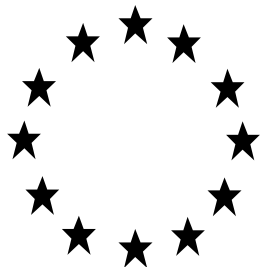
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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

(submitted by the evaluating Competent Authority)



Transfluthrin aerosols BPF

Product type 18

Transfluthrin as included in the Union list of approved active substances

Case Number in R4BP: [BC-VD056052-48]

Evaluating Competent Authority: DK

Date: [09/11/2022]

Table of Contents

1 CONCLUSION

The Applicant, knoell Germany GmbH submitted on 20.12.2019 an application (R4BP-3 Case nr. BC-VD056052-48) under Regulation (EU) No 528/2012 (BPR), application type NA-APP (rMS Denmark), for authorisation of Transfluthrin aerosols BPF in PT18.

The BPF Transfluthrin aerosols BPF consists of products containing the active substance Transfluthrin (CAS no. 118712-89-3). The products are aerosols. The BPF is used as an insecticide (PT18) for use indoor as a spatial treatment against flies and mosquitoes and as a driect spray against flies, mosquitoes, wasps and ants, and use outdoor as a [redacted], direct spray against flies, black flies, mosquitoes, ants, wasps and hornets and as a nest treatments against wasps by non-professional users.

The BPF consists of two meta-SPCs. The structure of the BPF into meta-SPCs was based on the general criteria for evaluation of similar use, risk and efficacy level according to the document CA-July19-Doc.4.2.

The applicant has applied for the following uses:

Meta SPC 1	Use 1: Insecticide for indoor use – spatial treatment	Not authorized
	Use 2: Insecticide for indoor use – direct spray	Not authorized
Meta SPC 2	[redacted]	[redacted]
	Use 4: Insecticide for outdoor use – direct spray	Authorized
	Use 5: Insecticide for outdoor use – nest treatment	Not authorized

The BPF falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(s). The overall conclusion of the evaluation is that use 4 of the BPF meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore can be authorised as insecticide for the outdoor use direct spray by non-professional users, as specified in the Summary of Product Characteristics (SPC). Use 1, 2, 3 and 5 does not meet the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012. Use 1 and 2 cannot be authozized due to unacceptable risk for the environment and does not meet the conditions in Article 19(1)(b) (iv). [redacted] Use 5 does not meet the conditions in Article 19(1)(b)(i) as the tested wasp species does not represent the target organism applied for.
The detailed grounds for the overall conclusion are described in this Product Assessment Report (PAR).

General

Detailed information on the intended uses of the BPF as applied for by the applicant and proposed for authorisation is provided in section 2.2.1 and 2.1.4 of the PAR, respectively.

Use-specific instructions for use of the BPF and use-specific risk mitigation measures are included in section 4 of the SPC. General directions for use and general risk mitigation measures are described in section 5 of the SPC. Other measures to protect man, animals, and the environment are reported in sections 4 and 5 of the SPC.

A classification according to Regulation (EC) No 1272/2008[1] is necessary. Detailed information on classification and labelling is provided in section 2.1.3 of the PAR. The hazard and precautionary statements of the BPF according to Regulation (EC) No 1272/2008 are available in the SPC, in section 3 for each meta-SPC.

The BPF does not contain any non-active substances (so called "co-formulants") which are considered as substances of concern.

The BPF should be considered not to have endocrine-disrupting properties. The BPF contains the active substance Transfluthrin, which has not yet been evaluated according to the scientific criteria set out in the Regulation (EU) 2017/2100. Based on the available information, no indications of endocrine-disrupting properties according to Regulation (EU) 2017/2100 were identified for the non-active substances contained in the BPF.

More information is available in sections 2.2.6.1 and 2.2.8 of the PAR and in the confidential annex.

The BPF contains Transfluthrin which does not meet the conditions laid down in Article 5 (1) and 10(1) of Regulation (EU) No 528/2012 and is not considered as a candidate for exclusion or substitution. Therefore, a comparative assessment of the BPF is not required.

Composition:

The qualitative and quantitative information on the non-confidential composition of the BPF is detailed in section 2.1 of the SPC. Information on the full composition is provided in the confidential annex. The manufacturers of the biocidal products are listed in section 1.3 of the SPC.

The chemical identity, quantity, and technical equivalence requirements for the active substance in the BPF are met. More information is available in section 2.1.2.1 of the PAR. The manufacturer of the active substance is listed in section 1.4 of the SPC.

Conclusions of the assessments for each area

The intended uses as applied for by the applicant have been assessed and the conclusions of the assessments for each area are summarised below.

Physical, chemical and technical properties

The physico-chemical properties are deemed acceptable for the appropriate use, storage and transportation of the products of the biocidal products family Transfluthrin aerosols BPF.

All products of the biocidal products family are white to slightly yellowish liquid emulsions with characteristic odours. The storage stability studies demonstrated acceptable variation in the parameters active substance content, pH, internal pressure, clogging, discharge

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

rate, spray pattern and appearance of the product and packaging material after storage for all three products of the BPF.

Based on the results during the storage stability studies, the following storage conditions are applicable for meta SPC 1: Do not expose to temperatures exceeding 50 °C, Protect from sunlight.

Based on the results during the storage stability studies, the following storage conditions are applicable for meta SPC 2: Do not expose to temperatures exceeding 50 °C, Protect from sunlight, Protect from frost.

Based on the acceptable results of the submitted storage stability studies, a shelf-life of 12 months in the packaging materials epoxy-lacquered tinplate can and tinplate can without epoxy lacquer can be accepted.

More information is available in section 2.2.2 of the PAR.

Physical hazards and respective characteristics

A physical hazard was identified in meta SPC 1 and 2. Since the products are aerosols and have not been submitted to the tests for flammable aerosols, the BPF is classified as Aerosol, Category 1 based on the CLP criteria. The following hazard statements are appropriate: H222 - Extremely flammable aerosol, H229 - Pressurised container: may burst if heated.

More information is available in section 2.2.3 of the PAR.

Methods for detection and identification

A validated analytical method for the determination of the concentration of active substance in the biocidal products of the BPF is available. No analytical methods for residues, relevant impurities or substances of concern were required. Validated analytical methods for monitoring of relevant components of the biocidal product and residues thereof in soil, air, water, animal, and human body fluids and tissues are available in the Transfluthrin PT18 CAR (CA NL, 2014). Analytical method for monitoring in/on food and feeding stuff is not required as the biocidal product is not intended to come into contact with food and feeding stuff when applied according to the instructions.

More information is available in section 2.2.4 of the PAR.

Efficacy against target organisms

The tests demonstrate efficacy of the product used as:

Indoor spraying, spatial treatment; with an effect against mosquitoes and houseflies, residual efficacy up to 7 h against mosquitoes.

Indoor direct spray; against flying insects and specifically *Musca domestica, Culex pipiens, Aedes albopictus, Linephitema humile, Lasius niger and Vespula germanica*.

Outdoor direct spray; against flying insects and specifically *Musca domestica, Culex pipiens, Aedes albopictus, Linephitema humile, Lasius niger, Vespula germanica, Vespa crabo* and *Simulium erythrocephalum.*

The following uses are not approved [redacted] and ii) outdoor treatment of wasp nests.

Risk assessment for human health

A human health risk assessment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 2.2.6 of the PAR.

Since no substance of concern has been identified, the risk assessment for the human health is based on the active substance.

Based on the risk assessment, it is unlikely that the intended uses cause any unacceptable acute or chronic risk to non-professional users and non-professional bystanders/general public, if the directions for use, as specified in the SPC, are followed.

Dietary risk assessment

Considering the uses, and the risk mitigation measures proposed to prevent food contamination, food or feed contamination is not expected. As a consequence, the exposure via food, via livestock exposure or via transfer of the active substance is considered as negligible, and no dietary risk assessment has been performed.

Risk assessment for animal health

Considering the uses, and the risk mitigation meausures proposed to prevent animal exposure, exposure to animals is not expected. Therefore, no risk assessment for animal health has been performed.

Risk assessment for the environment

Transfluthrin aerosols BPF is a PT18 aerosol spray intended for outdoor and indoor use. Both Meta SPC's in the family are not classified for aquatic hazards.

A risk assessment for the environment has been carried out for all the intended uses as applied for by the applicant. More information is available in section 2.2.8 of the PAR.

Since no substance of concern has been identified, the risk assessment for the environment is based on name of the active substance.

The risk assessment of indoor and outdoor uses has shown unacceptable risk in meta-SPC 1 (use 1; use 2) and meta-SPC 2 (use 1; use 2) for the sediment and freshwater compartment and therefore the uses of meta-SPC 1 are not proposed for authorisation as no risk mitigation measure can be applied to cover the risk. The risk from meta-SPC 2 uses can be mitigated with the risk mitigation measure: *"Only spray the product where it cannot release to (sewer) drains, surface water or ponds."*.

Based on the risk assessment, it is unlikely that the intended use 3 from meta-SPC 2 cause any unacceptable risk for the environment, if the directions for use, as specified in the SPC, are followed, hence this use can also be authorised.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier	**Country (if relevant)**
Transfluthrin aerosols BPF	Denmark

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Henkel Global Supply Chain B.V.
	Address	Gustav Mahlerlaan 2970 1081 LA Amsterdam, Netherlands
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturers of the products of the family

Name of manufacturer	Henkel Global Supply Chain B.V.
Address of manufacturer	Gustav Mahlerlaan 2970, 1081 LA, Amsterdam, Netherlands
Location of manufacturing sites	Laboratorio Chimico Farmaceutico Sanmarinese, Strada del Marano 95, 47896 Faetano, Republic San Marino

Name of manufacturer	Henkel Global Supply Chain B.V.
Address of manufacturer	Gustav Mahlerlaan 2970 , 1081 LA , Amsterdam, Netherlands
Location of manufacturing sites	Eugenio Santos Envasados y Servicios S.L., Polígono Industrial "Llanos de la Estación", Calle de Tomás Edison, S/N 50.800 Zuera, Zaragoza, Spain

2.1.1.4 Manufacturer of the active substance

Active substance	Transfluthrin
Name of manufacturer	Bayer SAS Division Crop Science Environmental Science Business Unit
Address of manufacturer	Bayer AG Division Crop Science 50, Alfred Nobel Straße, 40789 Monheim Am Rhein Germany

Location of manufacturing sites	Bayer Vapi Private Limited Plot No. 306/3, II Phase, GIDC, Vapi 396 195, Gujarat, India

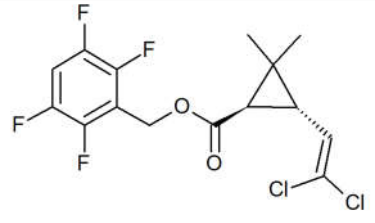
2.1.2 Product family composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent	
ISO name	Transfluthrin
IUPAC or EC name	(2,3,5,6-Tetrafluorophenyl)methyl (1*R*,3*S*)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate
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 % w/w
Structural formula	

2.1.2.2 Candidate(s) for substitution

According to the Assessment Report on Transfluthrin (March, 2014) the active substance has not been identified as candidate for substitution.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Transfluthrin	(2,3,5,6-tetrafluorophenyl)methyl (1*R*,3*S*)-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropane-1-carboxylate	Active substance	118712-89-3	405-060-5	0.102	0.104

2.1.2.4 Information on technical equivalence

The active substance supplier indicated in chapter 2.1.1 is listed in the article 95 list and participant in the review programme and therefore approved reference sources.

2.1.2.5 Information on the substances of concern

Please see the confidential annex for further details.

2.1.2.6 Type of formulation

AE – Aerosol Dispenser

2.1.3 Hazard and precautionary statements

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

Meta SPC1 – Not authorized

Classification	
Hazard category	Aerosol 1
Hazard statement	H222: Extremely flammable aerosol H229: Pressurized container: May burst if heated
Labelling	
Signal words	Danger
Pictogram	GHS02;
Hazard statements	H222: Extremely flammable aerosol H229: Pressurized container: May burst if heated
Precautionary statements	P102 - Keep out of reach of children. P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P211 – Do not spray on an open flame or other ignition source. P251 - Do not pierce or burn, even after use. P410 + P412 – Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.* P501 - Dispose of contents/container to … in accordance with local/regional/national/international regulations (to be specified).
Note	*Manufacturer/supplier to use applicable temperature scale

Meta SPC2

Classification	
Hazard category	Aerosol 1
Hazard statement	H222: Extremely flammable aerosol H229: Pressurized container: May burst if heated
Labelling	
Signal words	Danger
Pictogram	GHS02;
Hazard statements	H222: Extremely flammable aerosol H229: Pressurized container: May burst if heated
Precautionary statements	P102 - Keep out of reach of children. P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P211 – Do not spray on an open flame or other ignition source. P251 - Do not pierce or burn, even after use. P410 + P412 – Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.* P501 - Dispose of contents/container to … in accordance with local/regional/national/international regulations (to be specified).
Note	*Manufacturer/supplier to use applicable temperature scale.

2.1.4 Authorised uses

Table 4. Use # 2.18.4 – Insecticide for outdoor use – direct spray

Product Type	PT18 – Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	The product is intended for use directly on target insects on terraces or outdoor walls adjacent to terraces.
Target organism (including development stage)	Adult flies, black flies, mosquitoes, hornets and wasps. Direct kill. Culicidae – Culex pipiens, Aedes albopictus – adults. Muscidae – Musca domestica – adults. Formicidae – Linephitema humile, Lasius niger – adults. Vespidae – Vespula germanica, Vespa crabro – adults. Simuliidae – Simulium erythrocephalum – adults.
Field of use	Outdoors
Application method(s)	Aerosol spray - direct spray
Application rate(s) and frequency	Spray for approximately 1 second per application corresponding to a minimum of 1 g of product. A maximum of 10 applications of 1 second per day.

Category(ies) of users	Non-professional
Pack sizes and packaging material	Aerosol can; 300 mL 400 mL 500 mL 600 mL 750 mL

2.1.4.1 Use-specific instructions for use

For instant action, applications of 1 second is sufficient for flies, black flies, mosquitoes, ants, and wasps and hornets. Spray from a distance of 10 cm against wasps. Spray from a distance of 60 cm against mosquitoes, ants and flies. Spray from a distance of 1 meter against hornets. Spray directly a maximum of 10 applications of 1 second per day. Spray only on insects which are sitting or walking on a surface. If the infestation persists contact a professional. Inform the registration holder if the treatment is ineffective.

2.1.4.2 Use-specific risk mitigation measures

Only spray the product where it cannot release to (sewer) drains, surface water or ponds. Do not use on bare soil.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

2.1.5 General directions for use

2.1.5.1 Instructions for use

See use specific instructions for use.

2.1.5.2 Risk mitigation measures

Meta SPC 2

Comply with the instructions for use
Must be used outdoors only
Do not spray directly on people or pets
Contains transfluthrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms).
Keep cats away from treated surfaces. Due to their particular sensitivity to transfluthrin, the product can cause severe adverse reactions in cats.
Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.Remove or cover terrariums, aquariums and animal cages before application.
Turn off aquarium air-filter while spraying
Keep uninvolved persons, children and pets away from treated surfaces/areas until dried
Do not spray on an open flame or other ignition source

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

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
IF ON SKIN: Wash with water. 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.
Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of unused product, its packaging, and all other waste (i.d. dead insects) in accordance with local regulations.

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

Meta SPC 2

Store in a well-ventilated area and keep away from food and drinks.
Protect from sunlight.
Do no expose to temperatures exceeding 50ºC.
Protect from frost.
Shelf life: 12 months
Keep out of reach of children and non-target animals/pets

2.1.6 Packaging of the biocidal product

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

				non-professional)	packaging materials (Yes/No)
For products: H-21021, H-21024 and H-21025					
Aerosol Can	300 mL 400 mL 500 mL 600 mL 750 mL	Tinplate protected (epoxy lacquered)	Actuator, PP Valve Stem: Acetal, Body: Nylon 6.6, Int. Gasket: Buna Mounting, Cup: Tinplate Epoxy / PP, Lam. Tubing: LDPE	Non-professional	Yes
For products H-21021 and H-21024					
Aerosol Can	300 mL 400 mL 500 mL 600 mL 750 mL	Tinplate (no epoxy lacquer)	Actuator, PP Valve Stem: Acetal, Body: Nylon 6.6, Int. Gasket: Buna Mounting, Cup: Tinplate, Tubing: LDPE	Non-professional	Yes

2.1.7 Documentation

2.1.7.1 Data submitted in relation to product application

The study data submitted in relation to the application of the Transfluthrin based biocidal product family of Henkel Global Supply Chain B.V. are summarized in the concerned sections of this PAR and listed in the reference list in section 3.1 "List of studies for the biocidal product family".

2.1.7.2 Access to documentation

The applicant has access to the data on the active substance Transfluthrin (see IUCLID section 13, letters of access (LoA)).

2.1.8 Non-authorised uses

2.1.8.1 Use description Meta SPC 1[2]

2.1.8.1.1 Use 1

Table 1. Use # 1.18.1 – Insecticide for indoor use – spatial treatment

Product Type	PT18 – Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	n.a.
Target organism (including development stage)	Culicidae – mosquitoes – adults Muscidae -flies -adults
Field of use	Indoors
Application method(s)	Aerosol spray - spatial treatment
Application rate(s) and frequency	Spray 9 seconds corresponding to a minimum of 11.6 g of product per treatment in 30 m^3. Spray 0.3 seconds per m^3. Apply only four times per week. Spray 9 seconds corresponding to a minimum of 11.6 g of product per treatment. A maximum of 1 treatment per day.
Category(ies) of users	Non-professional
Pack sizes and packaging material	Aerosol can; 300 mL 400 mL 500 mL 600 mL 750 mL

2.1.8.1.1.1 USE-SPECIFIC INSTRUCTIONS FOR USE

For an optimum efficiency against mosquitoes and flies inside the house, shake the product before use, close the doors and windows of the room to be treated and press the actuator. Spray in a vertical position towards the ceiling for 9 seconds throughout the room. Once applied, leave the room, close the door and wait 10 minutes before entering again. Spray 0.3 seconds per m^3. This application will provide protection during 8 hours in the case of mosquitoes and 2 hours in the case of flies. Apply only once per day.

2.1.8.1.1.2 USE-SPECIFIC RISK MITIGATION MEASURES

Can only be used in rooms with sizes 30 m^3 or less. Do not treat more than one room. Apply only four times per weekSee general directions for use.

2.1.8.1.1.3 WHERE SPECIFIC TO THE USE, THE PARTICULARS OF LIKELY DIRECT OR INDIRECT EFFECTS, FIRST AID INSTRUCTIONS AND EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT

See general directions for use.

2.1.8.1.1.4 WHERE SPECIFIC TO THE USE, THE INSTRUCTIONS FOR SAFE DISPOSAL OF THE PRODUCT AND ITS PACKAGING

See general directions for use.

2.1.8.1.1.5 WHERE SPECIFIC TO THE USE, THE CONDITIONS OF STORAGE AND SHELF-LIFE OF THE PRODUCT UNDER NORMAL CONDITIONS OF STORAGE

See general directions for use.

2.1.8.1.2 Use 2

Table 2. Use # 1.18.2 – Insecticide for indoor use – direct spray

Product Type	PT18 – Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	n.a.
Target organism (including development stage)	Culicidae – mosquitoes – adults Muscidae -flies -adults Formicidae – ants / tropical ants -adults Vespidae – wasps - adults
Field of use	Indoors
Application method(s)	Aerosol spray - direct spray
Application rate(s) and frequency	Spray for approximately 1 second per application corresponding to a minimum of 1 g of product. A maximum of 10 applications of 1 second per day.
Category(ies) of users	Non-professional
Pack sizes and packaging material	Aerosol can; 300 mL 400 mL

	500 mL 600 mL 750 mL

2.1.8.1.2.1 USE-SPECIFIC INSTRUCTIONS FOR USE

For instant action, applications of 1 second is sufficient for flies, black flies, mosquitoes, ants, and wasps and hornets. Spray from a distance of 10 cm against wasps. Spray from a distance of 60 cm against mosquitoes, ants and flies. Spray from a distance of 1 meter against hornets. Spray directly a maximum of 10 applications of 1 second per day. Spray only on insects which are sitting or walking on a surface.

2.1.8.1.2.2 USE-SPECIFIC RISK MITIGATION MEASURES

See general directions for use.

2.1.8.1.2.3 WHERE SPECIFIC TO THE USE, THE PARTICULARS OF LIKELY DIRECT OR INDIRECT EFFECTS, FIRST AID INSTRUCTIONS AND EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT

See general directions for use.

2.1.8.1.2.4 WHERE SPECIFIC TO THE USE, THE INSTRUCTIONS FOR SAFE DISPOSAL OF THE PRODUCT AND ITS PACKAGING

See general directions for use.

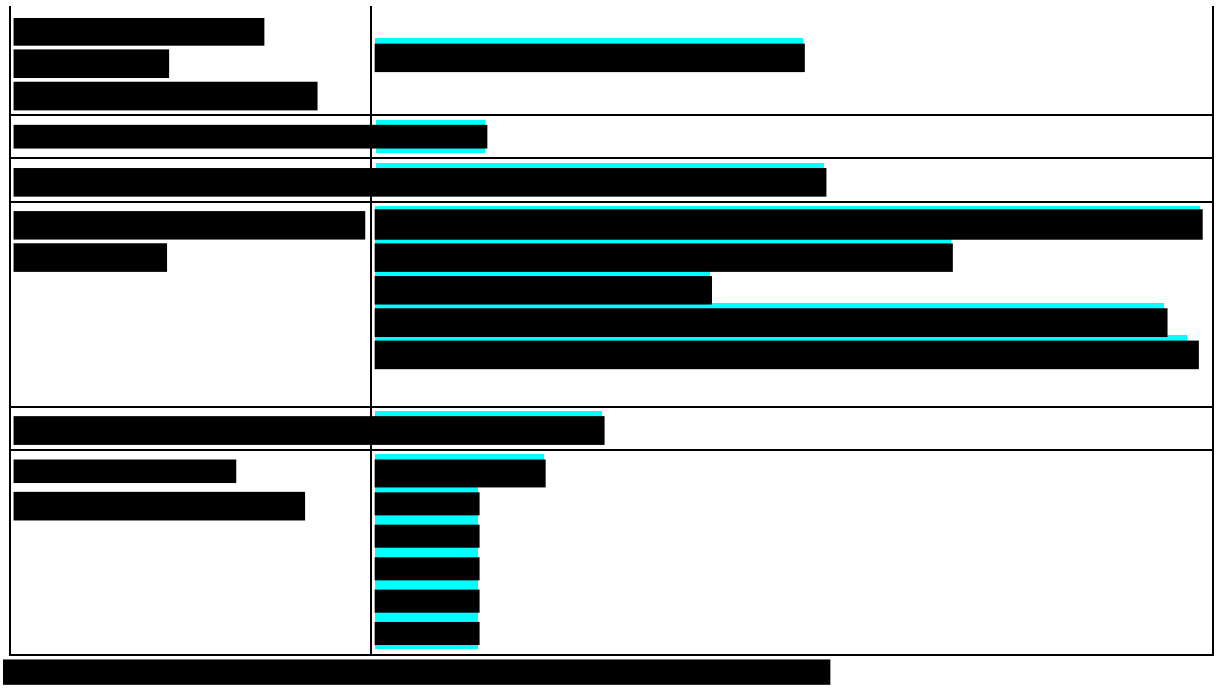
2.1.8.1.2.5 WHERE SPECIFIC TO THE USE, THE CONDITIONS OF STORAGE AND SHELF-LIFE OF THE PRODUCT UNDER NORMAL CONDITIONS OF STORAGE

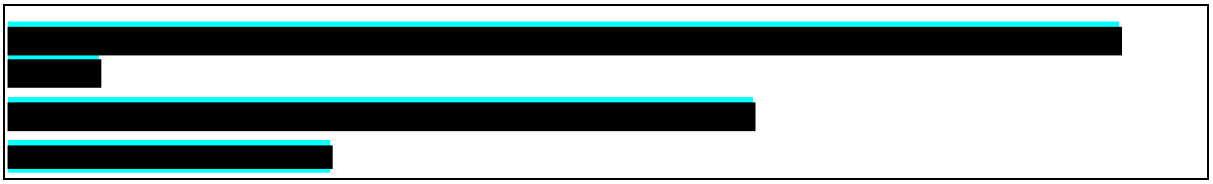
See general directions for use.

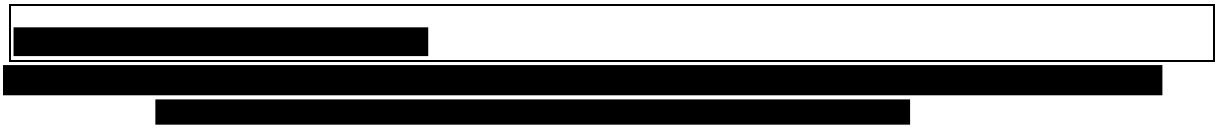
2.1.8.2 Use description Meta SPC 2[3]

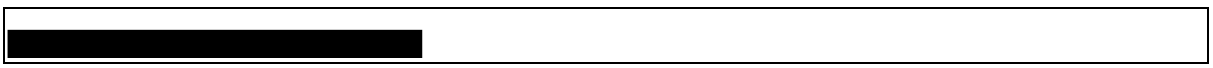
[redacted]

[redacted]	[redacted]
[redacted]	[redacted]









[redacted]

[redacted]

2.1.8.2.2 Use 5

Table 5. Use # 2.18.5 – Insecticide for outdoor use – nest treatment

Product Type	PT18 – Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	n.a.
Target organism (including development stage)	Vespidae – wasps – adults
Field of use	Outdoors
Application method(s)	Aerosol spray - nest treatment
Application rate(s) and frequency	Spray for 2 seconds on nest corresponding to approximately 3.4 g of product – A maximum of 1 treatment per day.
Category(ies) of users	Non-professional
Pack sizes and packaging material	Aerosol can; 300 mL 400 mL 500 mL 600 mL 750 mL

2.1.8.2.2.1 USE-SPECIFIC INSTRUCTIONS FOR USE

Shake the product before use. Spray directly towards the nest entrance from an acceptable distance. Spray uniformly for 2 seconds.
To prevent aggressive behaviour of the insects apply the product in the evening or in the early morning when there is less wasp activity and most wasps are in the nest.

2.1.8.2.2.2 USE-SPECIFIC RISK MITIGATION MEASURES

See general directions for use.

2.1.8.2.2.3 WHERE SPECIFIC TO THE USE, THE PARTICULARS OF LIKELY DIRECT OR INDIRECT EFFECTS, FIRST AID INSTRUCTIONS AND EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT

See general directions for use.

2.1.8.2.2.4 WHERE SPECIFIC TO THE USE, THE INSTRUCTIONS FOR SAFE DISPOSAL OF THE PRODUCT AND ITS PACKAGING

See general directions for use.

2.1.8.2.2.5 WHERE SPECIFIC TO THE USE, THE CONDITIONS OF STORAGE AND SHELF-LIFE OF THE PRODUCT UNDER NORMAL CONDITIONS OF STORAGE

See general directions for use.

2.1.8.3 General directions for use

2.1.8.3.1 Instructions for use

See use specific instructions for use.

2.1.8.3.2 Risk mitigation measures

Meta SPC 1 *Comply with the instructions for use.* *Do not use in the presence of people or pets.* *Do not apply directly on animals.* *Remove all food, feed and drinks prior to treatment.* *Do not apply directly to surfaces on which food or feed is stored, prepared or eaten.* *Cover aquariums/terrariums when spraying the product.* *Do not spray on an open flame or other ignition source.* **Meta SPC 2** *Comply with the instructions for use* *Must be used outdoors only* *Do not spray directly on people or pets* *Contains transfluthrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms).* *Keep cats away from treated surfaces. Due to their particular sensitivity to transfluthrin, the product can cause severe adverse reactions in cats.* *Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets.Remove or cover terrariums, aquariums and animal cages before application.* *Turn off aquarium air-filter while sprayingKeep uninvolved persons, children and pets away from treated surfaces/areas until dried* *Do not spray on an open flame or other ignition source*

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

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor. IF ON SKIN: Wash with water. 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.
Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

2.1.8.3.4 Instructions for safe disposal of the product and its packaging

Dispose of unused product, its packaging, and all other waste (i.d. dead insects) in accordance with local regulations.

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

Meta SPC 1

Store in a well-ventilated area and keep away from food and drinks.
Protect from sunlight.
Do no expose to temperatures exceeding 50ºC.
Shelf life: 24 months
Keep out of reach of children and non-target animals/pets

Meta SPC 2

Store in a well-ventilated area and keep away from food and drinks.
Protect from sunlight.
Do no expose to temperatures exceeding 50ºC.
Protect from frost.
Shelf life: 12 months
Keep out of reach of children and non-target animals/pets

2.2 Assessment of the biocidal product family

2.2.1 Intended uses as applied for by the applicant

Meta SPC 1

Table 6. Intended use # 1.18.1 – Insecticide for indoor use – spatial treatment

Product Type(s)	PT18 - Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Not relevant
Target organism (including development stage)	Culicidae – mosquitoes – adults Muscidae -flies -adults
Field of use	Indoors
Application method(s)	Aerosol spray - spatial treatment
Application rate(s) and frequency	Apply 11.6 g of product per treatment
Category(ies) of user(s)	Non-professional
Pack sizes and packaging material	Aerosol can; 300 mL 400 mL 500 mL 600 mL 750 mL

Table 7. Intended use # 1.18.2 – Insecticide for indoor use – direct spray

Product Type	PT18 – Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	n.a.
Target organism (including development stage)	Culicidae – mosquitoes - adults Muscidae -flies - adults Formicidae – ants / tropical ants - adults Vespidae – wasps - adults
Field of use	Indoors
Application method(s)	Aerosol spray - direct spray
Application rate(s) and frequency	Flies: 1.1 g product per application Mosquitoes: 1.0 g of product per application Ants: 1.2 – 1.4 g of product per application Wasps: 1.4 g of product per application
Category(ies) of users	Non-professional

Pack sizes and packaging material	Aerosol can; 300 mL 400 mL 500 mL 600 mL 750 mL

Meta SPC 2

[redacted]

Table 9. Intended use # 2.18.4 – Insecticide for outdoor use – direct spray

Product Type	PT18 – Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	n.a.
Target organism (including development stage)	Culicidae – mosquitoes – adults Muscidae – flies - adults Formicidae – ants / tropical ants - adults Vespidae – wasps and hornets – adults Simuliidae – black flies - adults
Field of use	Outdoors
Application method(s)	Aerosol spray - direct spray

Application rate(s) and frequency	Flies: 1.3 g product per application Mosquitoes: 1.3 g of product per application Ants: 1.4 g product per application Wasps: 1.4 g product per application and hornets: 1.7 g product per application Black flies: 1.2 g product per application
Category(ies) of users	Non-professional
Pack sizes and packaging material	Aerosol can; 300 mL 400 mL 500 mL 600 mL 750 mL

Table 10. Intended use # 2.18.5 – Insecticide for outdoor use – nest treatment

Product Type	PT18 – Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	n.a.
Target organism (including development stage)	Vespidae – wasps – adults
Field of use	Outdoors
Application method(s)	Aerosol spray - nest treatment
Application rate(s) and frequency	Apply 3.4 g of product on nest
Category(ies) of users	Non-professional
Pack sizes and packaging material	Aerosol can; 300 mL 400 mL 500 mL 600 mL 750 mL

2.2.2 Physical, chemical and technical properties

The biocidal products family consists of 3 products: H-21024 (meta SPC 1), H-21021 (meta SPC 2) and H-21025 (meta SPC 2). The biocidal product H-21024 belonging to meta SPC 1 and the product H-21021 belonging to meta SPC 2 are chemically identical and both are applied as an aerosol, therefore for the endpoint viscosity only one test was necessary in order to cover the data requirements of these two products. The product H-21025 has a different composition, hence separate tests were conducted for the relevant endpoints.

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual observation	H-21024-c[4] H-21024 AS content: 0.10%	Liquid emulsion	[redacted] 2022a, PS-21024.5
		H-21021-c H-21021 AS content: 0.10%	Liquid emulsion	[redacted] 2022b, PS-21021.5
		H-21025-c H-21025 AS content: 0.098%	Liquid emulsion	[redacted] 2022a, LR-LC-046.3
Colour at 20 °C and 101.3 kPa	Visual observation	H-21024-c H-21024 AS content: 0.10%	White to slightly yellowish	[redacted] 2022a, PS-21024.5
		H-21021-c H-21021	White to slightly yellowish	[redacted] 2022b, PS-21021.5

[4] '-c' means concentrate sample (no propellant). The formulation without propellant is considered a worst case compared with the total final formula (concentrate + propellant), so the results are a worse case and cover the performance of the final formula (concentrate + propellant).

