers for indoor use or insecticidal coils unless it can be demonstrated in the application for product authorisation that risks can be reduced to an acceptable level.

Composition and formulation:

The ready-to-use passive diffuser VANDAL Mottenhänger comprises the biocidal formulation with the active substance Transfluthrin and an article. Please refer to chapter 2.1.2.3 for further details on the rationale for the conclusion drawn by the eCA. The full composition of the biocidal product and the respective article are given in the confidential Annex.

Physical, chemical and technical properties

The physical-chemical properties and respective characteristics of the biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transport of the biocidal product.

Physical hazards and respective characteristics

As already reported in the AR (The Netherlands, 2014) submitted for active substance approval Transfluthrin does not show any physical hazards. Although it has to be noted, that the carrier material (paper) is a combustible solid.

Methods for detection and identification

Information on the analytical methods for the active substance is provided. The evaluation is based on the residue definitions and action levels derived from the Assessment Report. Analytical methods were described in sufficient detail to meet the information requirements as laid down in annex II of Regulation (EU) No. 528/2012.

Efficacy against target organisms

The product has been shown to be efficacious for the use appropriate for authorisation. The risk of resistance development is reduced if the product is used according to the instructions for use and additionally instructions from chapter 2.2.5.6 are followed.

Risk assessment for human health

The application of the biocidal product resulted in an acceptable risk for non-professional users. Risk characterization ratios for systemic effects for the general public (adults, children, infants and toddlers) were calculated. Based on the risk characterisation considering the worst case approach of 24 hours exposure it can be concluded that no adverse systemic health effects for adults and children are expected. Risks for infants and toddlers were also acceptable, if the residence time was refined to 16.2 hours. Also the scenario of an infant/toddler mouthing a piece of paper resulted in an acceptable risk, after adjustment to an area of 10 m^2 for mouthing. The risk for potential local effects for human health as well as domestic animals is considered acceptable for the use scenario considered in this PAR.

Risk assessment for the environment

Based on the risk assessment it is unlikely that the intended use cause any unacceptable risk for the environment if the directions for use according to chapter 2.1.5.1 are followed.

It can be concluded that all conditions of article 19 of Regulation (EU) No 528/2012 are fulfilled and that the product may be authorised.

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
VANDAL Mottenhänger	Austria

2.1.1.2 Authorisation holder

	Name	Nifra Parfumerie Gesellschaft m.b.H.
	Address	Bräuhausgasse 68 A-1050 Vienna
Authorisation number	AT-0013841-0000	
Date of the authorisation	See authorisation letter	
Expiry date of the authorisation	See authorisation letter	

2.1.1.3 Manufacturer of the products

Name of manufacturer	Nifra Parfumerie Gesellschaft m.b.H.
Address of manufacturer	Bräuhausgasse 68, 1050 Vienna
Location of manufacturing sites	Bräuhausgasse 68, 1050 Vienna

2.1.1.4 Manufacturer of the active substance

Active substance	Transfluthrin
Name of manufacturer	Bayer Crop Science AG
Address of manufacturer	Alfred-Nobel-Straße 50, 40789 Monheim am Rhein, Germany
Location of manufacturing sites	Alfred-Nobel-Straße 50, 40789 Monheim am Rhein, Germany

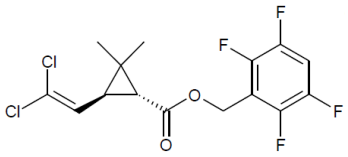
2.1.2 Product composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Transfluthrin
IUPAC or EC name	EC name: 2,3,5,6-tetrafluorobenzyl trans-2-(2,2-dichlorovinyl)-3,3-dimethylcyclopropanecarboxylate IUPAC names[1] 2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate, or, 2,3,5,6-tetrafluorobenzyl (1R)-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	405-060-5
CAS number	118712-89-3
Index number in Annex VI of CLP	607-223-00-8
Minimum purity / content	96.5%
Structural formula	

Transfluthrin (ISO) is produced at a minimum purity of 96.5%, referring to a 1R, trans-configuration. The cis/trans, S-isomers and 1R,cis-isomer are considered impurities (AR Transfluthrin; The Netherlands, 2014).

2.1.2.2 Candidate(s) for substitution

On basis of the provided data the biocidal product "Vandal Mottenhänger" does not contain a candidate active substance for substitution according to Reg. (EU) No 528/2012 Article 10, 1(d).

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

Qualitative information on the biocidal product

The biocidal product, in the form in which it is supplied to the user, consists of a paper strip which has been treated with the active substance Transfluthrin. The paper strip is fan folded (leporello type) and attached to a piece of cardboard which facilitates to attach the paper strip to cloth hangers and the like.

Differentiation between article and biocidal product

The product description indicates that the paper strip can be regarded as carrier for the active substance. Therefore it has to be decided if the paper strip can be regarded as an article or not.

Applying the decision tree as given in chapter 2.3 of the Guidance on requirements for substances in articles (ECHA 2017b) gives the following results:

Step 1	Identify the function of the object: The product is a passive diffuser for indoor use to protect clothes from moths. Released active substance: Transfluthrin.
Step 2	Are shape/surface/design more relevant for the function than the chemical composition? It is not possible to unambiguously conclude
Step 3	Does the object contain a substance/mixture that can be separated from the object? Yes
Question 4a	If the substance/mixture were to be removed or separated from the object and used independently from it, would the substance/mixture still be capable in principle (though perhaps without convenience or sophistication) of carrying out the function defined above? Yes
Question 4b	Does the object act mainly (i.e. according to the function defined under step 1) as a container or carrier for release or controlled delivery of the substance/mixture or its reaction products? Yes
Question 4c	Is the substance/mixture consumed (i.e. used up e.g. due to a chemical or physical modification) or eliminated (i.e. released from the object) during the use phase of the object, thereby rendering the object useless and leading to the end of its service life? Yes
Conclusion	**Object consists of a substance or mixture and an article**

Following the definitions set out in document CA-Nov16-Doc.4.3 – Final, which describes how to handle "carrier" products the product can be seen as Type A product. For type A products it has been agreed that the carrier component should not be considered as a part of the composition of the biocidal product. Therefore it should not be considered for the calculation of the active substance concentration to be indicated in the SPC. Furthermore the hazard and precautionary statements, as well as any other

labelling elements deriving from the CLP Regulation, are based on the classification of the active substance used in the product only.

Quantitative information on the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Transfluthrin	2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate, or, 2,3,5,6-tetrafluorobenzyl (1R)-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	118712-89-3	405-060-5	100

The active substance is applied to a paper strip which serves as carrier.

The paper strip has a dimension of 87.5 x 14.0 cm and contains a nominal concentration of 60 mg Transfluthrin. More details on the product properties are given in the confidential Annex.

2.1.2.4 Information on technical equivalence

The source of the active substances Transfluthrin is the same as the one evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation (EU) No. 528/2012.

2.1.2.5 Information on the substance of concern

As explained in section 2.1.2.3 the biocidal product, in the form in which it is supplied to the user, is a combination of an article and the active substance. Therefore only Transfluthrin has to be considered as a part of the composition of the biocidal product. Since no other co-formulant is used it can be concluded that no substance of concern is present in the biocidal product. Please see the confidential annex for further details.

2.1.2.6 Type of formulation

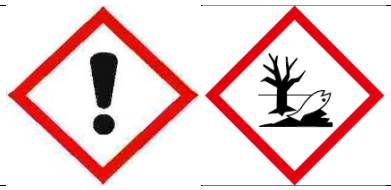
XX: passive diffuser

2.1.3 Hazard and precautionary statements

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

Please note that the biocidal product as supplied to the user is considered as a combination of an article and the active substance. Therefore only the active substance has to be considered for classification and labelling.

Classification	
Hazard category	Skin Irrit. 2, Aquatic Acute 1, Aquatic Chronic 1

Hazard statement	H315: Causes skin irritation H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.
Labelling	
Pictograms	
Signal words	Warning
Hazard statements	H315: Causes skin irritation H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P264: Wash hands thoroughly after handling. P273: Avoid release to the environment. P501: Dispose of contents/container to a special waste collection point in accordance with local/regional/national/international regulation (to be specified)

2.1.4 Authorised use

2.1.4.1 Use description

Table 1. Use # 1 – Insecticide – (adult and larvae) clothes moths – non-professional users – passive diffuser – indoor

Product Type	Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	VANDAL Mottenhänger is an insecticidal product (PT18) used indoor in wardrobes or drawers.
Target organism (including development stage)	Clothes moths (*Tineola bisselliella*) Adult and their larvae
Field of use	Indoor use
Application method(s)	Passive diffuser
Application rate(s) and frequency	1 paper strip per 1 m^3 of wardrobe or drawer for 6 months (1 paper strip contains 60 mg Transfluthrin)
Category(ies) of users	Non-professional user
Pack sizes and packaging material	Please see the relevant section.

2.1.4.2 Use-specific instructions for use

See general directions for use.

2.1.4.3 Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Store only carefully cleaned garments. The VANDAL Mottenhänger is a passive diffuser for the indoor use. It is to be placed inside wardrobes or drawers. Inside the wardrobes it is placed between the cloths by hanging on coat hangers. Use one strip per 1 m³.

For use on shelves or in drawers, place a single sheet between the pieces of laundry. For tall stacks, place two single sheets between the pieces of laundry. The product is intended for the general public (Consumers).

Vandal Mottenhänger is efficacious for 6 months.

2.1.5.2 Risk mitigation measures

Keep the product out of reach of children.

Wash hands after handling VANDAL Mottenhänger.

The product should be applied in such a manner, that pets, food, feedstuff and livestock do not come in contact with the product.

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:
None

First aid instructions:
General: In all cases of doubt, or when symptoms persist, get medical advice.
If on skin: Wash skin off with soap and water.
If in eyes: Rinse immediately with plenty of water at least 15 minutes also under the eyelid.

2.1.5.4 Instructions for safe disposal of the product and its packaging

The unused product must be disposed of as hazardous waste according to national regulations.

The empty packaging of the product and the product after 6 months of use can be disposed of with household waste according to national regulations.

Disposal of product and packaging: waste disposal key: EWC : 20 01 19

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

Store the product in a cool and dry place.

The product may be stored up to 72 months in the original packaging.

Keep away from food and feed.

Storage class: 11 combustible solids

2.1.6 Other information

None

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)
Bag	10 x 17 cm	Cellophane	none the product is sealed in foil	non-professional user	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

The applicant submitted new data (P. Blondaz, 2015) on relevant endpoints and PNEC derivation for environment and ecotoxicity. The data has been evaluated by NL, who is the refMS for Transfluthrin in collaboration with DE and FR. The new data was discussed at the BPC ENV WG-IV-2017 (item 6.6a and 6.6b) and new PNECs based on the results were agreed. For more details and a summary of the evaluation please see section 2.2.8.1.

2.1.8.2 Access to documentation

A letter of access concerning Transfluthrin as approved by Commission Implementing Regulation (EU) No. 1036/2013 as an existing substance for PT 18 has been submitted. The letter of access authorizes the competent authorities to use, refer to and rely on the proprietary data to assess the applicant's application for the authorization of VANDAL Mottenhänger in accordance with Regulation (EU) No. 528/2012 in the product type 18.

2.2 Assessment of the biocidal product

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

Table 2. Intended use # 1 – name of the use

Product Type	18
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Clothes moths Adults and their larvae
Field of use	Indoor use
Application method(s)	Passive diffuser
Application rate(s) and frequency	1 paper strip /m^3 for 6 months
Category(ies) of users	General public, non-professional
Pack sizes and packaging material	Pack size: 10x18 cm

2.2.2 Physical, chemical and technical properties

The biocidal product, in the form in which it is supplied to the user, consists of a paper strip which has been treated with the active substance Transfluthrin. According to the Guidance on requirements for substances in articles (ECHA, 2017b) the biocidal product has to be considered as combination of substance (Transfluthrin) and an article (paper strip). See section 2.1.2.3 for further explanation. As a consequence, with a few exemptions, only the physical, chemical and technical properties of Transfluthrin will be addressed. The data presented in the following, as not stated otherwise, are taken from the respective active substance CAR (The Netherlands, 2014) for which a respective Letter of Access (LoA) has been presented by the applicant.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20°C and 101.3 kPa		99.3% (w/w)	solid	LoA
Colour at 20°C and 101.3 kPa		99.3% (w/w) 99.1% (w/w)	White off-white	LoA
Odour at 20°C and 101.3 kPa		99.3% (w/w) 99.1% (w/w)	Transfluthrin has a toluene-like odour. The biocidal product containing 60 mg Transfluthrin per strip is odourless.	LoA
Acidity / alkalinity	OECD 112		Transfluthrin does not show basic or acidic properties in water	WHO Specifications and evaluation for public health

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				pesticides Report
Relative density / bulk density		99.1% (w/w)	1.3856 (20°C)	LoA
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Paper strips containing biocidal product	No appreciable changes in the appearance (physical state, color, odour) and packaging stability of the test item were observed after storage for 8 weeks at 40°C. The amount of Transfluthrin on the paper strip dropped by 4.96%.	A. Brux (2017)
Storage stability test – **long term storage at ambient temperature**	CIPAC MT 46.3 GIFAP Monograph No. 17	Paper strips containing biocidal product	No appreciable changes in the appearance (physical state, colour, odour) and packaging stability of the test item were observed after storage for 24 months at 20 °C. After 12 months a total loss of app. 7% of Transfluthrin was observed which remained stable within the next 12 month. A statistical evaluation of the data using a moving average model concluded that loss of active substance would still below the 10% cut off even after 60 months of storage.	A. Brux (2017) H. Puxbaum (2017)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			For details see discussion below in section 2.2.2.1	
Storage stability test – **low temperature stability test for liquids**			Not applicable. Transfluthrin is a solid substance.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Not applicable; no absorption above 290 nm	LoA
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			Transfluthrin: Melting Point 32°C and Boiling Point: 242°C. Nearly insoluble in water. No effects expected under normal conditions of storage.	LoA
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			No effects under normal conditions of storage.	
Wettability			Not applicable. Dispersing in water is not an intended use.	
Suspensibility, spontaneity and dispersion stability			Not applicable. Dispersing in water is not an intended use.	
Wet sieve analysis and dry sieve test			Not applicable. Dispersing in water is not an intended use.	
Emulsifiability, re-emulsifiability and emulsion stability			Not applicable. Emulsifying is not an intended use.	
Disintegration time			Not applicable. The biocidal product is neither a tablet nor is	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			disintegration in water an intended use.	
Particle size distribution, content of dust/fines, attrition, friability			Not applicable. The biocidal product is not a powder, Transfluthrin is bound to a carrier material (paper strips)	
Persistent foaming			Not applicable. The product is not applied in water if used as prescribed.	
Flowability/Pourability/Dustability			Not applicable. The biocidal product is not granular. Transfluthrin is bound to a carrier material (paper strips).	
Burning rate — smoke generators			Not applicable. Use of the biocidal product as smoke is not intended.	
Burning completeness — smoke generators			Not applicable. Use of the product as smoke is not intended.	
Composition of smoke — smoke generators			Not applicable. Use of the product as smoke is not intended.	
Spraying pattern — aerosols			Not applicable. Spraying is not an intended use of the product.	
Physical compatibility			Not applicable. The biocidal product should not be co-applied with other substances.	
Chemical compatibility			The biocidal product as supplied to the customer should not be co-applied with	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			other substances. No incompatible materials known.	
Degree of dissolution and dilution stability			Not applicable. Almost water-insoluble. No water soluble bag.	
Surface tension			Surface tension is not applicable. Transfluthrin is a solid substance and is almost insoluble in water 0.057 mg/L at 20°C).	
Viscosity			Solid biocidal product. Viscosity not applicable.	

2.2.2.1 Evaluation of the storage stability study

In the tables below the results and of the accelerated storage at 40°C are summarised.

The results of the long term storage at ambient temperature test show that major loss of the active substance occurs within the first 12 months. Between month 12 and 24 the content of Transfluthrin on the moth paper remains almost stable and amounts to 91.21% at month 24. The data shows that loss of Transfluthrin from the paper is mainly caused by migration of the active substance from the paper into the cellophane foil. The loss of total content of Transfluthrin of the packaged product amounts to 1.98%.

Results of long term storage at ambient temperature (A. Brux, 2017) mean value of 3 samples

compartment	unit	month			
		0	12	18	24
paper+cover	[mg]	59.7	55.4	55.9	55.7
foil	[mg]	1.29	4.17	3.86	4.13
sum	[mg]	61.0	59.6	59.8	59.8

The results of the accelerated storage test at 40 °C gives comparable results. The loss of Transfluthrin from the moth paper amounts to 90.74% at week 8. The loss of total content of Transfluthrin of the packaged product amounts to 2.62%.

