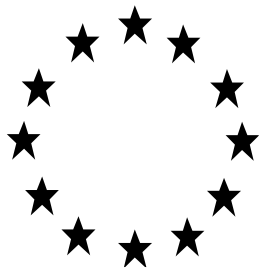
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



SPECIAL ONE

Product type 18

Transfluthrin, Piperonyl butoxide and Cyfluthrin as included in the Union list of approved active substances

Case Number in R4BP: [BC-KL040494-35]

Evaluating Competent Authority: Greece

Date: [April 2021]

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1 CONCLUSION

Special One is formulated as a ready-to-use product based on Transfluthrin, Cyfluthrin and Piperonyl Butoxide (PBO) under the form of an aerosol to be sprayed on the surfaces through the sprayer provided with the original pack. In Special One a liquid is ejected with suspension in a gas, containing nominal (pure) active ingredient of Trasfluthrin at 0.11 % w/, BPO at 0.2% w/w and Cyfluthrin at 0.025 % w/w.

Conclusion for Physico-chemistry:

Its physicochemical properties including the satisfactory operation of aerosol are con-cidered acceptable. The product is stable 6 weeks at 45°C, 8 weeks at 40°C and 48 months at 20°C. The product (spray version) should not be stored at a temperature lower that 0 °C and higher than 40°C.
An analytical method was provided for the determination of all three active substances in the formulation.
SPECIAL ONE is classified as Aerosol 1; H222 H229. Others physical hazards are not expected to CLP criteria.

Conclusion for Human Health

Regarding human health risk assessment, an acceptable risk is predicted for both the primary exposure of non-professional users and general public during product application and the indirect secondary exposure of the general public following application of the biocidal product SPECIAL ONE.

Conclusion for the Environment:

According to the environmental risk assessment, the risk for all relevant environmental compartments is acceptable for general, public use when the product is used according to label instructions, [redacted]

<u>For the Uses 1 & 2 a referral was raised by FR MS</u> on ENV section. Following the coordination group discussion on the 31 March 2021 teleconference, the conclusions regarding the points raised on Use 1 and Use 2 are as follows:

[redacted]

Use 2 PAR is updated including the partially revised environmental risk assessment considering a FCE value of 0.2 associated to emission from the floor. **The need for an additional RMM for not applying the product on wet cleaned areas, as proposed by FR MS, will be decided in view of the recalculation.**
The phrase "well-exposed nests" in the instructions of use was replaced by "nests accessible to treatment" in both the PAR and SPC.

Conclusion for Efficacy

Several efficacy studies (laboratory, simulated use and field studies) were submitted for Special One (Ready to Use product) containing transfluthrin 0.11%, cyfluthrin 0.025% and

PBO 0.2%. Based on the results of the submitted efficacy studies, the product was effective when applied by non-professionals as:

- Direct spray indoors on individual wasps (*Vespula germanica*) (Intended use 1) at 3 gr/ individual wasp (2 seconds spray) from 20 cm distance
- Spot treatment by direct spray against wasp nests indoor and outdoor (Intended uses 2 & 5) using a special jet valve on the product at 15gr/ nest (1 second spray) from 4 m distance. Against paper wasp nests, spray from 2-3 meters distance for 1 second. The product is applied on wasp nests accessible to the treatment, not hidden in cavities.
- Spot application indoors against crawling insects, including *Blatta orientalis*, *Blattela germanica* & *Lasius niger*, (Intended use 3) at 6 gr/ m^2 (4 seconds spray) for up to 4 weeks after treatment, with noticeable knockdown effect to be observed 4 hours after exposure of the insects to the treated surfaces
- Crack and crevice application against crawling insects, including *Blatta orientalis*, *Blattela germanica* & *Lasius niger*, (Intended use 4) at 6 gr/ m^2 (4 seconds spray) for up to 4 weeks after treatment
- Spot treatment against ant (*Lasius niger*) nests (Intended use 6) applying the product around and at the entrance of the nest at 6 gr/ m^2 (4 seconds spray)
- Spot treatment against tiger mosquitoes (*Aedes albopictus*) outdoor around buildings (Intended use 7) by 8 spot applications of 1 seconds (1,5 g of product in 1 sec) for 25 m^2 (0,5gr/ m^2), up to 5 hours post treatment.
  The claim by the applicant that "the product prevents the entrance of mosquitoes in the building" is not supported by the submitted efficacy studies.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
SPECIAL ONE	

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Activa S.r.l.
	Address	Via Feltre, 32 20123 - Milano Italy
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	Activa S.r.l.
Location of manufacturing sites	c/o Pharmac Italia s.r.l. Viale Umbria, 55/57 20089 Rozzano (Mi) tel. +39 02 8254082 fax +39 02 8243008 [redacted]

Name of manufacturer	Activa S.r.l
Location of manufacturing sites	c/o BERGEN SRL Via Roma, 90 37060 Castel d'Azzano Verona - Italy TEL +39 045 512 090 [redacted]

Name of manufacturer	Activa S.r.l
Location of manufacturing sites	c/o TOSVAR srl Via del Lavoro 10 20060 Pozzo d'Adda (MI) Tel 02.90960289 fax 02.90968148 [redacted]

Name of manufacturer	Activa S.r.l

Location of manufacturing sites	c/o Farmol Tunisie SARL Rte de Gabes km 9 , Cité Thyna Rue Kerkenah , 3084 Sfax - Tunisia [redacted]

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

Active substance	Transfluthrin
Name of applicant and Article 95 supplier	Bayer SAS (formerly Bayer Environmental Science SAS), 16 rue Jean-Marie Leclair, CS 90106, 69266 Lyon Cedex 09, France
Name of manufacturer	Bayer AG, Division Crop Science (formerly Bayer CropScience AG
Address of manufacturer	Alfred-Nobel Strasse 50, 40789 Monheim Am Rhein, Germany
Location of manufacturing sites	Bayer Vapi Private Limited (Formerly Bilag Industries Pvt. Ltd.) Plot No.306/3 Phase II G.I.D.C. Vapi 396195 Gujarat, INDIA Phone: +91 260 2407123, Fax: +91 260 2432774 The address of the manufacturing plant for the active substance has been evaluated in the dossier for Transfluthrin PT18. The manufacturer of the active substance is the same.

Active substance	Piperonyl Butoxide
Name of manufacturer	ENDURA S.p.A. ENDURA S.p.A. is the Article 95 listed supplier of Piperonyl Butoxide for Product Type 18.
Address of manufacturer	Via Pietramellara, 5 40121 Bologna Italy
Location of manufacturing sites	via Baiona 107-111 – 48123 Ravenna The address of the manufacturing plant for the active substance has been evaluated in the dossier for Piperonyl Butoxide PT18. The manufacturer of the active substance is the same.

Active substance	Cyfluthrin
Name of applicant and Article 95 supplier	Bayer SAS (formerly Bayer Environmental Science SAS), 16 rue Jean-Marie Leclair, CS 90106, 69266 Lyon Cedex 09, France
Name of manufacturer	Bayer AG, Division Crop Science (formerly Bayer CropScience AG
Address of manufacturer	Alfred-Nobel Strasse 50, 40789 Monheim Am Rhein, Germany

Location of manufacturing sites	Bayer Vapi Private Limited (Formerly Bilag Industries Pvt. Ltd.) Plot No.306/3 Phase II G.I.D.C. Vapi 396195 Gujarat, INDIA Phone: +91 260 2407123, Fax: +91 260 2432774 The address of the manufacturing plant for the active substance has been evaluated in the dossier for Cyfluthrin PT18. The manufacturer of the active substance is the same.

2.1.2 Product composition and formulation

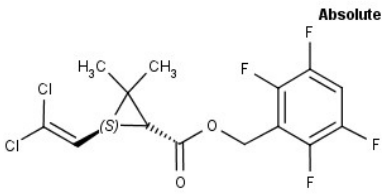
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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

Yes ☐
No ☑

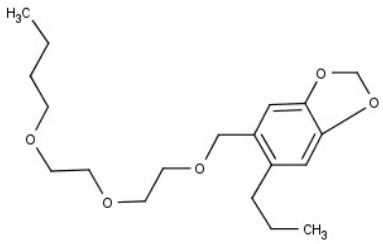
2.1.2.1 Identity of the active substance

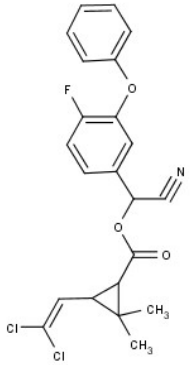
SPECIAL ONE is composed by 3 active substances, as detailed in tables below.

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

** The EU index no. and ELINCS no. refer to the 1R,trans and 1S,trans configurations, which is not in agreement with the definition of transfluthrin, which is exclusively the 1R,trans isomer. The CAS registry no. does refer to the correct isomer.*

Piperonyl butoxide	
ISO name	Piperonyl Butoxide
IUPAC or EC name	5-[2-(2-butoxyethoxy)ethoxymethyl]-6-propyl-1,3-benzodioxole
EC number	200-076-7
CAS number	51-03-6
Index number in Annex VI of CLP	not listed in Annex VI of CLP

Minimum purity / content	≥ 94.0 %w/w
Structural formula	

	Cyfluthrin
ISO name	cyfluthrin (ISO) α-cyano-4-fluoro-3-phenoxybenzyl-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
IUPAC or EC name	(RS)-α-Cyano-4-fluoro-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	269-855-7
CAS number	68359-37-5
Index number in Annex VI of CLP	607-253-00-1
Minimum purity / content	≥ 95.5 % w/w
Structural formula	

2.1.2.2 Candidate(s) for substitution

The product does not contain active substances considered as a candidate for substitution.

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

Common name	IUPAC name	Function	CAS number	EC number	Pure AS content (%)	Technical AS Content (%)
Transfluthrin	2,3,5,6-tetrafluorobenzyl (1R,3S)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate, or, 2,3,5,6-tetrafluorobenzyl (1R)-trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	118712-89-3	405-060-5	0.110	0.114
Piperonyl butoxide	5-[2-(2-butoxyethoxy)ethoxymethyl]-6-propyl-1,3-benzodioxole	Active substance	51-03-6	200-076-7	0.200	0.213
Cyfluthrin	(RS)-α-Cyano-4-fluoro-3-phenoxybenzyl (1RS,3RS;1RS,3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate	Active substance	68359-37-5	269-855-7	0.025	0.026

Complete composition of the product is reported in confidential annex.

2.1.2.4 Information on technical equivalence

It is not necessary to establish the technical equivalence since the active substances in SPECIAL ONE are the same substances of the reference source in respect of which the initial risk assessment was performed.

2.1.2.5 Information on the substance(s) of concern

Information on the substance(s) of concern: LPG (Mixture of N-butane, iso-butane, propane)

Note: Pressure in cans is due to content and composition of LPG. If the pressure does not change consequently the content and composition of LPG doesn’t change. The trials in Annex 10 show does not change in pressure during stability consequently not change in LPG occur.

Please see Confidential Annex for further details.

2.1.2.6 Type of formulation

AE Aerosol dispenser

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Flammable Aerosol Cat. 1, H222 Pressurized Container, H229 Aquatic Acute 1; H400 Aquatic Chronic 1; H410
Hazard statement	H222 Extremely flammable aerosol. H229 Pressurised container: May burst if heated. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.
Labelling	
Pictogram	GHS02: flame  GHS09: environment 
flammSignal words	Danger
Hazard statements	H222 Extremely flammable aerosol. H229 Pressurised container: May burst if heated. 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. P273 Avoid release to the environment. P391: Collect spillage P402 Store in a dry place. P410+P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F. P501 Dispose of container in accordance with national regulations.
Note	[redacted]

2.1.4 Authorised use(s)

2.1.4.1 Use 1 – Spot application indoor by direct spray on wasps' nests

Table 1. Use 2 – Spot application indoor by direct spray on wasps' nests

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Indoor treatment for eradication of wasp nests.
Target organism (including development stage)	Hymenoptera: *Vespula germanica* – German wasps – Adults *Vespula germanica* – German wasps - Nymphs *Polistes sp.* - Paper wasps - Adults *Polistes sp.* - Paper wasps - Larvae
Field of use	Indoor
Application method(s)	Spot application by direct spray on wasps' nests. The product container is equipped with a special jet valve that allows to operate at a distance of about 4 meters from the nest, in a safe way. In this way it is possible to reach wasp nests harboured in areas such as attics, ceiling corners, under the roofs and shingles. The product is applied on wasp nests accessible to the treatment, not hidden in cavities. Shake well before use. Spray from 4 meters distance for 1 second. It is normally enough to cover completely with foam the nest and achieve fast and quick mortality of all the wasps. Against paper wasp nests, spray from 2-3 meters distance for 1 second.
Application rate(s) and frequency	Apply for 1 second (15 g) directly on wasp nest Apply up to 2 times per year.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Please, refer to point 2.1.7 Packaging of Biocidal Product.

2.1.4.1.1 Use-specific instructions for use

For a better efficacy apply the product at dusk or dawn. Do not apply the product on electrical panel /cabinet. The product is equipped with special actuator wasps nests application.

2.1.4.1.2 Use-specific risk mitigation measures

During application floor has to be covered with an impermeable material that is disposed after treatment.

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

No direct or indirect effects are expected where product is used as indicated.

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

Dispose of contents/container in accordance with local regulations Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets..) nor down the drains. Floor covering material and nest should be disposed as a hazardous waste.

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

Recommended storage temperature*: "Store the product below 40 °C".*

2.1.4.3 Use 2 – Crack and crevice application against crawling insects

Table 2. Use 4 – Crack and crevice application against crawling insects

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Apply in crack and crevices Dosage: spray evenly for 3-4 seconds. Efficacy of the treatment can last up to 4 weeks.
Target organism (including development stage)	Crawling insects *Blatta orientalis* - Oriental cockroach - Adults *Blattella germanica* - German cockroach - Adults *Lasius niger* - black garden ant - Adults
Field of use	Indoor Apply where targets may find harbourage. Into crack and crevices. Domestic premises: Private housing,
Application method(s)	Spraying Spraying into crack and crevices
Application rate(s) and frequency	3-4 seconds spray (6 g)/m^2 Apply up to 11 times per year.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Please, refer to point 2.1.7 Packaging of Biocidal Product.

2.1.4.3.1 Use-specific instructions for use

Apply in closed areas such as below the kitchen furniture, under the fridge, under the kitchen sink, under the oven or the water heater

Do not apply the product near to or in presence of electrical outlets.

Apply on clean surfaces to obtain better results.

2.1.4.3.2 Use-specific risk mitigation measures

- "Use only in areas inaccessible to children and animals, in particular cats."
- "Keep children and pets, particularly cats, away during treatment."

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

No direct or indirect effects are expected when product is used as indicated.

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

See paragraph Directions for use. Dispose of contents/container in accordance with local regulations Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets..) nor down the drains

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

Recommended storage temperature*: "Store the product below 40 °C".*

2.1.5 General directions for use

2.1.5.1 Instructions for use

SPECIAL ONE is formulated as a Ready To Use product based on Transfluthrin, Cyfluthrin and PBO under the form of an aerosol to be sprayed on the surfaces through the sprayer provided with the original pack.

Comply with the instructions. Shake well the container before use.
Product should always be used in accordance with label recommendations.

This biocidal product contains PBO and transfluthrin which are dangerous for bees

Strategies for managing the development of resistance:

- Where possible, application treatments should be recommended to be combined with non-chemical measures
- Applications should always be made against the most susceptible stages in the pest life cycle
- Where an extended period of control is required, treatments should be alternated with products with different modes of action
- Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refugia can contribute to the risk of re-infestation.
- in cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing active substances with the same mode of action should cease.
The users should inform if the treatment is ineffective and report straightforward to the authorization holder. The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.
- The users should inform if the treatment is ineffective and report straightforward to the authorization holder. The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.1.5.2 Risk mitigation measures

Remove excess biocidal product from surfaces after treatment.
Do not exceed the use rates.

Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals.

. Do not apply on pets.

Use only in areas inaccessible to children and animals, in particular cats.

Keep children and pets, particularly cats, away during treatment.

Remove or cover terrariums, aquariums and animal cages before application. Turn off aquarium air-filter while spraying.

Do not wash treated surfaces.

Do not apply upwind or in rainy or windy days.

Protect from frost.

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

Direct or indirect negative effects are not expected when product is used according to label instructions.

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

If medical advice is needed, have product container or label at hand.

Do not release empty container in the environment.

Keep away from food, drink or animal feedstuff.

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

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

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

2.1.5.4 Instructions for safe disposal of the product and its packaging

Product must be stored at room temperatures, away from sunlight.

Dispose of contents/container in accordance with local regulations.

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets..) nor down the drains.

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

Product must be stored at room temperatures, away from sunlight. Do not store over 40°C or below 0°C. (see the results of accelerated storage stability studies, below).

Storage Life:
A shelf life for 4 years is proposed by the applicant on the SPC that is accepted based on the acceptable 48 months storage stability test in the original container under normal conditions (see below).

Keep out of reach of children and pets.

2.1.6 Other information

Application codes storage stability test

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging (*)	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Spray can pressure 3-4 bar reportes as *"Special One"*	from 300 to 1000 mL	Tinplate steel cans with epoxy phenolic coating.	PP (polypropylene) Horizontal spray cap Actuator Materials of the valves: PE, Rubber, Nylon, steel, tin plate.	non-professional (against flying and crawling insects)	Yes (see the results of long term and accelerated stability study)
Spray can pressure 5-6 bar reported as *"Vespa One"*	from 300 to 1000 mL	Tinplate steel cans with epoxy phenolic coating.	PP (polypropylene) wasp spray spout Actuator Materials of the valves: PE, Rubber, Nylon, steel, tin plate.	non-professional (against wasp nests)	Yes (see the results of long term and accelerated stability study)

(*) The net content of product is included from 50 ml to 750 ml, the liquid phase of product is always 60% of content.

Conclusion on the packaging of the biocidal product

Regarding the table presented above further data on container's and valve's specifications can be found on the certificates of their specifications that they have been uploaded on R4BP on 19.06.2020 and available on Confidential Annex.

Conclusion: Based on available data from accelerated storage stability studies at 45ºC, 40ºC, 30ºC and 4, 2, 5 years storage at ambient temperature, compatibility with the following package material could be accepted:

-Tinplate steel can (with internal coating: a layer of epoxy phenolic resin) and it is the same for both types of sprayers..

Furthermore, acceptable tests related wih the aerosol techical characteristics, have been conducted for Special One aerosol with Valve: [redacted] and for Vespa One aerosol with Valve: XXXXX[redacted]
Furthermore, for Special One aerosol based on the applicant's justification presented above, no changes in its technical characteristics are expected using the other two actuators.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

In relation to the product application, the following data on product are submitted:

- Physical state at 20 °C and 101.3 kPa; colour at 20 °C and 101.3 kPa and odour at 20 °C and 101.3 kPa
- Acidity / alkalinity
- Relative density
- Storage stability test – accelerated storage (2 studies)
- Storage stability test – long term storage at ambient temperature
- Particle size distribution, content of dust/fines, attrition, friability
- Spraying pattern — aerosols (3 studies, including spray rate)
- Surface tension
- Viscosity
- Explosives (2 tests: TEST A.14, BAM FALLHAMMER and TEST A.14, KOENEN TUBE)
- Flammable aerosols (2 tests for determination of the ignition distance)
- Corrosive to metals
- Auto-ignition temperatures of products (liquids and gases)
- Method for the identification and quantification of the active ingredient in the product.

For details please refer to separate reference list.

2.1.8.2 Access to documentation

The applicant submits a Letter of Access granted by the manufacturer of the active substances, Bayer SAS Environmental Science for Transfluthrin and Cyfluthrin and Endura S.p.A. for Piperonyl butoxide respectively, that cover the studies owned by the companies and other information that have been used for including Transfluthrin, Cyfluthrin and Piperonyl butoxide in the Union list of approved active substances under the Biocidal Products Regulation. With such Letters of Access Bayer SAS Environmental Science and Endura S.p.A. authorize the applicant to use, refer to and rely on its data in order to apply for the authorization of the product SPECIAL ONE. Letters of Access have been attached in section 13 of IUCLID dossier.

2.2 Assessment of the biocidal product

General remarks: Special one is a spray aerosol. In Special one a liquid is ejected with suspension in a gas.

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

2.2.1.1 Use 1 – Spot application indoor wasps nest

Table 3. Use 2 – Wasps nest

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Indoor treatment for eradication of wasps nests.
Target organism (including development stage)	Hymenoptera: Polistinae - *Polistes sp.* - Paper wasps - Adults Hymenoptera: Polistinae - *Polistes sp.* - Paper wasps - Larvae
Field of use	Indoor
Application method(s)	Direct spray on wasps' nest. The product container is equipped with a special jet valve that allows to operate at a distance of about 4 meters from the nest, in a safe way. In this way it is possible to reach wasp nests harboured in areas such as attics, ceiling corners, under the roofs or hidden cavities, under the shingles, gutters, cracks, under window sills. Shake well before use. Spray from 4 meters distance for 1 second. It is normally enough to cover completely with foam the nest and achieve fast and quick mortality of all the wasps.
Application rate(s) and frequency	15 g/nest Apply up to 2 times per year.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Please, refer to point 2.1.7 Packaging of Biocidal Product.

2.2.1.2 Use

2.2.1.3 Use 4 – Crack and crevice application crawling

Table 4. Use 4 – Crack and crevice application crawling

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Apply in crack and crevices Dosage: spray evenly for 3-4 seconds. The product shows prolonged efficacy. Efficacy of the treatment can last up to 4 weeks and so it should not be necessary to repeat the treatment before one month.
Target organism (including development stage)	Crawling insects Blatta orientalis - Oriental cockroach - Adults Blattella germanica - German cockroach - Adults Periplaneta americana - American Cockroach - Adults Lasius niger - black garden ant - Adults
Field of use	Indoor Apply where targets may find harbourage. Into crack and crevices. Domestic and public premises: Private housing and shops in all the facilities. Storage: warehouses. Animal husbandry: kennels, zoos, pet shops.
Application method(s)	Spraying Spraying into crack and crevices
Application rate(s) and frequency	6 gr /sqm meaning 3-4 seconds. Apply up to 11 times per year.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Please, refer to point 2.1.7 Packaging of Biocidal Product.

2.2.2 Physical, chemical and technical properties

Special One is formulated as a ready to Use product based on Transfluthrin, Cyfluthrin and PBO under the form of an aerosol to be sprayed on the surfaces through the sprayer provided with the original pack. In Special One a liquid is ejected with suspension in a gas, containing nominal (pure) active ingredient of Trasfluthrin at 0.11 % w/, BPO at 0.2% w/w and Cyfluthrin at 0.025 % w/w.
Special One is a yellowish liquid with a characteristic odour. Most phys chem property tests were tested on the liquid phase after elimination of the propellant.
The pH of the product was determined to be 7.30 at 20°C. The relative density was measured to be 0.997 g/mL and a surface tension of 23.5 mN/m at 20°C and its dynamic viscosity showed a Newtonian-like behaviour.
No changes in the sample appearance, colour, odour, content of the active ingredient and packaging was found after storage using its commercial packaging material (tinplate can) after storage for 8 weeks at 40°C and for 4 years at ambient temperature and shows no reactivity towards its container material.
The satisfactory operation of the aerosol was tested after storage of tinplate can at 45°C for 6 weeks and after storage for 2 and 5 years.

SPECIAL ONE is classified as Aerosol 1; H222 H229. Others physical hazards are not expected.

General Comments to be considred:

- 3 different storage stability studies are available for Special One:

- 4 years real time (236/2010)
- Accelerated storage stability at 40°C (235/2010)
- Accelerated storage stability 30 °C (2018/122 + amendment)

Taking into account Real time study and 40 °C study do not meet the requirements for satisfactory aerosol operation, the applicant run the 30°C study in order to cover missing data. However, in a second step applicant provided an additional accelerated storage stability study at 45°C has been provided in order to meet further requirements.

- Based on applicant' s declaration storage stability tests were prepared with tinplate tin cans. Furthermore, applicant confirmed that all samples used in all studies presented below, have the same composition that presented in Confidential Annex.

- In addition, applicant provided the following clatification to be condidered for the phys chem properties testing:

"Special One is a spray aerosol. In foam aerosol the foam has a technologic function for efficacy of the product, it is stable in time and produced by foaming agents. For Examples: shave foam and polyurethane foam. In "Special one" aerosol the foam is a natural result of the mixture emulsion and propellant gas. In our formulation we have not used anti foam agent to avoid foam, therefore during spray it is possible the formation of foam on the treated surfaces. Anyway, the foam vanishes in a few seconds when the propellent gas evaporate"

There are only two types of sprayer: **Vespa One "long jet spray"** and **Special One "normal" spray.**

In each aerosol packaging reported as "spray cans of aerosol" there are 3 different component:Tinpalate can, valve, actuator.
Tinplate canis the same for both Vespa One long jet spray and special One "normal" spray.
The valve and the actuator are what change. Fot further information please refer above, on point 2.1.7.

- Tests related wih the aerosol techical characteristics, have been conducted
-

1)for Special One aerosol with Valve: [redacted]

2) for Vespa One aerosol with Valve: [redacted]

- Tests regarding their satisfactory operation for both jet valves have been conducted before and after storage stability conditions.
-
- The other phys chem property test have been conducted on the liquid phase after elimination of propellant reported as liquid form, since both cans include the same liquid phase.

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**	**Acceptability**
Physical state at 20 °C and 101.3 kPa Colour at 20 °C and 101.3 kPa	OPPTS 830.6302; OPPTS 830.6303; OPPTS 830.6304	Content of the AS used for the formulation of the BP (technical content)	Physical state: Liquid; Colour: Yellowish; Odour: Characteristic odour.	Special one: determination of the accelerated storage stability and corrosion characteristics. CH-235/2010. May 2011.	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
Odour at 20 °C and 101.3 kPa Liquid form		Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w Batch number: T0024		GLP compliance: yes Tested on liquid phase after elimination of propellant.	
Acidity / alkalinity Liquid form	pH determination according to CIPAC MT 75.3.	Content of the AS used for the formulation of the BP (technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w Batch number FFA04004/B	pH was measured at about 20°C. MilliQ water was used. (N=2) pH at T0 (as it is /1%solution) = 7.30 / 7.60 Since the pH value ranged from 4 to 10, the acidity or alkalinity test was not performed	Accelarated stabilitystudy at 30°C for 18 WEEKS on thr test item "SPECIAL ONE". Final report No. 2018/122 AM. C. Belussi, March 25, 2019, under Annex 3, 3b GLP compliance: yes Tested on liquid phase after elimination of propellant.	**Acceptable**
Relative density / bulk density Liquid form	OECD 109 (Pycnometer method)	Content of the AS used for the formulation of the BP	Relative density at 20°C is 0.997	Accelarated stabilitystudy at 30°C for 18 WEEKS on thr test item "SPECIAL ONE". Final report No. 2018/122	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
		(technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w Batch number FFA04004/B		AM. C. Belussi, March 25, 2019, (under Annex 3,3b) GLP compliance: yes Tested on liquid phase after elimination of propellant.	
Storage stability test – **accelerated storage for 8 weeks at 40°C** **liquid form**	CIPAC MT 46 Active ingredients content (Internal Validated Analytical Method No. CH - 234/2010) OPPTS 830.6302; OPPTS 830.6303; OPPTS 830.6304 CIPAC MT 75.3.	Content of the AS used for the formulation of the BP (technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w Batch No. T0024	Storage stability tests were conducted with tinplate tin cans. The active ingredient content and the physical-chemical properties of Special One packaged in spray bottle after 8 weeks storage at 40°C are comparable to the relevant values obtained in the initial characterisation. Active ingredients content (Initial characterisation) Piperonyl Butoxide: 0.20 ± 0.01 % w/w Transfluthrin: 0.11 ± 0.01 % w/w Cyfluthrin: 0.028 ± 0.001 % w/w	Special one: determination of the accelerated storage stability and corrosion characteristics. S.Garafani, CH-235/2010. May 2011, under Annex 2 GLP compliance: yes Note:Tested on liquid phase after elimination of propellant.	**Acceptable regarding the liquid form** **please also refer to new data below..**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
			Active ingredients content (After 8 weeks at 40°C) Piperonyl Butoxide: 0.20 ± 0.01 % w/w Transfluthrin: 0.11 ± 0.01 % w/w Cyfluthrin: 0.028 ± 0.001 % w/w From the obtained results it can be concluded that no significant change was found in the active ingredient content after 8 weeks storage at 40°C in the test item from the 500 mL spray bottle "A". Weight variation: Technical balance 500 mL spray bottle "A" (Weight at the beginning (g)): 500.23 500 mL spray bottle "A" (Weight at the end (g)): 500.23 pH at the beginning: 6.814 pH after storage: 6.840 (pH was measured at about 22°C using HPLC grade water) **Relevant impurities:** No data submitted for the determination of relevant impurities before and after		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
			storage in Special One formulation. For further information, refer below on 4 years' storage stability data. No change in the sample appearance, colour or odour, was found for the test item stored in the 500 mL spray bottle for 8 weeks at 40°C and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena of packaging. Moreover, no significant change in physical properties (pH value and weight variation) was found for the sample stored for 8 weeks storage at 40°C, in respect to the initial characterisation. From the above reported data, it can be concluded that the test item is stable in its commercial packaging under the tested accelerated storage conditions.		
Storage stability test – **accelerated storage for 6 weeks at 45°C**	Spray rate: FEA 643 Spray pattern: FEA 644	Content of the AS used for the formulation of the BP	The product shows a complete stability in terms of resistance because after 6 weeks at 45°C doesn't show leaking and any modification on cans, valves and	SPECIAL ONE: Spray Performance evaluation after accelerated Storage Stability. Tosvar srl.	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
Spray Performance For SPECIAL ONE	Water bath: FEA 606 Internal pressure: FEA 604 Clogging valve: FAO 8.11.4.5 Note 11 Weight loss after 5 seconds spray test: Internal SOP 222	(technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w Batch number 119TSCA	actuators. The product shows a complete unchanged after stability in terms of spray performance because spray pattern, spray rate, internal pressure and quantity of product sprayed doesn't present any modification after 6 weeks at 45°C. Test - Initial characterisation - After 6 weekd of storage at 45°C Spray rate - 1.6 gr/sec - 1.5 gr/sec Spray pattern - 8.2 cm - 7.9 cm Water bath - CONFORM - CONFORM Internal pressure - 3.5 BAR - 3.5 BAR Clogging valve - CONFORM - CONFORM Weight loss after 5 seconds spray test - 8 g - 7.5 g	September 2020. Dr. Armando Cristilli. GLP compliance: no	
Storage stability test – **accelerated storage for 6 weeks at 45°C** **Spray Performance For VESPA ONE**	Spray rate: FEA 643 Spray pattern: FEA 644 Water bath: FEA 606 Internal pressure: FEA 604	Content of the AS used for the formulation of the BP (technical content) Transfluthrin 0.114 % w/w;	The product shows a complete stability in terms of resistance because after 6 weeks at 45°C doesn't show leaking and any modification on cans, valves and actuators. The product shows a complete unchanged after stability in terms of spray performance because spray pattern, spray rate, internal	VESPA ONE: Spray Performance evaluation after accelerated Storage Stability. Tosvar srl. September 2020. Dr. Armando Cristilli. GLP compliance: no	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
	Clogging valve: FAO 8.11.4.5 Note 11 Weight loss after 5 seconds spray test: Internal SOP 222	Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w Batch number 118TSCA	pressure and quantity of product sprayed doesn't present any modification after 6 weeks at 45°C. Test - Initial characterisation - After 6 weeks of storage at 45°C Spray rate - 14.9 gr/sec - 15.1 gr/sec Spray pattern - 21 cm - 20.7 cm Water bath - CONFORM - CONFORM Internal pressure - 6 BAR - 6 BAR Clogging valve - CONFORM - CONFORM Weight loss after 5 seconds spray test - 78 g - 77 g		
Storage stability test – **accelerated storage at 30°C for 18 weeks.** **liquid form including Spray Performance data for SPECIAL ONE**	CIPAC MT 46.3 CIPAC MT 75.3 CIPAC MT 191 OECD 109 FEA 644 (spray pattern) Internal method adapting FEA 643(discharge rate) Clogging FAO note 11	Content of the AS used for the formulation of the BP (technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w	The study was planned applying storage conditions (CIPAC method MT 46.3) of 30°C for 18 weeks. Packaging: Storage stability tests were conducted with tinplate tin cans. The parameters indicating the test item stability were the following: Appearance of the test item T0 = white opaque liquid T18w = white opaque liquid	Accelerated stability study at 30°C for 18 weeks on the test item "SPECIAL ONE". Eurofins Biolab Srl. Final report 2018/122 AM, C. Belussi, March 25, 2019 & Amendment to final report 2018/122 AM. May 29, 2019 (under Annex 3,3b) GLP compliance: yes	**Acceptable as additional data**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
	Active ingredients content (Internal Analytical Method No. CH - 234/2010)	Batch number FFA04004/B	Appearance of the packaging T0 = White metal can with yellow dispenser cap T18w = White metal can with yellow dispenser cap Weight loss (gravimetric) T0 = - T18w = 0.024% Relative density T0 = 0.997 T18w = 0.968 pH (as it is/1% solution) T0 = 7.30 / 7.60 T18w = 6.98 / 6.70 Discharge rate at 25°C T0 = 1.26 g/s T18w = 1.14 g/s Content of Transfluthrin active ingredient (%w/w) T0 = 0.1199 T18w = 0.1186 (98.9% of T0) Content of PBO active ingredient (%w/w) T0 = 0.2077 T18w = 0.2038 (98.1% of T0)	Testing the filling solution. Liquid phase only without propellant.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
			Content of Cyfluthrin active ingredient (%w/w) T0 = 0.0244 T18w = 0.0225 (92.2% of T0) Spray pattern (using oil sensitive paper) T0 = round shape T18w = round shape Note: miising data for diameter. Clogging (25 ^{0}C) T0 = Conforms T18w = Conforms On the test item "SPECIAL ONE" after 18 weeks at 30°C no important variations in the chemical-physical characteristics were observed; the content of Transfluthrin active ingredient was 98.9% with respect to T0, the content of PBO active ingredient was 98.1 % with respect to T0 and the content of Cyfluthrin active ingredient was 92.2% with respect to T0. Applicant's Justification for performing a second accelerated storage stability at lower temperature:		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
			"We confirm the accelerated storage stability study at 30 °C was conducted to cover other phys-chem properties (e.g spray pattern, Clogging) not covered in the report CH-235/2010. *The choose of new temperature for new trials is not linked at Phys chem properties but to internal safety and technical standard of labs."*		
eCA remark: The results regarding the storage stability study by S.Garafani, CH-235/2010, are considered acceptable regarding the liquid form. Missing storage stability data regarding the satisfactory operation of aerosols in terms of spray rate and patterns are covered by additional non GLP studies that have been conducted in spray versions (for both jet valves) after accelerated storage for 6 weeks at 45°C, by Armando Cristilli (2020). Furthermore, acceptable results on GLP accelerated storage study at 30°C for 18 weeks in SPECIAL ONE formulation by Belussi (2019) could be considered as additional data for confirmation purposes. Based on the available accelerated storage stability data the applicant's proposal "Do not store at temperatures above 40°C" could be considered as accepted					
Storage stability test – **long term storage 4 years at ambient temperature** **Liquid form**	- GIFAP Monograph No. 17, 2nd edition, June 2009 - OECD Guidelines No. 110 Active ingredients content (Internal Analytical Method No. CH - 234/2010)	Content of the AS used for the formulation of the BP (technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w;	Packaging: Storage stability tests were conducted with tinplate tin cans. a.i. content: Piperonyl Butoxide after 6 months 0.20 ± 0.01 % w/w 12 months 0.20 ± 0.01 % w/w 18 months 0.20 ± 0.01 % w/w 24 months 0.21 ± 0.01 % w/w 36 months 0.19 ± 0.01 % w/w 48 months 0.21 ± 0.01 % w/w	Special One: Four years storage stability and corrosion characteristics. CH - 236/2010. Jan 2015. GLP compliance: yes Tested on liquid phase after elimination of propellant.	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
		Cyfluthrin 0.026 % w/w Batch No. T0024	Transfluthrin 6 months 0.11 ± 0.01 % w/w 12 months 0.11 ± 0.01 % w/w 18 months 0.11 ± 0.01 % w/w 24 months 0.12 ± 0.01 % w/w 36 months 0.11 ± 0.01 % w/w 48 months 0.12 ± 0.01 % w/w Cyfluthrin 6 months 0.027 ± 0.001 % w/w 12 months 0.027 ± 0.001 % w/w 18 months 0.028 ± 0.001 % w/w 24 months 0.027 ± 0.001 % w/w 36 months 0.027 ± 0.001 % w/w 48 months 0.028 ± 0.001 % w/w Weight variation (%) 6 months C: 0.00 % 12 months D: - 0.04 % 18 months E: - 0.03 % 24 months F: 0.05 % 36 months G: - 0.08 % 48 months H: - 0.08 % pH value (1% w/v dilution) 6 months 6.8		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
			12 months 6.7 18 months 6.8 24 months 6.8 36 months 6.8 48 months 6.7 Seepage data: No leakage, no ballooning, no panelling of the packaging, no deformations. From the results obtained it can be concluded that no significant change was found in the Piperonyl Butoxide, Transfluthrin and Cyfluthrin active ingredient content for the test item stored in Spray bottles for 48 months at ambient warehouse temperature, compared with the results obtained in the validation study (GLP Study CH – 234/2010), and the analyses after 6, 12, 18, 24, 36 and 48 months comply with the tolerance and therefore is in accordance with the declared value. No change in the sample physical state (appearance) colour, odour and weight variation was found for the test		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
			item stored in the Spray bottles for 48 months at ambient warehouse temperature, and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena of packaging. **Relevant impurities:** No data submitted for the determination of relevant impurities before and after storage in Special One formulation. No relevant impurities have been identified for Transfluthrin (March 2014 AR) and for Cyfluthrin (AR updated 2018). The following ten relevant impurities have been reported for PBO in June 2016 BPC Opinion, January 2017 Assessment Report and September 2019 final updated Assessment Report : Safrole: max. content <0.004% w/w		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
			Dihydrosafrole: max. content <0.0085% w/w Dipiperonyl methane: max. content 1.95% w/w Dipiperonyl ether: max. content 0.9%w/w Isosafrole: max. content <0.004% w/w Methyl dihydrosafrole: max. content 0.5%w/w Piperonyl Butoxide-x (Piperonyl Butoxide homologue): max. content 0.47 % w/w ortho-Piperonyl Butoxide (Piperonyl Butoxide homologue): max. content 0.51 % w/w N,N-dimethylformamide: max.content <0.04%w/w Dichloromethane: max. content <0.05% w/w No methods have been submitted in the CAR for the determination of any of the proposed relevant impurities in the formulation. The WG members concluded that since the relevant impurities (except methyl dihydrosafrole) are not formed during storage, the methods for		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
			monitoring the relevant impurities in the biocidal product are not required under the BPR. Regarding methyl dihydrosafrole based on WG III (May 2016), it was decided that a justification or storage stability data must be submitted to prove that relevant impurity methyl dihydrosafrole is not formed during storage in the formulation (final AR September 2019). 		
Storage stability test – **long term storage at ambient temperature** 5 years storage at room temperature	Spray pattern FEA 644 Dicharge rate FEA 643 Internal pressure FEA 604 Water bath testing	Content of the AS used for the formulation of the BP (technical content)	Additional data (detailed in Annex 10 of IUCLID endpoint 3.4.1) Quality control data at manufacturing plants, recorded since production many years ago and submitted as additional data.	QC data on phys chem endpoints during storage; Annex 10, Pozzo d'Adda 2014-2019 GLP compliance: No	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
Spray version: Spray Performance for SPECIAL ONE & VESPA ONE	FEA 606 Clogging FAO note 11 Weight loss of cans No standard method (Internal SOP 222)	Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w Batches:188TSBE, 167TSBE	Four CoAs of analysis of two batches were checked after 5 years storage at room temperature are available (2014-2019) Product used against flying insects (named as *"Special one Insetticida"*, 600 ml, 188TSBE) - spray pattern: 8.1 cm and after 5 years 7.9 cm - Discharge rate: 1.4 g/s and after 5 years storage 1.6 g/s - Water bath testing before and after 5 years storage: conform - Clogging before and after 5 years storage: conform - Weight loss of can after 5 s: 7.2 g and after 5 years storage 7.6 g (conformed) Product used against wasp nests (named in Annex 10 as "*Special one VESPA*", 750ml, 167TSBE) - spray pattern: 20.8 cm and after 5 years 19.8 cm - Discharge rate: 15.4 g/s and after 5 years storage 15.2 g/s - Water bath testing before and after 5 years storage: conform	Data reported on CoAs	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
			- Clogging before and after 5 years storage: conform - Weight loss of can after 5 s: 78 g and after 5 years storage 77 g (conformed) **Conclusion:** • The data reported in CoAs show that the products doesn't chage in spray rate, spray pattern and internal pressure after 5 years from production. Considering that the composition is the same as presented in the Confidential Section and also that the 2 jet valves are the same used in the 2 years storage study reported below, this information could be taken into account.		
Storage stability test – **long term storage at ambient temperature** 2 years storage at room temperature **Spray version:**	Spray rate FEA-643 Spray pattern FEA-644	Content of the AS used for the formulation of the BP (technical content) Transfluthrin 0.114 % w/w;	Packaging: Storage stability tests were conducted with tinplate tin cans named as "*Vespa One".* Note: refer to section 2.1.7 Discharge rate (24/4/17 EXP.04/19) at 25 ± 0.5°C, N=5x10 sec - Discharge rate: 14.12 g/s and after 2 years storage 17.22 g/s Note:	VESPA_ONE__SPRAY_RATE_-_PATTERN-Annex_12, Armando Cristilli; Pozzo d'Adda 11/07/2019 GLP: No	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
Spray Performance for VESPA ONE		Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w Vespa One, Batch 114TSBH PROD.	Spray pattern (24/4/17 EXP.04/19) The following limits of acceptance are proposed by the applicant: Spray rate: 15 +/- 3,1 gr/sec -spray pattern: 18.8 cm and after 2 years 21.2 cm The following limits of acceptance are proposed by the applicant: Spray pattern: 20 +/- 4,3 cm		
Storage stability test – **long term storage at ambient temperature** 2 years storage at room temperature **Spray version: Spray Performance for SPECIAL ONE**	Spray rate FEA-643 Spray pattern FEA-644	Content of the AS used for the formulation of the BP (technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w	Packaging: Storage stability tests were conducted with tinplate tin cans named as "*Special One"*. Note: refer to section 2.1.7 above Discharge rate (24/4/17 EXP.04/19) at 25 ± 0.5°C, N=5x10 sec - Discharge rate: 1.48 g/s and after 2 years storage 1.56 g/s The following limits of acceptance are proposed by the applicant: Spray rate: 1.5 +/- 0.4 gr/sec	SPECIAL_ONE_SPRAY _RATE_-_PATTERN-Annex_11, Pozzo d'Adda 11/07/2019 Under Annex 11 GLP: No	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
		Special One, Batch LOT: 108TSBH PROD 18/4/17EXP18/ 4/1	Spray pattern(24/4/17 EXP.04/19) -spray pattern: 7.94 cm and after 2 years 7.9 cm The following limits of acceptance are proposed by the applicant: Spray pattern: 8 +/- 1,3 cm		
eCA remark: The results regarding the long-term storage stability study for 4 years at ambient temperature (CH 236/2010) are considered acceptable regarding the liquid form of the formulation. The required storage stability data for the spray version on Special One and Vespa One regarding their satisfactory operation in terms of spray rate and patterns were covered by 2- and 5-years storage tests at ambient temperature. Based on acceptable and comparable results (see also accelerated storage stability tests above), no furtheraction is required. Therefore, the proposed storage life at 4 years is considered acceptable.					
Storage stability test – **low temperature stability test for liquids**	-	-	Data on low temperature storage stability are not available. According to Guidance on BPR Volume I, Part A Chapter III version 1.1 Novembre 2014, in the label of the product there is steated that the product must not be stored under conditions of ≤0°C (e.g. protect from frost).	-	**Acceptable waiving**
eCA remark: *"The product must not be stored under conditions of ≤0°C"* should be added in the label					
SoC: stability of propellant	justification - calculation	-	In aerosols cans there is a directly relation between gas pressure and composition of gas mixture in the cans; this relation	PRESSURE AND COMPOSITION OF PROPELLANT GAS MIXTURES. Paolo	**Additional data**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
			demonstrates that if the pressure in cans doesn't change also with respect to time also the gas composition in the same cans are not changed. It was demonstrated that if the composition of gas mixture changes in the cans than also the pressure will change. In this way if the product has a pressure of 3.5 bar as starting pressure and it doesn't change during stability then also the composition of the product doesn't change during stability trials. For more information pleas refer on Confidential Annex.	Manella. September 2020.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	Data waiving, since the packaging characteristics (packaging materials are not transparent) protect the product from light; therefore, the effect of light does not need to be addressed.	-	**Acceptable waiving**
Effects on content of the active substance and technical characteristics of the biocidal	CIPAC MT 46 "Accellerated storage tests by heating".	Content of the AS used for the formulation of the BP	Temperature does not negatively affect the content of the active substance and technical characteristics of the biocidal product.	Special one: determination of the accelerated storage stability and corrosion characteristics. CH-	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
product – **temperature and humidity**	GLP compliance: yes	(technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w Batch number: T0024	No change in the sample appearance, colour or odour, was found for the test item stored in the 500 mL spray bottle for 8 weeks at 40°C and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena of packaging. Moreover, no significant change in physical properties (pH value and weight variation) was found for the sample stored for 8 weeks storage at 40°C, in respect to the initial characterisation. *Humidity* The product has been tested at 65% RH for 8 weeks. No changes in the samples have been recorded.	235/2010. May 2011. Tested on liquid phase after elimination of propellant. Accelarated stability study at 30°C for 18 weeks on the test item "SPECIAL ONE". Eurofins Biolab Srl. Final report 2018/122 AM, C. Belussi, March 25, 2019 & Amendment to final report 2018/122 AM. May 29, 2019 (under Annex 3,3b) Tested on liquid phase after elimination of propellant.	
Effects on content of the active substance and technical characteristics of the biocidal	CIPAC MT 46 "Accellerated storage tests by heating".	Content of the AS used for the formulation of the BP	No change in the sample appearance, colour or odour, was found for the test item stored in the 500 mL spray bottle for 8 weeks at 40°C and no variation was found in colour	Special one: determination of the accelerated storage stability and corrosion characteristics. CH-	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
product - **reactivity towards container material**		(technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w Batch number: T0024	or in either the internal or external configuration, or loss of sample or evident corrosion phenomena of packaging.	235/2010. May 2011. GLP compliance: yes	
Wettability	-	-	Data waiving since the data are required only for solid preparations which are to be dispersed in water.	-	**N/A**
Suspensibility, spontaneity and dispersion stability	-	-	Data waiving, since this assessment depends on the formulation type (nature) of the biocidal product. Suspensibility is determined to demonstrate that a sufficient amount of the active substance is suspended to give a homogeneous mixture during application: the biocidal product of interest is not a wettable powder, aqueous suspension concentrate, water dispersible granule, water dispersible powder or a formulations forming suspension on dilution with water.	-	**N/A**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
			The spontaneity of dispersion is determined to show that the preparation is rapidly dispersed when diluted with water; however, the biocidal product of interest is not a granular material or suspension concentrate.		
Wet sieve analysis and dry sieve test	-	-	Data waiving. Wet sieve test is applicable only to wettable powders, suspension concentrates, water dispersible granules, aqueous capsule suspensions, dispersible concentrates, suspo-emulsions, water soluble granules and water soluble powders; therefore, it is not applicable for this product. Dry sieve test is designed to determine the size distribution of dustable powders and granules for direct application to allow acceptable application; therefore this test is not applicable for this product.	-	**N/A**
Emulsifiability, re-emulsifiability and emulsion stability	-	-	Data waiving since it is a ready-to-use product.	-	**N/A**
Disintegration time	-	-	Data waiving since disintegration time is applicable only to products that are tablets	-	**N/A**

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Acceptability</th></tr>
<tr><td></td><td></td><td></td><td>(depend on disintegration of the tablet in a solvent).</td><td></td><td></td></tr>
<tr><td rowspan="2">Particle size distribution, content of dust/fines, attrition, friability</td><td rowspan="2">Test method MT 187 - Particle Size Analysis by laser diffraction reported on CIPAC Handbook K.</td><td rowspan="2">Content of the AS used for the formulation of the BP (technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w

Batch number FFA04004/B</td><td>Particle size distribution (MT 187):
According to test method CIPAC MT187, the Dv (50) is 49.17 µm.