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		AS content: 0.10%		
		H-21025-c H-21025 AS content: 0.098%	White to slightly yellowish	[redacted] 2022a, LR-LC-046.3
Odour at 20 °C and 101.3 kPa	Organoleptic	H-21024-c H-21024 AS content: 0.10%	Characteristic	[redacted] 2022a, PS-21024.5
		H-21021-c H-21021 AS content: 0.10%	Characteristic	[redacted] 2022b PS-21021.5
		H-21025-c H-21025 AS content: 0.098%	Characteristic	[redacted] 2022a, LR-LC-046.3
Acidity / alkalinity	CIPAC MT 75	H-21024-c H-21024 AS content: 0.10%	pH (neat): 6.10 ± 1.0 at 25 °C	[redacted] 2022a, PS-21024.5
		H-21021-c H-21021 AS content: 0.10%	pH (neat): 6.10 ± 1.0 at 25 °C	[redacted] 2022b PS-21021.5
		H-21025-c H-21025 AS content: 0.098%	pH (neat): 7.00 ± 1.0 at 25 °C	[redacted] 2022a, LR-LC-046.3
Relative density / bulk density		H-21024-c	0.954 ± 0.010 g/cm^3 at 20 °C	[redacted] 2022a,

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
	OECD 109 (oscillating densitometer)	H-21024 AS content: 0.10%		PS-21024.5
		H-21021-c H-21021 AS content: 0.10%	0.954 ± 0.010 g/cm^3 at 20 °C	[redacted] 2022b, PS-21021.5
		H-21025-c H-21025 AS content: 0.098%	0.992 ± 0.010 g/cm^3 at 20 °C	[redacted] 2022a, LR-LC-046.3
Storage stability test – **accelerated storage**	CIPAC MT 46.3 Sample stored at 50 ± 2 °C for 4 weeks in lacquered tinplate can (400 mL).	H-21024 Batch no.: C-632 Nominal AS content: 0.104% AS content: See results	**Active substance content** (GC-FID) Before storage: 0.099% After storage: 0.100% Change: +1.00% **Appearance** (formulation sprayed on a surface) Before storage: white After storage: white **Packaging Appearance** Before storage: no residues, can in good conditions After storage: external aspect is good, no signs of external or internal corrosion, no marks of leakage observed, no can deformation observed **Weight Loss** Before storage: 387.75 g After storage: 387.73 g	[redacted] 2022c, ASSR-21024.4

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Change: - 0.005% **Internal pressure** (FEA 604, tested at 25 °C) Before storage: 4.0 bar After storage: 4.0 bar **Clogging** (FAO/WHO 8.11.4.5) Before storage: no clogging observed After storage: no clogging observed. The spraying is continuous without observing any interruption. **pH** (CIPAC MT 75.3, neat) Before storage: 6.37 After storage: 6.17 **Discharge rate** (FEA 643) Before storage: 1.52 g/s After storage: 1.54 g/s **Spray pattern** (FEA 644) At 15 cm Before storage: 4.5 cm After storage: 4 cm At 25 cm Before storage: 6 cm After storage: 6 cm At 30 cm	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Before storage: 6.5 cm After storage: 7 cm The product is stable when stored at 50 °C for 4 weeks. The product should not be stored at temperatures above 50 °C.	
	CIPAC MT 46.3 Sample stored at 45 ± 2 °C for 6 weeks in tinplate can (400 mL). The determination of the spray pattern was performed after storage of a sample at 50 ± 2°C for 4 weeks.	H-21021 Batch no.: C-706 Nominal AS content: 0.104% AS content: See results	**Active substance content** (GC-FID) Before storage: 0.100% After storage: 0.099% Change: - 1.00% **Appearance** (formulation sprayed on a surface) Before storage: white After storage: white **Packaging Appearance** Before storage: no residues, can in good conditions After storage: external aspect is good, no signs of external or internal corrosion, no marks of leakage observed, no can deformation observed **Weight Loss** Before storage: 377.29 g After storage: 377.19 g Change: - 0.03% **Internal pressure** (FEA 604, tested at 25 °C)	[redacted] 2022d, ASSR-21021.4

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Before storage: 4.0 bar After storage: 4.5 bar **Clogging** (FAO/WHO 8.11.4.5) Before storage: no clogging observed After storage: no clogging observed. The spraying is continuous without observing any interruption. **pH** (CIPAC MT 75.3, neat) Before storage: 6.07 After storage: 6.17 **Discharge rate** (FEA 643) Before storage: 1.6 g/s After storage: 1.7 g/s **Spray pattern** (FEA 644) Storage for 4 weeks at 50 °C: At 15 cm Before storage: 5 cm After storage: 5 cm At 25 cm Before storage: 8 cm After storage: 7.5 cm At 30 cm Before storage: 8.5 cm After storage: 8.5 cm The deviation of temperature during the test for spray pattern is	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			considered as acceptable by the rMS, since the formulation of H-21021 is identical to H-21024 that was demonstrated to be stable for storage at 50 °C for 4 weeks (see entry above). The product is stable when stored at 45 °C for 6 weeks. The product should not be stored at temperatures above 50 °C.	
	CIPAC MT 46.3 Sample stored at 50 °C for 4 weeks in tinplate can (400 mL).	H-21025 Batch no.: C-633 Nominal AS content: 0.102% AS content: See results	**Active substance content** (GC-FID) Before storage: 0.095% After storage: 0.094% Change: - 1.05% **Appearance** (formulation sprayed on a surface) Before storage: white to yellowish After storage: white to yellowish **Packaging Appearance** Before storage: external aspect is good, no residues, can in good conditions After storage: external aspect is good, no signs of external or internal corrosion, no marks of leakage observed, no can deformation observed **Weight Loss** Before storage: 480.30 g	[redacted] (2022b) ASSR-21025.4.2

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			After storage: 480.06 g Change: - 0.05% **Internal pressure** (FEA 604, tested at 25 °C) Before storage: 5.0 bar After storage: 5.0 bar **Clogging** (FAO/WHO 8.11.4.5) Before storage: no clogging observed After storage: no clogging observed. The spraying is continuous without observing any interruption. **pH** (CIPAC MT 75.3, neat) Before storage: 6.90 After storage: 6.81 **Discharge rate** (FEA 643) Before storage: 2.0 g/s Afters storage: 1.9 g/s **Spray pattern** (FEA 644) At 15 cm Before storage: 6 cm After storage: 6 cm At 25 cm Before storage: 8 cm After storage: 8 cm At 30 cm Before storage: 8.5 cm	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			After storage: 8.5 cm The product is stable when stored at 50 °C for 4 weeks. The product should not be stored at temperatures above 50 °C.	
Storage stability test – **long term storage at ambient temperature**	According to requirements of BPR (Similar to GIFAP (Croplife International) Monograph No. 17). Storage in 400 mL epoxy-lacquered tinplate can at 25 ± 2°C for 2 years	H-21024 Batch no.: C-738 Nominal AS content: 0.104% Active substance content: See results.	**Active substance content** (GC-FID) Before storage: 0.095% After storage: 6 months: 0.097% (change: +2.1%) 12 months: 0.099% (change: +4.2%) 24 months: 0.096% (change: +1.1%) **Appearance** (formulation sprayed on a surface) Before storage: Not determined, please refer to initial determination before accelerated storage test. After storage: 24 months: Phases separated. After shaking is reemulsified as initial mix before preparing aerosol. Same color, no precipitates. **Packaging Appearance** Before storage: no signs of corrosion or degradation After storage: 6 months: no signs of corrosion or degradation	[redacted] 2022c, LTSS-21024.2

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			12 months: no signs of corrosion or degradation 24 months: no signs of corrosion or degradation **Weight Loss** After storage: 6 months: - 0.03% (mean, 12 samples) 12 months: - 0.04% (mean, 11 samples) 24 months: -0.08% (mean, 10 samples) **Internal pressure** (FEA 604) At 25 ±1 °C: Before storage: 5 bar After storage: 6 months: 4.4 bar 12 months: 4.6 bar 24 months: 4.8 bar At 30 ±1 °C: After storage: 24 months: 5.2 bar **Clogging** (FAO/WHO 8.11.4.5) Before storage: no clogging observed After storage: 6 months: no clogging observed 12 months: no clogging observed 24 months: no clogging observed	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			pH (CIPAC MT 75.3, neat) Before storage: 7.1 After 6 months: 5.3 After 12 months: 6.4 After 24 months: 6.5 **Discharge rate** (FEA 643) Before storage: 1.8 g/s After storage: 6 months: 1.8 g/s 12 months: 1.7 g/s 24 months: 1.8 g/s **Spray pattern** (FEA 644) Before storage: 15 cm: 5 cm 25 cm: 6 cm 30 cm: 6.5 cm After 6 months: 15 cm: 5.5 cm 25 cm: 6.5 cm 30 cm (calculated): 7.8 cm After 12 months: 15 cm: 5 cm 25 cm: 6 cm 30 cm: 7 cm After 24 months: 15 cm: 5 cm 25 cm: 6 cm 30 cm: 6.5 cm	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Appearance of the product was not initially monitored as part of this study. As the appearance of H-21024 was demonstrated to be in agreement with the endpoints physical state, colour and odour following storage for 2 years, rMS considers this deviation as acceptable.	
	According to requirement of BPR (Similar to GIFAP (Croplife International) Monograph No. 17). Storage in 400 mL tinplate can without epoxy-lacquer at 25 ± 2°C for 2 years.	H-21021 Batch no.: C-706 Nominal AS content: 0.104% AS content: See results.	**Active substance content** (GC-FID) Before storage: 0.100% After storage: 6 months: 0.106% (change: +6%) 12 months: 0.103% (change: +3%) 24 months: 0.096% (change: -4%) **Appearance** (formulation sprayed on a surface) Before storage: Not determined, please refer to initial determination before accelerated storage test, as the test items are produced in the same batch. After storage: 24 months: Whitish emulsion with a characteristic odour. Phase separation observed after storage, but a single phase was re-established after shaking. **Packaging Appearance** Before storage: no signs of corrosion or degradation	[redacted] 2022d, LTSS-21021.3

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			After storage: 6 months: no signs of corrosion or degradation 12 months: no signs of corrosion or degradation 24 months: no signs of corrosion or degradation **Weight Loss** After storage: 6 months: -0.04% (mean, 10 samples) 12 months: -0.08% (mean, 9 samples) 24 months: -0.18% (mean, 8 samples) **Internal pressure** (FEA 604) At 25 ± 1 °C: Before storage: 4 bar After storage: 6 months: 5 bar 12 months: 4.5 bar 24 months: 4.6 bar At 30 ±1 °C: After storage: 24 months: 4.8 bar **Clogging** (FAO/WHO 8.11.4.5) Before storage: no clogging observed After storage: 6 months: no clogging observed	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			12 months: no clogging observed 24 months: no clogging observed **pH** (CIPAC MT 75.3, neat) Before storage: 6.1 After storage: 6 months: 5.9 12 months: 5.4 24 months: 7.0 **Discharge rate** (FEA 643) Before storage: 1.6 g/s After storage: 6 months: 1.7 g/s 12 months: 1.7 g/s 24 months: 1.7 g/s **Spray pattern** (FEA 644) Before storage: 15 cm: 5 cm 25 cm: 8 cm 30 cm (calculated): 9.6 cm After 6 months: 15 cm: 5.5 cm 25 cm: 8 cm 30 cm (calculated): 9.6 cm After 12 months: 15 cm: 5.5 cm 25 cm: 7.5 cm 30 cm (calculated): 9 cm After 24 months:	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			15 cm: 5.5 cm 25 cm: 8.5 cm 30 cm: 9 cm	
	According to requirements of BPR (Similar to GIFAP (Croplife International) Monograph No. 17). Storage in 500 mL epoxy-lacquered tinplate can at 25 ± 2°C for 6 months and 1 year (**Interim results**)	H-21025 Batch no.: C-633 Nominal AS content: 0.102% AS content: See results	**Active substance content** (GC-FID) Before storage: 0.095% After storage: 6 months: 0.094% (change: -1.05%) 12 months: 0.095% (No change) **Appearance** (formulation sprayed on a surface) Before storage: White to slightly yellow liquid emulsion with a characteristic odour. Separation in layers observed after some time. After storage: 6 months: White to slightly yellow liquid emulsion. The emulsion is partially separated in layers. Initial aspect recovered upon shaking. 12 months: Slightly yellow liquid emulsion with a characteristic odour. The emulsion is partially separated in layers. Initial aspect recovered upon shaking. **Packaging Appearance** Before storage: no signs of corrosion or degradation After storage: 6 months: no signs of corrosion or degradation	[redacted] 2022d, LTSS-21025.3

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			12 months: no signs of corrosion or degradation **Weight Loss** After 6 months: -0.05% (mean, 13 samples) After 12 months: -0.116% (mean, 12 samples) **Internal pressure** (FEA 604) At 25 ± 1 °C Before storage: 5 bar After storage: 6 months: 4.4 bar 12 months: 4.8 bar At 30 ± 1°C After storage: 12 months: 5 bar **Clogging** (FAO/WHO 8.11.4.5) Before storage: no clogging observed After storage: 6 months: no clogging observed 12 months: no clogging observed **pH** (CIPAC MT 75.3, neat) Before storage: 6.9 After storage: 6 months: 7.11 12 months: 7.33 **Discharge rate** (FEA 643)	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Before storage: 2.0 g/s After storage: 6 months: 1.9 g/s 12 months: 2.1 g/s **Spray pattern** (FEA 644) Before storage: 15 cm: 6 cm 25 cm: 8 cm 30 cm: 8.5 cm After 6 months: 15 cm: 6 cm 25 cm: 8 cm 30 cm: 8.5 cm After 12 months: 15 cm: 6 cm 25 cm: 8 cm 30 cm: 8.5 cm	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	H-21024-c Batch no.: C-727	No freezing of any of the phases is observed. The emulsion is split in the two former phases (aqueous and organic) but they are emulsified again by soft shaking. The use specific instructions include 'shake before use'. As the emulsion is restored by shaking, the layering at 0°C is not expected to affect the formulation or performance of the	[redacted] 2019a, LR-C-727

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			product if a temperature of 0 ºC is reached.	
	-	H-21021	Since the product H-21021 is identical to H-21024, the low temperature stability of the products is identical. If a temperature of 0 °C is reached, this should not affect the performance of the formulation.	[redacted] 2019a, LR-C-727
	-	H-21025	Data waiving. The study does not need to be conducted as the biocidal product will include the statement 'Protect from frost' on its label.	-
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	Data on the effect of light on content of the active substance is not necessary because all products of this biocidal product family are packaged in opaque cans. Conditions of stage includes the phrase 'protect from sunlight'.	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	All meta SPCs	Please refer to the accelerated storage stability studies of the biocidal products. From the data available, a temperature up to 50 °C has no influence on content of the active substance and technical properties. Since the biocidal products are water based formulations, humidity effects are not relevant.	-
Effects on content of the active substance and technical characteristics of the biocidal	-	All Meta SPCs.	Please refer to storage stability studies of the biocidal products. From the data available, there is no	-

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
product - **reactivity towards container material**			interaction between container materials used and the content of active substance. Furthermore, there is no effect on the technical properties.	
Wettability	-	All meta SPCs	Data on wettability is required for solid preparations only and thus it is not necessary for the products of this biocidal product family because they are all liquids.	-
Suspensibility, spontaneity and dispersion stability	-	All meta SPCs	Data on suspensibility, spontaneity and dispersion stability are required for products to be suspended upon use. Waiving data on these properties is justified because the biocidal products of this family are ready to use products and are not to be suspended upon use.	-
Wet sieve analysis and dry sieve test	-	All meta SPCs	The biocidal products of this family are liquid. Waiving data on wet or dry sieve tests is justified because these properties are only relevant for solid preparations.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	All meta SPCs	Data on emulsifiability, re-emulsifiability and emulsion stability are required for products to be emulsified upon use. Waiving data on these properties is justified because the biocidal products of this family are ready to use products and not to be emulsified upon use.	-
Disintegration time	-	All meta SPCs	Data on disintegration time applies only to products that are tablets. Waiving data on this property is	-

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			justified because the biocidal products of this family are aerosol cans.	
Particle size distribution	CIPAC MT 187	H-21024 AS content: 0.10%	%V < 50 µm: 53.49 %V < 10 µm: 3.88 %V < 5 µm: 0.82 Dv (10): 14.83 µm Dv (50): 45.75 µm Dv (90): 190.69 µm D[4][3]: 76.80 µm D[3][2]: 29.78 µm	[redacted] 2022a, PS-21024.5 (Annex 3)
		H-21021 AS content: 0.10%	%V < 50 µm: 33.63 %V < 10 µm: 1.33 %V < 5 µm: 0.52% Dv (10): 22.73 µm Dv (50): 82.56 µm Dv (90): 260.19 µm D[4][3]: 115.05 µm D[3][2]: 47.39 µm	[redacted] 2022b, PS-21021.5 (Annex 3)
		H-21025 AS content: 0.098%	%V < 50 µm: 51.72 %V < 10 µm: 4.52 %V < 5 µm: 1.17 Dv (10): 16.62 µm Dv (50): 48.60 µm Dv (90): 101.88 µm D[4][3]: 54.81 µm D[3][2]: 30.51 µm	[redacted], 2022a, LR-LC-046.3 (Annex 3)
Dust Content	-	All meta SPCs	Studies technically not feasible since the biocidal products are aerosols.	-
Attrition, friability	-	All meta SPCs	Study scientifically not necessary to be conducted since none of the products belonging to the family is a granular formulation.	-

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Persistent foaming	-	All meta SPCs	The biocidal products of this family are ready to use formulations. Waiving data on persistent foaming is justified because this property is only relevant for formulations which are to be diluted in water upon use.	-
Flowability/Pourability/Dustability	-	All meta SPCs	Data on flowability, pourability and dustability apply only to granular materials, suspension concentrates, capsule suspension, suspoemulsions or dusts. Waiving data on these properties is justified because the biocidal products of this family are aerosols.	-
Burning rate — smoke generators	-	All meta SPCs	Data on burning rate is only relevant to smoke generators. Waiving data on this property is justified because the biocidal products of this family are aerosols.	-
Burning completeness — smoke generators	-	All meta SPCs	Data on burning completeness is only relevant to smoke generators. Waiving data on this property is justified because the biocidal products of this family are aerosols.	-
Composition of smoke — smoke generators	-	All meta SPCs	Data on composition of smoke is only relevant to smoke generators. Waiving data on this property is justified because the biocidal products of this family are aerosols.	-
Spraying pattern — aerosols	FEA 644	H-21024 AS content: 0.10%	From a distance of 15 cm: 4.5 cm From a distance of 25 cm: 6 cm From a distance of 30 cm: 6.5 cm	[redacted] 2022a, LR-C-632 (R9)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
		H-21021 AS content: 0.10%	From a distance of 15 cm: 5 cm From a distance of 25 cm: 8 cm From a distance of 30 cm: 8.5 cm	[redacted] 2022c, LR-C-652-B (R9)
		H-21025 AS content: 0.098%	From a distance of 15 cm: 6 cm From a distance of 25 cm: 7 cm From a distance of 30 cm: 8 cm	[redacted] 2022c LR-LC-022.1
Pressure in finished aerosol packs	FEA 604 (at 25 °C) FAO, 2010 (at 30 °C)	H-21024 AS content: 0.10%	4.7 bar at 25 °C 4.9 bar at 30 °C	[redacted] 2022a, PS-21024.5 (Annex 4)
		H-21021 AS content: 0.10%	4.4 bar at 25 °C 4.6 bar at 30 °C	[redacted] 2022b, PS-21021.5 (Annex 4)
		H-21025 AS content: 0.098%	4.5 bar at 25 °C 5.5 bar at 30 °C	[redacted] 2022a, LR-LC-046.3 (Annex 4)
Residue after use and clogging	-	H-21024 Batch no.: C-632 AS content: 0.10%	**Residue after use:** Initial weight: 491.90 g Weight after no more formulation is discharged: 113.48 g Weight after remaining formulation removed: 110.67 g Remaining formula weight: 2.81 g	[redacted] 2019b, LR-728.2-(H-21024)

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			0.7% of initial quantity in can after end of use.	
	FAO/WHO 8.11.4.5	H-21024 Batch no.: C-632 AS content: 0.10%	**Clogging:** No clogging observed	[redacted] 2022c, ASSR-21024.4
	-	H-21021 Batch no.: C-706 AS content: 0.10%	**Residue after use:** Initial weight: 387.75 g Weight after no more formulation is discharged: 95.24 g Weight after remaining formulation removed: 94.45 g Remaining formula weight: 0.79 g 0.3% of initial quantity in can after end of use.	[redacted] 2019c, LR-728-(H-21021)
	FAO/WHO 8.11.4.5	H-21021 Batch no.: C-706 AS content: 0.10%	**Clogging:** No clogging observed	[redacted] 2022d, ASSR-21021.4
	-	H-21025 AS content: 0.10%	**Residue after use:** Initial weight: 377.0 g Weight after no more formulation is discharged: 91.45 g	[redacted] 2019a, LR-LC-050

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Weight after remaining formulation removed: 90.60 g Remaining formula weight: 0.85 g 0.3% of initial quantity in can after end of use.	
	FAO/WHO 8.11.4.5	H-21025 AS content: 0.10%	**Clogging:** No clogging observed	[redacted] 2022b, ASSR-21025.4.2
Discharge rate	FEA 643	H-21024 (400 mL can) AS content: 0.10%	Average rate: 1.6 g/s Tolerance: +/- 0.2 g/s Minimum rate:1.3 g/s	[redacted] (2022a) LR-C-632 (R9)
		H-21021 (400 mL can) AS content: 0.10%	Average rate: 1.5 g/s Tolerance: +/- 0.2 g/s Minimum rate: 1.23 g/s	[redacted] (2022b) LR-C-652-B (R9)
		H-21025 (500 mL can) AS content: 0.098%	Average rate: 1.7 g/s Minimum rate: 1.3 g/s	[redacted] (2022c) LR-LC-022.1
Physical compatibility	-	All meta SPCs	Data on physical compatibility is not relevant. Waiving data on this endpoint is justified because mixing with other biocidal products is not recommended.	-
Chemical compatibility	-	All meta SPCs	Data on chemical compatibility is not relevant. Waiving data on this endpoint is justified because mixing with other biocidal products is not recommended.	-

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Degree of dissolution and dilution stability	-	All meta SPCs	Data on degree of dissolution is only required for biocidal products used in water soluble bags and for tablets. The dilution stability is required for products to be diluted upon use. Waiving data on these properties is justified because the biocidal products of this family are not used in water soluble bags nor are tablets or are to be diluted upon use. The biocidal products of this family are ready to use aerosol cans.	-
Surface tension	-	H-21024-c and H-21021-c	The kinematic viscosity of the product H-21021 (without propellant) is larger than 7 x 10^{-6} m²/s at 40 °C. Therefore it is not required to measure its surface tension. Since the product H-21024 is identical to H-21021, its kinematic viscosity will be the same, hence no surface tension measurement required.	[redacted] 2019f, LR-C-707.1
	-	H-21025-c	The kinematic viscosity of the product H-21021 (without propellant) is larger than 7 x 10^{-6} m²/s at 40 °C. Therefore it is not required to measure its surface tension.	[redacted] 2019e, LR-LC-023
Viscosity	OECD 114 using a rotational viscometer	H-21024-c H-21024 AS content: 0.10%	At 20 °C Dynamic viscosity: 9.13 ± 0.27 mPa.s (200 rpm and 30.45% torque) At 40 °C	[redacted] 2022a, PS-21024.5 (Annex 1) and

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Dynamic viscosity: 8.24 ± 0.19 mPa.s (200 rpm and 27.00% torque) Kinematic viscosity: 8.6 x 10^{-6} m^2/s	[redacted] (2019f). Report No. LR-C-707.1 (Kinematic Viscosity at 40 °C)
	-	H-21021-c H-21021 AS content: 0.10%	The product is chemically identical to H-21024-c, therefore its viscosity is the same as that of the product H-21024-c.	[redacted] 2022b, PS-21021.5 (Annex 1)
	OECD 114 using a rotational viscometer	H-21025-c H-21025 AS content: 0.098%	At 20 °C Dynamic viscosity: 10.90 ± 0.16 mPa.s (200 rpm and 32.40% torque) At 40 °C Dynamic viscosity: 7.50 ± 0.06 mPa.s (200 rpm and 25.00% torque) Kinematic viscosity: 7.56 x 10^{-6} m^2/s	[redacted] 2022a, LR-LC-046.3 (Annex 1) and [redacted]. (2019e) Report No. LR-LC-023 (Kinematic Viscosity at 40 °C)

Conclusion on the physical, chemical and technical properties of the product
The submitted studies for the physical, chemical and technical properties of the biocidal product family Transfluthrin aerosols BPF have been evaluated and the information is considered acceptable. The family comprises two meta SPCs containing 3 products in total. All three products have been tested for each relevant endpoint, thus representing the worst-case composition for each of the meta SPCs.

Meta SPC 1 (H-21024):
The product is a white to slightly yellowish liquid emulsion with a characteristic odour. The product contains 0.10% Transfluthrin, has a pH of 6.1 and a relative density of 0.954 g/cm^3 at 20 °C. The accelerated storage stability study demonstrated acceptable variation in the parameters active substance content, pH, internal pressure, clogging, discharge rate, spray pattern and appearance of the product and packaging material after storage at 50°C for 4 weeks. The long term storage stability study demonstrated an acceptable variation in active substance content and that the packaging material epoxy-lacquered tinplate can was stable after storage for 24 months at 25 °C. Additionally, the low temperature stability test demonstrated that the formulation is stable for storage at 0 °C. The kinematic viscosity of the product was determined to be 8.6 mm^2/s, and as the content of hydrocarbons in the product is > 10%, the viscosity may affect the toxicological risk assessment of the product.

The following storage conditions must be included on the product label:
- Do not expose to temperatures exceeding 50 °C.
- Protect from sunlight

Meta SPC 2 (H-21021 and H-21025):
Both products are white to slightly yellowish liquid emulsions with characteristic odours. H-21021 contains 0.10% Transfluthrin, has a pH of 6.1 and a relative density of 0.954 g/cm^3 at 20 °C. H-21025 contains 0.098% Transfluthrin, has a pH of 7.0 and a relative density of 0.992 g/cm^3 at 20 °C. The accelerated storage stability studies by Rigall (2022d, ASSR-21021.4) and Rovinetti (2022b, ASSR-21025.4.2) both demonstrated acceptable variation in the parameters active substance content, pH, internal pressure, clogging, discharge rate, spray pattern and appearance of the product and packaging material after storage. H-21021 was stored at 45°C for 6 weeks while H-21025 was stored at 50°C for 4 weeks. Since the chemical composition of H-21024 (meta SPC 1) and H-21021 is identical, the product is considered stable during storage at temperatures up to 50 °C. The submitted results of the storage stability study at ambient temperature for H-21021 demonstrated an acceptable variation in active substance content and that the packaging material tinplate can without epoxy lacquer was stable after storage for 2 years at 25 °C. Similarly, the submitted interim results for the long term storage stability study for H-21025 demonstrated an acceptable variation in active substance content and that the packaging material epoxy-lacquered tinplate can was stable after storage for 12 months at 25 °C. The kinematic viscosity of the products were determined to be 8.6 mm^2/s (H-21021) and 7.56 mm^2/s (H-21025), and as the content of hydrocarbons in the products is > 10%, the viscosity may affect the toxicological risk assessment of the product.

The following storage conditions must be included on the product label:
- Do not expose to temperatures exceeding 50 °C.
- Protect from sunlight
- Protect from frost

As the chemical composition of H-21024 (meta SPC 1) and H-21021 (meta SPC 2) is identical, the results of the packaging material can be extrapolated between these formulations. Thus, the stability of both proposed packaging materials, i.e. epoxy-lacquered tinplate can and tinplate can without epoxy lacquer, is tested in the long term storage stability studies. As the composition of H-21025 is similar to H-21021, the results of the packaging materials can also be extrapolated between these formulations.

A shelf-life of 48 months cannot be granted based on the submitted experimental results. Based on the acceptable results of the accelerated storage stability studies, the acceptable results of the long term storage stability study at ambient temperature of H-21024 and H-21021 and the acceptable results of the submitted 1 year interim results of the long term storage stability test at ambient temperature for H-21025, a shelf-life of 12 months in the packaging materials epoxy-lacquered tinplate can and tinplate can without epoxy lacquer can be accepted.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	-	-	Data waiving. The explosive properties of each ingredient of the formulation has been evaluated. The active substance is not explosive according to the PT18 CAR for Transfluthrin (NL, 2014). The remaining ingredients of the mixture either do not contain functional groups associated with explosive properties or demonstrates an oxygen balance lower than -200. Please refer to the confidential annex for details. Based on the theoretical assessment, a test for explosive properties is scientifically unjustified and the products is not	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			to be classified as explosive.	
Flammable gases	-	-	Data waiving. The study does not need to be conducted because the biocidal products of this family are aerosols.	-
Flammable aerosols	-	-	The study does not need to be conducted. Aerosols containing more than 1% flammable components or with a heat of combustion of at least 20 kJ/g, which are not submitted to the flammability classification procedures in this section shall be classified as Aerosols, Category 1 (extremely flammable aerosol). Therefore all products belonging to the biocidal family are classified as Aerosol, Category 1.	-
Oxidising gases	-	-	Data waiving. The study does not need to be conducted because the biocidal	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			products of this family are not gases.	
Gases under pressure	-	-	Data waiving The study does not need to be conducted because the biocidal products of this family are aerosol cans and these do not fall within the scope of flammable gases, gases under pressure, flammable liquids, and flammable solids.	-
Flammable liquids	-	-	Data waiving The study does not need to be conducted because the biocidal products of this family are aerosol cans and these do not fall within the scope of flammable gases, gases under pressure, flammable liquids, and flammable solids.	-
Flammable solids	-	-	Data waiving The study does not need to be conducted because the biocidal products of this family are aerosol cans and these do not fall within	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the scope of flammable gases, gases under pressure, flammable liquids, and flammable solids.	
Self-reactive substances and mixtures	-	-	Data waiving The explosive and self-reactive properties of each ingredient of the formulation has been evaluated. No components of the mixture is considered to be explosive (please refer to the separate endpoint for further considerations). The active substance contains a strained cyclopropane ring and a vinyl substituent. However, since the substance is highly diluted (max 0.104% w/w) in the formulations of this BPF, the possible self-reactive properties of this ingredient are very unlikely to affect the self-reactive properties	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			of the biocidal products of this family. The remaining ingredients either do not contain functional groups associated with self-reactive properties or are not considered to affect the self-reactive properties of the BPF due to the degree of dilution. Please refer to the confidential annex for further details. As such, the products of the BPF are not considered to be self-reactive.	
Pyrophoric liquids	-	-	Data waiving. The study does not need to be conducted since the corresponding products are stable in contact with air at room temperature for prolonged period of time (days). The classification procedure	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			does not need to be applied.	
Pyrophoric solids	-	-	Data waiving. The study does not need to be conducted because the biocidal products of this family are not solids.	-
Self-heating substances and mixtures	-	-	Data waiving. The study does not need to be conducted because the phenomenon of self-heating applies only to solids or to liquids adsorbed on a large surface. The biocidal products of this family are not solids or liquids adsorbed on a surface.	-
Substances and mixtures which in contact with water emit flammable gases	-	-	Data waiving. The study does not need to be conducted since based on the nature of products belonging to the family it can be excluded that during contact with water the flammable gases will occur (i.e. the products contain water as part of the formulation).	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Oxidising liquids	-	-	Data waiving. The test is scientifically unjustified, the products of the BPF is not oxidising liquids. Please refer to the confidential annex for a more detailed waiver.	-
Oxidising solids	-	-	Data waiving. The study does not need to be conducted because the biocidal products of this family are not solids.	-
Organic peroxides	-	-	Data waiving. The study does not need to be conducted because the biocidal products of this family do not contain organic peroxides.	-
Corrosive to metals	UN test C.1	H-21024-c H-21024 AS content: 0.10%	Exposure: 7 days Aluminium (7075-T6): Mass loss: 0% (all 3 metal species) Localised corrosion: not observed. Steel (1.0037): Mass loss: 0% (all 3 metal species)	[redacted] 2021, 21081002G979

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Localised corrosion: not observed. Since the uniform corrosion was < 13.5% and the localised corrosion was < 120 µm, the product is not corrosive to metals.	
	-	H-21021-c H-21021 AS content: 0.10%	The product is chemically identical to H-21024-c, therefore corrosive properties are the same as that of the product H-21024-c.	-
	UN test C.1	H-21025-c H-21025 AS content: 0.10%	Exposure: 7 days Aluminium (7075-T6): Mass loss: 0% (all 3 metal species) Localised corrosion: not observed. Steel (1.0037): Mass loss: 0% (all 3 metal species) Localised corrosion: not observed. Since the uniform corrosion was < 13.5% and the localised corrosion was < 120	[redacted] 2021, 21081003G979

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			µm, the product is not corrosive to metals.	
Auto-ignition temperatures of products (liquids and gases)	EC method A.15 and DIN 51794:2003	H-21024-c H-21024 AS content: 0.10%	AIT: 455 °C	[redacted], 2021, 21-11163
	-	H-21021-c H-21021 AS content: 0.10%	The product is chemically identical to H-21024-c, therefore its auto-ignition temperature is the same as that of the product H-21024-c.	-
	EC method A.15 and DIN 51794:2003	H-21025-c H-21025 AS content: 0.10%	AIT > 500 °C	[redacted] 2021, 21-11163
Relative self-ignition temperature for solids	-	-	Data waiving. The study does not need to be conducted because the biocidal products are not solids.	-
Dust explosion hazard	-	-	Data waiving. The study does not need to be conducted because the biocidal products of this family are liquids and they do not form dust.	-

Conclusion on the physical hazards and respective characteristics of the product
The submitted information on physical hazards and respective characteristics for the biocidal products family Transfluthrin aerosols BPF has been evaluated and was considered acceptable.