Results of accelerated storage at 40 °C (A. Brux, 2017)

mean value of 3 sample

compartment	unit	week	
		0	8
paper+cover	[mg]	59.7	55.4
foil	[mg]	1.3	4.0
sum	[mg]	61.0	59.4

The applicant claimed, that based on the data submitted it can be shown that the product would be stable up to72 months without losing more than 10% of the active substance. A statistical evaluation (A. Puxbaum, 2017) applying a moving average model showed that, even after 72 months the Transfluthrin content of the moth paper would amount to 54.5 mg, which corresponds to 90.83% of the initial concentration, which would still be below the 10% cut off value. The eCA therefore concluded that a shelf life of 72 months can be granted.

Conclusion on the physical, chemical and technical properties of the product
Vandal Mottenhänger is a passive diffuser for indoor use to protect clothes from moths. According to Regulation (EC) No 1907/2006 (REACH Regulation) the biocidal product as supplied to the customer has to be considered as combination of substance and an article. Therefore only the physical, chemical and technical properties of the active substance Transfluthrin has to be considered. Respective data has been taken from the CAR (The Netherlands, 2014) submitted for active substance approval The storage stability for the biocidal product as supplied to the customer has been set to 72 months, based on data and further statistical analysis.

2.2.3 Physical hazards and respective characteristics

As already explained the biocidal product, in the form in which it is supplied to the user a combination of substance (Transfluthrin) and an article (paper strip). As a consequence, with a few exemptions, only the physical hazards of Transfluthrin will be addressed. The data presented in the following, as not stated otherwise, are taken from the respective active substance AR (The Netherlands, 2014) for which a respective Letter of Access (LoA) has been presented by the applicant.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives			Not explosive.	LoA
Flammable gases			Not applicable. Solid.	LoA
Flammable aerosols			Not applicable. Solid.	LoA
Oxidising gases			Not applicable. Solid.	LoA
Gases under pressure			Not applicable. Solid.	LoA
Flammable liquids			Flammable liquid not applicable. Solid substance. Melting point 32°C.	LoA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Flashpoint: 119°C	
Flammable solids			Not classified as a flammable solid. Melting Point 32°C.	LoA
Self-reactive substances and mixtures			Not self-igniting.	LoA
Pyrophoric liquids			Not applicable. Solid substance.	LoA
Pyrophoric solids			Not classified.	LoA
Self-heating substances and mixtures			Not classified as a self-heating substance.	LoA
Substances and mixtures which in contact with water emit flammable gases			Not classified as a substance which in contact with water emit flammable gases.	LoA
Oxidising liquids			Not applicable. Solid substance.	LoA
Oxidising solids			Not classified as oxidising.	LoA
Organic peroxides			Not applicable. Substance do not contain a peroxide group (-O-O-) in the structure.	LoA
Corrosive to metals			Not classified as corrosive to metals.	LoA
Auto-ignition temperatures of products (liquids and gases)			Not applicable. Solid substance.	LoA
Relative self-ignition temperature for solids			Transfluthrin: Melting Point 32°C; Boiling point: 242°C Auto-ignition temperature: 415°C Flashpoint: 119°C	LoA
Dust explosion hazard			Transfluthrin: no dust explosion hazard is	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			reported in the Assessment Report. Whether or not in the present application form (Transfluthrin is bound on paper strips) formation of dust is not possible.	

Conclusion on the physical hazards and respective characteristics of the product
Since the biocidal product, in the form in which it is supplied to the user is a combination of substance and an article only Transfluthrin has to be addressed with regard to physical hazards. As already reported in the CAR (The Netherlands, 2014) submitted for active substance approval Transfluthrin does not show any physical hazards. Although it has to be noted, that the carrier material (paper) is a combustible solid.

2.2.4 Methods for detection and identification

A GLP compliant method for the determination of Transfluthrin in the biocidal product has been submitted by the applicant. The active substance content in the test item has been determined using gas chromatography with flame ionization detection. Validation parameters and acceptance criteria are in compliance with the requirements according to the European Commission document SANCO/3030/99 re. 4 11/07/2000.

The applicant did not submit additional monitoring methods for Transfluthrin. The following information has been taken from the CAR (The Netherlands, 2014) as submitted for active substance approval.

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 (MV057)	4 (standard solution) 2 (test solution)	1.00	Specific, interference from other substances <3% of total	96.5 %		0.75 %	Not required.	BioGenius GmbH, Study No. Mo4435

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
				peak					

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		
Active substance	GC-MS							0.005 mg/kg	GC-ECD method (DFG Method S 19 (extended Revision) DIN EN 12393 AR (The Netherlands, 2014)
An acceptable GC-ECD method (DFG Method S 19 (extended Revision)) is available for the analysis of the active substance in soil. It was tested in one soil type and has an LOQ of 0.005 mg/kg and confirmation is performed by GC-MS.									

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		
Active substance	GC-MS							0.5 µg/m^3	PTRL Europe Study No. 911 G AR (The Netherlands, 2014)
A valid GC-MS method (PTRL Europe Study No. 911 G) is available for the analysis of the active substance in air. This method has an LOQ of 0.5 µg/m^3. The method is considered highly specific as three mass fragments were monitored (target 163 m/z, confirmatory fragments 127 and 143 m/z).									

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		
Active substance	GC-MS							0.05 µg/L	analytical method 01026 AR (The Netherlands, 2014)
A study summary for a GC-MS method (analytical method 01026) to analyse the active substance in surface and in drinking water was submitted. This analytical method is considered to be valid at a LOQ of 0.05 µg/L. The method is considered highly specific as three mass fragments were monitored (target 207 m/z, confirmatory fragments 209 and 211 m/z).									

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		
Methods for analysis of Transfluthrin residues in animal and human body fluids and tissues are not required, since Transfluthrin is not classified as toxic or highly toxic.									

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		
The biocidal products will not be used on any food or feed of plant and/or animal origin. Indirect exposure to Transfluthrin as a result of contamination of food is possible. The estimation of potential exposure of the active substance to humans through diet and other means has been carried out. Worst case intake calculations showed that potential residue levels in food will be negligible. Therefore analytical methods for the analysis of Transfluthrin residues in food or feed of plant and/or animal origin are not required.									

Conclusion on the methods for detection and identification of the product
The active substance content of the moth paper has been determined using gas chromatography with flame ionization detection according to method MV057. Limit of detection and limit of quantitation are not required, because the method will be used only for testing of specification limits.

Validation parameters and acceptance criteria are in conformity with the requirements according to the European Commission document SANCO/330/99 rev. 4 11/07/2000.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

VANDAL Mottenhänger is a passive diffuser for indoor-use in wardrobes to protect clothes against clothes moths.

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

Target organisms: *Tineola bisselliella* (adults and larvae)
Protected object: clothes

2.2.5.3 Effects on target organisms, including unacceptable suffering

Mortality of the clothes moths (larvae and adults) occurs due to hyperexcitation of muscle and nerve cells induced by the active substance in the product formulation.

2.2.5.4 Mode of action, including time delay

Transfluthrin is a member of the pyrethroid family which is according to the IRAC Mode of Action Classification Scheme (IRAC 2016) group 3a. Pyrethroids act as sodium channel modulators. The mode of action comprises of deregulation of nerve and muscle cell membrane permeability to sodium and potassium ions. Affected insects rapidly develop hyperexcitation and tremors, which are followed by paralysis and finally death (T. Narahashi 1971).

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**
Household – Insecticide PT 18	Indoor use Non-professional user	VANDAL Mottenhänger EAN: 9003200100038 is a vapour based product, which works by passive diffusion. When the tight foil is removed from the product, Transfluthri	Clothes moth: *Tineola bisselliella*, strain BioGenius 04, adult, mixed sex and larvae (2nd – 3rd instar), Laboratory strain.	BioGenius Method BPD BioG B 940-03 (modified) Test of an anti-moth product in 0.5 m^3 cabinets: Each product is hung in the cabinet. Pieces of cloth (black lamb's wool,	An amount of ½ a strip (5 paper sheets) of "Vandal Mottenhänger" (3.38 g Transfluthrin/kg) 27.4 mg a.s. was used per 0.5 m^3 cabinet (Addendum Lüpkes). Test points Day 0 (fresh), months 2, 4 and 6	Results: Adults: On average, 100% mortality was achieved by day 3 at the 0 day test point. After 2 months from product activation, 100% mortality was	BIOLOGICAL TEST REPORT: SIMULATED-USE TEST: EFFICACY TEST AGAINST ADULT AND LARVAE OF CLOTHES MOTHS, TINEOLA BISSELLIELLA, WITH

		n starts to evaporate out of the paper into the air.		100% wool) are hung in the cabinet but not in contact with the product. As a control, cabinets not containing test products are used. To simulate cloth, in each cabinet 8 cotton towels (sized 40 x 80 cm) are hung. Prior to the test the Clothes moths (larvae and adults) are exposed to pieces of cloth, taken from their respective cabinets, in their respective containers. Moths and larvae are introduced into the system at the following test points: day 0 and months 2, 4 and 6 after product activation. The adult clothes moths are placed on pieces of cloth (each 5 x 5 cm in size) in their test container. The clothes moth larvae are placed	Test Days per Test point 1, 2, 3, 5, 7, 10 and 14 days after placing insects inside the test cabinet.	achieved within 1 day. After 4 months, 100% was achieved after 2 days. After 6 months, 100% was achieved after 1 day. The number of eggs laid after 1 day was >27 for test day 0, on average, and 14, >30 and >16 for test months 2, 4 and 6, respectively. The number of larvae that hatched by the end was >30 for test day 0, and 12, 11 and 8 for test months 2, 4 and 6, respectively. On average (mode) grub was present at all test days, except for the 6 month test point. Larvae: On average, 100% mortality was achieved by day 10 at the 0 day test point, by day 5 for the 2 month test point and by day 7 for the 4 and 6 month test point. Furthermore	A PRODUCT VANDAL Mottenpapier, BIOGENIUS GMBH, STUDYNO: MO5221 2015-10-28 ADDENDUM: STATEMENT AMOUNT OF ACTIVE INGREDIENT TRANSFLUTHRINPER 0.5 M³ CABINET, STUDY MO5221 PERFORMED BY BIOGENIUS GMBH, REPORTED AS BIO115D-15 AND DATED 2015-10-28

				on pieces of cloth (each 6 x 6 cm in size) in their larvae test boxes. For testing, the cabinets are opened for each test point and respectively after 24 hours and then after 2, 3, 5, 7, 10 and 14 days. The adult moths are evaluated in order to determine the knock-down effect / mortality rate (the number of eggs laid and hatched larvae are counted and the hatched larvae are evaluated for grub). The clothes moths larvae are evaluated for the knock down effect / mortality rate. Also the material is assessed for damage. Cabinets are opened and allowed to aerate for 10 seconds per day to simulate standard usage.		on average (mode) no wool damage was observed in the 2nd month and 6th month.	
Household –	Indoor use Non-	Active substance Transfluthri	Clothes moth: *Tineola*	Guideline 10-2.1 for the testing	Concentrations of 14, 21 and 28 mg active	Results: Adults: 100%	K. MRUSEK (1995)

Insecticide PT 18	professional user	n on paper (moth paper).	*bisselliella*, adult, and larvae (2nd – 3rd instar), Laboratory strain.	of sprays and automatic spray systems against clothes moths Test against clothes moths with the active substance on paper in a test cabinet (0.55 m³). Adult moths were introduced on black fabric and larvae on unbleached woollen fabric. Mortality/Knock-down on adult moths and larvae, Laid eggs and feeding damage was evaluated. The study duration was 26 weeks, after 0,1,2,4,6,8, 12,16,20 and 26 weeks fresh test organisms were introduced in the cabinet.	substance/m³ of wardrobe were tested.	mortality was achieved at all tested time points for all used concentrations (14, 21 and 28 mg/m³) after 1 day of exposure. Number of hatched larvae was 1 for concentration 21 at test point 0 and zero for all used concentrations until week 12. For concentration 14 larvae started to hatch at weeks 12 (5), 16 (5), 20 (1) and 26 (30). For the concentration 21 larvae hatched at week 20 (3) and at week 26 (30). For the concentration 28 larvae hatched at week 26 (3). For all 3 concentrations tested no feeding damage was observed until week 16. For concentration 14 feeding damage occurred from week 16 to 26.	NAK 4455 (TRANSFLUTHRIN) A FAST-ACTING INSECTICIDE FOR USE IN HOUSHOLD AND HYGIENE PRODUCTS. PFLANZEN SCHUTZ-NACHRICHTEN BAYER, SPECIAL EDITION 48. (66) CHAPTER 5.3.1

						For concentration 21 feeding damage occurred only at week 20. No feeding damage was observed for concentration 28. 100% mortality for larvae was achieved after 6–13 days of exposure for all used concentrations at time point 0. Starting from week 1 to 8 all concentrations lead to 100% mortality after 1 day of exposure. For concentration 14 at week 12 after 2 days of exposure 100% mortality was achieved. From week 16–26 mortality decreased from 95% to 65%. For concentration 21 at week 20 after 6 days mortality of 85% was achieved. For concentration 28 100% mortality was	

						achieved after 6 days of exposure at week 20 and 26.	

Conclusion on the efficacy of the product

"VANDAL Mottenhänger" with half a strip (5 sheets of the fanfold paper) per 0.5 m^3 of wardrobe has sufficient efficacy against adult clothes moths and larvae, even significantly affecting the number of larvae that hatch in months 2, 4 and 6. At test day 0 the product was able to achieve 100% mortality within 3 days for adults and 10 days for larvae. After 2 months 100% mortality was achieved after 1 day for adults and 5 days for larvae. After 4 months 100% mortality was achieved after 2 days for adults and 7 days for larvae. After 6 months 100% mortality was achieved after 1 day for adults and 7 days for larvae. Thus fulfilling the requirements of the guidance in force of more than 90% mortality at the end of the exposure time.

A respective laboratory assay displaying the susceptibility of the clothes moth against Transfluthrin applied as passively diffusing agent from a paper is included in a report published in the Pflanzenschutz Nachrichten BAYER (Mrusek, 1995). The tested concentrations of 14, 21 and 28 mg a.s/m^3 of wardrobe showed that at 28 mg a.s./m^3 100% mortality was achieved until the end of the test period after 24h of exposure. Thus, these literature data are used to fulfil the requirement for the biocidal product in this dossier.

2.2.5.6 Occurrence of resistance and resistance management

No known resistance in the target species (clothes moths) has been observed to-date for this active substance (Risk Assessment Report Transfluthrin).

However, resistance against pyrethroids in other insect pests has been observed. In the publication of Tan, J (Tan, J., McCaffery, A.R. (2007))
Resistance to pyrethroids and other types of insecticides in Helicoverpa armigera has been documented. In this study an isogenic metabolic resistance CMR strain was successfully isolated from a field pyrethroid-resistant population of *H. armigera*. With this strain, cross-resistance among 19 pyrethroid insecticides with varying chemical structures was analysed. The resistant strain isolated in the publication showed varying degree of susceptibility to different members of the pyrethroid family. For this dossier relevant was the observation that Transfluthrin still was able to overcome most of the resistance mechanism of the strain.

Management strategies to avoid resistance:

i) Always read the label or leaflet before use and follow all the instructions provided
ii) Adopt integrated pest management methods such as alternation between treatment strategies during the treatment regime (biological, chemical and cultural), taking into account local specificities (climatic conditions, target species, conditions of use, etc.)
iii) The users should report to the authorization holder if the treatment is ineffective

2.2.5.7 Known limitations

None.

2.2.5.8 Evaluation of the label claims

Information given on the label:	**Evaluation**
"wirksam gegen Motten…" (efficous against moths)	Efficacy was demonstrated in a simulated-use test against adults and larvae of clothes moths (*Tineola bisselliella*). The fresh product showed 100% mortality of adult moths after 3 days of exposure and for larvae after 10 days of exposure.
"wirkt zuverlässig 6 Monate lang" (reliable protection during 6 months of use)	Lasting efficacy was demonstrated in a simulated-use test against adults and larvae of clothes moths (*Tineola bisselliella*). The product was kept in the test cabinet for 6 months. The cabinet was aerated regularly. After 2 months the product showed 100% mortality against newly introduced adult moths after 1 day of exposure and larvae after 5 days of exposure. After 4 months 100% mortality was achieved after 2 days for adults and 7 days for larvae. After six months the product demonstrated sufficient lasting efficacy by leading to 100% mortality after 1 day for adults and 7 days for larvae.
"geruchlos" (odourless)	Product is odourless.
"In Kleiderschränken und Läden (in wardrobes and drawers)"	The intended use chapter does not sufficiently describe the place of application envisaged for the product. In the efficacy tests the product has been assessed in representative wardrobes (0.5 m^3) which may be used as proxy for wardrobes and drawers. Furthermore, wardrobes and drawers as place of application have been stated in several chapters throughout the document by the applicant (e.g. use description). Thus, wardrobes and drawers have been amended as claim.

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

Use with other biocidal products is not intended.

