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

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

(submitted by the evaluating Competent Authority)

INSECTICIDES FOR HOME USE

Product type 18

S-Methoprene

Permethrin

Case Number in R4BP: BC-TW023858-93

Evaluating Competent Authority: FR

Date: 05 July 2019

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1 CONCLUSION

The outcome of the assessment of the 'BPF Insecticides for Home Use' is specified in the BPC opinion following discussions at the BPC-31 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product family

Identifier[1]	**Country (if relevant)**
Insecticides for home use	European Union

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Agrobiothers Laboratoire
	Address	ZI Les Platières 71290 Cuisery France
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Agrobiothers
Address of manufacturer	ZI Les Platières 71290 Cuisery France
Location of manufacturing sites	AF3 16 rue de l'Oberwald 68360 Soultz France

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

Active substance	Permethrin
Name of manufacturer	Tagros Chemicals india Ltd. (Art.95 List: LIMARU NV (Acting for Tagros Chemicals India Private Limited)
Address of manufacturer	Jhaver Centre, Rajah Annamalai Bldg., IV floor 72 Marshal's road Egmore600008 Chennai, India
Location of manufacturing sites	A-4/1&2, Sipcot Industrial Complex, Pachayankuppam Cuddalore 607 005 Tamilnadu India

Active substance	S-Methoprene
Name of manufacturer	Babolna bio Ltd.
Address of manufacturer	Szallas u.6 H- 1107 Budapest Hungary
Location of manufacturing sites	Szallas u.6 H- 1107 Budapest Hungary

Origins of active substances are recognized for PT18 at EU level.

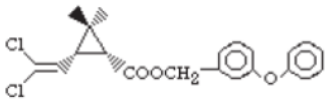
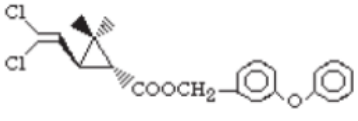
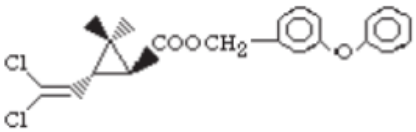
2.1.2 Product family composition and formulation

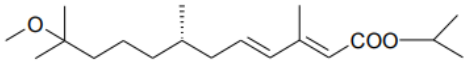
NB: the full composition of the product according to Annex III Title 1 is provided in the confidential annex.

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Permethrin
IUPAC or EC name	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2- dimethylcyclo-propanecarboxylate
EC number	258-067-9
CAS number	52645-53-1
Index number in Annex VI of CLP	/
Minimum purity / content	Permethrin has four stereoisomers: 1Rcis, 1Scis, 1Rtrans, and 1Strans. Two pairs of diastereomers (each consisting of a non racemic pair of enantiomers) are present in a ratio of ca. 25:75 Specification ≥93.0% w/w sum of all isomers
Structural formula	$C_{21}H_{20}Cl_2O_3$ 1Rcis isomer – 5-10% w/w  1Scis isomer – 15 – 20% w/w  1Rtrans isomer – 45 – 55% w/w  1Strans isomer – 17 – 27% w/w 

Main constituent(s)	
ISO name	S-Methoprene
IUPAC or EC name	Isopropyl-(2E,4E, 7S)-11-methoxy-3,7,11-trimethyl-2,4- dodecadienoate
EC number	Not Available
CAS number	65733-16-6
Index number in Annex VI of CLP	/
Minimum purity / content	Specification 95% w/w, minimum content 0.165%
Structural formula	$C_{19}H_{34}O_3$ 

2.1.2.2 Candidate(s) for substitution

Not applicable.

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Permethrin	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclo-propanecarboxylate	Active substance	52645-53-1	258-067-9	0.177	0.177
S-Methoprene	Isopropyl-(2E,4E, 7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate	Active substance	65733-16-6	613-834-0	0.00225	0.00225
Propan-2-ol *	Propan-2-ol	Non-active substance	67-63-0	200-661-7	3.33475	3.33475
Mixture of** n-butane (max 78%) propane (max 20%) isobutane (max 5%)	Mixture of *n-butane (max 78%)* *propane (max 20%)* *isobutane (max 5%)*	Non-active substance	*106-97-8* *74-98-6* *75-28-5*	*203-448-7* *200-827-9* *200-857-2*	*63.458* *16.271* *4.068*	*63.458* *16.271* *4.068*

Note: following the assessment, only product of meta SPC 1 is accepted. Consequently, the family is composed of one product.

(content including isopropanol from Technical S-methoprene premix)*

*(**For SoC, maximum content according to SDS have been used for the classification in the biocidal product. However, please note that for mixture of propellant (n-butane, propane and isobutane, the maximum content of each compound is a worst case since they cannot be found at the max content at the same time (the sum of the max contents would be higher than the one of the formulant which is not possible))*

2.1.2.4 Information on technical equivalence

Not applicable.

2.1.2.5 Information on the substance(s) of concern

Please see the confidential annex for further details.

The two products of the BPF INSECTICIDES FOR HOME USE contain biocidal active substances acting as solvent:

- Propan-2-ol;
- Another substance 1;
- Another substance 2.

Propan-2-ol was reviewed at the European level under BPR Regulation. Agreed reference values are available and the content in Propan-2-ol in the products is superior to 0.1%. Therefore, this substance is considered substance of concern in both products for human health. According to guidance on the BPR volume III part B + C, a fully quantitative risk assessment using EU reference values should be performed. Concerning the environment, propan-2-ol is a non-classified substance for the environmental organisms and presents PNEC values higher compared to the two active substances. Therefore, propan-2-ol is not considered as a SoC for the environment.

The other substances are under the BPR review program but no agreed reference value is available. Therefore, according to guidance on the BPR volume III and IV part B + C, these substances are not considered as SOC.

The products of the family INSECTICIDES FOR HOME USE contains mixture of propellant (n-butane, propane and isobutane) at 81.356 – 91.375%. This formulant is classified Flam. Gas 1 H220 according to the FDS. Therefore, a classification Aerosol Cat. 1 for the product family is needed. Mixture of propellant (n-butane, propane and isobutane) is considered as a substance of concern for analytical Methods and Physico-chemical Properties section.

Moreover, the product FOGGER INSECTICIDE FOR HOUSEHOLDS (meta SPC 2) contains nitromethane at 1.6% in the mixture without the propellant gaz. This formulant is classified Carc. 2 H351 according to the FDS. Therefore, a classification Carc. 2 H351 for the product FOGGER INSECTICIDE FOR HOUSEHOLDS is needed. Nitromethane is considered as a substance of concern for human heath.

2.1.2.6 Assessment of endocrine disruption (ED) properties of the biocidal products

According to our assessment, none of the formulants contained in the products of the BPF INSECTICIDES FOR HOME USE are identified as endocrine disruptors.

However, there are indications that one co-formulant shows some effect on endocrine organs. Base on available information, it is not possible to conclude whether this co-formulant should be considered to have ED properties or not. This should be further assessed in the frame of REACH Regulation. In case this co-formulant is finally identified as ED, the biocidal product will be considered as ED and the authorisation of the family products will have to be revised accordingly.

2.1.2.7 Type of formulation

AE - Aerosol dispenser

2.1.3 Meta SPC-1 administrative information

2.1.3.1 Meta SPC-1 identifier

Identifier	INSECTICIDE HOUSEHOLD SPRAY

2.1.3.2 1.2. Suffix to the authorisation number

Number 1	

2.1.3.3 1.3. Product type(s)

Product type(s)	18

2.1.4 Meta SPC 1 composition

2.1.4.1 Qualitative and quantitative information on the composition of the meta SPC 1

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**	
					Min	**Max**
Permethrin	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclo-propanecarboxylate	Active substance	52645-53-1	258-067-9	0.177	0.177
S-Methoprene	Isopropyl-(2E,4E, 7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate	Active substance	65733-16-6	613-834-0	0.00225	0.00225
Propan-2-ol*	Propan-2-ol	Non-active substance	67-63-0	200-661-7	3.33475	3.33475
Mixture of** n-butane (max 78%) propane (max 20%) isobutane (max 5%)	Mixture of *n-butane (max 78%)* *propane (max 20%)* *isobutane (max 5%)*	Non-active substance	*106-97-8* *74-98-6* *75-28-5*	*203-448-7* *200-827-9* *200-857-2*	*63.458* *16.271* *4.068*	*63.458* *16.271* *4.068*

(content including isopropanol from Technical S-methoprene premix)*

*(**For SoC, maximum content according to SDS have been used for the classification in the biocidal product. However, for mixture of propellant (n-butane, propane and isobutane), please note that the maximum content*

of each compound is a worst case since they cannot be found at the max content at the same time (the sum of the max contents would be higher than the one of the formulant which is not possible))

2.1.4.2 2.2. Type(s) of formulation of the meta SPC 1

Formulation	AE - Aerosol dispenser

2.1.5 Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1

Classification	
Hazard category	Aerosol Cat 1 Asp. cat 1 Eye Irrit 2 Aquatic Acute Cat 1; Aquatic Chronic Cat 1
Hazard statement	H222 Extremely flammable aerosol. H229 Pressurised container: May burst if heated. Category 1 H304 May be fatal if swallowed and enters airways H400 : Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects H319: Causes serious eye irritation.
Labelling	
Signal words	Danger
Pictogram	
Hazard statements	H222 Extremely flammable aerosol. H229 Pressurised container: May burst if heated. H304 May be fatal if swallowed and enters airways H319: Causes serious eye irritation. H410: Very toxic to aquatic life with long lasting effects
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P103: Read label before use. P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P211 Do not spray on an open flame or other ignition source. P251 Do not pierce or burn, even after use. P264: Wash … 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. P410 + P412 Protect from sunlight. Do no expose to temperatures exceeding 50 °C/122°F. P411: store at temperature not exceeding 40°C. P273:Avoid release to the Environment P391:Collect spillage P501: Dispose of contents/container to hazardous waste

Classification	
Note	EUH 208: Contains PERMETHRIN. May produce an allergic reaction.

2.1.6 Authorised use(s) of the meta SPC 1

2.1.6.1 Use description

Table 1. Use # 1 –Insecticide household spray

Product Type	PT18 – insecticide, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	-
Target organism (including development stage)	Fleas (larvae and adults): *e.g. Ctenocephalides felis* Ticks : *Ixodes ricinus* and *Rhipicephalus sanguineus*
Field of use	Indoor application Targeted treatment of non-washable furniture and home textile as carpets, mats, arm chairs
Application method(s)	After vacuuming the surface to be treated, the product is sprayed at a distance of 30 cm.
Application rate(s) and frequency	1.3 second spray treat for approximately 1 m² (2.1 g/m²) The minimum time interval between two treatments is 6 months.
Category(ies) of users	Non-professional users
Pack sizes and packaging material	Tin plate aerosol can with internal coating made of epoxy phenolic protective lacquer (250 or 500mL) Tin plate aerosol can without internal coating (300 mL)

2.1.6.2 Use-specific instructions for use

See general direction for use

2.1.6.3 Use-specific risk mitigation measures

See general direction for use

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

See general direction for use

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

See general direction for use

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

See general direction for use

2.1.7 General directions for use of the meta SPC 1

2.1.7.1 Instructions for use

- The product is to be used for targeted treatment of non-washable furniture and home textile as carpets, mats, arm chairs.
- Always read the label or leaflet before use and respect all the instructions provided.
- Respect the recommended application doses.
- Residual efficacy up to 6 months that can be lowered in case of normal cleaning (e.g. vacuum on carpets) or extensive use of the surfaces (e.g., walking, friction…).
- In case of continuous infestation, to avoid the occurance of resistance, alternate products containing active substances with a different mode of action, (to remove resistant individuals from the population).
- If the infestation persists despite following the instructions of the label/leaflet, contact a pest control professional.
- Inform the authorization holder if the treatment is ineffective.

2.1.7.2 Risk mitigation measures

- Do not use on wet washable surfaces and textile.
- Do not wash up furniture's with wet wiping clothes and do not wet clean carpets or mats to avoid discharges into the sewer system.
- Remove all food, feed and drinks prior treatment.
- Do no use on surfaces and facilities in vicinity or likely to be in contact with food, feed and drinks.
- Avoid contact to eyes.
- After spraying, leave the room and let act one hour before airing.
- Remove or cover terrariums, aquariums and animal cages before application.
- Turn off aquarium air-filter while spraying.
- *Keep cats away from treated surfaces due to high sensitivity to permethrin toxicity*.
- Keep children and pets away during treatment.

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

- Inhalation: Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
- Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
- Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with water. Contact poison treatment specialist if symptoms occur.
- Mouth contact: Wash out mouth with water. Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities.
- Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.
- Keep the container or label available.

- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

2.1.7.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations

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

- Shelf life: 24 months
- Do not store at a temperature higher than 40°C
- Do not expose to direct sunlight
- Protect from frost

2.1.8 6. Other information

- Establish a baseline and monitor levels of effectiveness on populations in key areas (at least one survey per year) in order to detect any significant changes in susceptibility to active substances.
- The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).

2.1.9 Meta SPC 1 composition: trade names, authorisation number and specific composition of each individual product

Trade name(s)	- FRONTLINE PET CARE SPRAY INSECTICIDE ET ACARICIDE POUR L'HABITAT - SPRAY ANTIPARASITAIRE POUR L'HABITAT 300 ML FRISKIES - INSECTICIDE HABITAT/ HOME VETOCANIS - FRONTLINE HOMEGARD SPRAY INSECTICIDE ET ACARICIDE POUR L'HABITAT - INSECTICIDE HABITAT/ HOME VITALVETO - SPRAY INSECTICIDE POUR L'HABITAT VITALVETO / INSECTICIDE HOUSEHOLD - SPRAY VITALVETO - SPRAY INSECTICIDE POUR L'HABITAT VETOCANIS / INSECTICIDE HOUSEHOLD - SPRAY VETOCANIS				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
Permethrin	3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-	Active substance	52645-53-1	258-067-9	0.177

Trade name(s)	- FRONTLINE PET CARE SPRAY INSECTICIDE ET ACARICIDE POUR L'HABITAT - SPRAY ANTIPARASITAIRE POUR L'HABITAT 300 ML FRISKIES - INSECTICIDE HABITAT/ HOME VETOCANIS - FRONTLINE HOMEGARD SPRAY INSECTICIDE ET ACARICIDE POUR L'HABITAT - INSECTICIDE HABITAT/ HOME VITALVETO - SPRAY INSECTICIDE POUR L'HABITAT VITALVETO / INSECTICIDE HOUSEHOLD - SPRAY VITALVETO - SPRAY INSECTICIDE POUR L'HABITAT VETOCANIS / INSECTICIDE HOUSEHOLD - SPRAY VETOCANIS				
Authorisation number					
Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (%)**
	(2,2-dichlorovinyl)-2,2-dimethylcyclo-propanecarboxylate				
S-Methoprene	Isopropyl-(2E,4E, 7S)-11-methoxy-3,7,11-trimethyl-2,4-dodecadienoate	Active substance	65733-16-6	613-834-0	0.00225
Propan-2-ol*	Propan-2-ol	Non-active substance	67-63-0	200-661-7	3.33475
Mixture of** n-butane (max 78%) propane (max 20%) isobutane (max 5%)	Mixture of *n-butane (max 78%)* *propane (max 20%)* *isobutane (max 5%)*	Non-active substance	*106-97-8* *74-98-6* *75-28-5*	*203-448-7* *200-827-9* *200-857-2*	*63.458* *16.271* *4.068*

(* content including isopropanol from Technical S-methoprene premix)
(**For SoC, maximum content according to SDS have been used for the classification in the biocidal product. However, for mixture of propellant (n-butane, propane and isobutane), please note that the maximum content of each compound is a worst case since they cannot be found at the max content at the same time (the sum of the max contents would be higher than the one of the formulant which is not possible))

2.1.10 Packaging of the biocidal products

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)
Aerosol can (INSECTICIDE HOUSEHOLD SPRAY) Meta SPC1	250ml	Tinplate with epoxy phenolic coating inside	Plastic top (polyamide)	Non-professional	Yes
Aerosol can (INSECTICIDE HOUSEHOLD SPRAY) Meta SPC1	300ml	Tinplate	Plastic top (polyamide)	Non-professional	Yes
Aerosol can (INSECTICIDE HOUSEHOLD SPRAY) Meta SPC1	500ml	Tinplate with epoxy phenolic coating inside	Plastic top (polyamide)	Non-professional	yes
Aerosol can (FOGGER INSECTICIDE FOR HOUSEHOLDS) Meta SPC2	150ml	Tinplate with epoxy phenolic coating inside	Plastic top (polyamide)	Non-professional	yes

Note: the fogger version is composed of an aerosol can with a ring which has to be pushed in order to active activate the diffusion. When activated, the users must leave the room and wait 4 hours before entering the room. The total diffusion time is about 2 minutes.

2.1.11 Documentation

2.1.11.1 Data submitted in relation to product application

Physico-chemistry:

The products family is not the representative formulation for the inclusion of permethrin and S-Methoprene. Therefore, new studies on physico chemical properties on this biocidal family have been provided in this dossier.

Efficacy data:

- Laboratory study according to CEB 135[2] and CEB 159[3] modified methodologies with the product SPRAY INSECTICIDE POUR L'HABITAT, on mosquitoes (*Aedes spp*. and *Culex spp*., adults), on fleas (*Ctenocephalides felis,* adults and larvae) and on ticks (*Ixodes ricinus* adults)

- Semi-field test according to an in-house method, with the product SPRAY INSECTICIDE POUR L'HABITAT on mosquitoes (*Aedes spp*. and *Culex spp*. adults), on fleas (*Ctenocephalides felis* adults and larvae) and on ticks (*Ixodes ricinus* and *Ripicephalus sanguineus* adults)
- Laboratory study according to CEB 135bis[4] modified methodology, with the product DIFFUSEUR INSECTICIDE POUR L'HABITAT, on mosquitoes (*Aedes spp*. and *Culex spp*. adults), on fleas (*Ctenocephalides felis* adults and larvae) and on ticks (*Ixodes ricinus* adults)
- Semi-field test according to an in house method, with the product DIFFUSEUR INSECTICIDE POUR L'HABITAT on mosquitoes (*Aedes spp*. and *Culex spp*. adults), on fleas (*Ctenocephalides felis* adults and larvae) and on ticks (*Ixodes ricinus* and *Ripicephalus sanguineus* adults)

Dietary exposition:
No specific residue data were submitted in the context of this dossier. Considering the intended uses and the proposed RMMs, no residues in food or feed are expected and no data is required.

2.1.11.2 Access to documentation

Letters of access from Tagros/Limaru NV for data on permethrin and from Babolna Bioenvironmental centre Ltd for S-Methoprene have been provided and grant access to AGROBIOTHERS LABORATORIES to these data.

2.2 Assessment of the biocidal product family

Please notice that the risk assessment **for the environment** (section 2.2.8) is reported as provided by the applicant. The FR CA position is presented in **green evaluation boxes**.

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

Table 1. Intended use # 1 –Insecticide household spray

Product Type	PT18
Where relevant, an exact description of the authorised use	/
Target organism (including development stage)	Fleas (adults, larvae) : e.g. *Ctenocephalides felis* Ticks : *Ixodes ricinus* (adult)*, Ripicephalus sanguineus* (adult) Mosquitoes : *Aedes aegypti* (adult)*, Culex pipiens* (adult)
Field of use	Indoor (rugs, carpets, non-washable floors, armchairs, baskets or kennels)
Application method(s)	Firstly vacuum the surfaces to be treated. Spray at a distance of 30 cm The spray allows to treat up to 70 m².
Application rate(s) and frequency	1.3 second spray treat approximately 1 m². (2.1 g/m²) The minimum time interval between two treatments is 6 months.
Category(ies) of users	Non professional
Pack sizes and packaging material	Tinplate aerosol can with internal coating made of epoxy phenolic protective lacquer 250 mL, 300 mL, 500 mL

Table 1. Use # 2 Diffuseur insecticide pour l'habitat/Fogger insecticide for households

Product Type	PT18
Where relevant, an exact description of the authorised use	/
Target organism (including development stage)	Fleas (adults, larvae) : e.g. *Ctenocephalides felis* Ticks : *Ixodes ricinus* (adult)*, Ripicephalus sanguineus* (adult) Mosquitoes : *Aedes aegypti* (adult)*, Culex pipiens* (adult)
Field of use	Indoor
Application method(s)	If possible, vacuum carpets, rugs and fabrics prior to application. Place the fogger in the centre of the area to be

	treated, preferably in a raised position (on a chair that has been previously protected). Push the ring to activate the diffusion. Leave the room and close the door behind you. Traited surface : 70m²
Application rate(s) and frequency	Single use product. Every 6 months
Category(ies) of users	Non professional
Pack sizes and packaging material	Tinplate aerosol can with internal coating made of epoxy phenolic protective lacquer 150 mL

2.2.2 Physical, chemical and technical properties

The biocidal family is composed of two meta-SPC and include one product in each meta SPC: insecticide household spray (Meta SPC 1) and insecticide household fogger (Meta SPC 2). The fogger device is for cold fogging. Physico chemical properties have been submitted for each formulation and are summarized below.

Meta SPC 1 - INSECTICIDE HOUSEHOLD SPRAY

Note that the determination of active substance contents has been performed in the liquid part of the product. Therefore, the contents of a.i in the biocidal product are the ones without content of the propellant (0.0115% of pure S-Methoprene and 0.8835% of purepermethrin)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
Physical state at 20 °C and 101.3 kPa	Visual	Test item: 22050816 - SPRAY INSECTICIDE POUR L'HABITAT Batch number: 004E	At 20°C and 101.3kPa : aerosol (gas and liquid mixture)	RPC161401 GLP	Acceptable.
Colour at 20 °C and 101.3 kPa	Visual		Colourless liquid	RPC161401 GLP	Acceptable.
Odour at 20 °C and 101.3 kPa	Smell		Lavender	RPC161401 GLP	Acceptable.
Acidity / alkalinity	OECD 122	Test item: 80050794 - SPRAY INSECTICIDE POUR L'HABITAT (Liquid formulation without propellant gas) Batch number: 160401 Methopren: 0.0128 Permethrin : 0.971	At 1% in water and at 20°C pH: 5.70+/-0.02	RPC161501 GLP	Acceptable.
Relative density / bulk density	UE Method A3	Test item: 22050816 - SPRAY INSECTICIDE POUR L'HABITAT Batch number: 155202	Relative density of the liquid formulation without propellant gas at 20°C: $D_4^{20}{}_f$=0.75 (see report number RPC161403) Relative density of the propellant gas at 20°C: $D_4^{20}{}_g$=0.56 (see fds 501007 of mixture of propellant (n-butane, propane and isobutane), 09/2013) Mass of liquid formulation in one finished product: m_f=27.5g Mass of propellant gas in one finished product: m_g=120.0g The relative density of the product aerosol $D_4^{20}{}_p$ is determined by a weighted average between the	RPC161405 GLP	Acceptable.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
			relative density of the liquid formulation without propellant gas $D_4^{20}{}_f$ (experimentally determined in the report number RPC161404) and the relative density of the propellant gas $D_4^{20}{}_g$. D_4^{20} of test item (gas and liquid): 0.6		
Storage stability test – **accelerated storage 8 weeks at 40°C**	CIPAC method MT 46.3 OECD 122 Analytical methods validated in report R16-901074-003	Test item: 80050794 - SPRAY INSECTICIDE POUR L'HABITAT (Liquid formulation without propellant gas) Batch number: 160401 Methopren: 0.0128 Permethrin : 0.971	<u>Test item:</u> liquid part of the product only <u>Packaging:</u> the liquid formulation was stored in glass bottles. <u>Appearance</u> Before and after storage 8 weeks at 40°C: colourless liquid, with lavender odour <u>pH at 1% w/v</u> before storage: 5.70 after storage 8 weeks at 40°C: 5.72 <u>active substance content:</u> S-Methoprene : 0.0128%w/w before storage and 0.0123% w/w (-3.9% from T0 value) after storage 8 weeks at 40°C Permethrin: 0.971%w/w before storage and 0.953%w/w (-1.9% from T0 value) after storage 8 weeks at 40°C Cis permethrin: 0.262%w/w before storage and 0.258% w/w (-1.5% from T0 value) after storage 8 weeks at 40°C Trans permethrin: 0.709% w/w before storage and 0.695% w/w (-2.0% from T0 value) after storage 8 weeks at 40°C	RPC161507 GLP	Acceptable. The product (liquid without propellant) is stable after storage 8 weeks at 40°C. The product should not be stored at a temperature higher than 40°C *Note: It should be noticed that the a.i contents are higher than the ones reported in the composition in the confidential annex, since in this study, the contents are related to the liquid formulation (0.8835% permethrin and 0.0115% S-methoprene, see confidential part) and do not include the gas content.*

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
	CIPAC method MT 46.3	Test item: 22050816 – Spray insecticide pour l'habitat Batch number 004E	Test item: aerosol (liquid + propellant) Packaging tested: 250mL tinplate can with internal epoxy phenolic coating (commercial packaging) Appearance Before and after storage 8 weeks at 40°C: white spray, with lavender odour packaging after storage 8 weeks at 40°C: no significant weight loss (-0.07%), no degradation outside nor inside, no leak Satisfactory operation of the spray and total emptying Before and after storage 8 weeks at 40°C: no difference	Report RPC161509 GLP	Acceptable. The product (liquid + propellant) is stable in the commercial packaging (tinplate can with internal epoxy phenolic coating) after 8 weeks at 40°C. Spraying pattern has been studied only before storage (see below). No data after accelerated storage has been submitted. However, data have been provided with shelf life studies. The product should not be stored at a temperature higher than 40°C
	CIPAC method MT 46.3	Test item: 22070082 – Spray insecticide pour l'habitat Batch number 153E	Test item: aerosol (liquid + propellant) Packaging tested: 300mL tinplate can without internal coating (commercial packaging) Appearance Before and after storage 8 weeks at 40°C: white spray, with lavender odour packaging after storage 8 weeks at 40°C: no significant weight loss (-0.06%), no degradation outside nor inside, no leak Satisfactory operation of the spray and total emptying Before and after storage 8 weeks at 40°C: no difference	Report RPC162201 GLP	Acceptable. The product (liquid + propellant) is stable in the commercial packaging (tinplate can without internal coating) after 8 weeks at 40°C. The product should not be stored at a temperature higher than 40°C

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
Storage stability test – **long term storage at ambient temperature**	*GIFAP (Croplife International) monograph no. 17 (Croplife, 2009)* OECD 122 Analytical methods validated in report R16-901074-003	Test item: 80050794 - SPRAY INSECTICIDE POUR L'HABITAT (Liquid formulation without propellant gas) Batch number: 160401 Methopren: 0.0128 Permethrin : 0.971	Packaging: the liquid formulation was stored in glass bottles. Appearance Before and after storage 1, 2, 12, 18 and 24 months at ambient temperature (20C): colourless liquid, with lavender odour pH at 1% w/v before storage: 5.68 after storage 1 month at ambient temperature (20°C): 5.68 after storage 2 months at ambient temperature (20°C): 5.66 after storage 12 months at ambient temperature (20°C): 5.75 after storage 18 months at ambient temperature (20°C): 5.33 after storage 24 months at ambient temperature (20°C): 5.33 active substance content: S-Methoprene : 0.0128%w/w before storage ,0.0130% w/w (+1.6% from T0 value) after 12 months and 0.0134%w/w (+4.6%) after 24 months at 20°C Permethrin: 0.971%w/w before storage , 0.96%w/w (-1.1% from T0 value) after 12 months and 0.983%w/w (+1.2%) after 24 months at 20°C Cis permethrin: 0.262%w/w before storage , 0.265% w/w (+0.1% from T0 value) after 12 months and 0.318%w/w (+21.3%) after 24 months at 20°C	Report RPC161507 GLP	The product (liquid formulation) is stable after 24 months at ambient temperature (20°C) in glass bottles. **Variations of active substance contents are acceptable upon storage. However, cis/trans ratio differs after 24 months and is outside the range set** Compatibility with packaging has been provided during the accelerated storage stability and in a separate shelf life study (see below). **According to approval under BPR, the ratio should have been included in the following range: 22-28 : 72-78 cis: trans.** **No explanation regarding variations of cis/trans ratio of permethrin has been provided by applicant. As permethrin is not known to isomerise, this is expected to be due to experimental deficiency.** **Consequently, a new shelf life study with the commercial packaging including a.i contents, cis/trans ratio of permethrin and determination of technical properties (all relevant properties for aerosol formulation, MMAD and discharge rate) before**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
			Trans permethrin: 0.709% w/w before storage , 0.694% w/w (-2.1% from T0 value) after 12 months and 0.671% w/w (-5.4%) after 24 months at 20°C Ratio cis/trans: 26.97 / 73.03 before storage 27.63 / 72.37 after 12 months 32.19 / 67.81 after 24 months		**and after storage should be provided in post authorisation with a time limit of 24 months.** *Note: It should be noticed that the a.i contents are higher than the one reported in the composition in the confidential annex, since in this study, the contents are related to the liquid formulation (0.8835% permethrin and 0.0115% S-methoprene, see confidential part) and do not include the gas content.*
	GIFAP (Croplife International) monograph no. 17 (Croplife, 2009) Analytical method validated in report 16-901074-003	Test item: 22050816 – Spray insecticide pour l'habitat Batch number 004E	<u>Test item:</u> aerosol (liquid + propellant) <u>Packaging tested:</u> 250mL tinplate can with internal epoxy phenolic coating (commercial packaging) <u>Appearance</u> Before and after storage 2, 12, 18, 24, 30 months at ambient temperature (20°c): white spray, with lavender odour <u>packaging</u> after storage 2, 12, 18, 24, 30 months at ambient temperature (20°C): no significant weight loss (approx -0.01 to -0.31% w:w), no degradation outside nor inside, no leak <u>Satisfactory operation of the spray and total emptying</u> Before and after storage 2, 12, 18, 24, 30 months at ambient temperature (20°C): no difference	Report RPC161509 GLP Report 18-901074-003 Report 18-901074-004	The product is stable in its commercial packaging (tinplate can with internal epoxy phenolic coating) following 30 months at ambient temperature (20°C). However, content of active substances have not been measured before storage and varations following 30 months cannot be determined. Only results before and after 24 months have been provided in the previous study. Additionally, discharge rate and MMAD are missing. Compatibility with the commercial packaging has been demonstrated.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
			Additional results following 30 months at room temperature provided in report 18-901074-003 (same test item and same batch) S methoprene content: 0.0109%w/w Permethrin (cis + trans) content: 0.910%w/w Cis-permethrin content: 0.251% w/w Trans-permethrin content: 0.651% w/w Spray pattern following 7 months (report 901074-004) : 12cm, circular shape		Additionally, in report 18-90174-004, the test item is described as a liquid packed in a glass flask, but the storage part has been performed by Agrobiothers in report RPC16150 with the aerosol (same batch 004E). For the analytical phase, only the liquid fraction has been sent to the laboratory. **A 36 months shelf life is claimed.** **According to the available results, a shelf life of 2 years can be granted. If the applicant wants to extend the shelf life, a dossier for minor change should be deposited.** **Due to a lack of information on a.i contents before storage, MMAD and dischare rate, a new study is required in post registration for confirmation with a time limit of 24 months.** *Note: It should be noticed that the a.i contents are higher than the one reported in the composition in the confidential annex, since in this study, the contents are related to the liquid formulation (0.8835% permethrin and 0.011% S-*

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
					methoprene, see confidential part) and do not include the gas content.
	GIFAP (Croplife International) monograph no. 17 (Croplife, 2009) Analytical method validated in report 16-901074-003	Test item: 22070082 – Spray insecticide pour l'habitat Batch number 153E	Test item: aerosol (liquid + propellant) Packaging tested: 300mL tinplate can without internal coating (commercial packaging) Appearance Before and after storage 2, 6 , 12, 18, 24 months at ambient temperature (20°C): white spray, with lavender odour packaging after storage 2, 6, 12, 18, 24 months at ambient temperature (20°C): no significant weight loss (-0.01 to -0.3% w/w), no degradation outside nor inside, no leak Satisfactory operation of the spray and total emptying Before and after storage 2, 6 ,12, 18, 24 months at ambient temperature (20°C): no difference Additional results following 26 months at room temperature (report 18-901074-001, same test item and same batch) S methoprene content: 0.0109%w/w Permethrin (cis + trans) content: 0.933%w/w Cis-permethrin content: 0.248% w/w Trans-permethrin content: 0.687% w/w Spray pattern (report 18-901074-002) following 25 months: 11cm, shape was circular	Report RPC162201 GLP report 18-901074-001 report 18-901074-002	The product is stable in its commercial packaging (tinplate can without internal coating) following 24 months at ambient temperature (20°C). Compatibility with the commercial packaging has been demonstrated. Additionally, in report 18-90174-002, the test item is described as a liquid packed in a glass flask, but the storage part has been performed by Agrobiothers. There is no indication if the storage has been performed with the commercial pack. For the analytical phase, only the liquid fraction may have been sent to the laboratory. **A 36 months shelf life is claimed.** **According to the available results, a shelf life of 2 years can be granted. If the applicant wants to extend the shelf life, a dossier for minor change should be deposited.** **Due to a lack of information on a.i contents before**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
					storage, MMAD and dischare rate, a new study is required in post registration for confirmation with a time limit of 24 months.
Storage stability test – **low temperature stability test for liquids**	Guidance on the BPR: Volume I. Part A Chapter III: Requirements for Biocidal Products Version 1.1 November 2014 section 3.4.1.3	/	Not performed as the product is intended to be stored by at ambient temperature (at distributor's and consumer's).	/	The product should be protected from frost.
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Guidance on the BPR: Volume I. Part A Chapter III: Requirements for Biocidal Products Version 1.1 November 2014 section 3.4.2.1	/	Not performed as the packaging is opaque.	/	Acceptable. Since the packaging is metallic, effect of light on a.i contents is not required. Moreover, according to the label, the applicant recommends to store the product away from direct sunlight, due to the nature of the product (aerosol containing flammable gases). RMS agrees with the mitigation measure "do not expose to direct sunlight".
Effects on content of the active substance and technical	In compliance with SANCO/3030/	Test item: 22050816 – Spray insecticide pour l'habitat	The product is stable after 8 weeks at 40°C.	Report RPC161509 GLP	Acceptable. The product should not be stored at a temperature higher than 40°C

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
characteristics of the biocidal product – **temperature and humidity**	99 rev. 4 from 11/07/00, method validated described in the report R16-901074-003	Batch number 004E			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	*GIFAP (Croplife International) monograph no. 17 (Croplife, 2009)*	Test item: 22050816 – Spray insecticide pour l'habitat Batch number 004E	See results of the accelerated storage. Compatibility with metallic can has been demonstrated.	Report RPC161509 GLP	Compatibility of the product (aerosol) with the commercial packaging (tinplate can with and without internal coating) has been demonstrated with the accelerated storage (8 weeks at 40°C) and shelf life study (24 months at ambient temperature). Since no loss of weight was noticed during storage of the product in the tinplate can without coating, it can be reasonably conclude that the product is not corrosive to metals.
Wettability		/	Not performed as the product is not a solid preparation to be dispersed in water.	/	Not applicable.
Suspensibility, spontaneity and dispersion stability		/	Not performed as the product is not a concentrate to be diluted.	/	Not applicable.
Wet sieve analysis and dry sieve test		/	Not performed as the product is not a powder.	/	Not applicable.
Emulsifiability, re-emulsifiability and emulsion stability		/	Not performed as the product is not to emulsify.	/	Not applicable.
Disintegration time		/	Not performed as the product is not a tablet.	/	Not applicable.
Particle size distribution, content of		/	Please refer to the section "drop size distribution"	/	Please refer to the section "drop size distribution"

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
dust/fines, attrition, friability					
Persistent foaming		/	Not performed as the product is not applied in water to use.	/	Not applicable.
Flowability/Pourability/Dustability		/	Not performed as the product is neither a granular material, neither to be rinsed nor to be dusted.	/	Not applicable.
Burning rate — smoke generators		/	Not performed as the product is not a smoke generator.	/	Not applicable.
Burning completeness — smoke generators		/	Not performed as the product is not a smoke generator.	/	Not applicable.
Composition of smoke — smoke generators		/	Not performed as the product is not a smoke generator.	/	Not applicable.
Spraying pattern — aerosols	FEA Method 644	Spray insecticide pour l'habitat, 22050816, batch 004E and 153E	Mean spray diameter of the aerosol was 12 cm (n=2, batch 004E). The shape of the spray on the wetted patch was circular. The aerosol was placed at 30cm to the spray pattern type from the vertical removable holder. Spray pattern (report 18-901074-002) following 25 months: 11cm, shape was circular (n=2, batch 153E) Spray pattern following 7 months (report 901074-004) : 12cm, circular shape (n=2, batch 004E)	R16-901074-011 18-901074-002 901074-004	Acceptable.
Mass generation rate - aerosol	/	Spray insecticide pour l'habitat, 22070082, batch 096E	The mass generation rate of the product is 1.34g/s.	RPC161701	Acceptable.
Drop size distribution	/	Spray insecticide pour l'habitat, 22050816, batch 069C	Results obtained from a mean of 3 series of drop size distribution: -Mean = 22.69µm -Median (=Dv(50))=17.51µm -DV (10)=6.14µm -DV (90)=32.63µm - Maximum particle size: Dv(99.9) = 165.79µm - %<10µm: 20.11%	RPC161301	Acceptable.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
			According to raw data - %<50µm: approx. 97% Spray duration = 150 s		
Physical compatibility		/	Not performed as the product is not intended to be applied with other substances, mixtures.	/	Not applicable.
Chemical compatibility		/	Not performed as the product is not intended to be applied with other substances, mixtures.	/	Not applicable.
Degree of dissolution and dilution stability		/	Not performed as the product is not to dissolve or dilute.	/	Not applicable.
Surface tension	EC A5 method and OECD Guideline No. 115	Test item: 80050794 - SPRAY INSECTICIDE POUR L'HABITAT (Liquid formulation without propellant gas) Batch number: 160401 Methopren: 0.0128 Permethrin : 0.971	Pure test item: 21.2 mN/m at 24.7°C	D16-901074-013 GLP	Acceptable. The test item is considered as surface active.
Viscosity	OECD Guideline No. 114 and ISO Standard 3219	Test item: 80050794 - SPRAY INSECTICIDE POUR L'HABITAT (Liquid formulation without propellant gas) Batch number: 160401 Methopren: 0.0128 Permethrin : 0.971	The mean dynamic viscosity of the test item was 1.43 mPa.s at 20.0 °C ± 0.2 °C (shear rate: 61.15 to 122.30 s^{-1}) 1.03 mPa.s at 40.0 °C ± 0.2 °C (shear rate: 61.15 to 122.30 s^{-1}) The mean kinematic viscosity of the test item was 1.91 x 10^{-6} m^2/s at 20.0 °C ± 0.2 °C and 1.37 x 10^{-6} m^2/s at 40.0 °C ± 0.2 °C.	D16-901074-013 GLP	Acceptable. The product (liquid part) is a newtonien fluid since the viscosity is not depending of the rotation speed. Moreover, the product contains more than 10% of compounds classified H304 and the viscosity is below 20.5mm^2/s. Therefore, the product is also classified H304 Category 1

Conclusion on the physical, chemical and technical properties of the product INSECTICIDE HOUSEHOLD SPRAY – meta SPC 1

The product INSECTICIDE HOUSEHOLD SPRAY is an aerosol containing a colorless liquid with lavender odour. Its pH at 1% in water and at 20°C is 5.70. It has a relative density 0.6. The surface tension of the product is 21.2mN/m at 24.7°C, therefore the product is considered as surface active. The viscosity of the product at 40°C is 1.37 x 10^{-6} m^2/s. Since the content of H304 compounds in the product is higher than 10%, the product is classified H304 Caterogy 1. However, since the product is an aerosol (container with sealed spray attachment), there is no need to label the product H304 as mentionned in CLP regulation.
The product is stable after storage 8 weeks at 40°C in glass bottle (liquid part of the aerosol) and in the commercial packaging (tinplate can with or without internal epoxy phenolic coating). The product should not be stored at a temperature higher than 40°C. Effect of low temperature has not been studied. Therefore the product should be protected from frost. Intermediate results of the shelf life study have been provided and are acceptable after 12 months at 20°C in both packaging (tinplate can with or without internal epoxy phenolic layer). Shelf life study with the liquid fraction has also been provided and allows to consider the liquid stable for 24 months at ambient temperature in glass bottles. Compatibility of the product with the commercial packaging has been demonstrated. Based on the results available, a shelf life of 2 years can be granted. **If the applicant claims a stability of 36 months, an application for minor change will have to be submitted.**
Significant variations of cis/trans ratio of permethrin during the shelf life study with glass bottle have been noticed and no rational explanation was provided by the applicant. Variations lead to a non conformity since the ratio cis/trans after storage is outside the range set following the approval of permethrin (cis/trans: 22-28:78-72). Furthermore, some data were missing in the shelf life study with the commercial packaging (tinplate can): the contents of active ingredients before storage, MMAD and discharge rate were not reported. Consequently, a complete shelf life study for INSECTICIDE HOUSEHOLS SPRAY with the commercial packaging (tinplate can), including active substance contents, cis/trans ratio of permethrin and determination of technical properties (all relevant properties for aerosol, discharge rate and MMAD) before and after storage is required in post registration with a time limit of 30 months.
Effect of light has not been investigated. Nevertheless, since the packaging is barrier to light, no data are required. Moreover, the applicant recommends to store the product away from direct sunlight due to the nature of the product (aerosol containing flammable gases). The mitigation measure ”do not expose to direct sunlight” should be mentionned. Technical properties are acceptable for the aerosol.

