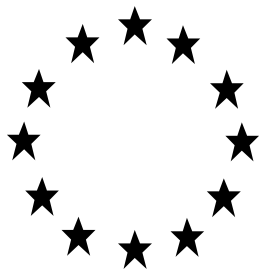
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FAMILY FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Anti-moths products

Product type 18

Transfluthrin as included in the Union list of approved active substances

Case Number in R4BP: N/A

Evaluating Competent Authority: eCA Austria

08/05/2024 (Final)

PUBLIC

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1 CONCLUSION

Austria was the Competent Authority responsible for evaluation of the biocidal product family Anti-moths products. The ready-to-use products from the product family Antimoths products contain the active substance transfluthrin (1.01 – 3.21% (w/w)). Identified substances of concern are Linalool (3,7-dimethylocta-1,6-dien-3-ol) at a concentration of 0-29.7% (w/w), Nopyl acetate (2-(6,6-dimethylbicyclo[3.1.1]-2-hepten-2-yl)ethyl acetate) at a concentration of 0-15.84% (w/w), Geraniol ((2E)-3,7-dimethylocta-2,6-dien-1-ol) at a concentration of 0-7.92% (w/w), alpha-iso-Methylionone ((3E)-3-methyl-4-(2,6,6-trimethylcyclohex-2-en-1-yl)but-3-en-2-one) at a concentration of 0-1.48% (w/w), Cineole (1,3,3-trimethyl-2-oxabicyclo[2.2.2]octane) at a concentration of 0-1.98% (w/w), Hydrocarbons, C11-C13 (isoalkanes, <2% aromatics) at a concentration of 0-21.5 % (w/w), Hydrocarbons, C12-C16 (isoalkanes, cyclics, <2% aromatics (Isoparafins C12-C16)) at a concentration of 0-64.5% (w/w), Terpinyl acetate (2-(4-methylcyclohex-3-en-1-yl)propan-2-yl acetate) at a concentration of 0-9.90% (w/w), Nerol ((2E)-3,7-dimethylocta-2,6-dien-1-ol) at a concentration of 0-2.97% (w/w), Habanolide (A mixture of: (E)-oxacyclohexadec-12-en-2-one; (E)-oxacyclohexadec-13-en-2-one; a) (Z)-oxacyclohexadec-(12)-en-2-one and b) (Z)-oxacyclohexadec-(13)-en-2-one) at a concentration of 0-1.48% (w/w), α-hexylcinnamaldehyde ((2E)-2-(phenylmethylidene)octanal) at a concentration of 0-0.32% (w/w), Hexyl salicylate (hexyl 2-hydroxybenzoate) at a concentration of 0-0.32% (w/w).

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 specific provisions from Inclusion Directive for the active substance Transfluthrin (The Netherlands, 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:

- The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance.

- Authorisations are subject to the following condition:
  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.

The authorised uses is as follows:
Meta SPC 1 Use # 1 – Insecticide – (adult and larvae) clothes moths and carpet beetles – non-professional users – passive diffuser – indoor – flavour bags

Meta SPC 2 Use #2 – Insecticide – (adult and larvae) clothes moths and carpet beetles – non-professional users – passive diffuser – indoor – flavour bags

Identity and analytical methods were described in sufficient detail to meet the information requirements as laid down in annex III of regulation (EU) no. 528/2012. 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 products.

Based on the authorised use including the general directions of use and any possibly defined risk mitigation measures and provided that there will be no misuse, the following can be concluded:

- Data on the biocidal product have demonstrated sufficient efficacy against the target organisms. No resistance is expected.
- The risk characterisation for the biocidal product family indicated acceptable risks with the proposed risk mitigation measures for human health. The assessment of the biocidal product family was conducted according to the common principles set out in Annex VI of Regulation (EC) No 528/2012 and considered the maximum risks to human health.
- Also for the environment, it could be demonstrated that the authorised uses are safe for all exposed environmental compartments and the assessment of secondary poisoning has shown that no adverse effects for birds and mammals are to be expected.

The product contains no active substances which are candidates for substitution.

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.

Note, May 2024: *Moth papers (originally meta SPC 1) are not authorised anymore due to change in classification and labelling in the 21st ATP (Reg. (EU) 2024/197). The Moth protection flavour bags type 1 and 2 (originally meta SPC 2 and 3) are now meta SPC 1 and 2. The PAR was adapted with regard to this aspect. All other parts of the PAR remain unchanged.*

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	**Country (if relevant)**
Anti-moths products	Austria cMS: CH, SL, SK, CZ, IE, HU, GE, FR, CY, GE, UK

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	ANnoWAtec GmbH
	Address	Münchener Str. 30, 85123 Karlskron, Germany
Authorisation number	Austria: AT-0014019-BPF for the BPF (authorisation numbers for the single products: See authorisation letter)	
Date of the authorisation	See authorisation letter	
Expiry date of the authorisation	See authorisation letter	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Annowatec GmbH
Address of manufacturer	Münchener Straße 30 D-85123 Karlskron Germany
Location of manufacturing sites	Münchener Straße 30 D-85123 Karlskron Germany

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

Active substance	Transfluthrin
Name of manufacturer	Bayer Vapi Private Limited
Address of manufacturer	306/3, II Phase, GIDC Vapi-396195, Gujarat India
Location of manufacturing sites	306/3, II Phase, GIDC Vapi-396195, Gujarat India

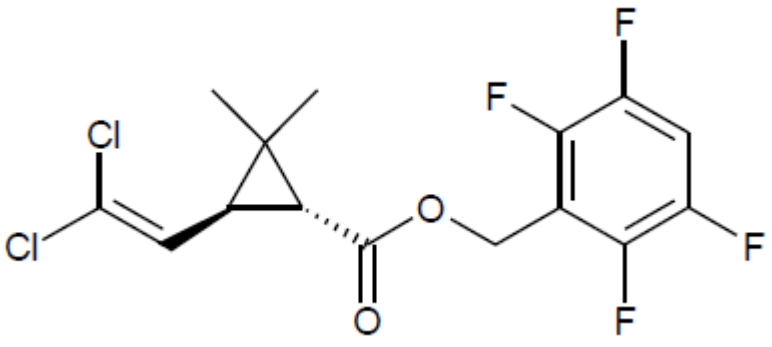
2.1.2 Product (family) composition and formulation

NB: the full composition of the product family 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*: 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	

*according to the entry in the active substance dossier for Transfluthrin (The Netherlands, 2014)

2.1.2.2 Candidate(s) for substitution

On basis of the provided data the biocidal product family 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 family

Qualitative information on the biocidal product family

The biocidal product family comprises of a liquid formulation which is applied onto a carrier material (granules). The treated carrier material that is supplied to the user represents an article. It is neither a treated article nor a biocidal product. Subsequently the carrier material is not part of the formulation but is part of the article and thus has not been stated in the tables below. The full composition of the biocidal product family and the individual products within the family is provided in the confidential annex. Full composition of the used mixtures is given in the confidential annex restricted for authorities.
The amount of Transfluthrin per article protection flavour bag ranges from 5.7 mg/bag – 15 mg/ bag.

Rationale for differentiation between article and biocidal product

The product description under the respective meta SPCs indicates that the granules from the protection flavour bags can be regarded as carrier for the active substance and co-formulants. Therefore it has to be decided if the granules 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, 2017e) 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 and beetles. 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.

LEVEL 1 - Biocidal product family

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (% w/w)**	
					Min	**Max**
Transfluthrin	2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	118712-89-3	405-060-5	1.01*	3.21*
Linalool	3,7-dimethylocta-1,6-dien-3-ol	Perfume	78-70-6	201-134-4	0	29.70
Nopyl acetate	2 - (6,6 - dimethylbicyclo < 3.1.1. > - 2 hepten - 2 - yl) ethyl acetate	Perfume	128-51-8	204-891-9	0	15.84
Geraniol	(2E)-3,7-dimethylocta-2,6-dien-1-ol	Perfume	106-24-1	203-377-1	0	7.92
Cineole	1,3,3-trimethyl-2-oxabicyclo[2.2.2]octane	Perfume	470-82-6	207-431-5	0	1.98
alpha-iso-Methylionone	(3E)-3-methyl-4-(2,6,6-	Perfume	127-51-5	204-846-3	0	1.48

Common name	IUPAC name	Function	CAS number	EC number	Content (% w/w)	
					Min	Max
	trimethylcyclohex-2-en-1-yl)but-3-en-2-one					
Hydrocarbons, C11-C13, isoalkanes, <2% aromatics	Hydrocarbons, C11-C13, isoalkanes, <2% aromatics	Solvent	246538-78-3	920-901-0	0	21.5
Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics	Isoparafins C12-C16	Solvent	-	927-676-8	0	64.5
Terpinyl acetate	2-(4-methylcyclohex-3-en-1-yl)propan-2-yl acetate	Perfume	80-26-2	201-265-7	0	9.90
Nerol	(2E)-3,7-dimethylocta-2,6-dien-1-ol	Perfume	106-25-2	203-378-7	0	2.97
Habanolide	A mixture of: (E)-oxacyclohexadec-12-en-2-one; (E)-oxacyclohexadec-13-en-2-one; a) (Z)-oxacyclohexadec-(12)-en-2-one and b) (Z)-oxacyclohexadec-(13)-en-2-one	Perfume	111879-80-2	422-320-3	0	1.48
α-hexylcinnamaldehyde	(2E)-2-(phenylmethylidene)octanal	Perfume	101-86-0	202-983-3	0	0.32
Hexyl salicylate	hexyl 2-hydroxybenzoate	Perfume	6259-76-3	228-408-6	0	0.32

*Amount of active substance without impurities (pure) 0.97 – 96.5 % (w/w)

LEVEL 2 – meta SPC 1 (Moth protection flavour bag type 1):

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (% w/w)**	
					Min	**Max**
Transfluthrin	2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	118712-89-3	405-060-5	1.01 *	3.2*
Linalool	3,7-dimethylocta-1,6-dien-3-ol	Perfume	78-70-6	201-134-4	29.04	29.70
Nopyl acetate	2 - (6,6 - dimethylbicyclo < 3.1.1. > - 2 hepten - 2 - yl) ethyl acetate	Perfume	128-51-8	204-891-9	15.49	15.84
Geraniol	(2E)-3,7-dimethylocta-2,6-dien-1-ol	Perfume	106-24-1	203-377-1	7.74	7.92
Cineole	1,3,3-trimethyl-2-oxabicyclo[2.2.2]octane	Perfume	470-82-6	207-431-5	1.94	1.98
alpha-iso-Methylionone	(3E)-3-methyl-4-(2,6,6-trimethylcyclohex-2-en-1-yl)but-3-en-2-one	Perfume	127-51-5	204-846-3	1.45	1.48
Terpinyl acetate	2-(4-methylcyclohex-3-en-1-yl)propan-2-yl acetate	Perfume	80-26-2	201-265-7	9.68	9.90
Nerol	(2E)-3,7-dimethylocta-2,6-dien-1-ol	Perfume	106-25-2	203-378-7	2.90	2.97
Habanolide	A mixture of: (E)-oxacyclohexadec-12-en-2-	Perfume	111879-80-2	422-320-3	1.45	1.48

Common name	IUPAC name	Function	CAS number	EC number	Content (% w/w)	
					Min	Max
	one; (E)-oxacyclohexadec-13-en-2-one; a) (Z)-oxacyclohexadec-(12)-en-2-one and b) (Z)-oxacyclohexadec-(13)-en-2-one					

*Amount of active substance without impurities (pure) 0.974 – 3.088 % (w/w); amount of Transfluthrin per article: 5.7 mg/ bag.

LEVEL 2 – meta SPC 2 (Moth protection flavour bag type 2):

Common name	IUPAC name	Function	CAS number	EC number	Content (% w/w)	
					Min	Max
Transfluthrin	2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	118712-89-3	405-060-5	3.21*	3.21*
Habanolide	A mixture of: (E)-oxacyclohexadec-12-en-2-one; (E)-oxacyclohexadec-13-en-2-one; a) (Z)-oxacyclohexadec-(12)-en-2-one and b) (Z)-oxacyclohexadec-(13)-en-2-one	Perfume	111879-80-2	422-320-3	0.54	0.54
α-hexylcinnamaldehyde	(2E)-2-(phenylmethylidene)octanal	Perfume	101-86-0	202-983-3	0.32	0.32

Common name	IUPAC name	Function	CAS number	EC number	Content (% w/w)	
					Min	Max
Linalool	3,7-dimethylocta-1,6-dien-3-ol	Perfume	78-70-6	201-134-4	0.32	0.32
Hexyl salicylate	hexyl 2-hydroxybenzoate	Perfume	6259-76-3	228-408-6	0.32	0.32
Geraniol	(2E)-3,7-dimethylocta-2,6-dien-1-ol	Perfume	106-24-1	203-377-1	0.22	0.22
alpha-iso-Methylionone	(3E)-3-methyl-4-(2,6,6-trimethylcyclohex-2-en-1-yl)but-3-en-2-one	Perfume	127-51-5	204-846-3	0.32	0.32
Hydrocarbons, C11-C13, isoalkanes, <2% aromatics	Hydrocarbons, C11-C13, isoalkanes, <2% aromatics	Solvent	246538-78-3	920-901-0	21.5	21.5
Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics	Isoparafins C12-C16	Solvent	-	927-676-8	64.5	64.5

*Amount of active substance without impurities (pure) 3.10 – 3.10 % (w/w); amount of Transfluthrin per article: 15 mg/bag.

LEVEL 3 – products in meta SPC 1 (Moth Protection Flavour bag type 1):

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (% w/w)**
Transfluthrin	2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	118712-89-3	405-060-5	1.01*
Linalool	3,7-dimethylocta-1,6-dien-3-ol	Perfume	78-70-6	201-134-4	29.70
Nopyl acetate	2 - (6,6 - dimethylbicyclo < 3.1.1. > - 2 hepten - 2 - yl) ethyl acetate	Perfume	128-51-8	204-891-9	15.84
Geraniol	(2E)-3,7-dimethylocta-2,6-dien-1-ol	Perfume	106-24-1	203-377-1	7.92
Cineole	1,3,3-trimethyl-2-oxabicyclo[2.2.2]octane	Perfume	470-82-6	207-431-5	1.98
alpha-iso-Methylionone	(3E)-3-methyl-4-(2,6,6-trimethylcyclohex-2-en-1-yl)but-3-en-2-one	n.a.	127-51-5	204-846-3	1.48
Terpinyl acetate	2-(4-methylcyclohex-3-en-1-yl)propan-2-yl acetate	n.a.	80-26-2	201-265-7	9.90
Nerol	(2E)-3,7-dimethylocta-2,6-dien-1-ol	n.a.	106-25-2	203-378-7	2.97
Habanolide	A mixture of: (E)-oxacyclohexadec-12-en-2-one; (E)-	n.a.	111879-80-2	422-320-3	1.48

Common name	IUPAC name	Function	CAS number	EC number	Content (% w/w)	
	oxacyclohexadec-13-en-2-one; a) (Z)-oxacyclohexadec-(12)-en-2-one and b) (Z)-oxacyclohexadec-(13)-en-2-one					

*Amount of active substance without impurities (pure) 0.97; amount of Transfluthrin per article: 5.7 mg/bag.

Common name	IUPAC name	Function	CAS number	EC number	Content (% w/w)
Transfluthrin	2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	118712-89-3	405-060-5	3.20*
Linalool	3,7-dimethylocta-1,6-dien-3-ol	Perfume	78-70-6	201-134-4	29.04
Nopyl acetate	2 - (6,6 - dimethylbicyclo < 3.1.1. > - 2 hepten - 2 - yl) ethyl acetate	Perfume	128-51-8	204-891-9	15.49
Geraniol	(2E)-3,7-dimethylocta-2,6-dien-1-ol	Perfume	106-24-1	203-377-1	7.74
Cineole	1,3,3-trimethyl-2-oxabicyclo[2.2.2]octane	Perfume	470-82-6	207-431-5	1.94
alpha-iso-Methylionone	(3E)-3-methyl-4-(2,6,6-	n.a.	127-51-5	204-846-3	1.45

Common name	IUPAC name	Function	CAS number	EC number	Content (% w/w)
	trimethylcyclohex-2-en-1-yl)but-3-en-2-one				
Terpinyl acetate	2-(4-methylcyclohex-3-en-1-yl)propan-2-yl acetate	n.a.	80-26-2	201-265-7	9.68
Nerol	(2E)-3,7-dimethylocta-2,6-dien-1-ol	n.a.	106-25-2	203-378-7	2.90
Habanolide	A mixture of: (E)-oxacyclohexadec-12-en-2-one; (E)-oxacyclohexadec-13-en-2-one; a) (Z)-oxacyclohexadec-(12)-en-2-one and b) (Z)-oxacyclohexadec-(13)-en-2-one	n.a.	111879-80-2	422-320-3	1.45

*Amount of active substance without impurities (pure) 3.09 % (w/w); amount of Transfluthrin per article: 15.0 mg/bag.

LEVEL 3 – products in meta SPC 2 (Moth Protection Flavour bag type 2):

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (% w/w)**
Transfluthrin	2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	118712-89-3	405-060-5	3.21*
Habanolide	A mixture of: (E)-oxacyclohexadec-12-en-2-one; (E)-oxacyclohexadec-13-en-2-one; a) (Z)-oxacyclohexadec-(12)-en-2-one and b) (Z)-oxacyclohexadec-(13)-en-2-one	Perfume	111879-80-2	422-320-3	0.54
α-hexylcinnamaldehyde	(2E)-2-(phenylmethylidene) octanal	Perfume	101-86-0	202-983-3	0.32
Linalool	3,7-dimethylocta-1,6-dien-3-ol	Perfume	78-70-6	201-134-4	0.32
Hexyl salicylate	hexyl 2-hydroxybenzoate	Perfume	6259-76-3	228-408-6	0.32
Geraniol	(2E)-3,7-dimethylocta-2,6-dien-1-ol	Perfume	106-24-1	203-377-1	0.22
alpha-iso-Methylionone	(3E)-3-methyl-4-(2,6,6-trimethylcyclohex-2-en-1-yl)but-3-en-2-one	Perfume	127-51-5	204-846-3	0.32
Hydrocarbons, C11-C13, isoalkanes, <2% aromatics	Hydrocarbons, C11-C13, isoalkanes, <2% aromatics	Solvent	246538-78-3	920-901-0	21.5
Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics	Isoparafins C12-C16	Solvent	-	927-676-8	64.5

*Amount of active substance without impurities (pure) 3.10 – 3.10 % (w/w), amount of Transfluthrin per article: 15 mg/bag.

2.1.2.4 Information on technical equivalence

The sources of the active substances are the same as the ones evaluated in connection with the approval for listing of the active substances on the Union list of approved active substances under Regulation No. 528/2012.

An assessment of technical equivalence of the active substances is therefore not required.

2.1.2.5 Information on the substance(s) of concern

Based on the classification as provided in the SDS submitted by the applicant and the concentrations of the co-formulants in the BPF Anti-moths products above the generic or specific concentration limits, the component listed below were identified as substances of concern in relation to human health (please see also confidential Annex restricted to authorities for detailed information):

Meta SPC 2 (update 2024: now Meta SPC 1)
Linalool (3,7-dimethylocta-1,6-dien-3-ol) CAS N° 78-70-6
Nopyl acetate
(2-(6,6-dimethylbicyclo[3.1.1]-2-hepten-2-yl)ethyl acetate) CAS N° 128-51-8
Geraniol ((2E)-3,7-dimethylocta-2,6-dien-1-ol) CAS N° 106-24-1
alpha-iso-Methylionone CAS N° 127-51-5
((3E)-3-methyl-4-(2,6,6-trimethylcyclohex-2-en-1-yl)but-3-en-2-one)
Cineole (1,3,3-trimethyl-2-oxabicyclo[2.2.2]octane) CAS N° 470-82-6
Nerol ((2E)-3,7-dimethylocta-2,6-dien-1-ol) CAS N° 106-25-2

Meta SPC 3 (update 2024: now Meta SPC 2)
Hydrocarbons, C11-C13, isoalkanes, <2% aromatics CAS N° 246538-78-3
Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics (Isoparafins C12-C16) EC N° 927-676-8

The first six substances contribute to the classification of the biocidal product of meta SPC 2 (Moth protection Flavour Bag type 1) with Eye Dam 1, H318 (Geraniol), Skin Sens 1, H317 (alpha-iso-Methylionone, Cineole, Geraniol, Nopyl acetate, Linalool, Nerol) and Skin Irrit 2 H315 (Linalool).
In addition Geraniol is a biocidal active substance currently under review for PT18 and PT19 by France[1]. By September 2019 no first Draft Competent Authority Report (dCAR) is available. However, the Risk Assessment Committee (RAC-46) discussed the harmonised classification and labelling of Geraniol in 2018 and concluded on Skin Sens. 1 (RAC, 2018).
The concentrations of hydrocarbons, C11-C13, isoalkanes, <2% aromatics and hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics are above the generic concentration limits for meta SPC 3 products (Moth protection flavour Bag type 2) for Asp. Tox. 1 (H304). Based on the package type labelling for Asp. Tox. 1 (H304) for the products as marketed can be omitted (please see confidential Annex restricted to authorities).

