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

DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

[KILLMETHRIN 2.5 WP]

Product type [18]

[Deltamethrin as included in the Union list of approved active substances]

Asset Number in R4BP: [GR-0002047-0000]

Evaluating Competent Authority: [GR]

Date: [April 2018]

In this template:

- **Explanatory notes are marked as follows:**

  [Times New Roman – Italics – brackets]

- **Examples provided for some areas are marked as follows:**

  Times New Roman – Italics – red writing

- **Other text that should be deleted is marked as follows:**

  [Times New Roman – Italics – brackets]

The eCA should delete all these texts when providing the PAR.

Explanatory note for the use of this template:

The PAR template should allow for a certain flexibility. Free text may be added, where necessary, and the content of the section may be adapted to the specific needs required for the different product types. Also tables can be added or deleted, when needed.

The PAR template is suitable for both a single biocidal product and a biocidal product family. The content of the template can be adapted accordingly.

Table of Contents

1. CONCLUSION

Killmethrin 2.5 WP is a Wettable Powder (WP) biocidal product containing 2.538% w/w deltamethrin. Its physicochemical properties are considered acceptable. Acceptable analytical methods have also been submitted.

Note: The applicant should update the List of Studies to include newly submitted studies.

Professional users are not at risk even when no PPE is worn during the time the product is used. However, chemical goggles should be used due to the toxicological properties of the formulation (Eye Da. 1; H318). Accumulated exposure leads to acceptable risk when a professional user is exposed to Deltamethrin during the whole day (in his job and re-entering in treated sites as any other bystander). Conclusively, the use of PPE (chemical goggles) is required for professionals when using the product KILLMETHRIN 2.5 WP. The use of gloves and coated coverall is recommended in order to minimize the exposure of PCOs to biocidal products.

No risk has been identified for non-professionals users for the examined scenario. Accumulated exposure after using KILLMETHRIN 2.5 WP and re-entering in treated sites was calculated to be well below the AEL. In addition, no risk has been identified for the amateur user for local effects with the prerequisite that a dosing system will be added in the packaging of the product and proper instructions for use will be included in the label.

The biocidal product KILLMETHRIN 2.5 WP is safe to general population after crack and crevice application in household or commercial premises. Main route of indirect contamination is by accidentally rubbing off treated surfaces, which is highly unlikely due to crack and crevice application characteristics. As a precautionary principle, it should be clearly stated that the product should be applied to places inaccessible to children.

2. ASSESSMENT REPORT

2.1. SUMMARY OF THE PRODUCT ASSESSMENT

2.1.1. ADMINISTRATIVE INFORMATION

A. PRODUCT NAME / PRODUCT FAMILY NAME

Product name	**Country**
Killmethrin 2.5 WP	GR, CY, UK
Trianos 2.5 WP	GR
Deltasect WP	GR
Deltamethrin Sharda Europe WP	GR

B. AUTHORISATION HOLDER

Name and address of the authorisation holder	**Name**	Sharda Europe B.V.B.A
	Address	Heedstraat 158, 1730 Asse, Belgium
Authorisation number	Not defined	
Date of the authorisation	Not defined	
Expiry date of the authorisation	Not defined	

C. MANUFACTURER(S) OF THE PRODUCT

Name of manufacturer	Sharda Europe B.V.B.A.
Address of manufacturer	Heedstraat 158, 1730 Asse, Belgium
Location of manufacturing sites	Site 1: DTS OABE. Polígono Industrial Zabale, Parcela 3, 48410 Orozco, Vizcaya, Spain Site 2: SPACHEM S.L., Polígono Industrial Guadasequies, S/N, 46839 Guadasequies, Valencia, Spain Site 3: LUQSA, Afores S/N, 25173 Sudanell, Lleida, Spain Site 4: Chemark Kft, Industrial Zone, H-8182 Peremarton – Gyarlep, Hungary Site 5: Organika Sarzyna S.A., ul Chemików 1, 37-310 Nowa Sarzyna, Poland Site 6: AGROL, ul. Lipowa16, Sicha Gora, 59-101 Polkowice, Poland Site 7: S.T.I. Solfotecnica Italia SpA, Via Evangelista Torricelli 2, Cotignola, Ravenna, Italy Site 8: Ellagret S.A., Thesis Xiropigado, 19600 Mandra Attikis, Greece Site 9: SINAPAK S.R.L, Viale Industria e Artigianato 7, 27049 Stradella, Padova, Italy

D. MANUFACTURER(S) OF THE ACTIVE SUBSTANCE(S)

Active substance	Deltamethrin
Name of manufacturer	Sharda Cropchem Limited
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, 400092 Borivali – (W), Mumbai, India

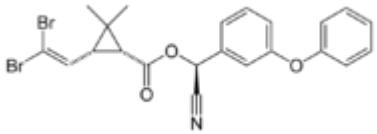
2.1.2. PRODUCT (FAMILY) COMPOSITION AND FORMULATION

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

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

Yes ☐
No X

A. IDENTITY OF THE ACTIVE SUBSTANCE

Main constituent(s)	
ISO name	Deltamethrin
IUPAC or EC name	(S)-α–cyano-3-phenoxybenzyl (1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate
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
Structural formula	

B. CANDIDATE(S) FOR SUBSTITUTION

Deltamethrin is not candidate for substitution

C. QUALITATIVE AND QUANTITATIVE INFORMATION ON THE COMPOSITION OF THE BIOCIDAL PRODUCT[1]

Please, refer to Annex 3.6 – Confidential annex

D. INFORMATION ON TECHNICAL EQUIVALENCE

Based on the assessment performed by ECHA, the alternative Deltamethrin source manufactured by Sharda Cropchem Limited (Formerly known as Sharda Worldwide Export Pvt. Ltd.) shows similar toxicity to human, animals and the environment compared to the EU reference source.
Therefore, the alternative Deltamethrin source manufactured by Sharda Cropchem Limited can be considered as equivalent to the EU reference source.

1

E. INFORMATION ON THE SUBSTANCE(S) OF CONCERN

IUPAC name or other accepted chemical name	**2-(2,6-dimethylanilino)-2-oxoethyl]-diethyl-(phenylmethyl)azanium benzoate**
EC number	223-095-2
CAS number	3734-33-6
Concentration (minimum and maximum, g/kg or g/l)	0.005%
Classification and Labelling according to Regulation (EC) No 1272/2008:	Acute Tox. 4; H302 Acute Tox. 4; H332 Skin Irrit. 2; H315 Eye Dam. 1; H318
Classification and Labelling according to the Directive 67/548/EEC	-
Relevant toxicological/ecotoxicological information	-
Other grounds for concern	-

IUPAC name or other accepted chemical name	**Sodium, 2-dodecylbenzenesulfonate**
EC number	246-680-4
CAS number	25155-30-0
Concentration (minimum and maximum, g/kg or g/l)	3%
Classification and Labelling according to Regulation (EC) No 1272/2008:	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318
Classification and Labelling according to the Directive 67/548/EEC	-
Relevant toxicological/ecotoxicological information	-
Other grounds for concern	-

IUPAC name or other accepted chemical name	**Sodium dodecylsulphate**
EC number	205-788-1
CAS number	151-21-3
Concentration (minimum and maximum, g/kg or g/l)	2%
Classification and Labelling according to Regulation (EC) No 1272/2008:	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318
Classification and Labelling according to the Directive 67/548/EEC	-
Relevant toxicological/ecotoxicological information	-
Other grounds for concern	-

F. TYPE OF FORMULATION

WP – Wettable powder

2.1.3. AUTHORISED USE(S)

Table 1. Use # 1 – Indoors spot, crack and crevices treatment by professional users

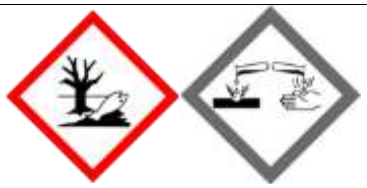
Product Type	18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Crawling insects: Application in cracks and crevices. Product solution shall be applied in cracks and crevices, corners, behind and under furniture and in other small spots where insects usually hide. Flying insects: Spot application in places where flying insects tend to rest. Product solution shall be applied in windowsills, joists, pipes, walls… Killmethrin 2.5 WP is suitable for pest control treatment of the following premises: houses*, apartments*, neighborhood centers, cinemas*, barracks*, hotels*, restaurants*, bars*, canteens*, hospitals*, industrial warehouses**... * With the exception of premises, equipment, vehicles, locations and dependencies used for the collection, transport and treatment of garbage and waste of animal or vegetable origine. ** Except premises, equipment, vehicles, locations and dependencies used: - for the transportation, receipt, maintenance and housing of pets or for the preparation and transportation of foods - for harvesting, transportation, storage, industrial processing and marketing of products of animal and plant origin.
Target organism (including development stage)	Flying insects (mosquitoes, flies and wasps); adults Crawling insects (cockroaches); adults
Field of use	Indoor use
Application method(s)	Spraying. KILLMETHRIN 2.5 WP shall be applied through devices such as pumps or sprays working at low pressures (1-5 bar).
Application rate(s) and frequency	50 g of product diluted in 5L of water to treat 100 m^2 surface Maximum 6-8 applications/year. Treatment can be repeated after 6 weeks.
Category(ies) of users	Professional users, Trained professional users
Pack sizes and packaging material	Bag /Sack, Plastic: HDPE , 5 - 5000 g Bag /Sack, Plastic: composite: , 5 - 5000g Bags/sacks of HDPE or complex composite: - Foil of complex material made of LDPE + Aluminium + Polypropylene or polyester or paper - Foil of complex material made of LDPE + metallic complex + Polypropylene or polyester or paper Bags can be supplied in cardboard boxes

Table 2. Use # 2 – Indoors spot, crack and crevices treatment by non-professional users

Product Type	18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Crawling insects: Application in cracks and crevices. Product solution shall be applied in cracks and crevices, corners, behind and under furniture and in other small spots where insects usually hide. Flying insects: Spot application in places where flying insects tend to rest. Product solution shall be applied in windowsills, joists, pipes, walls… Killmethrin 2.5 WP is suitable for pest control treatment of the following premises: houses*, apartments*, neighborhood centers, cinemas*, barracks*, hotels*, restaurants*, bars*, canteens*, hospitals*, industrial warehouses**... * With the exception of premises, equipment, vehicles, locations and dependencies used for the collection, transport and treatment of garbage and waste of animal or vegetable origine. ** Except premises, equipment, vehicles, locations and dependencies used: - for the transportation, receipt, maintenance and housing of pets or for the preparation and transportation of foods - for harvesting, transportation, storage, industrial processing and marketing of products of animal and plant origin.
Target organism (including development stage)	Flying insects (mosquitoes, flies and wasps); adults Crawling insects (cockroaches); adults
Field of use	Indoor use
Application method(s)	Spraying. KILLMETHRIN 2.5 WP shall be applied through devices such as pumps or sprays working at low pressures (1-5 bar).
Application rate(s) and frequency	50 g of product diluted in 5L of water to treat 100 m2 surface Maximum 2 applications/year. Treatment can be repeated after 6 weeks.
Category(ies) of users	Non-professional users
Pack sizes and packaging material	Bags/sacks of HDPE or complex composite 5 - 500g: - Foil of complex material made of LDPE + Aluminium + Polypropylene or polyester or paper - Foil of complex material made of LDPE + metallic complex + Polypropylene or polyester or paper Bags can be supplied in cardboard boxes

2.1.4. HAZARD AND PRECAUTIONARY STATEMENTS

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

Classification	
Hazard category	Eye Dam. – Cat. 1 Aquatic Acute – Cat. 1 Aquatic Chronic – Cat. 1
Hazard statement	H410 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects
Labelling	
Pictogram	
Signal words	Danger
Hazard statements	H318 Causes serious eye damage H410 Very toxic to aquatic life with long lasting effects
Precautionary statements	P101 If medical advice is needed, have product container or label at hand. P102 Keep out of reach of children. P103 Read label before use. P273 Avoid release to the environment P280 Wear protective gloves/protective clothing/eye protection/face protection P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER or doctor/physician. P391 Collect spillage P501 Dispose of contents/container in accordance with local/regional/national/international regulation.

Classification	
Note	Professional users should wear chemical goggles, protective gloves and protective clothing. The product should be applied to areas inaccessible to children. Avoid any contact with the eyes. Wash hands thoroughly after handling of the product. 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 with food/feedstuff during treatment. Keep away from food, drink and animal foodstuffs. Protect food, cooking utensils and cutlery contamination during application. Do not apply to surfaces where food is stored, prepared or consumed.

2.1.5 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)**
Bag/sack	5, 10, 50, 100, 200, 250, 300, 500, 1000, 2000 and 5000 g	Bags/sacks of HDPE or complex composite: - Foil of complex material made of LDPE + Aluminium + Polypropylene or polyester or paper - Foil of complex material made of LDPE + metallic complex + Polypropylene or Polyester	Thermosealed closure	Professional	yes

		or Paper Bags can be supplied in cardboard boxes			
Bag/sack	5, 10, 50, 100, 200, 250, 300, 500 g	Bags/sacks of HDPE or complex composite: - Foil of complex material made of LDPE + Aluminium + Polypropylene or polyester or paper - Foil of complex material made of LDPE + metallic complex + Polypropylene or Polyester or Paper Bags can be supplied in cardboard boxes	Thermosealed closure	Non-professional	Yes

2.1.6. DIRECTIONS FOR USE

G. INSTRUCTIONS FOR USE

It is advisable to use Killmethrin 2.5 WP (Deltamethrin 2.5% WP) through devices such as pumps or sprays, being careful to apply the solution in cracks and crevices, under or behind furniture and in general, in other small spots where insects can hide or rest. 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). Application must be performed to a band of 0.1 m width on the treated surfaces.
Keep continuous agitation during application

Strategies for managing the development of resistance:

- Where possible, application treatments should be recommended to be combined with non-chemical measures.
- Where an extended period of control is required, treatments should be alternated

with products having active substances with different modes of action.
- Establish a baseline and monitor levels of effectiveness on populations in key areas in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder or the distributor.
- The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

H. PARTICULARS OF LIKELY DIRECT OR INDIRECT EFFECTS, FIRST AID INSTRUCTIONS AND EMERGENCY MEASURES TO PROTECT THE ENVIRONMENT

Particulars of likely direct or indirect effects:
May cause transient irritation of skin, eyes and mucous membranes.
Poisoning can cause the following symptoms: paresthesia, which may be severe skin and eye. May cause irritation to eyes, skin and mucous membranes. Inhalation may cause irritation, cough. Risk of pulmonary edema. Excitation, gastrointestinal disorders, tremors, dizziness, headache, lethargy, vomiting, abdominal pain, muscular twitching, nausea, loss of consciousness ...

First aid instructions:
General: Remove victim to fresh air. Immediately remove all contaminated clothing. Keep patient at rest. Maintain body temperature. If the person is unconscious, shorten side with the head lower than the rest of the body and the knees bended. Control breathing, if necessary, artificial respiration. Do not just leave the patient under any circumstance. Remove to fresh to hospital and, whenever possible, take the container or label.
Ingestion: If swallowed do not induce vomiting. Summon a doctor immediately and show him the label or the safety data sheet.
Inhalation: Seek fresh air to the victim (move outdoors). If you notice discomfort, seek medical attention.
Skin Contact: After contact with skin, wash immediately with soap and water, without rubbing.
Eye Contact: Rinse immediately with plenty of water for at least 15 minutes with the eyelid held wide open, not forget to remove the lenses. If you notice discomfort, seek medical attention.

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.

I. INSTRUCTIONS FOR SAFE DISPOSAL OF THE PRODUCT AND ITS PACKAGING

Consider the product or its residues as hazardous waste and manage through a licensed hazardous waste manager.
Empty the container thoroughly. Do not use the package again.
Disposal of empty containers should be done according to local and national regulations.
When cleaning application equipment, RINSE CONTAINER THOROUGHLY by using an integrated pressure rinsing device or manually rinsing three times and spray rinses to target surfaces.

J. 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 up to 30°C. 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, KILLMETHRIN 2.5 WP can be stored for 2 years.

2.1.7 OTHER INFORMATION

Treated areas should be well-ventilated.

