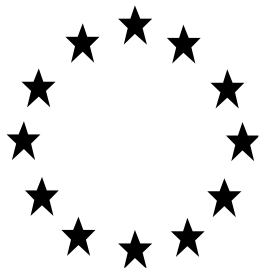
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



PROTEO EC

Product type(s) 18

Deltamethrin

Case Number in R4BP: BC-CT001304-45

Evaluating Competent Authority: SPAIN

December 2023

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1 CONCLUSION

The assessment presented in this report has shown that, PROTEO EC , with the active substance deltamethrin, at a level of 2.812% w/w, may be authorised for use as an insecticide (product-type 18) for the control against oriental cockroaches by trained professional and professional users. Please, note that this Assessment Report includes the uses requested by the applicant, as information for the concerned member states.

Physical-chemical properties and Analytical Methods

PROTEO EC is a EC (Emulsifiable Concentrate) product. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. Its technical characteristics are acceptable for an EC formulation.

The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in a white plastic can (commercial packaging material).

The analytical methods provided are fully validated for the determination of the active substance Deltamethrin. Methods for the determination of the residues are available in the CAR of the active substances.

Efficacy

Efficacy data submitted supports the use of PROTEO EC indoors (spot application in cracks and crevices) against oriental cockroaches (*Blatta orientalis*) by trained professional and professional users.

Two substances of concern has been identified for human health. The product contains 89.164% of the aromatic hydrocarbon solvent and 3.93% of phenylsulfonat Ca.

According to the SDS of aromatic hydrocarbon solvent, it is classified as Asp Tox 1; H304, STOT SE 3; H335 and STOT SE 3; H336. Moreover, according to database of registered substances under REACH in ECHA website, it must be classified as skin irritation, category 2;H315. In addition, other information has been checked, as Concawe report about "Hazard classification and labelling of petroleum substances in the European Economic Area – 2017".

According to the SDS of phenylsulfonat Ca (dodecyl benzene sulphonate in isobutanol), it is classified as Acute Tox 4; H312, Skin irrit 2; H315, Eye damage 1; H318, STOT SE 3; H335 and STOT SE 3; H336.

A full package of GLP compliant studies (2013) has been supplied to address the acute oral, dermal and inhalation toxicity, skin and eye irritation and skin sensitisation. These studies were conducted with the product Deltamethrin 2.5% EC (PROTEO EC). Based on these studies and the classification of the substances of concern, PROTEO EC must be classified as:

Acute toxicity (oral) and acute toxicity (inhalation), category 4; H302+H332

Serious eye damage, Category 1; H318

Specific target organ toxicity — single exposure, Category 3; H335
Specific target organ toxicity — single exposure, Category 3; H336

Aspiration hazard, Category 1; H304

PROTEO EC is a emulsifiable concentrate formulation for indoor use only, through devices such as pumps or sprays, being careful to apply the solution in cracks and crevices as spot application by trained professional and professional (non-trained professional) users. The product shall be diluted at a rate of 1:100 in water. The solutions obtained must be sprayed at a dose of 1 liter of in-use solution for 20 m^2.The in-use dilution will be applied through a low pressure sprayer (hand-held or knapsack sprayer). Spray as a spot treatment into crack and crevices only with max spray bandwidth of 0.1 m. In order to achieve this, application should be done by a pin-stream nozzle or special crack crevice extension and suitable distance between nozzle and sprayed surface should be maintained. Exposure takes places via inhalatory and dermal contamination throug hands and body taking into account the quantities that could potentially enter into contact with the users during mixing and loading and appliying the product and cleaning the spray equipment. Indirect exposure is expected for toddlers after spot type treatment application indoors and persons laundering contaminated work clothing by the biocidal product.

Primary and secondary exposure assessment performed with the mix, load and application of the liquid in drops into crack and crevices, using PPE for trained professional users and without PPE for the professional users.

Based on this risk assessment results, the use of PROTEO EC as an insecticide is considered safe for human health taking into account primary and secondary exposure to the biocidal product as a consequence of use.

Exposure of consumers via residues in food as result of product uses is not expected due to the application method and the physical properties of product. Moreover, some label restrictions to avoid this contamination have been included. See point 2.2.3.6. Risk for consumers via residues in food.

For the same reasons, neither is expected exposure of animals (companion animals, livestock) and some labels restrictions to avoid this exposure have been also included. See pont 2.2.7. Risk assessment for animal health.

Risk assessment for the environment

The environmental risk assement of this product has been based only on the active substance deltamethrin.
This product contains a substance of concern for the environment, however its contribution to the overall toxicity is insignificant , so it is has not been taken into account for the environmental risk assement of this product.

According to the use proposed for PROTEO EC , indoor in crack and crevice as spot application for private house and large buildings, an acceptable risk are predicted for all environmental compartments.

Hence the authorisation of the product can be granted from an environmental fate and behaviour perspective.

Overview of applications

Application type	Ref MS	Case number/Asset number in the ref MS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	ES	ES-0002081-0000	September 2018	First authorisation
NA-AAT	ES	BC-TN043784-14	October 2018	Amendment expiry date of the authorisation
NA-ADC	ES	BC-SU062647-98	February 2021	Classification, aditional names and manufacturer
NA-MIC	ES	BC-XB064617-32	June 2021	Deletion of Post-authorisation condition. Deletion of aditional names and manufacturer (BC-SU062647-98) by mistake.
NA-AAT	ES	BC-KY067023-15	June 2021	Correction: Re-inclusion of aditional names and manufacturer.
NA-APP	ES	BC-CT001304-45	April 2023	amended
NA-APP	ES	BC-CT001304-45	October 2023	amended
NA-AAT	ES	BC-US090415-07	November 2023	Amended PAR public & PAR Confid annex
NA-ADC	ES	BC-KN087301-33	December 2023	Product name Change: PROTEO EC GREEN to PROTEO EC.

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)**
PROTEO EC	SPAIN

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Sharda Europe B.V.B.A
	Address	Heedstraat 158, 1730 Asse, Belgium
Authorisation number	ES/APP(NA)-2018-18-00524	
Date of the authorisation	25/09/2018	
Expiry date of the authorisation	25/09/2028	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	Sharda Cropchem España S.L.
Address of manufacturer	Edificio Atalayas Business Center. Carril Condomina Nº3 Planta 12 30006 - Murcia - ESPAÑA
Location of manufacturing sites	1- I.R.C.A. Service SpA Strada Statale Cremasca 591, 10 24040 Fornovo San Giovanni (Bg) Italy 2- DTS OABE Pol. Bengoetxea, S/N 48419 , BENGOETXEA , OROZKO , Vizcaya, Spain 3- Lérida Unión Química S.A. (LUQSA) Afores s/n 25173, Sudanell Lleida, Spain 4-AGROTOTAL S.A., Pol. Ind. ADP Estrada Nacional 10, Salgados da Póvoa 2615-000 Alverca do Ribatejo Portugal

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

Active substance	Deltamethrin
Name of manufacturer	Sharda Europe B.V.B.A (acting for Sharda Cropchem Limited (India))

Address of manufacturer	Prime Business Park 2nd Floor Dashrathlal Joshi Road Vile Parle (West) 400056 Mumbai, India
Location of manufacturing sites	Heranba Industries Ltd. 101/102, Kanchanganga, Factory Lane, Borivali – (W), Mumbai – 400092 India

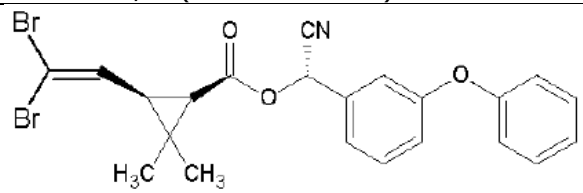
2.1.2 Product composition and formulation

NB: the full composition of the product has been provided in the confidential annex.

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Deltamethrin
IUPAC or EC name	α-cyano-3-phenoxybenzyl [1R-[1α(S*),3α]]-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate
EC number	258-256-6
CAS number	52918-63-5
Index number in Annex VI of CLP	607-319-00-X
Minimum purity / content	98.5 % w/w (Sharda source)
Structural formula	

2.1.2.2 Candidate(s) for substitution

Deltamethrin is not a candidate for substitution in accordance with Article 10(1) of Regulation 528/2012.

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

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (% w/w)**
Deltamethrin Technical a.s. (98.5%) Pure a.s.	(S)-α cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate	Active substance	52918-63-5	258-256-6	2.855 2.812
Phenylsulfonat Ca	Dodecylbenzene sulfonate in isobutanol	Emulsifying agent	11117-11-6/ 78-83-1	234-360-7/ 201-148-0	3.93
Aromatic hydrocarbon solvent	Hydrocarbons, C9, aromatics (Solvent naphtha (petroleum), light	solvent	Related CAS Nº 64742-95-6	Reach Registration provisional EC Nº:	89.164

Common name	IUPAC name	Function	CAS number	EC number	Content (% w/w)
	arom)			918-668-5	

The full formulation composition details are contained within the confidential annex.

2.1.2.4 Information on technical equivalence

The notified source of deltamehtrin (Sharda Europe B.V.B.A) is not the same as that considered for Annex I inclusion under Council Directive 98/8/EC (Bayer SAS Environmental Science). However, the Sharda source has been granted technically equivalent to the Annex I source by ECHA (Decision Nº TAP-D-1045815-30-00/F).

2.1.2.5 Information on the substance(s) of concern

Please see the confidential annex for further details.

The biocidal product contains also three compounds different from the active substance, deltamethrin, classified as dangerous for the environment. Two of them are not considered as substance of concern due to the low percentage in which they are present in the biocidal product. An the third one, the solvent, is classified as C2, is considered as a substance of concern for the environment since is present is a high percentage in the mixture. However its contribution to the overall toxicity of the product is insignificant so, it is not included in the environmental risk assement of this product, as it has been based only on the active substance deltamethrin.

2.1.2.6 Type of formulation

EC – Emulsifiable Concentrate

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Flammable liquids, Category 3 Acute toxicity (oral) category 4 acute toxicity (inhalation), category 4 Serious eye damage, Category 1 Specific target organ toxicity — single exposure, Category 3 Aspiration hazard, Category 1 Hazardous to the aquatic environment – Acute Hazard, Category 1 Hazardous to the aquatic environment – Chronic Hazard, Category 1

Hazard statement	H226 Flammable liquid and vapour. H302 Harmful if swallowed H332 Harmful if inhaled H318 Causes serious eye damage H335 May cause respiratory irritation H336 May cause drowsiness or dizziness. H304 May be fatal if swallowed and enters airways H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.
Labelling	
Pictogram	 GHS02 GHS05 GHS07 GHS08 GHS09
Signal words	Danger
Hazard statements	H226 Flammable liquid and vapour. H302+H332 Harmful if swallowed or if inhaled H304 May be fatal if swallowed and enters airways H318 Causes serious eye damage H335 May cause respiratory irritation H336 May cause drowsiness or dizziness. H410 Very toxic to aquatic life with long lasting effects. EUH066 Repeated exposure may cause skin dryness or cracking
Precautionary statements	P210 Keep away from heat/sparks/open flames/hot surfaces. – No smoking. P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P264 Wash hands thoroughly after handling P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or in a well-ventilated area. P273 Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection. P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor/… P330 Rinse mouth. P331 Do NOT induce vomiting. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338+P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor/ … P391 Collect spillage. P403+P233 Store in a well-ventilated place. Keep container tightly closed. P403 Store in a well-ventilated place P405 Store locked up. P501 Dispose of contents and/ or container in accordance with current regulations.

notes	The following P-statements were triggered by the included H-statements, but not included: •P301+P312 triggered by H302 is not assigned, as considered covered by the assigned P301+P310 triggered by H304. P312 triggered by H332, H335 and H336 is not assigned, as considered covered by the assigned P310 triggered by H304 and H318.

ES CA will apply article 37 according to BPR in the authorisation of this product including in this section the P statements that are recommended and highly recommended according to the result of the risk assessment of the product and considering the Guidance on labelling and packaging in accordance with Regulation (EC) No 1272/2008 (Version 4.2 March 2021).

2.1.4 Authorised use(s)

2.1.4.1 Use description. Table 1

Table 1. Use # 1 -Indoor-Spot application in crack and crevice-Trained professional

Product Type	18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide against oriental cockroaches (*Blatta orientalis*)
Target organism (including development stage)	Insecticide against the following target insects: - Oriental cockroaches (*Blatta orientalis*) all stages.
Field of use	Indoor
Application method(s)	Spot application in cracks and crevices
Application rate(s) and frequency	0.5 mL of product diluted in 50mL of water to treat 1 m² of cracks and crevices. The final spray solution quantity to be prepared *pro rata* shall be based on the actual treatment surface area Maximum 6 applications/year. Treatment can be repeted after 8 weeks
Category(ies) of users	Trained professional
Pack sizes and packaging material	Bottles made of PE/PA containing 50 and 100ml. Bottles made of PE/PA containing 250, 500 or 1000ml. Cans made of PE/PA containing 5000ml.

2.1.4.1.1 Use-specific instructions for use

If you suspect that the product is not effective, contact the authorisation holder. See section 2.1.5.1

2.1.4.1.2 Use-specific risk mitigation measures

Wear protective chemical resistant gloves, coverall and eye/face protection during

product handling phase (glove and coverall material to be specified by the authorisation holder within the product information) See section 2.1.5.2.

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

See section 2.1.5.3

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

See section 2.1.5.4

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

See section 2.1.5.5

2.1.4.2 Use description. Table 2

Table 2. Use # 2 -Indoor-Spot application in crack and crevice-professional

Product Type	18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide against oriental cockroaches (*Blatta orientalis*)
Target organism (including development stage)	Insecticide against the following target insects: - Oriental cockroaches (*Blatta orientalis*) all stages.
Field of use	Indoor
Application method(s)	Spot application in cracks and crevices
Application rate(s) and frequency	0.5 mL of product diluted in 50mL of water to treat 1 m² of cracks and crevices. The final spray solution quantity to be prepared pro rata shall be based on the actual treatment surface area Maximum 6 applications/year. Treatment can be repeted after 8weeks
Category(ies) of users	Professional
Pack sizes and packaging material	PE/PA bottle of 50 and 100ml PE/PA bottle of 250, 500 and 1000ml

2.1.4.2.1 Use-specific instructions for use

If you suspect that after two applications the product is not effective, contact a pest control company.

See section 2.1.5.1

2.1.4.2.2 Use-specific risk mitigation measures

Labelling instructions for use that minimise exposure or possible health effects.

It is recommended to wear protective chemical resistant gloves, coverall and eye/face protection during product handling phase (glove and coverall material to be specified by the authorisation holder within the product information).

See section 2.1.5.2

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

See section 2.1.5.3

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

See section 2.1.5.4

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

See section 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

Always read the label or leaflet before use and respect all the instructions provided.

PROTEO EC (Deltamethrin 2.5% EC) should be applied through devices such as pumps or sprays, being careful to apply the solution in cracks and crevices as spot application. The product shall be diluted at a rate of 1:100 in water. The solutions obtained must be sprayed at a dose of 1 liter of in-use solution for 20m^2.The in-use dilution will be applied through a low pressure sprayer (hand-held or knapsack sprayer). Spray as a spot treatment into crack and crevices only with max spray bandwidth of 0.1 m. In order to achieve this, application should be done by a pin-stream nozzle or special crack crevice extension and suitable distance between nozzle and sprayed surface should be maintained.

The infestation is expected to be controlled after 4 weeks of continuous exposure of Oriental cockroaches to the treated spots.

The product can be applied up to 6 times/year with an interval between applications of 8 weeks.

Shake before use.

2.1.5.2 Risk mitigation measures

Do not apply in livestock premises.

The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be a harborage for cockroaches.

Do not store near food, drink and feed.

Keep away from ignition sources (flames, hot surfaces, heat, sparks…).

Wash hands thoroughly after handling

Avoid breathing vapours/spray.

Use only in a well ventilated area.

Ensure correct ventilation during and after use.

Keep cats away from treated surfaces. Due to their particular sensitivity to deltamethrin, the product can cause severe adverse reactions in cats.

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

Keep out of reach of children and pets.

Keep uninvolved persons, children and pets away from treated surfaces/areas until dried.

Do not spray onto people and pets.

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

Remove all food, feed and drinks prior to treatment.

Please clean surfaces (including kitchenware) that are to come into contact with foodstuffs with a detergent.

Please apply the product outside the period of preparation and/or consumption of foodstuffs

Apply product out of the reach of children, birds, pets, farm animals and other non-target animals.

Do not throw the product on the ground, into a water course, into the sink or down the drain.

Avoid release to the environment (P273).

Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated.

Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc.).

Cover all surfaces and facilities likely to be in contact with food, feed and drinking water.

Check the efficacy of the product on site: if need be, cause of reduced efficacy must be

investigated to ensure that there is no resistance or to identify potential resistance.

Do not use the product in areas where resistance is suspected or established.

Inform the authorisation holder if the treatment is ineffective.

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

Poisoning may cause:

- Irritation of skin, Eye, mucous membranes, gastrointestinal and respiratory tract.
- Pulmonary aspiration hazard. Functional CNS disturbances.

Basic first aid procedures

- Move the person away from the contaminated area and remove contaminated or spattered clothing
- If contact in eyes, rinse with plenty of water for 15 minutes. Do NOT forget to remove the contact lenses.
- If contact on skin, wash with soap and plenty of water, without rubbing.
- If swallowed, do NOT induce vomiting unless told to do so by poison control or a health care professional.
- Keep the patient at rest and maintain the body temperature.
- Check the breath. If necessary give artificial respiration.
- If the person in unconscious, turn the patient sideways with the head at lower than the rest of the body and the knees bended.
- If necessary take the person to a hospital and show the label or packaging whenever possible.

DO NOT LEAVE THE POISENED PERSON ALONE UNDER ANY CIRCUMSTANCE

Medical advice for doctors and sanitary staff

- Symptomatic and supportive treatment.

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

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER.

Emergency measures to protect the environment:

Precautions: Prevent product from entering the environment (surface and ground water), sewerage, drainage, etc. with the construction of protective barriers and closing drains.

Communicate to the competent authorities or tipping leaks into waterways, drains, sewers ...

Methods and materials for containment and cleaning: Absorb spill on inert material (sand, kaolin ...), collect and place in containers for later properly identified as a hazardous waste management.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of contents and/ or container in accordance with current regulations (P501).

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

The product should be stored in tightly closed containers in a cool, dry, well-ventilated area. Avoid high temperatures and direct action of sunlight. Protect from moisture. The containers must be placed in such a way as to allow free air circulation. Do not store with oxidizers, alkalis (caustic solutions), or acids. Keep away from foodstuffs, beverages and feed. Check stocks regularly for damage. Under these conditions, the product can be stored for 2 years.

2.1.6 Other information

Packaging supplied to professional users shall be fitted with child-resistant fastenings and a tactile warning of danger. The product contains a bitter substance that makes it repulsive to people or pets. Definitions: Trained professional: pest control operators, having received specific training in insecticide control according to the national legislation in force. Professional: User applying biocidal products in the workplace. This user has some knowledge and skills in the handling of chemicals, and is able to correctly use personal protective equipment (PPE) if necessary.

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)
Bottle	50 and 100ml	PE/PA	Single neck induction seal cap	Trained professional and professional	Yes
Bottle	250, 500, 1000ml	PE/PA	Single neck induction seal cap or double neck temper evident caps	Trained professional and professional	Yes

Can	5000ml	PE/PA	Single neck induction seal cap	Trained professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data in support of the active substance or substances of concern have been submitted.
New data submitted in support of the evaluation of the biocidal product are listed in Annex 3.1.

2.1.8.2 Access to documentation

Bayer SAS Environmental Science owns the active substance (Annex II) dossier and has provided the applicant with a letter of access to these data and therefore no further consideration is required from a chemistry perspective.

