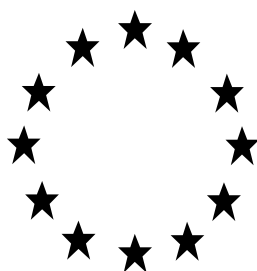


Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF A BIOCIDAL
PRODUCT FOR NATIONAL AUTHORISATION
APPLICATIONS**

(submitted by the evaluating Competent Authority)



Detrans Deltamethrin CIK

Product type 18

Deltamethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-KF010485-52

Evaluating Competent Authority: SPAIN

Septiembre 2019

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1. CONCLUSION

The assessment presented in this report has shown that, Detrans® Deltamethrin CIK, with the active substance deltamethrin, at a level of 0.02% w/w, may be authorised for use as an insecticide (product-type 18) for the control of crawling insects for the general public. Please, note that this Assessment Report includes the uses requested by the applicant, as information for the concerned member states.

Detrans® Deltamethrin CIK formulation was found to be a clear/colourless/transparent free-flowing liquid with a kerosene like odour. The density was 0.7694 g/cm³ and viscosity was 1.304 mm² s⁻¹ at 20.1°C. The formulation was also shown to be stable after accelerated storage at 45 ± 3°C for 3 months and 50°C ± 2°C for 6 months with the discharge rate from the aerosol consistent over the 3 and 6 month storage periods, respectively. Long term storage stability studies at 38 ± 2°C for 36 months and 25 ± 2°C for 36 months also showed the formulation to be stable, with the aerosol discharge rates consistent over both 36 month storage periods. The spray pattern, residual percentage after complete spray off and nozzle function was also tested in the accelerated storage stability study conducted at 45 ± 3°C for 3 months and found to be acceptable.

The formulation has been determined to have a flash point of 39.7°C and is, consequently, considered as extremely flammable aerosol. The self-ignition temperature is greater than 200°C. It is predicted to be neither explosive nor oxidizing. Additionally, no signs of corrosion or degradation determined by visual assessment initially and then after storage at 50 °C for 1, 3 and 6 months.

There are Substances of Concern in the biocidal product since these substances are classified as dangerous (Directive 67/548/EEC) or hazardous (Regulation No 1272/2008). However, the concentration of these substances in the preparation does not exceed the classification limits set in Regulation (EC) N° 1272/2008 and the biocidal product is not classified with regard to the physico chemical properties.

A validated analytical method has been submitted for determining the concentration of Deltamethrin in the biocidal product by the applicant. Validated analytical methods are also available for the determination of Deltamethrin in soil, water and air matrices. Other analytical methods are not required.

Detrans® Deltamethrin CIK is a ready-to-use product intended for use by non-professional/amateur users for the control of 'crawling insects' including cockroaches (*Periplaneta americana*; *Blatella germanica*) and black ants (*Lasius niger*). The product is supplied in a can with an aerosol spray dispenser that should be sprayed indoors as chemical barrier inside of windows and doors frames or treatment of 'cracks and crevices'. Efficacy is restricted to non-porous surfaces. Acute toxicity studies have been performed using a formulation different from Detrans® Deltamethrin CIK.

Human exposure takes place via dermal, oral and inhalation routes. Indirect exposure is expected for infants via dermal and hand to mouth contact during crawling after application of the product.

Product specific data such as spray duration, mass median aerodynamic diameter (MMAD) of the spray droplets from the representative product, and amount of product discharged per stroke are not provided. Hence the exposure of consumers during application, and the secondary

exposure of infants, is assessed with ConsExpo Web 1.0.3 using the default input parameters in RIVM Reports 320104005/2009 and 320005002/2006.

Based on the risk assessment results, the use of Detrans® Deltamethrin CIK as an insecticide is considered safe for human health taking into account primary exposure to the biocidal product as a consequence of use. Risk is envisaged for the indirect exposure scenarios considered in this assessment (children, companion animals). The following phrase on the label will be included as a risk management measure:

- For use only in areas inaccessible to children and animals.
- Do not allow children or animals access to treated surfaces.

Dietary exposure as result of use (i.e., food contamination and livestock exposure) can be excluded taking into account the above and following risk mitigation measures:

- Keep away from food/feed stuff, eating utensils or food/feed contact surfaces.
- Remove food/feed stuff prior to teatment.
- Do not apply directly to surfaces on which food/feed is stored, prepared or eaten.

Regarding the environment, since no substance of concern has been identified, the risk assessment of Detrans® Deltamethrin CIK has been based only on the active substance Deltamethrin. The risk assessment for the product has been carried out for the intended uses proposed by the applicant, i.e. uses indoors (scenario 1: cracks and crevices/targeted spots; scenario 2: windows and doors frames/barrier treatment) and outdoors (scenario 3: perimeter around a house).

Based on the outcome of the risk assessment, the intended indoor uses proposed following the directions for use and risk mitigation measures do not cause any unacceptable risk for the environment. However the intended outdoor uses posed unacceptable risks for the environment in urban areas. Nevertheless it should be noted that the targeted spot use as direct application onto insects poses risks for human health thus it cannot be authorised.

The Spanish CA concludes that indoor uses in cracks and crevices and in the inside part of windows and doors frames can be authorised following the directions for use and risk mitigation measures.

2. ASSESSMENT REPORT

2.1. Summary of the product assessment

2.1.1. Administrative information

2.1.1.1. Identifier of the product

Identifier ¹	Country (if relevant)
Detrans Deltamethrin CIK Protect Home Insecticida rastreros PROTECT HOME INSECTICIDA RASTREROS AE	Spain
Detrans Deltamethrin CIK Bayer Garten Ameisenspray Ameisenspray Ungezieferspray gegen kriechende Insekten Ungeziefer Spray	Austria
Detrans Deltamethrin CIK K-Othrine Plus Kruipende insecten - Insectes rampants Kruipende insecten - Insectes rampants Kruipende insectenspray Mierenspray Protect Home Kruipende insecten - Protect Home Insectes rampants	Belgium
Detrans Deltamethrin CIK na mravence a jiný lezoucí hmyz	Czech Republic
Detrans Deltamethrin CIK Bayer Jardin Fourmis et araignées Forminix aérosol rampants Fourmis et araignées	France
Detrans Deltamethrin CIK Ameisenspray Bayer Garten Ameisenspray Ungezieferspray gegen kriechende Insekten Ungeziefer Spray	Germany
Detrans Deltamethrin CIK K-Othrine Spray Formiche FORMINIX AE	Italy

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

Identifier¹	Country (if relevant)
Spray Formiche	
Detrans Deltamethrin CIK K-Othrine Plus Kruipende insecten – Insectes rampants Kruipende insecten - Insectes rampants	Luxembourg
Detrans Deltamethrin CIK Baythion Spray SBM mieren en kruipende insectenspray Protect kruipende insectenspray Protect zilvervisjesspray Protect Home mieren en kruipende insectenspray	Netherlands
Detrans Deltamethrin CIK na owady biegające i mrówki	Poland
Detrans Deltamethrin CIK Proteger Insecticida Rastejantes PROTECT HOME INSECTICIDA RASTREJANTES AE	Portugal
Detrans Deltamethrin CIK na mravce a iný lezúci hmyz	Slovakia
Detrans Deltamethrin CIK Kvitt D mot krypande insekter Radar Dos D Krypande Insekter Spray	Sweden
Detrans Deltamethrin CIK	United Kingdom

2.1.1.2. Authorisation holder

Name and address of the authorisation holder	Name	Sumitomo Chemical Agro Europe SAS
	Address	Parc d'Affaires de Crécy 10A Rue de la Voie Lactée 69370 Saint Didier au Mont d'Or France
Authorisation number	ES/APP(NA)-2019-18-XXXXX	
Date of the authorisation	25/09/2019	
Expiry date of the authorisation	25/09/2029	

2.1.1.3. Manufacturer(s) of the product

2.1.1.3.1. Manufacturer of the product 1

Name of manufacturer	TOSVAR srl
Address of manufacturer	Via del Lavoro, 10

	20060 Pozzo d'Adda, Milano Italy
Location of manufacturing sites	Via del Lavoro, 10, Pozzo d'Adda, 20060 Milano Italy

2.1.1.3.2. Manufacturer of the product 2

Name of manufacturer	Colep Portugal, S.A.
Address of manufacturer	Rua Comendador Arlindo Soares de Pinho, 1977 3730-423 Vale de Cambra Portugal
Location of manufacturing sites	Rua Comendador Arlindo Soares de Pinho, 1977 3730-423 Vale de Cambra Portugal

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

Active substance	Deltamethrin
Name of manufacturer	Bayer SAS
Address of manufacturer	16, rue Jean-Marie Leclair - 69266 Lyon France
Location of manufacturing sites	Bilag Industries Pvt Ltd 304/2, II Phase, GIDC, Vapi - 396 195. Gujarat. India

2.1.2. Product composition and formulation

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

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

Yes

No

2.1.2.1. Identity of the active substance

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%
Structural formula	

2.1.2.2. Candidate(s) for substitution

Deltamethrin is not candidate for substitution in accordance with Article 10 of BPR.

2.1.2.3. Qualitative and quantitative information on the composition of the biocidal product²

Common name	IUPAC name	Function	CAS number	EC number	Content (w/w%)
Deltamethrin	α -cyano-3-phenoxybenzyl [1R-[1 α (S*),3 α]]-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate	Active substance	52918-63-5	258-256-6	0.02 (technical) 0.0197 (pure)
Hydrocarbons, C11-C14, n-	Hydrocarbons, C11-C14, n-	Solvent		926-141-6	59.81

² Please delete as appropriate.

Common name	IUPAC name	Function	CAS number	EC number	Content (w/w%)
alkanes, isoalkanes, cyclics, <2% aromatics	alkanes, isoalkanes, cyclics, <2% aromatics				

2.1.2.4. Information on technical equivalence

The manufacturer of the active substance and the manufacturing site of the active substance used in the biocidal product are identical to the manufacturer of the active substance and the production site of the active substance included in Annex I of Directive 98/8/EC. Therefore no check for equivalence is necessary.

2.1.2.5. Information on the substance(s) of concern

Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics is considered a substance of concern for human health. Please see the confidential annex for further details.

2.1.2.6. Type of formulation

AE - Aerosol dispenser

2.1.3. Hazard and precautionary statements

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

Classification	
Hazard category	Aerosol . Category 1 Aspiration toxicity. Category 1 Aquatic acute 1 Aquatic Chronic 1
Hazard statement	H222: Extremely flammable aerosol. H229: Pressurised container: May burst if heated H304: May be fatal if swallowed and enters airways H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	Danger
Pictogram	 GHS02 GHS09

Hazard statements	H222: Extremely flammable aerosol. H229: Pressurized container. May burst if heated. H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P102: Keep out of reach of children. P103: Read label before use. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking P211: Do not spray on an open flame or other ignition source. P251: Do not pierce or burn, even after user. P273: Avoid release to the environment. P410+P412: Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F P501: Dispose of contents/container in accordance with local regulation.
Note	EUH066: 'Repeated exposure may cause skin dryness or cracking' Remove or cover terrariums, aquariums and animal cages before application. Turn off aquarium air-filter while spraying.

Note:- In accordance with the CLP regulation (Regulation (EC) No 1272/2008), Article 23(c) and Section 1.3.3, as the product will be placed on the market in aerosol containers it does not need to be labelled for aspiration hazard.

2.1.4. Authorised use(s)

2.1.4.1. Use description

Table 1. Use # 1 – Insecticide. Indoors. Cracks and crevices including inside window & door frames. Non-professionals/General public.

Product Type	PT18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide against crawling insects
Target organism (including development stage)	Crawling insects such as: - German cockroach (<i>Blattella germanica</i>). Adults - American cockroach (<i>Periplaneta americana</i>). Adults - Black garden ant (<i>Lasius niger</i>). Adults
Field of use	Indoors of private houses. Application on cracks and crevices including inside of window and door frames.
Application method(s)	Ready-to-use aerosol. Spray applicaton.
Application rate(s) and frequency	Spray for 7 seconds per square metre (14 g/m ²) in cracks

	and crevices and inside non-porous surfaces of window & door frames (barrier treatment). Residual efficacy can last up to 3 months after application. Use maximum up to 11 applications per year.
Category(ies) of users	General public (non-professional users)
Pack sizes and packaging material	Aerosol dispenser of 520 mL (nozzle and valve made of polyethylene)

2.1.4.2. Use-specific instructions for use

See section 2.1.5.1

2.1.4.3. Use-specific risk mitigation measures

See section 2.1.5.2

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

See section 2.1.5.3

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

See section 2.1.5.4

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

See section 2.1.5.5

2.1.5. General directions for use

2.1.5.1. Instructions for use

Always read the label or leaflet before use and respect all the instructions provided. Detrans® Deltamethrin CIK is a ready-to-use solvent based crawling insect killer product with aerosol dispenser containing deltamethrin for the control of crawling insects.

Detrans® Deltamethrin CIK may be used on Cracks and crevices inside non-porous surfaces of window & door frames (cracks and crevices; barrier treatment)

Insects will be knocked down from the first minutes until 2 hours later and will be killed after 2 hours of application and up to 3 days later. Residual activity on non-porous surfaces will be effective up to 3 months. Efficacy on porous surfaces may be limited or absent.

Do not direct the spray up into the air.

Over application may cause damage. Test in an inconspicuous area before applying.

Hold the product in an upright position and spray from a distance of about 30 cm.

Spray for 8 seconds per square metre on cracks and crevices (e.g. cracks and crevices suspected of harbouring crawling insects), or, at inside surfaces of window and door frames where insects may enter the home (barriers treatment) where crawling insects may enter the home (apply in a band of 10 cm width). Efficacy can last up to 3 months after application.

Inform the registration holder if the treatment is ineffective.

Apply only on infested area

Do not clean the treated area until the treatment is finished (up to 12 weeks).

If the infestation persists contact a professional

Retreat in case of new infestation without exceeding the maximum number of treatment authorized per year,

Avoid continuous use of the product

The product is not intended for large-scale application.

Vacate room and keep door closed for 15 minutes after application indoors. Ventilate before re-entry.

2.1.5.2. Risk mitigation measures

- For use only in areas inaccessible to children and animals.
- Do not allow children or animals access to treated surfaces.
- Keep away from food/feed stuff, eating utensils or food/feed contact surfaces.
- Remove food/feed stuff prior to treatment.
- Do not apply directly to surfaces on which food/feed is stored, prepared or eaten.
- Do not breathe spray.
- Use only in well ventilated areas.
- Avoid contact with skin.
- Use only as directed.
- Do not spray onto people or pets.
- Do not throw the product on the ground, into a water course, into the sink or down the drain.
- Remove or cover terrariums, aquariums and animal cages before application.
- Turn off aquarium air-filter while spraying.
-
-

Consider the following strategies for managing the development of resistance:

- where possible, application treatments should be recommended to be combined with non-chemical measures
- products should always be used in accordance with label recommendations
- complete elimination of insect pests should be attempted in infested areas
- applications should always be made against the most susceptible stages in the pest life cycle
- where an extended period of control is required, treatments should be alternated with products with different modes of action

levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance

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

Likely direct or indirect adverse effects:

- Eye, skin, mucous membrane, respiratory and gastrointestinal tract irritation.
- Confusion, headache, nausea and vomiting.

Basic first aid procedures:

- Remove the person from the exposure site and take off all contaminated clothing.
- If contact in eyes, rinse with plenty of water for at least 15 minutes. Do NOT forget to remove the contact lenses.
- If contact on skin, wash with soap and plenty of water, without rubbing.
- If swallowed, rinse mouth and do not induce vomiting unless told to do so by poison control or a health care professional.
- Keep person at rest in position comfortable for breathing.
- If necessary take person to a hospital and show the label or packaging when possible. Do not leave poisoned person alone.
-

Treatment advice for doctors and medical personnel:

- Symptomatic and supportive treatment

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

[☎ **INSERT LOCAL NUMBER HERE**]

Emergency measures to protect the environment:

Extremely flammable.

Very toxic to aquatic organisms may cause long term adverse effects in the aquatic environment.

2.1.5.4. Instructions for safe disposal of the product and its packaging

Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Eliminate those wastes in accordance with current regulations.

Do not release to soil, ground, surface water or any kind of sewer.

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

Keep away from sources of ignition - no smoking.
 Store away from food, beverages and pet food.
 Pressurised container: protect from sunlight and do not expose to temperatures exceeding 50°C.
 Store in the original container. Keep containers tightly closed in a dry, cool and well-ventilated place.
 It is recommended to store the product at a temperature preferably between 5° C and 45° C.
 Protect from frost.
 Shelf-life: 3 years

2.1.6. Other information

The product contains solvents and propellants.
General public (non-professional user): Users who are not professionals and who apply the product in the context of their private life.

2.1.7. Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Aerosol dispenser	520ml	Metal: tin plate with no internal lacquer	Nozzle – polyethylene Continuous valve raw material – Polyethylene Valve orifice Ø 0.5 mm	Non-profesional	Yes

2.1.8. Documentation

2.1.8.1. Data submitted in relation to product application

The reference list (including updates) for the studies submitted in support of the 2013 BPD dossier has been included in Annexes whilst the reference list for the studies considered confidential has been included in the confidential Annex .

2.1.8.2. Access to documentation

A letter of access has been submitted directly from Bayer S.A.S. to the Competent Authority.

No further letters of access are required as remaining data is owned by Sumitomo Chemical (UK) Plc.

The applicant has provided the Physical, Chemical and Technical Properties of the biocidal product for supporting the Physical hazards and respective characteristics.

The applicant has provided the suitable analytical method for identifying the active substance in the biocidal product.

The applicant has not provided the rest of analytical methods. This information is not necessary because it is possible to use the Competent Authority Report on the active substance deltamethrin supported by Bayer Environmental Science.

2.2. Assessment of the biocidal product

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

Table 1. Intended use # 1 – Crawling insect killing and barrier aerosol spray

Product Type(s)	PT 18 (insecticides, acaricides and products to control other arthropods)
Where relevant, an exact description of the authorised use	Crawling insect killing and barrier aerosol spray
Target organism (including development stage)	Blattodea (Cockroaches) - adults e.g. American cockroaches:- <i>Periplaneta Americana</i> ; German cockroaches:- <i>Blattella germanica</i> ; Oriental cockroaches:- <i>Blatta orientalis</i> Ants - adults e.g. Black ants, <i>Lasius niger</i>
Field of use	Indoor Outdoor
Application method(s)	Spraying
Application rate(s) and frequency	Spray can be used directly on visible insect pests or applied in cracks and crevices suspected of harbouring crawling insect pests. Repeat as necessary. Spray outside surfaces of window & door frames and other areas where crawling insects may enter the home. The product application rate is 2 g/s
Category(ies) of user(s)	Non-professional
Pack sizes and packaging material	The product application container dimensions are shown below:- Nozzle orifice Ø 0.5mm Nozzle raw material Polyethylene Continuous valve raw material Polyethylene Valve orifice Ø 0.5mm Canister Nominal capacity 520 ml Canister classic Tin plate with no internal lacquer Canister Weight 80g +/- 5% Canister Filling 400 ml with propane / butane mixture Canister Dimensions 57x207 mm Brim-full 520 ml

2.2.2. Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Physical state and nature at 20 °C and 101.3 kPa	Visual Determination	Deltamethrin CIK Aerosol Pack (TF2787) AE F032640 00 AE01 B3	<u>Initially:</u> Free-flowing liquid. Free from particulate matter. <u>After 1, 3 or 6 months at 50°C ± 2°C:</u> Free-flowing liquid. Free from particulate matter. <u>After 3, 6, 12, 18, 24 or 36 months at 38°C ± 2°C:</u> Free-flowing liquid. Free from particulate matter. <u>After 6, 12, 18, 24 or 36 months at 25°C ± 2°C:</u> Free-flowing liquid. Free from particulate matter.	Lumsden A.M. (2000)

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Colour at 20 °C and 101.3 kPa	Visual Determination	Deltamethrin CIK Aerosol Pack (TF2787) AE F032640 00 AE01 B3	<p><u>Initially:</u> Clear, colourless, transparent.</p> <p><u>After 1 or 3 months at 50°C ± 2°C:</u> Slightly Cloudy, colourless, transparent.</p> <p><u>After 6 months at 50°C ± 2°C:</u> Slightly Cloudy, colourless, translucent.</p> <p><u>After 3, 6, 12, 18, 24 or 36 months at 38°C ± 2°C:</u> Clear, colourless, transparent.</p> <p><u>After 6, 12, 18, 24 or 36 months at 25°C ± 2°C:</u> Clear, colourless, transparent.</p>	Lumsden A.M. (2000)
Odour at 20 °C and 101.3 kPa		Deltamethrin CIK Aerosol Filling Solution Batch 27-05-2013 Deltamethrin 0.0349%	Kerosene like odour	Foster B. (2014)
Acidity/Alkalinity	Not available	Not available	Not available	Not available

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Relative density/bulk density	EC Directive 92/69/EC Method A3	Deltamethrin CIK Aerosol Filling Solution Batch 27-05-2013 Deltamethrin 0.0349%	0.769	Foster B. (2014)
Storage stability test – accelerated storage (6 months at 50°C)	CIPAC MT 46.3: accelerated storage procedure	Deltamethrin CIK Aerosol Pack (TF2787) AE F032640 00 AE01 B3	Initially: 0.0214% w/w After 1 month at <u>50°C ± 2°C:</u> 0.0213% w/w Difference: - 0.46% After 3 months at <u>50°C ± 2°C:</u> 0.0214% w/w Difference: - 0.00% After 6 months at <u>50°C ± 2°C:</u> 0.0218% w/w Difference: +1.87%	Lumsden A.M. (2000)
Deltamethrin content	HPLC method			
Homogeneity of application	Not available	Not available	Not available	
Appearance and stability of the package			<u>Initially and after 1, 3 or 6 months at 50°C ± 2°C:</u> Green, metal	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
<p>Effects of temperature</p> <p>Effects of light</p> <p>Reactivity towards container material</p> <p>Other:- Gross weight change, discharge rate.</p>			<p>aerosol can with a white liquid. No signs of corrosion or degradation on the inside or outside.</p> <p>Stable at 50 ± 2°C for 6 months</p> <p>Stable when stored in product container.</p> <p>No effects were noted.</p> <p>There was no significant change to the appearance of the formulation.</p> <p>The discharge rate from the aerosol was found to be consistent over the 6 month storage period.</p>	
<p>Storage stability test – accelerated storage (3 months at 45°C)</p> <p>Deltamethrin content</p>	<p>CIPAC MT 46.3: accelerated storage procedure</p> <p>GC-FID method</p>	<p>DETRANS CIK - 0.02% Deltamethrin CIK oil-based aerosol</p> <p>Batch No. 251404</p>	<p>The product was found to be stable after 3 months storage at 45 ± 3°C.</p> <p><u>Initially:</u> 0.02% w/w</p> <p><u>After 3 months at 45°C ± 3°C:</u> 0.02% w/w</p> <p>Difference: -</p>	<p>. Giulia F. (2018)</p>

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
<p>Effects of light</p> <p>Effects of temperature</p> <p>Reactivity towards container material Other: Humidity, pH, appearance</p>	<p>FEA 604 I – Part 2 (Internal pressure) FEA 643 (Spray rate) Visual observation (nozzle)</p>		<p>0.00% Stable when stored in product container. Stable at 45 ± 3°C for 3 months.</p> <p>No effects were noted. The following parameters were tested and found not to have changed:- appearance, colour, odour, active ingredient content, internal pressure (3.5 bar), discharge rate(2.00 g/s) , spray pattern (oval – 9 cm) and residual percentage after complete spray off(<1%) . The nozzle was not found to block at any timepoint.</p>	
<p>Storage stability test – long term storage at 38°C ± 2°C</p>				<p>Lumsden A.M. (2000)</p>

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Deltamethrin content			Initially: 0.0214% w/w After 3 months at 38°C ± 2°C: 0.0213% w/w Difference: - 0.46% After 6 months at 38°C ± 2°C: 0.0211% w/w Difference: - 1.40% After 1 year at 38°C ± 2°C: 0.0214% w/w Difference: +0.00% After 1.5 years at 38°C ± 2°C: 0.0213% w/w Difference: - 0.46% After 2 years at 38°C ± 2°C: 0.0216% w/w Difference: +0.93% After 3 years at 38°C ± 2°C: 0.0212% w/w Difference: - 0.93%	
Homogeneity of application Appearance and			Not available Initially and after	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
<p>stability of the package</p> <p>Effects of temperature</p> <p>Effects of light</p> <p>Reactivity towards container material</p> <p>Other:- Gross weight change, discharge rate.....</p>			<p><u>3, 6, 12, 18, 24 or 36 months at 38°C ± 2°C:</u> Green, metal aerosol can with a white liquid. No signs of corrosion or degradation on the inside or outside. Stable at 38 ± 2°C for 36 months Stable when stored in product container. No effects were noted. There was no significant change to the appearance of the formulation. The discharge rate from the aerosol was found to be consistent over the 36 month storage period.</p>	
<p>Storage stability test – long term storage at ambient temperature</p>				Lumsden A.M. (2000)

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
<p>Deltamethrin content</p> <p>Homogeneity of application</p> <p>Appearance and stability of the package</p>	<p>HPLC Method</p>		<p><u>Initially:</u> 0.0214% w/w <u>After 6 months at 25°C ± 2°C:</u> 0.0216% w/w Difference: +0.93% <u>After 12 months at 25°C ± 2°C:</u> 0.0212% w/w Difference: - 0.93% <u>After 1.5 years at 25°C ± 2°C:</u> 0.0214% w/w Difference: +0.00% <u>After 2 years at 25°C ± 2°C:</u> 0.0211% w/w Difference: - 1.40% <u>After 3 years at 25°C ± 2°C:</u> 0.0215% w/w Difference: +0.93%</p> <p>Not available</p> <p><u>Initially and after 6, 12, 18, 24 or 36 months at 25°C ± 2°C:</u> Green, metal aerosol can with a</p>	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
<p>Effects of temperature</p> <p>Effects of light</p> <p>Reactivity towards container material</p> <p>Other:- Humidity, pH, appearance.....</p>			<p>white liquid. No signs of corrosion or degradation on the inside or outside.</p> <p>Stable at 25 ± 2°C for 36 months</p> <p>Stable when stored in product container.</p> <p>No effects were noted.</p> <p>There was no significant change to the appearance of the formulation.</p> <p>The discharge rate from the aerosol was found to be consistent over the 36 month storage period.</p>	
Storage stability test – low temperature stability test for liquids	Not available	Not available	Not available	Not available
Wettability	Only solid preparations	-	Not applicable	
Suspensibility, spontaneity and dispersion stability	Only solid preparations	-	Not applicable	
Wet sieve analysis	for WPs, SCs, granules,	-	Not applicable	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
and dry sieve test	tablets			
Emulsifiability, re-emulsifiability and emulsion stability	only for ECs and ready-to-use emulsions	-	Not applicable	
Disintegration time	only for tablets	-	Not applicable	
Particle size distribution, content of dust/fines, attrition, friability	Directive 75/324/EEC amended directive 2008/47/EC	CIK aerosol deltamethrin 0.02%, Detrans self-pressurised aerosol Batch number FFB03027/B Active content 0.0209%	The results for the percentage particles of <10 µm (the inhalable fraction) for both aerosol samples tested were <1%.	Foster B. (2014)
Persistence of foaming	-	-	Not applicable	
Flowability/Pourability/ Dustability	Flowability only for granular preparations, pourability only for suspensions, dustability only for dustable powders	-	Not applicable	
Burning rate — smoke generators			Not applicable	
Burning completeness — smoke generators			Not applicable	
Composition of smoke — smoke generators			Not applicable	
Spraying pattern — aerosols	-	Deltamethrin CIK Aerosol Pack (TF2787) AE F032640 00 AE01 B3	The discharge rate from the aerosol was found	Lumsden A.M. (2000)

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			to be consistent over a 6 month storage period following storage at $50 \pm 2^\circ\text{C}$, and for 36 months following storage at $38 \pm 2^\circ\text{C}$ and $25 \pm 2^\circ\text{C}$.	
	FEA 644 I	DETRANS CIK - 0.02% Deltamethrin CIK oil-based aerosol Batch No. 251404	The discharge rate of the 2 g/s from the aerosol was found to be consistent over a 3 month storage period following storage at $45 \pm 3^\circ\text{C}$.	Giulia F. (2018)
Compatibility with other products	-	-	Not applicable	
Surface tension	Not applicable	Not applicable	Not applicable	
Viscosity	OECD 114	Deltamethrin CIK Aerosol Filling Solution Batch 27-05-2013 Deltamethrin 0.0349%	$1.304 \text{ mm}^2 \text{ s}^{-1}$ at 20.10°C $0.9999 \text{ mm}^2 \text{ s}^{-1}$ at 40.00°C	Foster B. (2014)

Conclusion on the physical, chemical and technical properties of the product

IMPORTANT NOTE: the applicant has submitted the statement ensuring that all batches used in the dossier have the same composition as the formulation to be marketed.