Labelling mention: Do not store at a temperature higher than 40°C, store away from direct sunlight, protect from frost
Shelf life: 24 months.
Classification: H304 cat 1, Danger, GHS08 (liquid fraction). However, since the product is an aerosol (container with sealed spray attachment), there is no need to label the product H304 as mentionned in CLP regulation.

Meta SPC 2 - FOGGER INSECTICIDE FOR HOUSEHOLDS

Note that the determination has been performed in the liquid part of the product. Therefore, the contents of a.i in the biocidal product are the ones without the content of propellant (0.289% of pure S-Methoprene and 9.43% of pure permethrin)

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
Physical state at 20 °C and 101.3 kPa	Visual	Test item: 22070083 - DIFFUSEUR INSECTICIDE POUR L'HABITAT Batch number: 155201	Aerosol (Gas and liquid mixture)	RPC161402 GLP	Acceptable
Colour at 20 °C and 101.3 kPa	Visual		Colourless to light yellow	RPC161402 GLP	Acceptable
Odour at 20 °C and 101.3 kPa	Smell		Lavender	RPC161402 GLP	Acceptable
Acidity / alkalinity	OECD 122	80070034 - DIFFUSEUR INSECTICIDE POUR L'HABITAT (Liquid formulation without propellant gas) Batch number: 160302 Methopren: 0.303 Permethrin : 10.24	At 1%v/v in water and at 20°C 4.88+/-0.02	RPC161502 GLP	Acceptable

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
Relative density / bulk density	UE Method A3	80070034 - DIFFUSEUR INSECTICIDE POUR L'HABITAT (liquid formulation without propellant gas) Batch number: 155201 22070086 - DIFFUSEUR INSECTICIDE POUR L'HABITAT Batch number: 155201	Relative density of the liquid formulation without propellant gas at 20°C: $D_4^{20}{}_f$=0.82 Relative density of the propellant gas at 20°C: $D_4^{20}{}_g$=0.56 (see fds 501007 of mixture of propellant (n-butane, propane and isobutane), 09/2013) Mass of liquid formulation in one finished product: m_f=7.4g Mass of propellant gas in one finished product: m_g=78.4g The relative density of the product aerosol $D_4^{20}{}_p$ is determined by a weighted average between the relative density of the liquid formulation without propellant gas $D_4^{20}{}_f$ (experimentally determined in the report number RPC161404) and the relative density of the propellant gas $D_4^{20}{}_g$. The density of the 22070083 - DIFFUSEUR INSECTICIDE POUR L'HABITAT is D_4^{20}=0.58.	RPC161406 GLP	Acceptable
Storage stability test – **accelerated storage 8 weeks at 40°C**	CIPAC method MT 46.3 OECD 122 Analytical method	80070034 - DIFFUSEUR INSECTICIDE POUR L'HABITAT (liquid	<u>Packaging:</u> the liquid formulation was stored in glass bottles. <u>Appearance</u>	RPC161508 GLP	Acceptable. The product (liquid without propellant) is stable after storage 8 weeks at 40°C. The product should not be stored at a temperature higher than 40°C

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
	validated in report R16-901074-007	formulation without propellant gas) Batch number: 160302 Methopren: 0.303 Permethrin : 10.24	Before and after storage 8 weeks at 40°C: slightly yellow, limpid liquid, with lavender odour <u>pH at 1% w/v</u> before storage: 4.88 after storage 8 weeks at 40°C: 5.0 <u>active substance content:</u> S-Methoprene : 0.303%w/w before storage and 0.317% w/w (+4.6% from T0 value) after storage 8 weeks at 40°C Permethrin: 10.24%w/w before storage and 10.26%w/w (+0.2% from T0 value) after storage 8 weeks at 40°C Cis permethrin: 2.77%w/w before storage and 2.77% w/w after storage 8 weeks at 40°C Trans permethrin: 7.47% w/w before storage and 7.48% w/w (+0.1% from T0 value) after storage 8 weeks at 40°C		*Note: It should be noticed that the a.i contents are higher than the ones reported in the composition in the confidential annex, since in this study, the contents are related to the liquid formulation (0.289% for S-Methoprene and 9.43% for permethrin, see confidential part) and do not include the gas content.*
	CIPAC method MT 46.3 OECD 122 Analytical method validated in report R16-901074-007	22070083-DIFFUSEUR INSECTICIDE POUR L'HABITAT Batch number: 160403	<u>Test item:</u> aerosol (liquid + propellant) Packaging tested: tinplate can with internal epoxy phenolic coating (commercial packaging) <u>Appearance</u> Before and after storage 8 weeks at 40°C: white spray, with lavender odour	Report RPC161510 GLP	Acceptable. The product (liquid + propellant) is stable in the commercial packaging (tinplate can with internal epoxy phenolic coating) after 8 weeks at 40°C. Spraying pattern has been studied only before storage (see below). No data after accelerated

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
			Packaging after storage 8 weeks at 40°C: no significant weight loss (-0.15%), no degradation outside nor inside, no leak Satisfactory operation of the spray and total emptying Before and after storage 8 weeks at 40°C: no difference		storage has been submitted. However, data have been provided with shelf life studies. The product should not be stored at a temperature higher than 40°C
Storage stability test – **long term storage at ambient temperature**	*GIFAP (Croplife International) monograph no. 17 (Croplife, 2009)* OECD 122 Analytical method validated in report R16-901074-007	80070034 - DIFFUSEUR INSECTICIDE POUR L'HABITAT (liquid formulation without propellant gas) Batch number: 160302 Methopren: 0.303 Permethrin : 10.24	Packaging: the liquid formulation was stored in glass bottles. Appearance Before and after storage 1, 2, 12 ,18 and 24 months at ambient temperature (20°C): slightly yellow, limpid liquid, with lavender odour pH at 1% w/v and at ambient temperature before storage: 4.88 after storage 1 month at ambient temperature (20°C): 4.90 after storage 2 months at ambient temperature (20°C): 4.96 after storage 12 months at ambient temperature (20°C): 4.75 after storage 18 and 24 months at ambient temperature (20°C): 4.55 Active substance contents: S-Methoprene : 0.303%w/w before storage , 0.315% w/w (+4% from T0 value) after storage 12 months and	RPC161508 GLP	The product (liquid formulation) is stable after 24 months at ambient temperature (20°C) in glass bottles. **Variations of active substance contents are stable on storage. However, cis/trans ratio differs after 24 months and is outside the range set following approval under BPR (ratio: 22-28 : 72-78 cis: trans). No explanation has been submitted. A new shelf life study is not necessary since the product is not proposed for an authorisation.** Compatibility with packaging has been provided during the accelerated storage stability

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
			0.326%w/w (+7.6% from T0 value) after 24 months at ambient temperature (20°C) Permethrin: 10.24%w/w before storage , 10.13%w/w (-1.1% from T0 value) after storage 12 months and 9.99%w/w (-2.4% from T0 value) after 24 months at ambient temperature (20°C) Cis permethrin: 2.77%w/w before storage , 2.80% w/w (+1.1% from T0 value) after storage 12 months and 3.23%w/w (+16.6% from T0 value) after 24 months at ambient temperature (20°C) Trans permethrin: 7.47% w/w before storage , 7.33% w/w (-1.9% from T0 value) after storage 12 months and 6.82% w/w (-8.7% from T0 value) after 24 months at ambient temperature (20°C) Ratio cis/trans Before storage: 27.04 / 72.96 After 12 months: 27.62 / 72.38 After 24 months: 32.14 / 67.86		and in a separate shelf life study (see below). A 36 months shelf life is claimed. According to the available results, a shelf life of 2 years can be granted. Compability of the product with the commercial packaging has been demonstrated in a separate shelf life study (see below). **If the applicant wants to extend the shelf life, a dossier for minor change should be provided.** *Note: It should be noticed that the a.i contents are higher than the one reported in the composition in the confidential annex, since in this study, the contents are related to the liquid formulation (0.289% for S-Methoprene and 9.43% for permethrin, see confidential part) and do not include the gas content. Contents measured in the liquid formulation are in accordance wih the expected level in the composition.*

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
	GIFAP (Croplife International) monograph no. 17 (Croplife, 2009) OECD 122 Analytical method validated in report R16-901074-007	22070083-DIFFUSEUR INSECTICIDE POUR L'HABITAT Batch number: 160403	Test item: aerosol (liquid + propellant) Packaging tested: tinplate can with internal epoxy phenolic coating (commercial packaging) Appearance Before and after storage 2, 12, 18, 24, 30 months at ambient temperature (20°C): white spray, with lavender odour packaging after storage 2, 12,18, 24, 30 months at ambient temperature (20°C): no significant weight loss (-0.3% to -1.78%w/w), no degradation outside nor inside, no leak Satisfactory operation of the spray and total emptying Before and after storage 2, 12,18, 24, 30 months at ambient temperature (20°C): no difference Spray pattern (report 18-901074-002) following 29 months: 16cm, shape was circular	Report RPC161510 GLP Report 18-901074-006	The product is stable in its commercial packaging (tinplate can with internal epoxy phenolic coating) following 30 months at ambient temperature (20°C). However, contents of active substances have not been measured. Only results after 24 months have been provided for the liquid formulation in the previous study. Compatibility with the commercial packaging has been demonstrated. **A 36 months shelf life is claimed.** **According to the available results, a shelf life of 2 years can be granted. If the applicant wants to extend the shelf life, a dossier for minor change should be provided**.
Storage stability test – **low temperature stability test for liquids**	Guidance on the BPR: Volume I. Part A Chapter III: Requirements for Biocidal	/	Not performed as the product is intended to be stored by at ambient temperature (at distributor's and consumer's).	/	No test was provided. The product should be protected from frost.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
	Products Version 1.1 November 2014 section 3.4.1.3				
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	Guidance on the BPR: Volume I. Part A Chapter III: Requirements for Biocidal Products Version 1.1 November 2014 section 3.4.2.1	/	Not performed as the packaging is opaque.	/	Acceptable. Since the packaging is barrier to light, no further data are required. Moreover, according to the label, the applicant recommends to store the product away from direct sunlight due to the nature of the products (aerosol containing flammable gases). RMS agrees with the mitigation measure ”do not expose to direct sunlight”.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	CIPAC method MT 46.3 OECD 122 Analytical method validated in report R16-901074-007	80070034 - DIFFUSEUR INSECTICIDE POUR L’HABITAT (liquid formulation without propellant gas) Batch number: 160302 Methopren: 0.303 Permethrin : 10.24	Acceptable. A.i contents are stable after 8 weeks at a 40°C (see previous results).	RPC161508 GLP	Acceptable. The product (liquid without propellant) is stable after storage 8 weeks at 40°C. The product should not be stored at a temperature higher than 40°C

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	*GIFAP (Croplife International) monograph no. 17 (Croplife, 2009)* OECD 122 Analytical method validated in report R16-901074-007	22070083-DIFFUSEUR INSECTICIDE POUR L'HABITAT Batch number: 160403	The commercial packaging (metallic can) showed no modifications after storage 8 weeks at 40C° and 2 months at ambient temperature.	RPC161510 GLP	Acceptable. Compatibility with commercial packaging (tinplate can with and without internal epoxy phenolic coating) has been demonstrated. No loss of weight was noticed during storage of the product INSECTICIDE HOUSEHOLD SPRAY in the tinplate can without coating. Extrapolation to the fogger formulation can be made and it can be reasonably conclude that the fogger is also not corrosive to metals.
Wettability		/	Not performed as the product is not a solid preparation to be dispersed in water.	/	Not applicable.
Suspensibility, spontaneity and dispersion stability		/	Not performed as the product is not a concentrate to be diluted.	/	Not applicable.
Wet sieve analysis and dry sieve test		/	Not performed as the product is not a powder.	/	Not applicable.
Emulsifiability, re-emulsifiability and emulsion stability		/	Not performed as the product is not to emulsify.	/	Not applicable.
Disintegration time		/	Not performed as the product is not a tablet.	/	Not applicable.
Particle size distribution, content of dust/fines, attrition, friability		/	Please refer to the section "drop size distribution"	/	Please refer to the section "drop size distribution"

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
Persistent foaming		/	Not performed as the product is not applied in water to use.	/	Not applicable.
Flowability/Pourability/Dustability		/	Not performed as the product is neither a granular material, neither to be rinsed nor to be dusted.	/	Not applicable.
Burning rate — smoke generators		/	Not performed as the product is not a smoke generator.	/	Not applicable.
Burning completeness — smoke generators		/	Not performed as the product is not a smoke generator.	/	Not applicable.
Composition of smoke — smoke generators		/	Not performed as the product is not a smoke generator.	/	Not applicable.
Spraying pattern — aerosols	FEA Method 644	22070083-DIFFUSEUR INSECTICIDE POUR L'HABITAT Batch number: 160602 (before storage) and 160403 (following storage)	Mean spray diameter of the aerosol was 10 cm (n=2, batch 160602). The shape of the spray on the wetted patch was circular. The aerosol was placed at 30cm to the spray pattern type from the vertical removable holder. Spray pattern (report 18-901074-002) following 29 months: 16cm, shape was circular (n=2, batch 160403)	16-901074-012 18-901074-006	Acceptable. The diameter is higher following storage. However no malfunction has been noticed. The use of different batches may also explained the differences. *Note: the fogger version is composed of an aerosol can with a ring which has to be pushed in order to active activate the diffusion.*
Mass generation rate - aerosol	/	22070083-DIFFUSEUR INSECTICIDE POUR L'HABITAT Batch number: 160602	The mass generation rate of the product is 1.02g/s.	RPC161702	Acceptable.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
Drop size distribution	/	22070083-DIFFUSEUR INSECTICIDE POUR L'HABITAT Batch number: 160602	Results obtained from a mean of 3 series of drop size distribution: -Mean = 20.30µm -Median (=Dv(50))=15.53µm -DV(10)=2.87µm -DV(90)=41.47µm -Maximum particle size: Dv(99) = 54.55µm - %<10µm: 30% According to raw data - %<50µm: 86.59% Spray duration = 103 s	RPC161302	Acceptable.
Physical compatibility		/	Not performed as the product is not intended to be applied with other substances, mixtures.	/	Not applicable.
Chemical compatibility		/	Not performed as the product is not intended to be applied with other substances, mixtures.	/	Not applicable.
Degree of dissolution and dilution stability		/	Not performed as the product is not to dissolve or dilute.	/	Not applicable.
Surface tension	EC A5 method and OECD Guideline No. 115	80070034 Diffuseur insecticide pour l'habitat (liquid without propellant) Batch 155201	22.6 mN/m at 24.8 °C (neat test item)	D16-901074-014 GLP	Acceptable. The product (liquid part) is surface active.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
Viscosity	OECD Guideline No. 114 and ISO Standard 3219	80070034 Diffuseur insecticide pour l'habitat (liquid without propellant) Batch 155201	The mean dynamic viscosity of the test item was 2.47 mPa.s at 20.0 °C ± 0.2 °C ((shear rate: 36.69 to 207.91 s^{-1}) and 1.61 mPa.s at 40.0 °C ± 0.2 °C (shear rate: 61.15 to 134.53 s^{-1}) The mean kinematic viscosity of the test item was 3.01 x 10^{-6} m^2/s at 20.0 °C ± 0.2 °C and 1.96 x 10^{-6} m^2/s at 40.0 °C ± 0.2 °C.	D16-901074-014 GLP	Acceptable. Regarding, the product (liquid part) is a newtonien fluid since the viscosity is not depending of the rotation speed. Moreover, the liquid contains more than 10% of compounds classified H304 and the viscosity is below 20.5mm^2/s. However, the content of liquid in the final product is below 10% and the product is not classified H304.

Conclusion on the physical, chemical and technical properties of the product FOGGER INSECTICIDE FOR HOUSEHOLDS

The product FOGGER INSECTICIDE FOR HOUSEHOLDS is an aerosol containing a yellow liquid with lavender odour. Its pH at 1% in water and at 20°C is 4.88. It has a relative density 0.58. The surface tension of the product is 22.6nN/m at 24.8°C, therefore the product is considered as surface active. The viscosity of the product at 40°C is 1.96 x 10^{-6} m^2/s. Since the content of H304 compounds in the product is below than 10%, the product is not classified H304 Caterogy 1.
The product is stable after storage 8 weeks at 40°C in glass bottle (liquid part of the aerosol) and in the commercial packaging (tinplate can with and without internal epoxy phenolic coating). The product should not be stored at a temperature higher than 40°C. Effect of low temperature has not been studied. The product should be protected from frost. Shelf life study with the liquid fraction has also been provided and allows to consider the liquid stable for 24 months at ambient temperature in glass bottles. Compatibility of the product with the commercial packaging has been demonstrated. **If the applicant wants to extend the shelf life, a dossier for minor change should be submitted.**

Significant variations of cis/trans ratio of permethrin during the shelf life study with glass bottle have been noticed and no rational explanation was provided by the applicant. Variations lead to a non conformity since the ratio cis/trans after storage is outside the range set following the approval of permethrin (cis/trans: 22-28:78-72). Furthermore, some data were missing in the shelf life study with the commercial packaging (tinplate can): the content of active ingredient, MMAD and discharge rate were not reported. However, please note that the fogger formulation is not intended for an authorisation, then, no further data are necessary.

Effect of light has not been investigated. Nevertheless, since the packaging is barrier to light, no data are required. Moreover, the applicant recommends to store the product away from direct sunlight due to the nature of the product (aerosol containing flammable gases). The mitigation measure "do not expose to direct sunlight" should be mentionned. Technical properties are acceptable for the aerosol.

Labelling mention: do not store at a temperature higher than 40°C, store away from direct sunlight, protect from frost
Shelf life: 24 months.

Conclusion on the physico chemical properties of the biocidal family product
Physico chemical studies were provided for both products and cover this biocidal product family. The products are stable after accelerated storage 8 weeks at 40°C. The liquid fractions are stable for 24 months at ambient temperature in glass bottles. Compatibility of the products with their commercial packaging has been demonstrated. A shelf life of 24 months can be granted. If the applicant wants to extend the shelf life, a dossier for minor change should be provided. The products should not be stored at a temperature higher than 40°C.
However, significant variations of cis/trans ratio of permethrin during the shelf life studies with glass bottle have been noticed and no rational explanation was provided by the applicant. Variations lead to a non conformity since the ratio cis/trans after storage is outside the range set following the approval of permethrin (cis/trans: 22-28:78-72). Furthermore, some data were missing in the shelf life studies with the commercial packaging (tinplate can): the content of active ingredients before storage (and after storage for the fogger version), MMAD and discharge rate were not reported. Consequently, a complete shelf life study for INSECTICIDE HOUSEHOLS SPRAY with the commercial packaging (tinplate can), including active substance contents, cis/trans ratio of permethrin and determination of technical properties (all relevant properties for aerosol, discharge rate and MMAD) before and after storage is required in post registration with a time limit of 30 months. Since the fogger formulation is not intended for an authorisation, no further data are necessary.

Products of the meta-SPC1 are classified H304 Category 1 since they contain hydrocarbons compounds at a content >10% and their viscosity is below 20.5mm^2/s at 40°C.
All products should be kept away from direct sunlight due to their nature (aerosols containing flammable gases).
Conclusion on the physico chemical properties related to the range of the biocidal family is confidential and is presented in annex.

2.2.3 Physical hazards and respective characteristics

Meta SPC 1 - INSECTICIDE HOUSEHOLD SPRAY

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
Explosives	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.1 (ECHA)	/	Not performed as none of its compounds is an explosive.	/	Acceptable. According to the composition, the product does not contain explosive compounds. As stated in CLP regulation, it can be assumed that the product is not explosive.
Flammable gases	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.2 (ECHA)	/	Not performed as aerosols do not fall additionally within the scope of Sections 0 (flammable gases), 0 (gases under pressure), 0 (flammable liquids) and 2.7 (flammable solids).	/	Not applicable. A specific classification has been defined for aerosol (see below).
Flammable aerosols	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 Section 2.3 Aerosols (ECHA)	/	H222 and H229 Category 1 GHS02, Danger (FDS)	/	The applicant has not provided a test. However, by default, the classification H222 and H229 Category 1, GHS02 danger has been proposed in the FDS of this product due to its nature (aerosol containing flammable gases).
Oxidising gases	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.4 (ECHA)	/	Not performed as the product is not a gas.	/	Not applicable.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
Gases under pressure	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.5 (ECHA)	/	Not performed as aerosols do not fall additionally within the scope of Sections 0 (flammable gases), 0 (gases under pressure), 0 (flammable liquids) and 2.7 (flammable solids).	/	Not applicable. A specific classification has been defined for aerosol (see point for flammable aerosols).
Flammable liquids	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.6 (ECHA)	/	Not performed as aerosols do not fall additionally within the scope of Sections 0 (flammable gases), 0 (gases under pressure), 0 (flammable liquids) and 2.7 (flammable solids).	/	No results were provided for the liquid part. Nevertheless, the product is an aerosol and is already classified as flammable.
Flammable solids	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.7 (ECHA)	/	Not performed as aerosols do not fall additionally within the scope of Sections 0 (flammable gases), 0 (gases under pressure), 0 (flammable liquids) and 2.7 (flammable solids).	/	Not applicable since the product is an aerosol.
Self-reactive substances and mixtures	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.8 (ECHA)	/	Not performed as none of its compounds is self-reactive.	/	Acceptable. According to the composition, the product does not contain self reactive compounds. As stated in CLP regulation, it can be assumed that the product is not a self reactive mixtures.
Pyrophoric liquids	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015	/	Not performed as none of its compounds is pyrophoric.	/	Not applicable since the product is an aerosol. Moreover, no compounds in the product are considered as pyrophoric.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
	section 2.9 (ECHA)				
Pyrophoric solids	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.10 (ECHA)	/	Not performed as the product is not a solid.	/	Not applicable since the product is an aerosol. Moreover, no compounds in the product are considered as pyrophoric.
Self-heating substances and mixtures	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.11 (ECHA)	/	Not performed as none of its compounds is self-heating.	/	Acceptable since the product does not contain self heating substances.
Substances and mixtures which in contact with water emit flammable gases	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.12 (ECHA)	/	Not performed as the chemical structures of the substances contained in the mixture do not contain metals or metalloids.	/	Acceptable according to the justification for non submission defined in CLP regulation.
Oxidising liquids	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.13 (ECHA)	/	Not performed as none of its compounds is oxidising.	/	Acceptable. Regarding the composition (liquid formulation), the product does not contain oxidising substances. Therefore, as stated in CLP regulation, it can be assumed that the product (liquid part) has no oxidising properties.
Oxidising solids	Guidance on the Application of the	/	Not performed as the product is not a solid.	/	Not applicable since the product is not a solid.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
	CLP Criteria Version 4.1 – June 2015 section 2.14 (ECHA)				
Organic peroxides	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.15 (ECHA)	/	Not performed as none of its components contain a bivalent -O-O- structure.	/	Not applicable. The product does not contain organic peroxydes.
Corrosive to metals	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.16 (ECHA)	/	Not performed as none of its components is corrosive to metals.	/	No test was provided according to CLP. Nevertheless, eCA considers that the product is not corrosive to metals for the following reasons: - no compound in the product is classified as corrosive -an anti-corrosive agent is introduced. - Compatibility with metal can after accelerated storage has been demonstrated and no modifications in the state of the packaging was noticed (loss of weight<0.1%). - The product does not contain acids, bases nor complexing agents. - only a slight content of hagolen is present (<0.2%) - the pH is nearly neutral (approx. 6).

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
Auto-ignition temperatures of products (liquids and gases)	EC method A.15	Spray Insecticide pour l'habitat, batch 155202	Liquid fraction: 411°C (n=5)	16-901074-015 ([redacted] 2015) GLP	Acceptable. The product (liquid fraction) is not auto flammable up to 411°C. Results are acceptable according to CLP criteria.
Relative self-ignition temperature for solids	Guidance on the BPR: Volume I. Part A Chapter III: Requirements for Biocidal Products Version 1.1 November 2014 section 4.17.2	/	Not performed as the product is not a solid.	/	Not applicable.
Dust explosion hazard	Guidance on the BPR: Volume I. Part A Chapter III: Requirements for Biocidal Products Version 1.1 November 2014 section 4.17.3	/	Not performed as the product is neither a solid nor able to produce dust.	/	Not applicable.

Meta SPC 2 - FOGGER INSECTICIDE FOR HOUSEHOLDS

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	
Explosives	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.1 (ECHA)	/	Not performed as none of its compounds is an explosive.	/	Acceptable. According to the composition, the product does not contain explosive compounds. As stated in CLP regulation, it can be assumed that the product is not explosive.
Flammable gases	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.2 (ECHA)	/	Not performed as aerosols do not fall additionally within the scope of Sections 0 (flammable gases), 0 (gases under pressure), 0 (flammable liquids) and 2.7 (flammable solids).	/	Not applicable. A specific classification has been defined for aerosol (see below).
Flammable aerosols	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 Section 2.3 Aerosols (ECHA)	/	H222 and H229 Category 1, GHS02, Danger	/	The applicant has not provided a test. However, by default, the classification H222 and H229 Category 1, GHS02, Danger has been proposed in the FDS for this product.
Oxidising gases	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.4 (ECHA)	/	Not performed as the product is not a gas.	/	Not applicable.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
Gases under pressure	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.5 (ECHA)	/	Not performed as aerosols do not fall additionally within the scope of Sections 0 (flammable gases), 0 (gases under pressure), 0 (flammable liquids) and 2.7 (flammable solids).	/	Not applicable. A specific classification has been defined for aerosol (see point for flammable aerosols).
Flammable liquids	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.6 (ECHA)	/	Not performed as aerosols do not fall additionally within the scope of Sections 0 (flammable gases), 0 (gases under pressure), 0 (flammable liquids) and 2.7 (flammable solids).	/	No results were provided for the liquid part. Nevertheless, the product is an aerosol and is already classified as flammable.
Flammable solids	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.7 (ECHA)	/	Not performed as aerosols do not fall additionally within the scope of Sections 0 (flammable gases), 0 (gases under pressure), 0 (flammable liquids) and 2.7 (flammable solids).	/	Not applicable since the product is an aerosol.
Self-reactive substances and mixtures	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.8 (ECHA)	/	Not performed as none of its compounds is self-reactive.	/	Acceptable. According to the composition, the product does not contain self reactive compounds. As stated in CLP regulation, it can be assumed that the product is not a self reactive mixture.
Pyrophoric liquids	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015	/	Not performed as none of its compounds is pyrophoric.	/	Not applicable since the product is an aerosol. Moreover, no compounds in the product are considered as pyrophoric.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
	section 2.9 (ECHA)				
Pyrophoric solids	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.10 (ECHA)	/	Not performed as the product is not a solid.	/	Not applicable since the product is an aerosol. Moreover, no compounds in the product are considered as pyrophoric.
Self-heating substances and mixtures	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.11 (ECHA)	/	Not performed as none of its compounds is self-heating.	/	Acceptable since the product does not contain self heating substances.
Substances and mixtures which in contact with water emit flammable gases	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.12 (ECHA)	/	Not performed as the chemical structures of the substances contained in the mixture do not contain metals or metalloids.	/	Acceptable according to the justification for non submission defined in CLP regulation.
Oxidising liquids	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.13 (ECHA)	/	Not performed as none of its compounds is oxidising.	/	Acceptable. Regarding the composition (liquid formulation), the product does not contain oxidising substances. Therefore, as stated in CLP regulation, it can be assumed that the product (liquid part) has no oxidising properties.
Oxidising solids	Guidance on the Application of the	/	Not performed as the product is not a solid.	/	Not applicable since the product is not a solid.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
	CLP Criteria Version 4.1 – June 2015 section 2.14 (ECHA)				
Organic peroxides	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.15 (ECHA)	/	Not performed as none of its components contain a bivalent -O-O- structure.	/	Not applicable. The product does not contain organic peroxydes.
Corrosive to metals	Guidance on the Application of the CLP Criteria Version 4.1 – June 2015 section 2.16 (ECHA)	/	Not performed as none of its components is corrosive to metals.	/	No test was provided according to CLP. Nevertheless, eCA considers that the product is not corrosive to metals for the following reasons: - no compound in the product is classified as corrosive -an anti-corrosive agent is introduced. - Compatibility with metal can after accelerated storage has been demonstrated and no modifications in the state of the packaging was noticed (loss of weight<0.1%). - The product does not contain acids, bases nor complexing agents. - only a slight content of hagolen is present (<1%) - the pH is nearly neutral (approx. 5).

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	RMS evaluation
Auto-ignition temperatures of products (liquids and gases)	EC method A.15	Diffuseur insecticide pour l'habitat, batch 155201	Liquid fraction : 359°C (n=5)	16-901074-016 ([redacted] 2016) GLP	Acceptable. The product (liquid fraction) is not auto flammable up to 359°C. Results are acceptable according to CLP criteria.
Relative self-ignition temperature for solids	Guidance on the BPR: Volume I. Part A Chapter III: Requirements for Biocidal Products Version 1.1 November 2014 section 4.17.2	/	Not performed as the product is not a solid.	/	Not applicable.
					Not applicable.

Conclusion on the physical hazards and respective characteristics of the products
The product INSECTICIDE HOUSEHOLDS SPRAY and FOGGER INSECTICIDE FOR HOUSEHOLDS are not considered explosive nor having oxidizing properties and are not auto flammable in the conditions of uses. The product is classified by default H222 and H229 Category 1, GHS02, Danger.

Conclusion on the physico chemical dangers of the biocidal family product

Physico chemical dangers have been assessed for both products. They are classified by default H222 and H229 Category 1. The products of this family are not explosive, do not possess oxidizing properties and are not autoflammable in the conditions of uses.

Conclusion on the physico chemical dangers related to the range of the biocidal family is confidential and is presented in annex.