2.2 Assessment of the biocidal product

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

Table 2. Intended use # 1 – Trained professional and professional use

Product Type	18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Stored Product Protection/Food protection Health protection
Target organism (including development stage)	Crawling insects
Field of use	Indoor
Application method(s)	Application in cracks and crevices
Application rate(s) and frequency	50 mL of product diluted in 5L of water to treat 100 m^2 surface Maximum 11 applications/year. Treatment can be repeted after 5 weeks
Category(ies) of users	Trained professional and professional
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830 6303	Deltamethrin 2.5% EC (Batch SDM 105001)	liquid	[redacted]
	EPA OPPTS 830 6303	Deltamethrin 2.5% EC (Batch SI-581)	liquid	[redacted]
Colour at 20 °C and 101.3 kPa	EPA OPPTS 830 6302	Deltamethrin 2.5% EC (Batch SDM 105001)	Faint yellow	[redacted]
	EPA OPPTS 830 6302	Deltamethrin 2.5% EC (Batch SI-581)	Clear yellow	[redacted]
Odour at 20 °C and 101.3 kPa	EPA OPPTS 830 6304	Deltamethrin 2.5% EC (Batch SDM 105001)	Characteristic	[redacted]
	EPA OPPTS 830 6304	Deltamethrin 2.5% EC (Batch SI-581)	Terpene like	[redacted]
Acidity / alkalinity	CIPAC MT 75.3	Deltamethrin 2.5% EC (Batch SDM 105001)	pH=5.3 (1% v/v solution) (worst-case)	[redacted]
	CIPAC MT 75	Deltamethrin 2.5% EC (Batch SI-581)	pH=7.01 (1% v/v solution) pH=3.91 (neat solution) There is a difference between the values	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			obtained from the two studies but they were done in different facilities by different technicians. Although both were done according to the guidelines, in the study performed by Chemservice (CH-202-2011) the water used was HPLC grade water, and in study DNA0456 by David Norris analytical the analysis was done with deionized water (boiled to remove CO2). This could somehow explain a certain variation in the pH values obtained in this study.	
Relative density	EU Method A.3	Deltamethrin 2.5% EC (Batch SI-581)	0.8891 at room temperature	[redacted]
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Deltamethrin 2.5% EC (Batch SDM 105001)	Active content at t=0 and after 14 days of storage at 54ºC Initial: 2.74 ± 0.018% w/w 24.40 ± 0.162 g/L After: 2.71 ± 0.018% w/w 24.16 ± 0.162 g/L The appearance of the commercial packaging (aluminium and PE/PA bottles) and the weight of the test item in the commercial packaging did not change significantly. Physical state (appearance), colour and odour	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Initial: Faint yellow liquid with characteristic odour After: Faint yellow liquid with characteristic odour pH value Initial: 5.2 After: 5.2 Emulsion characteristics and re-emulsification properties Initial: Complete initial emulsification (0h) Complete re-emulsification (24h) After: Complete initial emulsification (0h) Complete re-emulsification (24h) Colorimetric method for the determination of the stability of diluted emulsions Initial: 99.3% After: 99.1% Pourability of emulsifiable concentrates Initial: Residue: 0.13% After: Residue: 0.17%	
	CIPAC MT 46.3	Deltamethrin 2.5% EC (Batch SI-581)	Active content at t=0 and after 14 days of storage at 54ºC Initial: 24.93 ± 0.13 g/L After: 24.81 ± 0.27 g/L The appearance of the commercial packaging (aluminium and PE/PA bottles) and the weight of the test item in the commercial packaging did not change	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			significantly. Physical state (appearance), colour and odour Initial: Clear yellow oil that smells like terpenes. There are no signs of separation, sedimentation or claying and no suspended solids After: No changes pH value Initial: 7.01 After: 7.11 Emulsifiability: Initial: 95.68% - 97.02%. After 30 sec. the material dissolves into water to form a white emulsion. After 24 hours the emulsion is separated into a layer of 4 mL of cream at the surface and white water at the bottom. After single inversion the product is fully re-emulsifiable. After: 95.65% - 103.48%. Identical emulsifiability after storage. Pourability of emulsifiable concentrates Initial: Poured residue: 1.002%; water rinsed residue: 0.156%. After: Poured residue: 0.737%; water rinsed residue: 0.148%	
Storage stability test – **long term storage at ambient**	EPA 830.6302 EPA 830.6304	Deltamethrin 2.5% EC	Active content Initial:	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
temperature	EPA 830.6303 CIPAC MT 75.3 CIPAC MT 148.1 CIPAC MT 36.3 CIPAC MT 173	(Batch SDM 105001)	2.74 ± 0.018% w/w 24.40 ± 0.162 g/L 24 months: 2.79 ± 0.018% w/w 24.86 ± 0.162 g/L The appearance of the commercial packaging (aluminium and PE/PA bottles (1 L) and the weight of the test item in the commercial packaging did not change significantly. Physical state (appearance), colour and odour Initial: Faint yellow liquid with characteristic odour 24 months: Faint yellow liquid with characteristic odour pH value Initial: 5.2 After: 5.2 Emulsion characteristics and re-emulsification properties Initial: Complete initial emulsification (0h) Complete re-emulsification (24h) 24 months: Complete initial emulsification (0h) Complete re-emulsification (24h) Colorimetric method for the determination	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			of the stability of diluted emulsions Initial: 99.3% 24 months: 99.0% Pourability of emulsifiable concentrates Initial: Residue: 0.13% 24 months: Residue: 0.16% Temperature: As a general guidance, the laboratories are retained at approximately 20°C	
	EPA 830.6302 EPA 830.6304 EPA 830.6303 CIPAC MT 75	Deltamethrin 2.5% EC (Batch SI-581)	Packaging Initial and after: Aluminium silver coloured bottles with white plastic outer rim with a tape seal and an inner plastic plug Active content Initial: 24.93 g/L After: 24.31 g/L Weight variation Initial: 1008.71 g After: 1004.68 g Physical state (appearance), colour and odour Initial and after: Clear yellow liquid, free flowing like oil and showed no sign of separation into oil, creams, sediment or claying. There were no signs of suspended solids. The sample smelt like terpenes.	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			State of the packaging material (visual examination of packaging both externally and internally) Initial and final: The bottle was closed, with no evidence of any leaks or panelling pH value Initial: 0.1% solution: 7.01 Neat formulation: 3.91 After: 0.1% solution: 6.92 Neat formulation: 4.30 Temperature: As a general guidance, the laboratories are retained at approximately 20°C	
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39	Deltamethrin 2.5% EC (Batch SI-581)	Appearance after 1 h at 0ºC: material remained unchanged (no separation into oils, creams or sediment. It is a clear yellow liquid). Appearance after 7 days at 0ºC: material remained unchanged (no separation into oils, creams or sediment. It is a clear yellow liquid). After centrifugation: material remained unchanged (no separation into oil, cream or sediment) Active content Initial: 24.93±0.13 g/L (99.71% of	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			declared amount) After: 25.03±0.09 g/L (100.11% of declared amount) pH Initial: 7.01 After: 7.09	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Not relevant. Opaque packaging	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			According to use experience no effects from temperature or humidity are expected if the product is stored according to label recommendations. Furthermore, based on the results of the long-term stability test, we can conclude that there are no effects on the active substance content.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Visual examination	Deltamethrin 2.5% EC (Batch SI-581)	No evidences of leaks or panelling before and after storage	[redacted]
	Visual examination	Deltamethrin 2.5% EC (Batch SDM 105001)	The container did not present any deformation in either bottom or lateral layers, or loss of sample or evident corrosion phenomena	[redacted]
Wettability			Not required. Relevant only for solid formulations to be dispersed in water	
Suspensibility, spontaneity and dispersion stability			Not relevant. The formulation is an Emulsifiable concentrate.	
Wet sieve analysis and dry sieve test			Not relevant. The formulation is an Emulsifiable concentrate.	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36.3 CIPAC MT 173	Deltamethrin 2.5% EC (Batch SDM 105001)	The product exhibited complete initial emulsification as well as complete re-emulsification after 24 hours at concentration of 0.03% v/v and 0.15% v/v Emulsion stability was good after 4 hours at 25ºC	[redacted]
	CIPAC MT 36.3 CIPAC MT 173	Deltamethrin 2.5% EC (Batch SI-581)	The product exhibited complete initial emulsification as well as complete re-emulsification after 24 hours at concentration of 5% v/v Emulsion stability was good. According to the BPR Guide, a maximum of 2 mL of cream after 30 minutes is acceptable and reemulsification should be complete after 24 hours. Therefore, as long as reemulsification can be achieved, the observation of 4 mL of cream after 24 hours does not contradict the conclusion that "emulsion stability was good". Furthermore, the instructions for use "Shake before use." has been included in both the PAR and the SPC.	[redacted]
Disintegration time			Not relevant. Formulation is an emulsion concentrate and is not intended for disintegration when applied	
Particle size distribution, content of dust/fines, attrition, friability	OECD 110	Deltamethrin 2.5% EC	The % volume of particles with a size equal to or less than 50 microns is 72,09. %.	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	Particle analyzer Malvern Master Sizer 3000 E		The human health assessment is considered not impacted.	
Persistent foaming	CIPAC MT 47.2	Deltamethrin 2.5% EC (Batch SI-581)	Initial time: 10 s, 1 min, 3 min, 12 min; the amount of the foam in the sample: 0 mL	[redacted]
Flowability/Pourability/Dustability	CIPAC MT 148.1	Deltamethrin 2.5% EC (Batch SDM 105001)	Mean value: 0.13% residue	[redacted]
	CIPAC MT 148.1	Deltamethrin 2.5% EC (Batch SI-581)	Mean poured residue: 1.002% Mean rinsed residue: 0.156% Although there is a difference between the values obtained from these two studies, we consider that the most relevant interpretation derived from these results is that, in both cases, the values obtained are well below the 5% limit of residue required in this determination as per the guidelines. Therefore, the product does not pose any significant risk in terms of waste disposal. Moreover, considering that these two studies were done with a two-year difference, by different laboratories (personnel, methodology, etc.) a small deviation in the results can be reasonable and expected.	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Burning rate — smoke generators			Not relevant, the product is not a smoke generator	
Burning completeness — smoke generators			Not relevant, the product is not a smoke generator	
Composition of smoke — smoke generators			Not relevant, the product is not a smoke generator	
Spraying pattern — aerosols			Considering that the product is not sold in pre-filled spraying bottles and without a pinstream nozzle or special crack and crevice extension, as well as the fact that it is only for professional and trained professional use, data regarding the spraying pattern is not needed.	
Physical compatibility			Not relevant. The product is not intended to be used in combination with other biocidal products	
Chemical compatibility			Not relevant. The product is not intended to be used in combination with other biocidal products	
Degree of dissolution and dilution stability			Considering the formulation type of the product, data regarding dilution stability is not needed.	
Surface tension	EU Method A.5	Deltamethrin 2.5% EC (Batch SI-581)	27.43 ± 0.41 mN/m at 20 ± 0.1ºC The product is to be considered as surface-active.	[redacted]
Viscosity	OECD Test Guideline 114	Deltamethrin 2.5% EC (Batch SI-581)	Dynamic viscosity: 1.958 ± 0.01 mPa.s at 20ºC 1.314 ± 0.029 mPa.s at 40ºC.	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			Kinematic at 20°C: 1.958 mPa◦s/0.8891 g/cm3 = 2.20 cSt Kinematic at 40°C: 1.314 mPa◦s/0.8891 g/cm3 = 1.48 cSt *Dynamic (cP) / Density = Kinematic (cSt)*	

Conclusion on the physical, chemical and technical properties of the product
Deltamethrin 2.5% EC is a yellow liquid (emulsion) with a characteristic terpene-like odour. The pH values of the neat formulation and of a 1% aqueous dispersion of test item are 3.91 and 7.01, respectively, according to 1 study. However, another study determined the 1% dilution to have a pH of 5.3. The relative density resulted in 0.8891. The formulation exhibited stability under accelerated storage and storage at low temperature, as well as for 2 years at room temperature. The formulation does not have a corrosive effect on aluminium, copper, zinc and polyethylene and it does not react with the packaging material polyethylene. Deltamethrin 2.5% EC exhibited complete initial emulsification as well as complete re-emulsification after 24 hours after mixing by inversion. Additionally, it suspended well in water and showed good emulsion stability after 4 hours at 25ºC. According to the results obtained in the pourability test, the average poured residue of the test sample was determined to be 0.13% or 1.002% depending on the study. The results of a persistent foam test indicated production of 0 mL of foam/froth after 12 minutes, which is within the acceptable limits required. The formulation has a mean effectiveness of cleaning result of <0.05% of residue in tank. The mean viscosity is 1.958 ± 0.01mPa.s at 20ºC and 1.314 ± 0.029 mPa.s at 40ºC. The mean surface tension for the formulation is 27.43 ± 0.41 mN/m.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Differential Scanning Calorimety (DSC)	Deltamethrin 2.5% EC	The DSC test proves that the product does not have explosive properties.	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Flammable gases			Not relevant. Formulation is not a gas.	
Flammable aerosols			Not relevant. The product is not supplied as a pressurized aerosol	
Oxidising gases			Not relevant. Formulation is not a gas.	
Gases under pressure			Not relevant. Formulation is not a gas.	
Flammable liquids	EU Method A.9	Deltamethrin 2.5% EC (Batch SI-581)	The test item has been determined to have a flash point of 37ºC.	[redacted]
Flammable solids			Not relevant. Formulation is not a solid	
Self-reactive substances and mixtures	Differential Scanning Calorimety (DSC)	Deltamethrin 2.5% EC	The DSC test proves that the product does not have explosive properties.	[redacted]
Pyrophoric liquids			Not relevant. The classification procedure for pyrophoric liquids need not be applied when experience in manufacture or handling shows that the liquid does not ignite spontaneously on coming into contact with air at normal temperatures.	
Pyrophoric solids			Not relevant. Formulation is not a solid	
Self-heating substances and mixtures			Not relevant. According to the additional classification considerations in CLP guidance 2.11.4.2**, 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.	
Substances and mixtures which in			Not relevant. According to experience of use the product does not react with ambiental moisture or	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
contact with water emit flammable gases			water	
Oxidising liquids	Manual of Test and Criteria Seventh revised edtion ST/SG/AC.10/11/Rev.7. United Nations	Deltamethrin 2.5% EC	Taking as a reference substance an aqueous solution of 65% nitric acid, the first reference of pressure rise time is obtained with which to compare the test sample. The mean pressure rise times calculated in M-23-0377 are well above those of the reference substance since at no time during the experiment was the maximun pressure of 2070 kPa no reached to be able to calculate the pressure rise time. Based on these results and according to UN test O.2 criteria, the test material is not an oxidizing liquid.	[redacted]
Oxidising solids			Not relevant. Formulation is not a solid	
Organic peroxides			Not relevant. Formulation does not contain peroxides	
Corrosive to metals	UN Test C.1	Deltamethrin 2.5% EC	The corrosion rate of steel at the temperature of 55ºC after 168 hour is below the threshold of 6,25 mm/yea, since the greatest mass loss was of 0,34% i.e below the threshold of 13,5 %. The corrosion rate of aluminium at the temperature of 55ºC after 168 hour is below the threshold of 6,25 mm/yea, since the greatest mass loss was of 0,11% i.e below the threshold of 13,5 % The study proves that the product is not corrosive to metals.	[redacted]

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Auto-ignition temperatures of products (liquids and gases)	EU Method A.15	Deltamethrin 2.5% EC (Batch SI-581)	> 400.0 °C	[redacted]
Relative self-ignition temperature for solids			Not relevant. Formulation is not a solid	
Dust explosion hazard			Not relevant. Formulation is not a solid	

Conclusion on the physical hazards and respective characteristics of the product
The formulation has been determined to have a flash point of 37ºC and is, consequently, considered flammable. The self-ignition temperature is greater than 400ºC. It is predicted to be neither explosive nor oxidizing. Additionally, it does not readily react with sodium hydroxide, hydrogen peroxide or zinc.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Active substance in biocidal product: Deltamethrin	HPLC-DAD	From 0 to 1.5 mg/ml 5 measurements in duplicate	The method is linear: Y=0.0006x R^2=0.9999	The specificity of the method was proven by comparing a blanc fomulation sample with a reference standard of	94.32-106.23	99.37	4.546	<1 g/L	[redacted]

				deltamethrin. The relevant chromatograms have been provided.					

Analytical methods for the monitoring of residues (soil, water, air, body fluids and tissues and food)

Monitoring methods were reported in the deltamethrin CAR. Methods in soil, air, water and body fluids and tissues were submitted and deemed acceptable. No methods for detecting deltamethrin in food and feeding stuffs of plant and animal origin were provided as the intended uses will not result in significant residues in those matrices when the label instruction is followed. The label states 'keep away from food, drink and animal'. However, two methods (GC-ECD and LC-MS/MS) were provided for food/feed of plant origin for use in the case of contamination and the method supplied for body tissues was deemed suitable for food/feed of animal origin. No further consideration is required from a chemistry perspective for product authorisation.

Conclusion on the methods for detection and identificationof the product

The assay of Deltarnethrin was performed using approximately 1 g of formulation. The mass ofthe formulated material was accurately recorded, transferred to a 100ml volumetric flask in duplicate, sonicated to ensure thorough dilution and made up to volume with Acetonitrile (HPLC) or Dichloromethane (GCMS). HPLC-DAD conditions for Deltamethrin: Instrument:

Column: Agilent Eclipse 4.6mm x 150mm

Packing: XDB-C8 5J.Lm

Eluant: 60% Acetonitrile: 40% Water adjusted to pH 3 with phosphoric acid

Wavelength: 254 nm

Flow Rate: 1.0 ml/min

Injection Volume: 10/11

Retention time: Approx 36.9 minutes

Data Collection: Chemstation

Furthermore, the method was validated according to the requirements of the SANCO 3030/99 rev.4 Guidelines. Based on the results obtained, the method can be considered valid (specific, linear and precise) for the determination of deltamethrin

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

PROTEO EC is an insecticide, PT 18.

The product is for use indoors by trained professional and professional. The product is for use in domestic, public and commercial premises.

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

PROTEO EC is intended to produce knockdown and mortality of oriental cockroaches (*Blatta orientalis*).

2.2.5.3 Effects on target organisms, including unacceptable suffering

Deltamethrin has a potent shock effect, acting by neurotoxic knockdown by blocking the transmission of nerve impulses.

In addition Deltamethrin causes killing, therefore producing a reduction in the population of insects.

2.2.5.4 Mode of action, including time delay

The active substance Deltamethrin, belonging to the Pyrethroid chemical family acts by contact and ingestion.

It acts on nerve membranes by delaying the closing of the activation gate for the sodium ion channel thus interfering with normal nerve functioning.

Deltamethrin has several effects on the insects:

-A knockdown effect or immediate effect.

Deltamethrin acts on the nervous system of the insect and leads to paralysis of the insect. This fast and rapid action flushes out the insects.

-A killing effect or "Kill" = mortality.

The insecticidal effect continues after the penetration into the organism of the insect and leads to its death.

- A long residual effect.

Deltamethrin is photostable and insoluble in water (0.002 ppm), its efficacy will last and the treatments are less frequent

-A "flushing effect". Insects are flushed out from their hidden places, thereby driving them into contact with the treated areas.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)					
Function and field of use envisaged	**Test substance**	**Test organism(s)**	**Test method/ Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
For use as indoor crack and crevice treatment against crawling insects.	Deltamethrin 2.5% SC (Read across product)	*Blatella germanica, Blatta orientalis* and *Lasius niger*	Laboratory trial against cockroaches and ants. 12.5 ml of product were diluted in 1.25 L of water and sprayed onto porous and non-porous surfaces (total surface area treated was 25 m^2). 5 replicates per treatment were conducted for each species along with an equal number of untreated controls. 10 cockroaches and 20 ants per replicate were placed in contact with the surfaces for a period of 60 minutes. Although food and water were provided before and after each contact period this was not available to target insects during the contact period. Knockdown and mortality were then recorded after 1 hour, 2, 4, 5, 6 and 7 days.	*B. germanica* Non-porous: 100 % knockdown/mortality after 60 minutes and remained unchanged for the remainder of the test period. Porous: 100 % knockdown/mortality after 60 minutes and remained unchanged for the remainder of the test period. *B. orientalis* Non-porous: 100 % knowckdown/mortality after 60 minutes and remained unchanged for the remainder of the test period. Porous: 100 % knockdown after 60 minutes. Final mortality of 98 % reached after 5 days. *L. niger* Non-porous: Maximum mortality of 84 % achieved after 7 days Porous: Maximum mortality of 84 % achieved after 7 days. All control results were sufficient to validate the test.	[redacted]
	Deltamethrin 2.5% SC (Read across product)	*B. germanica, B. orientalis,*	Field trials against cockroaches 3 sites were tested for each cockroach species with natural populations	The mean population reductions for each species were as follows: *B. germanica*: 93.9 % reduction after 4 weeks.	[redacted]

			Monitoring traps were used to assess the population of the target species for 2 days prior to treatment. The product was applied according to the label instructions at a rate of 50 ml product 100 m^2 for cockroaches. Monitoring traps in the same positions were then used to monitor the population at 2 week intervals for 8 weeks for cockroaches	*B. orientalis*: 97.6 % reduction after 4 weeks. The populations increased after these time periods. The applicant has stated that this was due to reinvasion.	
	Deltamethrin 2.5% SC (Read across product)	*L. niger*	Field trial against ants The trial was conducted on existing ant nests in 5 replicate sites. The product was applied at a rate of 50 ml 100 m^2 around nest entrances. The same number of control nests was treated with water only. Ant activity was recorded by monitoring the frequency of ants crossing a specified area before treatment and then 1, 3, 7, 14, 21 and 28 days after treatment. At the end of the test period, the nests were open to check for living adults and larvae.	Mean percentage reduction in ant activity: 1 day: 94.4 % 3 days: 98.6 % 7 days: 99.3 % 14 days: 99.5 % 21 days: 99.9 % 28 days: 99.7 % At the final count no living adults and no living larvae were found in the treated nests. All control results were sufficient to verify the test.	[redacted]
	Deltamethrin 2.5% EC	*P. americana* and *B. germanica*	Laboratory trial against cockroaches. Dose: 5 ml of product were diluted in water to achieve five concentrations: 20, 15, 10, 5 and 2.5 ml/L. 5 ml of the in-use solution was sprayed with an atomizer onto porous and non-porous surfaces (panels 20 x20 cm of wood, cement, mud, glass and tiles). The same treated panels were used for persistency 1, 2, 4, 6 & 8 weeks. 3 replicates per treatment were conducted for each species along with an equal number of untreated controls.	<u>*P. americana*</u> Week 0: 100% mortality in all surfaces with all dilutions Week 1: 100% mortality in all surfaces with all dilutions Week 2: ≥98.33% mortality in all surfaces with all dilutions Week 4: ≥96.67% mortality in all surfaces with all dilutions Week 6: ≥93.33% mortality in all surfaces with all dilutions Week 8: ≥90.00% mortality in all surfaces with all dilutions	[redacted]

			20 cockroaches per replicate were placed in contact with the surfaces for a period of 60 minutes. Knockdown was observed every 5 minutos up to 60 minutes and mortality was then recorded after 1 day.	*B. germanica* Week 0: 100 % mortality in all surfaces and dilutions Week 1: 100% mortality in all surfaces and dilutions Week 2: 100% mortality in all surfaces with all dilutions Week 4: 100% mortality in all surfaces with all dilutions Week 6: ≥96.67% mortality in all surfaces with all dilutions Week 8: ≥93.33% mortality in all surfaces with all dilutions All control results were sufficient to validate the test.	
	Deltamethrin 2.5% EC	*B. orientalis*	Laboratory trial against oriental cockroach. Dose: 5 ml of product were diluted in water to achieve five concentrations: 20, 15, 10, 5 and 2.5 ml/L. 5 ml of the in-use solution was sprayed with an atomizer onto porous and non-porous surfaces (panels 20 x20 cm of wood, cement, mud, glass and tiles) 3 replicates per treatment were conducted along with an equal number of untreated controls. 20 cockroaches per replicate were placed in contact with the surfaces for a period of 60 minutes. Knockdown was observed every 5 minutos up to 60 minutes and mortality was then recorded after 1 day.	*B. orientalis* Non-porous: 100 % knockdown/mortality after 60 minutes and remained unchanged for the remainder of the test period. Porous: 100 % knockdown/ mortality after 60 minutes and remained unchanged for the remainder of the test period. All control results were sufficient to validate the test.	[redacted]

Conclusion on the efficacy of the product

The label claim for the product is:

- Insecticidal emulsifiable concentrate against crawling insects (cockroaches and ants).