Odour

Odour was not determined directly due to health and safety considerations, however any strong, characteristic odour that was noted whilst handling the test substance was recorded.

Acidity / Alkalinity

The product does not contain any water and as such it will not be possible to measure the solvated hydrogen ion (pH). The product is "ready-to-use" and will not be diluted prior to use. It is contained in a self-pressurised container for indoor use. No testing is therefore considered for this type of product.

Relative density/bulk density

The relative density of Bulk DETRANS CIK (aerosol filling solution) was determined by a liquid density meter method. The procedure conformed to EC Directive 92/69/EEC Method A3. **Storage stability test – low temperature stability test for liquids**

Not required due to storage conditions instruction (Protect from frost)

Wettability

Detrans® Deltamethrin CIK is not be diluted prior to use, therefore this test is not required. The product is in a ready-to-use form.

Suspensibility, spontaneity and dispersion stability

Detrans® Deltamethrin CIK is not be diluted prior to use, therefore this test is not required. The product is in a ready-to-use form.

Wet sieve analysis and dry sieve test

Detrans® Deltamethrin CIK is not a WP, granule or a tablet, therefore this test does not apply.

Emulsifiability, re-emulsifiability and emulsion stability

Detrans® Deltamethrin CIK is not an EC or ready-to-use emulsion, therefore this test is not required.

Disintegration time

Detrans® Deltamethrin CIK is not a tablet therefore this test is not required.

Content of dust/fines, attrition, friability

Attrition, friability: Detrans® Deltamethrin CIK is not a granule or a tablet therefore this

test does not apply.

Persistence of foaming

Detrans® Deltamethrin CIK will not be diluted with water before use. This test is therefore not required.

Flowability/Pourability/ Dustability

Detrans® Deltamethrin CIK is not a granule or a suspension, therefore this test is not required. Detrans® Deltamethrin CIK is not a dusty powder therefore this test is not required.

Compatibility with other products

Detrans® Deltamethrin CIK is not to be used with other products, as specified on the label. There is, therefore, no requirement to assess any potential interaction.

Surface tension

A test for surface tension is not required as Detrans® Deltamethrin CIK contains the active substance Deltamethrin which has a water solubility of <1 mg/L (5 µg/L at 20°C) (Refer to OECD Guideline 115).

Viscosity

The viscosity of the test substance was measured by the conventional capillary method described in OECD 114, using a commercially available Ubbelohde viscometer. This was immersed in a thermostatic water bath set at the appropriate temperature. The viscosity was measured at nominally 20°C and 40°C.

Conclusion

The formulation was found to be a clear/colourless/transparent free-flowing liquid with a kerosene like odour. The density was 0.7694 g/cm³ and viscosity was 1.304 mm² s⁻¹ at 20.1°C.

The formulation was shown to be stable after accelerated storage at 45 ± 3°C for 3 months and 50°C ± 2°C for 6 months with the discharge rate from the aerosol consistent over the 3 and 6 month storage periods, respectively. Long term storage stability studies at 38 ± 2°C for 36 months and 25 ± 2°C for 36 months also showed the formulation to be stable, with the aerosol discharge rates consistent over both 36 month storage periods.

The spray pattern, residual percentage after complete spray off and nozzle function was also tested in the accelerated storage stability study conducted at 45 ± 3°C for 3 months and found to be acceptable.

2.2.3. Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Explosive properties			Product possesses no explosive potential	
Oxidising properties			Product does not have the potential to act as a strong oxidizing or reducing agent.	
Flammable aerosols			The product is classified in Category 1 because the formulation contains $\geq 85\%$ flammable components.	
Flash point	EC Method A9 (Flash point)	Deltamethrin CIK Aerosol Filling Solution Batch 27-05-2013 Deltamethrin 0.0349%	Flash point: 39.7°C	Foster B. (2014)
Corrosive to metals	The requirements of the UK Pesticide Safety Directorate for Storage Stability. Visual assessment	Deltamethrin CIK Aerosol Pack (TF2787) AE F032640 00 AE01 B3	No signs of corrosion or degradation determined by visual assessment initially and then after storage at 50 °C for 1, 3 and 6 months.	Lumsden A.M. (2000)
Auto-ignition	ASTM-E-659-78 EC Method A15 (Autoflammability)	Deltamethrin CIK Aerosol Filling Solution Batch 27-05-2013 Deltamethrin 0.0349%	Autoflammability: 229°C \pm 2°C at 99.02 kPa	Foster B. (2014)
Other indications of flammability				

Conclusion on the physical hazards and respective characteristics of the product

Explosive properties

An assessment of the explosive potential for each of the components in the product has been conducted. None of the components in the product present an explosion risk and therefore no further testing is considered necessary.

Oxidising properties

An assessment of the oxygen balance of the product has been conducted and indicates that the product does not have the potential to act as a strong oxidizing or reducing agent.

It is therefore considered unnecessary to perform a test using EC method A17.

From a paper by Shanley E.S and Meljem G.A. (Process Safety Progress, Volume 14, Issue 1, pages 29–31, January 1995) more than -240 indicates a low hazard ranking.

Flash-point and other indications of flammability or spontaneous ignition

The product does not contain any water and will not come into contact with water as it is contained in a self-pressurized container. It is therefore considered unnecessary to perform a test according to EC method A12.

Moreover, a test to determine the flash-point is technically not feasible due to the content of propellants. Furthermore, due to the fact that the product is a pressurized aerosol it should not be kept at temperatures above 50°C (noted on the label), and auto-flammability is hereby not an issue and no data for that parameter is therefore also not considered required.

Conclusion

It can be concluded that Detrans® Deltamethrin CIK is a flammable aerosol product containing $\geq 95\%$ flammable components, therefore the biocidal product is classified as H222 Extremely flammable aerosol and included in Category 1 (danger).

2.2.4. Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Active Substance: Deltamethrin content in CIK	HPLC with UV detection	100, 250, 500 µg/mL n = 5	9 conc. $r^2 = 0.999645$ Linearity range: 1-100 µg/mL	The detrans CIK Deltamethrin Free Solution solvent was free of any components that interfered with the analysis of deltamethrin. The method was therefore considered specific for deltamethrin. Chromatograms of diluting solvent and detrans CIK deltamethrin free solution are included in the study.	100.6 – 106.0	104.3	Precision (% RSD) = 1.058-1.894 Overall RSD = 1.36	Not Applicable	Foster B. (2014)
<i>coformulants</i>									

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Deltamethrin (Höfchen)	LC-MS/MS (1 transition) External calibration relative to internal standard (isotopically labelled deltamethrin)	0.1 µg/kg 1.0 µg/kg n = 5	0.03 to 10 µg/kg $r^2 = > 0.999$ for all soils	Highly specific. No interference shown	89-98	95	3.8	0.1 µg/kg	C. A. R. (2011)
98-102					101	1.5			
Deltamethrin (Laacher Hof)					83-99	91	7.7		
Deltamethrin (Sediment)					101-105	103	1.7		
					94-108	102	5.2		
					98-103	101	2.1		

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Deltamethrin (air, 36°C, 90% RH)	Quantification: GC-ECD Confirmation: GC-MS (253, 181, 172 m/z)	0.27 µg/m ³ 2.7 µg/m ³ n = 5	Lower end: 0.018 µg/m ³ (the upper end is 0.10 µg/mL and the Concentration of the higher fortified)	No interference shown. There are indications that GC-methods cannot distinguish	96-104 89-100	100 94	4 4	0.27 µg/m ³	C. A. R. (2011)

			sample is adjusted to be within this range) $r^2 = > 0.99$ (quadratic curve)	between tralomethrin and deltamethrin (see blood-method below)					
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Analytical methods for water									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Deltamethrin (drinking water)	LC-MS/MS (1 transition) External calibration relative to internal standard (isotopically labelled deltamethrin)	0.0059 µg/L 0.059 µg/L n = 5	0.004 to 118.1 mg/L $r^2 = 0.9990$	Highly specific. No interference shown	90-109 (n=10) 98-104	100 100	5.7 1.8	5.9 ng/L	C. A. R. (2011)
Deltamethrin (drinking water)	Quantification: GC-ECD (matrix matched standards) Confirmation: GC-ECD (different stationary)	0.05 µg/L 0.50 µg/L n = 5	2.5 to 50 µg/L r/r^2 : Not reported (quadratic curve)	No interference shown. There are indications that GC-methods cannot	108-1393 98-120 ⁷	1154 982	11 8	0.05 µg/L	C. A. R. (2011)

³ Uncorrected recovery range

⁴ Mean recovery corrected by matrix matched standards

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
	phase)			distinguish between tralomethrin and deltamethrin (see blood-method below)					
Deltamethrin (drinking and surface water)	Quantification: GC-ECD Confirmation: GC-MS/MS (1 transition)	0.003 µg/L 0.03 µg/L n = 5	0.1 to 100 µg/L $r^2 = > 0.99$ (quadratic curve)	No interference shown. There are indications that GC-methods cannot distinguish between tralomethrin and deltamethrin (see blood-method below)	65-71 62-74 (n=8)	68 67	3 7	3 ng/L	C. A. R. (2011)

Analytical methods for animal and human body fluids and tissues									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Deltamethrin (milk)	Quantification: GC-ECD Confirmation: GC-ECD (different column)	0.02 mg/kg 0.2 mg/kg n = 6	2.5-25 pg/ μ L (i.e. 50% of LOQ to 500% of LOQ)	No interferences shown. (independently validated for milk and fat). There are indications that GC-methods cannot distinguish between tralomethrin and deltamethrin (see blood-method below)	94-103	97	4	0.02 mg/kg	C. A. R. (2011)
94-115					105	7			
81-98					87	8			
102-108					105	3			
95-99					97	2			
Deltamethrin (eggs)					94-107	100	5		
Deltamethrin (meat)					77-91	85	6		
Deltamethrin (fat)					80-105	91	9		
Deltamethrin (liver)					85-93	88	4		
					99-121	109	7		

Analytical methods for animal and human body fluids and tissues									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Deltamethrin (kidney)					94-134 106-135	105 119	14 8		
Deltamethrin (whole blood)	GC-MS (m/z 253 used in the validation) Quantification based on peak height relative to the peak height for the known amount of internal standard. Confirmation possible, with full scan down to 1000 ng/L or by using the method presented below.	Primary validation: 100 µg/L 200 µg/L 500 µg/L 1000 µg/L 2000 µg/L (n = 5)	200-4000 µg/L $r^2 = 0.99774$ (curve not used for quantification)	No interference shown. The method could not distinguish between tralomethrin and deltamethrin due to decomposition of tralomethrin into deltamethrin in the injector.	Not reported	101 88 100 79 83	10 8 16 6 4	200 µg/L	C. A. R. (2011)
		ILV-study: 101 µg/L 202 µg/L 1008 µg/L (n=5)			65-82 81-87 77-91	76 82 83	8.6 3.4 6.6		
Deltamethrin (whole blood)	GC-MS (m/z 137 used in the validation) Quantification using the ratio of the peak area for deltamethrin to the peak	20-100 ng/L n=6	20-500 ng/L	No interference shown. There are indications that GC-methods cannot distinguish between	94-99	Not stated	2.4-3.7	20 ng/L	C. A. R. (2011)

Analytical methods for animal and human body fluids and tissues									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
	area of the internal standard			tralomethrin and deltamethrin (see blood-method above)					

Analytical methods for monitoring of active substances and residues in food and feed stuff									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Deltamethrin (rice)	GC-ECD Confirmation could be performed using the method below	0.02 mg/kg (n=4) 0.10 mg/kg (n=3)	0.005 to 0.05 ng injected on column (LOQ corresponds to 0.02 ng injected; the concentration of the higher fortification level is adjusted to fit into the calibration range)	hown. There are indications that GC-methods Cannot distinguish between tralomethrin and deltamethrin (see blood-method above)	71-111 80-88	91 85	18 5.1	0.02 mg/kg	C. A. R. (2011)
Deltamethrin (flour)		0.02 mg/kg (n=4) 0.10 mg/kg (n=3)			69-114 93-107	89 99	21.2 7.3		
Deltamethrin (bread)		0.02 mg/kg (n=6) 0.10 mg/kg (n=3)			95-119 101-107	106 104	8.2 2.9		
Deltamethrin (meat)		0.02 mg/kg (n=6) 0.10 mg/kg (n=3)			93-120 67-87	103 78	10.1 13		
Deltamethrin (candy)		0.02 mg/kg (n=4) 0.10 mg/kg (n=3)			106-120 97	112 110	5.6 10.3		

Analytical methods for monitoring of active substances and residues in food and feed stuff									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
					118				
Deltamethrin (butter)		0.02 mg/kg (n=6) 0.10 mg/kg (n=3)			74-124 78-99	97 95	19.3 17.1		
Deltamethrin (banana cream pie)		0.02 mg/kg (n=4) 0.10 mg/kg (n=3)			85-99 88-98	92 92	6.3 5.5		
Deltamethrin (lettuce)		0.02 mg/kg (n=3) 0.10 mg/kg (n=3)			73-84 86-91	79 89	7.2 2.8		
Deltamethrin (barley grain)	LC-MS/MS (1 transition) using SCX (S), GPC (G) or acetonitrile/hexane partitioning (olive fruit) for clean-up. Quantification using nonmatrix matched standards and the ratio of the peak area for	0.01 (G) (n=5) 0.1 (G) (n=5)	Tested for: wheat grain (0.5 µg-0.2 mg/kg). wheat rest plant (2.5 µg-1 mg/kg) wheat straw (5 µg-1 mg/kg) tobacco (2.5 µg-1 mg/kg) olive fruit (1 µg-0.2 mg/kg) r ² =0.9994 -	Highly specific. No interference shown	82-89 80-84	86 83	3.1 2.0	0.01 mg/kg for edible materials 0.05 for nonedible materials	
Deltamethrin (barley ear)		0.05 (G) (n=5) 0.5 (G) (n=5)			84-91 87 91	88 89	3.3 1.8		
Deltamethrin (barley rest plant)		0.05 (S) (n=5) 0.5 (S) (n=10)			89-102 88-94	97 91	5.1 2.8		
Deltamethrin (barley straw)		0.05 (G) (n=10) 0.5 (G) (n=5)			80-92 81-84	85 83	3.5 1.3		

Analytical methods for monitoring of active substances and residues in food and feed stuff									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Deltamethrin (broccoli curd)	deltamethrin to the peak area of the internal standard (isotopically labelled deltamethrin)	0.01 (S) (n=5) 0.1 (S) (n=5)	0.9999		89-95	92	3.1		
					76-91	86	8.5		
Deltamethrin (corn cob without husks)		0.01 (G) (n=5) 0.1 (G) (n=5)			82-85	84	1.7		
					81-83	82	1.2		
Deltamethrin (corn kernel)		0.01 (G) (n=5) 0.1 (G) (n=5)			81-87	84	3.3		
					80-85	83	2.5		
Deltamethrin (corn plant without roots)		0.05 (G) (n=5) 0.5 (G) (n=5)			77-88	85	5.4		
					86-89	88	1.3		
Deltamethrin (lettuce head)		0.01 (S) (n=5) 0.1 (S) (n=5)			89-98	94	3.8		
					89-91	90	0.9		
Deltamethrin (melon fruit)	0.01 (S) (n=10) 0.1 (S) (n=5)	80-96	87	6.5					
		80-89	85	3.4					
Deltamethrin (melon pulp)	0.01 (S) (n=5) 0.1 (S) (n=5)	85-93	90	3.4					
		84-91	88	3.1					
Deltamethrin (olive fruit)	0.01 (n=5) 0.1 (n=5)	74-76	75	1.5					
		66-80	71	8.2					

Analytical methods for monitoring of active substances and residues in food and feed stuff									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Deltamethrin (pepper fruit)		0.01 (S) (n=5)			79-83	81	1.8		
		0.1 (S) (n=5)			79-81	80	1.1		
Deltamethrin (sugar beet leaf with root collar)		0.05 (S) (n=5)			87-95	91	3.1		
		0.5 (S) (n=5)			83-88	85	2.8		
Deltamethrin (sugar beet body)		0.01 (S) (n=5)			82-92	86	4.6		
		0.1 (S) (n=5)			82-87	85	2.5		
Deltamethrin (tobacco leaf green)		0.05 (S) (n=7)			85-96	92	4.3		
		0.5 (S) (n=5)			92-98	95	2.5		
Deltamethrin (tobacco leaf cured)		0.05 (G) (n=5)			81-87	84	3.4		
		0.5 (G) (n=5)			79-82	80	1.8		
Deltamethrin (tomato fruit)		0.01 (S) (n=5)			87-95	91	3.9		
		0.1 (S) (n=5)			85-91	88	2.8		
Deltamethrin (wheat grain)		0.01 (G) (n=5)			81-85	83	1.9		
		0.1 (G) (n=5)			82-87	85	2.4		
Deltamethrin (wheat ear)		0.05 (G) (n=5)			80-84	82	1.8		
		0.5 (G) (n=5)			77-81	79	2.1		

Analytical methods for monitoring of active substances and residues in food and feed stuff									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Deltamethrin (wheat rest plant)		0.05 (S) (n=5)			74-88	80	6.6		
		0.5 (S) (n=5)			85-95	92	4.3		
Deltamethrin (wheat straw)		0.05 (G) (n=5)			80-85	82	2.5		
		0.5 (G) (n=5)			78-82	81	1.9		
Deltamethrin (zucchini fruit)	0.01 (S) (n=5)	87-94	90	4.4					
	0.1 (S) (n=7)	81-92	85	4.6					

Conclusion on the methods for detection and identification of the product

A method for the measurement of the content of deltamethrin in the formulation is available.

The applicant has showed that they have access rights to the analytical methods studies contained in the CAR. The LoA has been submitted. Therefore, validated analytical methods are also available for the determination of Deltamethrin in soil, water, air, food and feed stuffs matrices.

2.2.5. Efficacy against target organisms

2.2.5.1. Function and field of use

Detrans® CIK is an insecticide (PT18) containing 0.02% of Deltamethrin.

The product is for use indoors by general public (non-professional users). The product is for use in domestic, public and commercial premises.

The intended use submitted by the applicant was indoor use by spraying onto insects or onto non-porous surfaces for cracks and crevices/spot application (treatment as chemical barrier and in 'cracks & crevices').

Indoor use in areas where crawling insects may enter the home such as the inside surfaces of window and door frames and other areas.

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

Detrans® CIK is a ready-to-use aerosol spray intended to be used in domestic settings by consumers for the control of crawling insects such as German cockroaches (*Blattella germanica*), American cockroaches (*Periplaneta americana*) and garden black ants (*Lasius niger*) for the maintenance of human hygiene.

2.2.5.3. Effects on target organisms, including unacceptable suffering

Deltamethrin has a potent shock effect, acting by neurotoxic knockdown by blocking the transmission of nerve impulses. Detrans® CIK works by exerting a knockdown effect and mortality after direct spray onto insects (direct activity) and by contact with treated surfaces (including residual activity).

After contact with the product, insects will be knocked down from the first minutes until 2 hours later and will be killed after 2 hours of application and up to 3 days later.

2.2.5.4. Mode of action, including time delay

Deltamethrin is a pyrethroid insecticide which acts on nerve membranes by delaying the closing of the activation gate for the sodium ion channel thus interfering with normal nerve functioning.

This produces several effects:

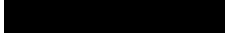

- A knockdown effect (paralysis).

Deltamethrin acts on the nervous system of the insect and leads to paralysis of the insect.

-A killing effect or "Kill" (mortality).


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

2.2.5.5. Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
Insecticide, direct application	Indoors/outdoors	Detrans® Deltamethrin CIK (0.02% Deltamethrin)	Black ants (<i>Lasius niger</i>) Oriental cockroaches (<i>Blatta orientalis</i>)	Non-standard own protocol	Laboratory study, 3 repl. treated and non-treated, 10-15 ants and 5 cockroaches Direct application by spraying. 2 seconds of spray. Av.measured <i>B. orientalis</i> 1.34g; <i>L. niger</i> 1g	<i>Lasius niger</i> : KDT95 = 2.6 min, 100% D after 24h. <i>B. orientalis</i> : KDT95 >20 min, 100% D after 24h.	 IUCLID/Sec. 6.7/Endpoint#001 Only supporting information
Insecticide, direct and residual application	Indoors/outdoors	Detrans® Deltamethrin CIK (0.02% Deltamethrin)	Black ants (<i>L. niger</i>) American cockroaches (<i>P. americana</i>), German cockroaches (<i>B. germanica</i>) Note: data on cat fleas not included, since App. withdrew fleas from claims.	Non-standard own protocol	Simulated use trial, 4 repl. treated and non-treated, 20 animals in direct, 50 ants and 20 cockroaches in residual Nominal doses: Direct use: 4g/spot (arena 0.56m ²). Residual use on ceramic (non-porous) or wood (porous) tiles: 7	<i>Lasius niger</i> : -Direct (2g): acceptable, 100% D after 2-4h; 100% KD after 30 min - Residual: non-porous(14g/m ²), acceptable up to 3 m ageing; 100% D after 24h; 97% KD after 2h. In porous (10 g/m ²), non-acceptable. 52% KD after 2 h;	 IUCLID/Sec. 6.7/Endpoint#006

					<p>seconds/m² (14 g/m²). (sprayed in half arena 0.28 m² (choice test with no harbourages).⁵. Ageing period 1 d and 1, 2, 3 m.</p> <p>In residual, continuous exposure up to 72h</p>	<p>up to 91%D after 24h.</p> <p>- Controls: 1d 6%, 1m 14%, 2m 4.5% and 3m 9%.</p> <p><i>P. americana</i>: -Direct(7g): acceptable 100% D after 24h; 100% KD after 30 min- Residual: non-porous (12 g/m²), acceptable up to 3 m ageing. 100%KD after 2h; 89%D after 72h.. In porous (11g/m²), not acceptable; up to 77% KD after 4h; up to 45%D after 72h. - Controls: 1d 4.16%, 1m 0.83%, 2m 5.83% and 3m 3.33%.</p> <p><i>B. germanica</i>: -Direct (3g) : acceptable; 100% D after 24h;</p>	
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⁵ Application rates mentioned here are the nominal values; measured values were different. Assessment of efficacy was based on measured values as indicated in section 3.5. In the table the maximum rates used and the corresponding results obtained are shown.

						<p>100% KD after 30 min</p> <p>- Residual: non-porous(13g/m²), acceptable up to 3 m ageing; 100% KD after 2h; 100%D after 48h. In porous (10g/m²), not acceptable; 28%KD after 2h; 36%D after 72h.</p> <p>- Controls: 1d 4.99%, 1m 8.33%, 2m 4.165% and 3m 13.33%.</p>	
Insecticide, residual application	Indoors/outdoors	Detrans CIK (0.02% Deltamethrin, different formulation)	American cockroaches (<i>P. americana</i>) German cockroaches (<i>B. germanica</i>)	Non-standard own protocol	Laboratory study, no-choice, 3 repl. treated, no controls, 10 German and 5 American cockroaches Exposure in plates with ceramic/plywood surface (size not reported).In ceramic tiles 0.5 sec., in wood: 2.5 sec. Ageing period 1, 8, 15, 22 and 29 days.	<p><i>P. americana</i>:</p> <p>- non-porous acceptable up to 8d ageing; 87% D after 24h; 87% KD after 30 min.</p> <p>- porous, not acceptable ; 0% D after 24h; 0% KD after 25 min.</p> <p><i>B. germanica</i>:</p> <p>- non-porous acceptable up to 29d ageing ; 100% D after 24h; 100% KD after 10 min.</p>	<p></p> <p>IUCLID/Sec. 6.7/Endpoint#003</p> <p>Only supporting information</p>

					Exposure time 30 min	- porous, not acceptable; 4% D after 1-6 d; 0% KD after 25 min	
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Conclusion on the efficacy of the product

Considering all the information available the eCA concludes the following:

- Efficacy against *Periplaneta americana*:

In both direct and residual applications of Detrans® Deltamethrin CIK on porous surfaces, efficacy was not sufficiently demonstrated.

In non-porous surfaces, efficacy after direct application was acceptable with at least 7 g of Detrans® Deltamethrin CIK (3-4 seconds of spray); residual efficacy was acceptable up to 3 months after spraying with at least 12 g/m² (6-7 seconds of spray).

Knockdown can take up to 30 min and up to 2 h in direct and residual use, respectively. Cockroaches will be killed in 24 h and 72 h in direct and residual use, respectively. Residual efficacy is accepted up to 3 months of ageing.