Experimental data on auto-ignition temperature (455 °C and > 500 °C) and corrosive to metals (no classification) were provided for the BPF.
The products family is not expected to have any explosive, self-reactive or oxidising properties. Based on experience in production and handling, it can be concluded that the products are not pyrophoric or does evolve flammable gases in contact with water.
Since the products are aerosols and have not been submitted to the tests for flammable aerosols, the BPF is classified as Aerosol, Category 1 based on the CLP criteria.
The following hazard statements are appropriate:
H222: Extremely flammable aerosol
H229: Pressurised container: may burst if heated.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Transfluthrin (Active substance)	GC-FID	Spiked at 0.10 – 0.20% w/w n = 3 (triplicate determinations) *Repeatability:* Tested using H-21021 AS Content: 0.096-0.103% w/w. Mean: 0.100% w/w %RSD: 2.678	Linearity established for the ratio between the concentration of Transfluthrin and the concentration of the internal standard: [Transfluthrin]/[Int. standard] in the range 0.1321-	No interference with matrix. *rMS note:* Chromatograms of samples can be found in the respective storage stability studies for each product.	Level: 0.10% 99.0-99.6 Level: 0.15% 99.8-102.3 Level: 0.20% 98.0 –99.1 Overall: 98.0-102.3	Level: 0.10% 99.37 Level: 0.15% 100.83 Level: 0.20% 98.83 Overall: 99.68	Level: 0.10% 0.3 Level: 0.15% 1.3 Level: 0.20% 0.7 Overall: 1.18	LOQ: 0.006 mg/mL LOD: 0.002 mg/mL	[redacted] (2019) LN-0723.2 [redacted] (2019) IN-01411/2019-3

			2.4576.[5] y = 0.831x +0.002 (x = Area(AS)/Area(Int. std), y = concentration(AS)/concentration(Int. std.)) R^2 = 0.99995 RSD < 2%						

Analytical methods for animal and human body fluids and tissues:

According to Annex III point 5.2.4 of Regulation (EU) No 528/2012 (BPR) information on analytical methods for monitoring purposes of relevant components of the biocidal product and/or residues thereof is required for animal and human body fluids and tissues. In the Guidance on the BPR: Volume I, Part A: Information Requirements (Version 2.0, May 2018) "components of the biocidal product classified as toxic or very toxic" are considered as toxicologically relevant components which must be analysed for monitoring purposes if human exposure cannot be excluded. According to Regulation (EC) No 1272/2008 (CLP Regulation), toxic (T) and very toxic (T+) as used in the classification under directive 67/548/EEC can be translated to the hazard clases Acute Tox. 1-3, STOT SE 1, and STOT RE 1 under the CLP regulation. The toxicological properties of the active substance and the co-formulants of the biocidal products of the Transfluthrin aerosols BPF are known. The harmonized classification of transfluthrin with respect to human health effects in Table 3.1 of Annex VI of the CLP regulation is as follows: Skin Irrit. 2. Thus, based on this harmonized classification of transfluthrin, an analytical method in human body fluids and tissues is not required. In addition, none of the co-formulants present at a concentration ≥0.1% in the biocidal products of the Transfluthrin aerosols BPF are classified as toxic or very toxic. It is, thus, concluded that an analytical method for monitoring purposes of transfluthrin or any other co-formulant in animal and human body fluids and tissues is not required.

[5] The content of Transfluthrin in a test sample prepared according to the sample preparation using the product containing a nominal content of 0.10% w/w of Transfluthrin corresponds to a [Transfluthrin]/[Int. Standard] ratio of 1.33. As such, linearity is acceptable, as the ratio for c(Transfluthrin) ± 20% corresponds to the following range of [Transfluthrin]/[Int. Standard] ratio: 1.067-1.600, which is well within the tested range.

Analytical methods for monitoring of active substances and residues in food and feeding stuff:

According to Annex III point 5.3 of Regulation (EU) No 528/2012 (BPR) information on analytical methods for monitoring purposes including recovery rates and the limit of quantification and detection for the active substance, and for residues thereof, in/on food of plant and animal origin or feeding stuffs and other products where relevant, are required. In chapter 2.8.3 of the Guidance on the BPR: Volume I, Part A: Information Requirements (Version 2.0, May 2018) it is stated that "*Analytical methods for the residues of the active substance may be required for monitoring purposes in various matrices, for control of MRL compliance, for the identification of misuse and for the estimation of human and animal exposure… Analytical methods for residues are required, presuming that the biocidal product may come into contact with food, foodstuffs and feeding stuffs. This is always the situation for product-types 3, 4, 5 and also for certain uses of other product-types. … The need for residue analytical methods for other product-types depends on the assessment of the transfer of the active substance into food and feeding stuffs*". Thus, analytical methods for the determination of active substance residues in/on food or feedstuffs are required if the active substance or the material treated with it is to be used in a manner which may cause contact with food or feedstuffs, or is intended to be placed on, in or near soils in agricultural or horticultural use. The active substance is not intended to be used in the above described manner. An exposure of the active substance to food and feedstuffs can be excluded when applied according to the recommended use. Therefore, analytical methods for the determination of the active substance in/on food or feeding stuffs are not required.

Analytical methods for soil, water and air:

Analytical methods for the determination of active substance residues in relevant environment media (soil, water and air) were not submitted for the biocidal products of the biocidal product family, as these are covered by the data set of the active substance transfluthrin.

Conclusion on the methods for detection and identification of the product
The analytical method allows for determination of the Transfluthrin content in the biocidal products of the BPF. The provided results demonstrate that the method is linear, precise, accurate and specific for determining the content of Transfluthrin. The validation parameters are in agreement with the requirements of SANCO/3030/99. Therefore, the method is considered acceptable for determination of transfluthrin in the products of the biocidal products family Transfluthrin aerosols BPF. Analytical methods for the determination of transflutrin and residues thereof in relevant environmental media (soil, air and water) were not submitted for the biocidal products since these endpoints are covered by the dataset of the active substance. Analytical methods for monitoring in animal and human body fluids and tissues are not required for the BPF, as the active substance and residues thereof are not classified as toxic or very toxic.

Analytical methods for determination of active substance residues in/on food or feedstuff are not required, as the products of the BPF will not be used in a manner which may cause contact with foos or feedstuffs or are intended to be placed on, in or near soils in agricultural or horticultural use.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Products in meta SPC 1 are insecticides used indoors as spatial treatment or direct spray treatment on insects.
The products in meta SPC 2 are insecticides used outdoors as direct spray treatment on insects, [redacted] and as nest spray on wasp nests.

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

The following groups of insects are to be controlled (in between brackets the tested organisms):

Use # 1.18.1 Indoor use, spatial treatment
mosquitoes (*Aedes albopictus, Culex pipiens)*
flies (*Musca domestica)*

Use # 1.18.2 Indoor use, direct spray
mosquitoes (*Aedes albopictus, Culex pipiens)*
flies (*Musca domestica)*
ants and tropical ants *(Lasius niger, Linephitema humile*)
wasps (*Vespula germanica*)

[redacted]

Use # 2.18.4 Outdoor use, direct treatment
mosquitoes (*Aedes albopictus, Culex pipiens)*
flies (*Musca domestica)*
black flies *(Simulium erythrocephalum*)
ants and tropical ants *(Lasius niger, Linephitema humile*)
wasps (*Vespula germanica*)
hornets *(Vespa crabro*)

Use # 2.18.5 Outdoor use, nest treatment
wasp nests *(Polistes gallicus*)

2.2.5.3 Effects on target organisms, including unacceptable suffering

Transfluthrin is an insecticide that, after contact and/or ingestion by insects, has a knockdown and killing effect. The effect is fast so no unacceptable suffering is expected.

2.2.5.4 Mode of action, including time delay

Transfluthrin is a synthetic pyrethroid which acts on harmful organisms by contact and ingestion. It expresses a strong knock-down effect. The primary site of activity of transfluthrin is the voltage sensitive sodium channel in nerve membrane. Transfluthrin prolongs the opening of the sodium channels (i.e. the channels directly responsible for generating nerve action potentials) leading to neuronal hyperexcitability. This causes muscular paralysis in the insect (knock down); death seems to follow a nervous system impairment that occurs a few minutes after pesticide absorption.

[redacted]

2.2.5.5 Efficacy data

Justification for testing and waivers

Efficacy tests have been performed with two representative products.

For the indoor use (meta SPC 1), tests were done with Aerosol FIK WB Premium Indoors BPR, formulation code H-21024, with 0.104 % transfluthrin. This product is representative for meta SPC 1 because all concentrations in this meta SPC (a.s. and coformulants) are fixed.

For the outdoor use (meta SPC 2), tests were done with Aerosol FIK WB Outdoors BPR, formulation code H-21021, with 0.104 % transfluthrin. The variation for the active substance within meta SPC 2 is rather small, therefore it can be expected that formulation H-21021 is representative for the whole meta SPC 2. Additionally, the coformulants within this BPF are not considered to impact the efficacy of the product and therefore, the possible concentration variations within this meta SPC can be neglected with regards to efficacy. This is further proven by six efficacy studies performed with the second product in this meta SPC, formulation H-21025, with 0.102 % transfluthrin. These simulated-use tests demonstrate that there are no differences for efficacy between both tested products. Based on the shown similar efficacy, efficacy results for formulation H-21025 can be bridged from Aerosol FIK WB Outdoors BPR, formulation code H-21021. Furthermore, as the tested products from meta SPC 1 (Aerosol FIK WB Premium Indoors BPR) and meta SPC 2 (Aerosol FIK WB Outdoors BPR) have the same composition, results can be bridged between these two products. This deviation is accepted.

Use # 2.18.5 – Insecticide for outdoor use – wasp nests: other than standard test organisms is used in the field test.

The tests with *Polistes* is not considered sufficient. In *Vespa germanica* or *Vespa vulgaris* the number of worker wasps can reach up to 1000-5000 in full season and the nest of paper wasps is different in structure from common wasp nests. Additionally, paper wasp's nests are usually placed outside structures and are clearly visible, whilst colonies of *Vespula* spp. and *Dolicovespula* spp. are usually found inside natural or artificial cavities. Therefore, we think that treating a wasp nest of *Polistes gallicus* is not acceptable and is not mentioned in the guidance document. Field test with nest of *Vespula* spp. or *Dolicovespula* spp. cannot be waived by the presented studies.

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**	**Test results: effects**	**Reference**

					applied / exposure time		
Insecticide	Indoor Spatial treatment	Aerosol FIK WB Premium Indoors BPR formulation code H-21024 0.104 % transfluthrin	*Musca domestica* 3-10 days old adult flies, mixed sexes	Simulated-use test Intra-company method "MB-005 Biological evaluation of an Aerosol used as Space treatment in Large Cabin (30 m^3)" 50 flies are released in a large cabin (30 m^3) with an air renovation rate of 60 m^3/h. After 15-30 min the aerosol was sprayed in the cabin, not less than 1 m from any surface. After 2 h the flies were transferred to clean containers for the evaluation of the killing effect after 24 h.	5 replicates treated, 5 replicates untreated (control); 50 flies for each replicate Dose: an average of 11.6 g product sprayed per cabin	Knockdown after 1 and 2 h was 100 % (KT95 =11.9 min). Mortality was 98.0 % after 24 h. Control: No knockdown or mortality observed.	[redacted] 2019k Report no: RB-242
Insecticide	Indoor	Aerosol FIK WB	*Culex pipiens*	Simulated-use test	5 replicates treated, 5	Direct after application, 2 h	[redacted] 2019j

	Spatial treatment	Premium Indoors BPR formulation code H-21024 0.104 % transfluthrin	mosquitoes 3-10 days old females	Intra-company method "MB-005.1: Biological evaluation of a long-lasting Aerosol used as Space treatment in Large Cabin (30m ^{3})" 50 female mosquitoes are released in a large cabin (30 m^3) with an air renovation rate of 60 m^3/h. After 15-30 min the aerosol was sprayed in the cabin, not less than 1 m from any surface. After 2 h the mosquitoes were transferred to clean containers for the evaluation of the killing effect after 24 h. Residual effect was tested by	replicates untreated (control); 50 females for each replicate Dose: an average of 11.7 g product sprayed per cabin	exposure time: 100 % knockdown after 1 and 2 h (KT95=5.3 min); 100 % mortality after 24 h 4 h after application, 2 h exposure time: 95.8 % knockdown after 1 h, 97.2 % knockdown after 2 h (KT95= 48.4 min); 94.3 % mortality after 24 h. 7 h after application, 2 h exposure time: 93.2 % knockdown after 1 h, 96.4 % and after 2 h (KT95=65.1 min); 94.2 % mortality after 24 h. Control: Knockdown after 1 and 2 h and mortality after 24 h <1 %	Report no: RB-242.1

				releasing 50 females into the cabin 4 and 7 hours after application of the product.			
Insecticide	Indoor, spatial treatment	Aerosol FIK WB Premium BPR formulation code H-21024 0.104 % transfluthrin	*Aedes albopictus* mosquitoes 3-10 days old females	Simulated-use test Intra-company method "MB-005.1: Biological evaluation of a long-lasting Aerosol used as Space treatment in Large Cabin (30 m^3)" 50 female mosquitoes are released in a large cabin (30 m^3) with an air renovation rate of 60 m^3/h. After 15-30 min the aerosol was sprayed in the cabin, not less than 1 m from any surface. Knockdown was recorded every 5 min up to 1 h.	5 replicates treated, 5 replicates untreated (control); 50 females for each replicate Dose: an average of 10.56 g product sprayed per cabin.	Direct after application, 2 h exposure time: 100 % knockdown after 1 and 2 h (KT95=5.7 min); 100 % mortality after 24 h 4 h after application, 2 h exposure time: 100 % knockdown after 1 and 2 h (KT95=33.4 min); 98.8 % mortality was after 24 h 7 h after application, 2 h exposure time: 97.4% knockdown after 1 h, 99.2 % knockdown after 2 h (KT95=55.9 min); 97.6% mortality 24 h. Control: Knockdown after 1 and 2 h and	[redacted] 2019i Report no:: RB-242.8

				After 2 h the mosquitoes were transferred to clean containers for the evaluation of the killing effect after 24 h. Residual effect was tested by releasing 50 females into the cabin 4 and 7 h after application of the product.		mortality after 24 h <1 %	
Insecticide	Indoor Direct spray on insects to knock down and kill	Aerosol FIK WB Premium Indoors BPR formulation code H-21024 0.104 % transfluthrin	*Musca domestica* 3-10 days old adult flies, mixed sexes	Laboratory test Intra-company method "MB-006.1: Aerosol used as Direct spray against flying insects" 25 flies are caged in a container (9 cm height, 9.5 cm diameter) with an opening in the top that is covered with a net. At a distance of at least 60 cm, the aerosol is	5 replicates treated, 5 replicates untreated (control); 25 adults for each replicate Dose: 1-2 sec spray treatment per container resulting in an average of 1.1 g product per container.	100 % knockdown 10 sec post-application, 100 % mortality after 5 min, and 100 % mortality after 24 h against common flies (*Musca domestica*) Control: No knockdown or mortality observed.	[redacted] 2019e Report no: RB-242.2

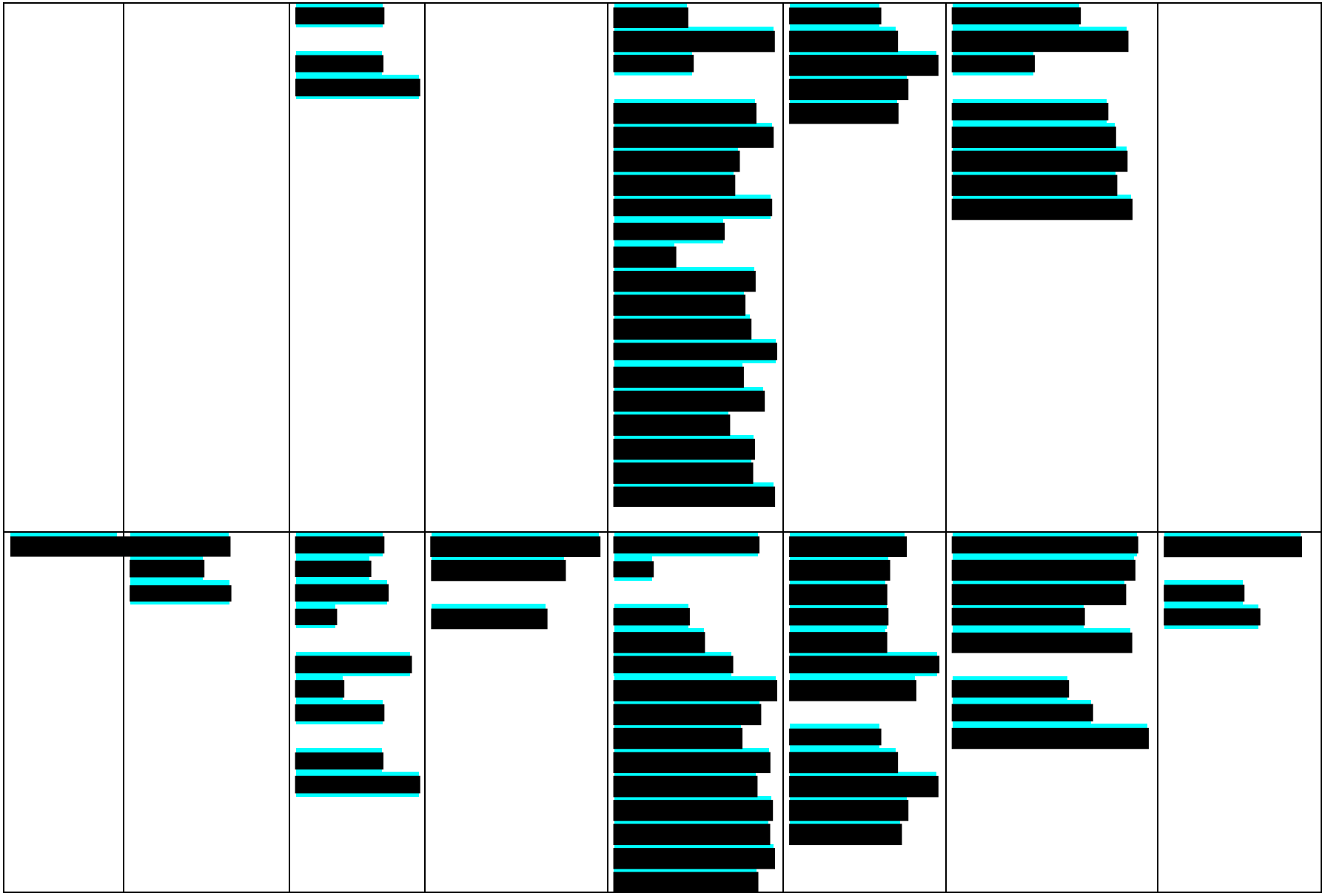
				sprayed into the open top of a container with insects. After spraying, the flies are transferred to clean containers for observation of knockdown and determination of mortality after 24 h.			
Insecticide	Indoor/outdoor Direct spray on insects to knock down and kill	Aerosol FIK WB Premium Indoors BPR formulation code H-21024 0.104 % transfluthrin	*Culex pipiens* mosquitoes 3-10 days old females	Laboratory test Intra-company method "MB-006.1: Aerosol used as Direct spray against flying insects" 25 female mosquitoes are caged in a container (9 cm height, 9.5 cm diameter) with an opening in the top that is covered with a net. At a distance of at least 60 cm, the aerosol is sprayed into	5 replicates treated, 5 replicates untreated (control); 25 females for each replicate Dose: 1-2 sec spray treatment per container resulting in an average of 1.0 g product per container.	100 % knockdown 5 sec post-application, 100 % mortality after 2 min, and 100 % mortality after 24 h Control: No knockdown or mortality observed.	[redacted] 2019g Report no: RB-242.3

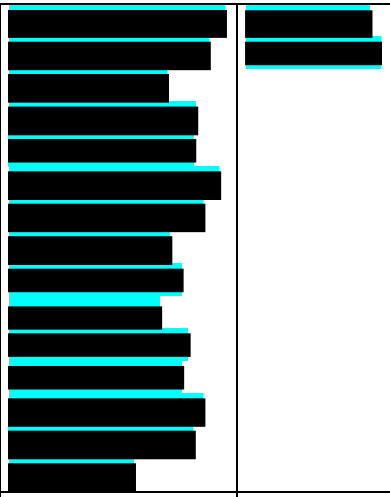
				the open top of a container with insects. After spraying, the insects are transferred to clean containers for observation of knockdown and determination of mortality after 24 h.			
Insecticide	Indoor/outdoor Direct spray on insects to knock down and kill	Aerosol FIK WB Premium BPR formulation code H-21024 0.104 % transfluthrin	*Aedes albopictus* mosquitoes 3-10 days old females	Laboratory test Intra-company method "MB-006.1: Aerosol used as Direct spray against flying insects" 25 female mosquitoes are caged in a container (9 cm height, 9.5 cm diameter) with an opening in the top that is covered with a net. At a distance of at least 60 cm, the aerosol is sprayed into the open top of	5 replicates treated, 5 replicates untreated (control); 25 females for each replicate Dose: 1-2 sec spray treatment per container resulting in an average of 1.0 g product per container.	100 % knockdown 5 sec post-application, 100 % mortality after 2 min, and 100 % mortality after 24 h Control: No knockdown was observed within the first hour, and mortality after 24 h less than 1 %.	[redacted] 2019f Report no: RB-242.4

				a container with insects. After spraying, the insects are transferred to clean containers for observation of knockdown and determination of mortality after 24 h.			
Insecticide	Indoor Direct spray on insects to knock down and kill	Aerosol FIK WB Premium BPR formulation code H-21024 0.104 % transfluthrin	*Linephitema humile* Worker ants	Laboratory test Intra company method" MB-006: Aerosol used as Direct spray against crawling insects" 30 ants are caged in a container (9 cm height, 9.5 cm diameter) with an opening in the top. At a distance of at least 60 cm the aerosol is sprayed into the open top of a container. After spraying, the ants are	5 replicates treated, 5 replicates untreated (control); 30 ants for each replicate Dose: 1-2 sec spray treatment per container resulting in an average of 1.2 g product per container.	100 % knockdown 30 sec post-application, 100 % mortality after 24 h. Control: No knockdown or mortality observed.	[redacted] 2019d Report no: RB-242.5

				transferred to clean containers for observation of knockdown and determination of mortality after 24 h.			
Insecticide	Indoor Direct spray on insects to knock down and kill	Aerosol FIK WB Premium BPR formulation code H-21024 0.104 % transfluthrin	*Lasius niger* Worker ants	Laboratory test 10 ants were inserted into plastic containers (12 cm diameter, 6 cm height). Immediately after treatment, the insects were moved to a tile with porous surface and confined under plastic transparent cups for observation of knockdown and determination of mortality after 24 h.	5 replicates treated, 5 replicates untreated (control); 10 ants for each replicate Dose: 1 sec spray treatment per cage from a distance of 20 cm, resulting in an average of 1.4 g product per cage. Knockdown is recorded after 2 min and then after several time intervals within the first hour post-application.	100 % knockdown 2 min post-application, 100 % mortality after 24 h. Control: No knockdown or mortality observed.	[redacted] 2019d Doc no: RB-242.6

					Mortality is recorded after 24 h.		
Insecticide	Indoor Direct spray on insects to knock down and kill	Aerosol FIK WB Premium BPR formulation code H-21024 0.104 % transfluthrin	*Vespula germanica* Wasps collected in the field	Simulated-use test The test was performed in the field directly after collecting the wasps. Wasps were inserted into small cages (4x8 cm, plastic frame with 2 mm mesh). From a distance of 10 cm the aerosol is sprayed directly into the cage. The time period until knockdown was achieved was recorded as well as mortality after 1 h.	15 replicates treated, 15 replicates untreated (control); 1 wasp for each replicate Dose: 1 sec spray treatment per cage resulting in an average of 1.4 g product per cage.	Complete knockdown was reached after 14 sec on average. Mortality was 100 % after 1 h. Control: No knockdown or mortality observed.	[redacted] 2019e Doc no: RB-242.7
[redacted]							



							
Insecticide	Outdoor Direct spray on insects to knock down and kill	Aerosol FIK WB Outdoors BPR formulation code H-21021 0.104 % transfluthrin	*Musca domestica* 2-5 days old adults mixed sexes	Laboratory test Intra company method: "MB-006.1 Aerosol used as Direct spray against flying insects". 25 flies are caged in a container (9 cm height, 9.5 cm diameter) with an opening in the top that is covered with a net. At a distance of at least 60 cm the aerosol is sprayed onto	5 replicates treated, 5 replicates untreated (control); 25 adults for each replicate Dose: 1-2 sec spray treatment per container resulting in an average of 1.3 g product per container.	100 % knockdown 5 sec post-application, 100 % killing after 5 min, and 100 % mortality after 24 h against common flies, *Musca domestica* Control: No knockdown or mortality observed.	[redacted] 2019c Report no: RB-245.2

				the open top of the container with insects. After spraying, the flies are transferred to clean containers for observation of knockdown and determination of mortality after 24 h.			
Insecticide	Outdoor Direct spray on insects to knock down and kill	Aerosol FIK WB Outdoors BPR formulation code H-21021 0.104 % transfluthrin	*Linephitema humile* Worker ants	Laboratory test Intra company method: "MB-006: Aerosol used as Direct spray against crawling insects" 30 ants are caged in a container (9 cm height, 9.5 cm diameter) with an opening in the top. At a distance of at least 60 cm the aerosol is sprayed onto the open top of the container.	5 replicates treated, 5 replicates untreated (control); 30 ants for each replicate Dose: 1-2 sec spray treatment per container resulting in an average of 1.2 g product per container.	100 % knockdown 30 sec post-application, 100 % mortality after 24 h. Control: No knockdown or mortality observed.	[redacted] 2019b Report no: RB-245.3

				After spraying, the ants are transferred to clean containers for observation of knockdown and determination of mortality.			
Insecticide	Outdoor Direct spray on insects to knock down and kill	H-21021 FIK WB Outdoors BPR formulation code H-21021 0.104 % transfluthrin	*Vespula germanica* Wasps collected in the field	Simulated-use test The test was performed in the field directly after collecting the wasps. Wasps were inserted into small cages (4x8 cm, plastic frame with 2 mm mesh). At a distance of 10 cm the aerosol is sprayed directly into the cage. The time period until knockdown was achieved was recorded as well as mortality after 1 h.	15 replicates treated, 15 replicates untreated (control); 1 wasp for each replicate Dose: 1 sec spray treatment per cage resulting in an average of 1.4 g product per cage.	Complete knockdown was reached after 14 sec on average. Mortality was 100 % after 1 h. Control: No knockdown or mortality observed.	[redacted] 2019b Doc no: RB-245.4

Insecticide	Outdoor Direct spray on insects to knock down and kill	H-21021 FIK WB Outdoors BPR formulation code H-21021 0.104 % transfluthrin	*Lasius niger* Worker ants	Laboratory test 10 ants were inserted into plastic containers (12 cm, diameter, 6 cm height). Immediately after spraying the insects were moved to a tile with porous surface and confined under plastic transparent cups. Knockdown is recorded after 2 min and after several time intervals within the first hour post-application. Mortality is recorded after 24 h.	5 replicates treated, 5 replicates untreated (control); 10 ants for each replicate Dose: 1 sec spray treatment per cage resulting in an average of 1.4 g product per cage.	Complete knockdown was reached after 2 min. Mortality was 100 % after 24 h. Control: No knockdown or mortality observed.	[redacted] 2019c Doc no: RB-245.5
Insecticide	Outdoor Direct spray on insects to knock down and kill	H-21021 FIK WB Outdoors BPR formulation code	*Simulium erythrocephalum* Black flies (adults) collected in the field, mixed sex.	Laboratory test Intra company method: "MB-006.1: Aerosol used as Direct	5 replicates treated, 5 replicates untreated (control); 25 adults for each replicate	100 % knockdown 5 sec post-application, 100 % killing after 5 sec, and 100 % mortality after 24 h.	[redacted] 2019h Report no: RB-245.6

		H-21021 0.104 % transfluthrin		spray against flying insects" 25 flies are caged in a container (9 cm height, 9.5 cm diameter) with an opening in the top that is covered with a net. At a distance of 50-60 cm the aerosol is sprayed onto the open top of the container with insects. After spraying, the flies are transferred to clean glass containers (1 L volume, with 10 % sugar solution) for observation of knockdown and determination of mortality after 24 h.	Dose: 1-2 sec spray treatment per container resulting in an average of 1.2 g product per container.	Control: No knockdown or mortality observed in the first hour, < 5% mortality after 24 h.	
Insecticide	Outdoor Direct spray on insects to knock down and kill	H-21021 FIK WB Outdoors BPR	*Vespa crabro* Hornets collected in the field	Simulated-use test The test was performed in	15 replicates treated, 15 replicates untreated (control);	Complete knockdown was reached in an average of 2.3 sec.	[redacted] 2019f Doc no: RB-245.7

		formulation code H-21021 0.104 % transfluthrin		the field directly after collecting the hornets. Hornets were inserted into small cages (4x8 cm, plastic frame with 2 mm mesh). At a distance of 1 m the aerosol is sprayed directly onto the cage. The time period until knockdown is achieved and mortality after 24 h are recorded.	1 wasp for each replicate Dose: 1 sec spray treatment per cage	Mortality was 100 % after 1 h. Control: No knockdown or mortality observed.	
Insecticide	Outdoor Nest treatment	H-21021 FIK WB Outdoors BPR formulation code H-21021 0.104% transfluthrin	*Polistes gallicus* Paper wasp nests treated in the field	Field test The test was performed spraying the nests from an acceptable distance allowing uniform treatment of the nest. Wasp activity was observed via video,	5 replicates treated, one replicate is one nest. Control: wasp activity before treatment Dose: 2 sec spray treatment, uniform treatment of the nest	No wasp activity was seen after treatment, from day 1 up to 2 weeks.	[redacted] 2019g Doc no: RB-245.8

				before treatment and 1 day, 1 and 2 weeks after treatment.			
Insecticide	Outdoor Direct spray on insects to knock down and kill	FIK WB Outdoors formulation code H-21025 0.102% transfluthrin	*Aedes albopictus* Adult mosquitoes	Laboratory test 10 mosquitoes are introduced into cages made of metallic net (1 mm mesh, 5.5 cm height, 5.5 cm diameter). At a distance of 20 cm the aerosol is sprayed into the cage. Observation of knockdown after 1, 2, and 5 min. One hour after spraying, the insects are transferred to clean containers for determination of mortality after 24 h.	5 replicates treated with product, 5 replicates treated with water (control); 10 adults for each replicate Dose: 1 sec spray treatment per container resulting in an average of 1.3 g product per container.	100 % knockdown 1 min post-application, and 100 % mortality after 24 h against Control: No knockdown or mortality observed.	[redacted] 2019h Doc no: RB-252
Insecticide	Outdoor Direct spray on insects to	FIK WB Outdoors formulation code	*Culex pipiens* Adult mosquitoes	Laboratory test 10 mosquitoes are introduced	5 replicates treated with product, 5 replicates	100 % knockdown 1 min post-application, and	[redacted] 2019i Doc no: RB-252.1

	knock down and kill	H-21025 0.102% transfluthrin		into cages made of metallic net (1 mm mesh, 5.5 cm height, 5.5 cm diameter). At a distance of 20 cm the aerosol is sprayed into the cage. Observation of knockdown after 1, 2, and 5 min. One hour after spraying, the insects are transferred to clean containers for determination of mortality after 24 h.	treated with water (control); 10 adults for each replicate Dose: 1 sec spay per container resulting in an average of 1.3 g product per container.	100 % mortality after 24 h Control: No knockdown or mortality observed.	
Insecticide	Outdoor Direct spray on insects to knock down and kill	FIK WB Outdoors formulation code H-21025 0.102% transfluthrin	*Musca domestica* adults	Laboratory test 10 flies are introduced into cages made of mosquito net (2 mm mesh, 8 cm height, 4 cm diameter). At a distance of 20 cm the aerosol is sprayed into	5 replicates treated with product, 5 replicates treated with water (control); 10 adults for each replicate Dose: 1 sec spray treatment per	100 % knockdown 5 min post-application, and 100 % mortality after 24 h Control: No knockdown or mortality observed.	[redacted] 2019j Doc no: RB-252.2

				the cage. Observation of knockdown after 1, 2, and 5 min. One hour after spraying, the flies are transferred to clean containers for determination of mortality after 24 h.	container resulting in an average of 1.3 g product per container.		
Insecticide	Outdoor Direct spray on insects to knock down and kill	FIK WB Outdoors formulation code H-21025 0.102% transfluthrin	*Vespula germanica* Wasps collected in the field.	Simulated-use test The test was performed in the field direct after collecting the wasps. Wasps were inserted into small cages (4x8 cm, plastic frame with 2 mm mesh). At a distance of 10 cm the aerosol is sprayed directly into the cage.	15 replicates treated, 15 replicates treated with water (control); 1 wasp for each replicate Dose: 1 sec spay per cage resulting in an average of 1.2 g product per cage.	Complete knockdown was reached after 10 sec on average. Mortality was 100 % after 1 h. Control: No knockdown or mortality observed.	[redacted] 2019k Doc no: RB-252.3
Insecticide	Outdoor	FIK WB Outdoors	*Lasius niger* adults	Laboratory test	5 replicates treated with	100 % knockdown 2 min post-	[redacted] 2019l

	Direct spray on insects to knock down and kill	formulation code H-21025 0.102% transfluthrin		20 adult ants are introduced into plastic cages (6 cm height, 11 cm diameter). At a distance of 20 cm the aerosol is sprayed into the cage. Observation of knockdown after 1, 2, and 5 min. Immediately after spraying, the ants are transferred to clean containers for determination of mortality after 24 h.	product, 5 replicates treated with water (control); 20 adults for each replicate Dose: 1 sec spray treatment per container resulting in an average of 1.1 g product per container.	application, and 100 % mortality after 24 h against ants. Control: No knockdown or mortality observed.	Doc no: RB-252.4
Insecticide	Outdoor Direct spray on insects to knock down and kill	FIK WB Outdoors formulation code H-21025 0.102% transfluthrin	*Linepithema humile* adults	Laboratory test 20 adult ants are introduced into plastic cages (6 cm height, 11 cm diameter). At a distance of 20 cm the aerosol is sprayed into the cage.	5 replicates treated with product, 5 replicates treated with water (control); 20 adults for each replicate Dose: 1 sec spray treatment per	100 % knockdown 1 min post-application and 100 % mortality after 24 h against ants. Control: No knockdown or mortality observed.	[redacted] 2019m Doc no: RB-252.5

				Observation of knockdown after 1, 2, and 5 min. Immediately after spraying, the insects are transferred to clean containers for determination of mortality after 24 h.	container resulting in an average of 1.2 g product per container.		