According to the CA-Nov14-Doc.5.11 document "Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products", the SoCs can be assigned to both band A and B. If the SoC can be assigned to more than one band, the evaluation/risk management requirements of the higher band will apply (band B in this case based on Eye Dam 1 (H318) and Skin Sens 1 (H317)). According to the guidance document a qualitative risk assessment is performed in section 2.2.6. Risk mitigation

[1] https://echa.europa.eu/de/information-on-chemicals/biocidal-active-substances?p_p_id=echarevbiocides_WAR_echarevbiocidesportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=1&p_p_col_count=2&_echarevbiocides_WAR_echarevbiocidesportlet_javax.portlet.action=searchBiocidesAction

measures in the form of precautionary statements triggered by hazards from these components are covered by the labelling of the products (please refer also to chapter 2.1.3). The banding evaluation scheme for Asp. Tox. 1 hazard is A according to ECHA (ECHA, 2015a). The local risk considerations for meta SPC 2 are considered to cover also meta SPC 3 based on similar proposed risk mitigation measures.

SoCs for the environment:

A SoC assessment for the co-formulants regarding the environment was performed according to the Risk Assessment Guidance Part B+C (ECHA, 2017). For the detailed assessment refer to the confidential Annex restricted to authorities. The following substances were identified for the environment and must be taken into account in the environmental risk assessment for the BPF Anti-moths products, however the eCA conclueded in the detailed SoC assessment that qualitiative risk assesssments are sufficient.

- Nopylacetate (CAS 128-51-8)
- Terpinylacete (CAS 80-26-2)
- Habanolide (CAS 11879-80-2)
- α-Hexylcinnamaldehyde (CAS 101-86-0)
- Hexyl salicylate (CAS 6259-76-3)

2.1.2.6 Type of formulation

XX: Passive Diffuser (granules)

2.1.3 Hazard and precautionary statements

Classification and labelling of the products of the family 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 biocidal product. Therefore only the active substance and respective co-formulants have to be considered for classification and labelling.

Level 2: meta SPC 1 – Moth protection flavour bag type 1 (perfume 1)

Classification	
Hazard category	Aquatic Acute 1, Aquatic Chronic 1, Skin Sens. 1, Eye Dam. 1, Skin Irrit. 2, STOT SE 2, Carc. 2
Hazard statement	H315 Causes skin irritation H317 May cause an allergic skin reaction H318 Causes serious eye damage H351 Suspected of causing cancer H371 May cause damage to organs (nervous system) H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects.
Labelling	
Pictograms	 GHS05, GHS07, GHS08, GHS09
Signal words	Danger
Hazard statements	H315 Causes skin irritation H317 May cause an allergic skin reaction H318 Causes serious eye damage H351 Suspected of causing cancer H371 May cause damage to organs (nervous system) 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. P103: Read label before use. P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P260: Do not breathe vapours. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P302 + P352: IF ON SKIN: Wash with plenty of water/... P333 + P313: If skin irritation or rash occurs: Get medical advice/attention. P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER or doctor. P308 + P313: IF exposed or concerned: Get medical advice/attention. P308 + P311: IF exposed or concerned: Call a POISON CENTER or doctor. P405: Store locked up. P501: Dispose of contents/container to a special waste collection point in accordance with local/regional/national/international regulation (to be specified)
Additional labelling	—

Level 2: meta SPC 2 – Moth protection flavour bag type 2 (Perfume 2)

Classification	
Hazard category	Carc. 2, STOT SE 2, Aquatic Acute 1, Aquatic Chronic 1,
Hazard statement	H351 Suspected of causing cancer H371 May cause damage to organs (nervous system) H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects.
Labelling	
Pictograms	 GHS 09, GHS 08
Signal words	Warning
Hazard statements	H351 Suspected of causing cancer H371 May cause damage to organs (nervous system) H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P102: Keep out of reach of children. P103: Read label before use. P201: Obtain special instructions before use. P202: Do not handle until all safety precautions have been read and understood. P260: Do not breathe vapours. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P308 + P313: IF exposed or concerned: Get medical advice/attention. P308 + P311: IF exposed or concerned: Call a POISON CENTER or doctor. P405: Store locked up. P501: Dispose of contents/container to a special waste collection point in accordance with local/regional/national/international regulation (to be specified)
Additional labelling	EUH208: Contains α-Hexylcinnamaldehyde, Linalool, p-t-Butylcyclohexyl acetate, Hexyl salicylate, alpha-iso-Methylionone, Amberonne, Eugenol, Cyclamen aldehyde, Pentadecan-15-olide, Geraniol, Citronellol, Benzyl salicylate, Aldehyde C-12 MNA, Aldehyde C-12 lauric. May produce an allergic reaction.

2.1.4 Authorised use(s)

2.1.4.1 Use description use #1

Table 1. Meta SPC 1 Use # 1 – Insecticide – (adult and larvae) clothes moths and carpet beetles – non-professional users – passive diffuser – indoor – flavour bags

Product Type	Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Scientific name: Tineidae: *Tineola bisselliella*, common name: clothes moth, development stage: adults and larvae Scientific name: Dermestidae: *Anthrenus verbasci*, common name: carpet beetle, development stage: adults and larvae
Field of use	Insecticide for indoor use
Application method(s)	Flavour bags with impregnated granules (passive diffuser) to be used in wardrobes and drawers against clothes moths and carpet beetles (open system).
Application rate(s) and frequency	Application rate: use number of bags until 15 mg of active substance per m³ of wardrobe or drawer is reached Application frequency: Effective for 3 months, only if necessary repeat treatment after recommended time and maximal application 4 times per year.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Paper box that contains 3 products with its own primary packaging. Packaging material: plastic, LDPE The bag is made of 60 % PP and 40 % viscose with an average weight of 60 g/m2 and an average thickness of 0.65 mm. Foil: 85-90x135-140mm; Folding box: 105x162x38mm. Transfluthrin: 5,7 mg/bag; this applies to: OPTIMUM MOTTEN AKTIVPERLEN RUBIN DUFTENDE MOTTENSCHUTZ-SÄCKCHEN Sachet Anti Mites (Lavande) Duftendes Mottensäckchen Foil: 85-90x135-140mm; folding box: 105x162x38mm or 94x165x40mm. Transfluthrin: 15 mg/bag; this applies to: inseko Textilschutz-Säckchen

2.1.4.2 Use-specific instructions for use

Put the arrowhead of the enclosed hook through the hole at the border of the flavour bag. Don't open the bags. OPTIMUM MOTTEN AKTIVPERLEN: Apply 3 bags per m³ wardrobe or drawer RUBIN DUFTENDE MOTTENSCHUTZ-SÄCKCHEN: Apply 3 bags per m³ wardrobe or drawer Sachet Anti Mites (Lavande): Apply 3 bags per m³ wardrobe or drawer

Duftendes Mottensäckchen: Apply 3 bags per m³ wardrobe or drawer

Inseko Textilschutz-Säckchen: Apply 1 bag per m³ wardrobe or drawer

Adapt the number of flavour bags according to the volume of the treated wardrobe or drawer.

Use the product for 3 months and repeat treatment only if necessary.

2.1.4.3 Use-specific risk mitigation measures

For use only in areas that are inaccessible to infants, children, companion animals (specifically cats) and non-target animals. (N114)

Do not store or use near food, drink and animal feedingstuffs.(N301+160)

No application in rooms, where fish tanks and terrariums are present.

Avoid contact with eyes.

During application, ventilate rooms on a regular basis.

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

First aid instructions:

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

IF EXPOSED: Call a POISON CENTRE or a doctor.

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

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

Storage stability: 4 years

2.1.4.7 Use description use #2

Table 1. Meta SPC 2 Use #2 – Insecticide – (adult and larvae) clothes moths and carpet beetles – non-professional users – passive diffuser – indoor – flavour bags

Product Type	Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide
Target organism (including development stage)	Scientific name: Tineidae: *Tineola bisselliella*, common name: clothes moth, development stage: adults and larvae Scientific name: Dermestidae: *Anthrenus verbasci*, common name: carpet beetle, development stage: adults and larvae
Field of use	Insecticide for indoor use
Application method(s)	Flavour bags with impregnated granules (passive diffuser) to be used in wardrobes and drawers against clothes moths and carpet beetles (open system).
Application rate(s) and frequency	Application rate: use number of bags until 15 mg of active substance per m³ of wardrobe or drawer is reached Application frequency: Effective for 3 months, only if necessary repeat treatment after recommended time and maximal application 4 times per year.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Paper box that contains 3 products with its own primary packaging. Packaging material: plastic, LDPE The bag is made of 60 % PP and 40 % viscose with an average weight of 60 g/m2 and an average thickness of 0.65 mm. Foil: 85-90x135-140mm; folding box: 105x162x38mm or 94x165x40mm . Transfluthrin: 15 mg/bag; this applies to: PROFISSIMO MOTTENSCHUTZ-DUFTSÄCKCHEN AEROXON TEXTILSCHUTZ SÄCKCHEN Profissimo vonné vrecká na ochranu proti moliam Profissimo Vonne sáčky proti šatnim molům Profissimo molyirtó tasak terrasan Home Textilschutz-Säckchen Vandal Blütenfrisch-Mottenkissen Nexa Lotte Mottenschutz Kissen Sachet Anti Mites (Parfum frais) Textilschutz-Säckchen Profissimo Kleidermottenduftsäckchen

2.1.4.8 Use-specific instructions for use

Put the arrowhead of the enclosed hook through the hole at the border of the flavour bag. Don't open the bags.

PROFISSIMO MOTTENSCHUTZ-DUFTSÄCKCHEN: Apply 1 bag per m³ wardrobe or drawer
AEROXON TEXTILSCHUTZ SÄCKCHEN:Apply 1 bag per m³ wardrobe or drawer
Profissimo vonné vrecká na ochranu proti moliam:Apply 1 bag per m³ wardrobe or drawer
Profissimo Vonne sáčky proti šatnim molűm:Apply 1 bag per m³ wardrobe or drawer
Profissimo molyirtó tasak:Apply 1 bag per m³ wardrobe or drawer
terrasan Home Textilschutz-Säckchen:Apply 1 bag per m³ wardrobe or drawer
Vandal Blütenfrisch-Mottenkissen:Apply 1 bag per m³ wardrobe or drawer
Nexa Lotte Mottenschutz Kissen:Apply 1 bag per m³ wardrobe or drawer
Sachet Anti Mites (Parfum frais) :Apply 1 bag per m³ wardrobe or drawer
Textilschutz-Säckchen:Apply 1 bag per m³ wardrobe or drawer
Profissimo Kleidermottenduftsäckchen: Apply 1 bag per m³ wardrobe or drawer

Adapt the number of flavour bags according to the volume of the treated wardrobe or drawer.

Use the product for 3 months and repeat treatment only if necessary.

2.1.4.9 Use-specific risk mitigation measures

For use only in areas that are inaccessible to infants, children, companion animals (specifically cats) and non-target animals. (N114)

Do not store or use near food, drink and animal feedingstuffs.(N301+160)

No application in rooms, where fish tanks and terrariums are present.

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

First aid instructions:

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.

IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.

IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.

IF EXPOSED: Call a POISON CENTRE or a doctor.

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

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

Storage stability: 3.5 years

2.1.5 General directions for use

2.1.5.1 Instructions for use

Cf. to use-specific instructions for use.

2.1.5.2 Risk mitigation measures

Cf. to use-specific risk mitigation measures.

2.1.5.3 Particulars of likely direct or indirect effects and emergency measures to protect the environment

Likely direct or indirect effects: Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice. **Emergency measures to protect the environment:** Do not allow to enter into surface water or drains. In case of entry into waterways, soil or drains in larger quantities, inform the responsible authorities. Methods and material for containment and cleaning up: take up mechanically and collect in suitable container for disposal.

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 local/national regulations. The empty packaging of the product and the product after 3 months of use can be disposed of with household waste or according to local/national regulations.

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

Store at dry and cool places. Protect from heat and direct sunlight. Do not store above 40°C. Protect from frost.

2.1.6 Other information

If further products are notified in the BPF at a later stage, the correct number of bags per m³ wardrobe or drawer, complying with the auhtorised application rate, has to be indicated.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material	Intended user (e.g. professional,	Compatibility of the product with

			of closure(s)	**non-professional)**	**the proposed packaging materials (Yes/No)**
Moth protection flavour bag type 1 and 2 meta SPC 1 and 2	LDPE foil: 85-90 x 135-140 mm Paper box: 105 x 162 x 38 mm 94 x 165 x 40 mm	primary packaging: plastic: LDPE secondary packaging: paper box that contains 3 bags The bag is made of 60 % PP and 40 % viscose with an average weight of 60 g/m2 and an average thickness of 0.65 mm.	Not applicable	Non-professional	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 Anti-moth products in accordance with Regulation (EU) No. 528/2012 in the product type 18.

2.2 Assessment of the biocidal product (family)

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

Intended use # 1 – Impregnated paper

Product Type(s)	EU BPR Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	To be used in wardrobes and drawers against clothes moths and carpet beetles for Non-professional users.
Target organism (including development stage)	Scientific name: Tineidae: *Tineola bisselliella*, common name: cloth moth, development stage: adults and larvae Scientific name: Dermestidae: *Anthrenus verbasci*, common name: carpet beetle, development stage: adults and larvae
Field of use	Insecticide for indoor use
Application method(s)	Open system: diffusion. Put one strip of 12 papers for wardrobe or drawer
Application rate(s) and frequency	Every 6 months
Category(ies) of user(s)	General public (non-professional)
Pack sizes and packaging material	Pack size 85x 150 mm, ready to use product , and the packaging material is plastic: LDPE

Intended use # 2 – Flavour bags

Product Type(s)	EU BPR Product type 18: Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	To be used in wardrobes and drawers against clothes moths and carpet beetles for Non-professional users.
Target organism (including development stage)	Scientific name: Tineidae: *Tineola bisselliella*, common name: cloth moth, development stage: adults and larvae Scientific name: Dermestidae: *Anthrenus verbasci*, common name: carpet beetle, development stage: adults and larvae
Field of use	Insecticide for indoor use
Application method(s)	Open system: diffusion. Put one bag for wardrobe or drawer
Application rate(s) and frequency	Every 3 months
Category(ies) of user(s)	General public (non-professional)

Pack sizes and packaging material	Packaging material: plastic, LDPE. Please refer to IUCLID dossier for individual pack sizes.

2.2.2 Physical, chemical and technical properties

The biocidal product family, in the form in which it is supplied to the user, consists of granules (bags) which have been treated with the biocidal product formulation. According to the Guidance on requirements for substances in articles (ECHA, 2017e) the biocidal product has to be considered as combination of formulation and an article (granules in a bag). See section 2.1.2.3 for further explanation. As a consequence, with a few exemptions, only the physical, chemical and technical properties of the biocidal product formulation will be addressed.

Moth protection flavour bag type 1 (meta SPC 1):

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	visual method	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: NA	Article: solid	NA
	visual method	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: NA	Moth protection flavour bag type 1 (Anti-moth bag liquid Perfume 1): liquid	Safety Data Sheet
Colour at 20 °C and 101.3 kPa	visual method	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: NA	Article: White granules impregnated with liquid mixture	Safety Data Sheet
	visual method	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: NA	Moth protection flavour bag type 1 (Anti-moth bag liquid Perfume 1): white	Safety Data Sheet
Odour at 20 °C and 101.3 kPa	visual method (weight of evidence)	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: NA	Article	Safety Data Sheet
	visual method (weight of evidence)	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: NA	Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1)	Safety Data Sheet
Acidity / alkalinity	NA	NA	Article: NA, the article is a granule	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	NA	NA	Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): The major part of the solution is made up of the perfume co-formulant (ref. confidential annex). According to the safety data sheet, the perfume is practically not soluble in water. Moreover, the a.s. solubility in water is < 0.01 mg/L. According to the ECHA guideline, the pH determination is required in the case of solid and non-aqueous liquid biocidal products which are to be applied as aqueous dilutions or dispersions. Since the formulation is not intended to be applied in this manner, the study is waived.	NA
Relative density / bulk density	NA	NA	Article: NA, the article is a granule	NA
	NA	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: NA	Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): The most of the solution is made up of the perfume co-formulant (ref. confidential annex). For this reason, it was assumed the density of the solution is determined by this component, and the study was not deemed necessary. According to the SDS of the perfume, the density at 20°C is 0.92 g/cm3.	Safety Data Sheet
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 14087	Article: Transfluthrin; nominal value 5.7 mg. The samples were stored at 40°C in the commercially available packaging.	Anonymous 2019a

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Analysis 0 point: 7.3 mg (128%) Analysis 4 weeks: 7.1 mg (125%) Analysis 8 weeks: 5.9 mg (104%) The SoCs originate from intentionally added co-formulants to the biocidal product. This co-formulant is used as supplied by a company. It is not expected that substances in the biocidal product can degrade to identified SoCs. Hence, it is expected that they cannot possibly increase during manufacture and storage of the biocidal product.	
	NA	NA	Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): NA, the liquid is not placed on the market but only used in the manufacturing process of the final article.	NA
Storage stability test – **long term storage at ambient temperature**	NA at the moment	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 14087	Article: Transfluthrin; nominal value 5.7 mg. The active substance is stored at 25°C in the commercially available packaging. The active substance is stable. T0: 7.3 mg (128%) T4 years: 6.9 mg (121%) After 4 years the sachets are slightly yellow and are intact. The sachets are made of non-woven viscose which are used as packaging materials. Inside of the sachets there is the support material with the active substance. Yellowing is a common phenomenon for viscose and is not related to the active substance. The	Anonymous 2019a