- Efficacy against *Blattella germanica*:

In direct application of at least 3 g (2 seconds) of Detrans® Deltamethrin CIK onto animals walking on porous surfaces, efficacy was not sufficiently demonstrated. However in non-porous surfaces, efficacy was demonstrated.

Residual efficacy in porous surfaces was not sufficient. In non-porous surfaces, efficacy was acceptable up to 3 months of ageing with doses of at least 11-13 g/m² (6-7 seconds).

Knockdown can take up to 30 min and up to 2 h in direct and residual use, respectively. Cockroaches will be killed in 24-48 h and 48 h in direct and residual use, respectively. Residual efficacy is accepted up to 3 months of ageing.

- Efficacy against *Lasius niger*:

In direct application onto ants of at least 2 g (1 second) of Detrans® Deltamethrin CIK, efficacy was sufficiently demonstrated.

In residual application on non-porous surfaces, efficacy was demonstrated with 10-14 g/m² (5-7 seconds of spray) up to 3 months of ageing. On porous surfaces, efficacy was proved up to 2 months of ageing 10-14 g/m².

Knockdown can take up to 30 min and up to 2 h in direct and residual use, respectively. Ants will be killed in 2 h and 24 h in direct and residual use, respectively. Residual efficacy is accepted up to 3 months of ageing.

Conclusion

Since the doses applied during the tests were very variable, the eCA considered the maximum amount of product actually used to assess whether required results were fulfilled. However, given that the intended use is for general public, the species tested are representative for a general claim (i.e. crawling insects) and the authorised dose should be efficacious for every crawling insect.

Detrans®CIK has demonstrated efficacy in direct use on visible insects and residual use through contact with treated surfaces, the eCA proposes to use only one application rate for direct use and another one for application on surface with residual effect which would warrant efficacy of the product against different crawling insects.

A restriction of the use of Detrans® Deltamethrin CIK to non-porous surfaces is justified, because on porous surfaces the product did not demonstrate the efficacy required for consumers according to the Guidance requirements.

Therefore in order to obtain sufficient efficacy, the eCA accepts the following doses:

- 8 g/spot (4 seconds of spray) for direct use onto crawling insects (i.e. application on targeted spots)
- 14 g/m² (7 sec/m²) for residual use against crawling insects on non-porous surfaces (i.e. application on cracks and crevices and as barrier treatment).

Residual efficacy is acceptable up to 3 months after application of the product on non-porous surfaces.

Since two key species of cockroaches (one small, one large) and one common ant species were tested and efficacy was demonstrated, the label claim for 'crawling insects' may be authorised.

Nevertheless, given that the environmental and human health risk assessment has been unacceptable risk for direct application (targeted spots), the use for this product will be: Application on cracks and crevices including inside of window and door frames being the application rate: 14 g/m² (7 sec/m²) against crawling insects on non-porous surfaces (on cracks and crevices and inside of windows and doors frames as barrier treatment).

During the commenting phase was agreed that for the renewal of this product a simulated used with a specific design in crack and crevice application should be submitted.

2.2.5.6. Occurrence of resistance and resistance management

The applicant has provided the following justification about the potential occurrence of resistance of the product:

'Pyrethroid resistance is known to occur and measures, such as those detailed below, are known to be effective in reducing the occurrence of resistance. There were no instances of resistance observed during the efficacy trials conducted and summarised within this dossier.

The principle strategies for managing the development of resistance are as follows:

- where possible, application treatments should be recommended to be combined with non-chemical measures
- products should always be used in accordance with label recommendations
- complete elimination of insect pests should be attempted in infested areas
- applications should always be made against the most susceptible stages in the pest life cycle
- where an extended period of control is required, treatments should be alternated with products with different modes of action
- levels of effectiveness should be monitored, and instances of reduced effectiveness should be investigated for possible evidence of resistance.'

The eCA accepts the strategies provided by the applicant. However in the literature additional information is available.

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

As a consequence, the authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.2.5.7. Known limitations

On porous surfaces (e.g. wood, concrete, plaster) Detrans® Deltamethrin CIK did not demonstrate the efficacy required for consumers.

2.2.5.8. Evaluation of the label claims

Efficacy data submitted supports the use of Detrans® Deltamethrin CIK (0.02% Deltamethrin) indoors against crawling insects (e.g. cockroaches, ants, etc.) by non professional users (general public).

Detrans® Deltamethrin CIK produces knock down and mortality of crawling insects.

Application on cracks and crevices including inside of window and door frames being the application rate: 14 g/m² (7 sec/m²) against crawling insects on non-porous surfaces (on cracks and crevices and inside of windows and doors frames as barrier treatment). Residual efficacy can last up to 3 months after application

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

Detrans® Deltamethrin CIK is not intended to be used with other biocidal products.

2.2.6. Risk assessment for human health


The oral and dermal acute toxicology studies, the eye and skin irritation studies and the skin sensitisation study were conducted with the product TF2786 (0.03% w/w Deltamethrin) which is also taken as the starting material (filling solution" in the production of the final aerosol . The co-formulant ingredients contained in Detrans® Deltamethrin CIK (TF2787) are essentially the same as the ingredients contained in TF2786 with the exception that Detrans® Deltamethrin CIK contains a propellant and contains one of the same solvents at a higher percentage. So, the applicant proposes to read-across from the results of these studies to the product Detrans® Deltamethrin CIK claiming that 'TF 2786 may be considered a worst case with respect to the higher concentrations of deltamethrin and the co-formulant of concern to human health'.

The CA considers that the identity of co-formulants provided is sufficient to establish the equivalence between formulations, so read-across of toxicology studies can be carried out.

2.2.6.1. Assessment of effects on Human Health

The CA accept this justification for no submission of data considering that the equivalence of the co-formulant of concern in both formulations is provided.


Skin corrosion and irritation

Summary table of animal studies on acute dermal irritation/ corrosion					
Method, Guideline, GLP status, Reliability	Species, Strain, Sex, No/group	Test substance, Vehicle, Dose levels, Duration of exposure	Results <i>Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings</i>	Remarks <i>(e.g. major deviations)</i>	Reference
Acute Dermal Irritation Study in the Rabbit OECD (404) GLP yes Reliable	Rabbit New Zealand White 6 female/1 group	Deltamethrin Aerosol CIK Filling solution (TF 2786) undiluted 0.5 ml 4 hr	Erythema The average score was 0.39 Edema The average score was 0 Very slight erythema was present in 4 of the 6 animals commencing one hour post dose in 1 animal and 24 hours post dose in 3 animals. This condition had resolved by 72 h in 3 animals and by 96 h in the remaining animal	Test substance contains 0.03%w/w Deltamethrin Identity of the coformulants was provided. Doc. IIB2.2 (IUCLID Section 13 attachment:- IIB2.2- Confidential Updated Jan 2017)	

			Reversibility yes		
			Not irritating		

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	In this study CIK Filling Solution TF 2786 Deltamethrin 0.033% w/w, does not meet the criteria for classification for dermal irritation
Justification for the value/conclusion	Study report IIIB6.2(S)
Classification of the product according to CLP and DSD	Not classified

Eye irritation

Summary table of animal studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	Species, Strain, Sex, No/group	Test substance, Dose levels, Duration of exposure	Results <i>Average score (24, 48, 72h)/ observations and time point of onset, reversibility</i>	Remarks <i>(e.g. major deviations)</i>	Reference
Acute Eye Irritation Study in the rabbit OECD (405) GLP yes Reliable	Rabbit New Zealand White, 6 Female/1 group	CIK Filling Solution TF 2786 Deltamethrin (TF2786) undiluted, 0.1mL 4 days	<p>Cornea The average score 0 and 0 at all timepoints</p> <p>Iris The average score 0 in 24, 48 and 72h 2/6 rabbits had a score of 1 at 30 min after dosing only.</p> <p>Redness Conjunctiva The average score was 0 in 24, 48 and 72h All animals showed transient redness and discharge (maximum score 1) at 30 and/or 60 min after dosing.</p> <p>Chemosis The average score 0 and 0 at all timepoints; Slight, reversible irritation observed but insufficient to merit classification</p> <p>Reversibility Yes, none of the findings recorded was present at 24h.</p>	Test substance contains 0.03%w/w Deltamethrin in Identity of the coformulants was provided. Doc. IIIB2.2 (IUCLID Section 13 attachment :- IIIB2.2- Confidential Updated Jan 2017	

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	In this study CIK Filling Solution TF 2786 Deltamethrin 0.033% w/w, does not meet the criteria for classification for ocular irritation
Justification for the value/conclusion	Study report IIIB6.2(E)
Classification of the product according to CLP and DSD	Not classified

Respiratory tract irritation

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	No study is presented
Classification of the product according to CLP and DSD	It is considered that Detrans® Deltamethrin CIK does not meet the criteria for respiratory tract irritation classification for according to Directive 67/548/EEC (as amended) or Regulation (EC) No 1272/2008 (as amended).

Skin sensitization

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	Species, Strain, Sex, No/group	Test substance, Vehicle, Dose levels, duration of exposure Route of exposure	Results <i>(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)</i>	Remarks <i>(e.g. major deviations)</i>	Reference
Guinea pig modified Buehler test OECD (406), GLP yes Reliable	Guinea Pig Dunkin/Hartley albino Male 10 control group/ 20 test group	Aerosol CIK Filling solution undiluted topical induction 0.5 ml (days 1, 8 & 15); Day 29 topical challenge w. 0.5 ml TF 2786, 50% v/v in Alembicol D	0/20 test animals at the 24-hour and 48-hour scoring intervals	Test substance contains 0.03%w/w Deltamethrin Identity of the coformulants was provided. Doc. IIIB2.2 (IUCLID Section 13 attachment:- IIIB2.2- Confidential Updated Jan 2017	IIIB6.3 Johnson, I.R. (1997)

Conclusion used in Risk Assessment – Skin sensitisation
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Value/conclusion	Under the conditions of this test, Aerosol CIK Filling solution TF 2786 (0.033% w/w deltamethrin) was not a skin sensitiser.
Justification for the value/conclusion	Study report IIIB6.3
Classification of the product according to CLP and DSD	Not classified.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory Sensitization	
Value/conclusion	No study is presented
Classification of the product according to CLP and DSD	It is considered that Detrans® Deltamethrin CIK does not meet the criteria for respiratory sensitization classification for according to Directive 67/548/EEC (as amended) or Regulation (EC) No 1272/2008 (as amended).

Acute toxicity

Acute toxicity by oral route

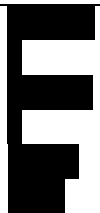
Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	Species, Strain, Sex, No/group	Test substance Dose levelsType of administrati on	Signs of toxicity (nature, onset, duration, severity, reversibility)	Value LD50	Remarks (e.g. major deviations)	Reference
Acute Oral Toxicity Study in Rats OECD (401) GLP yes Reliable	Sprague Dawley rats, CRL:CD(SD)B R; 5♂ and 5♀ in the control and treated group	Deltamethrin Aerosol CIK Filling Solution (TF2786); 5000 mg/kg bw, gavage, single exposure	Body soiling was seen in all treated animals at around 5 hours after dosing with recovery within 3 days except for 1 male that recovered within 6 days of dosing.	>5000 mg/kg bw	Test substance contains 0.033%w/w Deltamethrin Identity of the coformulants was provided. Doc. IIIB2.2 (IUCLID Section 13 attachment:- IIIB2.2- Confidential Updated Jan 2017	

Value used in the Risk Assessment – Acute oral toxicity

Value	>5000 mg/kg bw
Justification for the selected value	Study report IIIB6.1.1
Classification of the product according to CLP and DSD	In this study Deltamethrin Aerosol CIK Filling Solution (TF2786) does not meet the criteria for classification for acute oral toxicity.

Data waiving	
Information requirement	Identification of co-formulants in Deltamethrin Aerosol CIK Filling Solution (TF2786) and Detrans® Deltamethrin CIK
Justification	The applicant proposes to read-across from the results of this study to the product Detrans® Deltamethrin CIK (0.02% w/w) The CA accept this justification for no submission of data considering that the equivalence of the co-formulant of concern in both formulations is provided.

Acute toxicity by inhalation

Summary table of animal studies on acute inhalation toxicity						
Method, Guideline, GLP status, Reliability	Species, Strain, Sex, No/group	Test substance, form (gas, vapour, dust, mist) and particle size (MMAD) Actual and nominal concentration, Type of administration (nose only / whole body/ head only)	Signs of toxicity (nature, onset, duration, severity, reversibility)	LC50	Remarks (e.g. major deviations)	Reference
Acute Inhalation Toxicity Study in the Rat None specified GLP Yes Reliability 0	Sprague Dawley rats CRL:CD(SD)BR; 5♂ and 5♀ Female nulliparous and non-pregnant, 7-8 weeks, 2 groups (divided according to sex)	Aerosol CIK 0.02%w/w Deltamethrin (TF2787) released from spray can: test substance form and MMAD unknown; Actual conc. 0.178 µg/L deltamethrin in the chamber atmosphere; nominal conc. 261 mg/l. MMAD 6.3 µm in the chamber atmosphere; Snout-only	Mean food consumption was reduced for one day following exposure. Water intake was increased in treated females on Day I post exposure. No mortalities, no clinical signs of toxicity no effect on bodyweight,	> 0.89 mg/L*	Test substance contains 0.02%w/w Deltamethrin; *The value 0.89 mg/L of the formulation in the chamber atmosphere is estimated, total formulation is not measured, (co-formulants represent >99%w/w of	


		exposure chambers; Duration of exposure = 4h; 14 days observation period.	lung weight to bodyweight ratios unaffected, no macroscopic abnormalities observed at necropsy		the biocidal product and are/might be classified for toxicity via inhalation) Mass median aerodynamic diameter (MMAD) of the gas/vapour or aerosol droplets from the representative product Detrans® Deltamethrin CIK is unknown (previous characterisation of the test article is required to design the experiment properly)	
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Value used in the Risk Assessment – Acute inhalation toxicity	
Value	Not applicable
Justification for the selected value	<p>The study flaws according to OECD TG 403, 2009, are:</p> <p>Test product contains 0.02%w/w Deltamethrin;</p> <p>The study report sets a LC₅₀ value >0.89 mg/L of the formulation in the chamber atmosphere. This value is estimated from the measurement of a.i. in the chamber (0.178 ug/L) taking into account that the amount of a.s. in the product is 0.02%w/w. However, it is an estimated value not confirmed by the measurement of the total content of the formulation in the chamber.</p> <p>In addition, the nominal concentration (mass of generated test article divided by the total volume of air passed through the chamber system) is estimated as 261 mg/L: there is a great unexplained difference compared to the estimated amount of the formulation in the chamber.</p> <p>The study report concludes that 'Approximately 56% of the active ingredient, Deltamethrin, was associated with droplets of respirable size (<7µm aerodynamic diameter)' we disagree for the following reasons:</p> <p>According to the study report, the aerosol generation system was designed to produce and maintain the maximum attainable concentration of droplets <7µm removing larger droplets by an elutriator. It must be noted that the particle distribution of the test product is unknown, hence the formulation removed by the elutriator</p>

	<p>that does not reach the chamber is not identified.</p> <p>The toxicity of the test vehicle is not reported: data demonstrating that the vehicle does not interfere with the outcome of the study is lacking.</p> <p>The content of the formulation in the chamber atmosphere is not characterised/measured.</p> <p>The particle size distribution should be determined at least twice during the 4 hour exposure and a confirmatory method to demonstrate the collection efficiency of the primary instrument should be used in parallel. None of these requirements are met in this study.</p> <p>Particle size distribution and geometric standard deviation (σ_g), their methods of calculation and individual particle size analyses are not provided.</p>
Classification of the product according to CLP and DSD	It is considered that Detrans® Deltamethrin CIK does not meet the criteria for classification for acute inhalation toxicity according to Regulation (EC) No 1272/2008 (as amended).

Data waiving	
Information requirement	Data waiving is accepted: the inhalation toxicity study will not be used for classification purposes.
Justification	There is one co-formulant classified as aspiration toxicity cat. 1 which is present at c.a. 60%w/w and considered a substance of concern. This component is present in both formulations TF2786 and Detrans® Deltamethrin CIK.

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	Species, strain, Sex, No/group	Test substance, Vehicle, Dose levels, Surface area	Signs of toxicity (nature, onset, duration, severity, reversibility)	LD50	Remarks (e.g. major deviations)	Reference
Acute Dermal Toxicity Study in the Rat OECD (402), GLP yes, Reliable	Sprague Dawley rats CRL:CD(SD) BR; 5♂ and 5♀ in the control and treated group	Deltamethrin Aerosol CIK Filling Solution (TF2786); 5000 mg/kg bw single exposure, 6x10cm ²	A slight reduction in body weight gain in comparison to controls was noted in animals treated at	>5000 mg/ kg bw	Test substance contains 0.033%w/w Deltamethrin, Identity of the	

		area	5000 mg/kg, between study days 1 and 8.		coformulants was provided. Doc. IIB2.2 (IUCLID Section 13 attachment :- IIB2.2- Confidential Updated Jan 2017	
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Value used in the Risk Assessment – Acute dermal toxicity	
Value	>5000 mg/kg bw
Justification for the selected value	Study report IIB6.1.2
Classification of the product according to CLP and DSD	Deltamethrin Aerosol CIK Filling Solution (TF2786) does not meet the criteria for classification for acute dermal toxicity.

Data waiving	
Information requirement	Identification of co-formulants in Deltamethrin Aerosol CIK Filling Solution (TF2786) and Detrans® Deltamethrin CIK
Justification	The applicant proposes to read-across from the results of this study to the product Detrans® Deltamethrin CIK (0.02% w/w). The CA accept this justification for no submission of data considering that the equivalence of the co-formulant of concern in both formulations is provided..

Information on dermal absorption

No dermal absorption studies have been performed with Detrans® Deltamethrin CIK.

The applicant proposes the use of 2.0% as the dermal absorption value based on the studies submitted for Annex I inclusion. Dermal penetration studies reported within the active substance dossier were conducted in vitro in rats with deltamethrin as an oil/water emulsion (EW) and as an emulsifiable concentrate (EC) in rat and human skin and in an in vivo study in rats. Tested concentrations varied from 25 g/l to 0.12 g/l. Based on those results the figure of the EC formulation of 2% for dermal absorption as worst case was established.

The CA does not consider appropriate the use of these studies to establish the dermal absorption of the formulation Detrans® Deltamethrin CIK. The formulation under consideration here is not an emulsifiable concentrate but a liquid solution with no water in it ('oil based aerosol').

This equivalence is not demonstrated for Detrans® Deltamethrin CIK; hence, the use of a dermal absorption value of 2% is not supported.

Taking into account that according to the EFSA dermal absorption guidance 2012, a 10% value for dermal absorption may be applied because Deltamethrin has a MWt >500 amu (actual = 505.2 amu) and a log Pow >4 (actual = 4.6).

So a default value of 10% is used for exposure and risk assessment.

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Detrans® Deltamethrin CIK 0.02% w/w	Detrans® Deltamethrin CIK 0.02% w/w
Value(s)	10% Primary exposure	10% Secondary exposure
Justification for the selected value(s)	EFSA Guidance on Dermal Absorption; EFSA Journal 2012;10(4):2665	EFSA Guidance on Dermal Absorption; EFSA Journal 2012;10(4):2665

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

See confidential annex.

Available toxicological data relating to a mixture

See confidential annex.

Endocrine disruption

Assessment of the ED properties of the active substances:

The biocidal product contains only one active substance. Assessment report of Deltamethrin indicate "As part of the evaluation of the application for the inclusion of Deltamethrin in Annex I of the Biocidal Products Directive (98/8/EC), toxicology data were assessed and it was concluded that there was no evidence of endocrine disruption effects from these studies".

Assessment of the ED properties of non-active substances (co-formulants):

After reviewing the potential ED properties of co-formulants (please refer to the Confidential Annex), none of them are subject to an on-going evaluation or a decision regarding their ED properties. Based on the available information, ES CA considers that there is no concern regarding the ED properties of these co-formulants.

Overall conclusion on the biocidal product regarding ED properties:

Based on the existing knowledge and the Deltamethrin assessment report data provided , there is no indication of concern regarding the ED properties of the substances used in the biocidal product DETRANS ® DELTAMEHRIN CIK

If one or several components are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

Other

See confidential annex.

2.2.6.2. Exposure assessment

Detrans® Deltamethrin CIK is an insecticide containing 0.02% w/w Deltamethrin. The product is a ready-to-use aerosol spray for cracks and crevices/direct application onto visible insects-targeted spot application/ Inside non-porous surfaces of window & door frames treatment intended for use by the general public.

For the exposure assessment, the application on non-porous indoor surfaces of window or door frames is considered part of the application in cracks and crevices due to the small surfaces to be treated.

Spray can be used directly on visible insect pests. Spray directly at insect or onto surface for up to 2 seconds. The product can be applied as a surface/barrier treatment or applied in cracks and crevices suspected of harbouring crawling insect pests. Spray directly onto surface for 5 to 7 seconds spray per m². Repeat as necessary. Do not direct the spray up into the air. Vacate room and keep door closed for 15 minutes after application. Ventilate before re-entry. Spray inside non-porous surfaces of window & door frames and other areas where crawling insects may enter the home.

The technical specifications of the spray can are not provided. The data should include the spray pattern and the amount of spray delivered with each operation among others, which are essential to estimate the exposure of consumers. Hence, in absence of 'product-specific data' the human exposure is estimated using the default scenario in RIVM ConsExpo Web, version 1.0.3, 09-02-2018: Pest Control Products /Sprays /Crack & Crevice /Application (spray can) (the calculation is similar for targeted spot treatment).

Indirect exposure should be minimal following use of the product in accordance with the label conditions. An assessment has, however, been conducted to determine the worst case potential exposure to an infant following use of the ready-to-use product.

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 ¹	Professional use ²	Non-professional use	Industrial use ¹	Professional use ²	General public	Via food
Inhalation	n.a.	n.a.	Yes	n.a.	n.a.	Yes	No
Dermal	n.a.	n.a.	Yes	n.a.	n.a.	Yes	No
Oral	n.a.	n.a.	Yes	n.a.	n.a.	Yes	No

n.a. = not applicable;

¹ Deltamethrin and the biocidal product are produced in the EU. The exposure during the production of the active substance and the formulation of the biocidal product are not assessed by the CA under the requirements of the BPR. However, the CA assumes that the production is performed in conformity with national and European occupational safety and health regulations.

² The product is intended for non-professional uses.

List of scenarios

Summary table: scenarios			
Scenario number	Scenario	Primary or secondary exposure Description of scenario	Exposed group
1.	Non-professional application of spray	Primary exposure: application of ready-to-use aerosol spray for cracks and crevices/targeted spot treatment	Non-professionals
2.	Infant crawling on treated floor	Secondary exposure: infant crawling on treated surface and hand to mouth contact after cracks and crevices treatment	Bystanders (child)

Industrial exposure

Deltamethrin and the biocidal product are produced in the EU. The exposure during the production of the active substance and the formulation of the biocidal product are not assessed by the CA under the requirements of the BPR. However, the CA assumes that the production is performed in conformity with national and European occupational safety and health regulations.

Trained-professional and Professional exposure

No exposure is foreseen. The product is intended only for non-professional uses.

Non-professional exposure (General public)

Scenario [1] application of spray by non-professional

Description of Scenario [1]
<p>Detrans® Deltamethrin CIK is a ready-to-use aerosol spray containing 0.02% w/w Deltamethrin for cracks and crevices/targeted spot treatment against crawling insects, intended for use by the general public.</p> <p>The default scenario in ConsExpo Web, version 1.0.3, 09-02-2018: Pest Control Products /Sprays /Crack & Crevice /Application (spray can) is used to estimate the exposure to the consumer (the calculation is similar for targeted spot treatment).</p> <p>The inhalation exposure 'spray' model and the dermal exposure model 'constant rate' from ConsExpo Web are used to describe the scenario. The oral exposure is handled in the inhalation exposure model. ConsExpo assumes that the non-respirable fraction is taken in orally. Hence exposure via dermal, oral and inhalation route is expected.</p> <p>Other default parameters can be found in RIVM report 320005002/2006 Pest Control Products Fact Sheet and RIVM, March 2010. New default values for the spray model.</p> <p>The model assumes that the product is used 9 times a year maximum. Exposure on the day of application is estimated below (acute exposure is considered).</p> <p>.</p>

	Parameters	Value
Tier 1	Deltamethrin amount	0.02% w/w
	Dermal absorption ¹	10%
	Exposed body surface area ²	8,300 cm ²
	Contact rate ³	100 mg/min
	Oral absorption ⁴	75%
	Inhalation absorption	100%
	Density of non-volatile ⁵	0.769 g/cm ³
	Weight fraction non-volatile ³	0.2
	Airborne fraction ⁶	0.2
	Spray duration ³	4 min
	Mass generation rate ⁵	0.55 g/sec
	Initial particle size distribution [μ m] P ₅₀ (C.V.) ⁵	3.6 (0.57)
	Use frequency ³	9 days/year
	Body weight ⁷	60 kg

¹ Guidance on Dermal Absorption, EFSA Journal 2012;10(4):2665.

² Half of total adult body surface area in HEEG Opinion 17.

³ RIVM report 320005002/2006, pest control fact sheet.

⁴ CAR Deltamethrin.

⁵ Experimental value. Physical/chemical properties for the Biocidal product.

⁵ RIVM, March 2010. New default values for the spray model.

⁶ HEEG Opinion 17.

Calculations for Scenario [1]

Summary table: systemic exposure from non-professional uses as [mg/kg bw]					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [1]	Tier 1 /no PPE	5.2×10^{-3} mg/kg bw/day	1.3×10^{-4} mg/kg bw/day	1.5×10^{-6} mg/kg bw/day	5.3×10^{-3} mg/kg bw/day

Further information and considerations on scenario [1]

The most critical parameters that determine consumer's exposure are the emitted amount of material per second and the particle size distribution of the emitted material. This information is not available for Detrans® Deltamethrin CIK.

The exposure assessment presented here is done using the default values set in RIVM's reports which considers that the spray can is applied during 4 minutes, but the time during which spraying actually takes place is set at 60 seconds with a mass generation rate of 2.2 g/sec. Also, the scenario considers that this product is applied in a 20m³ room (8m² floor surface and 2.5m height).

The spray model from ConsExpo assumes that the more volatile components such as propellants evaporate from the aerosols immediately after the spray has been used. If the spray model is used for propellants substances the inhalation exposure will be underestimated, because exposure to vapour is not considered in the spray model.

Hence, the exposure of consumers to the volatile propellant (40% w/w), is not included in the assessment presented here.

