Application type	refMS/ eCA	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment / renewal)	Chapter/ page
SA-APP	*NL*	BC-SJ023954-26	02.04.2020	Initial assessment	
SA-MIC	*NL*	BC-ED063236-56	01.04.2021	*Addition of a packaging size*	See addendum '20210402_NL-0015509-0000_Addendum'

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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)

Entfloher

Product type 18

Active substance: Permethrin and pyriproxyfen as included in the Union list of approved active substances

Asset Number: NL-0015509-0000

Evaluating Competent Authority: NL

Date: 03 April 2020

Table of Contents

1 CONCLUSION

The biocidal product Entfloher contains the active substances permethrin and pyriproxyfen. The product is an insecticide for non-professional use.
It is concluded by the eCA that sufficient data have been provided to fulfil the conditions of Article 19 of regulation (EU) 528/2012. When using the product according to the conditions as stated in the SPC, the product will be efficacious and will not present an unacceptable risk to human and animal health nor to the environment.

The physico-chemical properties of the biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the biocidal product. The product in the commercial packaging (pressurized aluminium or tin plate with a bag on valve system) has a shelf-life of 3 years at ambient temperature. The product should be protected from frost and direct sunlight and kept below 40°C.

Studies were submitted for the product Entfloher (3.125 mL/m^2) in order to demonstrate the (residual) efficacy of the product in terms of knockdown and/or mortality.
Efficacy of treatment of pet areas (bedding, carpet, cushions) was demonstrated against eggs and larvae of fleas, including a residual efficacy of 24 weeks. Efficacy against adult fleas, ticks, mites, cockroaches, silverfishes, woodlice and ants was insufficiently demonstrated.

The overall conclusion of the human toxicology evaluation of the biocidal product, Entfloher, containing 0.6% (w/w) and 0.1% (w/w) of the biocidal active substances (a.s.) permethrin and pyriproxyfen, respectively and 4.95% (w/w) as well as 94.05% (w/w) of the substances of concern (SoCs) propan-2-ol and ethanol, is that neither the a.s. nor the SoCs will present an unacceptable risk to humans during and after the intended use of the product.

The environmental risk assessment has demonstrated that calculated concentrations of the active substances in environmental compartments present an acceptable risk for the STP, groundwater and primary and secondary poisoning of birds and mammals. However, for application of the product for the control of pet fleas, mites and ticks by spraying a safe use cannot be demonstrated as the PEC/PNECs for surface water and sediment are > 1. However this risk is considered acceptable provided that the following risk mitigation measure is included in the label: "Do not apply on wet washable surfaces or materials". Application of the product for the control of crawling insects by spraying is acceptable as for none of the environmental compartments the calculated concentrations present a risk.

In conclusion, only the use against eggs and larvae of fleas can be authorised.

2 ASSESSMENT REPORT

SUMMARY OF THE PRODUCT ASSESSMENT

Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country (if relevant)**
Entfloher	The Netherlands Germany Belgium

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	ConVet GmbH & Co. KG
	Address	Creative Campus Monheim Gebäude A01 Alfred-Nobel-Strasse 10 D-40789 Monheim Germany
Authorisation number	NL-001559-0000	
Date of the authorisation	03-04-2020	
Expiry date of the authorisation	03-04-2030	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	BIB PRODUCTION & PACKAGING B.V.
Address of manufacturer	Randweg 7 6045 JK Roermond Netherlands
Location of manufacturing sites	Randweg 7 6045 JK Roermond Netherlands

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

Active substance	Permethrin
Name of manufacturer	Tagros Chemicals India Limited
Address of manufacturer	72, Marshalls Road Jhaver Centre, Rajah Annamalai Building Egmore Chennai 600008 Tamil Nadu India
Location of manufacturing sites	72, Marshalls Road Jhaver Centre, Rajah Annamalai Building Egmore Chennai 600008 Tamil Nadu India

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

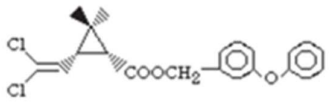
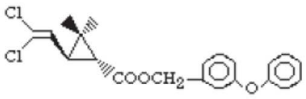
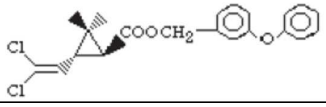
Active substance	Pyriproxyfen
Name of manufacturer	Sumitomo Chemical (UK) Plc
Address of manufacturer	Hythe House 200 Shepherds Bush Road Hammersmith London W6 7NL United Kingdom
Location of manufacturing sites	Sumitomo Chemical Co. Ltd. 27-1, Shinkawa 2-chome Chuo-ku Tokyo 104-8260 Japan

Product composition and formulation

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?

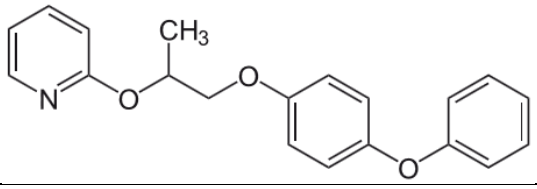
Yes ☐
No ☒

2.1.1.5 Identity of the active substance

Main constituent(s)	
ISO name	Permethrin
IUPAC or EC name	m-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	613-058-00-2
Minimum purity / content	>97 %(w/w)
Structural formula **1Rcis isomer**	
1Scis isomer	
1Rtrans isomer	
1Strans isomer	

2.1.1.6 Identity of the active substance

Main constituent(s)	
ISO name	Pyriproxyfen
IUPAC or EC name	2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)pyridine 4-phenoxyphenyl (RS)-2-(2- pyridyloxy)propyl ether
EC number	429-800-1
CAS number	95737-68-1

Index number in Annex VI of CLP	613-303-00-3
Minimum purity / content	>97 %(w/w)
Structural formula	

2.1.1.7 Candidate(s) for substitution

None of the active substance(s) contained in the biocidal product is a PBT candidate in accordance with Article 10 of BPR.

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	**Maximum technical content (tolerance limit)([%]**
Permethrin	m-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	52645-53-1	258-067-9	0.6 (technical) 0.56 (pure)	0.60 (0.51-0.69)
Pyriproxyfen	2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)pyridine 4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether	Active substance	95737-68-1	429-800-1	0.1 (technical) 0.097 (pure)	0.101 (0.085-0.115)
Ethanol	Ethanol	Non-active substance	64-17-5	200-578-6	94.05	-
Propan-2-ol	Isopropyl alcohol	Non-active substance	67-63-0	200-661-7	4.95	-

* Please see the confidential annex for further details.

2.1.1.9 Information on technical equivalence

An assessment of technical equivalence of the active substances contained in the product are not required since the active substance(s) suppliers are listed in the Union list of approved active substances under Regulation No. 528/2012.

eCA remark

The permethrin and pyriproxyfen manufacturers are approved reference sources, included in the corresponding evaluation of the substances.

2.1.1.10 Information on the substance(s) of concern

Please see the confidential annex for further details.

2.1.1.11 Type of formulation

AE (aerosol)

Hazard and precautionary statements

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

Classification	
Hazard category	Flam. Aerosol 1 Eye Irritation 2 Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H222: Extremely flammable aerosol H229: Pressurised container: May burst if heated. H319: Causes serious eye irritation H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long-lasting effects,
Labelling	
Signal words	Danger
Hazard statements	H222: Extremely flammable aerosol H229: Pressurised container: May burst if heated. H319: Causes serious eye irritation H410: Very toxic to aquatic life with long-lasting effects Additional warning phrases: EUH208: Contains permethrin. May produce an allergic reaction.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read label before use. P210: Keep away from heat/sparks/open flames/hot surfaces. – No smoking. P211: Do not spray on open flame or other ignition source. P251: Pressurized container: Do not pierce or burn, even after use. P410 + P412: Protect from sunlight. Do not expose to temperatures exceeding 50 °C. P261: Avoid breathing spray. P264: Wash hands thoroughly after handling. P305+ P351 +P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice/attention. P501: Dispose of contents/container according to national official regulations
Note	Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

Authorised use(s)

2.1.1.12 Use description

Table 1. Use # 1 – insecticide-general public-indoor – pet areas

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide / acaricide
Target organism (including development stage)	*Ctenocephalides*- Fleas- eggs & larvae
Field of use	Indoors; in small areas where pets (dogs and cats), mainly remain, including pet bedding, carpets, or cushions
Application method(s)	spraying
Application rate(s) and frequency	250 mL product/80 m^2. This amount corresponds to a spraying time of 2 seconds per m^2. Apply spraying from 30 cm distance onto preferred places of the fleas until the surface is slightly moistened. Maximum two applications per year. Residual efficacy is up to 24 weeks.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	250 mL pressurized metal can (aluminium or tin plate) with a Bag-on-Valve System using compressed air as propellant

2.1.1.13 Use-specific instructions for use

See the general directions for use

2.1.1.14 Use-specific risk mitigation measures

See the general directions for use

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

See the general directions for use

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

See the general directions for use

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

See the general directions for use

General directions for use

2.1.1.18 Instructions for use

Apply the product as soon as the first fleas are identified.
Clean area before using the product.
Apply spraying from 30 cm distance onto preferred places of the fleas until the surface is slightly moistened.
Spraying is done for 2 seconds per m^2.
After application leave the room immediately.
After application ensure adequate ventilation.
After contact with Entfloher the killing effect immediately starts.
Humans and domestic animals may not enter the room at least for an hour after the application.
Where possible, combine the treatment with non-chemical measures.
The infestation should be monitored to see whether the treatment is sufficient.
Products should always be used in accordance with label recommendations.
One can of product is sufficient for the treatment of 80 m^2.
If the problem persists, contact a professional pest control operator.
Do not apply on wet washable surfaces or materials.

2.1.1.19 Risk mitigation measures

Avoid contact to eyes.
Do not treat large areas.
No direct use on animals.
No bystanders are allowed to be present in the room when the product is applied.
Aquaria have to be covered and pets have to be removed from the room.
Do not apply on wet washable surfaces or materials
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, and drinks. No smoking. Do not pierce or burn, even after use. Do not spray on an open flame or other ignition source.

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

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice. Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice

2.1.1.21 Instructions for safe disposal of the product and its packaging

Disposal must be made according to official regulations.

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

Store in a cool location. Protect from sunlight and frost. Do not expose to temperatures exceeding 40 °C. Shelf-life: 3 years

Other information

Resistance management strategies: - where possible, application treatments should be recommended to be combined with non-chemical measures (e.g. glue strips, etc.) - products should always be used in accordance with label recommendations - infected areas should be treated as soon as possible - Complete elimination of insect pests should be attempted in infested areas - The infestation should be monitored to see whether the treatment is sufficient

Packaging of the biocidal product

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Can	250 mL	Aluminium or tin plate can (outer) Bag of aluminium (inner) Propellant of the bag-on-valve system consist of compressed air.	Aerosol valve with a bag welded on to it and positioned in the can	General public (non-professional)	Yes

Documentation

2.1.1.23 Data submitted in relation to product application

Complete information details on the references are given at the end of the document in the list of studies of section 3.1.

2.1.1.24 Access to documentation

The applicant has access to the data on the active substance permethrin (see IUCLID section 13, letter of access to permethrin dossier). Letter of access was provided by Limaru NV which is the supplier for permethrin to ConVet GmbH & Co. KG. Limaru NV is an authorised supplier included in the article 95 list according to the BPR.

A letter of access to the pyriproxifen active substance dossier was provided by Sumitomo Chemical (UK) Plc.

New data e.g. efficacy is property of ConVet GmbH & Co. KG.

2.2 Assessment of the biocidal product

Intended use(s) as applied for by the applicant

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

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

Table 2. Intended use # 1 – Non-professional use

Product Type(s)	PT 18 - Insecticides, acaricides & products to control arthropods
Where relevant, an exact description of the authorised use	The product is an insecticide designed for use indoors, intended for in-house treatment. The product is intended for spot application (aerosol) : in areas where pets (dogs and cats), mainly remain, including pet bedding, carpets, or cushions.
Target organism (including development stage)	Fleas: Eggs, larvs, adults Ticks: adults House dust mites: adults Poultry red mites: adults
Field of use	Used on dog and cat baskets, blankets and sleeping places; no direct use on animals
Application method(s)	spraying
Application rate(s) and frequency	Apply with a distance of 30 cm for some seconds to places dogs and cats prefer to stay
Category(ies) of user(s)	General public (non-professional)
Pack sizes and packaging material	Can 250 mL Metal (outter) Bag of aluminium (inner) valve with a bag welded on to it and positioned in the can

Table 4. Intended use # 2 – Non-professional use

Product Type(s)	PT 18 - Insecticides, acaricides & products to control arthropods
Where relevant, an exact description of the authorised use	The product is an insecticide designed for use indoors, intended for in-house treatment. The product is intended for spot application (aerosol) on cracks and crevices in the close vicinity of nests or trails.
Target organism (including development stage)	Cockroaches: adults Silverfishes: adults Ants: adults Woodlice: adults
Field of use	Used on cracks and crevices
Application method(s)	spraying
Application rate(s) and frequency	Apply with a distance of 30 cm for some seconds to places dogs and cats prefer to stay
Category(ies) of user(s)	General public (non-professional)

Pack sizes and packaging material	Can 250 mL Metal (outter) Bag of aluminium (inner) valve with a bag welded on to it and positioned in the can

Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	SOP-PR-015 Visual inspection	0.6 % permethrin 0.1 % pyriproxyfen	Liquid after 8 Weeks (40 °C): liquid	[redacted]
Colour at 20 °C and 101.3 kPa	SOP-PR-015 Visual inspection	0.6 % permethrin 0.1 % pyriproxyfen	Clear colorless, homogeneous. after 8 Weeks (40 °C): clear, colorless, homogeneous	[redacted]
Odour at 20 °C and 101.3 kPa	SOP-PR-015 olfactory	0.6 % permethrin 0.1 % pyriproxyfen	Medium for solvent **eCA remark** Acceptable. The classification 'medium for solvent' is irrelevant, but is accepted as the odour is a non-critical endpoint. The odour is likely comparable to that of the main solvent.	[redacted]
Acidity / alkalinity	CIPAC Method MT 75.3	0.6 % permethrin 0.1 % pyriproxyfen	pH: 6.4 at 20 °C (1 % w/v aqueous solution) $pH_{1\%}$ after storage at 40 °C for 8 weeks: 6.3 **eCA remark** Acceptable. The pH of the neat	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			product cannot be determined as it is not aqueous.	
Relative density / bulk density	EU Method A.3 (Relative Density)	0.6 % permethrin 0.1 % pyriproxyfen	Rel. density: 0.808 at 20 °C after storage at 40 °C for 8 weeks: 0.808	[redacted]
Storage stability test – **accelerated storage**	CIPAC MT 46.3 (storage stability)	0.6 % permethrin 0.1 % pyriproxyfen	No significant changes of physical-chemical properties occurred during the test. The product was tested in a can with bag-on-valve system. Weight loss of the package between 0.06 % and 0.10 %. Active substances 0.58 % w/w of permethrin, 0.092 % w/w of pyriproxyfen; after storage: 0.61 % w/w of permethrin, 0.096 % w/w of pyriproxyfen	[redacted]
eCA remark The individual properties determined before and after storage are reported under their respective entries. The analytical method used for determination of the active substances was GC-FID method MV137, which was validated in study Mo5436, evaluated in the analytical method section. The product is stable for 8 weeks at 40°C.				
Storage stability test – **long term storage at ambient temperature**	CIPAC MT 46.3 (storage stability)	0.6 % permethrin 0.1 % pyriproxyfen	Storage after 36 months at ambient temperature:	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			No significant changes of physical-chemical properties occurred during the test. The product was tested in a tin can with bag-on-valve system. **Active substance content*** Start: Permethrin: 0.58 % w/w Pyriproxyfen: 0.092 % w/w 36 months (20 °C): Permethrin: 0.59 % w/w Pyriproxyfen: 0.094 % w/w *Active substance content was also determined at: T0, T8wks, T3 months,T6 months, T9 months, T12 months, T24 months, T36 months. All active substance data points are within acceptable limits. **Appearance of the Test Item** Start: Clear, colorless, homogeneous liquid. Medium odour for solvent.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			36 months (20 °C): Clear, colorless, homogeneous liquid. Medium odour for solvent. **Stability of Packaging of the Test Item** Start: Test item in sound condition, sealed and without leakages. Height = 15.4 cm; diameter = 4.5 cm; internal wall appearance: clean without damage; can dome and base appearance: clean without damage. 36 months (20 °C): Test item in sound condition, sealed and without leakages. No ballooning or change of the paneling was observed. Height = 15.3 cm; diameter = 4.5 cm; internal wall appearance: clean without damage; can dome and base appearance: clean without damage. **Weight Loss** The weight loss for the test samples stored at	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			20 °C for up to 36 months was less than 0.17%. **pH** Start: 6.4 36 months (20 °C): 6.1 **Relative Density** Start: 0.808 36 months (20 °C): 0.808 **Viscosity** Start: <2 mPa.s at all rotor frequency tested** 36 months (20 °C): ≤3.8 mPa.s at all rotor frequency tested** **rotor frequencies: 181 mPa·s, 90.5 mPa·s, 45.2 mPa·s, 22.6 mPa·s, 11.3 mPa·s, 5.6 mPa·s **Pressure in finished aerosol packs (water bath testing)** Start: 6.9 bar (20 °C); 7.7 bar (50 °C) 36 months (20 °C): 6.7 bar (20 °C); 6.5 bar (50 °C) **Discharge rate**	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Start: 1.202 g/s 36 months (20 °C): 1.154 g/s **Clogging of Aerosol Dispenser and Residue after Total Discharge** Start: 1.37 g residue after total discharge 36 months (20 °C): 1.15 g residue after total discharge No clogging of aerosol dispenser valves was observed. **Spray diameter** Start: 13x17 cm; 16x19 cm 36 months (20 °C): 14x20; 20x22 In all cases, a clear transparent solution with an oval shape was deposited on the paper screen. **Particle size analysis** Start: Dv(10%): 24 µm Dv(50%): 50 µm Dv(90%): 104 µm 36 months (20 °C): Dv(10%): 26 µm Dv(50%): 51 µm	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Dv(90%): 98 µm The product is stable for 3 years at ambient temperature.	
eCA remark: The long term storage stability study describes a test item "ConVet Umgebungsspray". This is the public name of Entfloher.				
Storage stability test – **low temperature stability test for liquids**	-	-	The biocidal product is a liquid, the low temperature stability does not need to be tested due to the label claim "protect from frost".	-
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	Not applicable as the packaging is light-proof. Therefore, the formulation is not exposed to light during storage.	-
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	Not applicable because according to the label instructions the biocidal product has to be stored cool, dry and protected from frost in closed, original containers.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	CIPAC MT 46.3 (storage stability)	0.6 % permethrin 0.1 % pyriproxyfen	The biocidal product is stable in its commercial packaging at 40 °C for 8 weeks. No corrosion, no leakage, one phase and no agglomeration were visible.	[redacted]
Wettability	-	-	The wettability must be determined for solid biocidal products. Since	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the biocidal product is liquid, the wettability does not need to be performed.	
Suspensibility, spontaneity and dispersion stability	-	-	The suspensibility, spontaneity and dispersion stability must be determined for solid biocidal products or suspensions, respectively. Since the biocidal product is not solid and no suspension, these tests do not need to be performed.	-
Wet sieve analysis and dry sieve test	-	-	The wet sieve and dry sieve test must be performed for solid biocidal products, dispersible concentrates or suspensions, respectively. Since the biocidal product is not solid, no dispersable concentrate and no suspension, these tests do not need to be performed.	-
Emulsifiability, re-emulsifiability and emulsion stability	-	-	The data on emulsifiability, re-emulsifiability and emulsion stability are required to determine whether a preparation forms and	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			maintains a stable emulsion. Since the biocidal product will not form emulsions, these tests do not need to be performed.	
Disintegration time	-	-	The disintegration time must be determined for biocidal products supplied as tablets. Since the biocidal product is liquid, this test does not need to be performed.	-
Particle size distribution, content of dust/fines, attrition, friability	CIPAC: MT 187	0.6 % permethrin 0.1 % pyriproxyfen	Dv(0.1) = 24 µm Dv(0.5) = 50 µm Dv(0.9) =104 µm after storage for 8 weeks at 40 °C: Dv(0.1) = 23 µm Dv(0.5) = 48 µm Dv(0.9) =94 µm	[redacted]
Persistent foaming	-	-	The persistence of foaming must be investigated for biocidal products which have to be diluted with water before application. Since the biocidal product is not intended for dilution with water before use, this test does not need to be performed.	-
Flowability/Pourability/Dustability	-	-	The technical characteristics flowability and dustability have to be determined	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			for solid products like granular preparations or dustable powders and the pourability for suspensions that will be diluted before use. Since the biocidal product is a liquid formulation and no suspension, these tests do not apply.	
Burning rate — smoke generators	-	-	The burning rate must be determined for biocidal products intended to be used as smoke generators. Since the biocidal product is not a smoke generator, this test does not need to be performed.	-
Burning completeness — smoke generators	-	-	The burning completeness must be determined for biocidal products intended to be used as smoke generators. Since the biocidal product is not a smoke generator, this test does not need to be performed.	-
Composition of smoke — smoke generators	-	-	The composition of smoke must be determined for biocidal products intended to be used as smoke generators. Since	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the biocidal product is not a smoke generator, this test does not need to be performed.	
Spraying pattern — aerosols	CIPAC MT 46.3 (storage stability)	0.6 % permethrin 0.1 % pyriproxyfen	13x17, 16x19 (Oval spray pattern) 8 Weeks (40 °C): 20x21, 20x23 (Oval spray pattern) **eCA remark** The spray pattern appears to have changed somewhat during storage, but the eCA regards the change as insignificant. The shape of the spray pattern remains the same. Heating the nozzle may have had influence, which should become clear when the final shelf-life data is available.	[redacted]
Clogging, discharge rate	European Aerosol Federation (FEA) 643; WHO/FAO 8.11.4.5	0.6 % permethrin 0.1 % pyriproxyfen	No clogging of aerosol dispenser valves was observed. Residue after Use: Start: 1.368 g 8 Weeks (40 °C): 1.446 g Discharge Rate of the Test Item: Start: 1.202 g/s	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			8 Weeks (40 °C): 1.236 g/s	
Pressure in Finished Aerosol Packs	FEA 604 and 606	0.6 % permethrin 0.1 % pyriproxyfen	Start: 6.9 bar at 20 °C, 7.7 bar at 50 °C 8 Weeks (40 °C): 7.4 bar at 20 °C, 8.2 bar at 50 °C No appreciable changes in the pressure in finished aerosol packs of the test item were observed after storage for 8 weeks at 40 °C.	[redacted]
Physical compatibility	-	-	The biocidal product is not intended to be used with other products including other biocidal products. Therefore no information is submitted about its physical compatibility with other products.	-
Chemical compatibility	-	-	The biocidal product is not intended to be used with other products including other biocidal products. Therefore no information is submitted about its physical compatibility with other products.	-
Degree of dissolution and dilution stability	-	-	The degree of dissolution must be determined for water soluble bags and tablets, the dilution stability for	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			water-soluble preparations. Since the biocidal product is not a water soluble bag, tablet or a water-soluble preparation these tests do not need to be performed.	
Surface tension	-	-	It is not intended that the product will be diluted in water. It is an aerosol and possible surface activity is of no relevance. **eCA remark** The surface tension is not relevant to the application of the product nor classification and labelling. It is therefore considered acceptable no data was provided. The surface tension is expected to be comparable to that of the main solvent.	-
Viscosity	CIPAC MT 192, rotational viscometer (storage stability)	0.6 % permethrin 0.1 % pyriproxyfen	< 2 mPa*s after 8 Weeks (40 °C): < 2 mPa*s **eCA remark** The viscosity is not shear dependent between 5.6 and 181 min^{-1}, meaning it shows Newtonian flow characteristics.	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			The reported values were determined at 20°C.	