Conclusion on the efficacy of the product

Meta SPC 1 use # 1.18.1 Indoor use, spatial treatment

The use indoor spraying, spatial treatment was investigated against *Musca domestica* (Moreno 2019, Report no: RB-242), *Culex pipiens* (Moreno 2019, Report no: RB-242.1), and *Aedes albopictus* (Moreno 2019, Report no: RB-242.8). The test method was simulated-use test in a 30 m^3 cabin. The knockdown of all three species was 100 % after 1 and 2 h. The 24 h mortality for 2 h exposure time was 98 % (*Musca*) and 100 % (*Culex, Aedes*), respectively.

The residual activity was evaluated for *C. pipiens* 4 and 7 h after application with 2 h exposure time. The mortality was 94.3 % and 94.2 % after 4 and 7 h after application, respectively. The residual activity was evaluated for *A. alpopictus* 4 and 7 h after application with 2 h exposure time. The mortality was 98.8 % and 97.6 % after 4 and 7 h after application, respectively. The residual activity was not tested for houseflies.

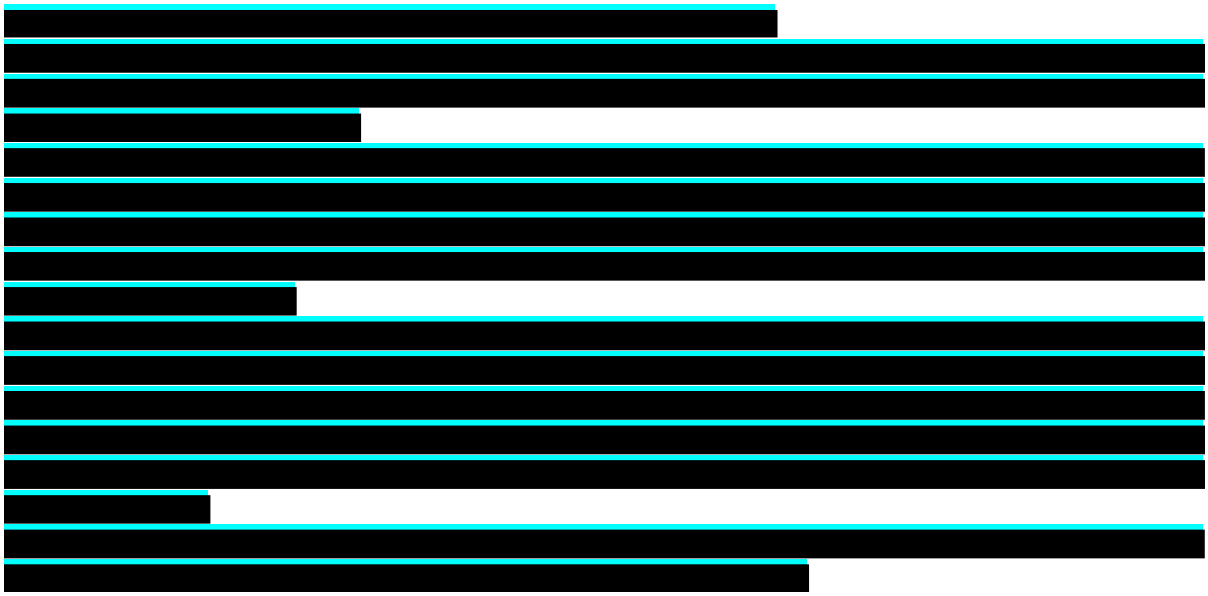
The tests demonstrate efficacy of the product used as "indoor spraying spatial treatment" against mosquitoes (*C. pipiens, A. albopictus*) and houseflies (*M. domestica*). A residual effect up to 7 h against mosquitoes (*C. pipiens, A. albopictus*) was shown.

Meta SPC 1 use # 1.18.2 Indoor use, direct spray

The indoor direct spray application was investigated with *M. domestica* (Moreno 2019, Report no: RB-242.2), *C. pipiens* (Moreno 2019, Report no: RB-242.3), *A. albopictus* (Moreno 2019, Report no: RB-242.4), *Linephitema humile* (Moreno 2019, Report no: RB-242.5), *Lasius niger* (Drago 2019, Report no: RB-242.6), and *Vespula germanica* (Drago 2019, Report no: RB-242.7).

The test method was laboratory/simulated-use test spraying directly at insects in cages or containers. Knockdown at 100 % was achieved after 5 sec (*C. pipiens, A. albopictus*) 10 sec (*M. domestica*), 14 sec (*V. germanica*), 30 sec (*L. humile*), and 2 min (*L. niger*). All species showed 100 % mortality after 24 h. Mortality at 100 % was observed for *C. pipiens* and *A. albopictus* after 2 min, for *M. domestica* after 5 min, and for *V. germanica* after 1 h.

The tests demonstrate efficacy of the product used as an "indoor direct spray" against flying insects and specifically *M. domestica, C. pipiens, A. albopictus, L. humile, L. niger* and *V. germanica*.



Meta SPC 2 use # 2.18.4 Outdoor use, direct spray

The outdoor direct spray application was investigated with *M. domestica* (Moreno 2019, Report no: RB-245.2; Drago 2019, Report no: RB-252.2), *L. humile* (Moreno 2019, Report no: RB-245.3; Moreno 2019, RB-252-5), *V. germanica* (Drago 2019, Report no: RB-245.4; RB-252-3), *L. niger* (Drago 2019, Report no: RB-245.5; RB-252-4), *S. erythrocephalum* (Moreno 2019, Report no: RB-245-6), *V. crabo* (Drago 2019, Report no: RB-245.7), *A. albopictus* (Drago 2019, Report no: RB-252) and *C. pipiens* (Drago 2019, Report no: RB-252.1).
The test method was simulated-use test spraying directly at insects in cages or containers. Knockdown at 100% was achieved after, 5 sec (*M. domestica, S. erythrocephalum*), 50 sec (*V. germanica*), 30-60 sec (*L. humile*), 1 min (*A. albopictus, C. pipiens*) and 2 min (*V. crabo*, *L. niger*). All species showed 100% mortality after 24 h. Mortality at 100% was observed for *M. domestica* after 5 min, and for *V. germanica* and *V. crabo* after 1 h.
The tests demonstrate efficacy of the product used as an "outdoor direct spray" against flying insects and specifically *M. domestica, C. pipiens, A. albopictus, L. humile, L. niger, V. germanica, V. crabo* and *S. erythrocephalum*.
Meta SPC 2 use # 2.18.5 Outdoor use, nest treatment
The outdoors wasp nest application was investigated with *Polistes gallicus* in a field test (Drago 2019, Report no: RB-245.8). The test was performed by spraying directly for 2 sec at the nest. Wasp activity was not seen after treatment from 1 day up to 2 weeks. The field test with *P. gallicus* nest is not accepted to represent *Vespula* spp. nest and a field test with *Vespula* spp. can't be waived. It is not recommended to approve this use. Furthermore a test performed on nest in holes is needed, if a generel treatment against wasp nest is claimed.

Conclusion
The tests demonstrate efficacy of the product used as:

Indoor spraying, spatial treatment; with an effect against mosquitoes and houseflies, residual efficacy up to 7 h against mosquitoes.

Indoor direct spray; against flying insects and specifically *Musca domestica, Culex pipiens, Aedes albopictus, Linephitema humile, Lasius niger and Vespula germanica*.

Outdoor direct spray; against flying insects and specifically *Musca domestica, Culex pipiens, Aedes albopictus, Linephitema humile, Lasius niger, Vespula germanica, Vespa crabo* and *Simulium erythrocephalum.*

It is not recommended to approve [redacted] outdoor treatment of wasp nests.

2.2.5.6 Occurrence of resistance and resistance management

Transfluthrin is a synthetic pyrethroid insecticide with the IRAC mode of action (MOA) classification 3A. Resistance to MOA 3A insecticides occur in multiple insect species including *Culex* spp., *Aedes* spp., *Anopheles* spp. and *Musca domestica*.
In the context of the proposed uses of this product, selection of pyrethroid resistance is not considered likely. Resistance risk assessment and development of a resistance management plan is thus not needed.

There is a demand for a general instruction:
"If the infestation persists contact a professional. Inform the registration holder if the treatment is ineffective."

2.2.5.7 Known limitations

No limitations have been identified for the products and uses in this family.

2.2.5.8 Evaluation of the label claims

The following claims would be acceptable considering the tests provided:
Indoors (meta SPC 1)

- direct spray: within a few seconds 100 % knockdown of flies, mosquitoes, wasps, ants and tropical ants / Fast killing / Fast action / Kills 100 % by contact
- spatial treatment: 100 % knockdown and kill of flies and mosquitoes
- spatial treatment: residual effect >90 % knockdown against flies and mosquitoes / kill of mosquitoes for at least 7 hours / long lasting killing action
-

Outdoors (meta SPC 2)

- direct spray: within a few seconds 100 % knockdown of flies, black flies, mosquitoes, wasps, hornets, ants and tropical ants / Fast killing / Fast action / Kills 100 % by contact

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

The product is not intended to be used with other biocidal products.

2.2.6 Risk assessment for human health

Human health effects of the a.s. Transfluthrin were evaluated by the Rapporteur Member State (RMS) The Netherlands. Details can be found in the Competent Authority Report (CAR) and in the Assessment Report (AR).

Acute toxicity tests as well as tests for skin or eye irritation and skin sensitisation have not been performed for the b.p. in the Transfluthrin aerosols BPF. The criteria for the classification of mixtures according to the Regulation 1272/2008 (CLP) were followed. According to CLP, the b.p. in the Transfluthrin aerosols BPF do not need to be classified for Acute Toxicity, Skin and Eye Irritation and Skin Sensitisation or for respiratory tract irritation or respiratory tract sensitisation.

The products in the biocidal product family are formulated as aerosols. According to the CLP regulation 1.1.3.7: In the case of the classification of mixtures covered by sections 3.1 (acute toxicity), 3.2 (skin corrosion/irritation), 3.3 (serious eye damage/eye irritation), 3.4 (respiratory or skin sensitization), 3.8 (specific target organ toxicity — single exposure) and 3.9 (specific target organ toxicity — repeated exposure), an aerosol form of a mixture shall be classified in the same hazard category as the non-aerosolised form of the mixture, provided that the added propellant does not affect the hazardous properties of the mixture upon spraying and scientific evidence is available demonstrating that the aerosolised form is not more hazardous than the nonaerosolised form. The propellant is not classified for any human health hazards.
According to the document "37th Meeting of Competent Authorities for REACH and CLP (CARACAL); Doc. CA/58/2020 Final", "In cases where the propellant or other gas is partially or fully released, the propellant or other gas is generally assumed to be separated from the other constituents of the mixture if the propellant or other gas either is not liquefied, or is liquefied and has a vapour pressure (20°C) ≥ 10 kPa". The propellant is a liquefied gas in the aerosol can, and will quickly vapourize upon release, since the vapour pressure is 872 kPA at 22°C (according to the REACH dossier). Thus, the propellant will be separated from the other constituents in the products and should not be taken into account regarding the aforementioned endpoints.

Due to the similarity of the co-formulants contained in meta SPCs 1 and 2, and taking into account that products in both meta SPCs are ready-to-use aerosol spray that only differ in the use pattern (indoors vs. outdoors), they can be clustered with view to the assessment of their potential toxicological profile.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Transfluthrin Aerosols BPF is not skin corrosive or irritating.
Justification for the value/conclusion	Based on the intrinsic properties of individual components of the biocidal product family. The additivity principle of the CLP Regulation applies to the hazard class skin corrosion/ irritation with a generic cut off for when the substances should be taken into account of 1 % (Table 1.1, in Annex I to Reg. no 1272/2008).

	Neither the active substance nor the co-formulants are classified for skin corrosion H314. The active substance Transfluthrin is classified for skin irritation H315, but is present at a maximum of 0,182% when the propellant is left out. This concentration is below the generic cut off, and Transfluthrin should not be taken into account for this endpoint. According to the RAC opinion adopted March 2021, the classification H315 for Transfluthrin is removed. The pH of the products in the product family is not extreme (≤ 2 and ≥ 11.5). Extreme pH indicates the potential to cause skin effects. Please refer to section 3.7.3 in the confidential annex for further information on classification of the biocidal product family.
Classification of the product(s) according to CLP	Transfluthrin Aerosols BPF does not require classification and labelling for skin corrosion and irritation according to Regulation (EC) No 1272/2008 (CLP).

Data waiving	
Information requirement	According to Chapter 3.1.1 "Skin corrosion or skin irritation" of the "Guidance on the Biocidal Products Regulation (BPR) Volume III, Part A: Information Requirements" (Version 1.2, May 2018), testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected.
Justification	The toxicological hazards of the a.s. and the co-formulants are known and no synergistic effects are expected. Thus, toxicological properties and the classification of the b.p. of the Transfluthrin aerosols BPF can be deduced from the respective properties of the a.s. as well as the co-formulants using the conventional method described in the guidance for classifying mixtures under the CLP Regulation. Based on the classification rules as provided for in the CLP Regulation for mixtures, b.p. of the Transfluthrin aerosols BPF do not need to be classified with respect to skin irritation / corrosion.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Transfluthrin Aerosols BPF is not eye irritating.
Justification for the value/conclusion	Based on the intrinsic properties of individual components of the biocidal product family.

	The additivity principle of the CLP Regulation applies to the hazard class serious eye damage/eye irritation with a generic cut off for when the substances should be taken into account of 1 % (Table 1.1, in Annex I to Reg. no 1272/2008). The pH of the products in the product family is not extreme (≤ 2 and ≥ 11.5). Neither the active substance nor the co-formulants are classified for eye damage H318. Three substances are classified for eye irritation H319. Only one co-formulant is taken into account because it is present at 3.51% in meta SPC 1 and at a maximum of 3.51% in meta SPC 2 when the propellant is left out. The concentration of the co-formulant is above the generic cut-off. The products shall be classified for eye irritation if ($C_{eye\text{-}irrit.}$ / 10%) ≥ 1. Since $C_{eye\text{-}irrit}$ / 10% is 0.351 for meta SPC 1 and one of the products in meta SPC 2 and 0 for one of the products in meta SPC 2, the products in the product family shall not be classified for eye irritation. Please refer to section 3.7.3 in the confidential annex for further information on classification of the biocidal product family.
Classification of the product(s) according to CLP	Transfluthrin Aerosols BPF does not require classification and labelling for eye irritation according to Regulation (EC) No 1272/2008 (CLP).

Data waiving	
Information requirement	According to chapter 3.1.2 "Eye irritation" of the "Guidance on the Biocidal Products Regulation (BPR) Volume III, Part A: information requirements" (Version 1.2, May 2018), testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected.
Justification	The toxicological hazards of the a.s. and the co-formulants are known and no synergistic effects are expected. Thus, toxicological properties and the classification of the b.p. of the Transfluthrin aerosols BPF can be deduced from the respective properties of the a.s. using the conventional method described in the CLP Regulation. Based on the classification rules as provided for in the CLP Regulation for mixtures, b.p. of the Transfluthrin aerosols BPF do not need to be classified with respect to eye irritation.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Transfluthrin Aerosols BPF is not irritating to the respiratory tract.
Justification for the conclusion	Based on intrinsic properties of individual components of Transfluthrin Aerosols BPF. Neither the active substance nor the co-formulants are classified for respiratory tract irritation H335. Please refer to section 3.7.3 in the confidential annex for further information on classification of the biocidal product family.
Classification of the product(s) according to CLP	Transfluthrin Aerosols BPF does not require classification and labelling for respiratory tract irritation according to Regulation (EC) No 1272/2008 (CLP).

Data waiving	
Information requirement	Based on the "Guidance on Information Requirements" for biocides, there are currently no standard tests and no OECD TG available for respiratory irritation and there is no testing requirement for respiratory irritation under the Biocides Regulation. Consequently respiratory irritation is not included in the testing strategies suggested.
Justification	For mixtures, testing does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected. Based on the classification rules as provided for in the CLP Regulation for mixtures, b.p. of the Transfluthrin aerosols BPF do not need to be classified with respect to tract irritation.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Transfluthrin Aerosols BPF is not skin sensitizing.
Justification for the value/conclusion	Based on intrinsic properties of individual components of Transfluthrin Aerosols BPF. Neither the active substance nor the co-formulants are classified for skin sensitization H317. Please refer to section 3.7.3 in the confidential annex for further information on classification of the biocidal product family.
Classification of the product(s) according to CLP	Transfluthrin Aerosols BPF does not require classification and labelling for skin sensitization according to Regulation (EC) No 1272/2008 (CLP), however a EUH208 statement is required.

Data waiving	
Information requirement	According to Chapter 3.1.3 "Skin sensitisation" of the "Guidance on the Biocidal Products Regulation (BPR) Volume III, Part A: information requirements" (Version 1.2, May 2018), testing on the product/mixture does not need to be conducted if: • there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected; • the available information indicates that the product should be classified for skin sensitisation or corrosion; or • the substance is a strong acid (pH < 2.0) or base (pH > 11.5)
Justification	The toxicological hazards of the a.s. and the co-formulants are known and no synergistic effects are expected. Thus, toxicological properties and the classification of the b.p. of the Transfluthrin aerosols BPF can be deduced from the respective properties of the a.s. as well as the co-formulants using the conventional method described in the guidance for classifying mixtures under the CLP Regulation. Based on the classification rules as provided for in the CLP Regulation for mixtures, b.p. of the Transfluthrin aerosols BPF do not need to be classified with respect to skin sensitization.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Transfluthrin Aerosols BPF is not sensitizing to the respiratory tract.
Justification for the value/conclusion	Neither the active substance nor the co-formulants are classified for respiratory sensitization H334, hence the products in the biocidal product family are not classified for respiratory sensitization. Please refer to section 3.7.3 in the confidential annex for further information on classification of the biocidal product family.
Classification of the product(s) according to CLP	Transfluthrin Aerosols BPF does not require classification and labelling for respiratory tract sensitization according to Regulation No 1272/2008 (CLP).

Data waiving	
Information requirement	According to Chapter 3.1.4 "Respiratory sensitisation (ADS)" of the "Guidance on the Biocidal Products Regulation (BPR) Volume III, Part A: information requirements" (Version 1.2, May 2018), testing on the product/mixture does not need to be conducted if:

	• There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected.
Justification	The toxicological hazards of the a.s. and the co-formulants are known and no synergistic effects are expected. Thus, toxicological properties and the classification of the b.p. of the Transfluthrin aerosols BPF can be deduced from the respective properties of the active substances as well as the co-formulants using the conventional method described in the guidance for classifying mixtures under the CLP Regulation. Based on the classification rules as provided for in the CLP Regulation for mixtures, b.p. of the Transfluthrin aerosols BPF do not need to be classified with respect to respiratory sensitization.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	Transfluthrin Aerosols BPF is not acute toxic by the oral route.
Justification for the selected value	Based on intrinsic properties of individual components of Transfluthrin Aerosols BPF. The additivity principle of the CLP Regulation applies to the hazard class acute toxicity with a generic cut off for when the substances should be taken into account of 0.1 % for category 1-3 and a generic cut-off of 1 % for category 4 (Table 1.1, in Annex I to Reg. no 1272/2008). One co-formulant is classified H301: Toxic if swallowed, but is present at 0.09% when the propellant is left out. This concentration is below the generic cut-off, and the co-formulant should not be taken into account. According to the RAC opinion for Transfluthrin adopted March 2021 the classification H302: Harmful if swallowed is added. Transfluthrin is present at a maximum of 0.182% when the propellant is left out in the product family, which is below the generic cut off and should not be taken into account. Please refer to section 3.7.3 in the confidential annex for further information on classification of the biocidal product family.
Classification of the product(s) according to CLP	Transfluthrin Aerosols BPF does not require classification and labelling for acute oral toxicity according to Regulation (EC) No 1272/2008 (CLP).

Data waiving

Information requirement	According to Chapter 3.1.5.1 "Acute toxicity by oral route" of the "Guidance on the Biocidal Products Regulation (BPR) Volume III, Part A: information requirements" (Version 1.2, May 2018), testing on a product/mixture does not need to be conducted if valid data on each of the components in the mixture are available sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected.
Justification	The toxicological hazards of the a.s. and the co-formulants are known and no synergistic effects are expected. Thus, toxicological properties and classification of the b.p. of the Transfluthrin aerosols BPF can be deduced from the respective properties of the a.s. as well as the co-formulants using the conventional method described in the CLP Regulation. Based on the classification rules as provided for in the CLP Regulation for mixtures, b.p. of the Transfluthrin aerosols BPF do not need to be classified with respect to acute toxicity by oral route.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Transfluthrin Aerosols BPF is not acute toxic by the inhalation route.
Justification for the selected value	Based on intrinsic properties of individual components of Transfluthrin Aerosols BPF. The additivity principle of the CLP Regulation applies to the hazard class acute toxicity with a generic cut off for when the substances should be taken into account of 0.1 % for category 1-3 and a generic cut-off of 1 % for category 4 (Table 1.1, in Annex I to Reg. no 1272/2008). Neither the active substance nor the co-formulants are classified for acute toxicity by inhalation. Please refer to section 3.7.3 in the confidential annex for further information on classification of the biocidal product family.
Classification of the product(s) according to CLP	Transfluthrin Aerosols BPF does not require classification and labelling for acute inhalation toxicity according to regulation No 1272/2008 (CLP).

Data waiving	
Information requirement	According to Chapter 3.1.5.2 "Acute toxicity by inhalation" of the "Guidance on the Biocidal Products Regulation (BPR) Volume III, Part A: information requirements" (Version 1.2, May 2018), testing on a product/mixture does not need to be conducted if valid data on each of the components in the mixture are available sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected.
Justification	The toxicological hazards of the a.s. and the co-formulants are known and no synergistic effects are expected. Thus, toxicological properties and classification of the b.p. of the Transfluthrin aerosols BPF can be deduced from the respective properties of the a.s. as well as the co-formulants using the conventional method described in CLP Regulation. Based on the classification rules as provided for in the CLP Regulation for mixtures, b.p. of the Transfluthrin aerosols BPF do not need to be classified with respect to acute toxicity by inhalation.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Transfluthrin Aerosols BPF is not acute toxic by the dermal route.

Justification for the selected value	Based on intrinsic properties of individual components of Transfluthrin Aerosols BPF. The additivity principle of the CLP Regulation applies to the hazard class acute toxicity with a generic cut off for when the substances should be taken into account of 0.1 % for category 1-3 and a generic cut-off of 1 % for category 4 (Table 1.1, in Annex I to Reg. no 1272/2008). Neither the active substance nor the co-formulants are classified for acute toxicity by dermal route, hence the products in the biocidal product family are not classified for acute toxicity by dermal route. Please refer to section 3.7.3 in the confidential annex for further information on classification of the biocidal product family.
Classification of the product(s) according to CLP	Transfluthrin Aerosols BPGF does not require classification and labelling for acute dermal toxicity according to regulation No 1272/2008 (CLP).

Data waiving	
Information requirement	According to Chapter 3.1.5.3 "Acute toxicity by dermal route" of the "Guidance on the Biocidal Products Regulation (BPR) Volume III, Part A: information requirements" (Version 1.2, May 2018), testing on a product/mixture does not need to be conducted if valid data on each of the components in the mixture are available sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected.
Justification	The toxicological hazards of the a.s. and the co-formulants are known and no synergistic effects are expected. Thus, toxicological properties and classification of the b.p. of the Transfluthrin aerosols BPF can be deduced from the respective properties of the a.s. as well as the co-formulants using the conventional method described in the CLP Regulation. Based on the classification rules as provided for in the CLP Regulation for mixtures, b.p. of the Transfluthrin aerosols BPF do not need to be classified with respect to acute toxicity by dermal route.

Information on dermal absorption

Data waiving	
Information requirement	According to chapter 3.1.6 "Guidance on the Biocidal Product Regulation (BPR) Volume III, Part A: Information Requirements," (Version 1.2, May 2018), testing on the product/mixture is not mandatory. If such data are not available, default values can be used and the EFSA Guidance Document on Dermal Absorption (EFSA, 2017) should be followed

	where applicable for the estimation of dermal absorption both for the biocidal product (b.p.) and the active substance (a.s.).
Justification	A study investigating the potential dermal absorption of the active substance transfluthrin from the b.p. of the Transfluthrin aerosols BPF is not available. According to the most recent EFSA Guidance on dermal absorption (2017), dermal absorption data on the a.s. could be used if the formulation under evaluation is very closely related to the formulation tested with regards to solvents, surfactant content, potential skin irritating properties, and a.s. content. However, due to the lack of detailed information on the available dermal absorption studies on the a.s. in the Assessment Report (AR NL; 2014), no read-across approach was applied. Therefore, the default dermal absorption value of 70% for diluted organic solvent-based formulations according to the EFSA Guidance on Dermal Absorption (2017) has been considered in the human health exposure and risk assessment for the a.s. transfluthrin

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

According to the Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Annex A, Version 4.0, December 2017) co-formulants should be considered as a SoC when:

- Classified substances that are taken into consideration when determining the classification of the product according to Directive 1999/45/EC, Article 3(3) or according to Article 11(2) of the CLP Regulation.

- Active substances, other than those included in Annex I of the BPR, for which a draft final Competent Authority Report (CAR) (with agreed reference values) is available (including draft final CARs for Product Types other than the one of the actual biocidal product under evaluation).

- Substances that enhance the effect of the active substance in the product, e.g. synergists.

- Substances that have been included in the list (the candidate list) established in accordance with the REACH Regulation, Article 59(1) or fulfil the criteria for inclusion in the candidate list, if not already covered by the criteria of Article 3(f) of the BPR. These substances should be considered SoCs if they are present in the biocidal product at a concentration ≥ 0.1%.

- Substances for which there are Community workplace exposure limits. A generic concentration cut-off value (for their presence in a product) applicable to all such substances cannot be specified. This should be determined on a case-by-case basis depending on the hazard profile, potency and exposure potential of the substance.

The BPF is not classified for human health hazards.
For some of the co-formulants an EU workplace exposure level has been set. However according to *FINAL DOCUMENT e-Consultation: Harmonized approach to consider a co-*

*formulant as a substance of concern (SoC) based on its workplace exposure limits, 29th January 2021*it was concluded that IOELVs are not relevant for the general public. Please refer to the confidential annex section 3.7.3 for more information.

Available toxicological data relating to a mixture

The toxicities of the a.s. and the co-formulants are generally known and no synergistic effects are expected. Thus, toxicological properties and the classification of the Transfluthrin-based b.p. of the Transfluthrin aerosols BPF can be deduced from the respective properties of the a.s. as well as the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation (EC) No 1272/2008 (CLP Regulation).

Since there are valid data available on each of the components in the mixture sufficiently allowing classification of the mixture and synergistic effects between any of the components are not expected, testing on the product/mixture is not essentially needed.

The acute toxicity, primary irritation as well as skin and respiratory sensitization potential have been described above. Details on the classification and labelling of each meta SPC are given in chapter 2.1.3 "Hazard and precautionary statements".

Potential endocrine disrupting properties of non-active substances

With respect to the identification of an indication of potential endocrine disrupting properties of non-active substances/components contained in the biocidal products of the Transfluthrin aerosols BPF, a tiered screening approach has been applied.

In the first screening step, all non-active substances/components considered non-relevant were pre-selected. These were for instance endogenous substances or simple food materials.

In the second screen, various databases including the US EPA comptox database were screened on the availability of information on potential endocrine disrupting properties of the respective non-active substances/components.

Based on the results obtained when applying this screening approach, the conclusion has been drawn that there is no indication for potential endocrine disrupting properties of non-active substances/components in the Transfluthrin aerosols BPF.

Details on the approaches applied for screening as well as the results obtained can be found in the Confidential Annex in the PAR and a summary provided in an EXCEL spreadsheet in the Confidential Annex.

Other

The toxicological properties of Transfluthrin for the other end points are summarized below.

