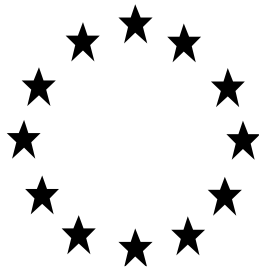
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Detrans® HPC3

Product type(s) 18

Deltamethrin as included in the Union list of approved active substances

Case Number in R4BP: BC-HT010603-35

Evaluating Competent Authority: SPAIN

April 2022

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1 CONCLUSION

The assessment presented in this report has shown that the ready-to-use product, Detrans® HPC3, with the active substance Deltamethrin, at a level of 0.030% w/w, may be authorised for use as an insecticide (product-type 18) for use by the general public for the control of houseflies and crawling insects in domestic premises.

Detrans® HPC3 formulation was found to be a slightly turbid, homogeneous white liquid without any odour at each test time point. The density was 1.00 g/cm^3, the pH was 5.9 to 6.1 and viscosity was 1098 mPa.s (23^{o}C).

The formulation was shown to be stable after accelerated storage at 54°C for 4 weeks. Stability at 2 years has been confirmed in HPDE material trigger spray.

Available information on corrosivity, flammability, explosivity and oxidising potential indicate that Detrans® HPC3 is unclassified with regard to these properties and does not represent an unacceptable risk to either professional users, non-professional users or the environment. Hence, there will not be hazards associated with the physico-chemical properties of the product under normal conditions of use.

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

The product has been shown to be effective against *Musca domestica, Lasius niger, Blattella germanica and Periplaneta americana* when applied in different areas/ treatments and substrates, according to the submitted tests. Barrier treatment cannot be authorised since efficacy of this application has not been desmonstrated.

Acute toxicity studies have been performed using a formulation different (reference formulation) from Detrans® HPC3. The CA considers that there is sufficient information to read-across from the studies submitted. Nevertheless, given that Detrans® HPC3 contains more than 15 ppm of CMIT/MIT (3:1) while the reference formulation contains less than 15 ppm, ES CA cannot accept the read across from the dermal Sensitization in Guinea Pigs study with reference formulation for Detrans® HPC3. Therefore, a new skin Sensitisation Local Lymph Node Assay has been required during the evaluation.

There are Substances of Concern in the biocidal product since these substances are classified as hazardous according to Regulation (EC) No 1272/2008. However, the concentration of these substances in the preparation does not exceed the classification limits set in CLP Regulation and the biocidal product is not classified with regard to toxicological properties.

CMIT/MIT(3:1) is present in the product in such proportion as to lead to classification of the product as Skin sens 1; H317. Therefore it should have been considered a substance of concern. In such situation, Detrans® HPC3 should not be authorized for non-professional users (general public). Nevertheless, the applicant has submitted a new skin Sensitisation Local Lymph Node Assay. According to this assay, Detrans® HPC3 should not be classified as skin sensitizer. Thus, CMIT/MIT(3:1) has not been considered a substance of concern. However in order to protect already sensitised individuals, *EUH 208: Contains "5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2Hisothiazol-3-one (3:1)". May produce an allergic reaction* is required.

According to our assessment, none of the co-formulants contained in the product Detrans HPC3 are identified as endocrine disruptors.

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

Based on the risk assessment results, the use of Detrans® HPC3 as an insecticide is considered safe for human health taking into account primary and secondary exposure to the biocidal product as a consequence of use.

Dietary exposure as result of use (*i.e.*, food contamination and livestock exposure) can be excluded. The label must include restrictions and instructions of use to avoid food contamination and exposure of animals (livestock and companion animals).

Conclusion of risk characterisation for Environment:
The environmental risk assessment has been based on the active substance deltamethrin. The assessment has been carried out for the intended indoor use of the product DETRANS HPC3 against cockcroaches (into crack and crevices, surface treatment), houseflies (spot treatment to a surface) and ants (surface treatment) by non professionals. Based on the outcome of the risk assessment the product, used according to the SPC, do not pose unacceptable risk to the environment. he following risk mitigation measures need to be provided, for this use, on the label:

Use 1:
The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be a harbourage for cockroaches.

Use 2:
The product has to be applied only in restricted areas inaccessible to children and pets (particularly cats), on surfaces not regularly wet cleaned, such as: window and door frames and walls (in localized resting areas where flies may rest.

Use 3:
The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater.

For all the uses:
- Apply the product only two times per year.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	Country
Detrans HPC3	Austria (cMS)
Raid® Insekten-Abwehr	
Celaflor Ungezieferspray	
Detrans HPC3	Belgium (cMS)
RAID® DEFENSE INSECTES / INSECTENAFWEER	
BAYGON® DEFENSE INSECTES / INSECTENAFWEER	
KB MIEREN / FOURMIS SPRAY	
Detrans HPC3	France (cMS)
RAID® DEFENSE INSECTES	
BAYGON® DEFENSE INSECTES	
CAFANET	
Detrans HPC3	Germany (cMS)
Raid® Insekten-Abwehr	
Celaflor Ungezieferspray	
Detrans HPC3	Greece (cMS)
RAID® BUG DEFENCE	
BAYGON® BUG DEFENCE	
Detrans HPC3	Ireland (cMS)
Raid® Bug Defence	
Raid® Bug Defense	
HOME DEFENSE ANT STOP! GUN	
Detrans HPC3	Italy (cMS)
RAID® INSECT DEFENCE	
BAYGON® INSECT DEFENCE	
NEXA AL	
Detrans HPC3	Luxembourg (cMS)
RAID® DEFENSE INSECTES	
BAYGON® DEFENSE INSECTES	
KB MIEREN / FOURMIS SPRAY	
Detrans HPC3	Poland (cMS)
Raid® Ochrona przed owadami	
SUBSTRAL ANT STOP NA PAJAKI I MRÓWKI	
Detrans HPC3	Portugal (cMS)
RAID® DEFESA ANTI-INSECTOS	
BAYGON® DEFESA ANTI-INSECTOS	
KB NEXA AL	

Detrans HPC3	**Spain (ref.MS)**
RAID® DEFENSA ANTI-INSECTOS	
BAYGON® DEFENSA ANTI-INSECTOS	
NEXA AL	
Detrans HPC3	Switzerland (cMS)
Raid® Insekten-Abwehr/ Raid Defense Insectes	
Celaflor Ungeziefer- Spray	

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)-2022-18-00817	
Date of the authorisation	22/04/2022	
Expiry date of the authorisation	22/04/2032	

2.1.1.3 Manufacturer of the product

Name of manufacturer 1	Denka International b.v.
Address of manufacturer 1	P.O. Box 337 3370 AH Barneweld Netherlands
Location of manufacturing sites 1	Denka International b.v. 3370 AH Barneweld, Netherlands

Name of manufacturer 2	S.C. Johnson Europlant B.V.
Address of manufacturer 2	Groot Mijdrechtstraat 81 3641 RV Mijdrecht Netherlands
Location of manufacturing sites 2	Groot Mijdrechtstraat 81 3641 RV Mijdrecht Netherlands

Name of manufacturer 3	Evergreen Garden Care France
Address of manufacturer 3	4 Allées des Sequoias 69760 Limonest France
Location of manufacturing sites 3	Usine de Fourneau 27580 Bourth France

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

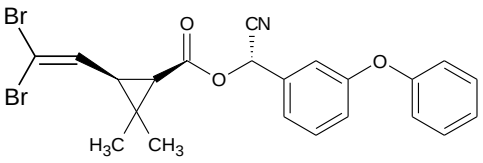
Active substance	Deltamethrin
Name of manufacturer	Bayer CropScience AG (Art. 95 list: Bayer S.A.S.)
Address of manufacturer	Alfred-Nobel-Strasse 50 40789 Monheim am Rhein (Germany)
Location of manufacturing sites	Bilag Industries Pvt Ltd 304/2, II Phase, GIDC, Vapi - 396 195 Gujarat India

2.1.2 Product composition and formulation

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

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

2.1.2.2 Candidate(s) for substitution

Deltamethrin is not candidate for substitution in accordance with the article 10 of BPR. According to the CAR for Deltamethrin, there some indications for potential endocrine disrupting properties of the active substance. However, a comprehensive ED-assessment for the active substance according to Regulation (EU) 2017/2100 and the EFSA/ECHA Guidance on endocrine disruptor will need to be performed at the renewal stage. For the time being it is concluded that the biocidal product DETRANS HPC3 does not have endocrine disrupting properties.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product[1]

Common name	IUPAC name	Function	CAS number	EC number	Content (w/w%)
Deltamethrin	(S)-α-cyano-3-phenoxybenzyl (1R,3R)3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylate	Active substance	52918-63-5	258-256-6	0.03 (technical) 0.02955 (pure)

1 Please delete as appropriate.

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

There are no substances of concern, at the concentrations present in the formulation, to be taken into account in the human health or environmental risk assessments.
For further information, see Confidential annex.

2.1.2.6 Type of formulation

AL – Any other liquid

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	Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H400 Very toxic to aquatic life H410 Very toxic to aquatic life with long lasting effects
Labelling	
Pictogram	GHS09
Signal words	Warning
Hazard statements	H410 Very toxic to aquatic life with long lasting effects EUH 208 "Contains 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction'
Precautionary statements	P273 Avoid release to the environment P391 Collect spillage P501 Remove the content and / or its container as hazardous waste according to the regulations in force.

2.1.4 Authorised use

2.1.4.1 Use description 1

Table 1. Use # 1 – Cockroaches, crack and crevices and surfaces not regularly cleaned

Product Type	Product type 18 (insecticides, acaricides and products to control other arthropods)
Where relevant, an exact description of the authorised use	Insecticide against crawling insects (cockroaches) for domestic premises.
Target organism (including development stage)	Cockroaches – adults - American cockroaches:- *Periplaneta Americana;* - German cockroaches:- *Blattella germanica;*

Field of use	Indoors, crack and crevices and surface not regularly cleaned.
Application method	Trigger spray
Application rate(s) and frequency	Spray from a distance of 30 cm (1 trigger spray pull = 0.9 g) at the rate of 41 g/m^2. (i.e 46 trigger spray pull/m^2) Use maximum up to 2 application per year
Category(ies) of users	Non-professional (general public).
Pack sizes and packaging material	Please see the relevant section.

2.1.4.1.1 Use-specific instructions for use

Residual activity will be effective up to 3 months The knockdown is reached after 2 h and mortality after 24h – 72h on surfaces and after 7 days in cracks and crevices. Apply the product preferably on non-porous surfaces. (that is, in ceramic, glass, metal or platics surfaces). See section 2.1.5.1.

2.1.4.1.2 Use-specific risk mitigation measures

The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be a harbourage for cockroaches. See section 2.1.5.2.

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

See section 2.1.5.3.

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

See section 2.1.5.4.

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

See section 2.1.5.5

2.1.4.2 Use description 2

Table 2. Use # 2 Flies-Indoor, spot treatment to a surface

Product Type	Product type 18 (insecticides, acaricides and products to control other arthropods)

Where relevant, an exact description of the authorised use	Insecticide against flies for domestic premises. Spot application in places where flies tend to rest.
Target organism (including development stage)	Houseflies*, Musca domestica (adults)*
Field of use	Indoors, Spot application to a surface.
Application method	Trigger spray
Application rate(s) and frequency	Spray from a distance of 30 cm (1 trigger spray pull = 0.9 g) at the rate of 41 g/m^2. (i.e 46 trigger spray pull/m^2) Use maximum up to 2 application per year
Category(ies) of users	Non-professional (general public).
Pack sizes and packaging material	Please see the relevant section.

2.1.4.2.1 Use-specific instructions for use

Residual activity will be effective up to 2 months. The knockdown is reached after 6-24 h and mortality after 24 hours. See section 2.1.5.1.

2.1.4.2.2 Use-specific risk mitigation measures

The product has to be applied only in restricted areas inaccessible to children and pets (particularly cats), on surfaces not regularly wet cleaned, such as: window and door frames and walls (in localized resting areas where flies may rest). See section 2.1.5.2.

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

See section 2.1.5.3.

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

See section 2.1.5.4.

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

See section 2.1.5.5

2.1.4.3 Use description 3

Table 3. Use # 3 – Ants, surfaces not regularly cleaned.

Product Type	Product type 18 (insecticides, acaricides and products to control other arthropods)
Where relevant, an exact description of the authorised use	Insecticide against crawling insects for domestic premises
Target organism (including development stage)	Ants (adults) - Black ants (*Lasius niger*)
Field of use	Indoors. Surfaces not regularly cleaned.
Application method	Trigger spray
Application rate(s) and frequency	Spray from a distance of 30 cm (1 trigger spray pull = 0.9 g) at the rate of 41 g/m^2. (i.e 46 trigger spray pull/m^2) Use maximum up to 2 application per year
Category(ies) of users	Non-professional (general public).
Pack sizes and packaging material	Please see the relevant section.

2.1.4.3.1 Use-specific instructions for use

Apply the product on non-porous surfaces.(that is, in ceramic, glass, metal or plastic surfaces).

Residual activity up to 2 months.

For ants, KD is reached at 6 hours and mortality at 48 hours.

See section 2.1.5.1.

2.1.4.3.2 Use-specific risk mitigation measures

The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater.

See section 2.1.5.2.

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

See section 2.1.5.3.

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

See section 2.1.5.4.

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

See section 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

Always read the label or leaflet before use and respect all the instructions provided.
Ready-to-use product with trigger spray. Shake well before use to deliver adequate amount of insecticide. Test in an inconspicuous area before applying.
Do not direct the spray up into the air or directly onto the insects.
Clean the excess of the product after the treatment with a moistened disposable wipe.
Hold the product in an upright position and spray onto surfaces from a distance of about 30 cm.
Carefully clean the rooms before treatment.
Apply on infested area only.
If the infestation persist, contact a professional.
Re-treat in case of new infestation without exceeding the maximum number of treatment authorized per year.
Avoid continuous use of the product.
Inform the authorisation holder if the treatment is ineffective.

2.1.5.2 Risk mitigation measures

Do not use the product more than 2 times per year.
Do not breathe spray.
Avoid contact with skin. In case of contact with skin wash immediately with plenty of soap and water without rubbing.
Keep cats away from treated surfaces. Due to their particular sensitivity to deltamethrin, the product can cause severe adverse reactions in cats.
Remove or cover terrariums, aquariums and animal cages before application. Turn off aquarium air-filter while spraying.
Keep out of reach of children and pets.
Keep uninvolved persons, children and pets away from treated surfaces/areas until dried.
Do not spray onto people and pets.
Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals.

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

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

IF SWALLOWED: If symptoms occur call a POISON CENTRE or a doctor.
IF ON SKIN: Take off all contaminated clothing and wash it before reuse. Wash skin with water. If skin irritation or rash occur: Get medical advice.
IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

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

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

Store out of reach of children and non-target animals/pets.

Do not store near food, drink and feed.

Protect from freezing and direct sunlight.

Keep in original container in a dry and cool place.

Shelf life: 2 years.

2.1.6 Other information

Definitions:

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

This product contains a bittering agent that makes it repulsive to people or pets.

The authorisation holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials

					(Yes/No)
Bottle with trigger spray	Up to 500 mL	HDPE	Not applicable as bottle has a trigger spray	Non-professional	Yes
Bottle with trigger spray	Up to 750 mL	HDPE	Not applicable as bottle has a trigger spray	Non-professional	Yes
Bottle with trigger spray	Up to 1000 mL	HDPE	Not applicable as bottle has a trigger spray	Non-professional	Yes
Bottle with trigger spray	Up to 750 mL	PET	Not applicable as bottle has a trigger spray	Non-professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substance itself or on the substances of concern have been submitted in function of this product application. All new information relates to the biocidal product described within this application.
The reference list (including updates) for the studies submitted in support of the BPD dossier has been included in Annex 3.1 whilst the reference list for the studies considered confidential has been included in the confidential Annex.

2.1.8.2 Access to documentation

The applicant has submitted the following letters of access:
-a letter of access from Bayer Environmental Science (notifier and having on all the data included in the dossier for Deltamethrin presented by Bayer SAS, Environmental Science) to all the documents about the active substance associated to the Annex I listing.
Efficacy test has been carried out with the product DETRANS HPC3 and the sponsor is Sumitomo Chemical (UK) plc .
Skin Sensitisation Local Lymph Node Assay has been carried out with the product DETRANS HPC3 and the sponsor is Sumitomo Chemical (UK) plc .

2.2 Assessment of the biocidal product

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

Table 2. Intended use # 1 – Flying and crawling insect killing and barrier trigger spray

Product Type(s)	PT 18(insecticides, acaricides and products to control other arthropods)
Where relevant, an exact description of the authorised use	Flying and crawling insect killing and barrier trigger spray.