Combined scenarios

Not applicable

Exposure of the general public

Scenario [2] Infant crawling on treated floor

Description of Scenario [2]

The scenario considers the oral and dermal exposure of children after the application of Detrans® Deltamethrin CIK (containing 0.02% Deltamethrin). The exposure after application is described for crawling children who are present in the room after a cracks and crevices/targeted spot treatment has been carried out. It is assumed that an infant (6 to 12 months) crawls over the treated surface for 1 hour a day. Exposure is modelled using the dermal exposure model 'rubbing off' and the oral exposure model 'constant rate' from ConsExpo Web.

By multiplying the mass generation rate and the spray duration, the total amount of sprayed formulation can be calculated (240 sec x 0.55 g/sec = 132 g). The scenario assumes that this amount is sprayed towards the floor. It is assumed that 85% of the total amount sprayed (0.85 x 132 = 112.2 g) ends up on the floor surface, and that of this amount, 30% is dislodgeable, i.e., it can be brushed away (default for cracks and crevices treatment with spray can, RIVM Report 320005002) (0.3 x 112.2 = 33.64 g). The surface is 2 m² (see rubbed surface below). The dislodgeable amount is calculated at 33.64/2 = 16.83 g/m².

The transfer coefficient (the surface that is wiped per unit time due to skin contact, TC) is 0.21 m²/hr. That means an infant would take 16.83g/m² x 0.21 m²/h = 3.53g/h on his skin.

Dermal exposure of children can take place on any uncovered skin, that is, on the head, the arms and hands, and on the legs and feet. The ingestion rate is calculated based on the assumption that from the total dermal exposure, 10% is taken in orally due to hand-to-mouth contact.

Taking into account 90% of this amount is taken dermally and 10% of this amount is taken orally due to hand-mouth contact, if you introduce 16.86g/m² as dislodgeable amount in ConsExpo, calculations are made using 3.53g/h as dermal load, which means 100% is entering dermally to the organism.

That is the reason value of 15.15 g/m² (90% of 16.63) is used for ConsExpo calculations.

For exposure assessment purposes chronic exposure is considered (i.e., exposure is not averaged over a year).

For a Tier 2 in exposure assessment, US EPA Residential SOPs criteria, which propose a dislodgeable amount of 6% instead of 30% from RIVM Report 320005002, have been followed.

	Parameters	Value
Tier 1	Content in a.s.	0.02%
	Dislodgeable amount ¹	(30%) 16.83 g/m ²
	Transfer coefficient ²	0.21 m ² /hr
	Dermal rate	3.18g/h

	Ingestion rate	0.353 g/h
	Exposed body area ³	2410.8 cm ²
	Body weight ³	8 kg
	dermal absorption ⁴	10%
	oral uptake ⁵	75%
	Rubbed floor surface ¹	2m ²
	Duration of exposure	1hr/day
Tier 2	Dislodgeable amount ⁵	(6%) 3.366 g/m ²
	Dermal rate	0.636 g/h
	Ingestion rate	0.071 g/h

¹ RIVM Report 320005002.

² Recommendation of Ad hoc Working Group on Human Exposure New default values for indoor Transfer Coefficient WGV2016_TOX_7-2b_Indoor TC

³ Default area of hands, head, arms, legs and feet and body weight for infant 6 to 12 months old in Ad hoc Working Group on Human Exposure, Recommendation No 14

⁴ Guidance on Dermal Absorption, EFSA Journal 2012;10(4):2665

⁵ CAR

⁶ US EPA Residential SOPs, October 2012 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide#sops>

Calculations for Scenario [2]

Summary table: systemic exposure for infant crawling on treated floor					
Exposure scenario	Tier/PPE	Estimated inhalation uptake	Estimated dermal uptake	Estimated oral uptake	Estimated total uptake
Scenario [2]	Tier 1/ 30% dislodgeability	-	8.0 × 10 ⁻³ mg/kg bw/day	6.6 × 10 ⁻³ mg/kg bw/day	1.5 × 10 ⁻² mg/kg bw/day
Scenario [2]	Tier 2/ 6% dislodgeability	-	1.6 × 10 ⁻³ mg/kg bw/day	1.3 × 10 ⁻³ mg/kg bw/day	2.9 × 10 ⁻³ mg/kg bw/day

Further information and considerations on scenario [2]

none

Monitoring data

none

Dietary exposure

The biocidal product is applied directly on localized spots in cracks and crevices. It is unlikely that there could be transference of residues to food. In addition, the label must include restrictions or instructions of use so that food contamination is precluded.

Conclusion

Dietary risk does not have to be further considered.

The following label restriction precludes food contamination: 'Keep away from foodstuff, eating utensils or food contact surfaces'.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses			
	Sector of use	Intended use	Reference value(s)
1.	Plant protection product	insecticide	MRL ^{1,2}
2.	Veterinary use	Antiparasitic agent/ Agent against ectoparasites	MRL ³

¹ Regulation (EU) No 396/2005. Other modifications: → Commission Regulation (EU) No 524/2011 of 26 May 2011 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for biphenyl, deltamethrin, ethofumesate, isopyrazam, propiconazole, pymetrozine, pyrimethanil and tebuconazole in or on certain products. OJ L 142, 28.5.2011, p. 1-56; → Commission Regulation (EU) No 441/2012 of 24 May 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, bifenthrin, boscalid, cadusafos, chlorantraniliprole, chlorothalonil, clothianidin, cyproconazole, deltamethrin, dicamba, difenoconazole, dinocap, etoxazole, fenpyroximate, flubendiamide, fludioxonil, glyphosate, metalaxyl-M, meptyldinocap, novaluron, thiamethoxam, and triazophos in or on certain products. OJ L 135, 25.5.2012, p. 4-56.

² Review of the existing maximum residue levels for deltamethrin according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(11):4309.

³ Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. OJ L 15, 20.1.2010, p. 1-72.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

The biocidal product is applied directly on localized spots difficult to access. It is unlikely that there could be transference of residues to feed. In addition, the product should be placed in spots inaccessible to animals; hence, exposure of livestock to residues of the biocidal product is not expected.

Conclusion

Livestock exposure does not have to be further considered. The label must include restrictions or instructions of use to avoid exposure of animals or contamination of feed stuff.

The following label restrictions preclude livestock exposure:

- The treatment must be restricted to areas out of reach of animals
- Keep away from feed stuff or feed contact surfaces.

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

Not applicable. The product is intended for non-professional uses.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

The biocidal product is applied directly on localized spots difficult to access. It is unlikely that there could be transference of residues to food. In addition, the label must include restrictions or instructions of use so that food contamination is precluded.

Conclusion

Dietary risk does not have to be further considered.

The following label restriction precludes food contamination:

'Keep away from foodstuff, eating utensils or food contact surfaces'.

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

Deltamethrin and the biocidal product are produced in the EU. The exposure during the production of the active substance and the formulation of the biocidal product are not assessed by the rapporteur under the requirements of the BPR. However, the rapporteur assumes that the production is performed in conformity with national and European occupational safety and health regulations.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	Exposed group (e.g. professionals, non-professionals, bystanders)	Tier/PPE	Estimated total uptake
1.	Non-professionals	Tier 1/ no PPE	5.3×10^{-3} mg/kg bw/day
2.	Infant	Tier 1/ 30% dislodgeability	1.5×10^{-2} mg/kg bw/day
2.	Infant	Tier 2/ 6% dislodgeability	2.9×10^{-3} mg/kg bw/day

2.2.6.3. Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF ¹	Correction for oral absorption	Value
AELshort-term	13-week dog study	1 mg/kg bw/day	100	75%	0.0075 mg/kg bw/day
AELmedium-term	13-week and 1-year dog studies	1 mg/kg bw/day	100	75%	0.0075 mg/kg bw/day
AELlong-term	1-year dog study	1 mg/kg bw/day	100	75%	0.0075 mg/kg bw/day
ARfD ²	-	-	-	-	-
ADI ²	-	-	-	-	-

¹ CAR.

² Setting of an ARfD is not considered necessary since no exposure of foodstuffs should occur when product label instructions are followed, and risk of contamination of drinking water is not considered.

³ Setting of an ADI is not considered necessary since no exposure of foodstuffs should occur during and after treatment of food handling areas with deltamethrin, when product label instructions are followed.

Maximum residue limits or equivalent

Uses	Reference	MRLs /Relevant commodities	Residue definition
Plant protection: Insecticide	Regulation (EC) No 396/2005	See ^{1, 2}	Deltamethrin
Veterinary: Antiparasitic agent/ Agent against ectoparasites	Regulation (EU) No 37/2010	See ³	Deltamethrin

¹ Commission Regulation (EU) No 524/2011; Commission Regulation (EU) No 441/2012.

² EFSA Journal 2015;13(11):4309.

³ Commission Regulation (EU) No 37/2010.

Risk for industrial users

Not applicable.

Risk for professional users

Not applicable.

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)
Application / scenario 1	Tier 1	1	0.0075	5.3×10^{-3}	70.7	yes

Local effects

Not applicable

Conclusion

This exposure assessment shows that no risk is envisaged for the use of Detrans® CIK by consumers.

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)
Post application, Infant crawling /[2]	Tier 1	1	0.0075	1.5×10^{-2}	200	no
Post application, Infant crawling /[2]	Tier 2	1	0.0075	2.9×10^{-3}	38.7	yes

Local effects

Not applicable.

Conclusion

The conclusion is that given the scenario above for the secondary exposure to infants, a theoretical risk may be identified as unacceptable level of exposure is reached in Tier 1 (30% of dislodgeable amount from RIVM Report 320005002 criteria), but not in Tier 2 (6% of dislodgeable amount from US EPA Residential SOPs criteria).

Taking into account this conclusion, that the product does not contain any deterrent agent and applying the precautionary principle, the following phrase will be included on the label as a risk management measure:

- For use only in areas that are inaccessible to children.

Risk for consumers via residues in food

No risk is envisaged.

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

The solvent used in the product is Exxsol D80 which is also known as "odourless kerosene" or "Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics" IUPAC name. ES CA considers it a substance of concern (SoC) for human health since it provides classification to the formulated, H304, although according with the CLP regulation (Regulation (EC) No 1272/2008), Article 23(c) and Section 1.3.3, it not labelled.

BPR requires that a risk assessment is performed for all active substances and SoCs in a biocidal product, but paragraph 4 of AnnexVI indicates that qualitative rather than quantitative risk assessments may be performed where a quantitative one cannot be produced.

According to Guidance on BPR: Volume III Parts B+C; Annex A: Substances of Concern – Proposed Human Health (Toxicology) Assessment Scheme for Authorisation of Biocidal Products, Version 4.0 December 2017, a banding evaluation scheme for SoC has been carrying out, finding that “Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics” is assigned to Band A, which means that appropriate risk mitigation measures, in the form of the precautionary (P)-statements normally associated with the concerned hazard (H)-statements under the CLP Regulation, should be applied.

However, in our case, the product is dispensed in a self-pressurized pump sprayer with non-removable valve that generate a fine aerosol. That means a product pool can not be formed in the mouth to be aspirated which is key to classifying this product with H304 (CLP regulation (Regulation (EC) No 1272/2008; Annex I, section 3.10.1.6.3 Clasificacion of aerosol/mist products).

Then, As there is no aspiration hazard we can consider “Hydrocarbons, C11-C14, n-alkanes, isoalkanes, cyclics, <2% aromatics” not to be a substance of concern and no risk assessment for SoC is required.

2.2.7. Risk assessment for animal health

A scenario is presented here where companion animal comes into contact with the applied product after spray application and ingests the residue licking the treated surface. This is a short-term oral exposure scenario.

The amount sprayed on the floor is estimated below using the scenario from ConsExpo: 85% of the total amount sprayed ends up on 2m² of the floor.

$$[0.85 * 0.55\text{g/sec} * 4 \text{ min} * 60 \text{ sec/min}] / 2\text{m}^2 = 112.2 \text{ g prod/m}^2$$

It is assumed that the companion animals consume the entire product applied in 1m² floor surface (112.2 g product). As an extreme worst case, the amount ingested of active substance assuming 100% extraction by saliva and 75% oral absorption, considering the content in active substance (0.02% w/w) is estimated as:

$$0.02\% * 75\% * 112.2 \text{ g prod/ pet bw,}$$

$$\text{Oral absorbed a.s.} = 16.83 \text{ mg deltamethrin}$$

Systemic exposure for a kitten (body weight assumed to be 0.5 kg), and a puppy (bodyweight assumed to be 5 kg) would be as follows. To assess risk no assessment factor is considered.

Scenario/ pet licking 1m ² surface	Estimated uptake mg/kg bw	Systemic NOAEL mg/kg bw	Estimated uptake/ NOAEL (%)	Acceptable yes/no
kitten	33.66	1	3366	no
puppy	3.366	1	336	no

Reverse reference scenario

Likewise, it can be calculated that to achieve the NOAEL of 1 mg/kg bw/day, a companion animal would need to ingest the following amounts of Deltamethrin (mg):

$$(\text{NOAEL (mg/kg/d)} * \text{pet bodyweight (kg)}) \div (\text{fraction oral absorption (0.75)}).$$

As the spray contains 0.02% w/w Deltamethrin, the amount of product an individual would need to ingest to reach the NOAEL would be:

$(\text{NOAEL (mg/kg/d)} \times \text{pet bodyweight (kg)}) \div (\text{fraction oral absorption (0.75)}) \times (\text{fraction of Deltamethrin in the product (0.0002)})$

Companion animal	Body weight (kg)	NOAEL mg/kg /d	amount of Deltamethrin ingested to achieve the NOAEL (mg)	Equivalent amount of product (g)
kitten	0.5	1	0.66	3.3
puppy	5	1	6.66	33.3

The conclusion is that given the scenarios above for the secondary exposure to companion animals, a theoretical risk may be identified specially for kittens that require less amount of product to reach unacceptable levels of exposure.

Taking into account this conclusion and that the product does not contain a deterrent agent, the following phrase will be included on the label as a risk management measure:

- For use only in areas that are inaccessible to companion animals.

In summary, to avoid possible risks for children, for consumers via diet or for animals, the following risk mitigation measures are proposed:

- For use only in areas inaccessible to children and animals.
- Do not allow children or animals access to treated surfaces.
- Keep away from food/feed stuff, eating utensils or food/feed contact surfaces.
- Remove food/feed stuff prior to teatment.
- Do not apply directly to surfaces on which food/feed is stored, prepared or eaten.

2.2.8. Risk assessment for the environment

The product contains only one active substance and no other substances of concern for the environment at the levels contained in the formulated product. Therefore all toxicity data can be obtained from the Competent Authority Report: Sweden, May 2011 of deltamethrin.

2.2.8.1. Effects assessment on the environment

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

Given that the only component of the product that is classified in relation to its potential to cause adverse effects in the environment is the active substance, at the levels contained in the formulated product, it is considered that this assessment need not address other components of the formulation. From studies conducted using the active substance and described in detail in the Competent Authority Report: Sweden, May 2011, the following environmental characteristics were established.

Abiotic degradation

The hydrolysis of Deltamethrin was shown to be insignificant at pH 5 and 7.

Biodegradation

Deltamethrin was not readily biodegradable in laboratory tests. In aquatic environments, Deltamethrin partitions rapidly into the sediment, suspended organic matter and biota. In water/sediment systems, the degradation DT₅₀ was estimated at 45/141 days in two different systems and the dissipation DT₅₀ in sediment at 55/133 days in two different systems at 20°C. In soil the DT₅₀ was 31-74 days at 12 °C, with a geometric mean of 48 days. The mean DT₅₀ of the major metabolite of Deltamethrin, Br₂CA, has been calculated to be 2.0 days.

Distribution

The K_{oc} for Deltamethrin ranges from 204000 to 577000 with a mean value of 408250. The metabolites are more mobile with a K_{oc} of 25.6 for Br₂CA and 115 for mPBacid.

Accumulation

The bioaccumulation of ¹⁴C-deltamethrin was investigated in bluegill sunfish (*Lepomis macrochirus*) and calculated bioconcentration factors (BCF) of 310, 2800 and 1400 as total ¹⁴C for edible, non-edible and whole body tissue were determined. After the 14-day depuration period 70, 75 and 76% of the ¹⁴C residues had been eliminated from the edible, non-edible and whole body tissue, respectively. The biological half-life was 4.3 days for whole body tissue.

Environmental metabolites

The metabolite Br₂CA was detected in soil but was not considered to be significant for exposure and risk assessment as the DT₅₀ is considerably shorter than Deltamethrin which represents the worst case, 2.0 days versus 48 days, respectively.

Predicted No Effect Concentrations (PNECs) for Deltamethrin, extracted from Competent Authority Report: Sweden, May 2011

PNEC	Value
PNEC _{STP}	0.030 mg/l
PNEC _{freshwater}	0.0000007 mg/l (7.0E-07 mg/l; 0.7 ng/l)
PNEC _{sediment,freshwater}	0.0062 mg/kg wwt
PNEC _{soil}	0.075 mg/kg wwt

Further Ecotoxicological studies

No further ecotoxicological studies are available for Detrans® Deltamethrin CIK.

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

No further studies on fate and behaviour in the environment are available for Detrans® Deltamethrin CIK.

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)

Detrans® Deltamethrin CIK will be used outside around the home. It is intended to be applied on "outside surfaces of window & door frames, and other areas where crawling insects may enter the home", as specified on the product label. The receiving compartment for the use of a ready-to-use insecticidal spray for outdoor spot application is primarily the soil and when used according to the label information on overspray behaviour is not required.

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

The routes of entry into the environment are discussed and considered in section 2.2.8.2.

Endocrine disruption

As part of the evaluation of the application for the inclusion of Deltamethrin in Annex I of the Biocidal Products Directive (98/8/EC), toxicology and ecotoxicology data were assessed and it was concluded that there was no evidence of endocrine disruption effects from these studies. Taking into account that the Deltamethrin concentrations of the representative biocides of CAR vary from 25% to 0.05%, and Detrans® Deltamethrin CIK has a concentration of 0.02%, it could be concluded that the use of the product does not cause endocrine disruption effects due to the presence of Deltamethrin as active substance.

2.2.8.2. Exposure assessment

General information

Detrans® Deltamethrin CIK may be applied by spraying with an aerosol dispenser. The product was initially intended to be authorised for use indoors and outdoors.

The following types of applications were considered in the emission scenarios:

Scenario 1.- Spraying in cracks and crevices, indoors.

This application can be considered similar to the standard scenario of surface treatment on targeted spots, represented by applications on cracks and crevices. The envisaged area of use is 2 m² (representing the area of cracks and crevices only in wet areas in a house, i.e. kitchen and bathroom). The default value of cleaning efficiency after application in cracks and crevices (i.e. $F_{CE} = 0.03$) is accepted for areas not accessible for cleaning. However due to the use of a self-pressurised aerosol dispenser by a consumer at a distance of 30 cm, it is expected that part of the product ends up in an area outside the cracks and crevices. Therefore the cleaning efficiency factor should be adapted to reflect the use pattern of Detrans® Deltamethrin CIK. It was considered that the cleaning efficiency factor for surface treatment reflects better this difference in the use pattern, hence $F_{CE} = 0.2$ was finally used in this scenario.

The authorised dose is 14 g prod./m², equivalent to 7 seconds of spray per square metre, assuming a discharge rate of 2 g prod/second.

Scenario 2.- Spraying on the inside surfaces of windows and doors frames, indoors.

This application can be considered similar to the standard scenario of surface treatment on bands (barrier treatment). The envisaged area (corrected to reflect only wet areas, i.e. kitchen and bathroom) is 5.9 m². Due to the use of a self-pressurised aerosol dispenser, the cleaning efficiency should be similar to that of general surface application (i.e. $F_{CE} = 0.2$).

The authorised dose is 14 g prod./m², equivalent to 7 seconds of spray per square metre, assuming a discharge rate of 2 g prod/second.

3.- Spray as perimeter treatment around a house, outdoors.

This application can be considered similar to the standard scenario of perimeter treatment around a house. The envisaged area is 25 m² for the application on the foundation and 26 m² for the application on the adjacent soil.

The authorised dose is 7 seconds of spray per square metre, equivalent to 14 g prod./ m², assuming a discharge rate of 2 g prod/second.

In the following, the scenarios as presented by the Applicant were revised by the eCA and proposed changes were included. Please note that during the evaluation, the Applicant asked the eCA to include additional scenarios. The eCA included in the PAR these additional scenarios in separate tables shaded in blue. The tables in Annex 3.2.2 come from the Applicant version.

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Indoor Spray application Scenario 2: Outdoor spray application
ESD(s) used	Emission Scenario Document for Product Type 18: Emission Scenario Document (ESD) for Insecticides, acaricides and products to control other arthropods for household and professional uses" (17th July 08)
Approach	Scenario 1: Average consumption Scenario 2: Average consumption
Distribution in the environment	Calculated based on TGD 2003 for indoor and outdoor use with distribution following release to waste water (indoor use) modelled with EUSES v. 2.1.2.
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Scenarios 1 & 2: Production: No Formulation No Use: Yes Service life: No
Remarks	

ESCA has decided to include a new scenario for the indoor use for the Detrans® Deltamethrin CIK to be applied on "inside surfaces of window & door frames and other areas where crawling insects may enter the home".

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Indoor Spray application, crack and crevices Scenario 2: Indoor Spray application, windows & doors frames Scenario 3: Outdoor spray application, windows & doors frames
ESD(s) used	Emission Scenario Document for Product Type 18: Emission Scenario Document (ESD) for Insecticides, acaricides and products to control other arthropods for household and professional uses" (17th July 08)
Approach	Scenario 1: Average consumption Scenario 2: Average consumption Scenario 3: Average consumption
Distribution in the environment	Calculated based on TGD 2003 for indoor and outdoor use with distribution following release to waste water (indoor use) modelled with EUSES v. 2.1.2.
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Scenarios 1, 2 & 3: Production: No Formulation No

	Use: Yes Service life: No
Remarks	

Emission estimation

Scenario 1 Crack and Crevice and Targeted Spot Use. Indoors

Based on the report compiled by the OECD Task Force on Biocides, entitled, "Emission Scenario Document (ESD) for Insecticides, acaricides and products to control other arthropods for household and professional uses" (17th July 08), the receiving compartments for the use of a ready-to-use insecticidal spray for indoor application are as follows:

Table 2.2.8.2.1: Receiving Compartments Following Indoor Application

Step	"Intermediate" receiving compartments	"Final" receiving compartments
Mixing loading step ¹	Not applicable	Not applicable
Application step	Indoor air Floor Applicator Treated surfaces	Outdoor air STP (surface water) (agricultural soil/groundwater)
Cleaning step	Indoor air Waste water Wastes	Outdoor air STP (surface water) (agricultural soil/groundwater) (sediment)

¹. The formulation is ready-to-use and therefore there is no mixing and loading step.

Cracks and Crevices Use Indoors

The scenario representing applications in cracks & crevices in a private house considers an area of 2 m² to be treated.

Detrans® Deltamethrin CIK Application Rates

Application rate Detrans® Deltamethrin CIK (kg/m ²)	0.014
Application rate Deltamethrin (kg/m ²)	4.20E-06
conc active ingredient in product (%w/w)	0.02

The following emissions were determined to occur during the application phase.

Application Step

Variable/parameter (units)	Symbol	Unit	Crack & Crevice/ Targeted Spot House
Emission to air during application step	E _{application, air}	kg/d	1.12E-07

$E_{\text{application, air}} = N_{\text{appl, building}} \times F_{\text{application, air}} \times Q_{\text{prod}} \times F_{\text{AI}} \times \text{AREA}_{\text{treated}}$			
Emission to applicator during application step	$E_{\text{application, applicator}}$	kg/d	2.24E-08
$E_{\text{application, applicator}} = N_{\text{appl, building}} \times F_{\text{application, applicator}} \times Q_{\text{prod}} \times F_{\text{AI}} \times \text{AREA}_{\text{treated}}$			
Emission to floor during application step	$E_{\text{application, floor}}$	kg/d	7.06E-07
$E_{\text{application, floor}} = N_{\text{appl, building}} \times F_{\text{application, floor}} \times Q_{\text{prod}} \times F_{\text{AI}} \times \text{AREA}_{\text{treated}}$			
Emission to treated surface during application step	$E_{\text{application, treated}}$	kg/d	4.76E-06
$E_{\text{application, treated}} = Q_{\text{prod}} \times F_{\text{AI}} \times N_{\text{application, building}} \times F_{\text{application, treated}} \times \text{AREA}_{\text{treated}}$			

Cleaning

The following emissions were determined to occur during the cleaning phase.

Cleaning step - First Case: Emission to solid wastes during the cleaning step

Variable/parameter (units)	Symbol	Unit	Crack & Crevice/ Targeted Spot House
Emission from applicator to solid waste during the cleaning step	$E_{\text{applicator, w}}$	kg/d	2.24E-08
$E_{\text{applicator, w}} = (E_{\text{prep, applicator}} + E_{\text{application, applicator}}) \times F_{\text{applicator, w}}$			
Emission from floor/treated surface to solid waste during the cleaning step	$E_{\text{treated, w}}$	kg/d	1.09E-06
$E_{\text{treated, w}} = (E_{\text{prep, floor}} + E_{\text{application, floor}} + E_{\text{application, treated}}) \times F_w \times F_{\text{CE}}$			

FCE = Based on a cleaning efficiency of 20%, ESD PT18 Table 3.3-8 (RTU Aerosol-surface treatment)

Cleaning step - Second case: Releases to waste water

Variable/parameter (units)	Symbol	Unit	Crack & Crevice/ Targeted Spot House
Emission from applicator to waste water during the cleaning step	$E_{\text{applicator, ww}}$	kg/d	2.24E-08
$E_{\text{applicator, ww}} = (E_{\text{prep, applicator}} + E_{\text{application, applicator}}) \times F_{\text{applicator, ww}}$			
Emission from floor/treated surface to waste water during cleaning step	$E_{\text{treated, ww}}$	kg/d	1.09E-06
$E_{\text{treated, ww}} = (E_{\text{prep, floor}} + E_{\text{application, floor}} + E_{\text{applicatin, treated}}) \times F_{\text{ww}} \times F_{\text{CE}}$			
Total ($E_{\text{treated, ww}}$)			1.12E-06
Simultaneity factor (3 to 11 times per year)	$F_{\text{simultaneit}}$ v		0.0081
Number of houses	$N_{\text{buildings}}$	-	4000
Output			
Local emission to waste water during episode	$E_{\text{local, ww}}$	kg/d	3.64E-05
$E_{\text{local, ww}} = E_{\text{total, ww}} \times N_{\text{house}} (4000) \times \text{Simultaneity factor}$			

FCE = Based on a cleaning efficiency of 20%, ESD PT18 Table 3.3-8 (RTU Aerosol-surface treatment).

Calculations for Scenario 1 are included in Annex 3.2.

ESCA: We agree with the calculations performed for the indoor use in crack and crevices. Following the commenting round, the exposure estimations of this scenario were revised. The new values were included in the PAR with tracked changes.

