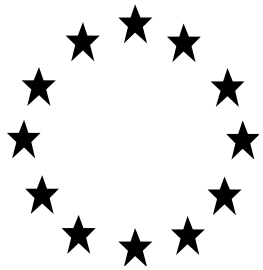
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



ZENITRIN EC

Product type(s) 18

ALPHA-CYPERMETHRIN as included in the Union list of approved active substances

Case Number in R4BP: BC-RX025706-02

Evaluating Competent Authority: Spain

Date: June 2024

Table of Contents

1 CONCLUSION

Efficacy

ZENITRIN EC is an insecticidal product in the form of suspension concentrate for surface treatment including crack and crevice treatment against crawling and flying insects.

The biocidal has shown to be effective against crawling insects as cockroaches, ants, litter beetles and poultry red mites in domestic, public and commercial premise and in livestock and breeding premises.

The biocidal product has shown to be effective against flying insects in domestic, public and commercial premises and against stable flies, wasps and mosquitoes in livestock and breeding premises. The use against flying insects in domestic, public and commercial premises has not been authorised due to MA restrictions.

Human Health

ZENITRIN EC contains the active substance alpha-cypermethrin (6%). For the classification and labelling of the biocidal product family the concentration of active substance and co-formulants in the product is taken into account. In addition to the active substance, other substances of concern for human health have been identified with regard to toxicological properties according to the CLP (Regulation (EC) No 1272/2008).

According to the CAR and BPC Opinion for alpha-cypermethrin, it is not considered to have endocrine disrupting properties. After reviewing the potential ED properties of co-formulants, none of them has been identified as having potential endocrine disrupting 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.

Risk mitigation measures are required to protect Professional users from excesive exposure to alpha-cypermethrin. Use of PPE are required. The use of ZENITRIN EC by Professionals is safe when gloves (PF 90%), protective clothes (coated coverall PF 80%) and face protection are worn.

In addition, the following risk mitigation measures and safety precautions are recommended in order to reduce the risk during the use of the product to professional users:

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

In order to assure the maximum safety for the consumer, the following Risk Mitigation Measures are proposed:

- The product should be applied away from animals. When possible, remove animals from the treated premises before treatment or cover animal cages with a plastic. DO NOT apply directly to animals.
- Avoid as much as possible contact of animals with treated surfaces.
- Cover water tanks, feed, troughs and other surfaces or equipment that may enter in contact with animal feed/foodstuffs before treatment to avoid any contamination

These RMM considerably reduce the exposure of animals when re-entering in treated sites, reducing and minimising possible exposure of consumers to Alpha-cypermethrin as consequence of the use of ZENITRIN EC in livestock premises (except broilers).

Physical-chemical properties

ZENITRIN EC is a yellow liquid with a pungent odour. The density is 0.8926 g/cm3.

The product is stable after 54ºC during 14 days. Regarding storage at low temperature there is not degradation after 7 days at 0ºC. The study of storage stability at long time shows that the product is stable at 24 months.
JC-CTPI-3 has been shown to be non-corrosive to metals (steel and aluminium).

This product has a flash point of 97,3ºC, so according to CLP Regulation it is not categorized as flammable. The auto-ignition temperature of the product is higher than 350°C.
Based on the mean pressure at the test carried out the product is non-oxidizing.

Regarding analytical methods, all acceptance criteria were satisfied: the applied method fit the requirements of the validation for the quantitative analysis of the active substance in the test item.

Risk assessment for the environment

The environmental risk assement of this product has been based only on the active substance alpha-cypermethrin.

This product contains two substances of concern for the environment, however its contribution to the overall toxicity is not significant, so it is has not been taken into account for the environmental risk assement of this product.

According to the uses proposed for ZENITRIN EC, an acceptable risk should be foreseen only for indoor use by professional against crawling insects and use as an insecticide in livestock and breeding premises except for those connected to STP. The following use instructions and the proposed risk mitigations measures need to be followed for each use.

Scenario 1 (only acceptable use for crawling insects):

Instrucction for use:

Do not use the product more than 2 times per year.

Risk mitigation measures:

Only for treat maximum 5.9 and 27 m2 of surface in household and commercial building.

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 crawling insects.

Scenario 2 (only acceptable use for livestock and breeding premises not connected to STP or WWTP systems):

Risk mitigation measure:

Do not use in animal housings where exposure to a STP and/ or direct emission to surface water cannot be prevented.

Additional information (only relevant in Spain):

Following the provisions of BPR art. 37(1), the Spanish Competent Authority (ES CA) will modify the conditions of the Authorisation of this b.p. in the Spanish market in order to adapt the User categories to our national legal requirements (i.e. Royal Decree 830/2010).

The conclusions reached in this PAR which affect the category of Professionals are regarded as applicable to the Spanish categories of **Professionals and Trained Professionals**.