<u>Germ Cell Mutagenicity, Carcinogenicity and Reproductive Toxicity</u>

Data of the a.s. transfluthrin were evaluated by the Rapporteur Member State The Netherlands (Assessment Report (AR) PT18; RMS NL; 2014). According to the AR transfluthrin is not classified with regard to mutagenicity / carcinogenicity. This is in line with the available harmonised classification in Annex VI of the CLP Regulation. However, according to the AR it is agreed that classification considering carcinogenicity will be further

discussed at ECHA. An Opinion of the Committee for Risk Assessment (RAC Opinion) was adopted March 18th 2021, proposing a classification of transfluthrin as Carc. 2; H351 "Suspected of causing cancer" but the entry is not included in CLP annex VI yet. However, since the concentration of transfluthrin in the b.p. of the Transfluthrin aerosols BPF is below the generic concentration limit of 1% as specified in the CLP Regulation, classification of the mixture as Category 2 carcinogen would not be required.

It is stated in the SDS for one co-formulant that it contains < 0.1% 1,3-butadiene and K note can be applied: The classification as a carcinogen or mutagen need not apply if it can be shown that the substance contains less than 0.1% w/w 1,3-butadiene (EINECS No 203-450-8). Neither the mixture nor the products in the product family shall be classified as carcinogenic.

Thus, the b.p. of the Transfluthrin aerosols BPF do not need to be classified with respect to mutagenicity or carcinogenicity.

Reproductive Toxicity

Neither the active substance or the co-formulants are classified for reproductive toxicity, hence the biocidal products in the family are not classified for reproductive toxicity.

Thus, the b.p. of the Transfluthrin aerosols BPF do not need to be classified with respect to reproductive toxicity.

Aspiration hazard

According to the CLP Regulation a mixture which contains a total of 10% or more of a substance or substances classified as Asp. Tox. 1, and has a kinematic viscosity of 20.5 mm²/s or less, measured at 40 °C, shall be classified as Asp. Tox. 1; H304.

Data of the a.s. transfluthrin were evaluated by the Rapporteur Member State (RMS) The Netherlands (AR PT18; RMS NL; 2014). According to the AR, transfluthrin is not classified with regard to aspiration hazard (toxicity). This is in line with the available harmonised classification in Annex VI of the CLP Regulation. According to the RAC opinion for Transfluthrin adopted March 2021 Transfluthrin is not classified H304.

However, two co-formulants in the b.p. of the Transfluthrin aerosols BPF are classified as Asp. Tox. 1; H304: "May be fatal if swallowed and enters airways" according to their respective MSDSs. The additivity approach applies for this endpoint, but they do not exceed 10% neither in Meta SPC 1 nor in Meta SPC 2 (as the two organic solvents classified H304 will be used ***alternatively*** in meta SPC 2, and that the maximum total amount of organic solvent classified H304 will not exceed 9.934%). Thus, the b.p. of the Transfluthrin aerosols BPF do not need to be classified with respect to aspiration hazard (toxicity).

Please refer to section 3.7.3 in the confidential annex for further information on classification of the biocidal product family.

Specific Target Organ Toxicity – Single Exposure (STOT-SE 3)

Data of the a.s. transfluthrin were evaluated by the Rapporteur Member State the Netherlands (AR PT18; RMS NL; 2014). According to the AR transfluthrin is not classified with regard to specific target organ toxicity (single exposure). This is in line with the available harmonised classification in Annex VI of the CLP Regulation. An Opinion of the Committee for Risk Assessment (RAC Opinion) was adopted March 18th 2021 considering classification of transfluthrin as STOT SE 1; H370 "Causes damage to organs" but the entry is not included in CLP annex VI yet. However, since the concentration of transfluthrin in the b.p. of the Transfluthrin aerosols BPF is below the GCL of 10% when the propellant is left out as specified in the CLP Regulation classification of the mixture as STOT SE 1 or STOT SE 2 would not be required.

With regards to the co-formulant classified as STOT SE 3; H336 (narcotic effects) its concentration in the b.p. of the Transfluthrin aerosols BPF is below the GCL of 20% when the propellant is left out as specified in the CLP Regulation regarding classification of the mixture as STOT SE Category 3.

Thus, the b.p. of the Transfluthrin aerosols BPF do not need to be classified with respect to specific target organ toxicity (single exposure).

Please refer to section 3.7.3 in the confidential annex for further information on classification of the biocidal product family.

Specific Target Organ Toxicity – Repeated Exposure (STOT-RE)

Data of the a.s. transfluthrin were evaluated by the Rapporteur Member State the Netherlands (AR PT18; RMS NL; 2014). According to the AR transfluthrin is not classified with regard to specific target organ toxicity (repeated exposure). This is in line with the available harmonised classification in Annex VI of the CLP Regulation. The Risk Assessment (RAC Opinion) adopted March 18th 2021 does not include the RMS submitted proposal for a revised harmonised classification considering classification of transfluthrin as STOT RE 2;

H373 "May cause damage to organs through prolonged or repeated exposure". Therefore, the current harmonised classification and labelling according to Annex VI of the CLP Regulation is taken into account. Furthermore, since the concentration of transfluthrin in the b.p. of the Transfluthrin aerosols BPF is below the GCL of 10% when the propellant is left out as specified in the CLP Regulation classification of the mixture as STOT RE 2 would not be required.
Neither the active substance or non-active substances in the products allow for classification for STOT RE of the b.p. of the Transfluthrin aerosols BPF as they are either not classified themselves for this endpoint or they are present in the product at a concentration below the cut off value according to the calculation rules laid down in Reg . (EC) no. 1272/2008.
Thus, the b.p. of the Transfluthrin aerosols BPF do not need to be classified with respect to specific target organ toxicity (repeated exposure).

Please refer to section 3.7.3 in the confidential annex for further information on classification of the biocidal product family.

Food and feedingstuff studies

The b.p. of the Transfluthrin aerosols BPF are intended for non-professional applications and are used in the product type (PT) 18: Insecticides, acaricides and products to control other arthropods. Considering the applications of transfluthrin containing products, and the proposed risk mitigation measure "Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets", a dietary and/or secondary exposure towards potential residues of transfluthrin via food in contact with contaminated surfaces is not considered relevant. Thus, a dietary risk assessment for exposure to the a.s. was not performed and no food and feeding stuff studies are required.

2.2.6.2 Exposure assessment

The b.p. in this Transfluthrin aerosols BPF are ready-to-use pre-pressurised aerosols applied by non-professional users by spraying as an insecticide in product type (PT) 18 against mosquitoes and flies (flying insects) indoors, and against mosquitoes, flies, wasps (flying insects) and ants (crawling insects) outdoors.

During the application of the b.p. by non-professional users exposure could theoretically occur by the dermal and inhalation routes. However, the potential for the exposure of users through ingestion of the b.p. during application is considered negligible and is, thus, not relevant. With regards to the secondary exposure scenarios, the three routes of exposure will be assessed.

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

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

In the intended exposure scenarios, a quantitative risk assessment is provided for systemic effects of Transfluthrin considering the relevant reference values, e.g. acceptable exposure level (AEL) for medium-term exposure (non-professional users).
Risk characterisation for local effects is triggered if a biocidal product is classified for local effects. Transfluthrin Aerosols BPF is not classified for local effect end-points (including sensitisation), and a risk assessment for local effects is not required. However pyrethroids are known to cause paraesthesia (burning and prickling of the skin without irritation) and the following instruction is included "Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice".

Since no data on the dermal absorption are available and as due to the lack of detailed information on the available dermal absorption studies, no read-across approach can be applied based on the data reported in the Assessment Report on Transfluthrin (AR NL, 2014), the default dermal absorption value of 70% according to the most recent EFSA Guidance on Dermal Absorption (2017) has been applied in the human health exposure and risk assessment on Transfluthrin.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
[1]	Air space application indoors	Primary exposure Low pressure spraying of the ready-to-use product	Non-professionals
[redacted]	[redacted]	[redacted]	[redacted]
[3]	Direct spraying on insects	Primary exposure Direct spraying on the insect during 1 second for an instant action	Non-professionals
[4]	Direct spraying on wasp nests	Primary exposure Direct spraying on the nest during 2 second	Non-professionals
[5]	Inhalation exposure to volatilised residues	Secondary exposure Post-application exposure of general public will take place *via* the inhalation route	General public (Adults, toddlers)
[6]	Dermal exposure to residues on surfaces	Secondary exposure Post-application exposure of general public will take place *via* the dermal route	General public (Adults, toddlers)
[7]	Oral exposure to residues on surfaces	Secondary exposure Post-application exposure of children will take place *via* the dermal and oral routes taking into account their hand-to-mouth behaviour	General public (Toddlers)

Industrial exposure

No industrial exposure is foreseen.

Professional exposure

No professional exposure is foreseen.

Non-professional exposure

Meta SPC 1 contains one product H21024 and is intended to be used indoor for spatial treatment and direct spraying on insects. The discharge rate of the product varies with the products service life (how much product is left in the can). For the product H21024 the average discharge rate is 1.6 g product/second, and the minimum discharge rate is 1.3 g/s. It is important that the spray duration corresponds to the tested efficient amount of product. For spatial treatment indoor an amount of 11.6 g product must be used, and to ensure that this amount is used, spraying must be done for 9 seconds. (11.6 g product / 1.3 g product per second = 8.92 seconds = 9 seconds). In some cases the exact minimum efficient product amount will be used, and in some cases more product is used because the discharge rate is higher. However if less than 11.6 g of product is used the product will not be effective and development of resistance could occur. In the risk assessment for human health and the environment the average discharge rate is used to assess if the product is safe to use. The product is used several times during the summer half-year and, the discharge rate will vary, and it is appropriate to use the average discharge rate. In the exposure scenario Indoor use, spatial treatment it is assumes that the spray duration is 9 seconds and the average discharge rate is 1.6 g / s which corresponds to 14.4 g product used. (9 seconds x 1.6 product per second).
Meta SPC 2 contains two products H21021 and H21025 which is intended to be used [redacted] direct spraying on insects and for nest treatment. The discharge rate of the products varies with the products service life (how much product is left in the can). For the product H21021 the minimum discharge rate is 1.23 g/s and the average discharge rate is 1.5 g/s. For the product H21025 the minimum discharge rate is 1.3 g/s and the average discharge rate is 1.7 g/s. For the exposure scenario direct spraying on insects indoor and outdoor the products can be used for 1 seconds 10 times a day corresponding to 10 seconds. The worst case discharge rate is 1.7 g/s, hence 17 g of product can be used in this scenario (10 seconds x 1.7 g product per second).
In the secondary exposure scenario Inhalation exposure of volatilised residues the worst case scenario is direct spraying on insects indoor and outdoor where 17 g of product is used and spraying is done for 10 seconds.
In the secondary exposure scenario Dermal exposure to residues on surfaces, we find that the spatial treatment indoor [redacted] are the worst case scenarios regarding dermal exposure and the product amount and spray duration are used from the considered worst case scenarios. This also applies for the secondary exposure scenario Oral exposure to residues on surfaces.

Scenario [1]: Air space application indoors

Description of Scenario [1]
Use # 1.18.1 Indoor use, spatial treatment The b.p. in this Transfluthrin aerosols BPF are sold as an aerosol spray to be used indoors against mosquitoes and flies for air space application. The calculations below represent a conservative scenario with regards to the intended application of the b.p. *Inhalation exposure:* The primary exposure of the non-professional users towards aerosols of Transfluthrinduring application of the insecticide is assessed by ConsExpo Web with the '*Air space-Sprays*' model according to the Pest Control Products Fact Sheet. The user is assumed to stay in the treated room for 4 h after application. To calculate the exposure

of the user during the application, the 'spray' model is used for the inhalatory exposure and the 'direct product contact' model is used for the dermal exposure. The label of the product recommends spraying 9 seconds to cover around 30 m^3. The default scenarios were adapted in terms of those spray duration (9 seconds) and room volume, as well as mass generation rate (1.6 g/s), and in terms of body weight (adult: 60 kg) and inhalation rate according to HEAdHoc Recommendation no. 14. The use frequency was set to "1 per day" so that the reported exposures reflect the recommendation of use in the label.

Dermal exposure:

The exposed skin surface is comprised of the back of the one hand holding the bottle/can. This is approximately 210 cm^2, i.e. 1/4 of the surface of both hands as given in the General Fact Sheet (Updated version 2014). A dermal penetration of 70% is considered for Transfluthrin. No personal protective equipment was considered.

The following parameters are considered:

	Parameters		Value
Tier 1	Concentration of a.s. (%)		0.104
	Vapour pressure (kPa)	Transfluthrin (1)	9×10^{-4}
	Molecular weight (g/mol)	Transfluthrin	371
	Inhalation exposure: Parameters used for: 'Air space-Sprays' model - Exposure to spray	Spray duration (s) (3)	9
		Exposure duration (min) (4)	240
		Room volume (m^3) (4)	30
		Room height (m) (4)	2.5
		Ventilation rate (1/hr) (4)	0.5
		Mass generation rate (g/s) (5)	1.6
		Inhalation rate (m^3/day) (6)	16
	Inhalation exposure (SoCs only)**:** Parameters used for 'Evaporation mode of release' model - Exposure to vapours	Product amount (g) (7)	14.4
		Spray duration (s) (3)	9
		Exposure duration (min) (4)	240
		Room volume (m^3) (4)	30
		Ventilation rate (1/hr) (4)	0.5
		Mass transfer coefficient (m/hr) (8)	10
		Release area (m^2) (4)	12
	Dermal exposure:	Exposed area (cm^2) (9)	210
		Release duration (s) (3)	9

	Parameters used for: direct product contact model	Contact rate (mg/min) [4]		269
		Dermal absorption (%) [10]	Transfluthrin	70
		Body weight (kg) [6]		60
Tier 2	n.a.			n.a.
Tier 3	n.a.			n.a.

[1] AR NL 2013
[2] MSDS
[3] Recommended spray duration according to label, determined based on the final/minimum discharge rate in meta SPC 1, in order to ensure that the product is efficacious both at the beginning and end of the service life of the biocidal product: 11.6 g / 1.3 g/s = 9 s
[4] Pest Control Products Fact Sheet
[5] Measured mean discharge rate in meta SPC 1
[6] Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure Default human factor values for use in exposure assessments for biocidal products
[7] Worst case product amount estimated from the mean discharge rate in meta SPC 1 (1.6 g/s) and the worst case spray duration (9 s): 1.6 g/s x 9 s = 14.4 g
[8] New value recommended in the Cleaning Products Fact Sheet Default - Updated version 2018
[9] General Fact Sheet General default parameters for estimating consumer exposure - Updated version 2014
[10] Default values in accordance with the Guidance on Dermal Absorption, EFSA 2017

Calculations for Scenario [1]

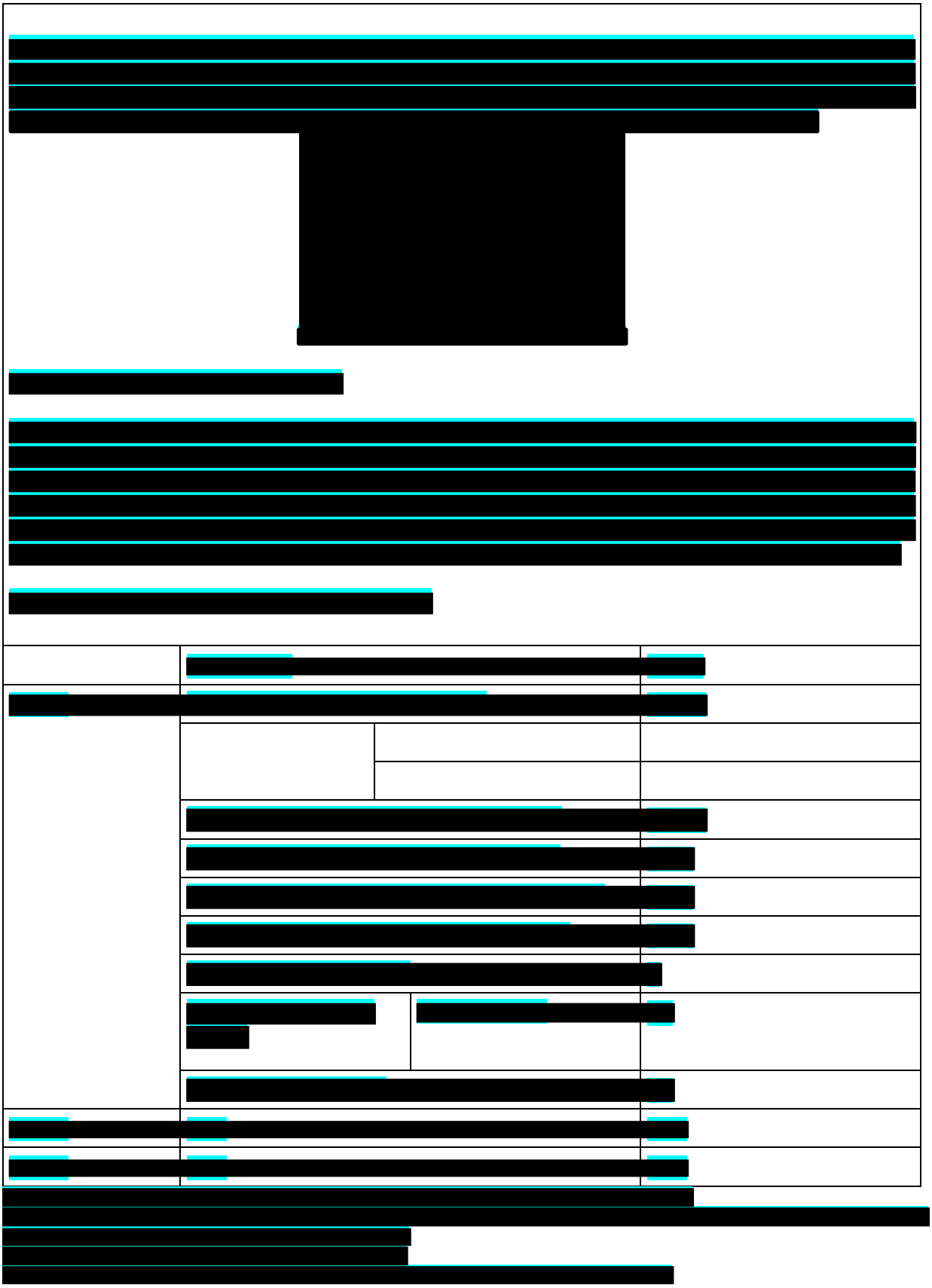
Summary table: systemic exposure towards Transfluthrin from non-professional uses [mg/kg bw/day]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	1 / No PPE	1.50×10^{-4}	4.90×10^{-4}	-	**6.40×10^{-4}**

Further information and considerations on scenario [1]

Risk characterisation for local effects is triggered if a biocidal product is classified for local effects. Transfluthrin Aerosols BPF is not classified for local effect end-points (including sensitisation), and a risk assessment for local effects is not required. However pyrethroids are known to cause paraesthesia (burning and prickling of the skin without irritation) and the following instruction is included "Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice".

[redacted]

[redacted]



Calculations for Scenario [2]

Summary table: systemic exposure towards Transfluthrin from non-professional uses [mg/kg bw/day]					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Further information and considerations on scenario [2]

Risk characterisation for local effects is triggered if a biocidal product is classified for local effects. Transfluthrin Aerosols BPF is not classified for local effect end-points (including sensitisation), and a risk assessment for local effects is not required. However pyrethroids are known to cause paraesthesia (burning and prickling of the skin without irritation) and the following instruction is included "Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice".

Scenario [3]: Direct spraying on insects

Description of Scenario [3]		
Use # 1.18.2 Indoor use, direct spray & Use # 2.18.4 Outdoor use, direct treatment The b.p. in this Transfluthrin aerosols BPF are sold as an aerosol spray to be used as direct application on the insect, against mosquitoes, flies, ants and wasps indoors, and against mosquitoes, flies, black flies, ants, wasps and hornets outdoors. The product is applied as direct spraying on the insect during 1 second for an instant action. As the indoor use is considered worst case with respect to inhalation exposure, exposure estimes are included only for the indoor applications. The product is applied as direct spraying on the insect and can be used a maximum of 10 times per day. Thus, the spray duration of 10 s (= 0.17 min) and the product amount of 17 g (1.7 g/s x 10 s) are considered. Inhalation and dermal exposure: For the estimation of the primary dermal and inhalation exposure towars aerosols of Transfluthrin during aerosol spraying, the hand-held low pressure (1-3 bar) spraying model (BHHEM, 2015, p. 204) is applied. This model covers spot applications, and thus, it reflects adequately the intended application of the biocidal product. The following parameters are considered:		
	Parameters	Value

Tier 1	Concentration a.s. (% (w/w))			0.104
	Parameters used for the hand-held low pressure (1-3 bar) spraying model	Potential body exposure (mg/min) (1)		92
		Potential hand exposure (mg/min) (1)		181
		Potential inhalation exposure (mg/m³) (1)		104
		Inhalation / respiration rate (m^3/h) (2)		1.25
		Duration of task (min) (3)		0.17
		Dermal absorption (%) (4)	Transfluthrin	70
	Inhalation exposure: Parameters used for 'Evaporation mode of release' model - Exposure to vapours	Product amount (g) (5)		17
		Spray duration (min) (3)		0.17
		Exposure duration (min) (6)		240
		Room volume (m^3) (6)		30
		Ventilation rate (1/hr) (6)		0.5
		Mass transfer coefficient (m/hr) (7)		10
		Release area (m^2) (6)		12
	Body weight (kg) (2)			60
Tier 2	n.a.			n.a.
Tier 3	n.a.			n.a.

[1] Recommendation No. 6 of the BPC Ad hoc Working Group on Human Exposure
[2] Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure Default human factor values for use in exposure assessments for biocidal products
[3] Maximum spray duration, considering 10 applications of 1s per day as maximun
[4] Default value in accordance with the Guidance on Dermal Absorption, EFSA 2017
[5] Worst case product amount estimated from the mean discharge rate in meta SPC 2 (1.7 g/s) and the worst case spray duration (10 s): 1.7 g/s x 10 s = 17 g
[6] Pest Control Products Fact Sheet
[7] New value recommended in the Cleaning Products Fact Sheet Default - Updated version 2018

Calculations for Scenario [3]

Summary table: systemic exposure towards Transfluthrin from non-professional uses [mg/kg bw/day]					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3]	1 / No PPE	6.26×10^{-6}	5.52×10^{-4}	-	**5.58×10^{-4}**

Further information and considerations on scenario [3]

Risk characterisation for local effects is triggered if a biocidal product is classified for local effects. Transfluthrin Aerosols BPF is not classified for local effect end-points (including sensitisation), and a risk assessment for local effects is not required. However pyrethroids are known to cause paraesthesia (burning and prickling of the skin without irritation) and the following instruction is included "Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice".

Scenario [4]: Direct spraying on wasp nests

Description of Scenario [4]
Use # 2.18.5 Outdoor use, nest treatment The b.p. in this Transfluthrin aerosols BPF are sold as an aerosol spray to be used outdoors for direct application on wasp nest during 2 second for an instant action. The exposure pattern can be considered the same as in the scenario [3] above and thus the same assumptions are made in this scenario [4] for the estimation of human exposure, with the exception of exposure duration. Inhalation and dermal exposure: For the estimation of the primary dermal and inhalation exposure towars aerosols of Transfluthrin during aerosol spraying, the hand-held low pressure (1-3 bar) spraying model (BHHEM, 2015, p. 204) is applied. This model covers spot applications, and thus, it reflects adequately the intended application of the biocidal product. The following parameters are considered:

	Parameters			Value
Tier 1	Concentration a.s. (% (w/w))			0.104
	Parameters used for the hand-held low pressure (1-3 bar) spraying model	Potential body exposure (mg/min) (1)		92
		Potential hand exposure (mg/min) (1)		181
		Potential inhalation exposure (mg/m³) (1)		104
		Inhalation / respiration rate (m^3/h) (2)		1.25
		Duration of task (s) (3)		2
		Dermal absorption (%) (4)	Transfluthrin	70
	Body weight (kg) (2)			60

Tier 2	n.a.	n.a.
Tier 3	n.a.	n.a.

[1] Recommendation No. 6 of the BPC Ad hoc Working Group on Human Exposure
[2] Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure Default human factor values for use in exposure assessments for biocidal products
[3] Recommended spray duration according to label, according to the efficacy trial
[4] Default value in accordance with the Guidance on Dermal Absorption, EFSA 2017

Calculations for Scenario [4]

Summary table: systemic exposure towards Transfluthrin from non-professional uses [mg/kg bw/day]					
Exposure scenario	**Tier/ PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [4]	1 / No PPE	Aerosol: 1.25×10^{-6}	Aerosol: 1.10×10^{-4}	-	Aerosol: **1.11×10^{-4}**

Further information and considerations on scenario [4]

Risk characterisation for local effects is triggered if a biocidal product is classified for local effects. Transfluthrin Aerosols BPF is not classified for local effect end-points (including sensitisation), and a risk assessment for local effects is not required. However pyrethroids are known to cause paraesthesia (burning and prickling of the skin without irritation) and the following instruction is included "Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice".

Combined scenarios

Although unlikely, exposure may occur to the same person applying the biocidal product as air space application and direct spraying on the insect indoors - [redacted], direct spraying on the insect and direct spraying on the wasp nest outdoors. Therefore, scenario [1] and [3], and scenario [2], [3] and [4] have to be combined. However, a combination of all relevant scenarios includes the exposure estimates of the secondary exposure. Therefore, the combined exposure, including as well scenarios [5] and [6] is reported in the section secondary exposure below.

Exposure of the general public

After the application it is assumed that secondary exposure affects adults, children, toddlers and infants via inhalation of volatilised residues and via dermal contact with contaminated areas. Moreover, post-application exposure of children will take place via the oral and dermal route as a result of the hand-to-mouth transfer.

Scenario [5]: Inhalation exposure of volatilised residues

Description of Scenario [5]
The vapour pressure of Transfluthrin is 9 x 10^{-4} Pa at 20 °C (AR NL 2013), indicating relatively low volatility. According to HEEG opinion 13 (2013), inhalation exposure of volatilised biocide a.s., that is the amount of a.s. volatilizing from surfaces after application with the product, can be considered negligible if the following is true for a toddler (worst case compared to adults) based on an inhalation rate of 8 m³/24 h and a bw of 10 kg and using an AEL in mg/kg bw/d: $0.328 \times MW \times VP / AEL_{long\text{-}term} \leq 1$ where MW denotes the molecular weight (371.2 g/mol) and VP the vapour pressure in Pa (9 x 10^{-4} Pa at 20 °C). Considering an $AEL_{Long\text{-}term}$ of 0.01 mg/kg bw/d, the assessment results in: 0.328 x 371.2 g/mol x 9 x 10^{-4} / 0.01 mg/kg bw/d = 10.96 and thus exceeds 1. Therefore the inhalation risk for toddlers as well as for infants, children and adults is not negligible in long-term exposure. Thus, the secondary exposure of members of the general public to Transfluthrin after the application of the insecticide indoors as direct spray treatment (Use # 1.18.2) is assessed by ConsExpo Web with the '*Exposure to vapour: Evaporation mode of release*' model according to the Pest Control Products Fact Sheet. The direct spray treatment (Use # 1.18.2) represents a worst case compared to the spatial treatment (Use # 1.18.1) in terms of amount of product used. As a worst case it is assumed that the bystander stays in the treated room for 12 h after application. To calculate the exposure of the bystander after the application, the 'exposure to vapour' model is used for the inhalatory exposure. The default scenario was adapted in terms of body weight (adult 60 kg and child 10 kg) and inhalation rate (adult 16 m^3/d and child 8 m^3/d) according to HEAdHoc Recommendation no. 14, and the use frequency was set to "1 per day" so that the reported exposures reflect the recommendation of use in the label. Since the solvent in the product is a mixture of water, hydrocarbons and acetone, the molecular weight of the matrix is set at 36 g/mol. The calculations below represent a conservative scenario with regards to the intended application of the b.p. indoors. With regards to the outdoors application, the TNsG on Human Exposure, Part 2, page 272 indicates for insect repellents: "*The inhalation route is excluded due to the use outdoors, and because use indoors only takes place in the summer in situations where there is a high ventilation rate. On these grounds, the* ***inhalation exposure to aerosol sprays is also considered to be negligible***". This same argument can be applied for the b.p. in this BPF intended to be used as spray aerosols outdoors. Therefore, indoor application is calculated as worst case and is also considered to cover the outdoor application. The following parameters are considered:

	Parameters	Value
Tier 1	Concentration of a.s. (%)	0.104

	Vapour pressure (kPa)	Transfluthrin	9×10^{-7}
	Molecular weight (g/mol)	Transfluthrin	371
	Parameters used for 'Evaporation mode of release' model - Exposure to vapours	Product amount (g) (1)	17
		Emission duration (h) (2)	24
		Exposure duration (min) (2)	720
		Room volume (m^3) (3)	30
		Ventilation rate (1/hr) (3)	0.5
		Mass transfer coefficient (m/hr) (4)	10
		Release area (m^2) (3)	12
	Body weight (kg) (5)	Adult	60
		Toddler	10
Tier 2	n.a.		n.a.
Tier 3	n.a.		n.a.

[1] Worst case product amount estimated from the mean discharge rate in meta SPC 2 (1.7 g/s) and the worst case spray duration (10 s): 1.7 g/s x 10 s = 17 g
[2] Worst case assumptions
[3] Pest Control Products Fact Sheet
[4] New value recommended in the Cleaning Products Fact Sheet Default - Updated version 2018
[5] Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure Default human factor values for use in exposure assessments for biocidal products

Calculations for Scenario [5]

Summary table: systemic exposure towards Transfluthrin from non-professional uses [mg/kg bw/day]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [5] Adult	Tier 1 / No PPE	1.6×10^{-6}	-	-	**1.6×10^{-6}**
Scenario [5] Toddler	Tier 1 / No PPE	4.80×10^{-6}	-	-	**4.80×10^{-6}**

Further information and considerations on scenario [5]

Risk characterisation for local effects is triggered if a biocidal product is classified for local effects. Transfluthrin Aerosols BPF is not classified for local effect end-points (including sensitisation), and a risk assessment for local effects is not required. However pyrethroids are known to cause paraesthesia (burning and prickling of the skin without irritation) and the following instruction is included "Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice".

Scenario [6]: Dermal exposure to residues on surfaces

Description of Scenario [6]

Secondary dermal exposure towards residues of Transfluthrin is expected to occur for people who stay in a treated room via direct contact to deposits of the a.s. on the surfaces. It is assumed that the contact time is 2.5 hours, which is the average value of the two suggested contact times in HEEG opinion 7 (found in ConsExpo and US EPA Standard Operating Procedure).

Based on TNsG part 2, p. 257 (Defaults for non-professional use and residential exposure to biocides) the dislodgeable residues of Transfluthrin are calculated from the emission formulation rate (1.6 g/s indoors and 1.7 g/s outdoors), the use duration (9 s indoors and outdoors), the airborne fraction (100% for air space spray indoors [redacted]), the transfer coefficient (18%[1]) and a surface area of 12 m² indoors [redacted]

Dislodgeable residues$_{indoors}$ = (1.6 g/s × 9s × 100% × 18%) / 12 m² = 0.216 g/m² = 0.0216 mg/cm²

[redacted]

The estimation herein assumes that the dislodgeable residue transfer is greater from [redacted] spatial treatment than direct spot treatment (i.e., residues from spraying an insect), and therefore exposure to these residues are considered as the worst case for this scenario.			
	Parameters		Value
Tier 1	Concentration of a.s. (%)		0.104
	Dislodgeable residues (mg/cm²)	Indoors	0.0216
		Outdoors	0.0041
	Transfer coefficient (cm²/h)(2)	Adult	7800
		Toddler	2000
	Contact duration (h/day)(3)		2.5
	Dermal absorption (%)(4)		70
	Body weight (kg) (5)	Adult	60
		Toddler	10
Tier 2	n.a.		n.a.
Tier 3	n.a.		n.a.

[1] Biocides Human Health Exposure Methodology
[2] According to Recommendation no. 12 of the BPC Ad hoc Working Group on Human Exposure New default values for indoor Transfer Coefficient
[3] HEEG opinion 7 on Choice of secondary exposure parameters for PTs 2, 3 and 4
[4] Default value in accordance with the Guidance on Dermal Absorption, EFSA 2017
[5] Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure Default human factor values for use in exposure assessments for biocidal products

Calculations for Scenario [6]

Summary table: systemic exposure towards Transfluthrin from non-professional uses [mg/kg bw/day]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [6] Adult indoors	Tier 1 / No PPE	-	5.11×10^{-3}	-	**5.11×10^{-3}**
Scenario [6] Adult outdoors	Tier 1 / No PPE	-	9.70×10^{-4}		**9.70×10^{-4}**

Scenario [6] Toddler indoors	Tier 1 / No PPE	-	7.86×10^{-3}	-	**7.86×10^{-3}**
Scenario [6] Toddler outdoors	Tier 1 / No PPE	-	1.49×10^{-3}		**1.49×10^{-3}**

Further information and considerations on scenario [6]

Risk characterisation for local effects is triggered if a biocidal product is classified for local effects. Transfluthrin Aerosols BPF is not classified for local effect end-points (including sensitisation), and a risk assessment for local effects is not required. However pyrethroids are known to cause paraesthesia (burning and prickling of the skin without irritation) and the following instruction is included "Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice".