2.2 ASSESSMENT OF THE BIOCIDAL PRODUCT

2.2.1 INTENDED USE(S) AS APPLIED FOR BY THE APPLICANT

Table 2. Use # 1 – Indoors spot, crack and crevices treatment by professional users

Product Type	18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Crawling insects: Application in cracks and crevices. Product solution shall be applied in cracks and crevices, corners, behind and under furniture and in other small spots where insects usually hide. Flying insects: Spot application in places where flying insects tend to rest. Product solution shall be applied in windowsills, joists, pipes, walls… Killmethrin 2.5 WP is suitable for pest control treatment of the following premises: houses*, apartments*, neighborhood centers, cinemas*, barracks*, hotels*, restaurants*, bars*, canteens*, hospitals*, industrial warehouses**... * With the exception of premises, equipment, vehicles, locations and dependencies used for the collection, transport and treatment of garbage and waste of animal or vegetable origine. ** Except premises, equipment, vehicles, locations and dependencies used: - for the transportation, receipt, maintenance and housing of pets or for the preparation and transportation of foods - for harvesting, transportation, storage, industrial processing and marketing of products of animal and plant origin.
Target organism (including development stage)	Flying insects (mosquitoes, flies and wasps); adults Crawling insects (cockroaches and ants); adults
Field of use	Indoor use
Application method(s)	Spraying. KILLMETHRIN 2.5 WP shall be applied through devices such as pumps or sprays working at low pressures (1-5 bar).
Application rate(s) and frequency	50 g of product diluted in 5L of water to treat 100 m^2 surface Maximum 6-8 applications/year. Treatment can be repeated after 6 weeks
Category(ies) of users	Trained professional and professional operators
Pack sizes and packaging material	Bags/sacks of HDPE or complex composite 5-5000g: - Foil of complex material made of LDPE + Aluminium + Polypropylene or polyester or paper - Foil of complex material made of LDPE + metallic complex + Polypropylene or polyester or paper Bags can be supplied in cardboard boxes

Table 3. Use # 2 – Indoors spot, crack and crevices treatment by non-professional users

Product Type	18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Crawling insects: Application in cracks and crevices. Product solution shall be applied in cracks and crevices, corners, behind and under furniture and in other small spots where insects usually hide. Flying insects: Spot application in places where flying insects tend to rest. Product solution shall be applied in windowsills, joists, pipes, walls… Killmethrin 2.5 WP is suitable for pest control treatment of the following premises: houses*, apartments*, neighborhood centers, cinemas*, barracks*, hotels*, restaurants*, bars*, canteens*, hospitals*, industrial warehouses**... * With the exception of premises, equipment, vehicles, locations and dependencies used for the collection, transport and treatment of garbage and waste of animal or vegetable origine. ** Except premises, equipment, vehicles, locations and dependencies used: - for the transportation, receipt, maintenance and housing of pets or for the preparation and transportation of foods - for harvesting, transportation, storage, industrial processing and marketing of products of animal and plant origin.
Target organism (including development stage)	Flying insects (mosquitoes, flies and wasps); adults Crawling insects (cockroaches and ants); adults
Field of use	Indoor use
Application method(s)	Spraying. KILLMETHRIN 2.5 WP shall be applied through devices such as pumps or sprays working at low pressures (1-5 bar).
Application rate(s) and frequency	50 g of product diluted in 5L of water to treat 100 m2 surface Maximum 2 applications/year. Treatment can be repeated after 6 weeks
Category(ies) of users	Non-professional users
Pack sizes and packaging material	Bags/sacks of HDPE or complex composite 5-500g: - Foil of complex material made of LDPE + Aluminium + Polypropylene or polyester or paper - Foil of complex material made of LDPE + metallic complex + Polypropylene or polyester or paper Bags can be supplied in cardboard boxes

2.2.2 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES

Use concentration: 1% w/v

Property	Guideline and Method	Purity of the test substance % (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	EPA 712-C-96-020 Handbook of chemistry and physics	Deltamethrin 2.51%	Solid (powder)	M. Berrios, 2015
Colour at 20 °C and 101.3 kPa	EPA 712-C-96-019 Handbook of chemistry and physics	Deltamethrin 2.51%	Pale green (2.5 GY 8/2 according to Munsell scale)	M. Berrios, 2015
Odour at 20 °C and 101.3 kPa	EPA 712-C-96-021 Handbook of chemistry and physics	Deltamethrin 2.51%	Characteristic	M. Berrios, 2015
Acidity / alkalinity	CIPAC MT 75.3	Deltamethrin 2.51%	pH=6.48 at (1% solution)	M. Berrios, 2015
Relative density / bulk density	OECD 109	Deltamethrin 2.51%	Pour density: 0.636 g/cm3 Bulk density: 0.846 g/cm3	M. Berrios, 2015
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Deltamethrin 2.51%	No changes were noted in the packaging (plastic bag of complex material). No significative change in the content of active substance was detected Initial: 1.96% After storage:1.99% The technical characteristics of the product have not been determined after accelerated storage period. Since no physical	M. Berrios, 2015

			properties where tested in the accelerated storage stability the Biocidal Product will be proposed not to be stored at temperatures above 30^{O}C. It should be noted that they are reported after long term storage at ambient temperature during 24 months.	
Storage stability test – **long term storage at ambient temperature**		Deltamethrin 2.51%	No changes were noted in the packaging (plastic bag of complex material). No stacking was observed. No significative change in the content of active substance was detected after 2 years storage. Deltamethrin content (initial): 1.99% w/w Deltamethrin content (24 months): 2.02% w/w pH (initial)=6.48 pH (24 months)=6.55 Suspensibility (initial): Without swirling: 0.4% w/v: 36% 2.0% w/v: 31% With swirling: 0.4% w/v: 71% 2.0% w/v: 76% Suspensibility (24 months):	M. Berrios, 2015 (Interim report) M. Berios, 2017 (Statement)

			Without swirling: 0.4% w/v: 41% 2.0% w/v: 51% With swirling: 0.4% w/v: 65% 2.0% w/v: 70% Wettability (initial): Without swirling: 26 sec With swirling: 19 sec Wettability (24 months): Without swirling: 60 sec With swirling: 46 sec Wet sieve test (initial): 0.09% above 75 μm Wet sieve test (24 months): 0.04% above 75 μm Based on the results in the label it should be added that: "The spraying solution must be under continuous agitation".	
Storage stability test – **low temperature stability test for liquids**			Not relevant. The product is a wettable powder formulation	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			Not relevant. Opaque package	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			Not available	M. Berrios, 2015
Effects on content of the active substance and technical characteristics of the	CIPAC MT 46.3		No changes were noted in the packaging material after 14 days	M. Berrios, 2015

biocidal product - **reactivity towards container material**			under accelerated storage conditions.	
Wettability	CIPAC MT 53.3	Deltamethrin 2.51%	Wettability with swirling: 19 sec Wettability without swirling: 26 sec	M. Berrios, 2015
Suspensibility, spontaneity and dispersion stability	CIPAC MT 15.1	Deltamethrin 2.51%	Suspensibility is in the acceptable range of 60 to 105 % with swirling Mean measured values were 76% and 71% for 2% and 0.4% concentrated solutions	M. Berrios, 2015
Wet sieve analysis	CIPAC MT 59.3	Deltamethrin 2.51%	Only 0.09% residue was retained in a 75 μm sieve	M. Berrios, 2015
Emulsifiability, re-emulsifiability and emulsion stability			Not relevant. The product is not an emulsifiable formulation	
Disintegration time		Deltamethrin 2.51%	Not relevant. Formulation is a wettable powder	M. Berrios, 2015
Particle size distribution, content of dust/fines, attrition, friability	CIPAC MT 59.1	Deltamethrin 2.51%	Granular fraction: 10.6% w/w Dust fraction (> 150μm): 13.7% Dust fraction (< 150μm): 75.6%	M. Berrios, 2015
Persistent foaming	CIPAC MT 47.2	Deltamethrin 2.51%	No foam was detected after 60 seconds in 2% and 0.4 % w/w test item solutions	M. Berrios, 2015
Flowability/Pourability/Dustability (Effectiveness of cleaning procedures)	HSE Efficacy guideline 305 – Cleaning application equipment. Small scale jar test protocol	Deltamethrin 2.51%	99.81% and 99.51% product removal from application equipment in 2% and 0.4% w/w test solutions after 3 rinses. The following statement should be added in the label: *On emptying the container, RINSE*	M. Berrios, 2015

			CONTAINER THOROUGHLY by using an integrated pressure rinsing device or manually rinsing three times. Add washings to sprayer.	
Burning rate — smoke generators		Deltamethrin 2.51%	Not relevant, the product is not a smoke generator	M. Berrios, 2015
Burning completeness — smoke generators		Deltamethrin 2.51%	Not relevant, the product is not a smoke generator	M. Berrios, 2015
Composition of smoke — smoke generators		Deltamethrin 2.51%	Not relevant, the product is not a smoke generator	M. Berrios, 2015
Spraying pattern — aerosols		Deltamethrin 2.51%	Not available	M. Berrios, 2015
Physical compatibility		Deltamethrin 2.51%	Not relevant. The product is not intended to be used in combination with other biocidal products	M. Berrios, 2015
Chemical compatibility		Deltamethrin 2.51%	Not relevant. The product is not intended to be used in combination with other biocidal products	M. Berrios, 2015
Degree of dissolution and dilution stability		Deltamethrin 2.51%	Not available	M. Berrios, 2015
Surface tension		Deltamethrin 2.51%	Not relevant. Product is a wettable powder formulation	M. Berrios, 2015
Viscosity		Deltamethrin 2.51%	Not relevant. Product is a wettable powder formulation	M. Berrios, 2015

Conclusion on the physical, chemical and technical properties of the product
Killmethrin 2.5 WP (Deltamethrin 2.5% w/w) is a pale green powder with characteristic odour. pH of a 1% product solution in water is 6.48. The density of the product was determined to be 0.636 g/cm^3 and 0.846 g/cm^3 (pour and bulk respectively). Technical characteristics (wettability, pourability, suspensibility, wet sieve analysis, particle size distribution and persistent foaming) were acceptable. Storage stability tests (accelerated and shelf life) demonstrated compatibility with package material and unchanged product

characteristics with regards to the content of the active substance in the product.

About the flexibility of the packaging materials the applicant has stated:
"The packing material in the storage stability studies is complex plastic bags. If they are built with aluminium or metallic complex or with polypropylene, polyester or paper - this is not affecting the package flexibility, since in all these cases the bags will not make any difference in the package consistency and flexibility".

Label Implications:
- Since no physical properties where tested in the accelerated storage stability the Biocidal Product will be proposed not to be stored at temperatures above 30^{O}C.
- On emptying the container, RINSE CONTAINER THOROUGHLY by using an integrated pressure rinsing device or manually rinsing three times. Add washings to sprayer.
- The spraying solution must be under continuous agitation.

2.2.3 PHYSICAL HAZARDS AND RESPECTIVE CHARACTERISTICS

Explosives	EU method A.14	Deltamethrin 2.51%	Non-explosive Thermal and mechanical (shock and friction) sensitivity test: negative	M. Berrios, 2015
Flammable gases			Not relevant. Formulation is not a gas	
Flammable aerosols			Not relevant. Formulation is not a gas	
Oxidising gases			Not relevant. Formulation is not a gas	
Gases under pressure			Not relevant. Formulation is not a gas	
Flammable liquids			Not relevant. Formulation is not a liquid	
Flammable solids	EU method A.9	Deltamethrin 2.51%	Non-flammable (Flash point=128.8ºC)	M. Berrios, 2015
Self-reactive substances and mixtures			Not relevant. According to experience of use the product does not react with ambiental	

			moisture or water	
Pyrophoric liquids			Not relevant. Formulation is not a liquid	
Pyrophoric solids			Not relevant. According to experience of use the product does not react with ambiental moisture or water	
Self-heating substances and mixtures			Not relevant. According to experience of use the product does not react with ambiental moisture or water	
Substances and mixtures which in contact with water emit flammable gases			Not relevant. According to experience of use the product does not react with ambiental moisture or water	
Oxidising liquids			Not relevant. Formulation is not a liquid	
Oxidising solids	EU method A.17	Deltamethrin 2.51%	Oxidising test: preliminary test: not vigorous. Main test not conducted therefore the study is not considered complete. There are no structural alerts within the components of the formulation that may indicate oxidizing properties.	M. Berrios, 2015 J. Lopez, 2017 (statement)
Organic peroxides			Not relevant.	

			Formulation does not contain peroxides	
Corrosive to metals			Not relevant. pH of the formulation in a 1% water solution is 6.48 and it is not expected to show corrosive properties to metals.	
Auto-ignition temperatures of products (liquids and gases)			Not relevant. Formulation is a wettable powder	
Relative self-ignition temperature for solids	Guideline and method: UN MTC Test N.4 Purity of test substance: Deltamethrin 2.5% GLP: Yes Results: 			Michalec-Minch M. (2017)
Dust explosion hazard			Not relevant. Product has shown no explosive properties	

Self-heating UN-MTC Test N.4	Deltamethrin 2,5 % WP 84.1/2017			
	Oven temperature, °C	Cube size, mm	Maximum temperature reached by sample, °C	Results
Test run 1	140	100	146.0	Not Division 4.2
Test run 2	140	100	139.5	Not Division 4.2

Conclusion on the physical hazards and respective characteristics of the product
Killmethrin 2.5 WP has shown to have a flash point of 128.8ºC, showing no flammability properties. No explosive or oxidizing properties of the product are expected. The product is not classified in Division 4.2 for self-ignition. Killmethrin 2.5 WP is not classified based on the physical/chemical properties.

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 (%)**		**Precision**	**Reference**
					Range	Mean RSD		

Active substance in biocidal product: Deltamethrin	GC-MS/MS	0.200 to 0.800 mg/L Seven measurements in duplicate	Method is linear y=277.66 x + 26893.94 (r^2)=0.9988	Method is specific	99.1-101 (n=2)	100.1	RSD%=0.05 (n=5)	M. Berrios, 2015

No analytical methods for determination of active substance in air, soil and water were developed. This information was already submitted in the active substance dossier.

Furthermore the analytical methods for the determination of Deltamethrin in food and feeding stuff, plants or plant products and animal and human body tissues and fluids are not relevant to the preparation Killmethrin 2.5 WP.

An analytical method for the determination of the active substance in food or feeding stuffs from animal/vegetal origin is not required as the product will not be in direct contact with food producing animals, food of plant and animal origin or feeding stuffs. This exposure is prevented according to the use instructions, where it is advised to remove all the food/feeding stuffs before treatment and restricting the application on surfaces where food/feedstuff is treated.

It should be noted that the applicant has access to the data submitted by the owner of the data reported in the CAR document.

Conclusion on the methods for detection and identification of the product
An analytical method for the determination of Deltamethrin in the formulation (2.5% WP) has been developed and validated. Additional analytical methods for determination of residues in different matrices (air, soil, water, animal body tissues and fluids and food/feedstuff from animal or vegetal origin) were reported in the CAR document.

2.2.5 EFFICACY AGAINST TARGET ORGANISMS

A. *FUNCTION AND FIELD OF USE*

According to the applicant, Killmethrin 2.5 WP (Deltamethrin 2.5% WP) is an insecticidal product for indoor use by professional and non-professional users.

B. *ORGANISMS TO BE CONTROLLED AND PRODUCTS, ORGANISMS OR OBJECTS TO BE PROTECTED*

According to the applicant, the product is intended to be used against adults of crawling (cockroaches and ants) and flying (mosquitoes, flies and wasps) insects.

C. *EFFECTS ON TARGET ORGANISMS, INCLUDING UNACCEPTABLE SUFFERING*

Deltamethrin acts on harmful organisms by contact and ingestion. It expresses a strong knock-down effect.

D. *MODE OF ACTION, INCLUDING TIME DELAY*

The active substance Deltamethrin, belonging to Pyrethroids is an insecticide which acts on harmful organisms by contact and ingestion. Pyrethroids impair ion transport through the membrane of nerve axons, causing muscular paralysis in the insect; death seems to follow a nervous system impairment that occurs a few minutes to several hours after pesticide absorption. The primary site of activity of deltamethrin is the voltage sensitive sodium channel in nerve membrane. Deltamethrin prolongs the opening of the sodium channels (i.e. the channels directly responsible for generating nerve action potentials) leading to neuronal hyperexcitability.