2.2.6 Risk assessment for human health

The product "Vandal Mottenhänger" consists of an article (coloured paper) which releases the biocidal product. The biocidal product is only the active substance Transfluthrin. Following information is a summary of the effect assessment concerning human health of Transfluthrin published in the Assessment Report (The Netherlands, 2014).

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to skin.
Justification for the value/conclusion	Testing of the biocidal product (=active substance Transfluthrin) revealed no skin-irritating potential (cf. The Netherlands, 2014). Data submitter has a Letter of Access.
Classification of the product according to CLP	The substance is harmonized classified as skin irritant category 2 (H315) acc. to Annex VI of Regulation (EC) No 1272/2008. The Netherlands will propose a change of the current classification to RAC[1].

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating to eyes.
Justification for the value/conclusion	Testing of the active substance Transfluthrin revealed no irritating potential to eyes (cf. The Netherlands, 2014). Data submitter has a Letter of Access.
Classification of the product according to CLP	According to Regulation (EC) No 1272/2008 no classification for eye irritation is necessary.

1 http://echa.europa.eu/registry-current-classification-and-labelling-intentions/-/substance-rev/1715/term?_viewsubstances_WAR_echarevsubstanceportlet_SEARCH_CRITERIA_EC_NUMBER=405-060-5&_viewsubstances_WAR_echarevsubstanceportlet_DISS=true

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the conclusion	According to Regulation (EC) No 1272/2008 no classification for respiratory tract irritation is necessary (cf. The Netherlands, 2014). Data submitter has a Letter of Access.
Classification of the product according to CLP	Not classified.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitizing to skin.
Justification for the value/conclusion	Transfluthrin does not have sensitising properties in several studies (Buehler, M & K) (cf. The Netherlands, 2014). Data submitter has a Letter of Access.
Classification of the product according to CLP	According to Regulation (EC) No 1272/2008 no classification for sensitization is necessary.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising.
Justification for the value/conclusion	Transfluthrin is not sensitising to skin (cf. The Netherlands, 2014). Data submitter has a Letter of Access.
Classification of the product according to CLP and DSD	According to Regulation (EC) No 1272/2008 no classification for respiratory sensitization is necessary.

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels Type of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks**	**Reference**
OECD 401 (1981)	Mice, NMRI, 5/sex/group mouse	Oral 100, 160, 250, 500, 630, 710, 1000, 1600 and 5000 mg/kg bw (females not exposed to 160 or 1600 mg/kg bw)	symptoms observed were neurological in nature and consisted of: apathy, tremor, prostration (250 mg/kg bw), spasmodic tremor, dyspnoea, and bristling coats (from 250 mg/kg bw)	LD50 (male): 583 mg/kg bw LD_{50} (female): 688 mg/kg bw	Data submitter has a Letter of Access.	The Nether-lands, 2014

Value used in the Risk Assessment – Acute oral toxicity	
Value	Harmful if swallowed
Justification for the selected value	The biocidal product (=active substance Transfluthrin) does not contain any other substances.
Classification of the product according to CLP	The substance has no harmonized classified for H302 acc. to Annex VI of Regulation (EC) No 1272/2008. The Netherlands will propose a change of the current classification to RAC with H302 (Acute Tox. 4).

Acute toxicity by inhalation

Summary table of animal studies on acute inhalation toxicity						
Method, Guideline, GLP status , Reliability	**Species, Strain, Sex, No/group**	**Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD) Actual/nominal concentration, Type of administration**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LC50**	**Remarks**	**Reference**
OECD 403 (1981) EC B.2 (1984) FIFRA § 81-3 (1984)	Rat, Wistar, 5/sex/ group rat	Analytical concentration: 513 mg/m^3 Aerosol (highest achievable), 4 hr exposure	--	>513 mg/m^3	Data submitter has a Letter of Access.	The Netherlands, 2014

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	No classification
Justification for the selected value	Transfluthrin is not acutely toxic by inhalation (cf. The Netherlands, 2014).
Classification of the product according to CLP and DSD	According to Regulation (EC) No 1272/2008 no classification for acute inhalation is necessary.

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity**	**LD50**	**Remarks**	**Reference**
OECD 402 (1987) US EPA OPPTS § 870.1200 (1998) EC B.3 (1992)	dermal	Mice, NMRI, 5/sex/group	--	>4000 mg/kg	Data submitter has a Letter of Access.	The Netherlands, 2014

Value used in the Risk Assessment – Acute dermal toxicity	
Value	No classification
Justification for the selected value	Transfluthrin is not acutely toxic by the dermal route (cf. The Netherlands, 2014).
Classification of the product according to CLP and DSD	According to Regulation (EC) No 1272/2008 no classification for acute dermal toxicity is necessary.

Information on dermal absorption

Dermal absorption of Transfluthrin is assumed to be 10%, on the basis of a MW of 371 and logKow of 5.4, and data from other pyrethroids in other formulations (cf. The Netherlands, 2014). Because the biocidal product consists only of the active substance the same dermal absorption value is applied for risk characterisation.

Assessment of endocrine-disrupting (ED) properties of the active substance in the product concerning human health

The assessment report on Transfluthrin concluded on endocrine disruptive properties that there are currently no indications for endocrine disrupting effects of the a.s. The information sources cited were the Commission staff working document on implementation of the Community Strategy for Endocrine Disrupters (COM (1999) 706) and the overview report incorporating the results from studies conducted with Cyfluthrin or Transfluthrin as part of the US EPA's Endocrine Disruption Screening Program (The Netherlands, 2014).
However this conclusion was reached before Commission Delegated Regulation (EU) 2017/2100 entered into force and may be subject to a revision once the ED evaluation according to the harmonised guidance and criteria is completed at EU level.

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

The biocidal product consists only of the active substance Transfluthrin.
Carrier material: coloured paper is declared as an article.

Available toxicological data relating to a mixture

Not applicable.

Other

A certificate of compliance of the paper and Safety Data Sheets of the pigments of the coloured paper are attached in IUCLID 13.

2.2.6.2 Exposure assessment

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	n.a.	yes	n.a.	n.a.	yes	no
Dermal	n.a.	n.a.	yes	n.a.	n.a.	yes[1]	no
Oral	n.a.	n.a.	no	n.a.	n.a.	yes[1]	no

[1] realistic worst case only

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Handling of the product (Mixing/ loading; Disposal)	**Primary exposure:** Dermal and inhalative exposure during opening the package, removing the foil, if applicable: cutting the paper strips into pieces, placing the paper into the wardrobe / drawers; removal of paper strips and disposal	Non-professional
2.	Use	**Secondary exposure:** Inhalative exposure during the whole application time of 6 months whenever wardrobe is opened. In addition consideration that a.s. may permeate out of the wardrobe through door gaps.	General public
3.	Use	**Secondary exposure:** Oral exposure by infants/toddlers when touching and mouthing a piece of paper (realistic worst case)	General public

Industrial exposure

No industrial exposure foreseen.

Professional exposure

No professional exposure foreseen.

Non-professional exposure

Scenario [1]

Description of Scenario [1]		
The biocidal product is a passive diffuser for indoor use by non-professionals. The product is classified with P102 Keep out of the reach of children to preclude a child is being asked to apply the product. It is placed inside closets and wardrobes (clothes hanging area, shelves, drawers). One paper strip is enough for 1 cubic meter inside the wardrobe. It is placed between the clothes by hanging on coat hanger. For use on shelves or drawers, place a single sheet between the pieces of laundry. The product releases Transfluthrin into the air by evaporation over a 6 month period of use. Handling of the product comprises: opening the package, removing the foil, taking out 1 or 2 paper strips removal of paper strips and disposal. During handling, dermal and inhalative exposure occurs. It is considered that handling of the product takes place for max. 5 minutes per day. The content of a.s. per paper strip is max. 60 mg, the size of one paper strip is 87.5 cm x 14 cm (1225 cm²)		
Dermal exposure		
	Parameters	**Value**
Tier 1	Content of a.s./paper strip[1]	60 mg
	Area of paper strip[1]	1225 cm²
	Transfer coefficient dried fluids[2,6]	0.18 g/g
	Area of palms[2]	410 cm²
	Number of manipulations[3]	2
	Body weight adult[2]	60 kg
	Dermal absorption[4]	10%
	Mean event concentration[7]	0.046 mg/m³
	Inhalation rate adult[2]	1.25 m³/h
	Exposure duration[3]	5 min/day (0.083 h/day)
Reverse reference scenario	AEL $_{acute, dermal}$ [5]	1 mg a.s./kg bw/day
	number of manipulations to achieve AEL$_{acute, dermal}$	**83**
	AEL $_{acute, inhalation}$ [5]	0.17 mg a.s./kg bw/day
	Number of manipulations to achieve AEL$_{acute, inhalation}$	**2129**

[1] Nifra Parfumerie GmbH, Company statement
[2] ECHA 2015c, Biocides Human Health Exposure Methodology v.1 Oct. 2015
[3] Agreed assumption, see The Netherlands, 2014, Assessment Report on Transfluthrin
[4] see chapter 2.2.6.1 of this document
[5] see chapter 2.2.6.3 of this document
[6] The Guidance indicates a transfer coefficient from 8 to 18% of dried fluids from various types of surface. Because no specific percentage is available for paper/cardboard, the transfer coefficient is set at the worst case value of 18%.
[7] Calculated with ConsExpo (cf. RIVM 2012, ConsExpo 5.0 beta), see Appendix 3.2.1

Calculations for Scenario [1]

$$\text{Dermal systemic exposure} = \frac{\text{Content of a. s.} \times \text{Area of palms} \times \text{Transfer coefficient} \times \text{Number of man.} \times \text{Derm. abs.}}{\text{Area of paper strip} \times \text{Body weight} \times 100}$$

$$\text{Inhalative systemic exposure} = \frac{\text{Mean event concentration} \times \text{Exposure duration} \times \text{Inhalation rate}}{\text{Body weight}}$$

Summary table: systemic exposure from non-professional uses (expressed as [mg a.s./kg bw /day)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	Tier 1 / no PPE	0.00008	0.01205	n.a.	0.01213

Further information and considerations on scenario [1]

In ConsExpo, the rationale lying behind the calculation of the mean event concentration is that there is a wardrobe with a room volume of 1.5 m³ (default; Bremmer et al. 2006, Pest Control Products Fact Sheet) and a ventilation rate of 0.3/h (default; Bremmer et al. 2006, Pest Control Products Fact Sheet). The product amount is 90 mg, the vapour pressure of the a.s. is 0.0009 Pa, the molecular weight is 370 g/mol, the application temperature is 25°C and the emission duration is 180 days. The maximum air concentration is limited to the vapour pressure of the pure a.s. Model: Exposure to vapour, evaporation model, model of release: constant rate (The chemical is released with a constant rate in a certain time.)

Information relevant for risk characterisation for local effects:

Considering an a.s. concentration of 60 mg a.s. per 1225 cm² paper, a transfer coefficient of 0.18 g/g for dried fluids and 2 manipulations, the dermal local exposure is **0.017 mg a.s. / cm² skin.**

$$\text{Dermal local exposure} = \frac{\text{Content of a. s.} \times \text{Transfer coefficient} \times \text{Number of man.}}{\text{Area of paper strip}}$$

Combined scenarios:
Not relevant for combination of solely non-professional uses.

Exposure of the general public

Scenario [2]

Description of Scenario [2]		
The moth paper strips are placed in closets and wardrobes. Inhalative exposure may occur during the whole application time of 6 months whenever closets and wardrobes are opened. Closets/wardrobes are not airtight and are often sited in occupied rooms (e.g. bedrooms). Therefore, in addition it is considered that the active substance may permeate out of the wardrobe through door gaps. As realistic worst case it is considered that bedrooms can be occupied (e.g. by people who are ill/invalid) for 24 hours per day for considerable periods. Affected population groups are: infants, toddlers, children and adults. The content of a.s. per paper strip is max. 60 mg.		
	Parameters	**Value**
Tier 1	Mean event concentration[3]	0.046 mg/m³
	Dilution factor bedroom[2,4]	10
	Exposure duration[2]	24 h/day
	Inhalation rate adult[1]	1.25 m³/h
	Body weight adult[1]	60 kg
	Inhalation rate infant[1]	0.84 m³/h
	Body weight infant[1]	8 kg
	Inhalation rate toddler[1]	1.26 m³/h
	Body weight toddler[1]	10 kg
	Inhalation rate child[1]	1.32 m³/h
	Body weight child[1]	23.9 kg
Tier 2	Exposure duration[5]	16.2 h/day

[1] ECHA 2015c, Biocides Human Health Exposure Methodology v.1 Oct. 2015
[2] Agreed assumption, see The Netherlands, 2014, Assessment Report on Transfluthrin
[3] Calculated with ConsExpo (cf. RIVM 2012, ConsExpo 5.0 beta), see Appendix 3.2.1
[4] Considers that the a.s. is "diluted" by permeation of the as. from an 1.5 m³ closet to an 16 m³ bedroom
[5] A residence time of 24 hours per day represents a worst case. A residence time of 18 hours per day is considered to be a more realistic assumption, cf. EC 2007, HUMAN EXPOSURE TO BIOCIDAL PRODUCTS, USER GUIDANCE version 1, part HUMAN EXPOSURE TO WOOD PRESERVATIVES (Product Type 8), chapter 5.4 Chronic Reference Scenarios, scenario 2. This value is used for refinement. Moreover, it is assumed that this residence time is distributed across different rooms which are not treated, and that only max. 90% of the time is spent in treated rooms (expert judgement), resulting in an exposure duration of 16.2h.

Calculations for Scenario [2]

$$\text{Inhalative systemic exposure} = \frac{\text{Mean event concentration} \times \text{Exposure duration} \times \text{Inhalation rate}}{\text{Body weight} \times \text{Dilution factor}}$$

Summary table: systemic exposure from general-public uses (values expressed as [mg a.s./kg bw/day])					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	Tier 1, adult / no PPE	0.002	n.a.	n.a.	**0.002**
Scenario [2]	Tier 1, child / no PPE	0.006	n.a.	n.a.	**0.006**
Scenario [2]	Tier 1, toddler / no PPE	0.014	n.a.	n.a.	**0.014**
Scenario [2]	Tier 1, infant / no PPE	0.012	n.a.	n.a.	**0.012**
Scenario [2]	Tier 2, adult / no PPE	0.002	n.a.	n.a.	**0.002**
Scenario [2]	Tier 2, child / no PPE	0.004	n.a.	n.a.	**0.004**
Scenario [2]	Tier 2, toddler / no PPE	0.009	n.a.	n.a.	**0.009**
Scenario [2]	Tier 2, infant / no PPE	0.008	n.a.	n.a.	**0.008**

Further information and considerations on scenario [2]

In ConsExpo, the rationale lying behind the calculation of the mean event concentration is that there is a wardrobe with a room volume of 1.5 m³ and a ventilation rate of 0.3/h (closet is opened once a day). The biocidal product amount applied for 1.5 m³ is 90 mg, the vapour pressure of the a.s. is 0.0009 Pa, and the emission duration is 180 days. The maximum air concentration is limited to the vapour pressure of the pure a.s.
Model: Exposure to vapour, evaporation model, model of release: constant rate (The chemical is released with a constant rate in a certain time.)
The ConsExpo pest control products fact sheet, chapter 3. Evaporation from strips and cassettes, states, "In the evaporation from pure substance model, it is assumed that only the pure substance, i.e., the active ingredient, is present. The model does not take into account the fact that the active ingredient is caught in a solid matrix. The evaporating surface is adapted to the percentage of active ingredient in the matrix. Using the evaporation from pure substance model, an overestimate of the exposure will be calculated. There is currently no model which better describes the exposure.

Scenario [3]

Description of Scenario [3]		
Secondary exposure: An infant or toddler opens the wardrobe / drawers, takes out the moth paper strip and puts it into the mouth. The content of a.s. per paper strip is max. 60 mg. The scenario is not considered to represent normal use, but a realistic worst case. As in the calculation it is assumed that all of the content of a.s. on the paper is taken up systemically, the step of touching the strip is included in this scenario.		
	Parameters	**Value**
Tier 1	Area of paper strip[2]	1225 cm²
	Content of a.s./paper strip[2]	60 mg
	Surface area of object mouthed[3,4]	50 cm²
	Oral absorption[5]	100%
	Body weight infant[1]	8 kg
	Body weight toddler[1]	10 kg
Tier 2	Surface area of object mouthed[6]	10 cm²

[1] ECHA 2015c, Biocides Human Health Exposure Methodology v.1 Oct. 2015

[2] Nifra Parfumerie GmbH, Company statement

[3] US EPA 2012, Standard Operating Procedures for Residential Pesticide Exposure Assessment, chapter 2.5 (as referenced in Biocides Human Health Exposure Methodology v.1 Oct. 2015)

[4] "Based on the area of hand mouthed by 2-5 years old as reported by Leckie et al. , (2000), and the assumption that children mouth a smaller area of an object than their hand, an exponential distribution with a minimum of 1 cm^2, a mean of 10 cm^2, and a maximum of 50 cm^2 was chosen." (Source: See [3])

[5] Default, see The Netherlands, 2014

[6] As paper is not considered to be palatable, calculating with the mean value of 10 cm² is considered acceptable for refinement of the assessment.