Conclusion on the physical, chemical and technical properties of the product
The product applied for is a liquid in a bag-on-valve type pressurized container. The liquid product is a homogeneous clear liquid. Its pH is 6.4 in a 1% aqueous dilution. The density of the liquid is 0.808 at 20°C, it has a viscosity of below 2 mPa.s. For this product, surface tension data is not considered relevant. Stability was tested in the commercial packaging (tin plate can) stored for 8 weeks at 40 °C. All relevant parameters were determined. The product remained physically and chemically stable and the discharge related properties showed no issues are expected with regard to the effectiveness of the bag-on-valve system. Stability of the biocidal product was further tested at 20 °C for a period of 36 months. All parameters tested showed acceptable variations. The stability of the biocidal product for this period (3 years) is ensured.

Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	-	-	The biocidal product does not contain components which are known to confer explosivity or to enhance explosibility properties. Therefore the biocidal product is incapable of exothermic reaction and rapid decomposition with evolution of gases or release of heat and does not	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			have explosive properties. Since the biocidal product does not present any risk for explosion, explosive properties do not need to be tested.	
Flammable gases	-	-	The parameter flammable gases must be determined for biocidal products that are gases. Since the biocidal product is not a gas, this test does not need to be performed.	-
Flammable aerosols	-	-	Aerosols containing more than 85% flammable components should be classified as Category 1. The product contains about 90 % of ethanol and ethanol is classified according to 1272/2008 CLP regulation as highly flammable liquid and vapour (H: 225). eCA remark: No combustion data was	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			provided and since the amount of alcohol (ethanol and propanol) is up-to 99%w/w, it is not unlikely that if the data had been provided, a category 2 aerosol would have been the outcome.	
Oxidising gases	-	-	The parameter oxidising gases must be determined for biocidal products that are gases. Since the biocidal product is not a gas, this test does not need to be performed.	-
Gases under pressure	-	-	The parameter gases under pressure must be determined for biocidal products that are gases. Since the biocidal product is not a gas this test does not need to be performed.	-
Flammable liquids	EU A.9	0.6 % permethrin 0.1 % pyriproxyfen	Flashpoint: 16°C under atmospheric conditions.	[redacted]
Flammable solids	-	-	The flammability has to be tested for solid biocidal products. Since	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			the biocidal product is liquid, this test does not need to be performed.	
Self-reactive substances and mixtures	-	-	-	-
Pyrophoric liquids	EU A.13	0.58 % permethrin 0.092 % pyriproxyfen	No pyrophoric properties	[redacted]
Pyrophoric solids	-	-	Pyrophoric properties have to be determined for solid biocidal products. Since the biocidal product is liquid this test does not need to be performed.	-
Self-heating substances and mixtures	-	-	The substance is a liquid. A liquid shows not self-heating behaviour if it is not absorbed on a large surface.	-
Substances and mixtures which in contact with water emit flammable gases	-	-	Based on experience in handling and use and molecular structure of constituents, emission of flammable gases is not expected when the preparation comes in contact with water.	-
Oxidising liquids	-	-	The biocidal product does not contain	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			components which are known to enhance oxidising properties. None of its ingredients is classified as oxidising. Therefore the formulation may not react exothermically with a combustible material and does not have oxidising properties. Since oxidising properties of the biocidal product are unlikely, the test does not need to be performed.	
Oxidising solids	-	-	The oxidising properties have to be determined for solid biocidal products. Since the biocidal product is liquid, this test does not need to be performed.	-
Organic peroxides	-	-	Since the biocidal product is not an organic peroxide, tests do not need to be performed.	-
Corrosive to metals	-	-	The product has been known for many years. It	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			has never been reported any significant corrosion with tank or applicability material which are partially made of metal. **eCA remark:** The product does not contain components known to cause corrosion to metals, it is non-aqueous and does not contain acids or bases.	
Auto-ignition temperatures of products (liquids and gases)	EU A.15	0.58 % permethrin 0.092 % pyriproxyfen	405 °C at 1003-1007 hPa	[redacted]
Relative self-ignition temperature for solids	-	-	The relative self-ignition temperature has to be determined for solid biocidal products. Since the biocidal product is liquid, this test does not need to be performed.	-
Dust explosion hazard	-	-	The dust explosion hazard must be determined for powders or biocidal products containing, or able to produce, dust. Since the	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			biocidal product is liquid, this test does not need to be performed.	

Conclusion on the physical hazards and respective characteristics of the product
The biocidal product Entfloher is a clear, colorless, homogeneous solution. It has no explosive and no oxidising properties. The product contains about 90 % of ethanol and ethanol is classified according to 1272/2008 CLP regulation as highly flammable liquid and vapour (H: 225). **eCA remark** Considering the product is marketed as a pressurized container, it is therefore treated as an aerosol for classification purposes. Tests with regard to classification of the aerosol are not available. The proposed classification is that of a cat 1 flammable aerosol, which is accepted by the eCA.

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		
ConVet Umgebungsspray with a.i. 0.6 % permethrin, 0.1 % pyriproxyfen	MV137, GC-FID with internal standard	Fortification level: 70% 100%, 130% n=9 (3x3 spiked solutions) **Precision**: Permethrin: Mean value (n=6): 0.5809 RSD = 0.59 % pyriproxyfen: mean	Permethrin: 1.8 – 4.8 g/L (n=6) Y=0.958 X+0.027 r = 1.00 pyriproxyfen: 0.3 – 0.8 g/L (n=6) Y=1.03X +0.0036 r = 1.00	no interference occured at the retention times of permethrin, pyriproxyfen or the internal standard.	100.1 – 100.7 % for permethrin and 100.1 - 100.7 % for pyriproxyfen	mean recovery for all fortification levels is 100.3 % for permethrin and 100.4 % for pyriproxyfen	0.2 % for permethrin and 0.2 % for pyriproxyfen*	Limit of detection and limit of quanification are not required, because the method will be	[redacted]

		value (n = 6): 0.0934 RSD = 0.58 % These results meet the acceptance criterion RSD < 2.89 % for permethrin and RSD < 3.79 % for pyriproxyfen						used only for testing of specification limits.	

** RSD over all recoveries determined at three levels with three samples each. At none of the recovery levels the RSD exceeded 0.3%.*

Methods for formulation analysis
An analytical method for determination of permethrin and pyriproxyfen in the product was provided (reference MV137). The method is based on GC-FID with a 30m Rtx-1 column (100% dimethylpolysiloxane), using dipentyl phthalate as internal standard. Method validation is summarised in the table above.

Sample preparation summary:
Approximately 25g sample is weighed into a 50mL volumetric flask. 1mL of IS solution is added, followed by addition of 20mL propan-2-ol and sonication for 15 minutes. Prior to analysis, the flask is filled to the mark with propan-2-ol and shaken.

Methods for monitoring
Analytical methods for the determination of active substance residues in relevant environmental media (soil, air and water) as well as in animal and human body fluids and tissues were not submitted for the biocidal product since this point is covered by the data set of the active substance.

In the coordination group meeting (number 22) of 22 March 2017 it was noted that the analytical method for residues in water, as submitted in the permethrin dossier, is not sensitive enough to enable monitoring at the PNEC. Therefore, new analytical methods for residues in surface water with an adequate limit of quantification should be submitted at the renewal of the active substance dossier.

Conclusion on the methods for detection and identification of the product
The analytical method MV137 has been successfully validated for specificity, linearity, precision and recovery for the active substance permethrin as well as pyriproxyfen and is therefore regarded valid for the determination of the content of both components in the biocidal product.

Efficacy against target organisms

2.2.1.1 Function and field of use

The product is authorised as insecticide for indoor use by the general public (non-professional users). The product can be applied as a residual spray for the following use:

- Use #1: in areas where pets (dogs and cats), mainly remain, including pet bedding, carpets, or cushions;

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

The following organisms are to be controlled by the product:
- Use #1: fleas (*Ctenocephalides) – eggs and larvae*

2.2.1.3 Effects on target organisms, including unacceptable suffering

Permethrin:
Permethrin is a contact insecticide which causes convulsions, paralysis and ultimately death in target organisms. Permethrin effects are characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. Permethrin also induces hepatic microsomal enzymes. It should be noted that permethrin may exhibit a mild contact repellent effect in conjunction with the insecticidal effect. This contact repellence effect is common to other pyrethroid insecticides (such as deltamethrin, cypermethrin, esfenvalerate and lamda-cyhalothrin) and is known as the "hot-foot effect" and may be relevant for some arthropods. The repellent effect is dose related and for insecticidal products the repellent effect of permethrin is considered as a side effect, since the toxic response of the insect is a delayed kill (insecticidal) effect.

Pyriproxyfen:
Pyriproxyfen acts as a juvenile hormone mimic to disrupt the normal development of insects. It displays no immediate killing effect on the target organisms but prevents eggs and larvae from maturing into adults. This breaks the life-cycle and results in long lasting control.

2.2.1.4 Mode of action, including time delay

Permethrin:
Permethrin is a type I axonic poison which exerts its effects by means of hyperexcitation of both the peripheral and central nervous systems of target insects. Pyrethroids act on the insect nervous system by slowing action potential decay and thereby initiating repetitive discharges in motor and sensory axons. Electrophysiological studies have suggested that these phenomena result from modification of the gating kinetics of neuronal, voltage-sensitive Na channels. Single channel studies have been conducted which have shown that pyrethroids slow the kinetics of opening and closing of Na channels.
Pyrethroids show high potency and selectivity for insects over mammals. The negative temperature dependence of pyrethroid action is partly responsible for the low mammalian toxicity of these compounds. Type 1 pyrethroids produce a distinct poisoning syndrome characterised by progressive fine whole body tremor, exaggerated start response, uncoordinated muscle twitching and hyperexcitability. The effects are generated largely by effects in the central nervous system. Permethrin also induces hepatic microsomal enzymes.

Pyriproxyfen:
Pyriproxyfen, rather than controlling target pests through direct toxicity, interferes with an insect's lifecycle and prevents it from reaching maturity or reproducing. Pyriproxyfen acts as an insect growth regulator, mimicking natural juvenile hormone. Juvenile hormone maintains a juvenile state. In hemimtabolous insects the level gradually decreases during

the development of the insect, allowing it to proceed to successive instars and the adult insect with each molt . In holometabolous insects, juvenile hormone must be absent for a pupa to molt to an adult. So pyriproxyfen-treated larvae will be unable to successfully change from different instar stages or pupae to adults. This breaks the biological life cycle of the insect, preventing recurring infestation.

2.2.1.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide & Acaricide	Insecticide; Control of crawling insects	Convet Entfloher; permethrin 0.6%, pyriproxyfen 0.1%, this product is identical in composition to Entfloher	Adults of: *Ctenocephalides felis* (cat flea), 10 per replicate *Blattella germanica* (German cockroach), 10 per replicate *Blatta orientalis* (Oriental cockroach), 10 per replicate *Lasius niger* (black garden ant), 10 per replicate *Lepisma saccharina* (silverfish), 10 per replicate 5 replicates per test organism	Laboratory test	Treatments were applied by manual spraying onto non-porous glazed tiles, porous unglazed tiles and carpet. The dose applied was 2.8 g/m² (3.13 mL/m²), which is 0.063 g per tile (15 * 15 cm = 225 cm²). The arthropods were exposed to the surfaces 1 day (fresh) and 2 weeks after treatment for 1 hour. The evaluations for knockdown and mortality were made at defined test points: 1, 2, 3, 4, 5, 6, and 7 days after exposure of individuals.	For details on results see the following row.	[redacted]
Details on results: *Blattella germanica*:							

	Knockdown or Mortality after 24 hours (1h exposure,1 day after treatment)		Knockdown or Mortality after 24 hours (1h exposure, 2 weeks after treatment)		Knockdown or Mortality after 24 hours (1h exposure, 4 weeks after treatment)		Knockdown or Mortality after 48 hours (1h exposure, 8 weeks after treatment)	
	knockdown	mortality	knockdown	mortality	knockdown	mortality	knockdown	mortality
Glazed tiles	100%	100%	100%	98%	100%	100%	86%	82%
Unglazed tiles	100%	100%	100%	100%	4%	4%	Not tested	Not tested
Untreated glazed tiles	0%	0%	0%	0%	0%	0%	0%	0%
Untreated unglazed tiles	0%	0%	0%	0%	0%	0%	Not tested	Not tested

Blatta orientalis:

	Knockdown or mortality after 24 hours (1h exposure, 1 day after treatment)		Knockdown or mortality after 24 hours (1h exposure, 2 weeks after treatment)		Knockdown or mortality after 24 hours (1h exposure, 4 weeks after treatment)		Knockdown or mortality after 24 hours (1h exposure, 8 weeks after treatment)	
	knockdown	mortality	knockdown	mortality	knockdown	mortality	knockdown	mortality
Glazed tiles	48%	76%	24%	20%	Not tested	Not tested	Not tested	Not tested
Unglazed tiles	6 %	4%	0 %	0%	Not tested	Not tested	Not tested	Not tested
Untreated glazed tiles	0%	0%	0%	0%	Not tested	Not tested	Not tested	Not tested
Untreated unglazed tiles	0%	0%	0%	0%	Not tested	Not tested	Not tested	Not tested

Lasius niger:

	Knockdown or mortality (1h exposure, 1 day after treatment)		Knockdown or mortality (1h exposure, 2 weeks after treatment)		Knockdown or mortality (1h exposure, 4 weeks after treatment)		Knockdown or mortality (1h exposure, 8 weeks after treatment)	
	Knockdown Day 1	mortality Day 1-7	Knockdown Day 1	mortality Day 1-7	Knockdown Day 1	mortality Day 1-7	Knockdown Day 1	mortality Day 1-7
Glazed tiles	100%	98%	100 %	88%	98%	92%	34%	19%
Unglazed tiles	100 %	96%	16 %	20%	16%	30%	Not tested	Not tested
Untreated glazed tiles	0%	0%	0%	0%	0%	0%	0%	0%
Untreated unglazed tiles	0%	0%	0%	0%	0%	0%	Not tested	Not tested

Lepisma saccharina:

	Knockdown or mortality (1h exposure, 1 day after treatment)		Knockdown or mortality (1h exposure, 2 weeks after treatment)		Knockdown or mortality (1h exposure,4 weeks after treatment)		Knockdown or mortality (1h exposure, 8 weeks after treatment)	
	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7
Glazed tiles	100%	100%	100 %	100%	100%	92%	90%	100%
Unglazed tiles	100 %	100 %	100 %	100 %	26%	56%	Not tested	Not tested
Untreated glazed tiles	0%	0%	0%	4%	0%	6%	0%	4%
Untreated unglazed tiles	0%	0%	0%	2%	0%	6%	Not tested	Not tested

Ctenocephalides felis:

	Knockdown or mortality s (1h exposure, 1 day after treatment)		Knockdown or mortality (1 hour exposure, 2 weeks after treatment)		Knockdown or mortality (1 hour exposure, 4 weeks after treatment)	
	Knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7
Carpet	96%	100%	46 %	96%	24 %	42%
Untreated carpet	0%	2%	0%	16 %	0%	0%

Insecticide & Acaricide	Insecticide; Control of other arthropods	Convet Entfloher; permethrin 0.6%, pyriproxyfen 0,1%, this product is identical in composition to Entfloher	*Porcellio scaber* (woodlice); adults, 10 per replicate	Laboratory test	A trial was performed to assess the efficacy of the product applied as a residual spray in terms of knockdown and / or mortality. Treatments were applied by manual spraying onto non-porous glazed tiles and porous unglazed tiles for woodlice. The dose applied was 2.8 g/m² (3.13	The results demonstrate that the applied product Convet Entfloher fulfills the requirements for the product intended for use as general surface treatment for consumers (according to the requirements of the relevant "Technical Notes for Guidance [TNsG]) against *Porcellio scaber* (woodlice), fresh (1 day after treatment)	[redacted]

					mL/m²), which is 0.063 g per tile (15 * 15 cm = 225 cm²). The arthropods were exposed to the surfaces 1 day (fresh) and 2 weeks after treatment for 1 hour. The evaluations for mortality were made at defined test points: 1, 2, 3, 4, 5, 6, and 7 days after exposure of individuals.	and 2 weeks after treatment. **For details on results see the following row.**	

Details on results:

Porcellio scaber:

	Knockdown or Mortality (1h exposure, 1 day after treatment)		Knockdown or Mortality (1h exposure, 2 weeks after treatment)		Knockdown or Mortality (1h exposure, 4 weeks after treatment)		Knockdown or Mortality (1h exposure, 8 weeks after treatment)	
	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7
Glazed tiles	100%	100%	100 %	100%	100%	100%	100%	100%
Unglazed tiles	84%	70 %	98%	94 %	64%	60%	Not tested	Not tested
Untreated glazed tiles	0%	0%	0%	2%	0%	0%	0%	0%
Untreated unglazed tiles	0%	0%	0%	2%	0%	0%	Not tested	Not tested

Insecticide & Acaricide	Acaricide; Control of ticks and mites	Convet Entfloher; permethrin 0.6%, pyriproxyfen 0,1%, this product is identical in	*Ixodes ricinus* (tick); adults, 10 per replicate *Dermanyssus gallinae* (poultry red	Laboratory test	A trial was performed to assess the efficacy of the product applied as a residual spray in	The results demonstrate that the applied product Convet Entfloher fulfills the requirements for the	[redacted]

		composition to Entfloher	mite), 20 per replicate, tested with populations of mixed age *Dermatophagoides pteronyssinus* (house dust mite), 50 per replicate tested with populations of mixed age 5 replicates per test organism		terms of knockdown and / or mortality. Treatments were applied by manual spraying onto non-porous glazed tiles and porous unglazed tiles for European sheep tick, and onto non-porous glazed tiles, porous unglazed tiles and plywood for Red poultry and House dust mites. The dose applied was 2.8 g/m² (3.13 mL/m²), which is 0.063 g per tile (15 * 15 cm = 225 cm²). The arthropods were exposed to the surfaces 1 day (fresh) and 2 weeks after treatment for 1 hour (Red poultry mites and House dust mites stayed continuously on the treated surface). The evaluations for mortality were made at defined test points: 1, 2, 3, 4, 5, 6, and 7 days after	product intended for use as general surface treatment for consumers (according to the requirements of the relevant "Technical Notes for Guidance [TNsG]) against *Dermanyssus gallinae*, *Dermatophagoides pteronyssinus* and *Ixodes ricinus* (based on the requirements for cockroaches), fresh (1 day after treatment) and 2 weeks after treatment. **For details on results see the following row.**	

					exposure of individuals.		

Details on results:

Dermanyssus gallinae:
* Under field conditions the complete area infested by red poultry mites is treated. In order to mimic this situation Red poultry mites stayed continuously on the treated surface.

	Knockdown or mortality (continuous exposure, 1 day after treatment)		Knockdown or mortality (continuous exposure, 2 weeks after treatment)		Knockdown or mortality (continuous exposure, 4 weeks after treatment)		Knockdown or mortality (continuous exposure, 8 weeks after treatment)	
	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7
Glazed tiles	100%	100%	100 %	100%	100%	100%	100 %	100%
Unglazed tiles	100%	100%	100%	100%	100%	100%	100%	100%
Plywood	100%	100%	100%	100%	100%	100%	100%	100%
Untreated glazed tiles	0%	0%	0%	0%	0%	0%	0%	0%
Untreated unglazed tiles	0%	0%	0%	0%	0%	0%	0%	0%
Untreated plywood	0%	0%	0%	0%	0%	0%	0%	0%

Dermatophagoides pteronyssinus:
* Under field conditions the complete area infested by red poultry mites is treated. In order to mimic this situation House dust mites stayed continuously on the treated surface.