Scenario [7]: Oral exposure to residues on surfaces

Description of Scenario [7]

Small children exhibit a great deal of hand-to-mouth (HTM) contact. Therefore, a part of the Transfluthrin residues present on the hands will be dislodged by saliva and eventually ingested. To provide a realistic estimate of this exposure, data on the frequency and extent of HTM contact of small children was used for the exposure estimate. Observations of children by videotape and subsequent analyses have shown that the average hand area contacting the mouth is 4.5 cm² per mouthing event for 1–2 year olds (reviewed in HESI, 2004, HEEG Opinion 7, (2009); see table below).

Surface area contacting the mouth per event as a function of age (from HESI, 2004)

Age [years]	Hand area contacted per HTM event [cm²/event]	
	Average	Range
1	4.1	2.6–5.8
2	4.9	4.0–6.7
1–2	4.5	2.6–6.7
3	7.9	6.5–10.3
4	7.4	4.0–10.0
3–4	7.7	4.0–10.3

Because of the low water solubility of Transfluthrin (0.057 mg/L (20 °C), it is unlikely that Transfluthrin can be completely dislodged from the hand with a finite number of hand-to-mouth contacts. Hence, the assumption of 100% removal efficiency from skin by saliva is excessively conservative. The following reasoning is intended to derive a more realistic estimate of saliva removal efficiency from human skin.

Measurements of the removal efficiency of pesticide residues by saliva were carried out for several different chemical classes (Camann *et al.*, 1995(1)). Because saliva predominantly consists of water, a reasonable assumption is that water solubility may

be an important rate limiting factor in removal efficiency of saliva; however, competing for solubilisation by saliva is the chemical's adsorption to skin and, to some degree, absorption through skin. Clearly, the amount of a chemical that is adsorbed (e.g., bound to the stratum corneum) and dermally absorbed would no longer be available for removal by saliva, and thus, the degree of adsorption is in competition with solubilisation by saliva and incidental ingestion. As shown in the table below, summary data for several pesticides suggest that removal efficiency by human saliva or artificial saliva is similar.

Removal efficiency of saliva for several compounds.

Pesticide	Water solubility [mg/L]	Reference	Removal by saliva [%]	Reference
Pyrethrins I	0.2 (temperature not specified)	HSDB[a]	50	Camann *et al.*, 1995
PBO	14.3 (at 25°C)	HSDB[a]	50	Camann *et al.*, 1995
Chlorpyrifos	1.4 (at 25°C)	HSDB[a]	50	Camann *et al.*, 1995

a) http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB

Based on the data shown, it may safely be assumed that Transfluthrin will not be completely removed via saliva and mouthing (simulated by wiping in Camann et al., 1995) based on data for other pyrethrins. Thus, the saliva removal efficiency of Transfluthrin would be expected not to be higher than 50%.

The bioavailability (oral absorption) of ingested Transfluthrin is 100% (AR NL 2014). HESI (2004) contains data on the frequency of hand-to-mouth events for children during indoor play. In a study conducted in 2002, HTM behaviour in 72 children (37 males, 35 females) was examined. Children (11–60 months of age) were observed for 5–60 minutes per day for 1–6 days. Eating events were specifically excluded from the post videotaping quantitation of HTM frequency. Children older than 24 months had a lower mouthing frequency than younger children. Therefore, only children below that age were considered for the current exposure assessment. For 1-2 year olds, a mean hand-to-mouth contact frequency of 18 events per hour was determined. The total daily duration of HTM behaviour was estimated to be 2 hours. This gives a daily number of 36 HTM events.

Based on these assumptions, oral exposure of infants towards Transfluthrin via HTM transfer can be calculated as presented in the table below.

$$E_{oral} = DF \times M \times SA \times RE \times F \times AR_{oral} / BW$$

where:

E_{oral} = Oral exposure (mg/kg bw/d)
DF = Dislodgeable residues [mg/cm²]
M = Concentration (%)
SA = Finger tip surface area (cm²)
RE = Efficiency of removal by saliva from skin (%)
F = Number of hand-to-mouth contacts (d^{-1})
AR_{oral} = Oral absorption rate (%)
BW = Body weight (kg)

	Parameters		Value
Tier 1	Concentration of a.s. (%)		0.104
	Dislodgeable residues (mg/cm²)	Indoors	0.0216
		Outdoors	0.0041
	Finger tip surface area (cm²)		4 (1)
	Efficiency of removal by saliva from skin (%)		50 (2)
	Number of hand-to-mouth contacts (d^{-1})		36 (3)
	Oral absorption (%)		100 (4)
	Body weight (kg)	Toddler	10 (5)
Tier 2	n.a.		n.a.
Tier 3	n.a.		n.a.

[1] According to the Do-It-Yourself Products Fact Sheet (RIVM report 320104007/2007) (which indicates a surface area of a fingertip of 1 cm^2) and considering 4 fingers as a worst case.
[2] Camann DE, Majumadar TK and Geno P, 1995. Determination of pesticide removal efficiency from human hands wiped with gauze moistened with three salivary fluids. Final Report to EPA by ManTech under Contract 68-D5-0049.
[3] See justification above
[4] AR NL 2014
[5] Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure Default human factor values for use in exposure assessments for biocidal products

Calculations for Scenario [7]

Summary table: systemic exposure towards Transfluthrin from non-professional uses [mg/kg bw/day]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [7] Indoors	Tier 1 / No PPE	-	-	1.62×10^{-4}	**1.62×10^{-4}**
Scenario [7] Outdoors	Tier 1 / No PPE	-	-	3.07×10^{-5}	**3.07×10^{-5}**

Further information and considerations on scenario [7]

Risk characterisation for local effects is triggered if a biocidal product is classified for local effects. Transfluthrin Aerosols BPF is not classified for local effect end-points (including sensitisation), and a risk assessment for local effects is not required. However pyrethroids are known to cause paraesthesia (burning and prickling of the skin without irritation) and

the following instruction is included "Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice".

Combined scenarios

As indicated in the chapter for non-professional users, exposure may occur to the same person applying the biocidal product as air space application and direct spraying on the insect indoors, followed by secondary exposure, [redacted] direct spraying on the insect outdoors followed by secondary exposure as well. Therefore, scenarios [1], [3], [5] and [6], and scenarios [2], [3], [4] and [6] have to be combined.

Summary table: combined systemic exposure towards Transfluthrin from non-professional uses [mg/kg bw/day]				
Combined scenario	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1, 3, 5, $6_{indoors}$]	1.58×10^{-4}	6.15×10^{-3}	-	**6.31×10^{-3}**
Scenarios [2, 3, 4, $6_{outdoors}$]	9.45×10^{-6}	1.83×10^{-3}	-	**1.84×10^{-3}**

Similarly, as a very worst case, it is assumed that toddlers can be exposed via the inhalation exposure of volatilised residues, the dermal exposure to residues on contaminated surfaces and the dermal and oral exposure to residues on contaminated surfaces via hand-to-mouth. Thus scenarios [5], [6] and [7] indoors, and [6] and [7] outdoors are combined below.

Summary table: combined systemic exposure towards Transfluthrin from non-professional uses [mg/kg bw/day]				
Combined scenario	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [5, $6_{indoors}$, $7_{indoors}$]	4.80×10^{-6}	7.86×10^{-3}	1.62×10^{-4}	**8.03×10^{-3}**
Scenarios [$6_{outdoors}$, $7_{outdoors}$]	-	1.49×10^{-3}	3.07×10^{-5}	**1.52×10^{-3}**

Monitoring data

No further information on surveys or studies with the actual product or with a surrogate is submitted.

Dietary exposure

Food, drinking water or livestock exposure towards the b.p. can be excluded when applied according to the recommended uses and the risk mitigation measures proposed: "Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets".

Information of non-biocidal use of the active substance

According to the information available to the applicant, the a.s. Transfluthrin is not used in further areas (plant protection products, veterinary use, food or feed additives, cosmetics, etc.) other than the biocidal area which would give rise to an aggregate exposure assessment.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Livestock exposure towards de b.p. can be excluded when applied according to the recommended uses.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

The biocidal product is not intended for professional and/or industrial applications.

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

Food, drinking water or livestock exposure towards the b.p. can be excluded when applied according to the recommended uses and complying with the risk mitigation measures: "Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pets".

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

The potential exposure of industrial workers during the production and formulation of the b.p. should be addressed under other EU legislation (e.g. REACh) and not repeated under Regulation (EU) 528/2012 (BPR). The Biocides Technical Meeting (TMI06) agreed that a risk assessment for production and formulation of the active substance was not required, unless the active substance was totally new to the EU market and manufactured in the EU. This is not the case for Transfluthrin which is an existing biocidal a.s. within the EU.

Aggregated exposure

Aggregated exposure is not relevant since Transfluthrin is only approved as PT 18, and then exposure from the use in other products types is not expected.

Summary of exposure assessment

Transfluthrin

Scenarios and values to be used in systemic risk assessment				
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**		**Tier/PPE**	**Estimated total uptake [mg/kg bw/day]**
[1] Air space application indoors	Non-professional		1/no PPE	**6.40 x 10^{-4}**
[redacted]	[redacted]		[redacted]	[redacted]
[3] Direct spraying on insects	Non-professional		1/no PPE	**5.58 x 10^{-4}**
[4] Direct spraying on wasp nests	Non-professional		1/no PPE	**1.11 x 10^{-4}**
[5] Inhalation exposure of volatilised residues	General Population	Adults	1/no PPE	**1.6 x 10^{-6}**
		Toddlers	1/no PPE	**4.80 x 10^{-6}**
[6] Dermal exposure to residues on surfaces	General Population Indoors	Adults	1/no PPE	**5.11 x 10^{-3}**
		Toddlers	1/no PPE	**7.86 x 10^{-3}**
	General Population Outdoors	Adults	1/no PPE	**9.70 x 10^{-4}**
		Toddlers	1/no PPE	**1.49 x 10^{-3}**
[7] Oral exposure to residues on surfaces	General Population Indoors	Toddlers	1/no PPE	**1.62 x 10^{-4}**
	General Population Outdoors	Toddlers	1/no PPE	**3.07 x 10^{-5}**
Combined scenarios [1, 3, 5, $6_{indoors}$]			1/no PPE	**6.31 x 10^{-3}**
Combined scenarios [2, 3, 4, $6_{outdoors}$]			1/no PPE	**1.84 x 10^{-3}**
Combined scenarios [5, $6_{indoors}$, $7_{indoors}$]			1/no PPE	**8.03 x 10^{-3}**
Combined scenarios [$6_{outdoors}$, $7_{outdoors}$]			1/no PPE	**1.52 x 10^{-3}**

2.2.6.3 Risk characterisation for human health

The toxicological profile of Transfluthrin is characterised by systemic effects. The main target organs are the kidney (where the critical effects are glomerulonephrosis, pigment deposition, increased absolute and relative weight of the kidneys at 200 ppm, equal to 9.9 mg/kg bw/day) and the liver (where the critical effects are increased weight, clinical chemistry parameters related to liver damage).

The following short- (acute), medium- and long-term AELs were derived in relation to the effects assessment and for determination of the risk characterisation for human health:

Reference values to be used in Risk Characterisation

Reference	**Study**	**NOAEL (LOAEL)** (mg/kg bw/day)	**AF[1]**	**Correction for oral absorption**	**Value** (mg/kg bw/day)
AELshort-term, oral	Developmental study, rabbit	15	100	n.a.	0.15
AELshort-term, dermal[2]	3-week, rabbit	1000	100	n.a.	1
AELmedium-term	2-year dietary, rat	1.0	100	n.a.	0.01
AELlong-term	2-year dietary, rat	1.0	100	n.a.	0.01
ARfD	Developmental study, rabbit	15	100	n.a.	0.15
ADI	2-year dietary, rat	1.0	100	n.a.	0.01

[1] The default 100-fold Assessment Factor (AF) is calculated as the product of a 10-fold factor for interspecies variation and a 10-fold factor for intraspecies variation.
[2] Correction for dermal absorption of 10%

Maximum residue limits or equivalent
Transfluthrin is not approved under the PPP regulation, MRLs were set in Regulation (EC) No 396/2005 at the lower limit of analytical quantification.

However, regarding the current application by aerosol spraying as an insecticide for non-professional use together with the appropriate risk mitigations, residues in food and setting of a MRL are not considered relevant.

Specific reference value for groundwater
No specific reference value for groundwater was established. Thus, 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.

Risk for industrial users

Not relevant, the products are only intended for non-professional users.

Risk for professional users

Not relevant, the products are only intended for non-professional users.

Risk for non-professional users

Since transfluthrin is characterized by systemic effects, the performance of a systemic exposure and risk assessment is required. Moreover, the risks resulting from the different exposure scenario have to be combined. Non-professional users can be assumed to apply the product every day according to the label, but this is only intended to occur in summer time. Thus the application regime for non-professionals resembles a medium-term exposure scenario, and a comparison of the estimated exposure with the reference value for medium-term exposure is, therefore, justified. No reduction of dermal exposure by clothing is assumed.
Risk characterisation for local effects is triggered if a biocidal product is classified for local effects. Transfluthrin Aerosols BPF is not classified for local effect end-points (including sensitisation), and a risk assessment for local effects is not required. However pyrethroids are known to cause paraesthesia (burning and prickling of the skin without irritation) and the following instruction is included "Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice".

Systemic effects Transfluthrin

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1] Air space application indoors	1/no PPE	0.01	**6.40×10^{-4}**	6.4	yes
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[3] Direct spraying on insects	1/no PPE	0.01	**5.58×10^{-4}**	6	yes
[4] Direct spraying on wasp nests	1/no PPE	0.01	**1.11×10^{-4}**	1	yes

Combined scenarios

A combination of all relevant scenarios includes the exposure estimates of the secondary exposure. Therefore, the combined scenarios is reported in the section Risk for the general public below.

Local effects

Risk characterisation for local effects is triggered if a biocidal product is classified for local effects. Transfluthrin Aerosols BPF is not classified for local effect end-points (including sensitisation), and a risk assessment for local effects is not required. However pyrethroids are known to cause paraesthesia (burning and prickling of the skin without irritation) and the following instruction is included "Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice".

Conclusion

The systemic exposure estimations demonstrate no unacceptable health risk for non-professionals for the a.s..

Risk for the general public

Secondary exposure may occur if persons (adults, children, toddlers and infants) enter rooms or stay on the terrace outdoors after the use of the b.p. Inhalation exposure of volatilised residues is expected, as well as dermal exposure to residues on contaminated surfaces, followed by oral exposure in the case of the toddlers. Although these persons will be exposed acutely, comparison of the estimated exposure with the reference value for medium-term exposure as presented for primary exposure assessment is proposed as a worst case.

Systemic effects Transfluthrin

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[5] General population: adults	1/no PPE	0.01	**1.6×10^{-6}**	< 1	yes
[5] General population: toddlers	1/no PPE	0.01	**4.80×10^{-6}**	< 1	yes
[6] General population indoors: adults	1/no PPE	0.01	**5.11×10^{-3}**	51	yes
[6] General population indoors: toddlers	1/no PPE	0.01	**7.86×10^{-3}**	79	yes
[6] General population outdoors: adults	1/no PPE	0.01	**9.70×10^{-4}**	10	yes
[6] General population outdoors: toddlers	1/no PPE	0.01	**1.49×10^{-3}**	15	yes
[7] General population indoors: toddlers	1/no PPE	0.01	**1.62×10^{-4}**	2	yes
[7] General population outdoors: toddlers	1/no PPE	0.01	**3.07×10^{-5}**	< 1	yes

Combined scenarios Transfluthrin

Scenarios combined	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1, 3, 5, $6_{indoors}$]	1/no PPE	0.01	**6.31×10^{-3}**	63	yes
[2, 3, 4, $6_{outdoors}$]	1/no PPE	0.01	**1.84×10^{-3}**	18	yes
[5, $6_{indoors}$, $7_{indoors}$]	1/no PPE	0.01	**8.03×10^{-3}**	80	yes
[$6_{outdoors}$, $7_{outdoors}$]	1/no PPE	0.01	**1.52×10^{-3}**	15	yes

Local effects

Risk characterisation for local effects is triggered if a biocidal product is classified for local effects. Transfluthrin Aerosols BPF is not classified for local effect end-points (including sensitisation), and a risk assessment for local effects is not required. However pyrethroids are known to cause paraesthesia (burning and prickling of the skin without irritation) and the following instruction is included "Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice".

Conclusion

The systemic exposure estimations demonstrate no unacceptable health risk for the general public when entering rooms or stay on the terrace outdoors after the use of the b.p. Inhalation exposure of volatilised residues as well as dermal exposure to residues on contaminated surfaces are below the $AEL_{medium\text{-}term}$ both for adults and toddlers. Pyrethroids are known to cause paraesthesia (burning and prickling of the skin without irritation) and the following instruction is included "Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice".

Risk for consumers via residues in food

Food, drinking water or livestock exposure towards Transfluthrin can be excluded when applied according to the recommended uses and complying with the risk mitigation measure "Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock/pet". Therefore no unacceptable risk to consumer health *via* residues in food needs to be expected.

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

According to Chapter 4 of the Guidance for Human Health Risk Assessement, Volume III, Part B+C (ECHA, ver 3, 2017) a combined/aggregated risk assessment shall be performed if the biocidal product contains several active substances or substances of concern requiring a quantitative systemic risk assessment. In case there is a common mechanism of action or if there are common target organs for individual substances in a product, the hazard index would be determined by the addition of the individual hazard quotients for each substance as estimated in the concerned scenarios.

The b.p. in the Transfluthrin aerosols BPF contains only one a.s. Transfluthrin and no SoCs. Thus, combined exposure to several active substances or substances of concern is not forseen.

2.2.7 Risk assessment for animal health

The b.p. of the Transfluthrin aerosols BPF are applied by non-professional users in domestic areas where livestock exposure can be excluded. Due to the application patterns and risk mitigation measures "Do not spray directly on people or pets" and "Contains transfluthrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms, no direct exposure of animals is foreseen when the b.p. is applied according to the recommended uses. Cats are particularly sensitive to pyrethroids, hence the following RMM is added "Keep cats away from treated surfaces. Due to their particular sensitivity to transfluthrin, the product can cause severe adverse reactions in cats". Therefore unacceptable risks with respect to animal safety are not to be expected, and a risk assessment for animal health is not deemed necessary.

2.2.8 Risk assessment for the environment

The biocidal products (b.p.) are ready-to-use (RTU) aerosol dispensers containing 0.104% (w/w) Transfluthrin to be used indoors and outdoors in PT 18 products by non-professionals in private areas against flying insects. The environmental risk assessment for the b.p. was based on the ESD for PT 18 (2008) as well as on the Guidance on Biocidal Products Regulations Volume IV Environment Part B+C (2017) and the Technical Agreements for Biocides (TAB, 2021).

2.2.8.1 Effects assessment on the environment

The environmental risk characterization of the active substance (a.s.) is performed using the PNECs from the assessment report (AR) of Transfluthrin (RMS, Netherlands, 2016[6]), and the Bayer report TFL-PAI-2018-v1 on "Relevant endpoints and PNEC derivation Environment & Ecotoxicity".

New ecotoxicological studies

New ecotoxicological studies for the aquatic and terrestrial compartments were submitted for the a.s Transfluthrin after the adoption of the AR.
The PNEC values proposed below are based on the available data and information, including the draft opinion of BPC (6-7 March 2018). As the updated CAR for Transfluthrin (2019) by refMS NL is available, the DK CA consider the new ecotoxilogical studies applicable.

The relevant PNECs used for the environmental risk assessment are summarized in the following table.

Summary table of the relevant PNECs for the environmental risk assessment taken from the AR (2014) of Transfluthrin and Bayer report TFL-PAI-2018-v1		
Compartment	**Unit**	**Transfluthrin**
		Value
Freshwater	[mg/L]	1.75E-06[a)]
STP	[mg/L]	5.7e-02[a)]
Sediment	[mg/kg ww]	3.57e-04 [a)]
Soil	[mg/kg ww]	8.8E-02 [a)b)]
Groundwater	[µg/L]	0.1[c)]
$PNEC_{oral,\ birds}$	[mg/kg food]	n.a.[d)]

6 https://echa.europa.eu/documents/10162/0afab843-45ba-258a-79ad-d8ef862a9600

Summary table of the relevant PNECs for the environmental risk assessment taken from the AR (2014) of Transfluthrin and Bayer report TFL-PAI-2018-v1		
Compartment	**Unit**	**Transfluthrin**
		Value
$PNEC_{oral,\ mammals}$	[mg/kg food]	6.67

[a)] Data from Bayer report TFL-PAI-2018-v1
[b)] Calculated by equilibrium partitioning method *(EPM)*
[c)] Pesticides drinking water standard of 0.1 µg/L (98/83/EC)
[d)] n.a: not available

The relevant PNECs of the major metabolites are summarized in the following table.

Summary table of the relevant metabolites PNECs for the environmental risk assessment taken from the AR (2014) of Transfluthrin			
Compartment	**Unit**	**Metabolite**	**Metabolite**
		TFB-COOH/TFB-OH	**DCVA**
Freshwater	[mg/L]	>0.1[a)]	0.0064[d)]
STP	[mg/L]	No data	No data
Sediment	[mg/kg ww]	Not relevant[b)]	Not relevant[b)]
Soil	[mg/kg ww]	0.012[c)]	0.0128[c)]

[a)] ecotoxicity studies performed on TFB-COOH metabolite. but in view of the chemical structure similarity and the comparable physico-chemical characteristics, it is proposed under the Bayer report TFL-PAI-2018-v1 that TFB-OH also has a $PNEC_{water}$ of >0.1 mg/L
[b)] The risk assessment for sediment is covered by that for water, an additional factor of 10 will be used in view of the log Pow of Transfluthrin being 5.94, taking into account the possible additional uptake via sediment ingestion
[c)] Derived based on the PNECwater using the Equilibrium Partitioning method
[d)] Based on data from Bayer report TFL-PAI-2018-v1 – Updated assessment report for Transfluthrin

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

Transfluthrin (CAS. Nr. 118712-89-3) is classified as both Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410). Both meta-SPC's of the biocidal product family contains a maximum of 0.104 % Transfluthrin and therefore no environmental classification is triggered by Transfluthrin alone.
One substance besides the active substance in the biocidal product family have an environmental classification of H400 (m-factor = 1) however the content of this substance does not classify the product alone or in combination with the active substance.

Substances of concern (SoC)
Transfluthrin aerosols BPF does not have any SoC for the environment according to Article 3(f) of Regulation (EU) No. 528/2012, and Annex A of the Guidance on the BPR: Volume IV Environment – Assessment & Evaluation, Parts B+C (Version 2.0, October 2017).

A co-formulant is considered a SoC if it has known or possible endocrine-disrupting properties. The product does not have endocrine disruption indications based on current scientific knowledge, including available toxicological- and ecotoxicological information (see Confidential Annex Section 3.7.4 for full evaluation).

Further Ecotoxicological studies

Data waiving	
Information requirement	No further ecotoxicological studies are required
Justification	No further ecotoxicity data are available for the b.p. of the BPF. The ecotoxicity of Transfluthrin and the co-formulants is known and no synergistic effects are expected. The individual products of the BPF contain only Transfluthrin as a.s. and no further substances of concern for the environment. Ecotoxicological properties and classification of the biocidal product can be deduced from the respective properties of the active substance and the co-formulants using the method described in the guidance for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). The formulation type of the biocidal product is not expected to change the mode of action of the a.s. or its bioavailability. The intended use of the biocidal product is in PT 18. The route of environmental exposure for the indoor use is mainly via sewage treatment plants to the aquatic environment. However, direct emissions to soil may occur as a result of the outdoor use. The risk assessment is done with the a.s. data from the AR (2014) and with newly environmental fate and ecotoxicity studies for Transfluthrin demonstrating safe uses for all applications (*i.e.* PEC/PNEC-ratios < 1) provided to the applicant by the supplier (Bayer report TFL-PAI-2018-v1 on "Relevant endpoints and PNEC derivation Environment & Ecotoxicity"). Hence, also in view of Article 21 (1(a)) of EU Regulation No 528/2012 (22 May 2012), and owing to the use and exposure considerations as mentioned above, there is no need to further investigate the ecotoxicological effects for the individual b.p.

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

Data waiving	
Information requirement	Further information on effects on any other specific, non-target organisms (flora and fauna) is not required.

Justification	Further information on effects on any other specific, non-target organisms (flora and fauna) is not required as no concerns are raised from the uses and emissions of the a.s. Therefore, the original data and PNECs from the assessment report of Transfluthrin (2014) as well as the new environmental fate and ecotoxicity studies for Transfluthrin that were provided to the applicant (Bayer report TFL-PAI-2018-v1 on "Relevant endpoints and PNEC derivation Environment & Ecotoxicity") are considered to be sufficient the risk assessment.

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

Data waiving	
Information requirement	Information on the risks to non-target organisms under field conditions is not required
Justification	Risks to non-target organisms are covered in the risk assessment for soil and aquatic compartment, which does not trigger further higher tier tests

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

Data waiving	
Information requirement	Information on acceptance by ingestion of the biocidal products by any non-target organisms is not required.
Justification	The product does not contain any lure which could be attractive for non-target organisms. Therefore, ingestion by non-target organisms is no matter of concern. Moreover, the products are marketed as a ready-to-use aerosol sprays and is not marketed in the form of granules.

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

The a.s. is not expected to persist in the environment and the products of the BPF are not intended for large scale treatment of habitats like water bodies, wetland, forest or fields and therefore information on secondary ecological effects is therefore not required.

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

The potential emissions of the a.s. Transfluthrin have been assessed in this PAR. Sources for emissions as well as target environmental compartments have been considered and concentrations in the compartments of concern have been calculated. For detailed information, please refer the relevant sections in the PAR.

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

Data waiving	
Information requirement	Further studies on fate and behaviour in the environment (ADS) are not required.
Justification	The data on a.s. provide sufficient information regarding its fate and behaviour in the environment and there are no indications of risk due to specific properties of the individual products of the BPF. The products of the BPF do not contain any substance of concern for the environment. The formulation type is not expected to change the mode of action of the active substance or its bioavailability. The fate of the b.p. is covered by the data provided for the a.s.

Leaching behaviour (ADS)

The performance of a leaching study from treated surfaces is neither applicable nor relevant for the intended uses of the b.p. within the BPF in PT18.

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	Information on distribution and dissipation in soil (ADS) is not required.
Justification	The data on the distribution and dissipation of the a.s. in soil provide sufficient information and there are no indications of risk due to specific properties of the b.p. Furthermore, the components of the b.p. are not expected to influence the distribution and degradation characteristics of the a.s. Further testing for distribution and dissipation in soil is not deemed necessary.

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

Data waiving	
Information requirement	Information on distribution and dissipation in water and sediment (ADS) is not required.
Justification	The data on the distribution and dissipation of the a.s. in surface water (incl. sediment) provide sufficient information and there are no indications of risk due to specific properties of the b.p. Furthermore, the components of the products are not expected to influence the distribution characteristics of the a.s., which is readily biodegradable. Further testing of the b.p. for distribution and dissipation in the environment is therefore not deemed reasonable.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	Information on distribution and dissipation in air (ADS) is not required.
Justification	No additional test on distribution and dissipation in air is needed based on intended uses, data availability on the a.s. or the outcome of the risk assessment.

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)

Acute aquatic toxicity

Data waiving	
Information requirement	Further information on risks to aquatic organisms or plants under field conditions (ADS) is not required.
Justification	The data on aquatic toxicity of the a.s. provide sufficient information and there are no indications of risk due to specific properties of the b.p. The products do not contain any substance of concern for the environment.

Chronic aquatic toxicity

Data waiving	
Information requirement	Further information on aquatic chronic toxicity is not required.
Justification	The data on aquatic toxicity of the a.s. provide sufficient information and there are no indications of risk due to specific properties of the b.p. The products do not contain any substance of concern for the environment.

Measured aquatic bioconcentration

Data waiving	
Information requirement	Further information on aquatic bioconcentration is not required.
Justification	The data of the a.s. on the bioconcentration provide sufficient information and there are no indications of risk due to specific properties of the b.p.

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 b.p. are liquid formulations and there is no potential for large-scale formation of dust. [redacted]. A large space application of the b.p. is not intended and an overspray behavior is therefore not required under field conditions.

It cannot be excluded that bees and/or arthropods are incidentally affected. Transfluthrin has a tendency to adsorb to surfaces, which may cause exposure of foraging bees at day time and surface dwelling non target arthropods. Due to lack of ecotoxicity data and scenarios to calculate exposure concentrations, it is at present not possible to determine the risk for bee populations or the arthropod community.

2.2.8.2 Exposure assessment

The b.p. are ready-to-use aerosol dispensers containing 0.104% (w/w) Transfluthrin to be used in PT 18 products by non-professionals in private areas against insects.
The b.p. are intended for both indoor and outdoor use with four types of application:

- Spatial spray application (Indoors; Meta-SPC1; use # 1.18.1)
- Direct spray on insects (Indoors and Outdoors; Meta-SPC1, use # 1.18.2 and Meta-SPC2, use # 1.18.4)
- [redacted]
- Direct spray application on wasp nests (Outdoors; Meta-SPC2, use # 1.18.5)

The environmental risk assessment for the b.p. was based on the ESD for PT 18 (2008) as well as on the Guidance on Biocidal Products Regulations Volume IV Environment Part B +C (2017) and the TAB (2021).

The assessed scenarios and uses of the b.p. within the BPF are described in the following table and in the specific sections for the emission estimation.

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 18.1: Air – space aerosol spray application indoors (covering use # 1.18.1) Scenario 18.2: Direct application on insects indoors (covering use # 1.18.2) [redacted] Scenario 18.4: Direct application on insects outdoors (covering use # 2.18.4) Scenario 18.5: Nest spray application outdoors (covering use # 2.18.5)
ESD(s) used	ESD PT18 for Insecticides, Acaricides and products to control other arthropods for household and professional uses (OECD, 2008)
Approach	All scenarios: Average consumption based
Distribution in the environment	Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C), v. 2.0, October 2017
Groundwater simulation	Yes
Confidential Annexes	No
Life cycle steps assessed	Scenarios 18.1 – 18.5: Production: No Formulation No Use: Yes

	Service life: No
Remarks	None

Emission estimation

Scenario 18.1: Air – space aerosol spray application indoors

The b.p are to be sprayed in vertical position towards the ceiling in private houses and can be applied up to one time per day.

According to the discharge rate study, the mean discharge rate measured was 1.6 g/s, taking into account a spray duration of 9 seconds (as previously derived in the human health section), the product amount estimated is 14.40 g per use for a 30 m^3 room.
This leads to an application rate of the biocidal product of (14.40g / 30 m^3) 0.48 g/m^3.
According to the ESD for PT 18 (2008), in the case of air-space treatments, there is no direct application on materials, neither is the air itself "treated". However, during the application of the product, the applicator, the air and the floor could be concerned. Since the insecticide particles fall on the floor at the day scale, emission to air is only temporarily as the particles generally reach the adjacent surface and the floor after a while.
Residues being removed by dry cleaning include vacuum cleaning as well as wiping with disposable clothes and they are emitted to municipal landfill.
In this scenario, the route of exposure of transfluthrin to the environment from insects control in private houses is via release from the facility drain to STP and subsequent compartments, after a wet cleaning event.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 18.1: Air – space aerosol spray application indoors			
Application rate of biocidal product	0.48	g/m3	Discharge rate of 1.6 g/s during 9 seconds
Concentration of active substance in the product	1.04	g/L	-
ber of applications per day per building ($N_{appl,building}$)	4/7	d^{-1}	According to the instructions of use, the product is to be applied 4 times per week
$VOLUME_{treated}$	58	m^3	ESD PT 18 default value

Calculations for Scenario 18.1: Air – space aerosol spray application indoors

In accordance with the ESD for PT18 (OECD, 2008), the application step is the only life-cycle stage relevant for the use pattern of the b.p. The input parameters used for the environmental exposure assessment for the air-spray treatment indoors are shown in the following table and the following assumptions have been made:

- The number of applications per day per building ($N_{appl,building}$) proposed at the ESD for volume sprays is 4. However, the information provided by the applicant on the instructions of use states that the product is to be applied 4 times per week.