At the beginning, the applicant also applied for the claim against flying insect (flies, mosquitoes and wasps) but finally, this claim was withdrawn by the applicant. ES CA has decided not to include in this Product Assessment Report studies against flying insect submitted by the applicant in order to not mislead the reader. In addition, it should note that studies against flying insect have not been evaluated.

According to the technical notes for guidance (TNGs), for the products with general claims against crawling insects,data must be provided on at least one small species of cockroach e.g. *Blatella germanica*, and one large cockroach species e.g. *Blatta orientalis.*

The TNGs states that products against ants for professional use, a field trial is always required. While laboratory and simulated use tests might be considered sufficient in some cases for consumer products.
No specific efficacy field trials were performed with the formulation Deltamethrin 2.5% EC (PROTEO EC) but with a similar formulation Deltamethrin 2.5% SC containing the same concentration of active substance and applied at the same application rate (including previous dilution) than PROTEO EC . The extrapolation between formulations is considered valid because the products are applied at the same rate in terms of active substance, following the same application instructions and against the same target organisms. In addition neither the SC nor EC formulations contain any ingredient intended to enhance the effect of the active substance or to attract or serve as nutrient to improve the ingestion of the product. The applicant has submitted a composition certificate in order to demonstrate that the read accross between both formulation is possible. ES CA accepts the justification and the read across. (See confidential annex)

Update **ES CA 11/04/2023**:
The Appliant has provided new bridging studies to demonstrate that Deltamethrin 2.5% SC and Deltamethrin 2.5% EC (PROTEO EC) formulations are similar in terms of efficacy.

<u>Efficacy against cockroaches.</u>
The applicant has submitted a laboratory trial and a field trial against two species: *Blattella germanica* and *Blatta orientalis*.

The laboratory trial performed with Deltamethrin 2.5% SC, demonstrates that the product is efficacious against *Blattella germanica* and *Blatta orientalis*. The methodology is acceptable but the test is a laboratory test nor a semifield test. The test was performed on non porous and porous surfaces. The number of insect is 10 cockroaches per replicate, being 5 replicates performed and untreated control were used in both surfaces with the same number of replicates and same number of individuals per replicate.
The results demonstrated 100% knockdown/mortality for *Blatella germanica* in all assessments performed and on both surfaces (porous and non porous).
In case of *Blatta orientalis* the results were 100% knockdown/mortality in all assessments on non-porous surfaces. On porous surfaces the result was 98% of mortality after 5 days.
Theses results comply with the criteria set out in the TNsG.

The laboratory test performed with Deltamethrin 2.5% EC shows efficacy against *Blattella germanica* and *Periplaneta americana*. The test was performed in porous and non-porous surfaces in panels of 20x20 cm, and the same panels were used for persistency at 1, 2, 4, 6 & 8 weeks of treatment. 3 replicates per treatment were conducted for each species along with an equal number of untreated controls. 20 cockroaches per replicate were placed in contact with the surfaces during 60 minutes. The results showed 100% knockdown/mortality in all assessments for *B. germanica* up to 4 weeks, and ≥96.67% after 6 weeks. These results comply with the criteria set out in the TNsG.

The laboratory test performed with Deltamethrin 2.5 EC against *Blatta orientalis* used five concentrations and five different suraces, porous and non-porous. 3 replicates per treatment were conducted along with an equal number of untreted controls. 20 cockroaches per replicate were placed in contact with the surfaces for a period of 60 minutes. Deltametrhin 2.5% EC showed 100% knockdown and mortality after 60 minutes in all assessments against B. orientalis. These results comply with the criteria set out in the TNsG.

The field trial also demostrated that the product is efficacious against *Blattella germanica* and *Blatta orientalis*. The methodology was deemed acceptable. The results obtained were mean population reductions of 93.9% for *Blatella germanica* and 97.6% for *Blatta orientalis* after 4 weeks. The population increased again after this point due to reinvasion. The product does not claim residual efficacy so data on mortality after 4 weeks are acceptable since the results meet the acceptability criteria in the TNsG.
However it should be noted that two out of three premises used for the study with *Blatella germanica* had previously been treated with another insecticide, whilst in the Guidance it is stated that sites with recent insecticide use should not be included in a field test. Therefore, the results of these trials against *B. germanica* cannot be considered acceptable. Only the efficacy against *B. orientalis* can be considered as proven.
Since a field trial and a laboratory trial against *B. orientalis* meet the acceptability criteria in the TNsG, ES CA considers these data as sufficient to demonstrate the efficacy of the product against oriental cockroaches at the requested application rate of 50 ml product diluted in 5 L of water to treat 100 $m^{2.}$

<u>Efficacy against ants.</u>

The applicant has submitted a laboratory trial and a field trial against one specie: *Lasius niger*.

The laboratory trial against ants is performed in laboratory conditions not in semifield condition but the methodology is acceptable for a laboratory study. The test was performed on porous and non-porous surfaces. The number of insect is 20 ants per replicate, being 5 replicates performed and untreated control were used in both surfaces with the same number of replicates and same number of individuals per replicate.
The results demonstrate a 84% after 7 days on both surfaces. The results do not meet the acceptability criteria set out in the TNsG, which state that the mortality must be 100% within 24 hours. ES CA considers that this study is complementary for demonstrating the efficacy of the product as insecticide.

The field trial against ants has been performed with the methodology acceptable. The results demonstrated 100% mortality after 4 weeks including the nest opening and parts of ground in order to check the nests' destruction.

As only a field trial has demonstrated the efficacy of the product against ants (*Lasius niger*) and

according to the label claim, ES CA considers that the efficacy data package against ants (*Lasius niger*) do not support the label claim of the product.

Decision

The former data shows that only efficacy against oriental cockroaches has been proven in field conditions. Therefore the general claim „against crawling insects" is not supported by adequate data.

The ES CA concludes that the data package submitted have demonstrated that the product, PROTEO EC , is effective as an insecticide against oriental cockroaches (*Blatta orientalis*) when used as spot application in cracks and crevices treatment.

2.2.5.6 Occurrence of resistance and resistance management

The applicant has provided the following justificacion about the potencial occurrence of resistance of the product:

"Deltamethrin is used in biocidal products in a limited extension and therefore it is not expected the development of resistance in target organisms. In order to avoid any resistance development in target organisms it is recommended to alternate the use of deltamethrin-based products with other insecticidal products not containing pyrethroids".

ES CA accepts the justification provided by the applicant. However in the literature additional information is available.

Deltamethrin is a pyrethroid insecticide. Deltamethrin products are widely used for various applications: veterinary medicine, crop protection, indoors and outdoors biocide, and against numerous arthropods target organisms. Resistance to deltamethrin has already been reported in several insects.

Resistant populations of house flies (*Musca domestica*) have been identified in the whole world (Asia, Europe, and America). Several mechanisms are involved in resistance to pyrethroids in house fly. This includes detoxification of the active substances, knockdown resistance (also called "kdr"), correlated with decrease nerve sensitivity, and decrease in the rate of penetration of the products. These mechanisms can co-exist in a resistant strain . Cross-resistance also exists in resistant strains, among pyrethroids, but also other insecticide types (chlorpyrifos and imidacloprid).

Concerning cockroaches, several mechanisms are also involved in resistance to pyrethroids, in particular cuticular penetration is one of the obstacles for the effectiveness of pyrethroids against German cockroaches. Resistant populations of German cockroaches have been identified in the entire world (Asia, Europe, and America). The Oriental cockroach has developed little resistance.

As a consequence, 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 no known limitations to consider for the product.

2.2.5.8 Evaluation of the label claims

Efficacy data submitted supports the use of PROTEO EC (Deltamethrin 2.5% EC) indoors against oriental cockroaches (*Blatta orientalis*) by professional and trained professional users.

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

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

2.2.6 Risk assessment for human health

PROTEO EC is as emulsifiable concentrate containing 2.812%(w/w) deltamethrin.

A full package of GLP compliant studies (2013) has been supplied to address the acute oral, dermal and inhalation toxicity, skin and eye irritation and skin sensitisation. These studies were conducted with the product Deltamethrin 2.5%(w/v) EC. Based on these studies, different hazard classification is triggered for the product.

Deltamethrin 2.5% EC formulation is identical to PROTEO EC , so data generated for this product can be referred to the product PROTEO EC (see confidential annex).

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline , GLP status, Reliability	**Species , Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD TG 404 and EU B.4/GLP/1	Rabbit, New Zealand White, Female, three animals/ group	Deltamethrin 2.5 EC 0.5ml No vehicle, 4 hours exposure	The individual mean score for erythema/eschar formation were 1, 1 and 2 for the three animals tested. The individual mean score for oedema for the three animals were 0.33, 0.00 and 1.00. (Erythema/eschar and oedema calculated as the mean scores following grading at 24, 48 and 72	None	[redacted]

			hours after patch removal). Test item caused a slight erythema in two animals at 24, 48, 72 hours and 7 days and a well defined erythema in the third animal at 72 hours which was reduced after 7 days. Very slight oedema was detected at 72 hours and day 7 in two animals. Observation times: Immediately after patch removal and 1, 24, 48, 72 hours and 7 and 14 days after exposure. No effects observed after 14 days (reversible effects) (exposure time=4h)./No hispatological or systemic effects were detected.		

No human data on skin corrosion/irritation is available

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Non-irritant
Justification for the value/conclusion	Based on primary irritation index
Classification of the product according to CLP	PROTEO EC is not classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation). However, due to the content of solvent in the biocidal product, the supplemental hazard statement EUH066 must be assigned.

Eye irritation

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, **GLP status, Reliability**	**Species, Strain, Sex, No/group**	**Test substance,Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD TG 405 and EU B.5/GLP/1	Rabbit, New Zealand White, Female, three animals/group	Deltamethrin 2.5 EC 0.1 ml, 1 second	Group mean scores: Redness of conjunctivae: 1.67, 2.33, 2.00; chemosis:1.33, 2.00, 1; corneal opacity: 1, 1, 1 iris lesions: 0, 0, 0 (calculated as the mean scores following grading	None	[redacted]

			at 24, 48 and 72 hours after installation of the test material). Observation times: 1, 24, 48, and 72 hours and 7 and 14 days after exposure. Effects persisted after observation period (21 days). No systemic effects nor hyspatological abnormalities were detected		

No human data on eye irritation is available

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The product shows non-reversible effects after post application observation period. Effects on the cornea, iris and conjunctiva were observed in one animal on day 21 after treatment.
Justification for the value/conclusion	Based on corneal opacicy, iris, conjunctivae and chemosis effects
Classification of the product according to CLP	PROTEO EC is classified as Serious eye damage Category 1 H318

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Based on the classification of the deltamethrin and the coformulants and, their respective content in the final formulation. PROTEO EC contains more than 20% of co-formulants classified as Specific target organ toxicity — single exposure category 3; H335
Classification of the product according to CLP	PROTEO EC is classified as "specific target organ toxicity - single exposure, Category 3 H335

Data waiving	
Information requirement	Not required
Justification	No data on respiratory tract irritation has been submitted. PROTEO EC contains more than 20% of co-formulants classified as Specific target organ toxicity — single exposure category 3; H335. This information has been included in the data sheets of the components and, in the case of the aromatic hydrocarbon solvent, according to database of registered substances under REACH in ECHA website and Concawe report about the "Hazard classification and labelling of petroleum substances in the European Economic Area – 2017".

	Regulation (EC) Nº 1272/2008 (CLP Regulation) establishes the following: "Care shall be exercised when extrapolating toxicity of a mixture that contains Category 3 ingredient(s). A generic concentration limit of 20 % is appropriate; however, it shall be recognised that this concentration limit may be higher or lower depending on the Category 3 ingredient(s) and that some effects such as respiratory tract irritation may not occur below a certain concentration while other effects such as narcotic effects may occur below this 20% value" On the other hand, the Guidance on the Application of the CLP Criteria; Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures; Version 4.1; June 2015 stablishes the following: "Classification in STOT-SE Category 3 for respiratory tract irritation and narcotic effects does not take potency into account and consequently does not have any guidance values. A pragmatic default generic concentration limit of 20% is suggested, although a lower or higher specific concentration limit may be used where it can be justified". Therefore, it can be concluded that PROTEO EC is classified with regards to respiratory tract irritation properties according to the criteria set out in the Regulation (EC) Nº 1272/2008 (CLP Regulation).

Skin sensitization

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle,** **Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD TG 406 and EU B.6 (Guinea pig maximization Test)/GLP/ 1	Guinea Pig/albino, Dunkin-Hartley, Male, 10 animals plus 5 additional animals for control group	Deltamethrin 2.5 EC, vehicle: water, Induction phase: Intradermal. 0.1ml of 10% dilution of the test item in distilled water and an emulsion 1:1 v/v FCA in saline solution. Epidermal application: Patches saturated with 0.2 ml of 100%	Two animals out of ten showed skin reactions after challenge phase at 75% concentration at 24 and 48hour observation post patch removal. No skin reactions.were observed in the animals from the control group No signs of systemic	None	[redacted]

		test item. Challenge phase: Patches of 0.2 ml of 75% non-irritating concentration of test item Positive control substance: 2-mercaptobenzothiazole.	toxicity were noted in the test or control animals during the test Positive control: Based on the finding in an adjuvant sensitization test (M&K test) in guinea pigs, 2-mercaptobenzothiazole is classified **positive: Moderate sensitizer, grade 3**		

No human data on skin sensitization is available

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	No skin sensitizer
Justification for the value/conclusion	Based on 20% of positive effects in the treatment group
Classification of the product according to CLP	PROTEO EC is not classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation)

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitizer.
Justification for the value/conclusion	Based on the classification of the deltamethrin and the coformulants and, their respective content in the final formulation.
Classification of the product according to CLP	PROTEO EC is not classified as respiratory sensitizer.

Data waiving	
Information requirement	Respiratory sensitization data
Justification	No animal or human data have been provided to assess the potential for respiratory sensitization. The active substance and the coformulants of the product are not classified as respiratory sensitisers and are not known to be respiratory sensitisers. Therefore, it can be concluded that PROTEO EC is not classified with regards to respiratory sensitizer properties according to the criteria set out in the Regulation (EC) Nº 1272/2008 (CLP Regulation).

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levels Type of administration** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD TG 423 and EU B1.tris /GLP/1	Rat, Whistar RccHanTM: WIST Female 3 animals at 2000 mg/Kg bw and 6 animals at 300 mg/Kg bw	Deltamethrin 2.5 EC, 2000 – 300 mg/Kg bw By gavage	All treated animals at 2000 mg/kg bw were found dead at day 1. Sympthoms: Convulsions, salivation, chromodacryorrhoea, lacrimation. No mortalities observed at the dose of 300 mg/Kg bw. All the animals appeared normal throughout the experimental period. All surviving animals had gained body weight by day 14 as compared to day 0. No abnormalities were detected for the animals necropsied at terminal sacrifice.	300<LD_{50} <2000mg/ Kg bw	None	[redacted]

No human data on acute oral toxicity is available

Value used in the Risk Assessment – Acute oral toxicity	
Value	300mg/kg bw≤LD_{50}<2000mg/kg bw.
Justification for the selected value	No toxicity effects in the acute oral toxicity study at the dose rate of 300 mg/Kg bw but full mortality at the maximum dose rate of 2000 mg/Kg bw
Classification of the product according to CLP	Classified as Acute toxicity (oral) Category 4, H302

Acute toxicity by inhalation

Summary table of animal studies on acute inhalation toxicity

Method, Guideline, GLP status , Reliability	**Species, Strain, Sex, No/group**	**Test substance, form** *(gas, vapour, dust, mist)* **and particle size (MMAD) Actual and nominal concentration, Type of administration** *(nose only / whole body/ head only)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LC50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD TG 403 and EU B.2/ GLP/ 1	Rat, Whistar RccHanTM: WIST Three groups of 10 rats male and female/5 animalsper sex and dose	Deltamethrin 2.5 EC Aerosol MMAD: 1.23-1.73 µm Nominal concentration: 10.22, 20.03 and 41.12 mg/l Actual concentration: 1.276, 2.646, 5.290 mg/l Nose only administration Exposure time: 4h	Rats exposed to 1.276 (group III), 2.646 (group II) and 5.290 (group I)mg/l showed 10, 40 and 90% mortality respectively. Death occurred during the exposure and following the observation period. Animals exhibited clinical signs such as dullness, severe salivation, tremors, gasping and paralysis. Clinical signs started 2nd hours after exposure in Group I, 3rd hour in Group II and 4th hour in Group III which disappeared on 2nd day after exposure in survivors. Gross pathology of the survivors sacrificed at the end of 14-day observation periods, did not reveal any lesion but animals those died during the exposure had externally, excess	2.74 mg/L air	None	[redacted]

			salivation, ventral surface wet with urine and nasal discharge. The same animals had internal lesions in the lungs: hemorrhage (group I-4/5 males, 3/4 females, group II-3/3 males), lungs-edema (group I -1/4 female, Group III-1/1 female), respectively. All animals had gained body weight by day 14 as compared to day 0			

No human data on acute inhalation toxicity is available

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	LC_{50} = 2.74 mg/l air
Justification for the selected value	Based upon the above mortality data, the LC_{50} of Deltamethrin 2.5 EC, as per Finney's probit was calculated as 2.74 mg/l and the fiducial limits at 95% level of significance, ranged between 1.91 and 3.56 mg /L.
Classification of the product according to CLP	Classified as Acute toxicity (inhalation) Category 4 H332.

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD TG 402 and EU B.3 / GLP/ 1	Rat, Whistar RccHanTM: WIST Male and female 5 animals per sex and dose	Deltamethrin 2.5 EC No vehicle (semiocclusive coverage). Single dose 2000 mg/Kg bw	After the 24 hour application period, no signs of systemic toxicity were observed during the experimental period. All animals survived until the end of the experimental period.	> 2000 mg/Kg bw	None	[redacted]

		10% of the total body surface.	The body weight of animals was within the normal range of variability commonly recorded for this strain and age. There was a transient reduction in body weght of one female after one week of test item administration, which is considered to be due to the experimental procedure rather than a test item-related effect. No abnormalities were detected for any of the animals at necropsy.			

No human data on acute dermal toxicity is available

Value used in the Risk Assessment – Acute dermal toxicity	
Value	LD_{50} >2000 mg/Kg bw
Justification for the selected value	No toxicity effects at the maximum dose rate of 2000 mg/Kg bw
Classification of the product according to CLP	PROTEO EC is not classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation)

Information on dermal absorption

No new data have been provided for PROTEO EC (Deltamethrin 2.5% EC).