E. *EFFICACY DATA*

Experimental data on the efficacy of the biocidal product against target organism(s)					
Test substance	**Test organism**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Deltamethrin 2.5% SC (Read across)	*Musca domestica* (house fly), developm. stage: adults (Laboratory strain)	Simulated-use test	Test performed in a test chamber of 20 m^3. 12.5 ml of product dissolved in 1.25 l of water and applied by spraying on cardboards covering the side walls of the room, which represents an approximate surface to be treated of 25 m^2 (50 ml product in 5 lt of water for 100 m^2). 100 free flying flies were released into the room. Knockdown and/or mortality, and mortality was recorded 8 and 24 hours, respectively, after exposure to treated surfaces. The tests were conducted 1 day after treatment and repeated with the treated cardboards stored for 2 weeks. 4 replicates were used. Untreated control was included.	Average knock down and/or mortality was 100% after 8 hours. Average mortality was 100% after 24 hours The same level of efficacy was observed when the flies were exposed to cardboard treated 2 weeks earlier. Mortality in untreated control: 0-2%.	K.-H. Lüpkes, 2013a
Deltamethrin 2.5% SC (Read across)	*Blatella germanica* (German cockroach), developm. stage: adults Laboratory strains. *Blatta orientalis* (Oriental cockroach), developm. stage: adults *Lasius niger* (black ant),	Simulated-use test	Test performed in a test chamber of 20 m^3. 0.5 ml of product dissolved in 50 ml of water for 1 m^2 to be treated and sprayed by spray robot on tiles (non-porous glazed tiles and porous plywood) 15 x 15 cm each. One day after treatment the insects were exposed on the treated surfaces (inside glass rings) for 1 hour and then the insects were transfered into clean beakers. Mortality and/or knockdown were recorded at various test days after treatment	100 % knockdown and/or mortality within 60 min and 24 hours after placing the cockroaches in the test area. In untreated controls no effect was observed. For ants 60 min and 24 hours after exposure to treated surfaces, 2-6% and 26-34% knockdown and/or mortality was recorded, respectively. An average 84% knock down and/or mortality of the black ant *Lasius niger* was observed 7 days after contact	K.-H. Lüpkes, 2013b

	developm. stage: adults Field collected.		(60 min, 1, 2, 4, 5, 6 and 7 days). 5 replicates were performed. 10 cockroaches or 20 ants per replicate were used. Untreated control was used.	with the biocide. In untreated controls knockdown and/or mortality 24 hours and 7 days after exposure was 0% and 2-16%, respectively.	
Deltamethrin 2.5% SC (Read across)	Mosquitoes: *Aedes aegypti*, *Culex quinquefasciatus* and *Anopheles gambiae*. Developm. stage: adults Laboratory strains.	Simulated-use test	Test performed in a test chamber of 20 m^3. 12.5 ml of product dissolved in 1.25 l of water and applied by spraying on cardboards covering the side walls of the room, which represents an approximate surface to be treated of 25 m^2 (50 ml product in 5 lt of water for 100 m^2). 100 free flying mosquitoes were released into the room. Knockdown and/or mortality, and mortality was recorded 8 and 24 hours, respectively, after exposure to treated surfaces. 4 replicates were used. Untreated control was included.	For all the mosquito species studied the average knock down and/or mortality was 100% after 8 hours. Average mortality was 100% after 24 hours. Mortality in untreated control: 7-13%.	K.-H. Lüpkes, 2013c
Deltamethrin 2.5% SC (Read across)	Wasps: *Vespula vulgaris*. Developm. stage: Adults from wild nests.	Laboratory test	Test performed in a test chamber of 60 m^3. Surfaces (porous and non-porous) were treated in a separate premise. Dose: 50 ml of product in 5L of water per 100 m^2 surface and applied on surfaces. 10 wasps were installed for 1 hour on the treated surface of the tiles and were covered by the cover of a Petri-dish. No choice test (the insects were forced to stay on the treated surface). The insects were transferred to untreated inert surfaces. knockdown effect during the 1-hour period and mortality 24 and 48 hours later were recorded. The persistence was measured by performing the same efficacy test after 4 and 8 weeks of storage of the panels. Wasps were also sprayed directly from a 30 cm distance. Knockdown within 30 min and mortality after 24 hours were recorded. 4 replicates were performed for each treatment. Untreated controls were used.	Product showed 100% knockdown 30 sec after direct application on wasps and 100% mortality 24 hours later. The product showed 100% knockdown 1h after exposure to 4 and 8 weeks aged porous and non-porous surfaces. 100% mortality was recorded 24 and 48 hours after the 1h exposure to 4 and 8-weeks aged porous and non-porous surfaces. Mortality in the untreated control for all tests was <5%.	B. Serrano, 2016a
Deltamethrin 2.5% SC (Read across)	*Musca domestica* (house fly), *Stomoxis calcitrnas* (stable fly), *Blatella germanica* (German cockroach), *Blatta*	Field test	<u>Cockroaches</u>: Field conditions in occupied apartments with infestation of German and Oriental cockroaches. 50 ml product dissolved in 5 L of water for 100 m^2 in crack and crevices. Three sites (replicates) with infestation of each cockroach species were treated. The population before and	<u>Cockroaches</u>: The product was highly effective against German and Oriental cockroaches in terms of population reduction over a period of 4 weeks (>93%). Mean percentage reduction in *B. germanica* and *B. orientalis* populations were 89.3% and 92.2%, respectively, 6 weeks after treatment.	H. Heaven, 2015

	orientalis (oriental cockroach)		after treatment was assessed at 2-weeks intervals over 8 weeks using monitoring traps. Flies: Field conditions in livestock facilities. 40 ml product in 5 L of water for 100 m^2 as spot treatment in places where flying insects tend to rest. Three sites (replicates) with infestation of each fly species were treated. One more site infested with each fly species was used as untreated control. The population before and after treatment was assessed over 21 days using monitoring traps.	83.5% and 96% population reduction was recorded against German cockroaches and Oriental cockroaches, respectively, after 8 weeks. Flies: Very good initial effect (84.4% and 90.7% population reduction in house flies and stable flies, respectively) was recorded 2-3 days post treatment. 75.7% and 78.5% population reduction of houseflies and stable flies, respectively, was recorded 7 days after treatment. A high decline in efficacy thereafter (45.7%-53.9%) is most likely due to fly re-infestation from neighbouring locations. High decline of housefly populations was observed in untreated control site, 2 and 7 days post treatment (24.4% and 38.6%, respectively). 7.5% reduction and 8.3% increase of stable fly population was recorded in untreated control site, 2-3 and 7 days after treatment, respectively.	
Deltamethrin 2.5% SC (Read across)	Ants: *Lasius niger*	Field test	Field conditions. Ant nests in South West of France were treated with 50 ml product in 5 L of water for 100 m^2. Treatment is performed in a zone of 5 m^2 around the nests. The frequency of ant's passage was counted for 5 min. on 1 m^2 surfaces around nest entrance 1 day before and 1 up to 28 days after the treatment. 4 weeks post treatment the nests were opened to check for any living insects/brood. Untreated nests were used for control. 5 treated and untreated nests were used as replicates.	More than 94% population reduction 1 day after treatment and up to 99.9% population reduction 28 days after treatment with total nest kill. In the untreated control nests 5.4% population reduction was recorded and over 1000 alive ants were counted.	B. Serrano, 2016b
Deltamethrin 2.5% WP and Deltamethrin 2.5% SC (Bridging trial)	Cockroach: *Blatta orientalis*. Laboratory strain.	Laboratory test	Laboratory conditions. No-choice test. The products are applied in different porous (concrete blocks, wood) and non-porous surfaces (ceramic tiles and steel) at a rate of 50 g of product in 5 l of water per 100 m^2. The cockroaches were forced to stay in contact with the treated surfaces for 1 hour. The insects were transferred to untreated inert surfaces with a nutritious substratum and water available. Assessments of knockdown and/or killing effect were performed up to 4 hours after	Similar results were obtained in both products. In all types of fresh surfaces, all the insects were knocked-down and/or killed 1 hour after exposure to both formulations. In porous and non porous aged surfaces, all the insects knocked-down and/or died 3.5-4 hours and 2 hours, respectively, after exposure to both formulations. In all types of surfaces (fresh, aged, porous and non-porous)	B. Serrano, 2017a

			exposure. Mortality was recorded 24 and 48 hours later. Fresh and 2-months aged surfaces were use in order to determine also the residual efficacy of the product. Untreated surfaces treated only with water were used as control. 4 replicates with 25 insects each (males, females and nymphs) were used per treatment.	both formulation resulted in 100% mortality of insects in 24 and 48 hours. Mortality in the untreated control was < 5%.	
Deltamethrin 2.5% WP and Deltamethrin 2.5% SC (Bridging trial)	Flies: *Musca domestica* Mosquitoes: *Culex pipiens*. Laboratory strains.	Simulated use test	10 fresh and 2-months aged porous and non-porous panels of 15x 15 cm size were treated at a rate of 50 g of product in 5 l of water per 100 m^2 and introduced in a 30 m^3 test chamber (12 m^2 floor surface). After placing the panels in different positions in the test chamber and placing harbourage and food/ water source to the insects, these were released in the test chamber free flying for 24 hours. The product was applied as a spotted treatment on preferred locations of insects. The insects had the choice not to be in contact with the product and were not forced to be in contact with the treatment to reach water and food sources. After 24 hours mortality was assessed. Untreated surfaces treated only with water in separate chambers were used as control. 5 replicates with 50 adults each were used per type of surface and insect species.	100% mortality was determined for mosquitoes and flies in porous and non-porous panels either fresh or aged, demonstrating the same efficacy of SC and WP formulations when applied under same conditions of use. Both SC and WP formulations provided 2-month residual effect when applied as spot treatement in walls and other surfaces where insects usually lay. Mortality in the untreated controls was <10%.	Serrano, B. 2017b
Deltamethrin 2.5% WP and Deltamethrin 2.5% SC (Bridging trial)	Wasps: *Vespula germanica.* Laboratory strains.	Simulated use test	10 fresh and 2-months aged porous and non-porous panels of 15x 15 cm size were treated at a rate of 50 g of product in 5 l of water per 100 m^2 and introduced in a 30 m^3 test chamber (12m^2 floor surface). After placing the panels in different positions in the test chamber and place harbourage and food and water source to the insects, these were released in the test chamber free flying for 24 hours. The product was applied as a spotted treatment on preferred locations of insects. The insects had the choice not to be in contact with the product and were not forced to be in contact with the treatment to reach water and food sources. Knock down was assessed after 1 hour and mortality was assessed after 24 hours. Untreated surfaces treated only with water in separate chambers were used as control.	100% KD was determined for wasps in porous and non-porous panels either fresh or aged, 1 hour after exposure. 100% mortality was determined in porous and non-porous panels 24 hours after exposure. Same results were observed for both WP and SC formulations, demonstrating the same efficacy of SC and WP formulations when applied under same conditions of use. 2-month residual effect of the product is demonstrated. Both SC and WP formulations provided 2-month residual effect when applied as spot treatement in walls and other surfaces where insects usually lay. Mortality in the untreated controls was <10%.	Serrano, B. 2017c

			5 replicates with 20 adult workers each were used per type of surface.		

Conclusion on the efficacy of the product
Based on the results of the submitted bridging and read across efficacy studies, the product was effective as indoor application at the rate of 50 g product in 5 L of water to treat 100 m² as crack and crevice treatment against German (*Blattella germanica*) and Oriental (*Blatta orientalis*) cockroaches for 6 weeks after treatment, and as spot application in places where insects tend to rest against houseflies (*Musca domestica*), mosquitoes (*Culex pipiens*) and wasps (*Vespula germanica*) for 8 weeks after treatment. Efficacy of the product against German and Oriental cockroaches supports the general claim for efficacy against crawling insects and the specific claim for efficacy against cockroaches, for 6 weeks post treatment. Also, efficacy of the product against *Culex* mosquitoes, houseflies and wasps (*Vespula germanica*) supports the general claim for efficacy against flying insects and the specific claim for efficacy against mosquitoes, flies and wasps, for 6 weeks post treatment.

F. *OCCURRENCE OF RESISTANCE AND RESISTANCE MANAGEMENT*

According to the Arthropod Pesticide Resistance Database provided by IRAC (http://www.pesticideresistance.org/search.php), some cases of resistance of cockroaches, mosquitoes and houseflies on deltamethrin have been reported in the literature.
Hence, the eCA proposes the following principles of strategies for managing the development of resistance:

- Where possible, application treatments should be recommended to be combined with non-chemical measures.
- Where an extended period of control is required, treatments should be alternated with products having active substances with different modes of action.
- Establish a baseline and monitor levels of effectiveness on populations in key areas in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder or the distributor.
- The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.
- Do not use/apply the product in areas where resistance to the active substance contained in this product is suspected or established.

G. *KNOWN LIMITATIONS*

No limitations are known.

H. *EVALUATION OF THE LABEL CLAIMS*

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

The product is intended to be used for indoor spot, crack and crevice treatmens by professional and non-professional users against adults of crawling (cockroaches and ants) and flying (mosquitoes, flies and wasps) insects.
Against crawling insects the product is to be applied in cracks and crevices, corners, behind and under furniture and in other small spots where insects usually hide. Against flying insects the product is intended to be applied as spot application in places where the insects tend to rest such as windowsills, joists, pipes and walls. Killmethrin 2.5 WP is suitable for pest control treatment of the following premises: houses, apartments, neighborhood centers, cinemas, barracks, hotels, restaurants, bars, canteens, hospitals, industrial warehouses.
The product shall be applied by spraying through devices such as pumps or sprays working at low pressures (1-5 bar) at 50 g of product diluted in 5L of water to treat 100 m^2 surface. The treatment can be repeated after 6 weeks.

Trials submitted by the applicant to substantiate label claims:

A number of efficacy laboratory studies, simulated-use tests and field studies were provided by the applicant with the submission of the dossier for Killmethrin 2.5 WP (Deltamethrin 2.5% WP). These studies included either read across efficacy studies with the product Deltamethrin 2.5% SC, or bridging efficacy studies with both formulations Deltamethrin 2.5% SC and Deltamethrin 2.5% WP.

The results of the simulated use test by Lüpkes 2013a show that Deltamethrin 2.5% SC was effective, in terms of knockdown and killing effect, when applied onto porous surfaces at 50 ml product in 5 lt of water for 100 m^2 against houseflies (*Musca domestica*) for 2 weeks post treatment.

The results of the simulated use test by Lüpkes 2013b show that Deltamethrin 2.5% SC was effective, in terms of knockdown and killing effect, when applied onto porous and non-porous surfaces at 50 ml product in 5 lt of water for 100 m^2 against German and Oriental cockroaches, 24 hours after exposure of insects to treated surfaces. The results of this study concerning ants do not meet the requirements of the TNsG for PT18&19 since knockdown and/or mortality values were much lower (26-34%) than the required 90%, 24 hours after exposure to treated surfaces.

The results of the simulated use test by Lüpkes 2013c show that Deltamethrin 2.5% SC was effective, in terms of knockdown and killing effect, when applied onto porous surfaces at 50 ml product in 5 lt of water for 100 m^2 against mosquitoes (*Aedes aegypti, Culex quinquefasciatus* and *Anopheles gambiae*), 8 and 24 hours after exposure of insects to the treated surfaces.

The results of the laboratory study by Serrano 2016a show that Deltamethrin 2.5% SC was effective as a surface treatment at 50 ml product in 5 lt of water for 100 m^2

against wasps (*Vespula vulgaris*), in terms of knockdown and killing effect, when applied onto porous and non-porous surfaces for 8 weeks post treatment.

The results of the field study by Heaven 2015 show that Deltamethrin 2.5% SC was effective as crack and crevice treatment at 50 ml product in 5 lt of water for 100 m^2 against German and Oriental cockroaches for 6 weeks post treatment. The mean percentage reduction of cockroaches 6 weeks after the treatment was 92.2% for *B. orientalis,* and 89.3% for *B. germanica* which is very close to the required 90% so that this could be considered acceptable efficacy level for a field study. 8 weeks post treatment the population reduction of Oriental cockroaches was 96%, whilst the population reduction of German cockroaches was 83.5%, which does not meet the required efficacy level of 90%. The product showed poor efficacy against houseflies and stable flies, in terms of population reduction, 7 and 21 days post treatment most likely due to fly re-infestation from neighbouring locations. Also, high reduction of housefly population was observed in the untreated control sites. Hence, the results of this study cannot be used in support of efficacy of the product against flies.

The results of the field study by Serrano 2016b show that Deltamethrin 2.5% SC was effective as general surface treatment (treated zone of 5 m^2 around the nests) at 50 ml product in 5 lt of water for 100 m^2 against ants (*Lasius niger*) with nest kill for 4 weeks post treatment.