Therefore, the number of applications per week is set to 4 ($N_{appl,building}$ = 4) for the calculations.

- The volume proposed by the ESD for air-space treatments is 58 m³, which corresponds to the average volume of e.g. a living room in EU countries.
- The fraction emitted to waste waters by the applicator during the cleaning step ($F_{applicator, ww}$) is equal to 1 as 100% of the coveralls are considered washable.
- The fraction emitted to waste waters from the floor during the cleaning step (F_{ww}) is equal to 1 as 100% of the floor surface is washed with water.
- The cleaning efficiency for the space-treatment RTU aerosol sprays (F_{CE}) is 1 according to Table 3.3-8 of the ESD for PT 18 (2008).
- The product is to be applied 4 times per week, therefore according to DK's calculations the Simultaneity factor is set to 4.33%

Using these assumptions the total emissions to waste water ($E_{applicator\ ww}$ + $E_{treated\ surface\ ww}$) from private houses is 1.45E-03 kg/d.

Scenario 18.1: Air-space aerosol spray application indoors	**Symbol**	**Unit**	**Value**
Application rate			
Amount of product (treatment rate)	Qprod	kg/m³	0.00048
Fraction of a.i.	F_{AI}	--	0.00104
Application rate of active substance	Qai	mg/m³	0.4992
Number of applications per day per building	Nappl,building	d^{-1}	4/7
Volume treated	VOLtreat	m³	58
Mixing/loading			Not relevant. RTU product
Application			
Fraction emitted to air	Fapplication, air	--	0.02
Fraction emitted to floor	Fapplication, floor	--	0.96
Fraction emitted to treated surface	Fapplication, treated	--	0
Fraction emitted to applicator	Fapplication, applicator	--	0.02
Emission to air	**Eappl,air**	**kg/d**	3.31E-07
Emission to applicator	**Eappl, applicator**	**kg/d**	3.31E-07
Emission to the floor	**Eappl, floor**	**kg/d**	1.59E-05
Emission to treated surface	**Eappl,treated**	**kg/d**	0
Cleaning			
Fraction ww from applicator	Fapplicator,ww	--	1
Fraction ww during cleaning	Fww	--	1
Cleaning efficiency	F_{CE}	--	1
Emission from air to ww	**Eair, ww**	**kg/d**	**Negligible**
Emission from applicator to ww	**Eapplicator, ww**	**kg/d**	3.31E-07
Emission from floor/treated surface to ww	**Etreated, ww**	**kg/d**	1.59E-05

Summary			
Emissions to ww (Eapplicator ww + Etreated ww)	**Elocal, ww**	**kg/d**	1.62E-05
Simultaneity factor	Fsim	%	4.33
Simultaneity factor	Fsim	--	0.0433
Number of treated houses	Nhouses	--	4000
Emissions to ww (Eapplicator ww + Etreated surfaceww)	**Eww**	**kg/d**	2.81E-03

The following formulas were used to calculate daily local emission to STP:

1) $E_{application,air} = N_{appl,building} \times F_{application,air} \times Q_{prod} \times F_{AI} \times VOL_{treat}$
2) $E_{application,applicator} = N_{appl,building} \times F_{application,applicator} \times Q_{prod} \times F_{AI} \times VOL_{treated}$
3) $E_{application,floor} = N_{appl,building} \times F_{application,floor} \times Q_{prod} \times F_{AI} \times VOL_{treated}$
4) $E_{application,treated} = N_{appl,building} \times F_{application,treated} \times Q_{prod} \times F_{AI} \times VOL_{treated}$
5) $E_{applicator,ww} = E_{application,applicator} \times F_{applicator,ww}$
6) $E_{treated,ww} = (E_{application,floor} + E_{application,treated}) \times F_{ww} \times F_{CE}$
7) $Elocal_{waste\ water,total} = (E_{applicator,ww} + E_{treated,ww}) \times N_{houses} \times F_{sim}$

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	2.81E-03	-

Scenario 18.2: Direct application on insects indoors

The b.p. is to be sprayed directly on insects considering a target surface diameter of 20 cm. As there is no standard emission scenario for direct application on insects indoors, the spray treatment is considered as target application, i.e., either spot or crack and crevice application, because the surfaces where insects can appear (near garbage cans, sinks, etc...) are exposed to the product. 1.6 g of product (discharge rate is 1.6 g/s) is to be sprayed from a distance not lower than 60 cm corresponding to a target surface diameter of 20 cm (according to the spray pattern laboratory report) and thus to a surface area of 314.16 cm^2 (π x 10 cm^2) leading to an application rate of 50.27 g/m^2. However as the ENV TAB #141 explains *"It is not possible to authorise products based on certain amount of m^2 where a safe use can be found"*, DK CA have instead modified the application rate so that one treatment with 1.6 g of the product covers 2 m^2, meaning the application rate of the product is 0.8 g/m^2.

Calculations for Scenario 18.2: Direct application on insects indoors

- No mixing/loading step to be considered since product is RTU.
- The number of applications per day per domestic house ($N_{appl,house}$) is 10.
- The application mode of the b.p. is considered a targeted spot application. The TAB (ECHA, 2017) provides a default size of treated surface of 2 m^2 for domestic houses.

- The fraction emitted to waste waters by the applicator during the cleaning step ($F_{applicator, ww}$) is equal to 1 as 100% of the clothes are considered washable.
- The fraction emitted to waste waters during the cleaning step (F_{ww}) is equal to 1 as 100% of the treated surfaces are washed with water.
- The cleaning efficiency for the RTU Aerosols – Surface treatment (F_{CE}) is 0.2.

Using these assumptions the total emissions to waste water ($E_{applicator\ ww}$ + $E_{treated\ surface\ ww}$) from private houses is 7.78E-04 kg/d.

Scenario 18.2: **Direct application on insects indoors**	**Symbol**	**Unit**	**Value**
Application rate			
Amount of product (treatment rate)	Qprod	kg/m^2	0.0008
Fraction of a.i.	F_{AI}	--	0.00104
Application rate of active substance	Qai	mg/m^2	0.83
Number of applications per day per building	Nappl,building	d^{-1}	10
Area treated	AREAtreat	m^2	2
Mixing/loading			Not relevant. RTU product
Application			
Fraction emitted to air	Fapplication, air	--	0.02
Fraction emitted to floor	Fapplication, floor	--	0.11
Fraction emitted to treated surface	Fapplication, treated	--	0.85
Fraction emitted to applicator	Fapplication, applicator	--	0.02
Emission to air	**Eappl,air**	**kg/d**	3.33E-07
Emission to applicator	**Eappl, applicator**	**kg/d**	3.33E-07
Emission to the floor	**Eappl, floor**	**kg/d**	1.83E-06
Emission to treated surface	**Eappl,treated**	**kg/d**	1.41E-05
Cleaning			
Fraction ww from applicator	Fapplicator,ww	--	1
Fraction ww during cleaning	Fww	--	1
Cleaning efficiency	F_{CE}	--	0.2
Emission from air to ww	**Eair, ww**	**kg/d**	**negligible**
Emission from applicator to ww	**Eapplicator, ww**	**kg/d**	3.33E-07
Emission from treated surface to ww	**Etreated, ww**	**kg/d**	2.83E-06
Emission from floor	**Efloor, ww**	**kg/d**	3.66E-07
Summary			
Emissions to ww (Eapplicator ww + Etreated ww + Efloor ww)	**Eww**	**kg/d**	3.53E-06
Simultaneity factor	Fsim	%	5.52
Simultaneity factor	Fsim	--	0.0552
Number of treated houses	Nhouses	--	4000

Emissions to ww (Eapplicator ww + Etreated surfaceww)	**$Elocal_{,water}$**	**kg/d**	7.79E-04

The calculations of the daily local emission to waste water were performed using the same formulas previously presented for the Scenario 18.1: Air-space treatment indoors.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	7.79E-04	-

[redacted]

[redacted]

[redacted]

Scenario 18.4: Direct application on insects outdoors

The b.p. is to be sprayed directly on insects considering a target surface diameter of 20 cm. As there is no standard emission scenario for direct application on insects outdoors, the DK CA have refined the outdoor spraying for crawling insects with input values from the spot application scenario, as a direct application on insect can be considered a spot application.
This refinement ensures that both direct emission to soil (rural) and emission via the STP (Urban) is considered (the spot application scenario only consider direct emission to soil).

According to the instructions for use and the efficacy test 1.7 g of the product (as the discharge rate is 1.7 g/s and 1 spray is estimated to last 1 second) is to be sprayed directly on the insect from a distance not lower than 60 cm corresponding to a target surface

diameter of 20 cm (according to the spray pattern laboratory report) and thus to a surface area of 314.16 cm^2 (π x 10 cm^2) leading to an application rate of 53.41 g/m².
As the product is intended to be used at maximum 10 times a day for this use, 17 g (1.7 g x 10) is the maximum amount of product used for this use per day.
The DK CA have derived the AREAsoil considered for this use from the spot application scenario, where an area of 0.25 m^2 is considered per application. For this use the 10 applications a day is considered different located "spots" at the same time, hence the total area treated is 2.5 m^2 (10 x 0.25 m^2).
Qprod for this use is therefore set at 6.8 g/m^2 (17 g / 2.5 m^2).

Calculations for Scenario 18.4: Direct application on insects outdoors

- The area of foundation treated per day was set to 0 since the product is applied exclusively on the ground and not on walls.
- The fraction emitted to soil (treated) during outdoor ground spray application ($F_{spray,soil}$) is equal to 0.99.
- The fraction emitted to soil (untreated) during outdoor ground spray application ($F_{spray,untreated\ soil}$) is equal to 0.0042.
- The area of paved ground treated per day ($AREA_{pavedground}$) was changed from 26 m² to 2.5 m² according to the instructions of use provided by the applicant.
- The area of untreated zone ($AREA_{untreated}$) was changed from 28 m^2 to 20 m^2 as a 50 cm zone in every direction around the treated area was considered ((1.5 m * 1.5 m) – 0.25 m2) * 10 applications). The unpaved ground volume deposition and application at 0.5 m (treated) was changed from 13 to 1.25 m^3 by applying a similar reduction as for the treated area.
- The unpaved ground volume deposition and application at 0.5 m (untreated) was changed from 14 to 10 m^3 by applying a similar reduction as for the treated area.
- In urban areas, the fraction emitted to waste waters (Fww) from hard surfaces during the first rain event is equal to 1.
- The product is to be applied until a maximum of 10 times per day, hence the Simultaneity factor is set at a maximum for outdoor use ~ 3 % (0.027462)

Using these assumptions the total emissions to waste water (E_{ww}) from private houses is 1.24E-03 kg/d.

Scenario 18.4: Direct application on insects outdoors	**Symbol**	**Unit**	**Value**
Application rate			
Amount of product	Q_{prod}	kg/m^2	0.0068
Fraction of a.i.	F_{AI}	--	0.00104
Quantity of active substance	Q_{ai}	mg/m^2	7.07
Mixing/loading			Not relevant. RTU product
Application			
Area of foundation treated per day	$AREA_{foundation}$	m^2/d	0
Area of soil treated per day	$AREA_{soil}$	m^2/d	2.5
Fraction emitted to soil during outdoor ground spray application	$F_{spray,soil}$	--	0.99

Fraction emitted to untreated soil during outdoor ground spray application	$F_{spray,untreated\ soil}$	--	0.0042
Fraction emitted to soil due to washing from rainwater	$F_{spray,wash-off}$	--	n.r.
Area untreated zone	$AREA_{untreated}$	m^2/d	20
Bulk density of wet soil	RHO_{soil}	kg/ww/ m^3	1700
Soil volume deposition and application at 0,5 m (treated)	$V_{spray,treated\ soil}$	m^3	1.25
Soil volume deposition and application at 0,5 m (untreated)	$V_{spray,untreated\ soil}$	m^3	10
Emission from outdoor spray application on foundations	$E_{spray,foundation}$	kg/d	0
Emission from outdoor spray application on foundations due to washing	$E_{spray,foundation,\ wash-off}$	kg/d	0
Emission from outdoor spray application on soil	$E_{spray\ soil}$	kg/d	1.75E-05
Emission from outdoor spray application on soil in untreated areas	$E_{spray,untreated\ soil}$	kg/d	5.94E-07
Concentration of the active substance in treated soil in the countryside	**$C_{spray,treated,\ soil}$**	**kg/kg wwt**	**8.24E-09**
Concentration of the active substance in untreated soil in the countryside	**$C_{spray,untreated,\ soil}$**	**kg/kg wwt**	**3.49E-11**
Cleaning			Not relevant
Summary			
Emission from outdoor spray application	**$E_{spray\ total}$**	**kg/d**	1.81E-05
Simultaneity factor	F_{sim}	%	~ 3
Simultaneity factor	F_{sim}	--	0.0.027462
Number of treated houses	N_{houses}	--	2500
Total Emissions to ww	**E_{ww}**	**kg/d**	**1.24E-03**

The calculations of the daily local emission to waste water and total concentration in soil in rural areas were performed using the same formulas previously presented for the Scenario 18.3: Spray treatment on floor areas outdoors.

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP (urban areas)	1.24E-03	-
Soil treated (rural areas)	1.20E-03	
Soil untreated (rural areas)	4.08E-05	

Scenario 18.5: Nest spray application outdoors

The b.p. is an aerosol spray to be used outdoors as direct application on wasp nest for 2 seconds (corresponding to a worst-case application rate of 3.4 g of product/nest).
According to the model presented on the ESD for PT18 the worst-case scenario for wasp/hornet nest treatment takes into account a nest attached to a tree in countryside. For such applications, only local releases to soil are considered and releases to rainwater in urban situation are not significant.
Further releases due to washing by rainwater are not relevant for this treatment because all hornets or wasps should be normally dead 24 to 48 hours following the spray application, and subsequently the nest is removed (if not, the application may need to be repeated). Furthermore, it is expected that outdoor treatments are not performed on rainy days.

Calculations for Scenario 18.5: Nest spray application outdoors

- The number of nests treated per day (N_{nests}) is equal to 1
- Fraction emitted to soil during nest spray due to deposition ($F_{spray,nest,deposition}$) is equal to 0.3
- The area exposed to insecticide ($A_{soil,exposed}$) corresponds to a 50 cm diameter circular surface and is equal to 0.196 m^2
- The soil volume for deposition and application at 3 m from the nest ($V_{spray,nest,soil}$) is equal to 0.1 m^3
- The depth of exposed soil ($DEPTH_{soil}$) is 0.5 m

Using these assumptions the local emission of the active substance to soil resulting of the nest spray application step in the countryside is 1.06E-06 kg/d.

Scenario 18.5: Nest spray application outdoors	**Symbol**	**Unit**	**Value**
Application rate			
Amount of product	Q_{prod}	kg/nest	0.0034
Fraction of a.i.	F_{AI}	--	0.00104
Quantity of active substance	Q_{ai}	g/nest	3.54E-03
Mixing/loading			Not relevant. RTU product

Application			
Number of nests treated per day	N_{nests}	-	1
Fraction emitted to soil during application due to deposition	$F_{spray,nest,deposition}$	-	0.3
Area exposed to insecticide (50 cm diameter circular surface)	$A_{soil,exposed}$	m^2	0.196
Depth of exposed soil	$DEPTH_{soil}$	m	0.5
Soil volume for application and deposition (at 50 cm from the nest)	$V_{spray,nest,soil}$	m^3	0.1
Bulk density of wet soil	RHO_{soil}	kg/ww/ m^3	1700
Local emission to soil (on the day of application)	$E_{soil,appl}$	kg/d	1.06E-06
Concentration of the a.s in soil in the countryside	$C_{soil,appl}$	kg/kg ww	6.36E-09
Cleaning			Not relevant

The local emission to soil resulting from the treatment of wasp nest for one spray application is derived from the following equation:

$E_{soil,appl} = Q_{prod} \times F_{AI} \times F_{spray,nest,deposition} \times N_{nests}$

The local concentration of the a.s. in soil resulting of the nest spray application step in the countryside is calculated using the following equations:

$C_{soil,appl} = E_{soil,appl} / (V_{spray,nest,soil} \times RHO_{soil})$

$V_{spray,nest,soil} = A_{soil,exposed} \times DEPTH_{soil}$

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Soil (rural areas)	1.06E-06	-

Identification of relevant receiving compartments based on the exposure pathway							
		Fresh-water	Freshwater sediment	STP	Air	Soil	Ground-water
Scenario 18.1: Air – space aerosol spray application indoors		Yes	Yes	Yes	n.a.	Yes	Yes
Scenario 18.2: Direct application on insects indoors		Yes	Yes	Yes	n.a.	Yes	Yes
[redacted]							
Scenario 18.4: Direct application on insects outdoors	urban areas	Yes	Yes	Yes	n.a.	Yes	Yes
	rural areas	No	No	No	n.a	Yes	Yes
Scenario 18.5: Nest spray application outdoors	urban areas	n.r	n.r	n.r	n.a	n.r	n.r
	rural areas	No	No	No	n.a	Yes	Yes

n.r. not relevant
n.a. not applicable

The following active substance specific parameter are taken directly from the AR for Transfluthrin (2014) and Bayer report TFL-PAI-2018-v1 on "Relevant endpoints and PNEC derivation Environment & Ecotoxicity" and used for the environmental exposure calculations:

Input parameters (only set values) for calculating the fate and distribution in the environment - Transfluthrin			
Input	Value	Unit	Remarks
Molecular weight	371.2	g/mol	
Melting point	32	°C	
Boiling point	242	°C	
Vapour pressure (at 20°C)	9E-04	Pa	
Water solubility (at 20°C)	0.057	mg/L	
Log Octanol/water partition coefficient	5.94	Log 10	

Organic carbon/water partition coefficient (Koc)	50119	L/kg	
Kom=koc/1.724	29071		
Henry's Law Constant (at 20º C)	5.86	Pa/m3/mol	
Biodegradability	Not biodegradable		
Rate constant for STP(21.7 ºC)	0.102	h^{-1}	Bayer report TFL-PAI-2018-v1
DT_{50} for degradation in soil (at 12 ºC)	5.17	d	Bayer report TFL-PAI-2018-v1
BCF_{fish}	1783		
BMF	1		
$BCF_{earthworms}$	10452 (estimated)		

In the AR for Transfluthrin, the distribution of the a.s. in STPs was calculated with SimpleTreat 3.1. According to TAB (ECHA, 2018), the new version SimpleTreat 4.0 is available to calculate the fate of chemicals in the STP. Therefore, the distribution is recalculated with the new version of the model and the results are used for the exposure assessment. As described in TAB, the concentration of suspended solids in the effluent is set to 30 mg/L. The distribution values are summarized in the following table and used for the environmental risk assessment.

Calculated fate and distribution in the STP		
Compartment	Percentage [%] Transfluthrin	Remarks
Air	0.228	-
Water	1.311	-
Sludge	59.94	-
Degraded in STP	38.53	Bayer report TFL-PAI-2018-v1. This value is based on a DT_{50} in sludge of 0.283 d (21.7°C) derived from an OECD314B study on biodegradation in activated sludge

Metabolites

According to the AR for Transfluthrin (2014) there were two major metabolites detected in amounts > 10 % of AR in the water phase: NAK 4452 (2,3,5,6-tetrafluorobenzyl alcohol; TFB-OH) and NAK 4723 (2,3,5,6-tetrafluorobenzoic acid; TFB-COOH) with 38 and 59% maximum levels of AR, respectively. The same metabolites were found in sediment, maximum level was 2.9% of AR for TFB-OH and 26% of AR for TFB-COOH. Bound residues after 100 days were 4.4 and 7.9% of AR, mineralisation after 100 days was 3.0 and 12.6% of AR for the respective systems.

The DT50,system of metabolite TFB-OH was estimated to be < 14 days, a reliable estimate of the DT50,system of metabolite TFB-COOH could not be obtained because of few data points. Analytical results obtained in the water/sediment system indicate that metabolite TFB-COOH has a low degradation rate and is persistent in a water/sediment system.

A new soil degradation study was performed in four soils under aerobic conditions at 20 °C and 55% of MWHC (data from Bayer report TFL-PAI-2018-v1). In soil, only one major degradation product (NAK 4723 - 2,3,5,6-tetrafluorobenzoic acid; TFB-COOH) was identified and amounted up to 36.5% of AR.
In a kinetic analysis of residue data of Transfluthrin that was conducted in order to derive kinetic parameters suitable for modelling and environmental risk assessments, DT50 values of Transfluthrin and its metabolite 2,3,5,6-tetrafluorobenzoic acid were calculated. Converted to 12°C, the DT50 were 5.17 days and 3.23 days for Transfluthrin and its metabolite 2,3,5,6-tetrafluorobenzoic acid respectively and the mean formation fraction of 0.6190.
Degradation of metabolite DCVA was not addressed in the study as only the fluorbenze moiety was labelled. Nevertheless, half-life for DCVA is available from a study submitted for cyfluthrin. In this study, degradation of all four isomers of DCVA was investigated in two soils. For PEC calculation, the worst case DT50 of 174.8 days at 12°C (61.8 days at 20°C) is used.

Input parameters for exposure assessment of major metabolites							
Metabolites	**Molecular mass (g/mol)**	**Molecular mass correction factor**	**k soil-water**	**DT50 soil (12°C)**	**Formation factor**		
					Water	sediment	Soil*
TFB-COOH	194.1	0.52	3.20	3.23	0.59	0.26	0.619
TFB-OH	180.1	0.49			0.38	0.029	-
DCVA**	209.1	0.56	5.86	174.8	1	1	1

*Data from Bayer report TFL-PAI-2018-v1

** From the "Harmonised_LoEP_Pyrethroids_Final_May_2020

Calculated PEC values

Predicted Environmental Concentrations (PECs) in all relevant compartments is calculated according to relevant exposure scenario documents (ESD PT18), the Guidance on biocides legislation, Part B+C, volume IV (distribution in the environment), the TAB (ECHA, 2021) and the SimpleTreat model by using the default values for the parameters, unless otherwise noted. Release of Transfluthrin during the waste phase of the end products is not assessed, because it is assumed that end-products to which the active substance is added are disposed as solid waste and usually incinerated. Possible pH effects on the environment is not considered, because the STP and receiving compartments are expected to have sufficient buffering.

Indirect emissions to environmental compartments – STP route

Scenario 18.1: Air – space aerosol spray application indoors, Scenario 18.2: Direct application on insects indoors, [redacted] Scenario 18.4: Direct application on insects outdoors (urban areas)

The **PEC_{STP}** (=$clocal_{effluent, STP}$) is calculated using an effluent of the STP and the $Fstp_{water}$ according to equations (35) and (36) of the Guidance on BPR IV/B+C (2017).

The **$PEC_{surface\ water}$** was calculated using a standard dilution factor of 10 after release from the STP. According to equation (48) of the Guidance on BPR IV/B+C (2017), a solid-water partition coefficient (Kp_{susp}) of 5011.9 L/kg was calculated using the Koc of 50119 L/kg. The concentration of suspended matter (dry weight) in river is by default 15 mg_{solid} per litre water (see Table 3 Definition of the standard environmental characteristics) of the guidance document.

$PEC_{sediment}$ was calculated according to equation (53) of the Guidance on BPR IV/B+C (2017). Default parameter as given in Table 3 of the guidance document were used together with the Koc of 50119 L/kg to calculate a bulk density of suspended matter (RHO_{susp}) of 1150 kg/m³ (equation 20) and a suspended matter-water partitioning coefficient ($K_{susp\text{-}water}$) of 1254 m^3/m^3 (equation 27).

For the soil compartment, emission occurs due to the indirect release via sewage sludge application from a STP. The initial concentrations in soil following 10 sludge applications are used to calculate time weighted average residues in soils (**PEC_{soil}**) of terrestrial ecosystems assuming 30 days degradation (averaging time).The soil pore water concentration is assessed using Guidance on BPR IV/B+C (2017) using default values for the PEC calculation in soil pore water according to equation 70 and using the time weighted concentrations in soil after 180 days as input.

Regarding **groundwater**, groundwater concentrations are assumed to be identical with soil pore water concentrations. Pore water concentrations were calculated according to equation (70) of the Guidance on BPR IV/B (2017), whereby the soil-water partitioning coefficient $K_{soil\text{-}water}$ was calculated according to equation (27) of the guidance document to be 1504 m^3/m^3. As an input, the $PEC_{local,agr,soil}$ after 10 consecutive sludge applications considering biodegradation over a period of 180 days after the last sludge application event was used.

No PEC in air was calculated as exposure is considered to negligible.

Direct emissions to environmental compartments

Soil

[redacted] *Scenario 18.4: Direct application on insects outdoors (rural areas)*

In rural areas, when the product is applied directly on ground surfaces, the fraction emitted to soil corresponds to both the quantity of the substance that is washed-off (by rainfall) from the treated surfaces and the emissions to the untreated zone (area adjacent to the treated soil) from drift deposition during the treatment.
Therefore, it is proposed under ESD PT18 to calculate two local concentrations of Transfluthrin in soil in the countryside: Concentration of the a.s in treated soil in the countryside ($C_{spray,treated, soil}$) and concentration of the a.s in untreated soil in the countryside ($C_{spray,untreated, soil}$).

The concentration in soil pore water, as a surrogate for groundwater concentrations, is calculated according the equation 71 from the Guidance on BPR IV/B+C (ECHA, 2017).

Scenario 18.5: Nest spray application outdoors

Wasp spray insecticides emit a powerful and narrow spray to reach the entrance of the nest. However, during nest spray application, a fraction of the spray droplets will not reach the nest but enter the soil compartment through deposition. It is proposed under ESD PT18 to use as default value the figure of 30% for soil deposition ($F_{spray,nest,soil}$ = 0.3).

The concentration in soil pore water, as a surrogate for groundwater concentrations, is calculated according the equation 71 from the Guidance on BPR IV/B+C (ECHA, 2017).

The calculated PECs for all scenarios are summarized in the following table:

Summary table on calculated PEC values* – Transfluthrin						
		PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
		[mg/L]	[mg/L]	[mg/kg ww]	[mg/kg ww]	[µg/L]
Scenario 18.1		1.84E-05	1.71E-06	1.87E-03	(Agri 30) 7.63-04 (Agri 180) 1.29E-04 (Grass 180) 5.16E-05	1.46E-04
Scenario 18.2		5.11E-06	4.75E-07	5.18E-04	(Agri 30) 2.12E-04 (Agri 180) 3.59E-05 (Grass 180) 1.43E-05	4.06E-05
[redacted]						
Scenario 18.4	Urban areas	8.13E-06	7.56E-07	8.24E-04	(Agri 30) 3.37E-04 (Agri 180) 5.72E-05 (Grass 180) 2.28E-05	6.46E-05
	Rural areas treated	-	-	-	8.24E-03	9.31E-03
	Untreated	-	-	-	3.49E-05	3.95E-05
Scenario 18.5	Urban areas	-	-	-	-	-
	Rural areas	-	-	-	6.36E-03	7.19E-03

*All PEC values have been calculated with the newest version of EUSES (2.2.0) from ECHA webpage.

Metabolites PEC

The PECwater, PECsed, PECsoil and PECgw of the major metabolites TFB-COOH, TFB-OH and DCVA were calculated based on the highest PECs calculated for the parent multiplied by a formation factor and a correction for the molecular weight. For the indirect emission to soil and groundwater the PEC was calculated according to the AHEE-1 document (ENV TAB entry #10). According to the document "*The amount of parent that is deposed via aerial deposition is usually very low*", as emission to air is considered negligible the deposition from air was considered to be 0 in the calculations.
STP is covered by the a.s. assessment

The calculated PECs of the major metabolites are presented on the below:

Summary table on calculated PEC values TFB-COOH					
		PEC_{water}	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
		mg/l	mg/kg wwt	mg/kg wwt	µg/l
Scenario 18.1		5.25E-07	2.53E-04	(Agri 30) 1.56E-04 (Agri 180) 2.61E-05 (Grass 180) 2.09E-05	1.39E-02
Scenario 18.2		1.46E-07	7.00E-05	(Agri 30) 4.34E-05 (Agri 180) 7.24E-06 (Grass 180) 5.79E-06	3.85E-03
[redacted]	[redacted]				
	[redacted]				
	[redacted]				
Scenario 18.4	Urban areas	2.32E-07	1.11E-04	(Agri 30) 6.91E-05 (Agri 180) 1.15E-05 (Grass 180) 9.23E-06	6.13E-06
	Rural areas (treated)			2.65E-03	3.00E-03
	Untreated			1.12E-05	1.27E-05
Scenario 18.5	Urban areas				
	Rural areas			2.05E-03	2.31E-03

Summary table on calculated PEC values TFB-OH				
	PEC_{water}	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	mg/l	mg/kg wwt	mg/kg wwt	µg/l
Scenario 18.1	3.18E-07	2.66E-05		
Scenario 18.2	8.84E-08	7.36E-06		
[redacted]				
Scenario 18.4 – Urban	1.41E-07	1.17E-05		

Summary table on calculated PEC values DCVA					
		PEC_{water}	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
		mg/l	mg/kg wwt	mg/kg wwt	µg/l
Scenario 18.1		9.58E-07	1.05E-03	(Agri 30) 2.16E-03 (Agri 180) 1.64E-03 (Grass 180) 1.31E-03	**4.76-01**
Scenario 18.2		2.66E-07	2.90E-04	(Agri 30) 6.00E-04 (Agri 180) 4.55E-04 (Grass 180) 3.64E-04	**1.32E-01**
[redacted]					
Scenario 18.4	Urban areas	4.23E-07	4.61E-04	(Agri 30) 9.55E-04 (Agri 180) 7.24E-04 (Grass 180) 5.79E-04	**2.10E-01**
	Rural areas (treated)			4.61E-03	5.21E-03
	Untreated			1.96E-05	2.21E-05
Scenario 18.5	Urban areas	-	-		
	Rural areas			3.56E-03	4.03E-03

Groundwater FOCUS PEARL

The PEC value in groundwater for the metabolite DCVA exceeded the 0.1 µg/l threshold in use 1, 2, 3 and 4, therefore a FOCUS PEARL refinement was performed - see annex 3.3 for further information.
Use 3 is considered the worstcase and the refinement from this use covers the other uses.
The result of the modelling is as follows:

PEC GW (FOCUS PEARL refined)	DCVA [µg/l]
Use 3 – Urban areas	< 0.001

Primary and secondary poisoning

Primary poisoning

The intended uses of b.p. will not result in primary poisoning of birds and mammals.

Secondary poisoning

According to the AR (2014), Transfluthrin has a potential to bioaccumulate demonstrated by the Log Pow>5 and BCF_{fish} =1783 L/kg and a $BCF_{earthworm}$ of 10452 L/kg ww.
Both metabolites TFB-OH and TFB-COOH are not expected to bioaccumulate: the estimated log P_{ow} is 1.85 for TFB-COOH and 1.54 for TFB-OH. Epiwin calculates for DCVA a log Pow of 3.38 - The metabolite is far less toxic than the active substance, and is considered covered by the assessment of the active substance.