The Swedish CAR for the active substance Deltamethrin used a dermal absorption value of 2% as the worst case for a range of formulations and dilutions. This dermal absorption value is based on EC tested formulation which can be assimilated to PROTEO EC (Deltamethrin 2.5% EC formulation). *EFSA Guidance Document on Dermal Absorption (EFSA, 2012)* clearly states that the test formulation and the formulation, which has to be assessed, should be sufficiently similar, hence it is reasonable to use the dermal absorption value of 2% for the exposure calculations for PROTEO EC . Therefore, we accept the justification of the applicant.
Further information, see confidential annex.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Deltamethrin
Value(s)	2%
Justification for the selected value(s)	Based on information in the Swedish CAR.

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

Several co-formulants are present in the product in such proportion as to lead to classification of the product. (See Annex 3.6.2 for more information). These co-formulants leading to classification are the following:

- Dodecylbenzene sulfonate in isobutanol
- Hydrocarbons, C9, aromatics (Solvent naphtha (petroleum), light arom).

Aromatic hydrocarbon solvent is classified in Annex VI according to CLP Regulation, among other hazard classes, as Aspiration hazard, Category 1 with the pictogram GHS08 and the hazard statement H304:May be fatal if swallowed and enters airways.

The CLP Regulation stablishes the following with this hazard:
In order to classify the mixtures, when data are available for all components or only some components of the mixture:
"A mixture which contains a total of 10 % or more of a substance or substances classified in Category 1, and has a kinematic viscosity of 20,5 mm^2/s or less, measured at 40ºC, shall be classified in Category 1." Taking into account this, PROTEO EC should be classified as Aspiration hazard, Category 1 with the pictogram GHS08 and the hazard statement H304:May be fatal if swallowed and enters airways.

Hazard statements H304 H318, H335, H336 and EUH066 define local effects with no threshold effects and require a qualitative assessment.

Available toxicological data relating to a mixture

Phenylsulphonat CA contained in the biocidal product PROTEO EC is a substance of concern in the form of mixture (See Annex 3.6.2 for more information).

Other

The applicant has submitted two mutagenicity assays:

- MUTAGENICITY: REVERSE MUTATION TEST USING BACTERIA (Ames test): According to the results, it can be stated that during the described mutagenicity test and under the experimental conditions reported, the test item, Deltamethrin 2.5 EC, did not induce gene mutations by base pair changes or frameshifts in the genome of the five tester strains.

Summary table of bacterial studies on reverse mutation					
Method, Guideline, **GLP status, Reliability**	**Species, Strain,**	**Test substance, Dose levels, Duration of exposure**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**

OECD TG 471 and EU B.13-B.14/GLP/1	*Salmonella typhimurium* strains TA 1535, TA 1537, TA 98, TA 100 and TA 102	Deltamethrin 2.5 EC 0.037; 0.075; 0.15; 0.3; 0.6 µl/plate in the presence of metabolic activation (+S9) and 0.004; 0.009; 0.018; 0.037; 0.075 µl/plate in the absence of metabolic activation (-S9)	No substantial increase in revertant colony numbers of any of the tester strains were observed following treatment with Deltamethrin EC at any dose level in both the confirmatory trials, neither in the presence nor absence of metabolic activation (S9 mix). There was also no tendency of higher mutation rates with increasing concentrations in the range below the generally acknowledged border of biological relevance. Whereas reference mutagens showed a distinct increase in induced revertant colonies in all the tester strains both in the presence as well as in the absence of metabolic activation, without showing cytotoxicity .	None	[redacted]

- MUTAGENICITY: IN VIVO MAMMALIAN ERYTHROCYTE MICRONUCLEUS TEST: According to the results, it can be stated that under the experimental conditions reported, the test item did not induce micronuclei as determined by the micronucleus test with bone marrow cells of the mouse. Therefore, Deltamethrin 2.5 EC is considered to be non-mutagenic in this micronucleus assay.

Summary table in vivo mammalian erythrocyte micronucleus test					
Method, Guideline, **GLP status, Reliability**	**Species, strain, Sex, No/group**	**Test substance, Dose levels, Duration of exposure**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD TG 474 and EU B.12/GLP/1	Mouse: NMRI; male; Seven males/test group. Five male/positive control test	Deltamethrin 2.5 EC. Volume administered orally 10ml/kg bw 24 h preparation interval: 93.75, 187.5, 375 and 750 mg/kg b.w. 48 h	No severe toxic symptoms occurred in the 1st pre-experiment with 750 mg/kg b.w. test item, therefore, this dose was chosen as highest test item treatment dose. However, in the main experiment, 7males treated with that dose died and 2 males which received 375mg/kg bw. After a repetition of the 2nd pre-experiment with 750 mg/kg b.w. test item with cases of death, it was decided to add a 48h treatment group for 375 mg/kg	None	Naveed H (2009)

		preparation interval: 375 and 750 mg/kg b.w. Positive control: 40 mg/kg b.w. cyclophosphamide	b.w. and a 93.75 mg/kg b.w. 24h treatment group in the 2nd main study. The mean number of polychromatic erythrocytes was not decreased after treatment with the test item as compared to the mean value of PCEs of the vehicle control, indicating that Deltamethrin 2.5 EC did not have any cytotoxic properties in the bone marrow. The mean values of micronuclei observed after treatment with Deltamethrin 2.5 EC were below or near to the value of the vehicle control group. 40 mg/kg b.w. cyclophosphamide administered orally was used as positive control which showed a statistically significant increase of induced micronucleus frequency		

2.2.6.2 Exposure assessment

The following risk assessments have been performed in line with those assessed within the PT 18 CAR for Deltamethrin. The same approaches to the risk assessment, but updated to reflect the default values within the HEEG Opinion 17, have been presented here for PROTEO EC , a product containing the same amount of active substance and same application rates and methods than one of the representative products assessed during the evaluation of the active substance deltamethrin.
Additional assessments for substances of concern present in the formulation are also provided according to Annex I of the *Guidance on the Biocidal Products Regulation*. *Volume III Human Health – Part Brisk Assessment*.

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

People using PROTEO EC (trained professional and professional users) may be primarily exposed to deltamethrin when mixing, loading and applying PROTEO EC indoors via spray application (high and low targets). The product is applied by trained professionals with hand held or backpack spray equipment with hydraulic nozzles (e.g. knapsack, 1-3 bars) and with trigger or handheld sprayers by professinals. Exposure after application as consequence of cleaning operations of the application system (sprayer) is also likely.

USE#1 TRAINED PROFESSIONAL INDOOR CRACK AND CREVICE TREATMENT	
APPLICATION METHOD	Spraying
DOSE RATE	Dilute 50 ml of product in 5l of water for

	treatment of 100 m^2 of surface
APPLICATION EQUIPMENT	Low pressure sprayer (handheld and backpack sprayer)
FREQUENCY OF USE	Máx 6 times/year (interval between applications 8 weeks).
REMARKS	Spot application in crack and crevices. The product is applied in a band width of approx. 0.1m.
USE#2 PROFESSIONAL INDOOR CRACK AND CREVICE TREATMENT	
APPLICATION METHOD	Spraying
DOSE RATE	Dilute 50 ml of product in 5L of water for treatment of 100 m^2 of surface
APPLICATION EQUIPMENT	Low pressure sprayer (handheld)
FREQUENCY OF USE	Máx 6 times/year (interval between applications 8 weeks).
REMARKS	Spot application in crack and crevices. The product is applied in a band width of approx. 0.1m.

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Trained professional use	**Professional use**	**Non-professional use**	**Trained professional use**	**Professional use**	**General public**	**Via food**
Inhalation	Yes	Yes	n.a	n.a	n.a	Yes	No
Dermal	Yes	Yes	n.a	n.a	n.a	Yes	No
Oral	No	No	n.a	n.a	n.a	Yes (only infants)	No

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Mixing and loading Application Cleaning spray equipment	Primary Exposure During application of PROTEO EC trained professional users are exposed to deltamethrin and relevant SoC during the different stages of the application process: mixing and loading the product in the application device, product application and cleaning of application devices.	Trainded professionals

2.	Mixing and loading Application Cleaning spray equipment	Primary Exposure During application of PROTEO EC professional users are exposed to Deltamethrin and relevant SoC during the different stages of the application process: mixing and loading the product in the application device, product application and cleaning of application devices.	Professionals
3.	Toddler playing in a treated room	Secondary exposure Exposure to a toddler after spot type treatment application indoors	Bystanders
4.	Laundery	Secondary exposure Exposure to persons laundering contaminated work clothing	Bystanders

Industrial exposure

The active substance deltamethrin is manufactured outside of the UE and therefore exposure to industrial operators during manufacturing does not falls under the scope of this assessment.
During formulation stage, industrial users are subjected to national worker protection legislations which have implemented residual risk controlled measures through control measures which may include, among others, the use of appropriate PPE and technical measures implemented in the manufacturing and working site in order to reduce exposure to chemical agents. Furthermore, industrial workers in the chemical industry and, in particular in the pesticide manufacturing industry usually have a high level of information, skills and knowledge about the risks derived from their work. Another consideration to take into account is that the production/formulation of biocidal products is usually performed in small batches and the amount of active substance in the product is very low. For the reasons stated above, it is not expected that industrial users are exposed to the active substance or the biocidal product as to lead to risk to industrial workers.

Scenario 1: Trained Professional exposure

Scenario 1 – Mixing and Loading, product application and cleaning spray equipment by trained professional users

Main routes of operator exposure to PROTEO EC during mixing/loading, application and cleaning are via inhalation and by the dermal route. Following the tiered approach, dermal and inhalation exposure during mixing/loading and application of PROTEO EC is calculated using generic exposure data published in the Technical Notes for Guidance (TNsG) to Directive 98/8/EC1 (model 1) which is in line with the ECHA guidance on Biocides Human health Exposure Methodology and also in line with the assessment presented in the relevant CAR. No specific exposure scenario has been defined for insecticidal products when cleaning spray application equipment, however, as best approach it is recommended to use the scenario developed for cleaning antifouling products (PT21). This scenario is defined in the Recommendation No 4 of the BPC Ad Hoc Working Group on Human Exposure (September 2014).

Description of Scenario 1.

The product will be used by trainded professionals. Operators may be exposed when mixing, loading and applying the deltamethrin product for spray applications. The following tasks are undertaken:
- Dilution of product in water,
- Application of product in compression sprayer (e.g. knapsack) overhead and downwards,
- Maintenance and cleaning of spraying equipment.

Mixing/loading and application scenario: TNsG; Technical notes for guidance; Human exposure to biocidal products, Guidance on human exposure assessment, June 2002 for the relevant exposure scenario: "Low pressure insecticide application. Professional operators mixing and loading liquids and powders in compression applicators, and applying at 1 or 3 bar pressure as a coarse or medium spray, indoors and outdoors, overhead and downwards; model 1.
Cleaning operations scenario: Recommendation No 4 of the BPC Ad Hoc Working Group on Human Exposure (September 2014).

Application equipment: Hand held application equipment
Surface condition: Impermeable surface*

	Parameters	Value
Tier 1	Spray concentration:	0.281 mg a.s./ml
	Application rate:	14.05 mg a.s./m^2
	Water rate:	50 ml spray solution per m^2
	Work rate:	108 L spray per day**
	Time of actual spraying:	120 min per day***
	Operator body weight:	60 kg
	Dermal absorption:	2%

*The exposure model considers exposure to the in use spray. Therefore, the application which covers the highest in use spray concentration (i.e. application to impermeable surfaces) represents the worst case.
**The value of 120 minutes was assumed for time of actual spraying in the estimate of operator exposure. For hand held application with hydraulic nozzles an average flow rate of about 0.9 l/minute can be assumed. For work rate the amount of 108 l spray applied per day (=2160 m^2) was assumed.
***For the professional operator it is reasonable to conclude that under usual conditions a considerable time period of a typical 8 hour working day is occupied by e.g. travelling from one site to the other, inspecting, liaison with the client, etc. The median duration "using pesticides" was 120 minutes (different types of treatment were used), this reported in the TNsG (Technical notes for guidance; Human exposure to biocidal products, Guidance on human exposure assessment, June 2002). For band spraying (crawling insects) the median duration reported in the guidance document was 48 minutes (range 10 to 120 minutes).

Calculations for Scenario 1

Exposure estimates for professional operators mixing and loading liquids and powders in compression applicators, and applying at 1 to 3 bar pressure as a coarse or medium spray, indoors and outdoors, overhead and downwards, without PPE:

Mixing/loading and application. Spray model 1	
Exposure description	**75th percentile**
Potential Hand	
Indicative value (rate of deposition of product)	192 mg in-use product/min*
Task duration (default value)	120 min/day
Product on hands	23040 mg /day
Rest of body potential dermal exposure	
Indicative value (rate of deposition of product):	92 mg in-use product/min
Task duration (default value)	120 min/day
Potential amount of product on rest of body	11040 mg/day
Clothing penetration (default value)	100 %
Actual dermal deposit of product on rest of body	11040 mg/day
Total actual dermal exposure to product via hands and body	34080 mg/day
Total dermal exposure to a.s. via hands and body *[given that the in-use product contains 0.0281% a.s.]*	9.58 mg
Skin penetration	2%
Total dermal systemic exposure to a.s. via hands and body	**0.1915 mg a.s./day**
Inhalation exposure	
Indicative value (exposure to product via inhalation)	104 mg in-use product/m^3
Breathing rate (default value)	1.25m^3/h
Task duration(default value)	120 min/day
Volume of air inhaled over task duration	2.5 m^3
Amount of product inhaled during task	260 mg
Total systemic exposure to a.s. via inhalation = amount of a.s. inhaled *[in-use product contains 0.0281% a.s.]*	**0.0731 mg a.s./day**
Cleaning application equipment. Recommendation No 4 of the BPC Ad Hoc Working Group on Human Expossure	
Exposure description	**75th percentile**
Potential Hand	
Indicative value (rate of deposition of product)	35.87 µl in-use product/min
Task duration (default value)	20 min/day
Product on hands	717.4 µl /day
Rest of body potential dermal exposure	
Indicative value (rate of deposition of product):	19.28 µl in-use product/min
Task duration (default value)	20 min/day
Potential amount of product on rest of body	385.6 µl /day
Clothing penetration (default value)	100 %
Actual dermal deposit of product on rest of body	385.6 µl /day
Total actual dermal exposure to product via hands and body	1103 µl /day
Total dermal exposure to a.s. via hands and body *[given that the in-use product contains*	0.310 mg

0.0281% a.s.]	
Skin penetration	2%
Total dermal systemic exposure to a.s. via hands and body	**$6.2x10^{-3}$ mg a.s./day**
TOTAL EXPOSURE	
Total systemic exposure via skin and inhalation to a.s.	**0.2712 mg a.s./person/day**
Total systemic exposure to a.s. for a 60 kg adult	**0.00451 mg a.s./kg bw/day**
Total systemic exposure as % of systemic AEL	**60.18%** **$AEL_{systemic}$= 0.0075 mg/kg bw/day**

*Maximum amount of in use product determined on gloves. Please note that the value used in the CAR is 192 mg in-use product/min it is the sum of the maximum amount of in use product determined on glove+ 75th percentile of in use product determined on hands inside gloves.

The estimated systemic exposure of trainded professional users **accounts for 60.18%** of the proposed systemic AEL (proposed systemic AEL=0.0075 mg/kg bw/day). This assessment is a worst case estimation of systemic effects derived from the active substance Deltamethrin not considering PPE.

Conclusion:
The estimated systemic exposure of trained professionals mixing and loading, applying and cleaning the applying equipments accounts for 60.18% of the proposed systemic AEL (proposed systemic AEL=0.0075 mg/kg bw/day).

Based on these calculations there is no unacceptable risk anticipated for trained professional users according to systemic effects caused by deltamethrin.

Summary table: estimated exposure from trained professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	No	0.0731mg a.s.	0.1976mg a.s.	--------	0.2712 mg a.s.

This scenario exposure has been calculated according to Deltamethin CAR methodology and will be re-assessed in the renewal phase.

Although the percentage of active substance in the product is not leading to classification for acute effects, acute toxicity tests have demonstrated that the product may be harmful by ingestion and inhalation (H302 and H332), being deltamethrin the only ingredient likely to provoke this classification. This risk is already covered by the assessment performed above, where systemic chronic effects are evaluated and considered acceptable.
The product PROTEO EC contains substances of concern leading to toxicological classification of the product as H304, H318, H335, H336 and EUH066.

The following mitigation measurements should be taken into account as recommended in the Annex A of the *Guidance on the Biocidal Products Regulation*. *Volume III Human Health – Part B Risk Assessment* as consequence of local effects derived from the presence of SoC in the formulation:

- Wash hands thoroughly after handling

- Do not eat, drink or smoke when using this product.
- Avoid breathing vapours/spray.
- Use only in a well ventilated area (ensure good ventilation during use).
- Wear protective gloves, clothing and face protection.

It must be noted that both the classification derived from experimental data (acute tox. oral and inhalation Cat. 4 and Eye Damage Cat. 1) and the classification derived from the presence of substances of concern leading to classification by calculation (STOT SE Cat 3 and Aspiration Hazard Cat. 1) are referred to the straight product. The product is diluted in a rate of 1:100 in water when sprayed and even more when successive rinses are performed for cleaning application devices. When the product is diluted it is not expected that the concentration of the individual ingredients lead to product classification and therefore no risk for local effects are expected when the product is applied or the application devices are cleaned (for instance, the dilution at a rate of 1:100 leads to a concentration of the ingredient(s) responsible of Severe eye damage Category 1 100 times lower, which is well below the threshold value setting classification with regards to irritant or corrosive effects to eye). Therefore the only relevant stage for local effects is during mixing and loading the product in the application system. This stage is usually of short duration (several seconds or a few minutes) and low volumes of product are used (typically 25-50 mL/day). Therefore, if the risk mitigation measures reported above are followed, no risk to trained professional operators derived from local effects is expected. In any case, the use of PPE and risk mitigation measures is recommended during the whole cycle of use of the product.

Scenario 2: Professional exposure

Scenario 2– Mixing and Loading, product application and cleaning spray equipment by professional users

Professional users: professionals that use the biocidal product in the context of his profession that is not pest control operator and that are unlikely to have received any specific training in the use of biocides.

To assess the exposure of professionals, we have considered the same contitions of use that would have a non-professional user.

Exposure of mixing/loading and application phases have been assessed using ConsExpo 5.0. Cleanning equipment phase has been assessed following the Recommendation No4 of the BPC Ad Hoc Working Group on Human Heath Exposure.
No specific exposure scenario has been defined for insecticidal products when cleaning spray application equipment, however, as best approach it is recommended to use the scenario developed for cleaning antifouling products (PT21). This scenario is defined in the Recommendation No 4 of the BPC Ad Hoc Working Group on Human Exposure (September 2014).

Description of Scenario 2.

The product will be used by professionals. Profesional users may be exposed when mixing, loading and applying the deltamethrin product for spray applications. The following tasks are undertaken:
- Dilution of product in water,
-Application of product in compression sprayer overhead and downwards,
- Maintenance and cleaning of spraying equipment.

Mixing/loading scenario: ConsExpo 5.0

Application scenario: ConsExpo 5.0.

Cleaning operations scenario: Recommendation No 4 of the BPC Ad Hoc Working Group on Human Exposure (September 2014).