2.2.4 Methods for detection and identification

Analytical methods for the determination of the active substance in the biocidal products

Meta SPC 1 - INSECTICIDE HOUSEHOLD SPRAY

Test item: Spray insecticide pour l'habitat, batch 160401
Blank formulation 80050794 spray insecticide pour l'habitat, batch 160402

Principle: samples are extracted with acetone. Final determination is performed using GC-FID using a Phenomenex column Zebron ZB-1.
Note that the determination has been performed in the liquid part of the product. Therefore, the content of a.i in the biocidal product is the one without taking account of the propellant (0.011% of S-Methoprene and 0.95% of permethrin)

Analytical methods for the analysis of the active substance in the product insecticide household spray								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Reference**
					Acceptable range	Mean (test item fortified)	RSD (n=5) Test item not fortified	
S-Methoprene	Assay validate method R16-901074-003	N=5 in duplicate (from 12.40 to 3651mg/L, eq to 50-150% of niminal concentration in the product)	The response of the detector during the analysis of S-Methoprene was linear (y = 114x + 18.7; r = 0.9994)	Chromatograms provided for calibration standards, blank formulation, test item and solvent. No inferferences were noticed.	Fortification at 0.012% w/w (approx 26 mg/L in solution before analysis) 90%-110% according to SANCO3030/ 99/ rev.4	104.9% (mean of two values for the first reconsituted samples) 104.9% (mean of two values for the second reconsituted samples)	RSD=1.59%for precision (5 samples of test item injected twice); mean=0.0129%w/w (approx 26 mg/L in solution before analysis) RSD=1.84% for reproductibility (2 series with n=5 in duplicate on different days and operators); mean=0.0126%	R16-901074-003

							w/w (approx 26 mg/L in solution before analysis)	
Permethrin (sum of cis and trans isomers)	Assay validate method R16-901074-003	N=5 in duplicate (245.80 to 719.34mg/L, eq to 50 -150% of nominal concentration in the product)	The response of the detector during the analysis of permethrin was linear (y = 125x - 2080; r = 0.9999)	Chromatograms provided for calibration standards, blank formulation, test item and solvent. No inferferences were noticed.	Fortification at 0.95% w/w (approx 460 mg/L in solution before analysis) : 95-105% according to SANCO3030/ 99/ rev.4	98.7% (mean of two values for the first reconsituted samples) 99.3% (mean of two values for the second reconsituted samples)	RSD=1.58% for precision (5 samples of test item injected twice); mean=0.953%w/w (approx 470 mg/L in solution before analysis) RSD=1.81% for reproductibility (2 series with n=5 in duplicate on different days and operators); mean=0.953%w/w (approx 470 mg/L in solution before analysis)	R16-901074-003
Cis-permethrin	Assay validate method R16-901074-003	N=5 in duplicate (66.67 to 194.88mg/L, eq 50-150% of nominal concentration in the product)	The response of the detector during the analysis of cis-permethrin was linear (y = 139x – 525; r = 0.9999)	Chromatograms provided for calibration standards, blank formulation, test item and solvent. No inferferences were noticed.	Fortification at 0.258% w/w: 95%-105% (approx 120 mg/L in solution before analysis) according to SANCO3030/ 99/ rev.4	98.6% (mean of two values for the first reconsituted samples) 99.1% (mean of two values for the second reconsituted samples)	RSD=1.33% for precision (5 samples of test item injected twice); mean=0.258%w/w (approx 130 mg/L in solution before analysis) RSD=1.61% for reproductibility (2 series with n=5 in duplicate on	R16-901074-003

							different days and operators); mean=0.258% w/w (approx 130 mg/L in solution before analysis)	
Trans-permethrin	Assay validate method R16-901074-003	N=5 in duplicate (179.11 to 524.45mg/L, eq 50-150% of nominal concentration in the product)	The response of the detector during the analysis of trans-permethrin was linear (y = 120x – 1550; r = 0.9999).	Chromatograms provided for calibration standards, blank formulation, test item and solvent. No inferferences were noticed.	Fortification at 0.694% w/w (approx 330 mg/L in solution before analysis) 95%-105% according to SANCO3030/ 99/ rev.4	98.8% (mean of two values for the first reconsituted samples) 99.4% (mean of two values for the second reconsituted samples)	RSD=1.70% for precision (5 samples of test item injected twice); mean=0.694%w/w(approx 350 mg/L in solution before analysis) RSD=1.90% for reproductibility (2 series with n=5 in duplicate on different days and operators); mean=0.695%w/w (approx 350 mg/L in solution before analysis)	R16-901074-003

Ratio permethrin :

- Mean=27.11% for Cis permethrin
- Mean=72.89% for trans permethrin

It should be noticed that the analytical method does not allow to determine each enantiomer of methoprene since no chiral column is used. Nevertheless, the active substance does not isomerize naturally into the R enantiomer. Therefore, the method for the determination of S-methoprene in the product is acceptable.
According to the Assessment report of permethrin, analytical method for the determination of each enantiomer of cis and trans permethrin is required.

Meta – SPC 2 FOGGER INSECTICIDE FOR HOUSEHOLDS

Test item: diffuseur insecticide pour l'habitat, batch 160302
Blank formulation 80070034 spray insecticide pour l'habitat, batch 80070034

Principle: samples are extracted with acetone. Final determination is performed using GC-FID using a Phenomenex column Zebron ZB-1.
Note that the determination has been performed in the liquid part of the product. Therefore, the content of a.i in the biocidal product is the one without taking account of the propellant (0.30% of S-Methoprene and 10.13% of permethrin)

Linearity has not been performed in this study. However, this criteria has been demonstrated during study report R16-901074-003. This is acceptable as contents of a.i in samples solutions are in the linearity range studied.

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 (%)**			**Reference**
					Range	Mean (test item fortified)	RSD (n=5) Test item not fortified	
S-Methopren	Assay validate method R16-901074-007	N=5 in duplicate (12.40 to 3651mg/L) See report R16-901074-003	The response of the detector during the analysis of S-Methoprene was linear (y = 114x + 18.7; r = 0.9994) See report R16-901074-003	Chromatograms provided for calibration standards, blank formulation, test item and solvent. No inferferences were noticed.	Fortification at 0.3% w/w (approx 25mg/L in solution before analysis) 95%-105% according to SANCO3030/99/ rev.4	104.8% (mean of two values for the first reconsituted samples) 104.1% (mean of two values for the second reconsituted samples)	RSD=0.77%for precision (5 samples of test item injected twice); mean=0.313%w/w (approx 25mg/L in solution before analysis) RSD=0.76% for reproductibility (2 series with n=5 in duplicate on different days and operators); mean=0.315% w/w (approx	R16-901074-007

							25mg/L in solution before analysis)	
Permethrin (sum of cis and trans)	Assay validate method R16-901074-007	N=5 in duplicate (12.40 to 3651mg/L) See report R16-901074-003	The response of the detector during the analysis of permethrin was linear (y = 125x - 2080; r = 0.9999) See report R16-901074-003	Chromatograms provided for calibration standards, blank formulation, test item and solvent. No inferferences were noticed.	Fortification at 10% w/w (approx 460mg/L in solution before analysis) 98%-102% according to SANCO3030/99/ rev.4	98.6% (mean of two values for the first reconsituted samples) 100.5% (mean of two values for the second reconsituted samples)	RSD=1.15%for precision (5 samples of test item injected twice); mean=10.04%w/w (approx 460mg/L in solution before analysis) RSD=0.82% for reproductibility (2 series with n=5 in duplicate on different days and operators); mean=10.12 % w/w (approx 460mg/L in solution before analysis)	R16-901074-007
Cis-permethrin	Assay validate method 16-901074-007	N=5 in duplicate (12.40 to 3651mg/L) See report R16-901074-003	The response of the detector during the analysis of cis-permethrin was linear (y = 139x – 525; r = 0.9999) See report R16-901074-003	Chromatograms provided for calibration standards, blank formulation, test item and solvent. No inferferences were noticed.	Fortification at 2.7% w/w (approx 130mg/L in solution before analysis) 97%-103% according to SANCO3030/99/ rev.4	99.1% (mean of two values for the first reconsituted samples) 100.9% (mean of two values for the second reconsituted samples)	RSD=1.10%for precision (5 samples of test item injected twice); mean=2.72%w/w (approx 130mg/L in solution before analysis) RSD=0.80% for reproductibility (2 series with n=5 in duplicate on	R16-901074-007

							different days and operators); mean=2.74% w/w (approx 130mg/L in solution before analysis)	
Trans-permethrin	Assay validate method 16-901074-007	N=5 in duplicate (12.40 to 3651mg/L) See report R16-901074-003	The response of the detector during the analysis of trans-permethrin was linear (y = 120x – 1550; r = 0.9999). See report R16-901074-003	Chromatograms provided for calibration standards, blank formulation, test item and solvent. No inferferences were noticed.	Fortification at 7% w/w (approx 350mg/L in solution before analysis) 97%-103% according to SANCO3030/99/ rev.4	98.4% (mean of two values for the first reconsituted samples) 100.3% (mean of two values for the second reconsituted samples)	RSD=1.17%for precision (5 samples of test item injected twice); mean=7.32%w/w (approx 350mg/L in solution before analysis) RSD=0.83% for reproductibility (2 series with n=5 in duplicate on different days and operators); mean=7.38% w/w (approx 350mg/L in solution before analysis)	R16-901074-007

Ratio permethrin :

- Mean=27.05% for Cis permethrin
- Mean=72.95% for trans permethrin

It should be noticed that the analytical method does not allow to determine each enantiomer of methoprene since no chiral column is used. Nevertheless, the active substance does not isomerize naturally into the R enantiomer. Therefore, the method for the determination of S-methoprene in the product is acceptable.

According to the Assessment report of permethrin, analytical method for the determination of each enantiomer of cis and trans permethrin is required.

Conclusion on the methods for detection and identification of the product
Acceptable. Analytical methods for the determination of active substances in the biocidal products family are validated according to guidance SANCO3030/99/rev.4. Conclusion on the analytical methods related to the range of the biocidal family is confidential and is presented in annex.

Analytical methods for the determination of permethrin residues

A letter of acces from Tagros Chemicals india Ltd to Agrobiothers laboratories has been granted for annex II data of permethrin.

Analytical methods for the determination of permethrin residues in air:
A validated method using HPLC/MS/MS was supplied for analysis of residues of permethrin in air. LOQ = 5 µg/m^3 air.
Another validated method using GC/ECD was supplied for analysis of residues in air. GC-MS/MS was used as a confirmatory method. LOQ = 0.0001 mg/m^3air

Analytical methods for the determination of permethrin residues in soil
A validated method using HPLC/MS/MS was supplied for analysis of residues of permethrin in soil. LOQ = 5.0 µg/kg in soil (permethrin)

Analytical methods for the determination of permethrin residues in water
A validated method using HPLC/MS/MS was supplied for analysis of residues of permethrin in drinking and surface water. LOQ = 0.05 µg/L for drinking and surface water.

Analytical methods for the determination of permethrin residues in food and feeding stuff
Food and feeding stuff will not be exposed to permethrin based on the proposed usage. No data required.

Analytical methods for the determination of permethrin residues in body fluids and tissues
Permethrin does not classify as toxic or highly toxic.

Analytical methods for the determination of S-Methoprene residues

A letter of access from Babolna Bio Ltd to Agrobiothers laboratories has been granted for annex II data of S-Methoprene.

Analytical methods for the determination of S-Methoprene residues in soil, food and feeding stuff
Analytical methods for determination of S-Methoprene in soil, food and foodstuffs were not submitted based on the specific use of the product (grain bait) of the CAR. Concerning the biocidal product family supported, food, feeding stuff and soil should not be exposed to S-Methoprene based on the proposed usage.

Analytical methods for the determination of S-Methoprene residues in water
An acceptable method was supplied for analysis of residues of parent S-Methoprene in surface, ground and drinking water to an LOQ of 0.1µg/L.

Analytical methods for the determination of S-Methoprene residues in air
A method for residues in air is not required based on the results of the vapour pressure study (v.p. <0.01 Pa) and the type of formulation of the representative product for the AS approval. In the CAR of S-Methoprene, the following results were reported:
Vapour Pressure: Pa at 20°C (OECD 104 – Effusion Method):
V.P. = 6.23x10^{-4} Pa at 20°C (0.623mPa)
V.P. = 1.08x10^{-3} Pa at 20°C (0.108mPa)

However, regarding the nature of the formulation for INSECTICIDES FOR HOME USE products (aerosol dispensers, so the active substance is sprayed), an analytical method for the determination of S-Methoprene residues in air with a LOQ≤0.023mg/m^3 (AOEL=0.076mg/kg/d) is needed. A new method has been provided by the applicant and is described below.

Because the molecule is not classified as either toxic or very toxic, a method for residues in body fluids and tissues is not required.

Title: Monitoring of S-Methoprene residues in the air after using biocide fogger, [redacted], 2017 Report: No QL2017-0495 Test facility: QUAD LAB, 26 Rue Leonard de Vinci, 91090, LISSES, France GLP: Yes

Test item : diffuseur insecticide pour l'habitat, batch 320E

Principle :

Virgin filters are doped with a solution of S-Methoprene. Residues are then extracted with ethanol by shaking for 1 hour. Determination is performed using HPLC-UV (360nm) using a C18 gemini column and GC-MS (Electron impact, m/z 111 and 73) using a ZB-5 column.

The back section is analyzed primarily to determine the extent of sample saturation. The filter is considered saturated when 5% of the amount found on the front section is found on the back section of the sampler, indicating if there is a lost during the analysis.

For repeatability, the method is performed following a test in real conditions: the fogger is place in the middle of chamber. 4 doubles filters are connecting with programmed pump (each pump is programmed to start and stop at different time). The fogger is switched 2 minutes (duration of spraying) before the start of the first pump. Pump 1 is samplings air during the first hour after spraying (pump 2 between 1h and 2h, pump 3 during 2h and 3h, pump 4 during 3h and 4h). Filters are then desorbed with ethanol and shaken for 1 hour, then residues are determined with HPLC-UV or GC-MS.

Findings

Specificity
Chromatograms have been provided for matrix matched calibration standards (doped filter), control filters, blank air sample before spraying and fortified samples at LOQ. Interferences were below 30% of the LOQ. Specificity is acceptable.

Linearity
Linearity was performed using with 5 calibration standards ranging from 1.2 to 300 µg/filters (eq to 0.02-5mg/m^3). Regression were linear (HPLC-UV) or quadratic (GC-MS) with a correlation coefficient >0.99. Linearity is acceptable for each detection mode.

Accuracy

Accuracy has been performed with filters fortified at different levels. 5 samples per level have been analysed at LOQ and one for other level. Results are presented hereunder:

Analyte	**Fortification levels (µg/filter)**	**Recovery (%)**	**Mean recovery (%)**	**RSD (%)**
S-Methoprene	1.2 (0.025µg/m^3)	122/127/123/126/125	125	1.75
	1.17	117.1	-	-
	2.92	102.4	-	-
	11.67	102.5	-	-
	58.36	101.8	-	-
	291.80	103.8	-	-
	583.60	99.6	-	-

According to Echa guidance on the BPR and guidance SANCO825/00/rev8.1 (2010), accuracy should be performed with samples fortified at two levels and 5 replicates per level. Therefore, accuracy is not fully validated. Additionally, some spiked levels are not in the linearity range which means that results cannot be considered as reliable.

Precision

Five essays of sampling air after spraying biocide fogger are realized. For each step of sampling, the five repetitions are compared and a RSD is determined.

	Result of quantification (µg/sample) – HPLC-UV				
	level 1 (t=0)	Level 2 (after approx. 3h treatment)	Level 3 (after approx. 4h treatment)	Level 4 (after approx. 5h treatment)	Level 5 (after approx. 6h treatment)
Rep 1	n.d	22.287	5.508	1.618	Trace <1.2
Rep 2	n.d	22.125	5.504	1.621	Trace <1.2
Rep 3	n.d	27.952	4.62	Trace <1.2	Trace <1.2
Rep 4	n.d	28.049	4.592	Trace <1.2	Trace <1.2
Rep 5	n.d	22.132	5.522	1.569	Trace <1.2
Mean	-	24.5096	5.1492	-	-
RSD	-	11.39%	8.44%	-	-

	Result of quantification (µg/m³) – HPLC-UV				
	level 1 (after approx. 7-8h)	Level 2 (after approx. 10h)	Level 3 (after approx. 11h)	Level 4 (after approx. 12h)	Level 5 (after approx. 13h)
Rep 1	n.d	0.377	0.093	0.027	<0.02
Rep 2	n.d	0.372	0.093	0.028	<0.02
Rep 3	n.d	0.472	0.078	<0.02	n.d
Rep 4	n.d	0.474	0.078	<0.02	n.d
Rep 5	n.d	0.372	0.093	0.027	<0.02
Mean	-	24.5096	5.1492	-	-
RSD	-	11.39%	8.44%	-	-

Confirmation was also performed with GC-MS and compared with HPLC-UV (for the first assay at each time point only).

	Result of quantification (µg/sample)		
	HPLC-UV	GC-MS	Gap (%)
Level 1	n.d	n.d	-
Level 2	22.29	20.99	-2.47
Level 3	5.51	5.66	-2.72
Level 4	1.62	1.66	5.83
Level 5	Trace <1	Trace <1	-

However, repeatability should be performed with spiked samples. Data provided by the applicant are related to the level of S-Methoprene in air following different times of spraying in the treated chamber. Therefore, the content of S-Methoprene is not known accurately. According to ECHA guidance on the BPR and guidance SANCO825/00/rev8.1 (2010), repeatability of the method should be done with 5 fortified samples at 2 known levels with S-Methoprene. According to the results for accuracy, precision is acceptable at LOQ. However, another level should be studied.

LOQ

The limit of quantification is 0.025µg/m^3 for S-methopren in air. However, a second fortified level should be studied.

Breakthrough

No data was submitted. For such method (determination of active ingredients in air), it should be demonstrated that there are no leak and no potential loss of active substance on the filters (resins) after passage of a defined volume of air (>100L) for at least 6 hours.

Conclusion
Analytical method for the determination of S-Methoprene in air is not fully validated according to guidance SANCO3030/99/rev.4. **Accuracy and precision should be performed with fortified samples at two levels and with 5 samples per level. Moreover, some level tested for accuracy are not in the linearity range. Additionally, data on breakthrough should be provided in order to demonstrate there are no leaks during the extraction of residues (containing in air samples) on the filters.**
Therefore, the validation of the method should be performed again to be in accordance with the criteria set in Echa guidance on the BPR and guidance SANCO825/00/rev8.1 (2010). New data have been generated to cover this data gap and results are reported below.

Title: Monitoring of S-methoprene residues in the air after using biocide fogger, [redacted], 2018
Report: QL2018-1228
Test laboratory: QUAD LAB, 26 Rue Leonard de Vinci, 91090 LISSES, France
GLP: Y

Principle: the same method as in report QL2017-495 is used. Virgin filters are doped with a solution of S-Methoprene. Residues are then extracted with ethanol by shaking for 1 hour. Determination is performed using HPLC-UV (360nm) using a C18 Gemini column.

Test substance: S-methoprene, standard with a min purity of 97.9%

Validation

Specificity
Chromatograms have been provided for matrix matched calibration standards (doped filter), control filters, blank air sample before spraying and fortified samples at LOQ. Interferences were below 30% of the LOQ. Specificity is acceptable.

Linearity
Linearity has been performed using 6 calibration standards ranging from 1.2 to 300µg/samples (equivalent to 0.02-5mg/m^3). Regression was linear with a correlation coefficient >0.99. Linearity is acceptable.

Accuracy
Accuracy has been performed using samples fortified at three levels.

Matrix	Fortification level (µg/sample)	Recoveries (%)	Mean (%)	RSD (%)
Air	38.89 (eq to 0.8µg/m^3)	95.67; 93.43; 97.42; 93.56; 90.25	94.07	2.86
Air	10.37 (eq to 0.2mg/m^3)	96.57; 94.40; 91.29; 93.98; 93.15	93.70	2.17

Air	1.04 (eq to 0.02mg/m^3)	96.38; 98.18; 92.98; 93.27; 96.73	95.60	2.44

Precision
According to the previous table, RSD were in acceptable range.

LOQ
The limit of quantification is 38.89 µg/samples, which is equivalent to 0.023mg/m^3 for S-méthoprène in air.

Breakthrough
2 replicates of filters are fortified at two levels, with S-methoprene standard. The solutions of level 1 and level 3 of the accuracy/repeatability test are used. A volume of 360L is passed through filters (1L/min during 6 hours). Good recoveries were obtained and no significant breakthrough was noticed.

Conclusion
The method is suitable for the determination of S-methoprene in air with a LOQ=0.02mg/m^3. The LOQ is in accordance with AEL (0.076mg/kg bw/day, equivalent to 0.023mg/m^3).

Conclusion on the methods for detection and identification of the product
Letters of access to Annex II data have been provided for permethrin and S-Methoprene. Methods are fully validated in the CAR of the active substances. A fully validated method for the determination of S-methoprene in air has been submitted and is validated according to ECHA guidance on the BPR and SANCO 825/00/rev8.1.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

MG 03: Pest Control

Product Type 18: Insecticides, acaricides and products to control other arthropods.
The products of the family INSECTICIDES FOR HOME USE are ready to use products used by non-professional users for treatment against fleas, ticks and mosquitoes indoor.

The family is separated in two META-SPCs:

- META-SPC1: the product INSECTICIDE HOUSEHOLD SPRAY (ready-to-use sprayer) is intended to be used on porous and non-porous surfaces by non-professional users
- META-SPC2: the product FOGGER INSECTICIDE FOR HOUSEHOLDS (one-shot aerosol) is intended to be used on porous and non-porous surfaces by non-professional users

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

According to the uses claimed by the applicant, the products of the family INSECTICIDES FOR HOME USE are used by non-professional users for the control of infestation of fleas, ticks and mosquitoes on carpets, rugs and fabrics in indoor environment.

The specific target organisms to be controlled are:

- Fleas (adults and larvae):e.g. *Ctenocephalides felis*

- Ticks : *Ixodes ricinus* and *Rhipicephalus sanguineus*
- Mosquitoes (adults): *Aedes spp*. and *Culex spp.*

2.2.5.3 Effects on target organisms, including unacceptable suffering

On adults insects, the product cause excitation followed by locomotor incoordination, instability and paralysis. Afterwards, the insects can recover or on the contrary fall in lethargy and die. This activity is brought by the permethrin
On immature stage (larvae), due to the presence of (S)-methoprene, the product leads to larvae death by disrupting their normal development.

2.2.5.4 Mode of action, including time delay

(S)-methoprene is a insect growth regulator (IGR) from the class of juvenile hormone analogues; it inhibits the development of the immature stages of insects. Mimicking the action of juvenile hormone, the compound causes impaired development and death of immature stages. Moreover, (S)-methoprene can include ovicidal activity, due to either its direct penetration into the shell flea eggs which have been laid or its absorption through the cuticle of the adult fleas. This one is not claimed in this dossier

Permethrin is a type 1 pyrethroid substance. Pyrethroids in general show a high potency and selectivity towards insects, especially in comparison to mammals. It is taken up by insects and arthropods via the whole body surface from where it spreads in the body.
Permethrin is a neurotoxic insecticide that affects the voltage-gated sodium channels (type I axonic poison) within the nervous system of insects upon contact with the substance.
Permethrin binds to the sodium channel triggering continuous stimulation ("hyperexcitation") of the respective nerve. Therefore, it affects both the peripheral and central nervous system.

Permethrin acts on the nervous system in several ways, e.g. by slowing action potential decay and inducing repetitive discharges in motor and sensory axons. This is due to the fact that Permethrin slows the kinetics of opening and closing of Na channels.
Permethrin may also exhibit a mild contact repellent effect in conjunction with the insecticidal effect. This contact repellence effect is also common to other pyrethroid insecticides (such as deltamethrin, cypermethrin, esfenvalerate and lambda-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.

2.2.5.5 Efficacy data

For the META-SPC 1:
The tests have been performed with the product INSECTICIDE HOUSEHOLD SPRAY:
French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the product INSECTICIDE HOUSEHOLD SPRAY according to the uses and the application rate claimed:

- Regarding the efficacy claim against mosquitoes (*Aedes spp*. and *Culex spp*. adults):
  - The product is efficient according the requirements of the TNsG on product evaluation for PT18/19 (2012), at the application rate of 2.1 g product /m², on porous and non-porous surfaces, with a Kd 100 of 15 minutes and a mortality of 100 % 24 hours after the treatment. A residual efficacy is also demonstrated until 3 months (Kd100: 1 hour, 100 % of mortality after 24 hours) in laboratory conditions. The residual efficacy at 6 months is not demonstrated as the mortality efficacy criterion is not met.

- In the semi-field test, a mortality of 100 % is observed after 24 hours on porous and non-porous surfaces until 6 months.

- Regarding the efficacy claim against fleas (e.g. *Ctenocephalides felis*, adults and larvae):
  - The product is efficient according to the requirements of the TNsG on product evaluation for PT18/19 (2012), at the application rate of 2.1 g product /m², on porous and non-porous surfaces, with a Kd 100 of 1 hour for adults, 30 minutes for larvae. A mortality of 100 % is observed 24 hours after the treatment. A residual efficacy is also demonstrated until 3 months (Kd100: 4 hours, 100% of mortality after 24 hours) in laboratory conditions. The residual efficacy at 6 months is not demonstrated as the mortality efficacy criterion is not met.
  - In semi field test, a mortality of 100% is observed after 24 hours on porous and non-porous surfaces until 6 months. It should be noted that in this efficacy study, the content of active substance in the formulation has been presented without taking into account the propellant in the calculation. Taking into account the proprellant, the concentration of active susbtances in the end product are 0.0021% S-Methopren and 0.165% Permethrin

- Regarding the efficacy claim against ticks (*Ixodes ricinus* and *Rhipicephalus sanguineus*):
  - The product is efficient according to the requirements of the TNsG on product evaluation for PT18/19 (2012), on Ixodes ricinus at the application rate of 2.1 g product /m², on porous and non-porous surfaces, with a Kd 100 of 2 hours and a mortality of 100 % 24 hours after the treatment. A residual efficacy is also demonstrated until 3 months (Kd100: 2 hours, 100% of mortality after 24 hours) in laboratory conditions. The residual efficacy at 6 months is not demonstrated as the mortality efficacy criterion is not met (100 % mortality at 24 hours).
  - A semi-field test demonstrated that for both species claimed, no blood-feed tick was observed after one hour of exposure. Kd 100 and 100 % of mortality are observed until 6 months. For Rhipicephalus sanguineus, it has to be noted that a laboratory efficacy study is missing according to the requirements of the TNsG on product evaluation for PT18/19 (2012). Nevertheless, FR CA consider that the laboratoty test can be waived as the efficacy is demonstrated in a semi-field test with conditions very closed to the real use with unambiguous results and 5 replicates performed.

Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC1							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
MG 3, Pest control	PT 18 Insecticide	Spray insecticide pour l'habitat/ INSECTICIDE HOUSEHOLD SPRAY (0.0022 % w/w S-Methoprene , 0.177 % w/w permethrin) Batch 155202	*Aedes aegypti* (adult females 2-4 days) *Culex pipiens* adult females 2-4 days) *Ixodes ricinus* (adult mixed sex 1-2 weeks) *Ctenocephalides felis* (larvae; adults mixed sex 1-2 weeks) For each mode of treatment and replicate 25 of each species 4 replicates	Lab test CEB 135 / 159 No choice test	Average conditions of a warehouse with typical surfaces treated measured 15 cm X 15 cm (carpet (100 % polyamide, 1420 g/m², height of the fibres = 4.5 mm and ceramic tiles) Constant temperature between 24 et 26 °C Relative humidity 70% ± 5% Photoperiod: 16h light / 8 h dark 1 hour of exposure time Direct spray: The application rate used (3.2 g/m²) was higher than the claimed one (2.1 g product / m²), then the results have not been taken into account. Controls were performed on typical surfaces untreated Residual efficacy The application rate used was 2.1 g/m²	**Direct spray trial :** Kd100: 1 min for mosquitoes, 5 min for ticks and fleas. 100 % mortality at 24 hours **Residual spray at 3 months:** Kd100: 1 hour for mosquitoes, 2 hours for ticks and 4 hours for fleas. 100 % of mortality at 24 hours **Residual spray at 6 months:** Mortality within 24h: < 44% for mosquitoes, 0 % for ticks, < 3 % for fleas Mortality in the controls: less than 2% ➔ **Residual efficacy demonstrated until 3 months on all the targets at the application rate of 2.1 g/m² in laboratory conditions (porous and non-porous surfaces). Residual efficacy until 6 months is not demonstrated.**	[redacted] 2016 *2033a/0116R* RI=1
MG 3, Pest control	PT 18 Insecticide	Spray insecticide pour l'habitat (0.0022 % w/w S-Methoprene , 0.177 % w/w permethrin) Batch 155202	*Aedes. aegypti* *Culex. pipiens* (adult females 2-4 days) *Ixodes. ricinus* (adult mixed sex 1-2 weeks) *Ctenocephalides. felis* (larvae; adults mixed sex 1-2 weeks)	Lab test CEB 135 / 159 No choice test	Room of 60 m^3 Average conditions of a warehouse with typical surfaces treated measured 15 cm X 15 cm (carpet (100 % polyamide, 1420 g/m², height of the fibres = 4.5 mm and ceramic tiles) Constant temperature: 24 - 26 °C Relative humidity: 70% ± 5% Photoperiod: 16h light / 8 h dark 1 hour of exposure time Controls were performed on typical surfaces untreated	Kd100: 15 minutes for mosquitoes, 2 hours for ticks, 1 hour for adult fleas and 30 minutes for larvae fleas. A mortality of 100% is observed after 24 hours. Mortality in the controls: less than 3% ➔ **Direct spray application: efficacy demonstrated at the application rate of 2.1 g/m² on all the target organisms in lab conditions (porous and non-porous surfaces)**	[redacted] 2016 *2033a2/0116R* RI=1

			25 of each species 4 replicates		Direct spray: 2.1 g product / m²		
MG 3, Pest control	PT 18 Insecticide	Spray insecticide pour l'habitat (0.0022 % w/w S-Methoprene , 0.177 % w/w permethrin) Batch 023F	*Aedes. aegypti* *Culex pipiens* (50 adult females, 2-4 days, for each species) *Ixodes ricinus* + *R. sanguineus* (50 mixed sex adult 1-2 weeks, for each species) *Ctenocephalides felis* (50 larvae; 50 adults mixed sex 1-2 weeks) 5 replicates for each species.	Semi-field test CEB 135bis	Room of 30 m^3 (12 m² floor – 3 m long x 4 m wide x 2.5 m high). Treated panels were set on the floor of the test chamber. These panels were constituted of two materials (varnished wood (non-porous) and carpet (porous). The treated tiles were covering 2 m² of the floor (ratio 16.7%). Food and water sources were not on the treated surfaces. Pests were able to reach water and food sources without being in contact with the treated surfaces. For ticks, a blood meal target was set in the test chamber on the treated area to measure if the ticks were knocked-down fast enough before biting this target. Kd was determined 1 hour after the introduction of ticks. Mortality was determined after 24 hours for all tested targets. After the trial, the room was vigorously washed. Untreated control: the same procedure was used but with untreated panels (5 replicates) The persistence was determined by using the same protocol, by reintroducing panels after 3, 5 and 6 months Constant temperature between 22 °C ± 1 Relative humidity: 60% ± 5% Smooth ventilation <1 m3/h Photoperiod: 8 h light / 16 h dark	**<u>For mosquitoes:</u>** Less than 2 % mortality is observed in the controls at day 0 to 6 months. 100% mortality is observed on porous and non-porous surfaces until 6 months. **<u>For fleas:</u>** No mortality was observed in the controls at day 0 until 6 months. 100% mortality is observed on porous and non-porous surfaces until 6 months. **<u>For ticks:</u>** No mortality was observed in the controls except one (2%) at 3 months In the control, blood-fed ticks and no Kd were observed. In the treated series, no blood-fed ticks were observed at D0 until 6 months. 100 % kd after one hour of exposure, and 100 % mortality within 24h until 6 months. ➔ **This study demonstrates the efficacy of the product on all the target organisms at the application rate of 2.1 g product / m², until 6 months.**	[redacted] 2017 2194a/0217R RI=2

					1 hour of exposure time. 2.1 g product / m²		

For the META-SPC 2:

The tests have been performed with the product FOGGER INSECTICIDE FOR HOUSEHOLDS:
French competent authorities considered that the data submitted in the dossier demonstrated the efficacy of the product FOGGER INSECTICIDE FOR HOUSEHOLDS according to the uses and the application rate claimed:

- Regarding the efficacy claim against mosquitoes (*Aedes spp*. and *Culex spp*. adults):
    - The product is efficient according the requirements of the TNsG on product evaluation for PT18/19 (2012), at the application rate of 150 mL product / 70 m², on porous and non-porous surfaces, with a Kd 100 of 15 minutes and a mortality of 100 % 24 hours after the treatment. A residual efficacy is also demonstrated until 3 months (Kd100: 1 hour, 100 % of mortality after 24 hours) in laboratory conditions. The residual efficacy at 6 months is not demonstrated as the mortality efficacy criterion is not met
    - In the semi-field test, a mortality of 100 % is observed after 24 hours, on porous and non-porous surfaces until 6 months.

- Regarding the efficacy claims against fleas (e.g. *C. felis*, adults and larvae):
    - The product is efficient according to the requirement of the TNsG on product evaluation for PT18/19 (2012), at the application rate of 150 mL product / 70 m², on porous and non-porous surfaces, with a Kd 100 of 15 minutes for adults and larvae. A mortality of 100 % is observed 24 hours after the treatment. A residual efficacy is also demonstrated until 3 months (Kd100: 4 hours, 100% of mortality after 24 hours) in laboratory conditions. The residual efficacy at 6 months is not demonstrated as the mortality efficacy criterion is not met
    - In the semi-field test, a mortality of 100 % is observed after 24 hours on porous and non-porous surfaces until 6 months.

- Regarding the efficacy claims against ticks (*I. ricinus* and *R. sanguineus*):
    - The product is efficient according to the requirement of the TNsG on product evaluation for PT18/19 (2012), on I. ricinus at the application rate of 150 mL product / 70 m², on porous and non-porous surfaces, with a Kd 100 of 15 minutes and a mortality of 100 % 24 hours after the treatment. A residual efficacy is also demonstrated until 3 months (Kd100: 2 hours, 100% of mortality after 24 hours) in laboratory conditions. The residual efficacy at 6 months is not demonstrated as the mortality efficacy criterion is not met.
    - A semi-field test, demonstrated that for both species claimed, no blood-feed tick was observed after one hour of exposure. Kd 100 and 100 % of mortality are observed until 6 months. For R. sanguineus, it has to be noted that a laboratory efficacy study is missing according to the requirements of the TNsG on product evaluation for PT18/19 (2012). Nevertheless, FR CA consider that the laboratoty test can be waived as the the efficacy is demonstrated in a semi field test with conditions very closed to the real use with unambiguous results and 5 replicates performed.

Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC2							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
MG 3, Pest control	PT 18 Insecticide	FOGGER INSECTICIDE FOR HOUSEHOLDS / Diffuseur insecticide pour l'habitat (0.026% w/w S-Methoprene 0.87 % w/w permethrin) Batch 155201	*Aedes aegypti.* *Culex pipiens* (adult females 2-4 days) *Ixodes ricinus* (adult mixed sex 1-2 weeks) *Ctenocephalides felis* (larvae; adults mixed sex 1-2 weeks) 25 of each species for each mode of treatment and replicate 4 replicates	Lab test CEB 135bis No choice test	Room of 70 m² // 175 m³ (10 m long x 7 m wide x 2.50 m high). 4 tiles (15 x 15 cm) of two materials (carpet (100 % polyamide, 1420 g/m², height of the fibres = 4.5 mm) and ceramic) were exposed on the floor during the treatment and kept in controlled climatic conditions for assessments of the residual efficacy after 3 and 6 months. Constant temperature: 20 ± 1°C Relative humidity: 65% ± 5% No ventilation Photoperiod: 16h light / 8 h dark Control: same batches of insects are handled in the same conditions to check any unexpected natural mortality 1 hour of exposure time. 1 diffuser 150 mL / 70 m²	**<u>One shot aerosol – curative treatment:</u>** Kd100: 15 minutes for all targets, mortality 100 % after 24 hours **<u>Residual one shot aerosol (3 months):</u>** Kd 100: 2 hours for mosquitoes, 4 hours for ticks and fleas Mortality: 100 % after 24 hours **<u>Residual one shot aerosol (6 months):</u>** Kd 100: 24 hours for mosquitoes, 7 days for ticks and fleas. Mortality after 24 hours: < 72 % for mosquitoes, 16 % for ticks and < 31% for fleas Controls: max. 2 % mortality. **→ Efficacy demonstrated on all target organisms until 3 months in laboratory conditions, on porous and non-porous surfaces.**	[redacted] 2016 2033b/0116 RI=1
MG 3, Pest control	PT 18 Insecticide	Diffuseur insecticide pour l'habitat (0.026% w/w S-Methoprene 0.87 % w/w	*Aedes aegypti* *Culex pipiens* (50 adult females, 2-4 days, for each species) *Ixodes ricinus* *Rhipicephalus sanguineus* (50 mixed sex adult	Semi field test In-house method	Room of 70 m² // 175 m³ (10 m long x 7 m wide x 2.50 m high). The arthropods were released free in the test chamber and the aerosol was set in the center on the floor at a 40-cm height and activated for the curative trial. Two elements were set. - A blood target to determine if the ticks were knocked- down fast enough before biting this target;	**<u>One shot aerosol – curative treatment:</u>** Kd 100: 1 hour and 100 % mortality after 24 hours for all target organisms. For ticks no blood-fed tick was observed in the treated series. **<u>Residual one shot aerosol (3, 5 and 6 months:</u>** For mosquitoes and fleas: 100 % mortality after 24 hours.	[redacted] 2017 2194b/0217R RI=1

		permethrin) Batch 155201	1-2 weeks, for each species) *Ctenocephalides. felis* (50 larvae; 50 adults mixed sex 1-2 weeks) 5 replicates for each species.		- Panels: varnished wood (non-porous) and hairy carpet (porous) for residual efficacy trial. Food and water sources were not on the treated surfaces. The pests were able to reach water and food sources without being in contact with the treated surfaces. harborages were also set on the floor Untreated control: the same procedure was used but with untreated panels Constant temperature: 22 ± 1°C Relative humidity: 60% ± 5% No ventilation Photoperiod: 8h light / 16 h dark 1 hour of exposure time. 1 diffuser 150 mL / 70 m²	For ticks: 100 % kd after 1 hour of exposure and 100 % mortality after 24 hours. No blood-fed ticks were observed in the treated series. Controls: < 2 % mortality after 24 hours. ➔ **This study demonstrates the efficacy of the product, until 6 months, on all target organisms at the application rate of 150 mL / 70 m² (equivalent to 175 m3).**	

Conclusion on the efficacy of the product
French competent authorities (FR CA) assessed that the family INSECTICIDES FOR HOME USE, separated in two META-SPC has shown a sufficient efficacy as following: • In META-SPC1: The efficacy of the products when used by spraying on surfaces against mosquitoes (*Aedes spp.* and *Culex spp. (adult)*), fleas (e.g. *Ctenocephalides felis (adult and larvae*) and ticks (*Ixodes ricinus* and *Rhipicephalus sanguineus*) at the application rate of 2.1 g product/m² for porous and non-porous surfaces, up to 6 months. • In META-SPC 2: The efficacy of the products when used by spraying on surfaces against mosquitoes (*Aedes spp. and Culex spp.*), fleas (e.g. *Ctenocephalides felis*) and ticks (*Ixodes ricinus* and *Rhipicephalus sanguineus*) at the application rate of 150 mL/70 m² or 175 m^3, for porous and non-porous surfaces, up to 6 months.