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			degradation rate of the active substance during long term storage is below 10%. There are no experiences in use that indicate a disintegration of the bags. The SoCs originate from intentionally added co-formulants to the biocidal product. This co-formulant is used as supplied by a company. It is not expected that substances in the biocidal product can degrade to identified SoCs. Hence, it is expected that they cannot possibly increase during manufacture and storage of the biocidal product.	
	NA	NA	Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): NA, the liquid is not placed on the market but only used in the manufacturing process of the final article.	NA
Storage stability test – **low temperature stability test for liquids**	NA	NA	Article: The test can be waived, the label gives clear instructions that the product must be protected from frost. Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): NA, the liquid is not placed on the market but only used in the manufacturing process of the final article.	NA
Effects on content of the active substance and technical characteristics of the biocidal	NA	NA	Article: No interaction with sunlight is expected during storage or during the use, since the package of the product is dark and the product will be used	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
product - **light**			into a wardrobe. Furthermore the active substance contained in the products do not absorb wavelengths greater than 290 nm. No reaction with the container material was observed. Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): The liquid is not expected to be exposed to sunlight during the manufacturing process of the article.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	NA	NA	Article: The effect of temperature was investigated in the accelerated stability studies. ~~The active substance content remained in the acceptable range~~. No reactivity towards container material was observed. The humidity parameter was taken into account during the efficacy testing, performed under controlled humidity conditions (65+/-5% RH); the products have proved to be effective under the experimental conditions. Anyway, the effect of humidity was not investigated by a specific experimental study, because the product is sealed during storage and used indoor in wardrobes or closets, where high levels of relative humidity is of little importance under normal conditions.	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): During the manufacturing process, temperature and humidity are controlled, so the effects of temperature and humidity are considered to be not relevant.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	NA	NA	Article: No reaction with the container material was observed during the stability studies. Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): No reaction with the container material was observed during the manufacturing process of the liquid.	NA
Wettability	NA	NA	Article: The test is only applicable to water dispersible products and has been waived. Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): The test is only applicable to water dispersible products and has been waived.	NA
Suspensibility, spontaneity and dispersion stability	NA	NA	Article: The study is expected to be performed in case of wettable powders, water dispersible granules, or water dispersible powders. The solution contained in the paper or in the bags, doesn't have this characteristics. The test has been waived	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): The study is expected to be performed in case of wettable powders, water dispersible granules, or water dispersible powders. The product is a liquid formulation. The test has been waived.	
Wet sieve analysis and dry sieve test	NA	NA	Article: The products are ready-to-use products. The study is expected to be performed on dust, wettable powders, suspension concentrates, and capsule suspensions. The products do not have these characteristics. The test has been waived. Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): The product is a liquid formulation. The study is expected to be performed on dust, wettable powders, suspension concentrates, and capsule suspensions. The product does not have these characteristics. The test has been waived.	NA
Emulsifiability, re-emulsifiability and emulsion stability	NA	NA	Article: The products are ready-to-use formulation. The study is expected to be performed in the case of an emulsifiable product. The test has been waived Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): The product is a liquid formulation. The study is expected to be performed in the case of emulsifiable	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			products The test has been waived.	
Disintegration time	NA	NA	Article: The products are ready-to-use formulations. The study is expected to be performed in the case of a product in tablets. The test has been waived. Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): The product is a liquid formulation. The study is expected to be performed in the case of a product in tablets. The test has been waived.	NA
Particle size distribution, content of dust/fines, attrition, friability	NA	NA	Article: The study is expected to be performed in the case of powder biocidal products and granules, and products that are applied in a manner that generates exposure to aerosols, particles or droplets. The products do not have these characteristics. Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): The study is expected to be performed in the case of powder biocidal products and granules, and products that are applied in a manner that generates exposure to aerosols, particles or droplets. The product is a liquid used to impregnate granules, so it does not have these characteristics.	NA
Persistent foaming	NA	NA	Article: The products are ready-to-use products. The study is expected to be	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			performed in the case of preparations to be dispersed in water. The test has been waived. Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): The data are required when the product is applied in water for use. The test has been waived.	
Flowability/Pourability/Dustability	NA	NA	Article: The products are ready-to-use products. The study is not expected to be performed. Data are only required for granular formulations applied through application equipment that would subject the granules to pressure and/or heat, on suspensions, or on dustable powders. The test has been waived. Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): The product is a liquid formulation. The study is not expected to be performed. Data are only required for granular formulations applied through application equipment that would subject the granules to pressure and/or heat, on suspensions, or on dustable powders. The test has been waived.	NA
Burning rate — smoke generators	NA	NA	Article and Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): Evidence is required that the preparation may be satisfactorily applied as a	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			smoke and that the burning rate and burning completeness support the proposed use. The products are not applied in such fashion.	
Burning completeness — smoke generators	NA	NA	Article and Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): Evidence is required that the preparation may be satisfactorily applied as a smoke and that the burning rate and burning completeness support the proposed use. The products are not applied in such fashion.	NA
Composition of smoke — smoke generators	NA	NA	Article and Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): The test is required for smoke generator products. The products are not applied in such fashion.	NA
Spraying pattern — aerosols	NA	NA	Article and Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): The products are not applied in such fashion.	NA
Physical compatibility	NA	NA	Article and Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): The use of the products in combination with other products is not intended.	NA
Chemical compatibility	NA	NA	Article and Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1):	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			The use of the products in combination with other products is not intended.	
Degree of dissolution and dilution stability	NA	NA	Article and Anti-moth sachet liquid (Perfume 1): The test is required for products used in a water soluble bag and for all tablets. The products under exam don't have these characteristics.	NA
Surface tension	NA	NA	Article: This test is provided for biocidal products in liquid formulation. The article consists of a bag containing granules impregnated with the solution. For this reasons the endpoint has been waived.	NA
	EU Method A.5 OECD 115	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 9052	Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): According to test method A.5, the surface tension of the sample labelled as Anti-moth sachet liquid containing "Perfume 1" is 29.1 mN/m, at 20°C.	Anonymous 2019a
Viscosity	NA	NA	Article: This test is provided for biocidal products in liquid formulation. The article consists of a bag containing granules impregnated with the solution. For this reasons the endpoint was waived.	NA
	OECD Test guideline 114	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 9010	Moth protection flavour bag type 1 (Anti-moth sachet liquid Perfume 1): Result for the given substance was: - dynamic viscosity: 7.33 mPas (at 20°C) and 4.5 mPas (at 40°C) - kinematic viscosity: 8.05 x 10-7 m2/sec (at 20°C) and 4.95 x 10-7 m2/sec (at 40°C).	Annowatec 2019

Moth protection flavour bag type 2 (meta SPC 2):

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	visual method	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: NA	Article: solid	NA
	visual method	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 6125	Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): liquid	Anonymous 2016a
Colour at 20 °C and 101.3 kPa	visual method	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: NA	Article: white	Safety Data Sheet
	visual method	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 6125	Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): Yellowish liquid	Anonymous 2016a
Odour at 20 °C and 101.3 kPa	visual method (weight of evidence)	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: NA	Article: fresh	Safety Data Sheet
	visual method (weight of evidence)	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: NA	Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): Fresh	Safety Data Sheet
Acidity / alkalinity	NA	NA	Article: NA, the article is a granule	NA
	CIPAC MT 75 OECD Guideline 122	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 6125	Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): pH of the test item "Anti-Moth Sachet Liquid" as it is, proved to be 5.33 at 20°C. A 1% sample solution in water possesses a pH of 5.47. Since the pH value fell between 4 and 10, test range of non-applicability, the acidity/alkalinity evaluation (OECD 122) cannot be performed.	Anonymous 2016a
	NA	NA	Article:	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Relative density / bulk density			NA, the article is a granule	
	OECD Guideline 109	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 6125	Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): Test item relative density at 20°C was equal to 0.8015, it's absolute density was 0.8032 g/cm3.	Anonymous 2016a
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 5131	Article: The active substance content (mg per bag) remains stable. Storage at 35°C in the commercially available packaging. Nominal content 15.0 mg. T0: 15.7 mg (105%) T2weeks: 14.5 mg (97%) T4weeks: 14.9 mg (100%) T12weeks: 14.3 mg (95%) During storage the bags became slightly yellowish. The sachets are made of non-woven viscose which are used as packaging materials. Inside of the sachets there is the support material with the active substance. Yellowing is a common phenomenon for viscose and is not related to the active substance. The degradation rate of the active substance during accelerated storage is below 10%.The SoCs originate from intentionally added co-formulants to the biocidal product. This co-formulant is used as supplied by a company. It is not expected that substances in the biocidal product can degrade to identified SoCs. Hence, it is expected that they cannot	Anonymous 2015 Anonymous 2019

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			possibly increase during manufacture and storage of the biocidal product.	
	NA	NA	Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): NA, the liquid is not placed on the market but only used in the manufacturing process of the final article.	NA
Storage stability test – **long term storage at ambient temperature**	CIPAC MT 46.3	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 5131	Article: The active substance content remains stable for 3.5 years. Nominal content 15.0 mg. Storage at 20°C in the commercially available packaging.T0: 15.7 mg (105%) 1 year: 15.1 mg (101% 3.5 years: 15.2 mg (101%) 4.5 years: 12.6 mg (84%) After storage for 4.5 years at 20°C the sachets appear slightly yellow. The sachets are made of non-woven viscose which are used as packaging materials. Inside of the sachets there is the support material with the active substance. Yellowing is a common phenomenon for viscose and is not related to the active substance. The degradation rate of the active substance during long term storage is higher 10% after 4.5 years of storage. Meta SPC 3 is considered stable at the above mentioned storage conditions for 3.5 years as the active substance degradation at this time was below 10%. There are no experiences	Anonymous 2019b

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			in use that indicate a disintegration of the bags. The SoCs originate from intentionally added co-formulants to the biocidal product. This co-formulant is used as supplied by a company. It is not expected that substances in the biocidal product can degrade to identified SoCs. Hence, it is expected that they cannot possibly increase during manufacture and storage of the biocidal product.	
	NA	NA	Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): NA, the liquid is not placed on the market but only used in the manufacturing process of the final article.	NA
Storage stability test – **low temperature stability test for liquids**	NA	NA	Article: The test can be waived, the label gives clear instructions that the product must be protected from frost. Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): NA, the liquid is not placed on the market but only used in the manufacturing process of the final article.	NA
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	NA	NA	Article: No interaction with sunlight is expected during storage or during the use, since the package of the product is dark and the product will be used into a wardrobe. Furthermore the active substances contained in the products does not absorb wavelengths	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			greater than 290 nm. No reaction with the container material was observed Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): The liquid is not expected to be exposed to sunlight during the manufacturing process of the article.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	NA	NA	Article: The effect of temperature was investigated in the accelerated stability studies. The active substance content remained in the acceptable range when stored at 35°C for 12 weeks. No reactivity towards container material was observed. The humidity parameter was taken into account during the efficacy testing, performed under controlled humidity conditions (65+/-5% RH); the products have proved to be effective under the experimental conditions. Anyway, the effect of humidity was not investigated by a specific experimental study, because the product is sealed during storage and used indoor in wardrobes or closets, where high levels of relative humidity is of little importance under normal conditions. Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): During the manufacturing process, temperature and humidity are controlled,	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			so the effects of temperature and humidity are considered to be not relevant.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	NA	NA	Article: No reaction with the container material was observed during the stability studies. Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): No reaction with the container material was observed during the manufacturing process of the liquid.	NA
Wettability	NA	NA	Article: The test is only applicable to water dispersible products and has been waived. Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): The test is only applicable to water dispersible products and has been waived.	NA
Suspensibility, spontaneity and dispersion stability	NA	NA	Article: The study is expected to be performed in case of wettable powders, water dispersible granules, or water dispersible powders. The solution contained in the paper or in the bags, doesn't have this characteristics. The test has been waived Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): The study is expected to be performed in case of wettable powders, water dispersible granules, or water dispersible powders.	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			The product is a liquid formulation. The test has been waived.	
Wet sieve analysis and dry sieve test	NA	NA	Article: The products are ready-to-use products. The study is expected to be performed on dust, wettable powders, suspension concentrates, and capsule suspensions. The products do not have these characteristics. The test has been waived. Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): The product is a liquid formulation. The study is expected to be performed on dust, wettable powders, suspension concentrates, and capsule suspensions. The product does not have these characteristics. The test has been waived.	NA
Emulsifiability, re-emulsifiability and emulsion stability	NA	NA	Article: The products are ready-to-use formulation. The study is expected to be performed in the case of an emulsifiable product. The test has been waived Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): The product is a liquid formulation. The study is expected to be performed in the case of emulsifiable products The test has been waived.	NA
Disintegration time	NA	NA	Article: The products are ready-to-use formulations. The study is expected to be performed in the case of a	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			product in tablets. The test has been waived. Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): The product is a liquid formulation. The study is expected to be performed in the case of a product in tablets. The test has been waived.	
Particle size distribution, content of dust/fines, attrition, friability	NA	NA	Article: The study is expected to be performed in the case of powder biocidal products and granules, and products that are applied in a manner that generates exposure to aerosols, particles or droplets. The products do not have these characteristics. Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): The study is expected to be performed in the case of powder biocidal products and granules, and products that are applied in a manner that generates exposure to aerosols, particles or droplets. The product is a liquid used to impregnate granules, so it does not have these characteristics.	NA
Persistent foaming	NA	NA	Article: The products are ready-to-use products. The study is expected to be performed in the case of preparations to be dispersed in water. The test has been waived.	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): The data are required when the product is applied in water for use. The test has been waived	
Flowability/Pourability/Dustability	NA	NA	Article: The products are ready-to-use products. The study is not expected to be performed. Data are only required for granular formulations applied through application equipment that would subject the granules to pressure and/or heat, on suspensions, or on dustable powders. The test has been waived. Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): The product is a liquid formulation. The study is not expected to be performed. Data are only required for granular formulations applied through application equipment that would subject the granules to pressure and/or heat, on suspensions, or on dustable powders. The test has been waived.	NA
Burning rate — smoke generators	NA	NA	Article and Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): Evidence is required that the preparation may be satisfactorily applied as a smoke and that the burning rate and burning completeness support the proposed use. The products are not applied in such fashion.	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Burning completeness — smoke generators	NA	NA	Article and Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): Evidence is required that the preparation may be satisfactorily applied as a smoke and that the burning rate and burning completeness support the proposed use. The products are not applied in such fashion.	NA
Composition of smoke — smoke generators	NA	NA	Article and Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): The test is required for smoke generator products. The products are not applied in such fashion.	NA
Spraying pattern — aerosols	NA	NA	Article and Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): The products are not applied in such fashion.	NA
Physical compatibility	NA	NA	Article and Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): The use of the products in combination with other products is not intended	NA
Chemical compatibility	NA	NA	Article and Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): The use of the products in combination with other products is not intended.	NA
Degree of dissolution and dilution stability	NA	NA	Article and Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2):	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			The test is required for products used in a water soluble bag and for all tablets. The products under exam don't have these characteristics.	
Surface tension	NA	NA	Article: This test is provided for biocidal products in liquid formulation. The article consists of a bag containing granules impregnated with the solution. For this reasons the endpoint has been waived.	NA
	EU Method A.5 OECD 115	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 9023	Article and Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): According to test method A.5, the surface tension of the sample labelled as Anti-moth sachet liquid containing is 25.4 mN/m, at 25°C.	Anonymous 2019b
Viscosity	NA	NA	Article: This test is provided for biocidal products in liquid formulation. The article consists of a bag containing granules impregnated with the solution. For this reasons the endpoint has been waived.	NA
	OECD Test guideline 114	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 9023	Article and Moth protection flavour bag type 2 (Anti-moth sachet liquid Perfume 2): Dynamic Viscosity (20°C): 2.75 mPas Dynamic Viscosity (40°C): 2.10 mPas Kinematic Viscosity (20°C): 3.42×10^{-7} m^2/s	Annowatec 2019 Wessel 2017

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Kinematic Viscosity (40°C): $2.61x10^{-7}$ m^2/s	

Conclusion on the physical, chemical and technical properties of the product
The conclusion on the physical, chemical and technical properties of the product is as follows: The products are liquid formulations. The bag formulations (meta SPC1 and 2) consist of a spunlace bag which is white or with small drawings. The biocidal products are applied onto the carriers. Meta SPC 2 consists of 2 products which differ only slightly in the active substance content and contain mainly co-formulants. Therefore, both formulations of meta SPC 2 can be considered as representative for this meta SPC as their physico-chemical properties are expected to be in very small margin. All physico-chemical tests are conducted with product 1 of meta SPC 2. For further information please refer to the confidential annex.

2.2.3 Physical hazards and respective characteristics

Moth protection flavour bag type 1 (meta SPC 1):

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	NA	NA	No chemical groups present which indicate explosive properties.	NA
Flammable gases	NA	NA	Article and Liquid: According to CLP Regulation 1272/2008 these tests are required for gas and gas mixtures. For this reason the test can be waived.	NA
Flammable aerosols	NA	NA	Article and Liquid: According to CLP Regulation 1272/2008 these tests are required for	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			aerosol products (with gas under pressure). For this reason the test can be waived.	
Oxidising gases	NA	NA	Article and Liquid: According to CLP Regulation 1272/2008 these tests are required for gas and gas mixtures. For this reason the test can be waived.	NA
Gases under pressure	NA	NA	Article and Liquid: According to CLP Regulation 1272/2008 these tests are required for gas and gas mixtures. For this reason the test can be waived.	NA
Flammable liquids	NA	Lot n° tested: NA	Anti-moth sachet liquid (Perfume 1): The majority of the biocidal product is the co-formulant perfume (ref. confidential annex). For this reason, it may be assumed that the flash point of the solution is determined by this component, and the study was not	Safety Data Sheet

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			deemed necessary. According to the SDS of the co-formulant, the flash point is 80°C, thus the solution is not classified as flammable liquid, according to CLP Regulation 1272/2008.	
Flammable solids	NA	NA	Article: According to Reg. CLP Regulation 1272/2008 "A flammable solid means a solid which is readily combustible, or may cause or contribute to fire through friction" The article comprises of a granule carrier and the liquid biocidal product which is impregnated onto the carrier Thus, the flash point of the article is mainly related to the carrier used. The study has been waived.	NA
Self-reactive substances and mixtures	NA	NA	No chemical groups present which indicate explosive properties.	NA
Pyrophoric liquids	NA	NA	Liquid: The biocidal product is not classified as	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			pyrophoric according to CLP Regulation 1272/2008. Furthermore no indication from use are accessible that demonstrate self-ignition after 5 minutes of exposure to air. The study has been waived.	
Pyrophoric solids	NA	NA	The article comprises of a granule carrier and the liquid biocidal product which is impregnated onto the carrier. The carrier is not classified as pyrophoric. The study has been waived.	NA
Self-heating substances and mixtures	UN test N.4 for self-heating substances	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 9351-1	Article: Due to the negative result at 140 °C (10 cm cube) the test item had not to be classified as "self-heating substance" in the sense of UN Manual of Tests and Criteria, Method N.4., and had not to be classified as "self-heating substance" according to chapter 2.11 of the GHS (CLP) regulations	Krack 2020a

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Substances and mixtures which in contact with water emit flammable gases	NA	NA	Liquid: The use of the product in water is not provided in normal conditions of use.	NA
Oxidising liquids	NA	NA	Oxygen and chlorine are present in the biocidal product but they are only bonded to carbon atoms. The study has been waived.	NA
Oxidising solids	NA	NA	The article comprises of a granule carrier and the liquid biocidal product which is impregnated onto the carrier. The carrier is not classified as oxidising. The study has been waived.	NA
Organic peroxides	NA	NA	Liquid: The biocidal product does not contain a bivalent –O-O- structure and no indication is given in the SDS.	NA
Corrosive to metals	NA	NA	Liquid: The liquid product is not intended to be in contact with metal neither in use nor in storage. It is impregnated onto a carrier.	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			The study has been waived.	
Auto-ignition temperatures of products (liquids and gases)	NA	NA	Liquid: Liquid products (without support) are only handled in the manufacturing plants, where conditions are controlled and monitored. Therefore, no ignition is expected when the liquid product is in contact with air and a hot surface during the manufacturing process. Additionally no contact to a hot surface is expected for the article if used according to use instructions. For these reasons the study was waived.	NA
Relative self-ignition temperature for solids	UN test N.4 for self-heating substances	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 9351-1	Article: Due to the negative result at 140 °C (10 cm cube) the test item had not to be classified as "self-heating substance" in the sense of UN Manual of Tests and Criteria, Method N.4., and had not to	Krack 2020a

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			be classified as "self-heating substance" according to chapter 2.11 of the GHS (CLP) regulations	
Dust explosion hazard	NA	NA	Liquid: The biocidal product is liquid and the article is not prone to dusting.	NA

Moth protection flavour bag type 2 (meta SPC 2):

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	NA	NA	No chemical groups present which indicate explosive properties.	NA
Flammable gases	NA	NA	Article and Liquid: According to CLP Regulation 1272/2008 these tests are required for gas and gas mixtures. For this reason the test can be waived.	NA
Flammable aerosols	NA	NA	Article and Liquid: According to CLP Regulation 1272/2008 these tests are required for aerosol products (with gas under pressure). For this reason the	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			test can be waived.	
Oxidising gases	NA	NA	Article and Liquid: According to CLP Regulation 1272/2008 these tests are required for gas and gas mixtures. For this reason the test can be waived.	NA
Gases under pressure	NA	NA	Article and Liquid: According to CLP Regulation 1272/2008 these tests are required for gas and gas mixtures. For this reason the test can be waived.	NA
Flammable liquids	Method A.9* Method ISO 3679:2015	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 6125	Anti-Moth Sachet Liquid: According to test method A.9, the flash point of sample labelled as Anti-moth sachet liquid is 77°C.	Anonymous 2016b
Flammable solids	NA	NA	Article: According to Reg. CLP Regulation 1272/2008 "A flammable solid means a solid which is readily combustible, or may cause or contribute to fire through friction" The article	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			comprises of a granule carrier and the liquid biocidal product which is impregnated onto the carrier Thus, the flash point of the article is mainly related to the carrier used. The study has been waived.	
Self-reactive substances and mixtures	NA	NA	No chemical groups present which indicate explosive properties.	NA
Pyrophoric liquids	NA	NA	Liquid: The biocidal product is not classified as pyrophoric according to CLP Regulation 1272/2008. Furthermore no indication from use are accessible that demonstrate self-ignition after 5 minutes of exposure to air. The study has been waived.	NA
Pyrophoric solids	NA	NA	The article comprises of a granule carrier and the liquid biocidal product which is impregnated onto the carrier. The carrier is not classified as pyrophoric. The	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			study has been waived.	
Self-heating substances and mixtures	UN test N.4 for self-heating substances	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 9346-2	Article: Due to the negative result at 140 °C (10 cm cube) the test item had not to be classified as "self-heating substance" in the sense of UN Manual of Tests and Criteria, Method N.4., and had not to be classified as "self-heating substance" according to chapter 2.11 of the GHS (CLP) regulations	Krack 2020b
Substances and mixtures which in contact with water emit flammable gases	NA	NA	Liquid: The use of the product in water is not provided in normal conditions of use.	NA
Oxidising liquids	NA	NA	Oxygen and chlorine are present in the biocidal product but they are only bonded to carbon atoms. The study has been waived.	NA
Oxidising solids	NA	NA	The article comprises of a granule carrier and the liquid biocidal product which is impregnated onto the carrier. The	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			carrier is not classified as oxidising. The study has been waived.	
Organic peroxides	NA	NA	Liquid: The biocidal product does not contain a bivalent –O-O- structure and no indication is given in the SDS.	NA
Corrosive to metals	NA	NA	Liquid: The liquid product is not intended to be in contact with metal neither in use nor in storage. It is impregnated onto a carrier. The study has been waived.	NA
Auto-ignition temperatures of products (liquids and gases)	NA	NA	Liquid: Liquid products (without support) are only handled in the manufacturing plants, where conditions are controlled and monitored. Therefore, no ignition is expected when the liquid product is in contact with air and hot surfaces during the manufacturing process. Additionally no contact to a hot surface is	NA

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			expected for the article if used according to use instructions. For these reasons the study was waived.	
Relative self-ignition temperature for solids	UN test N.4 for self-heating substances	Purity of transfluthrin: ≥98.5% (w/w) Lot n° tested: 9346-2	Article: Due to the negative result at 140 °C (10 cm cube) the test item had not to be classified as "self-heating substance" in the sense of UN Manual of Tests and Criteria, Method N.4., and had not to be classified as "self-heating substance" according to chapter 2.11 of the GHS (CLP) regulations	Krack 2020b
Dust explosion hazard	NA	NA	Liquid: The biocidal product is liquid and the article is not prone to dusting.	NA

**An experimental study as for method A.9 of Regulation n. 440/2008 was performed in order to establish the flash point of the liquid representative product. As described in Regulation n. 440/2008, the performance of method A.9 by equilibrium method has to be performed according to ISO 1516, ISO 3680, ISO 1523, ISO 3679. The ISO 3679 method has also been followed to conduct the study, as specified in the study report provided by the sponsor. The method is listed in the table 2.6.3 annex I of CLP Regulation (which lists methods for determining the flash point of flammable liquids). For this reasons, the provided study is considered suitable to the requirements of flammable liquids endpoint.