The results of the bridging laboratory study by Serrano 2017a with the products Deltamethrin 2.5% WP and Deltamethrin 2.5% SC demonstrated that both formulations SC and WP applied as surface treatment at 50 g product in 5 L of water to treat 100 m^2, showed similar and acceptable performance, in terms of knock down and killing effect, against Oriental cockroaches in fresh and 2-month aged porous and non-porous surfaces. Hence, the results of the submitted efficacy studies with Deltamethrin 2.5% SC against crawling insects can be extrapolated to the claimed product Killmethrin 2.5 WP (Deltamethrin 2.5% WP).

The results of the bridging simulated use test by Serrano 2017b with the products Deltamethrin 2.5% WP and Deltamethrin 2.5% SC demonstrated that both formulations SC and WP, at 50 g product in 5 L of water to treat 100 m^2, showed the same acceptable performance, in terms of killing effect, as spot surface treatment against houseflies (*Musca domestica*) and mosquitoes (*Culex pipiens*) in fresh and 2-month aged porous and non-porous surfaces. Also, the results of the bridging simulated use test by Serrano 2017c with the products Deltamethrin 2.5% WP and Deltamethrin 2.5% SC demonstrated that both formulations SC and WP, at 50 g product in 5 L of water to treat 100 m^2, showed the same acceptable performance, in terms of knockdown and killing effect, as spot surface treatment against wasps (*Vespula germanica*) in fresh and 2-month aged porous and non-porous surfaces. Hence, the results of the submitted efficacy studies with Deltamethrin 2.5% SC against flying insects can be extrapolated to the claimed product Killmethrin 2.5 WP (Deltamethrin 2.5% WP). Also, considering that the products were applied on spotted surfaces into the chamber, the results of this study adequately support efficacy of Killmethrin 2.5 WP at 50 g product in 5 lt of water for 100 m^2 against mosquitoes, houseflies and wasps as indoor spot application in places where insects tend to rest for 2 months after treatment.

Based on the results of the aforementioned bridging and read across efficacy studies, the intended uses of Killmethrin 2.5 WP (Deltamethrin 2.5% WP), from an efficacy point of view, are acceptable as applied for by the applicant (2.2.1, tables 2 & 3), noting however the following:

- It is claimed by the applicant that the product is intended to be used against ants with a residual activity of 6 weeks post treatment. According to the TNsG for products intended to be used by professionals as surface treatments against ants, a field study and either a lab or simulated use study against *Lasius niger* is required. The results of the read across field study by Serrano 2016b show that the product is effective as general surface treatment at 50 ml product in 5 lt of water for 100 m^2 against *Lasius niger* with nest kill for 4 weeks post treatment, whilst a crack and crevice treatment with 6 weeks residual activity against ants is claimed. Also, the results of the read across simulated use test by Lüpkes 2013b concerning ants do not meet the requirements of the TNsG for PT18&19 since knockdown and/or mortality values were much lower (26-34%) than the required 90%, 24 hours after exposure to treated surfaces. Hence, the eCA proposes not to include ants among the target organisms of the product.

Overall, based on the submitted efficacy studies and after evaluation process in all sections, the eCA concludes into the proposed authorized uses of the product as described in 2.1.3 (table 1 & 2).

I. *RELEVANT INFORMATION IF THE PRODUCT IS INTENDED TO BE AUTHORISED FOR USE WITH OTHER BIOCIDAL PRODUCT(S)*

KILLMETHRIN 2.5 WP is not intended to be used in combination with other biocidal products.

2.2.6 RISK ASSESSMENT FOR HUMAN HEALTH

A. ASSESSMENT OF EFFECTS ON HUMAN HEALTH

Skin corrosion and irritation

No human data on skin corrosion/irritation are available.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Non-irritant
Justification for the value/conclusion	No specific data on the product has been submitted. The calculation method according to Regulation (EC) No 1272/2008 is considered appropriate in order to conclude on the hazard identification of the product. No classification for skin irritation is triggered for Killmethrin 2.5 WP. For details please refer to the confidential annex (Point 3.6.1).
Classification of the product according to CLP and DSD	Not classified.

Eye irritation

No human data on skin corrosion/irritation is available

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causes serious eye damage.
Justification for the value/conclusion	No specific data on the product has been submitted. The calculation method according to Regulation (EC) No 1272/2008 is considered appropriate in order to conclude on the hazard identification of the product. Classification as eye irritant Category 1 is triggered for Killmethrin 2.5 WP. For details please refer to the confidential annex (Point 3.6.1).
Classification of the product according to CLP and DSD	Eye Dam.1; H318

Respiratory tract irritation

Data waiving	
Information requirement	Not required
Justification	No data on respiratory tract irritation is submitted. Neither the active substance nor any of the co-formulants contained in the product

	shows respiratory tract irritancy effects. Therefore this information is not considered necessary. Furthermore, this data is not required under Biocides Regulation

Skin sensitization

No human data on skin corrosion/irritation is available

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	No skin sensitizer
Justification for the value/conclusion	No specific data on the product has been submitted. The calculation method according to Regulation (EC) No 1272/2008 is considered appropriate in order to conclude on the hazard identification of the product. No classification for skin sensitization is triggered for Killmethrin 2.5 WP. For details please refer to the confidential annex (Point 3.6.1).
Classification of the product according to CLP and DSD	Not classified

Respiratory sensitization (ADS)

Data waiving	
Information requirement	Not required
Justification	Killmethrin 2.5 WP is not expected to show skin sensitizing properties and none of the components of the mixture shows respiratory sensitisation effects.

Acute toxicity

Acute toxicity by oral route

No human data on acute oral toxicity is available

Value used in the Risk Assessment – Acute oral toxicity	
Value	ATE_{mix} = 3030 mg/kg b.w.
Justification for the selected value	No specific data on the product has been submitted. The calculation method according to Regulation (EC) No 1272/2008 is considered appropriate in order to conclude on the hazard identification of the product. No classification for acute oral toxicity is triggered for Killmethrin 2.5 WP. For details please refer to the confidential annex (Point 3.6.1).
Classification of	Not classified.

the product according to CLP and DSD	

Acute toxicity by inhalation

No human data on acute oral toxicity is available

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	ATE_{mix} = 23.5 mg/L air
Justification for the selected value	No specific data on the product has been submitted. The calculation method according to Regulation (EC) No 1272/2008 is considered appropriate in order to conclude on the hazard identification of the product. No classification for acute inhalation toxicity is triggered for Killmethrin 2.5 WP. For details please refer to the confidential annex (Point 3.6.1).
Classification of the product according to CLP and DSD	Not classified.

Acute toxicity by dermal route

No human data on acute oral toxicity is available

Value used in the Risk Assessment – Acute dermal toxicity	
Value	ATE_{mix} >2000 mg/Kg bw
Justification for the selected value	No specific data on the product has been submitted. The calculation method according to Regulation (EC) No 1272/2008 is considered appropriate in order to conclude on the hazard identification of the product. No classification for acute dermal toxicity is triggered for Killmethrin 2.5 WP. For details please refer to the confidential annex (Point 3.6.1).
Classification of the product according to CLP and DSD	Not classified.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	DECIS EC 25 (See CAR Document)
Value(s)*	2%
Justification for the selected value(s)	No specific data regarding Deltamethrin 2.5% WP (Killmethrin 2.5 WP) formulation is available. However, the applicant has been granted with a LoA with the right to refer to this data in the assessment report.

	In deltamethrin CAR the dermal absorption was set at 2% based on *in vivo* rat and *in vitro* rat/human skin data using an EC formulation (DECIS EC 25). Considering that the presence of a light aromatic solvent enhances dermal absorption, it can be concluded that this represents a worst case compared to a WP formulation. In addition, the dose tested was lower compared to the in-use dilution (0.118 *vs* 0.25 g/L). Based on the above, a dermal absorption value of 2% is considered relevant for the current assessment.

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

IUPAC name or other accepted chemical name	**2-(2,6-dimethylanilino)-2-oxoethyl]-diethyl-(phenylmethyl)azanium benzoate**
EC number	223-095-2
CAS number	3734-33-6
Concentration (minimum and maximum, g/kg or g/l)	0.005%
Classification and Labelling according to Regulation (EC) No 1272/2008:	Acute Tox. 4; H302 Acute Tox. 4; H332 Skin Irrit. 2; H315 Eye Dam. 1; H318
Classification and Labelling according to the Directive 67/548/EEC	-
Relevant toxicological/ecotoxicological information	-
Other grounds for concern[2]	-

IUPAC name or other accepted chemical name	**Sodium, 2-dodecylbenzenesulfonate**
EC number	246-680-4
CAS number	25155-30-0
Concentration (minimum and maximum, g/kg or g/l)	3%
Classification and Labelling according to Regulation (EC) No 1272/2008:	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318
Classification and Labelling according to the Directive 67/548/EEC	-
Relevant toxicological/ecotoxicological information	-
Other grounds for concern[3]	-

IUPAC name or other accepted chemical name	**Sodium dodecylsulphate**
EC number	205-788-1
CAS number	151-21-3

2 Please include PBT, vPvB, POP and ED properties, if relevant.

3 Please include PBT, vPvB, POP and ED properties, if relevant.

Concentration (minimum and maximum, g/kg or g/l)	2%
Classification and Labelling according to Regulation (EC) No 1272/2008:	Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Dam. 1; H318
Classification and Labelling according to the Directive 67/548/EEC	-
Relevant toxicological/ecotoxicological information	-
Other grounds for concern[4]	-

Available toxicological data relating to a mixture

Not relevant.

B. *EXPOSURE ASSESSMENT*

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

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

4 Please include PBT, vPvB, POP and ED properties, if relevant.

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.	Indoor crack and crevice treatment by professional users	Primary exposure. Product is loaded into application portable vessels (handheld or backpack sprayer).Application is performed in cracks and crevices. Application equipment is cleaned after use.	Professional users
2.	Indoor crack and crevice treatment by non-professional users	Primary exposure. Product is loaded into application portable vessels (handheld or backpack sprayer).Application is performed in cracks and crevices. Application equipment is cleaned after use.	Non-professional users
3	Contact with treated surfaces	Secondary exposure as consequences of contact with treated surfaces. This exposure can be effective via deramal route but also via oral route (infants)	Professional users, non-professional users and bystanders (adults, children and infants as representative population)

Industrial exposure

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 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.

Professional exposure

Description of Scenario 1. Indoor crack and crevice treatment by professional users
Mixing/loading and application: According to the HEAdhoc Recommendation Number 3 the most suitable model to describe professional exposure to biocidal products when applied as spray upwards and downwards is the Spray Model No 1 as described in TNsG 2002.

Description of Scenario 1. Indoor crack and crevice treatment by professional users		
This model comprises both mixing/loading and application stages and therefore they are considered simultaneously in this assessment. Post-application (cleaning application equipment): 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 Expossure (September 2014). According to this scenario, the spray equipment is cleaned with water and later the parts that still remain dirty are rubbed with paper, rag or brush, using water or any cleaning solution.		
	Parameters	Value
Tier 1	**Mixing/loading and application stages. Spray Model No 1 as described in TNsG 2002**	
	In use formulation	Liquid
	In-use formulation characteristics	Like water
	Kinetic energy during mixing/loading process	Low energy process
	Distance from spray source	Handheld (< 30 cm)
	Mixing/loading process	Manual
	Orientation of application	Not specified
	Pressure of spray equipment	1-5 bar
	Work environment	Indoor – restricted spaces
	Ventilation	General or inadequate
	Segregation from exposure source	No
	Clothing type	Minimal clothing: 100% penetration
	RPE type	None
	Glove type	None
	Daily exposure duration	120 minutes/day
	Frequency of events per week	5
	Number of weeks per year	48
	Bodyweight	60 Kg
	Inhalation rate	1.25 m^3/h
	Dermal exposure hands (potential)	181 mg/min
	Dermal exposure body (potential)	92 mg/min
	Inhalation exposure	104 mg/m^3
	Dermal absorption	2%
	Concentration of a.s. in the in-use solution	0.025% w/v
	Cleaning application equipment. Recommendation No 4 of the BPC Ad Hoc Working Group on Human Expossure	
	Duration of exposure	20 min
	Dermal body exposure	19.28 µl/min
	Dermal hand exposure	35.87 µl/min
	Bodyweight	60 Kg
	Dermal absorption	2%
	Concentration of active substance in the in-use solution	0.025% w/v

Description of Scenario 1. Indoor crack and crevice treatment by professional users		
	Glove type	PF10 (10% dermal absorption)
	Clothing penetration	PF80 (20% penetration) coated coverall

Calculations for Scenario 1

Summary table: estimated exposure from professional uses (mg/Kg bw/d)							
Exposure scenario	**Application/cleaning equipment**	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**	**Sum**
Scenario 1	Application	1/No PPE	1.08×10^{-3}	2.73×10^{-3}	-	3.81×10^{-3}	3.9×10^{-3}
	cleaning	1/No PPE	-	$9.2\text{x}10^{-5}$	-	$9.2\text{x}10^{-5}$	
Scenario 1	Application	2/ Gloves PF10, coated coverall	1.08×10^{-3}	3.65×10^{-4}	-	1.45×10^{-3}	1.5×10^{-3}
	cleaning	1/No PPE	-	$9.2\text{x}10^{-5}$	-	$9.2\text{x}10^{-5}$	

Please, refer to Appendix 1 for the detailed calculations.

Non-professional exposure

Scenario 2

Description of Scenario 2. Indoor crack and crevice treatment by non-professional users		
Mixing/loading: Exposure during mixing/loading is of very short duration. This exposure has been calculated using the *mixing/loading scenario for powdered pest control products* in CONSEXPO. Inhalation is not a relevant route of exposure during this stage due to the low vapour pressure of the active substance Deltamethrin, the relatively low amount of product used by non-professional users and the particle size of the dust. *Application*: For the assessment of exposure to non-professional users during application stage CONSEXPO model *Pest control products applied as spray in crack and crevices with trigger sprays* completely fits to the use of KILLMETHRIN 2.5 WP. Application equipment used during product application is a portable vessel where the product solution is loaded working at low pressure (1-5 bar) with handheld or authomatic pressurized system. *Post-application (cleaning application equipment)*: No specific exposure scenario has been defined for insecticidal products when cleaning spray application equipment. For this reason, as a worst case estimation the same approach as for professional users has been taken into account (Recommendation No 4 of the BPC Ad Hoc Working Group on Human Expossure).		
	Parameters	Value
Tier 1	**Mixing/loading stage. CONSEXPO Mixing/loading pest control products scenario**	
	Population:	Adults
	Body weight:	60 Kg
	Weight fraction of product:	2.5%
	Exposure frequency:	2 times/year
	Dermal Model:	
	Exposed area:	840 cm^2 (Hands)
	Dermal loading:	Constant rate
	Contact rate:	0.033 mg/min
	Release duration:	80 seconds
	Uptake fraction:	2%
	Application stage. CONSEXPO Pest control products. Spray in crack and crevices scenario	
	Population:	Adults
	Body weight:	60 Kg
	Weight fraction of product:	0.025%
	Exposure frequency:	2 times/year
	Inhalation model:	
	Spray duration:	4 minutes
	Exposure duration:	240 minutes
	Room volume:	20 m^3
	Room height:	2.5 m
	Ventilation rate:	0.6 h^{-1}
	Mass generation rate:	0.38 g/sec
	Airborne fraction.	0.2
	Weight fraction of non-volatile:	100%

Description of Scenario 2. Indoor crack and crevice treatment by non-professional users		
	Weight fraction compound:	0.025%
	Density non-volatile:	1.8 g/cm^3
	Inhalation cut-off diameter:	15 µm
	Inhalation uptake fraction:	100%
	Inhalation rate:	33 m^3/day
	Oral uptake fraction:	0
	Dermal model:	
	Exposed area:	3050 cm^2 (head, hands and forearms)
	Fraction compound:	0.025%
	Contact rate:	46 mg/min
	Release duration:	240 seconds
	Uptake fraction:	2%
	Cleaning application equipment. Recommendation No 4 of the BPC Ad Hoc Working Group on Human Expossure	
	Duration of exposure	20 min
	Dermal body exposure	19.28 µl/min
	Dermal hand exposure	35.87 µl/min
	Bodyweight	60 Kg
	Dermal absorption	2%
	Concentration of active substance in the in-use solution	0.025% w/v

Calculations for Scenario 2

Summary table: estimated exposure from professional uses (mg/Kg bw/d)							
Exposure scenario	**Application/cleaning equipment**	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**	**Sum**
Scenario 2	Mix&load	1/No PPE	-	$3x10^{-9}$	-	$3x10^{-9}$	9.2×10^{-5}
	Application	1/No PPE	1.3×10^{-7}	3.8×10^{-7}	-	5.1×10^{-7}	
	cleaning	1/No PPE	-	$9.2x10^{-5}$	-	$9.2x10^{-5}$	

Please, refer to Appendix 1 to see outcome of relevant models used in the risk assessment.