2.2.5.6 Occurrence of resistance and resistance management

Resistance to permethrin has been reported for a number of pests both in agriculture and public health (German cockroach (*Atkinson et al.,* 1991)[5], house fly (Meyer *et al*., 1987)[6], stable fly (Pitzer et al.,2010)[7], *Culex* mosquitos (*Wan-Norafilack et al*., 2013)[8], *Aedes* mosquitos (*Saavedra-Rodriguez et al.*, 2008)[9], *Anopheles* mosquitos (Corbel *et al*., 2004)[10] when permethrin has been used as a general insecticide (PT18 use). 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 (see Assessment Report permethrin, PT18, April 2014).
In a study performed in Thailand, some populations of *Aedes aegypti* and *Culex quinquefasciatus* have been found to be resistant against permethrin. Permethrin had been introduced to the relevant region ten years before the study was conducted. Permethrin is among the main insecticides used in controlling vector-borne diseases throughout Thailand. If certain populations of mosquitoes are resistant to DDT, they might become resistant to permethrin as well, as cross-resistance has been observed (Somboon *et al*., 2003)[11].
Culex quinquefasciatus is a model organism for studying resistance due to its inherent ability to resists insecticides. Permethrin induces both killing and avoidance responses in *Culex* mosquitoes. Studies on the resistance of *C. quinquefasciatus* have been conducted for example in the US, India, Malaysia and Thailand. All these studies showed various levels of resistance against permethrin in these populations (Wan-Norafikah *et al*., 2013).

For fleas, resistance to permethrin has already been reported for field-derived isolates from Australia, Europe and the United States (Rust *et al*., 2015)[12].
Concerning ticks, resistance to permethrin has been reported at varied levels in different populations of brown dog ticks, *Rhipicephalus sanguineus*, in the United States (Eiden *et al*., 2015)[13].
Additionally, the reason for developing resistance against permethrin is species-dependent. In general it can be said that resistance develops due to uncontrolled use of the insecticide. It has been documented that resistance is occurring due to reduced neural sensitivity due to a specific mutation, enhanced metabolic detoxification of permethrin, and reduced penetration ratio. Other mechanisms are likely to exist but have not been described so far. Additionally, permethrin has been described to be less effective at higher temperatures, especially above 30 °C (Somboon *et al*., 2003; Wan-Norafikah *et al*., 2013).

Resistance to S-Methoprene has been reported for populations of *Aedes* mosquitoes in the United States (Marcombe et *al*., 2017)[14], in Malaysia (Lau *et al.*, 2015)[15] and in Cyprus for populations of *Culex* mosquitoes (Vasquez *et al*., 2009)[16]. However, regarding the fleas and the ticks, no literature reference has been found on the possible occurrence of resistance of these species to S-Methoprene .
According to Marcombe *et al*. (2017), Monooxygenases (cytochrome P-450s) enzyme systems could be involved an IGR resistance.

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

2.2.5.7 Known limitations

None.

2.2.5.8 Evaluation of the label claims

French competent authorities (FR CA) assessed that the product family INSECTICIDES FOR HOME USE has shown a sufficient efficacy as following:

- In META-SPC1:
  The efficacy of the product when used by spraying on surfaces against mosquitoes (*Aedes spp.* and *Culex spp. (adult)*), fleas (e.g. *Ctenocephalides felis (adult and larvae)*) and ticks (*Ixodes ricinus* and *Rhipicephalus sanguineus*) at the application rate of 2.1 g product / m² for porous and non-porous surfaces, up to 6 months.

- In META-SPC 2:
  The efficacy of the product when used by spraying on surfaces against mosquitoes (*Aedes spp. and Culex spp. (adult)*), fleas (e.g. *Ctenocephalides felis (adult and larvae)*) and ticks (*Ixodes ricinus* and *Rhipicephalus sanguineus*) at the application rate of 150 mL / 70 m² or 175 m^3 for porous and non-porous surfaces, up to 6 months.

The products are applied by non-professional users.

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

2.2.6 Risk assessment for human health

2.2.6.1 Assessment of effects on Human Health

The two products INSECTICIDE HOUSEHOLD SPRAY and FOGGER INSECTICIDE FOR HOUSEHOLDS are composed of active substances, formulants and a propellant gas.
Considering that people will be exposed to the products after spraying or fogging, the classification of the products is determined from the mixtures without the propellant gas according to CLP Regulation (paragraph 1.1.3.7).

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The mixtures (without gas) are not classified according to CLP regulation for corrosion/ irritation.
Justification for the value/conclusion	Data is available on each components of the mixture. Only the fragrance is classified as skin irritant and is present at a concentration below 1% in the product without the gas. The information is sufficient to allow the classification of the mixtures according to the rules laid down in the CLP regulation. Moreover, synergistic effects between any of the components are not expected.
Classification of the product according to CLP	Products of the BPF INSECTICIDE FOR HOME USE (INSECTICIDE HOUSEHOLD SPRAY and FOGGER INSECTICIDE FOR HOUSEHOLDS) are not classified according to CLP regulation for corrosion/ irritation.

Data waiving	
Information requirement	Only the fragrance is classified as skin irritant but it is present at a concentration below 1%.
Justification	Data is available on each components of the mixture. There is sufficient information to allow the classification of the mixtures according to the rules laid down in the CLP regulation. Moreover, synergistic effects between any of the components are not expected.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	After spraying or fogging, the products INSECTICIDE HOUSEHOLD SPRAY and FOGGER INSECTICIDE FOR HOUSEHOLDS are classified according to CLP regulation for eye irritation.
Justification for the value/conclusion	Data is available on each components of the mixture. The information is sufficient to allow the classification of the mixture according to the rules laid down in the CLP regulation. The mixtures contain several components classified irritant for eyes of category 2. The sum of their contents in the mixtures without gas is superior to the threshold of 10%.

	Therefore, a classification for Eye Irritation category 2 - H319: Causes serious eye irritation is needed for Insecticide household spray and Fogger insecticide for households. In consequence, the risk mitigation measure "Avoid contact to eyes" should be implemented.
Classification of the product according to CLP	Products of the BPF INSECTICIDE FOR HOME USE (INSECTICIDE HOUSEHOLD SPRAY and FOGGER INSECTICIDE FOR HOUSEHOLDS) are **classified Eye Irrit 2 - H319:** Causes serious eye irritation

Data waiving	
Information requirement	Products of the BPF INSECTICIDE FOR HOME USE are classified H319: Causes serious eye irritation according to the CLP regulation.
Justification	Data is available on each components of the mixture. There is sufficient information to allow the classification of the mixtures according to the rules laid down in the CLP regulation.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Products of the BPF INSECTICIDE FOR HOME USE are not classified according to the CLP regulation for respiratory tract irritation.
Classification of the product according to CLP	Data is available on each components of the mixture. The mixtures do not contain components classified irritant for respiratory tract. The information is sufficient to allow the classification of the mixture according to the rules laid down in the CLP regulation. Moreover, synergistic effects between any of the components are not expected.

Data waiving	
Information requirement	Products of the BPF INSECTICIDE FOR HOME USE are not classified according to the CLP regulation for respiratory tract irritation.
Justification	Data is available on each components of the mixture. There is sufficient information to allow the classification of the mixtures according to the rules laid down in the CLP regulation.

Skin sensitization

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
LLNA: BrdU-PH-16/093, According OECD Guideline 442-B, GLP Study, Reliable without restriction	CBA/J strain mouse, 3 groups of 4 animals, and one group for negative control.	Test substance: 2206083 Diffuseur insecticide pour l'habitat (after degassing) 3 concentrations: 100%, 25% and 50%, dilution are made with AOO (= acetone/olive oil (4 :1,v/v)). Topical application (25µL) to the dorsal surface of the ear	Dryness of the skin was noted in all animals at the concentration of 100%. Slight dryness was noted in one animal at 25%. An increase in ear tickness (+19.7%) and ear weight (+39.2%) was noted in all animals treated at 100%. Stimulation Index (SI) was respectively 0,93, 1,16 and 1,58 for the treated group 25%, 50% and 100% ➔ Not classified in category 1 for skin sensitization		LLNA:BrdU-PH-16/0093

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	INSECTICIDE HOUSEHOLD SPRAY: Not classified as skin sensitizer FOGGER INSECTICIDE FOR HOUSEHOLDS: Not classified as skin sensitizer
Justification for the value/conclusion	For INSECTICIDE HOUSEHOLD SPRAY: no study was perfomed. The classification is determined by calculation according to the CLP Regulation. Moreover, a read across with study on FOGGER INSECTICIDE FOR HOUSEHOLDS is proposed because INSECTICIDE HOUSEHOLD SPRAY contains similar formulants and less sensitising acive substances. For FOGGER INSECTICIDE FOR HOUSEHOLDS, a study (LLNA-BrdU-PH-16/093) is available.
Classification of the product according to CLP	The mixtures INSECTICIDE HOUSEHOLD SPRAY and FOGGER INSECTICIDE FOR HOUSEHOLDS are not classified as skin sensitizer category 1.

	However, the labelling of the two products INSECTICIDE HOUSEHOLD SPRAY and FOGGER INSECTICIDE FOR HOUSEHOLDS should present the mention: EUH 208 Contains PERMETHRIN. May produce an allergic reaction. The labelling of the product FOGGER INSECTICIDE FOR HOUSEHOLDS should also present the mention: EUH 208 Contains Linalool. May produce an allergic reaction as the linalool is present at a concentration superior to 0.1% in the product after evaporation of propellent.

Data waiving	
Information requirement	For INSECTICIDE HOUSEHOLD SPRAY, no study was perfomed. The classification is determined by calculation according to CLP Regulation. Moreover, a read across with study on FOGGER INSECTICIDE FOR HOUSEHOLDS is proposed.
Justification	Data is available on each components of the mixture. There is sufficient information to allow the classification of the mixture according to the rules laid down in CLP regulation. Moreover, the spray insecticide contains less sensitising substances than fogger insecticide (even after evaporation of gas propellant). Therefore, a read across is proposed.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	The mixtures are not classified according to the CLP regulation
Justification for the value/conclusion	According to the compositions, none of the component is toxicologically relevant for respiratory sensitisation.
Classification of the product according to CLP	Not classified

Data waiving	
Information requirement	The mixtures are not classified according to CLP regulation
Justification	No study of respiratory tract sensitisation is available. Classification is based on the available data on each component and the CLP Regulation.

Acute toxicity

Acute toxicity by oral route

Meta SPC 1 : INSECTICIDE HOUSEHOLD SPRAY

Value used in the Risk Assessment – Acute oral toxicity	
Value	ATE_{mix} > 2000 mg/kg
Justification for the selected value	Calculation of ATE_{mix} according to the CLP regulation.
Classification of the product according to CLP	The mixture INSECTICIDE HOUSEHOLD SPRAY is not classified according to the CLP regulation.

Data waiving	
Information requirement	According to the CLP Regulation (1272/2008/CE): the 'relevant ingredients' of a mixture are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater. An Oral LD_{50} is available for all ingredients.
Justification	Valid data available on each component in the mixture are sufficient to allow classification of the mixture according to the rules laid down in CLP regulation, and synergistic effects between any of the components are not expected.

Meta SPC 2 : FOGGER INSECTICIDE FOR HOUSEHOLDS

Value used in the Risk Assessment – Acute oral toxicity	
Value	ATE_{mix} = 3827 mg/kg
Justification for the selected value	Calculation of ATEmix according to CLP regulation. 100/ATE mix= (10.133/480) + (1.623/940) +(4.058/1230) = 0.026
Classification of the product according to CLP	The mixture FOGGER INSECTICIDE FOR HOUSEHOLDS is not classified according to the CLP regulation.

Data waiving	
Information requirement	According to the CLP Regulation (1272/2008/CE): the 'relevant ingredients' of a mixture are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater. An Oral LD_{50} is available for all ingredients.
Justification	Valid data available on each component in the mixture are sufficient to allow classification of the mixture according to the rules laid down in the CLP regulation.

Acute toxicity by inhalation

Meta SPC 1 : INSECTICIDE HOUSEHOLD SPRAY

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	ATE_{mix} > 5 mg/L
Justification for the selected value	Calculation of ATEmix according to the CLP regulation.
Classification of the product according to CLP	Not classified for acute inhalation toxicity

Data waiving	
Information requirement	According to the CLP Regulation (1272/2008/CE): the 'relevant ingredients' of a mixture are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater. A LC_{50} is available for ingredients at concentration of 1% or greater.
Justification	Valid data available on each component in the mixture are sufficient to allow classification of the mixture according to the rules laid down in

	the CLP regulation, and synergistic effects between any of the components are not expected.

Meta SPC 2 : FOGGER INSECTICIDE FOR HOUSEHOLDS

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	ATE $_{mix}$ > 5 mg/L
Justification for the selected value	Calculation of ATEmix according to the CLP regulation.
Classification of the product according to CLP	Not classified for acute inhalation toxicity

Data waiving	
Information requirement	According to the CLP Regulation (1272/2008/CE): the 'relevant ingredients' of a mixture are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater. A LC_{50} is available for ingredients at concentration of 1% or greater.
Justification	Valid data available on each component in the mixture are sufficient to allow classification of the mixture according to the rules laid down in CLP regulation, and synergistic effects between any of the components are not expected.

Acute toxicity by dermal route

Meta SPC 1: INSECTICIDE HOUSEHOLD SPRAY

Value used in the Risk Assessment – Acute dermal toxicity	
Value	ATE $_{mix}$ > 2000 mg/kg
Justification for the selected value	Calculation of ATEmix according to the CLP regulation.
Classification of the product according to CLP	Not classified for acute dermal toxicity

Data waiving	
Information requirement	According to the CLP Regulation (1272/2008/CE): the 'relevant ingredients' of a mixture are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater. A dermal LD_{50} is available for all ingredients.
Justification	Valid data available on each component in the mixture are sufficient to allow classification of the mixture according to the rules laid down in CLP regulation, and synergistic effects between any of the components are not expected.

Meta SPC 2 : FOGGER INSECTICIDE FOR HOUSEHOLDS

Value used in the Risk Assessment – Acute dermal toxicity	
Value	ATE $_{mix}$ > 2000 mg/kg

Justification for the selected value	Calculation of ATEmix according to the CLP regulation.
Classification of the product according to CLP	Not classified for acute dermal toxicity

Data waiving	
Information requirement	According to the CLP Regulation (1272/2008/CE): the 'relevant ingredients' of a mixture are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater. A dermal LD_{50} is available for all ingredients.
Justification	Valid data available on each component in the mixture are sufficient to allow classification of the mixture according to the rules laid down in CLP regulation, and synergistic effects between any of the components are not expected.

Information on dermal absorption

Data waiving	
Information requirement	No study has been performed for dermal absorption for both products. For exposure assessment, default values of 75 % has been used for S-methoprenee and permethrin for the product INSECTICIDE HOUSEHOLD SPRAY as the content in active substance is inferior to 5% even after evaporation of the propellant gas. For the product FOGGER INSECTICIDE FOR HOUSEHOLDS, a default value of 75% is used for S-methoprene as its content is inferior to 5% after evaporation of the propellant gas and 25% for permethrin as its content is superior to 5% after evaporation of the propellant gas.
Justification	See above

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

The two products of the BPF INSECTICIDE FOR HOME USE contain biocidal active substances acting as solvent:

- Propan-2-ol;
- Other substances;

Propan-2-ol was reviewed at the European level under BPR Regulation. Agreed reference values are available and the content in Propan-2-ol in the products is superior to 0.1%. Therefore, this substance is considered substance of concern in both products. According to guidance on the BPR volume III part B + C, a fully quantitative risk assessment using EU reference values should be performed.

The other substances are under the BPR review program but no agreed reference values are available. Therefore, according to guidance on the BPR volume III part B + C, these substances cannot be considered as SOC.

Moreover, the product FOGGER INSECTICIDE FOR HOUSEHOLDS (meta SPC 2) product contains nitromethane at 1.6% in the mixture without the propellant gaz which. This formulant is classified

Acute tox. 4 H302 according to the CLP Regulation (ATP 1). However, a classification Carc. 2 H351 is proposed in the MSDS of the co-formulant. Applicant justified this classification by the information available in the REACH registered dossier. The classification proposed in the MSDS is therefore used to determine the classification of the product.
A classification Carc. 2 H351 for the product FOGGER INSECTICIDE FOR HOUSEHOLDS is needed. Moreover, the nitromethane is considered as a SOC.

Available toxicological data relating to a mixture

No data.

The proposed classification and labelling of the products are as follows:

- **INSECTICIDE HOUSEHOLD SPRAY:**
  Eye Irrit 2 - H319;
  EUH 208: Contains PERMETHRIN. May produce an allergic reaction.

- **FOGGER INSECTICIDE FOR HOUSEHOLDS:**
  Eye Irrit 2 - H319;
  Carc. 2 - H351;
  EUH 208: Contains PERMETHRIN and LINALOOL. May produce an allergic reaction.

2.2.6.2 Exposure assessment

For meta SPC 1 product (Spray insecticide pour l'habitat/INSECTICIDE HOUSEHOLD SPRAY), the following modes of application are claimed:

- Use indoor.
- The household insecticide spray can be used on carpets, rugs, wooden floors, armchairs. After spraying, leave the room and allow acting at least one hour. Three types of container (250 mL, 300mL or 500 mL) are used.
  The 250ml is designed to be use for the treatment of surface up to 70m², and the 500ml is designed to treat surface up to 140m². Packaging materials (cans and valves) for 250 mL and 500 mL sprays are identical. Consequently, one can consider the mass generation rate is the same, as well as the particles size distribution.
  A 300 ml aerosol can is also presented, with a different valve, so the exposure evaluation has also been performed for this aerosol as the particles size distribution and mass generation rate are different.
- Product is efficient during 6 months. So, 2 times per year is the maximum frequency of use for each house.

For meta SPC 2 (Diffuseur insecticide pour l'habitat/FOGGER INSECTICIDE FOR HOUSEHOLDS), the following modes of application are claimed:

- Use indoor.
- Place the fogger in the centre of the area to be treated, preferably in a raised position (on a chair that has been previously protected). Push the ring to activate the diffusion. Leave the room and close the door behind you. For an optimal result, vacuum rugs, carpets, and fabrics before application. Total diffusion time is about 103 secondes. Wait 4 hours before entering the room. The fogger is a single use product and can be treated up to 70m².
- Product is efficient during 6 months. So 2 times per year is the maximum frequency of use for each house.

Two types of application are described in the instruction of use (indoor spraying considering a general surface treatment area and a fumigation application considering an air space treatment area).Therefore, for primary exposure, both scenarios will be assessed. As products are ready-to-use products, the mixing/loading phase will not be considered in the risk assessment.

Both products will not be used in the same room, as the consumer will choose the mode of application moste appropriate to treat the infestation. However, both types of products could be applied in parallel (not in the same room but applied during the same day by the same person). Therefore, for the application exposure, the addition of both exposure scenarios will be considered.

For the secondary exposure, the following scenarios are assessed:

- A toddler crawling on treated surface with a hand-to-mouth transfer,
- An adult touching a treated surface,
- Adults, children and toddlers sleeping in a contaminated bed. Indeed, this scenario is relevant for the fogger application. With this type of application, if the bed is not removed from the room, it will be contaminated.

The following assumptions are performed for risk assessment:

- Surface spraying: persons are exposed to the amount applied at the efficacy rate of 2.1g/m^2 for surface spraying.

- Fogger: persons are exposed to the amount of one fogger applied on a room of 22 m^2 (even if the claimed surface is 70 m^2). Indeed, a room of 22m^2 (default surface area for a living room in Consexpo) is considered most realistic than a room of 70m^2.
  - Mass generation rate: 1.02 g/sec
  - Spray duration: 103 sec → 105g for 22 m^2= 4.78g/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	NA	NA	YES	NA	NA	YES	NA
Dermal	NA	NA	YES	NA	NA	YES	NA
Oral	NA	NA	NO	NA	NA	YES	YES

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Application of INSECTICIDE HOUSEHOLD SPRAY	Primary exposure : application of Spray insecticide pour l'habitat (aerosol can)	Non-professionals
2.	Application of FOGGER INSECTICIDE FOR HOUSEHOLDS	Primary exposure : application of fogger	Non-professionals
3.	Exposure of children who crawl on treated surface with a hand to mouth transfer	Secondary exposure, dermal and oral In the post-application phase, children can be exposed, due to their specific time-activity pattern: crawling on treated surface and hand to mouth contact. As the product is efficient during 6 months, a chronic exposure is considered.	Non-professional (Children)
3a	For fogger application		
3b	For surface spraying		
4.	Exposure of adults touching a treated surface	Secondary exposure, dermal In the post-application phase, the treated surfaces can be touched by an adult with its hands. As the product is efficient during 6 months, a chronic exposure is considered.	Non-professional (Adults)
4a	For fogger application		
4b	For surface spraying		
5.	Exposure of adults, children and toddlers who sleep in a treated bed	Secondary exposure, dermal In the post-application phase, adults, children and toddlers could be exposed during sleeping in a treated bed. As the product is efficient during 6 months, a chronic exposure is considered.	Non-professional (Adults and children)
5a	For fogger application		
5b	For surface spraying		
6	Exposure to volatile residue	Secondary exposure, inhalation In the post-application phase, inhalation exposure of volatile residues is assessed for adults, children and toddlers.	Non-professional (Adults and children)

The physicochemical characteristics of permethrin and S-methoprene are presented in the following table. Moreover, the characteristics of the SOC: propan-2-ol is also mentionned.

	Permethrin	S-methoprene	Propan-2-ol
Molecular weight	391.29	310.48	60.09
Vapour pressure at 20°C	$2.1*10^{-6}$ Pa	0.000623-0.00108 Pa	5780 Pa

Oral absorption values available in the CARs are reported below:

	Permethrin	S-methoprene	Propan-2-ol
Molecular weight	100%	35%	100%

For dermal absoprtion, the used values are summarised below:

	Permethrin	S-methoprene	Propan-2-ol*
Surface spraying	75%	75%	25%
Fogger application	25%	75%	25%

*no dermal absorption is available for propan-2-ol. For propan-2-ol, considering its concentration superior to 5% in the mixtures without gaz, a dermal absorption value per default of 25% is considering for fogger application and surface spraying.

The concentrations in substances used for the risk assessment are

	Permethrin	S-methoprene	Propan-2-ol
FOGGER			
With gas	0.874%	0.026%	2.452%
Without gas	10.14%	0.301%	28.426%
Spraying			
With gas	0.177%	0.0022%	3.342%
Without gas	0.95%	0.0118%	17.924%

Industrial exposure

Not relevant

Professional exposure

Not relevant

Non-professional exposure

Scenario [1]: Application of "Spray insecticide pour l'habitat" (Aerosol Can)

Description of Scenario [1]			
This use is a surface application so the product is expected to go onto the surface and only a small fraction stay airborn. Exposure is calculated using Consumer spraying and dusting model 2 – pre-pressurised aerosol spray can. Consexpo aerosol model is based on the hypothesis that all the product released goes airborn. So this represents an overestimation for surface application and explained why it was not used to assess inhalation exposure.			
	Parameters[1]	Value	Reference
Exposure to spray			
Permethrin	Weight fraction compound (%)	0.95%	Applicant data without propelant

	Dermal absorption	75%	Default value
	Inhalation absorption	100%	CAR data
S-methoprene	Weight fraction compound (%)	0.012%	Applicant data without propelant
	Dermal absorption	75%	Default value
	Inhalation absorption	100%	CAR data
Propan-2-ol	Weight fraction compound (%)	17.92%	Applicant data without propelant
	Dermal absorption	25%	Default value
	Inhalation absorption	100%	CAR data
	Exposure duration (minutes)	10	Default value
	Hands/forearms exposure	64.7 mg/min	Biocides Human Health Exposure Methodology
	Legs feet face exposure	45.2 mg/min	Biocides Human Health Exposure Methodology
	Inhalation	35.9 mg/m^3	Biocides Human Health Exposure Methodology
	Body weight	60 kg	HEEG opinion No. 17, 2013
	Inhalation rate (m^3/hour)	1.25	HEEG opinion No. 17, 2013

Due to the high volatility of propan-2-ol, the exposure to vapor during spraying is also assessed.

Description of Scenario [1] exposure to vapor			
Due to the high volatility of propan-2-ol, the exposure to vapor during spraying has been assessed using ConsExpo web evaporation model.			
	Parameters	**Value**	**Source**
Propan-2-ol	Concentration of a.s in the product	3.34%	Applicant's data
	Vapor pressure (Pa)	5780	Substance data
	Product amount (g)	270	Applicant's data
	Task duration (min)	10	Duration of exposure proposed for application
	Release area (m^2)	22	Mean treated surface
	Room volume (m^3)	58	ConsExpo default value
	Emission duration (h)	24	ConsExpo default value
	Ventilation rate	0.5	ConsExpo default value
	Body weight (kg)	60	HEAD Hoc recommendation 14
	Inhalation rate (m^3/h)	1.25	HEAD Hoc recommendation 14

Calculations for Scenario [1]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [1]-permethrin	No PPE	1.18E-03	1.31E-01	-	1.32E-01
Scenario [1]-S-methoprene	No PPE	1.50E-05	1.65E-03	-	1.66E-03
Scenario [1]-Propan-2-ol	No PPE	2.23E-02	8.21E-01	-	8.43E-01 (6.43 mg/m3)
Scenario [1]-Propan-2-ol (volatilization)	No PPE	4.70E-01	-	-	4.70E-01 (130 mg/m3)

Further information and considerations on scenario [1]

None

Scenario [2]: Application of Diffuseur insecticide pour l'habitat

Description of Scenario [2]			
Exposure is calculated using ConsExpo web model, with the pest control products/sprays/air space/application scenario. This scenario is based on a private user who sprays with an aerosol can in the living room to control flies or mosquitoes. Normally user should leave the room as soon as the fogger is activated but as a worst case approach it is consider that the user will stay 10 min in the room. Default values are proposed by ConsExpo.			
	Parameters[1]	Value	Reference
Permethrin	Weight fraction compound (%)	0.874%	Applicant data
	Non-respirable uptake fraction (oral uptake fraction) (%)	100	CAR
	Uptake fraction	100%	Default value
	Dermal absorption (DA) (%)	25	Default value
S-methoprene	Weight fraction compound (%)	0.026%	Applicant data
	Non-respirable uptake fraction (oral uptake fraction) (%)	35	CAR
	Uptake fraction	100%	Default value
	Dermal absorption (DA) (%)	75	Default value

Description of Scenario [2]			
Propan-2-ol	Weight fraction compound (%)	2.45%	Applicant data
	Non-respirable uptake fraction (oral uptake fraction) (%)	100	CAR
	Uptake fraction	100%	Default value
	Dermal absorption (DA) (%)	25	Default value
Inhalation model: Exposure to spray			
Tier 1	Exposure duration (minutes)	10	It is assumed that the user stays in the treated room during spraying but leave out of the room for 4 hours after the application
	Room volume (m^3)	58	Default value proposed by ConsExpo for a living room
	Room height (m)	2.5	It corresponds also to the values of room surface and volume from the General Product fact sheet (2014)
	Ventilation rate (1/hour)	0.5	Default value proposed for a middle ventilation rate (General Product fact sheet (2014), page 31/102)
	Mass generation rate (g product/sec)	1.02	Applicant data
	Spray duration (seconds)	103	Applicant data
	Airborne fraction	1	Default value for the spray model ("air space, spray can" value), RIVM, March 2010.
	Weight fraction non-volatile (%)	8.625	The aerosol can contains 8.625% of liquid and 91.375% of propellant (volatile)
	Density non-volatile (g/cm^3)	0.82	Density of the active substance (after removal of propellent)
	Inhalation cut-off diameter (µm)	10	Default value proposed by ConsExpo
	Inhalation rate (m^3/hour)	1.25	HEEG opinion No. 17, 2013
Dermal model: constant rate			
Tier 1	Contact rate (mg/minutes)	270	Default value proposed by ConsExpo
	Release duration (seconds)	103	Equal to spray duration

Due to the high volatility of propan-2-ol, the exposure to vapor during spraying is also asessed.

Description of Scenario [2] – volatilisation of propan-2-ol			
Due to the high volatility of propan-2-ol (5780 Pa), the exposure to vapor during spraying has been assessed using ConsExpo web evaporation model.			
	Parameters	**Value**	**Source**

Propan-2-ol	Concentration of a.s in the product	2.45%	Applicant's data
	Vapor pressure (Pa)	5780	Substance data
Tier 1	Product amount (g)	105	Applicant's data
	Task duration (min)	10	Duration of exposure proposed for application
	Release area (m^2)	22	Mean treated surface
	Room volume (m^3)	58	ConsExpo default value
	Emission duration (h)	24	ConsExpo default value
	Ventilation rate	0.5	ConsExpo default value
	Body weight (kg)	60	HEAD Hoc recommendation 14
	Inhalation rate (m^3/h)	1.25	HEAD Hoc recommendation 14

Calculations for Scenario [2]

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/kg bw/d) (mean concentration en mg/m3)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [2]-permethrin	No PPE	1.00E-02	1.70E-02	1.70E-02	4.40E-02
Scenario [2]-S-methoprene	No PPE	3.10E-04	1.50E-03	1.70E-04	2.00E-03
Scenario [2]-Propan-2-ol	No PPE	1.20E-01 (8.4 mg/m3)	-	-	1.20E-01
Scenario [2]-Propan-2-ol (volatilisation)	No PPE	1.30E-01 (38 mg/m3)	-	-	1.30E-01

Further information and considerations on scenario [2]

For fogging application, applicant mentions to wait 4 hours before entering the room. In this context, the air concentration in active substance after 4 hours is determined according to Consexpo.

From the air concentration after 4 hours, considering a ventilation rate of 1.25 m^3/h, an exposure during 24h is determined:

	Air concentration after 4 hours (mg/m^3)	Systemic exposure (mg/kg bw/d)
Permethrin	$1.5 *10^{-2}$	0.0075
S-methoprene	$4.5 *10^{-4}$	0.000225
Propan-2-ol	$4.3 *10^{-2}$	0.0215

Exposure of the general public

Considering the high volatility of propan-2-ol, the secondary dermal exposure is considered negligible for this substance.

Scenario [3] Exposure of toddler crawling on a treated surface with a hand to mouth transfer

Description of Scenario [3]
In the post-application phase, toddlers are expected to be the most exposed, due to their specific time-activity pattern (crawling on treated surface, hand to mouth contact and relatively low body weight). This exposure was estimated based on the approach proposed in ConsExpo fact sheet "Cleaning products". ConsExpo software was not used for the calculation. Toddlers are exposed from any uncovered skin, that is: the head, the arms and hands, and on the legs and feet. According to ConsExpo and the Ad hoc Recommendation 12, the transfer coefficient of 0.21 m^2/h is to be used. From this surface a fraction of active substance is dislodgeable: - For dried surface, the value of 30 % proposed in the TNsG and ConsExpo will be used (Tier 1). - For carpets, the value of 9% proposed in the TNsG will be used (Tier 2). If dermal exposure of toddler occurs, they can also be exposed orally via hand–mouth contact. The hands form about 20 % of the total uncovered skin. It is assumed that 50 % of the product that ends up on the hands is taken in orally (ConsExpo: Pest control Fact Sheet). This means that 10 % of the calculated external dermal exposure is ingested via hand-mouth contact and that the internal dermal exposure is 90 % of the calculated external dermal exposure.

	Parameters[1]	Value	Reference
Permethrin			
	Oral absorption (%)	100%	CAR
Spraying application	Application rate (g product/m²)	2.1	Efficient dose
	Concentration of active substance (% w/w)	0.177%	Concentration of active substance after spraying and evaporation of propellant
	Dermal absorption	75%	Default value
Fogger application	Application rate (g product/m²)	4.78	Applicant data
	Concentration of active substance (% w/w)	0.874%	Concentration of active substance
	Dermal absorption	25%	Default value
S-methopren			
	Oral absorption (%)	35%	CAR
	Application rate (g product/m²)	2.1	Efficient dose

Spraying application	Concentration of active substance (% w/w)	0.0022%	Concentration of active substance after spraying and evaporation of propellant
	Dermal absorption	75%	Default value
Fogger application	Application rate (g product/m²)	4.78	Applicant data
	Concentration of active substance (% w/w)	0.026%	Concentration of active substance
	Dermal absorption	75%	Default value
Common parameters	Transfer coefficient (m²/hr)	0.21	2,100 cm²/hr for children from 1 to 2 years old (75th percentile) Ad hoc Working group on Human Exposure Recommendation 12
	Duration of crawling (hr)	1	Default value proposed by ConsExpo
	Hand to mouth transfer	10%	Default value proposed by ConsExpo
	Amount on skin	90%	Default value proposed by ConsExpo
	Body weight (kg)	10 (toddler)	HEEG opinion No. 17, 2013
Tier 1	Dislodgeable fraction from floor to skin (dried impervious surface) (Tier 1)	30%	Biocides Human Health Exposure Methodology
Tier 2	Dislodgeable fraction from floor to skin (carpet) (Tier 2)	9%	Biocides Human Health Exposure Methodology

Calculations for Scenario [3]

Summary table: systemic exposure from non-professional uses permethrin					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake mg/kg bw/d**	**Estimated oral uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Spraying application – general surface					
Scenario [3] **Efficient dose**	No PPE	-	1.58E-02	2.34E-03	1.81E-02
Fogger application – general surface					
Scenario [3]	No PPE	-	5.92E-02	2.63E-02	8.55E-02
Spraying application – carpet surface					
Scenario [3] **Efficient dose**	No PPE	-	4.74E-03	7.03E-04	5.44E-03
Fogger application – carpet surface					
Scenario [3]	No PPE	-	1.78E-02	7.90E-03	2.57E-02

Summary table: systemic exposure from non-professional uses S-methoprene					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake mg/kg bw/d**	**Estimated oral uptake mg/kg bw/d**	**Estimated total uptake mg/kg bw/d**
Spraying application – general surface					
Scenario [3] **Efficient dose**	No PPE	-	1.96E-04	1.02E-05	2.07E-04
Fogger application – general surface					
Scenario [3]	No PPE	-	5.29E-03	2.74E-04	5.56E-03
Spraying application –carpet surface					
Scenario [3] **Efficient dose**	No PPE	-	5.89E-05	3.06E-06	6.20E-05
Fogger application – carpet surface					
Scenario [3]	No PPE	-	1.59E-03	8.22E-05	1.67E-03

Further information and considerations on scenario [3]

No data

Scenario [4] Exposure of adults touching a treated surface

Description of Scenario [4]			
In the post-application phase, an adult can be exposed when touching a treated surface (wet or dried) with hands (palms of both hands). From this surface a fraction of active substance is dislodgeable: - For wet surface, the value of 100 % (default value) will be used (Tier 1). - For dried surface, the value of 30 % proposed in TNsG will be used (Tier 2).			
	Parameters	**Value**	**Reference**
Permethrin			
Spraying application	Application rate (g product/m²)	2.1	Efficient dose
	Concentration of active substance (% w/w)	0.177%	Concentration of active substance after spraying and evaporation of propellant
	Dermal absorption	75%	Default value
Fogger application	Application rate (g product/m²)	4.78	Applicant data
	Concentration of active substance (% w/w)	0.874%	Concentration of active substance
	Dermal absorption	25%	Default value

S-methopren			
Spraying application	Application rate (g product/m²)	2.1	Efficient dose
	Concentration of active substance (% w/w)	0.0022%	Concentration of active substance after spraying and evaporation of propellant
	Dermal absorption	75%	Default value
Fogger application	Application rate (g product/m²)	4.78	Applicant data
	Concentration of active substance (% w/w)	0.026%	Concentration of active substance after spraying and evaporation of propellant
	Dermal absorption	75%	Default value
Common parameters	Surface in contact with treated surface (palm of two hands) (cm²)	410	HEEG opinion No. 17, 2013
	Body weight (kg)	60 (adults)	HEEG opinion No. 17, 2013
Tier 1	Dislodgeable fraction from floor to skin (wet)	100%	Default value
Tier 2	Dislodgeable fraction from floor to skin (dried)	30%	TNsG

Calculations for Scenario [4]

Summary table: systemic exposure from non-professional uses permethrin					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Spraying – wet surface					
Scenario spraying [4] **Efficient dose**	No PPE	-	1.90E-03	-	1.90E-03
Fogger – wet surface					
Scenario fogger [4]	No PPE	-	7.14E-03	-	7.14E-03
Spraying – dried surface					
Scenario spraying [4] **Efficient dose**	No PPE	-	5.71E-04	-	5.71E-04
Fogger – dried surface					
Scenario fogger [4]	No PPE	-	2.14E-03	-	2.14E-03

Summary table: systemic exposure from non-professional uses S-methoprene					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Spraying – wet surface					
Scenario spraying [4] **Efficient dose**	No PPE	-	2.37E-05	-	2.37E-05
Fogger – wet surface					
Scenario fogger [4]	No PPE	-	6.37E-04	-	6.37E-04
Spraying – dried surface					
Scenario spraying [4] **Efficient dose**	No PPE	-	7.10E-06	-	7.10E-06
Fogger – dried surface					
Scenario fogger [4]	No PPE	-	1.91E-04	-	1.91E-04

Further information and considerations on scenario [4]
None.