Target organism (including development stage)	*Blattodea* (Cockroaches) - adults e.g. American cockroaches:- *Periplaneta Americana;* German cockroaches:- *Blattella germanica;* Oriental cockroaches:- *Blatta orientalis* Ants - adults *e.g.* Black ants, *Lasius niger* Flying Insects - adults *Houseflies,* Musca domestica
Field of use	Insecticide Field of Use: Indoors use by spraying onto surfaces as a spot and crack and crevice treatment. Outdoor use in areas such as the outside surfaces of window and door frames; other areas around the home where flies enter the home; localized resting areas, such as under eaves, porches, surfaces around light fixtures and railings where flies may rest.
Application method(s)	Trigger spray.
Application rate(s) and frequency	Spray only onto surfaces as a spot or crack & crevice treatment. Hold the product in an upright position and spray directly at insect or onto surface from a distance of about 25 to 30cm for 1 to 2 pulls of the trigger. Do not direct the spray up into the air. Spray can also be applied in cracks and crevices suspected of harbouring crawling insect pests. Repeat as necessary. Squeeze trigger to spray until surface is slightly moist but not to the point of runoff. Do not allow children or pets to approach treated surfaces until the spray has dried. Protect from freezing and direct sunlight.
Category(ies) of user(s)	General public(non-professional)
Pack sizes and packaging material	Please see the relevant section.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Physical state and nature at 20 °C and 101.3 kPa	Visual Determination	Detrans HPC3 CIK Trigger Spray Batch No: See PAR confidential 0.03% w/w Deltamethrin	Initially, after 2 weeks at 54°C and after 24 months at 20ºC: **Slightly turbid liquid**	See PAR confidential.
Colour at 20 °C and 101.3 kPa	Visual Determination	Detrans HPC3 CIK Trigger Spray Batch No: See PAR confidential 0.03% w/w Deltamethrin	Initially, after 2 weeks at 54°C and after 24 months at 20ºC: **Homogeneus white liquid**	See PAR confidential.
Odour at 20 °C and 101.3 kPa	Comparasion with other caracteristics odours	Detrans HPC3 CIK Trigger Spray Batch No: See PAR confidential 0.03% w/w Deltamethrin	Initially, after 2 weeks at 54°C and after 24 months at 20ºC: **No odour**	See PAR confidential.
Acidity/Alkalinity	Comparable to CIPAC MT 75.3	Detrans HPC3 CIK Trigger Spray Batch No: See PAR confidential 0.03% w/w Deltamethrin	Initially: **pH: 5.9** After 2 weeks at 54°C and after 24 months at 20ºC: **pH: 6.1**	See PAR confidential.
Relative density/bulk density	40 CFR 158.190: Pesticide Assessment Guidelines Subsection. D.; §63-7 (830.7300) Comparable to OECD Guideline No. 109	DTM 0.03% RTU R98-077 Lot See PAR confidential	0.9962 g/cm^3 at 21°C	See PAR confidential.
Storage stability test –	CIPAC MT 46.3:	Detrans HPC3 CIK	The product is stable after 14	See confidential

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
accelerated storage	accelerated storage procedure	Trigger Spray Batch No: See PAR confidential 0.03% w/w Deltamethrin	days at 54ºC.	annex
Deltamethrin content	HPLC method		Initially: **0.0288% w/w** After 2 weeks at 54°C: **0.0285% w/w** Diference: -1.04%	
Homogeneity of application			Not available	
Appearance and stability of the package			Initially and after 2 weeks at 54°C: **Samples in sound conditions, sealed and without leakages, ballooning or panelling, dimensionally stable**	
Storage stability test – **long term storage at ambient temperature**	Ambient Storage Stability (2 years)	Detrans HPC3 CIK Trigger Spray Batch No: See PAR confidential 0.03% w/w Deltamethrin	The biocidal product is stable after 24 months at 20ºC.	See PAR confidential.
Deltamethrin content	HPLC method		Initially: **0.0288% w/w** After 12 months at 20°C: **0.0285% w/w** Diference: -1.04% After 2 years at 20°C: **0.0288% w/w** Diference: 0.00%	
Homogeneity of application			Not available	
Appearance and stability			Initially and after 24 months at	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
of the package			20°C: **Samples in sound conditions, sealed and without leakages, ballooning or panelling, dimensionally stable**	
Storage stability test – **low temperature stability test for liquids**			No test conducted. Therefore, the label claim „Protect from freezing" is added to the storage conditions	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			No test conducted. Therefore, the label claim „Protect from direct sunlight" is added to the storage conditions	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**		Detrans HPC3 CIK Trigger Spray Batch No: See PAR confidential 0.03% w/w Deltamethrin	Not changes observed.	See PAR confidential.
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**		Detrans HPC3 CIK Trigger Spray Batch No: See PAR confidential 0.03% w/w Deltamethrin	Not changes observed.	See PAR confidential.
Wettability			Not required.	
Suspensibility, spontaneity and dispersion stability			Not applicable.	
Wet sieve analysis and dry sieve test			Not applicable.	
Emulsifiability, re-emulsifiability and			Not applicable.	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
emulsion stability				
Disintegration time			Not applicable.	
Attrition/friability of granules; integrity of tablets			Not applicable.	
Particle size distribution, content of dust/fines	Comparable to CIPAC guideline MT187	Detrans HPC3 CIK Trigger Spray Batch No: See PAR confidential 0.03% w/w Deltamethrin	Initially (finer setting): **Dv (50%) = 155 µm** Initially (beam/jet setting): **Dv (50%) = 176 µm**	See PAR confidential.
Persistence of foaming			Not required.	
Flowability/Pourability/ Dustability			Not applicable.	
Burning rate — smoke generators			Not applicable.	
Burning completeness — smoke generators			Not applicable.	
Composition of smoke — smoke generators			Not applicable.	
Spraying pattern		Detrans HPC3 CIK Trigger Spray Batch No: See PAR confidential 0.03% w/w Deltamethrin		See PAR confidential.
Spray pattern – trigger spray	Comparable to FEA method 644		Initially, after 2 weeks at 54°C and 24 months at 20ºC (finer setting): **Circular spray pattern of a white turbid aqueous liquid. Diameter: 21-23 cm.** Initially, after 2 weeks at 54°C and 24 months at 20ºC	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			(beam/jet setting): **Circular spray pattern of a white turbid aqueous liquid. Diameter: 6-8 cm.**	
Clogging of dispenser valves and residue after total discharge			Initially (finer setting): **0.86%** After 2 weeks at 54°C (finer setting): **0.62%** After 24 months at 20ºC (finer setting): **0.45%** Initially (beam/jet setting): **0.56%** After 2 weeks at 54°C and after 24 months at 20ºC (beam/jet setting): **Not available**	
Discharge rate	Comparable to FEA method 643		Initially (finer setting): **0.96 g/stroke** After 2 weeks at 54°C (finer setting): **0.94 g/stroke** After 24 months at 20ºC (finer setting): **0.92 g/stroke** Initially (beam/jet setting): **0.92 g/stroke** After 2 weeks at 54°C and 24 months at 20ºC (beam/jet setting): **Not available**	
Compatibility with other products			The product is not intended to be used in combination with other products	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Degree of dissolution and dilution stability			Not applicable.	
Surface tension			No test conducted due to the a.s. solubility.	
Viscosity	40 CFR 158.190: Pesticide Assessment Guidelines Subsection. D.; §63-18 (830.7100) Comparable to OECD Guideline 114	DTM 0.03% RTU R98-077 Lot See PAR confidential	1098 mPa·s @ 23°C Spindle No. 2 @ 20 rpm	See PAR confidential.
	OECD 114 (CIPAC MT 192)	Detrans HPC 3 Lot: See PAR confidential	124 mPa·s @ 20°C 45 mPa·s @ 40°C Spindle No. 21 @ 20 rpm	See PAR confidential.
		Detrans HPC 3 Lot: See PAR confidential	130 mPa·s @ 20°C 38 mPa·s @ 40°C Spindle No. 2 @ 20 rpm	

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

NOTE: the applicant has submitted the statement ensuring that all batches used in the dossier have the same compostion as the formulation to be marketed. All information submitted by the applicant (see reference list) has been assessed but the accepted studies has only included in the PAR.

Appearance
The biocidal product consist of a slightly turbid, homogeneous white liquid without any odour.

Acidity/alkalinity
This data is not required because the 4 < pH < 10. The pH-value of the biocidal product was determined of the undiluted sample by means of a pH-meter with a glass electrode.

Relative density/bulk density
Density of the product using the pycnometer.

Accelerated storage
No significant variations in active substance content was observed following the 14 day storage period at 54ºC. No significant variation in any technical characteristics of the product was observed following the 14 day storage period at 54ºC.

Long term storage at ambient temperature
No significant variation in any technical characteristics of the product was observed following the 24 months storage period at 20ºC.

Storage stability test – low temperature stability test for liquids
No test conducted due to storage conditions instruction (Protect from frost)

Effects of light
No test conducted due to storage conditions instruction (Protect from direct sunlight)

Effects of temperature and humidity
No effects noted according to the storage stability studies.

Technical characteristics of the biocidal
Particle size distribution: the particle size distribution was determined for both spray setting at start of the study only.
For the application of the product, the following characteristics are not relevant: wettability, suspensibility, emulsifiability, and other technical characteristics. Persistent foaming is not required because the product (Detrans® HPC3 0.03% Deltamethrin spray product) is ready to use and not applied in water for use or diluted with water prior to use.

Spraying pattern — trigger spray
The spray pattern was determined with both spray settings (finer setting and beam/jet setting). No significant differences were observed at the start for the parameters residue after use and the discharge rate. No solid deposits were observed on the spray heads and on the trigger mechanism.

Physical and chemical compatibility with other products
Detrans® HPC3 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 Deltamethrin has a water solubility of <1 mg/L (5 µg/L at 20°C) (Refer to OECD Guideline 115).

Viscosity
The type of viscometer is not specified in the report.

Conclusion
The formulation was found to be a slightly turbid, homogeneous white liquid without any odour at each test time point. The density was 0.9962 g/cm^3, the pH was 5.9 to 6.1 and viscosity was 124-130 mPa.s @20ºC and 38-45 mPa.s@ 40ºC.
No appreciable changes in the packaging (HPDE material trigger spray), pH value, spray pattern (finer and beam/jet setting), discharge rate (finer setting), residue after use and clogging of dispenser valves (finer setting) of the test item were observed after storage for 2 weeks at 54ºC and storage for 24 months at 20ºC.
The formulation was shown to be stable after accelerated storage at 54°C for 2 weeks and storage for 2 years at 20ºC.
The label phrase 'Protect from freezing and direct sunlight' must be included.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Explosives	40 CFR 158.190: Pesticide Assessment Guidelines Subsection. D.; §63-16 (830.6316) Equivalent to EC Method A.14.	DTM 0.03% RTU R98-077 Lot See PAR confidential	The biocidal product is not explosive.	See PAR confidential
	UN RTDG Manual of Tests and Criteria, Appendix 6.3	Detrans HPC3 Lot number: See PAR confidential		
Flammable gases			Not applicable.	
Flammable aerosols			Not applicable.	
Oxidising gases			Not applicable.	
Gases under pressure			Not applicable.	
Flammable liquids	40 CFR 158.190: Pesticide Assessment Guidelines Subsection. D.; §63-15 (830.6315) (the method used is ASTM 56 using the TAG Closed Cup - equivalent to the Pensky-Martens method) Equivalent to EC Method A9	DTM 0.03% RTU R98-077 Lot See PAR confidential	Not flammable (Flash point = 75ºC)	See PAR confidential
Flammable solids			Not applicable.	
Self-reactive substances and mixtures	UN RTDG Manual of Tests and Criteria, Appendix 6.3	Detrans HPC3 Lot number: See PAR confidential	Not self-reactive product.	See PAR confidential
Pyrophoric liquids			Not required.	
Pyrophoric solids			Not applicable.	
Self-heating substances and mixtures			Not required.	
Substances and mixtures which in contact with water emit flammable			Not required.	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
gases				
Oxidising liquids	40 CFR 158.190: Pesticide Assessment Guidelines Subsection. D.; §63-14 (830.6314) Equivalent to EC Method A.21	DTM 0.03% RTU R98-077 Lot See PAR confidential	The biocidal product has not oxidising properties.	See PAR confidential
Oxidising solids			Not applicable.	
Organic peroxides			Not applicable, the biocidal product formulation does not comprise any peroxide groups	
Corrosive to metals	UN RTDG Manual of Tests and Criteria, Test C.1	Detrans HPC3 Lot number: See PAR confidential	Not corrosive to metals.	See PAR confidential
Auto-ignition temperatures of products (liquids and gases)			Auto-ignition is not foreseen.	
Relative self-ignition temperature for solids			Not applicable.	
Dust explosion hazard			Not applicable.	

Conclusion on the physical hazards and respective characteristics of the product

NOTE: the applicant has submitted the statement ensuring that all batches used in the dossier have the same compostion as the formulation to be marketed. All information submitted by the applicant (see reference list) has been assessed but the accepted studies has only included in the PAR.

Explosiveness
The DSC study conclusions and the expert statement are included in the Confidential PAR, where it is concluded that the biocidal product can be regarded as not explosive.

Flammability
The Flash Point is 75°C.
The product contains a significant percentage of water and the other ingredients in the

formulation including Deltamethrin at the percentages included in the product are not classified as flammable.
No further testing has therefore been conducted to assess auto-flammability or flammability on contact with water.

Self-reactive substances and mixtures
The DSC study conclusions and the expert statement are included in the Confidential PAR, where it is concluded that the biocidal product can be regarded as not self-reactive.

Pyrophoric liquids
The study does not need to be conducted because experience in manufacture or handling shows that the liquid does not ignite spontaneously on coming into contact with air at normal temperatures and hence, the classification procedure does not need to be applied.

Self-heating substances and mixtures
In general, the phenomenon of self-heating applies only to solids. The surface of liquids is not large enough for reaction with air and the test method is not applicable to liquids.

Substances and mixtures which in contact with water emit flammable gases
The study does not need to be conducted because experience in handling and use shows that the substance or mixture does not react with water.

Oxidising properties
All present ingredients do not have oxidising properties of their own because the criteria b. (the substance or mixture contains oxygen, fluorine or chlorine and these elements are chemically bonded only to carbon or hydrogen) is fulfilled according to the CLP criteria for this endpoint.
From the aqueous nature of the product and the lack of oxidising properties of the ingredients it can safely be stated that Detrans® HPC3 does not have oxidising properties.

Organic peroxides
The study does not need to be conducted because none of the components does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual tests and criteria.

Corrosive to metals
On immersion, both the steel and the aluminium samples showed no reaction with Detrans HPC3 where the metal was in contact with the test substance.
The visual differences observed on the steel coupons was caused by light rusting. This is what we would expect to see on the ferrous samples on exposure to an aqueous Test Substance.
No pitting was evident on any of the coupons therefore the results were calculated on weight loss alone. The mass loss was less than 13.5% (0.06% for aluminium and 0.48% for steel) over a seven day period, therefore the Test Substance is not considered to be corrosive to metals.

Auto-ignition temperature (liquids and gases)
The product contains a significant percentage of water and the other ingredients in the formulation including Deltamethrin at the percentages included in the product are not classified as flammable.
No further testing has therefore been conducted to assess auto-flammability or flammability on contact with water.

Conclusions

Available information on corrosivity, flammability, explosivity and oxidising potential indicate that Detrans HPC3 is unclassified with regard to these properties and does not represent an unacceptable risk to either professional users, non-professional users or the environment. It can be concluded that Detrans® HPC3 is not classified and will not be labelled for physical hazards.

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 HPC3	HPLC	0.03 % n = 14	R^2= 0.99992 (0.3 to 0.7 mg) n = 5	No interference of inert materials with deltamethrin	98.3-101.7	100.1	Repeatability RSD = 0.88, 0.86 Intermediate precision RSD = 0.022	Not Reported	See PAR confidential.

Analytical methods for monitoring									
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		

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	0.1 µg/kg 1.0 µg/kg	0.03 to 10 µg/kg r^2 = >	Highly specific. No	89-98 98-102	95 101	3.8 1.5	0.1 µg/kg	C. A. R. (2011)

Deltamethrin (Laacher Hof)	Calibration relative to internal standard (isotopically labelled deltamethrin)	n = 5	0.999 for all soils	interference shown	83-99 101-105	91 103	7.7 1.7		
Deltamethrin (Sediment)					94-108 98-103	102 101	5.2 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 sample is adjusted to be within this range) 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)	96-104 89-100	100 94	4 4	0.27 µg/m^3	C. A. R. (2011)

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	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)

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		
	standard (isotopically labelled deltamethrin)								
Deltamethrin (drinking water)	Quantification: GC-ECD (matrix matched standards) Confirmation: GC-ECD (different stationary phase)	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 distinguish between tralomethrin and deltamethrin (see blood-method below)	108-139[2] 98-120[7]	115[3] 982	11 8	0.05 µg/L	C. A. R. (2011)
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)

2 Uncorrected recovery range

3 Mean recovery corrected by matrix matched standards

Analytical methods for animal and human body fluids and tisues									
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/µL (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 94-115	97 105	4 7	0.02 mg/kg	C. A. R. (2011)
Deltamethrin (eggs)					81-98 102-108	87 105	8 3		
Deltamethrin (meat)					95-99 94-107	97 100	2 5		
Deltamethrin (fat)					77-91 80-105	85 91	6 9		
Deltamethrin (liver)					85-93 99-121	88 109	4 7		
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	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	Not reported	101 88 100 79 83	10 8 16 6 4	200 µg/L	C. A. R. (2011)

Analytical methods for animal and human body fluids and tisues									
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		
	of internal standard. Confirmation possible, with full scan down to 1000 ng/L or by using the method presented below.	ILV-study: 101 µg/l 202 µg/l 1008 µg/l (n = 5)		due to decomposition of tralomethrin into deltamethrin in the injector.	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 area of the internal standard	20-100 ng/L n=6	20-500 ng/L	No interference shown. There are indications that GC-methods cannot distinguish between tralomethrin and deltamethrin (see blood-method above)	94-99	Not stated	2.4-3.7	20 ng/L	C. A. R. (2011)

Analytical methods for monitoring of active substances and residues in food and feeding 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	0.02 mg/kg (n=4) 0.10 mg/kg (n=3)	0.005 to 0.05 ng injected on	hown. There are	71-111 80-88	91 85	18 5.1	0.02 mg/kg	C. A. R. (2011)

Analytical methods for monitoring of active substances and residues in food and feeding 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 (flour)	could be performed using the method below	0.02 mg/kg (n=4) 0.10 mg/kg (n=3)	column (LOQ corresponds to 0.02 ng injected; the concentration of the higher fortification level is adjusted to fit into the calibration range)	indications that GC-methods Cannot distinguish between tralomethrin and deltamethrin (see blood-method above)	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 97 118	112 110	5.6 10.3		
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	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)	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 feeding 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)	standards and the ratio of the peak area for deltamethrin to the peak area of the internal standard (isotopically labelled deltamethrin)	0.01 (S) (n=5) 0.1 (S) (n=5)	olive fruit (1 µg-0.2 mg/kg) r2=0.9994 - 0.9999		89-95 76-91	92 86	3.1 8.5		
Deltamethrin (corn cob without husks)		0.01 (G) (n=5) 0.1 (G) (n=5)			82-85 81-83	84 82	1.7 1.2		
Deltamethrin (corn kernel)		0.01 (G) (n=5) 0.1 (G) (n=5)			81-87 80-85	84 83	3.3 2.5		
Deltamethrin (corn plant without roots)		0.05 (G) (n=5) 0.5 (G) (n=5)			77-88 86-89	85 88	5.4 1.3		
Deltamethrin (lettuce head)		0.01 (S) (n=5) 0.1 (S) (n=5)			89-98 89-91	94 90	3.8 0.9		
Deltamethrin (melon fruit)		0.01 (S) (n=10) 0.1 (S) (n=5)			80-96 80-89	87 85	6.5 3.4		
Deltamethrin (melon pulp)		0.01 (S) (n=5) 0.1 (S) (n=5)			85-93 84-91	90 88	3.4 3.1		
Deltamethrin (olive fruit)		0.01 (n=5) 0.1 (n=5)			74-76 66-80	75 71	1.5 8.2		
Deltamethrin (pepper fruit)		0.01 (S) (n=5) 0.1 (S) (n=5)			79-83 79-81	81 80	1.8 1.1		
Deltamethrin (sugar beet leaf with root collar)		0.05 (S) (n=5) 0.5 (S) (n=5)			87-95 83-88	91 85	3.1 2.8		
Deltamethrin (sugar beet body)		0.01 (S) (n=5) 0.1 (S) (n=5)			82-92 82-87	86 85	4.6 2.5		
Deltamethrin (tobacco leaf green)		0.05 (S) (n=7) 0.5 (S) (n=5)			85-96 92-98	92 95	4.3 2.5		

Analytical methods for monitoring of active substances and residues in food and feeding 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 (tobacco leaf cured)		0.05 (G) (n=5) 0.5 (G) (n=5)			81-87 79-82	84 80	3.4 1.8		
Deltamethrin (tomato fruit)		0.01 (S) (n=5) 0.1 (S) (n=5)			87-95 85-91	91 88	3.9 2.8		
Deltamethrin (wheat grain)		0.01 (G) (n=5) 0.1 (G) (n=5)			81-85 82-87	83 85	1.9 2.4		
Deltamethrin (wheat ear)		0.05 (G) (n=5) 0.5 (G) (n=5)			80-84 77-81	82 79	1.8 2.1		
Deltamethrin (wheat rest plant)		0.05 (S) (n=5) 0.5 (S) (n=5)			74-88 85-95	80 92	6.6 4.3		
Deltamethrin (wheat straw)		0.05 (G) (n=5) 0.5 (G) (n=5)			80-85 78-82	82 81	2.5 1.9		
Deltamethrin (zucchini fruit)		0.01 (S) (n=5) 0.1 (S) (n=7)			87-94 81-92	90 85	4.4 4.6		

Conclusion on the methods for detection and identification of the product

NOTE: the applicant has submitted the statement ensuring that all batches used in the dossier have the same compostion as the formulation to be marketed. All information submitted by the applicant (see reference list) has been assessed but the accepted studies has only included in the PAR.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues

The method submitted by the applicant for analising the active substance in the biocidal product could be considered acceptable.