	Knockdown or mortality (continuous exposure, 1 day after treatment)		Knockdown or mortality (continuous exposure, 2 weeks after treatment)		Knockdown or mortality (continuous exposure, 4 weeks after treatment)		Knockdown or mortality (continuous exposure, 8 weeks after treatment)	
	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7
Glazed tiles	100%	100%	100 %	100%	100%	100%	100%	100%
Unglazed tiles	100%	100%	100%	100%	100%	100%	100%	100%
Plywood	100%	100%	100%	100%	100%	100%	100%	100%
Untreated glazed tiles	0%	0%	0%	0%	0%	0%	0%	0%
Untreated unglazed tiles	0%	0%	0%	0%	0%	0%	0%	0%

Untreated plywood	0%	0%	0%	0%	0%	0%	0%	0%

Ixodes ricinus:

	Knockdown or Mortality (I hour exposure, 1 day after treatment)		Knockdown or Mortality (1 hour exposure, 2 weeks after treatment)		Knockdown or Mortality (1 hour exposure, 4 weeks after treatment)		Knockdown or Mortality (1 hour exposure, 8 weeks after treatment)	
	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7
Glazed tiles	100%	100%	100 %	100%	100%	100%	100%	100%
Unglazed tiles	100%	100 %	100%	100 %	100%	100 %	100%	100 %
Untreated glazed tiles	0%	0%	0%	0%	0%	0%	0%	0%
Untreated unglazed tiles	0%	0%	0%	0%	0%	0%	0%	0%

Insecticide & Acaricide	Acaricide; Control of cat flea eggs and larvae	Convet Entfloher; permethrin 0.6%, pyriproxyfen 0,1%, this product is identical in composition to Entfloher	*Ctenocephalides felis* (cat flea eggs and larvae), 20 per replicate, 5 replicates	Laboratory test	A trial was performed to assess the efficacy of the product applied as a residual spray in terms of inhibition of development. Treatments were applied by manual spraying onto carpet discs. Carpet discs were placed next to each other to almost cover up 1 m². By spraying out of a distance of 30 cm for a defined time (lead to an amount of approx. 2.8 g), an area of 1 m² is treated. Within 24 hours after	The results demonstrate that the applied product Convet Entfloher fulfills after 1 day, 2 weeks, 4 weeks, 12 weeks, and 24 weeks aging the requirements for an ovicidal and larvicidal product intended for use as general surface treatment (according to the requirements of the relevant "Technical Notes for Guidance [TNsG] for PT 18 and PT 19: CA-DEC 12-Doc.6.2.a – Final") against Cat flea, Ctenocephalides felis (larvae and eggs): ≥80% inhibition	[redacted]

					treatment insects are placed on the surfaces. The procedure was repeated 2 weeks, 4 weeks, 12 weeks, and 24 weeks after treatment.The evaluation for all the test units was made after development of the larvae or the eggs, respectively, into adult fleas in the untreated controls, which could be observed approx. 5 weeks after treatment or approx. 10 weeks after treatment for the last test point (24 weeks). For the evaluation the number of adult fleas was counted.	should occur of the development of produced eggs/larvae into adult fleas during the claimed ovicidal/larvicidal duration of action of the product. **For details on results see the following row.**	

Details on results:
Cat fleas, *Ctenocephalides felis* (larvae)

	Observed adult fleas within 39 days after continuous exposure , starting 1 day after treatment	Observed adult fleas within 39 days after continuous exposure , starting 2 weeks after treatment	Observed adult fleas within 39 days after continuous exposure , starting 4 weeks after treatment	Observed adult fleas within 39 days after continuous exposure , starting 12 weeks after treatment	Observed adult fleas within 67 days after continuous exposure , starting 24 weeks after treatment

Larvae on treated carpet	0%	0%	0 %	0%	0%
Larvae on untreated controls	75%	66%	75%	85%	62%

Cat fleas, *Ctenocephalides felis* (eggs)

	Observed adult fleas within 39 days after continuous exposure , starting 1 day after treatment	Observed adult fleas within 39 days after continuous exposure , starting 2 weeks after treatment	Observed adult fleas within 39 days after continuous exposure , starting 4 weeks after treatment	Observed adult fleas within 39 days after continuous exposure , starting 12 weeks after treatment	Observed adult fleas within 39 days after continuous exposure , starting 24 weeks after treatment
Eggs on treated carpet	0%	0 %	0 %	0%	0%
Eggs on untreated controls	82%	77%	75%	71%	55%

Insecticide & Acaricide	Acaricide; Control of crawling insects	Convet Entfloher; permethrin 0.6%, pyriproxyfen 0,1%, this product is identical in composition to Entfloher	Adults of: *Blattella germanica* (German cockroach), 10 per replicate, 3 replicates *Blatta orientalis* (Oriental cockroach), 10 per replicate, 3 replicates *Lasius niger* (black garden ant), 20 per replicate, 3 replicates	Simulated use (choice) test	A trial was performed to assess the efficacy of the product applied as a residual spray in terms of mortality. Treatments were applied by manual spraying onto glazed tiles and plywood. One half of the tiles is covered with aluminium foil to prevent contact with the product.	The results demonstrate that the applied product Convet Entfloher fulfills the requirements for a product intended for use as general surface treatment or aerosol for consumers (according to the Guidance on the Biocidal Products Regulation, Volume II Efficacy - Assessment and Evaluation (Parts	[redacted]

					Thereto, after spraying only one half of the tile is treated with the product. The spray jet hits the tiles sloping at an angle of 45° at a distance of 30 cm. The dosage is 2.8 g/m2 (approx. 0.071 g per test unit). The cockroaches are anaesthetized (with CO2) and placed inside a shelter (cardboard cup lying) which is placed on the untreated side. The cockroaches are then kept in the shelter, due to a plastic beaker pulled over the shelter, for 24 hours. Afterwards, the plastic beaker is removed and the cockroaches are able to move free inside the test unit. No acclimatization of ants is done before testing. Ants are placed directly on the top	B&C), ECHA 2017) against Blattella germanica (glaced tiles, plywood) and partly against Blatta orientalis and Lasius niger (glaced tiles only). No residual efficacy was demonstrated in this study. **For details on results see the following row.**	

					of their shelter (cardboard cup, two openings), so that they have to move downwards a certain way and get some time to explore their environment without getting into contact to the treated area. The crawling insects are kept inside the arena for 24 hours (free running). After 24 hours evaluation of mortality is done		

Details on results:

Blattella germanica (German cockroach), *Blatta orientalis* (Oriental cockroach), *Lasius niger* (black garden ant)

	Surface	% mortality after 24 hours	% mortality after 48 hours
Blattella germanica	Glazed tiles	100%	100%
Blatta orientalis	Glazed tiles	93%	100%
Lasius niger	Glazed tiles	100%	100%
Blattella germanica	Plywood	93%	Not tested
Blatta orientalis	Plywood	0%	Not tested
Lasius niger	Plywood	70%	Not tested

Acaricide	Acaricide	Convet Entfloher; permethrin 0.6%, pyriproxyfen 0,1%, this	Rhipicephalus sanguineus (dog tick); adults, 10 per replicate, 5 replicates	Laboratory test	Treatments were applied by manual spraying onto non-porous glazed tiles and porous unglazed	**For details on results see the following row.**	[redacted]

		product is identical in composition to Entfloher			tiles. The dose applied was 2.8 g/m² (3.13 mL/m²), which is 0.063 g per tile (15 * 15 cm = 225 cm²). The ticks were exposed to the surfaces 1 day (fresh), 1 month and 2 months after treatment for 1 hour. The evaluations for the control and for knockdown and mortality of treated individuals were made at defined test points: 1, 2, 3, 4, 5, 6, and 7 days after exposure of individuals.		

Details on results:

Rhipicephalus sanguineus (Brown dog tick)

	Knockdown or (I hour exposure, 1 day after treatment)		Knockdown or (1 hour exposure, 1 month after treatment)		Knockdown or Mortality (1 hour exposure, 2 months after treatment)	
	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7	knockdown Day 1	mortality Day 1-7
Glazed tiles	100%	100%	100 %	100%	100%	100%
Unglazed tiles	100%	100%	100%	100%	100%	100%
Untreated glazed tiles	0%	2%	0%	6 %	0%	0%
Untreated unglazed tiles	0%	2%	0%	4%	0%	0%

Conclusion on the efficacy of the product
To demonstrate efficacy against the intended target species, laboratory and simulated-use studies were submitted for Entfloher (permethrin 0.6%, pyriproxyfen 0.1% with 3.125 ml/m^2). With the tests provided the following use could be authorised: Indoor use against fleas (eggs and larvae), including a residual efficacy up to 24 weeks: in areas where pets (dogs and cats) mainly remain, including pet bedding, carpets or cushions. Fur a full evaluation of the label claims see section 2.2.1.8.

2.2.1.6 Occurrence of resistance and resistance management

Permethrin:
Resistance to permethrin has been documented in wide varieties of insects (http://www.pesticideresistance.org/search.php; April 2016). The level of resistance is different in the various species but high levels of resistance have been observed e.g. in cockroaches.
Resistance to permethrin has been documented in a wide variety of organisms. Several different biochemical pathways are suggested that might be involved in resistance to permethrin. In general, pyrethroid resistance has been attributed to reduced neural sensitivity, enhanced metabolism, and reduced penetration ratio in many insects. A substantial degree of resistance remaining after synergism suggests the presence of other resistance mechanisms. Cross-resistance to pyrethroids and the susceptibility to carbaryl suggested that a common site of pyrethroid action exists.

Pyriproxyfen:
Data from published studies has indicated that pyriproxyfen is unlikely to induce resistance. According to the Arthropod Pesticide Resistance Database (APRD) (http://www.pesticideresistance.org/search.php; April 2016) no resistance is known for the mentioned target insects.

It is extremely important to generate a pest management strategy in order to combat the onset of resistance in general and to permethrin in particular.
The principles of strategies for managing the development of resistance include:
- where possible, application treatments should be recommended to be combined with non-chemical measures
- products should always be used in accordance with label recommendations
- complete elimination of insect pests should be attempted in infested areas
- applications should always be made against the most susceptible stages in the pest life cycle
- where an extended period of control is required, treatments should be alternated with products with different modes of action
- levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance.

2.2.1.7 Known limitations

No undesirable or unintended side effects e.g. on beneficial and other non-target organisms were observed. No other limitations are known, nevertheless better results are expected if areas are cleaned before applying the biocidal product. Areas treated with the product should not be (wet) cleaned during the period of residual efficacy, as this will diminish the residual efficacy.. Treated pet areas (pet bedding, carpets or cushions) should not be washed or cleaned during this period.

2.2.1.8 Evaluation of the label claims

Per use the following claims have been intended
Use 1:
The product is an insecticide designed for use indoors, intended for in-house treatment. The product is intended for spot application (aerosol) : in areas where pets (dogs and cats), mainly remain, including pet bedding, carpets, or cushions.

-Fleas: Eggs, larvs, adults
-Ticks: adults
-House dust mites: adults
-Poultry red mites: adults

Use 2:
The product is an insecticide designed for use indoors, intended for in-house treatment. The product is intended for spot application (aerosol) on cracks and crevices in the close vicinity of nests or trails.

-Cockroaches: adults
-Silverfishes: adults
-Ants: adults
-Woodlice: adults

The provided efficacy data for these target species are evaluated below.

Use 1:

Fleas:

Test provided with Cat fleas (*Ctenocephalides felis*)

Laboratory test

Adults:up to 1 day (96% knockdown or mortality after 24 hours).
Eggs: up to 24 weeks (0% observed adult fleas after 39 days)
Larvea: up to 24 weeks (0% observed adult fleas after 39 days and 67 days)

The criterion for a ovicidal or larvicidal product were met, a claim against eggs and larvae of *Ctenocephalides felis* can be authorized, including a residual efficacy up to 24 weeks.

For an adulticidal claim against fleas insufficient efficacy was demonstrated.

Therefore no authorization can be given for an adulticidal claim against fleas.

Ticks:

-Tests provided with Sheep ticks (*Ixodes ricinus*) & Brown dog ticks (*Rhipicephalus sanguineus*)

Laboratory tests with both tick species:
Non-porous tiles: up to 8 weeks (100% mortality after 24 hours)
Porous tiles: up to 8 weeks (100% mortality after 24 hours)

Efficacy against *Ixodes ricinus* and *Rhipicephalus sanguineus* was demonstrated in laboratory tests. However, the Efficacy guidance part B/C states that an insecticide against ticks with knockdown or kill effect both laboratory and simulated use tests should be provided. As no separate simulated use test was provided against ticks the product claim against ticks cannot be authorized.

House Dust Mite (*Dermatophagoides pteronyssinus*)

Laboratory test
Non-porous tiles: up to 8 weeks (100% mortality after 24 hours)
Porous tiles: up to 8 weeks (100% mortality after 24 hours)

Efficacy against *Dermatophagoides pteronyssinus was* demonstrated in laboratory tests. However, as no data from mandatory simulated-use tests was provided the product claim against house dust mites cannot be authorized.

Red poultry Mite (*Dermanyssus gallinae*)

Laboratory test
Non-porous tiles: up to 8 weeks (100% mortality after 24 hours)
Porous tiles: up to 8 weeks (100% mortality after 24 hours)

Efficacy against *Dermanyssus gallinae* was demonstrated in laboratory tests. However, as no data from mandatory simulated-use tests was provided to demonstrate efficacy, the product claim against Red poultry mites cannot be authorized.

Use 2:

-Cockroaches: adults
-Silverfishes: adults
-Ants: adults
-Woodlice: adults

Cockroaches:

-Tests provided with German cockroaches (*Blattella germanica*)

Laboratory test
Non-porous tiles: up to 4 weeks (>90% mortality)
Porous tiles: up to 2 weeks (>90% mortality)

Simulated-use test
Non-porous tiles: >100% mortality after 24 and 48 hours
Plywood (porous surface): >93% mortality after 24 hours

Although both the laboratory test and the simulated use test showed efficacy against German cockroaches, the simulated use test did not sufficiently mimic the intended use of this product (spot application (aerosol) on cracks and crevices in the close vicinity of nests or trails). In the simulated use test half of the floor surface is treated, which is suitable for a general surface treatment, but not for a crack and crevice treatment.

Therefore, the provided efficacy data against German cockroaches is insufficient for a claim against this target species.

-Tests provided with Oriental cockroaches (*Blatta orientalis*)

Laboratory test
Non-porous tiles: <90% mortality

Porous tiles: <90% mortality

Simulated-use test
Non-porous tiles: >90% mortality after 24 and 48 hours
Plywood (porous surface): 0% mortality after 24 hours

The provided efficacy data is insufficient for a claim against *Blatta orientalis*, efficacy has not been demonstrated.

A general cockroach claim cannot be authorised as both for German cockroaches and for Oriental cockroaches efficacy is not sufficiently demonstrated.

Silverfishes (*Lepisma saccharina*)

Laboratory test
Non-porous tiles: up to 8 weeks (90% knockdown or mortality after 24 hours)
Porous tiles: up to 2 weeks (100% mortality)

Efficacy against *Lepisma saccharina* was demonstrated in laboratory tests. However, as no data from mandatory simulated-use tests was provided to demonstrate efficacy, the product claim against *Lepisma saccharina* cannot be authorized.

Ants:

Tests provided with Black garden ants (*Lasius niger*)

Laboratory test
Non-porous tiles: up to 4 weeks (98% knockdown or mortality after 24 hours)
Porous tiles:1 day (100% mortality)

Simulated-use test
Non-porous tiles: >100% mortality after 24 and 48 hours
Plywood (porous surface): <90% mortality after 24 hours

Although both the laboratory test and the simulated use test showed efficacy against *Lasius niger*, the simulated use test did not sufficiently mimic the intended use of this product (spot application (aerosol) on cracks and crevices in the close vicinity of nests or trails). In the simulated use test half of the floor surface is treated, which is suitable for a general surface treatment, but not for a crack and crevice treatment.

Therefore, the provided efficacy data against Black garden ants is insufficient for a claim against this target species and for a general ant claim.

Woodlice (*Porcellio scaber*)

Laboratory test
Non-porous tiles: up to 8 weeks (100% knockdown or mortality after 24 hours)
Porous tiles: up to 2 weeks (98% knockdown or mortality after 24 hours)

Efficacy against *Percellio scaber* was demonstrated in laboratory tests. However, as no data from mandatory simulated-use tests was provided to demonstrate efficacy, the product claim against *Percellio scaber* cannot be authorized.

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

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

Risk assessment for human health

The toxicological properties of the active substances in the biocide product Entfloher, permethrin and pyriproxyfen are summarised in the respective CA reports (RMS Ireland, 2014, RMS The Netherlands, 2014, respectively).

Acute toxicity tests as well as tests for skin or eye irritation and skin sensitisation with the product Entfloher have not been performed. The criteria for the classification of mixtures according to the Regulation 1272/2008 (CLP) were followed.

According to the calculation method, the biocidal product Entfloher does not need to be classified for Acute Toxicity, Skin Irritation and Skin Sensitisation.

However, the biocidal product does need to be classified as Eye Irrit. 2, H319 according to the calculation method. Since the b.p. is not classified as sensitizing but contains permethrin classified as sensitizing and present in a concentration greater than 0.1% (concentration limit for elicitation), the following EUH208 is required to be included in label: 'EUH208 – Contains permethrin. May produce an allergic reaction.'

2.2.1.9 Assessment of effects on Human Health

Skin corrosion and irritation

For skin corrosion and irritation no human data is available.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating to skin.
Justification for the value/conclusion	A skin irritation study with the biocidal product Entfloher has not been conducted. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the active substances and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP	No classification for skin irritation is necessary.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	According to Chapter 8.1 "Skin corrosion or skin irritation" of the "Guidance on information requirements" (Version 1.1, Nov. 2014), 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), and synergistic effects between any of the components are not expected. The toxicity of the active substances (a.s.) and the co-formulants is known. Thus, toxicological properties and classification of the biocidal product (b.p.) can be deduced from the respective properties of the a.s.

	and the co-formulants using the criteria for classifying mixtures under CLP. With respect to skin irritation/corrosion, all components contained in the mixture at a concentration > 1% are to be taken into account for the purpose of a classification for skin irritating/corrosive properties. Following evaluation of the a.s. permethrin by the Rapporteur Member State (RMS) Ireland and of the a.s. pyriproxyfen by the RMS The Netherlands, no classification with Skin Irrit. 2; H315 has been proposed in the Chemical Assessment Reports, respectively (CAR, IRL, 2014 and CAR, NL, 2012). Moreover, neither of the co-formulants of the b.p. is classified with respect to skin irritation.**Therefore, the b.p. does not need to be classified for skin corrosion/irritation according to the provisions of the CLP regulation.**

Eye irritation

For eye damage and eye irritation no human data is available.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Irritating to eyes.
Justification for the value/conclusion	An eye irritation study with the biocidal product Entfloher has not been conducted. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the active substances and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP	Eye Irrit. 2, H319

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	According to Chapter 8.2 "Eye irritation" of the "Guidance on information requirements" (Version 1.1, Nov. 2014), 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), and synergistic effects between any of the components are not expected. The toxicity of the active substances (a.s.) and the co-formulants is known. Thus, toxicological properties and classification of the biocidal product (b.p.) can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under CLP.

	According to CLP, all components contained in the mixture at a concentration > 1% are to be taken into account for the purpose of a classification with respect to eye irritating/corrosive properties. Following evaluation of the a.s. permethrin by the Rapporteur Member State (RMS) Ireland and of the a.s. pyriproxyfen by the RMS The Netherlands, no classification for eye irritation has been proposed in the Chemical Assessment Reports, respectively (CAR, IRL, 2014 and CAR, NL, 2012). According to MSDS, one co-formulant is classified as Eye Irrit. 2, H319. No specific concentration limits are given for this ingredient in Annex VI of CLP, so that the generic concentration limits of the CLP apply. The generic concentration limit of ingredients of a mixture classified as Category 2 for effects on the eye that trigger classification of the mixture for effects on eye is ≥ 10%. The concentration of the other co-formulant is above this generic concentration limit. Since the concentration of this ingredient exceeds the generic concentration limit, **the b.p. needs to be classified with Eye Irrit. 2; H319, according to the provisions of the CLP regulation.**

Respiratory tract irritation

For respiratory tract irritation no human data is available.

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the conclusion	No experimental data on respiratory tract irritation of the biocidal product Entfloher is available. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the active substances and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP	No classification for respiratory tract irritation is necessary.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	Based on information of the active substances and co-formulants the biocidal product does not need to be classified for respiratory tract irritation according to CLP.

Skin sensitization

For skin sensitisation no human data is available.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising. Since the b.p. is not classified as sensitizing but contains permethrin classified as sensitizing and present in a concentration greater than 0.1%, the following label is required: 'EUH208 – Contains permethrin. May produce an allergic reaction.'
Justification for the value/conclusion	A skin sensitisation study with the biocidal product Entfloher has not been conducted. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the active substances and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP	No classification for skin sensitisation is necessary.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	According to Chapter 8.3 "Skin sensitisation" of the "Guidance on information requirements" (Version 1.1, Nov. 2014), 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), 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 corrosivity; or • The substance is a strong acid (pH < 2.0) or base (pH > 11.5). The toxicity of the active substances (a.s.) and the co-formulants is known. Thus, toxicological properties and classification of the biocidal product (b.p.) can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under CLP. Data of the a.s. permethrin were evaluated by the Rapporteur Member State (RMS) Ireland and published as Chemical Assessment Report (CAR, IRL, 2014). A classification of permethrin as a skin sensitizer, Category 1B, H317 is proposed. Data of the a.s. pyriproxyfen were evaluated by the RMS The Netherlands and published as Chemical Assessment Report (CAR, NL, 2012). pyriproxyfen is not classified for skin sensitisation. No co-formulant is classified for skin sensitisation. For permethrin no specific concentration limits are given in Annex VI of CLP, so that the generic concentration limits of the CLP apply. The mixture shall be classified as a skin sensitizer when at least one ingredient has been classified as a skin sensitizer and is present at or above the appropriate generic concentration limit. The concentration of permethrin in the b.p. is below the generic concentration limit specified

	for a skin sensitizer, Sub-category 1B (1%). **Therefore, the b.p. does not need to be classified with respect to skin sensitization according to the provisions of the CLP regulation.** Some substances that are classified as sensitizers may elicit a response, when present in a mixture in quantities below the generic concentration limits in individuals who are already sensitized to the substance or mixture. This concentration limit for elicitation is used for the application of the special labelling requirements to protect already sensitized individuals. Since the b.p. is not classified as sensitizing but contains permethrin classified as sensitizing and present in a concentration greater than 0.1% (concentration limit for elicitation), the following EUH208 label is required: **'EUH208 – Contains permethrin. May produce an allergic reaction.'**

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising.
Justification for the value/conclusion	No data on respiratory sensitisation is available for the biocidal product Entfloher. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the active substances and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP	No classification for respiratory sensitisation is necessary.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	According to Chapter 8.4 "Respiratory sensitisation" of the "Guidance on information requirements" (Version 1.1, Nov. 2014), 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), and synergistic effects between any of the components are not expected. The toxicity of the active substances (a.s.) and the co-formulants is known. Thus, toxicological properties and classification of the biocidal product (b.p.) can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under CLP. Following evaluation of the a.s. permethrin by the Rapporteur Member State (RMS) Ireland and of the a.s. pyriproxyfen by the RMS The Netherlands, no indication was reported from the studies performed that permethrin or pyriproxyfen would cause respiratory sensitisation.

	Moreover, neither of the co-formulants of the b.p. is classified with respect to respiratory sensitisation. **Therefore, the b.p. does not need to be classified with respect to respiratory tract sensitisation according to the provisions of the CLP regulation.**

Acute toxicity

Acute toxicity by oral route

For acute oral toxicity no human data is available.