<table>
<tr><th rowspan="2">PARAMETER</th><th colspan="2">SAMPLE</th></tr>
<tr><th>A</th><th>B</th></tr>
<tr><td>Dv(10), µm</td><td>17.13</td><td>17.99</td></tr>
<tr><td>Dv(50), µm</td><td>49.17</td><td>52.24</td></tr>
<tr><td>Dv(90), µm</td><td>126.10</td><td>135.18</td></tr>
<tr><td>D[4,3], µm</td><td>63.19</td><td>67.21</td></tr>
<tr><td>D[3,2], µm</td><td>29.84</td><td>31.53</td></tr>
<tr><td>%V<10µ, %</td><td>3.70</td><td>3.48</td></tr>
<tr><td>%V<5µ, %</td><td>1.14</td><td>1.06</td></tr>
<tr><td colspan="3">The average weight for single actuation is 1.101 g</td></tr>
</table>
</td><td>Determination of Particle Size on the Sample SPECIAL ONE. Innovhub - Stazioni Sperimentali per l'Industria. GLP Study No. 404 of 2018. Report No. 1802727. Issue date August 27th, 2018. Annex 4

GLP compliance: yes

Note:
The trial was conducted by spraying the product directly from original packaging and not on liquid after elimination of propellant</td><td>Acceptable</td></tr>
<tr><td>MMAD:
It is possible to correlate the median particle size reported by laser diffraction with that reported by aerodynamic techniques if the true particle density is known.</td><td></td><td>Acceptable</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
			The product Special One is a water emulsion oil in water, in this kind of emulsion the emulsifiers produce a layer around a spherical droplets of oil phase. It is possible to consider all the droplets in the emulsion as spherical and the density of this emulsion is 0,997±0,10% (study 2018/122 AM Eurofin Spa). In this way we consider the density =1 and shape factor =1 Then if Dv50 of Special one is 49,17µm MMAD = 49,17 µm (1/1)^0,5= 49,17µm. Aplicant's statement: *"MMAD is deteminated before storage.* *Data on internal pressure from Storage stability test – long term storage at ambient temperature 5 years storage at room temperature Annex 10 show no change in internal pressure after stability consequently the MMAD doesn't change".*		

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
Applicant's Remark: *"There are only two types of sprayer:* *Vespa One long jet spray and special One "normal" spray.* *In each aerosol packaging reported as "spray cans of aerosol" there are 3 different component:* *1)Tinplate cans that it is the container in steel,* *2) the valve that is the part between the product and the out of cans, it is connect by tube the internal part of cans with actuator.* *3) the actuator that it is the place where the product goes out.* • *Tinplate cans are the same for both Vespa One long jet spray and special One "normal" spray.* • *Vespa One valve is described in annex 24* • *Vespa One actuator is described in annex 22* • *Special one valve is described in annex 25* • *Special One has *three model usable as actuator ant its described by annex 23A,23B,23C."* *Justificationfor waiving data:* *"The trials for MMAD were done for Special One formulation using model* [redacted] *described in annex 23C.* ***The three model of actuator in Special One are used with the same valve and are used only with a hole of 0,8mm diameter; in this way even if change the actuator the spray and consequently the MMAD will be the same.*** *In addition, Special One is considered the worst case aerosol in comparison to Vespa One for MMAD testing, as the Special One with normal spray is closer to the operator than the Vespa One with the long jet valve spray"* **eCA Remark**: Acceptable MMAD results provided using the Special One aerosol with Valve: [redacted] Based on applicant's justification no changes expected on the MMAD using the other two actuators for Special One In addition, a waiving justification for the MMAD test on Vespa One is available condidering Special One as the wort case scenario. **No further action is required.**					
Persistent foaming	-	-	Data waiving, since the product is ready to use and it is not applied in water for use.	-	**N/A**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
Flowability/Pourability/Dustability	-	-	Data waiving since the biocidal product is not in form of granular material or suspension concentrates, capsule suspensions and suspo-emulsions.	-	**N/A**
Burning rate — smoke generators	-	-	Data waiving since the preparation is not applied as a smoke.	-	**N/A**
Burning completeness — smoke generators	-	-	Data waiving since the preparation is not applied as a smoke.	-	**N/A**
Composition of smoke — smoke generators	-	-	Data waiving since the preparation is not applied as a smoke.	-	**N/A**
Spraying pattern — aerosols **SPECIAL ONE**	Not specified.	Content of the AS used for the formulation of the BP (technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w Special One spray (LOT:	*Special One spray* 1) The average of spray pattern = 7.895 cm 2) Standard deviation (0.645) and minimum (7) and maximun (9) values The limit of acceptance of spray patter should be 7.9 +/- 1 gr/sec Applicant's statement: *"Considering also that this method is affect by* *- error due to operator (distance, time, measure, handling..)* *- difference of the pressure of propellant (minimum and*	Special One spray (LOT: 108TSBH PROD.18/4/17EXP18/4/19) SPRAY PATTERN (FEA-644). Tosvar srl. 19/07/2019. Annex 11 GLP compliance: no	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
		108TSBH PROD.18/4/17 EXP18/4/19)	*maximum of acceptance range) We purpose to set the following limits of acceptance: Spray pattern: 8 +/- 1.3 cm"*		
Spraying pattern — aerosols **VESPA ONE**	Not specified. GLP compliance: no	Product with a special dispenser used only for wasp Content of the AS used for the formulation of the BP (technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w 114TSBH PROD.24/4/17 EXP.04/19	*Vespa One/Zanza spray vespe* 1) The average of spray pattern = 19.95 cm 2) Standard deviation (2.892) and minimum (16) and maximun (24) values The limit of acceptance of spray patter should be 20 +/- 4cm Applicant's statement: "Considering also that this method is affect by - error due to operator (distance, time, measure, handling.) - difference of the pressure of propellant (minimum and maximum of acceptance range) We purpose to set the following limits of acceptance: Spray pattern: 20 +/- 4.3 cm."	Vespa One/Zanza spray vespe (114TSBH PROD.24/4/17 EXP.04/19) SPRAY PATTERN (FEA-644). Tosvar srl. 19/07/2019. Annex 12 GLP compliance: no	**Acceptable**
Spraying pattern — aerosols SPECIAL ONE	FEA 644 Filled aerosols packs - Evaluation of aerosol spray patterns.	Content of the AS used for the formulation of the BP	Spray pattern: round shape. Note: No further data available.	Determination of Spray Pattern on the test item SPECIAL ONE. Eurofins Biolab S.r.l. 2018/122 AM. 2018-09-21.	**Additional data**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
	GLP compliance: yes	(technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w Batch number: FFA04004/B Container: 1 L aerosol cans		This study is reported in Addendum 2 of the study "ACCELERATED STABILITY STUDY AT 30°C FOR 18 WEEKS ON THE TEST ITEM "SPECIAL ONE". Annex 3b	
Physical compatibility	-	-	Not required. The product is not intended to be used with other products (including other biocidal products).	-	**N/A**
Chemical compatibility	-	-	Data waiving. Data to address the physical and chemical compatibility must not be provided since the biocidal product can not co-apply with other substances, mixtures or biocidal or non-biocidal products. Moreover, no possible incompatibility with any products is know.	-	**N/A**
Degree of dissolution and dilution stability	-	-	Data waiving. The product is not used in a water soluble bag or tablets. The dilution stability is	-	**N/A**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
			not determined since the product is not a water-soluble preparations.		
Surface tension	- Method A.5 - Surface Tension of Council Regulation (EC) No. 440/2008, Published in O.J. L 142, 2008; - OECD 115 - Surface Tension of Aqueous Solutions. (using ring method)	Content of the AS used for the formulation of the BP (technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w Batch number FFA04004/B *The test solution provided by the Sponsor has been obtained after degassing of the originai aerosol can.	According to test method A.5, the surface tension of the undiluted sample labelled as SPECIAL ONE is 23.5 mN/m, at 20°C.	Determination of Surface Tension on the Sample SPECIAL ONE. Innovhub - Stazioni Sperimentali per l'Industria. Report n. 1802728. 2018-07-05. (available under Annex 5) GLP compliance: yes Tested on liquid phase after elimination of propellant.	**Acceptable**
Viscosity	OECD 114 - Viscosity at 20°C and 40°C.	Content of the AS used for the	Based on Rheometer analysis performed applying a shear rate from 200 [1/s] to 1200 [1/s] the	Viscosity determination of the test item "SPECIAL	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
		formulation of the BP (technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w Batch number: FFA04004/B	test item showed a Newtonian-like behaviour. The viscosity mean proved to be 1.2 mPa*s at 20°C and 0.8 mPa*s at 40°C. ~~Study n°STULV18AA0473 show for Special One a Newtonian-like behavior.~~ ~~Form Study n°STULV18AA0473 Dynamic viscosity of 1,2mPa*s at 20°C and 0,8mPa*s at 40°C~~ ~~Kinematic viscosity = Dynamic viscosity / Density~~ ~~Kinematic viscosity = 1,2mPa*s/0,9 g/cm^3= 1,33 mm^2/s at 20°C~~ ~~Kinematic viscosity = 0,8mPa*s/0,9 g/cm^3= 0,88 mm^2/s at 40°C~~ As general comment using 0.9 instead of 0.997 does not affect the outcome for HH. New calculations below reported for consistency: Based on Rheometer analysis performed applying a shear rate from 200 [1s] to 1200 [1s] the	ONE". Eurofins Biolab S.r.l. Study Plan N° STULV18AA0473-1 GLP. 2018-12-10, (under Annex 4) GLP compliance: yes Tested on liquid phase after elimination of propellant.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
			test item showed a Newtonian-like behavior. The viscosity mean proved to be 1.2 mPa*s at 20°C and 0.8 mPa*s at 40°C. Study n°STULV18AA0473 show for Special One a Newtonian-like behavior. Form Study n°STULV18AA0473 Dynamic viscosity of 1,2mPa*s at 20°C and 0,8mPa*s at 40°C Kinematic viscosity = Dynamic viscosity / Density Kinematic viscosity = 1,2mPa*s/0,997 g/cm3= 1,20 mm2/s at 20°C Kinematic viscosity = 0,8mPa*s/0,997 g/cm3= 0,80 mm2/s at 40°C		

Conclusion on the physical, chemical and technical properties of the product
SPECIAL ONE is a ready-to-use spray insecticides with a characteristic odour, containing nominal (pure) active ingredient of Trasfluthrin at 0.11 % w/, BPO at 0.2% w/w and Cyfluthrin at 0.025 % w/w. The pH of the 1 % v/v dilution of the test item in water, from a spray bottle, was 7.30 at 20°C. The surface tension of the product without propellant is 23.5 mN/m at 20°C and the viscosity dynamic viscosity showed a Newtonian-like behaviour. 55% of the aerosol has a particle size of 49.17 µm. From the results obtained by long term storage stability test for 48 months at ambient warehouse temperature, no significant change was found in the Piperonyl Butoxide, Transfluthrin and Cyfluthrin active ingredient content for the test item stored in

Spray bottles (tin plate can), compared with the results obtained in the validation study (GLP Study CH – 234/2010). The analyses after 6, 12, 18, 24, 36 and 48 months comply with the tolerance and therefore is in accordance with the declared value. No change in the sample physical state (appearance) colour, odour and weight variation was found for the test item stored in the Spray bottles for 48 months at ambient warehouse temperature, and no variation was found in colour or in either the internal or external configuration, or loss of sample or evident corrosion phenomena of packaging.

All the spray patterns appear to be homogeneous. The discharge rate of the spray is 14. 2 g/s for "Vespa One" and 1.48 g/s for "Special One" at the start of the product use.

Storage stability test at 40°C for 8 weeks does not negatively affect the content of the active substance and some technical characteristics of the biocidal product. The satisfactory operation of the aerosol was tested after storage of tinplate can at 45°C for 6 weeks. Storage stability data are also available after storage for 2 and 5 years at ambient temperature and after storage at 30°C for 18 weeks and considered accepted.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
Explosives	Regulation EC n. 440/2008 – Method EC A.14 Explosive Properties Analysis	Content of the AS used for the formulation of the BP (technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w	The following two tests have been performed. *TEST A.14, BAM FALLHAMMER* Test Procedure The sample was placed in the impact device and the 10 kg weight dropped from a height of 40 cm which is equivalent to 40 J. If an "explosion" was observed, the impact energy was reduced to 7.5 J and further tests conducted. Test results	Liquid Flammability testing on sample of filling solution 1 (SpecialOne). Dekra-Chilworth Technology Ltd. Report n. GLP3016003918AR1V1/2018. 2018-09-17.	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
		Test Item Name: Filling Solution 1 (SpecialOne) Code: 184.004 Batch/ Lot Number: no1 Description: White liquid Expiry date: 05/06/2019 (One year from receipt of sample)	The sample of Filling Solution 1 (SpecialOne) was observed to exhibit no reaction at 40 J. The test result is therefore considered Negative (-) (according to the EC Classification, Packaging & Labelling of Dangerous Substances in the European Union Part 2, Testing Methods, Jan 97). *TEST A.14, KOENEN TUBE* The sample did not exhibit an explosion during any of the tests. The test result is therefore considered Negative.	(under Annex 7) GLP:yes	
	-	Theoretical Estimation	Theoretiical estimation: *"Following the Annex I, Part 2 paragraphs .2.1.4.3. of consolidated version of the Regulation (EC) No 1272/2008: A substance or mixture shall not be classified as explosive if: (a) There are no chemical groups associated with explosive pr kzoperties present in the molecule. Examples of groups which may indicate explosive properties are given in Table A6.1 in Appendix 6 of the ►M4 UN RTDG ◄, Manual of Tests and Criteria:* *- C-C unsaturation (Acetylenes, acetylides, 1,2-dienes)* *- C-Metal, N-Metal (e.g. Grignard reagents, organo-lithium compounds);* *- Contiguous nitrogen atoms (e.g. azides, aliphatic azo*	-	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
			compounds, diazonium salts, hydrazines, sulphonylhydrazides); *- Contiguous oxygenatoms (e.g. peroxides, ozonides);* *- N-O (e.g. hydroxyl amines, nitrates, nitro compounds, nitroso compounds, N-oxides, 1,2-oxazoles);* *- N-halogen (e.g. chloramines, fluoroamines);* *- O-halogen (e.g. chlorates, perchlorates, iodosyl compounds).* *According to the CLP there aren't inorganic substances in the formulation and all the substances inside the product doesn't present groups which may indicate explosive properties."*		
eCA remark: Based on the above theoretical estimation and the given results for A14 test we consider that no CLP classifications are expected for explosive property and no further consideration is required					
Flammable gases	-	-	Aerosols do not fall additionally within the scope of Sections 2.2 (flammable gases), 2.5 (gases under pressure), 2.6 (flammable liquids) and 2.7 (flammable solids).	-	**N/A**
Flammable aerosols	According to UN Manual of Tests and Criteria: Part III, section 31.4,	Content of the AS used for the formulation of the BP (technical content)	The product is a spray aerosol. According to Annex I of CLP Regulation, results of ignition distance test can be used to establish the classification of the product as flammable aerosol in	Determination of the ignition distance of the aerosol product called SPECIAL ONE. Innovhub -	**Acceptable** Classified for both jet valves with hazard statements: Extremely

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
	Ignition distance test for spray aerosol.	Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w	category 1 or 2. In SPECIAL ONE two different dispensing nozzle can be use, indeed when the product is used to control wasps nest the spray rate of the product is higher than the spray rate used to control mosquito: this is possible by using two different dispensing nozzle. Experimental results of tests conducted at room conditions (temperature: 21°C; relative humidity: 64%) at the distances established by the method starting from 15 cm for Special One and 60 cm for Vespa One. Regarding the second valve it is noted that results refer to the canister used with a white valve, but without a 15 cm long white thin cane. As a results two ignition distance are relevant for this product. • Ignition distance when product is used against mosquitoes (called SPECIAL ONE) is >15 cm. • Ignition distance when product (called VESPA ONE) is used against wasp nest is ≥ 75 cm.	Stazioni sperimentali per l'industria. 22 September 2014. And Determination of the ignition distance of the aerosol product called VESPA ONE. Innovhub - Stazioni sperimentali per l'industria. 22 September 2014. (Under Annex 8b, 9b , 9c, 13) GLP:No data available	Flammable Aerosol, H222; and Pressurised container: May burst if heated, H229; pictogram GHS02 is also assigned

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
			Overall, since the product is one, despite two dispensing nozzle can be use, the proposed classification is as Flammable Aerosol of Category 1. Additional data for information purposes: Flash point of active substances taken from CARs: - Transfluthrin Flash point = 119.0ºC under atmospheric conditions (1013.3 hPa) - not flammable. - PBO Flash point: 179.25 °C => Piperonyl Butoxide not flammable. - Cyfluthrin: flash point not reported in the CAR - substance not flammable. Further information regarding Flash points of the other components including in the aerosol is available in Annex 13.		
eCA remark: No data reported regarding the % of flammable components in Special One formulation and heat of combustion (kJ/g) measurements. Therefore, EL considers acceptable the applicant's proposal to classify the aerosol Extremely Flammable as worst-case scenario.					
Oxidising gases	-	-	Data waiving:The mixture is not a gas but an aerosol, furthermore all the gas content in the can are Hight flammable. The spray aerosol product is not classified in the class of Oxidizing gases	-	**N/A**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
Gases under pressure	-	-	Aerosols do not fall additionally within the scope of Sections 2.2 (flammable gases), 2.5 (gases under pressure), 2.6 (flammable liquids) and 2.7 (flammable solids).	-	**N/A**
Flammable liquids	-	-	Aerosols do not fall additionally within the scope of Sections 2.2 (flammable gases), 2.5 (gases under pressure), 2.6 (flammable liquids) and 2.7 (flammable solids).	-	**N/A**
Flammable solids	-	-	Aerosols do not fall additionally within the scope of Sections 2.2 (flammable gases), 2.5 (gases under pressure), 2.6 (flammable liquids) and 2.7 (flammable solids).	-	**N/A**
Self-reactive substances and mixtures	-	-	Data waiving based on the absence of chemical groups associated with explosive or self-reactive properties in the molecules contained in the product (examples of such groups are given in Tables A6.1 and A6.2 in the UN RTDG, Manual of Tests and Criteria, Appendix 6).	**-**	**N/A**
Pyrophoric liquids	-	-	Data waiving since the experience in manufacture or handling shows that the substance or mixture does not ignite spontaneously on coming into contact with air at normal temperatures (i.e. the substance is known to be stable at room temperature for prolonged periods of time (days)).	-	**N/A**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
Pyrophoric solids	-	-	Not applicable since the product is liquid.	-	**N/A**
Self-heating substances and mixtures	-	-	According to Guidance on Application of CLP criteria (v.5.0, July 2017), in general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids. Therefore liquids are not classified as self-heating.	-	**N/A**
Substances and mixtures which in contact with water emit flammable gases	-	-	Data waiving, since in the biocidal product all constituents molecules do not contain metals or metalloids; moreover, the product does not react with water.	-	**N/A**
Oxidising liquids	-	-	Data waiving:The final form of product is aerosol and not liquid. The liquid part content is sealed cans contains organic substances with oxygen, fluorine or chlorine bonded only with oxygen or halogen atoms. The only inorganic substance is the water. For this kind of substances, the classification procedure for this class shall not apply according with point 2.13.4.1. annex I CLP. The spray aerosol product is not classified in the class of Oxidizing liquids.	-	**N/A**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
Oxidising solids	-	-	Not applicable since the product is aerosol	-	**N/A**
Organic peroxides	-	-	Data waiving. Organic peroxides means liquid or solid organic substances which contain the bivalent -O-O- structure and may be considered derivatives of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term organic peroxide includes organic peroxide mixtures (formulations) containing at least one organic peroxide. The product does not contain organic peroxides.	-	**N/A**
Corrosive to metals	UN Test C.1 as described in Section 37.4 of the UN-MTC.	Content of the AS used for the formulation of the BP (technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w	The percentage mass losses on steel and aluminium were found to be < 13.5 % over 7 days and the maximum pit depth on the aluminium and steel coupons was < 120 µm. The sample is therefore exempt from classification as a corrosive substance of UN Class 8, Packing group III (according to the UN Transport of Dangerous Goods Recommendations	Testing on a Sample of Filllng solution 1 (Special one). Paolo Manella Report No: S3016006621R 1/2019. (under Annex 26)	**Acceptable**
Auto-ignition temperatures of products (liquids and gases)	EC A.15 Auto Ignition	Content of the AS used for the formulation of the BP	The autoignition temperature of Filling Solution 1 (SpecialOne) has been determined to be 464°C.	Liquid Flammability testing on sample of	**Acceptable**

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Acceptability
	Temperature Test	(technical content) Transfluthrin 0.114 % w/w; Piperonyl butoxide 0.213 % w/w; Cyfluthrin 0.026 % w/w Test Item Name: Filling Solution 1 (SpecialOne) Code: 184.004 Batch/ Lot Number: no1 Description: White liquid Expiry date: 05/06/2019 (One year from receipt of sample)		filling solution 1 (SpecialOne). Dekra-Chilworth Technology Ltd. Report n. GLP3016003918AR1V1/2018. 2018-09-17.	
Relative self-ignition temperature for solids	-	-	Not applicable since the product is liquid.	-	**N/A**
Dust explosion hazard	-	-	Not applicable since the product is liquid.	-	**N/A**

Conclusion on the physical hazards and respective characteristics of the product

SPECIAL ONE is classified as Aerosol 1; H222, H229 as proposed by the applicant (see below) and accepted as worst-case scenario. SPECIAL ONE is not expected to exhibit any other hazardous physico-chemical properties.

2.2.4 Methods for detection and identification

General remarks: the applicant states that the final concentrations of each biocidal component as expelled during aerosol's application is the one declared in the label of the product.

	Analytical methods for the analysis of the product as such including the active substance, impurities and residues						
Analyte	**Analytical method**	**Linearity**	**Specificity**	**Precision**	**Recovery rate (%)**		**Reference**
					Fortification range / Number of measurements	Mean	
Piperonyl butoxide	HPLC-UV/Vis (1)	five working standard solutions were prepared and each solution was injected four times. The obtained peak areas were used to determine the mean value, the standard deviation (S.D.) and the relative standard deviation (RSD%) of the analytical method at each level. These results showed that the analytical	A comparison between the chromatograms (see Figures from 1 to 11 of the final report CH-234/2010) of the solvent wash, acetone/acetonitrile 1/40, Dipropyl phthalate internal standard, Piperonyl butoxide, Transfluthrin and Cyfluthrin reference materials, Placebo, test item solution, Piperonyl butoxide, Transfluthrin and Cyfluthrin Technical Test Substances) shows that, following the operating conditions recommended in the analytical method,	N=6 2.95% Horwitz 3.42	Fortification at three levels, corresponding to 80, 100 and 120 % of the nominal concentration for each active ingredient. Since all recovery values for Piperonyl butoxide and Transfluthrin were in range 95 to 105 %, and for Cyfluthrin were in range 90 to 110 %, these criteria were fulfilled and therefore accuracy of the analytical method can be considered acceptable.	N=2 98.1% for 80%; N=2 104.4 % for 100%; N=2 100.5 % for 120%; N=6 overall mean 101.0%	Special one: Validation of the Analytical Method for the Determination of the Active Ingredients Content. CH – 234/2010. November 2010.
Transfluthrin	HPLC-UV/Vis (1)			N=6 0.16% Horwitz 3.74		N=2 95.2% for 80%; N=2 104.5 % for 100%; N=2 101.2 % for 120%; N=6 overall mean 100.3%	
Cyfluthrin	HPLC-UV/Vis (1)			N=6 RSD 0.39% Horwitz 4.59		N=2 95.7% for 80%; N=2 103.1 % for 100%; N=2 99.9 % for 120%; N=6 overall mean 99.6 %.	

		method is linear over the range tested for all three active ingredients (correlation coefficient > 0.99).	the three active ingredients and internal standard peaks are well separated and there is no evidence of interference with the Placebo peaks. Therefore, by using the conditions stated in the method, interferences can be avoided and the three active ingredients can be reliably determined in Special one formulation samples.				

Principle of the method
The determination of the active ingredient (a.i.) is performed by HPLC using an internal standard and the UV detector. The quantification of Piperonyl butoxide, Transfluthrin and Cyfluthrin is achieved by comparing the ratio of three reference material peak areas versus Dipropyl phthalate internal standard peak area and the same ratio determined for a sample containing a known amount of internal standard.

Chromatographic conditions
HPLC Column: Internal code No. 180; Supelco or equivalent: Ascentis Phenyl 5µm 250 x 4.6 mm
Detector: UV/Vis operating at 270 nm from 0 to 17 minutes
UV/Vis operating at 240 nm from 17 to 22.5 minutes
UV/Vis operating at 270 nm from 22.5 to 40 minutes
Column temperature: room temperature
Eluent B water
Eluent C acetonitrile
Eluent D phosphoric acid 1% v/v

Gradient B:C:D 30:60:10 v/v/v to B:C:D 0:90:10 v/v/v in 20 minutes
B:C:D 0:90:10 v/v/v from 20 to 35 minutes
to B:C:D 30:60:10 v/v/v from 35 to 37 minutes
B:C:D 30:60:10 v/v/v from 37 to 40 minutes

Eluent flow: 1.0 mL/min
Volume of injection: 10 µL
R.T. Dipropyl phthalate: 9.6 minutes
R.T. Piperonyl butoxide: 12.3 minutes
R.T. Transfluthrin: 16.1 minutes
R.T. Cyfluthrin: 18.6 minutes
Total Analysis Time: 40 minutes

Preparation of the stock mix standard solution
Using the analytical balance, 91.7 mg of Piperonyl butoxide reference material, 63.1 mg of Transfluthrin reference material and 12.4 mg of Cyfluthrin reference material were weighed into a 25.00 mL volumetric flask and then dissolved to volume with acetone. Taking into account their reference material relevant purities, 99.3 % for Piperonyl butoxide, 99.9 % for Transfluthrin and 99.8 % for Cyfluthrin, a 3642.3 µg/mL, a 2521.5 µg/mL and a 495.0 µg/mL stock standard solutions were respectively obtained.

Preparation of the diluted mix standard solution
Using a volumetric pipette, a 728.46 µg/mL for Piperonyl butoxide, a 504.30 µg/mL for Transfluthrin and a 99.00 µg/mL for Cyfluthrin diluted mix standard solution was prepared, transferring 10.00 mL from the stock standard solution into a 50.00 mL volumetric flask and then dissolving to volume with acetone.

Preparation of the stock and diluted internal standard solutions
Using the analytical balance, a 2096.0 µg/mL stock internal standard solution was prepared by weighing 52.4 mg of Dipropyl phthalate internal standard into a 25.00 mL volumetric flask, and dissolving to volume with acetone.
Using a volumetric pipette, a 419.20 µg/mL diluted internal standard solution was prepared, transferring 10.00 mL from the stock internal standard solution into a 50.00 mL volumetric flask and then dissolving to volume with acetone.

Preparation of the working standard solutions
Using volumetric flasks, volumetric pipettes, five working standard solutions for linear calibration were prepared as follows:
WSS 1. 3.00 mL of the diluted mix standard solution and 5.00 mL of the diluted internal standard solution were transferred into a 20 mL volumetric flask, making to volume with acetone (working standard solution at 109.27 µg/mL for Piperonyl butoxide, 75.64 µg/mL for
Transfluthrin, 14.85 µg/mL for Cyfluthrin and 104.80 µg/mL for internal standard).

WSS 2. 4.00 mL of the diluted mix standard solution and 5.00 mL of the diluted internal standard solution were transferred into a 20 mL volumetric flask, making to volume with acetone (working standard solution at 145.69 µg/mL for Piperonyl butoxide, 100.86 µg/mL for
Transfluthrin, 19.80 µg/mL for Cyfluthrin and 104.80 µg/mL for internal standard).
WSS 3. 5.00 mL of the diluted mix standard solution and 5.00 mL of the diluted internal standard solution were transferred into a 20 mL volumetric flask, making to volume with acetone (working standard solution at 182.12 µg/mL for Piperonyl butoxide, 126.07 µg/mL for Transfluthrin, 24.75 µg/mL for Cyfluthrin and 104.80 µg/mL for internal standard).
WSS 4. 6.00 mL of the diluted mix standard solution and 5.00 mL of the diluted internal standard solution were transferred into a 20 mL volumetric flask, making to volume with acetone (working standard solution at 218.54 µg/mL for Piperonyl butoxide, 151.29 µg/mL for Transfluthrin, 29.70 µg/mL for Cyfluthrin and 104.80 µg/mL for internal standard).
WSS 5. 7.00 mL of the diluted mix standard solution and 5.00 mL of the diluted internal standard solution were transferred into a 20 mL volumetric flask, making to volume with acetone (working standard solution at 254.96 µg/mL for Piperonyl butoxide, 176.50 µg/mL for Transfluthrin, 34.65 µg/mL for Cyfluthrin and 104.80 µg/mL for internal standard).

Linearity
The linearity test was performed with solutions from 109.27 to 254.96 µg/mL for Piperonyl butoxide, from 75.64 to 176.50 µg/mL
(about ± 40 % of the solution concentration used) for the quantification analysis for Transfluthrin (about ± 40 % of the solution concentration used) and from 14.85 to 34.65 µg/mL (about ± 40 % of the solution concentration used) for Cyfluthrin. From the lowest to the highest concentration, four series of injections were performed and a solvent wash was injected after each highest standard concentration solution, in order to verify if memory peaks were detected.
Means and standard deviations for each level were calculated using the data from the four replicate injections.

Linearity test on Piperonyl butoxide reference material
y = 52698x + 2039324
R2 = 0.99373

Linearity test. Ratio of Piperonyl butoxide reference material with internal standard
y = 0.5007x + 0.1886
R2 = 0.99611

Linearity test on Transfluthrin reference material
y = 38550x + 1702571
R2 = 0.98448

Linearity test. Ratio of Transfluthrin reference material with internal standard
y = 0.3658x + 0.1560
R2 = 0.99318

Linearity test on Cyfluthrin reference material
y = 208470x + 1032394
R2 = 0.99384

Linearity test. Ratio of Cyfluthrin reference material with internal standard
y = 1.9802x + 0.0947
R2 = 0.99625

Note: Linearity curves with internal standard have been used for quantification.

Precision
Test was performed by six determinations of the test item (labelled from A to F).

PBO
The relative standard deviation was 2.95% for Piperonyl butoxide and the Horwitz RSDr was 3.42 at a Piperonyl butoxide concentration of 0.20 % w/w. Since the relative standard deviation was lower than the Horwitz RSDr, the repeatability test for this active ingredient was acceptable.
The value of 0.01 % w/w for the precision of the analytical method for Piperonyl butoxide calculated as twice the standard deviation, can be considered acceptable for this test item with a declared nominal purity of 0.20 % w/w.
Data and results were used to determine the following precision: Piperonyl butoxide : 0.20 ± 0.01 % w/w.

Transfluthrin

The relative standard deviation was 0.16% for Transfluthrin and the Horwitz RSDr was 3.74 at a Transfluthrin concentration of 0.11 % w/w. Since the relative standard deviation was lower than the Horwitz RSDr, the repeatability test for this active ingredient was acceptable.
The value of 0.01 % w/w for the precision of the analytical method for Transfluthrin, can be considered acceptable for this test item with a declared nominal purity of 0.11 % w/w. Data and results were used to determine the following precision: Transfluthrin : 0.11 ± 0.01 % w/w.

Cyfluthrin
The relative standard deviation was 0.39% for Cyfluthrin and the Horwitz RSDr was 4.59 at a Cyfluthrin concentration of 0.028 % w/w. Since the relative standard deviation was lower than the Horwitz RSDr, the repeatability test for this active ingredient was acceptable.
The value of 0.001 % w/w for the precision of the analytical method for Cyfluthrin, can be considered acceptable for this test item with a declared nominal purity of 0.025 % w/w. Data and results were used to determine the following precision: Cyfluthrin : 0.028 ± 0.001 % w/w

Accuracy
The test was performed by spiking the Placebo with aliquots of the stock mix fortification solution at three levels in duplicate, corresponding to additions of 80, 100 and 120 % of the nominal concentration for all three active ingredients.

Preparation of the stock mix fortification solution
Using the analytical balance, 205.3 mg of Piperonyl butoxide Technical Test Substance, 128.8 mg of Transfluthrin Technical Test Substance and 23.8 mg of Cyfluthrin Technical Test Substance were weighed into a 25.00 mL volumetric flask and then dissolved to volume with acetone.
Considering their relevant purities, 95.2 % for Piperonyl butoxide, 99.1 % for Transfluthrin and 95.9 % for Cyfluthrin, a stock mix fortification solution containing respectively 7817.8 µg/mL, 5105.6 µg/mL and 912.9 µg/mL was obtained.

Preparation of the stock internal standard solution
Using the analytical balance, a 10152 µg/mL stock internal standard solution was prepared by weighing 253.8 mg of Dipropyl phthalate internal standard into a 25.00 mL volumetric flask, and dissolving to volume with acetone.

Fortified sample preparation and analysis
Using the technical balance, six 12.35 g aliquots of the Placebo were weighed in six 50 mL conical flasks, adding to each flask a 2.00 mL aliquot of the stock internal standard solution.
To obtain test item fortification at three levels, corresponding to 80, 100 and 120 % of the nominal concentration for each active ingredient, 4.00 mL, 5.00 mL and 6.00 mL aliquots of the stock mix fortification solution were added using volumetric pipettes.

The spiked samples were analysed as described for the test item in Internal Analytical Method No. 234/2010

PBO
For the accuracy, the SANCO/3030/99 rev. 4 guideline requires mean recovery values: in the range 95 to 105 % for active ingredient content between 0.1 % and 1.0 % w/w. Since all recovery values for Piperonyl butoxide were in range 95 to 105 %, this criterion was fulfilled and therefore accuracy of the analytical method can be considered acceptable.

Transfluthrin
For the accuracy, the SANCO/3030/99 rev. 4 guideline requires mean recovery values: in the range 95 to 105 % for active ingredient content between 0.1 % and 1.0 % w/w. Since all recovery values for Transfluthrin were in range 95 to 105 %, this criterion was fulfilled and therefore accuracy of the analytical method can be considered acceptable.

Cyfluthrin
For the accuracy, the SANCO/3030/99 rev. 4 guideline requires mean recovery values: in the range 90 to 110 % for active ingredient content between 0.01 % and 0.1 % w/w. Since all recovery values for Cyfluthrin were in range 90 to 110 %, this criterion was fulfilled and therefore accuracy of the analytical method can be considered acceptable.

Statement on impurity of PBO - [redacted]

[redacted]

Quality criteria
Piperonyl butoxide

Specificity:	The analytical method results to be specific for Piperonyl butoxide active ingredient in Special one formulation samples.
Linearity:	from 109.27 to 254.96 µg/mL (about ± 40 % of the solution concentration used for the quantification analysis).
Precision:	Piperonyl butoxide : 0.20 ± 0.01 % w/w
Accuracy:	recovery in range 95 to 105 %

Transfluthrin

Specificity	The analytical method results to be specific for Transfluthrin active ingredient in Special one formulation samples.
Linearity:	from 75.64 to 176.50 µg/mL (about ± 40 % of the solution concentration used for the quantification analysis).
Precision:	Transfluthrin : 0.11 ± 0.01 % w/w
Accuracy:	recovery in range 95 to 105 %

Cyfluthrin

Specificity	The analytical method results to be specific for Cyfluthrin active ingredient in Special one formulation samples.
Linearity:	from 14.85 to 34.65 µg/mL (about ± 40 % of the solution concentration used for the quantification analysis).
Precision:	Cyfluthrin : 0.028 ± 0.001 % w/w
Accuracy:	recovery in range 90 to 110 %

Summary:
The HPLC -UV analytical method showed determines Piperonyl butoxide, Transfluthrin and Cyfluthrin active ingredients in the Special one spray formulation samples.

Piperonyl butoxide
The range tested for Piperonyl butoxide, from 109.27 to 254.96 µg/mL, was found to be linear (correlation coefficient > 0.99). The relative standard deviation was 2.95% for

Piperonyl butoxide and the Horwitz RSDr was 3.42 at a Piperonyl butoxide concentration of 0.20 % w/w. Since the relative standard deviation was lower than the Horwitz RSDr, the repeatability test for this active ingredient was acceptable. The value of 0.01 % w/w for the precision of the analytical method for Piperonyl butoxidecalculated as twice the standard deviation, can be considered acceptable for this test item with a declared nominal purity of 0.20 % w/w. Data and results were used to determine the following precision: Piperonyl butoxide : 0.20 ± 0.01 % w/w For the accuracy, the SANCO/3030/99 rev. 4 guideline requires mean recovery values: in the range 95 to 105 % for active ingredient content between 0.1 % and 1.0 % w/w.Since all recovery values for Piperonyl butoxide were in range 95 to 105 %, this criterion was fulfilled and therefore accuracy of the analytical method can be considered acceptable.

Transfluthrin
The range tested for Transfluthrin, from 75.64 to 176.50 µg/mL, was found to be linear (correlation coefficient > 0.99). The relative standard deviation was 0.16% for Transfluthrin and the Horwitz RSDr was 3.74 at a Transfluthrin concentration of 0.11 % w/w. Since the relative standard deviation was lower than the Horwitz RSDr, the repeatability test for this active ingredient was acceptable. The value of 0.01 % w/w for the precision of the analytical method for Transfluthrin, can be considered acceptable for this test item with a declared nominal purity of 0.11 % w/w. Data and results were used to determine the following precision: Transfluthrin : 0.11 ± 0.01 % w/w For the accuracy, the SANCO/3030/99 rev. 4 guideline requires mean recovery values: in the range 95 to 105 % for active ingredient content between 0.1 % and 1.0 % w/w Since all recovery values for Transfluthrin were in range 95 to 105 %, this criterion was fulfilled and therefore accuracy of the analytical method can be considered acceptable.