Analytical methods for soil

An acceptable validated method for residues of Deltamethrin in soil was presented.

Analytical methods for air

Acceptable validated methods were provided for residues of Deltamethrin in air.

Analytical methods for water

Acceptable validated methods were provided for residues of Deltamethrin in water.

Analytical methods for animal and human body fluids and tissues

Acceptable validated methods were provided for residues of Deltamethrin in animal and human body fluids and tissues.

Analytical methods for monitoring of active substances and residues in food and feeding stuff

Food and feeding stuff will not be exposed to Deltamethrin based on the proposed usage.

Conclusions

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 method studies contained in the CAR. The LoA has been submitted. Therefore, validated analytical methods are also available for the determination of Deltamethrin in soil, air, food and feeding stuff matrices. Other analytical methods are not required.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Detrans® HPC3 is an insecticide (PT18) containing 0.03% of Deltamethrin.

The product was intended for use indoors in domestic premises by general public (non-professional users) againsts cockroaches (*Periplaneta Americana and Blattella germanica*) for surface application and cracks and crevices, ants (*Lasius niger*) for surface application and flies (*Musca domestica*) for spot application to a surface.

ES CA has concluded that efficacy data requirements were fulfilled for use against crawling insects.

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

Detrans® HPC3 is a ready-to-use spray intended to be used in domestic settings by consumers for the control of house flies (*Musca domestica*) and crawling insects (cockroaches and ants) for the maintenance of human hygiene.

2.2.5.3 Effects on target organisms, including unacceptable suffering

According to the CAR of Deltamethrin, this a.s. has a potent shock effect, acting by neurotoxic knockdown by blocking the transmission of nerve impulses. Knocked down insects will normally die within several days.

Detrans® HPC3 contains 0.03% of Deltamethrin and it works by exerting a knockdown effect and mortality after direct spray onto insects (direct activity) and by contact with treated surfaces (residual activity).

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	*Indoors*	*Detrans® HPC3, 0.03% Deltamethrin*	Black ants (*Lasius niger)* Mixed age workers 3 replic/treatm. 50 ants/replic	Simulated-use trial. Choice test. Residual activity after surface treatment. Observation: knockdown (KD) and mortality (D) Controls included.	Arenas (75x75 cm) with treated and untreated ceramic (non-porous) and plywood (porous) tiles (15x15 cm). Tiles were aged after application 1 day, 1, 2, 3 months. Exposure time: continuous up to 48h. Food & water included in both halves of arenas. Dose: 1 pump/tile = 0.9 g/tile = 36 g/m^2 (measured) ≈ 41 g/m^2 (calculated) KD and D observed at 2, 4, 6, 24 & 48 hours.	Ceramic tiles: -D≥90% in 24h in surfaces aged 1 day, and D≥90% after 48h in surfaces aged 1 & 2 months. -KD≥90% after 4-6h in tiles aged up to 2 months. Plywood tiles: - D≥90% in 24h in surfaces aged 1d & 2m and after 48 h in tiles aged 1 m. - KD >80% after 4-6h up to 2 months of ageing. Mortality in untreated wood surfaces was 3-16% at 24 h, and 20-23% at 48h. Moratlity in ceramic surface was 4-16% at 24 h, and 9-28% at 48h.	Test report: 12/034
Insecticide	*Indoors*	*Detrans® HPC3, 0.03% Deltamethrin*	House flies, (*Musca domestica)* Mixed sex flies, age 3-	Simulated-use trial. Choice test. Food available. Residual activity	Room (5.1x2.4x2.7m) with 88 treated and 88 untreated tiles (15x15 cm) mixed. Tiles fixed horizontaly (floor) or vertically (wall). Treated	Ceramic tiles: -D ≈ 90% in 24 h in all treatments. -KD>90% in 6-24 h -Controls: 23%D.	Test report: 12/034

			5d 6 replic/treatm. (3 horizontal/3 vertical) 100 flies/replic.	Observation: knockdown (KD) and mortality (D). Controls included.	tiles covered 2 m^2, untreated tiles another 2 m^2. Tiles were either ceramic (non-porous) or plywood (porous). Tiles were aged outdoors after application for 1 day, 1, 2, 3 months. Exposure time: continuous up to 48h. Dose: 1 pump/tile = 0.9 g/tile. Equiv. to 36 g/m^2 (average measured). 41 g/m^2 (calculated) KD and D observed at 2, 4, 6, 24 & 48 hours after introduction of insects.	Wood: -90% D in 24h in all treatments except in 3-month aged tiles (≈70%D). -KD >90% after 6-24 h in wood tiles. -Controls, 11%D Conclusion: acceptable. Product is efficacious up to 2 months of ageing.	
Insecticide	*Indoors*	*Detrans® HPC3, 0.03% Deltamethrin*	American cockroach *(Periplaneta americana)* Mixed sex and age adults 4 replic./treatm Direct: 20 indiv./replic. Residual: 30 indiv./replic.	Simulated-use trial. Choice test. Food available. No harbourages. Direct spray onto insects and residual activity Observation: knockdown (KD) and mortality (D). Controls included.	Arenas (0.56 m^2) with treated/untreated ceramic (non-porous) and plywood (porous) tiles. For residual activity, half of arena was treated (0.28 m^2) Ageing time after product application: 1 day, 1, 2, 3 months Dose: Direct 3-4 pumps (7.2 g)(2 seconds of spray); residual 2 pumps in half arena (equiv. 14 g/m2) KD and D observed up to	Direct spray: -100% KD in 1h. -100% D in 4h (ceramic); max. 85% D in 48h (plywood). Controls <7%D in 48h. Residual activity: In <u>ceramic:</u> 100% KD in 2h; 27%D in 24h and max. 70%D after 72h in 1-d ageing; D>80% with 1, 2, 3-m ageing in 72h while in 24h D 73%, 13% and 24%. Controls D<2.5%	Test report: 13/476 B

					72h Food and water have been placed in the center of each division, to encourange active foraging away from introducton sites.	after 24h and <6% after 72h. In <u>wood</u> -100% KD in 4h up to 3 m. after 72h 72% D in tiles aged 1 d and 3 m, 48% D in 1-m ageing and 33% D in 2-m ageing. After 24h, D was 2, 2, 14 and 5% in treated surfaces aged 1 d, 1, 2 and 3 m. Controls D<4% after 24h and <7% after 72h	
Insecticide	*Indoors*	*Detrans® HPC3, 0.03% Deltamethrin*	German cockroach (*Blattella germanica)* Mixed male, and female adults and nymphs 4 replic./treat. 30 indiv./replic.	Simulated-use trial. Choice test. Food available. Harbourages included. Direct spray onto insects and residual activity Observation: knockdown (KD) and mortality (D). Controls included.	Arenas (90x90 cm) with treated/untreated ceramic (non-porous) and plywood (porous) tiles (15x15cm). For residual activity, half of arena was treated (0.4 m2). Ageing time after product application: 1 day, 1, 2, 3 months. Dose: 13 pumps at 30 cm distance (mean measured 11-15 g/m^2 direct; 29-35 g/m^2 residual) KD and D observed up to 48 and 72h, resp.	Direct spray: 100% KD in 30 min. 72%D after 24h (ceramic), 47%D after 24h (plywood) 100% D after 48h (both). Residual: In plywood >90% KD after 2-6 h; 30, 44, 100 and 15.8%D in surfaces aged 1 d, 1, 2, 3 m >90% D after 24-72 h, up to 3 months of ageing. In ceramic, 100% KD after 2h; 60, 82, 100 and 61% D in surfaces aged 1 d, 1, 2, 3 m; 100% D after 24-96 h up to 3 months of ageing.	Test report: 17/014

						Controls: ≤15%D, except for ceramic tiles aged 1 month with 17.6%D.	
Insecticide	*Indoors*	*Detrans® HPC3, 0.03% Deltamethrin*	*Lasius niger*	Laboratory N=10 5 replicates per treatment and control. Dose rate: ≤41g/m^2 Direct spray onto insects and residual activity Observation: knockdown (KD) and mortality (D).	Untreated control: <u>Mortality (porous):</u> max 16% in 4 days up to 3 months. <u>Mortality(non-porous):</u> 12% in 4 days up to 3 months.	**Direct srpay:** KD=96% in 30 minutes. Mortality=100% in 4 hours. **Residual efficacy**: <u>KD(porous):</u> 100% in 2 hours up to 3 months. <u>KD(non-porous)</u>: 100% in 2 hours up to 3 months. <u>Mortality (porous):</u> 100% in 4 days up to 3 months. <u>Mortality(non-porous):</u> 100% in 2 days up to 3 months.	Test report: 19/396
			Blattella germanica			**Direct srapy:** KD= 90% in 30 minutes. Mortality=100% in 3 days. **Residual efficacy:** <u>KD(porous):</u>.100% in 2 hours up to 3 months. <u>KD(non-porous)</u>: 100% in 1 hour up to 3 months. <u>Mortality (porous):</u> 100% in 4 days up to 3 months. <u>Mortality(non-porous):</u>. 100% in 4	

						days up to 3 months.	
			Periplaneta americana			**Direct srapy:** KD= 100% in 30 minutes. Mortality=96% in 2 days. **Residual efficacy**: KD(porous):.100% in 1 hour up to 3 months. KD(non-porous): 100% in 45 minutes up to 3 months. Mortality (porous): 100% in 4 days up to 3 months. Mortality(non-porous):. 100% in 4 days up to 3 months	
Insecticide	*Indoors*	*Detrans® HPC3, 0.03% Deltamethrin*	*Blattella germanica*	Simulated-use trial. Choice test. Food available. Harbourages included. Direct spray onto insects and residual activity Observation: knockdown (KD) and mortality (D). Controls included.	Test ARENA 6m^2 N=30 Spray application in cracks an crevices. (3% of the total surface) Dose rate: 41g/m^2 Five (5) test replicates were performed for each test system (2), for each treatment condition (2), for each substrate per species (2) and for each ageing interval (4).	**Residual efficacy**: KD(porous):.68.7%-94% in 1 day up to 3 months. KD(non-porous): ≥90% in 1 day up to 3 months. Mortality (porous): ≥90% in 7 days up to 3 months. Mortality(non-porous):. 100% in 7 days up to 3 months	Test report: 20/106
			Periplaneta americana			**Residual efficacy**: KD(porous):. ≥90% in 4 hours up to 3 months. KD(non-porous): 100% in hours up to 3 months. Mortality (porous):	

						100% in 7 days up to 3 months. Mortality(non-porous):. 100% in 7 days up to 3 months	

Conclusion on the efficacy of the product

According to the evaluation (according t the TNsG 2008) of the results of the above studies the eCA concludes that:

Efficacy against houseflies (*Musca domestica*)

A simulated-use trial was available (choice test). The application rate was 1 pump/tile corresponding to 36 g/m^2 (average measured) (calculated theoretically as 41 g/m^2).

In the room, 12m^2 base and 33m^3 in volume, 88 treated tiles and 88 untreated tiles were randomly placed on the walls and on the floor, covering 2 m^2 treated and 2 m^2 untreated. For this room, therefore, 88 product pumps were applied.

Residual efficacy was demonstrated in surfaces aged up to 3 months. >90% of knockdown occurs after 6-24h (after 6-24 h in wood tiles) and ≥90% of mortality after 24h in both porous/non-porous surfaces, except in 3-month aged tiles in wood tiles. However controls in ceramic tiles had slightly high mortality (23%) and thereforethis mortality in the controls only allows to validate the data for porous surfaces with a residual efficacy of 2 months.

Laboratory tests were not available, but the Volumen II -Efficacy indicates that for consumers in case of products for spot to surface treatment in houses, simulated-use trials are sufficient to probe efficacy.

Even if efficacy was a little lower than required, ES CA considers that the label claim 'against houseflies' is acceptable up to 3 months of ageing and it may be authorised.

In the framework of the evaluation according to the 2008 guidelines, we can accept the claim of flies, however, we consider it appropriate for the applicant to provide a new test of simulated use for the renewal that meets the criteria in force at that time.

ES CA requested additional studies to demonstrate the efficacy of DETRANS HPC3 against flying insects, since the Applicant included initially this label claim. No test have been provided against mosquitoes and wasp, thus the eCA will not consider this label claim.

Efficacy against Black ants (*Lasius niger*)

The Applicant has submitted a laboratory test and a simulated use test. Both tests have been carried out by application on a large surface.

Laboratory test has shown:

- KD of> 90% in 30 minutes and a mortality of 100% in 4 hours with direct application on the organism.

-KD of 100% in 2 hours for both types of substrates (porous and non-porous) and a mortality of 100% in 2 days for porous substrate and 4 days for non-porous with a residual efficacy of up to 3 months.

Most of the controls do not reach a mortality greater than 10% when the minimum mortality required by the guide is reached.

The test has a deviation, since according to the requirements of the guide, the test should be done with 20 ants, not 10.

A simulated-use trial testing residual efficacy was available (choice test). The application rate was 1 pump/tile corresponding to 36 g/m^2 (average measured; calculated theoretically as 41 g/m^2). In ceramic tiles, knockdown was ≥90% after 4-6h in tiles aged up to 2 months and mortality was ≥90% in 24h in surfaces aged 1 day and in 48h in surfaces aged 1 and 2 months. In plywood tiles, mortality was ≥90% in 24h in surfaces aged 1d & 2m and in 48h in tiles aged 1 m. Knockdown was >80% after 4-6h up to 2 months of ageing. Mortality at 48h in untreated controls was a little high (20-23%).

In the framework of the evaluation according to the 2008 guidelines, laboratory and simulated use test have demonstrated a satisfactory residual efficacy in terms of percentage in surfaces aged up to 2 months. Note that the time to reach the KD and mortality is very high and these tests could not be accepted for trained professional users. However, the product is intended for use by general public only.

Efficacy against cockroaches

The Applicant has submitted a laboratory test and two simulated use tests, one has been carried out by large surface application and the other by application in cracks and crevices against *Blattella germanica* and *Periplaneta Americana*.

Blattella germanica

Laboratory test has shown:

- KD of> 90% in 30 minutes and a mortality of 100% in 3 days with direct application on the organism.

- KD of 100% in 2 hours for porous substrates and 1 hour for non-porous substrates and a mortality of 100% in 4 days for both substrates with a residual efficacy of up to 3 months.

Most of the controls do not reach a mortality greater than 10%.

The simulated-use trial 17/014 was carried out by surface application. Direct efficacy was tested with 13 pumps (i.e. measured as 11-15 g/m^2). 100% knockdown was achieved after 30 min. Mortality after 24h was 72% in ceramic surface and 47%D in plywood. 100% mortality was obtained after 48h in both surfaces.

Residual efficacy (choice test) was tested with 13 pumps (measured as 29-35 g/m^2).

- 100% knockdown was achieved after 2h in ceramic tiles, while in plywood >90% KD after 2-6 h.
- Mortality after 24h in plywood resulted in 30, 44, 100 and 15.8% in surfaces aged 1 d, 1, 2, 3 m and ≥85% of mortality up to 3 months after 72 hours.
- Mortallity in ceramic tiles, after 24h mortality was 60, 82, 100 and 61% D in surfaces aged 1 d, 1, 2, 3 m. and ≥85% of mortality up to 3 months after 48 hours.

According to the guide, both the KD and the mortality for consumers is according to the claim. We consider that mortalities greater than 80% are sufficient for this user.

Therefore, the product has shown efficacy against *Blatella germanica* with a surface application after 2 days on non-porous surfaces and after 3 days on porous surfaces with a residual efficacy of up to 3 months.

The simulated use trial 20/106 was carried out by cracks and crevices application.

The sand test was adapted to simulate cracks and crevices. It was carried out in a 6m^2 box. The sides were covered with plywood to simulate cracks. The cover strips of plywood were held above the ground by placement of 4x cm height spacers, thus creating a gap accessible only to foraging insects and to better simulate a crack and crevice application method.

Treatment was applied to three separate treated areas: two 30cm x 15cm strips + one 45cm x 15cm strip within the test arena.

The data shows:

- KD > 90% in 4 hours and > 90% mortality in 7 days on non porous surfaces up to 3 months.
- KD 64-96% in 1 day and > 90% mortality in 7 days on porous surfaces up to 3 mothns.

According to the guide, both the KD and the mortality for consumers is according to the claim.

Therefore, the product has shown efficacy against *Blatella germanica* with a surface application after 7 days on porous and non pororus surfaces with a residual efficacy of up to 3 months

The data regarding KD are not conclusive since only after three months of residual efficacy 94% is

reached in 24 hours.

We consider that this restriction should be added in the instructions for use: Place the product preferably on non pororus substrates.

Periplaneta americana

The tests carried out for *Periplaneta americana* are the same as those described for *Blattella germanica.*

Laboratory test has shown:

- KD of 100% in 30 minutes and a mortality of 96% in 2 days with direct application on the organism.
- KD of 100% in 1 hour for porous substrates and 45 minutes for non-porous substrates and a mortality of 100% in 4 days for both substrates with a residual efficacy of up to 3 months.

Most of the controls do not reach a mortality greater than 10%.

A simulated-use trial 13-476 by surface application. Direct efficacy was demonstrated with 3-4 pumps (i.e. 7.2 g).

Residual efficacy tests (i.e. 2 pumps, ca. 14 g/m^2) resulted in

- 100% knockdown after 2h in both surface types.
- Mortality was low after 24h, but increased to >80% in ceramic tiles after 1, 2, 3-m of after 72 hours.
- Mortality in plywood tiles was very low in 24h and after 72h increased to 72% D after 72h in tiles aged 3 months, ES CA did not consider this as adequate this level of efficacy in wood surfaces.

According to the guide, both the KD and the mortality for consumers is according to the claim. We consider that mortalities greater than 80% are sufficient for this user.

Therefore, in the framework of the evaluation according to the 2008 guidelines, the product has shown efficacy against *Periplaneta americana* with a surface application after 23 days on non-porous surfaces with a residual efficacy of up to 3 months.

The simulated use trial by application in crack and crevices shows:

- KD > 90% in 2 hours and > 90% mortality in 7 days on both substrates up to 3 months.

Conclusion:

With the tests provided and the data shown, the product has proven to be effective against *Musca domestica* for sopt application to a surface*, Lasius niger* for surface treatment*,* and *Blattella germanica and Periplaneta Americana* for surface treatment and cracks and crevices

Taking into account the simulated use of flies test, the product is authorized when applied on spot to surfaces only on porous surfaces with an residual efficacy of 2 months.

The ant test has been developed as a surface treatment and one of the cockroaches's test. Barrier treatment cannot be authorized because efficacy trials do not support such application.Please, note that the dose rate used for surface treatment is 35g/m^2 for *B. germanica* and 14g/m^2 for *P. Americana*Even so, the laboratory test has been carried out with the dose of 0.41 g/m^2.

On the other hand, simulated use tests for cockroaches have been done on the surface, spot in cracks and crevices.