Conclusion on the physical hazards and respective characteristics of the product
The products have no physical hazard statements.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Transfluthrin *Moth protection flavour bag type 1 meta SPC 1*	ICH Topic Q 2 B "Guideline on validation of analytical procedures methodology" Extraction followed by GC-ECD	2	0.9989	Sufficient separation existing according to system suitability, none interference peaks	-	110.4	1.23	0.0029 mg/kg	Anonymous 2014
Transfluthrin *Moth protection flavour bag type 2 meta SPC 2*	Extraction followed by ^{1}H-NMR	6 calibration mixtures	0.9987	a. TF will be clearly visible and identifiable within the mixture of TF, Cofromulant 1 and perfume 1 and in extracts from loaded polypropylene; b. the doublet signal at 5.6 ppm is free from any overlapping with other signals and can be used for	-	NMR: Mean 98,8% Extraction: mean 82,5%	-	0.35%	Anonymous 2016

				quantification					

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		
The test was not performed because in normal condition of use, soil contamination does not occur. The products are intended to be used indoor (inside the wardrobe). The products are disposable and all releases are directed to solid waste.									

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		
According to the ESD Guidance, under the proposed conditions of use, the active substance will be emitted in air. But the concentration in air will be not relevant because the instant dilution of transfluthrin. Furthermore, considering the relative small amount used and the volume of the atmospheric compartment, possible abiotic effects of transfluthrin on the atmosphere are expected to be negligible (from Risk Assessment report).									

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		
In The test was not performed because in normal condition of use, water contamination does not occour. The products are intended to be used indoor (inside the wardrobe). The products are disposable and all releases are directed to solid waste.									

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 for humans (The Netherlands, 2014).

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 (The Netherlands, 2014).									

Analytical methods for the analysis of the product as such including the Substances of concern									
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**		
Linalool	GC-FID	2 measurements	The calibration is linear.	The chromatograms of the standard solutions show no interference.		98,1			Anonymous 2020
Nopyl acetate	GC-FID	2 measurements	The calibration is linear.	The chromatograms of the standard solutions show no interference.		97,6			Anonymous 2020
Geraniol	GC-MS	2 measurements	The calibration is linear.	Quantification by FID signal not possible (peaks are not separated). MS signal of		69,8			Anonymous 2020

				standard is used for quantification.					
Alpha-iso-methylionone (Isoraldein 70)	GC-MS	2 measurements	The calibration is linear.	Quantification by FID signal not possible (peaks are not separated). MS signal of standard is used for quantification.		71,0			Anonymous 2020
Coformulant 1 (C12-C13)	GC-MS	2 measurements	The calibration is linear for low concentrations.	The chromatograms of the standard solutions show no interference.		64,8			Anonymous 2020

Conclusion on the methods for detection and identificationof the product
The method is suited for measuring the concentration of transfluthrin in moth sachets with a recovery rate of 110.4% and a relative standard deviation of 1.23%. Another method was developed in order to measure the concentration of transfluthrin in Moth protection flavour bag 2, based on NMR, and this was defined as method of choice. It can be assumed that the methods provided for meta SPC 1 and meta SPC 2 are applicable to the other meta SPC, because of the similarity of the biocidal products which differ mainly in the perfume and solvent used. The extraction from microporous material such as PP is more difficult as compared to other materials. Solvent penetration is restricted as PP micropores do not swell. A special hot extraction procedures ensure the complete extraction of transfluthrin from the loaded PP-polymer. With H-NMR method is possible to determine tarnsfluthrin in mixture together with Coformulant 1 and Perfume 2. The hot extraction with ethyl acetate is an efficent method to recover TF from loaded polymer, but only if the loading is ≤ 30%, the drying conditions are held at 50°C / 1h and the H-NMR determination of transfluthrin is performed with short notice. Under these conditions overall recovery including H-NMR quantification is 82% (at a target loading rate of ≤30%).

2.2.5 Efficacy against target organisms

Note, May 2024: *Moth papers (originally meta SPC 1) are not authorised anymore due to change in classification and labelling in the 21st ATP (Reg. (EU) 2024/197). The Moth protection flavour bags type 1 and 2 (originally meta SPC 2 and 3) are now meta SPC 1 and 2.*

2.2.5.1 Function and field of use

The products are insecticides (product type 18) intended for use in clothes moth and carpet beetle control to protect clothes. The products are foreseen to be used inside wardrobes drawers for non-professional users and indoor use. The products are used to eliminate clothes moths and carpet beetles.

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

Organisms to be controlled: clothes moths (*Tineola bisselliella*) and carpet beetles (*Anthrenus verbasci*), development stages: adults and larvae. Products to be protected: clothes and textiles.

2.2.5.3 Effects on target organisms, including unacceptable suffering

Transfluthrin is a highly effective fast-acting pyrethroid insecticide. Pyrethroids lead to reversible impairment of motor function and 'knockdown' in insect species that may be followed by death, depending upon the exposure level. Sublethal effects in insects, like incoordination and hyperactivity, may occur after acute exposure to about 1/10 of an insect LD50 dose. At higher exposure levels, the syndrome progresses from the initial period of hyperactivity and motor incoordination to tetanization, prostration, and convulsions followed by death (Wolansky, 2008).

2.2.5.4 Mode of action, including time delay

Pyrethroids target the nervous system of insects. All pyrethroids interact with the sodium channels; by keeping them open longer, they increase the likelihood of action potentials developping, thus creating a condition of hyperexcitability, whose main clinical symptom is tremors (Costa, 2015).

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**
Insecticide, PT18	*Indoor use; type of user: non-professional*	*Moth protection flavour bag type 2 meta SPC 3 (to be applied in wardrobe/ drawers for use; passive diffusers).* *Amount of a.s: 15 mg transfluthrin per 1000 dm³*	*Tineola bisselliella,* clothes moth *Anthrenus verbasci,* carpet beetle Adults and larvae were obtained from an in-house cultures of clothes moths *Tineola bisselliella* (strain origin University of Rennes, france) and carpet beetles *Anthrenus verbasci* (strain origin INRA France).	Simulation of the products' normal usage in wardrobes. Guidelines: - Manual for the Authorization of Pesticides - EU part – Biocides - Chapter 7 Efficacy - version 1.1; January 2013 at the § 11.2.2.2. - ISO 3998-1977 (E) - C.E.B. 135 bis French standard. Trial design: The trial is conducted in a testing volume representing a wardrobe : 150 cm high x 125 cm large x 50 cm wide (i.e. 1000 L = 1 m³). The product is set into the test volume and is allowed to evaporate during 30 minutes before introducing the insects and the wool parts. The products were set into the test volumes only during the trial (i.e. a total duration of 24 to 48 hours). In between they were relocated into special	DOSE: 1 sample in the test volume (1 m³) = 1 bag (sachet). Concentration applied in the chamber: 15 mg/m³. Exposure time: 1-24 h. The experiment has been performed at the day of opening "**opening of the product**", after 2 months **"+2 months**" and after 3 months **"+3 months**". The products were set into the test volumes only during the trial.	**Time of exposure to obtain 100% knockdown/mortality of the insects:** **Opening of the product** Clothes moths ADULTS<1h LARVAE<1h Carpet beetle ADULTS<1h LARVAE<1h **+2 months** Clothes moths ADULTS<1h LARVAE<4h Carpet beetle ADULTS<4h LARVAE<4h **+3 months** Clothes moth ADULTS<4h LARVAE<8h Carpet beetle ADULTS<24h LARVAE<24h **Damage to wool parts (due to larvae) rated according to the used standard documents:** **Opening of the product** 1 **+2 months** 1 **+3 months** 1 Untreated control serie has proved a low natural death rate of the insects during the trial (<10%) and a "4" rated class damage: the	Anonymous 2014a

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**
				chambers under controlled climatic conditions to evaporate freely. At set persistence assessment time points the product was reintroduced into new wardrobes. The death rate of both adults and larvae is assessed at regular time intervals until 24 hours (or more if necessary) after the insects' introduction. REPLICATES : 3 x 2 = 3 intra-block (3 batches of insects - adults + larvae - exposed in a same test volume) x 2 inter-block (Untreated control was performed using the same set-up with less test organisms).		trial is validated.	
Insecticide, PT18	*Indoor use; type of user: non-professional*	*Moth protection paper SPC 1 (to be applied in wardrobe/ drawers for use; passive diffusers).*	*Tineola bisselliella,* clothes moth *Anthrenus verbasci,* carpet beetle Adults and	Simulation of the products' normal usage in wardrobes. Guidelines: - Manual for the Authorization of Pesticides - EU part – Biocides - Chapter 7 Efficacy - version 1.1;	DOSE: 1 sample in the test volume (1 m^3) Concentration applied in the chamber: 30 mg/m^3. Exposure time: 1-48 h	**Time of exposure to obtain 100% knockdown/mortality of the insects:** **Opening of the product** Clothes moth ADULTS<1h LARVAE<1h Carpet beetle ADULTS < 2h	Anonymous 2014b

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**
		Amount of a.s: 30 mg transfluthrin per 1000 dm³	larvae were obtained from an in-house cultures of clothes moths *Tineola bisselliella* (strain origin University of Rennes, france) and carpet beetles *Anthrenus verbasci* (strain origin INRA France).	January 2013 at the § 11.2.2.2. - ISO 3998-1977 (E) - C.E.B. 135 bis French standard. Trial design: The trial is conducted in a testing volume representing a wardrobe : 150 cm high x 125 cm large x 50 cm wide (i.e. 1000 L = 1 m3). The product is set into the test volume and is allowed to evaporate during 30 minutes before introducing the insects and the wool parts. The products were set into the test volumes only during the trial (i.e. a total duration of 24 to 48 hours). In between they were relocated into special chambers under controlled climatic conditions to evaporate freely. At set persistence assessment time points the product was reintroduced into new wardrobes. The death rate of both adults	The experiment has been performed at the day of opening (**opening of the product**), after 3 months **(+3 months)** and after 6 months **(+6 months)**. The products were set into the test volumes only during the trial.	LARVAE < 2h +3 months Clothes moth ADULTS<1h LARVAE<4h Carpet beetle ADULTS<4h LARVAE<4h **+6 months** Clothes moth ADULTS<4h LARVAE<24h Carpet beetle ADULTS<48h LARVAE<48h **Damage to the wool parts (due to larvae) rated according to the used standard documents 1-4** **Opening of the product:** 1 **+3 months:** 1 **+6 months:** 2 The Untreated control series has proved a low natural death rate of the insects during the trial (<10%) and a "4" rated class damage: the trial is validated.	

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**
				and larvae is assessed at regular time intervals until 24 hours (or more if necessary) after the insects' introduction. REPLICATES : 3 x 2 = 3 intra-block (3 batches of insects - adults + larvae - exposed in a same test volume) x 2 inter-block (2 different test volumes per product, as for the Untreated control).			
Insecticide, PT18	*Indoor use; type of user: non-professional*	*Moth protection paper meta SPC 1 Transfluthrin concentration range: 0.2 g/m² paper (25 mg a.s. /1000 dm³); 0.3 paper (37 mg a.s. /1000 dm³); 0.4 g/m2 paper. paper (50 mg a.s. /1000 dm³)*	*Tineola bisselliella,* clothes moth (adults and second and third stage larvae) *Anthrenus fasciatus ,* carpet beetle (second and third stage larvae)	Guideline: "Guideline 10-2.1 for the testing of sparys and automatic spray systems against clothes moths". The study was performed in 0.555 m³ cupboards, divided at mid-height by a board leaving a 180 mm gap permitting air exchange between the upper and the lower shelves. The adult clothes moths (20 males/females) were kept on black fabric in glass dishes	***Tineola bisselliella*** (adults and larvae hatched from the eggs laid): Concentration applied: 14, 21 and 28 mg a.s./1000 dm³ of wardrobe Anthrenus fasciatus *(2nd and 3rd stage* larvae): Concentration applied: 14, 21 and 28 mg a.s./1000 dm³ of wardrobe	***Tineola bisselliella*** (adults): 14 mg/1000 dm³ Transfluthrin week 1-26: Days taken to reach 100% mortality: 1 d; Number of larvae hatched from the eggs laid at weeks 12 (5), 16 (5), 20 (1) and 26 (30) Feeding damage: none detected 21 mg/1000 dm³ transfluthrin, week 1 - 26: Days taken to reach 100% mortality: 1 d; Number of larvae hatched	Anonymous 1995

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**
				with rings, the larvae on unbleached woollen fabric. The beetle larvae (20 per batch) were kept on unbleached woollen fabric in glass dishes. The test vessels were positioned on the cupboard floor and on the board at half height. The fabric, moth paper and insect material were placed in the cupboards simultaneously at the start of the study. For adults moths the evaluation included mortality. The larvae hatching from the laid eggs were counted and the fabric was examined for feeding damage. Larvae were assessed for mortality. For carpet beetles the larvae were assessed for mortality and wool damage. The studies continued for 26 weeks. Efficacy was assessed after		from the eggs laid at week 20 (3) and week 26 (30); Feeding damage: none detected 28 mg/1000 dm³ transfluthrin week 1-26: Days taken to reach 100% mortality: 1 d; Number of larvae hatched from the eggs laid at week 26 (3); Feeding damage: none detected ***Larvae of Tineola bisselliella*** 14 mg/1000 dm³ transfluthrin week 0 days taken to reach 100% mortality: 6 , weeks 1–8: 1 day, week 12: 2 days, starting at week 16 only 95% Mortality was reached after 7 days, at week 20 only 65% after 14 days of exposure. Feeding damage did occur after week 0 and again after weeks 16 and 20. 21 mg/1000 dm³	

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**
				0,1,2,4,6,8,12, 16,20,26 weeks.		transfluthrin week 0 days taken to reach 100% mortality: 13 , weeks 1–12: 1 day, week 16: 2 days, starting at week 20 only 85% mortality was reached after 6 days, at week 20 again 100% after 6 days. Feeding damage did occur after week 0 and again after week 20. 28 mg/1000 dm^3 transfluthrin week 0 days taken to reach 100% mortality: 6, weeks 1–12: 1 day, week 16: 2 days, weeks 20-26: 6 days. Feeding damage did occur after week 0. ***Anthrenus fasciatus*** *(2nd and 3rd stage larvae):* 14 mg/1000 dm^3 transfluthrin week 0 days taken to reach 100% mortality: 5 , week 1–6: 2 days, week 8–12: 6 days, at week 16 only 85% mortality	

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**
						was reached after 13 days, week 20: 35% after 14 days and week 26: 50% mortality after 13 days was reached Feeding damage occurred at week 0 and again from weeks 16-26; 21 mg/1000 dm³ transfluthrin week 0 days taken to reach 100% mortality: 5 , week 1: 6 days, weeks 2-6 2 days, week 8–12 6 days, at week 16 13 days, starting at week 20 only 70% after 14 days and week 26 90% mortality after 13 days was reached Feeding damage occurred at weeks 20–26 28 mg/1000 dm³ transfluthrin week 0 days taken to reach 100% mortality: 5 , weeks 1–8: 2 days, week 12: 6 days, week 16: 7 days, at week 20: 14 days and at week 26: 13 days.	

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**
						Feeding damage did not occur.	

To fulfil the requirement of a laboratory trial set by the guidance in force (CA-Dec12-Doc.6.2.a – Final) for clothes moths and carpet beetles data from the included literature study (Anonymous 1995) are used for a read across. In this study efficacy of moth papers impregnated with transfluthrin against clothes moths and carpet beetles has been demonstrated. The study has been performed on adults and larvae of *Tineola bisselliella* and larvae of *Anthrenus fasciatus*; transfluthrin has been tested in the concentration range of 14, 21 and 28 mg a.s./m³ of wardrobe, for 26 weeks (one season). The results demonstrate that more than 90% of mortality at the end of the exposure time was reached for adult clothes moths at all concentrations tested during the whole test duration (26 weeks). For clothes moths larvae more than 90% mortality at the end of the exposure time was reached for 14 mg/m³ until week 12, for 21 mg/m³ until week 16 and for 28 mg/m³ until week 26.
For carpet beetle larvae more than 90% mortality at the end of the exposure time was reached for 14 mg/m³ until week 12, for 21 mg/m³ until week 16 and for 28 mg/m³ until week 26. Thus fulfilling the requirements for efficacy set by the guidance in force (CA-Dec12-Doc.6.2.a – Final).
The literature study (Mrsusek, 1995) does not include data on adult carpet beetles. We argue that due to the general lower susceptibility of larvae to the tested insecticide the tested concentrations are valid for adult members of the target species as well. Furthermore, in the simulated use trials (Anonymous 2014 a/b) adult and larvae were tested showing the same trend.

The presented literature study (Anonymous, 1995) was performed using *Anthrenus fasciatus* and the presented simulated use studies (Anonymous 2014 a/b) were performed using *Anthrenus verbasci* as test organism. The guidance in force (CA-Dec12-Doc.6.2.a – Final) states that for the claim protection against carpet beetles a species from either the Anthrenus genus or the Anthrenocerus genus has to be tested. Both carpet beetle species *Anthrenus fasciatus* Reitter (synonym: *Anthrenus flavipes*) and *Anthrenus verbasci* belong to the genus Anthrenus. The used species are closely related, and share the same ecological niche. Both species share significant similarities in feeding habits and behaviour (Peacock, 1993).
According to Peacock et al.: "Most Anthrenus larvae will damage wool, fur, skins and other material of animal origin.
"***Anthrenus verbasci*** **(Linnaeus)** is best known as a pest of woollen goods - carpets, bedding, clothes etc. -and it has been known to eat the glue of book bindings.
"***Anthrenus flavipes*** **LeConte** (the Furniture Carpet Beetle [USA]). Synonym: ***Anthrenus fasciatus*** **Reitter**. The larva feeds on any animal substances e.g. wool, hair, fur, feathers, bristles, horn, tortoise-shell, skins and dried insects.
Thus, based on the provided informations and comparable susceptibility behaviour shown in literature (Anonymous, 1995) and in the simulated use studies performed for this dossier (Anonymous 2014 a/b), it is assumed that the two species share enough characteristics regarding relation, feeding preferences, susceptibility to the tested biocidal product and behaviour to allow a read across.

The guidance in force (CA-Dec12-Doc.6.2.a – Final) states: "In tests with vapour based products the door should be opened with a frequency resembling normal opening of a closet, to show that this does not reduce efficacy: once a day during completion of the assay, 5 seconds for drawers and 10 seconds for closets". Considering a closet, a 3 months period (which is the total duration of the simulated use test with the Moth protection flavour bag type 1 and 2 SPC 2 and 3) would result in a total of 15 minutes opened; a 6 months period (which is the total duration of the simulated use test with the Moth protection paper SPC 1) would result in a total of 30 minutes opened.
The requirement of periodically opening and closing of the test wardrobe during the simulated use trial may be derrogated, due to the ventilation of the opened biocidal product in between the assays. In fact, the products were set into the test volumes only during the trial (i.e. a total duration of 24 to 48 hours). In between they were let to evaporation in a special chamber under controlled climatic conditions (smooth ventilation 1m³/h) and set into new wardrobes at each persistence assessment date for the respective exposure time (Anonymous, 2017). In these conditions, the period of free evaporation is much longer than 30 minutes; for this reason, the results obtained in the trial can be considered reliable.