Cyfluthrin
The range tested for Cyfluthrin, from 14.85 to 34.65 µg/mL, was found to be linear (correlation coefficient > 0.99). The relative standard deviation was 0.39% for Cyfluthrin and the Horwitz RSDr was 4.59 at a Cyfluthrin concentration of 0.028 % w/w. Since the relative standard deviation was lower than the Horwitz RSDr, the repeatability test for this active ingredient was acceptable. The value of 0.001 % w/w for the precision of the analytical method for Cyfluthrin, can be considered acceptable for this test item with a declared nominal purity of 0.025 % w/w. Data and results were used to determine the following precision: Cyfluthrin : 0.028 ± 0.001 % w/w For the accuracy, the SANCO/3030/99 rev. 4 guideline requires mean recovery values: in the range 90 to 110 % for active ingredient content between 0.01 % and 0.1 % w/w Since all recovery values for Cyfluthrin were in range 90 to 110 %, this criterion was fulfilled and therefore accuracy of the analytical method can be considered acceptable.

Conclusion on the methods for detection and identification of the product
The HPLC-UV analytical method with reversed phase chromatography, was found to be valid in terms of linearity, precision, accuracy in accordance with ECHA guidance, for the determination of transfluthrin, cyfluthrin and Piperonyl Butoxide, in Special One aerosol formulation. In addition, applicant provided a scientific statement regarding the Quantification of pyrethroids single isomers (e.g Trasfluthrin) in formulations. [redacted]

Analytical methods for the determination of relevant impurities are not required since a waiver argumentation is considered acceptable (Refer above on accelerated storage). EL is of the opinion that no further data need to be submitted on the current product authorization. Any further issues regarding an available validated analytical method for the determination of the relevant impurity should be addressed at active substance level for the renewal. No analytical method for the determination of the identified substance of concern (propellant) has been submitted. A scientific explanation that the formation of SoC is not expected during storage and its concentration remains unchanged is available (please refer on the Confidential Annex).

Residues analysis

Information on resudues analysis has been taken from the CAR of the three active substances.

Transfluthrin

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

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

Air
A valid GC-MS method (PTRL Europe Study No. 911 G) is available for the analysis of the active substance in air. This method has an LOQ of 0.5 µg/m3. The method is considered highly specific as three mass fragments were monitored (target 163 m/z, confirmatory fragments 127 and 143 m/z).

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

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

Piperonyl butoxide

Soil

20 g of the soil sample were weighed into a 250 mL glass bottle. 10 mL water and 100 mL acetonitrile were added, the flask closed with a screw cap and shaken on a flatbed shaker for at least 6 hours. Thereafter, at least 10 g of sodium chloride were added and the flasks were shaken again for approx. 1 min to separate the phases. An aliquot of about 1 mL was transferred into a 2 mL single-use syringe fitted with a 0.45 µm Nylon filter and the extract was filtered into a HPLC vial (1.8 mL). The final extracts were diluted 1:10 with acetonitrile (100 µL final extract + 900 mL acetonitrile) and used for HPLC/MS-MS analysis.
Two ion transitions (SRM 356→177 for quantification and SRM 356→119 for confirmation) have been validated.
LOQ: 0.05 mg/kg

Water
Surface water samples were diluted with acetonitrile to contain 25% of acetonitrile (v/v) to ensure analyte solubility in the analytical sample. In the current study, 1 mL water sample was used and diluted with 250 µL acetonitrile. After shaking this analytical sample, an aliquot is transferred into an HPLC vial and used directly for analysis by HPLC-MS/MS.
Two ion transitions (SRM 356→177 for quantification and SRM 356→119 for confirmation) have been validated.
LOQ: 0.1 µg/L
Provided that the proposed method has been successfully validated for surface water at the LOQ required for drinking water (0.1µg/L), no further validation in drinking water is required.

Air

Sampling of Piperonyl Butoxide on the front filter of the adsorbent tube, consisting of two units (front and back-up bed) filled with Tenax as adsorbent material. Sampling of air under constant flow. The humidity was > 80% in average and the temperature was 35 ± 2 °C. The sampling time was 8 h. Extraction of Piperonyl Butoxide from the adsorbent was made with 5 mL acetone on a flatbed shaker for 60 min at 100 rpm at a temperature around 20 °C. Analysis of Piperonyl Butoxide concentrations was performed by using GC/MS.
LOQ is 5.83 µg/m3

Body fluids and tissues

Not required as Piperonyl Butoxide is not indicated to be toxic or highly toxic.

Food and feed

Piperonyl Butoxide is an active substance in PT 18 (insecticides) used in public and private areas, as well as in areas where foodstuffs and other goods are stored, prepared and packaged. SPECIAL ONE cannot be used in areas where foodstuffs and other goods are stored, prepared and packaged.

Cyfluthrin

Soil

residue definition: cyfluthrin

GC-ECD LOQ = 0.05 mg/kg
GC-MSD LOQ = 0.05 mg/kg

Water

residue definition: cyfluthrin
GC-ECD LOQ = 0.05 µg/L (drinking water)
GC-ECD LOQ = 0.02 µg/L (surface water)
LC-MS/MS LOQ = 0.01 µg/L (surface water, confirmation and ILV available)

Air

residue definition: cyfluthrin
GC-ECD LOQ = 0.7 µg/m³
GC-MSD LOQ = 0.7 µg/m³

Body fluids and tissues
residue definition for body tissues: cyfluthrin
GC-ECD LOQ = 0.01 mg/kg (meat, liver (confirmation included by GC column of different polarity)

residue definition for body fluids (urine): metabolites DCCA and FPBA
GC-MSD LOQ = 0.5 µg/L (DCCA)
LOQ = 1 µg/L (FPBA)

Food and feed

Not required.

Conclusion on the methods for detection and identificationof the product
Acceptable validated analytical methods are available for detection of transfluthrin, cyfluthrin and piperonyl butoxide in soil, air and water reported in the CAR documents for transfluthrin (the Netherlands, 2014), cyfluthrin (Germany, updated 2018) and piperonyl butoxide (Greece, updated 2019. Analytical method for the detection of cyfluthrin in body fluids and tissues was also available. In the same documents, analytical methods for the detection of transfluthrin and piperonyl butoxide in body fluids and tissues, and residues in food and feeding stuff or further were not provided. For cyfluthrin methods for the detection of the active substance residues in food and feeding stuff were not considered to be required A letter of access covering the complete dossier of each active substance is available from Bayer and Endura.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

SPECIAL ONE is an insecticide used indoor, spot treatment by direct spray on wasp nests, for crack and crevice treatment against crawling instects All uses can be summarized as follow:

- Crack and crevice treatment against against crawling insects, including Oriental cockroaches, German cockroaches and black garden ants.
- Spot treatment by direct spray against wasp nests indoors

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

Efficacy of SPECIAL ONE has been determined in knock-down and killing activity against:

- *Lasius niger*
- *Blattella germanica*
- *Blatta orientalis*
- *Vespula germanica*
- *Polistes gallicus*

2.2.5.3 Effects on target organisms, including unacceptable suffering

Efficacy of SPECIAL ONE has been determined by the observation of these effects:

- knock-down effect
- killing effect

Therefore, the most important effect on target organisms is the mortality. Insects that appeared stunned or unable to coordinate movements were considered knocked down, the final mortality involved only insects that, when taken outside in an untreated environment, did not recover.

2.2.5.4 Mode of action, including time delay

Transfluthrin: Sodium channel modulator
Transfluthrin is a synthetic pyrethroid which acts on harmful organisms by contact and inhalation. It expresses a strong knock-down effect.
Pyrethroids impair ion transport through the membrane of nerve axons, causing muscular paralysis in the insect; death seems to follow a nervous system impairment that occurs a few minutes after pesticide absorption (Reigart & Roberts, 1999).
The primary site of activity of transfluthrin is the voltage sensitive sodium channel in nerve membrane. Transfluthrin prolongs the opening of the sodium channels (i.e. the channels directly responsible for generating nerve action potentials) leading to neuronal hyperexcitability.
Time delay: Knock-down effect (i.e. immediate).

Cyfluthrin
Cyfluthrin is a pyrethroid insecticide. Details of the mode of action of this group of insecticides are well investigated (Naumann K., Synthetic pyrethroid insecticides: Structures and properties. Springer Verlag 1990).
Once it has been taken up by contact or feeding, it exerts strong neurotoxic action, preferentially against insects, but to a lesser degree also against several species of mites.

In principal, cyfluthrin prevents the transmission of nervous impulses along nerve fibres by preventing sodium channel function. Thus, no transmission of impulses can take place. This interruption of the nervous system results in the death of the insects.
The behavioural and physiological manifestations are an initial period of sensory hyperexcitation leading successively to loss of coordination, ataxia, prostration, convulsions and finally to death.
Time delay: Rapid Knockdown.

Piperonyl Butoxide
The mode of action of Piperonyl Butoxide is complex. According to the literature, Piperonyl Butoxide stabilises the co-applied insecticide inside the insect body and potentiates more toxins to reach their target molecules. This results in an increased mortality of the target organism, and likewise, the same effect may be observed by using decreased amounts of insecticide, i.e. synergism. There is strong evidence from the literature, that Piperonyl Butoxide inhibits the oxidative and esterase-based metabolism (detoxyfication) of the co-applied insecticide.
Therefore, Piperonyl Butoxide delays the degradation of co-applied insecticidal substances and thereby prolongs the potential action of the compounds.
According to the literature Piperonyl Butoxide is usually applied at a dose that on its own is sublethal to the target species. When Piperonyl Butoxide is applied in combination with a known toxicant, the performance of the latter is enhanced at a rate that becomes lethal when on its own would be sublethal. Nevertheless, Piperonyl Butoxide on its own can exhibit some toxic effects, and hence at sublethal doses is likely to exert some stress on the insect [Piperonyl Butoxide. The Insecticide Synergist. Editor: Jones D. G., Published by Academic Press pp.323].

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)					
Test substance	**Test organism**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Transfluthrin 0.11 gr Cyfluthrin 0.025 gr PBO 0.20 gr (Ready To Use) (Special One)	*Blattella germanica* Development stage: adults & nymphs (L3) Laboratory strains	Laboratory test	Laboratory conditions. T: 24 ºC -26ºC, RH: 70%+/-5%. No-choice test. The product is applied in different porous (concrete blocks) and non-porous surfaces (ceramic tiles) at a dose of 6g per 1m2. 5 batches (replicates) of 25 adults + 5 batches of 25 nymphs were forced to stay in contact with the treated surfaces for 1 hour. The insects were transferred to untreated inert surfaces with a nutritious substratum and water available. Assessments of knockdown and/or killing effect were performed up to 4 hours after exposure. Mortality was recorded 24 hours later. The tests were conducted after treatment and repeated with the treated tiles stored for 4 weeks to measure the residual effect (1, 2, 3, 4 weeks after the first treatment). Untreated control was included. 5 replicates were conducted.	In all types of surfaces (porous and non-porous) knock down was 100% in 1-4 hours and mortality was 100% after 24 hours, for fresh and 4 weeks deposits. Mortality in untreated control: 0-1%.	[redacted] 2018a **Trial 6**
Transfluthrin 0.11 gr Cyfluthrin 0.025 gr PBO 0.20 gr (Ready To Use) (Special One)	*Blatta orientalis* Development stage: adults & nymphs (L3) Laboratory strains	Laboratory test	Laboratory conditions. T: 24 ºC-26ºC, RH: 70%+/-5%. No-choice test. The product is applied in different porous (concrete blocks) and non-porous surfaces (ceramic tiles) at a dose of 6g per 1m2. 5 batches (replicates) of 25 adults + 5 batches of 25 nymphs were forced to stay in contact with the treated surfaces for 1 hour. The insects were transferred to untreated inert surfaces with a nutritious substratum and water available. Assessments of knockdown and/or killing effect were performed up to 4 hours after exposure. Mortality was recorded 24 hours later. The tests were conducted after treatment and repeated with the treated tiles stored for 4 weeks to measure the residual effect (1, 2, 3, 4 weeks after the first treatment). Untreated control was included. 5 replicates were conducted.	In all types of surfaces knock down was 100% after 1-4 hours and mortality was 100% after 24 hours. The same level of efficacy was observed when the cockroackes were exposed to surfaces (porous and non-porous) treated 4 weeks earlier. Mortality in untreated control: 0%.	[redacted] 2018b **Trial 7**
Transfluthrin 0.11 gr Cyfluthrin 0.025 gr PBO 0.20 gr	*Lasius niger* Development stage: adult workers Field collected (Cardiff area)	Laboratory test	Laboratory conditions. T: 25ºC+/-1ºC, RH: 60%+/-5%. No-choice test. The product is applied in non-porous surfaces (ceramic tiles) at a dose of 6g per 1m^2.	The knock down was 99% after 30 minutes. Mortality was 94% after 48 hours and 97,9% after 72 hours. The knock down to the surfaces treated 1 week	[redacted] 2018 **Trial 7/ bis**

(Ready To Use) (Special One)			5 batches (replicates) of 25 adult worker ants were forced to stay in contact with the treated surfaces for 1 hour. The insects were then transferred to untreated inert surfaces with a nutritious substratum (10% sucrose solution). Assessments of knockdown and mortality were made at 1, 2, 3, 4, 5, 15 and 30 minutes and at 2, 4 and 6 hours. Further assessments were made at 24, 48 and 72 hours post initial exposure to treatments. The tests were conducted after treatment and repeated with the treated tiles stored for 2 weeks to measure the residual effect (1, 2 weeks after the first treatment). Untreated control was included. 4 replicates were conducted.	earlier was 95,8% after 2 hours. Mortality was 90,4% after 24 hours and 98,3% after 48 hours. The knock down to the surfaces treated 2 weeks earlier was 99% after 2 hours. Mortality was 97% after 24 hours and 99% after 72 hours. Mortality in untreated control: 0-1%.	
Transfluthrin 0.11 gr Cyfluthrin 0.025 gr PBO 0.20 gr (Ready To Use) (Special One)	*Blattella germanica* Development stage: adults & nymphs (L3) Laboratory strains	Simulated – use test	Test performed in a test chamber of 12 m^3 (T:25^oC +/-1^OC, RH: 60% +/- 5%, 8 hours lighting, smooth ventilation) Choice test: the insects had the choice not to be in contact with the product and weren't forced to be in contact with the treatment to reach water and food. Some panels of materials treated with the product were set on the half of the floor. 2 types of materials: porous (cement) and non-porous (ceramic tiles). A few cardboards (to give harborages to the insects) and water and food source were set on the untreated side of the floor of the test chamber. The product was applied on the panels with the provided aerosol at dose of 6gr of product for 1 m^2 to be treated. 24 hours after the treatment 5 batches of 25 adults mixed sex and 5 batches of nymphs 3rd instar were placed on the non-treated area and they remained for 24 hours more. Knockdown was measured 4 hours after treatment and mortality 24 hours after. The persistence was measured by performing the same efficacy test after 1, 2, 3 and 4 weeks of storage of the panels. 5 replicates were conducted (the test chambers). Untreated controls were used.	In all types of surfaces knock down was 100% after 4 hours and mortality was 100% after 24 hours. The same level of efficacy was observed when the cockroackes were exposed to surfaces (porous and non-porous) treated 4 weeks earlier. Mortality and knockdown in the untreated control for all tests was 0-1%.	[redacted] 2018c **Trial 8**
Transfluthrin 0.11 gr Cyfluthrin 0.025 gr PBO	*Blatta orientalis* Development stage: adults	Simulated – use test	Test performed in a test chamber of 12 m^3 (T:25^oC +/-1^OC, RH: 60% +/- 5%, 8 hours lighting, smooth ventilation)	In all types of surfaces knock down was 100% after 4 hours and mortality was 100% after 24 hours.	[redacted] 2018d **Trial 9**

0.20 gr (Ready To Use) (Special One)	& nymphs (L3) Laboratory strains		Choice test: the insects had the choice not to be in contact with the product and weren't forced to be in contact with the treatment to reach water and food. Some panels of materials treated with the product were set on the half of the floor. 2 types of materials: porous (cement) and non-porous (ceramic tiles). A few cardboards (to give harborages to the insects) and water and food source were set on the untreated side of the floor of the test chamber. The product was applied on the panels with the provided aerosol at dose of 6gr of product for 1 m^2 to be treated. 24 hours after the treatment 5 batches of 25 adults mixed sex and 5 batches of nymphs 3rd instar were placed on the non-treated area and they remained for 24 hours more. Knockdown was measured 4 hours after treatment and mortality 24 hours after. The persistence was measured by performing the same efficacy test after 1, 2, 3 and 4 weeks of storage of the panels. 5 replicates were conducted (the test chambers). Untreated controls were used.	The same level of efficacy was observed when the cockroackes were exposed to surfaces (porous and non-porous) treated 4 weeks earlier. Mortality and knockdown in the untreated control for all tests was 0%.	
Transfluthrin 0.11 gr Cyfluthrin 0.025 gr PBO 0.20 gr (Ready To Use) (Special One)	*Lasius niger* Development stage: adult workers Field collected	Simulated – use test	Test performed in a test chamber of 12 m^3 (T:25^{o}C +/-1^{O}C, RH: 60% +/- 5%, 8 hours lighting, smooth ventilation) Choice test: the insects had the choice not to be in contact with the product and weren't forced to be in contact with the treatment to reach water and food. Some panels of materials treated with the product were set on the half of the floor. 2 types of materials: porous (cement) and non-porous (ceramic tiles). A few cardboards (to give harborages to the insects) and water and food source were set on the untreated side of the floor of the test chamber. The product was applied on the panels with the provided aerosol at dose of 6gr of product for 1 m^2 to be treated. 24 hours after the treatment 5 batches of 25 adults mixed sex and 5 batches of nymphs 3rd instar were placed on the non-treated area and they remained for 24 hours more.	In all types of surfaces knock down was 100% after 4 hours and mortality was 100% after 24 hours. The same level of efficacy was observed when the ants were exposed to surfaces (porous and non-porous) treated 4 weeks earlier. Mortality and knockdown in the untreated control for all tests was 0-1%.	[redacted] 2018e **Trial 10**

			Knockdown was measured 4 hours after treatment and mortality 24 hours after. The persistence was measured by performing the same efficacy test after 1, 2, 3 and 4 weeks of storage of the panels. 5 replicates were conducted (the test chambers). Untreated controls were used.		
Transfluthrin 0.11 gr Cyfluthrin 0.025 gr PBO 0.20 gr (Ready To Use) (Special One)	*Ctenocephalides felis* Development stage: adult Laboratory strain	Laboratory test	Laboratory conditions. T: 21.1 °C-27°C, RH: 29%-74.8%+/-2%, 300 lux intensity. No-choice test. The product is applied in different short-fibre (pile depth 1-3mm) and long-fibre (pile depth 4-6mm) carpet surfaces (15cm x 15cm), using the aerosol provided, at a dose of 6g per $1m^2$, from a distance of around 40 cm. Circular discs measuring 90mm in diameter discs were then cut from the 15cm x 15cm tiles in order to line the floor of the test units. The test units comprised of a 90mm diameter petri dish attached to a 20 com high clear plastic tube in order to facilitate flea handling an prevent the fleas from escaping. 20 fleas were confined onto the treated surfaces for 24 hours. The insects were then transferred to untreated inert surfaces with water available. Assessments of knockdown and/or killing effect were carried out at 15, 30, 60 minutes, 2, 4, 6, hours and 1, 2 and 3 days, post initial exposure to treatments. The tests were conducted after treatment and repeated with the treated surfaces stored for 1 day and at 1, 2, 3 and 4 weeks to measure the residual effect. 4 replicates were conducted for each treatment (x2), for each carpet type (x2), for each ageing interval (x5). Untreated control was included.	- Efficacy on short-fibre carpet surfaces Mortality was 93,9% after 48 hours. At the aged surfaces (1, 2, 3, 4 weeks) mortality was 50.9-82.5% after 48 hours. Untreated control mean mortality, in all exposure times was <5% after 48 hours. - Efficacy on long-fibre carpet surfaces Mortality was 88,6% after 48 hours. At the aged surfaces (1, 2, 3, 4 weeks) mortality was 71.3-79.7% after 48 hours. Untreated control mean mortality, in all exposure times was 4-10% after 48 hours.	[redacted] 2018 **Trial 12**
Transfluthrin 0.11 gr Cyfluthrin 0.025 gr PBO 0.20 gr (Ready To Use) (Special One)	*Ctenocephalides felis*	Filed test	The test was performed in 3 naturally infested abandoned warehouse and non-habitable attics free from furniture, the floor was unpolished cement. A pre-treatment assessment to measure the flea's population was conducted counting the number of adult fleas jumping on the operator's legs, who wore a white suit so the insects where visible, along a 10-meters transect. The insects were counted at 3, 6 and 9 meters along the transect.	The Percentage of Reduction was always 90% for the four weeks post-treatment, in the specific: 24 hours: 99.22% 48 hours: 98.04% 1 week: 100.00% 2 weeks: 97.83% 3 weeks: 100.00% 4 weeks: 98.81%.	[redacted] 2018 **Trial 13**

			The infested sites were then treated with the provided aerosol, as spot treatment at a dose 6gr per $1m^2$. The population reduction was measured following the same protocol as for the pre-tratment assessment. Residual effect assessments were performed after 24 and 48 hours, 1, 2, 3 and 4 weeks after treatment. Untreated control was not included. Climatic parameters during the test: T: 22 °C-27°C, RH: 52%-64%.		
Transfluthrin 0.11 gr Cyfluthrin 0.025 gr PBO 0.20 gr (Ready To Use) (Vespa One – Special One with jet valve)	*Vespula germanica* Development stage: adult Field collected	Laboratory test	Laboratory conditions. T: 23.7°C, RH: 55%. 15 containers (250ml capacity) were sprayed with 3gr of product each and then the wasps were placed in for 1 hour (1 wasp in 1 container). The inner and top parts of the containers were ermined of a 2mm mesh glass fiber mosquito net. Wasps used in this trial were collected from the field. Knockdown within 5 sec and mortality after 1 hour were recorded. 15 replicates were performed for each treatment. 15 Untreated controls were used.	Product showed 100% knockdown 5 sec after introducing the wasps in the treated containers and 100% mortality 1 hour later. Mortality in the untreated control for all tests was 0%.	[redacted] 2017 **Trial 14**
Transfluthrin 0.11 gr Cyfluthrin 0.025 gr PBO 0.20 gr (Ready To Use) (Special One)	*Vespula germanica* Development stage: adult Field collected	Laboratory tes	Laboratory conditions. T: 24°C, RH: 35%. Wasps were inserted into small mono-use cylindrical cages made of 2mm-mesh mosquito net on a plastic frame (4cm diameter x 8cm height). Each cage contained a single insect. The product was applied spraying each cage from 20 cm for 2 sec (3 gr of product). Knockdown was recorded right after the treatment and mortality was measured after 1 hour. 15 cages were used as treated replications. 15 Untreated control was used.	Product showed 100% knockdown 9 sec after direct spray against the wasps and 100% mortality 1 hour later. Mortality in the untreated control for all tests was 0%.	[redacted] 2018 **Trial 15**
Transfluthrin 0.11 gr Cyfluthrin 0.025 gr PBO 0.20 gr (Ready To Use) (Vespa One – Special One with jet valve)	*Polistes gallicus*	Field test	Five wasp nests of *Polistes gallicus* were found outdoors the in field and then treated with the product. Each nest was sprayed uniformly applying the product for no more than 1 sec (15gr of product-foaming aerosol) from a distance of 2-3 m. The whole procedure was recorded (count the number of wasps present on the nest and observe if insects were able to escape).	169 wasps were present on the 5 nests at the moment of the treatment and only 1 flew away. The mean number (of 3 pictures) of wasps per nest was 24-45. 100% of the knocked down wasps collected to evaluate mortality were confirmed as dead after 1 hour. No wasp was found on the treated nests 24 hours, 1 week and 2 weeks after treatment.	[redacted] 2017 **Trial 16**

			The knocked down insects were collected and kept in cages to record the mortality. The activity of the wasp nest checked by counting wasps on the nest taking picture every 5 min up to have 3 pics for each nest. 5 replications were carried out (nests). Untreated control was used (5 nests). Climatic parameters during the tests: T: 8 °C-24°C, RH: 51%-62%.	Untreated control nests: at the date of the treatment the mean number (of 3 pictures) of wasps per nest was 22-46. Mean number of wasps per nest was 17-41, 14-45 and 18-39 24 hours, 1 week and 2 weeks later, respectively.	
Transfluthrin 0.11 gr Cyfluthrin 0.025 gr PBO 0.20 gr (Ready To Use) (Vespa One – Special One with jet valve)	*Polistes spp.*	Field test	Three wild wasp nests of *Polistes gallicus* were found outdoors the in field and then treated with the product. Each nest was sprayed from a distance of 4 m. Right after the treatment the knocked down insects were collected and kept in lab conditions to record the mortality after 24 hours. 3 replications were carried out (nests).	The product showed 100% knockdown after 76-90 seconds, sicne the treatment of the nests and 100% mortality after 24 hours.	[redacted] 2012 **Efficacy test Annex 18**
Transfluthrin 0.11 gr Cyfluthrin 0.025 gr PBO 0.20 gr (Ready To Use) (Vespa One – Special One with jet valve)	*Vespula germanica*	Field test	Five wild wasps nests of *Vespula germanica* were found outdoors (not in cavities) in the field and then treated with the product. Each nest was sprayed uniformly applying the product for no more than 1 sec (15gr of product-foaming aerosol) from a distance of 4 m. The knocked down insects were collected and kept in cages to record the mortality. The activity of the nest was determined 1 day before the treatment at three different times of day, measuring the wasps entering and leaving the colony in 15 minutes. The same counting was done and the day of the treatment, 24 hours, one week and two weeks after the treatment. Two weeks after the treatment the nest was opened to check that no wasp was alive. 5 replications were carried out (nests). Untreated control was used (5 nests). Climatic parameters during the tests: T: 22.1 °C-37.3°C, 44 mm rain.	72 wasps were counted right before the treatment. Five seconds after the treatment the product showed 100% knocked down wasps which were collected and recorded as dead after 24 hours. No wasp was found on the treated nests 20 min, 24 hours, 1 week and 2 weeks after treatment. Untreated control nests: at the date of the treatment the mean number of wasps per nest was 35-78. Mean number of wasps per nest was 32-79, 39-80 and 43-86 24 hours, 1 week and 2 weeks later, respectively.	[redacted] 2020 **Trial 17**
Transfluthrin 0.11 gr Cyfluthrin 0.025 gr PBO 0.20 gr (Ready To Use)	*Blatta orientalis* Development stage: adult & nymphs Laboratory strain	Simulated use test Choice test	Choice test. The trial was conducted in laboratory conditions (T: 25+/-1°C, RH: 60+/-5%, 800 lux intensity), in test chambers which measured 12 m^3. A "furniture" was built to represent the cracks and crevices, which was made of 5 non-porous lacquer wood	In all types of surfaces (porous and non-porous), for adults and nymphs mortality was 100% after 24 hours, for fresh and 1, 2, 3 & 4 weeks deposits. Mortality in untreated control: 0%.	[redacted] 2020a **Trial 18**

(Special One)			boards of 1 m x 1 m, assembled together but letting a 3 cm space between each other in order to create the cracks and crevices. The product was applied in 15cm x 5cm porous and non-porous surfaces at a dose of 6g per 1m^2 and they were introduced on the first 15 cm of these cracks and crevices of the "furniture". The product is applied into cracks and crevices for no more than 2 m^2 per test application (12gr). Once the surfaces were dry 25 adult and 25 nymphs cockroaches were placed in the not treated area and stayed in the test chamber for 24 hours. The insects had the opportunity not to get in contact with the insectide and were able to reach food and water without being in contact with the treated surfaces. After 24 hours the insects were transferred to untreated healthy environment to observe mortality. The tests were conducted after treatment and repeated with the treated tiles stored for 4 weeks to measure the residual effect (1, 2, 3, 4 weeks after the first treatment). 4 replications were carried out. Untreated control was used.		
Transfluthrin 0.11 gr Cyfluthrin 0.025 gr PBO 0.20 gr (Ready To Use) (Special One)	*Blattella germanica* Development stage: adult & nymphs Laboratory strain	Simulated use test Choice test	Choice test. The trial was conducted in laboratory conditions (T: 25+/-1°C, RH: 60+/-5%, 800 lux intensity), in test chambers which measured 12 m^3. A "furniture" was built to represent the cracks and crevices, which was made of 5 non-porous lacquer wood boards of 1 m x 1 m, assembled together but letting a 3 cm space between each other in order to create the cracks and crevices. The product was applied in 15cm x 5cm porous and non-porous surfaces at a dose of 6g per 1m^2 and they were introduced on the first 15 cm of these cracks and crevices of the "furniture". The product is applied into cracks and crevices for no more than 2 m^2 per test application (12gr). Once the surfaces were dry 25 adult and 25 nymphs cockroaches were placed in the not treated area and stayed in the test chamber for 24 hours. The insects had the opportunity not to get in contact with the insectide and were able to reach food and water without being in contact with the treated surfaces. After 24 hours the insects were	In all types of surfaces (porous and non-porous), for adults and nymphs mortality was 100% after 24 hours, for fresh and 1, 2, 3 & 4 weeks deposits. Mortality in untreated control: 0%.	[redacted] 2020b **Trial 19**

			transferred to untreated healthy environment to observe mortality. The tests were conducted after treatment and repeated with the treated tiles stored for 4 weeks to measure the residual effect (1, 2, 3, 4 weeks after the first treatment). 4 replications were carried out. Untreated control was used.		
Transfluthrin 0.11 gr Cyfluthrin 0.025 gr PBO 0.20 gr (Ready To Use) (Special One)	*Lasius niger* Development stage: adult workers Laboratory strain	Simulated use test Choice test	Choice test. The trial was conducted in laboratory conditions (T: 25+/-1°C, RH: 60+/-5%, 800 lux intensity), in test chambers which measured 12 m^3. A "furniture" was built to represent the cracks and crevices, which was made of 5 non-porous lacquer wood boards of 1 m x 1 m, assembled together but letting a 3 cm space between each other in order to create the cracks and crevices. The product was applied in 15cm x 5cm porous and non-porous surfaces at a dose of 6g per 1m^2 and they were introduced on the first 15 cm of these cracks and crevices of the "furniture". The product is applied into cracks and crevices for no more than 2 m^2 per test application (12gr). Once the surfaces were dry 50 adult workers were placed in the not treated area and stayed in the test chamber for 24 hours. The ants had the opportunity not to get in contact with the insectide and were able to reach food and water without being in contact with the treated surfaces. After 24 hours the ants were transferred to untreated healthy environment to observe mortality. The tests were conducted after treatment and repeated with the treated tiles stored for 4 weeks to measure the residual effect (1, 2, 3, 4 weeks after the first treatment). 4 replications were carried out. Untreated control was used.	In all types of surfaces (porous and non-porous) mortality was 100% after 24 hours, for fresh and 1, 2, 3 & 4 weeks deposits. Mortality in untreated control: 0%.	[redacted] 2020c **Trial 20**

Conclusion on the efficacy of the product
Several efficacy studies (laboratory, simulated use and field studies) were submitted for Special One (Ready to Use product) containing transfluthrin 0.11%, cyfluthrin 0.025% and PBO 0.2%. Based on the results of the submitted efficacy studies, the product was effective when applied by non-professionals as: • Spot treatment by direct spray against wasp nests indoor using a special jet valve on the product at 15gr/ nest (1 second spray) from 4 m distance. Against

paper wasp nests, spray from 2-3 meters distance for 1 second. The product is applied on wasp nests accessible to the treatment, not hidden in cavities.
- Crack and crevice application against crawling insects, including *Blatta orientalis*, *Blattela germanica* & *Lasius niger*, at 6 gr/ m^2 (4 seconds spray) for up to 4 weeks after treatment.

2.2.5.6 Occurrence of resistance and resistance management

Transfluthrin
Transfluthrin is a pyrethroid insecticide.
According to the literature some resistance cases to transfluthrin have been reported (Chutipong Sukkanon 201912, Amelia-Yap_20193) and the possibility of development of resistance cannot be excluded.

Cyfluthrin
Cyfluthrin is a pyrethroid insecticide. Some resistance to pyrethroids has been found to varying degrees, depending on the pest species and location (Anon. 1987). In Europe the main problems have occurred in some areas with pests of agricultural significance. Laboratory tests on resistant strains have shown, for Myzus persicae, a resistance factor of 200 (to control the resistant strain requires 200 times the dose required to control a sensitive strain).
A review by the WHO of Vector Resistance to Pesticides (WHO, 1992) identified no reports of resistance to synthetic pyrethroids in mosquitoes and other sucking insects in Europe. However, resistance among some species of flies and cockroach populations was more evident. Resistance to synthetic pyrethroids among European agricultural pest species, where insecticide use is more intensive, may be more widespread (IRAC, 2000).
Cross-resistance of pest species to the group of synthetic pyrethroids is to be anticipated due to a common mode of action (Staetz, 2004), and instances of cross-resistance (or multiple resistance) between pyrethroids and organochlorine insecticides have been reported (Brogdon & McAllister, 1998).

Piperonyl butoxide (PBO)
If PBO is used extensively in the field, in an effort to abrogate the effects of metabolic resistance, it is possible that resistance will occur to PBO itself.
Unlike others insecticides, the target of PBO is not a protein vital for continued life of the insect, but a protein that is conferring resistance. Therefore, to generate resistance to PBO the insect would have to produce a resistance mechanism to protect its resistance mechanism, rather than to protect a vital target.
That it could do so is not beyond belief, but the resulting phenotype of an insect generating such extreme metabolic resistance is likely to be extremely unfit.
PBO has been used extensively for many years as a tank mix in Australia and USA. Even so, there are scarce reports of resistance to the effects of this synergist. Only under extreme laboratory conditions, aimed to induce resistance by applying high doses, have

1 Discriminating Lethal Concentrations for Transfluthrin, a Volatile Pyrethroid Compound for Mosquito Control in Thailand, CHUTIPONG SUKKANON and al, J Am Mosq Control Assoc (2019) 35 (4): 258–266

2 Behavioral responses to transfluthrin by Aedes aegypti, Anopheles minimus, Anopheles harrisoni, and Anopheles dirus (Diptera: Culicidae), Sukkanon C and al. (2020) PLoS ONE 15(8):e0237353.

3 Efficacy of Mosquito Coils: Cross-resistance to Pyrethroids in Aedes aegypti (Diptera: Culicidae) From Indonesia, Amelia-Yap and al, J. of Economic Entomology, 111(6):2854-2860 (2018)

strains of Musca domestica and Plutella xylostella been reported to develop some form of insensitivity to PBO, and even then the mechanisms were not characterised. Furthermore, when the heavy selection regime that had been used to select for this resistance was removed, the population reverted back to susceptibility within 5 generations, presumably due to heavy fitness costs associated with this insensitivity (1).

(1) Graham Moores. The Mode of Action of Piperonyl Butoxide and the Science of Insecticide Resistance. Endura S.p.A. 17 March 2009.

Management strategies
Because resistance is well known to be a potential problem, strategies to avoid resistance are normal practice. For example, the use of alternating sequences, mixtures and avoidance of frequent repeated use are standard. General advice is provided by IRAC (Anon. 1987). The principles of strategies for managing the development of resistance are similar for cyfluthrin and transfluthrin as they are for other synthetic pyrethroids;
- Where possible, application treatments should be recommended to be combined with non-chemical measures
- Products should always be used in accordance with label recommendations
- Applications should always be made against the most susceptible stages in the pest life cycle
- Where an extended period of control is required, treatments should be alternated with products with different modes of action
- Levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance, noting that sanitary conditions and proximity of untreated refugia can contribute to the risk of re-infestation.
- in cases where label rates, correctly applied, fail to give the expected level of control and resistance is demonstrated, use of any product containing the same class of chemistry should cease.
- The users should inform if the treatment is ineffective and report straightforward to the authorization holder. The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.2.5.7 Known limitations

There are not limitations on efficacy of SPECIAL ONE. Underiderable and unintended side effects during the use of the product were not observed.

2.2.5.8 Evaluation of the label claims

According to the submitted PAR and SPC, the intended uses (label claims) as applied for by the applicant including target organisms, dose rates and application methods are as follows:

The product is intended for use indoors by non-professionals.
The product is intended to be used against wasps as spot application by direct treatment against wasp nests indoor at 15gr/ nest from 4 m distance, as crack and crevice treatment against crawling insects (*Blattella germanica, Blatta orientalis, Periplaneta americana, Lasius niger*) at 6gr/ m^2, m^2.

Trials submitted by the applicant to substantiate label claims:

Intended Use 1

Spot application by direct spray by non-professionals indoors, using a special jet valve on the product, against wasps' nests, from 4 meters distance at 1 second (15 g) per nest.

Efficacy test – Annex 18
The results of the field study by Martini 2012 show that Special One, equipped with a special jet valve, was effective as direct spray from 4 meters distance against 3 paper wasp nests, providing 100% knockdown 76-90 seconds after the treatment and 100% mortality 24 hours later.

According to the efficacy guidance, the efficacy of the product should be tested in at least 5 nests and a few like size nests should be monitored over the same test period as untreated controls. Also, after 24 hours, one week and two weeks post – treatment the activity or lack thereof should be recorded by determination of the traffic rate at the treated and untreated nests. In the study "efficacy test – annex 18", the number of nests treated were 3, no untreated control was included and the mortality was checked only after 24 hours. In addition, the duration of spray and the amount of released product were not clarified in the study.

Hence, this study does not support sufficiently the intended use.

Trial 16
The results of the field study by Drago 2017 show that Special One, equipped with a special jet valve, was effective as direct spray at 1 second (15 g) per nest from 2-3 meters distance against paper wasp nests outdoors, providing no visible signs of nest activity (100% mortality) against wasps in 24 hours, 1 week and 2 weeks after treatment in all treated wasp nests. According to the study report, the product was applied uniformly onto the nest, which implies that the nests were accessible to the treatment, not hidden in cavities. The performance of the product outdoors (Intended use 5) as a trial under worst case conditions can be extrapolated to the indoor use (Intended use 2).

Hence, this study supports the efficacy of the product against paper wasp nests from 2-3 meters, not the claimed application distance of 4 meters, and this should be addressed in the intended use against wasp nests.

Trial 17
The results of the field study by Serrano 2020 show that Special One, equipped with a special jet valve, was effective as spot treatment by direct spray at 1 second (15 g) per nest from 4 meters distance against German wasps nests outdoors, providing no visible signs of nest activity (100% mortality) 24 hours, 1 week and 2 weeks after treatment in all treated wasp nests. According to the study report, the nests were accessible to the treatment, not hidden in cavities. The performance of the product outdoors (Intended use 5) as a trial under worst case conditions can be extrapolated to the indoor use conditions (Intended use 2).

Based on the results of the aforementioned field studies, the intended uses 2 & 5 of Special One, equipped with a special valve, from an efficacy point of view, are acceptable as applied for by the applicant, noting however the following:

- For consistency reasons, the application method for both intended uses 2 & 5 against wasps' nests indoors and outdoors is proposed to be "Spot application by direct spray on wasps' nests".

- The application distance for paper wasp nests should align with the distance that the product was applied against this specific wasp species' nests in the field study by Drago 2017, i.e. 2-3 meters. Hence, we propose to clarify that "Against paper wasp nests, spray from 2-3 meters distance for 1 second".

- Considering the fact that in the field studies the wasp nests were accessible to the treatment, not hidden in cavities, we propose to add the following limitation in the application method against wasp nests indoors and outdoors: "The product is applied on wasp nests accessible to the treatment, not hidden in cavities".

Intended use 2
Crack and crevice application by non-professionals indoors against crawling insects, including Oriental cockroaches, German cockroaches, American cockroaches and black garden ants at 3-4 sec (6 g) /m^2 up to 4 weeks post treatment.

Lab studies (non-choice tests) by Serrano 2018a & 2018b (trials 6,7) against German and Oriental cockroaches and simulated use study (choice test) by Serrano 2018e (trial 10) against ants (Described in intended use 3).

Trial 18
The results of the simulated use test (choice test) by Serrano 2020a show that Special One was effective as crack and crevice treatment at 6 gr product/m^2 against Oriental cockroaches for up to 4 weeks post treatment, providing 100% mortality 24 hours after exposure of the insects to fresh and 4 week-aged porous and non-porous treated surfaces which were introduced in the construction that simulated the real cracks and crevices condition.

Trial 19
The results of the simulated use test (choice test) by Serrano 2020b show that Special One was effective as crack and crevice treatment at 6 gr product/m^2 against German cockroaches for up to 4 weeks post treatment, providing 100% mortality 24 hours after exposure of the insects to fresh and 4 week-aged porous and non-porous treated surfaces which were introduced in the construction that simulated the real cracks and crevices condition.

Trial 20
The results of the simulated use test (choice test) by Serrano 2020c show that Special One was effective as crack and crevice treatment at 6 gr product/m^2 against *Lasius niger* for up to 4 weeks post treatment, providing 100% mortality 24 hours after exposure of the insects to fresh and 4 week-aged porous and non-porous treated surfaces which were introduced in the construction that simulated the real cracks and crevices condition.

The crack and crevice treatment against *Blattella germanica* and *Blatta orientalis,* is supported by the lab (non choice tests) by Serrano 2018a & 2018b (trials 6,7) and the simulated use studies (choice tests) by Serrano 2018a and 2018b, where the product was efficacious at 6g/m^2 for up to 4 weeks after treatment on both porous and non porous surfaces against German and Oriental cockroaches. The crack and crevice treatment against black garden ants is supported by the simulated use studies (choice tests) by Serrano 2018e

and Serrano 2020c where the product was efficacious at 6g/m^2 for up to 4 weeks after treatment on both porous and non porous surfaces against German and Oriental cockroaches. It is noted that the requirement of the guidance for a lab test against ants is sufficiently fulfilled by the simulated use test (choice test) by Serrano 2018e against ants conducted under laboratory conditions.

Based on the results of the aforementioned lab and simulated use studies, the intended use 4, from an efficacy point of view, is acceptable as applied for by the applicant, noting however that no efficacy studies with the product against American cockroaches (*Periplaneta americana*) have been submitted. Hence, American cockroaches should be removed from the target organisms in the label claim.

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

SPECIAL ONE is not intended to be used with others biocidal product.

2.2.6 Risk assessment for human health

SPECIAL ONE is a ready-to-use spray insecticide constituted by three active substances:
- Transfluthrin (CAS No. 118712-89-3)
- Piperonyl butoxide (CAS No. 51-03-6)
- Cyfluthrin (CAS No. 68359-37-5).

The assessment of effects on human health was developed having as starting point the rules outlined in CLP Regulation. In particular, the article 11 of CLP Regulation states "where a mixture contains a substance classified as hazardous, whether as a component or in the form of an identified impurity or additive, this information shall be taken into account for the purposes of classification, if the concentration of that substance is equal to or greater than its cut-off value. The cut-off value referred shall be determined as set out in CLP Regulation, section 1.1.2.2 of Annex I". This approach was deemed as appropriate also in the light of the criteria outlined in article 3.1(f) of Biocidal Products Regulation to identify the substances of concern in a biocidal product.

The biocidal product SPECIAL ONE contains:
- several substances that are not classified (i.e. not hazardous)
- several substances classified for one or more endpoint(s), that are present in the biocidal product in concentration(s) below the cut-off values determined according to art. 11 of CLP Regulation.

Therefore, these substances can be realistically regarded as not relevant for the hazard assessment of the biocidal product and they will not be further taken into account in the following evaluation. The only relevant substances are the three active substances detailed above. Please see Confidential annex for more details.