The laboratory test against *Lasius niger* has a deviation in the number of organisms tested and we consider that a new laboratory test should be provided at the renewal.

The KD data for porous surfaces against *Blattella germanica* in cracks and crevices are low and we consider including in the instructions for use the phrase:

Use preferably on non-porous substrates.

The surface treatment includes both cockroaches and ants. ES CA considers that the product has shown efficacy only on non-porous surfaces against *Periplaneta americana*. Considering that mortality must be demonstrated for two cockroaches (large and small), its use is restricted to non-porous surfaces only.

In addition, a residual efficacy of 2 months has only been demonstrated for ants. Therefore for surface treatment only non-porous surfaces are accepted and a residual efficacy up to 2 months.

Please note that the evaluation has been assessed within the framework of the 2008 guidelines, therefore, in the renewal, the efficacy must be reviewed.

2.2.5.6 Occurrence of resistance and resistance management

Deltamethrin is a pyrethroid insecticide. Deltamethrin products are widely used for various applications: veterinary medicine, crop protection, indoors and outdoors biocide, and against numerous arthropods target organisms. Resistance to deltamethrin has already been reported in several insects.
Resistant populations of house flies (Musca domestica) have been identified in the whole world (Asia, Europe, and America). Several mechanisms are involved in resistance to pyrethroïds in house fly. This includes detoxification of the active substances, knockdown resistance (also called "kdr"), correlated with decrease nerve sensitivity, and decrease in the rate of penetration of the products. These mechanisms can co-exist in a resistant strain . Cross-resistance also exists in resistant strains, among pyrethroïds, but also other insecticide types (chlorpyrifos and imidacloprid).
Concerning cockroaches, several mechanisms are also involved in resistance to pyrethroids , in particular cuticular penetration is one of the obstacles for the effectiveness of pyrethroids against German cockroaches. Resistant populations of German cockroaches have been identified in the entire world (Asia, Europe, and America). The Oriental cockroach has developed little resistance.

The authorisation holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in 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. Detrans® HPC3 is a new product. 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.'

2.2.5.7 Known limitations

Known limitations of use are addressed by the label claims.

2.2.5.8 Evaluation of the label claims

The efficacy tests provided allow to authorize the product against cockroaches, flies and ants. The tests have been carried out in different areas and therefore the authorized uses have been adapted to the tests provided.
For the authorization of the labels claims, the residual efficacy, users and the different surfaces have also been taken into account.

- Product against cockroaches in crack and crevices and surfaces not regularly cleaned. With a residual efficacy up to 3 months, preferably on non porous substrates. Only for general public.
- Product against flies in spot to a surface treatment. Indoors. With a residual efficacy up to 2 months. Only for general public.
- Product against ants in surfaces not regularly cleaned. With a residual efficacy up to 2 months, only on non porous substrates and for general public.

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

Detrans® HPC3 is not intended to be used with other biocidal products.

2.2.6 Risk assessment for human health

No animal or human data on toxicological properties has been generated. However, acute toxicity studies have been performed using a formulation (Deltamethrin Gel Product RUC #1769) containing 0.06% w/w Deltamethrin. The applicant proposes to read across from these studies for the Detrans® HPC3 formulation containing 0.03% w/w Deltamethrin, claiming that the inert ingredients contained in RUC #1769 are "essentially the same" as the inert ingredients contained in Detrans® HPC3. ES CA accepts that data generated for this product can be referred to the product Detrans® HPC3. (see confidential annex).

Nevertheless, given that Detrans® HPC3 contains more than 15ppm of CMIT/MIT (3:1) while the formulation Deltamethrin Gel Product RUC#1769 contains less than 15ppm, ES CA cannot accept the read across from the dermal Sensitization in Guinea Pigs study with RUC #1769 for Detrans® HPC3. Therefore, a new skin Sensitisation Local Lymph Node Assay has been required during the evaluation.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Summary table of animal studies on skin corrosion /irritation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results**	**Remarks**	**Reference**
Acute dermal irritation study in the rabbit Guideline EPA F, 81-5 (1984) GLP Yes Reliable	New Zealand White Albino Rabbit 3♂ and 3♀	RUC #1769 (Deltamethrin 0.06% RTU Gel) 0.5 ml undiluted. 4 hr	average score for all animals at 24, 48, 72 h: Erythema = 0, Edema= 0 Very slight erythema was present in one male at the one hour observation only and a full recovery was observed. Edema was not present at any time during the study. No other dermal irritation was present.	None	IIIB6.2 See confidential annex

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The preparation RUC #1769 Deltamethrin 0.06% w/w is not skin corrosive, nor irritant to skin
Justification for the value/conclusion	Based on experimental results
Classification of the product according to CLP	The preparation RUC #1769 Deltamethrin 0.06% w/w, does not meet the criteria for classification for skin irritation

Data waiving	
Information requirement	Skin corrosion and irritation study for Detrans® HPC3 (0.03% w/w)

Justification	The applicant proposes to read-across from the results of the study using RUC #1769 Deltamethrin 0.06% w/w to the product Detrans® HPC3 (0.03% w/w) ES CA accepts that data generated for this product can be referred to the product Detrans® HPC3.

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**	**Remarks**	**Reference**
Primary Eye Irritation Study in Rabbits Guideline EPA F, 81-4 (1984) GLP Yes Reliable	Albino New Zealand White Rabbit 3♂ and 3♀	RUC #1769 (Deltamethrin 0.06% RTU Gel) 0.1 ml undiluted 24 hr	Cornea 0 Iris 0 Redness 0.166 Chemosis 0 The test material induced slight redness in conjunctiva "some blood vessels definitely hyperaemic (injected)" in four animals 1 hour after application. This reaction was not observed in three out of the four animals by 24 hours after application. Signs of slight redness continued to be visible in one animal until 72 hours post treatment. No abnormalities were observed in any animal at 4 days post treatment. This description matches the description in the OECD guideline which merits a score of 1.	None	IIIB6.2(E) See confidential annex

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The preparation RUC #1769 Deltamethrin 0.06% w/w is not irritant to eyes
Justification for the value/conclusion	Based on experimental results
Classification of the product according to CLP	The preparation RUC #1769 Deltamethrin 0.06% w/w, does not meet the criteria for classification for eye irritant

Data waiving	
Information requirement	Eye irritation study for Detrans® HPC3 (0.03% w/w)
Justification	The applicant proposes to read-across from the results of the study

	using RUC #1769 Deltamethrin 0.06% w/w to the product Detrans® HPC3 (0.03% w/w) ES CA accepts that data generated for this product can be referred to the product Detrans® HPC3

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Based on the classification of the deltamethrin and the different co-formulants and, their respective content in the final formulation
Classification of the product according to CLP	Detrans® HPC3 is not classified as "specific target organ toxicity single exposure, Category 3 (STOT SE 3); H335

Data waiving	
Information requirement	Respiratory tract irritation data
Justification	No data on respiratory tract irritation is available. Detrans® HPC3 contains less than 20% of co-formulants classified as STOT SE 3; H335. This information has been included in the data sheets of the components. Therefore, it can be concluded that the product Detrans® HPC3 is not classified with regards to respiratory tract irritation properties according to the criteria set out in the Regulation (EC) Nº 1272/2008 (CLP Regulation).

Skin sensitization

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle,** **Dose levels, duration of exposure** **Route of exposure**	**Results**	**Remarks**	**Reference**

Skin Sensitisation Local Lymph Node Assay OECD Nº 429 B.42 GLP Yes Reliable 1	Mice, CBA/CaOlaHsd Pre-test: 2 females Main study: 16 females 4 females/group. Test groups: 3 Control groups:1	Detrans HPC3 (0.03% deltamethrin) at concentrations of 25% and 50% in Dimethylformamide, and 100% (undiluted)	The animals did not show any signs of systemic toxicity during the course of the study and no cases of mortality were observed. On days 2 and 3, the animals treated with a test item concentration of 100% showed a very slight erythema of the ear skin (Score 1). Animals treated with 25% and 50% test item concentration did not show any signs of local skin irritation. In this study S.I. of 1.24, 0.90 and 0.94 were determined with the test item at concentrations of 25% and 50% in Dimethylformamide, and 100% (undiluted), respectively.	None	See confidential annex

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Detrans® HPC3 is not a skin sensitiser.
Justification for the value/conclusion	The LLNA experimental test conducted using the product confirmed that the product is not sensitizing. In this study S.I. of 1.24, 0.90 and 0.94 were determined with the test item at concentrations of 25%, 50% and 100%. The EC3 value could not be calculated, since none of the tested concentrations induced a S.I. greater than the threshold value of 3.
Classification of the product according to CLP	Detrans® HPC3 was found not to be a skin sensitizer under the test conditions of this study. Detrans® HPC3, therefore, does not meet the conditions to be classified as a skin sensitizer with associated hazard phrase H317. Hovewer, EUH208 will be included in the labelling to protect already sensitised individuals.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not respiratory sensitizer.
Justification for the value/conclusion	Based on the classification of the deltamethrin and the coformulants and, their respective content in the final formulation.
Classification of the product according to CLP	Detrans® HPC3 is not classified as respiratory sensitizer.

Data waiving	
Information requirement	Skin sensitisation study for Detrans® HPC3 (0.03% w/w)
Justification	No animal or human data have been provided to assess the potential for respiratory sensitization. The active substance and the coformulants of the product are not classified as respiratory sensitisers and are not known to be respiratory sensitisers. Therefore, it can be concluded that Detrans® HPC3 is not

	classified with regards to respiratory sensitizer properties according to the criteria set out in the Regulation (EC) Nº 1272/2008 (CLP Regulation).

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levelsType of administration**	**Signs of toxicity**	**Value LD50**	**Remarks**	**Reference**
Acute Oral Toxicity Study in Rats Guideline EPA F, 81-1 (1984) GLP yes Reliable	HSD: Sprague Dawley® SD® rats; 5♂ and 5 ♀	RUC #1769 (Deltamethrin 0.06% RTU Gel) 5050 mg/kg bw single dose Gavage	respiratory chirping in two females, crust around the eyes in males, and crust around the nose in both sexes. Reversible One female lost weight between day 7 and 14	>5050 mg/kg bw	None .	IIIB6.1.1 See confidential annex

Value used in the Risk Assessment – Acute oral toxicity	
Value	>5050 mg/kg bw
Justification for the selected value	Based on experimental results
Classification of the product according to CLP	The preparation Deltamethrin 0.06% RTU Gel (RUC #1769) is not classified for acute oral toxicity.

Data waiving	
Information requirement	Acute oral toxicity study for Detrans® HPC3 (0.03% w/w)
Justification	The applicant proposes to read-across from the results of the study using RUC #1769 Deltamethrin 0.06% w/w to the product Detrans® HPC3 (0.03% w/w). ES CA accepts that data generated for this product can be referred to the product Detrans® HPC3

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 and particle size (MMAD) Actual and nominal concentration, Type of administration	Signs of toxicity	LC50	Remarks	Reference
Acute Inhalation Toxicity Study in Rats Guideline US EPA F, Series 81-3 (1984) GLP Yes Reliable	HSD: Sprague Dawley® SD® rats; 5♂ and 5 ♀	RUC #1769 (Deltamethrin 0.06% RTU Gel) aerosol generated Average MMAD of 3.1 µm±2.5 Nominal conc. 5.0 mg/L Analytical conc. 3.1 mg/L; Duration of exposure = 4h Nose only	discoloration around the eyes in two males and one female. Reversible. One male and two females lost weight, and one female failed to gain weight between Days 0 and 7. No abnormalities were observed at gross necropsy examinations.	> 3.1 mg/L	None	IIIB6.1.3 See confidential annex

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	> 3.1 mg/L
Justification for the selected value	Based on experimental results However, ES CA has observed the following discrepancies: -According to the study report, the test substance from its container is sprayed directly into the exposure chamber. -The samples taken from the breathing zone of the animals are analysed for their content in the formulation. Test substance (RUC #1769) is quantified by UV using a spectrophotometer at 226 nm wavelength. The suitability of this method is not addressed (i.e., using a confirmatory method). -In addition, MMAD in the chamber is 3.1µm ± 2.5µm (reported as median ± geometric standard deviation). The coefficient of variation is approx. 80%. This value is too high to be acceptable.
Classification of the product according to CLP	The preparation Deltamethrin 0.06% RTU Gel (RUC #1769) is not classified for acute inhalation toxicity.

Data waiving	
Information requirement	Acute inhalation toxicity study for Detrans® HPC3 (0.03% w/w)
Justification	The applicant proposes to read-across from the results of the study using RUC #1769 Deltamethrin 0.06% w/w to the product Detrans® HPC3 (0.03% w/w). ES CA has observed discrepancies in the submitted assay. Moreover, mass median aerodynamic diameter (MMAD) of the gas/vapour or aerosol droplets from the representative product Detrans® HPC3 is

	unknown: the relevance of this test to the real conditions of use of the product cannot be established. Taken into account the criteria set out in the Regulation (EC) Nº 1272/2008 (CLP Regulation), two coformulants plus the active substance are classified with regards to their acute toxic properties by inhalation route. Calculation of ATEmix for inhalatory toxicity results in >5mg/l and no classification is triggered. Therefore, Detrans® HPC3 is not classified following criteria of the Regulation (EC) Nº 1272/2008 (CLP Regulation).

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**	**LD50**	**Remarks**	**Reference**
Acute Dermal Toxicity Study in Rats US EPA F, 81-2 (1984) GLP yes Reliable	New Zealand White rabbits; 5♂ and 5 ♀	Deltamethrin 0.06% RTU Gel 5050 mg/kg bw single exposure 20 X 10cm^2	None	>5050 mg/kg bw	None	IIIB6.1.2 See confidential annex

Value used in the Risk Assessment – Acute dermal toxicity	
Value	>5050 mg/kg bw
Justification for the selected value	Based on experimental results
Classification of the product according to CLP and DSD	The preparation Deltamethrin 0.06% RTU Gel (RUC #1769) is not classified for acute dermal toxicity.

Data waiving	
Information requirement	Acute dermal toxicity study for Detrans® HPC3 (0.03% w/w)
Justification	The applicant proposes to read-across from the results of the study using RUC #1769 Deltamethrin 0.06% w/w to the product Detrans® HPC3 (0.03% w/w). ES CA accepts that data generated for this product can be referred to the product Detrans® HPC3.

Information on dermal absorption

No new data have been provided for Detrans® HPC3. The applicant considers reasonable to use the 2% dermal absorption value for the exposure calculations Detrans® HPC3.

The Swedish CAR for the active substance Deltamethrin used a dermal absorption value of 2% as the worst case for a range of formulations and dilutions. This dermal absorption value is based on EW (oil/water emulsion) and EC (emulsifiable concentrate) tested formulations. The results of these studies indicated that dermal absorption was somewhat lower for the EW than for the EC formulations. Using data obtained in the dermal absoption studies on EC formulation, the dermal absoption was estimated to 2%.

According to the Guidance on the BPR (Volume III: Human health Part A: Information Requirements, Ver. 1.1, November 2014), "*before new studies are commenced, it should be checked whether the intended use is safe when the appropriate default value is applied. If no experimental data are available, studies with similar formulations should be looked for or further information used that may give at least a rough estimate……but in this case strict and transparent rules should be followed as to when another formulation or product can be considered similar"*

According to EFSA Guidance Document on Dermal Absorption (EFSA, 2012), a default value of 75% should be used for products containing ≤ 5% of active substance. However, if log Pow < -1 or > 4 and MW > 500 a default dermal absorption value of 10% may be applied.

EFSA Guidance Document on Dermal Absorption (EFSA, 2012) stablishes the following:
"*Use of data on similar formulations: Data on another (reference) formulation can be used if the formulation to be assessed is closely related. This occurs when all the following conditions are met:*
• *Synergist and safener content is within +/-25% w/v of that in the reference formulation*
• *Synergist and safener are closely related chemically and in terms of physical-chemical properties (e.g. toluene versus xylene; octanol versus nonanol) and interaction with the active substance (e.g. solubility of the active substance).*
• *Formulation is of the same or lower skin irritancy based on scores in studies. These must include initial findings (as dermal absorption is often significant within the first 24 hours), not just the classification. If no skin irritation study is available, a comparison based on the irritancy of the components can be performed, but the outcome should be interpreted with care as classification does not take initial irritation scores into account.*
• *Formulation having the same or no sensitising potential based on classification.*
•*Co-formulant (e.g. solvent, stabiliser, surfactant, detergent, emulsifier, adhesive, antifreezing substance) content is within +/- 25% w/w of that in the reference formulation.*
• *Co-formulant of similar chemical type (e.g. linear alkyl sulphonate is not replaced by an aromatic sulphonate derivative).*
It is considered unlikely that the above criteria will be met when moving from one formulation type to another (e.g. suspension concentrate to emulsifiable concentrate)."

In this case, the formulation tested in the CAR of deltamethin is a emulsifiable concentrate, nevertheless Detrans® HPC3 is another type of liquid formulation. Therefore, the criteria for using the data of a similar formulation are not met.

According to this, a dermal absorption value of 75% should be used. However, as MW of deltamethrin is 505.2 mg/mol and log.P_{ow} is 4.6 at 25ºC, a default dermal absorption value of 10% may be applied

ES CA do not accept the justification of the applicant and considers that a dermal absoption value of 10% must be used for the exposure calculations.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Deltamethrin
Value(s)	10%
Justification for the selected value(s)	According to EFSA Guidance Document on Dermal Absorption (EFSA, 2012), if log Pow < -1 or > 4 and MW > 500, a default dermal absorption value of 10% may be applied.

Data waiving	
Information requirement	Not required
Justification	There is no experimental data available on the dermal absorption of Detrans® HPC3 since no study has been conducted thus far. As a result, risk assessment calculations for human exposure have been made according to the EFSA guidance on dermal absorption (EFSA Journal, 2012;10(4):2665) using a default value of 10% dermal absorption for this product.

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

CMIT/MIT(3:1) is present in the product in such proportion as to lead to classification of the product as Skin sens 1; H317. Therefore it should have been considered a substance of concern. In such situation, Detrans® HPC3 should not be authorized for non-professional users (general public). Nevertheless, the applicant has submitted a new skin Sensitisation Local Lymph Node Assay. According to this assay, Detrans® HPC3 should not be classified as skin sensitizer. Thus, CMIT/MIT(3:1) has not been considered a substance of concern.

Available toxicological data relating to a mixture

Not applicable.

Endocrine disruption

Assessment of the ED properties of the active substances:

The biocidal product contains only one active substance. According to the CAR for Deltamethrin, initial work carried out under the EU Strategy for Endocrine Disruptors identified and included Deltamethrin in Group III of a list of 553 candidate priority substances with the potential to act as endocrine disruptors in both humans and animals.
In a follow-up to the first prioritising exercise, further information was gathered and presented for chemicals not previously prioritised. Substances were categorized specifically in relation to human health and wildlife. Overall, deltamethrin was identified as Category 1.
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 have been assessed. It is concluded that there was no evidence of endocrine disruption effects from these studies. However, it should be noted that due to limitations in the test guidelines available at the time, the potential for endocrine effects may not have been fully investigated. Therefore, a comprehensive ED-assessment for the active substance according to Regulation (EU) 2017/2100 and the EFSA/ECHA Guidance on endocrine

disruptor will need to be performed at the renewal stage. For the time being it is concluded that the biocidal product DETRANS HPC3 does not have endocrine disrupting properties.

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:

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.