Application equipment: Hand held application equipment
Surface condition: Impermeable surface*

	Parameters	Value
Tier 1	Spray concentration:	0.281 mg a.s./ml
	Application rate:	14.05 mg a.s./m^2
	Exposure duration:	2,4E2 minute
	Room volume:	20 m^3
	Time of actual spraying:	6 min per day
	Operator body weight:	60 kg
	Contact rate	46 mg/mim
	Dermal absorption:	2%

Calculations for Scenario 2
Exposure estimates for professional operators mixing and loading liquids by ConsExpo 5.0 and applying by target spot application on a private user who sprays an object from close by, carried out indoors:

Mixing/loading and application. ConsExpo 5.0	
Exposure description	
Mixing and loading	
Weigh fraction compound	0.0281 %
Exposures duration	1,3 mim
Room volume	20 m^3
Dermal model: Direct dermal contact with product: instant application	
Exposed area	16600 cm^2
Uptake fraction	2 %
Dermal chronic systemic dose	1.5E-8 mg s.a./Kg bw/day
Aggregate exposure for Non professionals	
Total chronic systemic dose	**1.5E-8 mg s.a./Kg bw/day**
Application	
Weigh fraction compound	0.028 %

Exposures duration	2,4E2 minutes
Room volume	20 m^3
Inhalation model: Exposure to spray : spraying	
Ventilation rate	0,6 l/h
Uptake fraction	100 %
Inhalation rate	1,25 m^3/h
Inhalation chronic systemic dose	1.5E-7 mg s.a./Kg bw/ day
Dermal model: Direct dermal contact with product: instant application	
Contact rate	46 mg/min
Uptake fraction	2%
Dermal chronic systemic dose	4.2E-7 mg s.a./Kg bw/ day
Aggregate exposure for Non professionals	
Total chronic systemic dose	**5.7E-7mg s.a./Kg bw/ day**
Cleaning application equipment. Recommendation Nº4 of the BPC Ad Hoc Working Group on Human Expossure	
Potential Hand	
Indicative value (rate of deposition of product):	35,87 µl in-use product/min
Task duration (default value)	20 min/day
Product on hands	717,4 µl /day
Rest of the body potential dermal exposure	
Indicative value (rate of deposition of product):	19,28 µl /min
Task duration (default value)	20 min/day
Potential amount of product on rest of body	385,6 µl /day
Clothing penetration (default value)	100%
Actual dermal deposit of product on rest of body	385,6 µl /day
Total actual exposure to product via hands and body	1103 µl /day
Total dermal exposure to a.s. via hands and body *[given that the in-use product contains 0.00025 mg a.s./µl]*	0.275 mg
Skin penetration	2%
Total dermal systemic exposure to a.s. via hands and body	**6.2x10^{-3}mg a.s./day**
Total dermal systemic exposure to a.s. via hands and body	**1.02x10^{-4}mg/kg/day**
TOTAL EXPOSURE	
Total systemic exposure to a.s. for a 60 kg adult	**1.03x10-4 mg a.s./kg bw/day**
Total systemic exposure as % of systemic AEL	**1.37%** **$AEL_{systemic}$= 0.0075 mg/kg bw/day**

The estimated systemic exposure of professional users **accounts for 1.37%** of the proposed systemic AEL (proposed systemic AEL=0.0075 mg/kg bw/day). This assessment is a worst case estimation of systemic effects derived from the active substance Deltamethrin not considering PPE, which under real conditions of use are mandatory due to other hazards leading to local effects (Severe eye irritation, Specific organ toxicity, skin driness and cracking after repeated exposure and aspiration hazard)

Conclusion:
The estimated systemic exposure of trained professionals mixing and loading, applying and cleaning the applying equipments accounts for 1.37% of the proposed systemic AEL (proposed systemic AEL=0.0075 mg/kg bw/day).

Based on these calculations there is no unacceptable risk anticipated for professional users according to systemic effects caused by deltamethrin.

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	No	1.5E-7 mg s.a./Kg bw/ day	1.02E-4 mg a.s/kg/day	---------	1.03x10-4 mg a.s./kg bw/day

This scenario has been calculated according to the Spanish definition of professionals at time of submission of the application for the authorisation and will be reassessed in the renewal phase.

Further information and considerations on scenario 2
Although the percentage of active substance in the product is not leading to classification for acute effects, acute toxicity tests have demonstrated that the product may be harmful by ingestion and inhalation (H302 and H332), being deltamethrin the only ingredient likely to provoke this classification. This risk is already covered by the assessment performed above, where systemic chronic effects are evaluated and considered acceptable.

The product PROTEO EC contains substances of concern leading to toxicological classification of the product as H304, H318, H335, H336 and EUH066.

The following mitigation measurements should be taken into account as recommended in the Annex A of the *Guidance on the Biocidal Products Regulation*. *Volume III Human Health – Part B Risk Assessment* as consequence of local effects derived from the presence of SoC in the formulation:

- Wash hands thoroughly after handling
- Do not eat, drink or smoke when using this product.
- Avoid breathing vapours/spray.
- Use only in a well ventilated area (ensure good ventilation during use).
- Wear protective gloves, clothing and face protection.

It must be noted that both the classification derived from experimental data (acute tox. oral and inhalation Cat. 4 and Eye Damage Cat. 1) and the classification derived from the presence of substances of concern leading to classification by calculation (STOT SE Cat 3 and Aspiration Hazard Cat. 1) are referred to the straight product. The product is diluted in a rate of 1:100 in water when sprayed and even more when successive rinses are performed for cleaning application devices. When the product is diluted it is not expected that the concentration of the individual ingredients lead to product classification and therefore no risk for local effects are expected when the product is applied or the

application devices are cleaned (for instance, the dilution at a rate of 1:100 leads to a concentration of the ingredient(s) responsible of Severe eye damage Category 1 100 times lower, which is well below the threshold value setting classification with regards to irritant or corrosive effects to eye). Therefore the only relevant stage for local effects is during mixing and loading the product in the application system. This stage is usually of short duration (several seconds or a few minutes) and low volumes of product are used (typically 25-50 mL/day). Therefore, if the risk mitigation measures reported above are followed, no risk to non-trained professionals derived from local effects is expected.

Non-professional exposure

Not relevant. Non-professional user has not been applied by the applicant.

Exposure of the general public

Scenario 3- Secondary exposure to a toddler after spot type application indoors

Persons (adults and/or children) may be secondarily exposed to PROTEO EC when re-entering rooms where the product has been applied. From the perspective of persons re-entering a treated room re-entry by a child – or in the context of the assumed body weight of 10 kg better characterised as toddler – in a private house is considered to represent the worst case exposure scenario and is therefore addressed in the following.

Secondary exposure as a result of use of deltamethrin may occur via the dermal route (transfer of surface bound residues to the skin) and by inhalation (while aerosol particles settle during the acute phase of the secondary exposure). However inhalation exposure (secondary) as a result of use of deltamethrin in the biocidal product is considered to be low since operator exposures are limited to professional pest control operators only and there are no relevant acute phase scenarios for adults or infants in professional applications where bystanders are kept out of the treatment areas until spray aerosols have dispersed or dust have settled. Further, vapour pressure of deltamethrin is low (1.24×10^{-8} Pa; 25ºC; according to Council Directive 1999/13/EC, a substance should be considered volatile when the vapour pressure >0.01 kPa at 20ºC). Thus, secondary exposure of deltamethrin is considered predominantly via the dermal route (transfer of surface bound residues to the skin). The transfer of residues to the skin depends on:

- The intensity of contact with surfaces which can be described by a generic transfer coefficient (cm^2/hour).
- The amount of transferable residues present on the surface (mg a.s./cm^2).
- The exposure duration (hours per day).

The relevant default values given in the Technical Notes for Guidance ("TNsG; Technical notes for guidance; Human exposure to biocidal products, Guidance on exposure assessment, June 2002; Defaults for non professional use and residential exposure to biocides") are presented below:

- Transfer Coefficient (TC): 6000 cm^2/hour
- Exposure period (EP): 1 hour per day

To calculate the amount of surface transferable residues in the absence of specific data the TNsG propose a default value of 30% of the residues present on the surface. However, for deltamethrin a study has been conducted to determine the amount of surface transferable residues when being applied to carpets: *"Determination of Dislodgeable Residues of*

Deltamethrin following a Broadcast Application of Suspend SC Speciality Insecticide, Maxey S.W., Murphey P.G., and Berbrick D.H.; February, 1996 " (See Appendix 1 to this document). In this study transfer of residues was determined using the drag sled technique. The results of the study demonstrate for carpets a very low transferability of surface residues. A transfer efficiency of about 2.5 % of the residues present on the surface can be assumed considering the residues are dry. Within the study transfer from hard surfaces was not determined. However, the default values used by US-EPA (i.e. 10 % for hard surfaces and 5 % for carpets) propose a two times higher transfer rate for hard surfaces than for carpets (Policy document to update many of the defaults within the SOPs: Policy number 12; February 22, 2001). As being the worst case hard surface with 10% transferable residues are considered for deltamethrin. Thus regarding transfer efficiency of surface residues the following figures apply for PROTEO EC :

- Hard surfaces: 10 % of the surface residues

Accordingly, re-entry exposure to PROTEO EC will be assessed based on a generic TC (value reported in the guidance document (TNsG)) together with compound specific transfer efficiencies.
The assumptions/considerations to calculate secondary exposure of a toddler to PROTEO EC are summarised below:

Scenario 3: Secondary exposure to a toddler after spot type- application indoors.	
Maximum application rate	0.05ml Product/m^2 (12.5 mg a.s./m^2)
Area treated: Spot type application (usual case)	10% of the area the toddler plays on during the relevant exposure period
Surface residues (SR): Spot type application:	0.000125 mg a.s./cm* (=12.5 mg/m^2/10)
Transfer Coefficient (TC):	6000 cm^2 per hour
Surface Transferable Residues (TR): Hard surfaces:	10% of the residues present on the surface**
Exposure Period (EP): - Hard surfaces:	1 hour per day
Body weight of the toddler:	10 kg

* To be consistent with the proposed transfer coefficient, in a conservative approach it is assumed that "virtually" the residues present in the spots are distributed to the whole surface the toddler can play on.
** As being the worst case hard surfaces with 10% surface transferable residues are considered for the spot type application.

Based on these assumptions/considerations dermal exposure (D) of the toddler is calculated as follows:

$$D = SR \times TR \times TC \times EP$$

Spot type application (normal case) = 0.000125 mg a.s./cm^2 x 0.10 x 6000 cm^2/hour x 1 hours/day

= 0.075 mg deltamethrin/toddler/day

Taking into account the dermal absorption of 2% systemic exposure by the dermal route (E_{dermal}) is calculated to be:
E_{dermal} = D x Dermal absorption / Body weightSpot type application (normal case) = 0.075 mg/toddler/day x 0.02 / 10 kg

= 0.00015 mg/kg bw/day

For the toddler one might in addition consider oral exposure via hand to mouth transfer. The TNsG propose to assume in a tier 1 approach that 10 % of the total amount of product that ends up on the skin of the toddler is taken in orally by hand to mouth contact (= 10 % of hand exposure).
The systemic exposure by the oral route (E_{oral}) is calculated as follows:

E_{oral} = D x Hand to mouth transfer x Oral absorption ÷ Body weight

Spot type application (normal case) = 0.075 mg/toddler/day x 0.1 x 0.75 / 10 kg

= 0.0005625 mg/kg bw/day

Considering the normal case (spot type application) the total systemic exposure of the **toddler** is estimated to be about 0.0007125 mg/kg bw/day (**9%** of systemic AEL).

For completeness the total secondary exposure of an adult person is expected to be less compared to the exposure of a toddler. Assuming a transfer coefficient of 16700 cm^2/hr (a default value used by US-EPA, (Policy document to update many of the defaults within the SOPs: Policy number 12, February 22, 2001)) and a body weight of 60 kg the dermal exposure of an adult person crawling across hard surface (full surface treatment) for 1 h will be estimated as follows:

Dermal exposure = surface residues x surface transferable residues x transfer coefficient x exposure period.

Dermal exposure= 0.000125 mg a.s./cm^2 x 0.1 x 16700 cm^2/hr
= 0.20875 mg deltamethrin/adult/day
= 6.95833E-05 mg/kg bw/day (0.20875 mg deltamethrin/adult/day x 0.02 (dermal absorption)/60 kg)

Assuming that 4% of the total amount of product that ends up on the skin of the adult is taken in orally by hand to mouth contact (conservative approach) the oral exposure of an adult person will be estimated as follows:

Systemic exposure by the oral route = dermal exposure x hand to mouth transfer x oral absorption.
= 0.20875mg deltamethrin/adult/day x 0.04 x 0.75/60 kg
= 0.000104375mg/kg bw/day.

The total secondary exposure (dermal exposure+oral exposure) estimated for the **adult** will then be about 0.000173958 mg/kg bw/day (6.95833E-05 + 0.000104375) (**2%** of AEL).

Conclusion:
The estimated systemic exposure of the toddler **accounts for 9% (spot type application)**
Based on these calculations there is no unacceptable risk anticipated for persons being secondary exposed after spot type- or surface treatment application indoors.

Further information and considerations on scenario 3
Although the product is classified by acute effects (oral and inhalation toxicity) and for other local effects (Eye Damage Cat. 1, STOT SE Cat 3 and Aspiration Hazard Cat. 1) the risk is covered by the estimation of systemic exposure, which is acceptable. In addition, in order reduce the possibility of exposure to bystanders when re-entry in treated premises immediately after application, the following recommendations are proposed:

- Treated areas can be re-occupied by the general public, pets and other animals once the sprayed surfaces are dry.
- Assure good ventilation before re-entry in treated premises.

Scenario 4: Secondary exposure to persons laundering contaminated work clothing

With respect to exposure of persons laundering contaminated work clothing the approach proposed by UKCA during its evaluation of bendiocarb under the Biocidal Products Directive 98/8/EC was considered.

In general this approach assumes that the laundering is undertaken in a domestic, automatic washing machine. Therefore, exposure will be by the dermal route, via the hands, from handling the contaminated clothing prior to and during introduction of the clothing into the washing machine. It is considered that laundering is undertaken after a five day work week: hence the total amount of active substance present on the work clothing is assumed to be five times the amount of one work day. For PROTEO EC this amounts to 55200 µL in use product (= 5 x 11040 µL in use product/day). Taking into account the in use concentration of 0.000281 mg deltamethrin/µL this corresponds to 15.5 mg deltamethrin present on the work clothing. The area of a medium-sized coverall is 22700 cm^2.

Therefore, expressed as mg deltamethrin/cm^2, the accumulated residues over 5 days would be 0.000683 mg deltamethrin/cm^2.

The total area of the palms and backs of both hands for an adult is 820 cm^2, the transfer coefficient for contamination (of dried fluid) from cotton or knitwear to wet hands is 30% (Technical notes for guidance; Human exposure risk assessment to biocidal products, Guidance on exposure estimation, June 2002") and using the dermal penetration figure of 2%, the systemic dose for a 60 kg adult can be calculated as:

a.s. residues on coverall x surface area of both hands x transfer coefficient x dermal absorption/body weight

$$= \frac{0.000683 \times 820 \times (30/100) \times (2/100)}{60}$$

The systemic dermal dose from **laundering** the contaminated work clothing is 0.000056 mg a.s./kg bw/day (= **0.74 %** of AEL (0.0075 mg/kg bw/day); MOE = 17911) .

Conclusion:
The estimated secondary dermal exposure of persons laundering contaminated work clothing accounts for 0.74 % of the proposed systemic AEL (proposed systemic AEL=0.0075 mg/kg bw/day).

Based on these calculations there is no unacceptable risk anticipated for persons laundering contaminated work clothing.

Further information and considerations on scenario 4
Local effects as consequence of contact with contaminated clothes is of very short duration and no adverse effects are likely after product is dried. Therefore assessment for local effects is nor required.

Combined exposure
Combined exposure is most relevant for a pest control operator who applies the product (representing the highest application rate of deltamethrin) and then returns to a home that has also been treated with deltamethrin and laundering his contaminated work clothings. In this respect, a comparison of potential exposure is made to the systemic AEL of 0.0075 mg/kg bw/day.

The worst-case potential exposure of systemic effects during application (treatment with PROTEO EC without PPE), has been used for the calculation of professional exposure. These effects are referred only to systemic effects derived from the presence of deltamethrin in the product and can be considered as the worst case situation if no PPE is used, however under real conditions of use PPE (gloves PF10, impermeable coverall, respiratory mask PF4 and face/eye protection) are required as consequence of other hazards (Aspiration hazard, respiratory irritation, drownizess and dizziness and severe eye irritation). Therefore the outcome of this assessment do not take into account local effects and calculations do not include the mitigation derived from the use of PPE.

Combined exposure to deltamethrin for trained professional users		
Exposure scenario for trained professional users	**Exposure estimates [mg/kg bw/day]**	**% of AEL [0.0075 mg/kg bw/day]***
Trained professional exposure (no PPE)	0.00451	**60.18**
Secondary Exposure (Adult secondary exposure scenario 3.)	0.000173958	**2**
Secondary Exposure (Adult secondary exposure scenario 4.)	0.000056	**0,74**
Total exposure	**0.00475**	**62.96**

*proposed systemic AEL= 0.0075 mg/kg bw/day (based on a NOAEL of 1 mg/kg bw/day (corrected for oral absorption of 75%, and a safety factor of 100).

Conclusion:
The estimated combined exposure of the trained professional user accounts for 60.96% of the proposed systemic AEL. Based on this calculation a trained professional applicator will not be at unacceptable risk from combined exposure for systemic effects, however this estimation can be considered as a worst case because professional users must use PPE during product application according to product classification (non-threshold and local effects) and systemic exposure can be widely reduced when using recommended PPE (gloves, impermeable workwear, respiratory mask and face/eye protection).

Combined exposure to deltamethrin for professional users		
Exposure scenario for professional users	**Exposure estimates [mg/kg bw/day]**	**% of AEL [0.0075 mg/kg bw/day]***
Professional exposure (no PPE scenario	1.04x10-4	**1.39**

2)		
Secondary Exposure (Adult secondary exposure scenario 3.)	0.000173958	**2**
Secondary Exposure (Adult secondary exposure scenario 4.)	0.000056	**0,74**
Total exposure	**0.000333**	**4. 3**

*proposed systemic AEL= 0.0075 mg/kg bw/day (based on a NOAEL of 1 mg/kg bw/day (corrected for oral absorption of 75%, and a safety factor of 100).

Monitoring data
Not applicable

Dietary exposure
The biocidal product PROTEO EC is not intended to be applied in livestock premises and therefore it is not expected that livestock animals may be exposed to the product. In addition different mitigation measures are proposed in the label in order to avoid any accidental contamination on food/feedstuff from animal or vegetal origin such as:

- Cover water tanks, feed, troughs and other surfaces or equipment that may enter in contact with feed/foodstuffs before treatment to avoid any contamination.
- Remove any tool that may enter in contact tith food/feedstuff during treatment.
- Do not apply the product in the direct vicinity of areas (work surfaces, dining tables, etc.) where food/feed is prepared and/or eaten.
- Please clean surfaces (including kitchenware) that are to come into contact with foodstuffs with a detergent.
- Please apply the product outside the period of preparation and/or consumption of foodstuffs

Therefore, no dietary exposure assessment is deemed necessary.

Information of non-biocidal use of the active substance
Deltamethrin is widely used in plant protection Products and in veterinary products. These uses are regulated by the corresponding legislation.

Summary table of other (non-biocidal) uses			
	Sector of use	**Intended use**	**Reference value(s)**
1.	Plant protection products	Insecticide	(1)
2.	Veterinary use	Antiparasitic agents/Agents againstectoparasites	(2)

(1) COMMISSION REGULATION (EU) 2016/1822 of 13 October 2016 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aclonifen, deltamethrin, fluazinam, methomyl, sulcotrione and thiodicarb in or on certain products

(2) COMMISSION REGULATION (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin

Estimating Livestock Exposure to Active Substances used in Biocidal Products
Not relevant. PROTEO EC is not intended to be applied in livestock facilities and therefore no exposure to animals during or after treatment is likely.

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

Not relevant. The application of the product in places where possible contamination of food/feedstuff is likely shall be performed taking appropriate risk mitigation measurements such as removing any food/feed source from the application site, covering food/feedstuff/water stores or tanks before treatment when it is not possible to remove them from the site or do not contaminate surfaces where the food/feed is going to be treated on or any other tool for food/feedstuff handling.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1.	Trained professional	1st tier without PPE	0.00451 mg a.s./kg bw/day
2.	Professional	1st tier without PPE	1.04E-4 mg a.s./kg bw/day
3.	Bystander - exposure to a toddler after spot type treatment application indoors	1st tier	0.000173958 mg a.s./kg bw/day
4.	Bystander - exposure to persons laundering contaminated work clothing	1st tier	0.000056 mg a.s./kg bw/day

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	**Study**	**NOAEL (LOAEL)**	**AF[1]**	**Correction for oral absorption**	**Value**
AELshort-term	13-week dog study	1.0 mg/kg bw/day	100 standard	75%	0.0075 mg/kg bw/day
AELmedium-term	13-week and 1 year dog studies	1.0 mg/kg bw/day	100 standard	75%	0.0075 mg/kg bw/day
AELlong-term	1 year dog study	1.0 mg/kg bw/day	100 standard	75%	0.0075 mg/kg bw/day
ARfD	No value in CAR				
ADI	No value in CAR				

[1]. safety factor of 100 was applied taking into account a factor for inter- and intraspecies differences of 100 (10 x 10).

Maximum residue limits or equivalent

Uses	Reference	MRLs /Relevant commodities	Residue definition
Plant protection: Insecticide	Regulation (EC) No 396/2005	See [1]	Deltamethrin
Veterinary: Antiparasitic agent/ Agent against ectoparasites	Regulation (EU) No 37/2010	See [2]	Deltamethrin

*[1] see COMMISSION REGULATION (EU) 2018/832 of 5 June 2018 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cymoxanil, **deltamethrin**, difenoconazole, fenamidone, flubendiamide, fluopicolide, folpet, fosetyl, mandestrobin, mepiquat, metazachlor, propamocarb, propargite, pyrimethanil, sulfoxaflor and trifloxystrobin in or on certain products*
[23] Commission Regulation (EU) No 37/2010.

Risk for industrial users

Not applicable. Deltamthrin is manufactured out from the EU and exposure during formulation is unlikely and limited.