Moreover, available toxicological information on active substances are deemed sufficient to assess SPECIAL ONE. For these reasons, in the sections below, the human health hazard assessment shortly summarizes the information discussed in detail in the Assessment Reports (PT18) of transfluthrin (The Netherlands, 2014), piperonyl butoxide (Greece, 2019) and cyfluthrin (Germany, 2016). The use of data on active substances and model formulations is covered by the Letter of Access.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritant.
Justification for the value/conclusion	No data for SPECIAL ONE is provided. The classification of the product was conducted using the endpoints included in the Assessment Reports (PT18) of transfluthrin (The Netherlands, 2014), piperonyl butoxide (Greece, 2019), cyfluthrin (Germany, 2016) and the MSDS of the other components of the product. According to the Assessment Report of transfluthrin, the a.s. is currently classified for skin irritation (Skin Irritant, Cat. 2).

	However, the concentration of transfluthrin in the product does not exceed the cut-off value determined according to art. 11 of CLP Regulation for skin corrosion and irritation. As a consequence, no classification for skin irritation is triggered for SPECIAL ONE, according to Regulation (EC) No. 1272/2008.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Skin corrosion and irritation. Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).
Justification	No data for SPECIAL ONE is provided. The classification of the product was conducted using the endpoints included in the Assessment Reports (PT18) of transfluthrin (The Netherlands, 2014), piperonyl butoxide (Greece, 2019), cyfluthrin (Germany, 2016) and the MSDS of the other components of the product. According to the Assessment Report of transfluthrin, the a.s. is currently classified for skin irritation (Skin Irritant, Cat. 2). However, the concentration of transfluthrin in the product does not exceed the cut-off value determined according to CLP Regulation for skin corrosion and irritation. Therefore, no classification for skin irritation is triggered for SPECIAL ONE, according to Regulation (EC) No. 1272/2008.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritant.
Justification for the value/conclusion	No data for SPECIAL ONE is provided. The classification of the product was conducted using the endpoints included in the Assessment Reports (PT18) of transfluthrin (The Netherlands, 2014), piperonyl butoxide (Greece, 2019), cyfluthrin (Germany, 2016) and the MSDS of the other components of the biocidal product. According to the Assessment Report of piperonyl butoxide, the a.s. is currently classified as an eye irritant category 2 (H319). However, as the concentration of piperonyl butoxide in the product does not exceed the cut-off value determined according to art. 11 of CLP Regulation for eye irritation, no classification is triggered for SPECIAL ONE.

Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Eye irritation. Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).
Justification	No data for SPECIAL ONE is provided. The classification of the product was conducted using the endpoints included in the Assessment Reports (PT18) of transfluthrin (The Netherlands, 2014), piperonyl butoxide (Greece, 2019), cyfluthrin (Germany, 2016) and the MSDS of the other components of the product. According to the Assessment Report of piperonyl butoxide, the a.s. is currently classified as an eye irritant category 2 (H319). However, as the concentration of piperonyl butoxide in the product does not exceed the cut-off value determined according to art. 11 of CLP Regulation for eye irritation, no classification is triggered for SPECIAL ONE.

Respiratory tract irritation

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	Not irritating to the respiratory tract.
Justification for the value/conclusion	There are no designated tests for respiratory tract irritation. The classification of the product was conducted using the endpoints included in the Assessment Reports (PT18) of transfluthrin (The Netherlands, 2014) and piperonyl butoxide (Greece, 2019) and the MSDS of the other components of the biocidal product. According to the Assessment Report of piperonyl butoxide, the a.s. is currently classified as irritating to the respiratory tract (STOT SE Category 3; H335). However, as the concentration of piperonyl butoxide in the product does not exceed the cut-off value determined according to art. 11 of CLP Regulation for respiratory irritation, the biocidal product is not classified as a respiratory tract irritant.
Classification of the product according to CLP and DSD	Not classified.

Data waiving

Information requirement	Respiratory tract irritation. Testing on the product/mixture does not need to be conducted, if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP). Please refer to the Confidential annex of this PAR.
Justification	There are no designated tests for respiratory tract irritation. The classification of the product was conducted using the endpoints included in the Assessment Reports (PT18) of transfluthrin (The Netherlands, 2014) and piperonyl butoxide (Greece, 2019) and the MSDS of the other components of the biocidal product. Piperonyl butoxide is currently classified as irritating to the respiratory tract (STOT SE Category 3; H335). However, as the concentration of piperonyl butoxide in the product does not exceed the cut-off value determined according to art. 11 of CLP Regulation for respiratory irritation, the biocidal product is not classified as a respiratory tract irritant.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising.
Justification for the value/conclusion	No data for SPECIAL ONE is provided. The classification of the product was conducted using the endpoints included in the Assessment Reports (PT18) of transfluthrin (The Netherlands, 2014), piperonyl butoxide (Greece, 2019), cyfluthrin (Germany, 2016) and the MSDS of the other components of the product. According to Regulation (EC) No. 1272/2008, a product shall be classified as skin sensitizer when at least one ingredient has been classified as skin sensitizer and is present at or above the appropriate generic concentration limit of ≥ 1%. Some substances that are classified as sensitizers may elicit a response, when present in a mixture in quantities below the generic concentration limit, in individuals who are already sensitized to the substance or mixture. Therefore, another concentration limit of ≥ 0,1% is generally used for the application of the special labelling requirements of Annex II section 2.8 of CLP Regulation to protect already sensitised individuals. The label on the packaging of mixtures containing at least one substance classified as sensitising and present in a concentration equal to or greater than 0.1 % shall bear the statement: EUH208 - 'Contains (name of sensitizing substance). May produce an allergic reaction'. Neither the active substances nor the co-formulants of SPECIAL ONE are classified for skin sensitisation, hence no classification is

	triggered for the product, according to Regulation (EC) No. 1272/2008. However, the active substance transfluthrin contains a component, that is classified as skin sensitizer (H317) but its concentration in SPECIAL ONE is < 0.1%. Therefore, EUH208 statement is not required according to the criteria of CLP Regulation. As a consequence, SPECIAL ONE is not classified as a skin sensitizer.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Skin sensitisation. Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).
Justification	No data for SPECIAL ONE is provided. The classification of the product was conducted using the endpoints included in the Assessment Reports (PT18) of transfluthrin (The Netherlands, 2014), piperonyl butoxide (Greece, 2019), cyfluthrin (Germany, 2016) and the MSDS of the other components of the product. Neither the active substances nor the co-formulants of SPECIAL ONE are classified for skin sensitization, hence no classification is triggered for the product, according to Regulation (EC) No. 1272/2008. However, the active substance transfluthrin contains a component, that is classified as skin sensitizer (H317) but its concentration in SPECIAL ONE is < 0.1%. Therefore, EUH208 statement is not required according to the criteria of CLP Regulation. As a consequence, SPECIAL ONE is not classified as a skin sensitizer.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising.
Justification for the value/conclusion	There is no data available from several years of human experience (human data e.g. market surveillance data, animal studies, open literature) which may be indicative of the potential of the product to cause respiratory sensitisation in humans.
Classification of the product according to CLP and DSD	Not classified.

Data waiving

Information requirement	Respiratory sensitization (ADS). Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).
Justification	Testing of the product is not deemed necessary. Classification may be based on read across to the active substances and reference to the components and their concentration in the biocidal product. As neither the active substances nor the other components of the biocidal product are classified for respiratory sensitisation, the mixture does not meet the criteria for classification for respiratory sensitisation.

Acute toxicity

Acute toxicity by oral route

Acute oral toxicity values of the active substances transfluthrin (Assessment report; The Netherlands, 2014), piperonyl butoxide (Assessment report; Greece, 2019) and cyfluthrin (Assessment report; Germany, 2016) are detailed below.

transfluthrin	
Mouse LD_{50} oral	583 mg/kg bw
Currently transfluthrin is not classified for acute oral toxicity. However, on the basis on the most recent review of the active substance (Assessment Report; The Netherlands, 2014), the RMS proposed classification of transfluthrin as Acute Tox. Cat. 4 (H302). A CLH intention, with proposed classification for Acute Tox. Cat. 4 (H302), has been submitted but has not officially been accepted.	
piperonyl butoxide	
Rat LD_{50} oral	> 2000 mg/kg bw (male)
Rat LD_{50} oral	> 5000 mg/kg bw (female)
Piperonyl butoxide is not classified for acute oral toxicity.	
cyfluthrin	
Rat LD_{50} oral	16.2 mg/kg bw (cremophor EL/H20)
Rat LD_{50} oral	155 mg/kg bw (peanut oil/acetone)
Cyfluthrin is classified as **Acute Tox. Cat. 2 (H300).**	

Value used in the Risk Assessment – Acute oral toxicity	
Value	Non-toxic *via* the oral route.
Justification for the selected value	Application of the rules of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula).

	Cyfluthrin is classified for acute oral toxicity (Assessment report; Germany, 2016), while transfluthrin is not currently classified for acute oral toxicity. However, on the basis on the most recent review of the active substance (Assessment Report; The Netherlands, 2014), the RMS proposed classification of transfluthrin as Acute Tox. Cat. 4 (H302). A CLH intention, with proposed classification for Acute Tox. 4 (H302), has been submitted but has not officially been accepted. However, as the concentration of cyfluthrin in the biocidal product is below 0.1%, SPECIAL ONE does not classify for acute oral toxicity, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Acute oral toxicity. Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).
Justification	SPECIAL ONE does not contain substances with acute oral toxicity hazards at a concentration equal or greater than 0.1%, therefore, no classification for acute oral toxicity is triggered for the product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).

Acute toxicity by inhalation

Acute inhalation toxicity values of the active substances transfluthrin (Assessment report; The Netherlands, 2014), piperonyl butoxide (Assessment report; Greece, 2019) and cyfluthrin (Assessment report; Germany, 2016) are detailed below.

transfluthrin	
Rat LC_{50} inhalation	> 513 mg/m3
Transfluthrin is not classified for acute inhalation toxicity.	
piperonyl butoxide	
Rat LC_{50} inhalation	> 5.9 mg/L/4h (male and female; whole body exposure)
Piperonyl butoxide is not classified for acute inhalation toxicity.	
cyfluthrin	
Rat LC_{50} inhalation	405 µg/L air (4 h)
Cyfluthrin is classified as **Acute Tox. Cat. 2 (H330).**	

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Non-toxic *via* the inhalation route.
Justification for the selected value	Application of rules of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula). Cyfluthrin is classified as Acute Tox. Cat. 2; H330 (Assessment report; Germany, 2016). However, as the concentration of cyfluthrin in the product is below 0.1%, SPECIAL ONE does not classify for acute inhalation toxicity, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Acute inhalation toxicity. Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).
Justification	SPECIAL ONE does not contain substances with acute inhalation toxicity hazards at a concentration equal or greater than 0.1%, therefore, no classification for acute inhalation toxicity is triggered for the product, according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).

Acute toxicity by dermal route

Acute dermal toxicity values of the active substances transfluthrin (Assessment report; The Netherlands, 2014), piperonyl butoxide (Assessment report; Greece, 2019) and cyfluthrin (Assessment report; Germany, 2016) are detailed below.

transfluthrin	
Mouse LD_{50} dermal	> 4000 mg/kg bw
Transfluthrin is not classified for acute dermal toxicity.	
piperonyl butoxide	
Rat LD_{50} dermal	> 2000 mg/kg bw (male and female)
Piperonyl butoxide is not classified for acute dermal toxicity.	
cyfluthrin	
Rat LD_{50} dermal	> 5000 mg/kg bw
Cyfluthrin is not classified for acute dermal toxicity.	

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Non-toxic *via* the dermal route.
Justification for the selected value	Application of the rules of CLP Regulation, Annex I, point 3.1.3.6. Classification of mixtures based on ingredients of the mixture (Additivity formula). There are not substances with acute dermal toxicity hazards in SPECIAL ONE. According to the data available and the rules laid down in Regulation (EC) No. 1272/2008 (CLP), SPECIAL ONE does not classify as acute dermal toxic.
Classification of the product according to CLP and DSD	Not classified.

Data waiving	
Information requirement	Acute dermal toxicity. Testing on the product does not need to be conducted if there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008 (CLP).
Justification	There are not substances with acute dermal toxicity hazards in SPECIAL ONE. According to the data available and the rules laid down in Regulation (EC) No. 1272/2008 (CLP), SPECIAL ONE does not classify as acute dermal toxic.

Additional information on the classification of the active substances

The current harmonised classification and labelling for transfluthrin has been used (Skin Irritation Cat. 2, H315). On the basis on the most recent review of the active substance (Assessment Report; The Netherlands, 2014), the RMS proposed a change of the current classification. A CLH intention, with proposed classification has been submitted but has not officially been accepted. If/when the proposed classification of transfluthrin is formally adopted, then the classification of the biocidal product may need to be revisited.

The classification of piperonyl butoxide has been discussed in RAC-53 (June 2020). The agreed classification (Eye Irritation. Cat 2, H319; STOT SE Cat. 3, H335; EUH066) has been used for the toxicological hazard assessment of the biocidal product.

The harmonised classification and labelling of cyfluthrin adopted by RAC (RAC opinion, May 2020) has been used for the toxicological hazard assessment of the biocidal product.

Information on dermal absorption

Dermal absorption data for SPECIAL ONE are not available; therefore, default values of dermal absorption have to be used in the risk assessment, as proposed in the current EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873].

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Transfluthrin
Value(s)	50%
Justification for the selected value(s)	A dermal study has not been performed with the biocidal product SPECIAL ONE, therefore a default value of dermal absorption has to be used. According to EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873], in order to choose the suitable default value, the formulation category of the product and the concentration of the active substance in the product must be taken into consideration. SPECIAL ONE is a water-based product and the concentration of transfluthrin in the biocidal product is 0.114%. As the percentage of the active substance in the product is below 5%, that is the threshold used to identify dilutions according to the previous EFSA Guidance on Dermal Absorption (2012, section 6.1), a default dermal absorption value of 50% will be considered in the risk assessment, as proposed in the current EFSA Guidance for dilutions of water-based formulations.
Substance	Piperonyl butoxide
Value(s)	50%
Justification for the selected value(s)	A dermal study has not been performed with the biocidal product SPECIAL ONE, therefore a default value of dermal absorption has to be used. According to EFSA "Guidance on dermal absorption" [EFSA Journal, 2017; 15(6): 4873], in order to choose the suitable default value, the formulation category of the product and the concentration of the active substance in the product must be taken into consideration. SPECIAL ONE is a water-based product and the concentration of piperonyl butoxide in the biocidal product is 0.213%. As the percentage of the active substance in the product is below 5%, that is the threshold used to identify dilutions according to the previous EFSA Guidance on Dermal Absorption (2012, section 6.1), a default dermal absorption value of 50% will be considered in the risk assessment, as proposed in the current EFSA Guidance for dilutions of water-based formulations.
Substance	Cyfluthrin
Value(s)	50%
Justification for the selected value(s)	A dermal study has not been performed with the biocidal product SPECIAL ONE, therefore a default value of dermal absorption has to be used. According to EFSA "Guidance on dermal absorption" [EFSA Journal, 2017; 15(6): 4873], in order to choose the suitable default value, the formulation category of the product and the concentration of the active substance in the product must be taken into consideration. SPECIAL ONE is a water-based product and the concentration of cyfluthrin in the biocidal product is 0.026%. As the percentage of the active substance in the product is below 5%, that is the threshold used to identify dilutions according to the previous EFSA Guidance on Dermal Absorption (2012, section 6.1), a default dermal

	absorption value of 50% will be considered in the risk assessment, as proposed in the current EFSA Guidance for dilutions of water-based formulations.

Data waiving	
Information requirement	Dermal absorption
Justification	In the absence of relevant dermal absorption data with SPECIAL ONE, the default value of 50% will be considered in the risk assessment for all three active substances, as proposed in the current EFSA Guidance on dermal absorption for dilutions of water-based formulations [EFSA Journal, 2017; 15(6): 4873].

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

Regarding human health, there are no substances of concern present in the biocidal product SPECIAL ONE.

Synergistic effects between the components of the product

The applicant has provided a White Paper describing the mode of action of natural pyrethrins, synthetic pyrethroids and piperonyl butoxide with regard to the synergistic effect that can be achieved in target species and non-target species such as other arthropods, aquatic organisms and mammalian organisms [4]. The full assessment report has been attached in section 8.7.1 of IUCLID. A detailed summary of the information available is presented below:

4.

Endocrine-distrupting properties for human health: screening for co-formulants

Summary

The assessment of the endocrine-disrupting properties of the co-formulants in the biocidal product SPECIAL ONE has been performed according to the instructions described in the document agreed in the Coordination Group (CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants).

To assess the endocrine-disrupting (ED) potential of each co-formulant in the biocidal product, a step-wise approach was performed, which included screening of relevant databases and searching for freely available information in reliable literature sources.

The information sources and the databases consulted as well as the results of the screening for endocrine-disrupting properties of the co-formulants in the biocidal product SPECIAL ONE are presented in detail in the Confidential Annex.

Conclusion of endocrine-disrupting assessment for co-formulants

The endocrine-disrupting assessment for the co-formulants of the biocidal product SPECIAL ONE has been performed using the information provided in the SDS by the supplier of the co-formulant and searching reliable literature sources. The information sources and the databases consulted are detailed in the Confidential Annex.

Based on existing knowledge and available scientific information, there is no indication of concern regarding endocrine-disrupting properties of any of the co-formulants, hence the biocidal product SPECIAL ONE is not an endocrine disruptor.

Available toxicological data relating to a mixture

Mixtures containing substances of concern are not present in SPECIAL ONE.

2.2.6.2 Exposure assessment

General remarks

SPECIAL ONE is a ready-to-use spray insecticide containing the following active substances:

- Transfluthrin (CAS No. 118712-89-3)
- Piperonyl butoxide (CAS No. 51-03-6)
- Cyfluthrin (CAS No. 68359-37-5)

SPECIAL ONE is a ready-to-use insecticide used by non-professionals for indoor and outdoor spot treatment against flying and crawling insects.

Expected patterns of exposure

SPECIAL ONE is used by non-professional users (consumers).
Exposure in workplace may be only expected during industrial formulation of the biocidal product; however, this use is out of the scope of this assessment.

Human exposure, both primary and secondary, arising from the use of the biocidal product for targeted spot applications by non-professional users can be summarised as follows:

Primary exposure

- Application of the product (non-professional users)
- Infants, toddlers and children being present in the room during application of the product

Secondary exposure

- Indirect exposure through re-entry to treated areas (infants, toddlers, children, adults).

Identification of main paths of human exposure towards active substances.

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use *	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.r.	n.a.	yes	n.a.	n.a.	yes	n.a.
Dermal	n.r.	n.a.	yes	n.a.	n.a.	yes	n.a.
Oral	n.r.	n.a.	n.a.	n.a.	n.a.	yes **	n.a.

n.r. = not relevant; n.a. = not applicable

* Industrial use (manufacture of active substances and formulation) is not covered by the BPR.

** Oral exposure is due to hand-to-mouth contact for infants and toddlers.

Maximum residue limits or equivalent

At the time of submission, the MRLs for transfluthrin in plant and animal commodities are set under Reg. (EU) No 37/2010 and for cyfluthrin under Reg. (EU) 2016/1902.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1(i)	Application	Primary exposure: targeted spot application of the product (considered as the worst-case scenario)	Non-professional users
1(ii)	Application	Primary exposure: infants, toddlers and children being present in the room during product application.	Infants, toddlers and children
2	Post-application	Secondary exposure is derived *via* inhalation, dermal and oral route (hand-to-mouth contact for infants and toddlers)	General public (infants, toddlers children, adults)
1(i)+2	Combined	Combined exposure: expected for the adult non-professional user who is exposed *via* the inhalation and dermal route during the spray application of the product and at the re-entry to treated areas following product application.	Adult non-professional user
1(ii)+2	Combined	Combined exposure: expected for infants, toddlers and children who are exposed *via* the inhalation route during product application and *via* the inhalation, dermal and oral route at the re-entry to treated areas following product application.	Infants, toddlers and children

Non-professional exposure

SPECIAL ONE is an insecticide used by non-professionals for indoor and outdoor spot treatment of surfaces against flying and crawling insects. All uses can be summarized as follows:

- spot treatment against crawling insects (crack and crevices included)
- wasp nests

Spot treatment against crawling insects is considered to be the worst-case scenario for the application of the product, therefore the exposure assessment was performed using the application rate of the product for this scenario (6 g/m^2 - 1.5 g/sec).

In the use named "spot application by direct spray on wasps' nests", the product is applied directly on a wasp nest; in this case the spray duration is 1 second and the spray rate of the product is 15 g/nest. Therefore, the total amount of product used is 15 g, that is less than the amount used in the spot application of the product against crawling insects, which represents the worst-case scenario among the different uses of the product.

More specifically, considering the default values of spray duration and mass generation rate as proposed from ConsExpo (see below, Scenario 1 – Tier 1), the total amount of product used was calculated to be 198 gr (0.55 g/sec x 6 min = 198 gr). Moreover, considering the product-specific parameters (see below, Scenario 1 – Tier 2) the total amount of product used was calculated to be 180 gr (1.5 g/sec x 2 min = 180 gr). In both cases, the total amount of product used is much more than the 15 g of product used per wasp nest.

The exposure estimation for the non-professional risk assessment has been performed using ConsExpo Web, version 1.0.6.

General input data for non-professional exposure estimation

General input data for each active substance used for non-professional exposure estimation are described in detail in the following table.

Table 17. General input data for the active substances transfluthrin, piperonyl butoxide and cyfluthrin.

General input data for the active substances			
Name of the active substance	transfluthrin	piperonyl butoxide	cyfluthrin
CAS number	118712-89-3	51-03-6	68359-37-5
Molecular weight	371.2 g/mol	338.43 g/mol	434.3 g/mol
logKow	5.4	4.8	6.0
Content of the a.s. in the product	0.114%	0.213%	0.026%
Dermal absorption *	50%	50%	50%
Inhalation absorption **	100%	100%	100%
Oral absorption **	100%	100%	100%

* Default dermal absorption value proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for dilutions of water-based formulations.
** According to the Assessment Reports of the three active substances; transfluthrin (The Netherlands, 2014), piperonyl butoxide (Greece, 2019) and cyfluthrin (Germany, 2016).

Scenario 1: Targeted spot application by non-professionals

Primary exposure for targeted spot application by non-professional users has been estimated using ConsExpo Web, version 1.0.6. The default values proposed in the pest control factsheet were used as Tier 1 (worst-case) and the specific parameters of the biocidal product were used as Tier 2 for the assessment of the primary exposure of the non-professional user. Input parameters used for the exposure assessment are reported in the table below.

Table 18. Input parameters for the targeted spot application by non-professional users.

Description of Scenario 1: targeted spot application - ConsExpo Web, version 1.0.6.		
Parameters	**Value**	**Comments**
Exposed group	Non – professional users	-
Product database	Pest control products	-
Product category	Sprays	-
Product	Targeted spot	-
Scenario	Application (spray can)	-
Frequency	9 per year	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (Table 5, p.20).

Description of Scenario 1: targeted spot application - ConsExpo Web, version 1.0.6.		
Body weight	60 kg	HEEG Opinion "Default human factor values for use in exposure assessments of biocidal products".
Inhalation exposure – Tier 1		
Model	Exposure to spray	-
Mode of release	Spraying	-
Spray duration	6 min	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 34).
Inhalatory exposure duration	240 min	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 34).
Room volume	20 m^3	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (pp. 34-35).
Room height	2.5 m	Standard room height as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 37).
Ventilation rate	0.6 per hour	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 35).
Inhalation rate	1.25 m^3/h	HEEG Opinion "Default human factor values for use in exposure assessments for biocidal products".
Mass generation rate	0.55 g/s	Default, as reported in "New default values for the spray model" RIVM, March 2010.
Airborne fraction	0.2	Default, as reported in "New default values for the spray model" RIVM, March 2010.
Density non volatile	1.8 g/cm^3	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 21).
Inhalation cut off diameter	15 µm	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 25).
Particle distribution - median diameter	3.6 µm	Default, as reported in "New default values for the spray model" RIVM, March 2010.
Particle distribution - coefficient of variation.	0.57	Default, as reported in "New default values for the spray model" RIVM, March 2010.
Inhalation absorption	100% for all three active substances	According to the Assessment Reports of the active substances: - transfluthrin (The Netherlands, 2014) - piperonyl butoxide (Greece, 2019)

Description of Scenario 1: targeted spot application - ConsExpo Web, version 1.0.6.		
		- cyfluthrin (Germany, 2016).
Inhalation exposure – Tier 2		
Spray duration	2 min	The application rate of the product is 6 g/m^2 corresponding to 1.5 g/sec. Assuming that 25 m^2 are treated in the case of a normal flat or apartment, the actual amount of product used is 150 gr and the actual spray duration of the product is 100 sec, according to the product label. As a worst-case, the spray duration was considered to be 2 min.
Inhalatory exposure duration	240 min	It was assumed that the non-professional user leaves the treated room 4 hours after the product application.
Room volume	60 m^3	As a worst-case, it was assumed that the volume of the treated room is 60 m^3.
Room height	2.5 m	Standard room height.
Mass generation rate	1.5 g/s	Actual application rate of the product.
Density non volatile	1 g/cm^3	Product-specific parameter.
Particle distribution - median diameter	49.17 µm	Product-specific parameter.
Dermal exposure – Tier 1		
Model	Direct product contact	-
Loading	Constant rate	-
Dermal contact rate	100 mg/min	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (Table 13, p. 28).
Release duration	6 min	Spray duration, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 37).
Dermal absorption	50% for all three active substances	Default dermal absorption value for all three active substances, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for dilutions of water-based formulations.
Dermal exposure – Tier 2		
Release duration	2 min	Actual spray duration of the product.

Calculations for Scenario 1: targeted spot application

Systemic acute exposure to the active substances transfluthrin, piperonyl butoxide and cyfluthrin from targeted spot application by non-professional users, as calculated by

ConsExpo Web, version 1.0.6, are reported in Table 19. For details on calculations please refer to Annex 3.2.

Table 19. Systemic acute exposure to transfluthrin, piperonyl butoxide and cyfluthrin from targeted spot application for the non-professional user.

Summary table: systemic acute exposure from targeted spot application (internal dose on day of exposure)				
	Inhalation dose	**Dermal dose**	**Oral non-respirable dose**	**Total systemic dose**
	mg/kg bw/day			
Transfluthrin				
Scenario 1 Tier 1	3.2×10^{-2}	5.7×10^{-3}	7.5×10^{-6}	3.8×10^{-2}
Scenario 1 Tier 2	2.8×10^{-5}	1.9×10^{-3}	1.9×10^{-4}	2.1×10^{-3}
Piperonyl butoxide				
Scenario 1 Tier 1	6.0×10^{-2}	1.1×10^{-2}	1.4×10^{-5}	7.0×10^{-2}
Scenario 1 Tier 2	5.2×10^{-5}	3.6×10^{-3}	3.6×10^{-4}	4.0×10^{-3}
Cyfluthrin				
Scenario 1 Tier 1	4.4×10^{-4}	1.3×10^{-3}	1.0×10^{-7}	1.7×10^{-3}
Scenario 1 Tier 2	6.4×10^{-6}	4.3×10^{-4}	4.4×10^{-5}	4.8×10^{-4}

For completeness, the mean event air concentrations for the three active substances during product application were estimated using ConsExpo and are presented below.

	Mean event air concentration mg/m³
Transfluthrin	
Scenario 1(i) Tier 1 - adult	3.8×10^{-1}
Scenario 1(i) Tier 2 - adult	3.4×10^{-4}
Scenario 1(ii) Tier 2 – infant, toddler, child	3.4×10^{-4}
Piperonyl butoxide	
Scenario 1(i) Tier 1 - adult	7.2×10^{-1}
Scenario 1(i) Tier 2 - adult	6.3×10^{-4}

Scenario 1(ii) Tier 2 – infant, toddler, child	6.3×10^{-4}
Cyfluthrin	
Scenario 1(i) Tier 1 - adult	8.7×10^{-2}
Scenario 1(i) Tier 2 - adult	7.7×10^{-5}
Scenario 1(ii) Tier 2 – infant, toddler, child	7.7×10^{-5}

Scenario 1(ii): Infants, toddlers and children being present in the room during product application.

Although it is unlikely that infants, toddlers and children will be present in the room during the application of the product by non-professional users, a risk assessment has been performed for completeness reasons.

Infants, toddlers and children being present in the room during product application are exposed to the active substances *via* the inhalation route. Primary exposure has been estimated using ConsExpo Web, version 1.0.6 and the specific parameters of the biocidal product. Input parameters used for the exposure assessment are reported in the table below.

Table 20. Input parameters for the primary exposure of infants, toddlers and children being present in the room during product application.

Description of Scenario 1(ii): primary exposure of infants, toddlers and children during product application		
Parameters	**Value**	**Comments**
Exposed group	Infants, toddlers, children	-
Product database	Pest control products	-
Product category	Sprays	-
Product	Targeted spot	-
Scenario	Application (spray can)	-
Frequency	9 per year	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (Table 5, p.20).
Body weight	Infant: 8 kg Toddler: 10 kg Child: 23.9 kg	HEEG Opinion "Default human factor values for use in exposure assessments of biocidal products".
Inhalation exposure		
Model	Exposure to spray	-
Mode of release	Spraying	-

Description of Scenario 1(ii): primary exposure of infants, toddlers and children during product application		
Spray duration	2 min	The application rate of the product is 6 g/m^2 corresponding to 1.5 g/sec. Assuming that 25 m^2 are treated in the case of a normal flat or apartment, the actual amount of product used is 150 gr and the actual spray duration of the product is 100 sec, according to the product label. As a worst-case, the spray duration was considered to be 2 min.
Inhalatory exposure duration	240 min	It was assumed that the infants, toddlers and children stay in the treated room for 4 hours after the product application.
Room volume	60 m^3	As a worst-case, it was assumed that the volume of the treated room is 60 m^3.
Room height	2.5 m	Standard room height.
Ventilation rate	0.6 per hour	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 35).
Inhalation rate	Infant: 0.84 m^3/h Toddler: 1.26 m^3/h Child: 1.32 m^3/h	HEEG Opinion "Default human factor values for use in exposure assessments for biocidal products".
Mass generation rate	1.5 g/s	Actual application rate of the product.
Airborne fraction	0.2	Default, as reported in "New default values for the spray model" RIVM, March 2010.
Density non volatile	1 g/cm^3	Product-specific parameter.
Inhalation cut off diameter	15 µm	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 25).
Particle distribution - median diameter	49.17 µm	Product-specific parameter.
Particle distribution - coefficient of variation.	0.57	Default, as reported in "New default values for the spray model" RIVM, March 2010.
Inhalation absorption	100% for all three active substances	According to the Assessment Reports of the active substances: - transfluthrin (The Netherlands, 2014) - piperonyl butoxide (Greece, 2019) - cyfluthrin (Germany, 2016).

Calculations for Scenario 1(ii): Primary exposure of infants, toddlers and children being present in the room during product application.

Systemic acute exposure to the active substances transfluthrin, piperonyl butoxide and cyfluthrin of infants, toddlers and children being present in the room during product application, as calculated by ConsExpo Web, version 1.0.6, are reported in Table 21. For details on calculations please refer to Annex 3.2.

Table 21. Systemic acute exposure to transfluthrin, piperonyl butoxide and cyfluthrin for infants, toddlers and children being present in the room during product application.

Summary table: systemic acute exposure for infants, toddlers and children being present in the room during product application. (internal dose on day of exposure)				
	Inhalation dose	**Dermal dose**	**Oral non-respirable dose**	**Total systemic dose**
	mg/kg bw/day			
Transfluthrin				
Infant	1.4×10^{-4}	-	9.6×10^{-4}	1.1×10^{-3}
Toddler	1.7×10^{-4}	-	1.2×10^{-3}	1.3×10^{-3}
Child	7.4×10^{-5}	-	5.1×10^{-4}	5.8×10^{-5}
Piperonyl butoxide				
Infant	2.6×10^{-4}	-	1.8×10^{-3}	2.1×10^{-3}
Toddler	3.2×10^{-4}	-	2.2×10^{-3}	2.5×10^{-3}
Child	1.4×10^{-4}	-	9.5×10^{-4}	1.1×10^{-3}
Cyfluthrin				
Infant	3.2×10^{-5}	-	2.2×10^{-4}	2.5×10^{-4}
Toddler	3.9×10^{-5}	-	2.6×10^{-4}	3.0×10^{-4}
Child	1.7×10^{-5}	-	1.2×10^{-4}	1.3×10^{-4}

Scenario 2: Secondary exposure for the general public

Exposure assessment has been performed according to Biocides Human Health Exposure Methodology (version 1, October 2015) and ECHA Guidance on Exposure Assessment (Chapter 3, Part B+C).

Indirect secondary exposure could occur in the residential environment following the application of SPECIAL ONE by the non-professional user. Secondary exposure is considered to be relevant to the general public and is derived *via* inhalation, dermal and oral route (hand-to-mouth contact).

Inhalation exposure to volatilised residues of active substances is expected to occur for infants, toddlers, children and adults entering to areas that have been treated by the non-professional user.

Dermal exposure is expected to occur for the general public *via* direct contact to deposits of the biocide on the surface of contact after product application. Dermal exposure may occur to infants, toddlers and children crawling on floor or playing around treated surfaces for a

significant time period and adults accidentally touching contaminated surfaces with their bare hands.

Oral exposure is relevant for infants and toddlers, that exhibit a great deal of hand-to-mouth contact. Therefore, a part of residues present on the hands will be dislodged by saliva and eventually ingested.

Secondary exposure of the general public was calculated using ConsExpo Web, version 1.0.6. The models used for the secondary exposure assessment for the general public are described in detail in the following table.

Table 22. Overview of models used for secondary human health exposure assessment.

Secondary exposure: Infant, Toddler, Child, Adult		
Inhalation route	**Models**	**Population**
Vapours (volatilised residues)	HEEG opinion 13 - Assessment of inhalation exposure of volatilised biocidal active substances. ConsExpo Web, version 1.0.6 - Evaporation model, for volatilised product.	Infant Toddler Child Adult
Dermal route	**Model**	**Population**
Dermal contact with treated surfaces	ConsExpo Web, version 1.0.6 - RIVM Pest Control Products Fact Sheet, 2006 - Secondary exposure - Rubbing off.	Infant Toddler Child Adult
Oral route	**Model**	**Population**
Oral (hand-to-mouth contact)	ConsExpo Web, version 1.0.6 - RIVM Pest Control Products Fact Sheet, 2006 - Secondary exposure - Constant rate.	Infant Toddler

Assessment of Inhalation Exposure of Volatilised Biocidal Active Substances

Tier-1 screening tool

As a Tier-1 screening tool whether inhalation exposure can be neglected or should be included into the risk assessment, the following screening test which is based on the toddler representing the worst case is proposed in HEEG Opinion 13 (Assessment of Inhalation Exposure of Volatilised Biocide Active Substance).

Let mw and vp denote the molecular weight (in g/mol) and the vapour pressure (in Pa). For toddler (based on an inhalation rate of 8 m^3/24 hr and body weight of 10 kg) and using an AEL in mg a.s./kg bw/d, if

$0.328 \times [(mw \times vp) / AEL_{long\text{-}term}] \leq 1$

then risk from inhalation exposure for the toddler is negligible, otherwise inhalation exposure should be included in the risk assessment. If the inhalation risk for the toddler is negligible, then the inhalation risk for the infant, child and for the adult can also be considered to be negligible.

Tier-1 screening tool has been applied for each active substance as detailed in Table 23.

Table 23. Screening tool of inhalation exposure for each active substance.

Screening tool of inhalation exposure of volatilised biocidal active substances					
Active substance	**MW (g/mol)**	**vp (Pa)**	**$AEL_{long-term}$ (mg/kg bw day)**	**0.328 × mw x vp/$AEL_{long-term}$**	**Result**
transfluthrin	371.2	0.0009 (20°C)	0.01	10.96	>1 inhalation exposure has to be included in the risk assessment
piperonyl butoxide	338.43	1.33×10^{-5} (25°C)	0.2	0.0074	<1 risk from inhalation exposure for the toddler is negligible
cyfluthrin	434.3	0.21×10^{-5} (25°C)	0.02	0.015	<1 risk from inhalation exposure for the toddler is negligible

As a result of the application of Tier-1 screening tool, the inhalation exposure for the active substance transfluthrin has to be included in the risk assessment.

Inhalation exposure of volatilised residues of transfluthrin

Following the use of the biocidal product, it is assumed that deposited residues of active substances are revolatilised into the air. Inhalation exposure from revolatilised residues was assessed for infants, toddlers, children and adults.

In a conservative approach it is assumed that the indoor air is saturated with active substances vapours. In order to calculate inhalation exposure to pesticide vapours following application, the saturable air concentration must first be determined with the following equation: Saturation Vapour Concentration (SVC) = (Vapour pressure * Volume of air * Molecular weight) / (Gas constant * Temperature)

The body weights and short-term inhalation rates for infant, toddler, child and adult are implemented from the HEEG Opinion "Default human factor values for use in exposure assessments for biocidal products". The inhalation absorption is 100% for both active substances.

Exposure parameters and estimates are summarised below.

Parameters	Value	Justification
Exposed group	Infants, toddlers, children, adults	-
Transfluthrin endpoints	Vapour pressure: 9 x 10^{-4} Pa (20 °C) Molecular weight: 371.2 g/mol	Assessment Report of transfluthrin (The Netherlands, 2014).
Exposure duration	Acute exposure: 8 hours	Reasonable assumption.
Inhalation rate	<u>Short-term values</u> Infant: 0.84 m^3/h Toddler: 1.26 m^3/h Child: 1.32 m^3/h Adult: 1.25 m^3/h	HEEG Opinion "Default human factor values for use in exposure assessments for biocidal products". .
Inhalation absorption	100%	Assessment Report of transfluthrin (The Netherlands, 2014).
Body Weight	Infant: 8 kg Toddler: 10 kg Child: 23.9 kg Adult: 60 kg	HEEG Opinion "Default human factor values for use in exposure assessments for biocidal products".

The Saturation Vapour Concentration for transfluthrin is calculated in the following table:

Saturable Air Concentration	
Parameter	**Transfluthrin**
Vapour pressure (Pa)	9×10^{-4}
Volume of air (m^3)	1
Molecular weight (g/mol)	371.2
Gas constant (J/mol/K)	8.314
Temperature of the air (K)	293
Saturation Vapour Concentration (g/m^3)	**1.37×10^{-4}**

Inhalation esposure to transfluthrin is calculated with the following equation:
Inhalation exposure = SVC × short-term inhalation rate × exposure time × inhalation absorption / body weight

Inhalation exposure to volatilised residues of transfluthrin for the infant, toddler, child and adult are summarised in the following table.

Inhalation exposure to volatilised residues of transfluthrin						
Exposed group	**SVC (g/m^3)**	**Inhalation rate (m^3/h)**	**Exposure time (h)**	**Inhalation absorption**	**Body weight (kg)**	**Inhalation exposure (mg/kg bw/d)**
Infant	1.37×10^{-4}	0.84	8	100%	8	1.15×10^{-4}
Toddler		1.26			10	1.38×10^{-4}
Child		1.32			23.9	0.61×10^{-4}
Adult		1.25			60	0.23×10^{-4}

Dermal and oral exposure to residues on the floor – infants, toddlers, children, and adults.

Dermal exposure is expected to occur for the general public *via* direct contact to deposits of the biocide on the surface of contact after product application. Dermal exposure may occur to infants, toddlers and children crawling on floor or playing around treated surfaces for a significant time period.

Oral exposure is relevant for infants and toddlers, that exhibit a great deal of hand-to-mouth contact. Therefore, residues present on the hands will be dislodged by saliva and eventually ingested. Oral exposure has been calculated using the assumption of Bremmer *et al*. (2002) that 10% of the amount ending up on the skin of the infant is taken up *via* hand-mouth contact. The hands form about 20% of the total uncovered skin and it is assumed that 50% of the product that ends up on the hands is taken in orally due to hand-mouth contact. This means that *via* hand-mouth contact 10% of the external dermal exposure is ingested.

The dermal and oral exposure assessments have been performed using ConsExpo Web, version 1.0.6, considering the actual application rate of the product for targeted spot application (6 g/m^2).

The parameters used to calculate the secondary exposure for infant, toddler and child following a spot application of the biocidal product are described in Table 24. For details on calculations please refer to Annex 3.2.

Table 24. Parameters used to calculate the secondary exposure following a spot application with ConsExpo Web, version 1.0.6.

Description of Scenario 2: secondary exposure after targeted spot application ConsExpo Web, version 1.0.6.		
Parameter	**Value**	**Calculation/Justification**
Exposed group	General public: infant, toddler, child, adult	-
Product database	Pest control products	-
Product category	Sprays	-
Product	Targeted spot	-
Scenario	Post application	
Weight fraction substance	transfluthrin: 0.114% piperonyl butoxide: 0.213% cyfluthrin: 0.026%	Concentration of the three active substances in the biocidal product.
Dermal exposure		
Model	Direct product contact	-
Loading	Rubbing off	-
Exposure frequency	126 per year	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 36).
Exposed area (palms and backs of both hands)	Infant: 196.8 cm^2 Toddler: 230.4 cm^2 Child: 427.8 cm^2 Adult: 820 cm^2	HEEG Opinion "Default human factor values for use in exposure assessments for biocidal products".
Transfer coefficient	Infant/toddler/child: 0.2 m^2/hr Adult: 0.78 m^2/hr	Recommendation no. 12 of the BPC Ad hoc Working Group on Human Exposure: "New default values for indoor Transfer Coefficient" (agreed at the Human Health Working Group V on 22 November 2016).
Dislodgeable amount	0.27 g/m^2	Dislodgeable amount has been calculated as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 36), using the actual application rate of SPECIAL ONE (i.e. taking into account label instruction). According to RIVM report 320005002 (p.28), "some of the

		formulation ends up on the object being sprayed and some ends up on the surfaces around it. It is assumed that 15% of the total amount sprayed ends up on the floor next to the object that is being sprayed. The 30% of the amount on the floor surface is dislodgeable". Therefore, dislodgeable amount for SPECIAL ONE is calculated as follows: 6 g/m^2 x 15% x 30% = 0.27 g/m^2
Contact time	60 min/day	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 36).
Contacted surface	2 m^2	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 36).
Dermal absorption	50% for all three active substances	Default dermal absorption value for all three active substances, as proposed by EFSA Guidance on dermal absorption [EFSA Journal, 2017; 15(6): 4873] for dilutions of water-based formulations.
Body weight	Infant: 8 kg Toddler: 10 kg Child: 23.9 kg Adult: 60 kg	HEEG Opinion "Default human factor values for use in exposure assessments for biocidal products".
Oral exposure: hand-to mouth contact		
Model	Direct product contact	-
Loading	Constant rate	-
Ingestion rate	0.09 mg/min (product)	Calculated as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 28). "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 due to hand-mouth contact. This means that via hand-mouth contact 10% of the external dermal exposure is ingested. The ingestion rate can be calculated based on the assumption that from the total dermal exposure 10% is taken in orally due to hand-mouth

		contact." Therefore, the ingestion rate for SPECIAL ONE is calculated as follows: transfer coefficient x dislodgeable amount x 10% = (0.2 m^2/hr x 0.27 g/m^2 x 1000 x 0.1) / 60 = 0.09 mg/min
Exposure duration	60 min	Default, as reported in RIVM report 320005002/2006: "Pest Control Products Fact Sheet" (p. 38).
Oral absorption	100% for all three active substances	According to the Assessment Reports of the active substances: - transfluthrin (The Netherlands, 2014) - piperonyl butoxide (Greece, 2019) - cyfluthrin (Germany, 2016).
Body weight	Infant: 8 kg Toddler: 10 kg	HEEG Opinion "Default human factor values for use in exposure assessments for biocidal products".