Scenario [5] Exposure of adults, children and toddlers who sleep in a treated bed

Description of Scenario [5]			
Adults, children and toddlers could be exposed during sleeping in a treated bed. In order to determine the exposure, as a worst case it is considered that they sleep naked and all the body surface can be exposed. The body surfaces were determined according to the HEEG opinion 17. It is not expected that the whole body is in direct contact with treated surfaces, as only the upper part of the bed will be treated and not the inner sheets. In this context, a protection factor of 50 % is considered (Ad hoc Working group on Human Exposure Recommendation 8). From this surface a fraction of active substance is dislodgeable: - For dried surface, the value of 30 % proposed in TNsG for dried surface will be used.			
	Parameters	**Value**	**Reference**
Permethrin			
Spraying application	Application rate (g product/m²)	2.1	Efficient dose
	Concentration of active substance (% w/w)	0.177%	Concentration of active substance
	Dermal absorption	75%	Default value

Fogger application	Application rate (g product/m²)	4.78	Applicant data
	Concentration of active substance (% w/w)	0.874%	Concentration of active substance
	Dermal absorption	25%	Default value
S-methoprene			
Spraying application	Application rate (g product/m²)	2.1	Efficient dose
	Concentration of active substance (% w/w)	0.0022%	Concentration of active substance
	Dermal absorption	75%	Default value
Fogger application	Application rate (g product/m²)	4.78	Applicant data
	Concentration of active substance (% w/w)	0.026%	Concentration of active substance
	Dermal absorption	75%	Default value
Common parameters	Body area in contact with bed (cm²)	16600 (adults) 9200 (children) 4800 (toddler)	HEEG opinion No. 17, 2013
	Protection factor (sheet)	50%	Ad hoc Working group on Human Exposure Recommendation 8
	Dislodgeable fraction from sheets to skin	30%	30% for dried surface (TNsG)
	Body weight (kg)	60 (adults) 23.9 (children) 10 (toddler)	HEEG opinion No. 17, 2013

Calculations for Scenario [5]

Summary table: systemic exposure from non-professional uses Permethrin					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Sleeping in a treated bed by spraying					

Summary table: systemic exposure from non-professional uses Permethrin					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [5] spraying **Adults Efficient dose**	1	n.a.	1.16E-02	n.a.	1.16E-02
Scenario [5] spraying **Children Efficient dose**	1	n.a.	1.61E-02	n.a.	1.61E-02
Scenario [5] spraying **Toddler Efficient dose**	1	n.a.	2.01E-02	n.a.	2.01E-02
Sleeping in a treated bed by fogging					
Scenario [5] fogger **Adults**	1	n.a.	4.33E-02	n.a.	4.33E-02
Scenario [5] fogger **Children**	1	n.a.	6.03E-02	n.a.	6.03E-02
Scenario [5] fogger **Toddler**	1	n.a.	7.52E-02	n.a.	7.52E-02

Summary table: systemic exposure from non-professional uses S-methoprene					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Sleeping in a treated bed by spraying					
Scenario [5] spraying **Adults Efficient dose**	1	n.a.	1.44E-04	n.a.	1.44E-04
Scenario [5] spraying **Children Efficient dose**	1	n.a.	2.00E-04	n.a.	2.00E-04

Summary table: systemic exposure from non-professional uses S-methoprene					
Exposure scenario	**Tier**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake (mg/kg bw/d)**
Scenario [5] spraying **Toddler Efficient dose**	1	n.a.	2.49E-04	n.a.	2.49E-04
Sleeping in a treated bed by fogging					
Scenario [5] fogger **Adults**	1	n.a.	3.87E-03	n.a.	3.87E-03
Scenario [5] fogger **Children**	1	n.a.	5.38E-03	n.a.	5.38E-03
Scenario [5] fogger **Toddler**	1	n.a.	6.71E-03	n.a.	6.71E-03

Further information and considerations on scenario [5]
None.

Scenario [6] Exposure to volatile residues (permethrin)

Description of Scenario [6]			
The exposure to volatile residues has been assessed using ConsExpo web evaporation model.			
	Parameters	**Value**	**Source**
Spraying application	Concentration of a.s in the product	0.177%	Applicant's data
	Product amount (g)	270	Applicant's data
Fogger application	Concentration of a.s in the product	0.874%	Applicant's data
	Product amount (g)	105	Applicant's data
Common parameters	Task duration (h)	24	Duration of exposure proposed for application
	Release area (m^2)	22	Mean treated surface
	Room volume (m^3)	58	ConsExpo default value
	Vapor pressure (Pa)	$2.1 * 10^{-6}$	Substance data
	Emission duration (h)	24	ConsExpo default value
	Ventilation rate	0.5	ConsExpo default value
	Body weight (kg)	60	HEAD Hoc recommendation 14

Scenario [6] Exposure to volatile residues (S-methoprene)

Description of Scenario [6]			
The exposure to volatile residue has been assessed using ConsExpo web evaporation model.			
	Parameters	**Value**	**Source**
Spraying application	Concentration of a.s in the product	0.0022%	Applicant's data
	Product amount (g)	270	Applicant's data
Fogger application	Concentration of a.s in the product	0.026%	Applicant's data
	Product amount (g)	105	Applicant's data
Common parameters	Task duration (h)	24	Duration of exposure proposed for application
	Release area (m^2)	22	Mean treated surface
	Room volume (m^3)	58	ConsExpo default value
	Vapor pressure (Pa)	$1.08 * 10^{-3}$	Substance data
	Emission duration (h)	24	ConsExpo default value
	Ventilation rate	0.5	ConsExpo default value
	Body weight (kg)	60	HEAD Hoc recommendation 14

Scenario [6] Exposure to volatile residues (propan-2-ol)

Description of Scenario [6]			
The exposure to volatile residue has been assessed using ConsExpo web evaporation model.			
	Parameters	**Value**	**Source**
Spraying application	Concentration of a.s in the product	3.34%	Applicant's data
	Product amount (g)	270	Applicant's data
Fogger application	Concentration of a.s in the product	2.45%	Applicant's data
	Product amount (g)	105	Applicant's data
Common parameters	Task duration (h)	24	Duration of exposure proposed for application
	Release area (m^2)	22	Mean treated surface
	Room volume (m^3)	58	ConsExpo default value
	Vapor pressure (Pa)	5780	Substance data
	Emission duration (h)	24	ConsExpo default value
	Ventilation rate	0.5	ConsExpo default value
	Body weight (kg)	60	HEAD Hoc recommendation 14

Calculations for Scenario [6]

Summary table: systemic exposure from non-professional uses permethrin						
Exposure scenario	**Tier**	**Estimated inhalation exposure (mg/m³)**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [6] spraying **Adults**	1	3.00E-04	8.00E-05	n.a.	n.a.	8.00E-05
Scenario [6] spraying **Children**	1	3.00E-04	1.51E-04	n.a.	n.a.	1.51E-04
Scenario [6] spraying **Toddler**	1	3.00E-04	1.62E-04	n.a.	n.a.	1.62E-04
Scenario [6] fogger **Adults**	1	3.00E-4	8.00E-05	n.a.	n.a.	8.00E-05
Scenario [6] fogger **Children**	1	3.00E-04	1.51E-04	n.a.	n.a.	1.51E-04
Scenario [6] fogger **Toddler**	1	3.00E-04	1.62E-04	n.a.	n.a.	1.62E-04

Summary table: systemic exposure from non-professional uses S-methoprene						
Exposure scenario	**Tier**	**Estimated inhalation exposure (mg/m³)**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [6] spraying **Adults**	1	8.30E-3	2.21E-03	n.a.	n.a.	2.21E-03
Scenario [6] spraying **Children**	1	8.30E-3	4.17E-03	n.a.	n.a.	4.17E-03
Scenario [6] spraying **Toddler**	1	8.30E-3	4.48E-03	n.a.	n.a.	4.48E-03
Scenario [6] fogger **Adults**	1	3.90E-02	1.04E-02	n.a.	n.a.	1.04E-02
Scenario [6] fogger **Children**	1	3.90E-02	1.96E-02	n.a.	n.a.	1.96E-02

Summary table: systemic exposure from non-professional uses S-methoprene						
Scenario [6] fogger **Toddler**	1	3.90E-02	2.11E-02	n.a.	n.a.	2.11E-02

Summary table: systemic exposure from non-professional uses Propan-2-ol						
Exposure scenario	**Tier**	**Estimated inhalation exposure (mg/m³)**	**Estimated inhalation uptake (mg/kg bw/d)**	**Estimated dermal uptake (mg/kg bw/d)**	**Estimated oral uptake (mg/kg bw/d)**	**Estimated total uptake (mg/kg bw/d)**
Scenario [6] spraying **Adults**	1	1.2E-01	3.2	n.a.	n.a.	3.2
Scenario [6] spraying **Children**	1	1.2E-01	6.03	n.a.	n.a.	6.03
Scenario [6] spraying **Toddler**	1	1.2E-01	6.48	n.a.	n.a.	6.48
Scenario [6] fogger **Adults**	1	3.5	9.33E-1	n.a.	n.a.	9.33E-1
Scenario [6] fogger **Children**	1	3.5	1.76	n.a.	n.a.	1.76
Scenario [6] fogger **Toddler**	1	3.5	1.89	n.a.	n.a.	1.89

Further information and considerations on scenario [6]
None.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario	**Permethrin (mg/kg/d)**	**S-methoprene (mg/kg/d)**	**Propan-2-ol (mg/kg/d)**
Application of meta SPC 1 product INSECTICIDE HOUSEHOLD SPRAY			
Scenario [1]-	1.32E-01	1.66E-03	8.43E-01
Scenario [1]- Propan-2-ol (volatilization)			4.70E-01
Application of FOGGER INSECTICIDE FOR HOUSEHOLDS, meta SPC 2 product			
Scenario [2]-	4.40E-02	2.00E-03	1.20E-01
Scenario [2]- Propan-2-ol (volatilisation)			1.30E-01

Scenarios and values to be used in risk assessment			
Scenario	**Permethrin (mg/kg/d)**	**S-methoprene (mg/kg/d)**	**Propan-2-ol (mg/kg/d)**
Exposure of children who crawl on treated surface with a hand to mouth transfer			
Scenario [3] general-spraying permethrin **Efficient dose**	1.81E-02	2.07E-04	
Scenario [3] general- fogger permethrin	8.55E-02	5.56E-03	
Scenario [3] carpet- spraying permethrin **Efficient dose**	5.44E-03	6.20E-05	
Scenario [3] carpet- fogger permethrin	2.57E-02	1.67E-03	
Exposure of adults touching a treated surface			
Scenario spraying [4] **Adults Wet permethrin Efficient dose**	1.90E-03	2.37E-05	
Scenario fogger [4] **Adults Wet permethrin**	7.14E-03	6.37E-04	
Scenario spraying [4] **Adults Dried permethrin Efficient dose**	5.71E-04	7.10E-06	
Scenario fogger [4] **Adults Dried permethrin**	2.14E-03	1.91E-04	
Exposure of adults, children and toddlers who sleep in a treated bed			
Scenario [5] spraying **Adults permethrin Efficient dose**	1.16E-02	1.44E-04	
Scenario [5] spraying **Children Permethrin Efficient dose**	1.61E-02	2.00E-04	
Scenario [5] spraying **Toddler Permethrin Efficient dose**	2.01E-02	2.49E-04	
Scenario [5] fogger **Adults permethrin**	4.33E-02	3.87E-03	
Scenario [5] fogger **Children permethrin**	6.03E-02	5.38E-03	

Scenarios and values to be used in risk assessment			
Scenario	**Permethrin (mg/kg/d)**	**S-methoprene (mg/kg/d)**	**Propan-2-ol (mg/kg/d)**
Scenario [5] fogger **Toddler permethrin**	7.52E-02	6.71E-03	
Exposure to volatile residue			
Scenario [6] spraying **Adults**	8.00E-05	2.21E-03	3.2
Scenario [6] spraying **Children**	1.51E-04	4.17E-03	6.03
Scenario [6] spraying **Toddler**	1.62E-04	4.48E-03	6.48
Scenario [6] fogger **Adults**	8.00E-05	1.04E-02	9.33E-01
Scenario [6] fogger **Children**	1.51E-04	1.96E-02	1.76
Scenario [6] fogger **Toddler**	1.62E-04	2.11E-02	1.89

Dietary exposure

The product INSECTICIDE HOUSEHOLD SPRAY is an insecticide for domestic indoor use, to be applied by spraying on non-washable furniture and home textile as carpets, mats, arm chairs. It is not intended to be used in the presence of food, feed, drinks or food-producing animals, and on food utensils or food-processing surfaces. Indeed, no direct or indirect contact with food, feed and drinks is expected according to the use of the product.
To avoid any contamination, the following risk mitigation measures are proposed:

- Do no use on surfaces and facilities in vicinity or likely to be in contact with food, feed and drinks
- Remove all food, feed and drinks prior treatment.

The PRODUCT FOGGER INSECTICIDE FOR HOUSEHOLDS is an insecticide for domestic indoor use, to be applied by fogging. It is not intended to be used in the presence of food, feed, drinks, food-producing animals and food utensils.

Nevertheless, surfaces likely to be in contact with food can be contaminated during fogging application. According to ECHA guidance[17], covering food or surfaces before use is unlikely to be followed for non professional. Therefore, for fogging application, the following RMM is proposed:

- Do not use in areas where food is stored and prepared such as kitchens.

Therefore, no further data are required concerning the residue behaviour.

[17] Guidance on estimating dietary risk from trasnfer of biocidal active substances into foods – Non professional uses (Chapter 5. Guidance on estimating dietary risk from transfer of biocidal active substance into foods – non professional uses)

Information of non-biocidal use of the active substance

permethrine
Residue definitions
Permethrin (sum of isomers)
This active substance is considered "Fat soluble".

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s) [2]**
1.	Plant protection products	EU Reg. 396/2005: not approved active substance Permethrin Review Report 13 July 2000: *"Technical evidence has been provided indicating that limited further use of permethrin in forestry could be allowed whilst research is ongoing in order to find efficient alternatives providing that appropriate risk mitigation measures are taken. To minimise potential risk for aquatic organisms it was proposed by the Rapporteur Member State that a buffer zone should be applied between treated areas and surface waters.* *In view of the fact that all notifiers of the substance, formally withdrew their support for permethrin within the EU Peer Review Programme and, therefore, no engagements are made to produce the necessary supplementary data, an inclusion of this active substance in Annex I of Directive 91/414 cannot be envisaged"*	Default MRL at 0.05* mg/kg or 0.1* mg/kg depending of the commodities (Reg. (EU) 2017/623)
2	Veterinary medicinal products	EU Reg. 470/2009 External application for the control of ectoparasites for cattle	MRL for bovine: Muscle, Liver, Kidney, Milk: 50 µg/kg Fat: 500 µg/kg (Reg (EU) 37/2010)

[1] e.g. plant protection products, veterinary use, food or feed additives
[2] e.g. MRLs. Use footnotes for references.

S-Methoprene:
S-Methoprene is only approved under biocidal regulation.

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Permethrin

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
AELshort-term	Rat 2 year oral study (acute effect)	50	100	100%	0.5 mg/kg/d
AELmedium-term	12-month dog study	5	100	100%	0.05 mg/kg/d
AELlong-term	12-month dog study	5	100	100%	0.05 mg/kg/d
ARfD					0.5 mg/kg/d
ADI					0.05 mg/kg/d

S-methoprene

Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value
AELshort-term	Rabbit developmental study	100	100	35%	0.35 mg/kg/d
AELmedium-term	90 day dog study	100	100	35%	0.35 mg/kg/d
AELlong-term	2-year rat study	65.4	100	35%	0.076 mg/kg/d
ARfD	Not applicable				
ADI	Not applicable				

Propan-2-ol

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort, medium and long-term (General population)	Inhalation, Human volonteer study	200 ppm or 68.2 mg/kg bw/d	6.4	100%	10.7 mg/kg bw/d
AELshort,medium and long-term (Professional workers)			3.8		17.9 mg/kg bw/d
Inhalation OEL		200 ppm or 0.49 mg/L air, 8h exposure*	n.a		200 ppm or 0.49 mg/L air, 8h exposure*
ARfD	Not neccessary				
ADI					

* Based on LOAEC of 400 ppm from study by Sethre *et al*. 2000a. For conversion to inhaled dose, default values for adult humans (average weight of 60 kg) and a respiratory volume of 1.044 m3/h (8.35 m3/8h) were employed.

The products of BPF INSECTICIDE FOR HOME USE contain 2 active substances (permethrin and S-methoprene) and 1 substance of concern (propan-2-ol).
Therefore a risk assessment from combined exposure to several active substances should be performed according to the Guidance on the Biocidal Product Regulation, Volume III Part B.
The first step (Tier 1) of this approach is to verify acceptability for each substance used in the product, corresponding to the comparison of the exposure values to the AEL of each substance as stated above and leading to the calculation of Hazard Quotients (HQ), corresponding to estimation of exposure/AEL.

In a Tier 2, additive effects were considered by summing up the HQ of each active substance, leading to the calculation of a HI (Hazard Index).
If HI ≤ 1 the risk related to use of the mixture will be considered acceptable;
If HI > 1 a refinement is needed.

Risk for industrial users

Not relevant

Risk for professional users

Not relevant

Risk for non-professional users

Considering that application can be done up to every 6 months, short-term AELs are used to characterise the risk.

Systemic effects

Permethrin

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Spraying application	1	0.5	1.32E-01	26%	*see Tier 2*
Fogger application	1	0.5	4.40E-02	9%	*see Tier 2*

S-methoprene

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Spraying application	1	0.35	1.66E-03	0.48%	*see Tier 2*
Fogger application	1	0.35	2.00E-03	1%	*see Tier 2*

Propan-2-ol

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Spraying application	1	10.7	8.43E-01	8%	
Spraying evaporation	1	10.7	4.70E-01	4%	
Spraying total	**1**	**10.7**	**1.31**	**12%**	*see Tier 2*
Fogger application	1	10.7	1.20E-01	1%	
Fogger Evaporation	1	10.7	1.30E-01	1%	
Fogger total	**1**	**10.7**	**2.50E-01**	**2%**	*see Tier 2*

Tier 2 (additivity)

	Permethrin	S-methoprene	Propan-2-ol	HI (Σ HQ a.s)	Risk
Spraying application	0.26	0.0048	0.12	0.38	Acceptable
Fogging application	0.09	0.01	0.02	0.12	Acceptable

Considering the mixture approach, the risk is acceptable for each scenario.

However, no exposure asssessment was performed for the children during the application of the product, by spraying or fogging. In consequence, the risk mitigation measure "keep children away during treatment" should be implemented.

Combined scenarios:

Combined exposure is determined, considering that a person applies products by fogging and by spraying the same day.

Permethrin

Scenarios combined	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Combined exposure: application by fogging + application by spraying	1	0.5	1.76E-01	35%	*see Tier 2*

S-methoprene

Scenarios combined	Tier	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)

Combined exposure: application by fogging + application by spraying	1	0.35	3.66E-03	1%	*see Tier 2*

Propan-2-ol

Scenarios combined	Tier	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Combined exposure: application by fogging + application by spraying	1	10.7	1.56	15%	*see Tier 2*

Tier 2 (additivity)

	Permethrin	S-methoprene	Propan-2-ol	HI (Σ HQ a.s)	Risk
Combined exposure	0.35	0.01	0.15	0.51	Acceptable

Considering the mixture approach, the risk is acceptable for combined scenario.

Local effects

The products of the BPF INSeCTICIDE FOR HOME USE are classified Eye irritant of category 2 H319. Therefore, a local risk assessment is performed according to the guidance document on the BPR: volume III parts B+C.

Hazard category	Effect	Frequency and duration of potential exposure	Degree of potential exposure under best practice conditions	Relevant RMMs (PPE are not relevant)
Low	Eye irrit. 2, H319	The exposure is less than one hour per day: Few minutes for fogger and around 10 min for spraying	Exposure during application: ➢ Fogger: it is recommended to leave out the room during 4 hours ➢ Spraying: : it is recommended to leave out the room during 1 hour	Labelleing, instructions for use that minimise exposure has to be provided.

For local effect of propan-2-ol:

Scenario	Air concentation mg/m^3
Spraying application	6.43
Spraying evaporation	130
Fogger application	8.4
Fogger Evaporation	38

The air concentration in propan-2-ol is inferior to the IOEL (490 mg/m3)

Conclusion

The risk is considered acceptable.

Risk for the general public

As the product is expected to be efficient during 6 months, a chronic exposure is considered for characterise the risk linked to the secondary exposure.

Systemic effects

Permethrin

Task/ Scenario	**Tier**	**AEL (mg/kg bw/d)**	**Estimated uptake (mg/kg bw/d)**	**Estimated uptake/ AEL (%)**	**Acceptable (yes/no)**
Toddler crawling on treated surface – general surface					
Spraying application at **efficient dose**	1	0.05	1.81E-02	36%	*see Tier 2*
Fogger application	1	0.05	8.55E-02	171%	NO
Toddler crawling on treated surface – carpet surface					
Spraying application at **efficient dose**	1	0.05	5.44E-03	11%	*see Tier 2*
Fogger application	1	0.05	2.57E-02	51%	*see Tier 2*
Adults touching surface wet surface					
Spraying application **Efficient dose**	1	0.05	1.90E-03	4%	*see Tier 2*
Fogger application	1	0.05	7.14E-03	14%	*see Tier 2*
Adults touching Dried surface					
Spraying application **Efficient dose**	1	0.05	5.71E-04	1%	*see Tier 2*
Fogger application	1	0.05	2.14E-03	4%	*see Tier 2*

Task/ Scenario	Tier	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Sleeping in treated bed					
Spraying application					
Adult Efficient dose	1	0.05	1.16E-02	23%	*see Tier 2*
Children Efficient dose	1	0.05	1.61E-02	32%	*see Tier 2*
Toddler **Efficient dose**	1	0.05	2.01E-02	40%	*see Tier 2*
Fogging application					
Adult	1	0.05	4.33E-02	87%	*see Tier 2*
Children	1	0.05	6.03E-02	121%	NO
Toddler	1	0.05	7.52E-02	150%	NO
Exposure to volatile residue					
Spraying application					
Adult	1	0.05	8.00E-05	0.16%	*see Tier 2*
Children	1	0.05	1.51E-04	0.30%	*see Tier 2*
Toddler	1	0.05	1.62E-04	0.32%	*see Tier 2*
Fogging application					
Adult	1	0.05	8.00E-05	0.16%	*see Tier 2*
Children	1	0.05	1.51E-04	0.30%	*see Tier 2*
Toddler	1	0.05	1.62E-04	0.32%	*see Tier 2*

For permethrin:

- The risk is unacceptable for toddler crawling on general surface treated by fogging.
- The risk for the scenario ”sleeping in a contaminated bed” treated by fogging is unacceptable for children and toddler.
-

S-methoprene

Task/ Scenario	Tier	AEL (mg/kg bw/d)	Estimated uptake (mg/kg (bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Toddler crawling on treated surface – general surface					
Spraying application at **efficient dose**	1	0.076	2.07E-04	0.27%	*see Tier 2*
Fogger application	1	0.076	5.56E-03	7%	*see Tier 2*
Toddler crawling on treated surface – carpet surface					
Spraying application at **efficient dose**	1	0.076	6.20E-05	0.8%	*see Tier 2*
Fogger application	1	0.076	1.67E-03	2%	*see Tier 2*
Adults touching Wet surface					

Task/ Scenario	Tier	AEL (mg/kg bw/d)	Estimated uptake (mg/kg (bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Spraying application **Efficient dose**	1	0.076	2.37E-05	0.03%	*see Tier 2*
Fogger application	1	0.076	6.37E-04	0.84%	*see Tier 2*
Adults touching Dried surface					
Spraying application **Efficient dose**	1	0.076	7.10E-06	0.01%	*see Tier 2*
Fogger application	1	0.076	1.91E-04	0.25%	*see Tier 2*
Sleeping in treated bed					
Spraying application					
Adult **Efficient dose**	1	0.076	1.44E-04	0.19%	*see Tier 2*
Children **Efficient dose**	1	0.076	2.00E-04	0.26%	*see Tier 2*
Toddler **Efficient dose**	1	0.076	2.49E-04	0.33%	*see Tier 2*
Fogging application					
Adult	1	0.076	3.87E-03	5%	*see Tier 2*
Children	1	0.076	5.38E-03	7%	*see Tier 2*
Toddler	1	0.076	6.71E-03	9%	*see Tier 2*
Exposure to volatile residue					
Spraying application					
Adult	1	0.076	2.21E-03	3%	*see Tier 2*
Children	1	0.076	4.17E-03	5%	*see Tier 2*
Toddler	1	0.076	4.48E-03	6%	*see Tier 2*
Fogging application					
Adult	1	0.076	1.04E-02	14%	*see Tier 2*
Children	1	0.076	1.96E-02	26%	*see Tier 2*
Toddler	1	0.076	2.11E-02	28%	*see Tier 2*

Propan-2-ol

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Exposure to volatile residue					
Spraying application					
Adult	1	10.7	3.2	30%	*see Tier 2*
Children	1	10.7	6.03	56%	*see Tier 2*
Toddler	1	10.7	6.48	61%	*see Tier 2*
Fogging application					
Adult	1	10.7	9.33E-1	9%	*see Tier 2*
Children	1	10.7	1.76	16%	*see Tier 2*
Toddler	1	10.7	1.89	18%	*see Tier 2*

Tier 2 (additivity)

For the acceptable scenarios, the additivity approach is performed:

	Permethrin	S-methoprene	Propan-2-ol	HI (∑ HQ a.s)	Risk
Toddler crawling Spraying application **at efficient dose** General surface	0.36	0.0027	n.r.	0.3627	Acceptable
Toddler crawling spraying application at efficient dose Carpet surface	0.11	0.008	n.r.	0.118	Acceptable
Toddler crawling fogging application Carpet surface	0.51	0.02	n.r.	0.53	Acceptable
Adults touching wet[1] surface Spraying application at **efficient dose**	0.04	0.0003	n.r.	0.0403	Acceptable
Adults touching wet[1] surface Fogger application	0.14	0.0084	n.r.	0.1484	Acceptable
Adult sleeping in a contaminated bed by spraying application a**t efficient dose**	0.23	0.0019	n.r.	0.2319	Acceptable
Adult sleeping in a contaminated bed by fogging application	0.87	0.05	n.r.	0.92	Acceptable
Children sleeping in a contaminated bed by spraying application at **efficient dose**	0.32	0.0026	n.r.	0.3226	Acceptable
Toddler sleeping in a contaminated bed by spraying application at **efficient dose**	0.40	0.0033	n.r.	0.4033	Acceptable
Exposure to volatile residue Spraying application Adult	0.0016	0.03	0.30	0.3316	Acceptable
Exposure to volatile residue Spraying application children	0.003	0.05	0.56	0.613	Acceptable
Exposure to volatile residue Spraying application toddler	0.003	0.06	0.61	0.673	Acceptable

	Permethrin	S-methoprene	Propan-2-ol	HI (∑ HQ a.s)	Risk
Exposure to volatile residue Fogging application Adult	0.0016	0.14	0.09	0.2316	Acceptable
Exposure to volatile residue Fogging application children	0.003	0.26	0.16	0.423	Acceptable
Exposure to volatile residue Fogging application toddler	0.003	0.28	0.18	0.463	Acceptable

1 Wet surface covers dried surface

For local effect of propan-2-ol after exposure to volatile residue:

Scenario	Air concentation (mg/m^3)
Spraying application	12
Fogger application	3.5

The air concentration in propan-2-ol is inferior to the IOEL (490 mg/m3)

For secondary exposure, unacceptable risks are identified due to permethrin exposure. Therefore, mitigation measures are proposed:

- Risk is unacceptable for toddler crawling on general surface treated by fogging. Therefore risk mitigation measure is needed:
  - For fogging application: "Do not apply on impervious surfaces"

- The risk linked to the scenario "sleeping in a contaminated bed" treated by fogging is unacceptable for children and toddler.
  - For fogging application: Do not treat the bed of children/toddler

Combined scenarios

The application of products is performed at maximum 2 times per year with an interval of 6 months and an efficacy during 6 months is claimed. Therefore, short term exposure is considered for application whereas secondary exposure is considered as a long term-exposure. In this context, the combination of the exposure during application and in post-application is not considered relevant. In this context, combined exposure is determined only for the secondary exposure combinations.

Permethrin

Scenarios combined	Tier	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Spraying application at efficient dose					
Adult: touching wet surface + sleeping in a contaminated bed+ exposure to volatile residue	1	0.05	1.36E-02	27%	see Tier 2
Toddler: crawling on general surface + sleeping on contaminated bed+ exposure to volatile residue	1	0.05	3.84E-02	77%	see Tier 2
Fogger application					
Adult: touching wet surface + sleepling in a contaminated bed + exposure to volatile residue	1	0.05	5.05E-02	101%	NO
Adult: touching dried surface + sleepling in a contaminated bed + exposure to volatile residue	1	0.05	4.55E-02	91%	see Tier 2
Toddler: crawling on carpet + exposure to volatile residue	1	0.05	2.59E-02	52%	see Tier 2

The risk for combined exposure of an adult touching a wet surface, sleeping in a contaminated bed and inhaling volatile residue after fogging application is unacceptable. Therefore, a mitigation measure is needed.

S-methoprene

Scenarios combined	Tier	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Spraying application at efficient dose					
Adult: touching wet surface + sleeping in a contaminated bed+ exposure to volatile residue	1	0.076	2.38E-03	3%	see Tier 2
Toddler: crawling on general surface + sleeping on contaminated bed+ exposure to volatile residue	1	0.076	4.94E-03	6%	see Tier 2

Scenarios combined	Tier	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Fogger application					
Adult: touching wet surface + sleepling in a contaminated bed + exposure to volatile residue	1	0.076	1.49E-02	20%	see Tier 2
Adult: touching dried surface + sleepling in a contaminated bed + exposure to volatile residue	1	0.076	1.45E-02	19%	see Tier 2
Toddler: crawling on carpet + exposure to volatile residue	1	0.076	2.28E-02	30%	see Tier 2

Tier 2 (additivity)

Additivity approach is performed:

	Permethrin	S-methoprene	HI (∑ HQ a.s)	Risk
Spraying application at efficient dose				
Adult: touching wet surface + sleeping in a contaminated bed+ exposure to volatile residue	0.27	0.03	0.30	Acceptable
Toddler: crawling on general surface + sleeping on contaminated bed+ exposure to volatile residue	0.77	0.06	0.83	Acceptable
Fogger application				
Adult: touching dried surface + sleepling in a contaminated bed + exposure to volatile residue	0.91	0.19	1.1	see Tier 3B
Toddler: crawling on carpet + exposure to volatile residue	0.52	0.30	0.82	Acceptable

Considering the additivity approach, the risk is acceptable for combined exposure except for the combined exposure for adult after fogging application;

➔ HI > 1 a refinement is needed.

A Tier 3B approach could be considered. However, the AELs of each active substance are based on liver effects. Therefore, no refinement of the AEL to organ AEL is possible.

Taking in consideration the combined secondary exposure and mixture approach, two scenarios are unacceptable for fogger application:

- Adult: touching wet surface + sleepling in a contaminated bed + exposure to volatile residue
- Adult: touching dried surface + sleepling in a contaminated bed + exposure to volatile residue

Considering that a mitigation measure to avoid contamination of children/toddler's bed is ever proposed for fogger application, the similar RMM is also proposed for adult.

In this context, the combined secondary exposure for fogger application is reviewed according to this proposal:

Permethrin:

Scenarios combined	Tier	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Fogger application					
Adult: touching wet surface + exposure to volatile residue		0.05	7.22E-03	14%	see Tier 2

S-methopren:

Scenarios combined	Tier	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Fogger application					
Adult: touching wet surface + exposure to volatile residue		0.076	1.10E-02	15%	see Tier 2

Tier 2 (additivity)

	Permethrin	S-methoprene	HI (∑ HQ a.s)	Risk
Fogger application				
Adult: touching wet surface + exposure to volatile residue	0.14	0.15	0.29	Acceptable

The risk is acceptable.

Morover, a RMM is proposed for fogging application:

- Push the ring to activate the diffusion. Leave the room and close the door behind you. Wait 4 hours before entering the room again.

Considering the air concentration in active substance after 4 hours and an exposure of 24 hours at this concentration the risk is considered acceptable for the 3 substances:

Substance	AEL (mg/kg bw/d)	Estimated uptake (mg/kg bw/d)	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Permethrin	0.05	7.50E-03	15%	YES
S-methoprene	0.076	2.25E-04	0.3%	YES
Propan-2-ol	10.7	2.15E-02	0.2%	YES

Conclusion

The risk during application by fogging or spraying is acceptable for non professional user.
Some scenarios for secondary exposure are unacceptable leading to the following RMMSs:

For meta SPC 2 – product applied by fogging:

Do not apply on impervious surfaces
Do not treat the beds

Moreover, other RMM were claimed by applicant and used to determine exposure:

- The two products must not be used in the same room.

For the product applied by fogging:

- Push the ring to activate the diffusion. Leave the room and close the door behind you. Wait 4 hours before entering the room again.

For the product applied by spraying:

- After spraying, leave the room and let act one hour before airing
- .

Risk for consumers via residues in food

Regarding the intended uses, food or feed contamination is not expected. As a consequence the exposure via food, via livestock exposure or via transfer of biocidal active substances is considered as negligible, and no dietary risk assessment was performed. The use is considered acceptable considering the proposed risk mitigation measured:

- Do no use on surfaces and facilities in vicinity or likely to be in contact with food, feed and drinks
- Remove all food, feed and drinks prior treatment.

For fogging application in order to avoid indirect contamination during nearby application, the following RMM is proposed:

- Do not use in areas where food is stored and prepared such as kitchens.