Local effects
Local effects as consequence of handling harmful ingedients during product formulation and of the product during packaging are likely, however this assessment falls out of the scope of this BPR.
During formulation stage, industrial users are subjected to national and European worker protection legislations which have implemented residual risk controlled measures through control measures which may include, among others the use of appropriate PPE and technical measures implemented in the manufacturing and working site in order to reduce exposure to chemical agents. Furthermore, industrial workers in the chemical industry and, in particular in the pesticide manufacturing industry usually have a high level of information, skills and knowledge about the risks derived from their work. Another consideration to take into account is that the production/formulation of biocidal products is usually performed in small batches

Conclusion
The active substance Deltamethrin is manufactured outside of the UE and therefore exposure to industrial operators during manufacturing falls under the scope of this assessment.
During formulation stage, industrial users are subjected to national and European worker protection legislations which have implemented residual risk controlled measures through control measures which may include, among others the use of appropriate PPE and technical measures implemented in the manufacturing and working site in order to reduce exposure to chemical agents. Furthermore, industrial workers in the chemical industry and, in particular in the pesticide manufacturing industry usually have a high level of information, skills and knowledge about the risks derived from their work. Another consideration to take into account is that the production/formulation of biocidal products is usually performed in small batches and the amount of active substance in the product is

very low. For the reasons stated above, it is not expected that industrial users are exposed to the active substance Deltamethrin contained in the product.

Risk for trained professional users

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Mixing, loading and applying the product for spray applications and cleaning application equipment	1st tier, NO PPE.	0.0075	0.00451	60.18	Yes

Combined scenarios
Not applicable as this is covered by the 1st tier assessment above.

Risk for Professional users

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Mixing, loading and applying the product for spray applications and cleaning application equipment	1st tier, NO PPE.	0.0075	1.04E-4	1.39	Yes

Combined scenarios
Not applicable as this is covered by the 1st tier assessment above.

Conclusion
Systemic exposure to Deltamethrin is acceptable even if no PPE are used.

Risk for non-professional users
Not relevant. The product is not intended for non-professional users.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 3 Secondary exposure to a toddler after application indoors	1st tier spot type	0.0075	0.0007125	9%	Yes
Scenario 4: Secondary exposure to persons laundering contaminated work clothing	1st tier	0.0075	0.000056	0.74%	Yes

Combined scenarios

Scenarios combined for trained professional users	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)
Scenario 1. Trained professional exposure (no PPE)	1st tier	0.0075	0.00451	60.18
Scenario 3. Secondary exposure for Adults after spot type or surface treatment application indoors		0.0075	0.000173958	2
Scenario 4. Secondary exposure to persons laundering contaminated work clothing		0.0075	0.000056	0.74
Total combined exposure		**0.0075**	**0.00475**	**62.96**

Scenarios combined for professional users	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)

Scenario 2. Professional exposure (no PPE)	1st tier	0.0075	1.04E-4	1.39
Scenario 3. Secondary exposure for Adults after spot type or surface treatment application indoors		0.0075	0.000173958	2
Scenario 4. Secondary exposure to persons laundering contaminated work clothing		0.0075	0.000056	0.74
Total combined exposure		**0.0075**	**0.000333**	**4.3**

Conclusion
The estimated combined exposure of the trained professional user (Scenario 1, 3 and 4) accounts for 62.96% of the proposed systemic AEL. Based on this calculation a trainded professional applicator will not be at unacceptable risk from combined exposure. In addition different mitigation measures and use of proper PPE are recommended in order to reduce the risk due to SoC presence.

The estimated combined exposure of the professional user (Scenario 2, 3 and 4) accounts for 4.3% of the proposed systemic AEL. Based on this calculation a professional applicator will not be at unacceptable risk from combined exposure. In addition different mitigation measures and use of proper PPE are recommended in order to reduce the risk due to SoC presence.

Risk for consumers via residues in food

No risk to consumers via food is likely as consequence of application of PROTEO EC . The product is not intended to be applied on livestock premises and therefore no contamination to housed animals is expected. In addition, the application of the product in places where possible contamination of food/feedstuff is likely shall be performed taking appropriate risk mitigation measurements such as:

- Cover water tanks, feed, troughs and other surfaces or equipment that may enter in contact with feed/foodstuffs before treatment to avoid any contamination.
- Remove any tool that may enter in contact tith food/feedstuff during treatment.
- Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals/pets.
- Remove all food, feed and drinks prior to treatment.

Risk characterisation from exposure tosubstances of concern within a biocidal product and local effects

Risk derived from the presence of substances of concern.

Although the percentage of active substance in the product is not leading to classification for acute effects, acute toxicity tests have demonstrated that the product may be harmful by ingestion and inhalation (H302 and H332), being deltamethrin the only ingredient likely to provoke this classification. This risk is already covered by the assessment performed above, where systemic chronic effects are evaluated and considered acceptable.
The product PROTEO EC contains substances of concern leading to toxicological classification of the product:

H304 May be fatal if swallowed and enters airways
H318 Causes serious eye damage
H335 May cause respiratory irritation
H336 May cause drowsiness or dizziness

H304, H335 and H336 are due to the presence of Hydrocarbons, C9, aromatics; Solvent naphta and H318 is due to the presence of Phenylsulfonat CA.
The use of the undiluted product is restricted to the mixing and loading phase.
According to *Annex A of Guidance on the BPR: Volume III Parts B+C Version 4.0 December 2017, Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products*, a product risk characterization has been developed.

Banding evaluation scheme for classified SoCs leading to the classification of the Biocidal product:

Band	Classification of biocidal product according to CLP Regulation due to classified SoC	Associated evaluation/risk management requirements
A	Asp Tox 1 (H304), EUH066, STOT SE 3 (H336) STOT SE 3 (H335)	Application of P-statements normally associated with concerned H statement
B	Eye Dam 1 (H318)	Qualitative exposure and risk assessment to determine whether P-statements normally associated with concerned H statements are sufficient or whether other risk mitigation measures should be applied

Hydrocarbons, C9, aromatics; Solvent naphta is assigned to product hazard classification band A and Phenylsulfonat CA is assigned to band B.
For hazards in bands A and B, a fully quantitative risk assessment is not usually performed because only qualitative or semi-quantitative dose-response information is normally available. It is proposed that for these SoCs, appropriate risk mitigation measures, in the

form of the precautionary (P)-statements normally associated with the concerned hazard (H)-statements under the CLP Regulation, should be applied.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P264 Wash hands thoroughly after handling
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P280: Wear protective gloves/protective clothing/eye protection/face protection.

The product is diluted in a rate of 1:100 in water when sprayed and even more when successive rinses are performed for cleaning application devices. When the product is diluted it is not expected that the concentration of the individual ingredients lead to product classification and therefore no risk for local effects are expected when the product is applied or the application devices are cleaned (for instance, the dilution at a rate of 1:100 leads to a concentration of the ingredient(s) responsible of Severe eye damage Category 1 100 times lower, which is well below the threshold value setting classification with regards to irritant or corrosive effects to eye). Therefore the only relevant stage for local effects is during mixing and loading the product in the application system. This stage is usually of short duration (several seconds or a few minutes) and low volumes of product are used (typically 25-50 mL/day). Therefore, the P-statements normally associated with concerned H statements are sufficient to reach a no concern situation for local effects for trained professional and professionals derived from presence of SoC in the product.

Taking into account the users for this product are trained professionals and professionals (Professionals according to Spanish definition: User applying biocidal products in the workplace. This user has some knowledge and skills in the handling of chemicals, and is able to correctly use personal protective equipment (PPE) if necessary. Their exposure an risk characterization is assessed according to methodology used for non-professional users), a qualitative risk characterization of local effects for profesionals has been developed in order to refine the acceptability conditions of its authorisation.

Guidance for concluding qualitatively on the acceptability of the risk for general public

HAZARD		EXPOSURE INFORMATION		
Hazard category	Effects	Frecuency and furation of potential exposure	Degree of potential exposure under best practice conditions	Relevant RMMs
High	Eye dam. 1 (H318)	Equal to or less than once per week and equal to or less than few minutes per day	Practically no exposure,	Labelling, instructions for use Child proof closure Packaging eliminating exposure
Low	STOT SE 3, H335 (may cause respiratory irritation)	Equal to or less than one hour per day	Very low volume of product handling	Labelling, instructions for use that minimise exposure or

				possible health effects

Therefore, for professionals, it is concluded that to reach a no-concern situation, the use of PEEs would not be mandatory, RMM "labelling instructions for use that minimite exposure or possible health effects" should be included and packaging with child proof closure added.

2.2.7 Risk assessment for animal health

Not relevant, the product PROTEO EC is not intended to be applied in livestock facilities and therefore no exposure to animals during or after treatment is likely.

2.2.8 Risk assessment for the environment

All the information concerning environmental exposure is based on data already submitted by the original data submitter BAYER SAS and for which the applicant Sharda Europe B.V.B.A. has full letter of access so no new data have been submitted. Risk assessment has been performed taking into account specific application patterns of the product PROTEO EC .

This product is similar to one of the representative products included in the deltamethrin assessment report- it is an insecticidal concentrate for professional indoor use in commercial and domestic housing, that is diluted into water prior to use and applied as spot application into cracks and crevices. The representative product at EU review contained deltamethrin at a concentration of 25 g a.s. l-1 w/v and 12.5 mg was applied per m2 of floor.

ESCA comments:

The applicant has not provided any study with the biocidal product. The environmental risk assessment for PROTEO EC has been done using the Competent Authority Report of the active substance deltamethrin. The whole assessment submitted by the applicant has been included and reviewed by the ES CA.

According to the applicant PROTEO EC is an emulsion concentrate (EC) insecticide formulation containing deltamethrin (2.5% W/V) as active substance. It si effective against flying and crawling insects. The applicant proposed use of PROTEO EC is by indoor spraying spot application in crack and crevices by trained professional users.

Further comments on this assessment are included in the relevant sections below in grey boxes.

2.2.8.1 Effects assessment on the environment

All the studies supporting environmental fate and toxicity properties of the product PROTEO EC are based on the active substance Deltamethrin as reported in the CAR document. In addition, no substances of concern regarding the environment are contained in the biocidal product in such quantity as to lead to classification and therefore this assessment is based only on the properties of the active substance Deltamethrin as reported in the CAR as well as specific characteristics related with product application.

The following PNEC values were derived in the Assessment Report of Deltamethrin:
$PNEC_{STP}$: 0.03 mg/L based on EC_{50} > 0.3 mg/L in microbial respiration in active sludge test and an assessment factor of 10
$PNEC_{surface\ water}$: 7.0×10^{-7} mg/L based on the lowest NOEC value from laboratory study (3.5 ng/L from Chironomus) and an assessment factor of 5.
$PNEC_{sediment}$: 6.20×10^{-3} mg/Kg wwt based on the Equilibrium Partitioning Method and a Koc value of 408250
$PNEC_{soil}$: 7.50×10^{-2} mg/Kg wwt based on NOEC from the reproduction test on springtails (0.75 mg/kw standard soil) and an assessment factor of 10

$PNEC_{secondary\ poisoning}$: 1.33 mg/Kg based on 1 year NOAEL in dogs (1 mg/Kg bw) converted into NOEC applying a conversion factor of 40 and to PNEC by an assessment factor of 30 according to the Guidance on the Biocidal Products Regulation Vol. IV Part B.

ESCA comments:

As it is stated in de CAR of deltamethrin, the metabolite Br_2CA was detected in water, sediment and soil. The majormetabolite (Br_2CA) sowed lower toxicity than the parent compound thus, the risk posed by this metabolite can be considered to be negligible an covered by the parent.

Agreed PNEC values for BR_2CA reported in the Deltamethrin Assessment report.

PNEC	Value	Notes
PNECSTP	0.03 mg/l	PNECSTP for active substance considered to also cover metabolite.
PNECwater	0.0104 mg/l	Based on the fish 96h LC50 (QSAR estimation) of 10.4 mg/l, with an assessment factor of 1000 applied.
PNECsediment	0.0139 mg/kg wwt	Calculated from PNECwater using the Equilibrium Partitioning Method with the mean Koc for Br2CA of 25.6.
PNECsoil	0.14 mg/kg wwt	

PNEC secondary poisoning:

According to deltamethrin CAR:

Considering the reproduction studies conducted in birds (bobwhite quail and mallard duck) with deltamethrin (Beavers et al., 1991a & b – III-A7.5.3.1.3/01-02), the lowest NOEC exceeds 450 ppm. Taking into account a safety factor of 30 (as indicated in Table 23 of the TGD on Risk Assessment Part II, page 130), a PNECbird of 15 mg/kg food is obtained.

Considering the reproduction study conducted in rats with deltamethrin (2 generation study; Hoberman, 1992 – A70863), the NOAEL was set at 80 ppm for parents and pups. Taking into account a safety factor of 30 (as indicated in Table 23 of the TGD on Risk Assessment Part II, page 130), a PNECsmall mammal of 2.67 mg/kg food is obtained.

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

The biocidal product PROTEO EC contains 2.5% Deltamethrin as the main ingredient leading to classification regarding environmental properties. Deltamethrin is classified as aquatic acute (H400) and aquatic chronic (H410) with an M factor of 1.000.000. The concentration of the active substance in the product leads to classification according to M factor multiplication as set out in the Regulation EC 1272/2008. The assessment referred

to Deltamethrin is considered as representative of the risk to the environment of the whole product. The biocidal product PROTEO EC is classified as Aquatic Chronic Category 1. H410.

ESCA comments:

The following classification/labelling have been proposed for PROTEO EC for professionals based on the calculation method according to Regulation (EC) 1272/2008 (CLP).

Classification	
Hazard category	Aquatic Acute- Cat. 1 Aquatic Chronic –Cat. 1
Hazard statement	H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
Labelling	
Hazard symbol	 GHS09
Signal word	Warning
Hazard statements	H410: Very toxic to aquatic life with long lasting effects
Precautionary statements	P273: Avoid release to the environment P391: Collect spillage P501: Dispose of contents and/ or container in accordance with current regulations.

Further Ecotoxicological studies

No further data is available. Ecotoxicological data has been extrapolated from the active substance as reported in the CAR.

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

No further data is available. Ecotoxicological data has been extrapolated from the active substance as reported in the CAR.

ESCA comments:

In the case on the product PROTEO EC which is going to be used indoor, plants are not going to be exposed, and there had not been risk to honey bees and other beneficial arthropods.

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

No additional trias to assess risk to non-target organisms have been conducted.

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

No additional studies on acceptance of ingestion of the biocidal product by non-target organisms have been performed. The biocidal product PROTEO EC is a Emulsion Concentrate to be used indoors and therefore this study is not required.

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

Not relevant

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

PROTEO EC is applied indoors in crack and crevices by spot application. Although it is unlikely that the product enters in the environment in significant amounts, an assessment to consider possible routes of exposure is necessary.

Exposure to the receiving environmental compartments such as soil, water and air depends on the physical-chemical properties of the active substance as well as its formulation type, mode of application, use and disposal.

Different release pathways are envisaged depending on the mode of application of the product according to the *Emission Scenario Document for Insecticides, Acaricides and Products to Control other Arthropods for Household and Professional Users* (*OECD Series of Emission Scenario Documents No.18*) and the *Guidance on the Biocidal Products Regulations, Vol. IV Environment – Part B Risk Assessment* (Version 1.0, April 2015).

According to the Exposure scenario document and the Guidance on Risk Assessment of Biocidal products, indoor application may result in indirect environmental exposure via the sewage system (i.e. during a cleaning operation following treatment). This poses a risk of the product entering sewage treatment plants (STPs) and subsequently being released via effluent into surface water. Different stages are involved during the whole use of the product PROTEO EC indoor: 1 – Loading the product in the application equipment, 2 – Product application and 3 - Cleaning operations of treated surfaces/articles. Depending on the product properties, during mixing/loading and application stages, the product can be released to air, target surfaces/objects and floor. These releases can be washed-off after wet cleaning operations in the treated premises, reaching sewer systems ending up in STP plants, where the active is released to different environmental compartments: surface water after effluent emission and soil after sludge application and subsequently ground water. Different organisms dwelling in affected compartments can also be affected transferring the chemical up through the trophic chain to top predators.

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

No new environmental fate & behaviour or leaching data on deltamethrin or product specific data are available as they have not been considered necessary. All agreed endpoints have been taken from the PT 18 AR for deltamethrin (2011).

Leaching behaviour (ADS)

The biocidal product PROTEO EC is an insecticide product and no additional data on leaching behaviour is deemed necessary.

Testing for distribution and dissipation in soil (ADS)

No further data is available. For more information please, refer to deltamethrin CAR document.

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

No further data is available. For more information please, refer to deltamethrin CAR document.

Testing for distribution and dissipation in air (ADS)

No further data is available. For more information please, refer to deltamethrin CAR document.

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)

No further data is available. For more information please, refer to deltamethrin CAR document.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

No further data is available. For more information please, refer to deltamethrin CAR document.

2.2.8.2 Exposure assessment

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Private house and large buildings. Indoor use. Spot application in crack and crevices
ESD(s) used	*Emission Scenario Document for Insecticides, Acaricides and Products to Control other Arthropods for Household and*

	Professional Users (OECD Series of Emission Scenario Documents No.18)
Approach	A consumption based approach has been used as a suitable protective measure at the local level.
Distribution in the environment	Calculated according the *Guidance on Biocidal Products Regulations, Vol. IV Environment – Part B Risk Assessment* (Version 1.0, April 2015)
Groundwater simulation	Tier 1 screening. No higher tier modelling has been performed
Confidential Annexes	No
Life cycle steps assessed	Production: No, as the active substance deltamethrin is manufactured outside the EU. Formulation: No PROTEO EC is formulated in small batches in the EU. The formulation process takes place in closed systems and with appropriate control measurements in place to exclude release of the active substance to the environment during formulation of the product. Use: Scenario 1 following the ESD Service Life: Yes, Scenario 1 following the ESD.
Remarks	None

A new environmental exposure assessment has been undertaken using all, up-to-date, available information from a number of sources, including the deltamethrin AR (2011), the Organisation for Economic Co-operation and Development (OECD) Emission Scenario Document (ESD) Number 18. Information and guidance was also taken from updated Guidance on the Biocidal Products Regulation, Volume IV Environment, Part B Risk Assessment (active substances) (version 1, April 2015). In addition, refinements to the exposure assessment have also been made in relation to cleaning efficiency as agreed at EU level in the deltamethrin AR.

Emission estimation

The active substance deltamethrin is manufactured outside the EU and therefore emissions derived from the manufacturing process falls out of the scope of this assessment. Furthermore, PROTEO EC is formulated in small batches in the EU. The formulation process takes place in closed systems and with appropriate control measurements in place to exclude release of the active substance to the environment during formulation of the product. It is therefore considered acceptable that the exposure during the production/ formulation of the insecticide product is not considered here and falls out of the scope of this assessment. Therefore, the only likely route of exposure to the environment is derived from the use and application of PROTEO EC .

During the use of PROTEO EC different operations may lead to releases of deltamethrin to the environment: Pouring the product in the spraying equipment may result in some leaks to the floor that may reach STP systems after wet cleaning. In addition, operator clothes may also be exposed to the product (product splash), resulting in releases to the environment after clothes cleaning in a wash machine. Releases to the environment may also occur during product application, where treated surfaces are a direct source of contamination, but also the surrounding non-target surfaces and operator clothes as well as air as consequence of spray drift.

All these releases ends up in STP plants, where the active is released to different environmental compartments: surface water after effluent emission and soil after sludge application and subsequently ground water. Although unlikely, different organisms dwelling in affected compartments can also be affected, transferring the chemical up through the trophic chain to top predators.

A major metabolite of Deltamethrin was identified during the a.s. revision stage. Br_2CA is identified in water, sediment and soil compartments. Even if it is assumed that 100 % of metabolite could form in each of these compartments (noting that levels of 13.3 % were identified in a microcosm study and 23 % were identified in a laboratory soil degradation study), then based on the lower molecular weight of Br_2CA (298 as compared to deltamethrin at 505.2) and reduced eco(toxicity) (please, refer to CAR document) the level of risk posed by Br_2CA can be considered to be negligible and covered by the risks calculated for parent. Hence no assessment of the levels of, or the risk posed by, Br_2CA have been calculated in this evaluation.

Scenario 1 – Private house and large buildings. Indoor use. Crack and crevices.