Silent active
The meta SPC 2 and 3 contain additionally to the active substance Transfluthrin one coformulant which is notified as biocidal active substance namely Geraniol which fulfils a different function in the formulation besides PT18 or 19. Geraniol is part of the used perfume mixture which is supplied to the applicant. According to the CA-Document CA-Sept13-Doc.6.2.b Rev.1 biocidal active substances are considered as silent active substances, if their use in the formulation does not significantly contribute to any of the biocidal functions of the product. Additionally, according to the CA-Document CA-Sept17-Doc.4.2 approved active substances used as co-formulants always requires an adequate justification demonstrating that the co-formulant is not an active substance in regard of the observed efficacy of the formulation.
Following the rational of both documents geraniol is not intentionally incorporated as active substance. Geraniol is part of a perfume mixture. The formulation of the perfume mixture is not known to the applicant due to confidentiality aspects.
So far no decision is available for the approval of Geraniol as active substance. Following literature the repellence effect of geraniol is well demonstrated and insecticidal effects have been indicated. Available literature data show that it is challenging to extrapolate an efficacious dosage which may be adapted for cloth moths and carpet beetles. Most of the available studies are linked to repellent effects on lice, fleas and mosquitoes. Common dosages range between 25 and 5 % (w/w) for a repellent effect. Insecticidal effects are usually linked to higher dosages. In the Moth protection flavour bags the concentration of geraniol ranges between 0.22 and 7.92 % (w/w). Thus, based on available literature for repellence effects it is unlikely that Geraniol has an insecticidal effect in the presented use.

Regarding a potential repellence effect the CA is of the opinion that the assessed PT 18 effect is not influenced and thus geraniol is to be regarded as silent active substance.

Conclusion on the efficacy of the product
In the conditions of the trials (simulated use trials Anonymous 2014 a/b), with the sample products provided, insects' strains and methodology used, 15 mg Transfluthrin per 1000 dm³ as bag product has proved a sufficient efficacy against adults and larvae of clothes moths (*Tineola bisselliella*) and carpet beetles (*Anthrenus verbasci*), until 3 months after opening of the product. The fresh product (0 months) lead to 100% mortality for the adult and larvae of the clothes moths and carpet beetles after 1 hour of exposure. After 2 months for freshly introduced target organisms 100% mortality was reached after 1 hour for adult clothes moths and after 4 hours 100% mortality

was reached for adult carpet beeltes and the larvae of both target pests. After 3 months for freshly introduced target organisms 100% mortality was reached after 4 hours for adult clothes moths and after 8 hours 100% mortality was reached for larvae of the clothes moths. Mortality of 100% was reached for adult and larvae of the carpet beetles after 24 hours of exposure.

30 mg Transfluthrin per 1000 dm³ as paper product has proved a sufficient efficacy against adults and larvae of clothes moths (*Tineola bisselliella*) and carpet beetles (*Anthrenus verbasci*), until 6 months after opening.
The fresh product (0 months) lead to 100% mortality for the adult and larvae of the clothes moths after 1 hour of exposure. The fresh product (0 months) lead to 100% mortality for the adult and larvae of the carpet beetles after 2 hours of exposure.
After 3 months 100% mortality was reached after 1 hour for adult clothes moths and after 4 hours 100% mortality was reached for the larvae.
After 3 months 100% mortality was reached after 4 hours for adult carpet beetles and larvae.
After 6 months 100% mortality was reached after 4 hours for adult clothes moths and 24 hours for the larvae.
After 6 months 100% mortality was reached after 48 hours for adult carpet beetles the larvae.
Thus both simulated use trials are fulfilling the requirements for efficacy set by the guidance in force (CA-Dec12-Doc.6.2.a – Final) of more than 90% of mortality at the end of the exposure period of 3 months for bag products and 6 months for paper products.

The requirement for laboratory studies for both target pests was fulfilled with a read across to the literature study of Anonymous 1995. The results of the literature study demonstrate efficacy of more than 90% mortality using 28 mg/m³ a.s. at the end of the exposure period against the tested target pests using a Transfluthrin impregnated paper.

Note, May 2024: *Moth papers (originally meta SPC 1) are not authorised anymore due to change in classification and labelling in the 21st ATP (Reg. (EU) 2024/197). The Moth protection flavour bags type 1 and 2 (originally meta SPC 2 and 3) are now meta SPC 1 and 2.*

2.2.5.6 Occurrence of resistance and resistance management

No known resistance in the target species has been observed to-date for the active substance transfluthrin (The Netherlands, 2014).
Transfluthrin is a pyrethroid insecticide. Some resistance to pyrethroids has been found, depending on the pest species and location. In Europe the main problems have occurred in some areas with pests of agricultural significance. Laboratory tests on resistant strains have shown, for Myzus persicae, a resistance factor of 200 (to control the resistant strain requires 200 times the dose required to control a sensitive strain).
A review by the WHO of Vector Resistance to Pesticides (WHO, 1992) identified no reports of resistance to synthetic pyrethroids in mosquitoes and other sucking insects in Europe. However, resistance among some species of flies and cockroach populations was more evident. Resistance to synthetic pyrethroids among European agricultural pest species, where insecticide use is more intensive, may be more widespread (IRAC, 2000).
Cross-resistance of pest species to the group of synthetic pyrethroids is to be anticipated due to a common mode of action (Staetz, 2004), and instances of cross-resistance (or multiple resistance) between pyrethroids and organochlorine insecticides have been reported (Brogdon & McAllister, 1998).

Management strategies:
Because resistance is well known to be a potential problem, strategies to avoid resistance development are normal practice. For example, the use of alternating sequences, mixtures and avoidance of frequent repeated use are standard. General advice is provided by IRAC. The principles of strategies for preventing and managing the development of resistance are similar for transfluthrin as they are for other synthetic pyrethroids;

To delay the development of resistance it is necessary to:

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
iv) If the infestation persists, contact a professional pest control operators.

2.2.5.7 Known limitations

No limitations observed.

2.2.5.8 Evaluation of the label claims

The following intended use claims for the product family are supported by the efficacy studies submitted:

- Against clothes moths and carpet beetles for Non-professional users, indoors
- To be used in wardrobes and drawers

In both performed efficacy tests (Anonymous 2014 a/b) the claimed target organisms clothes moths and carpet beetles (adult and larvae) were used. Both application types showed 100% mortality at the end of the exposure time (1-48h) until the end of the test duration of 3 months (bag products). Thus fulfilling the requirement set by the guidance in force of more than 90% mortality at the end of the exposure time.
The evaluation of the efficacy of the application type at concentrations of 15 for bag products was performed in representative wardrobes (1 m^3) indoors.

The following intended use claims or claims for the product family have been adapted:

- Put bag according to the product for wardrobe or drawer
- Application rate every 3 months (bag products)

The efficacy test for the bag products were performed with a concentration of 15 mg a.s./m^3 of wardrobe. Due to differences in concentration of the members of the product family the application method was adapted. The adapted authorised application method is: Apply the product at a rate of 15 mg of active substance per cubic metre of wardrobe or drawer and adapt the number of bag according to the amount of active substance respectively incorporated in the member of the product family The efficacy tests have shown effectiveness of the bag product for 3 months at the respective tested concentrations. The intended use claims for application rate and frequency are: every 3 months (bag products). The phrasing suggests the continuous use of the product for an extended time frame which may induce resistence development in the moth population. To avoid this secenario the phrasing was adapted to:

Effective for 3 months, only if necessary repeat treatment after recommended time (bag products)

The application of products from the biocidal product family in chests has been stated in several chapters (e.g. use-specific instructions for use) but not in the intended use chapter. Thus it was not included in the label claims.

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

The products are not intended to be used in combination with other biocidal products.

2.2.6 Risk assessment for human health

Note, May 2024: *Moth papers (originally meta SPC 1) are not authorised anymore due to change in classification and labelling in the 21st ATP (Reg. (EU) 2024/197). The Moth protection flavour bags type 1 and 2 (originally meta SPC 2 and 3) are now meta SPC 1 and 2.*

The formulations in the Biocidal Product Family (BPF) are divided in Moth protection paper meta SPC 1 (impregnated paper with Transfluthrin only) and Moth protection flavour bags type 1 and 2 meta SPC 2 and 3. The Moth protection flavour bag products can be described as spunlace bag (cellulose) containing granules impregnated with the active substance and other co-formulants.
The product group "Moth protection paper" chosen for the estimation of the systemic human exposure and risk assessment is representative for all the other products in the Biocidal Product Family (BPF) and is considered the worst case because it contains the higher percentage of active substance (cf. 2.2.6.2, see comparsion of systemic exposure scenario 1a and 1b). The biocidal product is the active substance Transfluthrin for Moth protection paper.
Please find below a summary of the effect assessment concerning human health of Transfluthrin published in the Assessment Report (The Netherlands, 2014). For the Moth protection paper a systemic and, based on the current classification of Transfluthrin, also a local risk assessment was performed.
The Moth protection flavour bag type 1 and type 2 formulations contain substances of concern (in the fragrance mixtures) including Geraniol, another active biocidal substance that is currently under review for PT18 and PT19 (cf. confidential Annex restricted to authorities). However because no harmonised assessment and List of Endpoint is available so far, a semi-qualitative local risk assessment according to the banding evaluation scheme (Band B) is performed.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
META SPC 1	
Value/conclusion	No classification
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	No classification according to COMMISSION DELEGATED REGULATION (EU) 2024/197
Meta SPC 2	
Value/conclusion	Causes skin irritation
Justification for the value/conclusion	Co-formulants are present in products of BPF meta SPC 2 which trigger classification as skin irritant category 2. Please see confidential Annex restricted to authorities, section 3.10.6 for detailed information.
Classification of the product according to CLP	Skin irritation category 2 (H315) is proposed for products in meta SPC 2.
Meta SPC 3	

Value/conclusion	No classification
Justification for the value/conclusion	No co-formulant or the active substance is present in products of BPF meta SPC 3 that trigger classification as skin irritant. Please see confidential Annex restricted to authorities, section 3.10.6 for detailed information.
Classification of the product according to CLP	According to Regulation (EC) No 1272/2008 no classification for skin corrosion/irritation is necessary for products meta SPC 3.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Meta SPC 1	
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.
Meta SPC 2	
Value/conclusion	Irreversible effects on the eye.
Justification for the value/conclusion	Co-formulants are present in products of BPF met SPC 2 ≥3% that trigger classification as eye dam. 1. Please see confidential Annex restricted to authorities, section 3.10.6 for detailed information.
Classification of the product according to CLP	Eye damage category 1 (H318) is proposed for meta SPC 2.
Meta SPC 3	
Value/conclusion	No classification
Justification for the value/conclusion	No co-formulant is present in products of BPF meta SPC 3 that triggers classification for eye irritation or serious eye damage. Please see confidential Annex restricted to authorities, section 3.10.6 for detailed information.
Classification of the product according to CLP	According to Regulation (EC) No 1272/2008 no classification for eye irritation or serious eye damage is necessary for meta SPC 3.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Meta SPC 1, meta SPC 2 and meta SPC 3	
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 for Transfluthrin (cf. The Netherlands, 2014). Data submitter has a Letter of Access. No co-formulant is classified for this hazard category (cf. confidential Annex restricted to authorities).
Classification of the product according to CLP	Not classified.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Meta SPC 1	
Value/conclusion	Not sensitizing to skin.
Justification for the value/conclusion	Transfluthrin does not have sensitising properties in several studies (Buehler assay, Guinea pig maximisation test) (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.
Meta SPC 2	
Value/conclusion	Sensitzing to skin
Justification for the value/conclusion	Co-formulants are present in products of BPF met SPC 2 ≥1% that trigger classification as skin sens. 1. Please see confidential Annex restricted to authorities, section 3.10.6 for detailed information.
Classification of the product according to CLP	Skin sens. category 1 (H317) is proposed for meta SPC 2.
Meta SPC 3	
Value/conclusion	No classification
Justification for the value/conclusion	No co-formulant is present in products of BPF meta SPC 3 that triggers classification as a skin sensitiser.
Classification of the product according to CLP	According to Regulation (EC) No 1272/2008 no classification for skin sensitization is necessary for meta SPC 3. However labelling with EUH208 is necessary based on co-formulants present in products of meta SPC 3. Please see confidential Annex restricted to authorities, section 3.10.6 for detailed information.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Meta SPC 1, meta SPC 2 and meta SPC 3	
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. No co-formulant contained in anti-moth products BPF is classified with H334.
Classification of the product according to CLP	According to Regulation (EC) No 1272/2008 no classification for respiratory sensitization is necessary.

Acute toxicity

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	
Meta SPC 1	
Value	Meta SPC 1 is classified for acute oral toxicity as category 4, H302: Harmful if swallowed
Justification for the selected value	The biocidal product (=active substance Transfluthrin) does not contain any other substances. The LD50 oral is available in the CAR for Transfluthrin PT 18: 583 mg/kg (The Netherlands, 2014).
Classification of the product according to CLP	Acute Tox. 4, H302 The substance has no yet 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).
Meta SPC 2 and meta SPC 3	
Value	No classification
Justification for the selected value	Please see confidential Annex restricted to authorities, section 3.10.6 for detailed calculation and information.
Classification of the product according to CLP	According to Regulation (EC) No 1272/2008 no classification for acute oral toxicity is necessary for meta SPC 2 and 3 products.

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 h exposure	--	>513 mg/m^3	Data submitter has a Letter of Access.	The Nether-lands, 2014

Value used in the Risk Assessment – Acute inhalation toxicity	
Meta SPC 1	
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.
Meta SPC 2 and 3	
Value	No classification
Justification for the selected value	Please see confidential Annex restricted to authorities, section 3.10.6 for detailed information.
Classification of the product according to CLP	According to Regulation (EC) No 1272/2008 no classification for acute inhalation toxicity is necessary for meta SPC 2 and 3 products.

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	
Meta SPC 1	
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.
Meta SPC 2 and 3	
Value	No classification
Justification for the selected value	Please see confidential Annex restricted to authorities, section 3.10.6 for detailed information.
Classification of the product according to CLP	According to Regulation (EC) No 1272/2008 no classification for acute dermal toxicity is necessary for meta SPC 2 and 3 products.

Information on dermal absorption

No dermal absorption studies with products of the Anti-moth BPF are available.Therefore the following default values were proposed:

Value used in the Risk Assessment – Dermal absorption			
Meta SPC	1	2	3
Active concentration (%)	100	3.2	3.21
Values (%)	10	50	50
Justification for the selected value(s)	Table 2, Chapter 6, EFSA, 2017; Default value for solid, concentrate	Table 2, Chapter 6, EFSA, 2017; Default value for solid, dilution	Table 2, Chapter 6, EFSA, 2017; Default value for solid, dilution

Default values can be applied in a first tier for dermal absorption. For meta SPC 1 products a 10% default value from Table 2, Chapter 6 of EFSA 2017 is applicable based on the dilution status and the type of formulation. Transfluthrin is solid according to its physical state and the products consist of 100% a.s. The proposed default value of 10% dermal absorption is in line with the value agreed in the CAR for Transfluthrin (The Neterhlands, 2014; value was based on a MW of 371 and log Kow of 5.4, but also on data and information from other pyrethroid on formulations.)
For meta SPC 2 and 3 a value of 50% for solid dilutions is proposed as worst case (cf. Table 2 of EFSA, 2017) and it should be noted that the dermal exposure to the consumer is always to the device/article. This value is considered as conservative based that dermal contact is limited to a spunlace bag (cellulose) containing granules impregnated with the active substance and other co-formulants.

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)

Based on the classification of the components of the Moth protection flavour bag type 1, in meta SPC 2, 6 substances of concern have been identified (please see also confidential Annex restricted to authorities):

- Linalool (CAS N° 78-70-6)
- Nopyl acetate (CAS N° 128-51-8)
- Geraniol (CAS N° 106-24-1)
- Alpha-iso-Methylionone (CAS N° 127-51-5)
- Cineole (CAS N° 470-82-6)
- Nerol (CAS N° 106-25-2)

Based on the classification of the components of the Moth protection flavour bag type 2 in meta SPC 3, 2 substances of concern have been identified (please see also confidential Annex restricted to authorities):

Hydrocarbons, C11-C13, isoalkanes, <2% aromatics (CAS N° 920-901-0)
Isoparafins C12-C16 (CAS N° 927-676-8)

Geraniol is an active biocidal substance currently under evaluation for Product type 18 and 19; however no first dCAR is currently available. The Risk Assessment Committee (RAC, 2018) concluded in its 46 Meeting that Geraniol meets the classification for Skin. Sens.1 (no subcategory). In addition the MSDS also reports classification for Eye Dam. 1 and Skin Irrit. 2.
Linalool has a harmonised classification as Skin Sens. 1B based on results from a LLNA performed with a commercial linalool product with an EC3 of 30% (weak sensitiser) and supported by the low exposure and frequency of sensitisation (based on CLP criteria) observed in human studies (RAC, 2015)[2]. Moreover, it contributes to the classification of the mixture with Skin irrit. 2.
Under the Cosmetics Regulation (Regulation (EC) No 1223/2009)[3] Geraniol and Linalool are subject to individual labelling in those products (0.001 % in leave-on products and 0.01 % in rinse-off products). In 2012 the Scientific Committee on Consumer Safety (SCCS) published an opinion on fragrance allergens in cosmetic products and examined available elicitation dose-response data to decide whether safe thresholds can be established for fragrance allergens. In addition in this opinion Geraniol and Linalool have

[2] https://echa.europa.eu/documents/10162/ac493be9-91d2-3c82-69bd-f31c2f8f1d0e
[3] https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32009R1223

been categorised as established contact allergens in humans and are of special concern as at least 100 reported cases occurred. Geraniol and Linalool amongst 10 other reported substances and 8 natural extracts pose a particularly high risk of sensitisation to consumers.
According to SCCS data from human dose elicitation experiments are very limited in several respects, so that no potentially "safe" level for the majority of contact allergic consumers could be established for individual substances. However, the studies and evidence available indicate that a general level of exposure of up to 0.8 µg/cm² (0.01% in cosmetic products) may be tolerated by most consumers, including these with contact allergy to fragrance allergens. The SCCS considers that this threshold based on elicitation levels in sensitised individuals will be sufficiently low to protect both the majority of sensitised individuals and most of the non-sensitised consumers from developing contact allergy (SCCS, 2012). However neither data from Geraniol nor Linalool confirmed that these substances have the potential to produce significant sensitisation in humans (Cat. 1A).
Nopyl acetate has been categorised as likely contact allergen by a combination of evidence according to SCCS (2012). The submitted MSDS indicated classification with Skin Sens. 1B and Eye irrit. 2.
alpha-iso-Methylionone is also a food flavouring included in the Union list of flavouring substances under FL No.07.036 according to Regulation (EC) No 1334/2008 in the currently valid version. The substance was addressed by the EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids in the falvouring group evaluation 210 for its genotoxic potential. The Panel concluded that for this substance the concern for genotoxic potential is ruled out (EFSA CEF Panel, 2014). From the submitted MSDS the applicant proposed human health classification for Skin Irrit. 2 and Skin Sens. 1.
Cineole was assessed as flavouring and component in the diet by Scientific Committee on Food (SCF, 2002). While the data base is not sufficient to derive an ADI the available animal data do not indicate a cause of concern associated with the daily intake (SCF, 2002). Cineole is a sensitiser with an EC3 of 65.90%[4] and displays eye and skin irritation properties according to the submitted SDS.
Nerol is considered as a fragrance substance categorised as likely contact allergen based on limited human evidence and structural alerts by SCCS (2012). An EC3 value of 23%[5] classifies Nerol as skin sensitiser in addition to skin irritating and eye damaging properties according to the submitted SDS.
Hydrocarbons, C11-C13, isoalkanes, <2% aromatics and isoparafins C12-C16 are UVCB substances classified for aspiration (Asp. Tox. 1, H304). No other classification has been proposed according to the REACH registration dossier[6][7] or SDS. The substances are also labelled with EUH066 (Repeated exposure may cause skin dryness or cracking) according to the submitted SDS.

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

Please see confidential annex.

Available toxicological data relating to a mixture

N.A.

4 https://echa.europa.eu/registration-dossier/-/registered-dossier/13231/7/5/2
5 https://echa.europa.eu/de/registration-dossier/-/registered-dossier/10345/7/5/2
6 https://echa.europa.eu/de/registration-dossier/-/registered-dossier/1932/7/1
7 https://echa.europa.eu/de/registration-dossier/-/registered-dossier/13655/2/1

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	n.a.
Dermal	n.a.	n.a.	yes	n.a.	n.a.	yes[1]	n.a.
Oral	n.a.	n.a.	no	n.a.	n.a.	yes[1]	n.a.