Total secondary exposure

Systemic acute exposure to the active substances transfluthrin, piperonyl butoxide and cyfluthrin for the general public, as calculated by ConsExpo Web, version 1.0.6, are reported in the following table. For details on calculations please refer to Annex 3.2.

Table 25. Total secondary exposure to transfluthrin, piperonyl butoxide and cyfluthrin for the general public following a spot application of SPECIAL ONE.

Transfluthrin					
Exposed population	**Type of exposure**	**Inhalation exposure**	**Dermal exposure**	**Oral exposure**	**Total systemic exposure**
		mg/kg bw/day			
Infant	Acute	1.15×10^{-4}	3.8×10^{-3}	7.7×10^{-4}	4.6×10^{-3}
Toddler	Acute	1.38×10^{-4}	3.1×10^{-3}	6.2×10^{-4}	3.7×10^{-3}
Child	Acute	0.61×10^{-4}	1.3×10^{-3}	Not relevant for child	1.3×10^{-3}
Adult	Acute	0.23×10^{-4}	2.0×10^{-3}	Not relevant for adult	2.0×10^{-3} 3.92×10^{-3}

PBO					
Exposed population	**Type of exposure**	**Inhalation exposure**	**Dermal exposure**	**Oral exposure**	**Total systemic exposure**
		mg/kg bw day			
Infant	Acute	negligible	7.2×10^{-3}	1.4×10^{-3}	8.6×10^{-3}
Toddler	Acute	negligible	5.8×10^{-3}	1.2×10^{-3}	6.9×10^{-3}
Child	Acute	negligible	2.4×10^{-3}	Not relevant for child	2.4×10^{-3}
Adult	Acute	negligible	3.7×10^{-3}	Not relevant for adult	3.7×10^{-3}
Cyfluthrin					
Exposed population	**Type of exposure**	**Inhalation exposure**	**Dermal exposure**	**Oral exposure**	**Total systemic exposure**
		mg/kg bw/day			
Infant	Acute	negligible	8.8×10^{-4}	1.8×10^{-4}	1.1×10^{-3}
Toddler	Acute	negligible	7.0×10^{-4}	1.4×10^{-4}	8.4×10^{-4}
Child	Acute	negligible	2.9×10^{-4}	Not relevant for child	2.9×10^{-4}
Adult	Acute	negligible	4.6×10^{-4}	Not relevant for adult	4.6×10^{-4}

2.2.6.3 Risk characterisation for human health

The reference values for the active substances transfluthrin (Assessment report; The Netherlands, 2014), piperonyl butoxide (Assessment report; Greece, 2019) and cyfluthrin (Assessment report; Germany, 2016) that were used in risk characterisation for human health are described in the following table.

Transfluthrin	
$AEC_{inhalation}$	0.5 mg/m^3
$AEL_{medium\text{-}term}$	0.01 mg/kg bw/day
$AEL_{chronic}$	0.01 mg/kg bw/day
Piperonyl butoxide	
$AEC_{inhalation}$	6.2 mg/m^3
$AEL_{medium\text{-}term}$	0.2 mg/kg bw/day
$AEL_{long\text{-}term}$	0.2 mg/kg bw/day
Cyfluthrin	
$AEC_{inhalation}$	0.01 mg/m³

$AEL_{medium-term}$	0.02 mg/kg bw
$AEL_{long-term}$	0.02 mg/kg bw

Primary exposure is relevant to the non-professional user during the product spot application and to infants, toddlers and children being present in the room during product application. Indirect exposure to the general public will be through entering areas that have been treated by the non-professional user. Therefore, the risk characterisation will focus on primary exposure of non-professional users and general public and secondary exposure of the general public.

Regarding primary exposure, based on the assumption that the frequency of spray applications is calculated to be 9 times per person per year, the $AEL_{medium-term}$ is used in the risk characterisation of acute exposure of the non-professional user and the general public.

Regarding secondary exposure, the $AEL_{medium-term}$ is used in the risk characterisation of acute exposure because it is estimated that the duration of exposure is more important than a single event. The exposure time for the general public is high, eight hours for inhalation of the volatilised residues and a dermal contact of one hour for children, toddlers and infants playing or crawling on the treated floor..

Risk for professional users

SPECIAL ONE is not intended for professional users.

Risk for non-professional users

Summary of risk assessment for primary exposure

Table 26. Risk assessment results for human health, primary exposure.

Scenario	Exposed group	Total uptake (mg/kg bw/d)	Relevant AEL (mg/kg bw/d)	Exposure/AEL	Acceptable
Transfluthrin					
Scenario 1(i) Tier 1	adult	3.8×10^{-2}	$AEL_{medium-term}$: 0.01	3.8	**No**
Scenario 1(i) Tier 2	adult	2.1×10^{-3}		2.1×10^{-1}	**Yes**
Scenario 1(ii)	infant	1.1×10^{-3}		1.1×10^{-1}	**Yes**
	toddler	1.3×10^{-3}		1.3×10^{-1}	**Yes**
	child	5.8×10^{-4}		5.8×10^{-2}	**Yes**
Piperonyl butoxide					
Scenario 1(i) Tier 1	adult	7.0×10^{-2}	$AEL_{medium-term}$: 0.2	3.5×10^{-1}	**Yes**
Scenario 1(i) Tier 2	adult	4.0×10^{-3}		2.0×10^{-2}	**Yes**
Scenario 1(ii)	infant	2.1×10^{-3}		1.05×10^{-2}	**Yes**
	toddler	2.5×10^{-3}		1.25×10^{-2}	**Yes**

	child	1.1 x 10^{-3}		5.5 x 10^{-3}	**Yes**
Cyfluthrin					
Scenario 1(i) Tier 1	adult	1.7 x 10^{-3}	$AEL_{medium-term}$: 0.02	8.5 x 10^{-2}	**Yes**
Scenario 1(i) Tier 2	adult	4.8 x 10^{-4}		2.4 x 10^{-2}	**Yes**
Scenario 1(ii)	infant	2.5 x 10^{-4}		1.25 x 10^{-2}	**Yes**
	toddler	3.0 x 10^{-4}		1.5 x 10^{-2}	**Yes**
	child	1.3 x 10^{-4}		6.5 x 10^{-3}	**Yes**

For completeness, the mean event air concentrations during product application were estimated using ConsExpo and compared to the AEC established for the three active substances.

	Mean event air concentration mg/m³	**$AEC_{inhalation}$ mg/m³**	**Air concentration/ $AEC_{inhalation}$**	**Acceptable**
Transfluthrin				
Scenario 1(i) Tier 1 Adult	3.8 x 10^{-1}	0.5 mg/m³	0.76	**Yes**
Scenario 1(i) Tier 2 Adult	3.4 x 10^{-4}		6.8 x 10^{-4}	**Yes**
Scenario 1(ii) Tier 2 Infant, toddler, child	3.4 x 10^{-4}		6.8 x 10^{-4}	**Yes**
Piperonyl butoxide				
Scenario 1(i) Tier 1 Adult	7.2 x 10^{-1}	6.2 mg/m³	0.12	**Yes**
Scenario 1(i) Tier 2 Adult	6.3 x 10^{-4}		1.0 x 10^{-4}	**Yes**
Scenario 1(ii) Tier 2 Infant, toddler, child	6.3 x 10^{-4}		1.0 x 10^{-4}	**Yes**
Cyfluthrin				
Scenario 1(i) Tier 1 Adult	8.7 x 10^{-2}	0.01 mg/m³	8.7	**No**
Scenario 1(i) Tier 2 Adult	7.7 x 10^{-5}		7.7 x 10^{-3}	**Yes**
Scenario 1(ii) Tier 2 Infant, toddler, child	7.7 x 10^{-5}		7.7 x 10^{-3}	**Yes**

Conclusion for the primary exposure

An acceptable risk at Tier 1 level (ConsExpo default values) has been identified for the non-professional user (adult), following exposure to piperonyl butoxide and cyfluthrin. In case of transfluthrin, no risk is anticipated for adults when product-specific parameters have been considered (Tier 2).
Moreover, primary exposure to all three active substances is acceptable for infants, toddlers and children even when they are present in the room during product application.

Summary of risk assessment for secondary exposure

Table 27. Secondary exposure as a result of use – risk characterisation for human health

Transfluthrin					
Exposed population	**Type of exposure**	**Total exposure (mg/kg bw/d)**	**AEL (mg/kg bw/d)**	**Exposure/AEL**	**Acceptable**
Infant	Acute	4.6×10^{-3}	0.01	4.6×10^{-1}	**Yes**
Toddler	Acute	3.7×10^{-3}	0.01	3.7×10^{-1}	**Yes**
Child	Acute	1.3×10^{-3}	0.01	1.3×10^{-1}	**Yes**
Adult	Acute	2.0×10^{-3}	0.01	2.0×10^{-1}	**Yes**
Piperonyl butoxide					
Exposed population	**Type of exposure**	**Total exposure (mg/kg bw/d)**	**AEL (mg/kg bw/d)**	**Exposure/AEL**	**Acceptable**
Infant	Acute	8.6×10^{-3}	0.2	4.3×10^{-2}	**Yes**
Toddler	Acute	6.9×10^{-3}	0.2	3.45×10^{-2}	**Yes**
Child	Acute	2.4×10^{-3}	0.2	1.2×10^{-2}	**Yes**
Adult	Acute	3.7×10^{-3}	0.2	1.85×10^{-2}	**Yes**
Cyfluthrin					
Exposed population	**Type of exposure**	**Total exposure (mg/kg bw/d)**	**AEL (mg/kg bw/d)**	**Exposure/AEL**	**Acceptable**
Infant	Acute	1.1×10^{-3}	0.02	5.5×10^{-2}	**Yes**
Toddler	Acute	8.4×10^{-4}	0.02	4.2×10^{-2}	**Yes**
Child	Acute	2.9×10^{-4}	0.02	1.45×10^{-2}	**Yes**
Adult	Acute	4.6×10^{-4}	0.02	2.3×10^{-2}	**Yes**

Conclusion for the general public

All ratios Exposure/AEL for the three active substances of the biocidal product are well below 1. Therefore, regarding the indirect secondary exposure, the use of the biocidal product SPECIAL ONE is considered safe for all the exposed groups, as the risk is acceptable for all three active substances.

Combined scenarios

Combined exposure is expected for the adult non-professional user who is exposed *via* the inhalation and dermal route during the application of the product (primary exposure) and at the re-entry to treated areas following product application (secondary exposure), as well as for infants, toddlers and children who are exposed *via* the inhalation route during product application and *via* the inhalation, dermal and oral route at the re-entry to treated areas following product application.

Table 28. Combined exposure to the active substances transfluthrin, piperonyl butoxide and cyfluthrin for the adult non-professional user and the general public.

Transfluthrin						
Exposed group	**Primary exposure**	**Secondary exposure**	**Total exposure**	**AEL** medium-term	**Exposure/AEL**	**Acceptable**
	mg/kg bw/day					
Infant	1.1×10^{-3}	4.6×10^{-3}	5.7×10^{-3}	0.01	5.7×10^{-1}	**Yes**
Toddler	1.3×10^{-3}	3.7×10^{-3}	5.0×10^{-3}		5.0×10^{-1}	**Yes**
Child	5.8×10^{-4}	1.3×10^{-3}	1.88×10^{-3}		1.88×10^{-1}	**Yes**
Adult	2.1×10^{-3}	2.0×10^{-3}	4.1×10^{-3}		4.1×10^{-1}	**Yes**
Piperonyl butoxide						
Exposed group	**Primary exposure**	**Secondary exposure**	**Total exposure**	**AEL** medium-term	**Exposure/AEL**	**Acceptable**
	mg/kg bw/day					
Infant	2.1×10^{-3}	8.6×10^{-3}	1.07×10^{-2}	0.2	5.35×10^{-2}	**Yes**
Toddler	2.5×10^{-3}	6.9×10^{-3}	9.4×10^{-3}		4.7×10^{-2}	**Yes**
Child	1.1×10^{-3}	2.4×10^{-3}	3.5×10^{-3}		1.75×10^{-2}	**Yes**
Adult	4.0×10^{-3}	3.7×10^{-3}	7.7×10^{-3}		3.85×10^{-2}	**Yes**
Cyfluthrin						
Exposed group	**Primary exposure**	**Secondary exposure**	**Total exposure**	**AEL** medium-term	**Exposure/AEL**	**Acceptable**
	mg/kg bw/day					
Infant	2.5×10^{-4}	1.1×10^{-3}	1.35×10^{-3}	0.02	6.75×10^{-2}	**Yes**
Toddler	3.0×10^{-4}	8.4×10^{-4}	1.14×10^{-3}		5.7×10^{-2}	**Yes**
Child	1.3×10^{-4}	2.9×10^{-4}	4.2×10^{-4}		2.1×10^{-2}	**Yes**
Adult	4.8×10^{-4}	4.6×10^{-4}	9.4×10^{-4}		4.7×10^{-2}	**Yes**

Conclusion for combined scenarios

All ratios Exposure/AEL for the three active substances of the biocidal product are well below 1. Therefore, regarding combined scenarios, the use of the biocidal product SPECIAL ONE is considered safe for the adult non-professional user and the general public, as the risk is acceptable for all three active substances.

Local effects

There is no need to consider local effects separately, since SPECIAL ONE is not classified due to its local effects.

Conclusion

Risk characterisation for primary exposure of non-professional users has been calculated by the ratio from exposure, predicted using ConsExpo Web, and the AELs medium term of the

active substances (transfluthrin, piperonyl butoxide and cyfluthrin), for targeted spot application of the biocidal product SPECIAL ONE. An acceptable risk at Tier 1 level (ConsExpo default values) has been identified for the non-professional user (adult), following exposure to piperonyl butoxide and cyfluthrin. In case of transfluthrin, no risk is anticipated for adults when product-specific parameters have been considered (Tier 2).

Regarding the primary exposure of infants, toddlers and children being present in the room during product application, all ratios Exposure/AEL for the three active substances of the biocidal product are well below 1, therefore the use of the biocidal product SPECIAL ONE is considered safe also for the general public.

Risk characterisation for secondary exposure of the general public has been calculated by the ratio from exposure and the AELs medium term of the active substances (transfluthrin, piperonyl butoxide and cyfluthrin). Regarding the indirect secondary exposure, the use of the biocidal product is considered safe for all the exposed groups, as the risk is acceptable for all three active substances.

Risk for consumers via residues in food

SPECIAL ONE can be used in rooms were food are stored (e.g. food storage) or prepared (e.g. kitchens) but on in places were food is directly places, thus residues in food is unlikely to occur. However as to prevent potential exposure to food from the proposed uses the following mitigation measures are proposed:

- Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals.

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

A risk characterisation from combined exposure to several active substances is relevant for the biocidal product SPECIAL ONE as it contains three active substances: transfluthrin, piperonyl butoxide and cyfluthrin.

Based on the ECHA BPR Guidance[5], a Tiered approach was implemented. According to the guidance, the "Tier 1" of this method is an intermediary step to verify risk acceptability for each substance used in the product. The calculations for this level were performed in the sections presented above. This step is to be followed by "Tier 2", which involves assessing the combined exposure to the substances of the biocidal product.

According to the ECHA guidance, the "Tier 1" step calculations must be undertaken in accordance with the methodology that is currently used for the assessment of products. Each active substance is assessed in terms of risks to primary and secondary exposure following all the scenarios which are relevant to the product use. The decision-making criterion for acceptability of risk remains as in the case of quantitative risk: the estimated level of exposure to each substance must be lower than its AEL. The Hazard Quotient which is defined by the ratio of internal exposure and AEL has to remain below 1.

5 ECHA (2017) Guidance on the BPR: Volume III Human Health Assessment & Evaluation (Parts B+C) V2.1, ECHA-17-G-04-EN

Risk characterisation from combined exposure to transfluthrin, piperonyl butoxide and cyfluthrin has been calculated and results are reported in the previous sections named "*Risk for non-professional users*". The calculations presented above have shown acceptable risks (and hazard quotients) for all relevant scenarios for the active substances when considered separately (for details see above).

According to the ECHA Guidance on BPR, the "Tier 2" - level assessment of combined exposure to mixture is performed by concentration (dose) addition. This means that the effects of the active substances in the biocidal product are assumed to be concentration or dose-additive.

In the Assessment Report of piperonyl butoxide (2019) it is concluded that the substance is a potent inhibitor of cytochrome P450 enzymes (and of esterases) and this is the proposed mechanism of acting as a synergist together with pyrethrins and synthetic pyrethroids, inhibiting the enzymatic degradation of these.

For the aforementioned reasons, it cannot be stated that transfluthrin, piperonyl butoxide and cyfluthrin have completely different modes of action and only have to be considered separately. Therefore, the assessment of their combined exposure should be conducted.

According to the ECHA guidance on BPR, the Tier 2 assessment is performed with the same parameters as the first tier. The HQ for each substance is used to calculate a HI (Hazard Index) for the biocidal product according to the following method:

HI = Σ HQa.s.

The Hazard Quotient (HQ) is defined as the ratio estimation of internal exposure/AEL.
The HI is the sum of the HQs for each substance. HI should be ≤1 to show an acceptable risk related to the use of the biocidal product.

Based on this approach, the additive risks from all three active substances have been calculated for the non-professional user and the general public (primary exposure) as well as for the general public (secondary exposure).

Primary exposure: non-professional user and general public

Combined risks from all three active substances for the primary exposure of the non-professional adult user and the general public (additive effect).

Scenario 1: targeted spot application - non-professional user and general public					
Scenario/ Exposed group	**HQ transflutrin**	**HQ piperonyl butoxide**	**HQ cyfluthrin**	**HI product**	**Acceptable**
1(i)/adult	2.1×10^{-1}	2.0×10^{-2}	2.4×10^{-2}	**2.54×10^{-1}**	**Yes**
1(ii)/infant	1.1×10^{-1}	1.05×10^{-2}	1.25×10^{-2}	**1.33×10^{-1}**	**Yes**
1(ii)/toddler	1.3×10^{-1}	1.25×10^{-2}	1.5×10^{-2}	**1.58×10^{-1}**	**Yes**
1(ii)/child	5.8×10^{-2}	5.5×10^{-3}	6.5×10^{-3}	**7.0×10^{-2}**	**Yes**

Conclusion for the non-professional user

The simple addition of the AEL coverage (= hazard quotient, HQ) by all three active substances leads to an HI (sum of HQs for the three active substances) which is below 1 for the non-professional adult user and the general public.

Therefore, combined additive risk calculations for all three active substances show acceptable risks for the primary exposure of the non-professional adult user and the general public.

Secondary exposure: general public

Combined risks from all three active substances for the secondary exposure of the general public (additive effect).

Scenario 2: secondary exposure – general public						
Scenario/ Exposed group	**Type of exposure**	**HQ transflutrin**	**HQ piperonyl butoxide**	**HQ cyfluthrin**	**HI product**	**Acceptable**
Scenario 2 - infant	Acute	4.6×10^{-1}	4.3×10^{-2}	5.5×10^{-2}	5.58×10^{-1}	**Yes**
Scenario 2 - toddler	Acute	3.7×10^{-1}	3.45×10^{-2}	4.2×10^{-2}	4.47×10^{-1}	**Yes**
Scenario 2 - child	Acute	1.3×10^{-1}	1.2×10^{-2}	1.45×10^{-2}	1.57×10^{-1}	**Yes**
Scenario 2 - adult	Acute	2.0×10^{-1}	1.85×10^{-2}	2.3×10^{-2}	2.33×10^{-1}	**Yes**

Combined scenarios						
Scenarios/ Exposed group	**Type of exposure**	**HQ transflutrin**	**HQ piperonyl butoxide**	**HQ cyfluthrin**	**HI product**	**Acceptable**
Scenarios 1(ii) & 2 Infant	Acute	5.7×10^{-1}	5.35×10^{-2}	6.75×10^{-2}	6.91×10^{-1}	**Yes**
Scenarios 1(ii) & 2 Toddler	Acute	5.0×10^{-1}	4.7×10^{-2}	5.7×10^{-2}	6.04×10^{-1}	**Yes**
Scenarios 1(ii) & 2 Child	Acute	1.88×10^{-1}	1.75×10^{-2}	2.1×10^{-2}	2.27×10^{-1}	**Yes**
Scenarios 1(i) & 2 Adult	Acute	4.1×10^{-1}	3.85×10^{-2}	4.7×10^{-2}	4.96×10^{-1}	**Yes**

Conclusion for the general public

The simple addition of the AEL coverage (= hazard quotient, HQ) by all three active substances leads to an HI (sum of HQs for the three active substances) which is below 1 for all the exposed groups.

Therefore, combined additive risk calculations for all three active substances show acceptable risks for the general public.

Considerations on synergistic effects

In the Assessment Report of piperonyl butoxide (2019) it is concluded that the substance is a potent inhibitor of cytochrome P450 enzymes (and of esterases) and this is the proposed mechanism of acting as a synergist together with pyrethrins and synthetic pyrethroids, inhibiting the enzymatic degradation of these.

The ECHA BPR guidance states that "if synergistic effects have been identified or are suspected between the substances in the product, the risk related to use of the mixture will be considered acceptable if the value of HI is less or equal to a reference HI (HI_{ref})". The reference HI should be derived on a case-by-case basis on the available data and should be determined with the use of a safety factor which takes into account the magnitude of the suspected synergistic effect.

In the Guidance BPR guidance Vol III Parts B+C, Section 4.4.1, "Specific case of synergistic effects", it is recommended to use the worst-case pragmatic factor of 10 to estimate the reference hazard index. This proposal is based on the publication by Boobis et al., 2011 showing that the magnitude of synergy at low doses did not exceed the levels predicted by additive models by more than a factor of 4. More specifically, Boobis et al (2011) estimated the ratio of measured / predicted (based on dose addition) mixture toxicity and it was found to be less than 4 in six examined cases. In the same publication it is concluded that synergisms at low doses (i.e. close to the POD) are rather rare and that synergisms cannot be predicted quantitatively on the basis of the toxicity of components. This conclusion is also taken up by the OECD (2018).

Therefore, component-based human health risk assessment of the product considering potential synergistic effects of piperonyl butoxide cannot be reliably performed.

In addition, it has been demonstrated in mechanistic studies in rodents that upon repeated exposure, piperonyl butoxide induced hepatic cytochrome P450 enzymes, resulting, at high dose levels, in hepatocellular hypertrophy, cell proliferation and hepatotoxicity (Assessment report of piperonyl butoxide). Hence, it appears that piperonyl butoxide exhibits its toxic effects at doses at which synergistic effects in mammals do not occur, as it is shown that instead of enzymatic inhibition, an induction is occurring. As a consequence, it is not reasonable to perform risk characterisation taking into account simultaneously both additive and synergistic effects.

There is also evidence from the literature encouraging this approach. Giddings et. al., 2016 have determined that the highest assumed factor of synergism was 1.7, which was found at very high piperonyl butoxide:permethrin ratios. In the publication edited by D. Glynne Jones (1998) it is stated that there is no evidence indicating that piperonyl butoxide increases the low toxicity of pyrethrins and pyrethroids to mammals. Moreover, piperonyl butoxide is not known to synergistically enhance the toxicity of pyrethroids in mammals (Moores and Thom, 2018). Interactions of piperonyl butoxide with mammalian esterase systems have not been reported. This may be due to the fact that the liver expresses large quantities of carboxylesterases, probably to compensate for the fact that these are relatively inefficient enzymes (Testa B, Mayer JM, 2003).

Studies have shown that oral administration of 0.71 mg PBO/ kg bw in humans did not affect the metabolism of antipyrine, a drug which is metabolised by CYP enzymes (Conney AH *et al.,* 1972). It is therefore unlikely that the maximum predicted piperonly butoxide exposure of 0.0086 mg/kg bw/day (worst-case, acute exposure for infants, Scenario 2 of SPECIAL ONE) will lead to a significant impairment of transfluthrin and cyfluthrin metabolism.

On these grounds, no synergism between piperonyl butoxide, transfluthrin and cyfluthrin is expected to occur in realistic exposure situations. Thus, the combined additive risk calculations are already sufficient to cover all expected risks.

2.2.7 Risk assessment for animal health

Risk assessment for animal health is not necessary since exposure of animals is not expected (i.e. SPECIAL ONE is not intended to be applied to animals).

The following risk mitigation measures should be added in order to ensure the safety of pets and cats in particular.

- "Use only in areas inaccessible to children and animals, in particular cats."
- "Keep children and pets, particularly cats, away during treatment."
- "Remove or cover terrariums, aquariums and animal cages before application. Turn off aquarium air-filter while spraying."

2.2.8 Risk assessment for the environment

General consideration

Risk assessment for the environment has been performed according requirements and approaches of Biocidal Products Regulation (BPR) EU No 528/2012. Moreover, the assessment has been performed following ECHA Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C), Version 2.0, October 2017.

For the identification of substances of concern in the biocidal product, it has been observed that SPECIAL ONE:

- contains several substances that are not classified (i.e. not hazardous)
- contains substances that are classified for one or more endpoint(s), that are present in the biocidal product in concentration(s) below the cut-off values determined according to art. 11 of CLP Regulation
- does not contains substances that are hazardous for the environment according to CLP regulation, except for the three active substances i.e. transfluthrin, piperonyl butoxide and cyfluthrin.

Therefore, all substaces in the biocidal product that are not active substances can be realistically regarded as not relevant for the risk assessment of the biocidal product and they will not be further taken into account in the following evaluation.

The only relevant substances are the active substances and their respective relevant metabolites.

For the assessment of effects on environment, there was no need to generate new data/information, because the assessment has been performed for the active substances.

For these reasons, in the sections below the environmental hazard assessment shortly summarizes the information discussed in detail in the Assessment Report of transfluthrin, piperonyl butoxide and cyfluthrin. The use of data on active substances are covered by the Letters of Access.

2.2.8.1 Effects assessment on the environment

Summary of Ecotoxicological relevant values (PNECs etc.)

Transfluthrin			
	Value	**Unit**	**Note and reference**
$PNEC_{STP}$	0.057	mg/L	CAR active substance.
$PNEC_{aquatic\ Freshwater}$	1.75×10^{-6}	mg/L	ENV WGIV2017
$PNEC_{sediment\ of\ freshwater}$	0.00164	mg/kg dwt	ENV WGIV2017
	0.000356	mg/kg wwt	Converted with the following formula: PNEC µg/kg dwt / 4.6 = PNEC µg/kg wwt
$PNEC_{soil}$	0.1	mg/kg dwt	ENV WGIV2017
	0.0882	mg/kg wwt	Converted with the following formula: PNEC mg/kg dwt / 1.13 = PNEC mg/kg wwt This value has been used in the risk assessment.
$PNEC_{oral,birds}$	-		CAR active substance.
$PNEC_{oral,mammals}$	6.67	mg/kg feed	CAR active substance.
BCF_{fish}	1783	L/kg	CAR active substance.
$BCF_{earthworm}$	10452	L/kg	CAR active substance.
BMF	1		CAR active substance.
Metabolite of transfluthrin: TFB-OH			
	Value	**Unit**	**Note and reference**
$PNEC_{STP}$	-	-	PNEC value not available.
$PNEC_{aquatic\ Freshwater}$	0.1	mg/L	CAR active substance.
$PNEC_{sediment\ of\ freshwater}$	-	-	PNEC value not available.
$PNEC_{soil}$	-	-	PNEC value not available.
Metabolite of transfluthrin: TFB-COOH			
	Value	**Unit**	**Note and reference**
$PNEC_{STP}$	-	-	PNEC value not available.
$PNEC_{aquatic\ Freshwater}$	0.1	mg/L	CAR active substance.
$PNEC_{sediment\ of\ freshwater}$	-	-	PNEC value not available.
$PNEC_{soil}$	0.012	mg/kg **wwt**	AR updated 2019

PBO			
	Value	**Unit**	**Note and reference**
$PNEC_{STP}$	2.89	mg/L	CAR active substance.
$PNEC_{aquatic\ Freshwater}$	0.00148	mg/L	CAR active substance.
$PNEC_{sediment\ of\ freshwater}$	0.04292	mg/kg **dwt**	ENV WGV2019
	0.00933	mg/kg **wwt**	Converted with the following formula: PNEC mg/kg dwt / 4.6 = PNEC mg/kg wwt
$PNEC_{soil}$	0.098	mg/kg wwt	CAR active substance.
$PNEC_{oral,birds}$	10	mg/kg feed	CAR active substance.
$PNEC_{oral,mammals}$	20	mg/kg feed	CAR active substance.

BCF_{fish}	290	L/kg	CAR active substance.
$BCF_{earthworm}$	757	L/kg	CAR active substance.
BMF	1		CAR active substance.
Metabolite of PBO: M1			
	Value	**Unit**	**Note and reference**
$PNEC_{STP}$	-	-	PNEC value not available.
$PNEC_{aquatic\ Freshwater}$	0.0028	mg/L	CAR active substance.
$PNEC_{sediment\ of\ freshwater}$	Not available	-	-
$PNEC_{soil}$	0.098	mg/kg wwt	PNEC of parent compound, as reported in CAR of PBO.
Metabolite of PBO: M2			
	Value	**Unit**	**Note and reference**
$PNEC_{STP}$	-	-	PNEC value not available.
$PNEC_{aquatic\ Freshwater}$	0.0033	mg/L	CAR active substance.
$PNEC_{sediment\ of\ freshwater}$	Not available	-	-
$PNEC_{soil}$	0.098	mg/kg wwt	PNEC of parent compound, as reported in CAR of PBO.
Metabolite of PBO: M8			
	Value	**Unit**	**Note and reference**
$PNEC_{STP}$	-	-	PNEC value not available.
$PNEC_{aquatic\ Freshwater}$	Not relevant	-	-
$PNEC_{sediment\ of\ freshwater}$	Not available	-	-
$PNEC_{soil}$	0.098	mg/kg wwt	PNEC of parent compound, as reported in CAR of PBO.
Metabolite of PBO: M12			
	Value	**Unit**	**Note and reference**
$PNEC_{STP}$	-	-	PNEC value not available.
$PNEC_{aquatic\ Freshwater}$	0.0023	mg/L	CAR active substance.
$PNEC_{sediment\ of\ freshwater}$	Not available	-	-
$PNEC_{soil}$	0.098	mg/kg wwt	PNEC of parent compound, as reported in CAR of PBO.
$PNEC_{oral,birds}$	10	mg/kg feed	PNEC of parent compound, as reported in CAR of PBO.
$PNEC_{oral,mammals}$	20	mg/kg feed	PNEC of parent compound, as reported in CAR of PBO.
BCF_{fish}	89.5	L/kg	CAR active substance.
$BCF_{earthworm}$	15.8	L/kg	CAR active substance.
BMF	1		CAR active substance.
Metabolite of PBO: EN 1-101/4			
	Value	**Unit**	**Note and reference**
$PNEC_{STP}$	-	-	PNEC value not available.

$PNEC_{aquatic\ Freshwater}$	Not relevant	-	-
$PNEC_{sediment\ of\ freshwater}$	Not available	-	-
$PNEC_{soil}$	0.098	mg/kg wwt	PNEC of parent compound, as reported in CAR of PBO.

Cyfluthrin			
	Value	**Unit**	
$PNEC_{STP}$	0.00023	mg/L	CAR active substance.
$PNEC_{aquatic\ Freshwater}$	4.1×10^{-8}	mg/L	CAR active substance.
$PNEC_{sediment\ of\ freshwater}$	2.7×10^{-5}	mg/kg wwt	CAR active substance.
$PNEC_{soil}$	0.0882	mg/kg wwt	CAR active substance.
$PNEC_{oral,birds}$	-	-	CAR active substance.
$PNEC_{oral,mammals}$	6.67	mg/kg feed	CAR active substance.
BCF_{fish}	1822	L/kg	CAR active substance.
$BCF_{earthworm}$	13159	L/kg	CAR active substance.
BMF	2		CAR active substance.
Metabolite of cyfluthrin: FPB-acid			
	Value	**Unit**	
$PNEC_{STP}$	-	-	PNEC value not available.
$PNEC_{aquatic\ Freshwater}$	-	-	PNEC value not available.
$PNEC_{sediment\ of\ freshwater}$	-	-	PNEC value not available.
$PNEC_{soil}$	2.63	mg/kg wwt	CAR active substance.
Metabolite of cyfluthrin: permethric acid (DCVA)			
	Value	**Unit**	
$PNEC_{STP}$	-	-	PNEC value not available.
$PNEC_{aquatic\ Freshwater}$	-	-	PNEC value not available.
$PNEC_{sediment\ of\ freshwater}$	-	-	PNEC value not available.
$PNEC_{soil}$	2.8	mg/kg wwt	CAR active substance.

Transfluthrin

The following information is related to ecotoxicity of transfluthrin and its metabolites, as reported in the Assessment Report of tranfluthrin.

Atmosphere
In view of the proposed uses significant exposure of the environment via air is not expected.

Non compartment specific effects relevant to the food chain (secondary poisoning)
The concentration in fish is calculated to be 0.86 µg/kg, the concentration in worms is 8.43

µg/kg for indoor use and 2.37 µg/kg for outdoor use. In the absence of short-term or long-term dietary toxicity data for birds, a PNECoral, bird cannot be derived. However, for the PNECoral,bird to fall below the PEC, the NOEC should be lower than the PECoral,bird x 30, and should thus be < 0.03 mg/kg feed in case of fish and < 0.26 mg/kg feed (indoor use) and < 0.07 mg/kg feed (outdoor use) in case of earthworms. Following a similar reasoning for short-term tests, the LC50 should be < 3, 26 and 7 mg/kg feed, respectively (< PECoral,bird x 3000). In view of the absence of acute toxicity to birds at doses up to 1890 mg/kg bw, it is not expected that chronic toxicity levels as low as 0.03 mg/kg feed will be reached. Furthermore, there are several reasons to assume that the calculated PECs in water and soil (and therefore the concentrations in fish and earthworms) may be worst-case estimates. In view of this, a risk of secondary poisoning of birds is not expected. From the viewpoint of animal welfare, it is not considered justified to require further studies on birds.

Fate and distribution in the environment

Biodegradation in water
Transfluthrin is considered not readily biodegradable. In natural water/sediments systems, the dissipation of transfluthrin from the water phase was dominated by sorption, the DT50,water was < 7 days. The average DT50,system was 11.1 days, the DT50,sediment 14.1 days. Transfluthrin is therefore Not P.
Metabolites NAK 4452 (2,3,5,6-tetrafluorobenzyl alcohol; TFB-OH) and NAK 4723 (2,3,5,6-tetrafluorobenzoic acid; TFB-COOH) were detected in amounts > 10 % of AR in the water phase, maximum levels were 38 and 59% of AR, respectively. The same metabolites were found in sediment, maximum level was 2.9% of AR for TFB-OH and 26% of AR for TFB-COOH. Bound residues after 100 days were 4.4 and 7.9% of AR, mineralisation after 100 days was 3.0 and 12.6% of AR for the respective systems.
The DT50,system of metabolite TFB-OH was estimated to be < 14 days, a reliable estimate of the DT50, system of metabolite TFB-COOH could not be obtained because of few data points.
Analytical results obtained in the water/sediment system indicate that metabolite TFB-COOH has a low degradation rate and is persistent in a water/sediment system.

Biodegradation in soil
No experimental data are available for the biodegradation of transfluthrin in soil. On the basis of available information for other (synthetic) pyrethroids (deltamethrin, permethrin, acrinathrin, cyfluthrin and cypermethrin), the route of degradation in soil can be assumed to be similar to that in water/sediment systems, i.e. the main metabolites to be expected in soil are 2,3,5,6-tetrafluorobenzyl alcohol (TFB-OH; NAK 4452) and 2,3,5,6-tetrafluorobenzoic acid (TFBCOOH; NAK 4723). Due to limited similarity of transfluthrin with the other pyrethroids, the rate of degradation of transfluthrin cannot be estimated from the DT50-values of the other pyrethroids.

Abiotic degradation
Transfluthrin is hydrolytically stable at 25 °C, pH 5 and 7. The DT50,hydrolysis at pH 9, 25 °C is 14 days. There is no reliable information on aqueous or soil photolysis, but this is not considered necessary for risk assessment. Furthermore, the notifier submitted a waiver for not repeating an aqueous photolysis study on transfluthrin concluding that direct photolytic degradation in water is not expected to be a relevant route of degradation of transfluthrin in water.

Distribution
Due to the low water solubility and high log Pow of transfluthrin, the sorption to soil could not be determined in a batch equilibrium experiment. A log Koc of 4.7 L/kg obtained at pH

6 using the HPLC-method according to OECD 121, is used in the environmental risk assessment.

Piperonyl butoxide

Fate and distribution in the environment
Hydrolysis: Piperonyl Butoxide is hydrolytically stable in solution in the dark at 25 °C at pH 5, 7 and 9 and its half-life under these conditions is greater than 500 days.
Photolysis: Photolysis of Piperonyl Butoxide in water was investigated in a study (Selim, 1995, report no. P0594010, Doc IIIA 7.1.1.1.2) and Piperonyl Butoxide was found to rapidly photolize in aqueous solution with a half-life of 8.4 hours.
Phototransformation in air: The chemical lifetime of Piperonyl Butoxide in the troposphere was calculated using the computer program Atmospheric Oxidation program V 1. 92. Based on the molecular structure of Piperonyl Butoxide, a half-life of 3.597 hrs has been estimated considering a 24 hr-day (based on an overall OH rate constant of 107.0380 x 10-12 cm3/molecule sec and 0.5x106 OH radicals/cm3).
Ready biodegradability: Piperonyl Butoxide was investigated for its ready biodegradability in a CO2 evolution test based on OECD 301 B. Under the test conditions Piperonyl Butoxide is considered as not biodegradable within 28 days. Accordingly, PBO is classified as not readily biodegradable.
Aerobic soil degradation in soil: Two studies (GLP) have been considered as valid regarding the degradation of Piperonyl Butoxide in soil.
In Mayo, B.C., 1995, (report no. PBT 7/951484), the aerobic degradation of Piperonyl Butoxide has been tested in a sandy loam soil under dark conditions at 250C. Two major metabolites have been identified during the duration of the test. M8 was found at 9% of AR after 30 days and metabolite M12 was found at maximum of 16.6% at the same day. Moreover, three minor metabolites (M4, M11 and M16) have been observed at levels below 5% of AR.
Non-extractable 14C-residues increased steadily and accounted for 37 % of the applied radioactivity after 128 days. After that, their rate decreased to 20 % at day 285.

The second study (Derz, K., 2006 (report no. GAB-011/7-90)) was performed according to OECD-Guideline 307 under GLP. The aerobic degradation behaviour of Piperonyl Butoxide has been tested in three soil types (loamy sand, silt loam and sandy loam). Sampling was performed after the following incubation times: 0 d (immediately after application), 1 d, 3 d, 7 d, 14 d, 28 d, 50 d, 70 d, 97 d and 120 d after application.

Four major metabolites have been observed in the three soils. Metabolite M12 (EN 1-93/3) amounted up to 16.1 % (soil IME 01-A) and 19.4 % of the applied radioactivity (soil IME 02-A).
In LUFA soil detected in max amount of 7.5%. Metabolite M2 was found up to 14.4% after 70 days in LUFA 3A, metabolite EN 1-101/4 was detected in maximum amount of 6.6% of AR in LUFA 3A, metabolite M1 amounted up to 5.9% in LUFA 3A. M8 was found at 9% of AR after 30 days.
In general, a normalised geometric mean value of 58.3 days should be considered for risk assessment purposes.

Anaerobic soil degradation: The degradation of Piperonyl Butoxide has been investigated under anaerobic conditions and a DT50 of 144 days at test temperature has been calculated. Metabolite F (EN 1-101 was identified as the major metabolite reaching a maximum concentration of about 36% on day 90.

Adsorption desorption Study: The Koc values in four soils varied between 788 and 9397. According to the Koc correction for PBO (as agreed in WG ENV/V/2019),6 the arithmetic mean of 2506.5 mL/g (n=4) was used for risk assessment purposes.
Aerobic aquatic degradation: Piperonyl Butoxide's degradation investigated in two water/sediment systems. Piperonyl Butoxide was degraded from the entire system with DT50 values calculated to be 102.4 and 104.3 days (should be used for risk assessment purposes) in creek and pond respectively at 12°C.
One major metabolite (M2) was detected in a maximum value of 40.7% of AR after 100 days in creek water/sediment system (21.4% in pond system). M12 was found at max 6.6% of AR in the total pond system and metabolite M1 reached up to 7.6% of total AR in pond system.

Cyfluthrin

Effects assessment

Atmosphere
Cyfluthrin is not considered to be used as fumigant. The vapour pressure of the diastereomers of cyfluthrin ranges from 1.4 x 10-8 to 9.6 x 10-7 Pa, direct evaporation is not expected, consequently. The Henry's Constants between 3.2 x 10-3 and 1.9 x 10-1 Pa × m3 mol-1 at 20°C point to potential of volatility from water. The strong tendency to soil partition minimizes atmospheric entry. The chemical lifetime of cyfluthrin in the troposphere was estimated to be 44.4 hours.
The atmosphere is no compartment of concern as there is no accumulation of cyfluthrin in the air expected.

Fate and distribution in the environment

Biodegradation
The active substance cyfluthrin is considered to be neither readily nor inherently biodegradable on the basis of higher tier simulation studies in aquatic and soil systems.

Surface water
In surface water under aerobic conditions, cyfluthrin dissipated rapidly during the first days of incubation with a DT50 of 17.8 days (converted to an average EU outdoor temperature of 12°C). After day 7, dissipation clearly decelerated. No mineralisation to 14CO2 was observed. The metabolite FPB-acid was formed up to 70 % of applied radioactivity.
In water/sediment systems (two Dutch and two German systems), cyfluthrin was rapidly transferred to a high extent from water to sediment. In the entire system, cyfluthrin showed fast metabolism mainly via cleavage of the ester bond with DT50-values <10 days (converted to an average EU outdoor temperature of 12°C). Dissipation of cyfluthrin seemed to be predominantly caused by abiotic chemical processes. Depending on the label position of cyfluthrin and therefore on the metabolic pathway examined, mineralization to carbon dioxide took place to a limited (14-37%) or high extent (61-67%). Three relevant metabolites (>10% of applied radioactivity) were detected (FPB-acid: max. 44.5%, FPB-ald: max. 15.7%, permethric acid (DCVA): max. 47.6%). Permethric acid can be considered as persistent in water/sediment systems (DT50 385 days, converted to an average EU outdoor temperature of 12°C).