Scenario 2 Windows & doors frames Use - Indoors

The receiving compartments are the same as for the scenario 1:

Table 2.2.8.2.2: Receiving Compartments Following Indoor Application

Step	“Intermediate” receiving compartments	“Final” receiving compartments
Mixing loading step ¹	Not applicable	Not applicable
Application step	Indoor air Floor Applicator Treated surfaces	Outdoor air STP (surface water) (agricultural soil/groundwater)
Cleaning step	Indoor air Waste water Wastes	Outdoor air STP (surface water) (agricultural soil/groundwater) (sediment)

^{1.} The formulation is ready-to-use and therefore there is no mixing and loading step.

Window & door frames Use Indoors

ESCA considers that for a domestic house, window and door frames applications are considered as a barrier treatment, so as is it stated at TAB-ENV v.2.0 (August 2018) the default treat area must be of 5.9 m².

Detrans® Deltamethrin CIK Application Rates

Application rate Detrans® Deltamethrin CIK (kg/m ²)	0.014
Application rate Deltamethrin (kg/m ²)	2.84E-06
Conc. active ingredient in product (%w/w)	0.02

The following emissions were determined to occur during the application phase.

Application Step

Parameters	
Q _{prod}	0.014
F _{AI}	0.0002
N _{appl.building}	1
AREA _{treated}	5.9
F _{appl.air}	0.02
F _{appl.treated}	0.85
F _{appl,floor}	0.126
F _{appl,applicator}	0.004

Releases to wastewater	
F _{applicator,ww}	1
F _{CE}	0.2
N _{buildings}	4000
F _{simultaneity (indoor)}	0.00815

Variable/parameter (units)	Symbol	Unit	Crack & Crevice/ Targeted Spot House
Emission to air during application step	E _{application, air}	kg/d	3.30E-07
$E_{\text{application, air}} = N_{\text{appl, building}} \times F_{\text{application, air}} \times Q_{\text{prod}} \times F_{\text{AI}} \times \text{AREA}_{\text{treated}}$			
Emission to applicator during application step	E _{application, applicator}	kg/d	6.61E-08
$E_{\text{application, applicator}} = N_{\text{appl, building}} \times F_{\text{application, applicator}} \times Q_{\text{prod}} \times F_{\text{AI}} \times \text{AREA}_{\text{treated}}$			
Emission to floor during application step	E _{application, floor}	kg/d	2.08E-06
$E_{\text{application, floor}} = N_{\text{appl, building}} \times F_{\text{application, floor}} \times Q_{\text{prod}} \times F_{\text{AI}} \times \text{AREA}_{\text{treated}}$			
Emission to treated surface during application step	E _{application, treated}	kg/d	1.40E-05
$E_{\text{application, treated}} = Q_{\text{prod}} \times F_{\text{AI}} \times N_{\text{application, building}} \times F_{\text{application, treated}} \times \text{AREA}_{\text{treated}}$			

Cleaning

The following emissions were determined to occur during the cleaning phase.

Cleaning step - First Case: Emission to solid wastes during the cleaning step

Variable/parameter (units)	Symbol	Unit	Crack & Crevice/ Targeted Spot House
Emission from applicator to solid waste during the cleaning step	E _{applicator, w}	kg/d	6.61E-08
$E_{\text{applicator, w}} = (E_{\text{prep, applicator}} + E_{\text{application, applicator}}) \times F_{\text{applicator, w}}$			
Emission from floor/treated surface to solid waste during the cleaning step	E _{treated, w}	kg/d	3.22E-06
$E_{\text{treated, w}} = (E_{\text{prep, floor}} + E_{\text{application, floor}} + E_{\text{application, treated}}) \times F_w \times F_{\text{CE}}$			

FCE = Based on a cleaning efficiency of 20%, ESD PT18 Table 3.3-8 (RTU Aerosol-surface treatment)

Cleaning step - Second case: Releases to waste water

Variable/parameter (units)	Symbol	Unit	Crack & Crevice/ Targeted Spot House
Emission from applicator to waste water during the cleaning step	E _{applicator, ww}	kg/d	6.61E-08
$E_{\text{applicator, ww}} = (E_{\text{prep, applicator}} + E_{\text{application, applicator}}) \times F_{\text{applicator, ww}}$			
Emission from floor/treated surface to waste water	E _{treated, ww}	kg/d	3.22E-06

during cleaning step			
$E_{\text{treated, ww}} = (E_{\text{prep, floor}} + E_{\text{application, floor}} + E_{\text{application, treated}}) \times F_{\text{ww}} \times F_{\text{CE}}$			
Total ($E_{\text{treated, ww}}$)			3.29E-06
Simultaneity factor (3 to 11 times per year)	$F_{\text{simultaneity}}$		0.00815
Number of houses	$N_{\text{buildings}}$	-	4000
Output			
Local emission to waste water during episode	$E_{\text{local, ww}}$	kg/d	1.07E-04
$E_{\text{local, ww}} = E_{\text{total, ww}} \times N_{\text{house}} (4000) \times \text{Simultaneity factor}$			
FCE = Based on a cleaning efficiency of 20%, ESD PT18 Table 3.3-8 (RTU Aerosol-surface treatment).			

Scenario [3] Outdoor Use

Detrans® Deltamethrin CIK was intended to be applied on “outside surfaces of window & door frames and other areas where crawling insects may enter the home”, as specified on the product label. The receiving compartment for the use of a ready-to-use insecticidal spray for outdoor spot application is primarily the soil.

There is currently no suitable scenario contained within the “Emission Scenario Document (ESD) for Insecticides, acaricides and products to control other arthropods for household and professional uses” (17th July 08), which covers this type of application. It was therefore considered appropriate to modify the scenario for flying insects where the entire wall is treated with insecticide. As documented in the CAR for Bifenthrin (France September 2009) the treatment area has been adjusted to 0.1 m in diameter and it has been assumed that one side of the house has been treated as the outdoor treatment area are likely to be limited.

Application Step Outdoor Use

Variable/parameter (units)	Symbol	Unit	Crack & Crevice/ Targeted Spot House
Input			
Local emission from outdoor spray application on wall due to deposition on soil $E_{\text{spray, wall, applic, soil}} = F_{\text{spray, wall}} \times Q_{\text{prod}} \times F_{\text{AI}} \times \text{AREA}_{\text{wall}}$	$E_{\text{spray, wall, applic, soil}}$	kg/d	2.21E-06
Local concentration of active ingredient in soil adjacent to the house due to wall application against flying insects $C_{\text{spray, wall, applic, soil}} = E_{\text{spray, wall, applic, soil}} / V_{\text{spray, soil}} \times \text{RHO}_{\text{soil}}$	$C_{\text{spray, wall, applic soil}}$	kg/kg wwt	2.96E-10

Wash off of the Treated Surface by Rainfall

Variable/parameter (units)	Symbol	Unit	Crack & Crevice/ Targeted Spot House
Input			
Local emission from outdoor spray application on	$E_{\text{spray, wall, wash-off}}$	kg/d	3.68E-06

wall due to wash off by rainfall $E_{\text{spray, wall, wash-off, soil}} = F_{\text{spray, wash off}} \times Q_{\text{prod}} \times F_{\text{AI}} \times \text{AREA}_{\text{wall}}$	soil		
Local concentration of active ingredient in soil adjacent to the house due to wash off by rainfall $C_{\text{spray, wall, wash off soil}} = E_{\text{spray, wall, wash-off, soil}} / V_{\text{spray, soil}} * \text{RHO}_{\text{soil}}$	$C_{\text{spray, wall, wash off soil}}$	kg/kg	4.94E-10
Local concentration of active ingredient in soil adjacent to the house due to washing and wall application against flying insects $C_{\text{spray, wall, applic, soil}} = E_{\text{spray, wall, applic, soil}} + E_{\text{spray, wall, wash-off, soil}} / V_{\text{spray, soil}} * \text{RHO}_{\text{soil}}$	$C_{\text{spray, flying, soil}}$	kg/kg wwt	7.91E-10
		mg/kg wwt	7.91E-04

ESCA: ES do not agree with the change proposed for the scenario, this scenario has been recalculated by ESCA according to the emission scenario for crawling insects.

ESCA has performed the default scenario proposed in OECD series on emission scenario documents n.18, "Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses", scenario for spray application, treatment around building, for crawling insects where the treatment of the perimeter is performed.

Application

Detrans® Deltamethrin CIK Application Rates

Application rate Deltamethrin (g/m ²)	0.014
Application rate Detrans®HPC3 (kg/m ²)	0.021
conc. active ingredient in product (%w/w)	0.02

The following emissions were determined to occur during the application phase.

Application step:

Local emissions related to the outdoor spray application of insecticide on the foundations and on the soil around the house (e.g. for crawling insect treatment) are derived from the following model calculation:

Parameters:

Application	
Q_{prod} (kg/m ²)	0.014
F_{AI}	0.0002
$\text{AREA}_{\text{foundation}}$	25
$\text{AREA}_{\text{soil}}$	26
$F_{\text{spray, foundation}}$	0.3
$F_{\text{spray, soil}}$	0.99
$F_{\text{spray, untreated soil}}$	0.0042
$F_{\text{spray, wash-off}}$	0.5

AREA _{untreated}	28
V _{spray,treatedsoil}	13
V _{spray,untreatedsoil}	14
RHO _{soil} (Bulk density of wet soil)	1700.00

Emission from outdoor spray application on foundations against crawling insects

$$(47) E_{spray, foundation} = Q_{prod} \times F_{AI} \times AREA_{foundation} \times F_{spray, foundation}$$

Espray, foundation= 2.10E-05 kg/d

Emission from outdoor spray application on soil:

$$(48) E_{spray, soil} = AREA_{soil} \times Q_{prod} \times F_{AI} \times F_{spray, soil}$$

Espray, soil= 7.21E-05 kg/d

Emission from outdoor spray application on soil in untreated area:

$$(49) E_{spray, untreated soil} = Q_{prod} \times F_{AI} \times F_{spray, untreated soil} \times AREA_{untreated}$$

Espray, untreated soil= 3.29E-07 kg/d

Wash-off of the treated surfaces by rainfall:

Local emissions related to the wash-off by rainwater of the foundations are derived from the following model calculation:

Local emission from outdoor spray application on foundation due to washing

$$(50) E_{spray, foundation, wash-off} = AREA_{foundation} \times Q_{prod} \times F_{AI} \times F_{spray, wash-off}$$

Espray, foundation, wash-off= 3.50E-05 Kg/d

Summary of emissions in urban and rural environments

Urban area:

In urban areas, releases to hard surfaces are directed to the rainwater/sewage system during the first rain event following application. Rainfall will then wash-off both quantities emitted to soil during application and from wall from wash-off. Emission are calculated as follow:

$$(51) E_{spray, crawling insects} = (E_{spray, foundation} + E_{spray, soil} + E_{spray, foundation, wall, wash-off})$$

Espray,crawling insects= 1.28E-04 kg/d

These emission rates, exposed in kg/d, can then be used further in exposure assessment as input values in sewage treatment models or surface water models.

N _{buildings} .	2500	TAB -ENV v. 2.0	
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$F_{simultaneity}$	0.02750	p. 40 ESD	
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Total emission to waste water:

$$E_{local,ww,total} = (E_{spray,crawling\ insects} \times N_{buildings}) \times F_{simultaneity}$$

$E_{local,ww,total} = 8.80E-03\text{kg/d}$

Rural area:
It is proposed to calculate two local concentrations of active substance in soil in the countryside, depending of the level of protection sought.

The local concentration of the active substance in soil in the countryside can be calculated from the following model calculation:

Treated area:
Concentration of active ingredient in treated soil at 0.5m from the house due to foundation and ground application against crawling insects.

$$(52) C_{spray,treated\ soil} = \left(\frac{E_{spray,foundation} + E_{spray,foundation,wash-off} + E_{spray,soil}}{V_{spray,treatedsoil} \times RHO_{soil}} \right)$$

$C_{spray,treated\ soil} = 5.80E-09\text{ kg/kg ww}$

Untreated area:
Concentration of active ingredient in untreated soil due to foundation and ground application against crawling insects.

$$(53) C_{spray,untreated\ soil} = \left(\frac{E_{spray,untreatedsoil}}{V_{spray,untreatedsoil} \times RHO_{soil}} \right)$$

$C_{spray,untreated\ soil} = 1.38E-11\text{ kg/kg ww}$

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1 & 2	Yes	Yes	No	No	Yes	Yes	Yes	Yes	
Scenario 3	No	No	No	No	No	No	Yes	No	

Scenario 1

The calculated emission to waste water ($E_{local, ww}$) can be inserted into EUSES Version 2.1.2 using the following input values and the $PEC_{STP\ micro-organisms}$, $PEC_{surface\ water}$ (due to indirect exposure from an STP, as no direct exposure is anticipated), $PEC_{sediment}$ and $PEC_{groundwater}$ can be calculated.

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	505.2	-	
Vapour pressure at 25°C	1.24E-08	Pa	CAR, May 2011
Water solubility (at 20°C)	5.00E-03	mg/l	CAR, May 2011
Log Octanol/water partition coefficient at 25°C	4.6	Log 10	CAR, May 2011
Organic carbon/water partition coefficient (Koc)	4.0825E+05	L/kg	CAR, May 2011
Henry's Law Constant (at 25°C)	1.252E-03	Pa/m ³ /mol	CAR, May 2011
Biodegradability	Not biodegradable	-	CAR, May 2011
Rate constant for biodegradation in aerated sediment (DT ₅₀ at 20°C)	133	d	CAR, May 2011
Rate constant for biodegradation in bulk soil (DT ₅₀ at 12°C)	48	d	CAR, May 2011

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
	Scenario 1	
Air	2.09E-05	-
Water	9.61	-
Sludge	90.4	-
Degraded in STP	0	-

The EUSES report is included in Annex 3.2.

Calculated PEC values for Scenario 1

Local Aquatic PEC Outputs (modelled with EUSES v 2.1.2)		
	Assessment	PEC
Scenario 1 Cracks & Crevices Indoor Use	PEC for micro-organisms in the STP (mg/L)	1.75E-06
	Local PEC in surface water during emission episode (dissolved) (mg/L)	1.08E-07
	Local PEC in fresh-water sediment during emission episode (mg/kg wwt)	9.61E-04
	Local PEC in groundwater under agricultural soil (mg/L)	3.38E-09

PEC in Air (modelled with EUSES v 2.1.2)

Deltamethrin has a very low predicted vapour pressure (1.24E-08 Pa at 25°C) and therefore it is expected that exposure to the air compartment will be negligible. Using EUSES Version 2.1.2 the emissions to air from Cracks & Crevices use were calculated. There are presented below.

Assessment		PEC
Scenario 1 Cracks & Crevices Indoor Use	Annual Average Local PEC in Air (total) (mg/m ³)	1.44E-18

Local Terrestrial PEC Outputs (modelled with EUSES v 2.1.2)

Following indoor use of Detrans® Deltamethrin CIK (containing 0.02% Deltamethrin) it is not anticipated that the product will have direct contact with soil at any point during normal usage. However, in the event that material enters the waste water system, there is the potential for contaminated sewage sludge from an STP to subsequently be spread on agricultural land. In view of this possibility, the following PEC values for soil have been calculated.

Assessment		PEC
Scenario 1 Cracks & Crevices Indoor Use	Local PEC in agricultural soil (total) averaged over 30 days (mg/kg wwt)	5.55E-05
	Local PEC in agricultural soil (total) averaged over 180 days (mg/kg wwt)	2.42E-05

Calculated PEC values for Scenario 2 (indoor – barrier treatment in the inside of windows and doors frames)

$$EFFLUENT_{STP} = CAPACITY_{STP} \times WASTE_{inhab} \quad (34)$$

Capacity of STP	10000	eq	D
Sewage flow per inhabitant	200	l.d ⁻¹ .eq ⁻¹	D

$$PEC_{STP} = Clocal_{inf} \text{ (Intermittent release)} = Elocal_{water} \times 10^6 / EFFLUENT_{STP} \quad (32)$$

INPUTS		Value	Unit	Origin
Local emission rate to wastewater	Elocal _{water}	1.07E-04	kg.d ⁻¹	D
Effluent discharge rate of STP (34)	EFFLUENT _{STP}	2,000,000	l.d ⁻¹	eq. (34)

Clocal_{inf}	5.36E-05	mg.L ⁻¹	O
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$$PEC_{STP} = Clocal_{eff} \text{ (Continuous release)} = Clocal_{inf} \times Fstp_{water} \quad (33)$$

INPUTS		Value	Unit	Origin
Concentration in untreated wastewater	Clocal _{inf}	5.36E-05	mg.L ⁻¹	eq. (32)
Fraction of emission directed to water by STP	Fstp _{water}	0,096	-	EUSES

PEC_{STP}	Clocal_{eff}	5.15E-06	mg.L ⁻¹	O
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$$PEC_{local,water} = C_{local,water} = C_{local,eff} / [(1 + k_{p,susp} \times SUSP_{water} \times 10^{-6}) \times DILUTION] \quad (45)$$

INPUTS		Value	Unit	Origin
Concentration of the substance in the STP effluent	$C_{local,eff}$	5.15E-06	$mg.L^{-1}$	eq. (33)
solids-water partitioning coefficient of suspended matter	$K_{p,susp}$	40,825	$l.kg^{-1}$	eq. (23)
Concentration of suspended matter in the river	$SUSP_{water}$	15	$mg.L^{-1}$	D
Dilution factor	DILUTION	10	-	D

$$PEC_{local,water} = C_{local,water} \quad 3.19E-07 \quad mg.L^{-1} \quad O$$

$$PEC_{local,sed} = (K_{susp-water} / RHO_{susp}) \times PEC_{local,water} \times 1000 \quad (50)$$

INPUTS		Value	Unit	Origin
Concentration in surface water during emission episode	$PEC_{local,water}$	3.19E-07	$mg.L^{-1}$	eq. (45)
Suspended matter-water partitioning coefficient	$K_{susp-water}$	10207.15	$m^3.m^{-3}$	eq. (24)
Bulk density of suspended matter	RHO_{susp}	1150	$kg.m^{-3}$	eq. (18)

$$PEC_{local,sed} = 2.83E-03 \quad mg.kg^{-1} \quad O$$

Agric. Soil: $PEC_{local,agr.soil} = C_{local,agr.soil} = (1/kT) \times C_{agr.soil 10} (0) \times (1 - e^{-kT})$ (66)(55)
(despreciamos emisiones al aire)

INPUTS		Value	Unit	Origin
Averaging time	T	180	d	Table 11
First order rate constant for removal from top soil	k	0.014440788	d^{-1}	eq. (56)
Initial concentration after 10 years	$C_{agr.soil 10} (0)$	6.84E-05	$mg.kg^{-1}$	eq. (63)

$$PEC_{local,agr.soil} = C_{local,agr.soil} \quad 7.19E-05 \quad mg.kg^{-1} \quad O$$

Groundwater: $PEC_{local,grw} = PEC_{local,agr.soil, porewater} = (PEC_{local,agr.soil} \times RHO_{soil}) / (K_{soil-water} \times 1000)$ (68)(67)

INPUTS		Value	Unit	Origin
Predicted environmental conc. in soil	PEC _{local,agr.soil}	7.19E-05	mg.kg ⁻¹	eq. (66)(55)
Soil-water partitioning coefficient	K _{soil-water}	12247.7	m ³ .m ⁻³	eq. (24)
Bulk density of wet soil	RHO _{soil}	1700	kg.m ⁻³	eq. (18)

PEC _{local,grw} =	PEC _{local,agr.soil, porewater}	9.98E-09	mg.L ⁻¹	0
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Calculated PEC values for Scenario 3 (Outdoors - Barrier treatment in the outside of windows and doors frames)

The Applicant proposed the following emission estimations for the intended outdoor use

Local Terrestrial PEC Outputs		
Detrans® Deltamethrin CIK (containing 0.02% Deltamethrin) can also be applied on “outside surfaces of window & door frames and other areas where crawling insects may enter the home” as specified on the product label. The receiving compartment for the use of a ready-to-use insecticidal spray for outdoor spot application is primarily the soil and the following PEC values for soil have therefore been calculated.		
Assessment		PEC
Scenario 3 Crack & Crevice and Targeted spot Outdoor Use	Local PEC in soil adjacent to the house due to washing and wall application to window & door frames and other areas where crawling insects may enter the home (mg/kg wwt)	7.91E-04

ESCA, Scenario 3 (Outdoors – Perimeter around house):
Urban environment

Indirect emission through STP.

PEC_{STP} = C_{local,eff} (Continuous release) = C_{local,inf} x F_{stp,water} (33)

INPUTS		Value	Unit	Origin
Concentration in untreated wastewater	C _{local,inf}	4.4E-03	mg.L ⁻¹	eq. (32)

Fraction of emission directed to water by STP	Fstp _{water}	0.096	-	EUSES
PEC_{STP}				
	Clocal _{eff}	4.23E-04	mg.L ⁻¹	O
PEClocal_{water} = Clocal_{water} = Clocal_{eff} / [(1 + k_{p,susp} x SUSP_{water} x 10⁻⁶) x DILUTION] (45)				
INPUTS				
		Value	Unit	Origin
Concentration of the substance in the STP effluent	Clocal _{eff}	4.23E-04	mg.L ⁻¹	eq. (33)
solids-water partitioning coefficient of suspended matter	K _{p,susp}	40825	l.kg ⁻¹	eq. (23)
Concentration of suspended matter in the river	SUSP _{water}	15	mg.L ⁻¹	D
Dilution factor	DILUTION	10	-	D
PEClocal_{water}				
	Clocal _{water}	2.62E-05	mg.L ⁻¹	O
PEClocal_{sed} = (K_{susp-water} / RHO_{susp}) x PEClocal_{water} x 1000 (50)				
INPUTS				
		Value	Unit	Origin
Concentration in surface water during emission episode	PEClocal _{water}	2.62E-05	mg.L ⁻¹	eq. (45)
Suspended matter-water partitioning coefficient	K _{susp-water}	10207.15	m ³ .m ⁻³	eq. (24)
Bulk density of suspended matter	RHO _{susp}	1150	kg.m ⁻³	eq. (18)
PEClocal_{sed}				
		2.33E-01	mg.kg ⁻¹	O
Agric. Soil: PEClocal_{agr.soil} = Clocal_{agr.soil} = (1/kT) x C_{agr.soil 10} (0) x (1 - e^{-kT}) (66)(55)				
INPUTS				
		Value	Unit	Origin
Averaging time	T	30	d	Table 11
First order rate constant for removal from top soil	k	0.014440788	d ⁻¹	eq. (56)
Initial concentration after 10 years	C _{agr.soil 10} (0)	0.024857471	mg.kg ⁻¹	eq. (63)

PEClocal_{agr.soil} =	Clocal_{agr.soil}	1.34E-02	mg.kg ⁻¹	0
Groundwater: $PEClocal_{grw} = PEClocal_{agr.soil, porewater} = (PEClocal_{agr.soil} \times RHO_{soil}) / (K_{soil-water} \times 1000)$ (68)(67)				
INPUTS				
Value	Unit	Origin		
Predicted environmental conc. in soil	PEClocal _{agr.soil}	1.34E-02	mg.kg ⁻¹	eq. (66)(55)
Soil-water partitioning coefficient	K _{soil-water}	12247.7	m ³ .m ⁻³	eq. (24)
Bulk density of wet soil	RHO _{soil}	1700	kg.m ⁻³	eq. (18)
PEClocal_{grw} =				
PEClocal_{agr.soil, porewater}	1.87E-06	mg.L ⁻¹	0	
<u>Rural environment</u>				
PEC calculations of direct exposure to the soil following wash off and application to outside surfaces of window and door frames has been performed:				
PEC soil (treated soil) = 5.80E-03 mg/kg				
PEC soil (untreated soil) = 1.38E-05 mg/kg				
Groundwater (treated soil): $PEClocal_{grw} = PEClocal_{agr.soil, porewater} = (PEClocal_{agr.soil} \times RHO_{soil}) / (K_{soil-water} \times 1000)$ (68)(67)				
INPUTS				
Value	Unit	Origin		
Predicted environmental conc. in soil	PEClocal _{agr.soil}	5.80E-03	mg.kg ⁻¹	eq. (66)(55)
Soil-water partitioning coefficient	K _{soil-water}	12247.7	m ³ .m ⁻³	eq. (24)
Bulk density of wet soil	RHO _{soil}	1700	kg.m ⁻³	eq. (18)
PEClocal_{grw} =				
PEClocal_{agr.soil, porewater}	8.04E-07	mg.L ⁻¹	0	
Groundwater (untreated soil): $PEClocal_{grw} = PEClocal_{agr.soil, porewater} = (PEClocal_{agr.soil} \times RHO_{soil}) / (K_{soil-water} \times 1000)$ (68)(67)				

INPUTS		Value	Unit	Origin	
Predicted environmental conc. in soil	PEC _{local,agr.soil}	1.328E-05	mg.kg ⁻¹	eq. (66)(55)	
Soil-water partitioning coefficient	K _{soil-water}	12247.7	m ³ .m ⁻³	eq. (24)	
Bulk density of wet soil	RHO _{soil}	1700	kg.m ⁻³	eq. (18)	
PEC _{local,grw} =		PEC _{local,agr.soil, porewater}	1.92E-09	mg.L ⁻¹	0

Primary and secondary poisoning

Primary poisoning

Primary poisoning is very unlikely for Detrans[®] Deltamethrin CIK intended for use indoors in crack and crevices and targeted spots and outdoors on window surfaces or areas where crawling insects enter the home. Even if a wild bird or mammal did gain access to the product the exposure would only be localised and would not result in widespread (population level) exposure.

Secondary poisoning

The assessment performed during the Annex I review states that “the potential for secondary poisoning *via* terrestrial and aquatic food chain indicate that there is no unacceptable risk for earthworm- and fish-eating birds and small mammals”. The product being supported only contains 0.02% Deltamethrin and is therefore not expected to result in any concern with regard to secondary poisoning.

Aquatic compartment

The log octanol/water partition coefficient of Deltamethrin (4.6) suggests that it may have significant potential for bioconcentration in the aquatic environment, with the possibility of bioaccumulation leading to secondary poisoning. This theoretical potential is further reflected in a calculated bioconcentration factor (BCF) of 310, 2800 and 1400 as total ¹⁴C for edible, non-edible and whole body tissue in bluegill sunfish (*Lepomis macrochirus*). However, after the 14-day depuration period 70, 75 and 76% of the ¹⁴C residues had been eliminated from the edible, non-edible and whole body tissue, respectively. The biological half-life was 4.3 days for whole body tissue demonstrating that, in practice, any Deltamethrin taken up by an aquatic organism will be rapidly eliminated once exposure ceases, thereby mitigating any perceived potential for biomagnification through the food chain that may otherwise lead to secondary poisoning.