Exposure of the general public

Scenario 3

Description of Scenario 3: Secondary exposure as consequence of contact with treated surfaces
Secondary exposure is defined as the exposure via the environment without the person

Description of Scenario 3: Secondary exposure as consequence of contact with treated surfaces		
exposed being aware, or having control over that exposure. Due to application patterns (indoor spraying in crack and crevices), exposure is very unlikely and may occur accidentally by dermal route to adults and children re-entering treated zones after treatment and by dermal and oral (hand-to-mouth transfer) to infants. Inhalation is not a relevant route of exposure due to the low vapour pressure of the active substance Deltamethrin and the aqueous nature of the formulation. A preliminary assessment of risk for inhalation exposure was performed according to *HEEG Opinion No 13 on Assessment of inhalation exposure of volatilized biocide active substance* with infant as worst case estimation population. Exposures to Killmethrin 2.5 WP after contact with treated surfaces has been performed using the rubbing-off model from ConsExpo.		
	Parameters[1]	Value
Tier 1	Application rate (mg/m^2)	12.5
	Material that may deposit on the floor away from the treated area after a targeted spot or crack and crevice application, (TNsG, part 2, pages 257-258)	15%
	Dislodged amount, (TNsG, version 2 page 102)	18%
	Transfer coefficient, (Recommendation No. 12 of the BPC Ad hoc Working Group on Human Exposure) (cm^2/hr)	2000
	Dermal absorption	2%
	Fraction on hands	0.2
	Hand to mouth transfer	0.5
	Oral absorption	75%
	Adult body weight (kg)	60
	Children body weight (kg)	23.9
	Infant body weight (kg)	8

Calculations for Scenario 3

Summary table: systemic exposure from non-professional uses (mg/Kg bw/d)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 3 (Adults)	1/No PPE	-	2.25×10^{-5}	-	2.25×10^{-5}
Scenario 3 (Children)	1/No PPE	-	5.6×10^{-5}	-	5.6×10^{-5}
Scenario 3 (Infant)	1/No PPE	-	1.69×10^{-4}	6.3×10^{-4}	8×10^{-4}

Inhalation is usually not a relevant route of exposure due to the low vapour pressure of the active substance Deltamethrin and the aqueous nature of the formulation, however, according to the *HEEG Opinion No 13 on Assessment of inhalation exposure of volatilized*

biocide active substance this route should be preliminarily assessed in order to determine if this risk can be discarded or not. Ventilation of treated premises is set in the label as mitigation measures. In addition, the treatment should be performed without the presence of persons or animals and therefore no risk to general population is envisaged from direct contact of spray droplets in the room volume.

This assessment is performed using the following equation:

$$0.328\times\frac{MW\times P_v}{AEL_{long\text{-}term}}$$

where:

- MW is the molecular weight of the active substance (505.2 g/mol)
- P_v is the Vapour pressure of the active substance (1.24×10^{-8} Pa)
- $AEL_{long\text{-}term}$ is the maximum acceptable exposure level to affected population (0.0075 mg/Kg bw/d)

If the result of this equation is ≤1 then the exposure to general population via inhalation is negligible. In this case, the outcome of the calculation is 2.74×10^{-4} and therefore risk derived from inhalation due to evaporation from treated surfaces after re-entering in treated premises is negligible.

Please, refer to Appendix 1 to see outcome of relevant models used in the risk assessment.

Combined scenarios

People (professional and non-professional) using biocidal products may be exposed not only during application stages but also after application as general population in their daily environment. For this reason it is necessary to assess the total exposure that a person may be exposed to.
Worst case scenarios have been considered for both professional and non-professional users.
For professional users relevant worst aggregated scenario is referred to all the stages involved during the application (with and without PPE) + re-entry in treated premises.
For non-professional users relevant worst aggregated scenario is also referred to crack and crevices treatment + re-entry in treated sites.

Summary table: combined systemic exposure from professionals & non-professional uses (mg/Kg bw/d)				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios 1 (Tier 1)/No PPE + 3	1.08×10^{-3}	2.84×10^{-3}	-	3.9×10^{-3}
Scenarios 1 (Tier 2)/PPE + 3	1.08×10^{-3}	4.8×10^{-4}	-	1.6×10^{-3}
Scenarios 2 + 3	$1.3\text{x}10^{-7}$	$1.1\text{x}10^{-4}$	-	$1.1\text{x}10^{-4}$

Monitoring data

No monitoring data is available

Dietary exposure

The biocidal product KILLMETHRIN 2.5 WP 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.
- Keep away from food, drink and animal foodstuffs.
- Protect food, cooking utensils and cutlery contamination during application.
- Do not apply to surfaces where food is stored, prepared or consumed

Therefore, no information was submitted by the applicant regarding residues in food/feedstuff nor are required since no dietary exposure assessment is deemed necessary.

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

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 Deltamethrin contained in the product.
Disposal of biocidal product shall be performed according to local, national or comunitary regulations

Summary of exposure assessment

Scenarios and values to be used in risk assessment (mg/Kg bw/d)			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1.	Professionals	1/No PPE	3.9×10^{-3}
	Professionals	2/ PPE (Gloves PF10 and coated coverall)	1.5×10^{-3}
2.	Non-Professionals	1/No PPE	9.2×10^{-5}
3	Bystanders (adult)	1	2.25×10^{-5}
	Bystanders (child)	1	5.6×10^{-5}
	Bystanders (infant)	1	8×10^{-4}

Scenarios and values to be used in risk assessment (mg/Kg bw/d)			
1+3	Professionals – Adult	1/No PPE	3.9×10^{-3}
	Professionals – Adult	2/ PPE (Gloves PF10 and coated coverall)	1.6×10^{-3}
2+3	Non-professionals - Adult	1/No PPE	1.1×10^{-4}

X. 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	Please, refer to CAR document	1 mg/Kg bw/d	100	0.75	0.0075 mg/kg bw/d
AELmedium-term	Please, refer to CAR document	1 mg/Kg bw/d	100	0.75	0.0075 mg/kg bw/d
AELlong-term	Please, refer to CAR document	1 mg/Kg bw/d	100	0.75	0.0075 mg/kg bw/d
ARfD					Not derived
ADI					Not derived

[1] Please refer to CAR document for explanation of background and reason for assessment factor.

Maximum residue limits or equivalent
Not relevant.

Risk assessment with regard to presence of SoCs

Killmethrin 2.5 WP has been classified as Eye Dam. 1 with H318, due to the toxicological properties of three (3) non-active substances. As a consequence, these substances are characterized as Substances of Concern and are assigned to product hazard classification band B. For these SoCs a qualitative risk assessment is performed. The P statements that are associated with H318 are the following: P280, P305+P351+P338, P310. The use of the proposed personal protective equipment is considered to adequately minimize exposure to the relevant substances.

Risk for industrial users

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

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 professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Treatment of crack and crevices (mixing/loading + application + cleaning appl.equip.)/ Scenario 1	1 (No PPE)	1	0.0075	3.9×10^{-3}	52	Yes
	2 PPE (Gloves PF 10, coated coverall)	1	0.0075	1.5×10^{-3}	20	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Treatment of crack and crevices (mixing/loading + application + cleaning appl.equip.) and re-entry in treated premises/ Scenarios 1+3	1 (No PPE)	1	0.0075	3.9×10^{-3}	52	Yes
	2 PPE (Gloves PF 10, coated coverall)	1	0.0075	1.6×10^{-3}	21	Yes

Local effects

A qualitative risk assessment for local effects should be performed for KILLMETHRIN 2.5 WP since it is classified as Eye Dam. 1 with H318 (please refer to the confidential annex) based on the toxicological properties of non-active substances. Based on its classification KILLMETHRIN 2.5 WP is assigned to the "high" category of hazard severity. Exposure to the concentrated product is possible to occur during the mixing/loading phase. The use of chemical goggles during mixing/loading is expected to minimize possible exposure, resulting in an acceptable risk.

Conclusion

According to the exposure assessment performed, professional users are not at risk even when no PPE is used. However, chemical goggles should be used during the mixing/loading phase due to the toxicological properties of the formulation (Eye Dam. 1; H318). Accumulated exposure leads to acceptable risk when a professional user is exposed to

Deltamethrin during the whole day (in his job and re-entering in treated sites as any other bystander).
Conclusively, the use of PPE (chemical goggles) is required for professional applicators when handling the undiluted product KILLMETHRIN 2.5 WP. The use of gloves and coated coverall is recommended in order to further minimize exposure.

Risk for non-professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Treatment of crack and crevices (mixing/loading + application + cleaning appl.equip.)/ Scenario 2	1 (No PPE)	1	0.0075	9.2×10^{-5}	1.2	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Treatment of crack and crevices (mixing/loading + application + cleaning appl.equip.) and re-entry in treated premises/ Scenarios 2+3	1 (No PPE)	1	0.0075	1.1×10^{-4}	1.5	Yes

Local effects

A qualitative risk assessment for local effects should be performed for KILLMETHRIN 2.5 WP as it is classified as Eye Dam. 1 with H318 (please refer to the confidential annex) based on the toxicological properties of non-active substances. Based on its classification, KILLMETHRIN 2.5 WP is assigned to the "high" category of hazard severity. Exposure to the concentrated product is possible to occur during the mixing/loading phase. The applicant has informed the eCA that is willing to add in the packaging a dosing system so that any contact with the product during the mixing/loading phase is avoided. Taking this into account and considering that only a short period of time is required for the mixing/loading phase, it can be concluded that there is no risk for the non-professional user. In addition, proper instructions for use can further minimize possible exposure.

Conclusion
Based on the result of the exposure assessment performed, no risk has been identified for non-professionals users for the examined scenario. Accumulated exposure after using KILLMETHRIN 2.5 WP and re-entering in treated sites was calculated to be 1.5% of AEL. In addition, no risk has been identified for the amateur user for local effects with the prerequisite that a dosing system will be added in the packaging of the product and proper instructions for use will be included in the label.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Re-entering in treated premises. Scenario 3	Adults	1	0.0075	2.25×10^{-5}	0.3	Yes
	Children	1	0.0075	5.6×10^{-5}	0.7	Yes
	Infant	1	0.0075	8×10^{-4}	11	Yes

Local effects
A qualitative risk assessment for local effects should be performed for KILLMETHRIN 2.5 WP as it is classified as Eye Dam. 1 with H318 (please refer to the confidential annex) based on the toxicological properties of non-active substances. Based on its classification KILLMETHRIN 2.5 WP is assigned to the "high" category of hazard severity. No risk is anticipated for the general public taking into account that the intended use is for crack and crevice treatment and considering also that any accidental exposure to the treated surfaces will be with the dried residues of the diluted product. In any case and as a precautionary principle, it should be clearly stated that the product should be applied to places inaccessible to children.

Conclusion
The biocidal product KILLMETHRIN 2.5 WP is safe to general population after crack and crevice application in household or commercial premises. Main route of indirect contamination is by accidentally rubbing off treated surfaces, which is highly unlikely due to crack and crevice application characteristics. As a precautionary principle, it should be clearly stated that the product should be applied to places inaccessible to children.

Risk for consumers via residues in food

No risk to consumers via food is likely as consequence of application of KILLMETHRIN 2.5 WP. 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 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

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

Not relevant. The product KILLMETHRIN 2.5 WP contains one (1) active substance. It is noted that according to the Guidance on the BPR (Volume III, Part B, Risk Assessment Version 2.0, October 2015), for the time being, a combined risk assessment should only be applied to multiple (2 or more) active substances (including those identified as SoCs under criterion (2)) within a product, and not to SoCs.

2.2.7 RISK ASSESSMENT FOR ANIMAL HEALTH

Not relevant, the product KILLMETHRIN 2.5 WP 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 Risk assessment has been performed taking into account specific application patterns of the product KILLMETHRIN 2.5 WP.

A. *EFFECTS ASSESSMENT ON THE ENVIRONMENT*

All the studies supporting environmental fate and toxicity properties of the product KILLMETHRIN 2.5 WP 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 EC50 > 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
$PNEC_{secondary\ poisoning}$: $PNEC_{bird}$ is 15mg/kg food and $PNEC_{small\ mammal}$ is 2.67mg/kg food based on CAR of Deltamethrin (Doc II C).

In the public CAR a major metabolite Br2CA 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 Br2CA (298 as compared to deltamethrin at 505.2) and reduced eco(toxicity) the level of risk posed by Br2CA 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, Br2CA is deemed necessary in this evaluation. However, and after the specific request of Greece as eMS of the product Killmethrin 2.5 WP the assessment of the environmental risk derived from the presence of the metabolite Br2CA is included in this report for the sake of consistency.

Limited data on the toxicity of the metabolites is reported in the CAR document for Deltamethrin (Sweden, May 2011):

Property	Br_2CA
DT_{50} (soil, normalized 12ºC)	5.6 days (geometric mean)
Koc	25.6 L/Kg (geometric mean)
LC_{50} (fish)	10.4 mg/L
LC_{50} (invertebrate)	84.9 mg/L
NOEC Soil organisms	10 mg/Kg dw soil

The metabolite Br2CA degrades much quickly in soil than parent compound (Deltamethrin). It is more mobile in soil and its aquatic toxicity is much lower than the aquatic toxicity of Deltamethrin to fish (in the order of 10^4 times less toxic) and to aquatic invertebrates (in the order of 10^8 times less toxic). Toxicity to soil organisms is also lower compared to the toxicity of parent compound.

The derivation of threshold environmental values for the metabolite Br2CA has been calculated as follows:

$PNEC_{STP}$: Not relevant No data on toxicity of metabolite Br2CA to microorganisms in STP systems is available. In addition, Deltamethrin is considered not readily biodegradable and it is not expected to suffer degradation in STP systems where it remains for a short time before being released to the environment.
$PNEC_{surface\ water}$: 10.4×10^{-3} mg/L based on the LC_{50} to fish and an assessment factor of 1000.
$PNEC_{sediment}$: 13.9×10^{-3} mg/Kg wwt based on the Equilibrium Partitioning Method and a Koc value of 25.6
$PNEC_{soil}$: 0.14 mg/Kg wwt based on NOEC from soil organism *Hypoaspis acualeifer* (10 mg/kw standard soil) and an assessment factor of 100 after correction to organic matter and conversion to wet soil.

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 KILLMETHRIN 2.5 WP contains 2.5% Deltamethrin as the only ingredient likely to lead classification regarding environmental properties. Deltamethrin is classified as aquatic acute 1 (H400) and aquatic chronic 1 (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 biocidal product KILLMETHRIN 2.5 WP is classified as Aquatic Acute Category 1 H400 and Aquatic Chronic Category 1 H410.

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.

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

No additional trials 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 KILLMETHRIN 2.5 WP is a Wettable Powder 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

KILLMETHRIN 2.5 WP is applied indoors in crack and crevices by spraying. 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 KILLMETHRIN 2.5 WP indoor: Loading the product in the application equipment, product application and 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.
In the case of the metabolite Br2CA, it is only present in water compartment (13.3% of parent compound) and in soil (23% of parent compound). The presence on Br2CA in water is relevant to surface water and sediment whilst the presence of the metabolite in soil is relevant to soil but also to ground water after leaching.

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

No further studies on fate and behaviour in the environment have been performed with the product. No additional data is available.

Leaching behaviour (ADS)

The biocidal product KILLMETHRIN 2.5 WP is an insecticide product and no additional data on leeching 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)

Not relevant. The product is not going to be sprayed near to surface waters. For more information about aquatic toxicity, 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)

Based on the use pattern of the biocidal product KILLMETHRIN 2.5 WP no outdoor use is intended and therefore, no risk to bees or other non-target arthropods is anticipated. Therefore no additional studies performed with bees or other arthropods are deemed necessary.