Calculations for Scenario [3]

$$\text{Oral systemic exposure} = \frac{\text{Content of a. s.} \times \text{Surface area of object mouthed} \times \text{Oral absorption}}{\text{Area of paper strip} \times \text{Body weight} \times 100}$$

Summary table: systemic exposure from general-public uses (expressed as [mg a.s./kg bw/day])					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
[3]	Tier 1, toddler / no PPE	n.a.	n.a.	0.245	**0.245**
[3]	Tier 1, infant / no PPE	n.a.	n.a.	0.306	**0.306**
[3]	Tier 2, toddler / no PPE	n.a.	n.a.	0.049	**0.049**
[3]	Tier 2, infant / no PPE	n.a.	n.a.	0.061	**0.061**

Further information and considerations on scenario [3]

None

Combined scenarios

Summary table: combined systemic exposure from non-professional and general public uses (expressed as [mg a.s./kg bw/day])				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1+2, adult, Tier 1]	0.00230 + 0.00008 = 0.00238	0.01205	n.a.	**0.014**

Monitoring data

No data available.

Dietary exposure

The biocidal product will not be used on any food or feed of plant and/or animal origin. Indirect exposure to Transfluthrin as a result of contamination of food is considered unlikely given the fact that the product is not used in kitchens or living room areas. In the active substance assessment, an estimation of potential exposure of the active substance to humans through diet and other means has been carried out. Worst case intake calculations showed that potential residue levels in food will be negligible. (See The Netherlands, 2014, as well as the underlying Document II-B.)

List of scenarios:
Not applicable. No dietary exposure.

Information of non-biocidal use of the active substance
No non-biocidal use is foreseen.

Estimating Livestock Exposure to Active Substances used in Biocidal Products
Livestock exposure is not foreseen.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)
Professional or industrial use is not intended.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

As published in the Transfluthrin Assessment Report: The biocidal products will not be used on any food or feed of plant and/or animal origin. Indirect exposure to Transfluthrin as a result of contamination of food is possible. The estimation of potential exposure of the active substance to humans through diet and other means has been carried out. Worst case intake calculations showed that potential residue levels in food will be negligible.

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

Occupational exposure during production and formulation of the biocidal product is not assessed under the requirements of the BPR. It is assumed that the production is performed in conformity with national and European occupational safety and health regulations.
In addition, production or formulation of biocidal products are already covered by REACH legislation, where the registrants (manufacturers/importers) of substances are obliged to consider human hazard and exposure and to provide RMMs/exposure scenarios for ensuring safe use (e.g. via SDS in the supply chain). Moreover, it is assumed that industrial production sites are subject to permit for installation. Therefore, it is not considered relevant to perform an additional exposure assessment under the biocide regime.

Aggregated exposure

Not applicable.

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 [mg a.s./kg bw/day]**
[1]	Non-professional[1]	Tier 1 / no PPE	adult: 0.012
[2]	General public[2]	Tier 1 / no PPE	infant: 0.012 toddler: 0.014 child: 0.006 adult: 0.002
[2]	General public[2]	Tier 2 / no PPE	infant: 0.008 toddler: 0.009 child: 0.004 adult: 0.002
[3]	General public[1]	Tier 1 / no PPE	infant: 0.306 toddler: 0.245
[3]	General public[1]	Tier 2 / no PPE	infant: 0.061 toddler: 0.049

[1] short-term exposure (acute)
[2] long-term exposure (chronic)

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation (cf. The Netherlands, 2014)

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
$AEC_{acute, inhalation}$	13-week inhalation study, rat	46.7 mg/m³ (equivalent to 17 mg/kg bw/day)	100 (default AF)	No correction.	0.5 mg/m³ (0.17 mg/kg bw/d)
$AEL_{acute, dermal}$	3 week dermal toxicity study rabbit	1000 mg/kg bw/day ($NOAEC_{local}$ 20 mg/kg bw/day)	100 (default AF)	10% dermal absorption	1 mg/kg bw/d
$AEL_{acute, oral}$	3 week, Prenatal Development Toxicity Study, rabbit	15 mg/kg bw/day	100 (default AF)	No correction	0.15 mg/kg bw/d
$AEL_{chronic, oral}$	2-year dietary study rat	1.0 mg/kg bw/day	100 (default AF)	No correction	0.01 mg/kg bw/d

[1] Please explain background and reason for assessment factor.

For Vandal Mottenhänger indirect exposure to Transfluthrin as a result of residues in food is considered negligible. Therefore it is not necessary to determine an ADI and ARfD in line with The Netherlands (2014)[2].

Specific reference value for groundwater

The European standard value of 0.1 µg/l for the maximum admissible concentration of pesticides in drinking water (Council Directive 98/83/EC) does apply. According to Directive 2006/118/EC the groundwater quality standard of 0.1 µg/l does apply for Transfluthrin as well.

[2] The Netherlands (2014): Assessment Report Transfluthrin (insecticides, acaricides and products to control other arthropods), 13 March 2014 https://circabc.europa.eu/sd/a/910c7533-aba6-4a93-87c3-31c5f2b04445/Transfluthrin%20-%20PT18%20(assessment%20report%20as%20finalised%20on%2013.03.2014).pdf

Risk for non-professional users

Systemic effects

The product is only used twice a year and therefore the acute AEL is used for assessing primary exposure. An internal N(O)AEL/starting point needs to be derived in order to assess combined exposure from different routes. Since the acute AEL is actually based on a 13-week inhalation study, even repeated exposure would be covered. Though the exposure routes are dermal and inhalation the AEL for inhalation was chosen for risk characterisation as a conservative estimate. Please note the $AEL_{acute,\ oral}$ is comparable to the $AEL_{acute,\ inhalation}$.

Task/ Scenario	Tier	Systemic NOAEC	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1]	1	46.7 mg/m^3 (=17 mg/kg bw/d)	0.17	0.01208	7.1%	yes

The acute internal systemic exposure is estimated for application of 2 strips in a wardrobe; however a user may treat several wardrobe/closets at the same time. Therefore, a reverse reference scenario was calculated that could help to assess the risk by determining the number of applications a user would need to handle in a day to achieve the acute acceptable exposure level (AEL). The dermal and inhalative systemic exposure for the application of 2 strips is 0.012 mg a.s/kg bw/d and 0.00008 mg a.s/kg bw/d, respectively. Compared with the $AEL_{acute,\ dermal}$ and the $AEL_{acute,\ inhalative}$ one must apply 83 and 2129 strips to exceed the threshold, which seems rather unrealistic.

Risk for the general public

Systemic effects

Inhalative, secondary exposure may occur during the whole application time of 6 months. In contrast to acute neurotoxic effects caused by Transfluthrin liver and kidney effects observed after repeated exposure are likely to be induced by metabolites of Transfluthrin (The Netherlands, 2014) and therefore dermal and inhalatory exposure values can be compared to the $AEL_{chronic,\ oral}$.
Also as a realistic worst case acute oral exposure after ingestion of a piece of strip by infants and toddlers is compared with the $AEL_{acute,\ oral}$.

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[2] adult	1	1	0.01	0.002	20	yes
[2] infant	1	1	0.01	0.012	120	no
[2] toddler	1	1	0.01	0.014	140	no
[2] child	1	1	0.01	0.006	60	yes
[3] toddler	1	15	0.15	0.245	163	no
[3] infant	1	15	0.15	0.306	204	no

Because a risk was identified for infant and toddlers, refinements concerning more realistic exposure duration (residence time of 16.2 h/day) for inhalation and a reduced area of the strip (10 cm^2) for the oral exposure scenario were calculated.

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[2] infant	2	1	0.01	0.008	80	yes
[2] toddler	2	1	0.01	0.009	90	yes
[2] child	2	1	0.01	0.004	40	yes
[3] toddler	2	15	0.15	0.049	33	yes
[3] infant	2	15	0.15	0.061	41	yes

Conclusion

Based on the risk characterisation considering the worst case approach of 24 hours exposure it can be concluded that no adverse systemic health effects for adults and children are expected. However for infants and toddlers risk ratios of above 1 are calculated. Therefore the exposure duration was adjusted to reflect a more realistic scenario of 16.2 hours residence time (max. of 90% of time is spent in the treated room) resulting in an acceptable risk for these sensitive subgroups.
Also the scenario of an infant/toddler mouthing a piece of paper gave, after adjustment to an area of 10 m^2 for mouthing, an acceptable risk.

Local risk assessment

The biocidal product Vandal Mottenhänger is classified for local effects, i.e. skin irritation category 2 according to the harmonized classification of Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation). Until a decision of RAC following the submission of the C&L proposal by The Netherlands is taken (proposing no classification for Transfluthrin concerning skin irritation) compliance with the existing harmonised C&L is legally required until the latter is formally changed by the Commission (cf. CA-May13-Doc.5.4.rev 1 (amended as per CA-March16-Doc.4.1) and CA/35/2013)[3] The existing harmonised C&L will therefore have to be reflected in any biocidal product authorisation granted before the entry into force of the ATP Regulation updating the C&L in Annex VI to the CLP Regulation.

[3] https://www.google.at/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0ahUKEwi9u-mnvZ3NAhUF7xQKHX1iAysQFggrMAE&url=https%3A%2F%2Fcircabc.europa.eu%2Fsd%2Fa%2Fe4e143d0-cae8-41cb-b4b6-c762e6f44622%2FCA-May13-Doc.5.4%2520-%2520Final.rev1%2520-%2520Classification%2520and%2520labelling%2520of%2520biocidal%2520products.doc&usg=AFQjCNFTT0xJbZ9cYLxQV3-EKSiN2pJEiq&bvm=bv.124088155,d.d24

In addition the hazard categorisation of local effects for skin irritation 2 (H315) is low according to ECHA (2015a)[4]. Exposure during normal use is anticipated for the general public. Handling of the product is limited to the mixing and loading task with a low frequency (twice a year) for adults only. Dermal contact is further limited by a short contact time and the type of formulation (active substance =biocidal product is impregnated on a paper strip). The potential exposure route relevant for local effects is skin.

Conclusion
As summarized in the table below the risk for potential local effects is considered as acceptable for the use scenario considered in this PAR.

[4]ECHA (2015a) Guidance on the BPR: Volume III Part B, Risk Assessment, Version 2.3, Oktober 2015 http://echa.europa.eu/de/guidance-documents/guidance-on-biocides-legislation

Risk characterisation for potential local effects: Mixing and loading, and disposal

Hazard		**Exposure**						**Risk**
Hazard Category	Local effects in terms of C&L	Who is exposed?	Tasks, uses, processes	Potential exposure route	frequency and duration of potential exposure	Rough degree of exposure	Relevant RMM & PPE	Conclusion on risk
low	H315 skin irritation	Non-professional	Manual handling of the product (dried fluid) of 60 mg Transfluthrin per strip	Skin	Twice a year (every 6 months), 5 minutes per days	6.97 mg a.s. / palm (0.017 mg a.s. / cm^2 skin x 410 cm^2 area of palm)	Technical and organisational RMM adequate for the hazard category Labelling as skin irritant Washing of hands after use Keep out of the reach of children	Acceptable, since +limited frequency and short duration for handling of product +reversibility of effects +recent data suggest a revision of the existing harmonized classification

Risk for consumers via residues in food

Not applicable. Residues in food are not foreseen if the product is used as intended.

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

Not applicable. The biocidal product is the active substance itself. No further substances of concern included.

Risk characterisation from combined scenarios

Primary and secondary exposure may occur by the exchange of the biocidal product after 6 month usage by an adult, thus acute exposures can be combined with chronic exposure. As this situation will be relevant two times a year, these combinations are considered acute exposures and the short-term AEL will be used for the risk characterisation. The exposure estimates from the chronic exposure scenario adults (Tier 1) is added to the tier 1 exposure estimates for acute exposures. These exposure estimates are based on the scenarios described in this PAR.

Tier	AEL mg/kg bw/d	Estimated uptake acute mg/kg bw/d	Estimated uptake chronic mg/kg bw/d	Combined uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Accept-able (yes/no)
1	0.17	0.01208	0.002	0.01408	8%	yes

Conclusion
The combined scenario of primary and secondary exposure resulted in an acceptable risk for non-professionals/adults.

2.2.7 Risk assessment for animal health

2.2.7.1 Assessment of effects on Animal Health

Domestic pets could be exposed to the biocidal product VANDAL Mottenhänger by inhalation. Therefore a risk characterisation was also performed for dogs and cats.

2.2.7.2 Exposure assessment

Identification of main paths of animal exposure towards active substance(s) and substances of concern from its use in biocidal product

Summary table: relevant paths of animal exposure		
Exposure path	**Secondary (indirect) exposure**	
	Dogs	**Cats**
Inhalation	yes[1]	yes[1]
Dermal	n.a.	n.a.
Oral	n.a.	n.a.

[1] Inhalative exposure is identified as the only relevant exposure of pets (dogs/cats). Other species are not considered in the assessment.

List of scenarios:

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
4.	Use	**Secondary exposure:** Inhalative exposure of domestic pets during the whole application time of 6 months whenever wardrobe is opened. In addition consideration that a.s. may permeate out of the wardrobe through door gaps.	General public

Scenario [4]

Description of Scenario [4]		
See scenario [2] in chapter 2.2.6.2.		
	Parameters	**Value**
Tier 2	All parameters as in Tier 2 of scenario [2] in chapter 2.2.6.2, except:	
	Inhalation rate cat[1]	0.096 m³/h
	Body weight cat[1]	3 kg
	Inhalation rate dog[1]	0.27 m³/h
	Body weight dog[1]	8 kg

[1] W. Engelhardt et al., Physiologie der Haustiere, Enke Verlag 2000; a small dog and a small cat are representing the worst case.

Calculations for Scenario [2]: See scenario [2] in chapter 2.2.6.2.

Summary table: systemic exposure of animals [mg/kg bw/day]					
Exposure scenario	**Tie**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [4]	Tier 2, cat	0.024	n.a.	n.a.	**0.024**
Scenario [4]	Tier 2, dog	0.025	n.a.	n.a.	**0.025**

2.2.7.3 Risk characterisation for animal health

Reference values to be used in Risk Characterisation

Reference	**Study**	**NOAEL (LOAEL)**	**AF[1]**	**Correction for oral absorption**	**Value**
PNEC $_{oral\ mammals}$	2-year dietary study rat	1.0 mg/kg bw/day	30 (default AF)	No correction	0.033 mg/kg bw/d

For the assessment of the risk to domestic pets during the usage of "Vandal Mottenhänger" (chronic exposure) the NOAEL of the 2-year dietary rat study was used as a starting point. According to the ECHA Guidance (2015b, p 148) an AF of 30 was applied to account for interspecies variation and lab-to-field extrapolation. A PNEC $_{oral\ mammal}$ of 0.033 mg/kg bw/d seems appropriate to protect non-targeted mammals including domestic pets from adverse effects caused by Transfluthrin.
Systemic exposure by the inhalation route is compared to this threshold based that route-to-route extrapolation for chronic/repeated exposure situations is possible according to The Netherlands (2014).

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	PNEC oral mammals mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[4] cat	2	1	0.033	0.024	73	yes
[4] dog	2	1	0.033	0.025	76	yes

Conclusion
The estimated exposure based on the assumption of an animal's residence time of 16.2 h/day resulted in acceptable risks for domestic animals. The refinement of 16.2 hour is considered appropriate because it is unlikely that a dog or cat will stay 24 hours a day in the same room.

2.2.8 Risk assessment for the environment

2.2.8.1 Effects assessment on the environment

The active substance Transfluthrin was evaluated according to Regulation (EU) No 528/2012 for the use as insecticide (PT 18). A final Assessment Report (The Netherlands, 2014) agreed by the EU Member States and the European Commission, including a list of endpoints is available. At product authorisation stage several MS (eCA from DE, FR and NL) received new studies for the active substance Transfluthrin. These studies were discussed at the BPC ENV WG-IV-2017 (item 6.6a and 6.6b) and new PNECs based on the results were agreed. An amended list of endpoints for Transfluthrin (LoEP) was agreed at the BPC-24 meeting in march 2018.
The following overview is a summary of the PNEC values, including the newly derived and agreed ones, which were used in the environmental risk assessment:

Transfluthrin:

$PNEC_{STP}$ microorganisms: **0.057 mg/L** (additionally 100 mg/L), (The Netherlands, 2014)

$PNEC_{surface\ water}$: Change from 7.0E-07 mg/l (The Netherlands, 2014) to **1.75E-06 mg/L** (table "Conclusion used in Risk Assessment – Further ecotoxicological studies")

$PNEC_{sediment}$: In the AR for Transfluthrin the $PEC/PNEC_{sed}$ was derived from the $PEC/PNEC_{surface\ water}$ with an additional assessment factor of 10. According to the new data the $PNEC_{sed}$ is 1.64E-03 mg/kg_{dwt}, equivalent to **3.57E-04 mg/kg_{wwt}** (table "Conclusion used in Risk Assessment – Further ecotoxicological studies").