Calculated Risk to Fish Eating Predators

The concentration in fish is a result of uptake from the aqueous phase and intake of contaminated food (aquatic organisms). Thus, PEC_{oral, predator} is calculated from the bioconcentration factor (BCF) and a biomagnification factor (BMF).

The concentration of contaminant in food (fish) of fish-eating predators (PEC_{oral, predator}) is calculated from the PEC for surface water (worst-case value from scenario 2), the measured or estimated BCF for fish and the biomagnification factor (BMF). As a measured value is available (BCF=1400 L/kg) this value will be used.

$$PEC_{oral, predator} = PEC_{water} * BCF_{fish} * BMF \text{ (Equ. 76)}$$

$$PEC_{oral, predator} = 3.19E-07 * 1400 * 2$$

$$PEC_{oral, predator} = 8.94E-04 \text{ mg/kg}_{wet fish}$$

Terrestrial compartment

The log octanol/water partition coefficient of Deltamethrin (4.6) suggests that it may have significant potential for bioconcentration in soil-dwelling organisms, with the possibility of bioaccumulation leading to secondary poisoning. This theoretical potential is further reflected in a calculated BCF for earthworms of 483 L/kg (estimated using the QSAR method of Jager et al 1998, as presented in the Technical Guidance Document on Risk Assessment (TGD, 2003)) and a default BMF of 2 (determined as set out in TGD, 2003).

Calculated Risk to Worm Eating Predators

According to the TGD, the most likely route of uptake of organic substances will be *via* the interstitial water and data suggest that the Jager (1998) model often overestimates uptake as it does not account for adsorption. It is acknowledged that substances adsorbed to soil particles can be ingested and may bioaccumulate in worms, however, they may also pass directly through the organism. As no study has been conducted the calculation method described in the TGD has been used to determine if there is a potential bioaccumulation issue.

Since birds and mammals consume worms and the gut of earthworms can contain substantial amounts of soil, the exposure of the predators may be affected by the quantity of active substance that is present in this soil.

The $PEC_{oral, predator}$ is calculated as follows:

$$PEC_{oral, predator} = C_{earthworm}$$

where $C_{earthworm}$ is the total concentration of the substance in the worm as a result of bioaccumulation in worm tissues and the adsorption of the substance to the soil present in the gut.

The total concentration in a full worm can be calculated as the weighted average of the worm's tissues (through BCF and porewater) and gut contents (through soil concentration):

$$C_{earthworm} = BCF_{earthworm} * C_{porewater} * W_{earthworm} + C_{soil} * W_{gut} / W_{earthworm} + W_{gut} \text{ (Equ. 81)}$$

The weight of the gut contents can be rewritten using the fraction of gut contents in the total worm:

$$W_{gut} = W_{earthworm} * F_{gut} * CONV_{soil} \text{ (Equ. 82a)}$$

where:

$$PEC_{local\ soil\ porewater} = PEC_{local\ soil} * RHO_{soil} / K_{soil_water} * 1000 \text{ (Equ. 67)}$$

$$PEC_{local\ soil\ porewater} = 1.34E-02 * 1700 / 1.22E+04 * 1000 = 1.87E-06 \text{ mg/l}$$

$PEC_{local\ soil}$ value calculated for outdoor use (urban areas) has been chosen as this represents the worst case.

$$CONV_{soil} = RHO_{soil} / F_{solid} * RHO_{solid} = 1700 / (0.6 * 2500) = 1.13 \text{ (Equ. 82b)}$$

Using this equation, the concentration in a full worm can be written as:

$$C_{earthworm} = ((BCF_{earthworm} * C_{porewater}) + (C_{soil} * F_{Gut} * CONV_{soil})) / (1 + (F_{Gut} * CONV_{soil})) \text{ (Equ. 82c)}$$

$$C_{earthworm} = ((483 * 1.87E-06) + (1.34E-04 * 0.1 * 1.13)) / (1 + (0.1 * 1.13))$$

$$C_{earthworm} = 7.56E-03 \text{ mg/kg wet earthworm} = PEC_{oral, predator}$$

2.2.8.3. Risk characterisation

Predicted No Effect Concentrations (PNECs) for Deltamethrin

PNEC	Value
PNEC _{STP}	0.030 mg/l

PNEC _{freshwater}	0.0000007 mg/l (7.0E-07 mg/l; 0.7 ng/l)
PNEC _{sediment,freshwater}	0.0062 mg/kg wwt
PNEC _{soil}	0.075 mg/kg wwt

Atmosphere

Conclusion: The vapour pressure of Deltamethrin is relatively low (1.24E-08 Pa at 25°C), therefore, emissions to the atmospheric compartment are expected to be negligible.

The emissions from consumer crack & crevice and targeted spot indoor use of Detrans® Deltamethrin CIK have, however, been calculated using EUSES Version 2.1.2 to be 1.44E-18 mg/m³.

Regarding emissions from intended outdoor uses, only in case of use in urban areas (indirect) emissions to the air compartment would be relevant. According to the risk assessment of outdoor uses (see below) risks cannot be excluded. Therefore the estimation of emissions to the air following outdoor uses is not relevant. It is however expected that emissions to the atmosphere are negligible due to the properties of Deltamethrin.

Aquatic Compartment including STP and groundwater

Summary of Local aquatic PECs		
Assessment		PEC
Scenario 1 Crack & Crevice Indoor Use	PEC for micro-organisms in the STP (mg/L)	1.75E-06
	Local PEC in surface water during emission episode (dissolved) (mg/L)	1.08E-07
	Local PEC in fresh-water sediment during emission episode (mg/kg wwt)	9.61E-04
	Local PEC in groundwater under agricultural soil (mg/L)	3.38E-09

Summary table of calculated PEC/PNEC values for the aquatic compartment				
Assessment		PEC	PNEC	PEC/ PNEC
Scenario 1 Crack & Crevice and Targeted spot Indoor Use	PEC for micro-organisms in the STP (mg/L)	1.75E-06	0.030	5.78E-05
	Local PEC in surface water during emission episode (dissolved) (mg/L)	1.08E-07	7.00E-07	1.54E-01
	Local PEC in fresh-water sediment during emission episode (mg/kg wwt)	9.61E-04	0.0062	1.54E-01
	Local PEC in groundwater under agricultural soil (mg/L)	3.38E-09		

Conclusion: The risk characterisation step is carried out by comparing the PEC derived for each exposure scenario with the relevant PNEC value. Scenarios for which the PEC/PNEC value is <1.0 are considered to pose no unacceptable risk to the aquatic environment.

The PEC/PNEC ratios indicate that there is no cause for concern to the aquatic environment from indoor use of Detrans® Deltamethrin CIK (containing 0.02% Deltamethrin).

Terrestrial Compartments

Summary of Local Terrestrial PECs		
Assessment		PEC
Scenario 1 Crack & Crevice and Targeted spot Indoor Use	Local PEC in agricultural soil (total) averaged over 30 days (mg/kg wwt)	5.52E-05
	Local PEC in agricultural soil (total) averaged over 180 days (mg/kg wwt)	2.42E-05
Scenario 3 Crack & Crevice and Targeted spot Outdoor Use	Local PEC in soil adjacent to the house due to washing and wall application to window & door frames and other areas where crawling insects may enter the home (mg/kg wwt)	7.91E-04

Summary table of calculated PEC/PNEC values for the terrestrial compartment				
Assessment		PEC	PNEC	PEC/PNEC
Scenario 1 Crack & Crevice Indoor Use	Local PEC in agricultural soil (total) averaged over 30 days (mg/kg wwt)	5.52E-05	7.50E-02	7.36E-04
	Local PEC in agricultural soil (total) averaged over 180 days (mg/kg wwt)	2.42E-05	7.50E-02	3.23E-04
Scenario 3 Crack & Crevice and Targeted Spot Outdoor Use	Local PEC in soil adjacent to the house due to wash off and wall application against flying insects (mg/kg wwt)	7.91E-04	7.50E-02	1.05E-02

Conclusion: The risk characterisation step is carried out by comparing the PEC derived for each exposure scenario with the relevant PNEC value. Scenarios for which the PEC/PNEC value is <1.0 are considered to pose no unacceptable risk to the terrestrial environment. The PEC/PNEC ratios indicate that there is no cause for concern to the terrestrial environment from indoor or outdoor use of Detrans® Deltamethrin CIK.

ESCA: PEC/PNEC values for Scenario 2.				
Summary table of calculated PEC/PNEC values				
Assessment		PEC	PNEC	PEC/PNEC
Scenario 2 Window & door frames Use Indoors	PEC for micro-organisms in the STP (mg/L)	5.15E-06	0.03	1.72E-04
	Local PEC in surface water during emission episode (dissolved) (mg/L)	3.19E-07	0.7E-06	4.56E-01
	Local PEC in fresh-water sediment during emission episode (mg/kg wwt)	2.83E-03	0.62E-02	4.57E-01

	Local PEC in agricultural soil (total) averaged over 180 days (mg/kg wwt)	7.19E-05	7.5E-02	9.59E-04
	Groundwater (mg/L)	9.98E-09		

Finally, the PEC/PNEC values for all the indoor use of the Detrans® Deltamethrin CIK are:

Summary table of calculated PEC/PNEC values				
Assessment		PEC/PNEC (Sc.1)	PEC/PNEC (Sc.2)	PEC/PNEC (Indoor)
Scenario 1 Crack & Crevice and Targeted spot Indoor Use and Scenario 2 Window & door frames Use Indoors	Micro-organisms in the STP (mg/L)	5.78E-05	1.72E-04	2.29E-04
	Local surface water during emission episode (dissolved) (mg/L)	1.54E-01	4.56E-01	6.10E-01
	Local fresh-water sediment during emission episode (mg/kg wwt)	1.54E-01	4.57E-01	6.11E-01
	Local agricultural soil (total) averaged over 180 days (mg/kg wwt)	7.36E-04	9.59E-04	9.98E-05
	PEC Groundwater (mg/L)	7.66E-09	9.98E-09	8.82E-09

Conclusion: The PEC/PNEC ratios indicate that there is no cause for concern to the environment about the use of the product Detrans® Deltamethrin CIK indoor (crack and crevice and targeted spot plus inside surfaces of window and door frames and other areas where crawling insects may enter the home).

ESCA: PEC values for Scenario 3. PEC values has been obtained for both, rural and urban areas:

Urban areas

Summary table of calculated PEC/PNEC values				
Assessment		PEC	PNEC	PEC/PNEC
Scenario 3 Outdoor Use – Urban areas	Micro-organisms in the STP (mg/L)	4.23E-04	0.03	1.41E-02
	Local surface water during emission episode (dissolved) (mg/L)	2.62E-05	0.7E-06	3.74E+01
	Local fresh-water sediment during emission episode (mg/kg wwt)	2.33E-01	0.62E-02	3.75E+01
	Local agricultural soil (total) averaged over 30 days (mg/kg wwt)	1.34E-02	7.5E-02	1.79E-01

	PEC Groundwater (mg/L)	1.87E-06		
Rural areas				
Summary table of calculated PEC/PNEC values				
	Assessment	PEC	PNEC	PEC/PNEC
Scenario 3 Outdoor Use – Rural areas	Local agricultural soil (total) averaged over 30 days (mg/kg wwt) (Treated soil)	5.80E-03	7.5E-02	7.73E-02
	PEC Groundwater (Treated soil)	8.04E-07		
	Local agricultural soil (total) averaged over 30 days (mg/kg wwt) (Untreated soil)	1.38E-05	7.5E-02	1.84E-04
	PEC Groundwater (Untreated soil) (mg/L)	1.92E-09		
Unacceptable risk has been found for the outdoor use of the product in urban areas in environmental compartments.				

Groundwater

The maximum local PEC in groundwater under agricultural soil calculated by EUSES v. 2.1.2 is 7.57E-10 mg/L which is less than the maximum permissible concentration of 0.1 µg/L laid down by Directive 98/83/EC. This demonstrates that there is no cause for concern for groundwater.

ES: The maximum local PEC in groundwater under agricultural soil which has been calculated for indoor use and for outdoor use on urban areas, is 1.87E-06 mg/L. As it is less than the maximum permissible concentration of 0.1 µg/L laid down by Directive 98/83/EC, there are no unacceptable risk that has been found for groundwater of Detrans® Deltamethrin CIK.

Primary and secondary poisoning

Primary poisoning

It is considered that the possibility of primary poisoning for Detrans® Deltamethrin CIK is very unlikely. Even if a wild bird or mammal did gain access to the product the exposure would only be localised and would not result in widespread (population level) exposure.

Secondary poisoning: Aquatic compartment

The log octanol/water partition coefficient of Deltamethrin (4.6) suggests that it may have significant potential for bioconcentration in the aquatic environment, with the possibility of bioaccumulation leading to secondary poisoning. This theoretical potential is further reflected in a calculated bioconcentration factor (BCF) of 310, 2800 and 1400 as total ¹⁴C for edible, non-edible and whole body tissue in bluegill sunfish (*Lepomis macrochirus*).

However, after the 14-day depuration period 70, 75 and 76% of the ^{14}C residues had been eliminated from the edible, non-edible and whole body tissue, respectively. The biological half-life was 4.3 days for whole body tissue demonstrating that, in practice, any Deltamethrin taken up by an aquatic organism will be rapidly eliminated once exposure ceases, thereby mitigating any perceived potential for biomagnification through the food chain that may otherwise lead to secondary poisoning.

Calculated Risk to Fish Eating Predators

$\text{PEC}_{\text{oral, predator}} = 8.94\text{E-}04$ mg/kg wet fish

Risk characterization for Secondary Poisoning the Aquatic Compartment

A predicted no effect oral concentration ($\text{PNEC}_{\text{oral}}$) can be calculated based on the results of the mammalian repeat dose toxicity tests and toxicity data for birds (LC_{50} dietary). The result of this calculation gives a predicted no-effect concentration in food that should be protective to other mammalian and avian species.

The 1 year dog study represents the most sensitive species and applying a conversion factor 40 to convert the NOAEL of 1 mg/kg bw/day to a NOEC via food a value of 40 mg/kg can be determined ($1 * 40$). Applying an assessment factor of 30 to this value gives a **$\text{PNEC}_{\text{oral, predator}}$ of 1.33 mg/kg bw/day (= 40 mgkg⁻¹/30).**

Comparing this value to the calculated $\text{PEC}_{\text{oral, predator}}$ of $8.94\text{E-}04$ mg/kg wet fish it can be determined that there is no unacceptable risk from fish eating birds or mammals (**$\text{PEC}/\text{PNEC} = 8.94\text{E-}04$ mg/kg wet fish/1.33 mg/kg bw/day = 6.72E-04**).

Secondary poisoning: Terrestrial compartment

The log octanol/water partition coefficient of Deltamethrin (4.6) suggests that it may have significant potential for bioconcentration in soil-dwelling organisms, with the possibility of bioaccumulation leading to secondary poisoning. This theoretical potential is further reflected in a calculated BCF for earthworms of 483 L/kg (estimated using the QSAR method of Jager *et al* 1998, as presented in the Technical Guidance Document on Risk Assessment (TGD, 2003)) and a default BMF of 2 (determined as set out in TGD, 2003).

Calculated Risk to Worm Eating Predators

Since birds and mammals consume worms and the gut of earthworms can contain substantial amounts of soil, the exposure of the predators may be affected by the quantity of active substance that is present in this soil.

$C_{\text{earthworm}} = 7.56\text{E-}03$ mg/kg wet earthworm = $\text{PEC}_{\text{oral, predator}}$

Risk characterization for Secondary Poisoning the Terrestrial Compartment

A predicted no effect oral concentration ($\text{PNEC}_{\text{oral}}$) can be calculated based on the results of the mammalian repeat dose toxicity tests and toxicity data for birds (LC_{50} dietary). The result of this calculation gives a predicted no-effect concentration in food that should be protective to other mammalian and avian species.

The 1 year dog study represents the most sensitive species and applying a conversion factor 40 to convert the NOAEL of 1 mg/kg bw/day to a NOEC via food a value of 40 mg/kg can be determined ($1 * 40$). Applying an assessment factor of 30 to this value gives a **$\text{PNEC}_{\text{oral, predator}}$ of 1.33 mg/kg bw/day (= 40 mgkg⁻¹/30).**

Comparing this value to the calculated $\text{PEC}_{\text{oral, predator}}$ of $7.56\text{E-}03$ mg/kg wwt earthworm it can be determined that there is no unacceptable risk for earthworm eating birds or mammals (**$\text{PEC}/\text{PNEC} = 7.56\text{E-}03$ mg/kg wwt earthworm/1.33 mg/kg bw/day = 5.68E-03**).

Secondary poisoning: Conclusion: It may be concluded that there is no unacceptable risk to fish eating predators or worm eating predators from the use of Detrans® Deltamethrin CIK.

Mixture toxicity

Mixture toxicity is not relevant for Detrans® Deltamethrin CIK.

Aggregated exposure (combined for relevant emission sources)

Aggregated exposure is not relevant for Detrans® Deltamethrin CIK since emissions from indoor uses in cracks and crevices and as barrier treatment in window and doors frames (the inside part) can occur simultaneously.

Aggregated exposure was addressed in section 2.2.8.3. by the summation of risks for environmental organisms. The resulting values are also included in the following table..

Summary table on calculated ΣPEC/PNEC values					
	ΣPEC/PNEC _{STP}	ΣPEC/PNEC _{water}	ΣPEC/PNEC _{sed}	ΣPEC/PNEC _{soil}	ΣPEC _{GW}
Scenarios 1 + 2 (Indoors, cracks & crevices plus window and doors frames)	2.29E-04 mg/L	6.10E-01 mg/L	6.11E-01 mg/kg wwt	9.98E-05 mg/kg wwt	8.82E-09 mg/L

Conclusion: According to the values presented in the table, the summation of RCR (PEC/PNEC) estimated for indoor uses shows no concern for any environmental compartment and their related organisms. Since outdoor uses pose unacceptable risks for organisms of surface waters and freshwater sediments, the RCR were not aggregated.

Overall conclusion on the risk assessment for the environment of the product
<p><u>Atmosphere:</u> The maximum PEC in air is negligible (1.44E-18 mg/m³) therefore, there is no concern for the atmospheric compartment following use of Detrans® Deltamethrin CIK.</p> <p><u>STP:</u> There is no concern for the STP following the indoor use of Detrans® Deltamethrin CIK.</p> <p><u>Aquatic compartment:</u> There is no concern for the aquatic compartment following the indoor use of Detrans® Deltamethrin CIK.</p> <p><u>Terrestrial compartment:</u> The proposed use of Detrans® Deltamethrin CIK does not result in direct release to soil following indoor use, therefore the risk assessment considered environmental exposure following the use of contaminated sludge spread onto soil. After outdoor use of Detrans® Deltamethrin CIK applied on "outside surfaces of window and door frames, and other areas where crawling insects enter the home" as specified on the product label, the receiving compartment for such a ready-to-use insecticidal spray was primarily the soil. The PEC/PNEC values for soil show no cause for concern.</p>

Secondary poisoning: The $PEC_{oral,predator}/PNEC_{oral}$ ratios determined for fish-eating predators/scavengers (6.72E-04) and for earthworm eating organisms (5.68E-03) indicate that there is no unacceptable risk of secondary poisoning following the use of Detrans® Deltamethrin CIK.

Therefore, it may be concluded that when Detrans® Deltamethrin CIK is used according to the label instructions there will be no cause for concern for the environment.

ES CA 06/2019: There is no concern about the use of the product Detrans® Deltamethrin CIK indoors (in cracks and crevices and in the inside of surfaces of window & door frames where crawling insects may enter the home). But unacceptable risk has been found for the use of this product outdoors in urban areas ; hence the use outdoors cannot be authorised.

2.2.9. Measures to protect man, animals and the environment

Methods and precautions concerning placing on the market	Observe good chemical hygiene practices. Provide good ventilation. Protect from freezing.
Methods and precautions concerning production, handling and use of the active substance and its formulations	<p><u>Precautions for safe handling</u> Observe good chemical hygiene practices. Provide good ventilation.</p> <p><u>Engineering measures</u> Provide adequate ventilation. Observe Occupational Exposure Limits and minimise the risk of inhalation of vapours.</p> <p><u>Respiratory equipment</u> If ventilation is insufficient, suitable respiratory protection must be provided.</p> <p><u>Hand protection</u> Use suitable protective gloves if risk of skin contact.</p> <p><u>Eye protection</u> If risk of splashing, wear safety goggles or face shield.</p> <p><u>Other Protection</u> Wear apron or protective clothing in case of splashes.</p> <p><u>Hygiene measures</u> No specific hygiene procedures noted but good personal hygiene practices are always advisable, especially when working with chemicals.</p> <p><u>Skin protection</u> Wear apron or protective clothing in case of splashes.</p>

<p>Methods and precautions concerning storage of the active substance and its formulations</p>	<p>Store in a cool and well-ventilated place. Store in tightly closed original container.</p>
<p>Methods and precautions concerning transport of the active substance and its formulations</p>	<p><u>UN number</u> UN No. (ADR/RID/ADN) 1950 UN No. (IMDG) 1950 UN No. (ICAO) 1950 <u>UN proper shipping name</u> Proper Shipping Name AEROSOLS Flammable <u>Transport hazard class(es)</u> ADR/RID/ADN Class 2 ADR/RID/ADN Class Class 2.1: Flammable gases. ADR Label No. 2.1 IMDG Class 2 ICAO Class/Division 2</p>
<p>Methods and precautions concerning fire of the active substance and its formulations</p>	<p><u>Extinguishing media</u> Carbon dioxide or dry powder.</p> <p><u>Special hazards arising from the substance or mixture</u> <u>Hazardous combustion products</u> During fire, toxic gases (CO, CO₂) are formed.</p> <p><u>Advice for fire fighters</u></p> <p><u>Special Fire Fighting Procedures</u> No specific fire fighting procedure given. Water spray should be used to cool containers.</p> <p><u>Protective equipment for fire-fighters</u> Self-contained breathing apparatus and full protective clothing must be worn in case of fire.</p>
<p>In case of fire, nature of reaction products, combustion gases, etc.</p>	<p><u>Hazardous combustion products</u> During fire, toxic gases (CO, CO₂) are formed.</p>
<p>Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available</p>	<p><u>Inhalation</u> Remove victim immediately from source of exposure.</p> <p><u>Ingestion</u> Rinse mouth thoroughly. Do not induce vomiting. Immediately give a couple of glasses of water or milk, provided the victim is fully conscious. Get medical attention.</p> <p><u>Skin contact</u> Remove contaminated clothing. Wash off promptly and</p>

	<p>flush contaminated skin with water. Promptly remove clothing if soaked through and flush skin with water.</p> <p><u>Eye contact</u> Consult a physician for specific advice.</p>
Emergency measures to protect the environment	<p><u>Environmental precautions</u> Do not discharge into drains, water courses or onto the ground.</p> <p><u>Methods and material for containment and cleaning up</u> Absorb spillage with suitable absorbent material.</p>
Possibility of destruction or decontamination following release in the air	<p>In view of the very low vapour pressure of the active substance, release into the air compartment is very unlikely. There is no possibility of decontamination or destruction.</p>
Possibility of destruction or decontamination following release in water, including drinking water	<p>There are no recommended decontamination procedures. Contact with water should be avoided.</p>
Possibility of destruction or decontamination following release in or on soil	<p>There are no measures to decontaminate soil.</p>
Procedures for waste management of the active substance for industry or professional users e.g. possibility of re-use or recycling, neutralisation, conditions for controlled discharge, and incineration	<p>Dispose of waste and residues in accordance with local authority requirements.</p>
Possibility of re-use or recycling	<p>The test substance cannot be recycled.</p>
Possibility of neutralisation of effects	<p>The test substance cannot be neutralised.</p>
Conditions for controlled discharge including leachate	<p>The product should not be allowed to enter drains, water courses or the soil.</p>

qualities on disposal	
Conditions for controlled incineration	In accordance with local and national regulations.
Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms	Detrans® Deltamethrin CIK is for use indoors. The product should not therefore have any effect on beneficial and non-target organisms.
Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of groundwater against pollution caused by certain dangerous substances	There are no substances present that are contained in these lists.

2.2.10. Assessment of a combination of biocidal products

Not applicable.

2.2.11. Comparative assessment

Not applicable.