[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/sachtes into the wardrobe / drawers; removal of paper strips/sachets 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 products are impregnated on carrier materials (paper strips or granules in sachets) which are passive diffusers for indoor use by non-professionals. The products are classified with P102 Keep out of the reach of children to preclude a child is being asked to apply the product. The biocidal product is placed inside closets and wardrobes (clothes hanging area, shelves, drawers The scenario is divided in [1a] for moth papers and [1b] for moth sachets. [1a]: Depending on the moth paper, 1 to 12 paper strips are applied per 1 cubic meter inside the wardrobe in order to achieve the application rate of 30 mg a.s./m³. The paper is placed between the clothes by hanging on coat hanger. For placing on shelves or inside drawers the paper strip is cut into pieces (minimum one quarter of a strip) and put between the laundry. The product releases Transfluthrin into the air by evaporation over a max. 6 month period of use. Handling of the product comprises: opening the package, removing the foil, taking out 1 to 12 paper strips; if applicable: cutting the paper strips into pieces, placing the paper into the wardrobe / drawers; 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. Of all moth papers, the worst case concentration is 0.039 mg/cm² (one sheet containing 5 mg a.s., size of paper: 127.5 cm²). The reverse reference scenario considers the numbers of stripes which have to be manipulated to achieve the $AEL_{acute, dermal}$. [1b]: The sachets are placed into the wardrobes / drawers. Depending on the sachets, 1 to 3 sachets are applied per cubic meter inside the wardrobe in order to achieve the application rate of 15 mg a.s. / m³. The product releases Transfluthrin into the air by evaporation over a max. 3 month period of use. The highest Transfluthrin content is 15 mg per bag, evenly spread over the granules. Assuming as a worst case that all amount of a.s. is only located on the outer 1 mm of the bag (on the surface of the granules), and assuming that the transfer from the dried liquid to the wrapping is 18% (ECHA, 2015c), the surface concentration results in 0.0187 mg/cm²,		
Dermal and inhalative exposure		
	Parameters	**Value**
Tier 1	Max. content of a.s. on paper strip[1]	~ 0.03922 mg/cm²
	Max. content of a.s. on sachet surface[3]	0.0187 mg/cm²
	Transfer coefficient dried fluids[2,6]	0.18 g/g
	Area of palms[2]	410 cm²
	Number of manipulations	max.12 (papers) max. 3 (sachets)
	Body weight adult[2]	60 kg
	Dermal absorption[4]	10% (papers) 50% (sachets)
	Peak concentration[7]	0.023 mg/m³
	Inhalation rate adult[2]	1.25 m³/h
	Exposure duration[3]	5 min/day (0.083 h/day)
	$AEL_{acute, dermal}$ [5]	1 mg a.s./kg bw/day

Reverse reference scenario	**number of manipulations (number of touched stripes) to achieve $AEL_{acute, dermal}$**	**207**
	number of manipulations (number of touched sachets) to achieve $AEL_{acute, dermal}$	**87**
	$AEL_{acute, inhalation}$ [5]	0.17 mg a.s./kg bw/day
	Number of manipulations to achieve $AEL_{acute, inhalation}$	**4257**

[1] cf. to chapter 3.6.4; rounded value; calculated by dividing content of a.s. (5 mg) / area of paper strip (127.5 cm²)

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

[3] Worst case assumption[4] see chapter 2.2.6.1 of this document

[5] see chapter 2.2.6.3 of this document

[6] The Guidance ECHA 2015c 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 web (cf. https://www.rivm.nl/en/Topics/C/ConsExpo), see Appendix 3.2.1

Calculations for Scenario [1]

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

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

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 [1a]	Tier 1 / no PPE	0.00004	0.0579	n.a.	0.0579[1]
Scenario [1b]	Tier 1 / no PPE	0.00004	0.0345	n.a.	0.0345

[1] This is the worst case for scenario 1, total.

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). For the application duration the default value is set at 10 minutes. (default; Bremmer et al. 2006, Pest Control Products Fact Sheet). The exposure duration is set to 18 hours (to reflect also long term exposures). The product amount is 45 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 max. 180 days (cf. to chapter 2.1.4.). 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.)

In reality, the active substance is only present on one side of the paper. There is a white edge free of active substance that the user should touch during the application of the product, so the real exposure will be even lower if the user follows this recommendation. Also for sachets, the spunlace will reduce the contact with the impregnated granules which leads to the expectation that the real exposure will be lower.

Information relevant for risk characterisation for local effects:

Considering an a.s. amount of 5 mg a.s., a paper area of 127.5 cm², a transfer coefficient of 0.18 g/g for dried fluids and 2 to 12 manipulations, the dermal local exposure is **0.014 to 0.085 mg a.s. / cm² skin.**

$$\text{Dermal local exposure} = \frac{\text{Amount of substance} \times \text{Transfer coefficient} \times \text{Number of man.}}{\text{Area of object}}$$

In addition, the substance of concerns (SoCs) have to be addressed, which are located in the Moth protection flavour bags of meta SPC 2. The calculation of dermal local exposure is analogue to the formula given above: the transfer coefficient amounts to 0.18 g/g for dried fluids, the number of manipulations is 3, and the bag area is 72.25 cm² (dimension of one bag: 85 x 85 mm, company's statement). With the following nominal amounts of substance per bag (cf. to chapter 3.6.4), the dermal local exposure is: (see table)

Dermal local exposure for substances of concern		
Substance	**Nominal amount (worst case) [mg per bag]**	**Estimated dermal local exposure [mg/cm²skin]**
Geraniol	44.7	0.33
Linalool	167.7	1.25
Nopyl acetate	89.4	0.67
alpha-iso-Methylionone	8.4	0.06
Cineole	11.7	0.09
Nerol	16.8	0.13

As the contact is not directly to the granules, but to the spunlace bag (cellulose), the actual exposure value is deemed to be even lower.

Combined scenarios:

Not relevant for combination of solely non-professional uses.

Exposure of the general public

Scenario [2]

Description of Scenario [2]		
The Moth protection paper strips or sachets are placed in closets and wardrobes. Inhalative exposure may occur during the whole application time of max. 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.		
	Parameters	**Value**
Tier 1	Peak event concentration[3]	0.023 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

[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 web (cf. https://www.rivm.nl/en/Topics/C/ConsExpo), 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

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	0.001	n.a.	n.a.	**0.001**
Scenario [2]	Tier 1, child / no PPE	0.003	n.a.	n.a.	**0.003**
Scenario [2]	Tier 1, toddler / no PPE	0.007	n.a.	n.a.	**0.007**
Scenario [2]	Tier 1, infant / no PPE	0.006	n.a.	n.a.	**0.006**

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 (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; closet is opened once a day). The applied biocidal product amount is 45 mg per 1.5 m³, the vapour pressure of the a.s. is 0.0009 Pa, and the emission duration is max. 180 days (cf. to chapter 2.1.4.) The maximum air concentration is limited to the vapour pressure of the pure a.s.. Model: Exposure to vapour, evapouration 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."

Please note that for evaporation of the a.s. only inhalative exposure was assessed. The transfer from transfluthrin to textiles and as consequence to human skin was not regarded for the following reasons: Although general public may be exposed to transfluthrin via transfer from textiles contained in treated draws/wardrobes, it is not envisaged that higher dermal exposure would result considering the transfer from paper (the product) to textiles would be lower than from direct handling of the product during application (cf. to scenario 1). As the biocidal products are impregnated on to the paper, dislodging of the formulation from the paper and transfer on to clothing whilst in the wardrobe will be minimal. Note that clothing will not be in direct contact with the biocidal product as this is placed on the hoof of the hanger or the biocidal product is contained within a sealed sachet. Therefore further consideration of general public exposure to contaminated textiles is not required.

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 max. content of a.s. per paper strip is 0.03922 mg/cm². 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	Concentration of a.s. on paper strip[2]	0.03922 mg/cm²
	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] cf. to scenario [1]; worst case compared to sachets

[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] Calculating with the mean value of 10 cm² is considered acceptable for refinement of the assessment, as paper is not considered to be palatable even without bittering agent. Moreover it is assumed that small toddlers will not stay unattended over longer periods of time, and any mother catching her child eating moth paper would immediately take the paper out of the toddler's mouth.

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.	0.196	**0.196**
[3]	Tier 1, infant / no PPE	n.a.	n.a.	0.245	**0.245**
[3]	Tier 2, toddler / no PPE	n.a.	n.a.	0.039	**0.039**
[3]	Tier 2, infant / no PPE	n.a.	n.a.	0.049	**0.049**

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 chronic uptake**	**Estimated acute uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1a+2, adult, Tier 1]	0.00104	0.05791	n.a.	**0.0591**

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 Netherlands, 2014): 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. However, the applicant provided the following information on the production processes:

Production process "Moth protection paper":
During the formulation process, mixing operations are performed in a dedicated equipment, placed in an area, separated from the other manufacturing steps. After mixing, the mixture is transported by tightly closed buckets to the offset printing press

for printing operation on paper. Paper sheets are cut, folded and shrink-wrapped through an automatic system.
Workers wear adequate personal protection equipments during the operations where exposure cannot be excluded. Workers involved have received specific task training, follow operating procedures and act under supervision.
Taking into account the operational conditions, the technical control measures and the risk management measures during the formulation process, worker exposure is estimated to be not significant.

Production process "Moth protection flavour bag"
Porous granules, impregnated with the active substance and the other co-formulants, are packaged into bags through a closed system.

Stepwise description how the solution is prepared and applied to the granules:

1. Perfume and active are mixed in a metal drum. After mixing this drum is closed with a lid with a tap hole.
2. The micro porous granules are filled in a drum mixer. The corresponding quantity of the perfume/active-mixture is added to the granules and the mixer is closed with a dust-tight-fitting lid.
3. Afterwards the mixer is running until the liquid is absorbed by the granules.
4. After mixing the granules are filled in aluminium compound foil bags to avoid evaporation of the perfume and the active.
5. For these first 4 steps the employees wear personnel protective equipment (standard coveralls and Category 3 Type 5 suit, safety glasses, respirator with filter mask type A and protective gloves) to avoid contamination with the active.
6. From now on nobody has direct contact with the impregnated granules during the following production process because it is a closed system.
7. After filling the granules in bags (nonwoven material) the bags are immediately shrink-wrapped in a special barrier foil.
8. Then the bags are packed manually in folding boxes and displays.

Workers wear adequate personal protection equipments during the steps where exposure cannot be excluded. Workers involved have received specific task training, follow operating procedures and act under supervision.
Taking into account the operational conditions, the technical control measures and the risk management measures during the process, worker exposure is estimated to be not significant.

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]**
[1a]	Non-professional[1]	Tier 1 / no PPE	adult: 0.0579
[1a]+[2]	Non-professional[1]	Tier 1 / no PPE	adult: 0.0591
[2]	General public[2]	Tier 1 / no PPE	infant: 0.006 toddler: 0.007 child: 0.003 adult: 0.001
[3]	General public[1]	Tier 1 / no PPE	infant: 0.245 toddler: 0.196
[3]	General public[1]	Tier 2 / no PPE	infant: 0.049 toddler: 0.039

[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)

Active substance

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
$AEC_{acute, inhalation}$	13-week inhalation study, rat	46.7 mg/m^3 (equivalent to 17 mg/kg bw/day)	100 (default AF)	No correction.	0.5 mg/m^3 (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
ADI	2-year dietary study rat	1.0 mg/kg bw/day	100	No correction	0.01 mg/kg bw/day
ARfD	Dev. Study rabbit	15 mg/kg bw/day	100	No correction	0.15 mg/kg bw/day

For Moth protection paper indirect exposure to Transfluthrin as a result of residues in food is considered negligible. An adequate statement for storage and use to avoid residues in food and feed is proposed for product labelling.

Substances of concern: skin sensitizers

While no reference values for sensitisation are set for a quantitative risk characterisation the information compiled below is used in a semi-qualitative approach in the local risk assessment.

Concerning the Geraniol and Linalool studies and available evidence indicate that a general level of exposure of up to 0.8 µg/cm² (0.01% in cosmetic products) may be tolerated by most consumers (SCCS, 2012).

In a recent peer review publication an AEC value of 55 µg/cm^2 were reported for Geraniol. This value was derived by determining an adequate "No Expected Sensitization Induction Level" from multiple local lymph node assays (LLNA) in mice and applying "Sensitization Assessment Factors" to account for differences and uncertainties (for more detail, see Nijkamp et al. 2015). Also a second AEC of 100 µg/cm^2 was derived based on Human Repeat Insult Patch Tests by the same authors for personal care products and household cleaning agents (Nijkamp et al. 2015). Though the methodology for derivation of these thresholds is not harmonized yet it may give an indication of possible thresholds and demonstrates at least the wide variation and uncertainties reported values. Inhalation

exposure of Geraniol did not lead to respiratory symptoms but at high dose the exposure elicits allergic reactions in the skin (Schnuch et al., 2009 cited in RIVM, 2011).
Linalool has a harmonised classification as Skin Sens. 1B based on results from a LLNA performed with commercial Linalool with an EC3 of 30% (weak sensitiser) and supported by the low exposure and frequency of sensitisation (based on CLP criteria) observed in human studies (RAC, 2015).
alpha-iso-Methylionone is a weak sensitiser according to the REACH registration dossier with an EC3 of 21.8% (ECHA dissemination website[8]). This value is also quoted in SCCS (2012).
Cineole (Eucalyptol) has an experimental EC3 value of 65.9% according the REACH registration dossier according to the ECHA dissemination website.[9] An EC3 value of 23% classifies Nerol as skin sensitiser.[10]

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 is also relevant for Transfluthrin.

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. The exposure routes are dermal and inhalation therefore comparsion with route-specific AELs of Transflutrhin ($AEL_{acute,\ inhalation}$ and $AEL_{acute,\ dermal}$) were chosen for risk characterisation.

Task/ Scenario	Tier	Systemic NOAEC	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1a] Inhalation route	1	46.7 mg/m^3 (=17 mg/kg bw/d)	0.17	0.00004	0.02%	yes
[1a] Dermal route	1	1000 mg/kg bw/d	1	0.0579	5.79%	yes

The acute internal systemic exposure is estimated for application of maximal 12 paper strips or 3 sachets 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). Sachets are in this reverse scenario considered as the worst case compared to moth paper. Compared with the $AEL_{acute,\ dermal}$

8 https://echa.europa.eu/registration-dossier/-/registered-dossier/18602/7/5/2
9 https://echa.europa.eu/registration-dossier/-/registered-dossier/13231/7/5/2
10 https://echa.europa.eu/de/registration-dossier/-/registered-dossier/10345/7/5/2

and the $AEL_{acute,\ inhalative}$ one must apply 87 and 4257 sachets, respectively. Thus an exceedance of the threshold 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 inhalation 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	0.001	10	yes
[2] child	1	1	0.01	0.003	30	yes
[2] toddler	1	1	0.01	0.007	70	yes
[2] infant	1	1	0.01	0.006	60	yes
[3] toddler	1	15	0.15	0.196	131	no
[3] infant	1	15	0.15	0.245	163	no

Because a risk was identified for infant and toddlers in scenario 3, refinements concerning 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)
[3] toddler	2	15	0.15	0.039	26	yes
[3] infant	2	15	0.15	0.049	33	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, children, infants and toddlers are expected.
Also the scenario of an infant/toddler mouthing a piece of Moth protection paper gave, after adjustment to an area of 10 cm^2 for mouthing, an acceptable risk.

Local risk assessment

The biocidal product **Moth protection paper** (meta SPC 1) is classified for local effects, i.e. skin irritation category 2 (Skin Irrit. 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 report 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)[11]. 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.

Note, May 2024: *The classification for skin irritation for Transfluthrin is no longer applicable according to COMMISSION DELEGATED REGULATION (EU) 2024/197*

In addition the hazard categorisation of local effects for skin irritation 2 (H315) is low according to ECHA (2015a)[12]. The potential exposure route relevant for local effects is skin. For Transfluthrin, the AEL $_{\text{acute dermal}}$ in the CAR (The Netherlands, 2014) is considered to be also adequately protective with respect to local effects. Transfluthrin is not classified for respiratory hazards or acute toxicity via inhalation.

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. Moreover the authorised use contains the provision that the repeat treatment after 6 months should be done only if necessary. 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). Where present, handle the paper strip on the white edge.

Note, May 2024: *Moth papers (originally meta SPC 1) are not authorised anymore due to change in classification and labelling in the 21st ATP (Reg. (EU) 2024/197). The Moth protection flavour bags type 1 and 2 (originally meta SPC 2 and 3) are now meta SPC 1 and 2. The PAR was adapted with regard to this aspect. All other parts of the PAR remain unchanged.*

[11] 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-EKSiN2pJEig&bvm=bv.124088155,d.d24

[12] 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

Moth protection paper: Risk characterisation for potential local effects: Mixing and loading (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 5 mg Transfluthrin per 127.5 cm^2 paper	Skin	Twice a year (every 6 months) 5 minutes per days	5.74 mg a.s. / palm (0.014 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 Use only in areas that are inaccessible to infants, children and companion animals (especially cats) Direction for use: white non impregnated edge as a touch point can further minimize dermal exposure	Acceptable, since +limited frequency and short duration for handling of product +reversibility of effects +recent data suggest a revision of the existing harmonized classification

The biocidal products **Moth protection flavour bags type 1** (meta SPC 2) are classified with Skin Sens. 1, Eye Dam. 1 and Skin Irrit. 2. The hazard categorisation of local effects for Eye Dam. 1 and Skin Sens. 1 is medium to high according to ECHA (ECHA, 2015a). In addition the banding evaluation scheme is B (ECHA, 2015a)[13] for the assessment of substances of concern. Therefore a qualitative exposure and risk assessment is performed and compared if the associated P-statements are sufficient or whether other risk mitigation measures should be applied.
The proposed P-statements are listed in chapter 2.1.3. Concerning potential exposure to skin sensitisers dermal exposure estimates were calculated. For Geraniol, Linalool, Nopyl acetate, alpha-iso-Methylionone, Cineole and Nerol a worst case quantitative dermal exposure estimates were calculated leading to 330 µg/cm^2, 1250 µg/cm^2, 670 µg/cm^2, 60 µg/cm^2 , 90 µg/cm^2 and 130 µg/m^{2}for these substances, respectively.

The values are therefore in exceedance of the generic threshold of 0.8 µg/cm^2 recommended by SCCS (2012) as well as other thresholds proposed in the public literature (Nijkamp et al. 2015) for skin sensitization. The SCCS value of 0.8 µg/cm^2 corresponds to 0.01% (100 ppm) limit in cosmetic products indicative for safe use (SCCS, 2012). However there are considerable uncertainties with predicted thresholds for human sensitisation (ECHA, 2017b). Nevertheless values <500 µg/m^2 are indicative for relatively low exposure according to Table 3.3 of the CLP guidance document (ECHA, 2017c).
The Linalool concentration in the Anti-moths products are higher but well below the EC3 value that indicates a weak sensitisation potential derived from animal data. For Geraniol RAC concluded that while classification as Skin Sens. 1 is warranted (several EC3 values are available), the data are not sufficient to support the establishment of a specific concentration limit because the data do not suggest that geraniol has an extreme potency (RAC, 2018).
Nopyl acetate has been categorised as likely contact allergen by a combination of evidence according to SCCS (2012). No agreed EC3 value or other indicative threshold from a regulatory body is available for this substance.
alpha-iso-Methylionone, Nerol and Cineole concentrations in the biocidal products meta SPC 2 are far below the EC3 values, however based on the current knowledge no quantitative risk assessment for sensitziers can be performed with an acceptable degree of uncertainty.
The products are also subject to special labelling requirement according to the CLP Regulation. The concentration limit for elicitation is used for the application of the special labelling requirements to protect already sensitised individuals also from other sensitizing substances contained in the fragrance formulation (applicable to meta SPC 2 and meta SPC 3).
Manufacture of the biocidal product and impregnation of the granules occurs on-site and are not considered in the risk characterisation.
The exposure to the non-professional users and general public during application and use is limited because the biocidal product is applied to granules that are inserted in a spunlace bag (cellulose). The direct contact with the granules (and with the active substance) can be excluded under normal conditions of use. Direct contact to eyes is also rather unlikely based on the formulation type passive diffuser. However sweating and diffusion of ingredients to the spunlace bag may facilitate dermal exposure. The proposed risk mitigation measures include washing of hands after handling. Direct handling of the biocidal product is once in three months by adults and represents a low application frequency. Moreover the authorised use contains the provision that the repeat treatment after 3 (or 6) months should only be done if necessary. Children are not supposed to come into contact with the product based on the proposed labelling and use instructions.

[13]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

Additional risk mitigation measure on the label prescribed adequate ventilation "During application, ventilate rooms on a regular basis" for meta SPC 2 products.Use only in areas that are inaccessible to infants, children and companion animals (especially cats) is proposed on the label to preclude mouthing of the products by a child or direct contact with pets.
The local risk assessment for meta SPC 2 products is considered also appropriate for **meta SPC 3** based on the same use pattern and similar proposed risk mitigation measures. Moreover SoCs identified for meta SPC 3 products would trigger band A (ECHA, 2015a) and thus a lower banding evaluation scheme for classified SoCs compared to band B for meta SPC 3 products.