$PNEC_{soil}$: Change from 6.17E-04 mg/kg_{wwt} soil (EPM) (The Netherlands, 2014) to 0.1 mg/kg_{dwt} soil, equivalent to **0.09 mg/kg_{wwt} soil** (table "Conclusion used in Risk Assessment – Further ecotoxicological studies")

$PNEC_{oral,\ mammal}$: **6.67 mg/kg diet** (The Netherlands, 2014)

Metabolites TFB-OH and TFB-COOH:

$PNEC_{surface\ water}$: **0.1 mg/L** (The Netherlands, 2014)

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

Valid effect data for the active substance Transfluthrin are available from the CAR (The Netherlands, 2014) and additional data were submitted at product authorisation stage. Acute and/or chronic toxicity studies with the product VANDAL Mottenhänger were not conducted. Ecotoxicological effects are solely based on the effects of the active substance Transfluthrin.
According to Regulation 1272/2008/EC (0.ATP) the harmonised classification of Transfluthrin for its environmental effects is Aquatic Acute 1, H400, Very toxic to aquatic life and Aquatic Chronic 1, H410 Very toxic to aquatic life with long lasting effects.

Based on the data in the CAR (The Netherlands, 2014) and the new data, Transfluthrin has to be classified with Aquatic Acute 1 (M=1000), H400 and Aquatic Chronic 1 (M=1000). According to the content of Transfluthrin (100% w/w) in the biocidal product the formulation VANDAL Mottenhänger has to be classified as Aquatic Acute 1 and Aquatic Chronic 1. Therefore the biocidal product has to be labelled with the pictogram GHS09, the signal word "Warning", the hazard statement H410 (H400 may be omitted) and the subsequent precautionary statements P273 and P501.

Further Ecotoxicological studies

During the evaluation of the active substance Transfluthrin only acute aquatic and terrestrial toxicity data were available (see LoEP, The Netherlands, 2014).
The applicant additionally submitted a document (Blondaz, 2015) to the eCA with summaries of new additional aquatic chronic and terrestrial toxicity studies. The original study reports were submitted to other MS (DE, FR and NL) at product authorisation stage. These studies are summarised in the tables below, including the new PNEC values agreed at the BPC ENV WG-IV-2017 (for the discussion table see item 6.6a and 6.6b).
The applicant submitted a full letter of access (LoA) for the new submitted data as referred to by Blondaz, 2015 and for the data of Transfluthrin reported in the AR (The Netherlands, 2014).

Summary table - Further ecotoxicological studies

Summary table of further ecotoxicological studies									
Method, Guideline, GLP status, Reliability	Species/ Inocu-lum	End point	Exposure		Results			Remarks	Refe-rence[1]
			Design	Dura-tion	EC_0	EC_{50}	EC_{100}		
OECD 210 and EPA OPPTS 850.1400 (fish early-life stage toxicity test) GLP	*Fathead minnow* (*Pimephales promelas*)	Hatching rate, Mortality, Growth in length and weight, Behaviour, Fish morphology	Flow through	36 d				NOEC: 0.399 µg/l, 399 ng/l (mean measured)	IUCLID section 9
OECD 211 (Reproduction Test under flow-through conditions) GLP	*Daphnia magna*	Survival and Termination time to the first brood, Living neonates per adult, Growth in length and weight, Reproduction	Flow through	21 d				NOEC: 17.5 ng/l based on the number of neonates per adult.	IUCLD section 9

OECD 218 (toxicity test with transfluthrin (tech.) in a water-sediment system using spiked sediment. GLP	*Chironomus riparius*	Emergence rate, Development rate	Spiked sediment	28 d				NOEC: 0.164 mg/kg_{dwt} sed emergence rate and development rate	IUCLID section 9
OECD 203 OECD 225 (Lumbriculus toxicity test using spiked sediment) GLP	*Lumbriculus variegatus*	Survival Reproduction Biomass (dry weight)		28 d				NOEC: 2.21 mg/kg_{dwt} sed EC_{10}: 0.302 mg/kg_{dwt} sed	IUCLID section 9
OECD 222 (Sublethal toxicity to the earthworm Eisenia fetia in artificial soil; GLP	*Eisenia fetida*	Mortality Reproduction Biomass (dry weight)	Four soils	28 d				NOEC: 10 mg /kg_{dwt} soil	IUCLID section 9
OECD 232 Effects on the reproduction of the collembolan Folsomia candida GLP	*Folsomia candida*	Adult mortality Mean number of juveniles per test vessel Reproduction		28 d				Reproduction NOEC: 18 mg/kg $_{dwt}$ soil EC_{10}: 23 mg/kg_{dwt} soil	IUCLID section 9
OECD 216 Effects on the activity of soil microflora (Nitrogen transformation test); GLP	Soil microorganisms	Nitrogen transformation		28 d				NOEC: 3.8 mg/kg_{dwt} soil (nominal)	IUCLID section 9

[1] Please include the reference to IUCLID.

Conclusion used in Risk Assessment – Further ecotoxicological studies	
Value/conclusion	**$PNEC_{aquatic}$, $PNEC_{sed}$, $PNEC_{soil}$**

Justification for the value/conclusion	At the BPC ENV WG-IV-2017 ENV (Final minutes, 6.6a) the new submitted studies for the active substance Transfluthrin were discussed by the MS and several PNECs were refined and agreed. An updated list auf endpoints for Transfluthrin (LoEP) was discussed and agreed at the BPC-24 meeting in march 2018. - the new derived **$PNEC_{surface\ water}$** was set to **1.75E-06 mg/L** on basis of a NOEC of 1.75E-05 mg/L with an AF of 10 - the new derived **$PNEC_{sed}$** was set to 1.64E-03 mg/kg_{dwt} (corresponding to **3.57E-04 mg/kg_{wwt}**) on basis of a NOEC of 0.164 mg/kg_{dwt} with an AF of 100 - the new derived **$PNEC_{soil}$** was set to 0.1 mg/kg_{dwt} (corresponding to **0.09 mg/kg_{wwt}**) on basis of a NOEC of 5.24 mg/kg_{dwt} with an AF of 50

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

No new data has been submitted.

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

No new data has been submitted.

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

No new data has been submitted.

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

No new data has been submitted.

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

The biocidal product is a passive diffuser for indoor use only and is placed inside wardrobes or drawers by hanging on coat hanger between the clothes. The major part of the active substance (90%) will be emitted to air and the remaining 10% will be emitted to the floor. The active substance will not directly reach the environmental compartments surface water (including sediment), groundwater and soil, but indirectly via STP as a result from cleaning of the floor where the active substance has been deposited. The cleaning step will therefore lead to releases to waste water (e.g. through wet cleaning methods). Therefore, in compliance with the ESD for PT18 (OECD, 2008), the compartment primarily

exposed is the STP. Although, under the proposed conditions of use, Transfluthrin will be emitted to air, the concentration in air upon indoor use will not be relevant because of instant dilution (c.f OECD, 2008).

No further substances of environmental concern are present in the product in relevant concentrations. Therefore the provided environmental exposure assessment has been performed only for the active substance Transfluthrin and its major metabolites (TFB-OH and TFB-COOH, detected in maximum levels of 38% and 59% of AR, respectively, in the water phase) and was conducted for the local scale only. The degradation of the active substance Transfluthrin is not taken into account. Information on frequency and intensity of use is outlined in chapter 2.2.8.2 Exposure Assessment.

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

In the AR (The Netherlands, 2014) no experimental data for the biodegradation of Transfluthrin in soil was available. A document with a summary report of a new performed study on aerobic biodegradation of Transfluthrin in soil and an additional kinetic evaluation of this study report was submitted by the applicant. The original study reports were submitted to other MS at product authorisation stage. The applicant submitted a full letter of access (LoA) for the new submitted data and for the data of Transfluthrin reported in the CAR (The Netherlands, 2014).

Summary table on further studies on fate and behaviour in the environment							
Method, Guideline, GLP status, Reliability	Compartment	pH	Temp [°C]	Initial TS concentra-tion, C_0[mol/l]	Half-life, DT_{50} [d] modelled at 20°C	Remarks	Re-ference[1]
OECD 307 GLP and Kinetic evaluation	Soil (4 different soils were tested) Sandy loam (Laacher Hof AXXa) Clay loam (Dollendorf) Silt loam (Hoefchen am Hohenseh) Loam (Wurmwiese)	 6.0 7.3 6.2 5.1	20±2 °C		Soil 1 (sandy loam): 1.3 d Soil 2 clay loam: 0.9 d Soil 3 silt loam: 0.9 d Soil 4 loam: 1.1 d DT_{90}: Soil 1 (sandy loam): 4.26d Soil 2 (clay loam): 3.10d Soil 3 (silt loam): 2.86d Soil 4 (loam): 3.51d	Application rate: 45 µg/kg soil dry weight	IUCLID section 9

[1] Please include the reference to IUCLID.

Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment	
Value/conclusion	**Transfluthrin: DT_{50} = 5.17 d (at 12°C)**
Justification for the value/conclusion	In an Ad hoc-follow up (written procedure) after the BPC ENV WG-IV-2017 the eCA DE raised a proposal on a statistical recalculation of the kinetic data from the soil aerobic degradation study (final minutes on BPC ENV WG-IV-2017 item 6.6a). A DT_{50} of 5.17 d (at 12°C) was agreed by the commenting member states. An amended list of endpoints for Transfluthrin (LoEP) was agreed at the BPC-24 meeting in march 2018.

Leaching behaviour (ADS)

Data on the leaching behaviour of VANDAL Mottenhänger is considered not relevant for the intended use of VANDAL Mottenhänger and thus, is not required.

Testing for distribution and dissipation in soil (ADS)

Summary table of identified relevant metabolites and transformation- or reaction products in soil				
Process	Metabolite/ transformation- or reaction product[2]	[%] of active substance	Remarks Half-lifes DT_{50} [d] modelled at 20°C	Reference[1]
OECD 307 GLP and Kinetic evaluation	2,3,5,6-tetrafluorobenzoic acid (NAK 4723)	Soil 1: 72.9% Soil 2: 66.9% Soil 3: 78.9% Soil 4: 53%	Soil 1: DT_{50}: 1.495d Soil 2: DT_{50}: 1.471d Soil 3: DT_{50}: 1.433d Soil 4: DT_{50}: 1.317d	IUCLID section 9

[1] Please include the reference to IUCLID.

[2] 2,3,5,6-tetrafluorobenzoic acid, TFB-COOH (NAK 4723)

Conclusion used in Risk Assessment – Distribution and dissipation in soil	
Value/conclusion	**Metabolite TFB-COOH: DT_{50} = 3.23 d (at 12°C)** **Formation fraction in soil for TFB-COOH: 0.619**
Justification for the value/conclusion	In an Adhoc-follow up (written procedure) after the BPC ENV WG-IV-2017 the eCA DE raised a proposal on a statistical recalculation of the kinetic data from the soil aerobic degradation study (final minutes on BPC ENV WG-IV-2017 item 6.6a). A DT_{50} of 3.23 d for the metabolite TFB-COOH (at 12°C) and a formation fraction of 0.619 was agreed by the commenting MSs. An amended list of endpoints for Transfluthrin (LoEP) was agreed at the BPC-24 meeting in march 2018.

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

No new data has been submitted.

Testing for distribution and dissipation in air (ADS)

No new data has been submitted.

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)

Since the intended use of VANDAL Mottenhänger is foreseen for indoor use only, no further data are considered necessary. No new data has been submitted.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

The biocidal product is not sprayed and no potential for large scale formation of dust is given. No new data has been submitted.

Assessment of endocrine-disrupting (ED) properties of the active substance in the product concerning environment

In the assessment report for the active substance Transfluthrin (NL, 2014) it was concluded that there are currently no indications for endocrine disrupting effects of the a.s.

Assessment of endocrine-disrupting (ED) properties of the co-formulants in the product

The biocidal product VANDAL Mottenhänger consists to 100% of the active substance only.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenario	Scenario [1]: Mothpaper: VANDAL Mottenhänger is a passive diffuser for indoor use by non-professionals only. It is placed inside closets and wardrobes (clothes hanging area, shelves, wardrobes and drawers). One paper strip is enough for 1 m³ inside the wardrobe. It is placed between the clothes by hanging on coat hanger. For use on shelves or drawers, place a single sheet between the pieces of laundry. The product releases Transfluthrin into the air by evaporation over a 6 month period of use.
ESD used	Emission Scenario Document for Product Type 18 (OECD Series on ESD no. 18): Emission Scenario Document for Insecticides, Acaricides and Products to Control Other Arthropods for Household and Professional Uses, OECD 2008.
Approach	Scenario [1]: Emission scenario for passive diffusor adapted for the particular application conditions of the biocidal product.
Distribution in the environment	Calculation based on Guidance on the Biocidal Products Regulation, Volume IV Environment - Part B Risk Assessment, Version 1.0, April 2015.
Groundwater simulation	The concentration of the active substance in groundwater was estimated via the pore water concentration. No additional simulation for leaching to groundwater is required.
Confidential Annexes	No
Life cycle steps assessed	Scenario [1]: Production: No Formulation: No Use: Yes Service life: No
Remarks	Although, under the proposed conditions of use, Transfluthrin will be emitted to air, the concentration in air upon indoor use will not be relevant because of instant dilution (c.f OECD, 2008).

Emission estimation

Exposure of environmental compartments is calculated on basis of the emission scenario for (passive) diffusors (chapter 3.4.6 Diffusers, OECD, 2008) which proposes a generic scenario for the application step.
The biocidal product is always sold in a ready-to-use form. Therefore, no emission is calculated for the preparation step of diffusers.

Scenario [1]

Calculations for Scenario [*1*]

For the indoor use of VANDAL Mottenhänger indirect emission to the environment is considered via discharge of waste water to the sewage treatment plant (STP) upon cleaning of floors to which part of the active substance has deposited. For the indoor use of diffusers in general, the ESD (OECD, 2008) considers that the major part of the active substance (90%) will be emitted to air and that the remaining 10% will be emitted to the floor. It is then assumed that cleaning of the floor will result in emissions to waste water. The daily emission to one STP is then calculated by correction for the number of houses connected to one STP and for the simultaneous use of the product by different households.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Marine sediment	STP	Air	Soil	Ground-water	Other
Scenario [1]	Yes +	Yes +	No -	No -	Yes ++	Yes (++) (Q)	Yes +	Yes +	No -

++ Compartment directly exposed, + Compartment indirectly exposed, (+) Compartment potentially exposed (but unlikely significant concern due to minimal scale of exposure), (Q) Qualitative assessment, depending on application or substance-specific properties. - Compartment not exposed

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	371.2 [1]	g/mol	Assessment Report
Melting point	32 [1]	°C	Assessment Report
Boiling point	242 [1]	°C	Assessment Report
Vapour pressure	9.00E-04 [1]	Pa (at 20°C)	Assessment Report
Water solubility	0.057 [1]	mg/L (at 20°C)	Assessment Report
Log Octanol/water partition coefficient	5.94 [1]	Log 10	Assessment Report

Organic carbon/water partition coefficient (Koc)	50119 [1]	L/kg	Assessment Report
Henry's Law Constant	5.86 [1]	Pa/m3/mol (at 20°C)	Assessment Report
Biodegradability	Not biodegradable[1]		Assessment Report
Rate constant for STP	0	h^{-1}	Default value
DT_{50} for biodegradation in surface water	7 [1]	d (at 20ºC)	Assessment Report
DT_{50} for hydrolysis in surface water	1.00E06	d (at 12ºC /pH)	Default value
DT_{50} for photolysis in surface water	1.00E06	d	Default value
DT_{50} for degradation in soil	5.17	d (at 12ºC)	Agreed at BPC ENV WG-IV-2017
DT_{50} for degradation in air	2.4 [1]	d	Assessment Report
Bioconcentration factor for earthworms	10452 [1]	L/kgwwt	Assessment Report
Bioconcentration factor for fish	1783 [1]	L/kgwwt	Assessment Report
Biomagnification factor in fish	1	-	Assessment Report

[1] *values extracted from Assessment Report of Transluthrin PT18 (The Netherlands, 2014)*

Calculated PEC values

The Predicted Environmental Concentrations (PECs) were calculated based on the equations presented in ECHA (2015b). The PECs of the major metabolites TFB-OH and TFB-COOH were calculated based on the PECs calculated for the parent multiplied by a formation factor and a correction for the molecular weight.