Value used in the Risk Assessment – Acute oral toxicity	
Value	Not harmful
Justification for the selected value	Acute toxicity studies with the biocidal product Entfloher have not been conducted. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the active substances and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP	No classification for acute oral toxicity is necessary.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	According to Chapter 8.5 "Acute toxicity" of the "Guidance on information requirements" (Version 1.1, Nov. 2014), 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), and synergistic effects between any of the components are not expected. The toxicity of the active substances (a.s.) and the co-formulants is known. Thus, toxicological properties and classification of the biocidal product (b.p.) can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under CLP. Data of the a.s. permethrin were evaluated by the Rapporteur Member State (RMS) Ireland and published as Chemical Assessment Report (CAR, IRL, 2014). The acute oral studies submitted had LD_{50} values ranging from 480 - 1623 mg/kg bw/day. Therefore, permethrin is classified for Acute Tox. 4, H302: Harmful if swallowed. Data of the a.s. pyriproxyfen were evaluated by the RMS The Netherlands and published as Chemical Assessment Report (CAR, NL, 2012). The rat oral LD_{50} value is > 5000 mg/kg bw. Therefore, pyriproxyfen does not need to be classified on the basis of its oral toxicity in rats.

	Moreover, neither of the co-formulants of the b.p. is classified with respect to acute oral toxicity.**Therefore, the b.p. does not need to be classified with respect to acute oral toxicity according to the provisions of the CLP regulation.**

Acute toxicity by inhalation

For acute inhalation toxicity no human data is available.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not harmful.
Justification for the selected value	Acute toxicity studies with the biocidal product Entfloher have not been conducted. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the active substances and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP	No classification for acute inhalation toxicity is necessary.

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	According to Chapter 8.5 "Acute toxicity" of the "Guidance on information requirements" (Version 1.1, Nov. 2014), 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), and synergistic effects between any of the components are not expected. The toxicity of the active substances (a.s.) and the co-formulants is known. Thus, toxicological properties and classification of the biocidal product (b.p.) can be deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under CLP. Data of the a.s. permethrin were evaluated by the Rapporteur Member State (RMS) Ireland and published as Chemical Assessment Report (CAR, IRL, 2014). The inhalative LC_{50} value of permethrin is > 4.638 – 23.5 mg/L. Although the inhalation studies submitted by the applicants indicated the substance did not require classification for inhalation, permethrin is currently classified under CLP as Acute Tox. 4, H332: Harmful if inhaled. This classification is based on a study referenced in PPP DAR. The rationale of the RMS was to apply the precautionary principal and retain the classification based on the aforementioned data. Data of the a.s. pyriproxyfen were evaluated by the RMS The Netherlands and published as Chemical Assessment Report (CAR, NL, 2012). The rat inhalative LC_{50} value is > 1.3 mg/L (max. attainable

	concentration). Pyriproxyfen does not need to be classified on the basis of its respiratory toxicity in rats. No co-formulant is classified for acute inhalation toxicity. No specific concentration limits are given for permethrin in Annex I of CLP, so that the generic cut-off value of the CLP apply. Since permethrin is present at a concentration below the concentration limit of 1%, **the b.p. does not need to be classified with respect to acute inhalation toxicity according to the provisions of the CLP regulation.**

Acute toxicity by dermal route

For acute dermal toxicity no human data is available.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not harmful
Justification for the selected value	Acute toxicity studies with the biocidal product Entfloher have not been conducted. Toxicological properties and classification of the biocidal product was deduced from the respective properties of the a.s. and the co-formulants using the criteria for classifying mixtures under Regulation (EC) No 1272/2008 (CLP).
Classification of the product according to CLP	No classification for acute dermal toxicity is necessary.

Data waiving	
Information requirement	Study scientifically unjustified.

Justification	According to Chapter 8.5 "Acute toxicity" of the "Guidance on information requirements" (Version 1.1, Nov. 2014), 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), and synergistic effects between any of the components are not expected. The toxicity of the active substances (a.s.) and the co-formulants is known. Thus, toxicological properties and classification of the biocidal product (b.p.) can be deduced from the respective properties of the a.s. and the co-formulants using the guidance for classifying mixtures under CLP. Data of the a.s. permethrin were evaluated by the Rapporteur Member State (RMS) Ireland and published as Chemical Assessment Report (CAR, IRL, 2014). The dermal LD_{50} value of permethrin is greater 2000 mg/kg bw, hence, permethrin did not classify as toxic or harmful by the dermal route. Data of the a.s. pyriproxyfen were evaluated by the RMS The Netherlands and published as Chemical Assessment Report (CAR, NL, 2012). The dermal LD_{50} value of pyriproxyfen is greater 2000 mg/kg bw. Therefore, pyriproxyfen does not need to be classified on the basis of its dermal toxicity in rats. No co-formulant is classified for acute dermal toxicity. **Therefore, the b.p. does not need to be classified with respect to acute dermal toxicity according to the provisions of the CLP regulation.**

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Permethrin	Pyriproxyfen
Value(s)	3%	75%
Justification for the selected value(s)	The dermal absorption value of 3% for permethrin as set by the RMS Ireland was adopted for the biocidal product.	The dermal absorption value of 75% for pyriproxyfen as default value according to EFSA Guidance on Dermal Absorption (2012) was adopted for the biocidal product.

Data waiving	
Information requirement	Other justification
Justification	In the Assessment Report on permethrin, a dermal absorption of 3% was derived for permethrin from an *in vivo* dermal absorption study performed in human volunteers. According to the information given in the DocIIIA study summary for this particular study (see Applicant B (Sumitomo Chemical (UK) PLC and Bayer Environmental Sciences) as disseminated on the ECHA website for the active substance permethrin) 0.8 mL of a propan-2-ol formulation containing 510 µg ^{14}C-permethrin

	was applied slowly until a total dose of 2040 µg was applied to the shaved back (total 256 cm²) of each of the 6 volunteers. The applied amount of 10 µL/cm² complies with the recommended amount in the current OECD 427 guideline. The concentration of 637.5 µg permethrin/mL corresponds to 0.081% considering a density of 0.785 g/mL for propan-2-ol. A mean of 1.24 ± 0.73% of the applied dose (range 0.30 – 2.08%) was absorbed and excreted almost entirely in urine after dosing. However, the dermal absorption has been corrected to 3% since the first two volunteers have been excluded from the derivation as they have a very low recovery and were regarded as outlines and since the values were normalised to 100% to correct for the low recovery. Propan-2-ol (IPA), the vehicle used in this *in vivo* human skin absorption study will have a comparable effect on the penetration of the chemical into and through the skin as compared to the ethanol/ IPA mixture (10% IPA) as vehicle. Moreover, the tested concentration of 0.081% permethrin is well below the in use-concentration of permethrin in the Convet product Entfloher (0.6% permethrin). Taken additionally into account the generally inverse relationship between concentration and dermal absorption, a dermal absorption value of 3% represents a worst case for the potential dermal absorption of permethrin from the b.p. Entfloher. For this reason, it is justified, to consider a dermal absorption value of 3% in the relevant scenarios of the human health exposure and risk assessment. Since no data on the dermal absorption are available and as no read-across approach can be applied based on the data reported in the Assessment Report on pyriproxyfen (AR NL, 2012), the default dermal absorption value of 75% according to EFSA (EFSA, Guidance on Dermal Absorption, 2012) is considered in the human health exposure and risk assessment on pyriproxyfen.

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

Two co-formulants are identified as SoCs in accordance with the EU SoC guidance (CA-Nov14-Doc.5.8).

Propan-2-ol (CAS No. 67-63-0, ingredient of the co-formulant ethanol) is an active substance for which a CAR for Product Types 1, 2 and 4 with agreed reference values is available. This substance is present in the b.p. at a concentration of 1-5%. Thus, according to Guidance on the BPR: Volume III Part B (ECHA; Oct 2015) propan-2-ol is identified as substance of concern (SoC). For further exposure estimations the highest concentration of 4.95% (w/w) was used for calculations. Propan-2-ol is classified with STOT SE 3, H336 (May cause drowsiness and dizziness) according to CLP but due to the low concentration (<20%) in the biocidal product it does not need to be classified with respect to STOT SE effects.
For the exposure assessment a default dermal absorption value of 75% for products containing <5% substance is used (EFSA, Guidance on Dermal Absorption, 2012).

An $AEL_{acute/medium\text{-}term/long\text{-}term}$ of 10.7 mg/kg bw/day (31.25 ppm for 8 hours/d) for the general public was derived from a human volunteer study (CAR, RMS DE, 2015). For professional

workers an $AEL_{acute/medium-term/long-term}$ of 17.9 mg/kg bw/d (52.6 ppm for 8 h/d) was derived. These reference values will be used for the risk assessment.

Ethanol (CAS No. 64-17-5) is a co-formulant in the biocidal product with a concentration of ≥92%. The classification as an Eye irritant Category 2 (H319) according to CLP was taken into consideration when determining the classification as an Eye Irritant Category 2. Thus, according to Guidance on the BPR: Volume III Part B (ECHA; Oct 2015) ethanol is identified as substance of concern (SoC).
Ethanol is identified as SoC also because of the presence of the OEL. In The Netherlands, an OEL (8-hours TWA) of 260 mg/m³ has been established and a short-term OEL (STEL, 15 min) is recommended at 1900 mg/m³ (2006/06OSH). A quantitative risk assessment for the inhalation route needs to be conducted in accordance with the EU SoC guidance (CA-Nov14-Doc.5.8). As this value is set for professional users the workplace limit value of professionals/industrial users needs to be corrected for differences between workers and the general population. This additional assessment factor of 3 is only applied to the 15 min exposure value resulting in 633 mg/m³ (1900 mg/m³ ÷ 3). The 8-hour OEL is already considered conservative enough to cover 24-hour exposure of the general public taking into account the advice of the Dutch Health Council.

The b.p. contains no further non-active substances that are identified as SoCs.

Assessment for endocrine disrupting properties

According to the ED (endocrine disruptor) criteria with respect to humans established in the Comission Delegated Regulation (EU) 2017/2100, a substance shall be considered as having endocrine disrupting properties if it meets all of the following criteria:

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

To examine if any of the co-formulants contained in the product may possess ED properties, a screening was performed by examining the co-formulants are

- Classified as CMR or PBT;
- Identified as ED in the DG Santé's Impact Assessment study on Screening of available evidence on chemical substances for the identification of endocrine disruptors;
- Identified as ED in the EU list of potential endocrine disruptors; or
- Listed in CoRAP linked to ED concerns.

As a result of the screening it was identified that an ED concern has been raised by France for one co-formulant, 2,6-di-tert-butyl-p-cresol and they propose to include this substance on the CoRAP list https://echa.europa.eu/documents/10162/7ddda8e5-d66c-4fad-b502-86cfdf2298bc. This substance is also known as butylated hydroxytoluene (BHT) and is approved as food additive (anti-oxidant) and as additive for animal feed (E 321).
CA NL considers that further ED assessment for this co-formulant does not need to be performed in this PAR but should await the outcome of the discussions at EU level.

Subsequently, it was examined if there are any concerns for adverse effects to meet the criterion a) as described above using ECHA REACH database. This examination showed that ethanol may have reproductive toxicity.

Regarding ethanol, there is an on-going consideration as an active substance under BPR. Therefore further ED assessment for ethanol does not need to be performed in this PAR but should await the outcome of the discussions at EU level.

Available toxicological data relating to a mixture

Available toxicological data relating to a mixture of which substance(s) of concern is a component are not required.

Other

The biocidal product is intended for the use as insecticide applied on places used by cats and dogs. It is not supposed to be applied onto humans or pets. Other test(s) related to the exposure to humans or pets are not available for the proposed biocidal use pattern. Exposure estimates and risk characterisations are given in the human risk assessment. The risk characterisation showed no concern when the b.p. is handled and applied. Therefore no other test related to the exposure to humans is necessary.

The biocidal product is not intended for direct application to foods or feedingstuff or to surfaces and areas where foods or feedingstuff are prepared or stored. Hence, an exposure of food and feedingstuff to b.p. can be excluded when applied according to the recommended uses. Additional food or feedingstuff studies are not required.

2.2.1.10 Exposure assessment

The biocidal product Entfloher is a ready-to-use pre-pressurised aerosol spray containing 0.6% (w/w) permethrin and 0.1% (w/w) pyriproxyfen as biocidal active substances (a.s.) and at maximum 4.95% (w/w) propan-2-ol as well as 94.05% (w/w) ethanol as substances of concern (SoCs). It is used by aerosol spraying as an insecticide (Product type 18) for amateur use against fleas and ticks. The biocidal product is only intended for indoor use. The biocidal product is sold as consumer product (non-professional use).
The spray should be used on surfaces where fleas and ticks live. With reference to fleas as the most important target organisms, the spray should be applied on pet bedding, carpets, under cushions, at the back of sofas, on rugs, upholstered furniture and in cracks and crevices. Hard flooring, such as tiles, concrete or linoleum will not typically require treatment. Prior to a treatment, aquaria have to be covered and pets have to be removed from the room.
The application rate is 250 mL product/80 m^2, equivalent to 3.13 mL product/m^2 or 2.47 g product/m^2 (density of product: 0.79 g/mL) , corresponding to 14.8 mg permethrin/m^2, 2.47 mg pyriproxyfen/m^2 and 122.3 mg propan-2-ol/m^2.

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	No

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
[1]	Spray application	Primary exposure; The b.p. should be applied on pet bedding, carpets, under cushions, at the back of sofas, on rugs, upholstered furniture and in cracks and crevices. Dermal and inhalative exposure is the most relevant route of exposure.	Non-professionals (adults)
[2]	Re-entry in treated rooms	Secondary exposure; Re-entry into treated rooms: dermal contact with treated surface areas after spray application pepe	General public (adults, children)
[3]	Hand-to-mouth transfer	Secondary exposure; post-application exposure of children will take place via the oral and dermal route taking into account their hand-to-mouth behaviour	General public (children)

Industrial exposure

No industrial exposure is foreseen.

Professional exposure

No professional exposure is foreseen.

Non-professional exposure

Scenario [1] Primary exposure - Spray application

Description of Scenario [1]

The biocidal product Entfloher is a ready-to-use liquid packaged in pre-pressurised aerosol spray, containing 0.6% (w/w) permethrin and 0.1% (w/w) pyriproxyfen as biocidal active substances (a.s.) and 4.95% (w/w) propan-2-ol as well as 94.05% (w/w) ethanol as substances of concern (SoCs). It is used by aerosol spraying as an insecticide (Product type 18) for amateur use against fleas and ticks. The biocidal product is only intended for indoor use.
The spray should be used on surfaces where the above mentioned insects live. With reference to fleas as the most important target organisms, the spray should be applied on pet bedding, carpets, under cushions, at the back of sofas, on rugs, upholstered furniture and in cracks and crevices. Hard flooring, such as tiles, concrete or linoleum will not typically require treatment. Prior treatment, aquaria have to be covered, pets and other person than the user should be removed from the room.

For the estimation of the primary dermal and inhalation exposure during aerosol spraying, the pre-pressurised aerosol spray can model (Consumer spraying and dusting model 2, TNsG 2007, p. 63; User Guidance version 1, 2002, p.33) is applied. This model covers non-professional surface spraying insecticide, indoors, on soft furnishings, carpets, skirting boards and shelves with dust applicator trigger sprays and aerosol cans.
The aerosol spray can model described above does not assess exposure to vapours potentially generated by evaporation. Due to the high vapour pressure of propan-2-ol and ethanol evaporation was considered relevant for application of the biocidal product for ethanol and propan-2-ol. Evaporation was considered using Cons Expo.
The dermal absorption value of 3% for permethrin as set in the assessment report by the RMS Ireland (2014) and 75% (default) for pyriproxyfen was adopted. A default absorption value of 75% for products containing <5% substance is used for propan-2-ol (EFSA, Guidance on Dermal Absorption, 2012).

	Parameters	Value
Tier 1	**Concentration of a.s. or SoC**	
	Permethrin	0.6% (w/w)
	Pyriproxyfen	0.1% (w/w)
	Propan-2-ol	4.95% (w/w)
	Ethanol	94.05% (w/w)
	Potential leg, feet, face exposure	45.2 mg/min(1)
	Potential hand and forearm exposure	64.7 mg/min(1)
	Potential inhalation exposure	35.9 mg/m³(1)
	Inhalation/respiration rate	1.25 m³/h(2)
	Duration of task per day	7 min(3)
	Dermal absorption	
	Permethrin	3% (see rational above)
	Pyriproxyfen	75% (default)
	Propan-2-ol	75% (default)

	Body weight	60kg[2]
	Penetration through work clothing	100%[4]

Parameters used for ConsExpo:

compound name:	Propan-2-ol	
CAS number:	67-63-0	
molecular weight	60.1	g/mol
vapour pressure	5.78E3	Pascal (25°C)
KOW	0.05	10Log
compound name:	Ethanol	
CAS number:	64-17-5	
molecular weight	46.1	g/mol
vapour pressure	7.87E3	Pascal (25°C)[5]
KOW	-0.35	10Log 4 [6]
General Exposure Data		
exposure frequency	365	1/year [worst case assumption]
body weight	60	kilogram
Inhalation model: Exposure to vapour : evaporation, increasing release area		
weight fraction compound		
Propan-2-ol	4.95	%
Ethanol	94.05	%
exposure duration	480	minute
room volume	20	m³ [default non specified room][7]
ventilation rate	0.6	1/hr [default non specified room][7]
applied amount	12.5	gram [treatment of 5 m² with application rate of 2.47 g/m²]
release area	5	m^2
application duration	7	minute[3]
mol weight matrix		
Propan-2-ol	46	g/mol [Ethanol is the main co-formulant]
Ethanol	72.2	g/mol [calculated][8]
mass transfer rate	5.5E3	m/min [worst case, Langmuir's method]
Uptake model: Fraction		
uptake fraction	1	fraction
inhalation rate	1.25	m^3/hour [default light exercise]

[1] According to TNsG 2007, p. 63; User User Guidance version 1, 2002, p.33
[2] HEEG opinion 17, 2014
[3] TNsG 2002, p. 114, worst case; calculated spray duration is only 2.2 min for a 250 mL can and a spray rate of 19 mL/10s
[4] HEAdhoc recommendation No. 8
[5] https://echa.europa.eu/registration-dossier/-/registered-dossier/16105/4/7
[6] MSDS: denaturated Ethanol with Isopropanol
[7] General Fact Sheet, General default parameters for estimating consumer exposure - Updated version 2014, RIVM report 090013003/2014
[8] Calculation according to RIVM Report 2016-0171 (ConsExpo Consumer exposure models)

$$Molecular\ weight\ of\ the\ matrix = \frac{1 - weight\ fraction\ of\ compound}{\sum i\ \frac{weight\ fraction\ i}{molecular\ weight\ i}}$$

i = summation index is over all substances in the mixture except for the substance in question. Since the rest of the material mainly comprises propan-2-ol (4.95%, molecular weight 60.1 g/mol), the molecular weight matrix is calculated as follows:

$$Molecular\ weight\ of\ the\ matrix = \frac{1 - 0.9405}{\frac{0.0495}{60.1\ g/mol}} = 72.2\ g/mol$$

Output table with detailed calculations is found in Annex 3.2.

Calculations for Scenario [1]

Summary table: systemic exposure from non-professional uses						
Exposure scenario	**Tier/ PPE**	**a.s., SoC**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/day]			
Scenario [1]	1 / no PPE	Permethrin	0.0005	0.0023	-	0.0028
		Pyriproxyfen	0.0001	0.0096	-	0.0097
		Propan-2-ol Consumer spraying and dusting model 2	0.0043 (aerosol)	0.476	-	0.4803
		ConsExpo	0.037 (vapour)	-	-	0.037

Ethanol

Summary table: estimated local exposure from non-professional uses			
Scenario number	**Method for exposure assessment**	**Inhalation exposure concentration in air [mg/m³]**	
		24-h TWA	**Peak concentration**
[1]	Consumer spraying and dusting model 2 ConsExpo	0.16 (aerosol) 40(vapour)*	33.8 480 (TWA 15 min)

*mean concentration on day of exposure

Further information and considerations on Scenario [1]

The biocidal product is classified as an Eye Irritant Category 2 (H319) according to CLP which is triggered by the co-formulant ethanol (>92%). Therefore, a qualitative risk assessment has to be performed regarding this possible local effect.

Exposure of the general public

Scenario [2] Secondary exposure – Dermal contact with treated surface areas / exposure to vapours

Description of Scenario [2]

The most likely secondary exposure scenario is the dermal contact with treated surface areas after spray application indoors by the general public. Secondary exposure via the inhalation route regarding non volatile components of the biocidal product is not considered relevant, since the treated rooms will have been well ventilated before re-entry and the product aerosol will have settled from the air to surfaces by the time of re-entry into the rooms. Inhalation exposure is considered not to be relevant as both active substances reveal a negligible vapour pressure (permethrin: 2.155 x 10^{-6} Pa at 20°C; pyriproxyfen: <1.33 x 10^{-5} Pa at 22.81°C) and evaporation from treated surfaces is unlikely to occur. Therefore, only the dermal exposure route is relevant and has been considered in the exposure estimations for the active substances. For the volatile substances of concern propan-2-ol and ethanol an inhalation exposure due to evaporation was considered whereas a dermal exposure is negligible due to rapid evaporation of p ropan-2-ol and ethanol.
As a realistic worst case, the secondary dermal exposure of adults and children residents via residues on treated upholstery was considered. Regarding children an exposure assessment was performed based on infants representing the worst case.
The application rate is 250 mL product/80 m^2, equivalent to 3.13 mL/m^2 or 2.47 g product/m² (density of product: 0.79 g/mL) , corresponding to 14.8 mg permethrin/m^2, 2.47 mg pyriproxyfen/m^2 and 122.3 mg propan-2-ol/m².
The following parameters are considered in the secondary exposure estimation following dermal contact with residues of permethrin and pyriproxyfen on treated indoor surfaces after spraying.
The dermal exposure is calculated according to the following formula:
E_{dermal} = surface area (SA) x application rate (AR) x Concentration (C) x Transfer efficiency (TE) × dermal absorption (DA) / body weight (BW)

Evaporation of propan-2-ol and ethanol is considered using ConsExpo. Considered were adults and infant which represent according to HEEG Opinion 13 the worst case regarding inhalation exposure.