Conclusion
The proposed risk mitigation measures and P-statements are sufficient to mitigate local effects for Anti-moth prducts BPF meta SPC 1, 2 and 3. Additional risk mitigation measures concerning the application areas (inaccessible to infancts, children and pets (especially cats)) are proposed for meta SPC 1, 2 and 3. Additional ventilation is prescribed for meta SPC 2 products.
The risk for potential local effects for the BPF, i.e. Moth protection paper and Moth protection flavour bags is considered as acceptable for the use scenario considered in this PAR.

Note, May 2024: *Moth papers (originally meta SPC 1) are not authorised anymore due to change in classification and labelling in the 21st ATP (Reg. (EU) 2024/197).*

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 in meta SPC 1 (Moth protection paper). For Moth protection flavour bags substances of concern are considered in a local risk assessment.

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.

Task/ Scenario / 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)
Scenarios [1a+2,	0.17 (=0.5	0.0579	0.00104	0.0591	35%	yes

adult, Tier 1]	mg/m^3, AEC)					

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

Note, May 2024: *Moth papers (originally meta SPC 1) are not authorised anymore due to change in classification and labelling in the 21st ATP (Reg. (EU) 2024/197). The Moth protection flavour bags type 1 and 2 (originally meta SPC 2 and 3) are now meta SPC 1 and 2.*

2.2.7 Risk assessment for animal health

A quantitative risk assessment for Anit-moth products BPF for pets is not considered necessary as the assessment performed for humans may cover companion animals as well. In addition there is no harmonised exposure scenario for domestic pets. Therefor the following risk mitigation measure appears on the label**: "**For use only in areas that are inaccessible to infants, children, companion animals (specifically cats) and non-target animals."

As poikilothermic animals like fish, amphibians and reptiles, are particularly susceptible towards the toxicity of pyrethroids like Transfluthrin, and as no data were provided for exposure assessment, the risk mitigation measure "No application in rooms, where fish tanks and terrariums are present" is set.

2.2.8 Risk assessment for the environment

Note, May 2024: *Moth papers (originally meta SPC 1) are not authorised anymore due to change in classification and labelling in the 21st ATP (Reg. (EU) 2024/197). The Moth protection flavour bags type 1 and 2 (originally meta SPC 2 and 3) are now meta SPC 1 and 2.*

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 (see item 6.6a and 6.6b) and new PNECs based on the results were agreed. An amended list of endpoints for Transfluthrin and its metabolite (LoEP) was agreed at the BPC-24 meeting in March 2018. The applicant submitted a full letter of access (LoA) for the new submitted data and for the data of Transfluthrin reported in the AR (The Netherlands, 2014). The new orginal studies were not submitted by the applicant.
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 CAR 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-04mg/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 any product of the BPF Anti-moth products were not conducted. Substances of concern for the environment were identified (see confidential Annex restricted to authorities) however the ecotoxicological effects of the products are solely based on the effects of the active substance Transfluthrin. Further effects from other components, including synergistic effects are not expected.

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). In May 2018, the Netherlands submitted a CLH dossier for accordance check with the following classification proposal for the environment: Aquatic Acute 1 (M=1000) and Aquatic Chronic 1 (M=1000).[14] According to the content of Transfluthrin (1.01 – 100% w/w) in the single products of the biocidal product family Anti-moth products they have to be classified as Aquatic Acute 1 and Aquatic Chronic 1. Therefore each product of the BPF family 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, P391 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).
At product authorisation stage several new study reports were submitted to other MS (DE, FR and NL). These studies were discussed at the BPC ENV WG-IV-2017 and new PNEC values were agreed (final minutes on BPC ENV WG-IV-2017 item 6.6a and 6.6b). These new PNEC values are summarised in the table below.
The applicant submitted a full letter of access (LoA) for the new submitted data and for the data of Transfluthrin reported in the AR (The Netherlands, 2014).

[14] https://echa.europa.eu/de/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e180681922

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 amended list of endpoints for Transfluthrin and its metabolite TFB-COOH (LoEP) was 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} (corresdponding 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 Family includes two formulations of passive diffuser for indoor use only. These are placed inside wardrobes 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 sediments), groundwater and soil, but indirect 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. According to the CAR of Transfluthrin (The Netherlands 2014) it is assumed that even no experimental data are available for the biodegradation of transfluthrin in soil, the route of degradation in soil can be assumed to be similar to that in water/sediment systems, i.e. the main metabolites to be expected in soil are TFB-OH and TFB-COOH. The environmental exposure assessment 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 CAR (The Netherlands, 2014) no experimental data for the biodegradation of Transfluthrin in soil was available. At product authorisation stage several MS (DE, FR and NL) received a new performed study on aerobic biodegradation of Transfluthrin in soil and an additional kinetic evaluation report. The applicant submitted a full letter of access (LoA) for the new submitted data and for the data of Transfluthrin reported in the AR (The Netherlands, 2014).

Conclusion used in Risk Assessment – Further studies on fate and behaviour in the environment	
Value/conclusion	Transfluthrin: DT50 = 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 DT50 of 5.17 d (at 12°C) was agreed by the commenting MSs. An amended list of endpoints (LoEP) was agreed at the BPC-24 meeting in march 2018.

Leaching behaviour (ADS)

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

Testing for distribution and dissipation in soil (ADS)

Conclusion used in Risk Assessment – Distribution and dissipation in soil	
Value/conclusion	Metabolite TFB-COOH: DT50 = 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 DT50 of 3.23 d for the metabolite TFB-COOH (at 12°C) and a formation fraction of 0.619 was agreed by the commenting MS. An amended list of endpoints (LoEP) of Transfluthrin and its metabolite TFB-COOH 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 biocidal products 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 CAR for Transfluthrin (NL, 2014) it was concluded that currently there are no indications for endocrine disrupting properties of the active substance based on 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. 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.

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

For details please see the confidential Annex of the PAR.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT18
Assessed scenarios	Scenario [1]: Moth protection paper – meta SPC 1 Scenario [2]: Moth protection flavour bags – meta SPC 2, 3 Insecticide, used in wardrobes as passive diffuser for indoor use by non-professionals only.
ESD(s) 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] & [2]: Emission scenario for passive diffusor adapted for the particular application conditions of the biocidal product. Since the product is designed for non-professional users only the private (domestic) use was considered. The biocidal products are ready-to-use products, no preparation step was considered in the calculation of the Predicted Environmental concentration (PEC). The products have to be applied in wardrobes. Scenario [1]:meta SPC 1 One impregnated paper strip (30 mg a.s.) is enough for 1 m³ inside the wardrobe. The product releases Transfluthrin into the air by evaporation over a 6 month period of use. Scenario [2]: meta SPC 2, 3 One flavour bag (15 mg a.s.) is enough for 1 m³ inside the wardrobe. The product releases Transfluthrin into the air by evaporation over a 3 month period of use.
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 according to ECHA (2017). No additional simulation for leaching to groundwater is required.
Confidential Annexes	No

Life cycle steps assessed	Scenario [1] & [2]: 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.

The biocidal products can either be an impregnated Moth protection paper (30 mg a.s. per m³, every 6 months) or an Moth protection flavour bag (15 mg a.s. per m³, every 3 months). The input parameters of both product formulations result in the same emission to the floor, because the impregnated moth paper contains the double amount of active substance, but the application time is half of the application time of the Moth protection flavour bag:

Eapplication, floor = Qas x (Tday/Tmax) x Fapplication, floor x 10-3 [kg/d]
Scenario [1] – moth paper
Eapplication, floor = 0.1125 x (24/4320) x 0.1 x 10-3 = 6.25E-08 kg/d
Scenario [2] – moth flavour bag
Eapplication, floor = 0.05625 x (24/2160) x 0.1 x 10-3 = 6.25E-08 kg/d

Scenario [1] – Moth protection paper – meta SPC 1

Calculations for Scenario [1] – Anti-moth Paper

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	6.25E-08	

Scenario [2] – Moth protection flavour bags type 1 and 2 – meta SPC 2, 3

Calculations for Scenario [2] – Anti-moth Flavour Bag

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	6.25E-08	

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	**Fresh-water sedi-ment**	**Sea-water**	**Marine sedi-ment**	**STP**	**Air**	**Soil**	**Ground-water**	**Other**
Scenario [1]: Moth protection paper	**Yes** (in-direct)	**Yes** (in-direct)	**No**	**No**	**Yes** (direct)	**Yes** (direct)	**Yes** (in-direct)	**Yes** (in-direct)	no
Scenario [2]: Moth protection flavour bags type 1 and 2	**Yes** (in-direct)	**Yes** (in-direct)	**No**	**No**	**Yes** (direct)	**Yes** (direct)	**Yes** (in-direct)	**Yes** (in-direct)	no

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 at test temperature	9.00E-04 [1]	Pa (at 20°C)	Assessment Report
Vapour pressure	9E-04 [1]	Pa (at 25°C)	Assessment Report
Water solubility at test temperature	0.057 [1]	mg/L (at 20°C)	Assessment Report
Water solubility	0.0611 [1]	mg/L (at 25°C)	Assessment Report
Log Octanol/water partition coefficient (log Kow)	5.94 [1]	Log 10	Assessment Report

Input parameters (only set values) for calculating the fate and distribution in the environment			
Organic carbon/water partition coefficient (Koc)	50119 [1]	l/kg	Assessment report of a.s
Henry's Law Constant	5.86 [1]	Pa/m3/mol (at 20°C)	Assessment report of a.s
Biodegradability	not biodegradable [1]		Assessment report of a.s
DT_{50} for biodegradation in surface water	7 [1]	d (at 12ºC)	Assessment report of a.s
DT_{50} for hydrolysis in surface water	1.00E+06	d (at 12ºC)	Default value (conservative approach)
DT_{50} for photolysis in surface water	1.00E+06	d	Default value (conservative approach)
DT_{50} for degradation in soil	5.17	d (at 12ºC)	Agreed at BPC ENV WG-IV-2017
Bioconcentration factor for earthworms	10452 [1]	L/kg_{wwt}	Assessment Report
Bioconcentration factor for fish	1783 [1]	L/kg_{wwt}	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 (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:

Transfluthrin: molecular weight 371.2 mg/mol

TFB-OH: molecular weight 180.1 mg/mol; 38% in water phase

TFB-COOH: molecular weight 194.08 mg/mol; 59% in water phase

TFB-OH: 180.1/371.2 = 0.485 x 0.38 = <u>0.184</u>

TFB-COOH: 194.08/371.2 = 0.523 x 0.59 = <u>0.308</u>

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 assumed in one house. The moth papers are used simultaneously.

The quantity of active substance in the diffusers per household is therefore calculated as follows:

<u>Scenario [1] – Anti-moth Paper – meta SPC 1</u>

Q_{AS} = 2.5 x 1.5 m³ x 30 mg = 112.50 mg a.s. (every 6 month)

<u>Scenario [2] – Anti-moth Flavour Bag – meta SPC 2, 3</u>

Q_{AS} = 2.5 x 1.5 m³ x 15 mg = 56.25 mg a.s. (every 3 month)

The biocidal products can either be an impregnated moth paper (30 mg a.s. per m³, every 6 months) or an Moth protection flavour Bag (15 mg a.s. per m³, every 3 months). The input parameters of both product formulations result in the same emission to the floor, because the impregnated moth paper contains the double amount of active substance, but the application time is half of the application time of the Moth protection flavour bag:

Eapplication, floor = Qas x (Tday/Tmax) x Fapplication, floor x 10^{-3} [kg/d]
Scenario [1] – Moth protection paper – meta SPC 1
Eapplication, floor = 0.1125 x (24/4320) x 0.1 x 10-3 = 6.25E-08 kg/d
Scenario [2] – Moth protection flavour bag – meta SPC 2, 3
Eapplication, floor = 0.05625 x (24/2160) x 0.1 x 10-3 = 6.25E-08 kg/d

Consequently, the calculated Predicted Environmental Concentrations (PECs) regarding both product formulations are equal.

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		
Compartment	Percentage [%] Scenario [1] & [2]	Remarks
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 Family and routed as waste water to the STP as result from cleaning 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 Moth protection paper: Passive diffuser for indoor use, only placed inside wardrobes				
Variable/parameter	**Symbol**	**Value**	**Unit**	**S/D/O/P**
Input				
Quantity of active substance in the diffuser	$Q_{a.s.}$ [1]	Moth protection paper: 0.1125 Moth protection flavour bag: 0.05625	g	S
Maximal duration of use of the diffuser [h]	T_{Max}	Moth protection paper: 4320 Moth protection flavour bag: 2160	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 [2]	-	D
$E_{application,\ floor} = Q_{a.s.} \times (T_{day}/T_{max}) \times F_{application,\ floor} \times 10^{-3}$				
Emission to the floor	**$E_{application,floor}$**	**6.25E-08**	**kg/d**	**O**
Fraction emitted to waste water	F_{ww}	1	-	D
Cleaning efficiency	F_{ce}	1 [2]	-	D
$E_{treated,\ ww} = E_{application,floor} \times F_{ww} \times F_{ce}$				
Emission from the treated floor to waste water	**$E_{treated,ww}$**	**6.25E-08**	**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 [2]	-	D
$E_{localSTP} = E_{treated,ww} \times N_{house} \times F_{simultaneity}$				
Daily emission to the STP	**$E_{localSTP}$**	**1.38E-05**	**kg/d**	**O**

1 *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.*

2 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	$Elocal_{water}$	1.38E-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	$Clocal_{inf} = \frac{\text{Elocal}_{\text{water,sim}} \text{ x } 10^6}{\text{EFFLUENT}_{\text{stp}}}$	**6.90E-06**	**mg/L**

Calculation of the STP effluent concentration (*cf.* ECHA, 2015b, equation 33)			
Parameter	**Definition**	**Value**	**Unit**
Cumulative concentration in untreated wastewater	$Clocal_{inf}$	6.90E-06	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 $Fstp_{water}$**	**1.32E-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. Due to the fact that degradation in water has not been taken into account, the calculations are thus conservative.
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	**$Kp_{susp} = Foc_{susp} \times K_{OC}$**	**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	$Clocal_{eff}$	1.32E-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})	**$Clocal_{water} = Clocal_{eff} \times ((1+Kp_{susp} \times SUSP_{water} \times 10^{-6}) \times DILUTION)^{-1}$**	**1.23E-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 m³/m³ for $Fsolid_{susp}$ (fraction solids in suspended matter), 2500 kg/m³ for RHOsolid (bulk density of the solid phase), 0.9 m³/m³ for $Fwater_{susp}$ (fraction water in suspended matter) and 1000 kg/m³ 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	m³/m³
Bulk density of the solid phase	RHO_{solid}	2500	kg/m³
Fraction water in suspended matter	$Fwater_{susp}$	0.9	m³/m³
Density of the water phase	RHO_{water}	1000	kg/m³
Bulk density of (wet) suspended matter	***RHOsusp = $Fsolid_{susp}$ x RHO_{solid} + $Fwater_{susp}$ x RHO_{water}***	**1150**	**kg/m³**

The suspended matter-water partitioning coefficient ($K_{susp\text{-}water}$) is derived taking default values of 0.9 m³/m³ for $Fwater_{susp}$, 0.1 m³/m³ for $Fsolid_{susp}$ and 2500 kg/m³ 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	m³/m³
Fraction solids in suspended matter	$Fsolid_{susp}$	0.1	m³/m³
Partition coefficient solid-water in suspended matter	Kp_{susp}	5011.9	L/kg
Density of the solid phase	RHOsolid	2500	kg/m³
Suspended matter-water partitioning coefficient	$K_{susp\text{-}water} = Fwater_{susp} + Fsolid_{susp} \times \frac{Kp_{susp}}{1000} \times RHOsolid$	**1253.88**	m³/m³

Calculation of PEClocal in sediment (*cf.* ECHA, 2015b, equation 50)			
Parameter	**Definition**	**Value**	**Unit**
Concentration in surface water during emission episode	$PECloca l_{water}$	1.23E-07	mg/L
Suspended matter-water partitioning coefficient	$K_{susp-water}$	1253.88	m^3/m^3
Bulk density of suspended matter	RHO_{susp}	1150	kg/m^3
Predicted Environmental Concentration in sediment	**$PECloca l_{sed} = (K_{susp-water} / RHO_{susp})$ x $PECloca l_{water}$ x 1000**	**1.34E-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[15] 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.

[15] 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 amounts 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	$Elocal_{water}$	1.38E-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	**$C_{sludge} = Fstp_{sludge} \times Elocal_{water} \times 10^6 \times SLUDGERATE^{-1}$**	**1.40E-02**	**mg/kg**

According to ECHA (2015b) default values were taken for the sludge application rate (5000 kg dry weight/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}	1.40E-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	$Csludge_{soil1}(0) = \frac{C_{sludge} \times APPL_{sludge}}{DEPTH_{soil} \times RHO_{soil}}$	**2.06E-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)	2.06E-05	mg/kg
Fraction accumulation in one year	Facc	5.59E-22	-
Concentration in soil due to sludge after 10 applications at t=0	$\boldsymbol{Csludge_{soil\ 10}\ (0) = Csludge_{soil1}\ (0) \times [1 + \sum_{n=1}^{9} Facc^n]}$	**2.06E-05**	**mg/kg**

According to Guidance on the BPR: Volume IV Environment, Part B+C (ECHA 2017a) regarding the performance of risk assessment for the terrestrial compartment, care should be taken that the PEC and PNEC soil are based on comparable exposure patterns. The results of standardised terrestrial ecotoxicity tests are generally expressed on the basis of initial, nominal concentrations in test with single applications. Consequently, a PNECsoil based on those tests is most accurately described in terms of initial concentrations too. In
that case the PNECsoil should be compared with the initial PECsoil, which is the PECsoil directly after the last sludge application. Therefore, the concentration in soil due to sludge after 10 applications at t=0 (directly after the last application) is used for the risk characterisation.

The initial concentrations following 10 sludge applications are used to calculate average residues in soils regarding secondary poisoning via contaminated earthworms, i.e., over a time period of 180 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	180	d
Initial concentration after sludge application	C_{soil} (0)	2.06E-05	mg/kg
Average concentration in soil over 180 days ($PEC_{soil,180d\ agric.}$)	**$Clocal_{soil}$ = (1/kT) x C_{soil} (0) x (1-e^{-kT})**	**8.54E-07**	**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 (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	$PECloca l_{agr.soil}$	8.54E-07	mg/kg
Bulk density of (wet) soil	RHO_{soil}	1700	kg/m³
Density of the solid phase	RHO_{solid}	2500	Kg_{solid}/m_{solid}^3
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 partition coefficient	$k_{soil-water} = F_{water,soil} + F_{solid,soil} \times \frac{k_{p,soil}}{1000} \times RHO_{solid}$	1503.77	m^3/m^3
Predicted environmental concentration in porewater	$\boldsymbol{PEClocal_{porewater} = \frac{PEClocal_{soil} \times RHO_{soil}}{k_{soil-water} \times 1000}}$	**9.65E-10**	**mg/L**

Summary table on calculated PEC values						
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**
	[mg/m³]	[mg/L]	[mg/kg_{wwt}]	[mg/m³]	[µg/l]	[mg/m³]
Transfluthrin						
Scenario [1] – Anti-moth Paper & Scenario [2] – Anti-moth Flavour Bag	1.32E-06	1.23E-07	1.34E-04	5.03E-06	9.65E-07	not relevant
Metabolite TFB-OH						
Scenario [1] - Anti-moth Paper & Scenario [2] - Anti-moth Flavour Bag	2.42E-07	2.25E-08	2.45E-05	9.20E-07	1.77E-07	not relevant
Metabolite TFB-COOH						
Scenario [1] - Anti-moth Paper & Scenario [2] - Anti-moth Flavour Bag	4.11E-07	3.83E-08	4.17E-05	1.56E-06	2.99E-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.

In the Biocidal Product Family includes two types of formulations: the Anti-moth Paper (impregnating paper) and the Anti-moth Flavour Bag (sealed bags containing granules). Both are indoor diffusers used in wardrobes, 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 this Biocidal Product Family.