The BPC ENV WG-I-2018 agreed the value of 1.5 m³ as default value for the size of the wardrobe to be in line with the human expose model ConsExpo. Furthermore, it was agreed that for the assessment of treatment of wardrobes a number of wardrobes per house is equal to 2.5. The assumption behind this value of 2.5 is that the number of dwellers per house was estimated to be 2.5: 10000 dwellers live in 4000 houses in a standard city (10000/4000 = 2.5 dwellers per house). Furthermore, it is assumed that one dweller uses one wardrobe and therefore, 2.5 wardrobes are considered in one house. These moth papers are assumed to be used simultaneously.

The quantity of active substance in the diffusers per household is therefore calculated as follows (intended use: one paper strip is enough for 1 m³, the content of a.s. per paper strip is max. 60 mg):

Q_{AS} = 2.5 x 1.5 m³ x 60 mg = 225 mg a.s.

PEC in air

Under the proposed conditions of use, Transfluthrin will be emitted to air. According to the ESD (OECD, 2008), the concentration in air upon indoor use will not be relevant because of instant dilution. No ecotoxicity data are available based on atmospheric exposures and there is no agreed method available to derive a PECair. Furthermore, Transfluthrin has a vapour pressure of 9.00E-04 Pa at 20°C, indicating relatively low volatility.

PEC in STP

The distribution of the active substance Transfluthrin in the environment after release to the sewer system is calculated according to the distribution indicated by Simple Treat, which is implemented in EUSES 2.1.2.

Calculated fate and distribution in the STP (EUSES 2.1.2, Simple Treat)		
Fractions	**Unit**	**Values**
Fraction of emission directed to air by STP	%	0.851
Fraction of emission directed to water by STP	%	19.2
Fraction of emission directed to sludge by STP	%	79.9
Fraction of the emission degraded in STP	%	0

The calculation for emissions to the floor during application of the biocidal product VANDAL Mottenhänger and routed as waste water to the STP as result from cleaning of the floor, is as follows (OECD, 2008, Section 3.4.6.2 Application step, p. 96):

Resulting local emission of Transfluthrin to the STP (cf. OECD, 2008)				
Scenario Mothpaper: Passive diffuser for indoor use, only placed inside wardrobes or drawers				
Variable/parameter	**Symbol**	**Value**	**Unit**	**S/D/O/P**
Input				
Quantity of active substance in the diffuser	Q_{as} [2]	0.225 [1]	g	S
Maximal duration of use of the diffuser [h]	T_{max}	4320	h	S
Duration of use per day [h]	T_{day}	24	h/d	S
Fraction emitted to the floor, default	$F_{application,floor}$	0.1 [3]	-	D
$\mathbf{E_{application,\ floor} = Q_{as} \times (T_{day}/T_{max}) \times F_{application,\ floor} \times 10^{-3}}$				
Emission to the floor	$E_{application,floor}$	**1.25E-07**	**kg/d**	**O**
Fraction emitted to waste water	F_{ww}	1	-	D

Resulting local emission of Transfluthrin to the STP (cf. OECD, 2008)				
Scenario Mothpaper: Passive diffuser for indoor use, only placed inside wardrobes or drawers				
Variable/parameter	**Symbol**	**Value**	**Unit**	**S/D/O/P**
Cleaning efficiency	F_{ce}	1 [3]	-	D
$E_{treated, ww} = E_{application,floor} \times F_{ww} \times F_{ce}$				
Emission from the treated floor to waste water	$E_{treated,ww}$	**1.25E-07**	**kg/d**	**O**
Number of houses connected to the STP	N_{house}	4000	-	D
Factor to correct for the simultaneous use of the product	$F_{simultaneity}$	0.055 [3]	-	D
$E_{localSTP} = E_{treated,ww} \times N_{house} \times F_{simultaneity}$				
Daily emission to the STP	$E_{localSTP}$	**2.75E-05**	**kg/d**	**O**

[1] *Nifra Parfumerie GmbH 2016, Company statement*

[2] *The formula for calculating the emission to floor in the ESD includes the parameter "Quantity of product in the diffuser" (Qprod) and "Fraction of active in the product" (FAI). For the product under consideration, the quantity of active per paper is given, so Qprod x FAI is replaced by QAI.*

3 These default vaues were agreed at an e-consultation of the ENV WG on the conclusions of the 2nd PT 18 Expert Group meeting (from 20 September to 31 October 2017). The results of this e-consultation were presented at BPC ENV WG-I-2018.

Calculation of the STP influent concentration (*cf.* ECHA, 2015b, equation 32)			
Parameter	**Definition**	**Value**	**Unit**
Local emission rate to wastewater	$Elocal_{water}$	2.75E-05	kg/d
Capacity of the STP	$CAPACITY_{stp}$	10000	eq
Sewage flow per inhabitant	WASTEWinhab	200	l/d*eq
Effluent discharge rate	$EFFLUENT_{stp}$ = $CAPACITY_{stp}$ x WASTEWinhab	2000000	l/d
Cumulative concentration in untreated wastewater	$Clocal_{inf} = \frac{Elocal_{watersim} \times 10^6}{EFFLUENT_{stp}}$	**1.38E-05**	**mg/L**

Calculation of the STP effluent concentration (*cf.* ECHA, 2015b, equation 33)			
Parameter	**Definition**	**Value**	**Unit**
Cumulative concentration in untreated wastewater	$Clocal_{inf}$	1.38E-05	mg/L
Fraction of emission directed to water by STP	$Fstp_{water}$	0.192	-
Concentration of substance in the STP effluent (PEC_{STP})	**$Clocal_{eff}$ = $Clocal_{inf}$ x $Fstp_{water}$**	**2.65E-06**	**mg/L**

The parameter $Clocal_{eff}$ can be regarded as the PEC_{STP} of Transfluthrin (cf. ECHA, 2015b, equation 38), under the prerequisite that only the dissolved concentration is bioavailable, i.e., it is the actual concentration to which the microorganisms in a sewage treatment plant are exposed to.

PEC in surface water

The effluent of the sewage treatment plant is diluted into the surface water. For the calculation of Predicted Environmental Concentrations for this compartment complete mixing of the effluent in surface water is assumed. Because of the short distance between the point of effluent discharge and the exposure location, volatilisation, degradation and sedimentation are ignored.
In order to assess the adsorption to suspended matter, the solid-water partition coefficient (Kp_{susp}) is calculated from the K_{OC} value. A default value of 0.1 kg/kg for Foc_{susp} (according to ECHA, 2015b, Chapter 2.3.4, table 5) and a K_{OC} value of 50119 L/kg are used for the calculation.

Calculation of the partition coefficient solid-water in suspended matter (*cf.* ECHA, 2015b, equation 23)			
Parameter	**Definition**	**Value**	**Unit**
Weight fraction organic carbon in susp. solids	Foc_{susp}	0.1	kg/kg
Partition coefficient organiccarbon-water	K_{OC}	50119	L/kg
Partition coefficient solid-water in suspended matter	**Kp_{susp} = Foc_{susp} x K_{OC}**	**5011.9**	**L/kg**

The resulting Kp_{susp} is used to calculate the local concentration in surface water ($Clocal_{water}$ corresponding to $PEC_{surface\ water}$). According to the BPR (ECHA, 2015b), a default value of 15 mg/L is taken for the concentration of suspended matter in the river ($SUSP_{water}$) and a dilution factor of 10 is used.

Calculation of the $Clocal_{water}$ concentration (corresponding to $PEClocal_{water}$) for Transfluthrin (*cf.* ECHA, 2015b, equation 45)			
Parameter	**Definition**	**Value**	**Unit**
Concentration of substance in the STP effluent	$Clocal_{eff}$	2.65E-06	mg/L
Solids-water partitioning coefficient of suspended matter	Kp_{susp}	5011.9	L/kg
Concentration of suspended matter in the river	$SUSP_{water}$	15	mg/L
Dilution factor	DILUTION	10	-
Local concentration in surface water during emission episode (PEC_{water})	$\mathbf{Clocal_{water} = Clocal_{eff} \times ((1+Kp_{susp} \times SUSP_{water} \times 10^{-6}) \times DILUTION)^{-1}}$	**2.46E-07**	**mg/L**

The calculated $Clocal_{water}$ concentrations correspond to the $PEClocal_{water}$ in the case of non-existing background concentrations.

PEC in sediment

Following ECHA (2015b) the PEC in sediment is assessed for freshly deposited sediments. Therefore, the properties of suspended matter are used. Accordingly, the bulk density of (wet) suspended matter (RHO_{susp}) and the suspended matter-water partitioning coefficient ($K_{susp\text{-}water}$) are calculated respectively, and the PEClocal for sediment is assessed.

The bulk density of (wet) suspended matter (RHO_{susp}) is calculated taking the following default values: 0.1 m^3/m^3 for $Fsolid_{susp}$ (fraction solids in suspended matter), 2500 kg/m^3 for RHOsolid (bulk density of the solid phase), 0.9 m^3/m^3 for $Fwater_{susp}$ (fraction water in suspended matter) and 1000 kg/m^3 for RHO_{water} (density of the water phase).

Calculation of RHO_{susp} (*cf.* ECHA, 2015b, equation 18)			
Parameter	**Definition**	**Value**	**Unit**
Fraction solids in suspended matter	$Fsolid_{susp}$	0.1	m^3/m^3
Bulk density of the solid phase	RHO_{solid}	2500	kg/m^3
Fraction water in suspended matter	$Fwater_{susp}$	0.9	m^3/m^3
Density of the water phase	RHO_{water}	1000	kg/m^3
Bulk density of (wet) suspended matter	$RHOsusp = Fsolid_{susp} \times RHO_{solid} + Fwater_{susp} \times RHO_{water}$	**1150**	**kg/m^3**

The suspended matter-water partitioning coefficient ($K_{susp\text{-}water}$) is derived taking default values of 0.9 m^3/m^3 for $Fwater_{susp}$, 0.1 m^3/m^3 for $Fsolid_{susp}$ and 2500 kg/m^3 for RHO_{solid}. The Kp_{susp} figure is taken from above.

Calculation of $K_{susp\text{-}water}$ (*cf.* ECHA, 2015b, equation 24)			
Parameter	**Definition**	**Value**	**Unit**
Fraction water in suspended matter	$Fwater_{susp}$	0.9	m^3/m^3
Fraction solids in suspended matter	$Fsolid_{susp}$	0.1	m^3/m^3
Partition coefficient solid-water in suspended matter	Kp_{susp}	5011.9	L/kg
Density of the solid phase	RHOsolid	2500	kg/m^3
Suspended matter-water partitioning coefficient	$K_{susp\text{-}water} = Fwater_{susp} + Fsolid_{susp} \times \frac{Kp_{susp}}{1000} \times RHOsolid$	**1253.88**	m^3/m^3

Calculation of PEClocal in sediment (*cf.* ECHA, 2015b, equation 50)			
Parameter	**Definition**	**Value**	**Unit**
Concentration in surface water during emission episode	$PEClocal_{water}$	2.46E-07	mg/L
Suspended matter-water partitioning coefficient	$K_{susp\text{-}water}$	1253.88	m^3/m^3
Bulk density of suspended matter	RHO_{susp}	1150	kg/m^3
Predicted Environmental Concentration in sediment (PEC_{sed})	**$PEClocal_{sed} = (K_{susp\text{-}water} / RHO_{susp}) \times PEClocal_{water} \times 1000$**	**2.68E-04**	**mg/kg**

PEC in soils

PEC in soil via the application of STP sludge (indirect exposure)
Soil contamination can arise indirectly, via the application of STP sludge; hence, the concentration in STP sludge has to be assessed at first.
The rate of sewage sludge production (SLUDGERATE) is estimated from the outflows of primary and secondary sludge. The following default values were chosen: 0.45 kg/m³ for $SUSPCONC_{inf}$ (concentration of suspended matter in STP influent), 0.019[5] kg/d for SURPLUSsludge (surplus sludge per inhabitant equivalent), and 10000 inhabitant equivalents for $CAPACITY_{stp}$ (capacity of the STP). The resulting SLUDGERATE is 790 kg/d.

[5] The version of the BPR, Vol IV Environment - Part B Risk Assessment (2015) lists for SURPLUSsludge (surplus sludge per inhabitant equivalent) a value of 0.011 kg/d. The resulting SLUDGERATE amount is then 710 kg/d. The modelling program EUSES 2.1.2 calculates with the actual value of 0.019 kg/d for SURPLUSsludge. The result for SLUDGERATE is in this case 790 kg/d. The PEC soil calculations for Transfluthrin are calculated with 0.019 kg/d for SURPLUSsludge and therefore 790 kg/d for SLUDGERATE. This follows a recommitation from the BPC WG-IV-2016 and this is also in line with the REACH Guidance R.16 and Simple Treat 3.1. The current version of the BPR Vol.IV Environment - Assessment and Evaluation (Part B+C), Version 2.0; October 2017 set the value for SURPLUSsludge equal to 0.019 kg/d.

Calculation of the rate of sewage sludge production in a model STP (cf. ECHA, 2015b, equation 37)			
Parameter	**Definition**	**Value**	**Unit**
Concentration of suspended matter in STP influent	$SUSPCONC_{inf}$	0.45	kg/m^3
Effluent discharge rate of STP	$EFFLUENT_{STP}$	2000	m^3/d
Surplus sludge per inhabitant equivalent	$SURPLUS_{sludge}$	0.019	kg/d*eq
Capacity of the STP	$CAPACITY_{STP}$	10000	eq
Rate of sewage sludge production	**$SLUDGERATE = 2/3 \times SUSPCONC_{inf} \times EFFLUENT_{STP} + SURPLUS_{sludge} \times CAPACITY_{STP}$**	**790**	**kg/d**

Calculation of the sludge concentration (cf. ECHA, 2015b), equation 36)			
Parameter	**Definition**	**Value**	**Unit**
Local emission rate to waste water during episode	$Elocal_{water}$	2.75E-05	kg/d
Fraction of emission directed to sludge by STP	$Fstp_{sludge}$	0.799	-
Rate of sewage sludge production	SLUDGERATE	790	kg/d
Concentration in dry sewage sludge	**$C_{sludge} = Fstp_{sludge} \times Elocal_{water} \times 10^6 \times SLUDGERATE^{-1}$**	**2.78E-02**	**mg/kg**

According to ECHA (2015b) default values were taken for the sludge application rate (5000 kg_{dwt}/ha/yr, corresponding to 0.5 $kg/m^2/yr$), the soil depth (0.2 m) and the bulk density of the soil (1700 kg/m^3).

Calculation of concentrations in the soil following a single STP sludge concentration (cf. ECHA, 2015b), equation 60)			
Parameter	**Definition**	**Value**	**Unit**
Concentration in dry sewage sludge	C_{sludge}	2.78E-02	mg/kg
Dry sludge application rate	$APPL_{sludge}$	0.5	kg/m²*yr
Mixing depth of soil	$DEPTH_{soil}$	0.2	m
Bulk density of soil	RHO_{soil}	1700	kg/m³
Concentration in soil due to sludge in first year at t=0	$Csludge_{soil\ 1}(0) = \frac{C_{sludge} \times APPL_{sludge}}{DEPTH_{soil} \times RHO_{soil}}$	**4.09E-05**	**mg/kg**

As a worst-case assumption for exposure, it is assumed that sludge applications take place for 10 consecutive years, each with one application. The fraction of Transfluthrin that remains in the top soil layer one year after an application is given in the table below. For the calculation of the rate constant for removal from top soil (k), a DT_{50} in soil of 5.17 days at 12°C is considered. This value was agreed at BPC ENV WG-IV-2017.

Calculation of the accumulated active substance fraction remaining in soils one year following a sludge application (cf. ECHA, 2015b, equation 61)			
Parameter	**Definition**	**Value**	**Unit**
First order rate constant for removal from top soil	k	0.134071	1/d
Fraction accumulation in one year	**Facc = e^{-365k}**	**5.59E-22**	**-**

Calculation of soil concentrations following a one-fold sludge application in each of ten years (concentration immediately after the tenth application, cf. ECHA, 2015b, equation 62)			
Parameter	**Definition**	**Value**	**Unit**
Concentration in soil due to sludge application in first year at t=0	$Csludge_{soil1}$ (0)	4.09E-05	mg/kg
Fraction accumulation in one year	Facc	5.59E-22	-
Concentration in soil due to sludge after 10 applications at t=0	$\boldsymbol{Csludge_{soil\ 10}\ (0) = Csludge_{soil1}\ (0) \times [1 + \sum_{n=1}^{9} Facc^n]}$	**4.09E-05**	**mg/kg**

The initial concentrations following 10 sludge applications are used to calculate average residues in soils of terrestrial ecosystems, i.e., over a time period of 30 days. The rate constant k only compasses the biodegradation, whereas volatilisation and leaching were not considered as relevant routes for removal.