2.2.6.2 Exposure assessment

Detrans® HPC3 is an insecticide containing 0.03% w/w Deltamethrin.

The product was intended for use indoors in domestic premises by general public (non-professional users) in accordance with the request of the applicant but the product is only effective for using against houseflies (*Musca domestica)* for spot application to a surface*,* ants *(Lasius niger)* for surface treatment*,* and cockroaches *(Blattella germanica and Periplaneta Americana)* for surface treatment and cracks and crevices by amateurs/consumers (general public) according to the submitted data in the section 2.2.5:

Indoors use by spraying from a distance of 30 cm (1 trigger spray pull = 0.9 g) at the rate of 41 g/m^2. (i.e 46 trigger spray pull/m^2)Using the default scenario in RIVM ConsExpo Web, version 1.1.0: Pest Control Products /Sprays /General Surface /Application (trigger spray) the exposure to the consumer is calculated. As the model for general surface spraying includes the highest room area to be treated and the highest exposure default values, the corresponding calculations are considered to be the reasonable worst case and hence to cover exposure from targeted spot applications or crack and crevice spraying.

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 toddler 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 [3]	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.
[3] Exposure via inhalation route is considered negligible due to the low vapour pressure of the active substance Deltamethrin (1.24E-08 Pa, 20ºC).

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Application of trigger spray	**Primary exposure:** Application of ready to use trigger spray for crack and crevice and targeted spot treatment	Non-professionals
2.	Post-application	**Secondary exposure:** Inhalation of volatilized residues	General public
3.	Post-application	**Secondary exposure:** Cleaning of treated surfaces by wiping	General public
4.	Post-application	Secondary exposure: Adults/toddlers playing/crawling on treated surfaces and hand to mouth contact after treatments.	General public

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.

Professional exposure

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

Non-professional exposure

Scenario [1] Non professional application of trigger spray

Description of Scenario [1]

Detrans® HPC3 is a ready to use trigger spray containing 0.03% w/w Deltamethrin for crack and crevice /targeted spot treatment against flying and crawling insects, intended for use by the general public.

In absence of appropriate product-specific data, the default scenario in RIVM ConsExpo Web, version 1.1.0: Pest Control Products /Sprays /General Surface /Application (trigger spray) is used to estimate the exposure to the consumer, so the corresponding calculations can be considered to be the reasonable worst case and hence to cover exposure from targeted spot applications or crack and crevice spraying.

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.

Parameters for the inhalation model are taken from RIVM report 320005002/2006 Pest Control Products Fact Sheet.

The model assumes that:

1. the product is used 9 times a year maximum.
2. the trigger spray is applied during 10 minutes with a mass generation rate of 0.8 g/s. Also, the scenario considers that this product is applied in a 58 m^3 room (with 22 m^2 floor surface). Hence the total amount applied according to this model would be 0.8 g/s x 10 min / 22 m^2 = 22 g/m^2

To our case:

1. the product is used 2 times a year.
2. The mass generation rate would be: 41 g/m^2 x 22 m^2 / 10 min = 1.5 g/s

for Tier 1.

	Parameters	**Value**	**Justification / Source**
Tier 1	Weight fraction of Deltamethrin	0.03%	Section 2.1.2
	Application rate	41 g/m^2	Section 2.2.5
	Frequency of use	2 days/year	Section 2.2.8
	Body weight	60 kg	Recommendation no. 14, 2017
	Dermal absorption		
	Exposed body surface area	8300 cm^2	Recommendation no. 14, 2017 (half of total adult body surface area)
	Contact rate	46 mg/min	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Release duration	10 min	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Dermal absorption	10%	Guidance on Dermal Absorption (EFSA, 2012)
	Inhalation exposure		
	Spray duration	10 min	RIVM report 320005002/2006 Pest Control Products Fact Sheet

	Exposure duration	240 min	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Room volume	58 m^3	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Room height	2.5 m	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Ventilation Rate	0.5 / h	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Inhalation rate	1.25 m^3/h	Recommendation 14, 2017
	Mass generation rate	1.5 g/s	Calculated value.
	Airborne fraction	0.008	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Density non-volatile	1.8 g/cc	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Inhalation cut off diameter	15 µm	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Aerosol diameter distribution	logNormal	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Median diameter	7.7 µm	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Arithmetic coefficient of variation	1.9	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Maximum diameter	50 µm	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Inhalation absorption	100%	Default value.
	Oral exposure		
	No parameters	Parameters are set in inhalation exposure route	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Oral absorption	100%	Default value

Calculations for Scenario [1]

Summary table: systemic exposure from non-professional uses as [mg/kg bw/d]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	Tier 1/ no PPE	3.56E-04	2.30E-04	4.87E-06	5.91E-04

Further information and considerations on scenario [1]

Not applicable

Combined scenarios

Not applicable

Exposure of the general public

Scenario [2] Inhalation of volatilized residues

Description of Scenario [2]

Professional and general public may be exposed to volatilised residues from deltamethrin residues will vaporise and could be available for inhalation by people present in the room. However, based on the document, HEEG opinion 13 on Assessment of Inhalation Exposure of volatilised biocide active substance, it might not be necessary to calculate the exposure to volatilised residues:

- For deltamethrin:

$$\mathbf{0.328} \times \frac{\mathbf{505.2} \times \mathbf{1.24}E\mathbf{-08}}{\mathbf{0.0075}} = \mathbf{0.000274} \leq 1$$

The result of this equation is lower than 1 for deltamethrin. The exposure to volatilised residues indoor can be considered negligible for non-professionals and general public for the biocidal product according to the assessment of effects on human health conclusions.

Chronic inhalation exposure to volatilised residues indoors should be assessed for adult considering the scenario: "assessment of Inhalation Exposure of Volatilised Biocide Active Substance" from the Opinion n°13 of HEEG with calculation of the Saturated Vapour Concentration (SVC) for 24 hours (worst-case) following this formula:

SVC = (Mw x Vp) / (R x T) (mg/m^3)

The exposure would be calculated with the following formula:

Exposure = SVC x inhalation rate / body weight (mg/kg bw/d)

	Parameters	Value / Units	Justification / Source
Tier 1	Weight of fraction	0.03%	Section 2.1.2.
	Body weight:	60 kg (adults) 23.9 kg (children) 10 kg (toddlers) 8 kg (infants)	Recommendation 14, 2017
	Inhalation rate:	16 m^3/24h (adults) 12 m^3/24h (children) 8 m^3/24h (toddlers) 5.4 m^3/24h (infants)	Recommendation 14, 2017
	Vapour pressure (Vp)	1.24E-08 Pa	AR/CAR.
	Molecular weight (Mw)	505.2 g/mol	AR/CAR.
	Gas constant (R)	8.31451 J.mol^{-1}.K^{-1}	HEEG opinion no. 13
	Temperature (T)	293 K	HEEG opinion no. 13

Calculations for Scenario [2]

No calculations are needed for the biocidal product.

Further information and considerations on scenario [2]

None.

Scenario [3] Cleaning of treated surfaces by wiping

Description of Scenario [3]

Description of Scenario [3]

Detrans® HPC3 is a ready to use trigger spray containing 0.03% w/w Deltamethrin for crack and crevice /targeted spot treatment against flying and crawling insects, intended for use by the general public.
In absence of appropriate product-specific data, the default scenario in RIVM ConsExpo Web, version 1.1.0: Disinfectants for use indoors / Exposure during wiping is used to estimate the exposure to the consumer during cleaning of treated surfaces, so the corresponding calculations can be considered to be the reasonable worst case.
The dermal exposure model 'instant application' from ConsExpo Web are used to describe the scenario. Parameters for the dermal model are taken from RIVM report 320005003/2006 Disinfectant Products Fact Sheet.
The model assumes that:

1. The worst-case estimate is that 0.1% of the amount on the surface area (i.e. 19.4 g) contacts the skin. This amount of 0.02 g is used as default value for product amount.
2. Assuming that hands aren't washed directly, the exposure time is larger than the cleaning/wiping duration; thus, the default value is set at 3 minutes for a surface area of 1.72 m^2.

To our case:

1. Considering that this product is applied in a 58 m^3 room (with 22 m^2 floor surface) according to the scenario of Pest Control Products /Sprays /General Surface /Application (trigger spray), the total product amount applied according to this model would be: 41 g/m^2 x 22 m^2 = 902 g BP.
2. So, if the 0.1% of the amount contacts the skin, the worst case estimate would be: 902 x 0.1% = 9.02E-01 g BP.
3. Finally, for a surface area of 22 m^2, the exposure time would be approx. 40 min.

for Tier 1.

	Parameters	**Value**	**Justification / Source**
Tier 1	Weight fraction of Deltamethrin	0.03%	Section 2.1.2
	Application rate	41 g/m^2	Section 2.2.5
	Body weight	60 kg	Recommendation no. 14, 2017
	Frequency of use	365 days/year	RIVM report 320005003/2006 Disinfectant Products Fact Sheet
	Dermal exposure		
	Exposed body area	215 cm^2	RIVM report 320005003/2006 Disinfectant Products Fact Sheet
	Contact time	40 min	Extrapolated value.
	Contact surface	22 m^2	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Dermal absorption	10%	Guidance on Dermal Absorption (EFSA, 2012)
	Amount contact with the skin – worst case	0.1%	RIVM report 320005003/2006 Disinfectant Products Fact Sheet
	Amount contact with skin	0.902 g	Calculated value.

Calculations for Scenario [3]

Summary table: indirect exposure of general public [mg/kg bw/d]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3]	Tier 1/ none	-	4.51E-04	--	4.51E-04

Further information and considerations on scenario [3]
none

Scenario [4] Adults/toddlers playing/crawling on treated surfaces

Description of Scenario [4]

The exposure after application is described for crawling children who are present in the room after a general surface treatment has been carried out. General surface application represents the worst case scenario and therefore no further assessment will be performed for crack and crevice / targeted spot use. It is assumed that a toddler (worst case) crawls over the treated surface for 1 hour a day and the model is also used to estimate the possible adult exposure after application playing with a toddler on the treated surface. Exposure is modelled using the dermal exposure model 'rubbing off' and the oral exposure model 'constant rate' from RIVM ConsExpo Web, version 1.1.0 described in Pest control Fact Sheet RIVM report 320005002/2006 (General surface application – Post Application).

Total amount sprayed is 41 g/m^2 as indicated by the maximum application rate. The scenario assumes that this amount is sprayed on the floor which is 22 m^2. The model also assumes that 100% of the amount sprayed ends up on the floor surface and 30% of this amount is dislodgeable (default values for exposure during general surface application with a trigger spray, RIVM Report 320005002/2006).
Hence, if the amount of formulation per surface unit is 41 g/m^2, assuming that 30% thereof will be dislodgeable, a dislodgeable amount of

- 41 g/m^2 x 0.3 = 12.3 g/m^2

is calculated.

In addition, dermal exposure of adults/toddlers can take place on any uncovered skin, that is, on the head, the arms and hands, and on the legs and feet. The ConsExpo model gives a transfer coefficient of 0.6 m²/h but a transfer factor of 0.20 m²/h for toddlers and 0.78 m^2/h for adults according to the Recommendation for indoor transfer coefficients no. 12 (2016) is considered The ingestion rate is calculated based on the assumption that from the total dermal exposure 10% is taken in orally due to hand-mouth contact:

- 12.3 g/m^2 x 0.20 m^2/h x 0.1 / 60 min = 4.10E-03 g/min for toddlers.
- 12.3 g/m^2 x 0.78 m^2/h x 0.1 / 60 min = 1.60E-02 g/min for adults.

These data are included in Tier 1, for Tier 2 the dislodgeable residue can be refined taking into account the US EPA Residential SOPs (2012), where, after the revision of complete datasets for some chemicals, it is concluded in table 7-9 that the dislodgeable residue for deltamethrin in hard surfaces is 6% (75th percentile). Therefore:

- the dislodgeable amount would be: 41 g/m^2 x 0.06 = 2.46 g/m^2

and

- the ingestion rate would be: 2.46 g/m^{2}x 0.2 m^2/h x 0.1 / 60 min = 8.20E-04 g/min for toddlers.

Description of Scenario [4]

- the ingestion rate would be: 2.46 g/m^{2}x 0.78 m^2/h x 0.1 / 60 min = 3.20E-03 g/min for adults.

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

	Parameters	**Value**	**Justification / Source**
Tier 1	Weight fraction of Deltamethrin	0.03%	Section 2.1.2
	Application rate	41 g/m^2	Section 2.2.5
	Body weight toddlers	10 kg	Recommendation no. 14, 2017
	Body weight adults	60 kg	Recommendation no. 14, 2017
	Frequency of use	126 days/year	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Transfer coefficient toddlers	0.20 m^2/h	Recommendation no. 12, 2016.
	Transfer coefficient adults	0.78 m^2/h	Recommendation no. 12, 2016.
	Dermal exposure		
	Exposed body area toddlers	2410 cm^2	Recommendation no. 14, 2017
	Exposed body area adults	9520 cm^2	Recommendation no. 14, 2017
	Contact time	60 min	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Contact surface	22 m^2	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Dermal absorption	10%	Guidance on Dermal Absorption (EFSA, 2012)
	Dislodgeable residue	30%	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Dislodgeable amount	12.3 g/m^2	Calculated value.
	Oral exposure		
	Exposure duration	60 min	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Transfer hand to mouth	10%	RIVM report 320005002/2006 Pest Control Products Fact Sheet
	Oral absorption	100%	Default value
	Ingestion rate toddlers	4.10E-03 g/min	Calculated value.

Description of Scenario [4]			
	Ingestion rate adults	1.60E-02 g/min	Calculated value.
Tier 2	Dislodgeable residue	6%	Standard Operating Procedures for Residential Pesticide Exposure Assessment - October 2012
	Dislodgeable amount	2.46 g/m^2	Calculated value.
	Ingestion rate toddlers	8.20E-04 g/min	Calculated value.
	Ingestion rate adultss	3.20E-03 g/min	Calculated value.

Calculations for Scenario [3]

Summary table: indirect exposure of general public [mg/kg bw/d]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [4] (toddlers)	Tier 1/ none	-	7.38E-03	7.38E-03	1.48E-02
Scenario [4] (adults)	Tier 1/ none	-	4.80E-03	4.80E-03	9.60E-03
Scenario [4] (toddlers)	Tier 2/ none	-	1.48E-03	1.48E-03	2.95E-03
Scenario [4] (adults)	Tier 2/ none	-	9.59E-04	9.60E-04	1.92E-03

Further information and considerations on scenario [4]
None.

Combined scenarios for adults

Summary table: indirect exposure of general public [mg/kg bw/d]					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1, 3, 4] (adults)	Tier 1/ none	3.56E-04	1.64E-03	9.65E-04	2.96E-03

Monitoring data
None.

Dietary exposure

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.

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.	Veterinary use	Antiparasitic agent/ Agent against ectoparasites	MRL[2]

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

[2] Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. 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 feedstuff.

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.

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 [mg/kg bw/d]**
1.	Non-professionals	Tier 1/ no PPE	5.91E-04
2.	General Public	Tier 1 / no PPE	Negligible
3.	General Public	Tier 1 / no PPE	4.51E-04
4.	General Public -toddlers	Tier 2 / no PPE	2.95E-03
4.	General Public - adults	Tier 2 / no PPE	1.92E-03

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]	-	-	-	-	0.01 mg/kg bw
ADI[2]	-	-	-	-	0.01 mg/kg bw/day

[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]	Deltamethrin
Veterinary: Antiparasitic agent/ Agent against ectoparasites	Regulation (EU) No 37/2010	See [3]	Deltamethrin

*[1] see COMMISSION REGULATION (EU) 2018/832 of 5 June 2018 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyantraniliprole, cymoxanil, **deltamethrin**, difenoconazole, fenamidone, flubendiamide, fluopicolide, folpet, fosetyl, mandestrobin, mepiquat, metazachlor, propamocarb, propargite, pyrimethanil, sulfoxaflor and trifloxystrobin in or on certain products*
[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 Non-professionals/ [1]	Tier 1	1	0.0075	5.91E-04	7.88	yes

Local effects
Pyrethroids are known to cause paresthesia (burning and prickling of the skin without irritation). This local effect is normally not severe and disappears when direct exposure is terminated. Therefore, this instruction for use is proposed:

- The biocidal product contains deltamethrin (synthetic pyrethroid). DO NOT USE if under medical advice NOT to work with such compounds; and/or

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

Residues of deltamethrin on treated surfaces are predicted to be low due to the presence of adequately ventilated areas. Hence, the final concentration of deltamethrin is assumed to be lower than 300 ppm.

Conclusion
Based on the results obtained in the risk assessment, the exposure of non-professionals results in level of exposure lower than the relevant reference values for systemic exposure and local inhalation and dermal exposure. Therefore, no unacceptable risk can be identified taking into account the instruction for use proposed.

Risk for the general public

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL	AEL mg/kg	Estimated uptake	Estimated uptake/	Acceptable (yes/no)

		mg/kg bw/d	bw/d	mg/kg bw/d	AEL (%)	
Cleaning of treated surfaces / [3]	Tier 1	1	0.0075	4.51E-04	6.01	Yes
Post application, Toddler crawling /[4]	Tier 1	1	0.0075	1.48E-02	197	No
Post application, Adult playing /[4]	Tier 1	1	0.0075	9.60E-03	128	No
Post application, Toddler crawling /[4]	Tier 2	1	0.0075	2.95E-03	39.3	Yes
Post application, Adult playing /[4]	Tier 2	1	0.0075	1.92E-03	25.6	Yes
Combined scenarios 1 + 3 + 4		1	0.0075	2.96E-03	39.5	Yes

Local effects
Indirect dermal exposure to BP is possible through contact treated surfaces.
Pyrethroids are known to cause paresthesia (burning and prickling of the skin without irritation). This local effect is normally not severe and disappears when direct exposure is terminated. Therefore, this instruction for use is proposed:

- The biocidal product contains deltamethrin (synthetic pyrethroid). DO NOT USE if under medical advice NOT to work with such compounds; and/or

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

Residues of deltamethrin on treated surfaces are predicted to be low due to the presence of adequately ventilated areas. Hence, the final concentration of deltamethrin is assumed to be lower than 300 ppm.

Conclusion
This exposure assessment is of not concern for Tier 2. However, as a theoretical risk may be identified for post application Tier 1, the following phrase on the label will be included as a risk management measure:

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

Risk for consumers via residues in food

The product is not intended to be used in places where food is kept or entrance in contact with food during its application. Therefore, no risk is derived for consumers via residues in food. In addition, in order to avoid any potential risk by its use, the following RMM is set on product's label:

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

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product
No risk is envisaged.

2.2.7 Risk assessment for animal health

The bittering agent is supposed to repel children from orally ingesting dangerous amounts of the biocidal product. It is not acceptable to conclude that it is working the same way on all pet species, limiting the oral uptake. However, due to the lack of appropriate guidance, exposure is assumed to be similar to these of toddlers and children and no specific measure is needed (except for cats). Especially cats may even increase their licking behaviour in case they detect unpleasant residues on their fur. Also, cats are known to have a preference to hide in hard to reach places

Cats are known to be more sensible to pyrethroids than others animals due to a slower metabolisation of these substances. Intoxication are very common and may be dangerous. In order to protect cats, the following Risk Mitigation Measure must be added on the label:

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

In addition, to prevent any exposure of animals the following RMMs are included:
- *Remove or cover terrariums, aquariums and animal cages before application. Turn off aquarium air-filter while spraying.*
- *Keep out of reach of children and pets.*
- *Keep uninvolved persons, children and pets away from treated surfaces/areas until dried.*
- *Do not spray onto people and pets.*
- *Do not use/apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and animals.*

2.2.8 Risk assessment for the environment

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

The applicant has not provided any new study with the biocidal product. The environmental risk assessment for DETRANS HPC3 has been done using the Competent Authority Report on the active substance deltamethrin. The whole assessment submitted by the applicant has been included and reviewed by the ES CA. The comments of the ES CA are included in grey boxes.