During the outdoor use of the b.p., birds and mammals may be poisoned secondarily through the ingestion of contaminated ants, insects and/or by the consumption of earthworms from contaminated soils (bait box stations release via wash-off).
Mammals and birds may consume contaminated worms and insects from the adjacent soil.
The concentration of the active substance in the earthworm is calculated according to the Guidance on the BPR Vol IV Environment (Parts B + C).
No short-term or long-term dietary toxicity data are available for birds, and therefore a $PNEC_{oral}$, bird cannot be derived.
As explained on the AR (2014) from Transfluthrin for the PNECoral,bird to fall below the PEC, the NOEC should be lower than the PECoral,bird x 30, and should thus be < 0.03 mg/kg feed in case of fish and < 0.26 mg/kg feed (indoor use) and < 0.07 mg/kg feed (outdoor use) in case of earthworms. Following a similar reasoning for short-term tests, the LC50 should be < 3, 26 and 7 mg/kg feed, respectively (< PECoral,bird x 3000). In view of the absence of acute toxicity to birds at doses up to 1890 mg/kg bw, it is not expected that chronic toxicity levels as low as 0.03 mg/kg feed will be reached.
Consequently as no risk of secondary poisoning is expected for birds, a quantitative secondary poisoning assessment was just performed for mammals.
The secondary poisoning assessment was performed for the worst case application rate of [redacted]

As input parameter the concentrations in the receiving soil compartment are included (without considering degradation of Transfluthrin) 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 the concentration (C) of active substance in insects the ESD PT18 is in line with document (SANCO/4145 2002), distinguishing residue concentrations in large insects and small insects

as a result of an application rate by spraying of 1 kg active substance per hectare (RUD = Residue per Unit Dose). Consequently, these figures have to be multiplied by the actual application rate (T_{appl}) to obtain the concentration per wet weight.
Depending on the time scale (acute or short term) either arithmetic means or 90th percentiles are used. The calculations were adapted in line with the approaches agreed at WG V 2016.
T_{appl} is calculated in line with the ESD PT18 as follows: =(Qprod_g ([redacted])*Fai (0.00104)/1000) * Number_application sites (1) / $Area_{treated}$ (5.04 m^2) = 2.63E-06 kg a.s./m_2.
The formula **$C_{insects}$ = RUD x T_{appl} x 10^{-4}**. is used to calculate the concentration in insects. Concentration in earthworms was calculated according to $BCF_{earthworm}$*$C_{porewater}$ + C_{soil}*F_{gut}*$CONV_{soil}$)/(1+F_{gut}*$CONV_{soil}$), where C_{soil} is set to 0.5 of the calculated PEC_{soil}.

Residue values per unit dose (mg a.s./kg bw at a dosage of 1 kg a.s./ha area) and relevant food sources derived from the ESD PT18, used for calculating the concentration (C) in indicator species			
Species	**Main food**	**Residue value per unit dose (RUD)**	
Mammals		Acute (90%)	Short-term (mean)
Pipistrelle	Large insects	14	5.1
Shrew	Large insects and worms	14	5.1
Mole	Worms		
Hedgehog	Large insects	14	5.1
Badger	Large insects and worms	14	5.1

Tier 1 calculations Predicted Environmental Concentrations in food for insect, earthworm and mammal eating mammals for Transfluthrin, when used as insecticide within b.p (Scenario 18.3: Spray treatment on floor areas outdoors)			
Species	**PECinsects (mg a.s./kg ww food)**		**PECearthworm (mg a.s./kg ww food)**
	Acute	Short-term	
Mammals			
Pipistrelle	3.68E-09	1.34E-09	-
Shrew	3.68E-09	1. 34E-09	1.78E-01
Mole			1. 78E-01
Hedgehog	3.68E-09	1. 34E-09	1. 78E-01
Badger	3.68E-09	1. 34E-09	1. 78E-01

In the ESD for PT 18 (OECD, 2008) a refinement is incorporated, where the calculated active substance in the earthworm $C_{earthworm}$ ($PEC_{earthworm}$) have to be replaced by the estimated theoretical exposure (ETE). For the food chain from earthworm to earthworm-eating mammals, the estimated residues in earthworm is converted to daily dose in the predator by multiplying a factor that relates the food intake rates and the body weight (FIR/bw). This factor corresponds to 1.4 for mammals and it is derived from the exposure scenario established for plant protection products in the EU (European Commission, 2002). The ETE values are calculated as a function of the content of the active substance Transfluthrin in worms and assuming the standardised worst-case scenario for the rest of the parameters.
For insectivorous species, the estimated theoretical exposure (ETE) is calculated, representing the estimated daily intake and corresponding to the PEC_{oral} per day (expressed as mg a.s./kg bw of the pray species/day of mg a.s./kg food/day).

ETE = (FIR / BW) * C * AV * PT * PD (mg.kg^{-1} bw/d)

Where,

FIR: Food intake rate of insectivorous or worm eating species (fresh weight) (g.d^{-1})
BW: Body weight of insectivorous or worm eating species (g)
C: Concentration of active compound in fresh diet (insects or worms) (mg. kg^{-1})
AV: Avoidance factor (1 = no avoidance, 0 = complete avoidance)
PT: Fraction of diet obtained in treated area (value between 0 and 1)
PD: Fraction of food type in diet (number between 0 and 1; one type or more types)

Food intake rates per body weight (FIR/bw) for indicator species of lawn/garden derived from the Table 5.2-5 of the ESD PT18					
Species	**Body weight**	**FIR**		**FIR/bw**	
Mammals		Insect	earthworm	Insect	earthworm
Pipistrelle	7.6	5.2	-	0.68	-
Shrew	10	6.3	5.25**	0.63	0.57
Mole	85	-	61.2	-	0.72
Hedgehog	1100	172.1	374.2	0.16	0.34
Badger	10100	822	1786.7	0.08	0.18

*: Extrapolated from FIR/BW data on "small insectivorous mammal 2- 10 g" (ESD PT18 p. 160);
**: Extrapolated from FIR insects correcting for percentage moisture (70.5/84.6)

The theoretical exposure of predators is a function of the estimated concentration of the insecticide found in food sources (insectivorous mammals). Concentrations are derived from the exposure scenario established for plant protection products in the EU (European Commission, 2002).
The total application rate of biocidal product per m² is [redacted]. As a first step, the actual application rate is calculated [redacted]. In a second step, the Transfluthrin concentration in the fresh diet is assessed for acute and short-term exposure, and the estimated theoretical exposure is calculated for the corresponding indicator species (insectivorous mammal).

Tier 2 calculations of Predicted Environmental Concentrations (in insect and earthworm eating mammals) for Transfluthrin, when used as insecticide within b.p (Scenario 18.3: Spray treatment on floor areas outdoors)

Species	ETEworm eater (mg/kg/d)	ETEinsectivorous (mg/kg/d)		ETE combined	
Mammals		Acute	Short term	Acute	Short term
Pipistrelle	-	2.50E-09	9.12E-10	2.50E-09	9.12E-10
Shrew	1.02E-01	2.32E-09	8.45E-10	1.02E-01	1.02E-01
Mole	1.28E-01	-	-	1.28E-01	1.28E-01
Hedgehog	6.07E-02	5.89E-10	2.15E-10	6.07E-02	6.07E-02
Badger	3.21E-02	2.95E-10	1.07E-10	3.21E-02	3.21E-02

Note that due to the imbalance in the calculations for insects and earthworms, risk assessment is driven by the exposure to earthworms

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: Under the proposed conditions of use, Transfluthrin will be emitted to air. According to the ESD, the concentration in air upon indoors and outdoors use will be not relevant because of instant dilution.
The estimated half-life time in air is 2.4 days (Atkinson calculation), which is borderline for the FOCUS air criteria, for long range transport requiring a further evaluation. However, the a.s. has a relatively low volatility (vapour pressure of 9 x 10^{-04} Pa at 20°C) and a high Koc value indicating that the substance has tendency to bind to soil and a low potential to evaporate from soils. Thus the long range transport in the air is expected to be rather limited. Therefore, the risk characterization for the atmosphere is of no relevance and air is not regarded as a compartment of concern for the proposed use patterns.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values for Transfluthrin	
	PEC/PNEC$_{STP}$
Scenario 18.1	3.23E-04
Scenario 18.2	8.96E-05
[redacted]	[redacted]
Scenario 18.4 (urban areas)	1.43E-04

Conclusion: There are no unacceptable risk in the STP compartment from the active substance.

Aquatic compartment

Summary table on calculated PEC/PNEC values for Transfluthrin		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
Scenario 18.1	9.77E-01	**5.24E+00**
Scenario 18.2	2.71E-01	**1.45E+00**
[redacted]	[redacted]	[redacted]
Scenario 18.4 (urban areas)	4.32E-01	**2.31E+00**

Metabolites - Calculated PEC/PNEC values			
Scenario	**PEC/PNEC$_{water}$**		
	TFB-COOH	**TFB-OH**	**DCVA**
Scenario 18.1	5.25E-06	3.18E-06	1.50E-05
Scenario 18.2	1.46E-06	8.84E-07	4.16E-05
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 18.4 (Urban areas)	2.32E-06	1.41E-06	6.62E-05

Conclusion:
There are unacceptable risk in both the freshwater and sediment compartment due to the active substance. For scenario 18.1 and 18.2 (indoor uses – MetaSPC 1 use 1 and use 2) no risk mitigation measure can be applied to mitigate the risk, hence the uses cannot be authorised.
For the outdoor uses [redacted] and 18.4) the product can be limited to being used where emission to drains (sewer) can be prevented. DK CA will apply the frequently used sentence N141 *"Do not use where releases to drains (sewer) and/or surface water cannot be prevented"*, as risk mitigation measures for both uses (MetaSPC 2, use 1 and use 2) (note that after NL referral 22.11.2022 the wording of the RMM is changed to: *"Only spray the product where it cannot release to (sewer) drains, surface water or ponds."*).

There are no unacceptable risk in the freshwater or sediment compartments from the metabolites of the active substance.

Terrestrial compartment

Calculated PEC/PNEC values for Transfluthrin	
Scenario	**PEC/PNEC$_{soil}$**
Scenario 18.1	5.86E-04
Scenario 18.2	1.63E-04

[redacted]	[redacted]	[redacted]
	[redacted]	[redacted]
Scenario 18.4	Urban areas	2.59E-04
	Rural areas	9.36E-02
Scenario 18.5	Rural areas	7.23E-02

Metabolites - Calculated PEC/PNEC values				
Scenario		**PEC/PNEC$_{soil}$**		
		TFB-COOH	**TFB-OH**	**DCVA**
Scenario 18.1		1.74E-03	-	1.02E-01
Scenario 18.2		4.83E-04	-	2.84E-02
[redacted]	[redacted]	[redacted]		
	[redacted]	[redacted]		
Scenario 18.4	Urban areas	7.69E-04	-	4.53E-02
	Rural areas	2.21E-01	-	3.60E-01
Scenario 18.5	Rural areas	1.71E-01	-	2.78E-01

Conclusion: There are no unacceptable risk in the soil compartments from the active substance or its metabolites.

Groundwater

The calculated groundwater concentrations are below the trigger value of 0.1 µg/L for the a.s and their metabolites (after PEARL refinement for DCVA see annex 3.3). Therefore, no elevated concentrations in groundwater can be expected.

Primary and secondary poisoning

Primary poisoning

The intended uses of b.p. will not result in primary poisoning of birds and mammals.

Secondary poisoning

Tier 1: Concentrations in insect and worm eating mammals tested against the PNEC food					
Species	**PECearthworm**	**PECinsects**		**PEC/PNEC combined**	
Mammals		Acute	Short term	Acute	Short term
Pipistrelle	-	3.68E-09	1.34E-09	5.52E-10	2.01E-10
Shrew	1.78E-01	3.68E-09	1.34E-09	2.68E-02	2.68E-02
Mole	1.78E-01	-	-	2.68E-02	2.68E-02
Hedgehog	1.78E-01	3.68E-09	1.34E-09	2.68E-02	2.68E-02
Badger	1.78E-01	3.68E-09	1.34E-09	2.68E-02	2.68E-02

Summary table on secondary poisoning				
Risk assessment for insect and worm eating mammals				
Exposure scenario	**PECoral [mg/kg]***	**PECoral [mg/kg]***	**PEC/PNEC**	
	Acute	Short term	Acute	Short term
Mammals feeding on worms	1.78E-01		2.68E-02	
Mammals feeding on insects	3.68E-09	1.34E-09	5.52E-10	2.01E-10

* mg/kg insects or earthworms;

Tier 2: At WGV 2016 it was clarified that the Tier 2 refinement in the ESD where food concentrations are transformed to concentrations based on body weights (ETE) at the PEC side induces that also at the PNEC side the units should be transformed to body weight. It should be noted, however, that this approach is not a higher tier, but only another way to do the risk assessment.

Summary table on secondary poisoning					
Species	**ETEworm (mg/kg/d)**	**ETEinsect (mg/kg/d)**		**PEC/PNEC combined**	
Mammals		Acute	Short term	Acute	Short term
Pipistrelle	-	2.50E-09	9.12E-10	3.76E-10	1.37E-10

Shrew	1.02E-01	2.32E-09	8.45E-10	1.52E-02	1.52E-02
Mole	1.28E-01	-	-	1.93E-02	1.93E-02
Hedgehog	6.07E-02	5.89E-10	2.15E-10	9.10E-03	9.10E-03
Badger	3.21E-02	2.95E-10	1.07E-10	4.82E-03	4.82E-03

Summary table on secondary poisoning				
Risk assessment for insect and worm eating mammals				
Exposure scenario	**PECoral [mg/kg]***	**PECoral [mg/kg]***	**PEC/PNEC**	
	Acute	Short term	Acute	Short term
Mammals feeding on worms	1.28E-01		1.93E-02	
Mammals feeding on insects	2.50E-09	9.12E-10	3.76E-10	1.37E-10

Conclusion: All scenarios for mammals indicate PEC/PNEC values below 1 indicating no unacceptable risk (i.e. due to a wash off event).

Mixture toxicity

Conclusion: The assessment for mixture toxicity is not relevant, as products of the BPF only contain Transfluthrin as a.s. and no further SoCs for the environment.

Aggregated exposure (combined for relevant emmission sources)

Conclusion: Aggregated exposure is not relevant since the a.s. is only used for PT 18 purposes.

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

On the basis of the calculations made with the environmental risk assessment, there is no unacceptable risk in any environmental compartment for the active substance Transfluthrin or its metabolites:

- The risk assessment for **sewage treatment plants** indicates safe use for the b.p (RCR < 1 in all scenarios).
- The risk assessment for **surface water** indicates safe use of the b.p. (RCR < 1) in all scenarios, except for MetaSPC 2; Use 1 (18.3 - outdoor), where the RCR is above 1. The risk can be mitigated with the risk mitigation: "*Only spray the product where it cannot release to (sewer) drains, surface water or ponds.*".
- The risk assessment **for sediment** indicates non-safe use of the b.p. (RCR > 1) in all scenarios, except MetaSPC 2; Use 3.
- For MetaSPC 1; Use 1 and Use 2 (indoor) there is no risk mitigation measure that can be applied to cover the risk, hence the uses are to be non-authorised.

For MetaSPC 2; [redacted] Use 2 (outdoor) the risk mitigation measure, "*Only spray the product where it cannot release to (sewer) drains, surface water or ponds.*", is applied to mitigate the risk.

- The risk assessment **for soil** indicates safe use of the b.p. (RCR < 1 in all scenarios).
- No risk for the **groundwater** is identified as calculated groundwater concentrations are below 0.1 µg/L for the assessed scenarios.

2.2.9 Measures to protect man, animals and the environment

See SPC and section 2.1.5 in the assessment report.

2.2.10 Assessment of a combination of biocidal products

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

2.2.11 Comparative assessment

Not required. Active substance does not fulfil exclusion or substitution criteria according to article 5(1) and 10(1) of the BPR.
Member State to see all the authorised uses and RMMs authorised for the product].

3 ANNEXES

3.1 List of studies for the biocidal product family

Author(s)	Year	Title	Testing Company	Report No.	GLP Study (Yes/No)	Published (Yes/No)	Data Protection Claimed (Yes/No)	Data Owner	Section No. in IUCLID / Non-key study/ Published
[redacted]	2022a	Product specifications of FIK WB Premium Indoors" "H-21024"	Henkel Iberica, S. A., Barcelona, Spain	PS-21024.5	No	No	Yes	Henkel Ibérica, S.A., Barcelona, Spain	3.1
[redacted].	2022b	PRODUCT SPECIFICATIONS FORMULA FIK WB Outdoors TFT BPR, H-21021	Henkel Iberica, S. A., Barcelona, Spain	PS-21021.5	No	No	Yes	Henkel Ibérica, S.A., Barcelona, Spain	3.1
[redacted]	2022a	PRODUCT SPECIFICATIONS FORMULA FIK WB Outdoors VAPE TFT BPR, H-21025	Laboratorio Chimico Farmaceutico Sammarinese L.C.S S.p.a., Faetano, Rep San Marino	LR-LC-046.3	No	No	Yes	Henkel Ibérica, S.A., Barcelona, Spain	3.1

[redacted]	2022c	ACCELERATED STORAGE STABILITY PHYSICO-CHEMICAL CHARACTERISTICS FORMULA FIK WB Premium Indoors H-21024	Henkel Ibérica S.A, Barcelona, Spain	ASSR-21024.4	No	No	Yes	Henkel Ibérica, S.A., Barcelona, Spain	3.4.1
[redacted]	2022d	ACCELERATED STORAGE STABILITY PHYSICO-CHEMICAL CHARACTERISTICS FORMULA FIK WB Outdoors TFT BPR H-21021	Henkel Ibérica S.A., Barcelona, Spain	ASSR-21021.4	No	No	Yes	Henkel Ibérica, S.A., Barcelona, Spain	3.4.1
[redacted]	2022b	ACCELERATED STORAGE STABILITY PHYSICO-CHEMICAL CHARACTERISTICS FORMULA FIK WB OUTDOORS Vape TFT H-21025	Laboratorio Chimico Farmaceutico Sammarinese L.C.S S.p.a., Faetano, Rep San Marino	ASSR-21025.4.2	No	No	Yes	Henkel Ibérica, S.A., Barcelona, Spain	3.4.1
[redacted]	2022c	LONG TERM STORAGE STABILITY PHYSICO-	Henkel Iberica, S. A.,	LTSS-21024.2	No	No	Yes	Henkel Ibérica, S.A.,	3.4.2

		CHEMICAL CHARACTERISTICS FIK WB Premium Indoors, H-21024	Barcelona, Spain					Barcelona, Spain	
[redacted]	2022d	LONG TERM STORAGE STABILITY PHYSICO-CHEMICAL CHARACTERISTICS FIK WB Premium Indoors, H-21021	Henkel Iberica, S. A., Barcelona, Spain	LTSS-21021.3	No	No	Yes	Henkel Ibérica, S.A., Barcelona, Spain	3.4.2
[redacted]	2022d	LONG TERM STORAGE STABILITY PHYSICO-CHEMICAL CHARACTERISTICS FIK WB Outdoors VAPE TFT BPR, H-21025	Laboratorio Chimico Farmaceutico Sammarinese L.C.S S.p.a., Faetano, Rep San Marino	LTSS-21025.3	No	No	Yes	Henkel Ibérica, S.A., Barcelona, Spain	3.4.2
[redacted]	2019a	DETERMINATION OF THE REMAINING QUANTITY OF FORMULA AFTER EMPTYING THE AEROSOL BY SEQUENTIAL SPRAYING OF	Laboratorio Chimico Farmaceutico Sammarinese L.C.S S.p.a., Faetano, Rep San Marino	LR-LC-050	No	No	Yes	Henkel Ibérica, S.A., Barcelona, Spain	3.5

		FORMULA H-21025							
[redacted]	2022c	Test for the Evaluation of the discharge rate and spray pattern of the formulation H-21025_Vape Outdoor-TFT	Laboratorio Chimico Farmaceutico Sammarinese L.C.S S.p.a., Faetano, Rep San Marino	LR-LC-022.1	No	No	Yes	Henkel Ibérica, S.A., Barcelona, Spain	3.5.12 3.5.13
[redacted]	2019a	LOW TEMPERATURE STABILITY TEST FOR LIQUID CONCENTRATES of H-21021 / H-21024	Henkel Insect Control Innovation center, Barcelona, Spain	LR-C-727	No	No	Yes	Henkel Ibérica SA, Barcelona, Spain	3.4.1
[redacted]	2019a	Particle size on aerosol sample labelled as H-21024-FIK WB Premium Indoors BPR	Stazione Sperimentale per i combustibili, Milan, Italy	RPT-SSC-190247	No	No	Yes	Henkel Ibérica, S.A., Barcelona, Spain	3.5.6a
[redacted]	2019b	Particle size on aerosol sample labelled as H-21021	Stazione Sperimentale per i combustibili, Milan, Italy	RPT-SSC-190508	No	No	Yes	Henkel Ibérica, S.A., Barcelona, Spain	3.5.6a
[redacted]	2019c	Particle size on aerosol sample labelled as H-21025	Stazione Sperimentale per i combustibili, Milan, Italy	RPT-SSC-190249	No	No	Yes	Laboratorio Chimico Farmaceutico Sanmarines	3.5.6a

								e L.C.S S.p.a., Faetano, Rep San Marino	
[redacted]	2022a	Discharge rate and spray pattern of aerosol FIK WB Premium Indoors BPR H-21024	Henkel Insect Control Innovation center, Barcelona, Spain	LR-C-632 (R9)	No	No	Yes	Henkel Ibérica, S.A., Barcelona, Spain	3.5.12 3.5.13
[redacted]	2022b	Discharge rate and spray pattern of aerosol FIK WB Outdoors BPR H-21021	Henkel Insect Control Innovation center, Barcelona, Spain	LR-C-652-B (R9)	No	No	Yes	Henkel Ibérica, S.A., Barcelona, Spain	3.5.12 3.5.13
[redacted]	2019d	Determination of the remaining quantity of formula after emptying the aerosol by sequential spraying for formula H-21024	Henkel Insect Control Innovation center, Barcelona, Spain	LR-728-(H-21024)	No	No	Yes	Henkel Iberica, S. A., Barcelona, Spain	3.5.13
[redacted]	2019e	Determination of the remaining quantity of formula after emptying the aerosol by	Henkel Insect Control Innovation center, Barcelona, Spain	LR-728-(H-21021)	No	No	Yes	Henkel Iberica, S. A., Barcelona, Spain	3.5.13

		sequential spraying for formula H-21021							
[redacted]	2019f	WAIVER to skip the SURFACE TENSION Determination of FORMULATION H-21021 and H-21024	Henkel Iberica, S. A., Barcelona, Spain	LR-C-707.1	No	No	Yes	Henkel Iberica, S. A., Barcelona, Spain	3.8
[redacted]	2019b	WAIVER to skip the SURFACE TENSION Determination of FORMULATION H-21025	L.C.S. R&D Laboratory, Faetano, San Marino	LR-LC-023	No	No	Yes	Laboratorio Chimico Farmaceutico Sanmarinese L.C.S S.p.a., Faetano, Rep San Marino	3.8
[redacted]	2021	Determination of the corrosion of metals by H-21024 following method 37.4 C.1 of the UN Handbook	Laus GmbH, Kirrweiler, Germany	21081002G979	Yes	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	4.16
[redacted]	2021	Determination of the corrosion of metals by H-21025 following method 37.4	Laus GmbH, Kirrweiler, Germany	21081003G979	Yes	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	4.16

		C.1 of the UN Handbook							
[redacted]	2021	Analyzing Report	Henkel, HSA-Corporate Analytics, Düsseldorf, Germany	21-11163	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	4.17.1
[redacted]	2019	Analytical method validation report for Transfluthrin, 1R-transphenothrin and Prallethrin insecticides products	Leitat, Terrassa (Barcelona), Spain	IN-01411/2019-3	No	No	Yes	Henkel Ibérica SA, Barcelona, Spain	5.1
[redacted]	2019	ANALYSIS OF TRANSFLUTRHIN, PRALLETHRIN AND 1R-TRANS-PHENOTHRIN IN AEROSOL	Henkel Ibérica SA, Barcelona, Spain	LN-0723.2	no	no	yes	Henkel Ibérica SA, Barcelona, Spain	5.1
[redacted]									

[redacted]	2019	Efficacy Evaluation of H-21021 FIK WB Outdoors BPR against Vespula germanica	Entostudio S.r.I., Ponte san Nicolò, Italy	RB-245.4	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]	2019	Evaluation of the efficacy of "H-21021 FIK WB Outdoors BPR" against Lasius niger (direct application)	Entostudio S.r.I., Ponte san Nicolò, Italy	RB-245.5	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]	2019	Evaluation of the efficacy of "H-21024 FIK WB Premium Indoors BPR" against Lasius niger (direct application)	Entostudio S.r.I., Ponte san Nicolò, Italy	RB-242.6	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]	2019	Efficacy evaluation of H-21024 FIK WB Premium Indoors BPR	Entostudio S.r.I., Ponte san Nicolò, Italy	RB-242.7	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]	2019	EFFICACY EVALUATION OF H-21021 FIK WB Outdoors BPR AGAINST VESPA CRABRO	Entostudio S.r.I., Ponte san Nicolò, Italy	RB-245.7	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]	2019	EFFICACY EVALUATION	Entostudio S.r.I., Ponte	RB-245.8	No	No	Yes	Henkel Ibérica S.A.,	6.7

		OF H-21021 FIK WB Outdoors BPR AGAINST NESTS OF POLISTES GALLICUS	san Nicolò, Italy					Barcelona, Spain	
[redacted]	2019	EFFICACY EVALUATION OF "H-21025 FIK WB Outdoors VAPE TFT BPR" AGAINST AEDES ALBOPICTUS (DIRECT APPLICATION)	Entostudio S.r.I., Ponte san Nicolò, Italy	RB-252	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]	2019	EFFICACY EVALUATION OF "H-21025 FIK WB Outdoors VAPE TFT BPR" AGAINST CULEX PIPIENS (DIRECT APPLICATION)	Entostudio S.r.I., Ponte san Nicolò, Italy	RB-252.1	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]	2019	EFFICACY EVALUATION OF "H-21025 FIK WB Outdoors VAPE TFT BPR" AGAINST MUSCA DOMESTICA	Entostudio S.r.I., Ponte san Nicolò, Italy	RB-252.2	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7

		(DIRECT APPLICATION)							
[redacted]	2019	EFFICACY EVALUATION OF "H-21025 FIK WB Outdoors VAPE TFT BPR" AGAINST VESPULA GERMANICA (DIRECT APPLICATION)	Entostudio S.r.I., Ponte san Nicolò, Italy	RB-252.3	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]	2019	EFFICACY EVALUATION OF "H-21025 FIK WB Outdoors VAPE TFT BPR" AGAINST LASIUS NIGER (DIRECT APPLICATION)	Entostudio S.r.I., Ponte san Nicolò, Italy	RB-252.4	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]	2019	EFEFFICACY EVALUATION OF "H-21025 FIK WB Outdoors VAPE TFT BPR" AGAINST LINEPITHEMA HUMILE (DIRECT APPLICATION)	Entostudio S.r.I., Ponte san Nicolò, Italy	RB-252.5	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]									

[redacted]	2019	FIK WB Outdoors BPR Code number: H-21021 Biological efficacy against Linephitema humile (Mayr 1868). (Hymenoptera, Formicidae) (R10)	Henkel Ibérica S.A., Barcelona, Spain	RB-231.3	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]	2019	FIK WB Outdoors BPR Code number: H-21021 Biological efficacy against Musca domestica (L.1758). Direct spray (Diptera, Muscidae) (R10)	Henkel Ibérica S.A., Barcelona, Spain	RB-245.2	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]	2019	Biological efficacy against Linephitema humile (Mayr 1868) (Hymenoptera, Formicidae) (R10)	Henkel Ibérica S.A., Barcelona, Spain	RB-242.5	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7

[redacted]	2019	FIK WB Premium Indoors BPR Code number: H-21024 Biological efficacy against Musca domestica (L.1758). Direct spray (Diptera, Muscidae) (R10)	Henkel Ibérica S.A., Barcelona, Spain	RB-242.2	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]	2019	Biological efficacy against Aedes albopictus (Skuse 1894). Direct spray (Diptera, Culicidae) (R10)	Henkel Ibérica S.A., Barcelona, Spain	RB-242.4	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]	2019	Biological efficacy against Culex pipiens (L.1758). Direct spray (Diptera, Culicidae) (R10)	Henkel Ibérica S.A., Barcelona, Spain	RB-242.3	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]	2019	Biological efficacy against Simulium erytrocephalum (Diptera, Simulidae)	Henkel Ibérica S.A., Barcelona, Spain	RB-245.6	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7

		(R10). Direct spray							
[redacted]	2019	Biological efficacy against Aedes albopictus (Skuse 1894). (Diptera, Culicidae) (R10)	Henkel Ibérica S.A., Barcelona, Spain	RB-242.8	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]	2019	Biological efficacy against Culex pipiens (L.1758). (Diptera, Culicidae) (R10)	Henkel Ibérica S.A., Barcelona, Spain	RB-242.1	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7
[redacted]	2019	Biological efficacy against Musca domestica (L.1758). (Diptera, Muscidae) (R10)	Henkel Ibérica S.A., Barcelona, Spain	RB-242	No	No	Yes	Henkel Ibérica S.A., Barcelona, Spain	6.7

3.2 Output tables from exposure assessment tools

Please refer to the Confidential Annex 3.6 for information on output tables from exposure assessment tools.

3.3 Environment: FOCUS PEARL modelling

FOCUS PEARL modelling:

The transformation scheme for Transfluthrin in soil considered 100 % transformation to DCVA in accordance with the *Harmonised List of Endpoints for pyrethroid metabolites* (BPC-35-2020-23).

The Simulation model FOCUS PEARL 4.4.4 is used for the refinement of the environmental exposure assessment of metabolite DCVA in the groundwater compartment. The emission of active substance from Use 3 was used, as this is the worstcase use compared to the other uses.

Input parameters for modelling with FOCUS PEARL			
Input			**Remarks**
Application rate of a.s. Transfluthrin	17.6 (Arable)) g/ha/year	3.52 (Grassland) g/ha/year	
Number of applications	1 (20 days before emergence – Incorporation into soil)	1 (1st. of March – Incoporation into soil)	
Crop	Arable (Maize and Winter Cereals)	Grassland (alfalfa)	
FOCUS PEARL Parameters	**Transfluthrin**	**DCVA**	
Molecular weight [g/mol]	371.2	209.07	
Water solubility [mg/L]	0.057 (20°C)	372.19 (25°C)	
Vapour pressure [Pa]	9.00E-04 (20°C)	0.26 (°25)	
Transformation			
half life DT_{50} [d]	5.17 (12°C)	174.8 (12°C)	
Formulation fraction (f_{ij})		1	
plant uptake factor	0	0	
Interception by plants	No	No	
Koc [l/kg]	50119	106	
Kom=Koc/1.724	29071	61.48	
Freundlich exponent	0.9	0.65	
Molar activation energy	65.4	65.4	TAB ENV 23 (February 2021)

For the calculation of PEC groundwater, the following application scheme is used: Sewage Sludge Application on soil. In case of running sewage sludge application scenarios in

FOCUS groundwater models it was agreed at WG-II-2014 that both grassland (alfalfa) and agricultural land (maize) should be used. In case of grassland application, the scenario considers one sewage sludge application per year on 1st of March (absolute application) and 10 cm incorporation depth. In case of agricultural land application, the scenario considers one sewage sludge application per year to maize and winter cereals 20 days before crop event "emergence" (relative application) and 20 cm incorporation depth.

The results of the simulation are as follows:

LOCATION	Transfluthrin [µg/L]		
	Arable land		Grassland
	Winter cereals	Maize	Alfalfa
CHATEAUDUN	0.000000	0.000000	0.000000
HAMBURG	0.000000	0.000000	0.000000
JOKIOINEN	0.000000	-	0.000000
KREMSMUENSTER	0.000000	0.000000	0.000000
OKEHAMPTON	0.000000	0.000000	0.000000
PIACENZA	0.000000	0.000000	0.000000
PORTO	0.000000	0.000000	0.000000
SEVILLA	0.000000	0.000000	0.000000
THIVA	0.000000	0.000000	0.000000

LOCATION	DCVA [µg/L]		
	Arable land		Grassland
	Winter cereals	Maize	Alfalfa
CHATEAUDUN	0.000000	0.000000	0.000000
HAMBURG	0.000000	0.000000	0.000000
JOKIOINEN	0.000000	-	0.000000
KREMSMUENSTER	0.000000	0.000000	0.000000
OKEHAMPTON	0.000000	0.000000	0.000000
PIACENZA	0.000000	0.000000	0.000000
PORTO	0.000000	0.000000	0.000000
SEVILLA	0.000000	0.000000	0.000000
THIVA	0.000000	0.000000	0.000000

3.4 New information on the active substance

No information on the active substance are available.

3.5 Residue behaviour

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

A summary and assessment of the efficacy studies performed in all intended uses of the products of the Biocidal Product Family TFT aersosols BPF in the Product Type 18 is provided in Section 2.2.5**Error! Reference source not found.** "Efficacy against target organisms".

3.7 Confidential annex

Please refer to the Confidential Annex document for information regarding the Methods for detection and identification, the composition of the biocidal products, the structure of the biocidal product family, information of the substances of concern, screening of potential endocrine disrupting properties of non-active substances and output tables from exposure assessment tools.

3.8 Other