3. ANNEXES⁶

3.1. List of studies for the biocidal product

⁶ When an annex is not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

Document IIB-IIC Reference list by section number

Section No.	Author(s)	Year	Title, Source (where different from company) Company	Report No.	GLP (where relevant)	(Un) Published	Data Protection Claimed (Yes/No)	Owner
B2_2(1)	Anon	2010	Deltamethrin Technical, Version 2 / EU Revision Date: 29.09.2010 Bayer CropScience	102000001388.0 0	No	No	No	Public Domain
B2_2(2)	Anon	2012	Arcosolv PM Acetate, Version 1.3, Revision Date 03/15/2012 Lyondell Chemie Nederland, BV., Weena 737, 3013 AM Rotterdam Netherlands	MSDS No.: BE126	No	No	No	Public Domain
B2_2(3)	Anon	2011	SOLVESCO 100, Revision Date: 07 Jan 2011 ExxonMobil Chemical Belgium, Cadland Road, Hardley, Southampton, SO45 3NP Hampshire, UK	-	No	No	No	Public Domain
B2_2(4)	Anon	2008	Kerosene Odorless, Revision #8 Date: 6/12/2008 Fisher Scientific, 1 Reagent Lane, Fair Lawn, NJ 07410		No	No	No	Public Domain
B2_2(5)	Anon	2013	Liquefied Petroleum Gas, Report Date : 24/04/2013 Sumitomo Chemical (UK) Plc, Horatio House, 77-85 Fulham Palace Road, Hammersmith, London W6 8JA, UK	-	No	No	No	Public Domain
B2_2(5b)	Anon	2003	Calor Aerosol Propellant, Data Sheet No. 3, Revision 3, April 2003 Calor Gas Ltd, Athena Drive, Tachbrook Park, Leamington Spa, CV34 6RL, UK	-	No	No	No	Public Domain
B3_1_1	Lumsden A.M.	2000	Deltamethrin CIK Aerosol Packs (TF2787) AE F032640 00 AE01 B3: Determination of Storage Stability Safepharma Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT, U.K.	SPL Project Number: 964/002 (C009414)	Yes	Yes	Yes	Sumitomo Chemical Co. Ltd

Section No.	Author(s)	Year	Title, Source (where different from company) Company	Report No.	GLP (where relevant)	(Un) Published	Data Protection Claimed (Yes/No)	Owner
B3_1_2	Lumsden A.M.	2000	Deltamethrin CIK Aerosol Packs (TF2787) AE F032640 00 AE01 B3: Determination of Storage Stability Safepharm Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT, U.K.	SPL Project Number: 964/002 (C009414)	Yes	Yes	Yes	Sumitom o Chemical Co. Ltd
B3_1_4	Ferrandi G.	2018	Final report: determination of the storage stability and shelf life data of detrans cik - 0.02% deltamethrin cik oil - based aerosol Tosvar srl; Via del lavoro 10, 20060 Pozzo d'Adda (MI) ITALY	Study Number: TS-7006	No	n.a.	Yes	Sumitom o Chemical Co. Ltd
B3_1_3	Foster B.	2013	Study Plan Title:- DETRANS CIK from Sumitomo Chemical: Validation of an Analytical Method and Evaluation of Selected Physico-Chemical Properties, Smithers Visient (ESG) Ltd., Otley Road, Harrogate, North Yorkshire HG3 1 PY, UK	Study Number: 3200354	n.a.	n.a.	n.a.	Sumitom o Chemical Co. Ltd
B3_4	Foster B.	2013	Study Plan Title:- DETRANS CIK from Sumitomo Chemical: Validation of an Analytical Method and Evaluation of Selected Physico-Chemical Properties, Smithers Visient (ESG) Ltd., Otley Road, Harrogate, North Yorkshire HG3 1 PY, UK	Study Number: 3200354	n.a.	n.a.	n.a.	Sumitom o Chemical Co. Ltd
B3_6	Lumsden A.M.	2013	Study Plan Title:- DETRANS CIK from Sumitomo Chemical: Validation of an Analytical Method and Evaluation of Selected Physico-Chemical Properties, Smithers Visient (ESG) Ltd., Otley Road, Harrogate, North Yorkshire HG3 1 PY, UK	Study Number: 3200354	n.a.	n.a.	n.a.	Sumitom o Chemical Co. Ltd
B3_7(1)	Lumsden A.M.	2000	Deltamethrin CIK Aerosol Packs (TF2787) AE F032640 00 AE01 B3: Determination of Storage Stability Safepharm Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT, U.K.	SPL Project Number: 964/002 (C009414)	Yes	Yes	Yes	Sumitom o Chemical Co. Ltd

Section No.	Author(s)	Year	Title, Source (where different from company) Company	Report No.	GLP (where relevant)	(Un) Published	Data Protection Claimed (Yes/No)	Owner
B3_7(2)	Lumsden A.M.	2000	Deltamethrin CIK Aerosol Packs (TF2787) AE F032640 00 AE01 B3: Determination of Storage Stability Safepharm Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT, U.K.	SPL Project Number: 964/002 (C009414)	Yes	Yes	Yes	Sumitomo Chemical Co. Ltd
B3_8	Foster B.	2000	Deltamethrin CIK Aerosol Packs (TF2787) AE F032640 00 AE01 B3: Determination of Storage Stability Safepharm Laboratories Limited, P.O. Box No. 45, Derby, DE1 2BT, U.K.	SPL Project Number: 964/002 (C009414)	Yes	Yes	Yes	Sumitomo Chemical Co. Ltd
B3_10_2	Foster B.	2014	Study Plan Title:- DETRANS CIK from Sumitomo Chemical: Validation of an Analytical Method and Evaluation of Selected Physico-Chemical Properties, Smithers Visient (ESG) Ltd., Otley Road, Harrogate, North Yorkshire HG3 1 PY, UK	Study Number: 3200354	Yes	Yes	Yes	Sumitomo Chemical Co. Ltd
B4_1	Kunkel S.; Andersen M.M.; Marks V.	2014	Study Plan Title:- DETRANS CIK from Sumitomo Chemical: Validation of an Analytical Method and Evaluation of Selected Physico-Chemical Properties Smithers Visient (ESG) Ltd., Otley Road, Harrogate, North Yorkshire HG3 1 PY, UK	Study Number: 3200354	n.a.	n.a.	n.a.	Sumitomo Chemical Co. Ltd

Section No.	Author(s)	Year	Title, Source (where different from company) Company		Report No.	GLP (where relevant)	(Un) Published	Data Protection Claimed (Yes/No)	Owner
B5_10(5)	Köhler P.	1997	Evaluation of the residual efficacy of two Crawling Insect Killer aerosols against <i>Ctenocephalides felis</i> for registration purposes	AgrEvo Environmental Health Biology, Frankfurt, Germany	Report No. EHF97-037 (Ref. A92444)	No	Yes	Yes	Sumitomo Chemical (UK) Plc
B5_10(1)	Köhler P.	2000	Comparative evaluation of water-based crawling insect killer (CIK) aerosols Detrans WB CIK 0200, Detrans WB CIK 0205, Detrans WB CIK 0215, Detrans WB CIK 0530 versus Detrans CIK and Detrans KD CIK containing DTM and DTM/PY against <i>Blatta orientalis</i> and <i>Lasius niger</i> in spraybox tests	Environmental Science Biology, Industriepark Höchst, H872, D - 65926 Frankfurt a.M.	Report No. EHF99 - 031R (Ref. C010502)	No	Yes	Yes	Sumitomo Chemical (UK) Plc
B5_10(2)	Leach A.M.; Duffield L.Z.; Miller A.J.; Deacon J.	2000	Comparative evaluation of water-based crawling insect killer (CIK) aerosols Detrans WB CIK 0200, Detrans WB CIK 0205, Detrans WB CIK 0215, Detrans WB CIK 0530 versus Detrans CIK and Detrans KD CIK containing DTM and DTM/PY against <i>Blatta orientalis</i> and <i>Lasius niger</i> in spraybox tests	Environmental Science Biology, Industriepark Höchst, H872, D - 65926 Frankfurt a.M.	Report No. EHF99 - 031R (Ref. C010502)	No	Yes	Yes	Sumitomo Chemical (UK) Plc

Section No.	Author(s)	Year	Title, Source (where different from company) Company		Report No.	GLP (where relevant)	(Un) Published	Data Protection Claimed (Yes/No)	Owner
B5_10(3)	Leach A.M.; Duffield L.Z.; Miller A.J.; Deacon J.	1997	Biological and chemical evaluations of a proposed residual aerosol formula for Europe against <i>Periplaneta americana</i> and <i>Blattella germanica</i>	AgrEvo Environmental Health Ltd., Berkhamsted, England, UK	Report No. GB97-0015 (Ref. A92360)	No	Yes	Yes	Sumitomo Chemical (UK) Plc
B5_10(4)	Lumsden A.M.	1997	Biological and chemical evaluations of a proposed residual aerosol formula for Europe against <i>Periplaneta americana</i> and <i>Blattella germanica</i>	AgrEvo Environmental Health Ltd., Berkhamsted, England, UK	Report No. GB97-0015 (Ref. A92360)	No	Yes	Yes	Sumitomo Chemical (UK) Plc
B6_1_1	██████████	1996a	Aerosol CIK Filling Solution TF2786 (Deltamethrin): Rat acute oral toxicity study (limit test), Study no. TOX 96183;	AgrEvo UK Ltd., Toxicology, Chesterford Park, Saffron Walden, Essex CB10 1XL, UK	TOX/96/248-54; Ref. A99776	Yes	Yes	Yes	Bayer (formerly Agrevo USA) Sumitomo have a LOA
B6_1_2	██████████	1996b	Aerosol CIK Filling Solution TF2786 (Deltamethrin): Rat acute dermal toxicity study (limit test), Study No. TOX 96184	AgrEvo UK Ltd., Toxicology, Chesterford Park, Saffron Walden, Essex CB10 1XL, UK	TOX/96/248-52; Ref. A99775	Yes	Yes	Yes	Bayer (formerly Agrevo USA) Sumitomo have a LOA

Section No.	Author(s)	Year	Title, Source (where different from company) Company		Report No.	GLP (where relevant)	(Un) Published	Data Protection Claimed (Yes/No)	Owner
B6_1_3(1)	████████	1997	Aerosol CIK (TF 2787) Deltamethrin 0.020% w/w, Ref: 11237X, Rat acute (4-hour) inhalation toxicity study, Study No. TOX 96209	Huntingdon Life Sciences Ltd. PO BOX 2, Huntingdon, Cambridgeshire PE18 6ES, UK	TOX/96/248-67; Ref. A99892	Yes	Yes	Yes	Bayer (formerly Agrevo USA) Sumitomo have a LOA
B6_1_3(2)	████████	1998	Overview of Acute Inhalation Toxicity Studies with Four Detrans Aerosol Products	AgrEvo UK Ltd., Toxicology, Chesterford Park, Saffron Walden, Essex CB10 1XL, UK	Ref. A92649	No	Yes	Yes	Bayer (formerly Agrevo USA) Sumitomo have a LOA
B6_2/E	████████	1996c	Aerosol CIK Filling Solution Deltamethrin 0.033% w/w, Code: TF 2787, Rabbit eye irritation study, study number TOX 96186	AgrEvo UK Ltd., Toxicology, Chesterford Park, Saffron Walden, Essex CB10 1XL, UK	TOX/96/248-54	Yes	Yes	Yes	Bayer (formerly Agrevo USA) Sumitomo have a LOA
B6_2/S	████████	1996d	Aerosol CIK Filling Solution Deltamethrin 0.033% w/w, Code: TF 2787, Rabbit skin irritancy study, Study number TOX 96185	AgrEvo UK Ltd., Toxicology, Chesterford Park, Saffron Walden, Essex CB10 1XL, UK	TOX/96/248-53; Ref. A99774	Yes	Yes	Yes	Bayer (formerly Agrevo USA) Sumitomo have a LOA

Section No.	Author(s)	Year	Title, Source (where different from company) Company		Report No.	GLP (where relevant)	(Un) Published	Data Protection Claimed (Yes/No)	Owner
B6_3	██████████	1997	Guinea-Pig skin sensitisation (Buehler test), Study Number TOX 96187	Huntingdon Life Sciences Ltd., PO Box 2, Huntingdon, Cambridgeshire PE18 6ES, UK	TOX/97/248-64; Ref. A99884	Yes	Yes	Yes	Bayer (formerly Agrevo USA) Sumitomo have a LOA
IUCLID 6.7_1	Köhler, P.	2000	Comparative evaluation of water-based crawling insect killer (CIK) aerosols Detrans WB CIK 0200, Detrans WB CIK 0205, Detrans WB CIK 0215, Detrans WB CIK 0530 versus Detrans CIK and Detrans KD CIK containing DTM and DTM/PY against against <i>Blatta orientalis</i> and <i>Lasius niger</i> in spraybox tests.	Aventis Environmental Science Biology, Industriepark Höchst, H872. Frankfurt, Germany.	Report No. EHF99 - 031R	No	Yes	Yes	Sumitomo Chemical (UK) Plc
IUCLID 6.7_3	Leach, A. M. et al.	1997	Biological and chemical evaluations of a proposed residual aerosol formula for Europe against <i>Periplaneta americana</i> and <i>Blattella germanica</i> .	AgrEvo Environmental Health Ltd., Berkhamsted, England, UK	Report No. GB97-0015.	No	Yes	Yes	Sumitomo Chemical (UK) Plc

Section No.	Author(s)	Year	Title, Source (where different from company) Company		Report No.	GLP (where relevant)	(Un) Published	Data Protection Claimed (Yes/No)	Owner
IUCLID 6.7_6	Kinsey, R.	2014 (amended 2017)	Simulated use trial to determine the efficacy of Sumitomo Chemical deltamethrin formulation Detrans® CIK oil-based aerosol against crawling insects.	i2LResearch Ltd, Capital Business Park Wentloog Cardiff CF3 2PX, UK	Study code 13/476 A.	No	Yes	Yes	Sumitomo Chemical (UK) Plc

3.2. Output tables from exposure assessment tools

3.2.1. HUMAN HEALTH

Non-professional application of spray can for cracks and crevices/targeted spot treatment

An exposure assessment was presented but the RMS cannot find a justification for the values chosen by applicant for spray duration, application rate and mass generation rate.

The mass generation rate (i.e., amount of product discharged per pull) is not settled (two values were given). Other data used in the estimation (i.e., the spray pattern diameter of ca 7.62 cm when sprayed from a height of approximately 25-30 cm, or a consumer application rate of 0.8 seconds per running metre (equivalent to 2 sec/2.5 running metres), are not supported by any study and can not be used to estimate exposure.

It is worth mentioning that these parameters play an important role to estimate the total exposure. The mass generation rate is defined by technical specifications of the spray can. The data should include the spray pattern and the amount of spray delivered with each operation among others.

Using the default scenario in ConsExpo Web 1.0.3: *Pest Control Products /Sprays /Crack & Crevice /Application (spray can)* the exposure to the consumer was calculated (the calculation is similar for targeted spot treatment).

Inhalation: Spray Model Parameters

Parameters for the inhalation model are taken from RIVM Report 320104005/2009; Delmaar, J.E., H.J. Bremmer 2009; 'The ConsExpo spray model. Modelling and experimental validation of the inhalation exposure of consumers to aerosols from spray cans and trigger sprays'.

Spray duration 4 min, Actual duration spraying 1min(see RIVM Report 320005002)

Mass generation rate 2.2 g/sec (1min), 0.55g/sec (4min) (New default values for the spray model, RIVM, march 2010)

Airborne fraction 0.2 g/g (New default values for the spray model, RIVM, march 2010)

The distribution of the particle size when using the spray can containing 0.02% Deltamethrin is unknown, hence the values set at RIVM report are used: initial droplet size distribution LogNormal P50[um] (CV) = 3.6 (0.57) (New default values for the spray model, RIVM, march 2010)

The value used for density non-volatile is 0.769mg/cm³ (experimental).

Weight fraction compound is 0.02% (content of Deltamethrin in formulation).

Inhalation uptake fraction is 1.

Non-respirable (oral) uptake fraction is 0.75.

Exposure duration is 4 hr (default).

Dermal Model: direct product contact, constant rate

Exposed area is set as 8,300 cm² area for in HEEG opinion 17 default human factor. This parameter is not decisive to estimate total exposure. No default is found in RIVM report.

Body weight is 60 kg (as in HEEG opinion 17).

Contact rate is 100 mg/min (default value for spray can; see RIVM Report 320005002).

Release duration is set as the duration of spray.

Dermal uptake is 10% (dermal absorption).

Default for number of applications is 9 days a year, although chronic exposure is considered.

Exposure estimation is shown below.

Exposure Scenario		Estimated Internal Exposure as [mg a.i./kg bw[d]]			
		Inhalation uptake	Dermal uptake	Oral uptake	Total uptake
Application, Targeted spot cracks crevices treatment, spray can					
Tier 1	No PPE	5.2×10^{-3}	1.3×10^{-4}	1.5×10^{-6}	5.3×10^{-3}

Report for assessment Detrans Deltamethin CIK
ConsExpo Web - Fri Oct 05 2018

Assessment settings	
Label	Value
Substance	
Name	Deltametrina
CAS number	52918-63-5
Molecular weight	505 g/mol
K _{ow}	4.6 10Log
Product	
Name	Detrans Deltamethin CIK
Weight fraction substance	0.02 %
Population	
Name	EU framework Biocides adult
Body weight	60 kg
Scenarios	
Scenario application (spray can)	
Label	Value
Frequency	9 per year
Description	
Inhalation	
Exposure model	Exposure to spray - Spraying
Label	Value
Exposure model	Exposure to spray - Spraying
Spray duration	4 minute
Exposure duration	240 minute
Product is substance in pure form	No
Molecular weight matrix	–
The product is used in dilution	No

Weight fraction substance	0.02 %
Room volume	20 m ³
Room height	2.5 m
Ventilation rate	0.6 per hour
Inhalation rate	1.25 m ³ /hr
Spraying towards person	No
Mass generation rate	0.55 g/s
Airborne fraction	0.2
Density non volatile	0.769 g/cm ³
Inhalation cut off diameter	15 µm
Aerosol diameter distribution	Log normal LogNormal
Median diameter	3.6 µm
Arithmic coefficient of variation	0.57
Maximum diameter	50 µm
Include oral non-respirable material exposure	yes
Absorption model	Fixed fraction
Absorption fraction	100%
Dermal	
Label	Value
Exposure model	Direct contact - Constant rate
Exposed area	8300 cm ²
Weight fraction substance	0.02 %
Contact rate	100 mg/min
Release duration	4 minute
Absorption model	Fixed fraction
Absorption fraction	10%
Oral	
Label	Value
Exposure model	Non-respirable spray model
No parameters	Parameters are set in Inhalation exposure route.
Absorption model	Fixed fraction
Absorption fraction	75%

Results for scenario application (spray can)	
Inhalation	
Mean event concentration	6.2 × 10 ⁻² mg/m ³
<i>(average air concentration on exposure event. Note: depends strongly on chosen exposure duration)</i>	
Peak concentration (TWA 15 min)	2.2 × 10 ⁻¹ mg/m ³
<i>(peak concentration (TWA 15 min) is the 15 minute time weighted average of the air concentration. In case the exposure duration is less than 15 minutes, the mean event air concentration is given instead.)</i>	
Mean concentration on day of exposure	1.0 × 10 ⁻² mg/m ³
<i>(average air concentration over the day (accounts for the</i>	

<i>number of events on one day))</i>	
Year average concentration <i>(mean daily air concentration averaged over a year)</i>	$2.6 \times 10^{-4} \text{ mg/m}^3$
External event dose <i>(the amount that can potentially be absorbed per kg body weight during one event)</i>	$5.2 \times 10^{-3} \text{ mg/kg bw}$
External dose on day of exposure <i>(the amount that can potentially be absorbed per kg body weight during one day)</i>	$5.2 \times 10^{-3} \text{ mg/kg bw}$
Internal event dose <i>(absorbed dose per kg body weight during one exposure event)</i>	$5.2 \times 10^{-3} \text{ mg/kg bw}$
Internal dose on day of exposure <i>(absorbed dose per kg body weight during one day. Note: these can be higher than the 'event dose' for exposure frequencies larger than 1 per day.)</i>	$5.2 \times 10^{-3} \text{ mg/kg bw/day}$
Internal year average dose <i>(daily absorbed dose per kg body weight averaged over a year.)</i>	$1.3 \times 10^{-4} \text{ mg/kg bw/day}$
Dermal	
Dermal load <i>(amount per cm² on the skin)</i>	$9.6 \times 10^{-6} \text{ mg/cm}^2$
External event dose <i>(the amount that can potentially be absorbed per kg body weight during one event)</i>	$1.3 \times 10^{-3} \text{ mg/kg bw}$
External dose on day of exposure <i>(the amount that can potentially be absorbed per kg body weight during one day)</i>	$1.3 \times 10^{-3} \text{ mg/kg bw}$
Internal event dose <i>(absorbed dose per kg body weight during one exposure event)</i>	$1.3 \times 10^{-4} \text{ mg/kg bw}$
Internal dose on day of exposure <i>(absorbed dose per kg body weight during one day. Note: these can be higher than the 'event dose' for exposure frequencies larger than 1 per day.)</i>	$1.3 \times 10^{-4} \text{ mg/kg bw/day}$
Internal year average dose <i>(daily absorbed dose per kg body weight averaged over a year.)</i>	$3.3 \times 10^{-6} \text{ mg/kg bw/day}$
Oral	
External event dose <i>(the amount that can potentially be absorbed per kg body weight during one event)</i>	$2.0 \times 10^{-6} \text{ mg/kg bw}$
External dose on day of exposure <i>(the amount that can potentially be absorbed per kg body weight during one day)</i>	$2.0 \times 10^{-6} \text{ mg/kg bw}$
Internal event dose	$1.5 \times 10^{-6} \text{ mg/kg bw}$

<i>(absorbed dose per kg body weight during one exposure event)</i>	
Internal dose on day of exposure	1.5×10^{-6} mg/kg bw/day
<i>(absorbed dose per kg body weight during one day. Note: these can be higher than the 'event dose' for exposure frequencies larger than 1 per day.)</i>	
Internal year average dose	3.6×10^{-8} mg/kg bw/day
<i>(daily absorbed dose per kg body weight averaged over a year.)</i>	
Integrated	
Internal event dose	5.3×10^{-3} mg/kg bw
<i>(absorbed dose per kg body weight during one exposure event)</i>	
Internal dose on day of exposure	5.3×10^{-3} mg/kg bw/day
<i>(absorbed dose per kg body weight during one day. Note: these can be higher than the 'event dose' for exposure frequencies larger than 1 per day.)</i>	
Internal year average dose	1.3×10^{-4} mg/kg bw/day
<i>(daily absorbed dose per kg body weight averaged over a year.)</i>	



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Indirect exposure

Post Application; RIVM report 320005002

The exposure after application is described for crawling infant who is present in the room after a cracks and crevices treatment has been carried out. It is assumed that a infant (6 to 12 months) crawls over the treated surface for 1 hour a day. Exposure after application is described using the dermal exposure model 'rubbing off' and the oral exposure model 'constant rate'.

Dermal exposure: rubbing off

Rubbed surface

ConsExpo Web 1.0.3 model assumes that the treated room has a standard surface of 22 m² with floor surface of 8 m². According to the scenario, 25% of the floor area is taken to be the treated surface; this is equivalent to 2 m².

Dislodgeable amount

Tier 1

Total amount sprayed is calculated by multiplying the mass generation rate and the spray duration:

$$0.55 \text{ g/sec} * 4 \text{ min} * 60 \text{ sec} = 132 \text{ g}$$

The scenario assumes that this amount is sprayed towards the floor.

It is assumed that 85% of the total amount sprayed ($0.85 \times 132 = 112.2 \text{ g}$) ends up on the floor surface, and that of this amount, 30% is dislodgeable, i.e., it can be brushed away (default for cracks and crevices treatment with spray can, RIVM Report 320005002) ($0.3 \times 112.2 = 33.64 \text{ g}$).

The surface is 2 m² (see rubbed surface below).

The dislodgeable amount is calculated at $33.64/2 = 16.83 \text{ g/m}^2$.

Tier 2 assumes that the percentage rub off is reduced from 30% to a maximum of 6% (based on US Environmental Protection Agency Office of Pesticide Programs, Standard Operating Procedures for Residential Pesticide Exposure Assessment (Residential SOPs), October 2012 <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide#sops>); pp 514: arithmetic mean of dislodgeable amount from hard surfaces is 6%.

The amount sprayed on the floor is $112.2 \text{ g} / 2\text{m}^2 = 56.1 \text{ g/m}^2$. and 6% of this amount is dislodgeable.

The dislodgeable amount (Tier 2) is then $56.1\text{g/m}^2 \times 0.06 = 3.366\text{g/m}^2$.

Transfer coefficient (TC)

The transfer coefficient is the surface that is wiped per unit time due to skin contact. The Recommendation of Ad hoc Working Group on Human Exposure New default values for indoor Transfer Coefficient (WGV2016_TOX_7-2b_Indoor TC) revising values from EPA, gives a value of 2,100 cm²/hr.

Parameters for hand-mouth contact

If dermal exposure of children occurs after the application of a pest control product, those children can also be exposed orally due to hand-mouth contact. Dermal exposure of children can take place on any uncovered skin, that is, on the head, the arms and hands,

and on the legs and feet. The hands form about 20% of the total uncovered skin. It is assumed that 50% of the product that ends up on the hands is taken in orally due to hand-mouth contact. This means that via hand-mouth contact 10% of the external dermal exposure is ingested. The ingestion rate can be calculated based on the assumption that from the total dermal exposure 10% is taken in orally due to hand-mouth contact.

Hence the ingestion rate is estimated as dislodgeable amount x 10% x TC:

Tier 1: $16.83 \text{ g/m}^2 * 0.10 * 0.21 \text{ m}^2/\text{h} = 0.3534 \text{ g/h} = 5.89\text{E-}3 \text{ g/min.}$

Tier 2: $3.366 \text{ g/m}^2 * 0.10 * 0.21 \text{ m}^2/\text{h} = 0.071 \text{ g/h} = 1.18\text{E-}3 \text{ g/min.}$

Then, dermal rate will be estimated as dislodgeable amount x 90% x TC:

Tier 1: $16.83 \text{ g/m}^2 * 0.90 * 0.21 \text{ m}^2/\text{h} = 3.18 \text{ g/h} = 5.3\text{E-}2 \text{ g/min.}$

Tier 2: $3.366 \text{ g/m}^2 * 0.90 * 0.21 \text{ m}^2/\text{h} = 0.636 \text{ g/h} = 1.06\text{E-}2 \text{ g/min.}$

In addition, the following parameters are used:

Body weight, 8 kg (default for infant 6 to 12 months old in HEEG opinion 17 default human factor values).

Exposed area is uncovered skin, 2410.8 cm² (default area of hands, head, arms, legs and feet for infant 6 to 12 months old in HEEG opinion 17 default human factor values).

Using the default scenario in ConsExpo Web 1.0.3:- Pest Control Products → Sprays → Crack & Crevice → Post Application (Child), the indirect exposure to the child is calculated.

Parameters applied to the model:

Parameters	Value
Body weight	8 kg
Exposed area	2410.8 cm ²
Weight fraction compound	0.02%
Transfer coefficient	0.21 m ² /hr
Rubbed surface	2 m ²
Release duration /Exposure time	1 hr
Dislodgeable amount (30%) Tier 1	15.2 g/m ²
Dislodgeable amount (6%) Tier 2	3.03 g/m ²
Dermal absorption	10%
Ingestion rate (Tier 1)	5.89E-3 g/min
Ingestion rate (Tier 2)	1.18E-3 g/min
Oral uptake	75%

Summary of exposure calculations is presented in Table below. Detailed calculations are shown in following pages. Chronic exposure is considered.