B. *EXPOSURE ASSESSMENT*

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Indoor crack and crevice treatment by professional users Scenario 2: Indoor crack and crevice treatment by non-professional users
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	*Scenario 1: Average consumption* *Scenario 2: Average consumption*
Distribution in the environment	Calculated according the *Guidance on Biocidal Products Regulations, Vol. IV Environment – Part B Risk Assessment* (Version 1.0, April 2015) and OECD ESD Nº 18 for PT 18
Groundwater simulation	No higher tier modelling has been performed
Confidential Annexes	No
Life cycle steps assessed	*For all the scenarios:* *Production: No* *Formulation No* *Use: Yes* *Service life: No*
Remarks	None

Emission estimation

For emission calculations the following formulas (ESD for PT18 products, July 2008) were used to calculate daily local emission to STP (as STP is regarded as the only pathway of direct Deltamethrin emissions after indoor use of Killmethrin):

Mixing/loading step

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

Application step

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

Releases to wastewater and STP

(7) $E_{applicator,ww} = (E_{prep,applicator} + E_{appl.,applicator}) \times F_{applicator,ww}$
(8) $E_{treated,ww} = (E_{prep,floor} + E_{appl.,floor} + E_{appl.,treated}) \times F_{ww} \times F_{CE}$
(9) $Elocal_{waste\ water} = E_{applicator,ww} + E_{treated,ww}$

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

Each approach warrants input values, as described below.

Scenario 1

KILLMETHRIN 2.5 WP is applied by professional users in the surface treatment of cracks and crevices, by spraying. The spraying mixture is previously prepared by diluting the concentrated product into an application vessel (handheld or snapsack sprayer).
Timing of application is 8 times/year (interval of 6 weeks for treatment against flies and mosquitoes and 6 weeks for treatment against crawling insects between applications) at a rate of 50 g of product diluted in 5L of water for 100m^2 surface treated.

Table 1. Input parameters for calculating the local emission				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Scenario: Indoor crack and crevice treatment by professional users				
Application rate of biocidal product	Q_{prod}	0.5	g/m²	
Fraction of active substance	F_{AI}	0.025		
Mixing/Loading stage				
Quantity of commercial product used during mixing/loading (houses)	$Q_{prod,prep}$	10	g	Based on typical preparation rate of product by professionals
Quantity of commercial product used during mixing/loading (larger buildings)	$Q_{prod,prep}$	10	g	Based on typical preparation rate of product by professionals
Number of preparations per day (houses)	N_{prep}	1	d^{-1}	
Number of preparations per day (larger buildings)*	N_{prep}	3	d^{-1}	Default value
	N_{prep}	1	d^{-1}	Although default value is 3 prep d^{-1}, 1 prep. d^{-1} is considered as a more realistic estimation taking into account the actual activities performed by PCOs during the working day (only 1 large building per day is usually treated) – Proposed by the

				Applicant
Fraction emitted to floor during preparation step	$F_{prep,floor}$	0.01	-	Default value
Application stage				
Number of applications per day (houses)	$N_{appl,building}$	1	d^{-1}	
Number of applications per day (larger buildings)	$N_{appl,building}$	1	d^{-1}	
Area treated (houses)	$AREA_{treated}$	2	m^2	
Area treated (larger buildings)	$AREA_{treated}$	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	$F_{applicator,ww}$	1		
Fraction of cleaning efficiency of wet cleaning	F_{CE}	0.15		Default value of 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	$F_{simultaneity}$	0.00815		6-8 applications/year
Number of buildings (houses)	$N_{buildings}$	4000		Default value
Number of buildings (larger buildings)	$N_{buildings}$	300		Default value

*Emissions and PECs derived from both N_{prep} values of 1 and 3 d^{-1} are presented in the exposure assessment hereafter.

Calculations for Scenario 1

Table 2. Resulting local emission to relevant environmental compartments		
Compartment	**$Elocal_{wastewater,total}$ [kg/d]**	**Remarks**
STP	1.92×10^{-4}	for Nprep=1 d^{-1}
	1.94×10^{-4}	for Nprep=3 d^{-1}

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).

Scenario 2

The use of KILLMETHRIN 2.5 WP by non-professional users differs from the use by professional users in the number of maximum applications allowed (maximum 2 applications/year), and therefore simultaneity factor is reduced to 0.204%. In the case of non-professional users only houses are considered in the assessment (excluding the treatment of larger buildings). In addition, the fraction of product emitted to the applicator during mixing and loading operations is one order of magnitude higher and therefore releases derived from pouring the product in the receiving vessel are a higher.

Table 3. Input parameters for calculating the local emission

Input	Symbol	Value	Unit	Remarks
Scenario: Indoor crack and crevice treatment by professional users				
Application rate of biocidal product	Q_{prod}	0.5	g/m²	
Fraction of active substance	F_{AI}	0.025		
Mixing/Loading stage				
Quantity of commercial product used during mixing/loading (houses)	$Q_{prod,prep}$	10	g	Based on typical preparation rate of product by non-professionals
Number of preparations per day (houses)	N_{prep}	1	d^{-1}	
Fraction emitted to floor during preparation step	$F_{prep,floor}$	0.01	-	Default value
Application stage				
Number of applications per day (houses)	$N_{appl,building}$	1	d^{-1}	
Area treated (houses)	$AREA_{treated}$	2	m²	
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	$F_{applicator,ww}$	1		

Fraction of cleaning efficiency of wet cleaning	F_{CE}	0.15		Default value of 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	$F_{simultaneity}$	0.00204		1 or 2 applications/year
Number of buildings (houses)	$N_{buildings}$	4000		Default value

Calculations for Scenario 2

Table 4. Resulting local emission to relevant environmental compartments		
Compartment	**($Elocal_{wastewater,total}$) [kg/d]**	**Remarks**
STP	3.65×10^{-5}	

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

Table 5. 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	
Scenario 2	Yes	Yes	No	No	Yes	Yes	Yes	Yes	

Table 6. Input parameters (only set values) for calculating the fate and distribution in the environment for parent compound			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	505.2	g/mol	
Melting point	92.5	°C	
Vapour pressure (at 25ºC)	<0.02 (1.24 x 10^{-8})	mPa	
Water solubility (at 25°C)	<0.01 (5.36 x 10^{-3})	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 x 10^{-3}	Pa/m3/mol	
Biodegradability	Not biodegradable	-	
DT_{50} for degradation in soil	48	d (at 12ºC)	

Table 7. Input parameters (only set values) for calculating the fate and distribution in the environment for metabolite (Br2CA)			
Input	**Value**	**Unit**	**Remarks**
Molecular weight	298	g/mol	
Vapour pressure (at 25ºC)	<0.01	mPa	Default value
Water solubility (at 25°C)	<0.01	mg/l	Default value
Organic carbon/water partition coefficient (Koc)	25.6	l/kg	
Biodegradability	Not biodegradable	-	
DT_{50} for degradation in soil	5.6	d (at 12ºC)	

Table 8. Calculated fate and distribution in the STP		
Compartment	**Percentage [%]**	**Remarks**
$F_{stp,air}$	2.09×10^{-5}	
$F_{STP,water}$	9.61	
$F_{STP,sludge}$	90.4	
$F_{STP,degraded}$	0	

Calculation of PECs

PEC$_{STP}$ and PEC$_{sw/sed}$

Equations and default values have been taken from the ECHA guidance on Environmental Risk Assessment (2015) to calculate the following emissions, using the equations below, based on a combined emission from domestic houses plus large buildings as previously calculated.

 and 

Where:

Clocal$_{inf}$ = concentration in untreated water (mg l^{-1})
Clocal$_{eff}$ = concentration of substance in the STP effluent so **PEC$_{STP}$** (mg l^{-1})
EFFLUENT$_{stp}$ = (2 x 10^6 l d^{-1}; default)
Elocal$_{water}$ = local emission to wastewater during episode (kg d^{-1})
F$_{STPwater}$ = fraction emission directed to water by SimpleTreat (0.096)

The indoor use pattern of Kilmethrin 2.5 WP does not allow for direct exposure to surface waters, only the potential for indirect exposure via an STP. The local concentration arising from the indirect emission to a watercourse via the STP during the proposed use of this product was calculated to take into account dilution and removal to suspended sediments (ECHA guidance on ERA).

Where:

Clocal$_{water}$ = local concentration in surface water during emission episode (mg l^{-1}) so

PEC$_{surface\ water}$

Clocal$_{eff}$ = concentration of substance in the STP effluent (mg l^{-1})
Kp$_{susp}$ = solids-water partitioning coefficient of suspended matter (40825 l kg^{-1}; calculated based on Koc 408250)
SUSP$_{water}$ = concentration of suspended matter in the river (default: 15 mg l^{-1})
DILUTION = dilution factor (default: 10).

The concentration of deltamethrin released to surface water from the STP (Clocal$_{eff}$) can be degraded in a maximum of 13.3% into the metabolite Br2CA when it reachs surface waters, achieving a total maximum concentration of the metabolite in surface water of 7.25x10^{-7} mg/L Br2CA in Scenario 1 and (degradation of deltamethrin in STP systems is considered negligible). The PEC$_{surface\text{-}water}$ for the metabolite Br2CA is calculated in the same way as shown above considering a Kp$_{susp}$ of 2.56 l Kg^{-1}.

The concentration of deltamethrin and its main metabolite in bulk sediment can be derived from the corresponding water body concentration, assuming thermodynamic partitioning equilibrium (EPM) as outlined in the (ECHA guidance on ERA equation 50):

Where:
$K_{susp-water}$ = suspended matter-water partitioning coefficient (1.02×10^{4} m^3 m^{-3} for parent compound and 1.54 for the metabolite)
RHO_{susp} = bulk density of suspended matter (1150 kg m^{-3})

Table 9. Calculation of $Clocal_{inf}$, $Clocal_{eff}$, PEC_{STP}, $PEC_{surface\ water}$ and PEC_{sed} concentrations for parent compound and its metabolite

Scenario	$Clocal_{inf}$ (mg l^{-1})	PEC_{STP} $Clocal_{eff}$ (mg.l^{-1})	$PEC_{surface\ water}$ (mg.l^{-1})	PEC_{sed} (mg.kg_{wwt}^{-1})	Remarks
Scenario 1 (parent)	9.6×10^{-5}	9.24×10^{-6}	5.73×10^{-7}	5.08×10^{-3}	*Nprep=1 d^{-1}*
Scenario 1 (metabolite)	-	7.25×10^{-7}	7.25×10^{-8}	9.70×10^{-8}	
Scenario 1 (parent)	9.7×10^{-5}	9.32×10^{-6}	5.78×10^{-7}	5.13×10^{-3}	*Nprep=3 d^{-1}*
Scenario 1 (metabolite)	-	7.32×10^{-7}	7.31×10^{-8}	9.80×10^{-8}	
Scenario 2 (parent)	1.83×10^{-5}	1.75×10^{-6}	1.09×10^{-7}	9.66×10^{-4}	
Scenario 2 (metabolite)	-	1.38×10^{-7}	1.38×10^{-8}	1.84×10^{-8}	

PEC_{soil}

Exposure of the soil compartment as a result of the indoor crack and crevice use of deltamethrin can be considered as coming indirectly via the application of sewage sludge to land.
The concentration of active substance in dry sewage sludge can be calculated using equations (36 and 37) taken from the ECHA guidance on ERA plus default parameters presented in the same guidance document:

where:

$$SLUDGERATE = 0.66 \times SUSPCONC_{inf} \times EFFLUENT_{stp} + SURPLUS_{sludge} \times CAPACITY_{stp}$$

and: $EFFLUENT_{stp} = CAPACITY_{stp} \times WASTEW_{inhab}$

Table 10. Input parameters for calculating the STP sludge conncentration				
Parameter	**Symbol**	**Value**	**Unit**	**S/D/ O/R***
Concentration of suspended matter in STP influent	$SUSPCONC_{inf}$	0.45	kg m^{-3}	D
Effluent discharge rate of STP	$EFFLUENT_{stp}$	2.0×10^{-6} (2000)	l d^{-1} m^3 d^{-1}	D
Surplus sludge per inhabitant equivalent	$SURPLUS_{sludge}$	0.011	kg d^{-1} eq^{-1}	D
Capacity of STP	$CAPACITY_{stp}$	10,000	eq	D
Sewage flow per inhabitant	$WASTEW_{inhab}$	200	l d^{-1} eq^{-1}	D
Rate of sewage sludge production	SLUDGERATE	710	kg d^{-1}	O
Local emission rate to water during treatment episode	$Elocal_{water}$		(kg d^{-1})	O
Fraction of emission directed to sludge by STP	$Fstp_{sludge}$	0.904		S
Concentration in dry sewage sludge	C_{sludge}		mg kg^{-1} dwt	O
*S=Set, D=Default, O=Output, R=Refinement				

According to ECHA guidance on ERA, three default values of $APPL_{sludge}$ and for $DEPTH_{soil}$ are used for the $Csludge_{soil\ 1}$ (0) calculation presented hereafter.

Soil	Depth of soil (m)	Averaging time (days)	$APPL_{sludge}$ (kg_{dwt} x m^2 x yr^{-1})
Local soil	0.20	30	0.50
Agricultural soil	0.20	180	0.50
Grassland soil	0.10	180	0.10

Moreover, in line with guidance presented in the ECHA guidance on ERA (equation 60), the concentration of a.s. in soil (represented as Csludge $_{soil\ 1}$ (0)) after the first year of manure application can be given as:

$$Csludge_{soil1}\ (0) = \frac{C_{sludge}\ x\ APPL_{sludge}}{DEPTH_{soil}\ x\ RHO_{soil}}$$

Where:

- C_{sludge} is the concentration in manure (in mg kg^{-1} dwt)
- $APPL_{sludge}$ is the sludge application rate (0.1 kg m^2 yr^{-1} for grass for cattle or 0.5 kg m^2 yr^{-1} for terrestrial ecosystems and crops for human consumption)
- $DEPTH_{soil}$ is the mixing depth of soil (0.1 for grass for cattle or 0.2 m for terrestrial ecosystems and crops for human consumption)
- RHO_{soil} is the bulk density (wet) of soil (1700 kg m^{-3}; default)
- Csludge $_{soil\ 1}$ (0) is the concentration in soil due to manure in first year at t = 0

Table 11. Calculation of the concentration in soil due to sludge in first year for parent compound					
Scenario	**C_{sludge} (mg.kg^{-1} dwt)**	**$Csludge_{soil\ 1}(0)$ Grassland (mg kg^{-1})**	**$Csludge_{soil\ 1}(0)$ Terrestrial (mg kg^{-1})**	**$Csludge_{soil\ 1}(0)$ Agricultural (mg kg^{-1})**	**Remarks**
Scenario 1	0.24	1.44×10^{-4}	3.59×10^{-4}	3.59×10^{-4}	*Nprep=1 d^{-1}*
	0.25	1.45×10^{-4}	3.63×10^{-4}	3.63×10^{-4}	*Nprep=3 d^{-1}*
Scenario 2	0.046	2.73×10^{-5}	6.84×10^{-5}	6.84×10^{-5}	

Where sewage sludge is applied to agricultural soil, an application rate of 5000 kg ha^{-1} per year has been assumed (based on typical application rates across the EU) whilst the rate for grassland is assumed to be lower at 1000 kg ha^{-1}yr^{-1} - these applications are considered to occur once per year. As deltamethrin does not appear to be readily biodegradable, there is potential for accumulation of the compound when sewage sludge is applied over consecutive years (as a realistic worst case, it is generally assumed that sludge is applied annually for 10 years).
Taking the degradation rate of deltamethrin from the CAR to be 48.2 days. Then if removal of deltamethrin via volatilisation and leaching from topsoil are ignored as being minor processes, losses would solely be as a result of soil degradation, then the pseudo-first order rate constant k (represented by $Kbio_{soil}$) can be derived from the following equation:

$$Kbio_{soil} = \frac{ln\ 2}{DT_{50}bio_{soil}}$$

Where $DT_{50}bio_{soil}$ is the half-life for (bio) degradation in aerobic soil (corrected to 12 °C).