	Parameters	Value
Tier 1	**Concentration of a.s. or SoC (C)**	
	Permethrin	0.6% (w/w)
	Pyriproxyfen	0.1% (w/w)
	Surface Area (SA) - adult	8300 cm²(1)
	Surface Aera (SA) -infants	2100 cm²(1)
	Dermal absorption (DA)	
	Permethrin	3% (see rational above)
	Pyriproxyfen	75% (default)
	Effective application rate (AR)	0.247 mg b.p./cm²
	Transfer efficiency (TE)	18%(2)
	Body weight (BW) - adults	60 kg (3)
	Body weight (BW) - infants	8 kg (3)

Parameters used for ConsExpo:

compound name	Propan-2-ol	
CAS number	67-63-0	
molecular weight	60.1	g/mol
vapour pressure	5.78E3	Pascal
KOW	0.05	10Log
compound name:	Ethanol	
CAS number:	64-17-5	
molecular weight	46.1	g/mol
vapour pressure	7.87E3	Pascal[4]
KOW	-0.35	10Log[5]
General Exposure Data		
exposure frequency	365	1/year [worst case assumption]
body weight (adult)	60	kilogram
body weight (infant)	8	kilogram
Inhalation model: Exposure to vapour (instantaneous release)		
weight fraction compound		
Propan-2-ol	4.95	%
Ethanol	94.05	%
exposure duration	480	minute [worst case assumption]
room volume	20	m³ [default for unspecified room][6]
ventilation rate	0.6	1/hr [default for unspecified room][6]
applied amount	12.5	gram [treatment of 5 m² with application rate of 2.47 g/m²]
Uptake model: Fraction		
uptake fraction absorption)	1	fraction (= 100% inhalation
inhalation rate (adult)	1.25	m³/hour [HEAd hoc recom. 14]
inhalation rate (infant)	0.84	m³/hour [HEAd hoc recom. 14]

[1] ½ of total body surface adult/toddler – HEEG opinion 17, 2013
[2] worst case; Dried fluids of various types of surface Table: Transfer coefficients – Dislodgeable residues (p 171), Biocides Human Health Exposure Methodology version 1, October 2015
[3] HEEG opinion 17, 2013
[4] https://echa.europa.eu/registration-dossier/-/registered-dossier/16105/4/7
[5] MSDS: denaturated Ethanol with Isopropanol
[6] General Fact Sheet, General default parameters for estimating consumer exposure - Updated version 2014, RIVM report 090013003/2014

Scenario [3] Secondary exposure - Dermal and oral contact with treated surface areas (infant, Hand-to-mouth transfer)

Description of Scenario [3]

The most likely secondary exposure scenario is the dermal contact with treated surface areas after spray application indoors by the general public. Secondary exposure via the inhalation route is not considered relevant for the active substances, since the treated rooms will have been well ventilated before re-entry and the product aerosol will have settled from the air to surfaces by the time of re-entry into the rooms. The exposure to vapourised propan-2-ol and ethanol was already considered above in scenario 2. An exposure to propan-2-ol or ethanol by oral or dermal route is negligible due to rapid evaporation of propan-2-ol and ethanol.
The exposure for crawling infants present in the room after the treatment is carried out according to HEEG opinion 7 (HEEG opinion on Choice of secondary exposure parameters for PTs 2, 3 and 4. Agreed in TM I 2009). It is assumed that an infant (body weight: 8 kg) crawls on treated surface for 1 h/day (worst case consideration).
Dermal exposure:
The ConsExpo model was used to estimate the dose for the infant after dermal contact of floors or spaces treated with the biocidal product Entfloher. From the treated surfaces and objects it can be assumed that after dermal contact only a fraction of the applied material is available for exposure. The proportion of dislodgeable residues available for dermal uptake from treated surfaces is considered to be 9% (average, transfer coefficient from carpets, dried fluid) (TNsG on Human Exposure, 2007, p. 102).
Oral exposure:
Small children will exhibit a more or less comprehensive hand-to-mouth behaviour. Therefore, a part of the a.s. residues present on the hands will be dislodged by saliva and eventually ingested. In accordance to HEEG opinion 7 (2009), it is assumed, that 10% of the calculated external dermal exposure is ingested.

	Parameters	Value
Tier 1 (dermal)	**Concentration of a.s. or SoC**	
	Permethrin	0.6% (w/w)
	Pyriproxyfen	0.1% (w/w)
	Effective application rate (AR)	0.247 mg b.p./cm²
	Transfer coefficient (Tc)	2100 cm²/h(1)
	Conctact time (t)	1 hour
	Dislogable fraction (F_{disl})	18%(5)
	Dermal absorption	
	Permethrin	3% (see rational above)
	Pyriproxyfen	75% (default)
	Child body weight (BW)	8 kg(2)
	Fraction ingested (F_{ing})	10%(3)
	Oral absorption	
	Permethrin	100%
	Pyriproxyfen	40% (CAR, NL, 2012)
	External dose (D)	

	Permethrin	0.80 mg(4)
	Pyriproxyfen	0.13 mg(4)

[1] HEAd hoc recommendation 12
[2] Default of a 10.5 month old child, HEEG opion 17
[3] HEEG opinion 7, 2009
[4] Output table with detailed calculation is found in Annex 3.2.
[5] Worst case; Dried fluids of various types of surface Table: Transfer coefficients – Dislodgeable residues (p 171), Biocides Human Health Exposure Methodology version 1, October 2015

Calculations for Scenarios [2, 3]

Summary table: systemic exposure from non-professional uses						
Exposure scenario	**Tier/ PPE**	**a.s., SoC**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
			[mg/kg bw/day]			
Scenario [2]	1 / no PPE	Permethrin Adult Infant	 - -	 0.0011 0.0024	 - -	 0.0011 0.0024
		Pyriproxyfen Adult Infant	 - -	 0.0046 0.01	 - -	 0.0046 0.01
		Propan-2-ol Adult Infant	 1.1 5.4	 - -	 - -	 1.1 5.4
Scenario [3]	1 / no PPE	Permethrin (Infant)	-	0.002	0.007	0.009
		Pyriproxyfen (Infant)	-	0.008	0.00045	0.008

Ethanol

Summary table: estimated local exposure from non-professional uses			
Scenario number	**Method for exposure assessment**	**Inhalation exposure concentration in air [mg/m³]**	
		24-h TWA	**Peak concentration (TWA 15 min)**
[2]	ConsExpo	41	550

Output table with detailed calculations is found in Annex 3.2.

Further information and considerations on Scenarios [2, 3]

The biocidal product is classified as an Eye Irritant Category 2 (H319) according to CLP which is triggered by the co-formulant ethanol (>92%). Secondary exposure of eyes to ethanol is not considered relevant, since ethanol has a high vapour pressure and will evaporate rapidly. No residues will be left on the surfaces thus no eye contact will occur through hand-eye-transfer.

Combined scenarios

Exposure may occur to one and the same person applying the biocidal product and re-entering the room after treatment. Therefore, Scenarios 1 and 2 for adults have to be combined. Children are not assumed to perform the treatment.

Summary table: combined systemic exposure from non-professional uses					
Scenarios combined		**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
		[mg/kg bw/day]			
Scenarios [1, 2] adult	Permethrin	0.0005	(0023 + 0.0011=) 0.0034	-	0.0039
	Pyriproxyfen	0.0001	(0.0096 + 0.0046=) 0.0142	-	0.0143
	Propan-2-ol	Not required, scenario 2 covers the worst case			
Scenarios [2, 3] infant	Permethrin	-	(0.0024 + 0.002=) 0.0044	0.007	0.0114
	Pyriproxyfen	-	(0.01 + 0.008=) 0.018	0.00045	0.0185

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 of the biocidal product can be excluded when applied according to the recommended uses. Furthermore, the following risk mitigation is prescribed: 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, and drinks..

Information of non-biocidal use of the active substance

The a.s. permethrin and pyriproxyfen are insectidies to protect from infestation of insects by application on infested areas. Permethrin is not approved as plant protection product. Pyriproxifen is approved as active substance for plant protection products.

Estimating Livestock Exposure to Active Substances used in Biocidal Products
Food, drinking water or livestock exposure of permethrin, pyriproxifen, propan-2-ol and ethanol 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 used in 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 of permethrin, pyriproxifen, propan-2-ol and ethanol can be excluded when applied according to the recommended uses.

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 permethrin and pyriproxifen which are existing biocidal active substances within the EU.

Summary of exposure assessment

Permethrin

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake [mg/kg bw/day]**
[1]	Non-professional	1/no PPE	0.0028
[2]	General Population Adult Infant (worst case)	1/no PPE	 0.0011 0.0024
[3]	General Population Infant	1/no PPE	 0.009
[1, 2]	General Population Adult	1/no PPE	 0.0039
[2, 3]	General Population Infant	1/no PPE	0.0114

Pyriproxyfen

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/kg bw/day]**
[1]	Non-professional	1/no PPE	0.0097
[2]	General Population Adult Infant (worst case)	1/no PPE	 0.0046 0.01
[3]	General Population Infant	1/no PPE	 0.008
[1, 2]	General Population Adult	1/no PPE	 0.0143
[2, 3]	General Population Infant	1/no PPE	0.0185

Propan-2-ol

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake [mg/kg bw/day]**
[1]	Non-professional	1/no PPE	0.52
[2]	General Population Adult Infant (worst case)	1/no PPE	 1.1 5.4
[3]	General Population Infant	1/no PPE	 -
[1, 2]	General Population Adult	1/no PPE	1.61

Ethanol

Scenarios and values to be used in risk assessment			
		Inhalation exposure concentration in air [mg/m³]	
Scenario number	**Method for exposure assessment**	**24-h TWA**	**Peak concentration 15 min TWA**
[1]	Consumer spraying and dusting model 2 ConsExpo Total	0.16 (aerosol) 40(vapour) 40.16	33.8 480 513.8
[2]	ConsExpo	41	550

2.2.1.11 Risk characterisation for human health

The critical endpoint of the a.s. permethrin in the toxicological studies are increased absolute and relative liver weights which were associated with hepatocellular hypertrophy and adaptive hepatic changes. The NOAELs have been derived from the studies in the most sensitive species: the dog.

Pyriproxyfen showed in the subacute studies preliminary indications of liver injury (hypertrophy) and in the semichronic studies marked liver injury was observed, leading to hepatocellular injury, hepatobiliary effects, cholestasis in rat and dog and secondary renal failure in the rat. In addition, in all rodent studies with oral exposure and dog studies, slight changes in haematological parameters were observed.

The critical endpoint of the SoC propan-2-ol in the toxicological studies is central nervous system depression. The NOAELs have been derived from human volunteer studies.

Carcinogenicity is the critical effect of ethanol at high concentrations and long-term exposure. Short-time exposure to higher concentrations will result in transient cough, dry throat, tickling in the nose and development of irritations. An OEL (8-h TWA) and a short-term OEL have been derived.

Reference values to be used in Risk Characterisation

Permethrin

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
$AEL_{short-term}$	Rat 2 year oral (acute effect)	50 mg/kg bw/day	100		0.5 mg/kg bw/day
$AEL_{medium-term}$	12-month dog study	5 mg/kg bw/day	100		0.05 mg/kg bw/day
$AEL_{long-term}$	12-month dog study	5 mg/kg bw/day	100		0.05 mg/kg bw/day
ARfD[2]	-	-	-	-	-
ADI[2]	-	-	-	-	-

[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] Not applicable, no residues in food or feed occur

Pyriproxyfen

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
$AEL_{short-term}$	28-day rat	29 mg/kg bw/day	100	40% oral absorption	0.12 mg/kg bw/day
$AEL_{medium-term}$	1-year dog	10 mg/kg bw/day	100	40% oral absorption	0.04 mg/kg bw/day
$AEL_{long-term}$	1-year dog	10 mg/kg bw/day	100	40% oral absorption	0.04 mg/kg bw/day
ARfD[2]	-	-	-	-	-
ADI[2]	-	-	-	-	-

[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] Not applicable, no residues in food or feed occur

Propan-2-ol

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
$AEL_{short-term, medium-term, long-term}$ General population	Human volunteer study	200 ppm / 8 h	6.4[1]		10.7 mg/kg bw/day (31.25 ppm for 8 h/d)
$AEL_{short-term, medium-term, long-term}$ Professional workers	Human volunteer study	200 ppm / 8 h	3.8-[2]		17.9 mg/kg bw/day (52.6 ppm for 8 h/d)
ARfD[3]	-	-		-	-
ADI[3]	-	-	-	-	-

[1] With respect to intraspecies (human) variability, it is proposed to substitute the partial assessment factor for toxicokinetics of 3.2 by a chemical-specific assessment factor of 2 for the general population, yielding overall intraspecies assessment factor of 6.4 (3.2 x 2) for the general population.
[2] With respect to intraspecies (human) variability, it is proposed to substitute the partial assessment factor for toxicokinetics of 3.2 by a chemical-specific assessment factor of 1.2 for professional workers, yielding overall intraspecies assessment factor of 3.8 (3.2 x 1.2) for professional workers.
[3] Not necessary, no residues in food expected

Ethanol

Reference	Value	Remarks
Inhalation reference value	260 mg/m³, 1900 mg/m³	8-h TWA, 15-min STEL (2006/06OSH[1])
Inhalation reference value for the general public	260 mg/m³ 633 mg/m³	TWA 24 hour TWA 15 min* *Correcting the TWA of workers for differences between professional workers and the general population (safety factor 3) and the differences in the exposure duration.

[1] https://www.ser.nl/en/grenswaarden/ethanol.aspx

Maximum residue limits or equivalent

Permethrin is not approved under the PPP regulation, MRLs were set in Regulation (EC) No 396/2005 at the lower limit of analytical quantification. For pyriproxyfen MRLs were set in Regulation (EC) No 396/2005, a.o. for tomato, courgette, stone fruits, bananas and tea.

However, regarding the current application by aerosol spraying as an insecticide for non-professional use against fleas and ticks 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, product is only intended for non-professional use.

Risk for professional users
Not relevant, product is only intended for non-professional use.

Risk for non-professional users
Since non-professional users can be assumed to apply the product occasionally and only if required, the application regime for non-professional users resembles an acute exposure scenario and a comparison of the estimated primary exposure with the reference value for acute exposures (i.e. $AEL_{short\text{-}term}$) is justified. No reduction of dermal exposure by clothing is assumed. As a worst case assumption a comparison with the respective medium-/long-term AEL derived for permethrin and pyriproxyfen is made. For propan-2-ol one AEL for short- and long-term effects was derived.

Systemic effects

Permethrin (a.s.)

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Spray application/[1] (acute)	1	50	0.5	0.0028	0.6	yes
Spray application/[1] (long-term)	1	5	0.05	0.0028	5.6	yes

Pyriproxyfen (a.s.)

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Spray application/[1] (acute)	1	29	0.12	0.0097	8.1	yes
Spray application/[1] (long-term)	1	10	0.04	0.0097	24.3	yes

Propan-2-ol (SoC)

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Spray application/[1]	1	68.5	10.7	0.52	4.8	yes

Combined scenarios

This will be addressed later in the next section "Risk for the general public".

Local effects

The biocidal product is classified as Eye Irrit. 2; H319 according to CLP. Due to the eye irritating properties the biocidal product is located to the low hazard category according to the recommendations in Section 4.3.2.5 Table 25 of the Guidance for Human Health Risk Assessment Volume III, Part B Version 1.1 (April 2015). According to Section 4.3.2.5 paragraph ii of this guidance document one should assess the frequency and duration of exposure, the potential degree of exposure as well as relevant Risk Management Measures (RMMs) and Personal Protective Equipment (PPEs) to conclude that a risk is adequately controlled via the qualitative risk assessment.

The biocidal product is intended for spray application on pet bedding, carpets, under cushions, at the back of sofas, on rugs, upholstered furniture and in cracks and crevices against flea and ticks. The eye irritating property of the product is triggered by the co-formulant ethanol (>92%). Due to the high vapour pressure of ethanol significant exposure to the eyes is therefore limited to the very short duration of the application itself. The spray should not be applied directly onto humans, thus, direct contact with eyes is not foreseen. The hazard eye irritation and relevant instructions for use that minimise exposure or possible health effects (washing of the hands after handling and washing of eye after accidental exposure) are labelled.

On the basis of the above considerations it can be concluded that the risk is controlled by the qualitative RMMs.

For the assessment of potential local effects of ethanol via the inhalation route, concentration on day of exposure estimated with Consumer spraying and dusting model 2 (aerosol) and ConsExpo (evaporation) is compared with the inhalative reference value for the general public (time weight average for the general public).

Ethanol (SoC)

Task/ Scenario	Tier	Inhalation reference value mg/m³	air conc. TWA 24 hour mg/m³	air conc./ inhalation reference value (%)	Acceptable (yes/no)
Spray application/[1]	1	260	40.2	15	yes

The inhalation peak concentration is compared with the short-term reference value (15-min STEL).

Ethanol (SoC)

Task/ Scenario	Tier	Inhalation reference value mg/m³	peak conc. TWA 15 min mg/m³	peak conc./ inhalation reference value (%)	Acceptable (yes/no)
Spray application/[1]	1	633	513.8	81	yes

Conclusion

No adverse health effects are expected for the unprotected non-professional users due to the exposure to the active substances and SoCs as a result of the application of Entfloher, when it is used in accordance with the SPC.

Risk for the general public

The human exposure assessment considers secondary exposure of adults after re-entry of the treated room (Scenario 2). This could be by the same person who did the spraying in first place. So a combined exposure is considered for Scenarios 1 and 2. Furthermore, exposure of children is also assessed since treated rooms may also be re-entered by children.

The exposure of infants regarding indirect dermal and oral exposure by crawling treated surfaces is also considered as Scenario 3. For both scenarios the long-term AEL was used since the biocidal product is stated to have a long-term effect on the target organisms. Therefore, an exposure to the active ingredients can be assumed for 6 months.

A combined exposure of the infant via inhalation upon re-entry to the room (Scenario 2) and via dermal and oral routes by crawling on treated surfaces (Scenario 3) is also assessed.

Systemic effects

Permethrin (a.s.)

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Re-entry/[2]						
Adult	1	5	0.05	0.0011	2	yes
Child	1	5	0.05	0.0024	5	yes
Hand-mouth transfer/[3]	1	5	0.05	0.0039	8	yes

Pyriproxyfen (a.s.)

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Re-entry/[2]						
Adult	1	10	0.04	0.0046	12	yes
Child	1	10	0.04	0.01	25	yes
Hand-mouth transfer/[3]	1	10	0.04	0.008	20	yes

Propan-2-ol (SoC)

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Re-entry/[2]						
Adult	1	68.5	10.7	1.1	10.3	yes
Child	1	68.5	10.7	5.4	50.5	yes

Combined scenarios

Permethrin (a.s.)

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1, 2] adult	1	5	0.05	0.0039	8	yes
[2, 3] infant	1	5	0.05	0.011	23	yes

Pyriproxyfen (a.s.)

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1, 2] adult	1	10	0.04	0.0143	36	yes
[2, 3] infant	1	10	0.04	0.0185	46	yes

Propan-2-ol (SoC)

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1, 2] adult	not required, scenario 2 covers the worst case					

Local effects

Regarding eye irritating effect please refer to "risk for non-professional users".

For the assessment of potential local effects of ethanol via the inhalation route, concentration on day of exposure estimated with ConsExpo (evaporation) is compared with the inhalative reference value for the general public (time weight average for the general public).

Ethanol (SoC)

Task/ Scenario	Tier	Inhalation reference value mg/m³	air conc. TWA 24 hour mg/m³	air conc./ inhalation reference value (%)	Acceptable (yes/no)
Re-entry/[2]	1	260	41	15.8	Yes

The inhalation peak event concentration is compared with the short-term reference value (15-min STEL).

Ethanol (SoC)

Task/ Scenario	Tier	Inhalation reference value mg/m³	Peak conc. TWA 15 min mg/m³	air conc./ inhalation reference value	Acceptable (yes/no)

				(%)	
Spray application/[1]	1	633	550	89	yes

Conclusion
No adverse health effects are expected for the general public including infants due to the exposure to the active substances and SoCs as a result of the application of Enthloher, when it is used in accordance with the SPC.
ingroom

Risk for consumers via residues in food
Food, drinking water or livestock exposure to permethrin, pyriproxyfen, propan-2-ol and ethanol can be excluded when applied according to the recommended uses. 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
Within the process of risk assessment the possibility of combined effects shall also be taken into account. The risk assessment from combined exposure to multiple biocidal active substances within a single biocidal product was conducted according to Guidance on the BPR: Volume III, Part B, Risk Assessment (Oct 2015).

In the first step each substance was assessed in terms of risks to primary and secondary exposure (Tier 1, see above). Since there are no indications for potential synergistic effects induced by the a.s. permethrin and pyriproxyfen, the toxicological effects of the combined substance are considered to be additive (default). In a second step the Hazard Quotient (ratio of internal exposure and AEL) will be used to calculate a Hazard Index (HI) for the biocidal product. The HI is the sum of the Hazard Quotients for each substance (Tier 2). As worst case the long-term AELs are considered.
If HI ≤1 the risk related to use of the b.p. will be considered acceptable;
If HI >1 the risk related to use of the b.p. will be considered unacceptable and refinement is needed.

Combined Risk Assessment TIER 1 and TIER 2				
Exposure scenario	**Permethrin (a.s.)**	**Pyriproxyfen (a.s.)**		**Acceptable (yes/no)**
Primary exposure, Spray application [1]				
Adults, TIER 1	HQ = 0.056	HQ = 0.243		yes
TIER 2	HI = 0.299			yes
Secondary exposure, Re-entry [2]				
Adults, TIER 1	HQ = 0.022	HQ = 0.115		yes
TIER 2	HI = 0.137			yes

Children, TIER 1	HQ = 0.048	HQ = 0.25		yes
TIER 2	HI = 0.298			yes
Combined exposure, Primary and secondary exposure to adults [1, 2]				
Adults, TIER 1	HQ = 0.078	HQ = 0.358		yes
TIER 2	HI = 0.436			yes
Indirect dermal and oral exposure to infants [2, 3]				
Infants, TIER 1	HQ = 0.228	HQ = 0.462		yes
TIER 2	HI = 0.69			yes

In conclusion, risk assessment is acceptable for each substance individually in the biocidal product (Tier 1).
The risk from combined exposure to a.s. permethrin and pyriproxyfen is acceptable for all scenarios. Therefore, it is not necessary to perform a Tier 3, in which information from the CAR regarding the critical endpoints of each substance will be used to refine the risk assessment.

Risk assessment for animal health

Based on the data requirements laid down in the Biocidal Products Regulation (BPR), the safety of non-target animals after application of biocidal products has to be addressed as well. For this reason, the safety of permethrin, pyriproxyfen, propan-2-ol and ethanol for cats and dogs which reside on treated pet bedding (or carpets, upholstered furniture etc.) is being assessed.