2.2.7 Risk assessment for animal health

No guidance document is available to assess the risk for the animals.
In this context, according to the discussion of the WG II tox 2019, only a qualitative risk assessment is performed.
The assessment proposed by applicant and commented by eCA is presented in the appendix of this PAR.

Considering the toxic property of the active substances and notably permethrin for cats, a risk for pets cannot be excluded.
Therefore, the following RMM are proposed:

- Remove or cover terrariums, aquariums and animal cages before application.
- Turn off aquarium air-filter while spraying.
- Keep cats away from treated surfaces due to high sensitivity to permethrin toxicity.Keep pets away during treatment.

2.2.8 Risk assessment for the environment

In the absence of substances of concern, the environmental risk assessment of this product is based on the information provided in the Competent Authority assessment Report (CAR) of Permethrin (2014) and S-Methoprene (2013). No additional ecotoxicological data on the formulated product have been developed.

Even, Isododecane is classified for the environment, Isododecane is extremely volatile, so during the use of biocidal products, will disseminate in the atmosphere and will stay in the atmosphere. The deposit on the soil (as well as surface water) is considered as negligible. Moreover, the level of toxicity of Isododecane compare to the aaquatic toxicity of active substance is very low. Considering these 2 informations, as well as the uses performed and the fact that Isododecane do not participate to the classification, Isododecane is not considered as a Substance of Concern.

Infobox 1 - FR CA position:

One substance of concern has been identified for human health. Nevertheless it is not relevant for an environmental risk assessment for the following reasons.

Propan-2-ol is a biocidal active substance approved in PT1, PT2 and 4. According to its CAR (2016), the substance is not classified for the environment. The PNEC values of propan-2-ol in each environmental compartment are the following $PNEC_{stp}$ = 10 mg/L, $PNEC_{water}$ = 2.82 mg/L, $PNEC_{sediment}$ = 2.41 mg/kg ww, $PNEC_{soil}$ = 0.496 mg/kg ww. Consequently the toxicity of product is principally linked to the toxicity of the active substances (Permethrin and S-Methopren) for the aquatic compartment, with relative toxicity units of more than 95% for permethrin concerning surface water and sediment organisms (i.e. comparison of PNEC values and concentrations in the product). For the terrestrial compartment, considering the very high volatility of propan-2-ol and its environmental behaviour profile and also considering that only small scale applications of the product will be authorised, a release to the STP and a soil contamination can be considered negligible. In fact, the product is intended to have a long-lasting effect and the cleaning of the treated surfaces and textiles are forbidden to limit the contamination of the environmental compartments; the most likely emission of propan-2-ol will be to the atmosphere. Therefore, propan-2-ol is not considered as a substance of concern for the environement in this formulation.

Another substances are under the BPR review program but no agreed reference values are available. Therefore, according to guidance on the BPR volume IV part B + C, these substances could not be considered as SOC for the environment.

The justification for the non-relevance of other co-formulants is presented in the Confidential PAR.

2.2.8.1 Effects assessment on the environment

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

Infobox 2 - FR CA position:

Classification for the environment of the Active Substance Permethrin	
Value/conclusion	Very toxic to aquatic life – H400 with M-factor = 100 Very toxic to aquatic life with long-lasting effects – H410 with M-factor = 10000
Justification for the value/conclusion	Daphnia was the most sensitive aquatic organism with the lowest acute ecotoxicity endpoint (48h): EC50 1.27E-03 mg/L and the lowest chronic ecotoxicity endpoint (21d): NOEC 4.7E-06 mg/L.

Classification for the environment of the Active Substance S-Methoprene	
Value/conclusion	Very toxic to aquatic life – H400 with M-factor = 1 Very toxic to aquatic life with long-lasting effects – H410 with M-factor = 1
Justification for the value/conclusion	Daphnia was the most sensitive aquatic organism with the lowest acute ecotoxicity endpoint (48h): EC50 0.22 mg/L and the lowest chronic ecotoxicity endpoint (21d): NOEC 0.019 mg/L.

Classification for the environment of the Product INSECTICIDES FOR HOME USE	
Value/conclusion	Aquatic Acute Cat 1; H400 Aquatic Chronic Cat 1; H410

Regarding the product composition presented in annex 2.6, the substances classified for environmental hazard are the following:

- **Permethrin**: harmonized classification Aquatic chronic 1 (H410) and Aquatic Acute 1 (H400) with an M-factor of 1000, in accordance with the applicant classification. Nevertheless, the CAR (2014) recommends "H400 (Acute Cat 1) will be changed to H410 (Acute Cat 1; Chronic Cat 1): Very toxic to aquatic life with long lasting effects, in accordance with the principles of precedence for hazard statements outlined in Article 27 of the CLP Regulation". This classification is based on the high toxicity to fish (0.0051 mg

a.s./L) and to aquatic invertebrates, with Daphnia 0.00127 mg a.s/L, being the most sensitive of the aquatic organisms tested. Chronic toxicity studies resulted in a NOEC of 0.0000047 mg/L for Daphnia magna.

- **S-Methopren**: Autoclassified Chronic Aquatic Cat 1 (H410) in accordance with ECHA C&L notification, CAR (2013) classification and the applicant classification with a M-factor of 1000. The active substance S-Methoprene classifies as very toxic to aquatic organisms as it has chronic toxicity of ≤ 1 mg/l to invertebrates, the logKow is > 6 and S-Methoprene is not readily biodegradable. The BCF is not experimentally determined it is estimated. It is recommended that its container be disposed of in a safe place.
- **Isododecane**: autoclassified H413 by the applicant and in a minority of C&L notifications. This substance has the EC number 297-629-8 and CAS number 93685-81-5 in the applicant documentation, but has several possible identifiers (CAS 31807-55-3/13475-82-6 and EC 250-816-8/236-757-0) as mentioned in ECB summary Fact Sheet n° 62[18] and Cosing database[19]. It is poorly to non soluble in water based on data from the REACH registration dossier on 2,2,4,6,6-pentamethylheptane (EC number: 236-757-0, CAS number: 13475-82-6) and ECB summary Fact Sheet n° 62. Therefore, the corresponding environmental hazard is not worrying.
- Components of **PARFUM[redacted]**: D-limonene and (S)-P-MENTHA-1,8-DIENE (harmonized classification H400, H410 with M-factor=1), BUTYLATED HYDROXYTOLUENE, ALPHA-PINENE and 3-METHYLCYCLOPENTADECENONE (autoclassified H400 and H410 with M-factor=1). Nevertheless, fragrance concentration is <0.05% m/m in the Insecticides for home use biocidal products family, below the 0.1% m/m threshold of consideration for classification.

Therefore, the products **are classified as Aquatic chronic 1 and Aquatic Acute 1** according to CLP regulation and the components which participate to the CLP classification are **the 2 actives substances** (Permethrin and S-Methoprene). **There is no other substance of concern in the product's formulations.**

Conclusion used in Risk Assessment – Environmental Hazards	
Value/conclusion	The products are classified as Aquatic chronic 1 (H410) and Aquatic Acute 1 (H400) according to CLP regulation.
Justification for the value/conclusion	The environmental hazard CLP classification is triggered by the the 2 actives substances only: - Permethrin - S-Methopren Therefore, these are considered as the susbtances of concern for risk assessment.

Further Ecotoxicological studies

Infobox 3 - FR CA position:
No new data is available.

The applicant's Insecticides for home use biocidal products family classification for environment hazard being triggered by the two active susbtances, and as there is no other substance of concern, no complementary study have been performed by the applicant, neither on ecotoxicology nor fate and behaviour of the co-formulants.
Therefore the environmental risk assessment is based on the active substances, and the applicant is also considering the metabolites of the Permethrin: 3-(2,2-dichlorovinyl)-2,2-dimethyl-(1-cyclopropane)carboxylate (DCVA) and 3-phenoxybenzoic acid (PBA).

Summary table - Further ecotoxicological studies
Aquatic organisms (including chronic)

Summary table of effect on aquatic organisms - Permethrin						
Method, Guideline, GLP status, Reliability	Species/ Inocu-lum	End point	Exposure duration	Results	Remarks	Refe-rence
Not mentioned in CAR 2014	Daphnia magna	Immobility and mortality, LC50	48 h	0.00127 mg/L	/	Bayer/Sumitomo in CAR 2014
Not mentioned in CAR 2014	Daphnia magna	Reproduction, NOEC EC50	21 d	0.0000047 mg/L 0.0001874 mg/L	/	Tagros in CAR 2014
Not mentioned in CAR 2014	Oncorhynchus mykiss	Mortality, LC50	96h	0.0051 mg/L	/	Bayer/Sumitomo in CAR 2014

Conclusion used in Risk Assessment – PNECaquatic – Permethrin	
Value/conclusion	The following PNEC have been identified: PNECaquatic = 0.00047 µg/l
Justification for the value/conclusion	Not detail in (CAR,2014) but environmental hazards are presented in Doc IIA along with PNEC derivations.

Concerning permethrin metabolites DCVA and PBA, this effect and corresponding PNECs elaboration is not detailed but described as far less toxic to aquatic organisms than the parent active ingredient and not considered to be ecotoxicologically relevant. The following the effects data presented for permethrin metabolites in CAR (2014):

- DCVA : PNECaquatic = 0.015 mg/l
- PBA : PNECaquatic = >0.010 mg/l

Summary table of effect on aquatic organisms – S-Methoprene						
Method, Guideline, GLP status, Reliability	Species/ Inocu-lum	End point	Exposure duration	Results	Remarks	Refe-rence
Not mentioned in CAR 2013	Daphnia magna	NOEC	Chronic	0.019 mg/L	/	Biopren® Pharaoh's ant Colony Eliminator dossier in
	Zebrafish, Brachydanio rerio,	LC50 NOEC	96 h	An LC50 value of 4.26 mg/l and NOEC value of 1.25 mg/l was determined.	/	

						CAR 2013

Conclusion used in Risk Assessment – PNECaquatic – S-Methoprene	
Value/conclusion	The following PNEC have been identified: PNECaquatic = 0.00019 mg/L.
Justification for the value/conclusion	According to (CAR, 2013), the PNEC for aquatic organisms was calculated using the reproduction, growth and mortality of Daphnia magna as this was the most sensitive aquatic organism tested. Based on these data, the PNECaquatic of S-Methoprene to aquatic invertebrates, following application of an assessment factor of 100, was established to be 0.00019 mg/L.

Sewage sludge microorganisms

Summary table of effect on sewage sludge microorganisms - Permethrin						
Method, Guideline, GLP status, Reliability	Species/ Inocu-lum	End point	Exposure duration	Results	Remarks	Refe-rence
Not mentioned in CAR 2014	Activated sewage sludge	EC50 NOEC	3 hours	> 1000 mg/l 0.00495 mg/l[20]	/	Tagros in CAR 2014
Not mentioned in CAR 2014	Activated sewage sludge	EC50 NOEC	3 hours	> 0.42 mg/l 0.00495 mg/l[10]	/	Bayer/ Sumitomo in CAR 2014

Conclusion used in Risk Assessment PNEC sludge organisms (STP) - Permethrin	
Value/conclusion	The following PNEC have been identified: PNEC-organisms (STP) = 0.00495 mg a.s/l
Justification for the value/conclusion	According to (CAR, 2014), for substances with low water solubility and if no effects on microorganisms are observed at the highest tested concentration, then water solubility is set as the NOEC

Concerning permethrin metabolites DCVA and PBA, this effect and corresponding PNECs elaboration are not described in (CAR, 2014) but in Section 4.2 of Document IIA. These are described as far less toxic to aquatic organisms than the parent active ingredient and not considered to be ecotoxicologically relevant: no PNEC is established for this compartment.

Summary table of effect on sewage sludge microorganisms – S-Methoprene						
Method, Guideline, GLP status, Reliability	Species/ Inocu-lum	End point	Exposure duration	Results	Remarks	Refe-rence
Not mentioned in CAR 2013	Activated sewage sludge	EC50	3h	6.85 mg/L[21]	/	CAR 2013

Conclusion used in Risk Assessment PNEC sludge organisms (STP) – S-Methoprene

Value/conclusion	The following PNEC have been identified: PNEC-organisms (STP) = 6.85 mg/L
Justification for the value/conclusion	Not detail in (CAR,2013) but environmental hazards are presented in Doc IIA along with PNEC derivations.

Soil organisms
Concerning permethrin and its metabolites DCVA and PBA, this effect and corresponding PNECs elaboration are not described in (CAR, 2014) but in Section 4.2 of Document IIA. The following the effects data presented:

- Permethrin: PNEC soil (wet weight) = >0.0876 mg a.s/kg soil wwt
- DCVA : PNEC soil (wet weight) = 4.6 mg/kg wwt
- PBA : PNEC soil (wet weight) = 1.44 mg/kg wwt

Conclusion used in Risk Assessment – PNEC soil organisms – S-Methoprene	
Value/conclusion	PNECsoil = 0.0003 mg/kg wwt
Justification for the value/conclusion	No detail in (CAR,2013), except that at risk assessment stage, according to the TGD, the PECsoil/PNECsoil ratio is increased by a factor of 10 due to the log Kow >5. This results in a PNECsoil = 0.0003 mg/kg wwt.

Sediment organisms

Summary table of effect on sediments organisms - Permethrin						
Method, Guideline, GLP status, Reliability	Species/ Inocu-lum	End point	Exposure duration	Results	Remarks	Refe-rence
Not mentioned in CAR 2014	Chironomus riparius	adult emergence, LC50 survival, LC50	10-d (spiked sediment) 96hr (spiked water)	2.110 mg/kg 0.00289 mg/L	/	Bayer/ Sumitomo in CAR 2014
Not mentioned in CAR 2014	Chironomus riparius	adult emergence, NOEC	5-d after last emergence (spiked sediment)	0.1 mg/kg	/	Bayer/ Sumitomo in CAR 2014

Concerning permethrin and its metabolites DCVA and PBA, this effect and corresponding PNECs elaboration are not described in (CAR, 2014) but in Section 4.2 of Document IIA. The following the effects data presented:

- Permethrin: PNECsediment = 0.001mg/kg dwt (2.17 x 10-4 wwt)
- DCVA : PNECsediment = 0.055 mg/kg dwt (0.012 mg/kg wwt)
- PBA : PNECsediment = 0.042mg/kg dwt (0.009 mg/kg wwt)

Conclusion used in Risk Assessment – PNEC sediment – S-Methoprene	
Value/conclusion	PNECsediment = 0.00038 mg/kg wwt
Justification for the value/conclusion	No detail in (CAR,2013), except at risk assessment stage, according to the TGD, the PECsoil/PNECsoil ratio is increased by a factor of 10 due to the log Kow >5. This results in a PNECsediment = 0.00038 mg/kg wwt.

Infobox 4 - FR CA position:

PNEC values proposed in the Assessment Report of Permethrin PT18 and in the Assessment Report of S-Methoprene PT18 are summarized below.

Summary table on PNEC for Permethrin	
Environmental compartment	PNEC value
STP	4.95E-03 $mg.L^{-1}$
Surface water	4.70E-04 $\mu g.L^{-1}$
Freshwater sediment	2.17E-04 $mg.kg_{wwt}^{-1}$
Soil	> 8.76E-02 $mg.kg_{wwt}^{-1}$
PNEC oral bird	≥16.7 $mg.kg_{food}$
PNEC oral small mammal	120 $mg.kg_{food}$

The PNEC value for soil has been recently revised to 0.168 mg/kg dwt (0.148 mg/kg wwt). Nevertheless, this change does not impact the conclusions of the risk assessment.

PNEC derivation- Metabolites of Permethrin

Summary table on PNEC for DCVA	
Environmental compartment	PNEC value
Surface water	1.50E-02 $mg.L^{-1}$
Freshwater sediment	1.20E-02 $mg.kg_{wwt}^{-1}$
Soil	4.60 $mg.kg_{wwt}^{-1}$

Summary table on PNEC for PBA	
Environmental compartment	PNEC value
Surface water	>1.00E-02 $mg.L^{-1}$
Freshwater sediment	9.00E-03 $mg.kg_{wwt}^{-1}$
Soil	1.44 $mg.kg_{wwt}^{-1}$

PNEC derivation- Active substance

Summary table on PNEC for S-Methoprene	
Environmental compartment	PNEC value
STP	6.85 $mg.L^{-1}$
Surface water	1.90E-04 $mg.L^{-1}$
Freshwater sediment*	3.80E-04 $mg.kg_{wwt}^{-1}$

Soil*	3.00E-04 mg.kg$_{wwt}^{-1}$
PNEC oral small mammal (calculated)	43.60 mg.kg $_{food}$

* An additional factor of 10 was directly included in the PNEC considering the use of the EPM method for PNEC derivation

No ecotoxicological data are available to set a PNEC value for birds for S-Methoprene.

The CAR addendum of S-Methoprene (June 2016) shows the presence of significant metabolites in water and sediment phases. However, the DT_{50} of S-Methoprene metabolites are lower than the S-Methoprene DT_{50}. Therefore, S-Methoprene metabolites are not considered in the environmental risk assessment.

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

Infobox 5 - FR CA position:

No data is available.

Data waiving	
Information requirement	/
Justification	No data available nor required as ecotoxicological data and intended uses do not indicate any specific risk which would not be covers by the endpoints here above. The products use will not lead to direct exposure of non-target organisms considering the treated surfaces are indoor, and the instructions in the labelling. In fact, the applicant considers the treated surfaces will not be water cleaned but only aspired (with a vacuum cleaner) and then removed as a solid waste.

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

Infobox 6 - FR CA position:

No data is available.

Data waiving	
Information requirement	/
Justification	No data available nor required as ecotoxicological data and intended uses do not indicate any specific risk which would not be covers by the endpoints here above. The products use will not lead to direct exposure of non-target organisms considering the treated surfaces are indoor, and the

	instructions in the labelling. In fact, the applicant considers the treated surfaces will not be water cleaned but only aspired (with a vacuum cleaner) and then removed as a solid waste.

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

Infobox 7 - FR CA position:

No data is available.

Data waiving	
Information requirement	/
Justification	No data available nor required as ecotoxicological data and intended uses do not indicate any specific risk which would not be covers by the endpoints here above. The products use will not lead to direct exposure of non-target organisms considering the treated surfaces are indoor, and the instructions in the labelling. In fact, the applicant considers the treated surfaces will not be water cleaned but only aspired (with a vacuum cleaner) and then removed as a solid waste.

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

Infobox 8 - FR CA position:

No data is available.

Data waiving	
Information requirement	/
Justification	No data available nor required as ecotoxicological data and intended uses do not indicate any specific risk which would not be covers by the endpoints here above. The products use will not lead to secondary ecological effect considering the treated surfaces are indoor, and the instructions in the labelling. In fact, the applicant considers the treated surfaces will not be water cleaned but only aspired (with a vacuum cleaner) and then removed as a solid waste.

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

Infobox 9 - FR CA position:

See the fate and distribution in exposed environmental compartments in infobox 18.

As presented in the here after section Fate and distribution in exposed environmental compartments:

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1 - fogger	No	No	No	No	No	No	Yes	Yes	No
Scenario 2 - spray	No	No	No	No	No	No	No	No	No

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

Infobox 10 - FR CA position:

An experimental characterisation of the insecticide aerosol cartridge application was provided by the applicant (see Confidential PAR to have a view of the studies). The droplet size and velocity distribution were measured, and a quantification of the deposit on floor after its use was proposed.
The test was performed to assess the quantity of product released to the floor. It was based on the weight of the dust collected around and under the aerosol device after treatment. First, the ground surface where the dust was collected was estimated at 1000 *1300 mm around the device. It should be noted this area is very restricted compared to the treated area claimed by the applicant (70 m^2). It could be considered that the product is supposed to settle in all the treated room and not only at one meter around the aerosol device. The proposed values seem therefore largely underestimated.
Moreover, the quantities of active substances (permethrin and S-Methoprene) are estimated according to the product composition compared to the collected dust mass. No specific analytical measures of the active substances were provided in the study report. This method of calculation based on dust mass, without any chemical dosing system is not valid. No mass balance was provided.
In conclusion, for the reason presented above, it was considered that information on product deposition could not be used for risk assessment.

Data waiving	
Information requirement	/
Justification	No data available nor required as ecotoxicological data and intended uses do not indicate any specific risk which would not be covers by the endpoints here above. The products use will not lead to extended exposure of environment considering the treated surfaces are indoor, and the instructions in the labelling. In fact, the applicant considers the treated surfaces will not be water cleaned but only aspired (with a vacuum cleaner) and then removed as a solid waste.

Leaching behaviour (ADS)

Infobox 11 - FR CA position:

No data is available.

Data waiving	
Information requirement	/
Justification	No data available and no data required as the product is used indoor and considering the type of surface treated, and the instruction of use in the labelling, the applicant considers the treated surfaces will not be water cleaned but only aspired (with a vacuum cleaner) and then removed as a solid waste.

Testing for distribution and dissipation in soil (ADS)

Infobox 12 - FR CA position:

eCA disagrees with the soil DT50 values for permethrin and DCVA, and the Koc value for permethrin proposed by the applicant here below. Please refer to the infobox 18.

Conclusion used in Risk Assessment –Distribution and dissipation in soil – Permethrin and its metabolites DCVA and PBA	
Value/conclusion	According to (CAR, 2014), DT_{50}s ranged from 77 d to ~141 d at 12° in one study or from 11.0 to 21.2 d at 12 °C in another : the median value chosen by the applicant DT_{50} for degradation in soil = 50 d (at 12°C) Mean K_{foc} for Permethrin = 73,441 L/kg (n=9) Mean K_{foc} for DCVA = 93.2 L/kg (n = 5) K_{foc} for PBA = 141.2 L/kg
Justification for the value/conclusion	Permethrin is strongly adsorbed to soil. The two major soil metabolites (DCVA & PBA) are more mobile than permethrin.

Conclusion used in Risk Assessment –Distribution and dissipation in soil – S-Methoprene	
Value/conclusion	In various studies in different conditions (PH levels, irradiation, …), DT_{50} range from 17hours to 5 days. According to (CAR, 2013), Koc adsorption values of 537 L/kg, 684 L/kg and 1407 L/kg were measured in three soil types, giving an average Koc value of 876 L/kg.
Justification for the value/conclusion	S-Methoprene is readily adsorbed to and desorbed from soil.

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

Infobox 13 - FR CA position:

No data is available.

Data waiving

Information requirement	/
Justification	No data available nor required as ecotoxicological data and intended uses do not indicate any specific risk which would not be covers by the endpoints here above. The products use will not lead to extended exposure of environment (not in water and sediments in particular) considering the treated surfaces are indoor, and the instructions in the labelling. In fact, the applicant considers the treated surfaces will not be water cleaned but only aspired (with a vacuum cleaner) and then removed as a solid waste.

Testing for distribution and dissipation in air (ADS)

Infobox 14 - FR CA position:

eCA agrees with the data presented by the applicant here below.

Conclusion used in Risk Assessment –distribution and dissipation in air	
Value/conclusion	In accordance with (CAR 2013), the vapour pressure (0.623 mPa at 20 ºC) and molecular weight (310.5) indicate that S-Methoprene will not readily volatilise into the atmosphere at ambient temperature and pressure. If atmospheric exposure did occur a very short half life would be expected given the propensity for S-Methoprene to undergo rapid photodegradation. Volatilization of permethrin is considered to be negligible based on the vapour pressure (2.155 x 10^{-6} Pa at 20°C, 25:75 *cis:trans*) and Henry constant (4.6 x 10^{-3} - > 4.5 x 10^{-2} Pa m^3 mol^{-1}). Besides, conclusion presented in (CAR 2014) states permethrin is rapidly degraded.
Justification for the value/conclusion	The products use will not lead to extended exposure of environment (not in air in particular) considering the treated surfaces are indoor, and the instructions in the labelling. In fact, the applicant considers the treated surfaces will not be water cleaned but only aspired (with a vacuum cleaner) and then removed as a solid waste.

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)

Infobox 15 - FR CA position:

No data is available.

Data waiving	
Information requirement	/
Justification	No data available nor required as ecotoxicological data and intended uses do not indicate any specific risk which would not be covers by the endpoints here above.

	The products use will not lead to spraying near to surface waters considering the treated surfaces are indoor, and the instructions in the labelling.

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)

Infobox 16 - FR CA position:

Not relevant.

Data waiving	
Information requirement	/
Justification	No data available and no data required as the product is used indoor and considering the type of surface treated, and the instruction of use in the labelling, the applicant considers the treated surfaces will not be water cleaned but only aspired (with a vacuum cleaner) and then remove as a solid waste.

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1: application as as a "fumigant indoor application" - Scenario 2: application as a "indoor spraying application for indoor general surface treatment"
ESD(s) used	Scenario 1: ESD TP 18" for insecticides, acaricides and products to control other arthropods for household and professional uses.", for the fumigation application - Scenario 2: ESD TP 18" for insecticides, acaricides and products to control other arthropods for household and professional uses", for the spraying applications
Approach	Scenario 1: Average consumption (Whole product dose released) Scenario 2: Average consumption, (ready-to-use product, no mixing/loading phase)
Distribution in the environment	Calculated based on Guidance on the Biocidal Products Regulation, Volume IV Environment - Part B Risk Assessment, Version 1.0, April 2015 Modelisation with EUSES software
Groundwater simulation	No specific simulation for groundwater
Confidential Annexes	NO / YES: In the confidential Annex 1 to Part B the tonnage based scenarios 2 and 3 are provided
Life cycle steps assessed	Application phase and service-life were assessed
Remarks	/

Infobox 17 - FR CA position:

General information

Assessed PT	PT 18
Assessed scenarios	Insecticides for home use are ready to use biocidal products containing Permethrin and S-Methoprene as active substances. Two intended uses are claimed for the biocidal product family: - The use 1 is a **one shot aerosol cartridge** insecticide for households (named 'fogger' by the applicant). The product is intended to be used by non-professional consumers for indoor applications. This product is claimed to eradicate adult fleas and also their eggs and larvae in the animal's environment, thus avoiding reinfestation with the parasites. It also kills ticks and mosquitoes. To treat the infested area, the device is placed in a raised position in the centre of the treated area. The ring is pushed to activate the diffusion. The only pack size of 150 mL is used to treat a surface of 70 m^2, with one application every 6 months. The application rate of product is 0.490 g/m^3. The quantity of active substance in this product is 0.874 % of permethrin and 0.02625% of S-Methoprene. - The use 2 is an insecticide **spray** for households. The product is intended to be used by non-professional consumers for indoor applications in order to kill cat fleas, ticks and mosquitoes. The spray can be used on carpets, rugs, wooden floors (or "non-washable floor"), armchairs, insisting on areas expected to be highly infested. The largest pack size of 500 mL is used to treat a surface of 140 m^2, with one application every 6 months. The application rate claimed by the applicant is 2.1 g product/m^2. The quantity of active substance in the product is 0.177 % of permethrin and 0.00225% of S-Methoprene.
ESD(s) used	Emission scenario document for insecticides, acaricides and products to control arthropods for household and professional use (ESD for PT18, OECD, 17/07/2008)
Approach	Average consumption approaches
Distribution in the environment	Calculated based on ECHA Guidance on the BPR Vol IV Part B ; April 2015
Confidential Annexes	No
Life cycle steps assessed	Releases to the environment can take place from the following steps: ✓ Preparation step Not relevant for these ready to use products. ✓ Application step <u>One shot aerosol</u> For the indoor one shot aerosol application, the product Insecticides for home use reaches untargeted areas, as an air space treatment, and the applicator clothes. <u>Spray</u> During the indoor spray application on surfaces, the product Insecticides for home use reaches directly the targeted surfaces (as described above)

		and also the adjacent floor by spray drift, the applicator clothes and the indoor air. ✓ Cleaning step Cleaning events result only in emission to wastewater considering that the floor and clothes of the applicator are washable. Treated surfaces are considered wet cleaned or not according to the scenario investigated. To conclude, 3 scenarios are proposed for the environmental risk assessment: - **Scenario 1**: For the indoor one shot aerosol application to treat air and untargeted surfaces. - **Scenario 2**: For the indoor spray application considering a whole surface treatment to cover the application on floors. - **Scenario 3**: For the indoor spray application for the treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (covered by the barrier treatment).
	Remarks	

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1-fogger	No	No	No	No	No	No	Yes	Yes	No

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 2	No	No	No	No	No	No	No	No	No

Input parameters (only set values) for calculating the fate and distribution in the environment - Permethrin			
Input	Value	Unit	Remarks/Source
Molecular weight	391.29	g/mol	Permethrin CAR, 2014
Melting point	34	°C	
Boiling point	305	°C	
Vapour pressure at 25°C	3.04x10-6	Pa	
Water solubility at 25°C	0.193	mg/l	
Log Octanol/water partition coefficient	6.1	Log 10	
Organic carbon/water partition coefficient (Koc)	80000	l/kg	
Henry's Law Constant (20 °C)	-	Pa/m3/mol	
Biodegradability	-	/	
Rate constant for STP	-	h-1	

DT50 for biodegradation in surface water		d (at 12ºC)	
DT50 for hydrolysis in surface water	200	d (at 12ºC /pH 9)	
DT50 for photolysis in surface water	118	d (at 25°C)	
DT50 for degradation in soil	50	d (realistic outdoor condition)	
DT50 for degradation in air	0.99	d (at 25°C)	

Input parameters (only set values) for calculating the fate and distribution in the environment - DCVA			
Input	Value	Unit	Remarks/Source
Molecular weight	209.07	g/mol	Episuite modelidation + Permethrin CAR, 2014
Melting point	72.88	°C	
Boiling point	280.29	°C	
Vapour pressure at 25°C	0.26	Pa	
Water solubility at 25°C	128	mg/l	
Log Octanol/water partition coefficient	3.38	Log 10	
Organic carbon/water partition coefficient (Koc)	Non hydrophobic (default QSAR)	l/kg	
Henry's Law Constant (20 °C)	-	Pa/m3/mol	
Biodegradability	-	/	
Rate constant for STP	-	h-1	
DT50 for biodegradation in surface water	-	d (at 12ºC)	
DT50 for hydrolysis in surface water	-	d (at 12ºC /pH 9)	
DT50 for photolysis in surface water	-	d (at 25°C)	
DT50 for degradation in soil	50	d (realistic outdoor condition)	
DT50 for degradation in air	-	d (at 25°C)	

Input parameters (only set values) for calculating the fate and distribution in the environment - PBA			
Input	Value	Unit	Remarks/Source
Molecular weight	214.22	g/mol	Episuite modelidation + Permethrin CAR, 2014
Melting point	127.48	°C	
Boiling point	365.14	°C	
Vapour pressure at 25°C	4.21x10-4	Pa	
Water solubility at 25°C	16.9	mg/l	
Log Octanol/water partition coefficient	3.91	Log 10	
Organic carbon/water partition coefficient (Koc)	Non hydrophob	l/kg	

	ic (default QSAR)		
Henry's Law Constant (20 °C)	-	Pa/m3/mol	
Biodegradability	-	/	
Rate constant for STP	-	h-1	
DT50 for biodegradation in surface water	-	d (at 12ºC)	
DT50 for hydrolysis in surface water	-	d (at 12ºC /pH 9)	
DT50 for photolysis in surface water	-	d (at 25°C)	
DT50 for degradation in soil	2.5	d (realistic outdoor condition)	
DT50 for degradation in air	-	d (at 25°C)	

Input parameters (only set values) for calculating the fate and distribution in the environment - S-Methopren			
Input	Value	Unit	Remarks/Source
Molecular weight	310.48	g/mol	S-Methopren CAR, 2013
Melting point	53.8	°C	
Boiling point	279.9	°C	
Vapour pressure at 25°C	0.0316	Pa	
Water solubility at 25°C	6.85	mg/l	
Log Octanol/water partition coefficient	6.34	Log 10	
Organic carbon/water partition coefficient (Koc)	Non hydrophobic (default QSAR)	l/kg	
Henry's Law Constant (20 °C)	-	Pa/m3/mol	
Biodegradability	-	/	
Rate constant for STP	-	h-1	
DT50 for biodegradation in surface water	-	d (at 12ºC)	
DT50 for hydrolysis in surface water	-	d (at 12ºC /pH 9)	

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1 - fogger	No	No	No	No	No	No	Yes	Yes	No
Scenario 2 - spray	No	No	No	No	No	No	No	No	No

Although air emission is expected, it is not a relevant receiving compartment as justified previously with the "Testing for distribution and dissipation in air (ADS)" endpoint.

Infobox 18 - FR CA position:

Identification of relevant receiving compartments based on the exposure pathway						
	STP	Freshwater	Freshwater sediment	Air	Soil	Groundwater
Scenario1 – One shot aerosol	++	+	+	-	+	+
Scenario 2 – Spray on large surface	++	+	+	-	+	+
Scenario 3 – Spray non-washable furniture and home textile	++	+	+	-	+	+

++ Direct emissions expected
+ Indirect emissions expected
- No emission expected

Active substance: Permethrin

Input parameters used in the environmental exposure assessments according to the CAR (April, 2014)		
Input	Value	Unit
Permethrin		
CAS number	52645-53-1	-
Molecular weight	391.29	$g.mol^{-1}$
Vapour pressure (at 20°C)	2.16E-06	Pa
Water solubility (at 20°C)	4.95E-03	$mg.L^{-1}$
Partition coefficient (log P_{OW}) (pH 7)	4.67	Log 10
Biodegradability	Not Ready biodegradable	
Degradation in soil (DT_{50}) (at 12°C)	106*	days
Adsorption / desorption Koc	26930**	$L.kg^{-1}$
BCF fish	570	$L.kg^{-1}$
BMF fish	1	-
BCF earthworms	15108	$L.kg^{-1}$
Metabolites		
DCVA		
Molecular weight	209.07	$g.mol^{-1}$
Degradation in soil (DT_{50}) (at 12°C)	175*	days
Max. % occurrence water	62.6	%
Max. % occurrence soil	11.3	%
Koc	188.53	$L.kg^{-1}$
PBA		
Molecular weight	214.22	$g.mol^{-1}$
Degradation in soil (DT_{50}) (at 12°C)	2.5	days
Max. % occurrence water	28.8	%
Max. % occurrence soil	15	%
Koc	37.55	$L.kg^{-1}$

* The applicant has proposed DT50 values for soil under ‚realistic outdoor condition. Nevertheless, these values are not stated in the CAR and no information on the ’realistic outdoor condition’ was given by the applicant. Therefore, eCA prefers to keep the DT50 values normalised at 12°C, extracted from the CAR of permethrin.
** The Koc value proposed by the applicant is 80000. This value is not mentioned in the CAR of permethrin (2014). Therefore, the Koc value of 26930 calculated in doc IIB of the combined CAR PT18 of permethrin (2014) is used for risk assessment.

Calculated fate and distribution of Permethrin in the STP (EUSES model 2.1)	
Compartment	Percentage [%]
Air	0
Water	27.6
Sludge	72.4
Degraded in STP	0

Calculation method of metabolites emissions

Following the permethrin releases to STP, metabolites concentrations in effluent were estimated considering the ratio of the molecular weight of the metabolite compared to the molecular weight of permethrin (0.534 for DCVA and 0.547 for PBA). PECs surface water and soil were further estimated considering the metabolite formation fraction (max. % occurrence) in the aquatic and terrestrial compartment. To estimate PEC in soil and groundwater for the metabolites DCVA and PBA, their own DT_{50} in soil and Koc values have been considered.

Active substance: S-Methoprene

Input parameters used in the environmental exposure assessments according to the CAR (December, 2013) and update data from 2016 (DT_{50} soil)		
Input	Value	Unit
S-Methoprene		
CAS number	65733-16-6	-
Molecular weight	310.48	$g.mol^{-1}$
Vapour pressure (at 20°C)	6.23E-04	Pa
Water solubility (at 20°C)	6.85	$mg.L^{-1}$
Partition coefficient (log P_{OW}) (pH 7)	6.34	Log 10
Biodegradability	Inherently biodegradable, not fulfilling the criteria	
Degradation in soil (DT_{50}) (at 12°C)	1.55	days
Adsorption / desorption Koc	876	$L.kg^{-1}$
BCF fish	516	$L.kg^{-1}$
BMF fish	1	-
BCF earthworms	26253.98	$L.kg^{-1}$

Calculated fate and distribution of S-Methoprene in the STP (EUSES model 2.1)	
Compartment	Percentage [%]
Air	0
Water	90.2
Sludge	9.8
Degraded in STP	0

Emission estimation

Scenario 1 - application as as a "fumigant indoor application"

The product intend to be fogged by non-professionals consumers indoor of houses:

Fogger generator (one shot aerosol cartridge)

Considering the definition of use in the ESD for TP 18, applicant consider its use as a fumigation use in EUSES software.
The application on labelling I described as "Close windows and cupboard doors. Place the fogger in the centre of the zone to be treated, preferably slightly raised (on a protected chair). Push in the ring to trigger the diffusion. Leave the room, closing the door behind you. Total diffusion time is about 2 minutes. The insecticide Fogger for home use eradicates adult fleas and also their eggs and larvae in the animal's environment, thus avoiding reinfestation with the parasites. It also kills ticks and mosquitoes.
Product is efficient during 6 months. So 2 times per year is the maximum frequency of use for each house. The fogger can treat an area of 70m².”