Calculation of the average concentration in soils of terrestrial ecosystems (Clocalsoil, cf. ECHA, 2015b), equation 55)			
Parameter	**Definition**	**Value**	**Unit**
First order rate constant for removal from top soil	k	0.134071	1/d
Averaging time	T	30	d
Initial concentration after sludge application	C_{soil} (0)	4.09E-05	mg/kg
Average concentration in agric. soil over 30 days	$\boldsymbol{Clocal_{soil} = (1/kT) \times C_{soil}\ (0) \times (1-e^{-kT})}$	**9.99E-06**	**mg/kg_{wwt}**
Average concentration in agric. soil over 180 days	$\boldsymbol{Clocal_{soil} = (1/kT) \times C_{soil}\ (0) \times (1-e^{-kT})}$	**1.69E-06**	**mg/kg_{wwt}**

Under the prerequisite that a background concentration for Transfluthrin does not exist, the $Clocal_{soil}$ values represent the $PEClocal_{soil}$ values.

Groundwater

According to ECHA (2015b) the concentration of a substance in groundwater is equivalent to the concentration in the pore water of the potentially affected soil volume.
The concentration in pore water can be calculated assuming simple adsorption processes following ECHA (2015b), equation 67:

Calculation of the concentration in pore water (cf. ECHA, 2015b, equation 67)			
Parameter	**Definition**	**Value**	**Unit**
Average concentration in soil over 180 days	$PEClocal_{agr.soil}$	1.69E-06	mg/kg
Bulk density of (wet) soil	RHO_{soil}	1700	kg/m³
Volume fraction water in soil	$F_{water,soil}$	0.2	m_{water}^3/m_{soil}^3
Volume fraction solids in soil	$F_{soild,soil}$	0.6	m_{solid}^3/m_{soil}^3
Weight fraction organic carbon in soil solids	$F_{oc,soil}$	0.02	kg_{oc}/kg_{solid}
Partition coefficient organic carbon-water	K_{oc}	50119	L/kg
Partition coefficient solid-water in soil	$K_{p,soil} = F_{oc,soil} \times K_{oc}$	1002.38	L/kg
Soil-water partitioning coefficient	$k_{soil-water} = F_{water,soil} + F_{solid,soil} \times \frac{k_{p,soil}}{1000} \times RHO_{solid}$	1022.63	m^3/m^3
Predicted environmental concentration in porewater	$\boldsymbol{PEClocal_{porewater} = \frac{PEClocal_{soil} \times RHO_{soil}}{k_{soil-water} \times 1000}}$	**2.81E-09**	**mg/L**

Summary table on calculated PEC values						
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}** Agric., 30d	**PEC_{GW}**	**PEC_{air}**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]	[mg/m^3]
Scenario [1]: Transfluthrin	2.65E-06	2.46E-07	2.68E-04	9.99E-06	2.81E-06	not relevant
Scenario [1]: metabolite TFB-OH	4.83E-07	4.50E-08	4.90E-05	1.83E-06	5.14E-07	not relevant
Scenario [1]: metabolite *TFB-COOH*	8.24E-07	7.65E-08	8.33E-05	3.11E-06	8.74E-07	not relevant

Primary and secondary poisoning

Non-target animals are potentially at risk in two ways: a) from direct consumption of a biocidal product (primary poisoning) or b) through eating organisms that have taken up/accumulated a poison (secondary poisoning).

Primary poisoning

Primary poisoning as direct consumption of insecticide by birds or mammals may mainly occur in the following cases: if insecticides are applied together with food attractant or insecticides are applied as granular formulation.

The anti-moth paper (impregnating paper) VANDAL Mottenhänger is an indoor diffuser used in wardrobes or in drawers, without any attractants. In normal condition of use, no primary poisoning is foreseen during application. Therefore, primary poisoning is not applicable regarding the intended use of VANDAL Mottenhänger.

Secondary poisoning

Secondary poisoning via contaminated EARTHWORMS
Mammals and birds may consume contaminated worms. As input parameter the concentration in the receiving soil compartment as a result of sludge application (indirect contamination) is included as well as the BCF in earthworms, the concentration in pore water, the fraction of gut loading in worm and the conversion factor for soil concentration wet-dry/weight soil. For calculating the bioconcentration factor, an octanol/water partition coefficient of log K_{ow} = 5.94 is taken.

Calculation of the predicted environmental concentration for Transfluthrin in earthworms (cf. ECHA, 2015b, equation 82c)			
Parameter	**Definition**	**Via sludge application**	**Unit**
Local concentration in soil (agric, 180 days)	$PECloca l_{soil}$	1.69E-06	mg/kg_{wwt}
Octanol/water partition coefficient [-]	K_{ow}	870964	-
Density of earthworm [kg_{wwt}/L]	$RHO_{earthworm}$	1	kg_{wwt}/L
Bioconcentration factor for earthworm on wet weight basis [$L/kg_{wet\ earthworm}$]	$BCF = (0.84 + 0.012\ K_{ow})/RHO_{earthworm}$	10452	$L/kg_{wet\ earthworm}$
Fraction of gut loading in worm	F_{gut}	0.1	kg/kg
Conversion factor for soil concentration wet-dry weight soil	$CONV_{soil}$	1.13	kg_{wwt}/kg_{dwt}
Predicted Environmental Concentration in pore water	$PECloca l_{soil,porewater}$	2.81E-09	mg/L
Predicted Environmental Concentaration in earthworms	$C_{earthworm} = \frac{BCF_{earthworm} \times C_{porewater} + C_{soil} \times F_{gut}\ x\ CONV_{soil}}{1 + F_{gut}\ x\ CONV_{soil}}$	**2.66E-05**	**$mg/kg_{wet\ earthworm}$**

Secondary poisoning via contaminated FISH

As given in the assessment report of Transfluthrin (The Netherlands, 2014), a log K_{ow} equal to 5.94 indicates potential bioaccumulation, hence also a potential for secondary poisoning via the consumption of contaminated fish may be given.
The assessment of secondary poisoning is calculated according to ECHA (2015b).

The concentration of contaminant in food (fish of fish-eating predators ($PECoral_{predator}$) is calculated based on PEC for surface water.

Calculation of the predicted environmental concentration for Transfluthrin in fish (cf. ECHA, 2015b, equation 76)			
Parameter	**Definition**	**Value**	**Unit**
Predicted environmental concentration in surface water	PEC_{water}	2.46E-07	mg/L
Bioconcentration factor for fish on wet weight basis	BCF_{fish}	1783	$L/kg_{wet\ fish}$
Biomagnification factor in fish	BMF	1	-
Predicted Environmental Concentaration in fish	$PEC_{oral,\ predator} = PEC_{water} \cdot BCF_{fish} \cdot BMF$	**4.39E-04**	**$mg/kg_{wet\ fish}$**

Summary table on PEC oral in fish and earthworm		
	PEC oral fish	**PEC oral earthworm**
	[mg/kg*d^{-1}]	[mg/kg*d^{-1}]
Scenario [1]: Transfluthrin	4.39E-04	2.66E-05

Metabolites TFB-OH and TFB-COOH

The major metabolites TFB-OH and TFB-COOH are not expected to bioaccumulate since the estimated $logK_{ow}$ is equal to 1.85 for TFB-COOH and 1.54 for TFB-OH. Therefore, secondary poisoning is not expected.

2.2.8.3 Risk characterisation

Atmosphere

Under the proposed conditions of use, Transfluthrin will be emitted to air. According to the ESD (OECD, 2008), the concentration in air upon outdoor use will not be relevant because of instant dilution. This also applies to indoor use. Furthermore, no ecotoxicity data are available based on atmospheric exposures and there is no agreed method available to derive a PEC_{air}. Therefore, a $PEC/PNEC_{air}$ cannot be calculated. The estimated atmospheric half-life time with 2.4 d is short (The Netherlands, 2014). Due to the relative small amounts used compared to the volume of the atmospheric compartment possible abiotic effects of Transfluthrin or significant exposure to the atmosphere are expected to be negligible.

Conclusion

In concordance with the intended use of the biocidal product significant exposure of the air is not expected.

Sewage treatment plant (STP)

The $PNEC_{STP}$ for Transfluthrin is 0.057 mg/L (see AR, The Netherlands, 2014) based on the water solubility. The PEC values were taken from the table "Summary on calculated PEC values" in chapter 2.2.8.2 of this document.

Summary table on calculated $PEC/PNEC_{STP}$ values		
Scenario [1]	**PEC_{STP}**	**$PEC/PNEC_{STP}$**
	$PNEC_{STP}$ = 0.057 mg/L	
Passive diffuser, indoor		
Transfluthrin	2.65E-06 mg/L	4.65E-05

Conclusion

The risk ratio for Transfluthrin is <1 demonstrating acceptable risk for microorganisms for direct exposure to STP.

Aquatic compartment

PEC/PNEC ratios were calculated for surface water and sediment for Transfluthrin. For the main metabolites TFB-OH and TFB-COOH risk ratios were calculated for surface water.

For the used PNECs see chapter "2.2.8.1 Effects assessment on the environment". For the metabolites TFB-OH and TFB-COOH no effect data for sediment organisms are available, therefore no PNECs can be derived. Both metabolites are less toxic than the parent

compound Transfluthrin (see LoEP, The Netherlands, 2014) Hence, the PEC/PNEC$_{surface\ water}$ of both metabolites covers the risk assessment for the sediment.

Summary table on calculated PEC/PNEC$_{aquatic}$ values				
Scenario [1]	**PEC$_{surface\ water}$**	**PEC/PNEC$_{surface\ water}$**	**PEC$_{sed}$**	**PEC/PNEC$_{sed}$**
Passive diffusor, indoor	**PNEC$_{surface\ water}$ = 1.75E-06 mg/L (Transfluthrin)**		**PNEC$_{sed}$ = 3.57E-04 mg/kg$_{wwt}$ (Transfluthrin)**	
Transfluthrin	2.46E-07 mg/L	1.41E-01	2.68E-04 mg/kg$_{wwt}$	7.51E-01
	PNEC$_{surface\ water}$ = 0.1 mg/L (TFB-OH and TFB-COOH)		**No PNECs available for TFB-OH and TFB-COOH**	
Metabolite TFB-OH	4.50E-08 mg/L	4.50E-07	4.90E-05 mg/kg$_{wwt}$	Covered by PEC/PNEC$_{surface\ water}$
Metabolite TFB-COOH	7.65E-08 mg/L	7.65E-07	8.33E-05 mg/kg$_{wwt}$	Covered by PEC/PNEC$_{surface\ water}$

Conclusion

The risk ratios for the aquatic compartment (indirect exposure to freshwater and sediment) for Transfluthrin and its metabolites TFB-OH and TFB-COOH (indirect exposure to freshwater) are <1 indicating acceptable risk for aquatic and sediment organisms.

Terrestrial compartment

A PEC/PNEC ratio for Transfluthrin for indirect exposure of soil via sludge application was calculated. Due to the absence of effect data for the metabolites TFB-OH and TFB-COOH in soil PNECsoil values cannot be derived.

Calculated PEC/PNEC$_{soil}$ values		
Scenario [1]	**PEC$_{soil}$**	**PEC/PNEC$_{soil}$**
	PNEC$_{soil}$ = 0.09 mg/kg$_{wwt}$	
Passive diffusor, indoor		
Transfluthrin	9.99E-06 mg/kg$_{wwt}$	1.11E-04

Conclusion

The PEC/PNEC ratio for Transfluthrin is <1 indicating no unacceptable risk for terrestrial organisms.

Groundwater

No specific limit values are established for Transfluthrin or its metabolites under Directive 98/83/EC (Drinking Water Directive), and therefore the general limit value of 0.1 µg/L for organic pesticides applies.

For Transfluthrin a PEC for groundwater of 2.81E-06 µg/L was calculated. For the metabolites TFB-OH and TFB-COOH PEC groundwater values of 5.14-07 µg/L and 8.74E-07 µg/L were calculated, respectively. These values do not exceed the limit of 0.1 µg/L and therefore no unacceptable risk for groundwater is expected.

Primary and secondary poisoning

Primary poisoning

Not relevant.

Secondary poisoning

Due to the intrinsic properties of the active substance ($logK_{ow}$ of 5.94) and the foreseeable routes into the environment secondary poisoning may occur via bioaccumulation over time in the aquatic and terrestrial food chain. The relevant metabolites TFB-OH and TFB-COOH, which were identified in the water and sediment phase and TFB-COOH in the soil compartment (see The Netherlands, 2014 and submitted new data) were not expected to be bioaccumulative due to their low estimated $logK_{ow}$ of 1.54 and 1.85, respectively. These values are beneath the bioaccumulation trigger value of a log KoW of 3 (ECHA 2017a).

Due to the absence of short term or long term dietary toxicity data for birds, a $PEC/PNEC_{oral}$ bird for Transfluthrin cannot be derived. The acute LD_{50} of Transfluthrin for birds is >1890 mg/kg bw (CAR of Transfluthrin, The Netherlands, 2014) and cannot be used for extrapolation to chronic toxicity, as this is not a dietary test (ECHA 2017a).

The PEC_{oral} is calculated to be 4.39E-04 mg/kg in fish and 2.66E-05 mg/kg in worms. For the $PNEC_{oral\ bird}$ to fall below the PEC, the NOEC should be lower than the $PEC_{oral\ bird}$ x 30, hence it should be <1.32E-02 mg/kg feed in the case of fish and <7.98E-04 mg/kg feed in case of earthworms. Following a similar reasoning for short term tests, the LC_{50} should be <1.32 mg/kg feed (fish) and <7.98E-02 mg/kg feed (earthworm), respectively ($<PEC_{oral,\ bird}$ x 3000). In view of the absence of acute toxicity to birds at doses >1890 mg/kg bw it is not expected that chronic toxicity levels as low as 1.32E-02 mg/kg feed will be reached.

It can be expected that chronic NOEC values will not be low enough to pose a significant risk for secondary poisoning for birds.

The $PNEC_{oral\ mammal}$ is taken from the CAR of Transfluthrin (The Netherlands, 2014). The PEC values are taken from the table "Summary table on PEC oral in fish and earthworm" in chapter 2.2.8.2.

Summary table on secondary poisoning for bioaccumulation via the aquatic and terrestrial food chain				
Scenario [1]	**PEC_{oral} mammals via fish**	**PEC/PNEC mammals via fish**	**PEC_{oral} mammals via earthworms**	**$PEC/PNEC_{mammals}$ via earthworms**
	$PNEC_{mammals}$ = 6.67 mg/kg_{diet}*day			
Passive diffusor, indoor				
Transfluthrin	4.39E-04 mg/kg*d	6.58E-05	2.66E-05 mg/kg*d	3.99E-06

Conclusion

The PEC/PNEC ratios for secondary poisoning for mammals via ingestion of contaminated fish and earthworms are (expected to be) by far <1 and therefore no unacceptable risk is expected. For birds back calculations were performed indicating that an acceptable risk can be expected for secondary poisoning.

Mixture toxicity

Mixture toxicity is not relevant for the biocidal product VANDAL Mottenhänger.

Aggregated exposure (combined for relevant emission sources)

At the time of preparation of this PAR, no EU agreed guidance was available on how to perform a full aggregated exposure assessment. Therefore no assessment has been made at this stage. This chapter of the PAR has to be reassessed once an agreed guidance has been made available. This could take place at active substance renewal stage or at product authorisation stage, depending on when such guidance becomes available.

Overall conclusion on the risk assessment for the environment of the product
Risk ratios for Transfluthrin were calculated for direct exposure to the STP and indirect exposure to surface water, sediment, soil and groundwater. For the relevant metabolites TFB-OH and TFB-COOH risk ratios for surface water were calculated. Regarding secondary poisoning risk ratios were calculated for Transfluthrin for mammals and back calculations were performed for birds for the bioaccumulation via the aquatic and terrestrial food chain indicating that acceptable risk can be expected. For all exposed compartments and secondary poisoning for mammals all calculated risk ratios are <1, indicating acceptable risks. All calculated groundwater concentrations are <0.1 µg/L.

Therefore the authorised use of the biocidal product VANDAL Mottenhänger shows acceptable risk for all exposed environmental compartments, secondary poisoning and for groundwater for the active substance Transfluthrin and its relevant metabolites TFB-OH and TFB-COOH.

2.2.9 Measures to protect man, animals and the environment

2.2.9.1 Recommended methods and precautions concerning storage of active substance (biocidal product; shelf-life of biocidal product*)*

Please see chapter 2.1.5.5 Conditions of storage and shelf-life of the product.

2.2.9.2 Recommended methods and precautions concerning handling and transport

Please see chapter 2.1.5 General directions for use.

Additionally keep only carefully cleaned garments in your wardrobe and drawers.

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

Suitable extinguishing media
water-spray, CO2, foam, sand
Extinguishing media which must not be used for safety reasons:
Water jet

Fire may cause evolution of carbon monoxide. Do not breathe gases. Advice for fire fighters:
Wear self-containing breathing apparatus and chemical protective clothing.
Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

2.2.9.4 Particulars of likely direct or indirect adverse effects

Not known if the product is used properly according to the product label.

2.2.9.5 First aid instructions, antidotes

Please see section 2.1.5.3

2.2.9.6 Emergency measures to protect environment in case of accident

Please see section 2.1.5.3

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

None.