Pets may be intermittently exposed towards residues of the biocidal product via animal bedding. For this reason, these exposure scenarios for the animals are considered as chronic scenarios as a worst-case and the NOAEL value for a chronic exposure duration was used to derive an orientating reference value for the animal safety assessment.

Permethrin:

Especially cats are known to be sensitive to permethrin toxicity. For permethrin, no acceptable exposure levels for other animal species have been derived. Only animal studies in rodents and dogs are available from which the respective NOAELs were derived. From the complete toxicological data package of permethrin, the NOAEL of 5 mg/kg bw/day as derived from a 12-month oral toxicity study in dogs has been identified to be the most relevant point of departure for the animal safety assessment. In accordance with the EFSA Guidance on "Risk Assessment for Birds and Mammals" (first published Dec. 2009), this NOAEL value is corrected by an inter-species assessment/safety factor of 5 since a margin of safety of 5 is considered sufficiently safe for long-term/chronic exposure of animals in this guidance. As a result, an **orientating reference value of 1 mg/kg bw/day** is derived for permethrin for

the purpose of the animal safety assessment which will be applicable to other animal species such as cats as well.

Pyriproxyfen:

Similarly, no acceptable exposure level for other animal species has been derived for pyriproxyfen. Only animal studies in rodents and dogs are available from which the respective NOAELs were derived. From the complete toxicological data package of pyriproxyfen, the NOAEL of 10 mg/kg bw/day as derived from a 52-week oral toxicity study in dogs has been identified to be the most relevant point of departure for the animal safety assessment. In accordance with the EFSA Guidance on "Risk Assessment for Birds and Mammals" (2009), this NOAEL value is corrected by an inter-species assessment/safety factor of 5 since a margin of safety of 5 is considered sufficiently safe for long-term/chronic exposure of animals in this guidance. Considering in addition an oral absorption value of 40%, an **orientating reference value of 0.8 mg/kg bw/day** is derived for pyriproxyfen for the purpose of the animal safety assessment which will be applicable to other animal species such as cats as well.

Propan-2-ol:

Similarly, no acceptable exposure level for other animal species has been derived for propan-2-ol. Only animal studies in rodents are available from which the respective NOAELs were derived. From the complete toxicological data package of propan-2-ol, the NOAEL of 286 mg/kg bw/day as derived from a subchronic inhalation study in rats has been identified to be the most relevant point of departure for the animal safety assessment. In accordance with the EFSA Guidance on "Risk Assessment for Birds and Mammals" (2009), this NOAEL value is corrected by an inter-species assessment/safety factor of 5 since a margin of safety of 5 is considered sufficiently safe for long-term/chronic exposure of animals in this guidance. As result, an **orientating reference value of 57.2 mg/kg bw/day** is derived for propan-2-ol for the purpose of the animal safety assessment which will be applicable to other animal species such as cats as well.
ppSince propan-2-ol has a high vapour pressure (5780 Pa) no dermal contact is assumed due to rapid evaporation.

Ethanol:

To derive an inhalation reference value for cats and dogs, the workplace exposure limit value of professionals/industrial users was corrected for differences in the respiratory rate between workers and pets and the differences in the exposure duration (i.e. 8 h versus 24 h). Cats and dogs have an inhalation rate of 1.2 m^3/day (0.05 m^3/h) and 4.3 m^3/day (0.18 m^3/h), respectively (Derelanko, MJ (2008), The Toxicologist's Pocket Handbook, Second Edition, Informa Healthcare USA, Inc.; Table 138). Thus, the time weighted average for cats and dogs should not exceed 2167 mg/m^3 and 602 mg/m^3, respectively.

Secondary Animal Safety assessment:

The biocidal product is not intended to be directly applied to non-target animals such as domestic animals.

Domestic animals are allowed to return into the treated rooms after 1 hour and access their bedding after a sufficiently long ventilation period and after the product has dried. Inhalation exposure of the active substances is not considered relevant for pets as permethrin and pyriproxyfen are not volatile and exhibit negligible vapour pressures (permethrin: 2.155 x 10^{-6} Pa at 20°C; pyriproxyfen: <1.33 x 10^{-5} Pa at 22.81°C). Exposure via the inhalation route is, therefore, unlikely to occur after ventilation of the rooms and has not been assessed for both active substances. Propan-2-ol and ethanol (SoCs) are volatile substances and therefore inhalative exposure was assessed.
Oral exposure from licking on the fur and/or bedding material which may be contaminated with residues of the active substances as well as dermal exposure through contact with treated surfaces such as the bedding material are taken into account. From the treated surfaces and objects it can be assumed that after dermal contact only a fraction of the applied material is available for exposure.
Therefore, the proportion of dislodgeable residues available for dermal uptake from treated surfaces is considered to be equivalent to 9% (transfer coefficient for dried fluids from carpets; please refer to rationale provided above). It is further assumed that the complete body surface of dogs/cats comes into contact with the treated pet bedding.
Oral and dermal uptake of propan-2-ol and ethanol is considered to be negligible due to rapid evaporation.

Dermal exposure

The secondary dermal exposure of cats and dogs through dermal contact with treated pet bedding and/or surfaces is calculated as follows:

E_{dermal} = AR × C × TC × BS × DA / BW

Application rate (AR):	0.247 mg product/cm²
Concentration (C):	Permethrin: 0.6% (w/w) Pyriproxyfen: 0.1% (w/w)
Transfer coefficient (TC):	9% (for dried fluids from carpets, acc. to TNsG 2007, p. 102)
Body surface area (BS):	Cat: 1380 cm² Dog: 5770 cm² (Derelanko, MJ (2008). The Toxicologist's Pocket Handbook, Second Edition, Informa Healthcare USA, Inc.; Table 27)
Dermal absorption (DA):	Permethrin: 75% (default) Pyriproxyfen: 75% (default)
Body weight of animal (BW):	Cat: 2 kg Dog: 12 kg (Derelanko, MJ (2008). The Toxicologist's Pocket Handbook, Second Edition, Informa Healthcare USA, Inc.; Table 27)

The secondary dermal exposure estimations for the respective animal species after application of the biocidal product Entfloher are presented in the following tables.

Secondary dermal exposure of <u>cats</u> towards permethrin and pyriproxyfen after application of the biocidal product Entfloher

Parameter	Definition	Permethrin	Pyriproxyfen
Application rate [mg/cm²]	AR	0.247	0.247
Concentration	C	0.006	0.001
Transfer coefficient	TC	0.09	0.09
Body surface [cm²]	BS	1380	1380
Dermal absorption	DA	0.75	0.75
Body weight [kg]	BW	2	2
Systemic dermal exposure [mg/kg bw/day]	E_{dermal} = AR × C × TC × BS × DA / BW	**0.069**	**0.012**

Secondary dermal exposure of <u>dogs</u> towards permethrin and pyriproxyfen after application of the biocidal product Entfloher

Parameter	Definition	Permethrin	Pyriproxyfen
Application rate [mg/cm²]	AR	0.247	0.247
Concentration	C	0.006	0.001
Transfer coefficient	TC	0.09	0.09
Body surface [cm²]	BS	5770	5770
Dermal absorption	DA	0.75	0.75
Body weight [kg]	BW	12	12
Systemic dermal exposure [mg/kg bw/day]	E_{dermal} = AR × C × TC × BS × DA / BW	**0.048**	**0.008**

<u>Oral exposure (licking)</u>

The secondary oral exposure of cats and dogs from licking on the fur is calculated in analogy to the DRAWG livestock draft guidance document. The tongue surface area and licking events were adapted. In accordance with HEAdhoc recommendation 5 for the oral uptake of dried paint proportions, the transfer coefficient of residues from fur and/or treated bedding to mouth was considered to be equivalent to 50%.
E_{oral} = AR × C × TS × LE × F_{ing} × OA / BW

Application rate (AR): 0.247 mg/cm²

Concentration (C):	Permethrin: 0.6% (w/w) Pyriproxyfen: 0.1% (w/w)
Tongue surface area (TS):	20 cm²
Assumed licking events per day (LE):	Cat: 30 Dog: 20
Fraction ingested (F_{ing}):	50% (HEAdhoc recommendation 5)
Oral absorption (OA):	Permethrin: 100% Pyriproxyfen: 40% (AR NL, 2012)
Body weight of animal (BW):	Cat: 2 kg Dog: 12 kg (Derelanko, MJ (2008). The Toxicologist's Pocket Handbook, Second Edition, Informa Healthcare USA, Inc.; Table 27)

The secondary oral exposure estimations for the respective animal species after application of the biocidal product Entfloher are presented in the following tables.

Secondary oral exposure of <u>cats</u> towards permethrin and pyriproxyfen after application of the biocidal product Entfloher

Parameter	Definition	Permethrin	Pyriproxyfen
Application rate [mg/cm²]	AR	0.247	0.247
Concentration	C	0.006	0.001
Tongue surface area [cm²]	TS	20	20
Licking events per day	LE	30	30
Fraction ingested	F_{ing}	0.5	0.5
Oral absorption	OA	1	0.4
Body weight [kg]	BW	2	2
Systemic oral exposure [mg/kg bw/day]	E_{oral} = AR × C × TS × LE × OA x F_{ing} / BW	**0.22**	**0.015**

Secondary oral exposure of <u>dogs</u> towards permethrin and pyriproxyfen after application of the biocidal product Entfloher

Parameter	Definition	Permethrin	Pyriproxyfen
Application rate [mg/cm²]	AR	0.247	0.247
Concentration	C	0.006	0.001
Tongue surface area [cm²]	TS	20	20

Licking events per day	LE	20	20
Fraction ingested	F_{ing}	0.5	0.5
Oral absorption	OA	1	0.4
Body weight [kg]	BW	12	12
Systemic oral exposure [mg/kg bw/day]	E_{oral} = AR × C × TS × LE × OA x F_{ing} / BW	**0.025**	**0.0017**

Combined secondary oral and dermal exposure of animals

A summary of the combined exposure estimations and the resulting animal health risk characterization is provided in the following tables.

Combined secondary oral and dermal exposure of cats towards permethrin and pyriproxyfen after application of the biocidal product Entfloher

Parameter	Definition	Permethrin	Pyriproxyfen
Systemic dermal exposure [mg/kg bw/day]	E_{dermal}	0.069	0.012
Systemic oral exposure [mg/kg bw/day]	E_{oral}	0.22	0.015
Combined systemic exposure [mg/kg bw/day]	$E_{total} = E_{dermal} + E_{oral}$	**0.289**	**0.027**
Orientating reference value for cats	RfD_{cat}	1	0.8
Hazard Quotient	E_{total} / RfD_{cat}	**0.289**	**0.034**
NOAEL [mg/kg bw/day]	NOAEL	5	4 (corrected for oral absorption)
Margin of exposure*	MoE = NOAEL / E_{total}	**17.3**	**148**

*Based on the EFSA guidance document on birds and mammals, a toxicity-exposure-ratio (TER) of ≥ 5 (= MOS) is sufficient for chronic/long-term exposure

Combined secondary oral and dermal exposure of dogs towards permethrin and pyriproxyfen after application of the biocidal product Entfloher

Parameter	Definition	Permethrin	Pyriproxyfen
Systemic dermal exposure [mg/kg bw/day]	E_{dermal}	0.048	0.008

Systemic oral exposure [mg/kg bw/day]	E_{oral}	0.025	0.0017
Combined systemic exposure [mg/kg bw/day]	$E_{total} = E_{dermal} + E_{oral}$	**0.073**	**0.010**
Reference value for dogs	RfD_{dog}	1	0.8
Hazard Quotient	E_{total} / RfD_{dog}	**0.073**	**0.012**
NOAEL [mg/kg bw/day]	NOAEL	5	4 (corrected for oral absorption)
Margin of exposure*	$MoE = NOAEL / E_{total}$	**68**	**400**

*Based on the EFSA guidance document on birds and mammals, a TER of ≥ 5 (= MOS) is sufficient for chronic/long-term exposure

Inhalation exposure

Inhalation exposure is only estimated for the SoCs propan-2-ol and ethanol. Due to their high vapour pressure, propan-2-ol and ethanol are present in vapour form in a treated room at the time of re-entry of domestic animals.

Regarding ethanol external concentration in air needs to be compared with the reference values. The long-term (480 min after application) average concentration of ethanol was already calculated using ConsExpo in Scenario 2 for the general public. The concentration was 41 mg/m^3. These values are used for the risk assessment for dogs and cats.

The exposure estimation for propan-2-ol is assessed in the same manner as for children or adults using the inhalation rates and body weights of cats and dogs using ConsExpo as described in the secondary exposure described above in Scenario 2.

ConsExpo report

Product

Der Entfloher

Compound

compound name	Propan-2-ol	
CAS number	67-63-0	
molecular weight	60.1	g/mol
vapour pressure	5.78E3	Pascal
KOW	0.05	10Log

General Exposure Data

exposure frequency	365	1/year
body weight (cats)	3	kilogram (1)
body weight (dogs)	12.7	kilogram (1)

Inhalation model: Exposure to vapour (evaporation)

weight fraction compound	4.95	%
exposure duration	480	minute
room volume	20	m^3
ventilation rate	0.6	1/hr
applied amount	12.5	gram
release area	5	m^2
application duration	7	minute
mol weight matrix	46	g/mol
mass transfer rate	4.82E3	m/min

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate (cats)	1.2	m^3/day (1)
inhalation rate (dogs)	4.3	m^3/day (1)

Output (cats)

Inhalation (point estimates)

inhalation mean event concentration:	6.33	mg/m^3
inhalation mean concentration on day of exposure:	2.11	mg/m^3
inhalation air concentration year average:	2.11	mg/m^3/day
inhalation acute (internal) dose:	0.844	mg/kg bw
inhalation chronic (internal) dose:	0.844	mg/kg bw/day

Integrated (point estimates)

total external dose:	0.844	mg/kg bw
total acute dose (internal):	0.844	mg/kg bw
total chronic dose (internal):	0.844	mg/kg bw/day

Output (dogs)

Inhalation (point estimates)

inhalation mean event concentration :	6.33	mg/m^3
inhalation mean concentration on day of exposure:	2.11	mg/m^3
inhalation air concentration year average :	2.11	mg/m^3/day
inhalation acute (internal) dose :	0.715	mg/kg bw
inhalation chronic (internal) dose :	0.714	mg/kg bw/day

Integrated (point estimates)

total external dose:	0.715	mg/kg bw
total acute dose (internal):	0.715	mg/kg bw
total chronic dose (internal):	0.714	mg/kg bw/day

(1) Derelanko, MJ (2008). The Toxicologist's Pocket Handbook, Second Edition, Informa Healthcare USA, Inc.; Table 22.39

This results in an inhalation exposure of 0.844 mg/kg bw/day propan-2-ol for cats and 0.714 mg/kg bw/day propan-2-ol for dogs.
e

Secondary inhalation exposure of <u>cats and dogs</u> towards propan-2-ol after application of the biocidal product Entfloher

Parameter	**Definition**	**Cat**	**Dog**
Systemic dermal exposure [mg/kg bw/day]	$E_{inhalation}$	0.844	0.714
Orientating reference value for propan-2-ol	RfD	57.2	57.2
Hazard Quotient	$E_{inhalation}$ / RfD_{cat}	**0.015**	**0.012**
NOAEL [mg/kg bw/day]	NOAEL	286	286
Margin of exposure*	MoE = NOAEL / $E_{inhalation}$	**339**	**401**

*Based on the EFSA guidance document on birds and mammals, a toxicity-exposure-ratio (TER) of ≥ 5 (= MOS) is sufficient for chronic/long-term exposure

Secondary inhalation exposure of <u>cats and dogs</u> towards ethanol after application of the biocidal product Entfloher

Parameter	**Definition**	**Cat**	**Dog**
Inhalation exposure concentration [mg/m³]	$C_{inhalation}$	41	41
Inhalation reference value for ethanol [mg/m³]	RfD	2167	602
Hazard Quotient	$C_{inhalation}$ / RfD	**0.019**	**0.068**

Conclusion:
The systemic inhalation exposure and the combined systemic secondary dermal and oral exposure of domestic animals (pets) following indoor treatment of surfaces with the biocidal product Entfloher has been demonstrated to be safe. All exposure estimates are below the conservatively derived orientating reference values of 1 mg/kg bw/day (permethrin), 0.8 mg/kg bw/day (pyriproxyfen), 57.2 mg/kg bw/day (propan-2-ol) and 2167/602 mg/m³ (ethanol cats/dogs). Furthermore, the margins of safety calculated for cats and dogs are sufficiently high as the a.s. and the SoC propan-2-ol have a toxicity-exposure-ratio (TER) of ≥ 5 (= MOS), which is considered sufficient for chronic/long-term exposure in according to the EFSA Guidance document on "Risk Assessment for Birds and Mammals".

<u>Risk assessment for the environment</u>

Entfloher is a ready-to-use pre-pressurised aerosol spray containing 0.6% w/w permethrin and 0.1% w/w pyriproxyfen as biocidal active substances (a.s.). It is used as an insecticide (Product type 18) for amateur use against German cockroaches, silverfish, ants, fleas, acarids (sheep ticks, house dust mites and poultry red mites) and woodlice. The biocidal product (b.p.) is only intended for indoor use.
An environmental risk assessment has been conducted for the Entfloher aerosol spray product with respect to Regulation (EU) No. 528/2012 (BPR), considering the Emission

Scenario Document for PT 18 (OECD, 2008)[2] and the Guidance on the Biocidal Products Regulation Volume IV Part[3].

The spray should be used in cracks and crevices or spot application. The application amount is 250 mL product/80 m^2, equivalent to 3.13 mL/m^2 product.

2.2.1.12 Effects assessment on the environment

The PNECs values for permethrin and pyriproxyfen, and their metabolites have been taken from the Assessment Reports[4] for the active substances when used for PT18 purposes. The PNECs are summarized in the following table:

Predicted No Effect Concentration used for the risk assessment

	$PNEC_{stp}$ (mg/L)	**$PNEC_{sw}$ (mg/L)**	**$PNEC_{sediment}$ (mg/kg wwt)**	**$PNEC_{soil}$ (mg/kg wwt)**	**$PNEC_{Oral\ bird}$ (mg/kg food)**	**$PNEC_{Oral\ mammal}$ (mg/kg food)**
Permethrin	4.95E-03	4.7E-07	2.17E-04	0.175*	16.7	120
DCVA	-	1.5E-02	1.2E-02	4.6	-	-
PBA	-	1.0E-02	9.0E-03	1.44	-	-
Pyriproxyfen	10	3.0E-06	1.4E-03	1.1E-03	19	6.7
4-OH-Pyriproxyfen	-	2.7E-04	1.5E-02		-	-
PYPAC	-	3.0E-02	-	-	-	-
DPH-Pyr	-	5.1E-03	-	-	-	-

* The IE (RMS for permethrin) evaluation of the permethrin confirmatory data was discussed at the BPC Meeting of March 2017. IE informed the CG members that an Env WG e-consultation was requested by BPC Members during the this BPC meeting, regarding the PNECsoil. The e-consultation was concluded on the 13th March. It was agreed that the conclusions of this e-consultation could be announced at CG-22 in the event of a clear majority opinion. The opinions received from MSs in the e-consultation provided a clear majority opinion in relation to the proposed PNECsoil.
The MSs were in favour of using an AF of 50 and deriving the PNECsoil for permethrin on the soil micro-organism study. The new PNECsoil is 0.198 mg/kg dwt, corresponding to 0.175 mg/kg wwt.

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

[2] OECD (2008): OECD Series on Emission Scenario Documents Number 18, Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses. ENV/JM/MONO(2008)14.

[3] http://echa.europa.eu/documents/10162/15623299/bpr_guidance_ra_vol_iv_part_b_en.pdf

[4] (EU 2014) Assessment Report Permethrin, Product type 18, April 2014
(EC 2012) Assessment Report Pyriproxifen, Product type 18, 21st September 2012

The b.p. contains < 1% (w/w) of the co-formulant 2,6 Di-Tert-Butyl-P-Cresol (BHT; CAS No.: 128-37-0), which is classified with H410. The b.p. is classified with H410 due to the a.s. permethrin (H410; M-factor: 10000; 0.6% (w/w)) and pyriproxyfen (H410; 0.1% (w/w)). No other components of the b.p. contribute to this classification.
The co-formulant BHT (CAS No.: 128-37-0) has a several magnitudes lower aquatic toxicity than permethrin and therefore, the environmental risks are expected to be solely driven by exposure to the a.s.

The content of ethanol in the product is 91-99% w/w and the approval status under the Biocidal Products Regulation (BPR; Regulation (EU) No 528/2012) is ''initial application for approval in progress''. Hence, this substance should be considered as substance of concern (SoC). The product also contains propan-2-ol (0.99-4.95% w/w), which is an approved active substance under BPR.
As the product is used indoors and both substances are very volatile and fast degradation is expected, exposure of the environment is considered to be low/negligible. Hence, a qualitative risk assessment for the SoCs ethanol and propan-2-ol is included in the PAR.

Further Ecotoxicological studies

Data waiving	
Information requirement	Further Ecotoxicological studies
Justification	No further ecotoxicity data are available for the biocidal product (b.p.). The toxicity of the active substances (a.s.) and the co-formulants is known and no synergistic effects are expected. Ecotoxicological properties and classification of the b.p. can be deduced from the respective properties of the a.s. and the co-formulants using the conventional method described in the guidance for classifying mixtures under Regulation (EC) No 1272/2008 (CLP). Permethrin is classified for the environment with Aquatic Acute 1 (H400), M-factor 100 and Aquatic Chronic 1 (H410), M-factor 10000. Pyriproxyfen is classified for the environment with Aquatic Acute 1 (H400), and Aquatic Chronic 1 (H410). The b.p. contains < 1% (w/w) of the co-formulant 2,6 Di-Tert-Butyl-P-Cresol (BHT; CAS No.: 128-37-0), which is classified with H410. Permethrin is also classified with H410 but the additional ingredients are only present at a lower concentration compared to the a.s., permethrin alone is driving the environmental classification of the b.p. as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410). The intended use of the biocidal product is indoor use by amateurs, the route of environmental exposure of the biocidal product is via STP to surface water (incl. sediment) and soil (incl. groundwater). For the active substances, data on sludge microorganisms, on acute and chronic toxicity to fish, invertebrates, algae as well as chronic studies with sediment dwelling organisms are available. For the terrestrial compartment, acute studies with earthworms and a nitrogen/carbon mineralization studies are available. Studies with terrestrial vertebrates and honeybees are also available. The BCF

	was also determined experimentally. The formulation type of the b.p. is not expected to change the mode of action of the active substances or their bioavailability. 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 b.p..