As the product is used indoor and not cleaned with water, expected environmental emissions are very limited. No emission is expected when applied because the windows and doors are closed. During service life, no direct emissions are to be considered except possible emissions to air when windows are opened to bring fresh air. Possible emission were assessed based on the ESD PT18 for insecticides, acaricides and products to control other arthropods for household and professional uses (OECD, 2008).

Exposure scenario follows EMISSION SCENARIO DOCUMENT FOR INSECTICIDES, ACARICIDES AND PRODUCTS TO CONTROL OTHER ARTHROPODS FOR HOUSEHOLD AND PROFESSIONAL USES (number 18) – "Emission models for indoor application scenarios – fumigator application".
Exposure is modelled with EUSES 2.1.2 software, with module "Assessment of biocides on a local scale only" and scenario biocides products PT "(18) insecticides"+ "(18.3.2) indoor, fumigator".
Default values and calculations are used, unless listed among input parameters mentioned below.

Input parameters for calculating the local emission			
Input	Value	Unit	Remarks
Scenario 1: application as as a "fumigant indoor application"			
Application rate of biocidal product [alternative: annual tonnage in the EU]	1	Fogger/70m 2	Product informations
Concentration of active substance in the product PERMETHRIN	5.05	g/l (m/v)	Product informations
Concentration of active substance in the product S-METHOPRENE	0.15	g/l (m/v)	Product informations
Concentration of active substance in the product PERMETHRIN	0.75	g per 150 ml fogger	Calculated from the values here above for clarity purpose
Concentration of active substance in the product S-METHOPRENE	0.0225		
Concentration of active substance in the product PERMETHRIN	0.0012	g/m^2	
Concentration of active substance in the product S-METHOPRENE	0.00032		
Duration of service life	24	weeks	
Surface of a typical house	70	m^2	Product characteristics

Number of houses connected to one STP	4000		ESD 18
Simultaneity factor	0.204	%	ESD 18 - Frequency for application is 2 times per year (calculation: 0.54*37.82/100)
Number of emission days per year - Napp	2	/	ESD 18
Fraction of retention in goods - Fretention	0.02	/	ESD 18
Fraction of disintegration - Fdisintegration	0.001	/	ESD 18

Update assessment of the applicant

- ✓ **For the fogger application**, the following modes of application can be forecasted:
  - Used indoor house.

Considering the definition of use in the ESD for TP 18, applicant considers its use as a fumigation use in EUSES software in the first version. Nevertheless, considering the ANSES expert question, the applicant applies a spray air space treatment to model the scenario which are not discussed in the ESD PT 18.
In addition, the applicant performed tests to assess the quantity of product release to the floor. The mean quantity release to the floor corresponds to 0.39% of the starting product. This information is considered in the update risk assessment.
Product is efficient during 6 months. So **2 times per year** is the maximum frequency of use for each house.
Exposure is modelled with EUSES 2.1.2 software, with module "Assessment of biocides on a local scale only" and scenario biocides products PT "(18) insecticides"+ "(18.3.2) indoor, spray air space treatment".
Default values and calculations are used, unless listed among input parameters mentioned below

Emission during application –Indoor spray application			
Input	Symbol	Value	Source
Treatment rate, amount of product per area	Qprod	85.8g	Product information
Fraction of active substance in the commercial product	FAI	0.87% for permethrin and 0.026% for S-Methopren	
Number of application	Napp	2 per year	ESD 18
Area of treated surface	Atreated	$58m^3$	Product information
Fraction emitted to air during application	Fair	0.956	ESD 18
Fraction emitted to the applicator during application	Fapplicator	0.04	ESD 18

Fraction emitted to the floor during application	FFloor	0.0039[22]	ESD 18
Fraction emitted to the treated surfaces during application	Ftreated	0	ESD 18
Fraction emitted to solid waste from applicator	Fwaste applicator	1	ESD 18
Fraction emitted to waste water from cleaning surfaces	Fwaste cleaning	0.5	ESD 18
Cleaning efficiency	Effcleaning	100%	Standard value ESD 18

The frequency for application is 2 times per year. Then, the simultaneity factor of 0,204% has been taken into account.

Infobox 19 - FR CA position:

Emission calculation

The environmental assessment provided by the applicant is based on an unvalidated experimental value used to determine the fraction emitted to the floor during application. As explained in the infobox10, the accuracy of the provided data is not sufficient to validate the proposed value for refined deposition. The following assessment was proposed for the use of one shot aerosol FOGGER INSECTICIDE FOR HOUSEHOLDs.

Scenario 1: One shot aerosol indoor application to treat air and untargeted surfaces.

The calculated emissions with the equation (30) from the ESD for PT 18 for a fumigant or gas is not relevant to an active substance distributed within the building in a smoke or aerosol plume which is be expected to deposit onto all available surfaces. Indeed, the chosen model based on eq. 30 ignores any emission to the aquatic environment resulting from the subsequent wet cleaning of indoor surfaces as this model is relevant for substances under gas form with no deposition to surfaces[23]. For the active substances that are not volatile or gaseous, it was concluded that, in the absence of any measured information on deposition, a precautionary value of 100 % is assumed and all the content in active substances for the treatment is considered deposited.

In this context, for the product Insecticides for home use under one shot aerosol, it is considered that 100% of the remaining product after applicator exposure is deposited (knowing that the vapour pressure of Permethrin and S-Methopren are respectively 2.16E-06 Pa and 6.23E-04 Pa, these substances are not volatile). Concerning the other parameters, the ESD was applied considering this product as an RTU Aerosols – Space Spray/diffuser.

Input parameters for calculating the local emission in scenario 1 - One shot aerosol				
Parameter	Symbol	Value	Unit	Remarks
Scenario 1 - One shot aerosol FOGGER INSECTICIDE FOR HOUSEHOLDs**:**				
INPUT SCENARIO 1				
Fraction of active substance (Permethrin) in the product (tech)	**F_{AI}**	0.874	[% w/w]	Permethrin (sum of all isomers)
Fraction of active substance (S-Methoprene) in the product (tech)	**F_{AI}**	0.02625	[% w/w]	S-Methoprene (sum of all isomers)
Surface or air space treatment	**Air space treatment**			-
Quantity of product applied	**Q prod**	4.90E-04	[kg.m-3]	150 mL corresponding to 85.8 g. / 175 m3 (70 m2 x 2.5 m) -Efficacy
Volume treated per house	VOLUME **treated**	325	[m3]	= 130 m2 * 2.5 m
Volume cleaned per house	VOLUME **cleaned**	96.25	[m3]	= 38.5 m2 * 2.5 m
Number of applications per day per house	N appl	1	[d-1]	Intended use
Fraction emitted to applicator during application step	F applicator	0.012	[-]	Table 3.3-1 - ESD PT18 (self-pressurised aerosol dispenser for air space treatment)
Fraction emitted to floor during application step	F floor	0.988	[-]	1 – Fapplicator
Fraction emitted to treated area during application step	F treated	0	[-]	Default value - ESDP PT18 (self-pressurised aerosol dispenser for air space treatment)
Fraction emitted to wastewater during cleaning	Fww	1	[-]	-
Cleaning efficiency of the applicator's clothes	FCE appl	1	[-]	ESDP PT18
Cleaning efficiency of the floor	FCE floor	1	[-]	Table 3.3-8 - ESD PT18 (RTU Aerosols – space spray)
Number of private houses connected to a STP	N HOUSE	4 000	[-]	Default value – Technical Agreements for Biocides (2016)
Simultaneity factor	F simultaneity	0.204	[%]	Once to twice per year.

OUTPUTS FOR THE ACTIVE SUBSTANCES				
Parameter	Symbol	Value for Permethrin	Value for S-Methoprene	Unit

Emission during the application				
Emission to the applicator	E applicator	1.67E-05	5.02E-07	[kg.d-1]
Emission to the floor	E floor	4.07E-04	1.22E-05	[kg.d-1]
Emission during the cleaning step for one house				
Emission from treated area/floor to wastewater for one house	E floor, ww	4.07E-04	1.22E-05	[kg.d-1]
Emission from applicator to wastewater for one house	E applicator, ww	1.67E-05	5.02E-07	[kg.d-1]
Total emission to the wastewater	E total,ww	4.24E-04	1.27E-05	[kg.d-1]
Total Emission to the wastewater for one STP				
Total emission to the STP	E local water	3.46E-03	1.04E-04	[kg.d-1]

Scenario 2 - Application as a "indoor spraying application for indoor general surface treatment"

These products intend to be sprayed or fogged by non-professionals consumers:

Aerosol (In-can sprayer)

- ✓ **For the spraying**, the following modes of application can be forecasted:
- Used indoor house.

The indoor insecticide spray can be used on carpets, rugs, wooden floors, armchairs. Insists on areas expected to be highly infested. After spraying leave the room and allow acting at least one hour. Two types of container (250 mL or 500 mL) are used and the applicant consider the most exposing one to perform the assessment (the larger volume, 500mL).
Product is efficient during 6 months. So 2 times per year is the maximum frequency of use for each house.

Exposure scenario follows EMISSION SCENARIO DOCUMENT FOR INSECTICIDES, ACARICIDES AND PRODUCTS TO CONTROL OTHER ARTHROPODS FOR HOUSEHOLD AND PROFESSIONAL USES (number 18) – "Emission models for indoor application scenarios - spray application – general surface treatment".
Exposure is modelled with EUSES 2.1.2 software, with module "Assessment of biocides on a local scale only" and scenario biocides products PT "(18) insecticides"+ "(18.3.2) indoor spraying".
Default values and calculations are used, unless listed among input parameters mentioned below.

<table>
<tr><th colspan="5">Input parameters for calculating the local emission</th></tr>
<tr><th colspan="2">Input</th><th>Value</th><th>Unit</th><th>Remarks</th></tr>
<tr><td colspan="5">Scenario: application as a "indoor spraying application for indoor general surface treatment"</td></tr>
<tr><td colspan="2" rowspan="2">Application rate of biocidal product</td><td rowspan="2">1</td><td>250ml spray/70m2</td><td rowspan="2">Product informations</td></tr>
<tr><td>500ml spray/140m 2</td></tr>
<tr><td rowspan="2">Concentration of active substance</td><td>Permethrin</td><td>1.06</td><td rowspan="2">g/l (m/v)</td><td rowspan="2">Product informations</td></tr>
<tr><td>S-Methoprene</td><td>0.013</td></tr>
<tr><td rowspan="2">Application rate of the active substance</td><td>Permethrin</td><td>0.0038</td><td rowspan="2">g/m^2</td><td rowspan="4">Calculated from the values here above for clarity purpose</td></tr>
<tr><td>S-Methoprene</td><td>0.000046</td></tr>
<tr><td rowspan="2">Fraction of active substance in the commercial product - F_{AI}</td><td>Permethrin and its metabolites (DCVA and PBA) considering that 100% of Permethrin is metabolized</td><td>0.177</td><td rowspan="2"></td></tr>
<tr><td>S-Methoprene</td><td>0.0022</td><td>%</td></tr>
<tr><td colspan="2">Duration of service life</td><td>6</td><td>months</td><td></td></tr>
<tr><td colspan="2">Number of application - N_{app}</td><td>2</td><td>per year</td><td>ESD 18</td></tr>
<tr><td colspan="2">Area of treated surface - $A_{treated}$</td><td>140</td><td>m²/d</td><td>Product information</td></tr>
<tr><td colspan="2">Number of houses connected to one STP</td><td>4000</td><td>/</td><td>ESD 18</td></tr>
<tr><td colspan="2">Simultaneity factor</td><td>0.204</td><td>%</td><td>Frequency for application is 2 times per year. (calculation: 0.54*37.82/100)</td></tr>
<tr><td colspan="2">Fraction emitted to air during application - Fair</td><td>0.02</td><td>/</td><td>ESD 18</td></tr>
<tr><td colspan="2">Fraction emitted to the applicator during application - Fapplicator</td><td>0.02</td><td>/</td><td>ESD 18</td></tr>
<tr><td colspan="2">Fraction emitted to the floor during application - FFloor</td><td>0.11</td><td>/</td><td>ESD 18</td></tr>
</table>

Fraction emitted to the treated surfaces during application - Ftreated	0.85	/	ESD 18
Fraction emitted to solid waste from applicator - Fwaste applicator	1	/	ESD 18
Fraction emitted to waste water from cleaning surfaces - Fwaste cleaning	0	/	ESD 18
Fraction emitted to solid waste from cleaning treated surfaces - FSolid waste cleaning	1	/	ESD 18
Cleaning efficiency - Effcleaning	20	%	ESD 18

Update assessment of the applicant

- ✓ **For the spraying**, the following modes of application can be forecasted:
  - Used indoor house.

Considering the question of ANSES, for this scenario, the applicant has chosen to update the labelling. The applicant removes the word "parquet" and replace it by "sol non lavable à l'eau". Product is efficient during 6 months. So **2 times per year** is the maximum frequency of use for each house.
Exposure is modelled with EUSES 2.1.2 software, with module "Assessment of biocides on a local scale only" and scenario biocides products PT "(18) insecticides"+ "(18.3.2) indoor spraying".
Default values and calculations are used, unless listed among input parameters mentioned below.

Emission during application –Indoor spray application			
Input	Symbol	Value (private house)	Source
Treatment rate, amount of product per area	Qprod	2.1 g/m2 (294g of total product for the 500mL container)	Product information
Fraction of active substance in the commercial product	FAI	0.177% for permethrin 0.177% for permethrin metabolites (DCVA and PBA considering that 100% of Permethrin is metabolized) 0.0022% for S-	
Number of application	Napp	2 per year	ESD 18
Area of treated surface	Atreated	20 m²	Product information
Fraction emitted to air during application	Fair	0.02	ESD 18

Fraction emitted to the applicator during application	Fapplicator	0.02	ESD 18
Fraction emitted to the floor during application	FFloor	0.11	ESD 18
Fraction emitted to the treated surfaces during application	Ftreated	0.85	ESD 18
Fraction emitted to solid waste from applicator	Fwaste applicator	1	ESD 18
Fraction emitted to waste water from cleaning surfaces	Fwaste cleaning	03	ESD 18
Fraction emitted to solid waste from cleaning treated surfaces	FSolid waste cleaning	1	ESD 18
Cleaning efficiency	Effcleaning	20%	Standard value ESD 18

Considering the type of surface treated, and the instruction of use in the labelling, the applicant consider that the treated surfaces will be not water cleaned but only aspired (with a vacuum cleaner) and then remove as a solid waste.
The frequency for application is **2 times per year**. Then, the **simultaneity factor of 0,204%** has been taken into account.

Infobox 20 - FR CA position:

Scenario 2: Indoor spray considering a total surface application on floors

In order to cover the intended use on wooden floors that are potentially wet cleaned, a scenario considering a total surface treatment is applied. In fact, the 2nd PT18 Expert group has concluded that no wet cleaning can be assumed only if there is a specific restriction to treatment in confined areas which are not wet cleaned (e.g. closed bath tubes, areas below the kitchen furniture which are closed), but not wet-cleaned floors are not realistic.

A treated surface of 130 m^2 with a wet cleaning zone of 38.5 m^2 and a default cleaning efficiency of 20 % (for self-pressurised aerosol dispenser for surface treatment) are proposed below. As claimed by the applicant, 1-2 applications per year have been applied (Fsimultaneity of 0.204%). The product is intended for non-professional applications; only houses have been taken into account.

Input parameters for calculating the local emission in scenario 2				
Parameter	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario 2: Ready-for-use spray product used by non-professionals considering a total surface application on floors				
INPUT SCENARIO 2				

Fraction of active substance (Permethrin) in the product (tech)	F_{AI}	0.177	[% w/w]	Permethrin (sum of all isomers)
Fraction of active substance (S-Methoprene) in the product (tech)	F_{AI}	0.0022	[% w/w]	S-Methoprene (sum of all isomers)
Surface or air space treatment	**Surface treatment (area)**			**-**
Quantity of product applied	Q prod	2.10	[g.m-2]	Intented use
Area treated per house	AREA treated	130	[m2]	Default value for a treated area in a domestic home- TAB
Area wet cleaned per house	AREA wet cleaned	38.5	[m2]	Reflect the area wet cleaned in a domestic home – Technical Agreements for Biocides (2017)
Number of applications per day per house	N appl	1	[d-1]	-
Fraction emitted to air during application step	F air	0.02	[-]	Default value - ESDP PT18
Fraction emitted to applicator during application step	F applicator	0.004	[-]	Table 3.3-1 - ESDP PT18 (Self-pressurised aerosol dispenser for surface treatment)
Fraction emitted to floor during application step	F floor	0.126	**[-]**	Table 3.3-3 - ESDP PT18 (Self-pressurised aerosol dispenser for surface treatment)
Fraction emitted to treated area during application step	F treated	0.85	**[-]**	=(1 – (0.02 + 0.004 + 0.126))
Fraction emitted to wastewater during cleaning	F ww	1	**[-]**	-
Cleaning efficiency of the applicator's clothes	FCE appl	1	**[-]**	ESDP PT18
Cleaning efficiency of the floor	FCE floor	0.2	**[-]**	Table 3.3-8 - ESDP PT18 (RTU Aerosols – surface)
Number of private houses connected to a STP	N HOUSE	4 000	**[-]**	Default value – Technical Agreements for Biocides (2016)

Simultaneity factor	F simultaneity	0.204	**[%]**	Once to two times per year

OUTPUTS FOR THE ACTIVE SUBSTANCES				
Parameter	**Symbol**	**Value for Permethrin**	**Value for S-Methoprene**	**Unit**
Emission during the application				
Emission to air	E air	9.66E-06	1.20E-07	[kg.d-1]
Emission to the applicator	E applicator	1.93E-06	2.40E-08	[kg.d-1]
Emission to the wet washable floor	E floor	1.80E-05	2.24E-07	[kg.d-1]
Emission to treated surface	E treated	1.22E-04	1.51E-06	[kg.d-1]
Emission during the cleaning step for one house				
Emission from treated area/floor to wastewater for one house	E treated/floor, ww	2.79E-05	3.47E-07	[kg.d-1]
Emission from applicator to wastewater for one house	E applicator, ww	1.93E-06	2.40E-08	[kg.d-1]
Total emission to the wastewater for one house	E total,ww	2.99E-05	3.71E-07	[kg.d-1]
Total Emission to the wastewater for one STP				
Total emission to the STP	E local water	2.44E-04	3.03E-06	[kg.d-1]

Scenario 3: Indoor spray application for the treatment of non-washable furniture and home textile as carpets, mats, arm chairs, … (covered by the barrier treatment)

Tier 1:

Refinements to the environmental risk assessment about wet cleaning are taken into account if uses are restricted to non-wet cleaned furniture and home textile. In

domestic premises, an area of 20 m^2 has been proposed as a suitable size to reflect the total area that could be treated when a targeted pet pest treatment has been applied on non-washable fabric, with a cleaning efficiency (FCE) of 20%. This scenario based on the standard 'barrier scenario' has been applied as proposed by UK (adoption in WG-IV-2017). The targeted treatment is intended to take place on objects and furnishings which are not expected to be subject to regular wet cleaning. As proposed in the previous scenario, 1 - 2 applications per year have been applied (Fsimultaneity of 0.204%). The product is intended for non-professional applications; only houses have been taken into account.

Tier 2:

For products specifically used against pet pests, an additional Tier 2 refinement based on pet ownership can be proposed[24]. It must be highlighted this type of refinement only covers uses against pet fleas and ticks (but not mosquitoes).

To determine the simultaneity factor in this case, a number of factors are taken into account and details in the table below.

Parameter	Value	Units
Households owning cats and/or dogs	50*	%
Frequency of use	2 / 365	day $^{-1}$
Pets requiring treatment for fleas	50	%
Market penetration value	50	%

* This value was further refined to 0.45 (TAB, 2018)

With this refinement, the simultaneity factor is Fsimult = 0.5 x (2/365) x 0.5 x 0.5 = 6.84E-04

Input and output values are presented in the following tables:

Input parameters for calculating the local emission in scenario 3				
Parameter	Symbol	Value	Unit	Remarks
Scenario 3: Ready-for-use spray product used by non-professionals considering the treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (covered by the barrier treatment)				
INPUT SCENARIO 3				
Fraction of active substance (Permethrin) in the product (tech)	**FAI**	0.177	[% w/w]	Permethrin (sum of all isomers)
Fraction of active substance (S-Methoprene) in the product (tech)	**FAI**	0.0022	[% w/w]	S-Methoprene (sum of all isomers)
Surface or air space treatment	**Surface treatment (area)**			-
Quantity of product applied	**Q prod**	2.10	[g.m-2]	Intented use

Area treated per house	AREA **treated**	20	[m2]	Default value for barrier treatment – Technical Agreements for Biocides (2016)
Area wet cleaned per house	AREA **wet cleaned**	5.9	[m2]	WG I 2017, reflect the area wet cleaned in a domestic home (barrier)
Number of applications per day per house	**N** appl	1	[d-1]	Intended to be used once to two times per year
Fraction emitted to air during application step	**F** air	0.02	[-]	Default value - ESDP PT18
Fraction emitted to applicator during application step	**F** applicator	0.004	[-]	Table 3.3-1 - ESDP PT18 (self-pressurised aerosol dispenser for surface treatment)
Fraction emitted to floor during application step	**F** floor	0.126	[-]	Table 3.3-3 - ESDP PT18 (self-pressurised aerosol dispenser for surface treatment)
Fraction emitted to treated area during application step	**F** treated	0.85	[-]	(1 – (0.02 + 0.004 + 0.126))
Fraction emitted to wastewater during cleaning	F ww	1	[-]	-
Cleaning efficiency of the applicator's clothes	**F**CE appl	1	[-]	ESDP PT18
Cleaning efficiency of the floor	**F**CE floor	0.2	[-]	Table 3.3-8 - ESDP PT18 (RTU Aerosols – surface)
Number of private houses connected to a STP	**N** HOUSE	4 000	[-]	Default value – Technical Agreements for Biocides (2016)
Simultaneity factor for the Tier 1	F simultaneity	0.204	[%]	Insecticides for home use may be applied by spraying on surfaces once to two times per year.
Simultaneity factor for the Tier 2	F simultaneity	0.068	[%]	Refinement based on pet ownership (see above)

OUTPUTS FOR THE TIER 1 & 2 FOR ACTIVE SUBSTANCES

Parameter	Symbol	Value for Permethrin	Value for S-Methoprene	Unit
Emission during the application				
Emission to air	E air	1.49E-06	1.85E-08	[kg.d-1]
Emission to the applicator	E applicator	2.97E-07	3.70E-09	[kg.d-1]
Emission to the floor + treated surface	E floor+treated	2.14E-05	2.66E-07	[kg.d-1]
Emission during the cleaning step for one house				
Emission from treated area/floor to wastewater for one house	E treated/floor, ww	4.28E-06	5.32E-08	[kg.d-1]
Emission from applicator to wastewater for one house	E applicator, ww	2.97E-07	3.70E-09	[kg.d-1]
Total emission to the wastewater	E total,ww	4.58E-06	5.69E-08	[kg.d-1]
Total Emission to the wastewater for one STP				
Total emission to the STP for Tier 1	E local water	3.74E-05	4.64E-07	[kg.d-1]
Total emission to the STP for Tier 2	E local water	1.25E-05	1.56E-07	[kg.d-1]

Calculated PEC values

Update assessment of the applicant

	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}	PEC_{air}
	[mg/m^3]	[mg/l]	[mg/kg_{wwt}]	[mg/m^3]	[µg/l]	[mg/m^3]

Scenario 1	Permethrin	9.3E-07	8.3E-08	1.44E-04	2.08E-05	1.05E-08	0
	DCVA	0	5.5E-07	7.59E-06	1.64E-06	1.06E-07	0
	PBA	0	5.2E-07	1.32E-05	8.73E-07	7.66E-09	0
	S-Methoprene	5.63E-08	5.46E-09	2.46E-06	4.38E-06	1.2E-08	0
Scenario 2		0	0	0	0	0	0

Scenario1: Detail of the calculation (modelisation - EUSES 2 Full report) is provided in Annex 3.3 of the Product Assessment Report.

Scenario 2: As no emission is expected for the various compartments, no PEC is calculated for this scenario.

Infobox 21 - FR CA position:

Scenario 1: For the indoor one shot aerosol application to treat air and untargeted surfaces.

The concentrations in the different environmental compartments following releases to the STP for the active substance (permethrin) and metabolites (DCVA and PBA) are summarised in the following table.

Summary table on calculated PEC values for the scenario 1					
	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}
	[$mg.L^{-1}$l]	[$mg.L^{-1}$]	[$mg.kg_{wwt}^{-1}$]	[$mg.kg_{wwt}^{-1}$]	[$\mu g.L^{-1}$]
Permethrin	4.78E-04	4.59E-05	2.69E-02	4.66E-03	6.34E-03
DCVA	-	1.54E-05	7.50E-05	3.31E-04	7.08E-02
PBA	-	7.24E-06	1.16E-05	4.61E-05	9.83E-03

The concentrations in the different environmental compartments following releases to the STP for the active substance (S-Methoprene) are presented in the following table.

Summary table on calculated PEC values for the scenario 1					
	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}
	[$mg.L^{-1}$l]	[$mg.L^{-1}$]	[$mg.kg_{wwt}^{-1}$]	[$mg.kg_{wwt}^{-1}$]	[$\mu g.L^{-1}$]
S-Methoprene	4.69E-05	4.68E-06	9.28E-05	1.41E-06	1.51E-05

Scenario 2: For the indoor spray application considering a total surface application on floors

The concentrations in the different environmental compartments following releases to the STP for the active substance (permethrin) and metabolites (DCVA and PBA) are summarised in the following table.

Summary table on calculated PEC values for the scenario 2					
	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}
	[$mg.L^{-1}$l]	[$mg.L^{-1}$]	[$mg.kg_{wwt}^{-1}$]	[$mg.kg_{wwt}^{-1}$]	[$\mu g.L^{-1}$]
Permethrin	3.36E-05	3.23E-06	1.90E-03	3.28E-04	4.46E-04
DCVA	-	1.08E-06	5.28E-06	2.33E-05	4.98E-03
PBA	-	5.10E-07	8.15E-07	3.24E-06	6.92E-04

The concentrations in the different environmental compartments following releases to the STP for the active substance (S-Methoprene) are presented in the following table.

Summary table on calculated PEC values for the scenario 2					
	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}
	[$mg.L^{-1}$l]	[$mg.L^{-1}$]	[$mg.kg_{wwt}^{-1}$]	[$mg.kg_{wwt}^{-1}$]	[$\mu g.L^{-1}$]
S-Methoprene	1.37E-06	1.36E-07	2.71E-06	4.12E-08	4.41E-07

Scenario 3: Indoor spray application the treatment of non-washable furniture and home textile as carpets, mats, arm chairs, … (covered by the barrier treatment)

Tier 1 (Standard Fsimultaneity)

The results for the active substance (permethrin) and metabolites (DCVA and PBA) are summarised in the following tables.

Summary table on calculated PEC values for the scenario 3					
	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}
	[$mg.L^{-1}$l]	[$mg.L^{-1}$]	[$mg.kg_{wwt}^{-1}$]	[$mg.kg_{wwt}^{-1}$]	[$\mu g.L^{-1}$]
Permethrin	5.16E-06	4.96E-07	2.90E-04	5.03E-05	6.84E-05
DCVA	-	1.66E-07	8.09E-07	3.57E-06	7.64E-04
PBA	-	7.81E-08	1.25E-07	4.97E-07	1.06E-04

The concentrations in the different environmental compartments following releases to the STP for the active substance (S-Methoprene) are presented in the following table.

Summary table on calculated PEC values for the scenario 3					
	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}
	[$mg.L^{-1}$l]	[$mg.L^{-1}$]	[$mg.kg_{wwt}^{-1}$]	[$mg.kg_{wwt}^{-1}$]	[$\mu g.L^{-1}$]
S-Methoprene	2.09E-07	2.09E-08	4.15E-07	6.31E-09	6.75E-08

Tier 2 (Refined Fsimultaneity based on pet ownership)

The results for the active substance (permethrin) and metabolites (DCVA and PBA) are summarised in the following tables.

Summary table on calculated PEC values for the scenario 3					
	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}

	[mg.L^{-1}l]	[mg.L^{-1}]	[mg.kg$_{wwt}^{-1}$]	[mg.kg$_{wwt}^{-1}$]	[µg.L^{-1}]
Permethrin	1.73E-06	1.66E-07	9.74E-05	1.69E-05	2.29E-05
DCVA	-	5.56E-08	2.71E-07	1.20E-06	2.56E-04
PBA	-	2.62E-08	4.19E-08	1.67E-07	3.55E-05

The concentrations in the different environmental compartments following releases to the STP for the active substance (S-Methoprene) are presented in the following table.

Summary table on calculated PEC values for the scenario 3					
	PEC_{STP}	PEC_{water}	PEC_{sed}	PEC_{soil}	PEC_{GW}
	[mg.L^{-1}l]	[mg.L^{-1}]	[mg.kg$_{wwt}^{-1}$]	[mg.kg$_{wwt}^{-1}$]	[µg.L^{-1}]
S-Methoprene	7.02E-08	7.01E-09	1.39E-07	2.12E-09	2.26E-08

Primary and secondary poisoning

Primary poisoning

As mentioned previously, the products use will not lead to direct exposure of non-target organisms considering the treated surfaces are indoor, and the instructions in the labelling. In fact, the applicant considers the treated surfaces will not be water cleaned but only aspired (with a vacuum cleaner) and then removed as a solid waste

Infobox 22 - FR CA position:

Not relevant

Secondary poisoning

Products active substances are unlike to bioaccumulate in aquatic or terrestrial environment:

- According to the S-Methoprene CAR (2013) conclusions, considering Regulation (EC) No. 1907/2006, REACH Annex XIII, the criteria for a substance to be considered as bio-accumulative, the BCF value must be higher than 2000. From the calculation the BCF of S-Methoprene is 516, therefore, based on these results, S-Methoprene does not meet the B (bioaccumulative) criteria.
- according to the Permethrin CAR (2014) conclusions, bioconcentration Factors BCFfish and BCFchironomid values < 2000. Therefore, it is concluded that permethrin does not meet the B nor vB (very bioaccumulative) screening criteria.

As a consequence, no further assessment of secondary exposure via the food chain is therefore considered necessary.

Infobox 23 - FR CA position:

The active substance permethrin has a log Kow > 3 (log Kow = 4.67) and a BCF > 100 (BCF in fish = 570 L.kg^{-1}, BMF = 1 and BCF in earthworm = 15108 L.kg^{-1}). According to the scenario secondary poisoning may occur via the aquatic food chain and/or via the terrestrial food chain. The concentration of permethrin in food (i.e. in

fish and in earthworm) of fish-eating and worm-eating predators (birds or mammals) has been calculated.

The results for each scenario are summarised in the following table.

Summary table on estimated theoretical exposition for the Permethrin		
	PEC in fish [mg.kg $_{wet\ fish}^{-1}$]	PEC in earthworm [mg.kg $_{wet\ earthworm}^{-1}$]
Scenario 1: Indoor one shot aerosol – Treatment of air and untargeted surfaces	1.31E-02	4.32E-02
Scenario 2: Indoor large spray application – Treatment of floors	9.21E-04	3.04E-03
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 1)	1.41E-04	4.66E-04
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 2 based on pet owners)	4.74E-05	1.56E-04

The active substance S-Methoprene has a log Kow > 3 (log Kow = 4.34) and a BCF > 100 (BCF in fish = 516 $L.kg^{-1}$, BMF = 1 and BCF in earthworm = 26253.9 $L.kg^{-1}$). According to the scenario secondary poisoning may occur via the aquatic food chain and/or via the terrestrial food chain. The concentration of S-Methoprene in food (i.e. in fish and in earthworm) of fish-eating and worm-eating predators (mammals) has been calculated.

The results for each scenario are summarised in the following table.

Summary table on estimated theoretical exposition for the S-Methoprene		
	PEC in fish [mg.kg $_{wet\ fish}^{-1}$]	PEC in earthworm [mg.kg $_{wet\ earthworm}^{-1}$]
Scenario 1: Indoor one shot aerosol – Treatment of air and untargeted surfaces	1.21E-03	1.78E-04
Scenario 2: Indoor large spray application – Treatment of floors	3.52E-05	5.19E-06
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 1)	5.40E-06	7.97E-07
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 2 based on pet owners)	1.81E-06	2.67E-07

2.2.8.3 Risk characterisation

Regarding the risk characterisation, the applicant considers the exposure cumulated from emissions by the two scenarios.

Nevertheless, as no emission is expected in scenario n°2 (spray application), worst case scenario n°1 of fogger application can be considered as cumulated exposure to estimate the associated risk.

The products use will not lead to extended exposure of environment for athmosphere, STP nor aquatic compartment considering the treated surfaces are indoor, and the instructions in the labelling. In fact, the applicant considers the treated surfaces will not be water cleaned but only aspired (with a vacuum cleaner) and then removed as a solid waste.
Therefore, the corresponding risks are not assessed. The only relevant compartments for which the risk is assessed are terrestrial and groundwater compartments.

Update assessment of the applicant
Regarding the risk characterization, we only consider the worst case scenario to estimate the associate risk, the addition of fogger + spraying application.

Calculated PEC/PNEC values (Risk Caracterisation Ratio, RCR) - Permethrin				
Compartment	PEC scenario 1 (fogger)	PEC scenario 2 (spraying)	PNEC	RCR
STP	9.3E-07	0	$PNEC_{stp}$: 0.00495mg/L	1.88E-04
Freshwater	8.3E-08	0	$PNEC_{aquatic}$: $4.7x10^{-7}$ mg/L	0.177
Soil	2.08E-05	0	$PNEC_{soil}$: > 0.0876 mg/kg wwt	2.37E-04
Sediment	1.44E-04	0	$PNEC_{sed}$: $2.17x10^{-4}$ mg/kg wwt	0.66
Groundwater	1.05E-08	0	PNEC gw : 0,0001 mg/kg wwt[25]	1.05E-04

Calculated PEC/PNEC values (Risk Caracterisation Ratio, RCR) – S-Methoprene				
Compartment	PEC scenario 1 (fogger)	PEC scenario 2 (spraying)	PNEC	RCR
STP	5.63E-08	0	$PNEC_{stp}$: 6.85 mg/L	8.22E-09
Freshwater	5.46E-09	0	$PNEC_{aquatic}$: 0.00019 mg/L	2.87E-05
Soil	4.38E-06	0	$PNEC_{soil}$: 0.00038 mg/kg wwt	0.012
Sediment	2.46E-06	0	$PNEC_{sed}$: 0.0003 mg/kg wwt	0.0082
Groundwater	1.2E-08	0	PNEC gw : 0,0001 mg/kg wwt	1.2E-04

Calculated PEC/PNEC values (Risk Caracterisation Ratio, RCR) - DCVA				
Compartment	PEC scenario 1 (fogger)	PEC scenario 2 (spraying)	PNEC	RCR
Freshwater	5.5^{E}-07	0	$PNEC_{aquatic}$: 0.015 mg/L	3.67E-05
Soil	1.64^{E}-06	0	$PNEC_{soil}$: 4.6 mg/ kg wwt	3.57^{E}-07

Calculated PEC/PNEC values (Risk Caracterisation Ratio, RCR) - DCVA				
Compartment	PEC scenario 1 (fogger)	PEC scenario 2 (spraying)	PNEC	RCR
Sediment	7.59^{E}-06	0	$PNEC_{sed}$: 0.055 mg/ kg wwt	1.38^{E}-04
Groundwater	1.06^{E}-07	0	PNEC gw : 0,0001 mg/kg wwt	0.00106

Calculated PEC/PNEC values (Risk Caracterisation Ratio, RCR) - PBA				
Compartment	PEC scenario 1 (fogger)	PEC scenario 2 (spraying)	PNEC	RCR
Freshwater	5.2E-07	0	$PNEC_{aquatic}$: >0.01 mg/L	5.2E-05
Soil	8.73E-07	0	$PNEC_{soil}$: 1.44 mg/ kg wwt	6.06E-07
Sediment	1.32E-05	0	$PNEC_{sed}$: 0.042 mg/ kg wwt	3.14E-04
Groundwater	7.66E-09	0	PNEC gw : 0,0001 mg/kg wwt	7.66E-05

Conclusion: Considering the value of risk characterisation ratio for the all the susbtances described above (Permethrin, S-Methopren, DCVA, PBA), the use of this family of product is not unsafe regardless the different environment compartments.