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

Air

Ventilate the room well.

Water, including drinking water

Remove mechanically and dispose in a safe way.
Do not drink contaminated water.

Soil

Remove mechanically and dispose in a safe way.

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

Possibility of reuse or recycling

No reuse or recycling.

Possibility of neutralisation of effects

Take care for good ventilation.

Conditions for controlled discharge including leachate qualities on disposal

Dispose the unused product as hazardous waste.

Conditions for controlled incineration

Dispose the unused product as hazardous waste.

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

Disposal of the product:

The product contains the active substance Transfluthrin classified with Aquatic Acute 1, M=1000 and Aquatic Chronic 1, M=1000 - connected with the hazard statements H400 and H410, respectively.

Therefore according to Annex III of Directive 2008/98/EC the product is regarded as waste "which presents or may present immediate or delayed risks for one or more sectors of the environment" (H 14).

As of 5 July 2018, according to Council Reg. (EU) 2017/997 amending Annex III to Dir. 2008/98/EC, "HP 14: Ecotoxic" (waste which presents or may present immediate or delayed risks for one or more sectors of the environment, which classifies the product as hazardous waste) has to be applied based on the classification with Aquatic Chronic 1, as the concentration of Transfluthrin in the biocidal product (100%w/w) exceeds the concentration limit of 25%.

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

Not applicable

2.2.10 Assessment of a combination of biocidal products

Not applicable. No intended use with other biocidal products.

2.2.11 Comparative assessment

Not relevant since the active substance Transfluthrin is no candidate for substitution.

3 ANNEXES

3.1 List of studies for the biocidal product

Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
	A.Brux	2017	Determination of Physico-Chemical Properties and Storage Stability Tests for VANDAL Mottenpapier	BioGenius GmbH	AQ065-17	Yes	Yes	Nifra Parfümerie Ges.m.bH
	E. Gundalai	2015	BIOLOGICAL TEST REPORT: SIMULATED-USE TEST: EFFICACY TEST AGAINST ADULT AND LARVAE OF CLOTHES MOTHS, TINEOLA BISSELLIELLA, WITH A PRODUCT VANDAL Mottenpapier, BIOGENIUS GMBH, STUDYNO: MO5221 ADDENDUM: STATEMENT AMOUNT OF ACTIVE INGREDIENT TRANSFLUTHRINPER	BioGenius GmbH	Mo5221	Yes	Yes	Nifra Parfümerie Ges.m.b.H.

Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
			0.5 M³ CABINET, STUDY MO5221 PERFORMED BY BIOGENIUS GMBH, REPORTED AS BIO115D-15 AND DATED 2015-10-28					
	Blondaz P.	2015	NEW RELEVANT ENDPOINTS AND PNEC DERIVATION ENVIRONMENT & ECOTOXICITY FOR TRANSFLUTHRIN (CAS: 118712-89-3), BAYER SAS ENVIRONMENTAL SCIENCE – (STRICTLY CONFIDENTIAL)	BAYER SAS, ENVIRONMENTAL SCIENCE	REF. TFL-PAI-VERSION 9	No	Yes	BAYER SAS, ENVIRONMENTAL SCIENCE
5	MRUSEK K.	1995	K. MRUSEK 1995, NAK 4455 (TRANSFLUTHRIN) A FAST-ACTING INSECTICIDE FOR USE IN HOUSHOLD AND HYGIENE PRODUCTS. PFLANZENSCHUTZ-NACHRICHTEN BAYER, SPECIAL EDITION 48. (66)	BAYER SAS, ENVIRONMENTAL SCIENCE	PFLANZENSCHUTZ-NACHRICHTEN BAYER, SPECIAL EDITION 48. (66) CHAPTER 5.3.1	NO	NO	NONE

Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
			CHAPTER 5.3.1					
	MATLOCK, D. AND S. MOORE	2015	EARLY LIFE STAGE TOXICITY OF TRANSFLUTHRIN TECHNICAL TO THE FATHEAD MINNOW (PIMEPHALES PROMELAS) UNDER FLOW-THROUGH CONDITIONS	BAYER CROP SCIENCE AG	REPORT NO: EBTBL007	Yes	Yes	BAYER CROP SCIENCE AG
	MATLOCK, D. AND S. MOORE	2015	CHRONIC TOXICITY OF TRANSFLUTHRIN TECHNICAL TO DAPHNIA MAGNA UNDER FLOW-THROUGH CONDITIONS	BAYER CROP SCIENCE AG	REPORT NO: EBTBL006	Yes	Yes	BAYER CROP SCIENCE AG
	KUHL K.	2015	CHIRONOMUS RIPARIUS 28-DAY CHRONIC TOXICITY TEST WITH TRANSFLUTHRIN (TECH.) IN A WATER-SEDIMENT SYSTEM USING SPIKED SEDIMENT	BAYER CROP SCIENCE AG	REPORT NO: EBTBL005	Yes	Yes	BAYER CROP SCIENCE AG

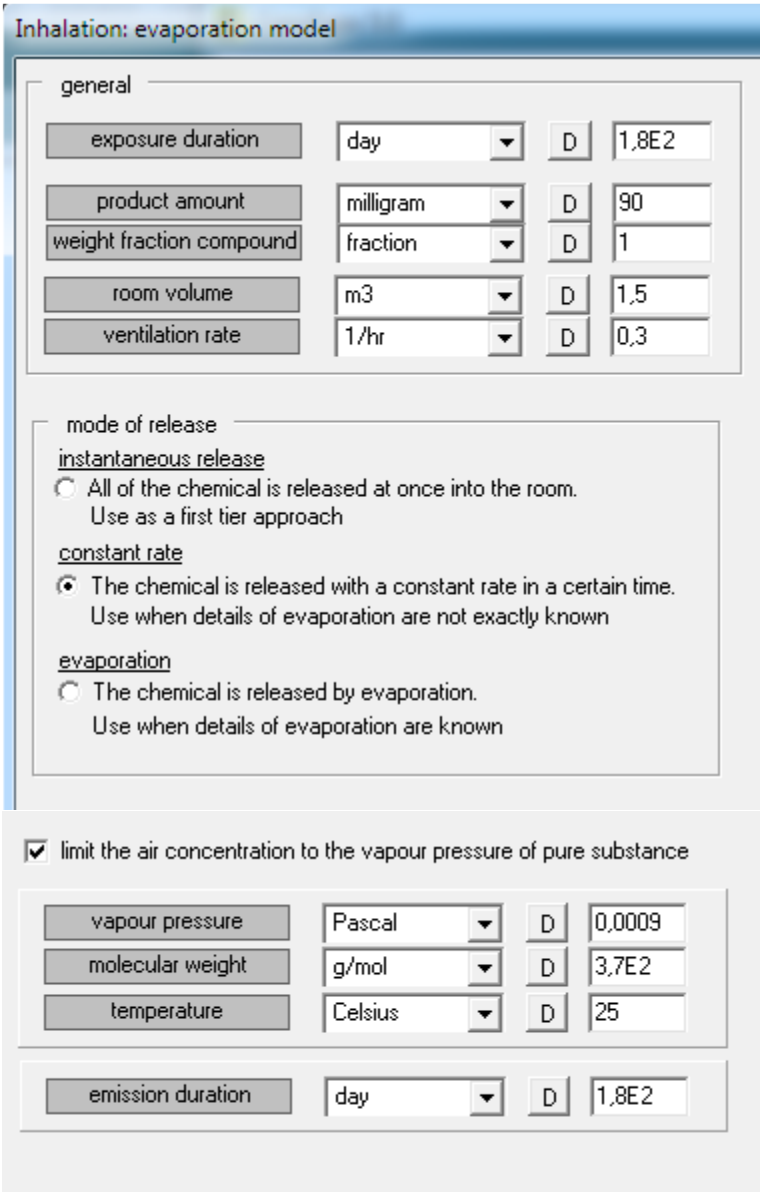
Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
	EGELER P.	2015	A STUDY ON THE CHRONIC TOXICITY TO THE SEDIMENT DWELLER LUMBRICULUS VARIEGATUS	ECT OEKOTOXIKOLOGIE GMBH	STUDY NO. 14P4LA	Yes	Yes	ECT OEKOTOXIKOLOGIE GMBH
	SCHULZ L.	2014	TRANSFLUTHRIN A.S. (BCS-AW53131): EFFECTS ON THE ACTIVITY OF SOIL MICROFLORA (NITROGEN TRANSFORMATION TEST)	BIOCHEM AGRAR GMBH	REPORT NO: 14 10 48 069 N	Yes	Yes	BIOCHEM AGRAR GMBH
	FRIEDRICH S.	2014	EFFECTS ON THE REPRODUCTION OF THE COLLEMBOLAN FOLSOMIA CANDIDA	BIOCHEM AGRAR GMBH	REPORT NO: 14 10 48 204 S;	Yes	Yes	BIOCHEM AGRAR GMBH
	FRIEDRICH S.	2014	SUBLETHAL TOXICITY TO THE EARTHWORM EISENIA FETIDA IN ARTIFICIAL SOIL	BIOCHEM AGRAR GMBH	REPORT NO.: 14 10 48 205 S	Yes	Yes	BIOCHEM AGRAR GMBH
	HEIN, E-M & JUNGE, T.	2015	[METHYLENE-^{14}C]TRANSFLUTHRIN: AEROBIC	BAYER CROP SCIENCE AG	STUDY NO. M1253376-5	Yes	Yes	BAYER CROP SCIENCE AG

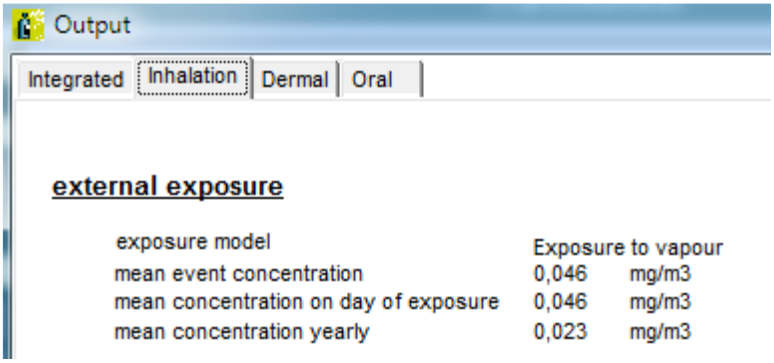
Section No. in IUCLID	Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner
			DEGRADATION / METABOLISM IN FOUR SOILS					

3.2 Output tables from exposure assessment tools

3.2.1 Human Exposure Assessment

Calculations performed with ConsExpo v.5:




Output
Integrated
Inhalation
Dermal
Oral
external exposure
exposure model
Exposure to vapour
mean event concentration
0,046
mg/m3
mean concentration on day of exposure
0,046
mg/m3
mean concentration yearly
0,023
mg/m3

SCENARIO [1]		
Parameters	**Value**	**Unit**
Dermal exposure:		
Content of a.s./paper strip	60	mg
Area of paper strip	1225	cm²
Transfer coefficient dried fluids	0,18	g/g
Area of palms	410	cm²
Number of manipulations	2	day^{-1}
Body weight adult	60	kg
Dermal absorption	10	%
Dermal systemic exposure, Tier 1	**0,01205**	**mg a.s. /kg bw/day**
Inhalative exposure:		
mean event concentration	0,046	mg/m³
Exposure duration	5	min/day
Inhalation rate adult	0,02083	m³/min
Body weight adult	60	kg
Inhalative systemic exposure, Tier 1	**0,00008**	**mg a.s. /kg bw/day**
TOTAL systemic exposure, Tier 1	**0,01213**	**mg a.s. /kg bw/day**
Reverse reference scenario:		
AEL acute, dermal	1	mg a.s. /kg bw/day
Dermal systemic exposure for manipulating 2 strips	0,0120	mg a.s. /kg bw/day
Number of manipulations to achieve AEL	**83,0**	
AEL acute, inhalative	0,17	mg a.s. /kg bw/day
Inhalative systemic exposure	0,00008	**mg a.s. /kg bw/day**
Number of manipulations to achieve AEL	**2129**	

SCENARIO [2]		
Parameters	**Value**	**Unit**
mean event concentration	0,046	**mg/m³**
exposure duration	24	h/day
inhalation rate adult	1,25	m³/h
body weight adult	60	kg
inhalation rate child	1,32	m³/h
body weight child	23,9	kg
inhalation rate toddler	1,26	m³/h
body weight toddler	10	kg
inhalation rate infant	0,84	m³/h
body weight infant	8	kg
dilution factor bedroom	10	
inhalative systemic exposure, adult, Tier 1	**0,002**	**mg a.s. /kg bw/day**
inhalative systemic exposure, child, Tier 1	**0,006**	**mg a.s. /kg bw/day**
inhalative systemic exposure, toddler, Tier 1	**0,014**	**mg a.s. /kg bw/day**
inhalative systemic exposure, infant, Tier 1	**0,012**	**mg a.s. /kg bw/day**
exposure duration	16,2	h/day
inhalative systemic exposure, adult, Tier 2	**0,002**	**mg a.s. /kg bw/day**
inhalative systemic exposure, child, Tier 2	**0,004**	**mg a.s. /kg bw/day**
inhalative systemic exposure, toddler, Tier 2	**0,009**	**mg a.s. /kg bw/day**
inhalative systemic exposure, infant, Tier 2	**0,008**	**mg a.s. /kg bw/day**

SCENARIO [3]		
Parameters	**Value**	**Unit**
Infant body weight	8	kg
Toddler body weight	10	kg
Content of a.s./paper strip	60	mg
Area of paper strip	1225	cm²
Surface area of object mouthed	50	cm²
Oral absorption	100	%
Inhalative systemic exposure, infant, Tier 1	**0,306**	**mg a.s. /kg bw/day**
Inhalative systemic exposure, toddler, Tier 1	**0,245**	**mg a.s. /kg bw/day**
Surface area of object mouthed	10	cm²
Inhalative systemic exposure, infant, Tier 2	**0,061**	**mg a.s. /kg bw/day**
Inhalative systemic exposure, toddler, Tier 2	**0,049**	**mg a.s. /kg bw/day**

SCENARIO [4]		
Parameters	**Value**	**Unit**
mean event concentration	0,046	mg/m³
inhalation rate dog	0,27	m³/h
body weight dog	8	kg
inhalation rate cat	0,096	m³/h
body weight cat	3	kg
exposure duration	16,2	h/day
inhalative systemic exposure, dog, Tier 1	**0,025**	**mg a.s. /kg bw/day**
inhalative systemic exposure, cat, Tier 1	**0,024**	**mg a.s. /kg bw/day**

3.2.2 Environmental Exposure Assessment

Detailed calculations are reported in chapter 2.2.8.2 Environmental Exposure.

3.3 New information on the active substance

The applicant submitted a document (Blondaz, 2015) to the eCA with summaries of new additional chronic aquatic and terrestrial toxicity studies for the active substance.

BLONDAZ, 2015: RELEVANT ENDPOINTS AND PNEC DERIVATION ENVIRONMENT & ECOTOXICITY, TRANSFLUTHRIN (CAS: 118712-89-3), BAYER SAS ENVIRONMENTAL SCIENCE

3.4 Residue behaviour

Not applicable. For further information please see the AR for Transfluthrin (The Netherlands, 2014)

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

Please see the respective IUCLID file.

3.6 Confidential annex

Please see the respective file.

3.7 Other

NONE

3.7.1 Reference list (excluding list of studies, cf. to chapter 3.1)

Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council

COUNCIL DIRECTIVE 98/83/EC of 3 November 1998 on the quality of water intended for human consumption. Available at: http://eur-

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ECHA 2015b, Guidance on the BPR: Volume IV Environment - Part B Risk Assessment, Version 1.0, April 2015.

ECHA 2015c, Biocides Human Health Exposure Methodology v.1 Oct. 2015

ECHA 2017a, Guidance on the BPR: Volume IV Environment, Part B+C, Risk Assessment, Version 2.0, Oktober 2017. Available at: http://echa.europa.eu/de/guidance-documents/guidance-on-biocides-legislation 2017-10-25

ECHA 2017b, Guidance on requirements for substances in articles, Version 4.0, June 2017.

OECD 2008, OECD SERIES ON EMISSION SCENARIO DOCUMENTS Number 18: Emission scenario document for insecticides, arcaricides and products to control other arthropods for household and professional uses.
Available at: https://echa.europa.eu/documents/10162/16908203/pt18_oecd_esd_household_professional_uses_en.pdf/bb353df7-5606-41d2-b799-ea15717a8d4b 2018-02-13

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The Netherlands 2014, Assessment Report Transfluthrin (insecticides, acaricides and products to control other arthropods), 13 March 2014. Available at: https://circabc.europa.eu/sd/a/910c7533-aba6-4a93-87c3-31c5f2b04445/Transfluthrin%20-%20PT18%20(assessment%20report%20as%20finalised%20on%2013.03.2014).pdf, 2017-09-17

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