PROTEO EC is applied by professional users in the surface tereatment of cracks and crevices as spot application. The spraying mixture is previously prepared by pouring the concentrated product into an application vessel (handheld or snapsack sprayer).
Timing of application is up to 11 times/year (interval of 5-6 weeks between applications) at a rate of 50 ml of product diluted in 5L of water for 100 m^2 surface treated.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Indoor, spot application in crack and crevice treatment by trained professional users			
Application rate of biocidal product	0.5	ml/m²	
Concentration of active substance in the product	25	g/l	
Mixing/Loading stage			
Quantity of commercial product used during mixing/loading (houses) ($Q_{prod,prep}$)	25	g	Based on typical preparation rate of product by professionals . To calculate the grames of product use for emissions calculations, it has been used a density of 1 g/cm3 which deviates from the actual product density of 0.8891 g/cm3.
Quantity of commercial product used during mixing/loading (larger buildings)	25	g	Based on typical

($Q_{prod,prep}$)			preparation rate of product by professionals. To calculate the grames of product use for emissions calculations, it has been used a density of 1 g/cm3 which deviates from the actual product density of 0.8891 g/cm3.
Number of preparations per day (houses) (N_{prep})	1	d^{-1}	
Number of preparations per day (larger buildings) (N_{prep})	1	d^{-1}	Althoug the default value for this scenario for large buildings is 3, one preparation is enough to cover all the treatment
Fraction emitted to floor during preparation step ($F_{prep,floor}$)	0.0004	-	Default value
Fraction emitted to the applicator during preparation step ($F_{prep,applicator}$)	0.0012	-	Default value
Application stage			
Number of applications per day (houses) ($N_{appl,bulding}$)	1	d^{-1}	
Number of applications per day (larger buildings)($N_{appl,bulding}$)	1	d^{-1}	
Area treated (houses)	2	m^2	
Area treated (larger buildings)	9.3	m^2	
Fraction emitted to air during application ($F_{appl.air}$)	0.02		Default value
Fraction emitted to treated surfaces during application ($F_{appl.treated}$)	0.85		Default value
Fraction emitted to floor during application ($F_{appl.floor}$)	0.11		Default value
Fraction emitted to applicator during application ($F_{appl.applicator}$)	0.02		Default value
Cleaning and release parameters			
Fraction emitted to wastewater ($F_{applicator\ ww}$, F_{ww})	1		
Fraction of cleaning efficiency of wet	0.15		Default value of

cleaning (F_{CE})			25% for crack and crevice application can be reduced to 15% if the application is performed in a 0.1 m band width.
Simultaneity factor	0.00815		Up to 11 applications/year
Number of buildings (houses)	4000		Default value
Number of buildings (larger buildings)	300		Default value

Calculations for Scenario 1

Relevant emissions to the environment have been calculated using the *Emission Scenario Document for Insecticides, Acaricides and Products to Control other Arthropods for Household and Professional Users (OECD Series of Emission Scenario Documents No.18*), according to the following equations:

Mixing/loading

(1) $E_{prep,applicator} = Q_{prod,prep} \times F_{AI} \times N_{prep} \times F_{prep,applicator} \times 10^{-3}$

(2) $E_{prep,floor} = Q_{prod,prep} \times F_{AI} \times N_{prep} \times F_{prep,floor} \times 10^{-3}$

Houses:

($E_{prep,\ applicator}$)=(25*0.02855*1*0.0012)/1000

($E_{prep,\ floor}$)=(25*0.02855*1*0.0004)/1000

Large buildings:

($E_{prep,\ applicator}$)=(25*0.02855*1*0.0012)/1000

($E_{prep,\ floor}$)=(25*0.02855*1*0.0004)/1000

Mixing/loading		
House		
Emission to air during mixing/loading	0	[kg a.s./d]
Emission to applicator during mixing/loading ($E_{prep,\ applicator}$)	8.57×10^{-7}	[kg a.s./d]
Emission to floor during mixing/loading ($E_{prep,\ floor}$)	2.86×10^{-7}	[kg a.s./d]
Large buildings:		
Emission to air during mixing/loading	0	[kg a.s./d]
Emission to applicator during mixing/loading ($E_{prep,\ applicator}$)	2.57×10^{-6}	[kg a.s./d]
Emission to floor during mixing/loading ($E_{prep,\ floor}$)	8.57×10^{-7}	[kg a.s./d]

Application

(3) $E_{appl,air} = Q_{prod} \times F_{AI} \times AREA_{treated} \times F_{appl.air} \times N_{appl,building} \times 10^{-3}$

(4) $E_{appl,treated} = Q_{prod} \times F_{AI} \times AREA_{treated} \times F_{appl.treated} \times N_{appl,building} \times 10^{-3}$

(5) $E_{appl,floor} = Q_{prod} \times F_{AI} \times AREA_{treated,floor} \times F_{appl.floor} \times N_{appl,building} \times 10^{-3}$

(6) $E_{appl,applicator} = Q_{prod} \times F_{AI} \times AREA_{treated} \times F_{appl.applicator} \times N_{appl,building} \times 10^{-3}$

Application		
House (Area treated: 2m²)		
Emission to applicator during application step	5.71×10^{-7}	[kg a.s./d]
Emission to air during application step	5.71×10^{-7}	[kg a.s./d]
Emission to floor during application step	3.14×10^{-6}	[kg a.s./d]
Emission to treated surface during application step	2.43×10^{-5}	[kg a.s./d]
Large buildings (Area treated: 9.3m²)		
Emission to applicator during application step	2.66×10^{-6}	[kg a.s./d]
Emission to air during application step	2.66×10^{-6}	[kg a.s./d]
Emission to floor during application step	1.46×10^{-5}	[kg a.s./d]
Emission to treated surface during application step	1.13×10^{-4}	[kg a.s./d]

As explained in the OECD ESD PT 18, during the cleaning step, two cases are considered:

- cleaning events resulting only in emissions to waste: 100 % of the surfaces are cleaned by vacuum/broom and the clothes of the operator are disposable,

- cleaning events resulting only in emissions to wastewater: 100 % of the surfaces are washable (Fww = 1) and the clothes of the operator are washed (Fapplicator,ww=1).

The first case is not considered further in the risk assessment, because it is considered that this route of exposure is much less likely to be of concern when compared to exposure due to wet cleaning with emissions *via* the STP. In addition, dilution with other wastes, biodegradation of the active substance and the significant containment measures at landfill sites according to European Union (EU) waste regulations (EU Directive 99/31/EC) reduces any further concerns (see also public minutes of TM 11).

Although a default cleaning efficiency is normally applied to spray products applied into crack and crevices, a reduced cleaning efficiency has been agreed at TM for deltamethrin. When the subject was discussed at TMIII 2009 it was stated that OMS agreed in general with a refined value for cleaning efficacy if a specific pattern of use is clearly stated on the label. This related to a refined bandwidth of 0.1 m (in place of the assumed default of 0.2), so as this has been included on the label for PROTEO EC a refined F_{CE} of 0.15 was applied in this evaluation.

According to the label, a maximum of 11 applications per year may be applied, also with a minimum application interval of 5-6 weeks, in this case a simultaneity value of 0.00815 (relating to use 3 -11 times per year) has been applied.

The emissions from professional uses (domestic + larger building) were scaled up as shown below and a total emission to STP from professional use was calculated. It must be accepted that using the summing of large and small buildings from professional use forms a worst case assessment as it is extremely unlikely in practice for both domestic and large buildings to be treated and undergo wet cleaning on the same day.

Emissions to the environment have been calculated using the Emission Scenario Document for Insecticides, Acaricides and Products to Control other Arthropods for Household and Professional Users (OECD Series of Emission Scenario Documents No.18), according to the following equations:

Releases to wastewater

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

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

(9) $E_{local,ww} = (E_{treated,ww} + E_{applicator,ww})$

Parameter	Tier 1	Unit
Cleaning efficiency (crack and crevice) F_{CE}	15	[%]
Total emissions from houses to waste water during cleaning step	$5x10^{-6}$	[kg/d]
Total emissions from large buildings to waste water during cleaning step	$5.99x10^{-5}$	[kg/d]
Accumulated emissions (house + larger building)	$6.49x10^{-5}$	[kg/d]

Releases to STP

(10) $E_{local,ww,total} = (E_{local,ww,houses} \times N_{buildings}) \times F_{simultaneity}$

Parameter	Tier 1	Unit
Simultaneity factor $F_{simultaneity}$	0.815	[%]
Total emissions from houses to STP	$1.63x10^{-4}$	[kg/d]
Total emissions from large buildings to STP	$1.46x10^{-4}$	[kg/d]
Accumulated emissions (house + larger building)	$3.09x10^{-4}$	[kg/d]

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
STP	1.82×10^{-4}	Houses
STP	5.54×10^{-5}	Large buildings
STP	2.37×10^{-4}	Houses + large buildings

After product application emissions are released to the environment through the sewer system either after cleaning contaminated clothes and/or after cleaning operations performed on the treated surfaces (basically wet cleaning). These releases end up in a STP where they are treated before they are released to the environment (Surface water by effluent stream and soil after sludge deposition).

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway

	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	Yes	Yes	No	No	Yes	Yes	Yes	Yes	

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	505.2	g/mol	
Melting point	98.1-99.4 °C (98.9-99.3%w/w)	°C	
Vapour pressure (at 25ºC)	<0.02	mPa	
Water solubility (at 25°C)	<0.01	mg/l	
Log Octanol/water partition coefficient	4.6	Log 10	
Organic carbon/water partition coefficient (Koc)	408250	l/kg	
Henry's Law Constant	1.252×10^{-3}	$Pa/m^3/mol$	
Biodegradability	Not biodegradable	-	
DT_{50} for degradation in soil	48	d (at 12ºC)	

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
	Scenario 1	
Air	1.57×10^{-3}	
Water	9.61	
Sludge	90.4	
Degraded in STP	0	

Calculated PEC values

Equations and default values have been taken from the ECHA guidance on Environmental Risk Assessment (2015) to calculate the following emissions, using the software EUSES v.2.1.2, based on a combined emission from domestic houses plus large buildings for professional users.

Summary table on calculated PEC values					
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/Kgwwt]	[µg/l]
House	$8.73x10^{-6}$	$5.42x10^{-7}$	$4.81x10^{-3}$	$2.78x10^{-4}$	$4.75x10^{-5}$
Large buildings	$2.66x10^{-6}$	$1.65x10^{-7}$	$1.46x10^{-3}$	$8.47x10^{-5}$	$1.45x10^{-5}$
House +Large buildings	$1.14x10^{-5}$	$7.06x10^{-7}$	$6.27x10^{-3}$	$3.63x10^{-4}$	$6.21x10^{-5}$

Exposure assessment for the major metabolite

PEC in soil

Degradation of the deltamethrin residue may result in the formation of a quantity of the major metabolite Br2CA in soil. However, it is difficult to predict the actual quantity of metabolite Br2CA present in soil after sludge application, since the parent will potentially have been subject to transformation either in soil or in the sludge itself under very different environmental conditions. Initial concentrations of Br2CA in soil following application of sewage sludge to land were estimated on the worst-case assumption that the metabolite is formed in the sludge at a quantity equivalent to 100% of the parent (adjusted to take into account the molecular weights of the compounds). The estimates of potential local soil exposure presented above have been adjusted by a factor of 0.59 (i.e. 298.0 / 505.2) to provide estimates of exposure to the metabolite Br2CA. Corresponding PECsoil values for Br2CA following other treatments can be calculated in the same way and are presented in the following table:

Type of treatment	Max. Csludge soil (0) for agricultural soil (mg/kg ww)
House	2.01×10^{-4}
Large buildings	6.12×10^{-5}
House +Large buildings	2.62×10^{-4}

These calculations have been carried out using the geometric mean DT50 for the metabolite Br2CA of 5.6 days taken from the three soils normalised to 12°C and PF2 (field capacity).
PECsoil values for Br2CA are showed in the following table

Type of treatment	PECsoil Br_2CA (mg/kg ww)
House	4.82×10^{-5}
Large buildings	1.47×10^{-5}
House +Large buildings	1.07×10^{-5}

PEC in groundwater

It is recognised that there may be some potential for residues of deltamethrin and the major metabolite Br_2CA in soil to be transported via leaching to groundwater. In accordance with the guidance presented in the TGD (EC, 2003), the concentration in porewater of soil has been calculated to provide an indication for potential groundwater contamination risk. This approach is recognised as a suitable firsttier method of estimating groundwater exposure. It should be noted that this is a worst-case assumption, neglecting transformation and dilution.

PEClocalgrw = PEClocalsoil, porew

The following parameter have been used:

Variable / parameter	Nomenclature	Unit	Value	Remarks
Bulk density of solid	RHO_{soil}	$kg \cdot m^{-3}$	1700	D
Soil-water equilibrium partition	$K_{soil-water}$	$m^3 \cdot m^{-3}$	0.97	O

distribution coefficient				

The resulting predicted environmental concentrations in groundwater (PEC_{GW}) values for major metabolite Br_2CA are presented below. It should be noted that these PEC_{GW} values were calculated on the basis of PEC_{soil} values that had been calculated on the unrealistically worst-case assumption that 100% of the parent compound is transformed to Br_2CA (corrected for molecular weight). The higher concentrations predicted for Br_2CA, compared to those for deltamethrin, are consistent with the high mobility of the compound.

PEC_{GW} Br_2CA = $PEC_{soil,porew}$ Br_2CA = $(PEClocal_{soil} \cdot RHO_{soil})/(K_{soil\text{-}water})$ [µg · L^{-1}]

Type of treatment	PEC_{GW} Br_2CA (µg · L^{-1})
House	3.53
Large buildings	1.08
House +Large buildings	4.6

Conclusion: As can see in the table above, the risk is unacceptable, PECgw are above the maximum permissible. Hence, as a tier 2, a FOCUS modelling was realized to refine the PEC groundwater for the metabolite Br_2CA.

Parameters use in FOCUS (Br2CA):

Model used	FOCUS PEARL
Years of simulation	1
Application rate (worst case, house + large buildings) Arable land (grassland	 0.0015 kg/ha 0.0003 Kg/ha
Standard crop for arable land	Maize (for agricultural soil) Grass (alfalfa)
Application depth	Incorporation 0 cm
Date of application	1 application per year
Molar mass	298 g.mol-1
Vapour pressure	0.00082 Pa at 25°C
Water solubility	60.5 mg.L-1 at 25°C
Kom (koc/1724)	14.85 L.kg-1 at 20°C
Freundlich exponent	1
DT50soil	5.6 d at 12°C
Coefficient for uptake for plant	0

Predicted 80th percentile concentrations for Br2CA in groundwater

FOCUS Scenarios		
	Concentration closest to the 80th percentile [µg·L^{-1}]	
	Alfalfa (grassland)	**Maize (arable land)**
Châteaudun	0.00	0.00
Hamburg	0.00	0.00
Jokioinen	0.00	0.00

Kremsmünster	0.00	0.00
Okehampton	0.00	0.00
Piacenza	0.00	0.00
Porto	0.00	0.00
Sevilla	0.00	0.00
Thiva	0.00	0.00

The calculated PECgw values of Br_2CA was several orders of magnitude below the groundwater trigger value of 0.1 µg/l in all scenarios. It is therefore concluded that Br2CA not represent a risk to groundwater following the application of sewage sludge to land.

Primary and secondary poisoning

Primary poisoning

The product is applied indoors as spot application in crack and crevices and therefore primary poisoning caused by product ingestion by animals is unlikely.

Secondary poisoning

Although it is highly unlikely that top predators might be contaminated though the trophic chain, secondary exposure to predators (mammals and birds) is also assessed after consuming different soil dwelling organisms such as earthworms or insects. It is considered that the product, after reaching STP is partitioned between aqueous and sludge compartments (air compartment is negligible). According to the models sludge is scattered onto agricultural soil and grassland, leading to exposure to non-target insects and earthworms living in the soil which are the main diet of some birds and mammals. Due to the high potential of bioaccumulation of the active substance Deltamethrin (log Kow =4.6) it is necessary to assess secondary exposure of animals through food chain.

PEC for fish and earthworm eating predators has been calculated following the *Guidance on Biocidal Products Regulation Vol. IV – Environment. Part B (Section 3.8)*.

A measured value of BCF_{fish} = 1400 $L.kg_{wet\ fish}^{-1}$ is available from the deltamethrin AR, which will be used in risk assessment.
An assessment of the secondary poisoning is then made by calculating $PEC_{oral,predator}$ as below:

$$PEC_{oral,\,predator} = PEC_{water} \times BCF_{fish} \times BMF$$

Where:
- $PEC_{oral,predator}$ is the predicted environmental concentration in food (in $mg/kg_{wet\ fish}$)
- BCF_{fish} is the bioconcentration factor for fish (1400 $L/kg_{wet\ fish}$)
- PEC_{water} is the predicted environmental concentration in water
- BMF is the biomagnification factor in fish (taken to be 2 from the AR)

In a similar fashion $BCF_{earthworm}$ can be calculated using the following equation:

$$BCF_{earthworm} = (0.84 + 0.012\ K_{ow}) / RHO_{earthworm}$$

Where $RHO_{earthworm}$ has been assumed to have a default value of 1 (kg_{wwt}/L), giving:

$$BCF_{earthworm} = 483 \text{ L/kg}_{\text{wet earthworm}}$$

An assessment of the secondary poisoning is then made by calculating $PEC_{oral,predator}$ as below:

$$PEC_{oral,\,predator} = \frac{(BCF_{earthworm} \times C_{porewater}) + (C_{soil} \times F_{gut} \times CONV_{soil})}{1 + (F_{gut} \times CONV_{soil})}$$

Where: $CONV_{soil} = RHO_{soil} / F_{solid} \times RHO_{solid}$

And:

- $PEC_{oral,\,predator}$ is the predicted environmental concentration in food (in mg $kg_{wet\ earthworm}^{-1}$)
- $BCF_{earthworm}$ is the bioconcentration factor for earthworms (calculated as 120 000 $L.kg_{wet\ earthworm}^{-1}$)
- $C_{porewater}$ is the concentration of substance in porewater
- C_{soil} is the concentration of substance in soil
- F_{gut} is the fraction of gut loading in worm (default of 0.1)
- $CONV_{soil}$ is the conversion factor for soil concentration wet-dry weight soil (calculated as 1.133)
- F_{solid} is the volume fraction of solids in soil (default of 0.6)
- RHO_{soil} is the bulk density of wet soil (default of 1700 kg m^{-3})
- RHO_{solid} is the bulk density of solid phase (default of 2500 kg m^{-3})

Summary table on calculated $PEC_{oral\ predator}$ values[1]		
	PEC_{oral} predator earthworm	**$PEC_{oral\ predator}$** fish
	[mg/ kg earthworm]	[mg/ kg fish]
Scenario 1[#]	3.62×10^{-5}	1.72×10^{-3}

[1] Calculated using equations in the ECHA guidance on ERA;
[#] Refers to total professional emissions i.e. domestic + large buildings summed

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: Releases to air are considered to be negligible due to the low vapour pressure of deltamethrin (1.24×10^{-8} Pa at 25 °C) and the level of risk to this compartment is expected to be negligible.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
House	2.91×10^{-4}

Large buildings	$8.87x10^{-5}$
House + large buildings	$3.80x10^{-4}$

Conclusion: As the PEC/ PNEC value is less than 1, an acceptable level of risk to STP is predicted from application scenarios.

Aquatic compartment

Summary table on calculated PEC/PNEC values		
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**
House	$7.74\ x10^{-1}$	$7.74\ x10^{-1}$
Large buildings	$2.36x10^{-1}$	$2.36x10^{-1}$
House + large buildings	1.01	1.01

Conclusion:

The PEC/ PNEC values are less than 1 except for he sum of both scennarios houses+ large buildings, but taking into account the RMM "The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be a harborage for cockroaches" an acceptable level of risk to the aquatic compartment is predicted from application scenarios.

Terrestrial compartment

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
House	$1.63\ x10^{-3}$
Large buildings	$4.95\ x10^{-4}$
House + large buildings	$2.12\ x10^{-3}$

Conclusion: As the PEC/ PNEC values are less than 1, an acceptable level of risk to soil is predicted from application scenarios.

Groundwater

Groundwater values	
House	1.69×10^{-8}
Large buildings	5.15×10^{-9}
House + large buildings	2.20×10^{-8}

Using the simplistic approach detailed in the ECHA guidance on ERA to calculate the concentration of deltamethrin in groundwater, levels below the groundwater drinking trigger concentration of 0.1 µg l^{-1} (directive 98/83/EC) were predicted for all use patterns. Hence an acceptable level of risk to groundwater is predicted for this product.

Risk characterization for the major metabolite

Terrestrial compartment

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
House	5.83×10^{-5}
Large buildings	1.78×10^{-5}
House + large buildings	7.61×10^{-5}

Conclusion: As the PEC/ PNEC values are less than 1, an acceptable level of risk to soil is predicted from application scenarios.

Primary and secondary poisoning

Primary poisoning

No primary poisoning as consequence of the application of PROTEO EC is envisaged. The product is an EC formulation and only indoor use is recommended so possibility to be ingested by animals (mammals or birds) is highly unlikely if proper handling and storage recommendations are followed. In addition the product contains a bittering agent that prevents the consumption of the product by animals up in the food chain (vertebrates).

Secondary poisoning

Summary table on secondary poisoning		
	$PNEC_{oral\ predator}$ [mg/ kg]	**PEC/PNEC**
Scenario 1[#] - earthworm	1.33	$2.72x10^{-5}$
Scenario 1[#] - fish	1.33	$1.29x10^{-3}$

[#]Refers to total professional emissions i.e. domestic + large buildings summed.