Atmosphere

Infobox 24 - FR CA position:

Significant exposure of the environment via air is not expected whatever the considered use.
Volatilization of permethrin and S-Methoprene are considered to be negligible based on their respective vapour pressure (2.155E-06 Pa and 6.23E-04 Pa at 20°C) and Henry constant (4.5E-02 and 1.78E-02 $Pa.m^3.mole^{-1}$). Permethrin and S-Methoprene would not be transported over large distances in the atmosphere in gaseous phase.

Conclusion: Emissions and PECs in air are considered as negligible. It can be concluded that the use of the product Insecticides for home use will not pose a significant risk to the atmospheric compartment.

Sewage treatment plant (STP)

Infobox 25 - FR CA position:

Risk ratios for the STP are presented in the following tables:

Summary table on calculated STP PEC/PNEC values for Permethrin		
	$PEC/PNEC_{STP}$	Conclusion

Scenario 1: Indoor one shot aerosol – Treatment of air and untargeted surfaces	9.65E-02	Acceptable
Scenario 2: Indoor large spray application – Treatment of floors	6.79E-03	Acceptable
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 1)	1.04E-03	Acceptable
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 2 based on pet owners)	3.49E-04	Acceptable

The assessment of permethrin metabolites is not relevant for the STP compartment.

Summary table on calculated STP PEC/PNEC values for S-Methoprene		Conclusion
	$PEC/PNEC_{STP}$	
Scenario 1: Indoor one shot aerosol – Treatment of air and untargeted surfaces	6.84E-06	Acceptable
Scenario 2: Indoor large spray application – Treatment of floors	1.99E-07	Acceptable
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 1)	3.05E-08	Acceptable
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 2 based on pet owners)	1.02E-08	Acceptable

Conclusion:

For all the assessed scenarios, risks to the STP compartment are acceptable for permethrin and S-Methoprene.

Aquatic compartment

Infobox 26 - FR CA position:

Risk ratios for surface water and sediment are presented in the following tables:

Summary table on calculated surface water and sediment PEC/PNEC values for Permethrin				Conclusion
		$PEC/PNEC_{water}$	$PEC/PNEC_{sed}$	
Scenario 1: Indoor one shot aerosol – Treatment of air and untargeted surfaces	Permethrin	**9.76E+01**	**1.24E+02**	**Unacceptable**
	DCVA	1.02E-03	6.24E-03	Acceptable
	PBA	7.23E-04	1.28E-03	Acceptable
Scenario 2: Indoor large spray application – Treatment of floors	Permethrin	**6.87**	**8.73**	**Unacceptable**
	DCVA	7.20E-05	4.39E-04	Acceptable
	PBA	5.10E-05	9.05E-05	Acceptable
Scenario 3: Indoor spray application - Treatment	Permethrin	**1.05**	**1.34**	**Unacceptable**

of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 1)	DCVA	1.11E-05	6.75E-05	Acceptable
	PBA	7.82E-06	1.39E-05	Acceptable
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 2 based on pet owners)	Permethrin	3.53E-01	4.48E-01	Acceptable
	DCVA	3.70E-06	2.26E-05	Acceptable
	PBA	2.62E-06	4.65E-06	Acceptable

Summary table on calculated surface water and sediment PEC/PNEC values for S-Methoprene				Conclusion
		$PEC/PNEC_{water}$	$PEC/PNEC_{sed}$	
Scenario 1: Indoor one shot aerosol – Treatment of air and untargeted surfaces	S-Methoprene	2.46E-02	2.44E-01	Acceptable
Scenario 2: Indoor large spray application – Treatment of floors	S-Methoprene	7.18E-04	7.11E-03	Acceptable
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 1)	S-Methoprene	1.10E-04	1.09E-03	Acceptable
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, , ... (Tier 2 based on pet owners)	S-Methoprene	3.69E-05	3.65E-04	Acceptable

Conclusion:

For all the considered scenarios in Tier 1, the risk characterisation ratios for permethrin in water and sediment are above 1. The risks related to the use of Insecticides for home use are not acceptable for the aquatic compartments.

A Tier 2 refinement based on the pet ownership leads to acceptable risks for the treatment of non-washable furniture and home textile as carpets, mats, arm chairs,...

Risks are acceptable for S-Methoprene whatever the scenario.

Terrestrial compartment

Infobox 27 - FR CA position:

Risk ratios for the terrestrial compartment are presented in the following tables:

Summary table on calculated PEC/PNEC soil values			Conclusion
		$PEC/PNEC_{soil}$	
Scenario 1: Indoor one shot aerosol – Treatment of air and untargeted surfaces	Permethrin*	5.32E-02	Acceptable
	DCVA	7.19E-05	Acceptable
	PBA	3.20E-05	Acceptable
Scenario 2: Indoor large spray application – Treatment of floors	Permethrin*	3.75E-03	Acceptable
	DCVA	5.07E-06	Acceptable
	PBA	2.25E-06	Acceptable
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs,... (Tier 1)	Permethrin*	5.75E-04	Acceptable
	DCVA	7.76E-07	Acceptable
	PBA	3.45E-07	Acceptable
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs,... (Tier 2 based on pet owners)	Permethrin*	1.93E-04	Acceptable
	DCVA	2.60E-07	Acceptable
	PBA	1.15E-07	Acceptable

* The PNEC value for soil has been recently revised to 0.168 mg/kg dwt (0.148 mg/kg wwt). The RCR soil for Permethrin are now lower than those presented in the table.

Summary table on calculated PEC/PNEC soil values			Conclusion
		$PEC/PNEC_{soil}$	
Scenario 1: Indoor one shot aerosol – Treatment of air and untargeted surfaces	S-Methoprene	4.71E-03	Acceptable
Scenario 2: Indoor large spray application – Treatment of floors	S-Methoprene	1.37E-04	Acceptable
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 1)	S-Methoprene	2.10E-05	Acceptable
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 2 based on pet owners)	S-Methoprene	7.05E-06	Acceptable

Conclusion:

Risks ratios for the terrestrial compartment are below 1 for all the assessed senarios. Acceptable risks are foreseen for soil considering permethrin and S-Methoprene.

Groundwater

Infobox 28 - FR CA position:

Concentrations in groundwater are presented in the following tables:

Summary table on calculated PEC groundwater (µg/L) Acceptable risks for PEC < the limit value of 0.1 µg/L			**Conclusion**
		PEC_{GW}	
Scenario 1: Indoor one shot aerosol – Treatment of air and untargeted surfaces	Permethrin	6.34E-03	Acceptable
	DCVA	7.08E-02	Acceptable
	PBA	9.83E-03	Acceptable
Scenario 2: Indoor large spray application – Treatment of floors	Permethrin	4.46E-04	Acceptable
	DCVA	4.98E-03	Acceptable
	PBA	6.92E-04	Acceptable
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 1)	Permethrin	6.84E-05	Acceptable
	DCVA	7.64E-04	Acceptable
	PBA	1.06E-04	Acceptable
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 2 based on pet owners)	Permethrin	2.29E-05	Acceptable
	DCVA	2.56E-04	Acceptable
	PBA	3.55E-05	Acceptable

Summary table on calculated PEC groundwater (µg/L) Acceptable risks for PEC < limit value of 0.1 µg/L.			**Conclusion**
		PEC_{GW}	
Scenario 1: Indoor one shot aerosol – Treatment of air and untargeted surfaces	S-Methoprene	1.51E-05	Acceptable
Scenario 2: Indoor large spray application – Treatment of floors	S-Methoprene	4.40E-07	Acceptable
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 1)	S-Methoprene	6.75E-08	Acceptable
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 2 based on pet owners)	S-Methoprene	2.26E-08	Acceptable

Conclusion:

Concentrations of permethrin (parent and metabolites) and S-Methoprene in groundwater are lower than the trigger value of 0.1 µg/L set by Directive 98/83/EC whatever the scenario, leading to acceptable risks for the groundwater compartment.

Primary and secondary poisoning

Primary poisoning

Infobox 29 - FR CA position:

Not relevant

Secondary poisoning

Infobox 30 - FR CA position:

Birds (PNEC $_{oral\ bird}$≥16.7 mg.kg $_{food}$) are more sensitive species than mammals (PNEC $_{oral\ small\ mammals}$ =120 mg.kg $_{food}$). Thus, only the most conservative ratio PEC/PNEC$_{birds}$ are presented.
The results for each scenario are summarised in the following table.

	PEC/PNEC$_{birds}$ (aquatic)	PEC/PNEC$_{birds}$ (terrestrial)
Scenario 1: Indoor one shot aerosol – Treatment of air and untargeted surfaces	7.84E-04	2.59E-03
Scenario 2: Indoor large spray application – Treatment of floors	5.52E-05	1.82E-04
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs,... (Tier 1)	8.46E-06	2.79E-05
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs,... (Tier 2 based on pet owners)	2.84E-06	9.36E-06

No ecotoxicological studies on bird are available in the CAR of S-Methoprene. Only data on small mammals are used to set a PNEC $_{oral\ small\ mammals}$ = 43.6 mg.kg $_{food}$ and only the PEC/PNEC$_{mammals}$ ratios are presented below.

	PEC/PNEC$_{mamals}$ (aquatic)	PEC/PNEC$_{mammals}$ (terrestrial)
Scenario 1: Indoor one shot aerosol – Treatment of air and untargeted surfaces	2.77E-05	4.09E-06
Scenario 2: Indoor large spray application – Treatment of floors	8.07E-07	1.19E-07
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 1)	1.24E-07	1.83E-08
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 2 based on pet owners)	4.15E-08	6.13E-09

Conclusion:

The risks of secondary poisoning are acceptable for permethrin and S-Methoprene when using the product Insecticides for home use for all the uses.

Mixture toxicity

Mixture toxicity assessment is performed in accordance with the decision tree (figure 2) presented in Transitional Guidance on mixture toxicity assessment for the environment (May 2014), and the Figure 2 decision tree.
In fact, it is recommended to start with tier 1 when at least the PEC/PNEC- ratios are available for all relevant substances for all relevant compartments and scenarios. In the absence of ecotoxicological data for groundwater compartment (PNEC based on Maximum permissible concentration laid down by Directive 98/83/EC), and data on synergistic effects between the active substances, only Tier 1 assessment can be performed.
The risk quotients RQ calculation are the following:

This carries on the 2 active substances Permethrin and S-Methoprene , as well as the two Permethrin metabolites PBA and DCVA for every compartment and scenario (conservative and maximizing approach).
Then, $RQ_{Product}$ STP= 0,00019

Then, $RQ_{Product}$ freshwater= 0,177

Then, $RQ_{Product}$ soil= 0,012

Then, $RQ_{Product}$ sediment= 0,67

Then, $RQ_{Product}$ gw= 0,0014

Therefore, risk quotients for each compartment and globally is $\mathbf{RQ_{Product}} < 1$.
Conclusion: Considering the value of risk quotients for all the substances described above (Permethrin, S-Methopren, DCVA, PBA), the use of this family of product is not unsafe regardless the different environment compartments exposed.

Infobox 31 - FR CA position:

The result of mixture toxicity assessment of the product containing two active substances (Permethrin and S-Methoprene) is summarised in the following table.

Summary table on calculated ΣPEC/PNEC values

	$PEC/PNEC_{STP}$	$PEC/PNEC_{water}$	$PEC/PNEC_{sed}$	$PEC/PNEC_{soil}$	PEC_{GW}
Scenario 1	9.65E-02	**9.76E+01**	**1.24E+02**	5.79E-02	6.35E-03
Scenario 2	6.79E-03	**6.87**	**8.74**	3.89E-03	4.46E-04
Scenario 3 - Tier1	1.04E-03	**1.05**	**1.34**	5.96E-04	6.85E-05
Scenario 3 - Tier 2	3.49E-04	3.53E-01	4.48E-01	2.00E-04	2.29E-05

Conclusion:

Only the combined RCR values of permethrin and S-Methoprene for scenario 3 - Tier 2 are below 1 for all the assessed compartments.

The risks related to the use of Insecticides for home use for the other scenarios are not acceptable for the aquatic compartments.

Aggregated exposure (combined for relevant emmission sources)

Infobox 32 - FR CA position:

Aggregated exposure is not relevant for the product Insecticides for home use as there is only one acceptable scenario (scenario 3 – Tier 2).

Figure 1: Decision tree on the need for estimation of aggregated exposure

Infobox 33 - FR CA position:

Overall conclusion on the risk assessment for the environment of the product considering combined RCR between permethrin and S-Methoprene

Summary table for the risk assessment of the product Insecticides for home use						Conclusion
	$PEC/PNEC_{stp}$	$PEC/PNEC_{water}$	$PEC/PNEC_{sed}$	$PEC/PNEC_{soil}$	$PEC/PNEC_{GW}$	
Scenario 1: Indoor one shot aerosol – Treatment of air and untargeted surfaces	Acceptable	**Unacceptable**	**Unacceptable**	Acceptable	Acceptable	**Unacceptable risks**
Scenario 2: Indoor large spray application – Treatment of floors	Acceptable	**Unacceptable**	**Unacceptable**	Acceptable	Acceptable	
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 1)	Acceptable	**Unacceptable**	**Unacceptable**	Acceptable	Acceptable	
Scenario 3: Indoor spray application - Treatment of non-washable furniture and home textile as carpets, mats, arm chairs, ... (Tier 2 based on pet owners)	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

For the indoor use of the INSECTICIDE HOUSEHOLD SPRAY product (meta SPC 1) **for large spray application (treatment of floors)**, calculated RCR values were < 1 for STP and soil, indicating acceptable risks to these environmental compartments. However, for surface water and sediment, RCR values were > 1, indicating unacceptable risks in the conditions of use proposed by the applicant. Concentrations in groundwater related to this use of the product were lower than the trigger value set by Directive 98/83/EC.

For the indoor use of the INSECTICIDE HOUSEHOLD SPRAY product **for spray application with a restriction to treatment of non-washable furniture and home textile as carpets, mats, arm chairs,...** , calculated RCR values were < 1 for STP and soil, and concentrations in groundwater were lower than the trigger value set by Directive 98/83/EC, indicating acceptable risks to these environmental compartments. However, for surface water and sediment, RCR values were > 1.

A refinement of the scenario based on pet ownership that only covers uses against pet fleas and ticks was also assessed. In consequence, the number of houses where the treatment can occur is reduced (only houses where pet are present are taken into account). With this refinement, calculated RCR values were < 1 for all the environmental compartments and concentrations in groundwater are below the trigger value of 0.1µg/L, indicating acceptable risks to the environment, when the product Insecticides for home use is only apply on non-washable furniture and home textile.

For the indoor use of the FOGGER INSECTICIDE FOR HOUSEHOLD product **(meta SPC 2) (spatial treatment of air and untargeted surfaces)**, calculated RCR values were < 1 for STP and soil, indicating acceptable risks to these compartments. Nevertheless, levels of exposure for non-target species of the aquatic compartment (surface water and sediment) were higher than the PNEC values in the conditions of use proposed by the applicant. Concentrations in groundwater related to this use were lower than the trigger value set by Directive 98/83/EC.

- **In conclusion, for the BPF INSECTICIDE FOR HOME USE, risks to the environment are acceptable only for product INSECTICIDE HOUSEHOLD SPRAY (meta SPC 1, one single product) used for targeted spray application to treat non-wet washable furniture and home textile against only pet fleas and ticks. The following risk mitigation measures are therefore proposed for this product: "Do not use on wet washable surfaces and textile" and "Do not wash up furniture's with wet wiping clothes and do not wet clean carpets or mats to avoid discharges into the sewer system".**

2.2.9 Measures to protect man, animals and the environment

Please refer to summary of the product assessment and to the relevant sections of the assessment report.

2.2.10 Assessment of a combination of biocidal products

3 ANNEXES

3.1 List of studies for the biocidal product family

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)	Date of first submission
[redacted]	2017	Laboratory measurement of the effectiveness of an insecticide speciality intended for the destruction of fleas, ticks and mosquitoes in household environment Report No. 2033a/0116R			
[redacted]	2017	Laboratory measurement of the effectiveness of an insecticide speciality intended for the destruction of fleas, ticks and mosquitoes in household environment Report No. 2033a2/0116R			
[redacted]	2016	Laboratory assessment of an insecticide speciality intended to control pests as a space treatment Report No. 2033b/0116R			
[redacted]	2017	Simulated use trial of an insecticide product intended to control fleas, ticks and mosquitoes in household environment Report No. 2194a/0217R			
[redacted]	2017	Simulated use trial of an insecticide product intended to control fleas, ticks and mosquitoes in household environment Report No. 2194b/0217R			

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner (PUB / ORG)	Date of first submission
[redacted]	2016	Auto-ignition temperature of liquids test on 80070034 Diffuseur insecticide pour l'habitat Report 16-901074-016 GLP	Y	Agrobiothers laboratories	07/2017
[redacted]	2015	Auto-ignition temperature of liquids test on 80070034 Spray insecticide pour l'habitat Report 16-901074-015 GLP	Y	Agrobiothers laboratories	07/2017
[redacted]	2016	Surface tension and viscosity tests on 80050794 Spray insecticide pour l'habitat Report 16-901074-014 GLP	Y	Agrobiothers laboratories	11/2016
[redacted]	2016	Surface tension and viscosity tests on 80070034 Diffuseur insecticide pour l'habitat Report 16-901074-014 GLP	Y	Agrobiothers laboratories	11/2016
[redacted]	2016	Spray diameter and pattern on 22050816 Spray insecticide pour l'habitat Report 16-901074-011	Y	Agrobiothers laboratories	11/2016
[redacted]	2016	Spray diameter and pattern on 22070083 Diffuseur insecticide pour l'habitat Report 16-901074-012	Y	Agrobiothers laboratories	11/2016
[redacted] 2016		Appearance test item 22050816 Spray insecticide pour l'habitat Report RPC161401 GLP	Y	Agrobiothers laboratories	11/2016
[redacted]	2016	Appearance test item 22070083 Diffuseur insecticide pour l'habitat RCP 161402 GLP	Y	Agrobiothers laboratories	11/2016
[redacted] 2016		pH measurement test item 80050794 Spray insecticide pour l'habitat report RPC161501	Y	Agrobiothers laboratories	11/2016

[redacted]	2017	pH measurement test item 80070034 Diffuseur insecticide pour l'habitat report RPC161502	Y	Agrobiothers laboratories	07/2017
[redacted]	2016	Storage and stability tests: test item 80050794 Spray insecticide pour l'habitat Report RPC161507 GLP	Y	Agrobiothers laboratories	11/2016
[redacted]	2017	Storage and stability tests: test item 80070034 Diffuseur insecticide pour l'habitat Report RPC161508 GLP	Y	Agrobiothers laboratories	07/2017
[redacted]	2017	Packaging suitability tests: test item 80050794 Spray insecticide pour l'habitat Report RPC161509 GLP	Y	Agrobiothers laboratories	07/2017
[redacted]	2017	Packaging suitability tests: test item 22070082 Spray insecticide pour l'habitat, 300mL Friskies Report RPC162201 GLP	Y	Agrobiothers laboratories	07/2017
[redacted]	2017	Packaging suitability tests: test item 80070034 Diffuseur insecticide pour l'habitat Report RPC161510 GLP	Y	Agrobiothers laboratories	07/2017
[redacted]	2016	Drop size distribution : test item 22050816 Spray insecticide pour l'habitat Report RPC161301	Y	Agrobiothers laboratories	11/2016
[redacted]	2016	Drop size distribution test item 22070083 Diffuseur insecticide pour l'habitat Report RPC161302	Y	Agrobiothers laboratories	11/2016
[redacted]	2016	Mass generation rate : test item 22070082 spray insecticide pour l'habitat Report RPC161701	Y	Agrobiothers laboratories	11/2016

[redacted]	2016	Mass generation rate : test item 22070083 Diffuseur insecticide pour l'habitat Report RPC161702	Y	Agrobiothers laboratories	11/2016
[redacted]	2016	Density measurement: test item 80050794 Spray insecticide pour l'habitat Report RPC161405	Y	Agrobiothers laboratories	11/2016
[redacted]	2016	Density measurement tests: test item 80070034 Diffuseur insecticide pour l'habitat Report RPC161404	Y	Agrobiothers laboratories	11/2016
[redacted]	2016	Density determination : test item 22050816 Spray insecticide pour l'habitat Report RPC161405	Y	Agrobiothers laboratories	11/2016
[redacted]	2016	Density determination test item 22070083 Diffuseur insecticide pour l'habitat Report RPC161404	Y	Agrobiothers laboratories	11/2016
[redacted]	2018	Determination of the content of S-methoprene and permethrin after 26 months of a storage procedure at room temperature made by the Study Sponsor on 22070082 Spray insecticide pour l'habitat 300mL Friskies Report 18-901074-001 GLP	Y	Agrobiothers laboratories	11/2016
[redacted]	2018	Determination of the content of S-methoprene and permethrin after 30 months of a storage procedure at room temperature made by the Study Sponsor on 22050816 Spray insecticide pour l'habitat 300mL Friskies Report 18-901074-003 GLP	Y	Agrobiothers laboratories	11/2016
[redacted]	2018	Packaging suitability tests Test item: 22050816 – Spray insecticide pour l'habitat Study report RPC161509	Y	Agrobiothers laboratories	11/2016
[redacted]	2018	Packaging suitability tests Test item: 22070083 – Spray insecticide pour l'habitat Study report RPC161510	Y	Agrobiothers laboratories	11/2016
[redacted]	2018	Packaging suitability tests Test item: 22070082 – Spray insecticide pour l'habitat 300mL Friskies	Y	Agrobiothers laboratories	11/2016

		Study report RPC162201			
[redacted]	2018	Spray diameter and pattern on 22070082 Spray insecticide pour l'habitat 300mL Friskies Report 18-901074-002 DEFITRACES GLP	Y	Agrobiothers laboratories	11/2016
[redacted]	2018	Spray diameter and pattern on 22070083 Spray insecticide pour l'habitat 300mL Friskies Report 18-901074-006 DEFITRACES GLP	Y	Agrobiothers laboratories	11/2016
[redacted]	2018	Spray diameter and pattern on 22050816 Spray insecticide pour l'habitat Report 18-901074-004 DEFITRACES GLP	Y	Agrobiothers laboratories	11/2016
[redacted]	2016	Validation of the analytical method for the determination of S methoprene and permethrin in 80070034 Diffuseur insecticide pour l'habitat Report R16-901074-007 DEFITRACES GLP	Y	Agrobiothers laboratories	11/2016
[redacted]	2016	Validation of the analytical method for the determination of S methoprene and permethrin in 80070094 Spray insecticide pour l'habitat Report R16-901074-003 DEFITRACES GLP	Y	Agrobiothers laboratories	11/2016
[redacted]	2017	Monitoring of S-Methoprene residues in the air after using biocide fogger – Quantificaiton and validation of analytical method Report No QL2017-0495 QUAD LAB GLP	Y	Agrobiothers laboratories	07/2017
[redacted]	2018	Monitoring of S-methoprene residues in the air after using biocide fogger – Validation of analytical method (further testing of QL2017-0495 report) Report QL2018-1228 QUAD LAB	Y	Agrobiothers laboratories	07/2017

		GLP			

3.2 Output tables from exposure assessment tools


expo primaire.xlsx


expo secondaire -v2.xlsx

3.3 New information on the active substance

No new information on the active substances has been provided by the applicant.

3.4 Residue behaviour

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[26]

3.6 Confidential annex

You can find page 13 of the confidential annex, the environmental study provided by the applicant and discussed in the infobox 10 of the FR assessment (20170718.pdf). A second report related to the environmental assessment provided during the step of consultation is also available (study-report-2018.pdf).

3.7 Other

3.7.1 Risk assessment for animal health

The following risk assessments is included only for information, as agreed at the WG II 2019.

eCA: No guidance document is available to assess the risk for animal.
The applicant assessment is reported below and commented by eCA in the orange boxes.

Fogger insecticide for households is the most concentrated product from the products family INSECTICIDES FOR HOME USE (Permethrin: 0,87% and S-methoprene 0,026%). The risk assessment for the biocidal products family is performed on this product as a worst case exposure.

eCA comment: The concentrations of active substance in the product with the gas have to be used to assess the risk for animals: Permethrin: 0.874% and S-methoprene 0.026%).

1. Permethrin

Permethrin is a contact insecticide with a wide safety margin when used appropriately. It might be expected it would be relatively safe for pets given the difference between mammals and insects and the high selectivity and potency for insects over mammals[1] (the action of permethrin on sodium channels shows a negative temperature coefficient, favouring effects in cold blooded insects over warm blooded mammals)[2,3].
Cats and dogs are non-target organisms. Between cats and dogs, cats can be considered as the most sensitive specie to products with high concentrations of permethrin, possibly due to insufficient glucuronide conjugation capability[4] (they have a less efficient detoxification process than dogs). Besides, the relatively high surface area to weight ratio of cats means that smaller individuals tend to receive higher doses on a mg/kg basis.

1.1. Risk assessment for dogs:
-A lot of veterinary medicines (to apply directly on the animals) are formulated to control pests infestations on dogs. Permethrin is commonly present at dose of 50 to 100 mg/Kg/bw and applied on less than 1 m² of animals (as medicines are usually applied on one point for spot on or some points not exceeding 1m² for sprays).

Exposure assessment:
Dermal exposure is evaluated considering animal laying in room treated, and oral exposure occurring during licking air action.

The quantity of released finished product from the fogger insecticide is 105,6 g; the product is intended to be used in a 70m² room. According to RIVM report 320005002/2006 Pest control Products Fact Sheet, the quantity present on the floor will be 1.508g/m² and 30% of this quantity is considered as dislogeable amount. Consequently for the finished product, the dislogeable amount is 0.45g/m² equivalent to 3.9mg/m² for permethrin.

eCA comment: For human exposure, a room of 22 m^2 was used. Therefore, the same room volume should be used for animal risk assessment (application rate of 4.78 g/m2).
Considering a dislodgeable amount of 30% and an active concentration of 0.874%, the amount of active substance dislodgeable is 12.5 mg/m^2.

Total dermal exposure can be evaluated using the calculation from RIVM report 32005002, as Total dermal exposure = dislogeable amount x transfert coefficient. The transfert coefficient is assumed to be 2.3 m²/day.
Total dermal exposure = 8,97mg/day. This quantity is considered to be the external dose available for skin absorption, and for oral absorption following grooming.

eCA comment: The origin and relevance of the transfer coefficient of 2.3 m^2/day is not provided.
Considering the previous comment, a total dermal exposure of 28.83 mg/d is obtained.

This quantity is between 6 and 10 times less than the dose applied directly on animals via vet medicines. As a consequence, one can consider permethrin is safe for dogs in contact with a treated room or surface.

-The permethrin absorption in dogs is rapid after oral intake. The determined NOAEL on dogs for a 6 months study is 10 mg/kg /day[1]. Consequently, one can consider the use of biocidal products family "Insecticides for home use", is safe for dogs relative to permethrin content.

eCA comment: In the permethrin dossier, two studies were performed on dogs:
- A 180 days study with a NOAEL of 10 mg/kg/d
- A one year study with a NOAEL of 5 mg/kg/d (high range between the lowest doses)
Therefore, considering a NOAEL of 10 mg/kg/d and an exposure of 2.62 mg/kg/d for an external exposure of 28.83 mg/day and a body weight of 11kg (TGD default value), the MOE is of 3.8. This MOE is inferior to the intaspecies safety factor of 10. Therefore based on the available data, a risk cannot be excluded.

- Inhalation exposure : Vapour pressure of permethrin is low (2,155.10^{-6} Pa at 20°C). According to Council Directive 1999/13/EC, it is considered a substance should be considered volatile at the vapour pressure of > 0,01 kPa at 20°C. As a consequence, inhalation exposure is considered as negligible for dogs and consequently the risk for dogs is acceptable.

1.2 Risk assessment for cats:
-Cats intoxication frequently follows inappropriate application of spot on formulations intended for use in dogs. Some cats may also be affected by close contact with dogs treated with a spot on formulation. To sum up, toxicity on cats or adverse reactions usually occur when label instructions are not followed. This was supported in a study on 20 cats. 75% of cats were affected after dermal application. The outcome after treatment was generally favourable[6].
If we consider toxicological data, the dermal LD50 for permethrin in rabbits and rats is over 2000 mg/kg[3,1]. The acute toxicity in rabbits (which is the reference species for dermal toxicity studies) is then low (Permethrin is not classified for acute dermal toxicty[1]).
Concerning the sub-acute toxicity, rabbits given 21 daily dermal doses of permethrin ranging from 0.1 to 1g/kg/bw showed signs of skin irritation but no additional signs of toxicity were observed[3].
A dermal NOAEL of 1000mg/kg bw has been determinated in a 90-days study in rats[1]. As a conservative approach considering an Assessment factor of 10 for Inter-species variability and one of 10 in intra-species variability, a dose of 10 mg/kg bw can be considered as a non adverse effect dose for cats.
As the dislogeable amount of permethrin for the fogger insecticide for households is 3,9 mg/m² and the total dermal exposure 8,97mg/day which is less than the estimated non adverse effect dose for cats. As a consequence, one can consider dermal exposure to permethrin following use of biocidal family "Insecticides for home use" is less that dose showing toxicity and so the risk is acceptable for cats in contact with a treated room or surface.
- No acute oral toxicity was performed on cats. An oral NOAEL of 1000mg/kg/bw[1] was determined on rats in a days study was determined.
As a conservative approach considering an Assessment factor of 10 for Inter-species variability and one of 10 in intra-species variability, a dose of 10 mg/kg bw can be considered as a non adverse effect dose for cats. This dose is more than the 8,97mg/day considered as total dermal exposure. As the oral exposure is the consequence of grooming, it is normal to consider oral intake less than 8,97g/day.
- Inhalation exposure :. Vapour pressure of permethrin is low (2,155.10-6 Pa at 20°C). According to Council Directive 1999/13/EC, it is considered a substance should be considered volatile at the vapour pressure of > 0,01 kPa at 20°C. As a consequence, inhalation exposure is a negligible risk for cats.

Conclusion : The use of biocidal family "Insecticides for home use" is safe for cats and dogs relative to permethrin content in the recommended and appropriate use of the products.

eCA comment: Concerning the exposure, the same comment as before (for the dog) could be applied. However, no data is available in the CAR on this species. As a risk cannot be excluded for dogs, it cannot be excluded for cats.

2. S-methoprene

This active substance is commonly used as an IGR in numerous vet medicines for dogs and cats and its toxicity is widely documented. The poisoning risk is all the more minor as the products are not used directly on animals but only in their environment contrary to a direct application. The discussion will be done for dogs and cats together and for the fogger insecticide for households (as it is the most concentrated product in active substances).

-Dermal and oral exposure
Dermal exposure is evaluated considering animal laying in room treated, and oral exposure occurring during grooming.
The quantity of released finished product from the fogger insecticide is 105,6 g; the product is intended to be used in a 70m² room. According to RIVM report 320005002/2006 Pest control Products Fact Sheet, the quantity present on the floor will be 1.508g/m² and 30% of this quantity is considered as dislogeable amount. Consequently for the finished product, the dislogeable amount is 0.45g/m² equivalent to 0,17mg/m² for S methoprene.

eCA comment: For human exposure, a room of 22 m^2 was used. Therefore, the same room volume should be used for animal risk assessment (application rate of 4.78 g/m^2).
Considering a dislodgeable amount of 30% and an active concentration of 0.026%, the amount of active substance dislodgeable is 0.37 mg/m^2.

Total dermal exposure can be evaluated using the calculation from RIVM report 32005002, as Total dermal exposure = dislogeable amount x transfert coefficient . The transfert coefficient is assumed to be 2.3 m²/day.
Total dermal exposure = 0,26mg/day. This quantity is considered to be the external dose available for skin absorption and for oral absorption following grooming.

eCA comment: The origin and relevance of the transfer coefficient is 2.3 m^2/day is not provided.
Considering the previous comment, a total dermal exposure of 0.86 mg/d is obtained

*S-methoprene*e shows little acute toxicity. The LD_{50} values for *S-methoprene*e are > 5050 mg/kg bw (oral, rat) and > 5050 mg/kg bw (dermal, rat)[7].
The NOAEL in a dog 90-day study is 100 mg/kg/day and 65.4 mg/kg/day for rat 90-day study[7].
In our knowledge, there is no proof that the mechanisms of toxicity in cats and dogs are different, as a consequence we can only use an assessment factor of 10 to describe intra-species variability. The result is an acceptable exposure of 10mg/kg bw/day for cats and dogs for S-methoprenee.
Maximal daily exposure is estimated to 0,26mg/day that is less than the estimated acceptable exposure of 10 mg/kg bw/day.
Consequently, dermal and oral exposure to S-methoprene can be considered as acceptable using the biocidal products family "Insecticides for home use".
Assessment factors are used risk assessment in order to anticipate the variability inter-species and intra-species (diet, age, sex, genetic polymorphisms…). An assessment factor of 10 is used to describe Human intra-specie variability.[5]

eCA comment: In the S-methoprene dossier, 1 study were performed on dogs:
- A 90 days study with a NOAEL of 100 mg/kg/d
Therefore, considering a NOAEL of 100 mg/kg/d and an exposure of 0.078 mg/kg/d for an external exposure of 0.86 mg/day and a body weight of 11kg (TGD default value), the MOE is 1283. Considering the MOE, no risk is expected in regards of s-methoprene for dogs.

-Inhalation exposure : Vapour pressure of permethrin is low (2,155.10-6 Pa at 20°C). According to Council Directive 1999/13/EC, it is considered a substance should be considered volatile at the vapour pressure of > 0,01 kPa at 20°C. As a consequence, inhalation exposure is a negligible risk for dogs and cats.
Conclusion on S methopren: the use biocidal products family "Insecticides for home use" is safe for cats and dogs relative to S-methoprene content in the recommended and appropriate use of the products.

General conclusion: Use of biocidal products family "INSECTICIDES FOR HOME USE" is considered safe, in the recommended and appropriate use, for cats and dogs.

eCA comment: considering the exposure to permethrin RMS disagree with applicant and considers that risk for cats and dogs cannot be excluded.
For information, the fogging application leads to unacceptable risk for environment, and thus cannot be authorised.

References
1 Competent Authority Report On Permethrin, April 2014
2 EMEA Committee for veterinary medicinal products, Permethrin, Summary report (3), 2002, EMEA/MRL/843/02-FINAL
3 Permethrin Technical fact Sheet, National Pesticide Information center
4- Richardson, J.A. (2000) Permethrin Spot On Toxicoses in Cats, The journal of Veterinary Emergency and critical care.
5 ECETOC (2003), Derivation of Assessment factors for Human Health risk assessment. Technical report N° 86
6 Dymond NL and Swift IM, (2008), Permethrin toxicity in cats: a retrospective study of 20 cases. Austrian Veterinary journal, Vol 86. N°6.
7 Competent Authority report On S-methoprene, December 2013[27]

During the WG, it was requested to apply the same approach for spray application.
The specific parameters for this type of application are summarised in the table below:

	Permethrin	S-methoprene
Concentration in active substance	0.177%	0.002%
Application rate	2.1 g/m^2	2.1 g/m^2
Systemic exposure	0.23 mg/kg/d	0.0026 mg/kg/d
NOAEL	10 mg/kg/d	100 mg/kg/d
MOE	42	37957

For permethrin, considering a NOAEL of 10 mg/kg/d (180 days on dog) and an exposure of 0.23 mg/kg/d, the MOE is of 42. This MOE is superior to the intraspecies safety factor of 10.

However, regarding cats, the MOE is inferior to the combined safety factor of 100 when considering a safety factor of 10 for intraspecies and 10 for interspecies.

To conclude:
- no risk is expected for dogs exposed during 6 months
- a risk cannot be excluded for the cats.

For S-methoprene, considering a NOAEL of 100 mg/kg/d (dog) and an exposure of 0.0026 mg/kg/d, the MOE is 37957. Considering the MOE no risk is expected in regards to s-methoprene for dogs and cats.