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

Data waiving	
Information requirement	Information on the risks to any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)
Justification	Please see justification under point *"Further Ecotoxicological studies"*.

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	Please see justification under point *"Further Ecotoxicological studies"*.

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 the acceptance by ingestion of the biocidal product by any non-target organisms is not need required
Justification	Please see justification under point *"Further Ecotoxicological studies"*.

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

The b.p. is a Product Type 18 intended to be used by amateurs. The mode of application is spraying for indoor use in private households. The b.p. as such will therefore not enter the environment directly but only via the STP route. Thus, non-target organisms are not directly exposed to the b.p. A large space application of the biocidal product to water body, wetland, forest or field is not intended and information on secondary ecological effects is therefore not required.

Endocrine disruption activity of non-active substances

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No

528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides (https://www.ctgb.nl/onderwerpen/hormoon-verstoorders).

No further ecotoxicological studies are available for Entfloher. The product was not tested for potential endocrine disruption properties. Entfloher contains the active substances permethrin and pyriproxyfen and various co-formulants (see confidential annex).

For permethrin and pyriproxyfen, no ED assessment is required because for active substances which have been approved, the EU assessment should be followed. As discussed in the Assessment Report for permethrin (April 2014), the acute and chronic exposure to permethrin show that this substance is highly toxic to the three groups of aquatic organisms, affecting reproduction and survival in fish and D*aphnia* (Daphnia was the most sensitive species in the acute and chronic tests). No studies including specific endocrine parameters are available, however, the available data do not indicate endocrine activity. According to the Assessment Report for pyriproxyfen (September 2012), pyriproxyfen is not included in the Commission Staff working document on implementation of the Community Strategy for Endocrine Disrupters – range of substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706)). However, the substance is included in "CA-March18-Doc.7.5.a-Final – Eds approved active substances" on the list of substances triggered by the Commission for an early review. The decision on an early review will be taken based on the outcome of the ED assessment for the renewal under PPP-legislation. CA NL considers that the ED assessment should await the outcome of the discussions at EU level.
For the co-formulants a screening was performed by consulting:

- ECHA data for identification of ED and PBT, under REACH or BPR or CLP
- Identified as ED by United States EPA (https://comptox.epa.gov/dashboard/)
- Identified as ED by the United Nations Environment (July 2017) Programme(http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y and https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)

Only the co-formulant 2,6-di-tert-butyl-p-cresol an alert for ED property was found. This co-formulant is included in the United Nations Environment Programme and this is the same co-formulant that raised a concern based on the available toxicological information (see Section 2.2.1.9). As discussed in Section 2.2.6.1, CA NL considers that the ED assessment should await the outcome of the discussions at EU level. If this co-formulant 2,6-di-tert-butyl-p-cresol is concluded to possess ED potency the authorisation granted for Entfloher concentrate needs to be re-evaluated.

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

The ESD for PT 18 on insecticides for household amateur use covers the following life-cycle steps as being potentially relevant for environmental emissions:

- Mixing/loading
The b.p. is a ready-to-use (RTU) product, therefore mixing and loading is not necessary. Exposure of environmental compartments during this life-cycle step is therefore not relevant.

- Application
The biocidal product is intended to be used indoors in private houses.

The application mode of the b.p. is considered a targeted application, i.e., either spot or crack and crevice application.

- Releases from indoor treated surfaces by cleaning
Since the aerosol spray is used in cracks and crevices the emissions to the environment may take place due to wet cleaning operations of accessible areas of the cracks and crevices.

In the household scenario, the route of the exposure of a.s. to the environment is via STP, which is the primary receiving compartment, to surface water, sediment, soil and groundwater (via sludge application).
Given the physical-chemical properties of the SoCs ethanol and propan-2-ol, emission to the sewage treatment plant (STP) and subsequently to surface water (incl. sediment) and soil (incl. groundwater) is regarded as negligible. However, the SoCs may enter the aquatic and terrestrial environment due to deposition of airborne product.

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

Data waiving	
Information requirement	Further studies on fate and behaviour in the environment are not required
Justification	Direct emissions of the biocidal product to the environmental compartments surface water (incl. sediment) and soil (incl. groundwater) are unlikely. The data on the active substance gives sufficient information regarding its fate and behaviour in the environment and there are no indications of risk due to specific properties of the biocidal product as it does not contain any substance of concern for the environment. The formulation type is not expected to change the mode of action of the active substances or their bioavailability. The fate of the b.p is covered by the data provided for the active substances.

Leaching behaviour (ADS)
Leaching is not relevant for the use of the biocidal product in PT 18.

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	Information on distribution and dissipation in soil is not required.
Justification	The data on the distribution and dissipation of the a.s. gives sufficient information and there are no indications of risk due to specific properties of the b.p.. Furthermore, the components of the biocidal product do not influence the distribution characteristics of the a.s.. The formulation types are not expected to change the model of action of the a.s or its bioavailability. Further testing for distribution and dissipation in the environment is therefore not deemed reasonable.

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

Data waiving	
Information requirement	Information on distribution and dissipation in water and sediment is not required.
Justification	The data on the distribution and dissipation of the a.s. gives sufficient information and there are no indications of risk due to specific properties of the b.p.. Furthermore, the components of the product do not influence the distribution characteristics of the a.s. Further testing 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 is not required
Justification	Volatilisation to the atmosphere following normal biocidal use of the b.p. is limited due to the very low vapour pressure of the active substances Permethrin: 2.16E-06 Pa at 20ºC Pyriproxyfen: <1.33E-05 Pa at 22.81ºC Accumulation in air does not occur due to the low air photolysis DT_{50}: Permethrin: 0.701 days (based on a 24-hour day and hydroxyl radical concentration of 5 x 10^5 radicals/cm^3) Pyriproxyfen: 0.307 days (0.701 days (based on a 24-hour day and hydroxyl radical concentration of 5 x 10^5 radicals/cm^3) Thus, accumulation and transport in air can be excluded and further testing is not deemed reasonable.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Data waiving	
Information requirement	It concerns indoor treatment. Therefore information on risks to aquatic organisms or plants under field conditions is not required.
Justification	The b.p. is only applied via spraying in closed facilities (private houses). No outdoor use is foreseen. An overspray study is therefore considered to be unnecessary.

Chronic aquatic toxicity

Data waiving	
Information requirement	Information on aquatic chronic toxicity is not required.
Justification	It concerns indoor treatment. Therefore no direct emissions of the b.p. to surface water occur. Moreover, chronic data on aquatic toxicity of the a.s. gives sufficient information about the ecotoxicity of the b.p. as there are no indications of risk due to specific properties of the biocidal product.

Data waiving	
Information requirement	Information on aquatic bioconcentration is not required.
Justification	It concerns indoor treatment. Therefore no direct emissions of the b.p. to surface water occur. Moreover, a bioconcentration study was conducted with the a.s. giving sufficient information about the bioconcentration potential of the b.p. as there are no indications of bioconcentration due to specific properties of the biocidal product.

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. is not intended to be used outside and there are is no potential for large scale formation of dust. Therefore, the risk to bees and non-target arthropods under field conditions has not further been assessed.

2.2.1.13 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	Pest control in private houses by non-professionals Scenario 1: control of pet fleas, mites and ticks by spraying Scenario 2: control of crawling insects by spraying
ESD(s) used	Emission Scenario Documents for Product Type 18: Emission Scenario Document for Insecticides, Acaricides and Products to Control Other Arthropods for Household and Professional use; July 2008[5]
Approach	Average consumption

5 http://echa.europa.eu/documents/10162/16908203/pt18_oecd_esd_household_professional_uses_en.pdf

Distribution in the environment	Calculated based on the ESDs for PT18 and on Guidance on the Biocidal Products Regulation, Volume IV Environment - Part B Risk Assessment (active substances), April 2015
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation: No Use: Yes Service life: No
Remarks	No remarks

Emission estimation

Input parameters for calculating the local emission				
Input		**Value**	**Unit**	**Remarks**
Scenario: control of pet fleas, mites and ticks by spraying				
Application rate of biocidal product		3.13	mL/m²	250 mL product (one spray can)/80 m^2
Concentration of active substance in the product	Permethrin	4.85	g/L	Corresponding to 0.6 % w/w and a relative product density of 0.808 at 20°C
	Pyriproxyfen	0.81		Corresponding to 0.1 % w/w and a relative product density of 0.808 at 20°C
Active substance concentration per treated m^2	Permethrin	15.2	mg/m^2	-
	Pyriproxyfen	2.54		

The route of exposure of permethrin and pyriproxyfen to the environment from pest control in private houses is via release from the facility drain to STP and subsequent compartments. The primary receiving compartment is the STP and subsequently exposed compartments are surface water, sediment, soil and groundwater (via sludge application) as well as biota.

Calculations for scenario 1: control of pet fleas, mites and ticks by spraying

The input parameters used for the environmental exposure assessment for the control of pet fleas, mites and ticks by spraying in private houses are shown in the following table. The following assumptions have been made:

- The number of applications per day per building ($N_{appl,building}$) is 1.
- The application mode of the b.p. is considered a targeted surface application as it is not expected that a relatively large surface like a floor will be treated. The fraction emitted to waste waters by the applicator during the cleaning step ($F_{applicator, ww}$) is equal to 1 as 100% of the applicators' clothing is 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 targeted surface treatment for RTU spray (F_{CE}) is 0.20

According to the label, a use of the products every six month can be anticipated.
Hence, according to the ESD for PT 18 (2008), the simultaneity factor is 0.002.

Scenario: control of pet fleas, mites and ticks by spraying	**Symbol**	**Unit**	**Active substance**	
			Permethrin	**Pyriproxyfen**
Application rate				
Treatment rate	Qprod	mg/m^2	3.13	
Fraction of a.i.	F_{AI}	--	0.00485	0.00081
Number of applications per day per building	Nappl,building	d-1	1	
Area treated (wet cleaning)	AREAtreat wet	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	6.07E-07	1.01E-07
Emission to applicator	**Eappl, applicator**	kg/d	6.07E-07	1.01E-07
Emission to the floor	**Eappl, floor**	kg/d	3.34E-06	5.58E-07
Emission to treated surface	**Eappl,treated**	kg/d	2.58E-05	4.31E-06
Cleaning				
Fraction ww from applicator	Fapplicator,ww	--	1	
Fraction ww during cleaning	Fww	--	1	
Cleaning efficiency	F_{CE}	--	0.20	
Emission from air to ww	**Eair, ww**	kg/d	negligible	
Emission from applicator to ww	**Eapplicator, ww**	kg/d	6.07E-07	1.01E-07
Emission from floor/treated surface to ww	**Etreated, ww**	kg/d	5.83E-06	9.74E-07
Summary				
Emissions to ww (E applicator ww + E treated surface ww)	**Elocal, ww**	kg/d	6.44E-06	1.07E-06
Simultaneity factor	Fsim	-	0.002	

Number of treated houses	Nhouses	-	4000	
Simultaneously treated houses			8	
Emissions to ww (Eapplicator ww + E treated surfaceww)	**Eww**	kg/d	5.15E-05	8.60E-06

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

1) $E_{application,air} = N_{appl,building} \times F_{application,air} \times Q_{prod} \times F_{AI} \times AREA_{treated}$
2) $E_{application,applicator} = N_{appl,building} \times F_{application,applicator} \times Q_{prod} \times F_{AI} \times AREA_{treated}$
3) $E_{application,floor} = N_{appl,building} \times F_{application,floor} \times Q_{prod} \times F_{AI} \times AREA_{treated}$
4) $E_{application,treated} = N_{appl,building} \times F_{application,treated} \times Q_{prod} \times F_{AI} \times AREA_{treated}$
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) $Elocal_{waste\ water,total} = (E_{applicator,ww} + E_{treated,ww}) \times N_{houses} \times F_{simultaneity}$

Resulting local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**		**Remarks**
	Permethrin	**Pyriproxyfen**	
STP	5.15E-05	8.60E-06	STP is the only directly exposed compartment

Calculations for Scenario 2: control of crawling insects by spraying

The input parameters used for the environmental exposure assessment for the control of crawling insects by spraying in private houses are shown in the following table. The following assumptions have been made:

- The number of applications per day per building ($N_{appl,building}$) is 1.
- The application mode of the b.p. is considered a targeted application. The ESD for PT18 (2008) gives a default size of treated surface of 2 m² 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 applicators' clothing 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 cracks and crevices treatment for RTU spray (F_{CE}) is 0.03

According to the label, a use of the products every six month can be anticipated. Hence, according to the ESD for PT 18 (2008), the simultaneity factor is 0.002.

Scenario: control of crawling insects by spraying	**Symbol**	**Unit**	**Active substance**	
			Permethrin	**Pyriproxyfen**
Application rate				
Treatment rate	Qprod	mg/m²	3.13	

Fraction of a.i.	F_{AI}	--	0.00485	0.00081
Number of applications per day per building	Nappl,building	d-1	1	
Area treated (wet cleaning)	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	6.07E-07	1.01E-07
Emission to applicator	**Eappl, applicator**	kg/d	6.07E-07	1.01E-07
Emission to the floor	**Eappl, floor**	kg/d	3.34E-06	5.58E-07
Emission to treated surface	**Eappl,treated**	kg/d	2.58E-05	4.31E-06
Cleaning				
Fraction ww from applicator	Fapplicator,ww	--	1	
Fraction ww during cleaning	Fww	--	1	
Cleaning efficiency	F_{CE}	--	0.03	
Emission from air to ww	**Eair, ww**	kg/d	negligible	
Emission from applicator to ww	**Eapplicator, ww**	kg/d	6.07E-07	1.01E-07
Emission from floor/treated surface to ww	**Etreated, ww**	kg/d	8.74E-07	1.46E-07
Summary				
Emissions to ww (E applicator ww + E treated surface ww)	**Elocal, ww**	kg/d	1.48E-06	2.47E-07
Simultaneity factor	Fsim	-	0.002	
Number of treated houses	Nhouses	-	4000	
Simultaneously treated houses			8	
Emissions to ww (Eapplicator ww + E treated surfaceww)	**Eww**	kg/d	1.19E-05	1.98E-06

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

8) $E_{application,air} = N_{appl,building} \times F_{application,air} \times Q_{prod} \times F_{AI} \times AREA_{treated}$

9) $E_{application,applicator} = N_{appl,building} \times F_{application,applicator} \times Q_{prod} \times F_{AI} \times AREA_{treated}$

10) $E_{application,floor} = N_{appl,building} \times F_{application,floor} \times Q_{prod} \times F_{AI} \times AREA_{treated}$

11) $E_{application,treated} = N_{appl,building} \times F_{application,treated} \times Q_{prod} \times F_{AI} \times AREA_{treated}$

12) $E_{applicator,ww} = E_{application,applicator} \times F_{applicator,ww}$

13) $E_{treated,ww} = (E_{application,floor} + E_{application,treated}) \times F_{ww} \times F_{CE}$

14) $Elocal_{waste\ water,total} = (E_{applicator,ww} + E_{treated,ww}) \times N_{houses} \times F_{simultaneity}$

Resulting local emission to relevant environmental compartments			
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**		**Remarks**
	Permethrin	**Pyriproxyfen**	
STP	1.19E-05	1.98E-06	STP is the only directly exposed compartment

Fate and distribution in exposed environmental compartments

In the following table, the compartments, which are exposed from the use of b.p in pest control in private houses, are given:

Identification of relevant receiving compartments based on the exposure pathway								
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP*	Air	Soil	Ground-water
Scenario 1: control of pet fleas, mites and ticks by spraying	Yes	Yes	No	No	Yes	n.a.	Yes	Yes
Scenario 2: control of crawling insects by spraying	Yes	Yes	No	No	Yes	n.a.	Yes	Yes

*Only STP is directly exposed. All other compartments are indirectly exposed

n.a.: not applicable as volatilisation to the atmosphere following normal biocidal use of the product is limited due to the very low vapour pressure (2.16E-06 Pa at 20°C for permethrin and < 1.33E-05 Pa at 22.81ºC for pyriproxyfen).

The following active substances specific parameter are taken directly from the Assessment Report for permethrin and pyriproxyfen and used in the environmental exposure calculations:

Input parameters (only set values) for calculating the fate and distribution in the environment

Parameter	Permethrin	Pyriproxyfen
Molecular mass	391.29 g/mol	321.37 g/mol
Melting point	35°C	48°C
Vapour pressure	2.16E-06 Pa (20°C; 25/75)	< 1.33E-05 Pa (22.81°C)
Henry constant	> 0.05 Pa m^3/mol	< 0.0423 Pa m^3/mol (20-23°C)
Water solubility	< 0.00495 mg/L (20°C)	0.101 mg/L (20°C, pH 7)
Log Pow	4.67±0.01 (25°C)	4.86 (25°C, pH 7)
Hydrolysis	Stable at relevant pH values	Stable at relevant pH values
Ready biodegradability	Non readily biodegradable	Non readily biodegradable
Degradation in soil	DT_{50} (12°C): geomean 106 d	DT_{50} (12°C): geomean 14.8 d
Koc	26930 L/kg	21175 L kg
BCF	15108 L/kg (wet earthworm) 570 L/kg (fish)	870 L/kg (calculated; wet earthworm) 1495 L/kg (fish)

Calculated fate and distribution in the STP			
Compartment	Percentage [%]		Remarks
	Permethrin	**Pyriproxyfen**	
Air	0.05	0.01	-
Water	27.6	31.6	-
Sludge	72.4	68.4	-
Degraded in STP	0	0	-

Metabolites

The CARs of both substances reveals metabolites being formed in the course of the degradation of the a.s. in surface water, sediment and soil.
Permethrin has two major metabolites 3-(2,2-dichorovinyl)-2,2-dimethylcyclopropane carboxylic acid (DCVA) and 3-phenoxybenzoic acid (PBA), which are relevant for the water (maximum observed levels 62.6% DCVA, 28.8% PBacid and 38.2% PBalcohol), sediment (maximum observed levels of 21.7% DCVA and 16.4% (PBacid, PBA)) and soil (maximum observed levels of DCVA 21.7% and 15% PBA).

Pyriproxyfen has three metabolites 4-OH'-pyriproxyfen, [((RS)-2-(2-pyridiloxy) propionic acid] (PYPAC) and DPH-Pyr relevant for water/sediment system (>10% AR) and for soil 4-OH-Pyr and PYPAC (5% AR at two consecutive time points).
The ecotoxicity of the metabolites of permethrin and pyriproxyfen is significantly lower compared to the a.s (see PNECs table above) and the potential adverse effects arising from the metabolites are covered by the risk assessment of the a.s. Therefore, these metabolites will not be addressed in the risk assessment.
In laboratory incubated soil, the maximum level of the main degradation products of permethrin, 4'-OH-pyriproxyfen and PYPAC, in any of the investigated soils was <10% AR. Therefore, these metabolites do not need to be assessed either.
The two major metabolites (DCVA and PBA) of permethrin are expected to be more mobile in soil with mean Koc for DCVA of 93.2 L/kg and for PBA of 141.2 L/kg, which may result

in leaching to the groundwater. Therefore, the risk for the groundwater is quantitatively assessed for the major metabolite DCVA (worst case DT_{50} soil [20°C]: 92.2 d) covering the significantly more rapidly degrading PBA (DT_{50} soil [20°C]: 1.3 d), see table below for the input parameters. The fraction of permethrin transformed into *trans*-DCVA was 0.113.

Parameter	Permethrin metabolites	
	DCVA	**PBA**
Molecular mass	209.1 g/mol	214.2 g/mol
Vapour pressure	0.26 Pa (20°C)	4.21E-04 Pa (20°C)
Water solubility	127.6 mg/L (20°C)	16.9 mg/L (20°C)
Degradation in soil	92.2 days (20°C)	1.3 days (20°C)
Koc	93.2 L/kg	141.2 L/kg

Calculated PEC values

Active substances specific parameters, the results of SimpleTreat modelling and default values as well as equations given in the Guidance on BPR IV/B+C (2017) were used to calculate PEC values in STP (Clocal $_{effluent,\ STP}$), surface water, sediment, soil, groundwater and biota. No PECs in air were calculated as exposure is considered negligible.

The results of the PECs are summarized in the following table:

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}[2]**	**PEC_{GW}[1]**
	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]
Scenario 1: control of pet fleas, mites and ticks by spraying					
Permethrin	7.10E-06	6.82E-07	4.00E-04	7.64E-05	1.46E-04
Pyriproxyfen	1.36E-06	1.32E-07	6.07E-05	1.10E-05	1.57E-05
DCVA	-	-	-	-	6.65E-05
Scenario 2: control of crawling insects by spraying					
Permethrin	1.64E-06	1.58E-07	9.24E-05	1.77E-05	3.37E-05
Pyriproxyfen	3.13E-07	3.03E-08	1.40E-05	2.52E-06	3.62E-06
DCVA	-	-	-	-	1.54E-05

[1] No simulation with e.g. one of the FOCUS models was conducted

[2] Concentration in top soils after ten successive sludge applications-initial concentration

Primary and secondary poisoning

Primary poisoning

Primary poisoning is not relevant for the foreseen use of Entfloher.

Secondary poisoning
According to the assessment report, permethrin and pyriproxyfen have the potential to bioaccumulate.

Permethrin
The potential to bioaccumulate is shown by the log Pow of 4.67 and bioconcentration factor of 500-570 L/kg from a 28-day bioconcentration study in bluegill fish, although the rapid depuration (50% in 4.7 days) indicates that any permethrin taken up by aquatic or terrestrial organisms will be rapidly eliminated once exposure ceases, which mitigates potential for biomagnification up the food chain.
A BCF fish of 570 L/kg and a BCF earthworm of 15108 L/kg_{wwt} was applied for permethrin in the assessment of secondary poisoning through the consumption of fish or earthworms by birds and mammals.

Pyriproxyfen
Pyriproxyfen has a log Pow of 4.86 and a BCF for fish of 1495 L/kg_{wwt} for radioactivity. An experimental BCF for earthworms exposed to pyriproxyfen is not available. The BCF earthworm of 870 L/kg_{wwt} is calculated according to formula 82d of the Guidance on BPR IV/B (2015).