Soil
Cyfluthrin degraded moderately to slowly in aerobic laboratory soil studies. Half-lives from 11.4 to 67.9 days at 20°C were derived from the laboratory key studies (corresponding to

21.7 - 128.6 days at 12°C average EU outdoor temperature). Another key study, performed at 10°C, resulted in a DT50 of 53 days (equivalent to 43.6 days converted to 12°C). The extent of CO2 formation under aerobic conditions was 18% (after 365 days) – 48.5% (after 122 days) and depended on a high degree upon the water content of the soil samples In the dry soil only 18% CO2 were formed. The amount of bound residues formed was between 24% and 34%. Two relevant metabolites, FPB-acid (4-fluoro-3-phenoxy-benzoic acid) and DCVA (permethric acid) were identified. For FPB-acid a DT50 of 39.1 days at 20°C (corresponding to 74.2 days converted to 12°C) was calculated. In a further study investigating the fate of DCVA in two Japanese soils, half-lives between 11.7 and 61.8 days were determined for the 1R- and 1S-trans isomers of DCVA at 25°C. For 1R-, 1S-cis isomers of DCVA DT50 values ranged from 13.5 to 16 days. The longest half-life times were found for 1S, trans-DCVA, showing DT50 values of 23.1 days and 61.8 days at test temperature (25°C) (corresponding to 34.5 days and 92.2 days converted to 12°C). The DT50-modelling for DCVA amounted to 174.8 days at 12°C average EU outdoor temperature. In the two Japanese soils mineralisation rates of 20% CO2 were observed for DCVA, the bound residues ranged from 20 – 35%.
The results of the studies demonstrated that the major degradation path of cyfluthrin was hydrolysis at the ester linkage or diphenyl ether bond, hydroxylation at the phenoxy ring and hydrolysis of the cyano group leading to the formation of the major metabolites FPB-acid and DCVA. Further degradation mainly resulted in generation of CO2 and bound residues.
Under anaerobic conditions cyfluthrin decreased from 39.1% after 30 days to 21.3% after 60 days. Mineralisation was not detected. The amount of bound residues increased to 64% after 60 days. FPB-acid was identified as relevant metabolite.

Abiotic Degradation
Cyfluthrin is stable at pH 4 and relatively stable at pH 7. The hydrolysis rates increase at pH 9, mean half-life of around 2.6 days was calculated at EU outdoor temperature of 12°C. Significant hydrolysis products were 4-fluoro-3-phenoxy benzaldehyd (FPB-ald, FCR 1260) and permethric acid (DCVA). While FPB-ald was found stable to hydrolysis, the hydrolysis half-life for DCVA is greater than 1 year.
In pure water cyfluthrin is directly photolytically degraded with half-lives between 2 and 60 days in dependence on degree of latitude and seasonal conditions. Photolysis of cyfluthrin results in rapid cleavage of the ester bond and formation of FPB-ald and 4-fluoro-3-phenoxybenzoic acid (FPB-acid), which are formed sequentially. However, indirect photodegradation should also contribute to degradation processes in the environment. In conclusion, solar radiation will contribute to the degradation of cyfluthrin in aquatic systems.
A photodegradation study of cyfluthrin in one soil provides an indication that cyfluthrin adsorbed to soil will be readily degraded if exposed to sunlight. A biphasic degradation pattern was derived with half-life of 12.3 days (converted to an average EU outdoor temperature of 12°C).
In air cyfluthrin will be degraded by indirect photodegradation.

Distribution and Mobility
Based on the adsorption/desorption study, cyfluthrin could be classified as being immobile in soil. The substance is strongly adsorbed to the soil (arithmetic mean KaOC: 123930 mL/g). The value for arithmetic mean of KdOC is 122146 mL/g. Cyfluthrin as well as the distribution of isomers of cyfluthrin (diastereomers I-IV) remained unchanged in the soil. The KOC of DCVA is 133.7 mL/g. Therefore, the metabolite is classified as mobile in soil.

DCVA was stable during the adsorption/desorption study. The metabolite FPB-acid was found to be mobile in soil (KOC = 73 mL/g).

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

Information related to the ecotoxicity of the biocidal product is not available.

Further Ecotoxicological studies

Further Ecotoxicological studies are not available.

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

Available information effects on terrestrial organisms is detailed in previous sections.

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

No data available. SPECIAL ONE is not in the form of bait or granules.

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

No data available. SPECIAL ONE is not in the form of bait or granules.

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

Due to the pattern of use of SPECIAL ONE, a refinement higher tier field studies (soil and/or water-sediment compartment) are not required since large portion of specific habitat (such as water body, wetland, forest or field) are not treated with the product.

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

The main emission route of the product is via wastewater from sewage treatment plants after the cleaning of the treated area or the applicators clothing. There are no direct emissions to surface water or sediment. Consequently, aquatic or sediment organisms are not directly exposed to the active substances. Direct exposure of the air compartment is considered negligible due to the half-life of active substances in the trophosphere.
Soil and groundwater maybe indirectly contaminated via the land application of sewage sludge. Direct exposure of the soil compartment is also foreseen for the outdoor uses (application in ants/nest wasps nest). The concentration of active substances in porewater

of agricultural soil has been calculated to provide an indication for potential groundwater contamination risk.

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

Further studies on fate and behaviour in the environment are not available.

Leaching behaviour (ADS)

Information on leaching behaviour is not available. Transflutrin, piperonyl butoxide and cyfluthrin are strongly adsorbed to soil (trasfluthrin Koc = 50119, 79433 L/kg ; piperonyl butoxide Koc = 3745.3 L/kg and cyfluthrin Koc = 123930 mL/g). Therefore, leaching is not expected.

Testing for distribution and dissipation in soil (ADS)

No other information is available respect to that reported in section "2.2.8.1 Effects assessment on the environment".

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

No other information is available respect to that reported in section "2.2.8.1 Effects assessment on the environment".

Testing for distribution and dissipation in air (ADS)

No other information is available respect to that reported in section "2.2.8.1 Effects assessment on the environment".

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)

SPECIAL ONE is not sprayed near to surface waters.

Acute aquatic toxicity

Conclusion used in Risk Assessment – Acute aquatic toxicity	
Value/conclusion	Aquatic Acute 1 H400: Very toxic to aquatic life.
Justification for the value/conclusion	The classification system for mixtures covers all classification categories which are used for substances, i.e. categories Acute 1 and Chronic 1 to 4. In order to make use of all available data for purposes of classifying the aquatic environmental hazards of the mixture, the following is applied where appropriate: The 'relevant components' of a mixture are those which are classified 'Acute 1'or 'Chronic 1' and present in a concentration of 0,1 % (w/w) or greater, and those which are classified 'Chronic 2', 'Chronic 3' or 'Chronic 4' and present in a concentration of 1 % (w/w) or greater, unless there is a presumption (such as in the case of highly toxic components (see section 4.1.3.5.5.5 of CLP Regulation)) that a component present in a lower concentration can still be relevant for classifying the mixture for aquatic environmental hazards. Generally, for substances classified as 'Acute 1' or 'Chronic 1' the concentration to be taken into account is (0,1/M) %. The approach for classification of aquatic environmental hazards is tiered, and is dependent upon the type of information available for the mixture itself and for its components. Elements of the tiered approach include: - classification based on tested mixtures, - classification based on bridging principles, - the use of 'summation of classified components' and/or an 'additivity formula'. The classification of SPECIAL ONE was obtained as reported in section "4.1.3.5. Classification of mixtures when toxicity data are available for some or all components of the mixture", Annex I of CLP Regulation. Relevant toxicity data used are related to transfluthrin, piperonyl butoxide and cyfluthrin; the three active substances.

Data waiving	
Information requirement	Acute aquatic toxicity
Justification	According to the specific adaptation rules described in Annex III of BPR, tests on the product were not conducted because there are valid data available on each of the components in the mixture sufficient to allow the classification according to the rules of CLP Regulation (EC) n. 1272/2008.

Chronic aquatic toxicity

Conclusion used in Risk Assessment- Chronic Aquatic toxicity	
Value/conclusion	Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects.
Justification for the value/conclusion	The classification system for mixtures covers all classification categories which are used for substances, i.e. categories Acute 1 and Chronic 1 to 4. In order to make use of all available data for purposes of classifying the aquatic environmental hazards of the mixture, the following is applied where appropriate: The 'relevant components' of a mixture are those which are classified 'Acute 1'or 'Chronic 1' and present in a concentration of 0,1 % (w/w) or greater, and those which are classified 'Chronic 2', 'Chronic 3' or 'Chronic 4' and present in a concentration of 1 % (w/w) or greater, unless there is a presumption (such as in the case of highly toxic components (see section 4.1.3.5.5.5 of CLP Regulation)) that a component present in a lower concentration can still be relevant for classifying the mixture for aquatic environmental hazards. Generally, for substances classified as 'Acute 1' or 'Chronic 1' the concentration to be taken into account is (0,1/M) %. (For explanation M-factor see section 4.1.3.5.5.5.) The approach for classification of aquatic environmental hazards is tiered, and is dependent upon the type of information available for the mixture itself and for its components. Elements of the tiered approach include: - classification based on tested mixtures, - classification based on bridging principles, - the use of 'summation of classified components' and/or an 'additivity formula'. The classification of SPECIAL ONE was obtained as reported in section "4.1.3.5. Classification of mixtures when toxicity data are available for some or all components of the mixture", Annex I of CLP Regulation. Relevant toxicity data used are related to transfluthrin, piperonyl butoxide and cyfluthrin; the three active substances.

Data waiving	
Information requirement	Chronic aquatic toxicity
Justification	According to the specific adaptation rules described in Annex III of BPR, tests on the product were not conducted because there are valid data available on each of the components in the mixture sufficient to allow the classification according to the rules of CLP Regulation (EC) n. 1272/2008.

Aquatic bioconcentration

Conclusion used in Risk Assessment –Aquatic bioconcentration	
Value/conclusion	Transfluthrin, piperonyl butoxide and cyfluthrin do not meet the B or vB screening criteria.
Justification for the value/conclusion	**Transfluthrin** *Transfluthrin* The experimentally derived BCF for fish is 1704 to 1861 L/kg ww, based on Total Radioactive Residues in whole fish. *Metabolites* Both metabolites TFB-OH and TFB-COOH are not expected to bioaccumulate: the estimated log Pow is 1.85 for TFB-COOH and 1.54 for TFB-OH1. Epiwin calculates for DCVA a log Pow of 3.38. On basis of this information the B and vB criterion is not fulfilled for transfluthrin and its metabolites. **Piperonyl butoxide** The fish bioconcentration factor (BCF_K) for Piperonyl Butoxide was experimentally determined to be 290 L/kg (whole fish; 1992; A7.4.3.3), e.g. lower than the both trigger values of 2000 and 5000 L/kg. Thus, nor B neither vB criterion was found to be fulfilled for Piperonyl Butoxide. Regarding Piperonyl Butoxide metabolites, no testing data on their bioaccumulation potential have been provided. However, considering that the log K_{OW} values estimated via QSAR analysis are below the trigger of 4.5 and no specific uptake mechanism apart from lipophilic partitioning is known or suspected, Piperonyl Butoxide metabolites were considered as not fulfilling the B or vB criterion. **Cyfluthrin** The measured bioconcentration factor in fish of 1822 L/kgwet fish was lower than the calculated values for the four isomers of 21062 to 27164 L/kgwet fish. Based on the available data, neither the B-criterion (BCF > 2000 L/kgww) nor the vB-criterion (BCF > 5000 L/kgww) are fulfilled. *Metabolites*

	No bioaccumulation studies are available for the metabolites. The bioaccumulation study for the active substance suggests that bioaccumulation is only relevant for the parent substance. By estimating the octanol-water partitioning coefficient with KOWWIN (EPIWEB v4.1), a log Kow value of 3.4 for DCVA, 3.3 for FPB-acid and 3.1 for FPB-ald has been calculated. Based on screening criteria, the metabolites FPB-acid, FPB-ald and permethric acid (DCVA) are therefore not B and vB.

Data waiving	
Information requirement	Aquatic bioconcentration.
Justification	Data suggest that transfluthrin, piperonyl butoxide and cyfluthrin do not meet the B or vB screening criteria.

Synergistic effects between the components of the product

Mode of action of natural pyrethrins, synthetic pyrethroids and Piperonyl Butoxide has been reviewed and analyzed by Endura S.p.A [6] with regard to the synergistic effect that can be achieved in target species and non-target species such as other arthropods, aquatic organisms and mammalian organisms. The full assessment report [4] has been attached in section 8.7.1 of IUCLID.

Synergistic effect in terrestrial non-target arthropods

Summary

The mode of action of PBO implies that the corresponding enzyme systems of non-target insects may also be affected. This has been shown in several experiments, which are further described below.

Relevant data

EPA suggested a figure of 11x for PBO synergism of terrestrial target insects.
However, since beneficial insects are not routinely selected by insecticides to the same extent as target insects and have not in general built up the levels of metabolic enzymes to the extent of target insects, exposure to PBO would not be expected to confer as high a level of synergism.
The honey bee (*Apis mellifera*) is a global pollinator of many crop plants, and as such will inadvertently encounter insecticide exposure. Since honey bees also have P450s and esterases as defence enzymes, it could be expected that PBO will sensitise these insects in common with pest insects. In general, pyrethrins and synthetic pyrethroids are regarded

6 Moores G., Thom E. Piperonyl butoxide: Synergism with natural pyrethrins and synthetic pyrethroids. Version 1.0. Endura S.p.A. 14 June 2018.

as harmful to honey bees, but tau-fluvalinate is relatively non-toxic with an LD50 of around 9 µg per bee (Johnson et al., 2006 [7]). In common with many insects the P450 enzyme system was invoked to provide defence against pyrethroids when synergism was observed between P450-inhibiting fungicides and pyrethroids (Pilling and Jepson, 1993). If honey bees were subjected to a (just) sub-lethal dose of PBO followed by tau-fluvalinate, the LD50 was reduced from 9450 ng to 9.64 ng, a synergism ratio of 980 (Johnson et al., 2006 [7]).
If an intact honey bee abdomen was incubated in PBO, it was found that 50% of the P450 activity was inhibited.
Semi-purified esterase from honey bee was found incapable of interacting with tau-fluvalinate, unlike the resistance-associated esterase from Myzus persicae (Alptekin et al, 2015 [8]).
Many studies (like those discussed above) were using concentrations of PBO unlikely to be encountered in field conditions. In a field study conducted in Poland over 2 seasons, 4 isolator cages containing a hive were placed in oilseed rape fields and subjected to a spray regime comparing a field dose of tau-fluvalinate and a field dose of tau-fluvalinate + PBO, no discernable effect was found on bee mortality or behaviour (Moores et al, 2012 [9]).
Indeed, it has been found in a laboratory study with a formulation containing pyrethrins and PBO, that an LC50 of 5.1 µg formulation per bee was determined, equivalent to 0.3 µg pyrethrins/bee (Patnaude, 2014 [10]). The LC50 of PBO alone to honey bees was determined to be 294 µg/bee (ECHA, 2017 [**Errore. Il segnalibro non è definito.**]). The LC50 for pyrethrins alone is reported to be 0.022 µg/bee (EFSA, 2013 [11]). Consequently, an apparent 10-fold reduction of the toxicity was observed for the synergized formulation. Although the LC50 values of PBO and pyrethrins alone were determined in separate studies, it appears from this comparison that the addition of PBO has not overly sensitised the bees to the effects of the pyrethrins.

Synergistic effect in aquatic organisms

Summary

Aquatic organisms have different enzyme systems than insects. However, pyrethrins and pyrethroids and to a lesser extent PBO, are toxic to aquatic organisms. Consequently,

7 Johnson RM, Wen Z, Schuler MA, Berenbaum MR, Mediation of pyrethroid insecticide toxicity to honey bees (Hymenoptera: Apidae) by cytochrome P450 monooxygenases, J Econ Ent 99: 1046-1050 (2006).
8 Alptekin S, Philippou D, Field L, Wegorek P, Zamojska J, Moores G, Insecticide synergists: good or bad for honey bees? Outlooks on Pest Management 26: 75-77 (2015).
9 Moores GD, Wegorek P, Zamojska J, Field L, Philippou D, The effect of a piperonyl butoxide/ tau-fluvalinate mixture on pollen beetle (Meligethes aeneus) and honey bees (Apis mellifera). Pest Manag Sci 68: 795-800 (2012)
10 Patnaude, M. (2014) Evergreen® Crop Protection EC 60-6 – Acute Contact Toxicity Test with the Honey Bee (Apis mellifera). Smithers Viscient, MA, USA, unpublished report No. 13513.6161.
11 EFSA, Conclusion on the peer review of the pesticide risk assessment of the active substance pyrethrins, European Food Safety Authority (EFSA), Parma, Italy, 2013.

synergistic effects have also been studied in aquatic organisms, which are further described below.

Relevant data

It can be important to consider whether the ratio of PBO: insecticide or the absolute concentration of PBO is the critical factor in calculating synergism. Historically, and especially with pyrethrins, it has tended to be a ratio; but since the synergist is inhibiting an enzyme that would otherwise metabolise the insecticide, the absolute concentration of PBO could be seen as the more critical factor (Wickham, 1998).
Mortality of H. azteca has been assessed in creeks surrounding Sacramento, California, following aerial spraying of pyrethrins and PBO to control West Nile Virus. This resulted in PBO concentrations of 2 – 4 µg/L, which in laboratory tests was found to be sufficient to confer a 1.6-fold increase in the toxicity of bifenthrin. Further laboratory assays demonstrated that the 10 day LC50 of permethrin could be decreased from around 14 µg/g to 4 µg/g (synergism factor of 3.5) if PBO were present at 55 µg/L, and the 10 day LC50 of bifenthrin from 0.6 µg/g to 0.25 µg/g (synergism factor of 2.4) if PBO were present at 25 µg/L (Weston et al, 2006 [12]).

A series of acute toxicity tests with the amphipod Hyalella azteca was performed to quantify the synergistic effect of PBO on pyrethrins toxicity. Concentrations of PBO <4 mg/L caused no toxicity enhancement, whereas toxicity increased with PBO concentrations between 4 mg/L and 15 mg/L. Additive toxicity calculations showed that true synergism accounted for an increase in pyrethrins toxicity of 1.4-fold to 1.6-fold and varied only slightly between 4mg/L and 15 mg/L PBO (Giddings, 2016 [13]).

EPA (2017 [14]) concluded that the PBO-synergized toxicity enhancement factor for aquatic invertebrates was 1.7X.
A similar study was conducted to measure the synergism of PBO to pyrethrins toxicity using rainbow trout, Oncorhynchus mykiss (EPA, 2017 [14]). A 3.2X factor was derived from toxicity data at a 81.3:1 PBO:Pyrethrins ratio, which is far above the usual 10:1 ratio used in formulated products and an estimate made at a 10:1 ratio did not show synergism. Although the 1.0X factor shows a lack of synergism, it is included in the FOS estimate to show that the 3.2 value is not definitive but the true value likely lies somewhere in the range of 1.0-3.2X.
Based on these data interpretations, 1.7-fold was determined as the best estimate for the FOS by PBO with pyrethrins for aquatic invertebrate risk calculations. A value of 1.0-3.2X was determined for fish. This is substantially less than that for terrestrial invertebrates,

12 Weston DP, Amweg EL, Mekebri A, Ogle RS, Lydy MJ, Aquatic effects of aerial spraying for mosquito control over an urban area, Environ Sci Technol 40: 5817-5822 (2006)
13 Giddings J, SYNERGISTIC EFFECT OF PIPERONYL BUTOXIDE ON ACUTE TOXICITY OF PYRETHRINS TO HYALELLA AZTECA, Environmental Toxicology and Chemistry, Vol. 9999, No. 9999, pp. 1–6 (2016)
14 Environmental Protection Agency, Piperonyl butoxide (PBO): preliminary ecological risk assessment for registration review (EPA 51-03-6). Washington, US Environmental Protection Agency (2017).

probably as a result of the intrinsic sensitivity of aquatic invertebrates for pyrethrins (EPA, 2017).
When mixtures of pyrethrin and PBO are applied over wetlands for mosquito control, there is concern that deposition may contaminate the wetlands and result in mortality of aquatic invertebrates. However, when tests were carried out in Sacramento, although some sediments revealed levels of pyrethrin and PBO following repeated spraying (34.5 ng/g and 14.9 ng/g respectively), mortality of aquatic invertebrates (Daphnia magna and Callibaetis californicus) were unchanged between those exposed to the sprays and those in a protected environment (Lawler et al, 2008 [15]).
It should also be remembered that with other classes of actives, the effects of PBO in an aquatic environment may not be synergistic and may even be antagonistic. Using Ceriodaphnia dubai, Daphnia magna and Daphnia pulex, coadministration of PBO with organophosphates requiring oxidative activation (parathion, methyl parathion, diazinon and malathion) it was found that the presence of PBO reduced acute toxicity. Further, when coadministered with organophosphates not requiring activation (dichlorvos, chlorfenvinphos and mevinphos) the presence of the PBO did not significantly increase toxicity (Ankley et al, 1991 [16]).

Relevance of synergistic effects against non-target organisms

The synergistic effect of PBO - both in susceptible as well as in resistant insects - results from the inhibition of enzymes, which are then no longer available to detoxify insecticides such as pyrethrins and pyrethroids.
It is important to understand whether synergistic effect can be observed in non-target species and if yes, whether they must be considered for mixture toxicity assessments under the European regulatory frameworks. Here, synergistic effects are generally considered relevant when they are greater than a factor of 5X for environmental effects (ECHA, 2014 [17]) and greater than a factor 2X for effects in mammalian organisms (DG SANCO, 2012 [18]).

Conclusion

In conclusion, synergistic effects towards non-target organisms should not be considered relevant with regard to mixture toxicity assessments under the European regulatory frameworks.

15 Lawler SP, Dritz DA, Johnson CS, Wolder M, Does synergised pyrethrin applied over wetlands for mosquito control affect Daphnia magna zooplankton or Callibaetis californicus mayflies? Pest Manag Sci 64: 843-847 (2008)
16 Ankley GT, Dierkes JR, Jensen DA, Peterson GD, Piperonyl butoxide as a tool in aquatic toxicological research with organophosphate insecticides, Ecotox Environ Safety 21: 266-274 (1991)
17 ECHA Guidance on the Biocidal Products Regulation, Volume IV: Environment, Part A: Information Requirements, Version 1.1, November 2014.
18 DG SANCO, Guidance document on the assessment of the equivalence of technical materials of substances regulated under Regulation (EC) No 1107/2009; 2012.

Endocrine-distrupting properties for environment: screening for co-formulants

Conclusion of ED assessment for co-formulants

Screening of endocrine-distruptors properties of co-formulants has been performed using the information provided in the SDSs by the supplier of the co-formulant and consulting reliable literature sources. The information sources consulted are detailed in above table. Overall, the product does not contain co-formulants with endocrine distruptor properties for environment.

Summary

The assessment of the endocrine-disrupting properties of the co-formulants in the biocidal product SPECIAL ONE has been performed according to the instructions described in the document agreed in the Coordination Group (CG-34-2019-02 AP 16.5 e-consultation ED potential of co-formulants).

To assess the endocrine-disrupting (ED) potential of each co-formulant in the biocidal product, a step-wise approach was performed, which included screening of relevant databases and searching for freely available information in reliable literature sources.

The information sources and the databases consulted as well as the results of the screening for endocrine-disrupting properties of the co-formulants in the biocidal product SPECIAL ONE are presented in detail in the Confidential Annex.

Conclusion of endocrine-disrupting assessment for co-formulants

The endocrine-disrupting assessment for the co-formulants of the biocidal product SPECIAL ONE has been performed using the information provided in the SDS by the supplier of the co-formulant and searching reliable literature sources. The information sources and the databases consulted are detailed in the Confidential Annex. Based on existing knowledge and available scientific information, there is no indication of concern regarding endocrine-disrupting properties of any of the co-formulants, hence the biocidal product SPECIAL ONE is not an endocrine disruptor.

2.2.8.1.1 Exposure assessment

General aspects

SPECIAL ONE is a biocidal product used as insecticide, containing the active substances: Transfluthrin 0.114% w/w, Piperonyl butoxide 0.213% w/w and Cyfluthrin 0.026% w/w (% w/w technical grade active ingredients, TGAI). The product is an aerosol and it is a ready to use product (RTU).

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1 – Spot application indoor wasps nest Scenario 2 – Crack and crevice application crawling
ESD(s) used	Emission Scenario Documents (for Product Type 18) for Insecticides, Acaricides and Products to Control Other Arthropods for Household and Professional use; OECD July 2008. Technical Agreements for Biocides (TAB) Version 2.0, August 2018) & (TAB ENV 2.1, December 2019)
Distribution in the environment	Calculated based on the ESDs for PT18 and on Guidance on the Biocidal Products Regulation, Volume IV Environment - Assessment & Evaluation, Part B+C, Version 2.0 (October 2017). Fate and distribution in the STP was estimated using Simple Treat 4 (EUSES 2.2.0).
Groundwater simulation	The concentration of active substances in porewater of agricultural soil has been calculated to provide an indication for potential groundwater contamination risk. Higher tier modelling, using FOCUS-PEARL was performed
Life cycle steps assessed	Scenarios 2, 4, Production: No Formulation: No Use: Yes Service Life: No

Production of SPECIAL ONE is an industrial formulation process. Exposure estimation for the formulation of SPECIAL ONE was not performed since:

- ✓ releases into the environment can not take place from formulation process, since in the formulation plants typically automated equipment is used to add the formulation ingredients and to fill the formulated product into the respective vessels (closed system). Since a close system is used, no emission is expected; in any case eventual (i.e. accidental or due to maintenance) releases of the product are managed as waste;
- ✓ emissions from the product formulation are considered less relevant (since potentially covered by other legislations) compared to emissions from the application – and in service phase of the product, as reported in "Guidance on the Biocidal Products Regulation, Volume IV Environment – Part B Risk Assessment, version 1.0".

Exposure assessment of the product has been performed for the claimed Uses by the applicant under the following Scenarios, as presented in the table below:

Exposure scenarios
Scenario 2 – Spot application indoor wasps nest, indoor application
Scenario 4 – Crack and crevice application crawling, indoor application

Emission estimation

General aspects for the emission calculations:

- Special One is used by non-professional users and it is applied using a jet valve spray can, with two different dispensing nozzles. Depending on the type of jet valve, there are two possible spray rates for the product:
  - a spray rate of 15g/s when the product is used for wasps nest, with a special jet valve, where,
  - a spray rate of 1.5g/s when the product is used for all other claimed uses with a simple jet valve.
- For all Scenarios applied indoors, [redacted], intended uses considers applications in <u>domestic premises only</u>.

- The estimations of environmental emissions of Special One indoors are based on targeted, crack and crevices treatment approach.

- In the claimed targeted applications, crack and crevice scenario (either spot or barrier treatment), the product is only sprayed on targeted spots with a limited area. The total surface treated in crack and crevices application, depending on the way the product is applied, is either 2.0 m^2 in spot applications, or >2m^2 in larger scale treatments (i.e., barrier treatments) (TAB, ENV 142 & 144 ENV v.2.1, December 2019).

- For the cleaning efficiency, Fce, for RTU aerosol spray, the max % exposed to cleaning area is 3, for the crack and crevice application (including foams), whereas for RTU aerosol surface application is 20 (TAB, ENV 149 ENV v.2.1, December 2019).

- The relevant scenarios adapted for each use were after the 'Generic Treatment Areas assigned to each specific pest' (WGII2018_ENV_7.3e 1 (11), ENV-A21 TAB-ENV v.2.1, December, 2019).

- As regards insecticides used outdoors, such as sprays around building, none of them is intended to be used daily. In order to take into account the simultaneity of the treatment for indoor uses and outdoor use the calculated local emission rates were multiplied by:
  - the number of houses connected to STP (4000 for private houses for indoor use, whereas 2500 houses for the outdoor use, Urban)
  - the simultaneity factor Fsim (as claimed by the applicant) for indoor uses, and no more then 0.03 for the outdoor uses (if not differently specified the max value of 0.03 was taken for the outdoor use).

  (Technical Agreement for Biocides (TAB), August 2018 and ESD).

- For emission calculations of the RTU product, Special One, the following formulas (ESD for PT18 products, July 2008) were used to calculate **<u>daily local emission</u>** <u>to STP</u> (as STP is regarded as the unique point source of direct active ingredients emissions to environmental compartments per day, after indoor use, Scenarios 1-4.

<u>Application step</u>

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

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

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

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

Releases to wastewater and STP

(8) $E_{applicator,ww} = (E_{prep,applicator} + E_{appl.,applicator}) \times F_{applicator,ww}$

(9) $E_{treated,ww} = (E_{prep,floor} + E_{appl.,floor} + E_{appl.,treated}) \times F_{ww} \times F_{CE}$

(10) $E_{waste\ water} = E_{applicator,ww} + E_{treated,ww}$

(11) $Elocal_{waste\ water,total} = ((E_{waste\ water} \times N_{houses}) + (E_{waste\ water} \times N_{larger\ buildings})) \times F_{simultaneity}$

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Scenario 1 – Spot application indoor wasps nest

The use named "Spot application indoor wasps nest" refers to the direct application of SPECIAL ONE to wasp nest in an indoor environment i.e. the product is applied directly on a wasp nest that is indoor, in domestic premises.

In this case the spray duration is 1 second with a spray rate of the product of 15 g/s for a given application rate of 15g/nest.

According to 'Generic Treatment Areas assigned to each specific pest' (WGII2018_ENV_7.3e 1 (11), ENV-A21 TAB-ENV v.2.1, December, 2019) for wasps/nest, indoor, the spot scenario has been adapted.

As RMM to prevent emissions to floor from spot treatment, floor should be covered with an impermeable material. After treatment, floor covering and nest material should be removed and disposed as hazardous waste.

The input parameters for calculating the local emission of transfluthrin, piperonyl butoxide & cyfluthrin arising from domestic use of SPECIAL ONE are reported in the table below.

Input parameters for calculating the local emission of transfluthrin, piperonyl butoxide & cyfluthrin			
Input	Value	Unit	Remarks
Scenario 1: Spot application indoor wasps nest			
General			
Fraction of **transfluthrin** in the product	0.114	%	Technical grade active ingredient (TGAI).
Fraction of **piperonyl butoxide** in the product	0.213	%	Technical grade active ingredient (TGAI).
Fraction of **cyfluthrin** in the product	0.026	%	Technical grade active ingredient (TGAI).
Application method	Targeted spot spraying application 'Generic Treatment Areas assigned to each specific pest' (WGII2018_ENV_7.3e 1 (11), ENV-A21 TAB-ENV v.2.1, December, 2019) for wasps/nest		
Quantity of product used /nest	0.015	kg/nest	Claimed by the applicant
Application			
Number of applications per day, house	1	-	As reported in ESD
Area for **treated floor**, house	2	m^2	Relevant area for **indoor wet cleaning for wasps indoor** scenario (Generic Treatment Areas)
Fraction emitted to air during application	0.02	-	As reported in ESD, p 51
Fraction emitted to the applicator during application	0.004	-	According to ESD for PT18, p. 53 and 54. Values used corresponds to the type of sprayer for surface treatment with an aerosol dispenser.
Fraction emitted to treated surfaces during application	0.85	-	

Fraction emitted to the floor during application	0.126	-	
Cleaning			
Washable or disposable applicators	Washable	-	Default value.
Cleaning efficiency	0.03	%	For 'RTU aerosols-crack and crevice (including foams)' the max % exposed to cleaning is 3 (TAB, ENV 149 ENV v.2.1, December 2019)
Number of houses per STP	4000	-	Agreed in MOTA (Technical Agreements for Biocides (TAB) version 1.3, August 2017).
Simultaneity factor	0.204	%	Frequency of use: 1-2 times per year

Calculations of Total local Emissions of the a.i. for Use 1 – Spot application indoor wasps nest

Resulting total local emission of *Transfluthrin* to wastewater		
Local emission ($Elocal_{ww}$) [kg/d]	9.12E-06	Remarks

Resulting total local emission of *Piperonyl butoxide* to wastewater		
Local emission ($Elocal_{ww}$) [kg/d]	1.74E-05	Remarks

Resulting total local emission of *Cyfluthrin* to wastewater		
Local emission ($Elocal_{ww}$) [kg/d]	2.12E-06	Remarks

**NOTE: A referral was raised by FR MS for Use 2, considering the FCE of 0.2 as a more appropriate cleaning efficiency fraction, considering to the 0.03 applied by eCA for the ERA for the claimed use.
In line with the conclusion of the coordination group, following discussions upon the raised point, eCA provides a partially revised environmental risk assessment considering a FCE value of 0.2 associated to emission from the floor (Eappl.floor), neglecting emission from the treated area (Eappl.treated=0).
Following the CG conclusion upon referral, the revised emission estimation calculations show that the revised values (considering FCE of 0.2) for Elocalww, for each of the a.i., are slightly lower than the ones estimated by the eCA approach (followed by the scenario using the FCE of 0.03). The outcome indicates the same conclusion regarding the safe use of the product to the environment, in either scenario approaches for use 2.

The values obtained for comparison for each a.i. are as follows:

Elocal$_{ww}$	**Transfuthrin**	**PBO**	**Cyfluthrin**
Final PAR by eCA (FCE=0.03)	9.12E-06	1.74E-05	2.12E-06
After referral recalculations (FCE=0.2)	8.01E-06	1.52E-05	1.86E-06

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Scenario 2 – Crack and crevice application crawling

The use named "Crack and crevice application crawling" refers to the targeted application of SPECIAL ONE to crawling insects in domestic premises only, where insects may find harbourage, into crack and crevices.

The claimed by the applicant application rate is 6gr/m^2 (3-4 seconds of spraying), applied up to 11 times per year.

The input parameters for calculating the local emission of transfluthrin, piperonyl butoxide & cyfluthrin arising from domestic use, indoors of SPECIAL ONE are reported in the table below.

Input parameters for calculating the local emission of transfluthrin, piperonyl butoxide & cyfluthrin			
Input	Value	Unit	Remarks
Scenario: Spot application crawling			
General			
Fraction of **transfluthrin** in the product	0.114	% w/w	Technical grade active ingredient (TGAI).
Fraction of **piperonyl butoxide** in the product	0.213	% w/w	Technical grade active ingredient (TGAI).
Fraction of **cyfluthrin** in the product	0.026	% w/w	Technical grade active ingredient (TGAI).
Application method	Spraying, targeted, crack and crevice treatment		
Application rate of biocidal product	$6.0x10^{-3}$	kg/m^2	Claimed by the applicant
Application			
Area of treated surface, house	2	m^2	Spot application (TAB, ENV 142 & 144 ENV v.2.1, December 2019)
Number of applications per day, house	1	-	As reported in ESD.
Fraction emitted to air during application	0.02	-	As reported in ESD.
Fraction emitted to the applicator during application	0.004	-	According to ESD for PT18, p. 53 and 54. Values used corresponds to the type of sprayer for surface treatment with an aerosol dispenser.
Fraction emitted to the floor during application	0.126	-	
Fraction emitted to treated surfaces during application	0.85	-	
Cleaning			
Washable or disposable applicators	Washable	-	Default value.
Fraction emitted to wastewater from cleaning treated surfaces	1	-	
Cleaning efficiency	0.03	%	For 'RTU aerosols-crack and crevice' the max % exposed to cleaning is 3 (TAB, ENV 149 ENV v.2.1, December 2019)

Number of houses per STP	4000	-	For indoor use a number of 4000 households will be used as default. Agreed in MOTA (Technical Agreements for Biocides (TAB) version 1.3, August 2017).
Simultaneity factor	0.815	%	Frequency of use: three to eleven time per year

Calculations for Use 2 – Crack and crevice application crawling

Resulting total local emission of *Transfluthrin* to wastewater		
Local emission ($Elocal_{ww}$) [kg/d]	1.48E-05	Remarks

Resulting total local emission of *Piperonyl butoxide* to wastewater		
Local emission ($Elocal_{ww}$) [kg/d]	2.77E-05	Remarks

Resulting total local emission of *Cyfluthrin* to wastewater		
Local emission ($Elocal_{ww}$) [kg/d]	3.38E-06	Remarks

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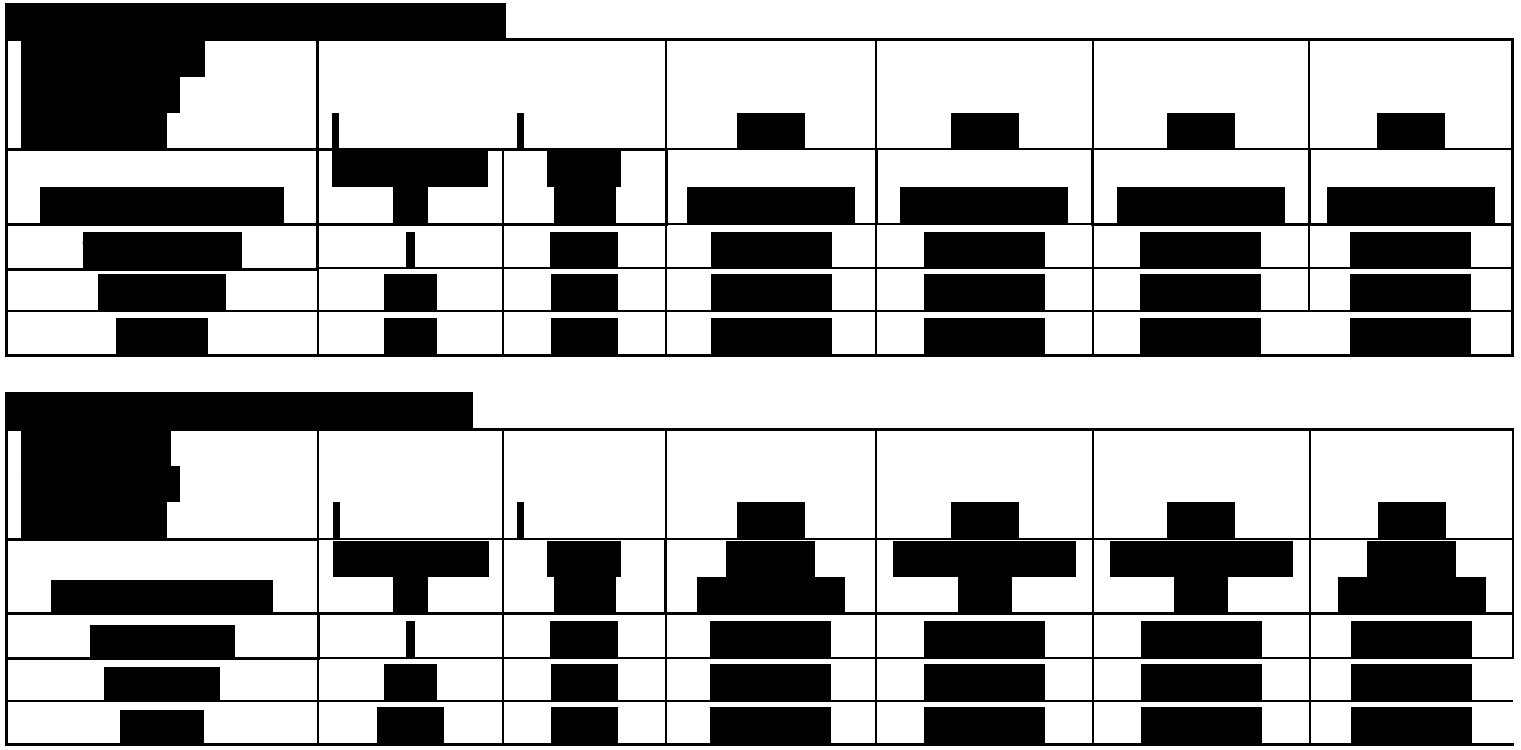

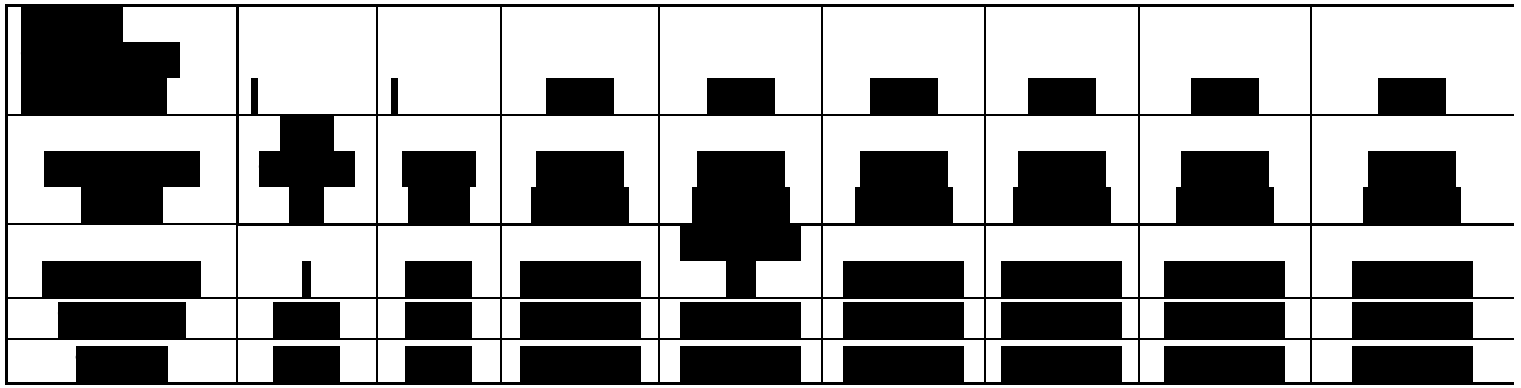

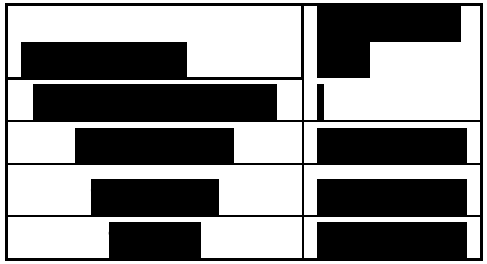

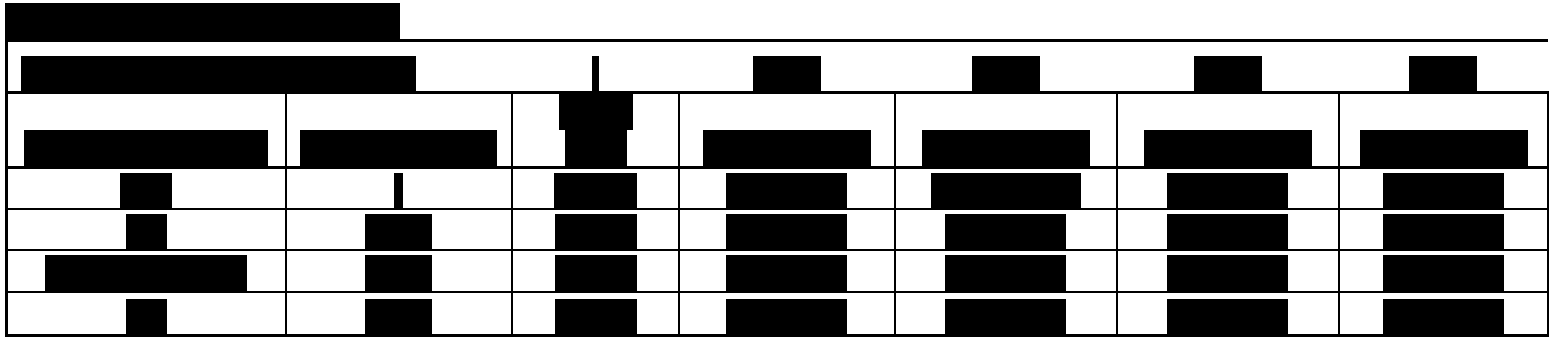

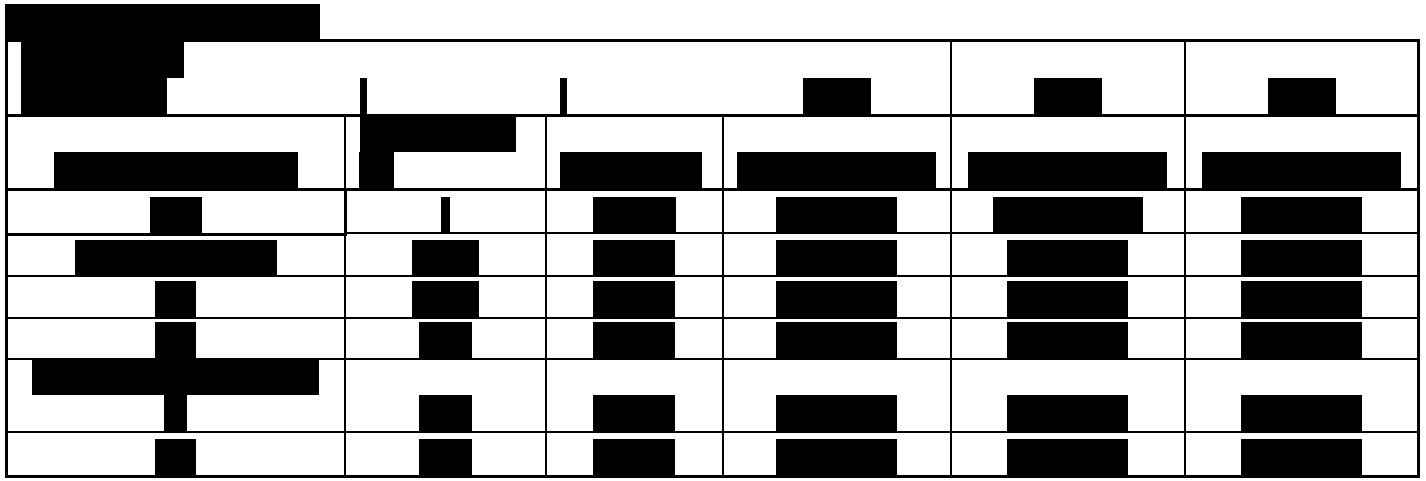

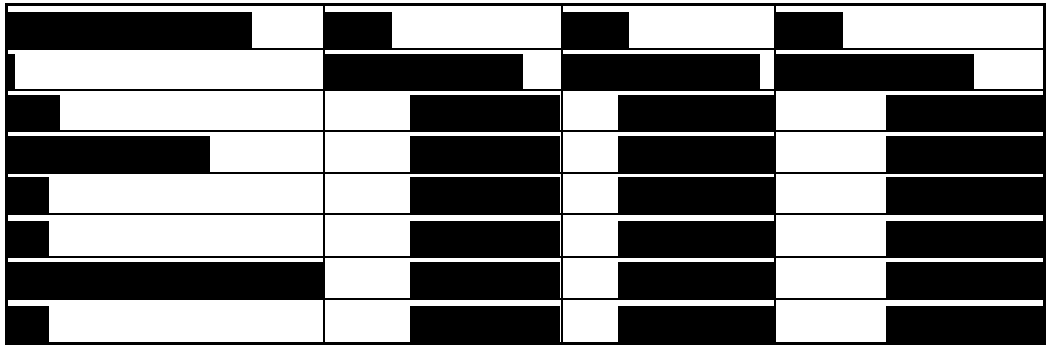

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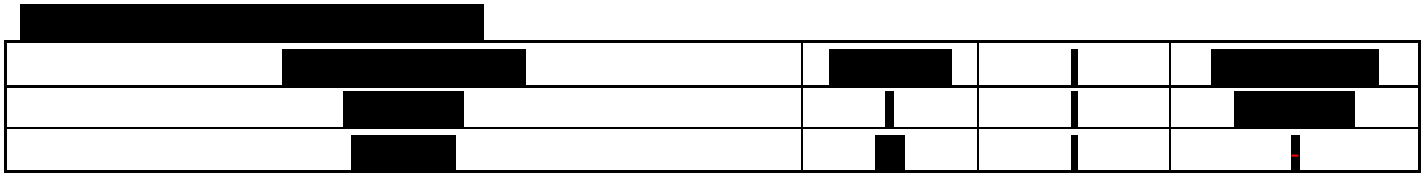