Indirect exposure of infants crawling on treated surface after application of spray for targeted spot treatment

Exposure Scenario		Estimated Internal Exposure as [mg a.i./kg bw[d]]			
		Oral uptake	Inhalation uptake	Dermal uptake	Total uptake
Tier 1	30% dislodgeable	6.6×10^{-3}	-	8.0×10^{-3}	1.5×10^{-2}
Tier 2	6% dislodgeable	1.3×10^{-3}	-	1.6×10^{-3}	2.9×10^{-3}

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Assessment settings	
Label	Value
Substance	
Name	Deltametrina
CAS number	52918-63-5
Molecular weight	505 g/mol
K _{ow}	4.6 10Log
Product	
Name	Detrans Deltamethrin CIK
Weight fraction substance	0.02 %

Population	
Name	EU framework Biocides infant (6-12 months)
Body weight	8 kg
Scenarios	
Scenario Post application infant 30% dislodgeable	
Label	Value
Frequency	–
Description	
Inhalation	
Label	Value
Exposure model	n.a.
Absorption model	n.a.
Dermal	
Label	Value
Exposure model	Direct contact - Rubbing off
Exposed area	2410.8 cm ²
Weight fraction substance	0.02 %
Transfer coefficient	0.21 m ² /hr
Dislodgeable amount	15.15 g/m ²
Contact time	60 minute
Contacted surface	2 m ²
Release duration	–
Absorption model	Fixed fraction
Absorption fraction	10%
Oral	
Label	Value
Exposure model	Direct product contact - Direct oral intake
Weight fraction substance	0.02 %
Amount ingested	0.3534 g

Absorption model	Fixed fraction
Absorption fraction	75%
Results for scenario Post application infant 30% dislodgeable	
Dermal	
Dermal load (amount per cm ² on the skin)	2.6 × 10 ⁻⁴ mg/cm ²
External event dose (the amount that can potentially be absorbed per kg body weight during one event)	8.0 × 10 ⁻² mg/kg bw
Internal event dose (absorbed dose per kg body weight during one exposure event)	8.0 × 10 ⁻³ mg/kg bw
Oral	
External event dose (the amount that can potentially be absorbed per kg body weight during one event)	8.8 × 10 ⁻³ mg/kg bw
Internal event dose (absorbed dose per kg body weight during one exposure event)	6.6 × 10 ⁻³ mg/kg bw
Integrated	
Internal event dose (absorbed dose per kg body weight during one exposure event)	1.5 × 10 ⁻² mg/kg bw

Scenario post application infant 6% dislodgeable	
Label	Value
Frequency	–
Description	
Inhalation	
Label	Value
Exposure model	n.a.
Absorption model	n.a.
Dermal	
Label	Value
Exposure model	Direct contact - Rubbing off
Exposed area	2410 cm ²
Weight fraction substance	0.02 %
Transfer coefficient	0.21 m ² /hr
Dislodgeable amount	3.029 g/m ²
Contact time	60 minute
Contacted surface	2 m ²
Release duration	–
Absorption model	Fixed fraction

Absorption fraction	75%
Oral	
Label	Value
Exposure model	Direct product contact - Direct oral intake
Weight fraction substance	0.02 %
Amount ingested	0.071 g
Absorption model	Fixed fraction
Absorption fraction	75%
Results for Scenario post application infant 6% dislodgeable	
Dermal	
Dermal load <i>(amount per cm² on the skin)</i>	5.3×10^{-5} mg/cm ²
External event dose <i>(the amount that can potentially be absorbed per kg body weight during one event)</i>	1.6×10^{-2} mg/kg bw
Internal event dose <i>(absorbed dose per kg body weight during one exposure event)</i>	1.6×10^{-3} mg/kg bw
Oral	
External event dose <i>(the amount that can potentially be absorbed per kg body weight during one event)</i>	1.8×10^{-3} mg/kg bw
Internal event dose <i>(absorbed dose per kg body weight during one exposure event)</i>	1.3×10^{-3} mg/kg bw
Integrated	
Internal event dose <i>(absorbed dose per kg body weight during one exposure event)</i>	2.9×10^{-3} mg/kg bw



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3.2.2. ENVIRONMENT

Cracks and Crevices Use Indoors

Emission to Applicator - Treated Surface- Equation (11)

Variable/parameter (units)	Symbol	Unit	Default	Spot / Crack & Crevice Treatment	S/D/O/P
Input					
Number of applications per day per building	$N_{\text{appl, buildings}}$	d^{-1}			
- Non-professional			1	1	D
- Professional			-		S
Fraction emitted to applicator during application*	$F_{\text{application, applicator}}$	-	0.02	0.004	D*
Quantity of commercial product applied	Q_{prod}	Kg/m^2	-	0.021	S
Fraction of active substance in the commercial product	F_{AI}	-	-	0.0002	S
Area treated with the product	$\text{AREA}_{\text{treated}}$	m^2			P
- target spot application (household)			2	2	
- general spray application (household)					
Output					
Emission to applicator during application step	$E_{\text{application, applicator}}$	Kg/d	-	3.36E-08	-
$E_{\text{application, applicator}} = N_{\text{appl, building}} \times F_{\text{application, applicator}} \times Q_{\text{prod}} \times F_{\text{AI}} \times \text{AREA}_{\text{treated}}$					

*Table 3.3-1 self pressurised aerosol dispenser surface treatment

Crack and Crevice and Targeted Spot Use Indoors

Emission to Floor - Treatment of a Surface - Equation (9)

Variable/parameter (units)	Symbol	Unit	Default	Spot / Crack & Crevice Treatment	S/D/O/P
Input					
Number of applications per day per building	$N_{\text{appl. buildings}}$	d^{-1}			
- Non-professional			1	1	D
- Professional			-		S
Fraction emitted to floor during application	$F_{\text{application, floor}}$	-	0.11	0.126	D*
Quantity of commercial product applied	Q_{prod}	Kg/m^2	-	0.021	S
Fraction of active substance in the commercial product	F_{AI}	-	-	0.0002	S
Area treated with the product	$\text{AREA}_{\text{treated}}$	m^2			P
- target spot application (household)			2	2	
- general spray application (household)					
Output					
Emission to floor during application step	$E_{\text{application, floor}}$	Kg/d	-	1.06E-06	-
$E_{\text{application, floor, 1}} = N_{\text{appl, building, 1}} \times F_{\text{application, floor, 1}} \times Q_{\text{prod, 1}} \times F_{\text{AI}} \times \text{AREA}_{\text{treated, 1}}$					

*Table 3.3-3 self pressurised aerosol dispenser surface treatment

Crack and Crevice and Targeted Spot Use Indoors

Emission to treated area - Equation (12)

Variable/parameter (units)	Symbol	Unit	Default	Spot / Crack & Crevice Treatment	S/D/O/P
Input					
Number of applications per day per building:	$N_{\text{application, building}}$	d^{-1}			
- non-professional			1		D
- professional			-	1	S
Fraction emitted to treated surfaces during the application	$F_{\text{application, treated}}$	-	0.85	0.85	D
Quantity of commercial product applied	$Q_{\text{prod, 1}}$	Kg/m^2	-	0.021	S
Fraction of active substance in the commercial product	F_{AI}	-	-	0.0002	S
Area treated with the product	$AREA_{\text{treated}}$	m^2			P
- target spot application (household)			2	2	
- general spray application (household)					
Output					
Emission to treated surface during application step	$E_{\text{application, treated}}$	Kg/d	-	7.14E-06	-
$E_{\text{applicatoion, treated, 1}} = Q_{\text{prod}} \times F_{\text{AI}} \times N_{\text{application, building}} \times F_{\text{application, treated}} \times AREA_{\text{treated}}$					

Crack and Crevice and Targeted Spot Use Indoors

Cleaning

Emission to solid wastes and to waste water during the cleaning step: Emissions from the applicator - Equation (33)

Variable/parameter (units)	Symbol	Unit	Default	Spot / Crack & Crevice Treatment	S/D/O /P
Input					
Emission to applicator during the preparation step	$E_{\text{prep, applicator}}$	Kg/d		0.00E+00	O
Emission to applicator during the application step	$E_{\text{application, applicator}}$	Kg/d		3.36E-08	O
Fraction emitted to solid wastes from applicator after the application	$F_{\text{applicator, w}}$	-			P
Disposable coveralls			1	1	
Washable coveralls			0		
Output					
Emission from applicator to solid waste during the cleaning step	$E_{\text{applicator, w}}$	Kg/d	-	3.36E-08	-
$E_{\text{applicator, w}} = (E_{\text{prep, applicator}} + E_{\text{application, applicator}}) \times F_{\text{applicator, w}}$					

Emission from Floor/Treated- Equation (34)

Variable/parameter (units)	Symbol	Unit	Default	Spot / Crack & Crevice Treatment	S/D/O /P
Input					
Emission to Floor during the preparation step	$E_{\text{prep, floor}}$	kg.d ⁻¹		0.00E+00	O
Emission to Floor during the application step	$E_{\text{application, floor}}$	kg.d ⁻¹		1.06E-06	O
Emission to treated surfaces during the application step	$E_{\text{application, treated}}$	kg.d ⁻¹		7.14E-06	O
Fraction emitted to solid waste during the cleaning step	F_w	-	1	1	D
Cleaning Efficiency	F_{CE}	-		0.03	P*
Output					
Emission from floor/treated to solid waste during the cleaning step	$E_{\text{treated, w}}$	kg.d ⁻¹	-	2.46E-07	-
$E_{\text{treated, w}} = (E_{\text{prep, floor}} + E_{\text{application, floor}} + E_{\text{application, treated}}) \times F_w \times F_{\text{CE}}$					

* Table 3.3-8 (RTU Aerosol - crack and crevice)

Crack and Crevice and Targeted Spot Use Indoors**Second case: Releases to waste water - Equation (35)**

Variable/parameter (units)	Symbol	Unit	Default	Spot / Crack & Crevice Treatment	S/D/O /P
Input					
Emission to applicator during the preparation step	$E_{\text{prep, applicator}}$	Kg/d		0.00E+00	O
Emission to applicator during the application step	$E_{\text{application, applicator}}$	Kg/d		3.36E-08	O
Fraction emitted to waste water from applicator after the application	$F_{\text{applicator, ww}}$	-			P
Disposable coveralls			0		
Washable coveralls			1	1	
Output					
Emission from applicator to waste water during the cleaning step	$E_{\text{applicator, ww}}$	Kg/d	-	3.36E-08	-
$E_{\text{applicator, ww}} = (E_{\text{prep, applicator}} + E_{\text{application, applicator}}) \times F_{\text{applicator, ww}}$					

Emission from Floor/Treated - Equation (36)

Variable/parameter (units)	Symbol	Unit	Default	Spot / Crack & Crevice Treatment	S/D/O /P
Input					
Emission to Floor during the preparation step	$E_{\text{prep, floor}}$	kg.d-1		0.00E+00	O
Emission to Floor during the application step	$E_{\text{application, floor}}$	kg.d-1		1.06E-06	O
Emission to treated surfaces during the application step	$E_{\text{application, treated}}$	kg.d-1		7.14E-06	O
Fraction emitted to waste water during the cleaning step	F_{ww}	-	1	1	D
Cleaning Efficiency	F_{CE}	-		0.03	P*
Output					
Emission from floor/treated surface to waste water during cleaning step	$E_{\text{treated, ww}}$	kg.d ⁻¹		2.46E-07	-
$E_{\text{treated, ww}} = (E_{\text{prep, floor}} + E_{\text{application, floor}} + E_{\text{application, treated}}) \times F_{\text{ww}} \times F_{\text{CE}}$					

* Table 3.3-8 (Spray-crack and crevice)

Crack and Crevice and Targeted Spot Use Indoors**Total emissions to waste water**

Variable/parameter (units)	Sym bol	Un it	Defa ult	Spot / Crack & Crevice Treatment	S/D/O/P
Emission from floor/treated surface to waste water during cleaning step				2.46E-07	
Emission from applicator to waste water during the cleaning step				3.36E-08	
Total				2.80E-07	
Simultaneity factor – indoor	$F_{\text{simultaneity}}$		*	0.0081	
Number of	$N_{\text{buildings}}$				
- houses	q_s	-	4000	4000**	
- buildings		-	300		
Output					
Local emission to wastewater during episode (combined)	$E_{\text{local,ww}}$	Kg		9.02E-06	
$E_{\text{local,ww}} = E_{\text{treated,ww}} * \text{Household} * N_{\text{buildings}} * F_{\text{simultaneity}}$					

* Three to eleven time per year.

** Non-professional use therefore houses.

Outdoor Use**Application**

Variable/parameter (units)	Symbol	Unit	Crack & Crevice/ Targeted Spot House
Input			
Fraction emitted to soil during outdoor spray application against flying insects	$F_{\text{spray, wall}}$	-	0.3
Quantity of commercial product applied	Q_{prod}	kg/m ²	0.021
Fraction of active substance in the commercial product	F_{AI}	-	0.0002
Area of exterior wall treated per day	$\text{AREA}_{\text{wall}}$	m ² /d	1.75
Soil volume around the building	$V_{\text{spray, soil}}$	m ³	4.375
Bulk density of wet soil	RHO_{soil}	kg wwt/m ³	1700
Local emission from outdoor spray application on wall due to deposition on soil $E_{\text{spray, wall, applic, soil}} = F_{\text{spray, wall}} \times Q_{\text{prod}} \times F_{\text{AI}} \times \text{AREA}_{\text{wall}}$ (Equation 41)	$E_{\text{spray, wall, applic, soil}}$	kg/d	2.21E-06
Local concentration of active ingredient in soil adjacent to the house due to wall application against flying insects $C_{\text{spray, wall, applic, soil}} = E_{\text{spray, wall, applic, soil}} / V_{\text{spray, soil}} \times \text{RHO}_{\text{soil}}$ (Equation 44)	$C_{\text{spray, wall, applic, soil}}$	kg/kg wwt	2.96E-10

Outdoor Use**Wash off of the Treated Surface by Rainfall**

Variable/parameter (units)	Symbol	Unit	Crack & Crevice/ Targeted Spot House
Input			
Fraction emitted to soil due to wash off by rainfall	$F_{\text{spray, wash-off}}$	-	0.5
Quantity of commercial product applied	Q_{prod}	kg/m ²	0.021
Fraction of active substance in the commercial product	F_{AI}	-	0.0002
Area of exterior wall treated per day	$\text{AREA}_{\text{wall}}$	m ² /d	1.75
Soil volume around the building	$V_{\text{spray, soil}}$	m ³	4.375
Bulk density of wet soil	RHO_{soil}	kg wwt/m ³	1700
Local emission from outdoor spray application on wall due to wash off by rainfall $E_{\text{spray, wall, wash-off, soil}} = F_{\text{spray, wash-off}} \times Q_{\text{prod}} \times F_{\text{AI}} \times \text{AREA}_{\text{wall}}$ (Equation 42)	$E_{\text{spray, wall, wash-off, soil}}$	kg/d	3.68E-06
Local concentration of active ingredient in soil adjacent to the house due to wash off by rainfall $C_{\text{spray, wall, wash off soil}} = E_{\text{spray, wall, wash-off, soil}} / V_{\text{spray, soil}} * \text{RHO}_{\text{soil}}$ (Equation 45)	$C_{\text{spray, wall, wash off soil}}$	kg/kg	4.94E-10
Local concentration of active ingredient in soil adjacent to the house due to washing and wall application against flying insects $C_{\text{spray, wall, applic, soil}} = E_{\text{spray, wall, applic, soil}} + E_{\text{spray, wall, wash-off, soil}} / V_{\text{spray, soil}} * \text{RHO}_{\text{soil}}$ (Equation 46)	$C_{\text{spray, flying, soil}}$	kg/kg wwt	7.91E-10
		mg/kg wwt	7.91E-04

EUSES v 2.1.2 Report for Scenario 3.



Detrans CIK.docx

3.3. New information on the active substance

New information on the active substance has not been submitted.

3.4. Residue behaviour

The intended use descriptions of the Deltamethrin-containing biocidal products for which authorisation is sought indicate that these uses are not relevant in terms of residues in food and feed. No further data are required concerning the residue behaviour.

3.5. Summaries of the efficacy studies

The following studies were submitted by the Applicant to support the label claims proposed for Detrans CIK:

1. R. Kinsey. Simulated use trial to determine the efficacy of Sumitomo Chemical deltamethrin formulation Detrans® CIK oil-based aerosol against crawling insects. Study code 13/476 A. Amended final report 2017. i2LResearch Ltd, UK. 2014. (IUCLID/Sec. 6.7/Endpoint#006).

A series of simulated use trials were conducted to assess the efficacy of direct and residual application of Detrans® CIK oil-based aerosol, against cat fleas (*Ctenocephalides felis*), American cockroaches (*Periplaneta americana*), German cockroaches (*Blattella germanica*) and black ants (*Lasius niger*).

In the direct application tests, arenas with either ceramic (non-porous) or wood (porous) substrates were constructed and a population of ants, cockroaches or fleas were introduced into each arena. There were 4 replicates with same number of controls, and around 20 animals per replicate. The arena was sprayed with the treatment for a 2 second period (theoretically this should be 4 g Detrans®CIK/m²). Knockdown (KD) and mortality (D) was assessed after 30 minutes and then at 1-hour intervals up to 48 hours following treatment application.

For residual efficacy tests, for each ageing interval (1 day and 1, 2, 3 months), the treated tiles were placed in one half of the test arena with the remaining half containing untreated tiles of the same surface type (ceramic or wood). Treated tiles were sprayed for 5-7 seconds (theoretically this should be 10-14 g Detrans®CIK/m²). There were 4 replicates with controls. Around 50 ants, 30 cockroaches or 20 fleas were placed in the centre of the test arena and knockdown and mortality was assessed at 2-hour intervals following insect introduction up to 72 hours.

The application rates were checked by the eCA since measured data on the amount of product applied per replicate was available. There was a high variability in the applied doses in each replicate, and most of them were below the expected (and recommended) rates. Percentage data of affected insects (knocked down and dead) were calculated in the laboratory report for each time point of each treatment. The eCA assessed the results considering knockdown and mortality data (mean of 4 replicates) independently according to the Guidance.

The table below shows the results of the study re-calculated by the eCA from the raw data of the laboratory report. Doses different from the recommended ones are marked in green. Efficacy data that do not comply with the TNsG criteria are marked in red

	<i>Periplaneta americana</i>	<i>Blattella germanica</i>	<i>Lasius niger</i>
Direct application onto insects (Dose 2 seconds of spray = 4 g b.p.)			
Ceramic tiles	Dose: 7 g 100% KD after 30 min 100% D after 24h	Dose: 3 g 100% D after 24h 100% KD after 30 min	Dose: 2 g 100% D after 2 h 100% KD after 30 min
Wood tiles	Dose: 4 g 100% KD after 30 min 68% D after 48h	Dose: 3 g 96% D after 48h 100% KD after 30 min	Dose: 2 g 100% D after 4 h 100% KD after 30 min
Residual treatment (Dose 5-7 seconds of spray/m ² = 10-14 g b.p./m ²)			
1 day ageing			
Ceramic tiles	Dose 7 g/m ² 100% KD after 2h	Dose 11 g/m ² 100% KD after 2h	Dose 8 g/m ² 29% KD after 2h

	9% D after 24h (<90%D after 72h)	15% D after 24h (80% D after 72h)	(79% KD after 6h) 100% D after 24h
Wood tiles	Dose 5 g/m ² 97% KD after 4h 0%D after 24h (57%D after 72h)	Dose 4 g/m ² 14% KD after 2h 27% D after 24h (72%D after 72h)	Dose 8 g/m ² 0% KD after 2h (12% KD after 6h) 29% D after 24h (93% D after 72h)
1 month ageing			
Ceramic tiles	Dose 10 g/m ² 100%KD after 2h 9%D after 24h (52% D after 72h)	Dose 9 g/m ² 100%KD after 2h 19% D after 24h (97% D after 72h)	Dose 9 g/m ² 93%KD after 2h 100%D after 24h
Wood tiles	Dose 10 g/m ² 100% KD after 6h 3% D after 24h (37% after 72h)	Dose 9 g/m ² 81% KD after 24h 6% D after 24h (72% D after 72h)	Dose 9 g/m ² 12% KD after 2h 29% D after 24h (80% D after 72h)
2 months ageing			
Ceramic tiles	Dose 11 g/m ² 100%KD after 2h 3% D after 24h (60% D after 72h)	Dose 9 g/m ² 100%KD after 2h 9%D after 24h (88% D after 72h)	Dose 10 g/m ² 97%KD after 2h 100%D after 24h
Wood tiles	Dose 11 g/m ² 79% KD after 4h 30% D after 24h (31% D after 72 h)	Dose 10 g/m ² 28% KD after 2h (max. at 24-48h) 4% D after 24h (36% D after 72h)	Dose 10 g/m ² 52% KD after 2h (max at 6h) 91% D after 24h
3 months ageing			
Ceramic tiles	Dose 12 g/m ² 100% KD after 2h 3% D after 24h (89% D after 72h)	Dose 13 g/m ² 100%KD after 2h 65%D after 24h (100% D after 48h)	Dose 14 g/m ² 97%KD after 2h 100%D after 24h
Wood tiles	Dose 10 g/m ² 77% KD after 4h (max. at 24h) 5% D after 24h (45% D after 72h)	Dose 8 g/m ² 21% KD after 2h (max. at 6-24h) 27% D after 24h (66% D after 72h)	Dose 8 g/m ² 22% KD after 2h (max. at 6h) 79% D after 24h (100% D after 48h)

From the results above, the eCA concluded:

- *Periplaneta americana*:

. Direct application: in ceramic tiles the required efficacy was achieved with 7 g of spray (100%KD after 30 minutes and 100%D after 24h). In wood tiles, with 4 g of spray, <70% D was achieved after 48h; therefore required efficacy in porous surfaces was not proved.

. Residual efficacy: in ceramic tiles, with recommended doses and below, >90% KD was obtained after 2h. However D was only acceptable (89% D after 72h) after 3 months of ageing, with the highest dose tested (12 g/m²). In wood tiles, with recommended doses, KD effects were enough after 4-6h. However mortality results after 72h were not sufficient in all ageing periods; the highest value was 31% D after 72h, at 2-month ageing with the highest tested dose (11 g/m²).

In conclusion, efficacy in porous surfaces was not sufficient at all. In non-porous surfaces, efficacy after direct application was acceptable with 7 g (3-4 seconds); residual efficacy was acceptable up to 3 months of ageing with a minimum dose of 12 g/m².

- *Blattella germanica*:

. Direct application: 100% KD was obtained after 30 minutes and >90% D after 24-48h in ceramic and wood tiles, with doses as recommended (3 g).

. Residual efficacy: in ceramic tiles, 100% KD was obtained after 2h with every tested dose, while mortality was $\geq 80\%$ after 72h with product residues aged up to 2 months (doses 9-11 g/m²). After 3 months of ageing, there was 100% D after 48h because the dose was 13 g/m². Therefore it is expected that efficacy is acceptable up to 3 months of ageing when doses are ≥ 13 g (6-7 seconds of spray). In wood tiles, KD was acceptable up to 1 month of ageing independently of the tested dose. Mortality did not achieve 90% after 72h, independently of the dose and ageing period.

In conclusion, residual efficacy in porous surfaces was not sufficient, but direct application was efficacious. In non-porous surfaces, efficacy after direct application was acceptable with 3 g (2 seconds); residual efficacy was acceptable up to 3 months of ageing with recommended doses.

- *Lasius niger*:

. Direct application: with dose of 2 g (1 second) satisfactory efficacy in terms of KD and D (i.e. 100%KD after 30 minutes and 100%D after 2-4h) was achieved in both surface types.

. Residual efficacy: in ceramic tiles, $\geq 90\%$ KD after 2h and 100% D after 24h was obtained with doses 9-14 g/m² up to 3 months of ageing. In wood tiles, there was a high variability in the results and acceptable efficacy (91%D after 24h, 52% KD after 2h) was achieved only with surfaces aged 2 months (10 g/m²). All other samples yielded low efficacy due to the low doses tested (8-9 g/m²).

In conclusion, direct application was efficacious in both types of surfaces with at least 2 g of spray. Residual efficacy in non-porous surfaces is acceptable up to 3 months of ageing. Residual efficacy in porous surfaces is acceptable up to 2 months of ageing.

Note: The data on efficacy against cat fleas were not included, since the Applicant withdrew the claim against fleas, when the eCA requested representative data according to the Guidance to support a label claim against these animals.

The following studies were not considered reliable enough by the eCA, but they were used as supporting information to help in the evaluation of efficacy of Detrans®CIK.

2. P. Köhler. Comparative evaluation of water-based crawling insect killer (CIK) aerosols Detrans WB CIK 0200, Detrans WB CIK 0205, Detrans WB CIK 0215, Detrans WB CIK 0530 versus Detrans CIK and Detrans KD CIK containing DTM and DTM/PY against against *Blatta orientalis* and *Lasius niger* in spraybox tests. Report No. EHF99 - 031R. Aventis Environmental Science Biology, Germany. November 2000. (IUCLID/Sec. 6.7/Endpoint#001).

This laboratory study tried to show efficacy of several products after direct application onto *B. orientalis* and *L. niger*. The application rates of 2 seconds of spray of Detrans CIK (0.02% Deltamethrin) were measured to be in average 1.34 g for *B. orientalis* and 1.1 g for *L. niger* (raw data not available). There were 3 replicates per treatment and untreated controls with 10-15 ants and 5 cockroaches per replicate. Controls data were not available. Knockdown was recorded at regular intervals up to 15 minutes post-treatment or until 100% KD was achieved. Mortality was assessed at 1 and 6 days post-treatment.

In *L. niger* tests, KDT95 was 2.6 min, and 100% D was obtained after 24h. In *B. orientalis* tests, KDT95 was >20 min, and 100% D was obtained after 24h. Therefore efficacy after direct application may be considered acceptable. However the number of replicates and

individuals was scarce and controls data were not available. The eCA considers this study as not reliable enough.

3. A. M. Leach, L.Z. Duffield, A. J. Miller, J. Deacon. Biological and chemical evaluations of a proposed residual aerosol formula for Europe against *Periplaneta americana* and *Blattella germanica*. Report No. GB97-0015. AgrEvo Environmental Health Ltd., UK. August 1997. (IUCLID/Sec. 6.7/Endpoint#003).

A laboratory test with a formulation containing 0.02% Deltamethrin was set up to test residual efficacy. The formulation was different to Detrans®CIK in its content of propellants and solvents. There were 3 replicates per treatment, with no negative controls, and 10 male German cockroaches and 5 female American cockroaches per batch. These conditions do not fulfil the requirements of the Guidance. The eCA considers this study as not reliable enough.

Ceramic surfaces were sprayed for 0.5 seconds and emulsion painted plywood surfaces for 2.5 seconds; the amount of product delivered was not weighted nor stated in the report. Considering the recommendations of the Applicant, these doses should be equivalent to 1g and 5g of product, respectively. After 24h of drying, the cockroaches were exposed to the aged treated plate by leaving them walk onto the surface. The surfaces were aged during 1, 8, 15, 22 and 29 days post treatment. Knockdown was recorded up to 30 minutes. Then the animals were brought to a non-treated surface and mortality was observed after 1 and 6 days.

For German cockroaches, 100% KD was achieved after 10 min in ceramic surfaces aged up to 29d. 100% D occurred after 24h. In plywood surfaces, 0% KD up to 25 min and 4% D after 1 and 6 days was obtained. Therefore only non-porous surfaces showed acceptable efficacy up to 29-day ageing. For American cockroaches, KD was maximum 87% after 30 min in ceramic surfaces aged 1 and 8 days. In all other ageing period KD was low. 100% D after 24h was obtained in surfaces aged 1 and 8 d and in all other periods mortality <90%. Therefore in non-porous surfaces aged up to 8d efficacy was acceptable. While in plywood surfaces 0% KD was recorded up to 25 min and 0% D at 24h post-exposure, then the test was stopped. Therefore in porous surfaces residual efficacy was negligible.