Using the aerobic degradation DT_{50} value of 48.2 d and equivalent rate constant k of 1.44 x 10^{-2} d^{-1}: this would crudely represent the removal rate of a.s. from top soil. At the end of each year, a fraction of the initial concentration (Facc) may potentially remain in the top soil layer and this can be determined by use of the equation stating:

$$Facc = e^{-365k}$$

Where:
- Facc = fraction accumulation in 1 year
- k = first order rate constant for removal from top soil via degradation, volatilisation and leaching (1.44 x 10^{-2} d^{-1})

In the case of deltamethrin, Facc = 5.25 x 10^{-3} and soil accumulation is not expected to occur.
The PEC for local soil (referred to as $Clocal_{soil}$) has been calculated using the following equation taken from the ECHA guidance on ERA (equation 55):

$$Clocal_{soil} = \frac{D_{air}}{k} + \frac{1}{kT}\left[C_{soil}(0) - \frac{D_{air}}{k} \right] \cdot \left[1 - e^{-kT} \right]$$

Where:
- D_{air} is the aerial deposition flux per kg of soil (taken to be zero mg.kg^{-1}.d^{-1})

- T is the averaging time (180 d for arable land and grassland as a representative growing period for crops and 30 days for terrestrial ecosystems)
- C_{soil} (0) is the initial concentration in soil after sludge application (calculated in $mg.kg^{-1}$)
- $Clocal_{soil}$ is the average concentration in soil over T days

Table 12. Calculation of the concentration in soil from combined indoor applications after T days for parent compound

Scenario	$PEClocal_{soil}$ Grassland 180 d TWA [mg kg^{-1} wwt]	$PEClocal_{soil}$ Terrestrial 30 d TWA [mg kg^{-1} wwt]	$PEClocal_{soil}$ Agricultural 180 d TWA [mg kg^{-1} wwt]	Remarks
Scenario 1	5.25×10^{-5}	2.94×10^{-4}	1.31×10^{-4}	*Nprep=1 d^{-1}*
	5.30×10^{-5}	2.97×10^{-4}	1.33×10^{-4}	*Nprep=3 d^{-1}*
Scenario 2	9.98×10^{-6}	5.58×10^{-5}	2.49×10^{-5}	

In the case of the metabolite Br2CA, we will assume as a rough and worst case approach that no degradation occurs in sludge and that maximum degradation of parent compound (up to 23% deltamethrin is converted into metabolite Br2CA) in soil is reached at t=0. Moreover, the estimates of potential local soil exposure of deltamethrin presented above have also been adjusted by a factor of 0.59 (i.e. 298.0 / 505.2) to provide estimates of exposure of the metabolite Br2CA.

Table 13. Calculation of the concentration in soil due to sludge in first year for metabolite

Scenario	$Csludge_{soil\ 1}(0)$ Grassland (mg kg^{-1})	$Csludge_{soil\ 1}(0)$ Terrestrial (mg kg^{-1})	$Csludge_{soil\ 1}(0)$ Agricultural (mg kg^{-1})	Remarks
Scenario 1	1.95×10^{-5}	4.88×10^{-5}	4.88×10^{-5}	*Nprep=1 d^{-1}*
	1.97×10^{-5}	4.93×10^{-5}	4.93×10^{-5}	*Nprep=3 d^{-1}*
Scenario 2	3.71×10^{-6}	9.28×10^{-6}	9.28×10^{-6}	

Using the same equation as above and considering the aerial deposition flux as negligible and biological degradation process as the only relevant mechanism involved in the degradation of the metabolite Br2CA (considering volatilisation and leaching negligible) the estimated PEC values of the metabolite for soil compartment are:

Table 14. Calculation of the concentration in soil from combined indoor applications after T days for metabolite

Scenario	$PEClocal_{soil}$ Grassland 180 d TWA [mg kg^{-1} wwt]	$PEClocal_{soil}$ Terrestrial 30 d TWA [mg kg^{-1} wwt]	$PEClocal_{soil}$ Agricultural 180 d TWA [mg kg^{-1} wwt]	Remarks
Scenario 1	8.77×10^{-7}	1.28×10^{-5}	2.19×10^{-6}	*Nprep=1 d^{-1}*
	8.85×10^{-7}	1.30×10^{-5}	2.21×10^{-6}	*Nprep=3 d^{-1}*
Scenario 2	1.67×10^{-7}	2.44×10^{-6}	4.16×10^{-7}	

$PEC_{groundwater}$ (via the application of sludge to agricultural land)

Guidance within the EU TGD on risk assessment allows the predicted concentration of deltamethrin in local agricultural soil to be used to crudely indicate groundwater levels. The calculation outlined below is very simplistic, takes no account of soil characterisation and neglects consideration of transformation plus dilution in deeper soil layers:

$$PEClocal_{soil,\ porewater} = \frac{PEClocal_{soil} \times RHO_{soil}}{K_{soil\text{-}water} \times 1000}$$

Where:

- $PEClocal_{soil,\ porewater}$ is the predicted environmental concentration in porewater (calculated in mg l^{-1})
- $PEClocal_{soil}$ is the highest predicted environmental concentration in agricultural soil (Arable soil mg kg_{wwt}^{-1})
- RHO_{soil} is the bulk density of wet soil (default of 1700 kg m^{-3})
- $K_{soil\text{-}water}$ is the soil-water partitioning co-efficient (calculated as 12248 m^3 m^{-3})

Table 15. Calculation of the concentration in soil porewater for parent compound

Scenario	$PEClocal_{soil\ porewater}$ [µg l^{-1}]	Remarks
Scenario 1	4.99×10^{-5}	*Nprep=1 d^{-1}*
	5.04×10^{-5}	*Nprep=3 d^{-1}*
Scenario 2	9.49×10^{-6}	

Whilst noted as being a simplistic approach, these values represent concentrations in porewater of non-specific "agricultural soil" significantly below the current quality standard set at 0.1 µg l^{-1} by the EU Drinking Water Directive (98/83/EC).

Though it is unlikely considering its short degradation time, the metabolite Br2CA may lead to contamination of groundwater after releases to the soil due to the high mobility in soil. The concentration in porewater has been calculated as shown above using a soil-water partitioning coefficient of 0.968, leading to the following results:

Table 16. Calculation of the concentration in soil porewater for metabolite

Scenario	$PEClocal_{soil\ porewater}$ [µg l^{-1}]	Remarks
Scenario 1	0.086	*Nprep=1 d^{-1}*
	0.086	*Nprep=3 d^{-1}*
Scenario 2	0.016	

The concentrations in porewater of the metabolite Br2CA are higher than those found with the parent compound (deltamethrin) due to its higher mobility. However the concentrations estimated in porewater are below the threshold value set out by the EU Drinking Water Directive (98/83/EC).

PEC_{air}

Based on the vapour pressure (1.24 x 10^{-8} Pa at 25 °C), volatilisation of deltamethrin is negligible. The calculation of $PECA_{ir}$ is therefore of no relevance.

Calculated PEC values

Table 17. Summary table on calculated PEC values - Scenario 1					
PECs	**Deltamethrin**		**Br2CA**		**Units**
	Nprep=1 d^{-1}	***Nprep=3 d^{-1}***	***Nprep=1 d^{-1}***	***Nprep=3 d^{-1}***	
PEC_{STP}	9.23×10^{-6}	9.32×10^{-6}	7.25×10^{-7}	7.31×10^{-7}	mg/L
PEC_{sw}	5.73×10^{-7}	5.78×10^{-7}	7.25×10^{-8}	7.31×10^{-8}	mg/L
PEC_{sed}	5.08×10^{-3}	5.13×10^{-3}	9.70×10^{-8}	9.80×10^{-8}	mg/kg
$PEC_{soil\ (t=0)}$	3.59×10^{-4}	3.63×10^{-4}	4.88×10^{-5}	4.93×10^{-5}	mg/kg
PEC_{soil10}	3.59×10^{-4}	3.63×10^{-4}	4.88×10^{-5}	4.93×10^{-5}	mg/kg
$PEC_{soil(30\ TWA)}$	2.94×10^{-4}	2.97×10^{-4}	1.28×10^{-5}	1.30×10^{-5}	mg/kg
$PEC_{soil(180\ TWA)}$	1.31×10^{-4}	1.33×10^{-4}	2.19×10^{-6}	2.21×10^{-6}	mg/kg
$PEC_{soil,porewater}$	4.99×10^{-5}	5.04×10^{-5}	0.086	0.086	µg/L

Table 18. Summary table on calculated PEC values - Scenario 2			
PECs	**Deltamethrin**	**Br2CA**	**Units**
PEC_{STP}	1.75×10^{-6}	1.38×10^{-7}	mg/L
PEC_{sw}	1.09×10^{-7}	1.38×10^{-8}	mg/L
PEC_{sed}	9.66×10^{-4}	1.84×10^{-8}	mg/kg
$PEC_{soil\ (t=0)}$	6.84×10^{-5}	9.28×10^{-6}	mg/kg
PEC_{soil10}	6.84×10^{-5}	9.28×10^{-6}	mg/kg
$PEC_{soil(30\ TWA)}$	5.58×10^{-5}	2.44×10^{-6}	mg/kg
$PEC_{soil(180\ TWA)}$	2.49×10^{-5}	4.16×10^{-7}	mg/kg
$PEC_{soil,porewater}$	9.49×10^{-6}	0.016	µg/L

Primary and secondary poisoning

Primary poisoning

The product is applied indoors by surface spraying in crack and crevices and therefore primary poisoning caused by product ingestion by animals is unlikely.

Secondary poisoning

Deltamethrin has a potential for bioaccumulation in aquatic and terrestrial non-target organisms (log K_{OW} 4.6). Thus, an estimation of the theoretical exposure of top predators via the aquatic and terrestrial food chain has been performed and is presented in the following tables. In accordance with the ECHA Guidance on the BPR (Volume IV Environment – Part B Risk Assessment (active substances), Version 1.0, April 2015), the predicted environmental concentration in fish- and earthworm-eating top predators has been estimated according to the following relationships:

$PEC_{oral,\ fish\text{-}eating\ predator} = PECwater \times BCF_{fish} \times BMF$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Predicted Environmental Concentration in fish-eating predators	$PEC_{oral,\ fish\text{-}eating\ predator}$	[$mg.kg_{wet\ fish}^{-1}$]	-	Output
Predicted Environmental Concentration in water	PEC_{water}	[$mg.L^{-1}$]	[1]	Input
Bioconcentration Factor for fish on wet weight basis	BCF_{fish}	[$L.kg_{wet\ fish}^{-1}$]	1400[2]	Input
Biomagnification factor in fish	*BMF*	[-]	2[3]	Default

[1] PEC_{water} 5.78E-07 $mg.L^{-1}$ for Scenario 1 (Nprep 3, worst case, default value in line with exposure section) and 1.09E-07 $mg.L^{-1}$ for Scenario 2 for deltamethrin

[2] EU agreed fish BCF (whole fish) for deltamethrin

[3] worst-case BMF value agreed for deltamethrin during the EU peer review based on the TGD (Part II, 2003) recommendations and the log K_{OW} of 4.6 for the active substance

$PEC_{oral,\ earthworm\text{-}eating\ predator} =$

$C_{earthworm} = (BCF_{earthworm} \times C_{porewater} + C_{soil} \times F_{gut} \times CONV_{soil}) / (1 + F_{gut} \times CONV_{soil})$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Predicted Environmental Concentration in earthworm-eating predators	$PEC_{oral,\ earthworm\text{-}eating\ predator}$	[$mg.kg_{wet\ earthworm}^{-1}$]	-	Output
Concentration in earthworm on wet weight basis	$C_{earthworm}$	[$mg.kg_{wet\ earthworm}^{-1}$]	-	Output
Bioconcentration Factor for earthworms on wet weight basis	$BCF_{earthworm}$	[$mg.kg_{wet\ earthworm}^{-1}$]	483 [1]	Input
Concentration in porewater	$C_{porewater}$	[$mg.L^{-1}$]	[2]	Input
Concentration in soil	C_{soil}	[$mg.kg_{wwt}^{-1}$]	[3]	Input
Fraction of gut loading in worm	F_{gut}	[$kg_{dwt}.kg_{wwt}^{-1}$]	0.1 [4]	Default
Conversion factor for soil concentration wet-dry weight soil	$CONV_{soil}$	[$kg_{wwt}.kg_{dwt}^{-1}$]	1.13 [4]	Default

[1] EU agreed earthworm BCF for deltamethrin; estimated according to the equation of Jager (1998)

[2] $PEC_{porewater}$ 5.04×10^{-8} mg/L in Scenario 1 and 9.49×10^{-9} mg/L in Scenario 2.

[3] 30 days TWA PEC_{soil} 2.97×10^{-4} mg/L in Scenario 1 and 5.58×10^{-5} mg/L in Scenario 2.

[4] Default values were obtained from ECHA Guidance on the BPR (April 2015)

Based on the above the Predicted Environmental Concentration in fish-eating and earthworm-eating predators are presented in the following table.

Summary table on estimated theoretical exposition values (ETE) via food chain		
Scenario	***PEC*$_{oral,\ fish\text{-}eating\ predator}$**	***PEC*$_{oral,\ earthworm\text{-}eating\ predator}$**
Scenario 1	1.62E-03	5.20E-05
Scenario 2	3.05E-04	9.78E-06

C. *RISK CHARACTERISATION*

The eCA has performed calculations considering the PEC values of 3 preparations/day (default value) as a worst case in line with the exposure assessment section.

Atmosphere

Conclusion: KILLMETHRIN 2.5 WP is a Suspension Concentrate formulation to be applied indoors by professional and non-professional users by surface spraying treatment in cracks and crevices. The active substance Deltamethrin has a low vapour pressure (<0.1 mPA) and high molecular weight (505.2 g/mol) meaning that Deltamethrin will not readily volatilise into the atmosphere at ambient temperature and pressure. Application of spray droplets directed to surfaces leads to low persistence of droplets in the air. Therefore risk to air compartment is not foreseen and the assessment of air compartment after application of KILLMETHRIN 2.5 WP is deemed not necessary.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1	3.1×10^{-4}
Scenario 2	5.83×10^{-5}

Conclusion: Biocidal product applied indoor may enter into drains during cleaning operations following treatment. This implies a possible risk of exposure to STPs if the activity of the microorganisms in the STP system is inhibited or even supressed. PEC values for STP compartment calculated by EUSES modelling were compared with PNEC values agreed in the Assessment Report of Deltamethrin, resulting in an estimated concentration of deltamethrin in STP in the range of 10^{-4} – 10^{-5} times below PNEC value.

In conclusion, indoor application of KILLMETHRIN 2.5 WP in crack and crevices following label indications for both professional and non-professional users does not lead to risk to STP compartment. Deltamethrin is not readily or inherently biodegradable and there is not evidence of biotic or abiotic degradation in STP systems so it is assumend that during the residence time of deltamethrin in STP systems no metabolites or degradation products are formed.

Aquatic compartment

Summary table on calculated PEC/PNEC values		
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**
Scenario 1 (Deltamethrin)	0.826	0.827
Scenario 1 (Br2CA)	$7.03\text{x}10^{-6}$	$7.05\ \text{x}10^{-6}$
Scenario 2 (Deltamethrin)	0.156	0.156
Scenario 2 (Br2CA)	$1.33\text{x}10^{-6}$	$1.32\text{x}10^{-6}$

Conclusion: Water and sediment compartments are exposed to biocidal products after being released from an STP effluent stream into river courses and subsequently partitions into solid and liquid phases. Deltamethrin has shown very high toxicity to aquatic invertebrates and a PNEC of 7 ng/L was derived in the Assessment Report of Deltamethrin. This low PNEC value limits the use of Deltamethrin with regards to its hazard to aquatic organisms, being water and sediment the most sensitive compartments

in the assessment of deltamethrin-based products. In the case of KILLMETHRIN 2.5 WP, where 6-8 applications year are envisaged for professional users and a maximum of 2 applications/year are envisaged for non-professional users at a rate of 50 ml of product/100 m^2 surface in crack and crevices application the comparison of PEC values for water and sediment compartments with the corresponding PNEC values is very close to the threshold value, accounting for almost 1 in the combined assessment professional + non-professional use. In the case of the formation of the relevant metabolite Br2CA in water (maximum 13.3%) the risk is lower than the expected for the parent compound as it was expected from the analysis of the aquatic toxicity and degradation patterns of this metabolite.

We can conclude that application of KILLMETHRIN 2.5 WP in cracks and crevices by professional and non-professional users does not lead to risk to aquatic compartments (water and sediment).

Terrestrial compartment

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Scenario 1 (Deltamethrin)	3.96×10^{-3}
Scenario 1 (Br2CA)	9.29×10^{-5}
Scenario 2 (Deltamethrin)	7.44×10^{-4}
Scenario 2 (Br2CA)	1.74×10^{-5}

Conclusion: Biocidal products applied indoors may enter into soil compartment mainly after STP sludge deposition. PEC values have been obtained as the output of EUSES models premediated at 30 days in agricultural soil. These PEC values were compared to the relevant PNEC value agreed in the Assessment Report of Deltamethrin (0.075 mg/Kg wwt). Exposures as consequence of STP sludge deposition are well below the PNEC value, indicating the safe use of the product for soil organisms. As expected, the risk caused by the presence of the metabolite Br2CA to soil compartment is lower than the parent compound.