According to the applicant the product is a ready to use spray containing one active substance, deltamethrina (0.03% w/w). intended to control crawling (cockcroaches and ants) and flying (house flies) insects indoors and flying insects outdoor in houses by non-professional.

Based in the efficacy studies the product is effective for killing crawling insects such as cockcroaches, as a spot treatment into crack and crevices, and ants and also

cockroaches,, in a barrier treatment, and for a reduction of fly populations as a spot treatment to a surfaces.

With the exception of the active substance deltamethrin, there are no substances of environmental concern (SoC) in the biocidal product DETRANS HPC3. For details on the SoC assessment please refer to the Confidential Annex.

2.2.8.1 Effects assessment on the environment

ES CA:

The estudies supporting the environmetal fate and toxicity properties of the biocidal product DETRANS HPC3 are based on information of the active substance deltamethrin as provided in the Competent Authority Assessment Report of this substance. Deltamethrin was evaluated at the EU level in the scope of the Biocidal Product Directive 98/8/EC with Sweden as the rapporteur Member State.

According to the CAR the following PNEC values are relevant for the effects assessment for the biocidal product DETRANS HPC3.

PNEC values for deltamethrin

Compartment	PNEC deltamethrin	Remarks
STP	0.03 mg x L^{-1}	-
surface water	7 x 10^{-7} mg x L^{-1}	-
sediment	6.2 x 10^{-3} mg x kg wwt^{-1}	-
soil	7.5 x 10^{-2} mg x kg wwt^{-1}	-
birds	15 mg x kg $food^{-1}$	Considering the reproduction studies conducted in birds (bobwhite quail and mallard duck) with deltamethrin (Beavers et al., 1991a & b – III-A7.5.3.1.3/01-02), the lowest NOEC exceeds 450 ppm. Taking into account a safety factor of 30 (as indicated in Table 23 of the TGD on Risk Assessment Part II, page 130), a PNECbird of 15 mg/kg food is obtained.
mammals	2.67 mg x kg $food^{-1}$	Considering the reproduction study conducted in rats with deltamethrin (2 generation study; Hoberman, 1992 – A70863), the NOAEL was set at 80 ppm for parents and pups.

		Taking into account a safety factor of 30 (as indicated in Table 23 of the TGD on Risk Assessment Part II, page 130), a PNECsmall mammal of 2.67 mg/kg food is obtained. -

PNEC values for the major metabolite Br2CA

Compartment	PNEC deltamethrin	Remarks
STP	0.03 mg x L^{-1}	$PNEC_{STP}$ for deltamethrin covers also $PNEC_{STP}$ for metabolite (Br_2CA)
surface water	1.04 x 10^{-2} mg a.s. x L^{-1}	Based on the fish 96h LC50 (QSAR estimation) of 10.4 mg/l, with an assessment factor of 1000 applied.
sediment	1.39 x 10^{-2} mg x kg wwt^{-1}	Calculated from PNECwater using the Equilibrium Partitioning Method with the mean Koc for Br2CA of 25.6.
soil	0.14 mg x kg wwt^{-1}	An overall NOEC of 10 mg.kg-1 (dry weight soil) was found. According to the TGD for Risk Assessment (2003) an assessment factor of 100 is appropriate as a NOEC is available for a species representing one trophic level, The resulting PNECsoil for the major metabolite Br2CA is 0.10 mg.kg-1 dry soil (0.14 mg.kg-1 wet soil).
birds	-	-
mammals	-	-

In a microcosm study, in water Br_2CA accounted for a maximum of 13.3% of the total applied rate of deltamethrin 7 days after the last treatment. Degradation of deltamethrin in soil also resulted in formation of this major metabolite at a maximum of 23%.

The study based BCF_{fish} for deltamethrin is 1400 with the biological half-life of 4.3 days for the whole body tissue. The estimated BCF value for earthworm is 483.

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 DT_{50} was estimated at 45/141 days in two different systems and the dissipation DT_{50} in sediment at 55/133 days in two different systems at 20ºC. In soil the DT_{50} was 31-74 days at 12 ºC, with a geometric mean of 48 days. The mean DT_{50} of the major metabolite of Deltamethrin, Br_2CA, 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 Br_2CA and 115 for mPBacid.

Accumulation
The bioaccumulation of ^{14}C-deltamethrin was investigated in bluegill sunfish (*Lepomis macrochirus*) and calculated bioconcentration factors (BCF) of 310, 2800 and 1400 as total ^{14}C for edible, non-edible and whole body tissue were determined. 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.

Environmental metabolites
The metabolite Br_2CA was detected in soil but was not considered to be significant for exposure and risk assessment as the DT_{50} is considerably shorter than Deltamethrin which represents the worst case, 2.0 days versus 48 days, respectively.

ESCA:

No ecotoxicological studies on DETRANS HPC3 have been provided, but it can be assumed that the data for the active substance are sufficient. The biocidal product DETRANS HPC3 contains 0.03% w/w deltamethrin. Deltamethrin is classified as Aquatic Acute (H400) and Aquatic Chronic (H410) with an M factor of 1000000. The concentration of the active substance in the product leads to classification according to M factor multiplication as set out in the Regulation EC 1272/2008. The biocidal product DETRANS HPC3 is classified as Aquatic Acute Category 1 with a hazard statement H400 and Aquatic Chronic Category 1 with a hazard statement H410.

Further Ecotoxicological studies

No further ecotoxicological studies are available for Detrans® HPC3.

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

No further studies on fate and behaviour in the environment are available for Detrans® HPC3.

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® HPC3 will be used outside around the home. It is intended to be applied on "outside surfaces of window & door frames, and other areas where house flies 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.

ESCA:
The applicant submitted initially an application for National Authorisation for this product to be used outside around the home, however, during the evaluation of the efficacy of DETRANS HPC3, no efficacy studies for using DETRANS HPC3 outdoor has been performed so, ESCA has concluded that only the use of this product indoor can be authorises.

ESCA conclude that this is not relevant for DETRANS HPC3.

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.

2.2.8.2 Exposure assessment

ESCA:
According to the applicant , the product DETRANS HPC3 is intended for indoor and outdoor use by non-professionals, but as explain previously no efficacy studies has support the outdoor use of this product so, the outdoor use has not been taken into account in the risk assessment.

ES CA does not agree with the assessment carried out by the applicant. In the evaluation presented by the applicant only one scenario, crack and crevices, has been taken into account to determine the risk to the environment due to the use of this product but, taking into account the efficacy studies, this scenario would only cover the risk of treating cockroaches in cracks and crevices and therefore would not cover the risk of all the uses requested for the biocidal product DETRANS HPC3.

ESCA has concluded that DETRANS HPC3 has demonstrate sufficient efficacy against crockoaches, ants and flies. The risk assessment for the environment has been carried out taking into account the efficacy studies and the more realistic scnerios available for the user proposed, general public. Regarding to the efficacy studies, for crockoaches, the biocidal product has desmostrated to be effective when used both in crack and crevices and on the surface, for ants and flies the biocidal has shown to be effective on surfaces

so, the following scenarios has been assessed:
1. Scenario 1. Crack and crevices applied as a barrier as a worst case.
2. Scenario 2. Spot application to a surface
3. Scenario 3. Barrier treatment, this scenario has been choosed in order to evaluate the risk assement for the environment when the surfaces are treated to control crockcoaches or/and ants. This scenario has been chosen since ES CA considers that to treat the entire flat, as propose the surface scenario, is a no realistic one for a general public and it is not a propose scenario accorditng to TAB ENV 204. The barrier scenario covers a total surface of 20 m2 for domestic house. These values for barrier treatment were corrected for wet cleaned zone. The area values selected were 5,9 m2.

ESCA has carried out the environmental exposure assessement for DETRASN HPC3 on the basis of the ECHA guidance on the Biocidal Product Regulation (2017), The OCDE PT18 emission scenario document (ESD) for household and professional uses (OECD Series on Emission Scenario Documents, Number 18 (ENV/JM/MONO(2008)14), and the TAB v.2.1 (ECHA 2019).

The assessment conducted by ESCA is presented in grey boxes.

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 3: Indoor Use Scenario 4: Outdoor Use
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 3: Average consumption Scenario 4: 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 3 & 4: Production: No Formulation No Use: Yes Service life: No
Remarks	

ESCA:

As explain above only indoor use is considered in the risk assessment.

According to the uses applied by the applicant, the following scenarios are assessed:

Scenario 1: Indoor Use, crack and crevices as barrier treatment.
Scenario 2: Indoor Use, spot treatment to a surface

Scenario 3: Indoor Use, barrier treatment.

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Indoor Use, crack and crevices as barrier treatment. Scenario 2: Indoor Use, spot treatment to a surface Scenario 3: Indoor Use, barrier treatment
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) Technical Agreements for Biocides Environment (ENV) Version 2.1, December 2019.
Approach	For all scenarios proposed: Average consumption
Distribution in the environment	Calculated based on TGD 2017 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	Scenar1, 2 & 3: Production: No Formulation No Use: Yes Service life: No
Remarks	

Emission estimation

Scenario [3] Crack and Crevice and Targeted Spot Use Indoors (Scenario 1 for ES CA)

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:-

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	Outdoor air STP (surface water) (agricultural soil/groundwater)

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

Crack and Crevice and Targeted Spot Use Indoors

Both crack & crevice and targeted spot applications for a house are considered to treat an area of 2 m^2.

Application

Detrans®HPC3 Application Rates

Application rate Deltamethrin (g/m^2)	0.0123
Application rate Detrans®HPC3 (kg/m^2)	0.041
% active ingredient	0.03

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	4.92E-07
$E_{application, air} = N_{appl, building} \times F_{application, air} \times Q_{prod} \times F_{AI} \times AREA_{treated}$			
Emission to applicator during application step	$E_{application, applicator}$	kg/d	1.48E-07
$E_{application, applicator} = N_{appl, building} \times F_{application, applicator} \times Q_{prod} \times F_{AI} \times AREA_{treated}$			
Emission to floor during application step	$E_{application, floor}$	kg/d	3.05E-06
$E_{application, floor} = N_{appl, building} \times F_{application, floor} \times Q_{prod} \times F_{AI} \times AREA_{treated}$			
Emission to treated surface during application step	$E_{application, treated}$	kg/d	2.09E-05
$E_{application, treated} = Q_{prod} \times F_{AI} \times N_{application, building} \times F_{application, treated} \times AREA_{treated}$			

Cleaning

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

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	1.48E-07

$E_{applicator, ww} = (E_{prep, applicator} + E_{application, applicator}) \times F_{applicator, ww}$			
Emission from floor/treated surface to waste water during cleaning step	$E_{treated, ww}$	kg/d	5.99E-06
$E_{treated, ww} = (E_{prep, floor} + E_{application, floor} + E_{applicator, treated}) \times F_{ww} \times F_{CE}$			
Total ($E_{treated, ww}$)			**6.14E-06**
Simultaneity factor (3 to 11 times per year)	$F_{simultaneity}$		0.0081
Number of houses	$N_{buildings}$	-	4000
Output			
Local emission to waste water during episode	$E_{local, ww}$	kg/d	**1.99E-04**
$E_{local, ww} = E_{total, ww} \times N_{house}$ (4000) x Simultaneity factor			

F_{CE} = Based on a cleaning efficiency of 0.25%, ESD PT18 Table 3.3-8 (Spray- Crack & Crevice)

Calculations for Scenario [3]

Calculations for Scenario 3 are included in Annex 3.2.

ESCA:
ES CA does not agree with the calculated scenario. This scenario has been recalculated by ESCA (scenario 1: Indoor Use, crack and crevices as barrier treatment) considering 1-2 applications per yer.

Crack and Crevice and Targeted Spot Use Indoors

Both crack & crevice as barrier applications for a house are considered to treat an area of 5.9 m^2.

Application

Detrans®HPC3 Application Rates

Application rate Deltamethrin (g/m^2)	0.0123
Application rate Detrans®HPC3 (kg/m^2)	0.041
% active ingredient	0.03

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	1.45E-06
$E_{application, air} = N_{appl, building} \times F_{application, air} \times Q_{prod} \times F_{AI} \times AREA_{treated}$			
Emission to applicator during application step	$E_{application, applicator}$	kg/d	4.35E-07

$E_{application,\ applicator} = N_{appl,\ building} \times F_{application,\ applicator} \times Q_{prod} \times F_{AI} \times AREA_{treated}$			
Emission to floor during application step	$E_{application,\ floor}$	kg/d	9.00E-06
$E_{application,\ floor} = N_{appl,\ building} \times F_{application,\ floor} \times Q_{prod} \times F_{AI} \times AREA_{treated}$			
Emission to treated surface during application step	$E_{application,\ treated}$	kg/d	6.17E-05
$E_{application,\ treated} = Q_{prod} \times F_{AI} \times N_{application,\ building} \times F_{application,\ treated} \times AREA_{treated}$			

Cleaning

Cleaning step: 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	4.35E-07
$E_{applicator,\ ww} = (E_{prep,\ applicator} + E_{application,\ applicator}) \times F_{applicator,\ ww}$			
Emission from floor/treated surface to waste water during cleaning step	$E_{treated,\ ww}$	kg/d	1.77E-05
$E_{treated,\ ww} = (E_{prep,\ floor} + E_{application,\ floor} + E_{applicator,\ treated}) \times F_{ww} \times F_{CE}$			
Total ($E_{treated,\ ww}$)			**1.81E-05**
Simultaneity factor (1 to 2 times per year)	$F_{simultaneity}$		0.00204
Number of houses	$N_{buildings}$	-	4000
Output			
Local emission to waste water during episode	$E_{local,\ ww}$	kg/d	**1.48E-04**
$E_{local,\ ww} = E_{total,\ ww} \times N_{house}$ (4000) x Simultaneity factor			

F_{CE} = Based on a cleaning efficiency of 0.25%, ESD PT18 Table 3.3-8 (Spray- Crack & Crevice)

ESCA:
Scenario [2] Indoor Use, spot treatment to a surface

Input parameters for calculating the local emission		
Scenario 2: Indoor Use, spot treatment to a surface		
Application rate of biocidal product	41	g/m2
% active ingredient in the product	0.03	%
Application rate Deltamethrin (g/m2)	0.0123	g/m2

Mixing and loading:
It is a ready-to-use product so this step is not necessary.

Application step:

Imput	**Symbol**	**Unit**		**S/D/O**
Amount of product	Q_{prod}	g/m^2	41	S
Fraction of active substance in the commercial product	F_{AI}	-	0,0003	S
Number of preparations per day	$N_{appl.building}$	-	1	D
Area treated	$AREA_{treated}$	m^2	2	D
Fraction emitted to air during application step.	$F_{appl.air}$	-	0,02	D
Fraction emitted to treated surfaces during application	$F_{appl.treated}$	-	0,85	D
Fraction emitted to floor during application	$F_{appl,floor}$	-	0,1240	D
Fraction emitted to applicator during application	$F_{appl,applicator}$	-	0,0060	D

Emission to the air during application step (1)	$E_{application,air}$	kg/d	4.92E-07	O
Emission to the applicator during application step (2)	$E_{application,applicator}$	kg/d	1.48E-07	O
Emission to floor during application step (3)	$E_{application,floor}$	kg/d	3.05E-06	O
Emission to treated surfaces during application (4)	$E_{application,treated}$	kg/d	2.09E-05	O

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

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

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

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

Cleaning and releases to wastewater:

Imput	Symbol	Unit		S/D/O
Fraction ww from applicator	$F_{applicator,ww}$	-	1	D
Fraction ww during cleaning	F_{ww}	-	1	D
Cleaning efficiency for floor and treated surfaces	F_{CE}	-	0.5	D
Emission to waste water from air	$E_{air,\ ww}$	Kg/d	Negligible	
Emission to waste water from applicator (5)	$E_{applicator,\ ww}$	kg/d	1.48E-07	O
Emission to waste water from floor and treated surfaces (6)	$E_{treated,ww}$	kg/d	1.20E-05	O
Emission to waste water (Eapplicator, ww + Etreated surface, ww) (7)	E_{ww}	kg/d	1.21E-05	O
Simultaneity factor	$F_{simultaneity}$	-	0.00815	S
Number of treated houses	N_{houses}	-	4000	D
Local Emission to waste water (8)	**$Elocal_{ww}$**	**kg/d**	**3.95E-04**	**O**

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

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

(7) $E_{local,ww} = \left(E_{treated,ww} + E_{applicator,ww}\right)$

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

Total local emissions to waste water resulting from spot treatment to a surface:

Local Emission to waste water	**Elocal$_{ww}$**	**3.95E-04 kg/d**

ESCA:
Scenario [3] Indoor Use, barrier treatment

Input parameters for calculating the local emission		
Scenario 2: Indoor Use, spot treatment to a surface		
Application rate of biocidal product	41	g/m2
% active ingredient in the product	0.03	%
Application rate Deltamethrin (g/m2)	0.0123	g/m2

Mixing and loading:
It is a ready-to-use product so this step is not necessary.