The relevant secondary poisoning PECs required for the risk characterisation are shown in the table below:

Summary table on estimated $PEC_{oral\ predator}$		
	$PEC_{oral\ predator}$ Aquatic	$PEC_{oral\ predator}$ Terrestrial
	[mg/kg_{wwt}]	[mg/kg_{wwt}]
Scenario 1: control of pet fleas, mites and ticks by spraying		
Permethrin	1.94E-04	9.94E-04
Pyriproxyfen	9.87E-05	6.69E-06
Scenario 2: control of crawling insects by spraying		
Permethrin	4.50E-05	2.30E-04
Pyriproxyfen	2.26E-05	1.54E-06

2.2.1.14 Risk characterisation

Atmosphere

Volatilisation to the atmosphere following normal biocidal use of the product is limited due to the very low vapour pressure (2.16E-06 Pa at 20°C for permethrin and < 1.33E-05 Pa at 22.81ºC for pyriproxyfen). Accumulation in air does not occur due to the low air photolysis DT50 of 0.701 and 0.307 days (based on a 24-hour day and hydroxyl radical concentration of 5 x 10^5 radicals/cm^3) for permethrin and pyriproxyfen respectively. Accumulation and transport in air can be excluded and no exposure of the atmosphere is expected.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{STP}$
Scenario 1: control of pet fleas, mites and ticks by spraying	
Permethrin	0.001
Pyriproxyfen	< 0.001
Scenario 2: control of crawling insects by spraying	
Permethrin	< 0.001
Pyriproxyfen	< 0.001

Conclusion: the risk to the microorganisms in STPs is acceptable for the intended uses of the product. The PEC/PNEC ratios are below 1 for both scenarios.

Aquatic compartment

Summary table on calculated PEC/PNEC values		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
Scenario 1: control of pet fleas, mites and ticks by spraying		
Permethrin	**1.45**	**1.84**
Pyriproxyfen	0.044	0.043
Scenario 2: control of crawling insects by spraying		
Permethrin	0.336	0.426
Pyriproxyfen	0.010	0.010

Conclusion: For pyriproxyfen and permethrin, the PEC/PNEC values are below the trigger of 1 for the control of crawling insects by spraying (scenario 2).

However, for permethrin the PEC/PNEC values for water and sediment for the control of pet fleas, mites and ticks by spraying (scenario 1) are above 1. The risk to the aquatic compartment (surface water and sediment) is considered acceptable provided that the following risk mitigation measure is included in the label: '' Do not apply on wet washable surfaces or materials".

Terrestrial compartment

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Scenario 1: control of pet fleas, mites and ticks by spraying	
Permethrin	< 0.001
Pyriproxyfen	0.010
Scenario 2: control of crawling insects by spraying	
Permethrin	< 0.001
Pyriproxyfen	0.002

Conclusion: the risk to the terrestrial compartment is acceptable for the intended uses of the product. The PEC/PNEC ratios are below 1 for both scenarios.

Groundwater

Calculated PEC groundwater	
	PEC_{gw} [µg/L]
Scenario 1: control of pet fleas, mites and ticks by spraying	
Permethrin	1.46E-04
Pyriproxyfen	1.57E-05
DCVA	6.65E-05
Scenario 2: control of crawling insects by spraying	
Permethrin	3.37E-05
Pyriproxyfen	3.62E-06
DCVA	1.54E-05

Conclusion: There is no concern to groundwater from the use of Entfloher in accordance with label instructions as the concentrations in groundwater for permethrin, its major metabolite DCVA and pyriproxyfen are well below the drinking water limit of 0.1 µg/L for both scenarios.

Primary and secondary poisoning

Primary poisoning

Primary poisoning is not relevant for the foreseen use of Entfloher.
Secondary poisoning

Summary table on secondary poisoning			
		PEC/PNEC$_{birds}$	**PEC/PNEC$_{mammals}$**
Scenario 1: control of pet fleas, mites and ticks by spraying			
Permethrin	**Aquatic**	<0.001	<0.001
	Terrestrial	<0.001	<0.001
Pyriproxyfen	**Aquatic**	<0.001	<0.001
	Terrestrial	<0.001	<0.001
Scenario 2: control of crawling insects by spraying			
Permethrin	**Aquatic**	<0.001	<0.001
	Terrestrial	<0.001	<0.001
Pyriproxyfen	**Aquatic**	<0.001	<0.001
	Terrestrial	<0.001	<0.001

Conclusion: The PEC/PNEC ratios are far below 1 for both scenarios. The risk to birds and mammals is acceptable for the intended uses of the product.

SoCs ethanol and propan-2-ol
Criteria for the examination of environmental risks to air are not specified in the form of a numerical standard. The assessment of potential impacts on air quality is aimed to minimize the risk for stratospheric ozone depletion. There are no indications that ethanol and propan-2-ol contribute to depletion of the ozone layer as the compounds are not listed as 'controlled substance' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. The half-lives for ethanol and propan-2-ol are 4.3 and 3.1 days, respectively. These values are above the trigger value of 2 days, which is used as cut-off value to identify chemicals that could be of potential concern for long range transport through the atmosphere. However, as discussed in the draft CAR for ethanol (2013) and the Assessment Report for propan-2-ol (2015), a low to moderate contribution to tropospheric ozone creation is concluded for both active substances, especially considering the intended uses indoors only. Consequently, the environmental risk to air is considered acceptable.

As treated areas and objects are not rinsed (directly) after use of the product and SoC ethanol completely evaporates to the air, no emission to the sewer is expected. In addition, subsequent emissions to the STP and the aquatic compartment are also not expected. However, the SoC may enter the aquatic environment due to deposition of airborne product. Considering that the SoC is diluted in the air and moreover degraded quickly once deposited, concentrations above environmental risks limits are not expected and the accompanied risks are considered acceptable. Regarding the SoC propan-2-ol: due to the substance's reactive nature, this substance is likely to react with organic matter in the sewer, limiting its emission to the STP. This results in acceptable levels in the STP and consecutive compartments. The standards for the STP and aquatic environment are therefore met.

Deposition of airborne active substance on soils may occur. However, possible risks for terrestrial organisms are expected to be low as the SoCs are highly diluted in air, and quickly degraded once entering the soil compartment. Hence, the risk for soil organisms is considered acceptable.

Assessment of the drinking water criterion defines that the concentration of the active substances and the relevant metabolites in groundwater for the preparation of drinking water needs to be < 0.1 µg/L. Deposition of airborne SoC ethanol on soils may occur. However, considering that significant contamination of the soil compartment is not expected and the SoCs ethanol and propan-2-ol are quickly degraded, transport to groundwater is expected to be negligible. Hence, the risk for groundwater is considered acceptable for the intended uses.

The log K_{ow} values for SoCs ethanol and propan-2-ol are < 3 which indicates that indirect exposure of birds and mammals to these substances through consumption of aquatic or soil organisms is considered low.

Mixture toxicity

	Summary table on calculated PEC/PNEC values						
	PEC/ $PNEC_{STP}$	**PEC/ $PNEC_{water}$**	**PEC/ $PNEC_{sed}$**	**PEC/ $PNEC_{soil}$**	**PEC_{gw}**	**PEC/ $PNEC_{birds}$**	**PEC/ $PNEC_{mammals}$**
Scenario 1: control of pet fleas, mites and ticks by spraying							
Mixture	0.002	**1.49**	**1.88**	0.011	< 0.001	< 0.001	< 0.001
Scenario 2: control of crawling insects by spraying							
Mixture	0.002	0.346	0.436	0.003	< 0.001	< 0.001	< 0.001

Conclusion:
The PEC/PNEC values for STP, soil and birds and mammals are below the trigger value of 1. However, the PEC/PNECs ratios are above 1 in the mixture, in the aquatic compartments for the control of pet fleas, mites and ticks by spraying (scenario 1). The risk to the aquatic compartment (surface water and sediment) is considered acceptable provided that the following risk mitigation measure is included in the label: '' Do not apply on wet washable surfaces or materials".

Aggregated exposure (combined for relevant emmission sources)

Aggregated exposure is not relevant since the active substances are only used for PT 18 purposes.

The biocidal product is intended for the non-professional PT 18 use in private houses only. With this, the criteria as described in the UBA decision scheme for the estimation of an aggregated exposure do not apply. Consequently, an aggregated exposure is not required and was not conducted for Entfloher.

Overall conclusion on the risk assessment for the environment of the product
• The risk assessment for **sewage treatment plants** indicates a acceptable risk for the b.p applied for the control of pet fleas, mites and ticks and crawling insects by spraying.

- The risk assessment for **surface water and sediment** indicates **an unacceptable risk** for the b.p. applied for the control of pet fleas, mites and ticks by spraying. However this risk is considered acceptable provided that the following risk mitigation measure is included in the label: '' Do not apply on wet washable surfaces or materials".
- The risk for **surface water and sediment** is acceptable for the control of crawling insects by spraying.
- The risk assessment **for soil** indicates an acceptable risk for the b.p. applied for the control of pet fleas, mites and ticks and crawling insects by spraying.
- The risk for **groundwater** is acceptable.
- The risk of **primary and secondary poisoning** is acceptable.

Measures to protect man, animals and the environment

To protect man:
Avoid contact to eyes. 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, and drinks.. No smoking. Do not pierce or burn, even after use. Do not spray on an open flame or other ignition source.

To protect animals:

No direct use on animals

To protect the environment:
The application is restricted to indoors to cracks and crevices as well as in small areas where pets (dogs and cats), mainly remain, including pet bedding, carpets, or cushions.

Do not apply on wet washable surfaces or materials.

Assessment of a combination of biocidal products

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

Comparative assessment

Not relevant.

3 ANNEXES

LIST OF STUDIES FOR THE BIOCIDAL PRODUCT

Endpoint	Author	Year	Titel	Laboratory	Study No.	Data owner	Protection claimed
3.4.1 Storage stabilityaccelerated	[redacted]	2016	Determination of physico-chemical Properties and Storage Stability Tests for ConVet Umgebungsspray: 8 weeks at 40 °C and up to 36 months at 20 °C Amendement No. 1 to 8 weeks interim report (25 August 2016)	[redacted]	Mo5437	ConVet GmbH & Co. KG	yes
3.4.1 Storage stability, long term at ambient temperature	[redacted]	2019	Determination of physico-chemical Properties and Storage Stability Tests for ConVet Umgebungsspray: 8 weeks at 40 °C and up to 36 months at 20 °C	[redacted]	Mo5437	ConVet GmbH & Co. KG	yes
4.2 Flammability	[redacted]	2016	Flash Point A.9. of Convet Umgebungsspray	[redacted]	Mo5489	ConVet GmbH & Co. KG, Monheim, Germany	yes
4.17.1 Auto-ignition temperature (liquids and gases)	[redacted]	2016b	ConVet Umgebungsspray: Auto-Ignition Temperature (Liquids and Gases) A.15	[redacted]	Mo5462	ConVet GmbH & Co. KG, Monheim, Germany	yes
4.17.3 (Cf. 4.2) Dust explosion hazard	[redacted]	2016a	ConVet Umgebungsspray: Pyrophoric Properties (Liquids) A.13	[redacted]	Mo5462	ConVet GmbH & Co. KG, Monheim, Germany	yes
5 Methods of detection and identification	[redacted]	2016	Validation of Method: MV137-CVT: GC-Determination Permetrin and Pyriproxyfen in Umgebungsspray	[redacted]	Mo5436	ConVet GmbH & Co. KG	yes
6.7 Efficacy data	[redacted]	2016a	Residual efficacy of an aerosol product on treated surfaces against crawling arthropod species	[redacted]	Mo5387	ConVet GmbH & Co. KG	yes
6.7 Efficacy data	[redacted]	2016b	Residual efficacy of an aerosol product on carpet against Flea eggs and larvae	[redacted]	Mo5387	ConVet GmbH & Co. KG	yes
6.7 Efficacy data	[redacted]	2017	Simulated use test (choice-test) to determine the residual efficacy of an aerosol product on treated surfaces against crawling arthropod species	[redacted]	Mo5116	ConVet GmbH & Co. KG	yes
6.7 Efficacy data	[redacted]	2018	Residual efficacy of an aerosol product on treated surfaces against Brown dog tick	[redacted]	Mo6162	ConVet GmbH & Co. KG	yes

3.1 Output tables from exposure assessment tools

Scenario [1] Primary exposure – Spray application

Pre-pressurised aerosol spray can ***TNsG 2007, p. 63*** ***User Guidance version 1, 2002, p.33***	**Permethrin**	**Pyriproxyfen**	**Propan-2-ol**	**Ethanol**
Active substance % (w/w)	0.6	0.1	4.95	94.05
Potential leg, feet, face exposure				
Indicative value mg/min	45.2	45.2	45.2	NA*
Duration min	7	7	7	7
Potential dermal deposit mg	316.4	316.4	316.4	0
Clothing penetration %	10	100	100	100
Actual dermal deposit [product] mg	316.4	316.4	316.4	0
Potential hand and forearm exposure				
Indicative value mg/min	64.7	64.7	64.7	NA*
Duration min	7	7	7	7
Potential dermal deposit mg	452.9	452.9	452.9	0
Mitigation by gloves	1	1	1	1
Actual dermal deposit [product] mg	452.9	452.9	452.9	0
Total dermal exposure				
Total dermal deposit [product] mg	769.3	769.3	769.3	0
Total dermal deposit [a.s.] mg	4.62	0.77	38.08	0
Dermal absorption %	3	75	75	25
Systemic exposure via dermal route mg	0.1385	0.5770	28.56	0
Systemic exposure via dermal route mg/kg	0.0023	0.0096	0.4760	0
Exposure by inhalation				
Indicative value mg/m³	35.9	35.9	35.9	35.9**
Duration min	7	7	7	7
Inhalation rate m³/h	1.25	1.25	1.25	1.25
Mitigation by RPE (PF)	1	1	1	1
Inhaled [product] mg	5.24	5.24	5.24	5.24
Systemic exposure via inhalation route mg	0.0314	0.0052	0.259	4.924
Systemic exposure via inhalation route mg/kg	0.0005	0.0001	0.0043	0.0821
Systemic exposure				
Total systemic exposure a.s. mg	0.1699	0.5822	28.8194	4.924
Body weight kg	60	60	60	60
Systemic exposure mg/kg bw/day	**0.0028**	**0.0097**	**0.4803**	**0.0821**

* For ethanol, only a quantitative risk assessment for the inhalation route was conducted.
** During spraying the ethanol (94.05%) inhalation exposure concentration in air is 33.76 mg/m³. The exposure duration is 7 min and thus the 24-hour TWA for this task is 33.76 mg/m³ x 7/1440 min = **0.1641 mg/m³**

Scenario [1] Primary exposure - Evaporation of Propan-2-ol

ConsExpo Web 1.0.3

Report date: 12/4/2018

Product

Der Entfloher

Compound

compound name :	Propan-2-ol	
CAS number :	67-63-0	
molecular weight	60.1	g/mol
vapour pressure	5.78E3	Pascal
KOW	0.05	10Log

General Exposure Data

exposure frequency	12	1/year [worst case]
body weight	60	kilogram

Inhalation model: Exposure to vapour (evaporation)

weight fraction compound	4.95	%
exposure duration	480	minute [worst case]
room volume	20	m^3 [default non specified room, RIVM 2014 general fact sheet]
ventilation rate	0.6	1/hr [default non specified room, RIVM 2014, general fact sheet]
applied amount	12.5	gram [treatment of 5 m^2 with application rate of 2.47 g/m^2]
release area	5	m^2
application duration	7	minute
mol weight matrix	46	g/mol [Ethanol is the main co-formulant]
mass transfer rate	4.82E3	m/min [worst case, Langmuir's method]

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	1.25	m^3/hour [light exercise]

Output

Inhalation (point estimates)

inhalation mean event concentration:	6.3	mg/m^3
inhalation peak concentration (TWA 15min):	25	mg/m^3
inhalation mean concentration on day of exposure:	2.1	mg/m^3
inhalation air concentration year average:	0.069	mg/m^3/day

Integrated (point estimates)

Internal event dose:	1.0	mg/kg bw
Internal dose on day of exposure (internal):	1.0	mg/kg bw
Internal year average dose:	0.035	mg/kg bw/day

Scenario [1] Primary exposure - Evaporation of Ethanol

ConsExpo Web 1.0.3

Report date: 12/04/2018

Product

Der Entfloher

Compound

compound name :	Ethanol	
CAS number :	64-17-5	
molecular weight	46.1	g/mol
vapour pressure	7.87E3	Pascal
KOW	-0.35	10Log

General Exposure Data

exposure frequency	12	1/year [worst case]
body weight	60	kilogram

Inhalation model: Exposure to vapour (evaporation)

weight fraction compound	94.1	%
exposure duration	480	minute [worst case]
room volume	20	m^3 [default non specified room, RIVM 2014 general fact sheet]
ventilation rate	0.6	1/hr [default non specified room, RIVM 2014, general fact sheet]
applied amount	12.5	gram [treatment of 5 m^2 with application rate of 2.47 g/m^2]
release area	5	m^2
application duration	7	minute
mol weight matrix	72.2	g/mol [calculated]
mass transfer rate	5.5E3	m/min [worst case, Langmuir's method]

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	1.25	m^3/h

Output

Inhalation (point estimates)

inhalation mean event concentration:	120	mg/m^3
inhalation peak concentration (TWA 15 min)	480	mg/m^3
inhalation mean concentration on day of exposure:	40	mg/m^3
inhalation air concentration year average:	1.3	mg/m^3/day

Scenario [2] Secondary exposure – Dermal contact with treated surface areas (adults)

Paramter	Definition	Value Permethrin	Value Pyriproxyfen
Surface area [cm^2]	SA	8300	8300

Application rate [mg/cm²]	AR	0.247	0.247
Concentration	C	0.006	0.001
Transfer efficiency	TE	0.18	0.18
Dermal absorption	DA	0.03	0.75
Body weight [kg]	BW	60	60
Dermal exposure [mg/kg bw/day]	$E_{(dermal)}$ = SA x AR x C x TE × DA / BW	**0.0011**	**0.0046**

Scenario [2] Secondary exposure – Dermal contact with treated surface areas (infants)

Paramter	Definition	Value Permethrin	Value Pyriproxyfen
Surface area [cm²]	SA	2400	2400
Application rate [mg/cm²]	AR	0.247	0.247
Concentration	C	0.006	0.001
Transfer efficiency	TE	0.18	0.18
Dermal absorption	DA	0.03	0.75
Body weight [kg]	BW	8	8
Dermal exposure [mg/kg bw/day]	$E_{(dermal)}$ = SA x AR x C x TE × DA / BW	**0.002**	**0.01**

Scenario [2] Secondary exposure –Exposure to vapours

ConsExpo Web 1.0.3 report

Report date: 12/04/2018

Product

Der Entfloher

Compound

compound name:	Propan-2-ol	
CAS number	67-63-0	
molecular weight	60.1	g/mol
vapour pressure	5.78E3	Pascal
KOW	0.05	10Log

General Exposure Data

exposure frequency	365	1/year [worst case assumption]
body weight (adult)	60	kilogram
body weight (infant)	8	kilogram

Inhalation model: Exposure to vapour (instantaneous release)

weight fraction compound	4.95	%
exposure duration	480	minute [worst case assumption]
room volume	20	m^3 [default for unspecified room, RIVM 2014 general fact sheet]
ventilation rate	0.6	1/hr [default for unspecified room, RIVM 2014, general fact sheet]
applied amount	12.5	gram [treatment of 5 m^2 with application rate of 2.47 g/m^2]

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate (adult)	1.25	m^3/h
inhalation rate (toddler)	0.84	m^3/h

Output (Adult/Toddler)

Inhalation (point estimates)

inhalation mean event concentration:	6.4	mg/m^3
inhalation peak concentration (TWA 15 min)	25	mg/m^3inhalation mean
concentration on day of exposure:	2.1	mg/m^3
inhalation air concentration year average:	2.1	mg/m^3/day

Integrated (point estimates)

Internal event dose:	1.1 / 5.4	mg/kg bw
Internal dose on day of exposure (internal):	1.1 / 5.4	mg/kg bw
internal year average dose (internal):	1.1 / 5.4	mg/kg bw/day

Scenario [2] Secondary exposure –Exposure to vapours

ConsExpo Web 1.0.3 report

Report date: 12/04/2018

Product

Der Entfloher

Compound

compound name:	Ethanol	
CAS number	64-17-5	
molecular weight	46.1	g/mol
vapour pressure	7.87E3	Pascal
KOW	-0.35	10Log

General Exposure Data

exposure frequency	365	1/year [worst case assumption]

Inhalation model: Exposure to vapour (instantaneous release)

weight fraction compound	94.1	%
exposure duration	480	minute [worst case assumption]
room volume	20	m^3 [default for unspecified room, RIVM 2014 general fact sheet]
ventilation rate	0.6	1/hr [default for unspecified room, RIVM 2014, general fact sheet]
applied amount	12.5	gram [treatment of 5 m^2 with application rate of 2.47 g/m^2]

Output (Adult/infant)

Inhalation (point estimates)

inhalation mean event concentration:	120	mg/m^3
inhalation peak concentration (TWA 15 min)	550	mg/m^3
inhalation mean concentration on day of exposure:	41	mg/m^3
inhalation air concentration year average:	1.3	mg/m^3/day

Scenario [3] Secondary exposure - Dermal and oral contact with treated surface areas (infant, Hand-to-mouth transfer)

Parameter	**Definition**	**Value Permethrin**	**Value Pyriproxyfen**
Application rate [mg/cm²]	AR	0.00148	0.000247
Dislogable fraction	$F_{(disl)}$	0.18	0.18
Transfer conefficient [cm²/h]	Tc	2100	2100
Contact time [h/day]	t	1	1
External dose [mg a.s. or SoC]	$D = AR \times F_{(disl)} \times Tc \times t$	0.28	0.05
Dermal absorption	DA	0.03	0.75
Body weight [kg]	BW	8	8
Systemic dermal exposure [mg/kg bw/day]	$E_{(dermal)} = D \times DA / BW$	0.002	0.008
Fraction ingested	$F_{(ing)}$	0.1	0.1
Oral absorption	OA	1	0.4
Systemic oral exposure [mg/kg bw/day]	$E_{(oral)} = D \times F_{(ing)} \times OA / BW$	0.007	0.00045
Total systemic exposure [mg/kg bw/day]	$E_{(total)} = E_{(dermal)} + E_{(oral)}$	**0.009**	**0.008**

3.2 New information on the active substance

Not applicable.

3.3 Residue behaviour

Not applicable.

3.4 Summaries of the efficacy studies

For summaries of the efficacy studies please refer to the table shown above in Chapter 2.2.1.5.

3.5 Other

Not applicable.