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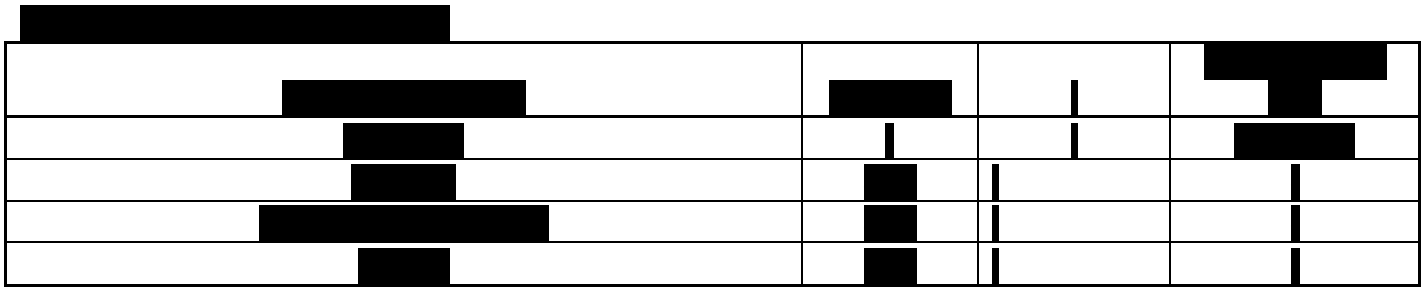

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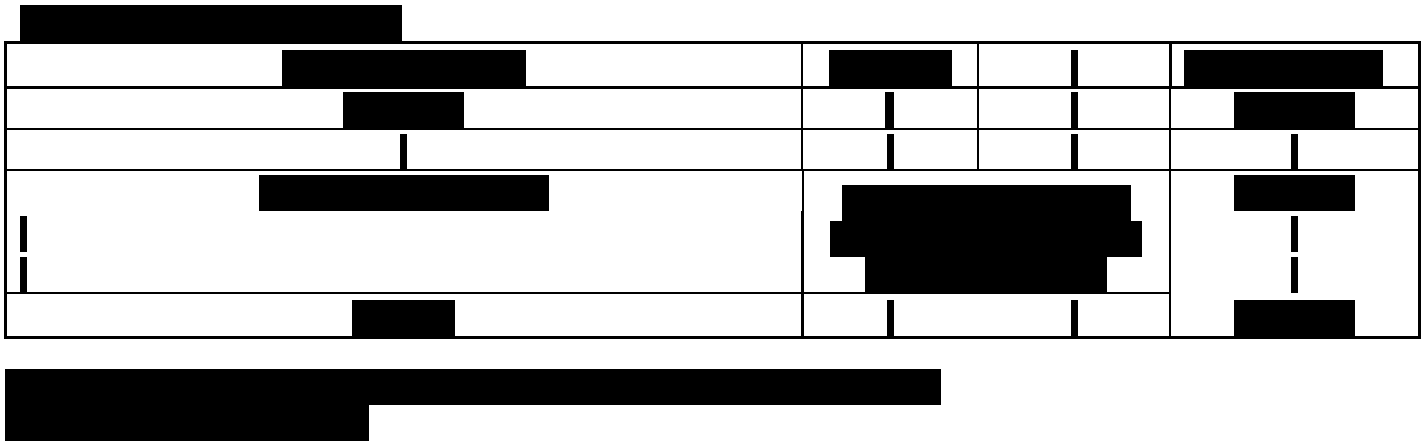

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2.2.8.2 Risk characterisation

Atmosphere

Transfluthrin

Under the proposed conditions of use, transfluthrin will be emitted to air. According to the ESD, the concentration in air upon outdoor use will be not relevant because of instant dilution.
This also applies to indoor use. No ecotoxicity data are available based on atmospheric exposures and there is no agreed method available to derive a PECair. A PECair/PNECair cannot be calculated.
The FOCUS Working group on Pesticides (EC Document Reference SANCO/10553/2006 Rev 2 June 2008) recommends a trigger of a DT50 in air of 2 days to identify substances of potential concern for long-range transport. Substances having a longer DT50 require further evaluation to assess their potential impact upon remote areas; recommendations on how to assess and evaluate transport at the extremes of the range were provided in the FOCUS Air Group.
Additionally the FOCUS air working group developed a guidance methodology to determine the potential of a substance for atmospheric ozone depletion. The following issues are considered relevant:
1. The atmospheric life time of a substance should be long enough to transport the substance to the atmosphere;
2. The substance contains one or more of the following substituents: F, Cl of Br;
3. Substances containing N and S are relevant in stratospheric ozone depletion (e.g. N20);

Exemplified substances are CFCh, tetrachloromethane, HCFC142b, Halon 1211 and methyl bromide with a atmospheric life time of 2 to 50 year.
The estimated half-life time in air is 2.4 days (24-hr day; 0.5E06 OH/cm3) (Atkinson calculation), which is borderline for the FOCUS air criteria, for long range transport requiring a further evaluation. Transfluthrin has a vapour pressure of 9×10^{-4} Pa at 20°C,

indicating relatively low volatility. The calculated Remy's law constant is 5.86 Pa.m3.mole-1 indicating that the substance has a tendency to volatilise from water.
Transfluthrin has a high Koc value indicating that the substance has tendency to bind to solid particles, hard surfaces and soils and a low tendency to evaporate from soils. Thus the long range transport in the air is expected to be rather limited. Transfluthrin has a potential for short to medium-range environmental transport.
As for the atmospheric ozone depletion potential transfluthrin fulfils the criteria, because it
contains "F" substituents. Its atmospheric life time is, however, too short and transfluthrin is not listed by the FOCUS air group as causing ozone depletion. Furthermore, considering the relative small total amounts of product used and the volume of the atmospheric compaitment, possible abiotic effects of transfluthrin on the atmosphere are expected to be negligible.

Piperonyl butoxide

The chemical lifetime of Piperonyl Butoxide in the troposphere was calculated using the computer program Atmospheric Oxidation program V 1. 92. Based on the molecular structure of Piperonyl Butoxide, a half-life of 3.597 hrs has been estimated
considering a 24 hr-day (based on an overall OH rate constant of 107.0380 x 10^{-12} cm_3/molecule sec and 0.5x10^6 OH radicals/cm_3). Furthermore, considering the relative small total amounts of product used and the volume of the atmospheric compaitment, possible abiotic effects of piperonyl butoxide on the atmosphere are expected to be negligible.

Cyfluthrin

The vapour pressure of the diastereomers of cyfluthrin ranges from 1.4 x 10^{-8} to 9.6 x 10^{-7} Pa, direct evaporation is not expected, consequently. The Henry's Constants between 3.2 x 10^{-3} and 1.9 x 10^{-1} Pa × m^3 mol^{-1} at 20°C point to potential of volatility from water. The strong tendency to soil partition minimizes atmospheric entry. The chemical lifetime of cyfluthrin in the troposphere was estimated to be 44.4 hours.
The atmosphere is no compartment of concern as there is no accumulation of cyfluthrin in the air expected.

Sewage treatment plant (STP)

The local effluent from a STP has been calculated, where relevant, for uses of SPECIAL ONE.

Transfluthrin

Use	PEC (mg/L)	PNEC (mg a.s./L)	PEC / PNEC
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	5.9766E-08	0.057	1.05E-06
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	9.7214E-08	0.057	1.71E-06
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Piperonyl butoxide

Use	PEC (mg/L)	PNEC (mg a.s./L)	PEC / PNEC
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	6.58E-06	2.89	2.276E-06
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	1.05E-05	2.89	3.64E-06
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Cyfluthrin

Use	PEC (mg/L)	PNEC (mg a.s./L)	PEC / PNEC
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	1.28E-07	0.00023	5.567E-04
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	2.045E-07	0.00023	8.889E-04
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[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Risk assessment based on refined PEC values according to OECD314

Use	PEC (mg/L)	PNEC (mg a.s./L)	PEC / PNEC
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	4.812E-08	0.00023	2.092E-04
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	7.684E-08	0.00023	3.341E-04
[redacted]	[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]	[redacted]

Metabolites of transfluthrin

Not relevant for STP, moreover PNECs values for metabolites are not available.

Metabolites of piperonyl butoxide

Not relevant for STP, moreover PNECs values for metabolites are not available.

Metabolites of cyfluthrin

Not relevant for STP, moreover PNECs values for metabolites are not available.

Risk characterisation of the product

Use	**PEC / PNEC Transfluthrin**	**PEC / PNEC PBO**	**PEC / PNEC Cyfluthrin**	**Σ product**
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	1.05E-06	2.276E-06	5.567E-04	5.60E-04
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	1.71E-06	3.64E-06	8.889E-04	8.94E-04
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[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Risk characterisation of the product – with refined PEC values according to OECD314

Use	**PEC / PNEC Transfluthrin**	**PEC / PNEC PBO**	**PEC / PNEC Cyfluthrin**	**Σ product**
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	1.05E-06	2.276E-06	2.092E-04	2.13E-04
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	1.71E-06	3.64E-06	3.341E-04	3.39E-04
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Conclusion

Risk characterisation ratios for the STP are below 1 for all uses of SPECIAL ONE; therefore, there is no risk for microorganisms of sewage treatment plant when the product is used as detailed on the label.

Aquatic compartment

Surface water

Transfluthrin

Use	PEC (mg/L)	PNEC (mg a.s./L)	PEC / PNEC
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	5.56E-09	1.75E-06	3.18E-03
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	9.04E-09	1.75E-06	5.17E-03
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Piperonyl butoxide

Use	PEC (mg/L)	PNEC (mg a.s./L)	PEC / PNEC
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	6.577E-07	0.00148	4.444E-04
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	1.051E-06	0.00148	7.101E-04
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Cyfluthrin

Use	PEC (mg/L)	PNEC (mg a.s./L)	PEC / PNEC
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	1.28E-08	4.10E-08	3.12E-01
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	2.045E-08	4.10E-08	4.99E-01
[redacted]	[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]	[redacted]
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Risk assessment based on refined PEC values according to OECD314

Use	PEC (mg/L)	PNEC (mg a.s./L)	PEC / PNEC
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	4.812E-09	4.10E-08	1.17E-01
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	7.684E-09	4.10E-08	1.87E-01
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Metabolites of transfluthrin

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Scenario 1			
	PEC aquatic (mg/L)	PNEC Aquatic (mg/L)	PEC/PNEC
Transfluthrin	5.56E-09	1.75E-06	3.18E-03
TFB-OH	1.02E-09	>0.1	1.02E-08
TFB-COOH	1.72E-09	>0.1	1.72E-08
		Sum of a.s. and its metabolites	3.176E-03

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Scenario 2			
	PEC aquatic (mg/L)	PNEC Aquatic (mg/L)	PEC/PNEC
Transfluthrin	9.04E-09	1.75E-06	5.17E-03
TFB-OH	1.67E-09	>0.1	1.67E-08
TFB-COOH	2.80E-09	>0.1	2.80E-08
		Sum of a.s. and its metabolites	5.167E-03

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Metabolites of piperonyl butoxide

Scenario 1			
	PEC aquatic (mg/L)	PNEC Aquatic (mg/L)	PEC/PNEC
Piperonyl butoxide	6.58E-07	0.00148	4.44E-04
M1	3.73E-08	0.0028	1.33E-05
M2	2.34E-07	0.0033	7.10E-05
M8	Not relevant	Not relevant	-
M12	2.67E-08	0.0023	1.16E-05
EN 1-101/4	only soil	Not relevant	-
		Sum of a.s. and its metabolites	5.403E-04

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

Scenario 2			
	PEC aquatic (mg/L)	PNEC Aquatic (mg/L)	PEC/PNEC
Piperonyl butoxide	1.05E-06	0.00148	7.10E-04
M1	5.95E-08	0.0028	2.13E-05
M2	3.75E-07	0.0033	1.13E-04
M8	Not relevant	Not relevant	-
M12	4.27E-08	0.0023	1.86E-05
EN 1-101/4	only soil	Not relevant	-
		Sum of a.s. and its metabolites	8.634E-04

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

Metabolites of cyfluthrin

Not relevant for surface water, according to assessment report of cyfluthrin.

Risk characterisation of the product - surface water

Use	PEC / PNEC Transfluthrin and metabolites	PEC / PNEC PBO and metabolites	PEC / PNEC Cyfluthrin and metabolites	Σ product
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	3.18E-03	5.403E-04	3.12E-01	3.16E-01
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	5.17E-03	8.634E-04	4.99E-01	5.05E-01
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Risk characterisation of the product – with refined PEC values according to OECD314

Use	PEC / PNEC Transfluthrin and metabolites	PEC / PNEC PBO and metabolites	PEC / PNEC Cyfluthrin and metabolites	Σ product
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	3.18E-03	5.403E-04	1.17E-01	1.21E-01
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	5.17E-03	8.634E-04	1.87E-01	1.93E-01
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Sediment

Transfluthrin

Use	PEC (mg/kg wwt)	PNEC (mg/kg wwt)	PEC / PNEC
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	6.0608E-06	0.000356	1.70E-02
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	9.85835E-06	0.000356	2.77E-02
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Piperonyl butoxide

Use	PEC (mg/kg wwt)	PNEC (mg/kg wwt)	PEC / PNEC
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	3.64E-05	0.00933	3.896E-03
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	5.81E-05	0.00933	6.226E-03
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Cyfluthrin

Use	PEC (mg/kg wwt)	PNEC (mg/kg wwt)	PEC / PNEC
[redacted]	[redacted]	[redacted]	[redacted]

Scenario 1	3.451E-05	2.70E-05	**1.28E+00**
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	5.51E-05	2.70E-05	**2.04E+00**
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
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[redacted]	[redacted]	[redacted]	[redacted]

Risk assessment based on refined PEC values according to OECD314

Use	**PEC (mg/kg wwt)**	**PNEC (mg/kg wwt)**	**PEC / PNEC**
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	1.297E-05	2.70E-05	4.80E-01
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	2.071E-05	2.70E-05	7.67E-01
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Metabolites of transfluthrin

No PNECsed calculation for major metabolites has been conducted; according to the assumption made in the Assessment report of the active substance, the risk to sediment-dwelling organisms from transfluthrin metabolites is considered to be covered by the risk assessment for metabolites for aquatic organisms with an addictional factot of 10.

Metabolites of piperonyl butoxide

No PNECsed calculation for major metabolites has been conducted; according to the assumption made in the Assessment report of the active substance PBO, the risk to sediment-dwelling organisms from Piperonyl butoxide metabolites is considered to be covered by the risk assessment for aquatic organisms.

Metabolites of cyfluthrin

Not relevant for sediment, according to assessment report of cyfluthrin.

Risk characterisation of the product – sediment

Use	**PEC / PNEC Transfluthrin**	**PEC / PNEC PBO**	**PEC / PNEC Cyfluthrin**	**Σ product**
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	1.70E-02	3.896E-03	**1.28E+00**	**1.30E+00**
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	2.77E-02	6.226E-03	**2.04E+00**	**2.07E+00**
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Risk characterisation of the product – with refined PEC values according to OECD314

Use	**PEC / PNEC Transfluthrin**	**PEC / PNEC PBO**	**PEC / PNEC Cyfluthrin**	**Σ product**
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	1.70E-02	3.896E-03	4.80E-01	5.01E-01
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	2.77E-02	6.226E-03	7.67E-01	8.01E-01
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

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Conclusion on surface water

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Terrestrial compartment

Transfluthrin

Use	PEC (mg/kg wwt)	PNEC (mg/kg wwt)	PEC / PNEC
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	9.9E-06	0.0882	1.123E-04
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	1.61E-05	0.0882	1.826E-04
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Piperonyl butoxide

Use	PEC (mg/kg wwt)	PNEC (mg/kg wwt)	PEC / PNEC
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	7.81E-06	0.098	7.970E-05
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	1.25E-05	0.098	1.274E-04
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Cyfluthrin

Use	PEC (mg/kg wwt)	PNEC (mg/kg wwt)	PEC / PNEC

[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	3.469E-06	0.0882	3.93E-05
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	5.539E-06	0.0882	6.28E-05
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Risk assessment based on refined PEC values according to OECD314

Use	**PEC (mg/kg wwt)**	**PNEC (mg/kg wwt)**	**PEC / PNEC**
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	2.861E-06	0.0882	3.24E-05
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	4.568E-06	0.0882	5.18E-05
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Metabolites of transfluthrin

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

(*) No relevant toxicity data are available; as a worst-case approach, TFB-OH have been considered as toxic as TFB-COOH.

Scenario 1			
	PEC soil (mg/kg ww soil)	PNEC soil (mg/kg ww soil)	PEC/PNEC
Transfluthrin	9.9025E-06	0.0882	1.123E-04
TFB-OH	1.754E-06	0.012 (*)	1.461E-04
TFB-COOH	3.217E-06	0.012	2.681E-04
		Sum of a.s. and its metabolites	5.265E-04

(*) No relevant toxicity data are available; as a worst-case approach, TFB-OH have been considered as toxic as TFB-COOH.

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		[redacted]	[redacted]

(*) No relevant toxicity data are available; as a worst-case approach, TFB-OH have been considered as toxic as TFB-COOH.

Scenario 2			
	PEC soil (mg/kg ww soil)	PNEC soil (mg/kg ww soil)	PEC/PNEC
Transfluthrin	1.6107E-05	0.0882	1.826E-04
TFB-OH	2.852E-06	0.012 (*)	2.377E-04
TFB-COOH	5.232E-06	0.012	4.360E-04
		Sum of a.s. and its metabolites	8.563E-04

(*) No relevant toxicity data are available; as a worst-case approach, TFB-OH have been considered as toxic as TFB-COOH.

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		[redacted]	[redacted]

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

[redacted]

(*) No relevant toxicity data are available; as a worst-case approach, TFB-OH have been considered as toxic as TFB-COOH.

Metabolites of piperonyl butoxide

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

	PEC soil (mg/kg ww soil)	PNEC soil (mg/kg ww soil)	PEC/PNEC
Scenario 1			
Piperonyl butoxide	7.8108E-06	0.098	7.970E-05
M1	3.493E-07	0.0980 (*)	3.565E-06
M2	9.8474E-07	0.0980 (*)	1.005E-05
M8	7.4021E-07	0.0980 (*)	7.553E-06
M12	9.3223E-07	0.0980 (*)	9.513E-06
EN 1-101/4	5.1845E-06	0.0980 (*)	5.290E-05
		Sum of a.s. and its metabolites	1.633E-04

(*) No relevant toxicity data are available; as a worst-case approach, Piperonyl Butoxide metabolites have been considered as toxic to the respective non-target organisms as the parent compound.

	PEC soil (mg/kg ww soil)	PNEC soil (mg/kg ww soil)	PEC/PNEC
Scenario 2			
Piperonyl butoxide	1.2482E-05	0.098	1.274E-04
M1	5.583E-07	0.0980 (*)	5.697E-06
M2	1.5737E-06	0.0980 (*)	1.606E-05
M8	1.1829E-06	0.0980 (*)	1.207E-05
M12	1.4897E-06	0.0980 (*)	1.520E-05
EN 1-101/4	8.2851E-06	0.0980 (*)	8.454E-05
		Sum of a.s. and its metabolites	2.609E-04

(*) No relevant toxicity data are available; as a worst-case approach, Piperonyl Butoxide metabolites have been considered as toxic to the respective non-target organisms as the parent compound.

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[redacted]			

Metabolites of cyfluthrin

[redacted]			
	[redacted]	[redacted]	

Scenario 1			
	PEC soil (mg/kg ww soil)	PNEC soil (mg/kg ww soil)	PEC/PNEC
Cyfluthrin	2.8611E-06	0.0882	3.24E-05
FPB-acid	2.8611E-06	2.63	1.09E-06
permethric acid (DCVA)	2.8611E-06	2.8	1.02E-06
		Sum of a.s. and its metabolites	3.45E-05

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Scenario 2			
	PEC soil (mg/kg ww soil)	PNEC soil (mg/kg ww soil)	PEC/PNEC
Cyfluthrin	4.5683E-06	0.0882	5.18E-05
FPB-acid	4.5683E-06	2.63	1.74E-06
permethric acid (DCVA)	4.5683E-06	2.8	1.63E-06
		Sum of a.s. and its metabolites	5.52E-05

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		[redacted]	[redacted]

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Use	**PEC / PNEC Transfluthrin and metabolites**	**PEC / PNEC PBO and metabolites**	**PEC / PNEC Cyfluthrin and metabolites**	**Σ product**
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	5.265E-04	1.633E-04	3.45E-05	7.24E-04
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Scenario 2	8.563E-04	2.609E-04	5.52E-05	1.17E-03
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Conclusion:

Risk characterisation ratios for soil calculated for transfluthrin, piperonyl butoxide, cyfluthrin their metabolites and the mixrure of the a.s's and their metabolites (product) are below 1 for Scenario 1, 2, 3, 4 and 7 indicating no risk for terrestrial compartment during use of special one.

For Scenario 5 and 6 risk characterisation ratios are higher than 1 for the mixture of PBO and its metabolites as well as the mixture of transfluthrin and its metabolites. Concequentrly product risk characterisation ratios are higher than 1 as well, indicating no safe use for terrestrial compartment during use of special one in these Scenarios.

Groundwater

Transfluthrin

Use	PEC (mg/L)	EU trigger value (mg/L)
[redacted]	[redacted]	[redacted]
Scenario 1	4.296E-09	0.0001
[redacted]	[redacted]	[redacted]
Scenario 2	7.719E-10	0.0001
[redacted]	3.352E-05	[redacted]
[redacted]	3.575E-05	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Piperonyl butoxide

Use	PEC (mg/L)	EU trigger value (mg/L)
[redacted]	[redacted]	[redacted]
Scenario 1	7.351E-08	0.0001
[redacted]	[redacted]	[redacted]
Scenario 2	1.178E-07	0.0001
[redacted]	1.271E-03	[redacted]
[redacted]	1.356E-03	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

Cyfluthrin

Use	PEC (mg/L)	PEC (mg/L) Refined by OECD314B	EU trigger value (mg/L)
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 1	9.690E-10	**7.992E-10**	0.0001
[redacted]	[redacted]	[redacted]	[redacted]
Scenario 2	1.548E-09	**1.193E-09**	0.0001
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
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Primary and secondary poisoning

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Mixture toxicity

The risk assessment presented above has been performed following a tiered approach according to TGD 2003 and ECHA Guidance on assessment of biocidal product.

In order to assess the product a TIER 1 evaluation with PEC/PNEC summation for transfluthrin, piperonyl butoxide and cyfluthrin has been performed, for each relevant compartment.

Aggregated exposure (combined for relevant emmission sources)

Aggregated exposure is not relevant based on the decision scheme developed by UBA.

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

The exposure assessment was performed based on the guidance documents, default and adapted Scenarios. For the PEC calculations of Transfluthrin, its fate in wastewater treatment was taken into account, as reported in the kinetic analysis of the OECD314 study, already evaluated and agreed, the outcome of which has been addended to the TFL-CAR endpoints (CAR_NL of transfluthrin, 2019, list of endpoints updated with the OECD314B study). For cyfluthrin, the OECD314B study for its degradation in the STP activated sludge was only used as a refinement, as evaluated and agreed in e-consultation by the member states but not yet addended in the CAR of cyfluthrin (Env-e consultation on cyfluthrin_DL 15 Nov. 2019).

Risk characterisation ratios for PBO and its metabolites for all relevant environmental compartments are below one indicating no risk for environment from PBO.

[redacted]

No risk of secondary poisoning via the food chain is identified.

Overall, the risk for all relevant environmental compartments is acceptable when the product is used according to label instructions [redacted]**.** Therefore, according to the environmental risk assessment, the risk for

all relevant environmental compartments is acceptable for general, public use when the product is used according to label instructions, [redacted]

2.2.9 Measures to protect man, animals and the environment

Recommended methods and precautions concerning storage of active substance/biocidal product; shelf-life of biocidal product

Store in a place where adequate ventilation is ensured, away from direct sunlight at a temperature below 50°C / 122°F, away from any combustion sources. Shelf-life of SPECIAL ONE is two years.

Recommended methods and precautions concerning handling and transport

Avoid bunching of electrostatic charges. Do not spray on flames or incandescent bodies. Vapours may catch fire and an explosion may occur; vapour accumulation is therefore to be avoided by leaving windows and doors open and ensuring good cross ventilation. Do not eat, drink or smoke during use. Do not breathe spray.

Transport information

UN number
ADR / RID, IMDG, IATA: 1950

UN proper shipping name
ADR / RID: AEROSOLS
IMDG: AEROSOLS
IATA: AEROSOLS, FLAMMABLE

Transport hazard class(es)
ADR / RID: Class: 2 Label: 2.1
IMDG: Class: 2 Label: 2.1
IATA: Class: 2 Label: 2.1

Environmental hazards
ADR / RID: Environmentally Hazardous
IMDG: Marine Pollutant
IATA: NO
For Air transport, environmentally hazardous mark is only mandatory for UN 3077 and UN 3082.

ADR / RID: HIN - Kemler: -- Limited Quantities: 1 L Tunnel restriction code: (D) Special Provision: - IMDG: EMS: F-D, S-U Limited Quantities: 1 L IATA: Cargo: Maximum quantity: 150 Kg Packaging instructions: 203 Pass.: Maximum quantity: 75 Kg Packaging instructions: 203 Special Instructions: A145, A167, A802

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

SUITABLE EXTINGUISHING EQUIPMENT
The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.
UNSUITABLE EXTINGUISHING EQUIPMENT
None in particular.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE
If overheated, aerosol cans can deform, explode and be propelled considerable distances. Put a protective helmet on before approaching the fire. Do not breathe combustion products.

Advice for firefighters
GENERAL INFORMATION
Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear.
SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS
Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

Particulars of likely direct or indirect adverse effects.

No particulars of likely direct or indirect adverse effects.

First aid instructions, antidotes.
No episodes of harm to the staff authorised to use the product have been reported. The following general measures should be adopted as necessary:
INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention.
INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Do not give anything by mouth to an unconscious person.
EYES and SKIN: Wash with plenty of water. In the event of persistent irritation, get medical advice/attention.

Indication of any immediate medical attention and special treatment needed: Information not available.

Emergency measures to protect environment in case of accident

Eliminate all sources of ignition (cigarettes, flames, sparks, etc.) from the leakage site. Send away individuals who are not suitably equipped. Wear protective gloves / protective clothing / eye protection / face protection.

Do not disperse in the environment.
Use inert absorbent material to soak up leaked product. Make sure the leakage site is well aired.

2.2.10 Assessment of a combination of biocidal products

SPECIAL ONE is not intended to be authorised for the use with other biocidal products.

2.2.11 Comparative assessment

Not relevant.

3 ANNEXES

3.1 List of studies for the biocidal product

In relation to the product application, the following data on product are submitted:

- Physical state at 20 °C and 101.3 kPa; colour at 20 °C and 101.3 kPa and odour at 20 °C and 101.3 kPa
- Acidity / alkalinity
- Relative density
- Storage stability test – accelerated storage (2 studies)
- Storage stability test – long term storage at ambient temperature
- Particle size distribution, content of dust/fines, attrition, friability
- Spraying pattern — aerosols (3 studies, including spray rate)
- Surface tension
- Viscosity
- Explosives (2 tests: TEST A.14, Bam Fallhammer and TEST A.14, Koenen tube)
- Flammable aerosols (2 tests for determination of the ignition distance)
- Corrosive to metals (study plan)
- Auto-ignition temperatures of products (liquids and gases)
- Method for the identification and quantification of the active ingredient in the product.

3.2 Output tables from exposure assessment tools

3.2.1 Human health

[redacted]

[redacted]

Substance		
Name	Transfluthrin	
CAS number	118712-89-3	
Molecular weight	371	g/mol
Kow	5.4	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.114	%
Population		
Name	adult	
Body weight	60	kg

Scenarios

> Scenario *application (spray can)*

Scenario *application (spray can)*

Frequency	9	per year

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	6	minute
Exposure duration	240	minute
Weight fraction substance	0.114	%
Room volume	20	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	1.25	m^3/hr
Spraying towards person	No	
Mass generation rate	0.55	g/s
Airborne fraction	0.2	
Density non volatile	1.8	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	3.6	µm
Arithmetic coefficient of variation	0.57	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	Direct contact - Constant rate	
Exposed area	–	
Weight fraction substance	0.114	%
Contact rate	100	mg/min
Release duration	6	minute
Absorption model	Fixed fraction	
Absorption fraction	50	%

Oral

Exposure model	Non-respirable spray model	
No parameters	Parameters are set in Inhalation exposure route.	
Absorption model	Fixed fraction	
Absorption fraction	100	%

[redacted]

Inhalation

Mean event concentration	3.8×10^{-1}	mg/m³
Peak concentration (TWA 15 min)	1.7	mg/m³
Mean concentration on day of exposure	6.4×10^{-2}	mg/m³
Year average concentration	1.6×10^{-3}	mg/m³
External event dose	3.2×10^{-2}	mg/kg bw
External dose on day of exposure	3.2×10^{-2}	mg/kg bw
Internal event dose	3.2×10^{-2}	mg/kg bw
Internal dose on day of exposure	3.2×10^{-2}	mg/kg bw/day
Internal year average dose	7.9×10^{-4}	mg/kg bw/day

Dermal

Dermal load	–	
External event dose	1.1×10^{-2}	mg/kg bw
External dose on day of exposure	1.1×10^{-2}	mg/kg bw
Internal event dose	5.7×10^{-3}	mg/kg bw
Internal dose on day of exposure	5.7×10^{-3}	mg/kg bw/day
Internal year average dose	1.4×10^{-4}	mg/kg bw/day

Oral

External event dose	7.5×10^{-6}	mg/kg bw
External dose on day of exposure	7.5×10^{-6}	mg/kg bw
Internal event dose	7.5×10^{-6}	mg/kg bw
Internal dose on day of exposure	7.5×10^{-6}	mg/kg bw/day
Internal year average dose	1.8×10^{-7}	mg/kg bw/day

Integrated

Internal event dose	3.8×10^{-2}	mg/kg bw
Internal dose on day of exposure	3.8×10^{-2}	mg/kg bw/day
Internal year average dose	9.3×10^{-4}	mg/kg bw/day

[redacted]

Substance		
Name	Transfluthrin	
CAS number	118712-89-3	
Molecular weight	371	g/mol
Kow	5.4	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.114	%
Population		
Name	adult	
Body weight	60	kg

Scenarios

> Scenario *application (spray can)*

Scenario *application (spray can)*

Frequency	2	per year

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	2	minute
Exposure duration	240	minute
Weight fraction substance	0.114	%
Room volume	60	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	1.25	m^3/hr
Spraying towards person	No	
Mass generation rate	1.5	g/s
Airborne fraction	0.2	
Density non volatile	1	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	49.2	µm
Arithmetic coefficient of variation	0.57	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	Direct contact - Constant rate	
Exposed area	–	
Weight fraction substance	0.114	%
Contact rate	100	mg/min
Release duration	2	minute
Absorption model	Fixed fraction	
Absorption fraction	50	%

Oral

Exposure model	Non-respirable spray model	
No parameters	Parameters are set in Inhalation exposure route.	
Absorption model	Fixed fraction	
Absorption fraction	100	%

[redacted]

Inhalation

Mean event concentration	3.4×10^{-4}	mg/m³
Peak concentration (TWA 15 min)	4.0×10^{-3}	mg/m³
Mean concentration on day of exposure	5.6×10^{-5}	mg/m³
Year average concentration	3.1×10^{-7}	mg/m³
External event dose	2.8×10^{-5}	mg/kg bw
External dose on day of exposure	2.8×10^{-5}	mg/kg bw
Internal event dose	2.8×10^{-5}	mg/kg bw
Internal dose on day of exposure	2.8×10^{-5}	mg/kg bw/day
Internal year average dose	1.5×10^{-7}	mg/kg bw/day

Dermal		
Dermal load	–	
External event dose	3.8×10^{-3}	mg/kg bw
External dose on day of exposure	3.8×10^{-3}	mg/kg bw
Internal event dose	1.9×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.9×10^{-3}	mg/kg bw/day
Internal year average dose	1.0×10^{-5}	mg/kg bw/day
Oral		
External event dose	1.9×10^{-4}	mg/kg bw
External dose on day of exposure	1.9×10^{-4}	mg/kg bw
Internal event dose	1.9×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.9×10^{-4}	mg/kg bw/day
Internal year average dose	1.0×10^{-6}	mg/kg bw/day
Integrated		
Internal event dose	2.1×10^{-3}	mg/kg bw
Internal dose on day of exposure	2.1×10^{-3}	mg/kg bw/day
Internal year average dose	1.2×10^{-5}	mg/kg bw/day

[redacted]

Substance		
Name	Transfluthrin	
CAS number	118712-89-3	
Molecular weight	371	g/mol
Kow	5.4	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.114	%
Population		
Name	infant	
Body weight	8	kg

Scenarios

› Scenario *application (spray can)*

Scenario *application (spray can)*

Frequency	2	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	2	minute
Exposure duration	240	minute
Weight fraction substance	0.114	%
Room volume	60	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	0.84	m^3/hr
Spraying towards person	No	
Mass generation rate	1.5	g/s
Airborne fraction	0.2	
Density non volatile	1	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	49.2	µm
Arithmetic coefficient of variation	0.57	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	100 %

[redacted]

Results for scenario *application (spray can)*

Show dose descriptions

Inhalation

Mean event concentration	3.4×10^{-4}	mg/m³
Peak concentration (TWA 15 min)	4.0×10^{-3}	mg/m³
Mean concentration on day of exposure	5.6×10^{-5}	mg/m³
Year average concentration	3.1×10^{-7}	mg/m³
External event dose	1.4×10^{-4}	mg/kg bw
External dose on day of exposure	1.4×10^{-4}	mg/kg bw
Internal event dose	1.4×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.4×10^{-4}	mg/kg bw/day
Internal year average dose	7.7×10^{-7}	mg/kg bw/day

Oral		
External event dose	9.6×10^{-4}	mg/kg bw
External dose on day of exposure	9.6×10^{-4}	mg/kg bw
Internal event dose	9.6×10^{-4}	mg/kg bw
Internal dose on day of exposure	9.6×10^{-4}	mg/kg bw/day
Internal year average dose	5.3×10^{-6}	mg/kg bw/day
Integrated		
Internal event dose	1.1×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.1×10^{-3}	mg/kg bw/day
Internal year average dose	6.1×10^{-6}	mg/kg bw/day

[redacted]

Substance		
Name	Transfluthrin	
CAS number	118712-89-3	
Molecular weight	371	g/mol
Kow	5.4	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.114	%
Population		
Name	toddler	
Body weight	10	kg

Scenarios

> Scenario *application (spray can)*

Scenario *application (spray can)*

Frequency	9	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	2	minute
Exposure duration	240	minute
Weight fraction substance	0.114	%
Room volume	60	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	1.26	m^3/hr
Spraying towards person	No	
Mass generation rate	1.5	g/s
Airborne fraction	0.2	
Density non volatile	1	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	49.2	µm
Arithmetic coefficient of variation	0.57	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	100 %

[redacted]

Results for scenario *application (spray can)*

Show dose descriptions

Inhalation

Mean event concentration	3.4×10^{-4}	mg/m³
Peak concentration (TWA 15 min)	4.0×10^{-3}	mg/m³
Mean concentration on day of exposure	5.6×10^{-5}	mg/m³
Year average concentration	1.4×10^{-6}	mg/m³
External event dose	1.7×10^{-4}	mg/kg bw
External dose on day of exposure	1.7×10^{-4}	mg/kg bw
Internal event dose	1.7×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.7×10^{-4}	mg/kg bw/day
Internal year average dose	4.2×10^{-6}	mg/kg bw/day

Oral		
External event dose	1.2×10^{-3}	mg/kg bw
External dose on day of exposure	1.2×10^{-3}	mg/kg bw
Internal event dose	1.2×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.2×10^{-3}	mg/kg bw/day
Internal year average dose	2.9×10^{-5}	mg/kg bw/day
Integrated		
Internal event dose	1.3×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.3×10^{-3}	mg/kg bw/day
Internal year average dose	3.3×10^{-5}	mg/kg bw/day

Substance		
Name	Transfluthrin	
CAS number	118712-89-3	
Molecular weight	371	g/mol
Kow	5.4	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.114	%
Population		
Name	child	
Body weight	23.9	kg

Scenarios

> Scenario *application (spray can)*

Scenario *application (spray can)*

Frequency	2	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	2	minute
Exposure duration	240	minute
Weight fraction substance	0.114	%
Room volume	60	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	1.32	m^3/hr
Spraying towards person	No	
Mass generation rate	1.5	g/s
Airborne fraction	0.2	
Density non volatile	1	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	49.2	µm
Arithmetic coefficient of variation	0.57	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	100 %

[redacted]

Results for scenario *application (spray can)*

Show dose descriptions

Inhalation

Mean event concentration	3.4×10^{-4}	mg/m³
Peak concentration (TWA 15 min)	4.0×10^{-3}	mg/m³
Mean concentration on day of exposure	5.6×10^{-5}	mg/m³
Year average concentration	3.1×10^{-7}	mg/m³
External event dose	7.4×10^{-5}	mg/kg bw
External dose on day of exposure	7.4×10^{-5}	mg/kg bw
Internal event dose	7.4×10^{-5}	mg/kg bw
Internal dose on day of exposure	7.4×10^{-5}	mg/kg bw/day
Internal year average dose	4.1×10^{-7}	mg/kg bw/day

Oral		
External event dose	5.1×10^{-4}	mg/kg bw
External dose on day of exposure	5.1×10^{-4}	mg/kg bw
Internal event dose	5.1×10^{-4}	mg/kg bw
Internal dose on day of exposure	5.1×10^{-4}	mg/kg bw/day
Internal year average dose	2.8×10^{-6}	mg/kg bw/day
Integrated		
Internal event dose	5.8×10^{-4}	mg/kg bw
Internal dose on day of exposure	5.8×10^{-4}	mg/kg bw/day
Internal year average dose	3.2×10^{-6}	mg/kg bw/day

[redacted]

Substance		
Name	Piperonyl butoxide	
CAS number	51-03-6	
Molecular weight	338	g/mol
Kow	4.8	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.213	%
Population		
Name	adult	
Body weight	60	kg

Scenarios

> Scenario *application (spray can)*

Scenario *application (spray can)*

Frequency	9	per year

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	6	minute
Exposure duration	240	minute
Weight fraction substance	0.213	%
Room volume	20	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	1.25	m^3/hr
Spraying towards person	No	
Mass generation rate	0.55	g/s
Airborne fraction	0.2	
Density non volatile	1.8	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	3.6	µm
Arithmetic coefficient of variation	0.57	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	Direct contact - Constant rate	
Exposed area	–	
Weight fraction substance	0.213	%
Contact rate	100	mg/min
Release duration	6	minute
Absorption model	Fixed fraction	
Absorption fraction	50	%

Oral

Exposure model	Non-respirable spray model	
No parameters	Parameters are set in Inhalation exposure route.	
Absorption model	Fixed fraction	
Absorption fraction	100	%

[redacted]

Inhalation

Mean event concentration	7.2×10^{-1}	mg/m³
Peak concentration (TWA 15 min)	3.1	mg/m³
Mean concentration on day of exposure	1.2×10^{-1}	mg/m³
Year average concentration	2.9×10^{-3}	mg/m³
External event dose	6.0×10^{-2}	mg/kg bw
External dose on day of exposure	6.0×10^{-2}	mg/kg bw
Internal event dose	6.0×10^{-2}	mg/kg bw
Internal dose on day of exposure	6.0×10^{-2}	mg/kg bw/day
Internal year average dose	1.5×10^{-3}	mg/kg bw/day

Dermal

Dermal load	–	
External event dose	2.1×10^{-2}	mg/kg bw
External dose on day of exposure	2.1×10^{-2}	mg/kg bw
Internal event dose	1.1×10^{-2}	mg/kg bw
Internal dose on day of exposure	1.1×10^{-2}	mg/kg bw/day
Internal year average dose	2.6×10^{-4}	mg/kg bw/day