ESCA comments:
According to the values of $PNEC_{oral\ predator}$ for birds and mammals indicated in the deltamethrin CAR, the PEC/PNEC values for scenarios 1 is shown in the following table:

Sumary table on secondary poisoning				
	$PNEC_{oral\ predator}$ Bird (mg/kg diet)	$PNEC_{oral\ predator}$ Mammal (mg/kgdiet)	$PEC/PNEC_{bird}$	$PEC/PNEC_{mammal}$
Scnario 1- earthworm	15	2.67	$0.24x10^{-5}$	$1.35x10^{-3}$
Scnario 1- fish	15	2.67	$0.11x10^{-3}$	$0.64x10^{-3}$

Conclusion: As the PEC/ PNEC values are less than 1, an acceptable level of risk from the consumption of contaminated earthworms or fish contaminated with deltamethrin is predicted.

Mixture toxicity

As this product contains only deltamethrin as biocidal active, there is no need to perform a "multiple active" assessment- however, the presence of any relevant "Substances of Concern" in the formulation must be considered for any contribution they may give to overall environmental risk. In this case, Deltamethrin is the main responsible of classification as dangerous to the environment, showing very restrictive PNEC values. Therefore, it is considered that the assessment of Deltamethrin as the only relevant ingredient leading to risk for the environment and it is not required to perform any further assessment.

Overall conclusion on the risk assessment for the environment of the product by the applicant
The biocidal product PROTEO EC is a Emulsificable Concentrate formulation based on deltamethrin (2.5% w/v) and is applied as an insecticide against flying and crawling insects in places where insects usually hide (cracks and crevices, behind or under furniture, corners…) PROTEO EC is applied indoors by professional users by spraying the target surfaces with a low pressure sprayer. The product shall be previously diluted with water in a rate of 1:100, applying 50 ml of in use dilution per m^2 of treated surface. It is important to bear in mind that the application shall be performed on a 0.1 m width band in

order to minimize releases to the environment. The maximum number of applications/year is 3-11.

The environmental risk assessment was performed according to the *Emission Scenario Document for Insecticides, Acaricides and Products to Control other Arthropods for Household and Professional Users* (*OECD Series of Emission Scenario Documents No.18*) and the *Guidance on the Biocidal Products Regulations, Vol. IV Environment – Part B Risk Assessment* (Version 1.0, April 2015) to determine emission estimations and using EUSES v.2.1.2 for PEC calculations. Agreed PNEC values from Assessment Report of Deltamethrin (Sweden, 2011) were used for comparison and RCR derivation purposes. The applicant has been granted with access to the whole data package of deltamethrin by the data owner.

For professional users a total release of 207 mg a.s./L to STP systems is calculated when 3-11 applications/year are assumed leading to acceptable PEC valued for all the environmental compartments.

Deltamethrin has a high potential for bioaccumulation so a secondary poisoning assessment of mammals and birds was performed in order to assess the risk for predators in the trophic chain after eating earthworms and insects contaminated with the product after releases to soil. The results showed no risk to animals high in the trophic chain.

Therefore, the use of PROTEO EC by trained professional users is safe with regards to the environment

ES CA comments:

According to the use proposed for PROTEO EC , indoor in crack and crevice for private house and large buildings, an acceptable risk are predicted for all environmental compartments.

Hence the authorisation of the product can be granted from an environmental fate and behaviour perspective.

2.2.9 Measures to protect man, animals and the environment

Poisoning may cause:

- Irritation of skin, Eye, mucous membranes, gastrointestinal and respiratory tract.
- Pulmonary aspiration hazard. Functional CNS disturbances.

Basic first aid procedures

- Move the person away from the contaminated area and remove contaminated or spattered clothing
- If contact in eyes, rinse with plenty of water for 15 minutes. Do NOT forget to remove the contact lenses.
- If contact on skin, wash with soap and plenty of water, without rubbing.
- If swallowed, do NOT induce vomiting unless told to do so by poison control or a health care professional.
- Keep the patient at rest and maintain the body temperature.

- Check the breath. If necessary give artificial respiration.
- If the person in unconscious, turn the patient sideways with the head at lower than the rest of the body and the knees bended.
- If necessary take the person to a hospital and show the label or packaging whenever possible.

DO NOT LEAVE THE POISENED PERSON ALONE UNDER ANY CIRCUMSTANCE

Medical advice for doctors and sanitary staff

- Symptomatic and supportive treatment.

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER.

Emergency measures to protect the environment:

Precautions: Prevent product from entering the environment (surface and ground water), sewerage, drainage, etc. with the construction of protective barriers and closing drains. Communicate to the competent authorities or tipping leaks into waterways, drains, sewers ...
Methods and materials for containment and cleaning: Absorb spill on inert material (sand, kaolin ...), collect and place in containers for later properly identified as a hazardous waste management.

2.2.10 Assessment of a combination of biocidal products

Not relevant. PROTEO EC is not intended to be used in combination with other biocidal products.

2.2.11 Comparative assessment

Not relevant. Deltamethrin is not a candidate for substitution.

3 ANNEXES

3.1 List of studies for the biocidal product

Section No. (IUCLID dossier)	**Authors**	**Year**	**Title, Source (where different from company) Company, Report No. GLP (where relevant) / (Un) Published**	**Data Protection Claimed (Yes/No)**	**Owner**
3 and 4	[redacted]	2009	Title: Determination of storage stability and shelf life specification data for an emulsifiable concentrate formulation containing 2.5% deltamethrin stored at 54ºC±2ºC for 14 days, in compliance with good laboratory practice, Study No DNA0456 Test Institute: David Norris Analytical Laboratories LtdL. GLP Not published	Yes	Sharda Cropchem Limited
3	[redacted]	2010	Title: Determination of storage stability and shelf life specification data for an emulsifiable concentrate formulation containing 2.5% deltamethrin stored at ambient temperature for 2 years, in compliance with good laboratory practice, Study No DNA0457 Test Institute: David Norris Analytical Laboratories Ltd. GLP Not published	Yes	Sharda Cropchem Limited
3	[redacted]	2023	Tittle: "Test for determining the particle size ditribution" on DELTAMETHRIN 2.5% EC (PROTEO EC) – M-23-0337	Yes	Sharda Cropchem Limited
4	[redacted]	2023	Tittle: Test for determining the corrosive properties to metals	Yes	Sharda Cropchem Limited

4	[redacted]	2023	Tittle: Determination of self-reactive mixtures properties (DSC Method)	Yes	Sharda Cropchem Limited
4	[redacted]	2023	Tittle: Test for determining the oxidizing properties of liquids	Yes	Sharda Cropchem Limited
5	[redacted]	2023	Tittle: Partial Validation of the Method of Determination for Deltamethrin in Formulated Materials, in Compliance with Good Laboratory Practice	Yes	Sharda Cropchem Limited
5	[redacted]	2008	Title: Validation of the method of determination for deltamethrin in formulated materials, in compliance with good laboratory practice, Study No DNA0458 Test Institute: David Norris Analytical Laboratories Ltd. GLP Not published	Yes	Sharda Cropchem Limited
5	[redacted]	2011	Title: Partial validation of the method of determination for deltamethrin in formulated materials, in compliance with good laboratory practice, Study No DNA1293 Test Institute: David Norris Analytical Laboratories Ltd. GLP Not published	Yes	Sharda Cropchem Limited
3	[redacted]	2011	Title: Deltamethrin 2.5% EC: determination of accelerated storage stability and corrosion characterisitcs, Study No CH202/2011 Test Institute: Chemservice S.r.l. GLP Not published	Yes	Sharda Cropchem Limited

3	[redacted]	2013	Title: Deltamethrin 2.5% EC: Two years storage stability and corrosion characterisitcs, Study No CH017/2011, 2013 Test Institute: Chemservice S.r.l. GLP Not published	Yes	Sharda Cropchem Limited
6.7.	[redacted]	2013	Title: Efficacy of a Deltamethrin 2.5% SC product against German Cockroach *Blatella germanica*, oriental cockroach *Blatta orientalis* and black ants *Lasius niger*; BIO047-I-13 Test Institute: BioGenius GmbH GLP Not published	Yes	Sharda Cropchem Limited
6.7.	[redacted]	2015	Title: Field trial to determine the efficacy of Deltamethrin 2.5 SC against four species; 14/286 Test Institute: i2LResearch Ltd GLP Not published	Yes	Sharda Cropchem Limited
6.7.	[redacted]	2015	Title: Field assessment of the efficacy of an insecticidal treatment against ants, Study No 2008-DELTASECT2.5CS-ANTS-FIELD/1015R, Test Institute: Laboratoire TEC GLP Not published	Yes	Sharda Cropchem Limited
8.1.1	[redacted]	2008	Title: Acute dermal irritation/corrosion study in rabbits with Deltamethrin EC; Study No 0675 Test Institute: RCC Laboratories India Pvt. Ltd. GLP Not published	Yes	Sharda International FZE
8.1.2	[redacted]	2008	Title: Acute eye irritation/corrosion study in rabbits with Deltamethrin EC; Study No 0676 Test Institute: RCC Laboratories India Pvt. Ltd. GLP	Yes	Sharda International FZE

			Not published		
8.3.1	[redacted]	2008	Title: Contact hypersensitivity in albino Guinea Pigs, maximization test with Deltamethrin EC (Magnussonand Kligman method); Study No 0677, Test Institute: RCC Laboratories India Pvt. Ltd. GLP Not published	Yes	Sharda International FZE
8.5.1	[redacted]	2008	Title: Acute oral toxicity study in rats with Deltamethrin EC; Study No 0673 Test Institute: RCC Laboratories India Pvt. Ltd. GLP Not published	Yes	Sharda International FZE
8.5.2	[redacted]	2008	Title: Acute inhalation toxicity study in rats with Deltamethrin EC; Study No 0678 Test Institute: RCC Laboratories India Pvt. Ltd GLP Not published	Yes	Sharda International FZE
8.5.3	[redacted]	2008	Title: Acute dermal toxicity study in rats with Deltamethrin EC; Study No 0674 Test Institute: RCC Laboratories India Pvt. Ltd GLP Not published	Yes	Sharda International FZE
8.7.1	[redacted]	2008	Title: Bacterial Reverse Mutation Assay with Deltamethrin EC; Study No 0679 Test Institute: RCC Laboratories India Pvt. Ltd GLP Not published	Yes	Sharda International FZE
8.7.1	[redacted]	2009	Title: Micronucleus Assay in Bone Marrow Cells of the Mouse with Deltamethrin EC Study No 1238016 Test Institute:Harlan Cytotest Cell Research GmbH (Harlan CCR) GLP Not published	Yes	Sharda International FZE

3.2 Output tables from exposure assessment tools

Please, refer to Section 13 of the IUCLID dossier (*Annex I Environmental Risk Assessment*):

Scenario 1 – Mixing and Loading, product application and cleaning spray equipment by trained professional users

Mixing/loading and application. Spray model 1	
Exposure description	**75th percentile**
Potential Hand	
Indicative value (rate of deposition of product)	192 mg in-use product/min*
Task duration (default value)	120 min/day
Product on hands	23040 mg /day
Rest of body potential dermal exposure	
Indicative value (rate of deposition of product):	92 mg in-use product/min
Task duration (default value)	120 min/day
Potential amount of product on rest of body	11040 mg/day
Clothing penetration (default value)	100 %
Actual dermal deposit of product on rest of body	11040 mg/day
Total actual dermal exposure to product via hands and body	34080 mg/day
Total dermal exposure to a.s. via hands and body *[given that the in-use product contains 0.0281% a.s.]*	9.58 mg
Skin penetration	2%
Total dermal systemic exposure to a.s. via hands and body	**0.1915 mg a.s./day**
Inhalation exposure	
Indicative value (exposure to product via inhalation)	104 mg in-use product/m^3
Breathing rate (default value)	1.25m^3/h
Task duration(default value)	120 min/day
Volume of air inhaled over task duration	2.5 m^3
Amount of product inhaled during task	260 mg
Total systemic exposure to a.s. via inhalation = amount of a.s. inhaled *[in-use product contains 0.0281% a.s.]*	**0.0731** mg a.s.
Cleaning application equipment. Recommendation No 4 of the BPC Ad Hoc Working Group on Human Expossure	
Exposure description	**75th percentile**
Potential Hand	
Indicative value (rate of deposition of product)	35.87 µl in-use product/min
Task duration (default value)	20 min/day
Product on hands	717.4 µl /day
Rest of body potential dermal exposure	
Indicative value (rate of deposition of product):	19.28 µl in-use product/min

Task duration (default value)	20 min/day
Potential amount of product on rest of body	385.6 µl /day
Clothing penetration (default value)	100 %
Actual dermal deposit of product on rest of body	385.6 µl /day
Total actual dermal exposure to product via hands and body	1103 µl /day
Total dermal exposure to a.s. via hands and body *[given that the in-use product contains 0.0281% a.s.]*	0.310 mg
Skin penetration	2%
Total dermal systemic exposure to a.s. via hands and body	**$6.2x10^{-3}$ mg a.s./day**
TOTAL EXPOSURE	
Total systemic exposure via skin and inhalation to a.s.	**0.2712 mg a.s./person/day**
Total systemic exposure to a.s. for a 60 kg adult	**0.00451 mg a.s./kg bw/day**
Total systemic exposure as % of systemic AEL	**60.18%** **$AEL_{systemic}$= 0.0075 mg/kg bw/day**

Scenario 2 –

Mixing and Loading by professional users- ConsExpo 5.0

ConsExpo 5.0 report

Report date: 27/06/2017

Compound

Compound name :	Deltamethrin		
CAS number :	52918-63-5		
molecular weight		5,1E2	g/mol
vapour pressure		1,2E-8	Pascal
KOW		10Log	

Populations

Professional

body weight	60	kilogram

Products

PROTEO EC

weight fraction compound	0,028	%

Aggregate Exposures

Aggregate exposure for Professional :

Total chronic potential dose (mg/kg/day):
5,9E-5

Total chronic systemic dose (mg/kg/day):
5,8E-5

Inhalation chronic potential dose (mg/kg/day):

5,8E-5

Inhalation chronic systemic dose (mg/kg/day):
5,8E-5

Dermal chronic potential dose (mg/kg/day):
7,7E-7

Dermal chronic systemic dose (mg/kg/day):
1,5E-8

Oral chronic potential dose (mg/kg/day):
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Oral chronic systemic dose (mg/kg/day):
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Details for scenario: Professional, PROTEO EC : mixing and loading, liquid

Inhalation model: Exposure to vapour : instantaneous release

weight fraction compound	0,028		%
exposure duration	1,3	minute	
room volume	20	m3	
ventilation rate	0,6	1/hr	
applied amount	5E2	gram	

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	33	m3/day

Dermal model: Direct dermal contact with product : instant application

weight fraction compound	0,028		%
exposed area	1,7E4		cm2
applied amount	0,01	gram	

Uptake model: fraction

uptake fraction	2	%

Product application by professional users- ConsExpo 5.0:

ConsExpo 5.0 report

Report date: 27/06/2017

Compound

Compound name :	undefined		
CAS number :			
molecular weight			g/mol
vapour pressure			Pascal
KOW		linear	

Populations

professional

body weight	60		kilogram

Products

PROTEO EC

weight fraction compound	0,028	%

Aggregate Exposures

Aggregate exposure for professional :

Total chronic potential dose (mg/kg/day):
2,2E-5

Total chronic systemic dose (mg/kg/day):
5,8E-7

Inhalation chronic potential dose (mg/kg/day):
1,5E-7

Inhalation chronic systemic dose (mg/kg/day):
1,5E-7

Dermal chronic potential dose (mg/kg/day):
2,1E-5

Dermal chronic systemic dose (mg/kg/day):
4,2E-7

Oral chronic potential dose (mg/kg/day):
0

Oral chronic systemic dose (mg/kg/day):
0

Details for scenario: professional, PROTEO EC : application (trigger spray)

Inhalation model: Exposure to spray : spraying

weight fraction compound	0,028		%
exposure duration	2,4E2		minute
room volume	20	m3	
ventilation rate	0,6	1/hr	
mass generation rate	0,38	g/sec	
spray duration	4	minute	
airborn fraction	0,2	fraction	
weight fraction non-volatile	0,2	fraction	
density non-volatile	1,8	g/cm3	
room height	2,5	meter	
inhalation cut-off diameter	15	micrometer	

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	33	m3/day

Dermal model: Direct dermal contact with product : constant rate

weight fraction compound	0,028		%
exposed area	1,7E4		cm2
contact rate	46	mg/min	
release duration	2,4E2		second

Uptake model: fraction

uptake fraction	2	%

Cleaning spray equipment by professional users:

Cleaning application equipment. Recommendation No 4 of the BPC Ad Hoc Working Group on Human Expossure	
Exposure description	**75th percentile**
Potential Hand	
Indicative value (rate of deposition of	35.87 µl in-use product/min

product)	
Task duration (default value)	20 min/day
Product on hands	717.4 µl /day
Rest of body potential dermal exposure	
Indicative value (rate of deposition of product):	19.28 µl in-use product/min
Task duration (default value)	20 min/day
Potential amount of product on rest of body	385.6 µl /day
Clothing penetration (default value)	100 %
Actual dermal deposit of product on rest of body	385.6 µl /day
Total actual dermal exposure to product via hands and body	1103 µl /day
Total dermal exposure to a.s. via hands and body *[given that the in-use product contains 0.00025 mg a.s./µl]*	0.275 mg
Skin penetration	2%
Total dermal systemic exposure to a.s. via hands and body	0.00620 mg a.s./day

Total Exposure for scenario 2:

Total systemic exposure to a.s. for a 60 kg adult	1.04 E-04 mg a.s./kg bw/day
Total systemic exposure as % of systemic AEL	1.39% $AEL_{systemic}$ = 0.0075 mg/kg bw/day

Scenario 3 – Secondary exposure to a toddler after spot type application indoors

Scenario 3: Secondary exposure to a toddler and adult after spot type-application indoors.	
Maximum application rate	500 mg Product/m^2 (12.5 mg a.s./m^2)
Area treated Spot type application (usual case)	10% of the area the toddler plays on during the relevant exposure period
Surface residues (SR) Spot type application	0.000125 mg a.s./cm* (=12.5 mg/m^2/10)
Transfer Coefficient (TC)of the toddler	6000 cm^2 per hour
Transfer Coefficient (TC)of the adult	16700 cm^2 per hour
Surface Transferable Residues (TR) Hard surfaces	10% of the residues present on the surface**
Exposure Period (EP) Hard surfaces	1 hour per day
Body weight of the toddler	10 kg
Body weight of the adult	60 Kg
Dermal exposure of the toddler	0.075 mg of a.s./toddler/day
Systemic dermal exposure of the toddler	0.00015 mg/Kg bw/ day
Transfer coeficienty hand to mouth of the toddler	10%
Systemic exposure by oral rute of the toddler	0.0005625 mg/Kg bw/ day

Total systemic exposure of the toddler	0.0007125 mg/Kg bw/ day
Total systemic exposure of the toddler as % of systemic AEL	**9%** **AELsystemic= 0.0075 mg/kg bw/day**
Dermal exposure of the adult	0.20875 mg/Kg bw/ day
Systemic dermal exposure of tha adult	6.95833E-05 mg/Kg bw/ day
Transfer coeficienty hand to mouth of the adult	4%
Systemic exposure by oral rute of the adult	0.000104375 mg/Kg bw/ day
Total systemic exposure of the adult	0.000173958
Total systemic exposure of the adult as % of systemic AEL	**2%** **AELsystemic= 0.0075 mg/kg bw/day**

Scenario 4 – Secondary exposure to a person laundering contaminated work clothing

Scenario 4: Secondary exposure to a person laundering contaminated work clothing.	
Frecuency of exposure	5 days/week
Amount the product in contaminated work clothing	11040 µl/ day
Amount of the product in contaminated work clothing afer a work week	55200 µl
Concentration of a.s.	0.000281 mg of a.s./ µl
Amount of a.s. in the contaminated work clothing	15.5 mg of a.s.
Area of medium-size coverall	22700cm^2
Amount of accumulated residues of a.s.	0.000683 mg of a.s./cm^2
Total area of palms and back of both hands	820 cm^2
Transfer coefficient of dried fluid from cotton to wet hands	30%
Dermal penetration	2%
Body weight of the adult	60 Kg
Systemic exposure of the adult	0.000056 mg/Kg bw/ day
Total systemic exposure of the adult as % of systemic AEL	**0.74%** **AELsystemic= 0.0075 mg/kg bw/day**

3.3 New information on the active substance

No new information about active substance has been provided in support of this biocidal product

3.4 Residue behaviour

Not relevant. PROTEO EC is not intended to be used in livestock facilities or in conditions that may lead to contamination of food/feestuff

3.5 Summaries of the efficacy studies (B.5.10.1)

Information on the efficacy studies has been reported in Section 6 of the IUCLID dossier.