Application step:

Imput	**Symbol**	**Unit**		**S/D/O**
Amount of product	Q_{prod}	g/m^2	41	S
Fraction of active substance in the commercial product	F_{AI}	-	0,0003	S
Number of preparations per day	$N_{appl.building}$	-	1	D
Area treated	$AREA_{treated}$	m^2	5,9	D
Fraction emitted to air during application step.	$F_{appl.air}$	-	0,02	D
Fraction emitted to treated surfaces during application	$F_{appl.treated}$	-	0,85	D
Fraction emitted to floor during application	$F_{appl,floor}$	-	0,1240	D
Fraction emitted to applicator during application	$F_{appl,applicator}$	-	0,0060	D

Emission to the air during application step (1)	$E_{application,air}$	kg/d	1.45E-06	O
Emission to the applicator during application step (2)	$E_{application,applicator}$	kg/d	4.35E-07	O
Emission to floor during application step (3)	$E_{application,floor}$	kg/d	9.00E-06	O
Emission to treated surfaces during application (4)	$E_{application,treated}$	kg/d	6.17E-07	O

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

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

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

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

Cleaning and releases to wastewater:

Imput	**Symbol**	**Unit**		**S/D/O**
Fraction ww from applicator	$F_{applicator,ww}$	-	1	D
Fraction ww during cleaning	F_{ww}	-	1	D
Cleaning efficiency for floor and treated surfaces	F_{CE}	-	0.5	D
Emission to waste water from air	$E_{air, ww}$	Kg/d	Negligible	
Emission to waste water from applicator (5)	$E_{applicator, ww}$	kg/d	4.35E-07	O
Emission to waste water from floor and treated surfaces (6)	$E_{treated,ww}$	kg/d	3.53E-05	O

Emission to waste water (Eapplicator, ww + Etreated surface, ww) (7)	E_{ww}	kg/d	3.58E-05	O
Simultaneity factor	$F_{simultaneity}$	-	0.0085	S
Number of treated houses	N_{houses}	-	4000	D
Local Emission to waste water (8)	**$Elocal_{ww}$**	**kg/d**	**1.17E-03**	**O**

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

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

(7) $E_{local,ww} = \left(E_{treated,ww} + E_{applicator,ww}\right)$

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

Total local emissions to waste water resulting from barrier treatment

Local Emission to waste water	**$Elocal_{ww}$**	**1.17E-03 kg/d**

Scenario [4] Outdoor Use

Detrans® HPC3 is intended to be applied on "outside surfaces of window & door frames, and other areas where house flies 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 $E_{spray, wall, applic, soil} = F_{spray, wall} \times Q_{prod} \times F_{AI} \times AREA_{wall}$	$E_{spray, wall, applic, soil}$	kg/d	6.46E-06
Local concentration of active ingredient in soil adjacent to the house due to wall application against flying insects $C_{spray, wall, applic, soil} = E_{spray, wall, applic, soil} / V_{spray, soil} * RHO_{soil}$	$C_{spray, wall, applic soil}$	kg/kg wwt	8.68E-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 wall due to wash off by rainfall $E_{spray, wall, wash-off, soil} = F_{spray, wash off} \times Q_{prod} \times F_{AI} \times AREA_{wall}$	$E_{spray, wall, wash-off, soil}$	kg/d	1.08E-05
Local concentration of active ingredient in soil adjacent to the house due to wash off by rainfall $C_{spray, wall, wash off soil} = E_{spray, wall, wash-off, soil} / V_{spray, soil} * RHO_{soil}$	$C_{spray, wall, wash off soil}$	kg/kg wwt	1.45E-09
Local concentration of active ingredient in soil adjacent to the house due to washing and wall application against flying insects $C_{spray, wall, applic, soil} = E_{spray, wall, applic, soil} + E_{spray, wall, wash-off, soil} / V_{spray, soil} * RHO_{soil}$	$C_{spray, flying, soil}$	kg/kg w wt	2.32E-09
		mg/kg wwt	2.32E-03

ES CA:
As it has been explain above this use (outdoor use) is not going to be taking into account. Nevertheless, ES CA does not agree with the refinement proposed by the applicant for the scenario for flying insects. In the scenario for flying insects for non professional users, the entire wall is treated with insecticide. As it is stated in the ESD for PT18 "The general public may use insecticide sprays, typically aerosol sprays, to control flying insects such as flies or mosquitoes, but in outdoor conditions, the efficacy of such treatment is of local and time limited action. Due to the limited scale of the application and the dilution of the application in the air compartment, no specific scenario will be developed for this application" and according to the document "Generic treatment areas assigned to each specific pest" agreed in the Technical Agreements for Biocides Environment (ENV) Version 2.1, December 2019, the area proposed for controlling flies by non professional user is the area of a wall (125 m^2) and no refinement is proposed for this kind of users.

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 3	Yes	Yes	No	No	Yes	Yes	Yes	Yes	
Scenario 4	No	No	No	No	No	No	Yes	No	

ESCA: Fate and distribution in expoed environmental compartmens of the scenarios proposed by ES CA:

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, idoor use, crack and crevices	Yes	Yes	No	No	Yes	Yes	Yes	Yes	
Scenario 2, spot application to a surface	Yes	Yes	No	No	Yes	Yes	Yes	Yes	
Scenario 3, barrier treatment	Yes	Yes	No	No	Yes	Yes	Yes	Yes	

Scenario 3

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 $PEC_{STP\ micro\text{-}organisms}$, $PEC_{surface\ water}$ (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	g/mol	
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 (d, DT_{50} at 20°C)	133	d	CAR, May 2011
Rate constant for biodegradation in bulk soil (d, DT_{50} at 12°C)	48	d or hr (at 12ºC)	CAR, May 2011

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
	Scenario 3	
Air	2.09E-05	
Water	9.61	
Sludge	90.4	
Degraded in STP	0	

The EUSES report is included in Annex 3.2.

ESCA:

ES CA agree with the use simple treat 3.1 model to calculate fate and distribution in the STP but, since no impact on the environmental risk assessment the distribution of a.s. in the STP has been calculated according to Simpel Treat 4.0. by the ES CA.

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
Air	0	
Water	8.8	
Sludge	91.2	
Degraded in STP	0	

The major, but transient, soil metabolite of deltamethrin is Br_2CA. The key input parameters of Br_2CA are presented below:

Molecular weight	298.0 g/mol
Laboratory degradation in soil at 12°C and Field capacity	DT50 = 5.6 days (geometric mean, n=3) Range: 2.1-32.3 days
Sorption to organic carbon	Koc = 25.61 L/kg

Calculated PEC values for Scenario 3

Local Aquatic PEC Outputs (modelled with EUSES v 2.1.2)

Assessment		PEC
Scenario 3 Crack & Crevice and Targeted spot Indoor Use	PEC for micro-organisms in the STP (mg/L)	9.55E-06
	Local PEC in surface water during emission episode (dissolved) (mg/L)	5.92E-07
	Local PEC in fresh-water sediment during emission episode (mg/kg wwt)	5.26E-03
	Local PEC in groundwater under agricultural soil (mg/L)	1.67E-08

PEC in Air (modelled with EUSES v 2.1.2)		
Assessment		**PEC**
Scenario 3 Crack & Crevice and Targeted spot Indoor Use	Annual Average Local PEC in Air (total) (mg/m^3)	3.17E-17

Local Terrestrial PEC Outputs (modelled with EUSES v 2.1.2)
The spray will not come into direct contact with soil at any point during normal indoor 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 extracted from the outputs contained in Scenario 3.

Assessment		PEC
Scenario 3 Crack & Crevice and Targeted spot Indoor Use	Local PEC in agricultural soil (total) averaged over 30 days (mg/kg wwt)	2.73E-04
	Local PEC in agricultural soil (total) averaged over 180 days (mg/kg wwt)	1.20E-04

Calculated PEC values for Scenario 4

Direct exposure to the soil following wash off and application to outside surfaces of window & door frames has been assessed.

Local Terrestrial PEC Outputs		
Assessment		**PEC**
Scenario 4 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)	2.32E-03

ES CA:

The concentrations in the different environmental compartments for the different scenarios calculated by ES CA are summarized in the folloeing table:

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}**	**PEC_{air}**

	[mg/L]	[mg/l]	[mg/kg$_{wwt}$]	[mg/l]	[mg/kg$_{wwt}$]	[mg/kg]	[µg/l]	[mg/m^3]
Scenario 1, indoor use crack and crevices	$6.5x10^{-6}$	$4.03x10^{-7}$	$3.58x10^{-3}$	-	-	$2.04x10^{-4}$	$1.22 x10^{-5}$	-
Scenario 2, indoor use, spot treatment to a surface	$1.74x10^{-5}$	$1.08x10^{-6}$	$9.58x10^{-3}$	-	-	$5.45x10^{-4}$	$3.27x10^{-5}$	-
Scenario 3, idoor use, barrier treatment	$5.13x10^{-5}$	$3.18x10^{-6}$	$2.82x10^{-2}$	-	-	$1.61x10^{-3}$	$9.66x10^{-5}$	-

Exposure assessment for the major metabolite Br_2CA

To estimate the potential environmental exposure to the major metabolite Br_2CA associated with losses to the wastewater compartment during the service life of DETRANS HPC3, it was assumed that the metabolite is formed at the point of emission (i.e. in the STP effulent) at an amount equivalent to 100% of the parent (adjusted to take into account the molecular weights of the compounds). The parent compound has a molecular mass of 505.2 g x mol^{-1}, whilst the metabolite Br_2CA has a molecular mass of 298.0 g x mol^{-1}. Therefore, the estimate of potential local surface water exposure presented above was adjusted by a factor of 0.59 (i.e. 298.0 / 505.2) to provide an estimate of exposure to the metabolite:

PEC_{water} Br_2CA = PEC_{STP} deltamethrin x ($MOLW_{Br2CA}/MOLW_{deltamethrin}$)/10 [mg x L-1]

Corresponding PEC water values for Br2CA are presented in the table below.

	PEC_{water}
	[mg/L]
Scenario 1, indoor use, crack and crevices	$3.83x10^{-7}$
Scenario 2, indoor use, spot treatment to a surface	$1.03 x10^{-6}$
Scenario 3, idoor use, barrier treatment	$3.03 x10^{-6}$

The PEC values presented above are an extreme worst-case estimations of exposure to surface water since experimental data has shown that the metabolite is formed at only a fraction of parent deltamethrin applied under a range of environmental conditions.

The calculations of PECsed for Br_2CA are presented below:

PECsed Br_2CA = (Ksusp-water Br_2CA / RHO susp) x PECwater Br_2CA x 1000

	PEC_{sed}
	[mg/Kg]
Scenario 1, indoor use, crack and crevices	$5.13x10^{-7}$
Scenario 2, indoor use, spot treatment to a surface	$1.37\ x10^{-6}$
Scenario 3, idoor use, barrier treatment	$4.05\ x10^{-6}$

Degradation of the deltamethrin residue may result in the formation of a quantity of the major metabolite Br_2CA in soil. However, it is difficult to predict the actual quantity of metabolite Br_2CA present in soil after sludge application, since the parent will potentially have been subject to transformation either in soil or in the sludge itself under very different environmental conditions. Initial concentrations of Br_2CA in soil following application of sewage sludge to land were estimated on the worst-case assumption that the metabolite is formed in the sludge at a quantity equivalent to 100% of the parent (adjusted to take into account the molecular weights of the compounds). The estimates of potential local soil exposure have been adjusted by a factor of 0.59 (i.e. 298.0/505.2) to provide estimates of exposure to the metabolite Br_2CA. The estimated initial concentrations of metabolite Br_2CA after ten applications of sludge are presented in the table below:

	$Csludge_{soil\ 10}(0)$= PEC intial soil 10(0)
	[mg x kg_{wwt}^{-1}]
Scenario 1, indoor use, crack and crevices	$1.48x10^{-4}$
Scenario 2, indoor use, spot treatment to a surface	$3.97x10^{-4}$
Scenario 3, idoor use, barrier treatment	$1.17x10^{-3}$

For further calculations DT50 soil for Br2CA of 5.6 days at 12ºC was taken into account. The estimated PECsoil al indicated below:

	PEC_{soil} (30)	**PEC_{soil} (180)**
	[mg x kg_{wwt}^{-1}]	**[mg x kg_{wwt}^{-1}]**
Scenario 1, indoor use, crack and crevices	$3.88x10^{-5}$	$6.62x10^{-6}$

Scenario 2, indoor use, spot treatment to a surface	$1.04x10^{-4}$	$1.78x10^{-5}$
Scenario 3, idoor use, barrier treatment	$3.08x10^{-4}$	$5.25x10^{-5}$

The resulting predicted environmental concentrations in groundwater (PECGW) values for major metabolite Br_2CA are presented in the table below. It should be noted that these PECGW values were calculated on the basis of PECsoil values that had been calculated on the unrealistically worst-case assumption that 100% of the parent compound is transformed to Br2CA (corrected for molecular weight). The higher concentrations predicted for Br_2CA compared to those for deltamethrin are consistent with the high mobility of the compound.

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

	PEC_{GW}
	[µg x L^{-1}]
Scenario 1, indoor use, crack and crevices	$9.2x10^{-2}$
Scenario 2, indoor use, spot treatment to a surface	$3.13x10^{-2}$
Scenario 3, idoor use, barrier treatment	$9.23x10^{-2}$

Primary and secondary poisoning

Primary poisoning

Primary poisoning is very unlikely for Detrans® HPC3 intended for use indoors in crack and crevices and targeted spots and outdoors on window surfaces or areas where house flies 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.

ESCA: since no outdoor use is goin to be authorized, primary poisoning is very unlikely for this biocidal product.

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 0.03% 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 ^{14}C 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

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, the measured or estimated BCF for fish and the biomagnification factor (BMF). As a measured value is available (BCF=1400) this value will be used.

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

$PEC_{oral,\ predator} = 5.92E\text{-}07 * 1400 * 2$

$PEC_{oral,\ predator} = 1.66E\text{-}03$ 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 (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):
$C_{earthworm} = BCF_{earthworm} * C_{porewater} * W_{earthworm} + C_{soil} * W_{gut} / W_{earthworm} + W_{gut}$ (Equ. 81)
The weight of the gut contents can be rewritten using the fraction of gut contents in the total worm:
$W_{gut} = W_{earthworm} * F_{gut} * CONV_{soil}$ (Equ. 82a)

where:
$PEC_{local\ soil\ porewater} = PEC_{local\ soil} \times RHO_{soil} / K_{soil\_water} \times 1000$ (Equ. 67)
$PEC_{local\ soil\ porewater} = 2.32E\text{-}03 * 1700 / 1.22E+04 * 1000 = 3.23E\text{-}07$ mg/l
$PEC_{local\ soil}$ value calculated for outdoor use has been chosen as this represents the worst case.
$CONV_{soil} = RHO_{soil} / F_{solid} * RHO_{solid} = 1700 / (0.6 * 2500) = 1.13$ (Equ. 82b)
Using this equation, the concentration in a full worm can be written as:
$C_{earthworm} = ((BCF_{earthworm} * C_{porewater}) + (C_{soil} * F_{Gut} * CONV_{soil})) / (1 + (F_{Gut} * CONV_{soil}))$ (Equ. 82c)
$C_{earthworm} = ((483 * 3.23E\text{-}07) + (2.32E\text{-}03 * 0.1 * 1.13)) / (1 + (0.1 * 1.13))$
$C_{earthworm} = 3.67E\text{-}04$ mg/kg $_{wet\ earthworm} = PEC_{oral,\ predator}$

ESCA:
Sencondary poisoning has been calculated for the worst case, scenario 3 (barrier treatment).
In accordance with the equations of the Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C) Version 2.0, 2017, $PEC_{oral,predator}$ for both food chain were calculated as followed:

Parameter / variable	Symbol	Unit	Value
Aquatic food chain:			
Predicted environmental concentration during episode	$PEC_{local,water}$	$[mg.l^{-1}]$	3.18E-06
Bioconcentration factor for fish on wet weight basis	BCF_{fish}	$[l.kg^{-1}_{wet\ fish}]$	1400
Biomagnification factor in fish	BMF	[-]	2
Predicted environmental concentration in food (considering that predators feed at 50% on local level)	**$PEC_{oral,predator}$**	**$[mg.kg^{-1}_{wet\ fish}]$**	**8.9E-03**
Terrestrial food chain :			
log of partition coefficient n-octanol-water	Log K_{ow}	[-]	40200
Bioconcentration factor for earthworm on wet weight basis	$BCF_{earthworm}$	$[l.kg^{-1}_{wet\ earthworm}]$	483
Concentration in porewater	$C_{porewater}$	$[mg.l^{-1}]$	9.66E-08
Concentration in soil	C_{soil}	$[mg.kg^{-1}_{wwt}]$	1.61E-03
Fraction of gut loading in worm	F_{gut}	$[kg_{dwt}.kg^{-1}_{wwt}]$	0.1
Conversion factor for soil concentration wet-dry weight soil	$CONV_{soil}$	$[kg_{wwt}.kg^{-1}_{dwt}]$	1.13
Predicted environmental concentration in food (considering that predators	**$PEC_{oral,predator}$**	**$[mg.kg^{-1}_{wet\ earthworm}]$**	**2.05E-04**

feed at 50% on local level)			

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®HPC3 have, however, been calculated using EUSES Version 2.1.2 to be 3.17E-017 mg/m^3.

Aquatic Compartment

Summary of Local aquatic PECs		
Assessment		**PEC**
Scenario 3 Crack & Crevice and Targeted spot Indoor Use	PEC for micro-organisms in the STP (mg/L)	9.55E-06
	Local PEC in surface water during emission episode (dissolved) (mg/L)	5.92E-07
	Local PEC in fresh-water sediment during emission episode (mg/kg wwt)	5.26E-03
	Local PEC in groundwater under agricultural soil (mg/L)	1.66E-08

Summary table of calculated PEC/PNEC values for the aquatic compartment				
Assessment		**PEC**	**PNEC**	**PEC/ PNEC**
Scenario 3 Crack & Crevice and Targeted spot Indoor Use	PEC for micro-organisms in the STP (mg/L)	9.55E-06	0.030	0.0003
	Local PEC in surface water during emission episode (dissolved) (mg/L)	5.92E-07	7.0E-07	0.85
	Local PEC in fresh-water sediment during emission episode (mg/kg wwt)	5.26E-03	0.0062	0.85
	Local PEC in groundwater under agricultural soil (mg/L)	1.66E-08	0.0001	0.0002

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®HPC3.

Terrestrial Compartments

Summary of Local Terrestrial PECs		
Assessment		**PEC**
Scenario 3 Crack & Crevice and Targeted spot Indoor Use	Local PEC in agricultural soil (total) averaged over 30 days (mg/kg wwt)	2.73E-04
	Local PEC in agricultural soil (total) averaged over 180 days (mg/kg wwt)	1.20E-04
Scenario 4 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	2.32E-03

Summary table of calculated PEC/PNEC values for the terrestrial compartment				
Assessment		**PEC**	**PNEC**	**PEC/PNEC**
Scenario 3 Crack & Crevice and Targeted spot Indoor Use	Local PEC in agricultural soil (total) averaged over 30 days (mg/kg wwt)	2.73E-04	7.50E-02	0.004
	Local PEC in agricultural soil (total) averaged over 180 days (mg/kg wwt)	1.20E-04	7.50E-02	0.002
Scenario 4 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)	2.32E-03	7.50E-02	0.03

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®HPC3.

Groundwater

The maximum local PEC in groundwater under agricultural soil calculated by EUSES v. 2.1.2 is 1.66E-08 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 CA:

ES CA agrees with the conclusion of the applicant.

ES CA:
PEC/PNEC values obtained by the ES CA.

	STP	SW	SED	SOIL
Deltametrhin				
Scenario 1, indoor use crack and crevices	2.17E-04	5.76E-01	5.77E-01	2.71E-03
Scenario 2, indoor use, spot treatment to a surface	5.80E-04	1.54	1.54	7.26E-03
Scenario 3, indoor use, barrier treatment	1.71E-03	4.55	4.56	2.14E-02
Metabolite Br_2Ca				
Scenario 1, indoor use crack and crevices		3.68E-05	3.69E-05	2.7E-04
Scenario 2, indoor use, spot treatment to a surface		9.88E-04	9.89E-05	7.45E-04
Scenario 3, indoor use, barrier treatment		2.91E-04	2.92E-04	2.20E-03

Conclusion:
For scenario 1, acceptable level of risk to the environment has been predicted. For scenario 2 and 3 unnaceptable risk has been identified for water and sediment.