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 ($PEC_{agric,\ 180\ days}$)	$PEClocal_{soil}$	8.54E-07	mg/kg_{wwt}
Octanol/water partition coefficient	K_{ow}	870964	-
Density of earthworm	$RHO_{earthworm}$	1	kg_{wwt}/L
Bioconcentration factor for earthworm on wet weight basis	$BCF = (0.84 + 0.012\ K_{ow})/RHO_{earthworm}$	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	$PEClocal_{soil,porewater}$	9.65E-10	mg/L
Predicted Environmental Concentaration in earthworms	$C_{earthworm} = \frac{BCF_{earthworm} \times C_{porewater} + C_{soil} \times F_{gut}\ x\ CONV_{soil}}{1 + F_{gut}\ x\ CONV_{soil}}$	**9.15E-06**	**$mg/kg_{wet\ earthworm}$**

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}	1.23E-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	$PEC_{oral,\ predator} = PEC_{water} \cdot BCF_{fish} \cdot BMF$	**2.19E-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	2.19E-04	9.15E-06

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		
Scenarios	**PEC_{STP}**	**$PEC/PNEC_{STP}$**
	$PNEC_{STP}$ = 0.057 mg/L	
Scenario [1] & Scenario [2] – meta SPC 1,2,3	1.32E-06 mg/L	2.32E-05

Conclusion

The PEC/PNEC ratio for Transfluthrin is <1 demonstrating no unacceptable 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 $PEC/PNEC_{surface\ water}$ values of both metabolites cover the risk assessment for the sediment compartment.

Summary table on calculated $PEC/PNEC_{aquatic}$ values				
Scenario	**$PEC_{surface\ water}$**	**$PEC/PNEC_{surface\ water}$**	**PEC_{sed}**	**$PEC/PNEC_{sed}$**
Transfluthrin				
	$PNEC_{surface\ water}$ = 1.75E-06 mg/L		**$PNEC_{sed}$ = 3.57E-04 mg/kg_{wwt}**	
Scenario [1] & Scenario [2] meta SPC 1,2,3	1.23E-07 mg/L	7.03E-02	1.34E-04 mg/kg_{wwt}	3.75E-01
Major metabolite TFB-OH				
	$PNEC_{surface\ water}$ = 0.1 mg/L		No PNEC available	

Summary table on calculated PEC/PNEC$_{aquatic}$ values				
Scenario [1] & Scenario [2] meta SPC 1,2,3	2.25E-08 mg/L	2.25E-07	2.45E-05 mg/kg$_{wwt}$	Covered by PEC/PNEC$_{surface\ water}$
Major metabolite TFB-COOH				
	PNEC$_{surface\ water}$ = 0.1 mg/L		No PNEC available	
Scenario [1] & Scenario [2] meta SPC 1,2,3	3.83E-08 mg/L	3.83E-07	4.17E-05 mg/kg$_{wwt}$	Covered by PEC/PNEC$_{surface\ water}$

Conclusion

The PEC/PNEC 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 no unacceptable 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	**PEC$_{soil}$**	**PEC/PNEC$_{soil}$**
	PNEC$_{soil}$ = 0.09 mg/kg$_{wwt}$	
Scenario [1] & Scenario [2] meta SPC 1,2,3	2.06E-05 mg/kg$_{wwt}$	2.29E-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 of 0.1 µg/L for organic pesticides applies.

For Transfluthrin a PEC for groundwater of 9.65E-07 µg/L was calculated. For the metabolites TFB-OH and TFB-COOH PEC groundwater values of 1.77E-07 µg/L and 2.99E-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 TBF-OH and TBF-COOH, which were identified in the aquatic and sediment phase and TFB-COOH in the soil compartment (see The Netherlands, 2014 and new submitted 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 3 for $logK_{ow}$ stated in 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} in fish is calculated to be 2.19E-04 mg/kg and in worms is 9.15E-06 mg/kg. 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 <6.57E-03 mg/kg feed in the case of fish and <4.02E-04 mg/kg feed in case of earthworms. Following a similar reasoning for short term tests the LC_{50} should be <0.66mg/kg feed and <4.02E-02 mg/kg feed 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 6.57E-03 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 referred to the CAR for 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] & Scenario [2] meta SPC 1,2,3	**PEC_{oral} mammals** **fish**	**PEC/PNEC** **mammals** **via fish**	**PEC_{oral}** **mammals** **earthworms**	**$PEC/PNEC_{mammals}$** **via earthworms**
	$PNEC_{mammals}$ = 6.67 mg/kg_{diet}*day			

Passive diffusor, indoor				
Transfluthrin	2.19E-04 mg/kg*d	3.28E-05	9.15E-06 mg/kg*d	1.37E-06

Conclusion

The PEC/PNEC ratios for secondary poisoning for mammals via ingestion of contaminated fish and earthworms far <1 and therefore no unacceptable risk is expected. Regarding 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 BPF Anti-moths products.

Aggregated exposure (combined for relevant emmission 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 BPF Anti-moths products

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 regarding 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 no unacceptable risk can be expected.

For all exposed compartments and the secondary poisoning for mammals and birds all calculated risk ratios are <1, indicating no unacceptable risks. All calculated groundwater concentrations are <0.1 µg/L.

The authorised uses of the BPF Anti-moths products show no unacceptable 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.

Note, May 2024: *Moth papers (originally meta SPC 1) are not authorised anymore due to change in classification and labelling in the 21st ATP (Reg. (EU) 2024/197). The Moth protection flavour bags type 1 and 2 (originally meta SPC 2 and 3) are now meta SPC 1 and 2.*

2.2.9 Measures to protect man, animals and the environment

Please cf. to chapter 2.1.4 and 2.1.5.

2.2.10 Assessment of a combination of biocidal products

The products are not intended to be authorised for the use with other biocidal products.

2.2.11 Comparative assessment

Not relevant.

3 ANNEXES

3.1 List of studies for the biocidal product family

Author(s)	Year	Title	Reference	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Anonymous	2016	**Chemical and physical characterisation on test item "Anti-moth sachet liquid"**	Anonymous 2016a	Eurofins Biolab Srl	S-2016-02485 AM	Yes	Yes	Annowatec GmbH	3.2 3.3
Anonymous	2016	**Chemical and physical charcterization on test item "Mothpaper liquid"**	Anonymous 2016b	Eurofins Biolab Srl	S-2016-02486 AM	Yes	Yes	Annowatec GmbH	3.2 3.3

Author(s)	Year	Title	Reference	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Anonymous	2015	**Analyses of clothes moth killer - sachets**	Anonymous 2015	Gortler analytical services	V153365	No	Yes	Annowatec GmbH	3.4.1
Anonymous	2015	**Analyses of moth paper**	Anonymous 2015	Gortler analytical services	V151601-40	No	Yes	Annowatec GmbH	3.4.1
Anonymous	2017	**Analyses of moth paper (interim report)**	Anonymous 2017	Gortler analytical services	V145149-022017-1	No	Yes	Annowatec GmbH	3.4.1

Author(s)	Year	Title	Reference	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Anonymous	2016	**Flash Point on the sample Mothpaper liquid**	Anonymous 2016a	Innovhub – Stazioni Sperimentali per l'Industria Divisione Stazione Sperimentale Combustibili	S-SSC-1601036	Yes	Yes	Annowatec GmbH	4.2

Author(s)	Year	Title	Reference	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Anonymous	2016	**Flash Point on the sample Anti-moth sachet liquid**	Anonymous 2016b	Innovhub – Stazioni Sperimentali per l'Industria Divisione Stazione Sperimentale Combustibili	S-SSC-1601035	Yes	Yes	Annowatec GmbH	4.2

Author(s)	Year	Title	Reference	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Anonymous	2014	**Relative self-ignition temperature testing on a sample of Moth protection paper**	Anonymous 2014	Chilworth Technology Limited, Beta house Southampton science park	GLP112028R1V1/2014	Yes	Yes	Annowatec GmbH	4.17.1
Anonymous	2014	**Validation of the measurement of transfluthrin in moth paper**	Anonymous 2014	Gortler analytical services	V144429-A	Yes	Yes	Annowatec GmbH	5

Author(s)	Year	Title	Reference	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Anonymous	2014	**Prüfbreicht Gehaltsbestimmung an Mottensäckchen**	Anonymous 2020	ASO	CHG 4999, PAA 8596, TN7703 914	Yes	Yes	Annowatec GmbH	5
Anonymous	2016	**Validation transfluthrin determination in moothproofing agents**	Anonymous 2016	Mainsite services	ASO-PA B16044	No	Yes	Annowatec GmbH	5

Author(s)	Year	Title	Reference	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Anonymous	2014	**Laboratory evaluation of the efficacy of a product for use in the control of clothes moths and carpet beetles**	Anonymous 2014a	T.E.C. LABORATORY	1792/0514R	Yes (GEP)	Yes	Annowatec GmbH	6.7
Anonymous	2014	**Laboratory evaluation of the efficacy of products for use in the control of clothes moths and carpet beetles**	Anonymous 2014b	T.E.C. LABORATORY	1730/0214	Yes (GEP)	Yes	Annowatec GmbH	6.7

Author(s)	Year	Title	Reference	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
Anonymous	2017	**Statement**	Anonymous 2017	T.E.C. LABORATORY	n.a	n.a	Yes	Annowatec GmbH	6.7
Anonymous	1995	**NAK 4455 (transfluthrin): a fast-acting insecticide for use in household and hygiene products**	Anonymous 1995	n.a	n.a (literature)	No	No	Bayer Environmental Science	6.7

Author(s)	Year	Title	Reference	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
ANONYMOUS	2015	EARLY LIFE STAGE TOXICITY OF TRANSFLUTHRIN TECHNICAL TO THE FATHEAD MINNOW (PIMEPHALES PROMELAS) UNDER FLOW-THROUGH CONDITIONS	ANONYMOUS, 2015	BAYER CROP SCIENCE AG	REPORT NO: EBTBL 007	YES	YES	BAYER CROP SCIENCE AG	13

Author(s)	Year	Title	Reference	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
ANONYMOUS	2015	CHRONIC TOXICITY OF TRANSFLUTHRIN TECHNICAL TO DAPHNIA MAGNA UNDER FLOW-THROUGH CONDITIONS	ANONYMOUS, 2015	BAYER CROP SCIENCE AG	REPORT NO: EBTBL 006 Yes	YES	YES	BAYER CROP SCIENCE AG	13

Author(s)	Year	Title	Reference	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
ANONYMOUS	2015	CHIRONOMUS RIPARIUS 28-DAY CHRONIC TOXICITY TEST WITH TRANSFLUTHRIN (TECH.) IN A WATER-SEDIMENT SYSTEM USING SPIKED SEDIMENT	ANONYMOUS, 2015	BAYER CROP SCIENCE AG	REPORT NO: EBTBL005 Yes	Yes	Yes	BAYER CROP SCIENCE AG	13
ANONYMOUS	2015	A STUDY ON THE CHRONIC TOXICITY TO THE SEDIMENT DWELLER LUMBRICULUS VARIEGATUS	ANONYMOUS, 2015	ECT OEKOTOXIKOLOGIE GMBH	STUDY NO. 14P4LA	Yes	ECT Yes	ECT OEKOTOXIKOLOGIE GMBH	13

Author(s)	Year	Title	Reference	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
ANONYMOUS	2014	TRANSFLUTHRIN A.S. (BCS-AW53131): EFFECTS ON THE ACTIVITY OF SOIL MICROFLORA (NITROGEN TRANSFORMATION TEST)	ANONYMOUS, 2014	BIOCHEM AGRAR GMBH	REPORT NO: 14 10 48 069 N	Yes	Yes	BIOCHEM AGRAR GMBH	13
ANONYMOUS	2014	EFFECTS ON THE REPRODUCTION OF THE COLLEMBOLAN FOLSOMIA CANDIDA	FRIEDRICHS., 2014	BIOCHEM AGRAR GMBH	REPORT NO: 14 10 48 204 S;	Yes	Yes	BIOCHEM AGRAR GMBH	13

Author(s)	Year	Title	Reference	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
ANONYMOUS	2014	SUBLETHAL TOXICITY TO THE EARTHWORM EISENIA FETIDA IN ARTIFICIAL SOIL	ANONYMOUS, 2014	BIOCHEM AGRAR GMBH	REPORT NO.: 14 10 48 205 S	Yes	Yes	BIOCHEM AGRAR GMBH	13
ANONYMOUS	2015	[METHYLENE-^{14}C]TRANSFLUTHRIN: AEROBIC DEGRADATION / METABOLISM IN FOUR SOILS	ANONYMOUS ,2015	BAYER CROP SCIENCE AG	STUDY NO. M1253376-5	Yes	Yes	BAYER CROP SCIENCE AG	13

Author(s)	Year	Title	Reference	Testing Company	Report No.	GLP Study (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
ANONYMOUS	2020	**Optimum Mottenaktivperlen** **TEST FOR SELF–HEATING SUBSTANCES (UN N.4)**	ANONYMOUS, 2020a	SIEMENS AG	PS20200011-1	Yes	Yes	Annowatec GmbH	4.17.1
ANONYMOUS	2020	**Aeroxon Textilschutz-Säckchen** **TEST FOR SELF–HEATING SUBSTANCES (UN N.4)**	ANONYMOUS, 2020b	SIEMENS AG	PS20200010-1	Yes	Yes	Annowatec GmbH	4.17.1

3.2 Output tables from exposure assessment tools

3.2.1 Human and animal exposure

SCENARIO [1]		
Parameters	**Value**	**Unit**
Dermal exposure:		
Max. content of a.s. on paper strip	~ 0.03922	mg/cm²
Max. content of a.s. on sachet surface	0.0187	mg/cm²
Transfer coefficient dried fluids	0,18	g/g
Area of palms	410	cm²
Number of manipulations	max. 12 (papers) max. 3 (sachet)	day^{-1}
Body weight adult	60	kg
Dermal absorption	10 (papers) 50 (sachets)	%
Dermal systemic exposure, Tier 1 (papers, [1a])	**0,0579**	**mg a.s. /kg bw/day**
Dermal systemic exposure, Tier 1 (sachets, [1b])	**0,0345**	
Inhalative exposure:		
Peak concentration (TWA 15 min)	0,023	mg/m³
Exposure duration	5	min/day
Inhalation rate adult	0,02083	m³/min
Body weight adult	60	kg
Inhalative systemic exposure, Tier 1	**0,00004**	**mg a.s. /kg bw/day**
TOTAL systemic exposure, Tier 1 (papers, [1a])	**0,0579**	**mg a.s. /kg bw/day**
TOTAL systemic exposure, Tier 1 (sachets, [1b])	**0,0345**	**mg a.s. /kg bw/day**
Reverse reference scenario:		
AEL acute, dermal	1	mg a.s. /kg bw/day
Dermal systemic exposure for manipulating 1 paper strip		mg a.s. /kg bw/day
Dermal systemic exposure for manipulating 1 sachet	0,0115	
Number of manipulations to achieve AEL (number of touched paper strips)	**207**	
Number of manipulations to achieve AEL (number of touched sachets)	**87**	
AEL acute, inhalative	0,17	mg a.s. /kg bw/day
Inhalative systemic exposure per manipulation	0,00004	**mg a.s. /kg bw/day**
Number of manipulations to achieve AEL	**4257**	
Dermal local exposure:		
Transfer coefficient dried fluids	0,18	g/g
Number of manipulations	3	-
Area of object	72,25	cm²
Amount of substance (Geraniol)	44,7	mg (per bag)

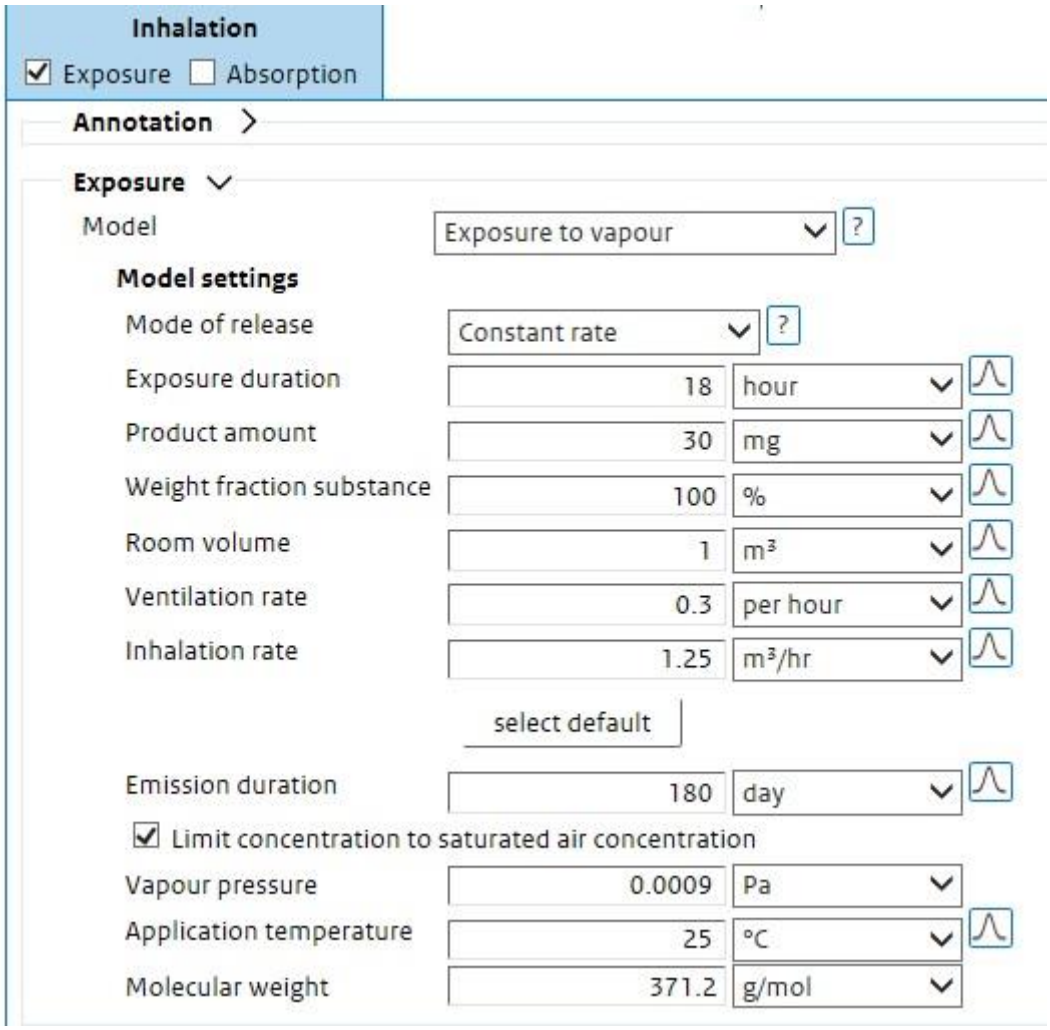
Amount of substance (Linalool)	167,7	mg (per bag)
Amount of substance (Nopyl acetate)	89,4	mg (per bag)
Amount of substance (alpha-iso-Methylionone)	8,4	mg (per bag))
Amount of substance (Cineole)	11,7	mg (per bag)
Amount of substance (Nerol)	16,8	mg (per bag)
Dermal local exposure (Geraniol)	**0,33**	**mg/cm² skin**
Dermal local exposure (Linalool)	**1,25**	**mg/cm² skin**
Dermal local exposure (Nopyl acetate)	**0,67**	**mg/cm² skin**
Dermal local exposure (alpha-iso-Methylionone)	**0,06**	**mg/cm² skin**
Dermal local exposure (Cineole)	**0,09**	**mg/cm² skin**
Dermal local exposure (Nerol)	**0,13**	**mg/cm² skin**

SCENARIO [2]		
Parameters	**Value**	**Unit**
mean event concentration	0,019	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	**0,001**	**mg a.s. /kg bw/day**
inhalative systemic exposure, child, Tier 1	**0,003**	**mg a.s. /kg bw/day**
inhalative systemic exposure, toddler, Tier 1	**0,006**	**mg a.s. /kg bw/day**
inhalative systemic exposure, infant, Tier 1	**0,005**	**mg a.s. /kg bw/day**

SCENARIO [3]		
Parameters	**Value**	**Unit**
Infant body weight	8	kg
Toddler body weight	10	kg

Max. content of a.s. on paper strip	0,039	mg/cm²
Surface area of object mouthed	50	cm²
Oral absorption	100	%
Inhalative systemic exposure, infant, Tier 1	0,245	mg a.s. /kg bw/day
Inhalative systemic exposure, toddler, Tier 1	0,196	mg a.s. /kg bw/day
Surface area of object mouthed	10	cm²
Inhalative systemic exposure, infant, Tier 2	0,049	mg a.s. /kg bw/day
Inhalative systemic exposure, toddler, Tier 2	0,039	mg a.s. /kg bw/day

CONSEXPO Input and Output tables:



Results for scenario *Inhalation Application*

☐ Show dose descriptions

Inhalation

Mean event concentration	1.9×10^{-2}	mg/m³
Peak concentration (TWA 15 min)	2.3×10^{-2}	mg/m³
Mean concentration on day of exposure	–	
Year average concentration	–	
External event dose	–	
External dose on day of exposure	–	

3.2.2 ENVIRONMENTAL EXPOSURE

Detailed calculations are reported in chapter 2.2.8.2 Environmental Exposure.

3.3 New information on the active substance

All the informations are available in the CAR of the active substance and available through letter of access.

3.4 Residue behaviour

No data available.

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

Refer to the IUCLID dossier.

3.6 Confidential annex

Please see seperate document

3.7 Other

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

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