Oral

External event dose	1.4×10^{-5}	mg/kg bw
External dose on day of exposure	1.4×10^{-5}	mg/kg bw
Internal event dose	1.4×10^{-5}	mg/kg bw
Internal dose on day of exposure	1.4×10^{-5}	mg/kg bw/day
Internal year average dose	3.4×10^{-7}	mg/kg bw/day

Integrated

Internal event dose	7.0×10^{-2}	mg/kg bw
Internal dose on day of exposure	7.0×10^{-2}	mg/kg bw/day
Internal year average dose	1.7×10^{-3}	mg/kg bw/day

[redacted]

Substance		
Name	PBO	
CAS number	51-03-6	
Molecular weight	338	g/mol
Kow	4.8	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.213	%
Population		
Name	adult	
Body weight	60	kg

Scenarios

> Scenario *application (spray can)*

Scenario *application (spray can)*

Frequency	2	per year

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	2	minute
Exposure duration	240	minute
Weight fraction substance	0.213	%
Room volume	60	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	1.25	m^3/hr
Spraying towards person	No	
Mass generation rate	1.5	g/s
Airborne fraction	0.2	
Density non volatile	1	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	49.2	µm
Arithmetic coefficient of variation	0.57	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	Direct contact - Constant rate	
Exposed area	–	
Weight fraction substance	0.213	%
Contact rate	100	mg/min
Release duration	2	minute
Absorption model	Fixed fraction	
Absorption fraction	50	%

Oral

Exposure model	Non-respirable spray model	
No parameters	Parameters are set in Inhalation exposure route.	
Absorption model	Fixed fraction	
Absorption fraction	100	%

[redacted]

Results for scenario *application (spray can)*

Show dose descriptions

Inhalation

Mean event concentration	6.3×10^{-4}	mg/m³
Peak concentration (TWA 15 min)	7.6×10^{-3}	mg/m³
Mean concentration on day of exposure	1.0×10^{-4}	mg/m³
Year average concentration	5.7×10^{-7}	mg/m³
External event dose	5.2×10^{-5}	mg/kg bw
External dose on day of exposure	5.2×10^{-5}	mg/kg bw
Internal event dose	5.2×10^{-5}	mg/kg bw
Internal dose on day of exposure	5.2×10^{-5}	mg/kg bw/day
Internal year average dose	2.9×10^{-7}	mg/kg bw/day

Dermal		
Dermal load	–	
External event dose	7.1×10^{-3}	mg/kg bw
External dose on day of exposure	7.1×10^{-3}	mg/kg bw
Internal event dose	3.6×10^{-3}	mg/kg bw
Internal dose on day of exposure	3.6×10^{-3}	mg/kg bw/day
Internal year average dose	1.9×10^{-5}	mg/kg bw/day
Oral		
External event dose	3.6×10^{-4}	mg/kg bw
External dose on day of exposure	3.6×10^{-4}	mg/kg bw
Internal event dose	3.6×10^{-4}	mg/kg bw
Internal dose on day of exposure	3.6×10^{-4}	mg/kg bw/day
Internal year average dose	2.0×10^{-6}	mg/kg bw/day
Integrated		
Internal event dose	4.0×10^{-3}	mg/kg bw
Internal dose on day of exposure	4.0×10^{-3}	mg/kg bw/day
Internal year average dose	2.2×10^{-5}	mg/kg bw/day

[redacted]

Substance		
Name	Piperonyl butoxide	
CAS number	51-03-6	
Molecular weight	338	g/mol
Kow	4.8	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.213	%
Population		
Name	infant	
Body weight	8	kg

Scenarios

> Scenario *application (spray can)*

Scenario *application (spray can)*

Frequency	9	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	2	minute
Exposure duration	240	minute
Weight fraction substance	0.213	%
Room volume	60	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	0.84	m^3/hr
Spraying towards person	No	
Mass generation rate	1.5	g/s
Airborne fraction	0.2	
Density non volatile	1	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	49.2	µm
Arithmetic coefficient of variation	0.57	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	100 %

[redacted]

Results for scenario *application (spray can)*

Show dose descriptions

Inhalation

Mean event concentration	6.3×10^{-4}	mg/m³
Peak concentration (TWA 15 min)	7.6×10^{-3}	mg/m³
Mean concentration on day of exposure	1.0×10^{-4}	mg/m³
Year average concentration	2.6×10^{-6}	mg/m³
External event dose	2.6×10^{-4}	mg/kg bw
External dose on day of exposure	2.6×10^{-4}	mg/kg bw
Internal event dose	2.6×10^{-4}	mg/kg bw
Internal dose on day of exposure	2.6×10^{-4}	mg/kg bw/day
Internal year average dose	6.5×10^{-6}	mg/kg bw/day

Oral

External event dose	1.8×10^{-3}	mg/kg bw
External dose on day of exposure	1.8×10^{-3}	mg/kg bw
Internal event dose	1.8×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.8×10^{-3}	mg/kg bw/day
Internal year average dose	4.4×10^{-5}	mg/kg bw/day

Integrated

Internal event dose	2.1×10^{-3}	mg/kg bw
Internal dose on day of exposure	2.1×10^{-3}	mg/kg bw/day
Internal year average dose	5.1×10^{-5}	mg/kg bw/day

[redacted]

Substance		
Name	Piperonyl butoxide	
CAS number	51-03-6	
Molecular weight	338	g/mol
Kow	4.8	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.213	%
Population		
Name	toddler	
Body weight	10	kg

Scenarios

> Scenario *application (spray can)*

Scenario *application (spray can)*

Frequency	9	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	2	minute
Exposure duration	240	minute
Weight fraction substance	0.213	%
Room volume	60	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	1.26	m^3/hr
Spraying towards person	No	
Mass generation rate	1.5	g/s
Airborne fraction	0.2	
Density non volatile	1	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	49.2	µm
Arithmetic coefficient of variation	0.57	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	100 %

[redacted]

Results for scenario *application (spray can)*

Show dose descriptions

Inhalation

Mean event concentration	6.3×10^{-4}	mg/m³
Peak concentration (TWA 15 min)	7.6×10^{-3}	mg/m³
Mean concentration on day of exposure	1.0×10^{-4}	mg/m³
Year average concentration	2.6×10^{-6}	mg/m³
External event dose	3.2×10^{-4}	mg/kg bw
External dose on day of exposure	3.2×10^{-4}	mg/kg bw
Internal event dose	3.2×10^{-4}	mg/kg bw
Internal dose on day of exposure	3.2×10^{-4}	mg/kg bw/day
Internal year average dose	7.8×10^{-6}	mg/kg bw/day

Oral

External event dose	2.2×10^{-3}	mg/kg bw
External dose on day of exposure	2.2×10^{-3}	mg/kg bw
Internal event dose	2.2×10^{-3}	mg/kg bw
Internal dose on day of exposure	2.2×10^{-3}	mg/kg bw/day
Internal year average dose	5.3×10^{-5}	mg/kg bw/day

Integrated

Internal event dose	2.5×10^{-3}	mg/kg bw
Internal dose on day of exposure	2.5×10^{-3}	mg/kg bw/day
Internal year average dose	6.1×10^{-5}	mg/kg bw/day

[redacted]

Substance		
Name	Piperonyl butoxide	
CAS number	51-03-6	
Molecular weight	338	g/mol
Kow	4.8	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.213	%
Population		
Name	child	
Body weight	23.9	kg

Scenarios

> Scenario *application (spray can)*

Scenario *application (spray can)*

Frequency	9	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	2	minute
Exposure duration	240	minute
Weight fraction substance	0.213	%
Room volume	60	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	1.32	m^3/hr
Spraying towards person	No	
Mass generation rate	1.5	g/s
Airborne fraction	0.2	
Density non volatile	1	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	49.2	µm
Arithmetic coefficient of variation	0.57	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	100 %

[redacted]

Results for scenario *application (spray can)*

Show dose descriptions

Inhalation

Mean event concentration	6.3×10^{-4}	mg/m³
Peak concentration (TWA 15 min)	7.6×10^{-3}	mg/m³
Mean concentration on day of exposure	1.0×10^{-4}	mg/m³
Year average concentration	2.6×10^{-6}	mg/m³
External event dose	1.4×10^{-4}	mg/kg bw
External dose on day of exposure	1.4×10^{-4}	mg/kg bw
Internal event dose	1.4×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.4×10^{-4}	mg/kg bw/day
Internal year average dose	3.4×10^{-6}	mg/kg bw/day

Oral		
External event dose	9.5×10^{-4}	mg/kg bw
External dose on day of exposure	9.5×10^{-4}	mg/kg bw
Internal event dose	9.5×10^{-4}	mg/kg bw
Internal dose on day of exposure	9.5×10^{-4}	mg/kg bw/day
Internal year average dose	2.3×10^{-5}	mg/kg bw/day
Integrated		
Internal event dose	1.1×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.1×10^{-3}	mg/kg bw/day
Internal year average dose	2.7×10^{-5}	mg/kg bw/day

Substance		
Name	Cyfluthrin	
CAS number	68359-37-5	
Molecular weight	434	g/mol
Kow	6	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.026	%
Population		
Name	adult	
Body weight	60	kg

Scenarios

› Scenario *application (spray can)*

Scenario *application (spray can)*

Frequency	9	per year

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	6	minute
Exposure duration	240	minute
Weight fraction substance	0.026	%
Room volume	20	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	1.25	l/min
Spraying towards person	No	
Mass generation rate	0.55	g/s
Airborne fraction	0.2	
Density non volatile	1.8	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	3.6	µm
Arithmetic coefficient of variation	0.57	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	Direct contact - Constant rate	
Exposed area	–	
Weight fraction substance	0.026	%
Contact rate	100	mg/min
Release duration	6	minute
Absorption model	Fixed fraction	
Absorption fraction	50	%

Oral

Exposure model	Non-respirable spray model	
No parameters	Parameters are set in Inhalation exposure route.	
Absorption model	Fixed fraction	
Absorption fraction	100	%

[redacted]

Inhalation

Mean event concentration	8.7×10^{-2}	mg/m³
Peak concentration (TWA 15 min)	3.8×10^{-1}	mg/m³
Mean concentration on day of exposure	1.5×10^{-2}	mg/m³
Year average concentration	3.6×10^{-4}	mg/m³
External event dose	4.4×10^{-4}	mg/kg bw
External dose on day of exposure	4.4×10^{-4}	mg/kg bw
Internal event dose	4.4×10^{-4}	mg/kg bw
Internal dose on day of exposure	4.4×10^{-4}	mg/kg bw/day
Internal year average dose	1.1×10^{-5}	mg/kg bw/day

Dermal		
Dermal load	–	
External event dose	2.6×10^{-3}	mg/kg bw
External dose on day of exposure	2.6×10^{-3}	mg/kg bw
Internal event dose	1.3×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.3×10^{-3}	mg/kg bw/day
Internal year average dose	3.2×10^{-5}	mg/kg bw/day
Oral		
External event dose	1.0×10^{-7}	mg/kg bw
External dose on day of exposure	1.0×10^{-7}	mg/kg bw
Internal event dose	1.0×10^{-7}	mg/kg bw
Internal dose on day of exposure	1.0×10^{-7}	mg/kg bw/day
Internal year average dose	2.5×10^{-9}	mg/kg bw/day
Integrated		
Internal event dose	1.7×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.7×10^{-3}	mg/kg bw/day
Internal year average dose	4.3×10^{-5}	mg/kg bw/day

[redacted]

Substance		
Name	Cyfluthrin	
CAS number	68359-37-5	
Molecular weight	434	g/mol
Kow	6	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.026	%
Population		
Name	adult	
Body weight	60	kg

Scenarios

> Scenario *application (spray can)*

Scenario *application (spray can)*

Frequency	2	per year

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	2	minute
Exposure duration	240	minute
Weight fraction substance	0.026	%
Room volume	60	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	1.25	m^3/hr
Spraying towards person	No	
Mass generation rate	1.5	g/s
Airborne fraction	0.2	
Density non volatile	1	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	49.2	µm
Arithmetic coefficient of variation	0.57	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	Direct contact - Constant rate	
Exposed area	–	
Weight fraction substance	0.026	%
Contact rate	100	mg/min
Release duration	2	minute
Absorption model	Fixed fraction	
Absorption fraction	50	%

Oral

Exposure model	Non-respirable spray model	
No parameters	Parameters are set in Inhalation exposure route.	
Absorption model	Fixed fraction	
Absorption fraction	100	%

[redacted]

Results for scenario *application (spray can)*

Show dose descriptions

Inhalation

Mean event concentration	7.6×10^{-5}	mg/m³
Peak concentration (TWA 15 min)	9.2×10^{-4}	mg/m³
Mean concentration on day of exposure	1.3×10^{-5}	mg/m³
Year average concentration	7.0×10^{-8}	mg/m³
External event dose	6.4×10^{-6}	mg/kg bw
External dose on day of exposure	6.4×10^{-6}	mg/kg bw
Internal event dose	6.4×10^{-6}	mg/kg bw
Internal dose on day of exposure	6.4×10^{-6}	mg/kg bw/day
Internal year average dose	3.5×10^{-8}	mg/kg bw/day

Dermal

Dermal load	–	
External event dose	8.7×10^{-4}	mg/kg bw
External dose on day of exposure	8.7×10^{-4}	mg/kg bw
Internal event dose	4.3×10^{-4}	mg/kg bw
Internal dose on day of exposure	4.3×10^{-4}	mg/kg bw/day
Internal year average dose	2.4×10^{-6}	mg/kg bw/day

Oral

External event dose	4.4×10^{-5}	mg/kg bw
External dose on day of exposure	4.4×10^{-5}	mg/kg bw
Internal event dose	4.4×10^{-5}	mg/kg bw
Internal dose on day of exposure	4.4×10^{-5}	mg/kg bw/day
Internal year average dose	2.4×10^{-7}	mg/kg bw/day

Integrated

Internal event dose	4.8×10^{-4}	mg/kg bw
Internal dose on day of exposure	4.8×10^{-4}	mg/kg bw/day
Internal year average dose	2.6×10^{-6}	mg/kg bw/day

[redacted]

Substance		
Name	Cyfluthrin	
CAS number	68359-37-5	
Molecular weight	434	g/mol
Kow	6	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.026	%
Population		
Name	infant	
Body weight	8	kg

Scenarios

> Scenario *application (spray can)*

Scenario *application (spray can)*

Frequency	9	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	2	minute
Exposure duration	240	minute
Weight fraction substance	0.026	%
Room volume	60	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	0.84	m^3/hr
Spraying towards person	No	
Mass generation rate	1.5	g/s
Airborne fraction	0.2	
Density non volatile	1	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	49.2	µm
Arithmetic coefficient of variation	0.57	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	100 %

[redacted]

Results for scenario *application (spray can)*

Show dose descriptions

Inhalation

Mean event concentration	7.6×10^{-5}	mg/m³
Peak concentration (TWA 15 min)	9.2×10^{-4}	mg/m³
Mean concentration on day of exposure	1.3×10^{-5}	mg/m³
Year average concentration	3.1×10^{-7}	mg/m³
External event dose	3.2×10^{-5}	mg/kg bw
External dose on day of exposure	3.2×10^{-5}	mg/kg bw
Internal event dose	3.2×10^{-5}	mg/kg bw
Internal dose on day of exposure	3.2×10^{-5}	mg/kg bw/day
Internal year average dose	7.9×10^{-7}	mg/kg bw/day

Oral

External event dose	2.2×10^{-4}	mg/kg bw
External dose on day of exposure	2.2×10^{-4}	mg/kg bw
Internal event dose	2.2×10^{-4}	mg/kg bw
Internal dose on day of exposure	2.2×10^{-4}	mg/kg bw/day
Internal year average dose	5.4×10^{-6}	mg/kg bw/day

Integrated

Internal event dose	2.5×10^{-4}	mg/kg bw
Internal dose on day of exposure	2.5×10^{-4}	mg/kg bw/day
Internal year average dose	6.2×10^{-6}	mg/kg bw/day

[redacted]

Substance		
Name	Cyfluthrin	
CAS number	68359-37-5	
Molecular weight	434	g/mol
Kow	6	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.026	%
Population		
Name	toddler	
Body weight	10	kg

Scenarios

> Scenario *application (spray can)*

Scenario *application (spray can)*

Frequency	9	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	2	minute
Exposure duration	240	minute
Weight fraction substance	0.026	%
Room volume	60	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	1.26	m^3/hr
Spraying towards person	No	
Mass generation rate	1.5	g/s
Airborne fraction	0.2	
Density non volatile	1	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	49.2	µm
Arithmetic coefficient of variation	0.57	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	100 %

[redacted]

Results for scenario *application (spray can)*

Show dose descriptions

Inhalation

Mean event concentration	7.6×10^{-5}	mg/m³
Peak concentration (TWA 15 min)	9.2×10^{-4}	mg/m³
Mean concentration on day of exposure	1.3×10^{-5}	mg/m³
Year average concentration	3.1×10^{-7}	mg/m³
External event dose	3.9×10^{-5}	mg/kg bw
External dose on day of exposure	3.9×10^{-5}	mg/kg bw
Internal event dose	3.9×10^{-5}	mg/kg bw
Internal dose on day of exposure	3.9×10^{-5}	mg/kg bw/day
Internal year average dose	9.5×10^{-7}	mg/kg bw/day

Oral

External event dose	2.6×10^{-4}	mg/kg bw
External dose on day of exposure	2.6×10^{-4}	mg/kg bw
Internal event dose	2.6×10^{-4}	mg/kg bw
Internal dose on day of exposure	2.6×10^{-4}	mg/kg bw/day
Internal year average dose	6.5×10^{-6}	mg/kg bw/day

Integrated

Internal event dose	3.0×10^{-4}	mg/kg bw
Internal dose on day of exposure	3.0×10^{-4}	mg/kg bw/day
Internal year average dose	7.5×10^{-6}	mg/kg bw/day

Substance		
Name	Cyfluthrin	
CAS number	68359-37-5	
Molecular weight	434	g/mol
Kow	6	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.026	%
Population		
Name	child	
Body weight	23.9	kg

Scenarios

› Scenario *application (spray can)*

Scenario *application (spray can)*

Frequency	9	per year
Description		

Inhalation

Exposure model	Exposure to spray - Spraying	
Spray duration	2	minute
Exposure duration	240	minute
Weight fraction substance	0.026	%
Room volume	60	m^3
Room height	2.5	m
Ventilation rate	0.6	per hour
Inhalation rate	1.32	m^3/hr
Spraying towards person	No	
Mass generation rate	1.5	g/s
Airborne fraction	0.2	
Density non volatile	1	g/cm^3
Inhalation cut off diameter	15	µm
Aerosol diameter distribution	LogNormal	
Median diameter	49.2	µm
Arithmetic coefficient of variation	0.57	
Maximum diameter	50	µm
Include oral non-respirable material exposure	yes	
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal

Exposure model	n.a.
Absorption model	n.a.

Oral

Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	100 %

[redacted]

Results for scenario *application (spray can)*

Show dose descriptions

Inhalation

Mean event concentration	7.6×10^{-5}	mg/m³
Peak concentration (TWA 15 min)	9.2×10^{-4}	mg/m³
Mean concentration on day of exposure	1.3×10^{-5}	mg/m³
Year average concentration	3.1×10^{-7}	mg/m³
External event dose	1.7×10^{-5}	mg/kg bw
External dose on day of exposure	1.7×10^{-5}	mg/kg bw
Internal event dose	1.7×10^{-5}	mg/kg bw
Internal dose on day of exposure	1.7×10^{-5}	mg/kg bw/day
Internal year average dose	4.2×10^{-7}	mg/kg bw/day

Oral		
External event dose	1.2×10^{-4}	mg/kg bw
External dose on day of exposure	1.2×10^{-4}	mg/kg bw
Internal event dose	1.2×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.2×10^{-4}	mg/kg bw/day
Internal year average dose	2.9×10^{-6}	mg/kg bw/day
Integrated		
Internal event dose	1.3×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.3×10^{-4}	mg/kg bw/day
Internal year average dose	3.3×10^{-6}	mg/kg bw/day

[redacted]

[redacted]

Substance		
Name	Transfluthrin	
CAS number	118712-89-3	
Molecular weight	371	g/mol
Kow	5.4	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.114	%
Population		
Name	infant	
Body weight	8	kg

Scenarios

> Scenario *post application (child)*

Scenario *post application (child)*

Frequency	126	per year

Dermal

Exposure model	Direct contact - Rubbing off	
Exposed area	197	cm^2
Weight fraction substance	0.114	%
Transfer coefficient	0.2	m^2/hr
Dislodgeable amount	0.27	g/m^2
Contact time	60	minute
Contacted surface	2	m^2
Release duration	–	
Absorption model	Fixed fraction	
Absorption fraction	50	%

Oral

Exposure model	Direct product contact - Constant rate	
Weight fraction substance	0.114	%
Ingestion rate	0.09	mg/min
Exposure duration	60	minute
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal		
Dermal load	3.1×10^{-4}	mg/cm²
External event dose	7.7×10^{-3}	mg/kg bw
External dose on day of exposure	7.7×10^{-3}	mg/kg bw
Internal event dose	3.8×10^{-3}	mg/kg bw
Internal dose on day of exposure	3.8×10^{-3}	mg/kg bw/day
Internal year average dose	1.3×10^{-3}	mg/kg bw/day
Oral		
External event dose	7.7×10^{-4}	mg/kg bw
External dose on day of exposure	7.7×10^{-4}	mg/kg bw
Internal event dose	7.7×10^{-4}	mg/kg bw
Internal dose on day of exposure	7.7×10^{-4}	mg/kg bw/day
Internal year average dose	2.7×10^{-4}	mg/kg bw/day
Integrated		
Internal event dose	4.6×10^{-3}	mg/kg bw
Internal dose on day of exposure	4.6×10^{-3}	mg/kg bw/day
Internal year average dose	1.6×10^{-3}	mg/kg bw/day

Substance		
Name	Transfluthrin	
CAS number	118712-89-3	
Molecular weight	371	g/mol
Kow	5.4	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.114	%
Population		
Name	toddler	
Body weight	10	kg

Scenarios

> Scenario *post application (child)*

Scenario *post application (child)*

Frequency	126	per year

Dermal

Exposure model	Direct contact - Rubbing off	
Exposed area	230	cm^2
Weight fraction substance	0.114	%
Transfer coefficient	0.2	m^2/hr
Dislodgeable amount	0.27	g/m^2
Contact time	60	minute
Contacted surface	2	m^2
Release duration	–	
Absorption model	Fixed fraction	
Absorption fraction	50	%

Oral

Exposure model	Direct product contact - Constant rate	
Weight fraction substance	0.114	%
Ingestion rate	0.09	mg/min
Exposure duration	60	minute
Absorption model	Fixed fraction	
Absorption fraction	100	%

[redacted]

Dermal		
Dermal load	2.7×10^{-4}	mg/cm²
External event dose	6.2×10^{-3}	mg/kg bw
External dose on day of exposure	6.2×10^{-3}	mg/kg bw
Internal event dose	3.1×10^{-3}	mg/kg bw
Internal dose on day of exposure	3.1×10^{-3}	mg/kg bw/day
Internal year average dose	1.1×10^{-3}	mg/kg bw/day
Oral		
External event dose	6.2×10^{-4}	mg/kg bw
External dose on day of exposure	6.2×10^{-4}	mg/kg bw
Internal event dose	6.2×10^{-4}	mg/kg bw
Internal dose on day of exposure	6.2×10^{-4}	mg/kg bw/day
Internal year average dose	2.1×10^{-4}	mg/kg bw/day
Integrated		
Internal event dose	3.7×10^{-3}	mg/kg bw
Internal dose on day of exposure	3.7×10^{-3}	mg/kg bw/day
Internal year average dose	1.3×10^{-3}	mg/kg bw/day

[redacted]

Substance		
Name	Transfluthrin	
CAS number	118712-89-3	
Molecular weight	371	g/mol
Kow	5.4	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.114	%
Population		
Name	child	
Body weight	23.9	kg

Scenarios

› Scenario *post application (child)*

Scenario *post application (child)*

Frequency	126	per year

Dermal

Exposure model	Direct contact - Rubbing off	
Exposed area	428	cm^2
Weight fraction substance	0.114	%
Transfer coefficient	0.2	m^2/hr
Dislodgeable amount	0.27	g/m^2
Contact time	60	minute
Contacted surface	2	m^2
Release duration	–	
Absorption model	Fixed fraction	
Absorption fraction	50	%

[redacted]

Dermal

Dermal load	1.4×10^{-4}	mg/cm^2
External event dose	2.6×10^{-3}	mg/kg bw
External dose on day of exposure	2.6×10^{-3}	mg/kg bw
Internal event dose	1.3×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.3×10^{-3}	mg/kg bw/day
Internal year average dose	4.4×10^{-4}	mg/kg bw/day

Integrated

Internal event dose	1.3×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.3×10^{-3}	mg/kg bw/day
Internal year average dose	4.4×10^{-4}	mg/kg bw/day

[redacted]

Substance		
Name	Transfluthrin	
CAS number	118712-89-3	
Molecular weight	371	g/mol
Kow	5.4	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.114	%
Population		
Name	adult	
Body weight	60	kg

Scenarios

> Scenario *post application (child)*

Scenario *post application (child)*

Frequency	126	per year

Dermal

Exposure model	Direct contact - Rubbing off	
Exposed area	820	cm^2
Weight fraction substance	0.114	%
Transfer coefficient	0.78	m^2/hr
Dislodgeable amount	0.27	g/m^2
Contact time	60	minute
Contacted surface	2	m^2
Release duration	–	
Absorption model	Fixed fraction	
Absorption fraction	50	%

[redacted]

Dermal

Dermal load	2.9×10^{-4}	mg/cm²
External event dose	4.0×10^{-3}	mg/kg bw
External dose on day of exposure	4.0×10^{-3}	mg/kg bw
Internal event dose	2.0×10^{-3}	mg/kg bw
Internal dose on day of exposure	2.0×10^{-3}	mg/kg bw/day
Internal year average dose	6.9×10^{-4}	mg/kg bw/day

Integrated

Internal event dose	2.0×10^{-3}	mg/kg bw
Internal dose on day of exposure	2.0×10^{-3}	mg/kg bw/day
Internal year average dose	6.9×10^{-4}	mg/kg bw/day

[redacted]

Substance		
Name	Piperonyl butoxide	
CAS number	51-03-6	
Molecular weight	338	g/mol
Kow	–	
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.213	%
Population		
Name	infant	
Body weight	8	kg

Scenarios

> Scenario *post application (child)*

Scenario *post application (child)*

Frequency	126	per year
Description		

Dermal

Exposure model	Direct contact - Rubbing off	
Exposed area	197	cm^2
Weight fraction substance	0.213	%
Transfer coefficient	0.2	m^2/hr
Dislodgeable amount	0.27	g/m^2
Contact time	60	minute
Contacted surface	2	m^2
Release duration	–	
Absorption model	Fixed fraction	
Absorption fraction	50	%

Oral

Exposure model	Direct product contact - Constant rate	
Weight fraction substance	0.213	%
Ingestion rate	0.09	mg/min
Exposure duration	60	minute
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal		
Dermal load	5.8×10^{-4}	mg/cm²
External event dose	1.4×10^{-2}	mg/kg bw
External dose on day of exposure	1.4×10^{-2}	mg/kg bw
Internal event dose	7.2×10^{-3}	mg/kg bw
Internal dose on day of exposure	7.2×10^{-3}	mg/kg bw/day
Internal year average dose	2.5×10^{-3}	mg/kg bw/day
Oral		
External event dose	1.4×10^{-3}	mg/kg bw
External dose on day of exposure	1.4×10^{-3}	mg/kg bw
Internal event dose	1.4×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.4×10^{-3}	mg/kg bw/day
Internal year average dose	5.0×10^{-4}	mg/kg bw/day
Integrated		
Internal event dose	8.6×10^{-3}	mg/kg bw
Internal dose on day of exposure	8.6×10^{-3}	mg/kg bw/day
Internal year average dose	3.0×10^{-3}	mg/kg bw/day

Substance		
Name	Piperonyl butoxide	
CAS number	51-03-6	
Molecular weight	338	g/mol
Kow	4.8	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.213	%
Population		
Name	toddler	
Body weight	10	kg

Scenarios

> Scenario *post application (child)*

Scenario *post application (child)*

Frequency	126	per year

Dermal

Exposure model	Direct contact - Rubbing off	
Exposed area	230	cm^2
Weight fraction substance	0.213	%
Transfer coefficient	0.2	m^2/hr
Dislodgeable amount	0.27	g/m^2
Contact time	60	minute
Contacted surface	2	m^2
Release duration	–	
Absorption model	Fixed fraction	
Absorption fraction	50	%

Oral

Exposure model	Direct product contact - Constant rate	
Weight fraction substance	0.213	%
Ingestion rate	0.09	mg/min
Exposure duration	60	minute
Absorption model	Fixed fraction	
Absorption fraction	100	%

[redacted]

Dermal		
Dermal load	5.0×10^{-4}	mg/cm²
External event dose	1.2×10^{-2}	mg/kg bw
External dose on day of exposure	1.2×10^{-2}	mg/kg bw
Internal event dose	5.8×10^{-3}	mg/kg bw
Internal dose on day of exposure	5.8×10^{-3}	mg/kg bw/day
Internal year average dose	2.0×10^{-3}	mg/kg bw/day
Oral		
External event dose	1.2×10^{-3}	mg/kg bw
External dose on day of exposure	1.2×10^{-3}	mg/kg bw
Internal event dose	1.2×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.2×10^{-3}	mg/kg bw/day
Internal year average dose	4.0×10^{-4}	mg/kg bw/day
Integrated		
Internal event dose	6.9×10^{-3}	mg/kg bw
Internal dose on day of exposure	6.9×10^{-3}	mg/kg bw/day
Internal year average dose	2.4×10^{-3}	mg/kg bw/day

Substance		
Name	Piperonyl butoxide	
CAS number	51-03-6	
Molecular weight	338	g/mol
Kow	4.8	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.213	%
Population		
Name	child	
Body weight	23.9	kg

Scenarios

> Scenario *post application (child)*

Scenario *post application (child)*

Frequency	126	per year

Dermal

Exposure model	Direct contact - Rubbing off	
Exposed area	428	cm^2
Weight fraction substance	0.213	%
Transfer coefficient	0.2	m^2/hr
Dislodgeable amount	0.27	g/m^2
Contact time	60	minute
Contacted surface	2	m^2
Release duration	–	
Absorption model	Fixed fraction	
Absorption fraction	50	%

[redacted]

Dermal

Dermal load	2.7×10^{-4}	mg/cm^2
External event dose	4.8×10^{-3}	mg/kg bw
External dose on day of exposure	4.8×10^{-3}	mg/kg bw
Internal event dose	2.4×10^{-3}	mg/kg bw
Internal dose on day of exposure	2.4×10^{-3}	mg/kg bw/day
Internal year average dose	8.3×10^{-4}	mg/kg bw/day

Integrated

Internal event dose	2.4×10^{-3}	mg/kg bw
Internal dose on day of exposure	2.4×10^{-3}	mg/kg bw/day
Internal year average dose	8.3×10^{-4}	mg/kg bw/day

[redacted]

Substance		
Name	Piperonyl butoxide	
CAS number	51-03-6	
Molecular weight	338	g/mol
Kow	4.8	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.213	%
Population		
Name	adult	
Body weight	60	kg

Scenarios

› Scenario *post application (child)*

Scenario *post application (child)*

Frequency	126	per year

Dermal

Exposure model	Direct contact - Rubbing off	
Exposed area	820	cm^2
Weight fraction substance	0.213	%
Transfer coefficient	0.78	m^2/hr
Dislodgeable amount	0.27	g/m^2
Contact time	60	minute
Contacted surface	2	m^2
Release duration	–	
Absorption model	Fixed fraction	
Absorption fraction	50	%

[redacted]

Dermal

Dermal load	5.5×10^{-4}	mg/cm²
External event dose	7.5×10^{-3}	mg/kg bw
External dose on day of exposure	7.5×10^{-3}	mg/kg bw
Internal event dose	3.7×10^{-3}	mg/kg bw
Internal dose on day of exposure	3.7×10^{-3}	mg/kg bw/day
Internal year average dose	1.3×10^{-3}	mg/kg bw/day

Integrated

Internal event dose	3.7×10^{-3}	mg/kg bw
Internal dose on day of exposure	3.7×10^{-3}	mg/kg bw/day
Internal year average dose	1.3×10^{-3}	mg/kg bw/day

[redacted]

Substance		
Name	Cyfluthrin	
CAS number	68359-37-5	
Molecular weight	434	g/mol
Kow	6	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.026	%
Population		
Name	infant	
Body weight	8	kg

Scenarios

> Scenario *post application (child)*

Scenario *post application (child)*

Frequency	126	per year

Dermal

Exposure model	Direct contact - Rubbing off	
Exposed area	197	cm^2
Weight fraction substance	0.026	%
Transfer coefficient	0.2	m^2/hr
Dislodgeable amount	0.27	g/m^2
Contact time	60	minute
Contacted surface	2	m^2
Release duration	–	
Absorption model	Fixed fraction	
Absorption fraction	50	%

Oral

Exposure model	Direct product contact - Constant rate	
Weight fraction substance	0.026	%
Ingestion rate	0.09	mg/min
Exposure duration	60	minute
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal		
Dermal load	7.1×10^{-5}	mg/cm²
External event dose	1.8×10^{-3}	mg/kg bw
External dose on day of exposure	1.8×10^{-3}	mg/kg bw
Internal event dose	8.8×10^{-4}	mg/kg bw
Internal dose on day of exposure	8.8×10^{-4}	mg/kg bw/day
Internal year average dose	3.0×10^{-4}	mg/kg bw/day
Oral		
External event dose	1.8×10^{-4}	mg/kg bw
External dose on day of exposure	1.8×10^{-4}	mg/kg bw
Internal event dose	1.8×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.8×10^{-4}	mg/kg bw/day
Internal year average dose	6.1×10^{-5}	mg/kg bw/day
Integrated		
Internal event dose	1.1×10^{-3}	mg/kg bw
Internal dose on day of exposure	1.1×10^{-3}	mg/kg bw/day
Internal year average dose	3.6×10^{-4}	mg/kg bw/day

[redacted]

Substance		
Name	Cyfluthrin	
CAS number	68359-37-5	
Molecular weight	434	g/mol
Kow	6	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.026	%
Population		
Name	toddler	
Body weight	10	kg

Scenarios

> Scenario *post application (child)*

Scenario *post application (child)*

Frequency	126	per year

Dermal

Exposure model	Direct contact - Rubbing off	
Exposed area	230	cm^2
Weight fraction substance	0.026	%
Transfer coefficient	0.2	m^2/hr
Dislodgeable amount	0.27	g/m^2
Contact time	60	minute
Contacted surface	2	m^2
Release duration	–	
Absorption model	Fixed fraction	
Absorption fraction	50	%

Oral

Exposure model	Direct product contact - Constant rate	
Weight fraction substance	0.026	%
Ingestion rate	0.09	mg/min
Exposure duration	60	minute
Absorption model	Fixed fraction	
Absorption fraction	100	%

Dermal		
Dermal load	6.1×10^{-5}	mg/cm²
External event dose	1.4×10^{-3}	mg/kg bw
External dose on day of exposure	1.4×10^{-3}	mg/kg bw
Internal event dose	7.0×10^{-4}	mg/kg bw
Internal dose on day of exposure	7.0×10^{-4}	mg/kg bw/day
Internal year average dose	2.4×10^{-4}	mg/kg bw/day
Oral		
External event dose	1.4×10^{-4}	mg/kg bw
External dose on day of exposure	1.4×10^{-4}	mg/kg bw
Internal event dose	1.4×10^{-4}	mg/kg bw
Internal dose on day of exposure	1.4×10^{-4}	mg/kg bw/day
Internal year average dose	4.8×10^{-5}	mg/kg bw/day
Integrated		
Internal event dose	8.4×10^{-4}	mg/kg bw
Internal dose on day of exposure	8.4×10^{-4}	mg/kg bw/day
Internal year average dose	2.9×10^{-4}	mg/kg bw/day

[redacted]

Substance		
Name	Cyfluthrin	
CAS number	68359-37-5	
Molecular weight	434	g/mol
Kow	6	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.026	%
Population		
Name	child	
Body weight	23.9	kg

Scenarios

› Scenario *post application (child)*

Scenario *post application (child)*

Frequency	126	per year

Dermal

Exposure model	Direct contact - Rubbing off	
Exposed area	428	cm^2
Weight fraction substance	0.026	%
Transfer coefficient	0.2	m^2/hr
Dislodgeable amount	0.27	g/m^2
Contact time	60	minute
Contacted surface	2	m^2
Release duration	–	
Absorption model	Fixed fraction	
Absorption fraction	50	%

[redacted]

Dermal

Dermal load	3.3×10^{-5}	mg/cm^2
External event dose	5.9×10^{-4}	mg/kg bw
External dose on day of exposure	5.9×10^{-4}	mg/kg bw
Internal event dose	2.9×10^{-4}	mg/kg bw
Internal dose on day of exposure	2.9×10^{-4}	mg/kg bw/day
Internal year average dose	1.0×10^{-4}	mg/kg bw/day

Integrated

Internal event dose	2.9×10^{-4}	mg/kg bw
Internal dose on day of exposure	2.9×10^{-4}	mg/kg bw/day
Internal year average dose	1.0×10^{-4}	mg/kg bw/day

[redacted]

Substance		
Name	Cyfluthrin	
CAS number	68359-37-5	
Molecular weight	434	g/mol
Kow	6	10Log
Product		
Name	SPECIAL ONE	
Weight fraction substance	0.026	%
Population		
Name	adult	
Body weight	60	kg

Scenarios

> Scenario *post application (child)*

Scenario *post application (child)*

Frequency	126	per year

Dermal

Exposure model	Direct contact - Rubbing off	
Exposed area	820	cm^2
Weight fraction substance	0.026	%
Transfer coefficient	0.78	m^2/hr
Dislodgeable amount	0.27	g/m^2
Contact time	60	minute
Contacted surface	2	m^2
Release duration	–	
Absorption model	Fixed fraction	
Absorption fraction	50	%

Dermal		
Dermal load	6.7×10^{-5}	mg/cm²
External event dose	9.1×10^{-4}	mg/kg bw
External dose on day of exposure	9.1×10^{-4}	mg/kg bw
Internal event dose	4.6×10^{-4}	mg/kg bw
Internal dose on day of exposure	4.6×10^{-4}	mg/kg bw/day
Internal year average dose	1.6×10^{-4}	mg/kg bw/day
Integrated		
Internal event dose	4.6×10^{-4}	mg/kg bw
Internal dose on day of exposure	4.6×10^{-4}	mg/kg bw/day
Internal year average dose	1.6×10^{-4}	mg/kg bw/day

3.2.2 Enviromental Risk Assessment

Transfluthrin

ST4.0, Koc = 50119 L/Kg

New SimpleTreat transfluthrin.refinec

Piperonyl Butoxide

ST 4.0, Koc=2506.2 mL/g

New SimpleTreat PBO.pdf

Cyfluthrin

ST 4.0, Koc=123930 L/Kg

New SimpleTreat Cyfluthrin.refined.p

3.3 New information on the active substance

New information on the active substances is not available.

3.4 Residue behaviour

No residues of SPECIAL ONE in food or feed occur.

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

The label claim of SPECIAL ONE is to be an effective insecticide against:
[redacted]

- *Blattella germanica*
- *Blatta orientalis*
[redacted]

- *Vespula germanica*
- *Polistes gallicus*
[redacted]

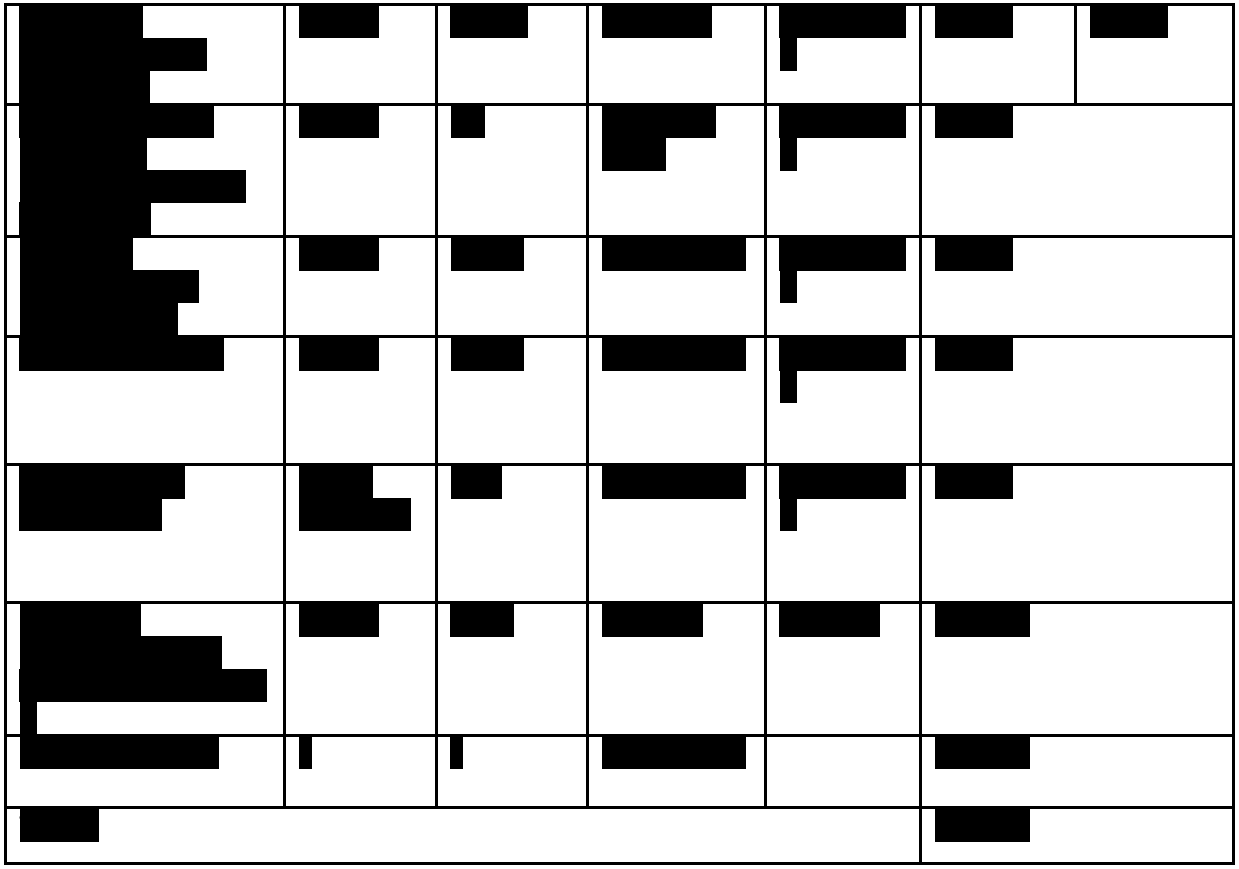
3.6 Confidential annex

For more details see separate Confidential Annex file.

3.7 Other

Flash point of active substances and coformulants.

[redacted]						
[redacted]						
[redacted]						



CONSIDERATIONS:

All the components of liquid phase have a flash point >60°C; therefore, they are not considered as flammable; the gas under pressure is a gas flammable as classify by producers. The quantity of flammable materials contained in the aerosol dispensers is 40 grams each 100 grams of net content in final product.