Recalculation of Scenario 2
Spot application to a surface has shown unnaceptable risk to fresh water and sediment. Therefore, ESCA has decided to restrict the use of this product to 1-2 applications per year (Fsim=0.00204). In this case the emission to locasl STP is:

Local Emission to waste water	**$Elocal_{ww}$**	**1.16E-04 kg/d**

PEC values

	STP	SW	SED	SOIL	GW
Deltamethrin					
Scenario 2, indoor use, spot treatmet to a surface	5,12E-06	3,18E-07	2,82E-03	1,60E-04	9,64E-06
Metabolite Br2CA					

Scenario 2, indoor use, spot treatmet to a surface		3,02E-07	4,05E-07	1,04E-04	3,13E-02

PEC/PNEC values:

	STP	SW	SED	SOIL
Deltametrhin				
Scenario 2, indoor use, spot treatment to a surface	1.71E-04	4.54E-01	4.55E-01	2.14E-03
Metabolite Br_2Ca				
Scenario 2, indoor use, spot treatment to a surface		2.89E-05	2.90E-05	7.45E-04

In this case, PEC/PNEC values indicate that the risk is no unacceptable to fresh water and sediment.

Recalculation Scenario 3
Barrier treatment has shown unacceptable risk to fresh water and sediment so, the following risk mitigation measure is proposed for both target orgnisems, crockoaches and ants:

For cockoaches:
-The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be an harbourage for cockroaches.
-Apply the product only two times per year.

For ants:

-The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater.
-Apply the product only two times per year.

These risk mitigation measures reduce the risk but not exclude emission through the STP so the following scenario is assess using an area of 5,9 m^2 and a FCE of 25% in order to assess the risk to the environment. This scenario e consequently covered by environmental scenario for use 1 and no extra calculations have been performed.

Primary and secondary poisoning

Primary poisoning
Primary poisoning is very unlikely for Detrans® HPC3 intended for use indoors in crack and crevices and targeted spots and outdoors on window surfaces or areas where house flies 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: 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 ^{14}C 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
$PEC_{oral,\ predator}$ = 1.66E-03 mg/kg $_{wet\ fish}$

Risk characterization for Secondary Poisoning the Aquatic Compartment
A predicted no effect oral concentration ($PNEC_{oral}$) 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 **$PNEC_{oral,\ predator}$ of 1.33 mg/kg bw/day (40 mg/kg/30).**

Comparing this value to the calculated $PEC_{oral,\ predator}$ of 1.66E-03 mg/kg $_{wet\ fish}$ it can be determined that that there is no unacceptable risk from fish eating birds or mammals. **PEC/PNEC = 1.66E-03 mg/kg $_{wet\ fish}$ /1.33 = 1.25E-03**

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 (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.
$C_{earthworm}$ = 3.67E-04 mg/kg wet earthworm = $PEC_{oral,\ predator}$

Risk characterization for Secondary Poisoning the Terrestrial Compartment
A predicted no effect oral concentration ($PNEC_{oral}$) 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 **$PNEC_{oral,\ predator}$ of 1.33 mg/kg bw/day (40 mg/kg/30).**

Comparing this value to the calculated $PEC_{oral,\ predator}$ of 3.67E-04 mg/kg $_{wwt\ earthworm}$ it can be determined that that there is no unacceptable risk for earthworm eating birds or mammals.
PEC/PNEC = 3.67E-04 mg/kg $_{wwt\ earthworm}$ /1.33 = 2.76E-04

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® HPC3.

ESCA:

Secondary poisoning,

		PEC/PNEC
Aquatic	Birds	5.94E-04
	Mammals	3.33E-03
Terrestre	Birds	1.37E-05
	Mammals	7.69E-05

Conclusion: It may be concluded that there is no unacceptable risk for secondary poisoning from the use of Detrans® HPC3.

Mixture toxicity

Mixture toxicity is not relevant for Detrans® HPC3.

ES CA:
ES CA does not agree with the conclusion of the applicant. For each scenario the values obtained for the parent and the metabolite have been summed.

	STP	SW	SED	SOIL	GW
Scenario 1 and 3	2.93E-04	5.7.80E-01	5.77E-01	2.91E-03	9.10E-02
Scenario 2*	1,71E-04	4,54E-01	4,54E-01	2,89E-03	3,13E-02

*mixture toxicity for scenario 2 has been performed taking into account only when the producto is applied 1-2 times/year, scenario 3 has been also performed according to the RMM proposed, and the new scenario is covered by scenario 1.

Conclusion:
No riks has been found for the environment.

Aggregated exposure (combined for relevant emmission sources)

Aggregated exposure is not relevant for Detrans® HPC3.

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

Atmosphere: The maximum PEC in air is negligible (3.17E-17 mg/m^3) therefore, there is no concern for the atmospheric compartment following use of Detrans® HPC3.
STP: There is no concern for the STP following the indoor use of Detrans® HPC3.

Aquatic compartment: There is no concern for the aquatic compartment following the indoor use of Detrans® HPC3.

Terrestrial compartment: The proposed use of Detrans® HPC3 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® HPC3 applied on "outside surfaces of window and door frames, and other areas where house flies 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.
Secondary poisoning: The $PEC_{oral,predator}/PNEC_{oral}$ ratios determined for fish-eating predators/scavengers (1.25E-03) and for earthworm eating organisms (2.76E-04) indicate that there is no unacceptable risk of secondary poisoning following the use of Detrans® HPC3.

Therefore, it may be concluded that when Detrans® HPC3 is used according to the label instructions there will be no cause for concern for the environment.

ES CA:
Overall conclusion on the risk assessment for the environment of the product is summarized in the table bellow:

Summary table for the risk assessment of this product.					
	$PEC/PNEC_{stp}$	$PEC/PNEC_{water}$	$PEC/PNEC_{sed}$	$PEC/PNEC_{soil}$	$PEC/PNEC_{GW}$
Scenario 1, indoor crack and crevices	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable
Scenario 2, indoor use, spot treatment to a surface	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable
Scenario 3, indoor use, barrier treatment	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable

ES CA concludes the product DTRANS HPC3, used according to the SPC, poses no risk to the terrestrial or aquatic environmental compartments neither for all the uses proposed.

The following risk mitigation measures are proposed:

Use 1:

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

Use 2:

The product has to be applied only in restricted areas inaccessible to children and pets (particularly cats), on surfaces not regularly wet cleaned, such as: window and door frames and walls (in localized resting areas where flies may rest.

Use 3:

The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater.For all the uses:

Apply the product only two times per year.

2.2.9 Measures to protect man, animals and the environment

Methods and precautions concerning placing on the market	Avoid spilling, skin and eye contact. Provide good ventilation. Protect against freezing and direct sunlight.
Methods and precautions concerning production, handling and use of the active substance and its formulations	Engineering Controls Provide adequate ventilation. Observe Occupational Exposure Limits and minimise the risk of inhalation of vapours Hygiene Measures Wash promptly if skin becomes contaminated. Promptly remove non-impervious clothing that becomes contaminated. When using do not eat, drink or smoke. Protective Equipment *Respiratory Equipment:* No specific recommendation made, but respiratory protection may still be required under exceptional circumstances when excessive air contamination exists. *Hand protection:* Use suitable protective gloves if risk of skin contact. *Eye protection:* If risk of splashing, wear safety goggles or face shield. *Skin protection:* Wear apron or protective clothing in case of splashes. *Other Protection:* Wear appropriate clothing to prevent any possibility of skin contact. *The Protection Of Bystanders:* No special protection required.
Methods and precautions concerning storage of the active substance and its	Store in tightly closed original container in a dry and cool place. Keep in original container.

formulations	
Methods and precautions concerning transport of the active substance and its formulations	Land transport ADR/RID/ADN Class 9: Miscellaneous dangerous substances and articles. Sea transport IMDG: Class 9 Air transport ICAO/IATA: Class 9
Methods and precautions concerning fire of the active substance and its formulations	Extinguishing media This product is not flammable. Use fire-extinguishing media appropriate for surrounding materials. Specific hazards In case of fire, toxic gases may be formed (COx, NOx). Advice for fire-fighters Special Fire Fighting Procedures: - Not relevant Protective equipment for fire-fighters: - Wear full protective clothing.
In case of fire, nature of reaction products, combustion gases, etc.	Hazardous decomposition products Fire creates: Carbon monoxide (CO). Carbon dioxide (CO_2).
Specific treatment in case of an accident, e.g. first-aid measures, antidotes, medical treatment if available	Inhalation Move the exposed person to fresh air at once. Remove victim immediately from source of exposure. Ingestion NEVER MAKE AN UNCONSCIOUS PERSON VOMIT OR DRINK FLUIDS! Rinse mouth thoroughly. Get medical attention if any discomfort continues. Skin contact Remove affected person from source of contamination. Remove contaminated clothing. Wash the skin immediately with soap and water. Get medical attention if any discomfort continues. Eye contact Make sure to remove any contact lenses from the eyes before rinsing. Promptly wash eyes with plenty of water while lifting the eye lids. Continue to rinse for at least 15 minutes. Get medical attention if any discomfort continues.
Emergency measures to protect the environment	Environmental precautions Do not discharge onto the ground or into water courses. Methods and material for containment and cleaning up Stop leak if possible without risk. Absorb in vermiculite, dry sand or earth and place into containers. Flush with plenty of

	water to clean spillage area. Do not contaminate water sources or sewer.
Possibility of destruction or decontamination following release in the air	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.
Possibility of destruction or decontamination following release in water, including drinking water	There are no recommended decontamination procedures. Contact with water should be avoided.
Possibility of destruction or decontamination following release in or on soil	There are no measures to decontaminate soil.
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	Product : The product should not be allowed to enter drains, water courses or the soil. Disposal should be in accordance with local, state or national legislation. Please recycle empty packaging. Contaminated packaging : Do not re-use empty containers.
Possibility of re-use or recycling	The test substance cannot be recycled.
Possibility of neutralisation of effects	The test substance cannot be neutralised.
Conditions for controlled discharge including leachate qualities on disposal	The product should not be allowed to enter drains, water courses or the soil. Contaminated packaging: Do not re-use empty containers.
Conditions for controlled incineration	In accordance with local and national regulations.
Observations on undesirable or unintended side-effects, e.g. on beneficial and other	Detrans®HPC3 is for use indoors primarily with some limited outdoor use on window and door frames, and other areas where house flies enter the home. The product should not therefore have any effect on beneficial and non-target organisms.

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 for Detrans® HPC3.

2.2.11 Comparative assessment

Not applicable for Detrans® HPC3.

3 ANNEXES

3.1 List of studies for the biocidal product

See confidential annex.

Document IIB-IIC Reference list by section number

3.2 Output tables from exposure assessment tools

Exposure Assesment Detrans I

Crack and Crevice and Targeted Spot Use Indoors

Application

Emission to air - Treatment of Surface - Equation (7)

Variable/parameter (units)	Symbol	Unit	Default	Spot / Crack & Crevice Treatment	S/D/O/P
Inputv					
Number of applications per day per building	$N_{appl, buildings}$	d^{-1}			
- Non-professional			1	1	D
- Professional			-		S
Fraction emitted to air during application	$F_{application, air}$	-	0.02	0.02	D
Quantity of commercial product applied	Q_{prod}	Kg/m^2	-	0.041	S
Fraction of active substance in the commercial product	F_{AI}	-	-	0.0003	S
Area treated with the product	$AREA_{treated}$	m^2			P
- target spot application (household)			2	2	
- general spray application (household)					
Output					
Emission to air during application step $E_{application, air} = N_{appl, building} \times F_{application, air} \times Q_{prod} \times F_{AI} \times AREA_{treated}$	$E_{application, air}$	Kg/d	-	4.92E-07	-

Crack and Crevice and Targeted Spot 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	$N_{appl, buildings}$	d^{-1}			
- Non-professional			1	1	D
- Professional			-		S
Fraction emitted to applicator during application*	$F_{application, applicator}$	-	0.02	0.006	D*
Quantity of commercial product applied	Q_{prod}	Kg/m^2	-	0.041	S
Fraction of active substance in the commercial product	F_{AI}	-	-	0.0003	S
Area treated with the product	$AREA_{treated}$	m^2			P
- target spot application (household)			2	2	
- general spray application (household)					
Output					

Emission to applicator during application step $E_{application, applicator} = N_{appl, building} \times F_{application, applicator} \times Q_{prod} \times F_{AI} \times AREA_{treated}$	$E_{application, applicator}$	Kg/d	-	1.48E-07	-

*Table 3.3-1

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	$N_{appl, buildings}$	d^{-1}			
- Non-professional			1	1	D
- Professional			-		S
Fraction emitted to floor during application	$F_{application, floor}$	-	0.11	0.124	D*
Quantity of commercial product applied	Q_{prod}	Kg/m^2	-	0.041	S
Fraction of active substance in the commercial product	F_{AI}	-	-	0.0003	S
Area treated with the product	$AREA_{treated}$	m^2			P
- target spot application (household)			2	2	
- general spray application (household)					
Output					
Emission to floor during application step $E_{application, floor, 1} = N_{appl, building, 1} \times F_{application, floor, 1} \times Q_{prod, 1} \times F_{AI} \times AREA_{treated, 1}$	$E_{application, floor}$	Kg/d	-	3.05E-06	-

*Table 3.3-3

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:	$N_{application, building}$	d^{-1}			
- non-professional			1		D
- professional			-	1	S
Fraction emitted to treated surfaces during the application	$F_{application, treated}$	-	0.85	0.85	D
Quantity of commercial product applied	$Q_{prod, 1}$	Kg/m^2	-	0.041	S
Fraction of active substance in the commercial product	F_{AI}	-	-	0.0003	S
Area treated with the product	$AREA_{treated}$	m^2			P
- target spot application (household)			2	2	
- general spray application (household)					
Output					
Emission to treated surface during application step $E_{applicatoion, treated, 1} = Q_{prod} \times F_{AI} \times N_{application, building} \times F_{application, treated} \times AREA_{treated}$	$E_{application, treated}$	Kg/d	-	2.09E-05	-

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	$E_{prep, applicator}$	Kg/d		0.00E+00	O
Emission to applicator during the application step	$E_{application, applicator}$	Kg/d		1.48E-07	O
Fraction emitted to solid wastes from applicator after the application	$F_{applicator, w}$	-			P
Disposable coveralls			1	1	
Washable coveralls			0		
Output					
Emission from applicator to solid waste during the cleaning step $E_{applicator, w} = (E_{prep, applicator} + E_{application, applicator}) \times F_{applicator, w}$	$E_{applicator, w}$	Kg/d	-	1.48E-07	-

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	$E_{prep, floor}$	$kg.d^{-1}$		0.00E+00	O
Emission to Floor during the application step	$E_{application, floor}$	$kg.d^{-1}$		3.05E-06	O
Emission to treated surfaces during the application step	$E_{application, treated}$	$kg.d^{-1}$		2.09E-05	O
Fraction emitted to solid waste during the cleaning step	F_w	-	1	1	D
Cleaning Efficiency	F_{CE}	-		0.25	P*
Output					
Emission from floor/treated to solid waste during the cleaning step $E_{treated, w} = (E_{prep, floor} + E_{application, floor +} E_{application, treated}) \times F_W \times F_{CE}$	$E_{treated, w}$	$kg.d^{-1}$	-	5.99E-06	-

* Table 3.3-8 (Spray-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	$E_{prep, applicator}$	Kg/d		0.00E+00	O
Emission to applicator during the application step	$E_{application, applicator}$	Kg/d		1.48E-07	O
Fraction emitted to waste water from applicator after the application	$F_{applicator, ww}$	-			P
Disposable coveralls			0		
Washable coveralls			1	1	
Output					
Emission from applicator to waste water during the cleaning step $E_{applicator, ww} = (E_{prep, applicator} + E_{application, applicator}) \times F_{applicator, ww}$	$E_{applicator, ww}$	Kg/d	-	1.48E-07	-

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	Eprep, floor	kg.d-1		0.00E+00	O
Emission to Floor during the application step	Eapplication, floor	kg.d-1		3.05E-06	O
Emission to treated surfaces during the application step	Eapplication, treated	kg.d-1		2.09E-05	O
Fraction emitted to waste water during the cleaning step	Fww	-	1	1	D
Cleaning Efficiency	FCE	-		0.25	P*
Output					
Emission from floor/treated surface to waste water during cleaning step $E_{treated, ww} = (E_{prep, floor} + E_{application, floor} + E_{applicator, treated}) \times F_{ww} \times F_{CE}$	$E_{treated, ww}$	$kg.d^{-1}$		5.99E-06	-

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

Crack and Crevice and Targeted Spot Use Indoors

Total emissions to waste water

Variable/parameter (units)	Symbol	Unit	Default	Spot / Crack & Crevice Treatment	S/D/O/P
Emission from floor/treated surface to waste water during cleaning step				5.99E-06	
Emission from applicator to waste water during the cleaning step				1.48E-07	
Total				**6.14E-06**	
Simultaneity factor – indoor	$F_{simultaneity}$		*	0.0081*	
Number of					
- houses	$N_{buildings}$	-	4000	4000**	
- buildings		-	300		
Output					
Local emission to wastewater during episode (combined) $E_{local,ww} = E_{treated,\ ww}$ * Household * $N_{buildings}$ * $F_{simultaneity}$	$E_{local,ww}$	Kg/d		**1.99E-04**	

* 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	$F_{spray, wall}$	-	0.3
Quantity of commercial product applied	Q_{prod}	kg/m^2	0.041
Fraction of active substance in the commercial product	F_{AI}	-	0.0003
Area of exterior wall treated per day	$AREA_{wall}$	m^2/d	1.75
Soil volume around the building	Vspray, soil	m^3	4.375
Bulk density of wet soil	RHOsoil	kg wwt/m^3	1700
Local emission from outdoor spray application on wall due to deposition on soil $E_{spray, wall, applic, soil} = F_{spray, wall} \times Q_{prod} \times F_{AI} \times AREA_{wall}$ (Equation 41)	$E_{spray, wall, applic, soil}$	kg/d	6.46E-06
Local concentration of active ingredient in soil adjacent to the house due to wall application against flying insects $C_{spray, wall, applic, soil} = E_{spray, wall, applic, soil} / V_{spray, soil} * RHO_{soil}$ (Equation 44)	$C_{spray, wall, applic soil}$	kg/kg wwt	8.68E-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	$F_{spray, wash-off}$	-	0.5
Quantity of commercial product applied	Q_{prod}	kg/m^2	0.041
Fraction of active substance in the commercial product	F_{AI}	-	0.0003
Area of exterior wall treated per day	$AREA_{wall}$	m^2/d	1.75
Soil volume around the building	Vspray, soil	m^3	4.375
Bulk density of wet soil	RHOsoil	kg wwt/m^3	1700
Local emission from outdoor spray application on wall due to wash off by rainfall $E_{spray, wall, wash-off, soil} = F_{spray, wash off} \times Q_{prod} \times F_{AI} \times AREA_{wall}$ (Equation 42)	$E_{spray, wall, wash-off, soil}$	kg/d	1.08E-05
Local concentration of active ingredient in soil adjacent to the house due to wash off by rainfall $C_{spray, wall, wash off soil} = E_{spray, wall, wash-off, soil} / V_{spray, soil} * RHO_{soil}$ (Equation 45)	$C_{spray, wall, wash off soil}$	kg/kg	1.45E-09
Local concentration of active ingredient in soil adjacent to the house due to washing and wall application against flying insects $C_{spray, wall, applic, soil} = E_{spray, wall, applic, soil} + E_{spray, wall, wash-off, soil} / V_{spray, soil} * RHO_{soil}$ (Equation 46)	$C_{spray, flying, soil}$	kg/kg wwt mg/kg wwt	2.32E-09 2.32E-03

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Detrans HPC3-c&c applic.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

All efficacy tests information is summarised in the efficacy table, section 2.2.5.5.