Summing up, application of KILLMETHRIN 2.5 WP in crack and crevices both by professional and non-professional users leads to acceptable risk for soil organisms and therefore this use is considered safe with regards to the soil compartment.

Groundwater

No specific limit for the active substance Deltamethrin in groundwater has been set, therefore typical limit set by Directive 2006/118/EC (0.1μg/L) is used as reference value to determine the safety of the product KILLMETHRIN 2.5 WP when applied according to recommended rates. PEC_{GW} for parent deltamethrin and metabolite Br2CA are below the maximum acceptable concentration of chemicals in drinking water in all the scenarios and therefore the use of KILLMETHRIN 2.5 WP is considered acceptable and no risk with regards to the contamination of groundwaters is envisaged.

Primary and secondary poisoning

Primary poisoning

No primary poisoning as consequence of the application of KILLMETHRIN 2.5 WP is envisaged. The product is a WP 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 via the aquatic food chain					
Scenario	***PEC*$_{oral,\ fish\text{-}eating\ predator}$**	**PNEC$_{birds}$[1]**	**PNEC$_{mammals}$ [2]**	**PEC/PNEC$_{birds}$**	**PEC/PNEC$_{mammals}$**
1	1.62E-03	15	2.67	1.08E-04	6.06E-04
2	3.05E-04	15	2.67	2.03E-05	1.14E-04
Summary table on secondary poisoning via the terrestrial food chain					
Scenario	***PEC*$_{oral,\ earthworm\text{-}eating\ predator}$**	**PNEC$_{birds}$[1]**	**PNEC$_{mammals}$ [2]**	**PEC/PNEC$_{birds}$**	**PEC/PNEC$_{mammals}$**
1	5.20E-05	15	2.67	3.47E-06	1.95E-05
2	9.78E-06	15	2.67	6.52E-07	3.66E-06

[1] $PNEC_{bird}$ is 15mg/kg food based on CAR of Deltamethrin (Doc II C)
[2] $PNEC_{small\ mammal}$ is 2.67mg/kg food based on CAR of Deltamethrin (Doc II C)

According to the above PEC/PNEC ratios secondary risk to top predators and insect and earthworm eating vertebrates is considered negligible.

Mixture toxicity

Not relevant. KILLMETHRIN 2.5 WP contains only one active substance (Deltamethrin) and does not contain any substance of concern. Therefore mixture toxicity assessment is not required.

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

The biocidal product KILLMETHRIN 2.5 WP is a wettable powder formulation based on deltamethrin (2.5% w/w) 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…) KILLMETHRIN 2.5 WP is applied indoors by professional and non-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 6-8 for professional users and 2 for non-professional users.

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 192 mg a.s./L to STP systems is calculated when 6-8 applications/year are assumed leading to acceptable PEC valued for all the environmental compartments. Non-professional use of KILLMETHRIN 2.5 WP leads to releases of Deltamethrin to STP of 36.5 mg/L taking into account a maximum of 2 applications/year resulting also in acceptable PEC values. Aggregated exposures (professional + non-professional) leads to RCR below the threshold value for all the environmental compartments affected (RCR < 1). The presence of degradation products such as the metabolite Br2CA in the environment and exposures (professional + non-professional) leads to RCR below the threshold value for all the environmental compartments affected (RCR < 1) thus it does not lead to risk to the environment.

Therefore, it can be considered that the simultaneous use of KILLMETHRIN 2.5 WP by professional and non-professional users is safe with regards to the environment.

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.

2.2.9 MEASURES TO PROTECT MAN, ANIMALS AND THE ENVIRONMENT

Particulars of likely direct or indirect effects:
May cause transient irritation of skin, eyes and mucous membranes.
Poisoning can cause the following symptoms: paresthesia, which may be severe skin and eye. May cause irritation to eyes, skin and mucous membranes. Inhalation may cause irritation, cough. Risk of pulmonary edema. Excitation, gastrointestinal disorders, tremors, dizziness, headache, lethargy, vomiting, abdominal pain, muscular twitching, nausea, loss of consciousness ...

First aid instructions:
General: Remove victim to fresh air. Immediately remove all contaminated clothing. Keep patient at rest. Maintain body temperature. If the person is unconscious, shorten side with the head lower than the rest of the body and the knees bended. Control breathing, if necessary, artificial respiration. Do not just leave the patient under any circumstance. Remove to fresh to hospital and, whenever possible, take the container or label.
Ingestion: If swallowed do not induce vomiting. Summon a doctor immediately and show him the label or the safety data sheet.
Inhalation: Seek fresh air to the victim (move outdoors). If you notice discomfort, seek medical attention.
Skin Contact: After contact with skin, wash immediately with soap and water, without rubbing.
Eye Contact: Rinse immediately with plenty of water for at least 15 minutes with the eyelid held wide open, not forget to remove the lenses. If you notice discomfort, seek medical attention.

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. KILLMETHRIN 2.5 WP is not intended to be used in combination with other biocidal products.

3. ANNEXES[5]

3.1 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT

Note: The applicant should update the List of Studies to include newly submitted studies.

Author; title; report number; date of report **Test institute** **Owner of the report** **Submitted by**	**GLP** **GEP**	**Published** **Data protection claimed (Y/N)**
Berrios, M.; Accelerate stability study, room storage stability study and physic-chemical properties of deltamethrin 2.5% WP (Wettable Powder 2.5% deltamethrin); E-13-0019, 2015 (Interim report) Test Institute: Labs & Technological Services AGQ S.L. Owner: Sharda Cropchem Limited Submitted by Sharda Europe B.V.B.A.	Yes	Not published Y
Lüpkes, K-H.; Efficacy of a Deltamethrin 2.5% SC product against house flies; BIO046c-13; 2013 Test Institute: BioGenius GmbH Owner: Sharda Cropchem Limited Submitted by Sharda Europe B.V.B.A.	Yes	Not published Y
Lüpkes, K-H.; 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; 2013 Test Institute: BioGenius GmbH Owner: Sharda Cropchem Limited Submitted by Sharda Europe B.V.B.A.	Yes	Not published Y
Lüpkes, K-H.; Efficacy of a Deltamethrin 2.5% SC product against various mosquito species; BIO053a-13; 2013 Test Institute: BioGenius GmbH Owner: Sharda Cropchem Limited Submitted by Sharda Europe B.V.B.A.	Yes	Not published Y
Heaven, H.; Field trials to determine the efficacy of Deltamethrin 2.5% SC against four species; 14-286; 2015 Test Institute: i2L research Ltd Owner: Sharda Cropchem Limited Submitted by Sharda Europe B.V.B.A.	Yes	Not published Y

5 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

Serrano, B., Laboratory trial to determine the efficacy against wasps of a Deltamethrin 2.5% SC formulation; Study No 2008-DELTASECT-LAB/1015, 2016 Test Institute: Laboratoire TEC Owner: Sharda Cropchem Limited Submitted by Sharda Europe B.V.B.A.	Yes	Not published Y
Serrano, B., Field assessment of the efficacy of an insecticidal treatment against ants, Study No 2008-DELTASECT2.5CS-ANTS-FIELD/1015R, 2015 Test Institute: Laboratoire TEC Owner: Sharda Cropchem Limited Submitted by Sharda Europe B.V.B.A.	Yes	Not published Y
Bradshaw, J.; Deltamethrin 2.5% SC: Acute dermal irritation in the rabbit; Study No 41204565, 2013 Test Institute: Harlan Laboratories Ltd. Owner: Sharda Cropchem Limited Submitted by Sharda Europe B.V.B.A.	Yes	Not Published Y
Bradshaw, J.; Deltamethrin 2.5% SC: Acute eye irritation in the rabbit; Study No 41204566, 2013 Test Institute: Harlan Laboratories Ltd. Owner: Sharda Cropchem Limited Submitted by Sharda Europe B.V.B.A.	Yes	Not Published Y
Bradshaw, J.; Deltamethrin 2.5% SC: Local Lymph Node Assay in the Mouse; Study No 41204567, 2013 Test Institute: Harlan Laboratories Ltd. Owner: Sharda Cropchem Limited Submitted by Sharda Europe B.V.B.A.	Yes	Not Published Y
Bradshaw, J.; Deltamethrin 2.5% SC: Acute oral toxicity in the rat – acute toxic class method; Study No 41204562, 2013 Test Institute: Harlan Laboratories Ltd. Owner: Sharda Cropchem Limited Submitted by Sharda Europe B.V.B.A.	Yes	Not Published Y
Griffiths, D.R., Whatson, P.; Deltamethrin 2.5% SC: Acute inhalation toxicity (nose only) study in the rat; Study No 41204563, 2013 Test Institute: Harlan Laboratories Ltd. Owner: Sharda Cropchem Limited Submitted by Sharda Europe B.V.B.A.	Yes	Not Published Y
Bradshaw, J.; Deltamethrin 2.5% SC: Acute dermal	Yes	Not Published

toxicity (limit test) in the rat; Study No 41204564, 2013 Test Institute: Harlan Laboratories Ltd. Owner: Sharda Cropchem Limited Submitted by Sharda Europe B.V.B.A.		Y

3.2 OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS

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

3.3 NEW INFORMATION ON THE ACTIVE SUBSTANCE

No new information on the risk assessment has been provided in support of this biocidal product

3.4 RESIDUE BEHAVIOUR

Not relevant. KILLMETHRIN 2.5 WP 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-XX)[6]

Not relevant. Information on efficacy studies has been reported in the IUCLID dossier (Section 6)

6 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

3.6 CONFIDENTIAL ANNEX

See separate Confidential Annex.

3.7 OTHER

APPENDIX 1

Professional exposure – no PPE

Low pressure spraying

Product	**Deltamethrin 2.5 WP**
active substance % (w/v)	0.025%
Potential body exposure	
Indicative value mg/min	92.0
Duration min	120
Potential dermal deposit mg	11040
Clothing type	Minimal clothing, 100% penetration
Clothing penetration %	100%
Actual dermal deposit [*product*] mg	11040
Hand exposure	
Indicative value mg/min (potential)	181
Duration min	120
Hand deposit mg	21720
Mitigation by gloves	1
Actual hand deposit [*product*] mg	21720
Total dermal exposure	
Total dermal deposit [*product] mg*	32760
Active substance mg	8.19
Dermal absorption %	2.00%
Systemic exposure via dermal route mg	0.1638
Exposure by inhalation	
Indicative value mg/m^3	104.00
Duration	120.00
Inhalation rate m^3/h	1.25
Mitigation by RPE (PF)	1.00
Inhaled [*product*] mg	260.00
Systemic exposure via inhalation route mg	0.065
Systemic exposure	
Total systemic exposure a.s. mg	0.2288
Body weight kg	60
Systemic exposure mg kg^{-1} day^{-1}	**0.00381**

Professional exposure – PPE

Low pressure spraying

Product	**Deltamethrin 2.5 WP**
active substance % (w/v)	0.025%
Potential body exposure	
Indicative value mg/min	92.0
Duration min	120
Potential dermal deposit mg	11040
Clothing type	Minimal clothing, 20% penetration
Clothing penetration %	20%
Actual dermal deposit [*product*] mg	2208
Hand exposure	
Indicative value mg/min (potential)	181
Duration min	120
Hand deposit mg	21720
Mitigation by gloves	0.1
Actual hand deposit [*product*] mg	2172
Total dermal exposure	
Total dermal deposit [*product] mg*	4380
Active substance mg	1.095
Dermal absorption %	2.00%
Systemic exposure via dermal route mg	0.0219
Exposure by inhalation	
Indicative value mg/m^3	104.00
Duration	120.00
Inhalation rate m^3/h	1.25
Mitigation by RPE (PF)	1.00
Inhaled [*product*] mg	260.00
Systemic exposure via inhalation route mg	0.065
Systemic exposure	
Total systemic exposure a.s. mg	0.0869
Body weight kg	60
Systemic exposure mg kg^{-1} day^{-1}	**0.00145**

Post-application exposure (cleaning equipment) – no PPE, Professionals & non-Professionals

Product	**Deltamethrin 2.5 WP**
active substance % (w/v)	0.025%
Potential body exposure	
Indicative value µl/min	19.3
Duration min	20
Potential dermal deposit mg	385.6
Clothing type	
Clothing penetration %	100%
Actual dermal deposit [*product*] mg	385.6
Hand exposure	
Indicative value µl/min	35.87
Duration min	20
Hand deposit mg	717.4
Mitigation by gloves	1
Actual hand deposit [*product*] mg	717.4
Total dermal exposure	
Total dermal deposit [*product] mg*	1103
Active substance mg	0.27575
Dermal absorption %	2.00%
Systemic exposure via dermal route mg	0.0055
Systemic exposure	
Total systemic exposure a.s. mg	0.0055
Body weight kg	60
Systemic exposure mg kg^{-1} day^{-1}	**0.00009**

Non-Professional exposure – no PPE

Mixing/loading powder

ConsExpo 5.0 report

Report date: 5/5/2017

Compound

Compound name :	Deltamethrin		
CAS number :	52918-63-5		
molecular weight		5.1E2	g/mol
vapour pressure		2E-8	Pascal
KOW	5.6	10Log	

Populations

Adult

body weight	60	kilogram

Products

KILLMETHRIN

weight fraction compound	2.5	%

Aggregate Exposures

Aggregate exposure for Adult :

Total chronic potential dose (mg/kg/day):
1.5E-7

Total chronic systemic dose (mg/kg/day):
3E-9

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

Inhalation chronic systemic dose (mg/kg/day):
--

Dermal chronic potential dose (mg/kg/day):
1.5E-7

Dermal chronic systemic dose (mg/kg/day):
3E-9

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

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

Details for scenario: Adult, KILLMETHRIN : mixing and loading, powder

Dermal model: Direct dermal contact with product : constant rate

weight fraction compound	0.025		fraction
contact rate	0.033		mg/min
release duration	80	second	

Uptake model: fraction

uptake fraction	0.02	fraction

Non-Professional exposure – no PPE

Application (trigger spray)

ConsExpo 5.0 report

Report date: 5/5/2017

Compound

Compound name :	Deltamethrin		
CAS number :	52918-63-5		
molecular weight		5.1E2	g/mol
vapour pressure		2E-8	Pascal
KOW	5.6	10Log	

Populations

Adult

body weight	60	kilogram

Products

Killmethrin

weight fraction compound	2.5	%

Aggregate Exposures

Aggregate exposure for Adult :

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

Total chronic systemic dose (mg/kg/day):
5.1E-7

Inhalation chronic potential dose (mg/kg/day):
1.3E-7

Inhalation chronic systemic dose (mg/kg/day):
1.3E-7

Dermal chronic potential dose (mg/kg/day):
1.9E-5

Dermal chronic systemic dose (mg/kg/day):
3.8E-7

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

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

Details for scenario: Adult, Killmethrin : application (trigger spray)

Inhalation model: Exposure to spray : spraying

weight fraction compound	0.025		%
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	1	fraction	
density non-volatile	1.8	g/cm3	
room height	2.5	meter	
inhalation cut-off diameter	15	micrometer	
non-respirable uptake fraction	0	fraction	

Uptake model: Fraction

uptake fraction	1	fraction
inhalation rate	1.3	m3/hour

Dermal model: Direct dermal contact with product : constant rate

weight fraction compound	0.025		%
exposed area	3.1E3		cm2
contact rate	46	mg/min	
release duration	2.4E2		second

Uptake model: fraction

uptake fraction	0.02	fraction

Secondary exposure

Product	**Deltamethrin 2.5 WP**
Application rate mg/m^2	12.5
Material that may deposit on the floor away from the treated area after a targeted spot or crack and crevice application, (TNsG, part 2, pages 257-258)	15%
Dislodged amount, (TNsG, version 2 page 102)	18%
Transfer coefficient, (Recommendation No. 12 of the BPC Ad hoc Working Group on Human Exposure)	2000 cm^2/hr
Dermal absorption	2%
Fraction on hands	0.2
Hand to mouth transfer	0.5
Oral absorption	75%
Adult body weight (kg)	60
Children body weight (kg)	23.9
Infant body weight (kg)	8
Systemic exposure via dermal route mg/kg b.w./d - Adult	0.0000225
Systemic exposure via dermal route mg/kg b.w./d - child	0.000056
Systemic exposure via dermal route mg/kg b.w./d - infant	0.000169
Systemic exposure hand-to-mouth mg/kg b.w./d - infant	0.00063