See more details in section 2.2.6.2.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country (if relevant)**
ZENITRIN EC	SPAIN

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Sharda Cropchem España S.L.
	Address	Edificio Atalayas Business Center Carril Condomina Nº3 Planta 12th floor 30006 – Murcia SPAIN
Authorisation number	ES/APP(NA)-2024-18-00942	
Date of the authorisation	10/06/2024	
Expiry date of the authorisation	10/06/2034	

2.1.1.3 Manufacturer(s) of the product

Name of manufacturer	Sharda Cropchem España S.L.
Address of manufacturer	Edificio Atalayas Business Center, Carril Condomina 3, 12th floor 30006 Murcia Spain
Location of manufacturing site 1	DTS-OABE, S.L. Pol. Ind. Zabale, Parcela 3 48410 Orozco, Vizkaya Spain
Location of manufacturing site 2	LABORATORIOS ZOTAL Ctra. Nacional 630, Km 809, Camas 41900 Sevilla Spain
Location of manufacturing site 3	Asplant Skotniccy Spółka Jawna ul. Chopina 78A 43-600 Jaworzno Poland
Location of manufacturing site 4	Productos Flower S.A. Pol. Ind. la Canaleta, s/n, Tàrrega 25300 Lleida Spain
Location of manufacturing site 5	I.R.C.A. Service SpA Strada Statale Cremasca 591, 10 24040 Fornovo San Giovanni (Bg) Italy
Location of manufacturing site 6	FERBI Srl Srl Viale 1° Maggio – C.da Ripoli, Mosciano 64023 S. Angelo (Te) Italy

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

Location of manufacturing site 7	Vebi Istituto Biochimico s.r.l. Via Desman, 43 35010 Borgoricco (PD) Italy
Location of manufacturing site 8	AgroSmart Limited Unit 1C Victoria Court, Colliers Way, Clayton - West Huddersfield, HD8 9TR West Yorkshire United Kingdom
Location of manufacturing site 9	Van Moer SRL Streer Ithaca N200, Bolintin Deal 087015 Judet Giurgiu Romania
Location of manufacturing site 10	Ellagret S.A Thesis Xiropigada, 196 00 Manda Attikis Greece
Location of manufacturing site 11	Lérida Unión Química S.A. (LUQSA) Afores S/N, Sudanell, 25173 Lleida Spain
Location of manufacturing site 12	REA S.r.l. Zona Ind. ASI NORD Aggl. S. Marco - Via L. Einaudi S.S. 87 – KM 20.700, 81025 Marcianise (CE) Italy
Location of manufacturing site 13	GMB Internacional SA Avenida del Mas de l'Oli, 144, Manises 46940 Valencia Spain

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

Active substance	Alpha-Cypermethrin
Name of manufacturer	Sharda Cropchem España S.L. (Acting for Sharda Cropchem Limited (India))
Address of manufacturer	Heedstraat 58, 1730 Asse, Belgium
Location of manufacturing sites	Sharda Cropchem Limited, Domnic HoIm 29th Road, 400050 Bandra, India Plant Location: Heranba Industries Limited. Unit II, Plot NO: A2-2214/15, III Phase, GIDC, Vapi Dist Valsad GUJARAT 396195 -INDIA

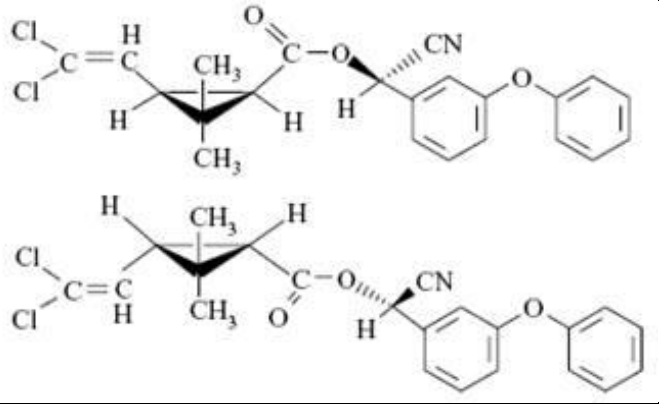
2.1.2 Product composition and formulation

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

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Alpha-cypermethrin
IUPAC or EC name	Reaction mass of (S)-α-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2 dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(1S,3S)-3-(2,2-dichlorovinyl)-2,2 imethylcyclopropanecarboxylate (1:1)
EC number	Not available
CAS number	67375-30-8
Index number in Annex VI of CLP	607-422-00-X
Minimum purity / content	Minimum purity of the active substance evaluated: ≥ 930 g/kg (93.0 % w/w) (sum of the isomers in a 1:1 ratio)
Structural formula	

	AS content
Formulation recipe: Content of the AS used for the formulation of the BP (%)	6%
AS content in the BP to be indicated in the SPC (%)	6%
Minimum purity in the source of the AS (%)	93%
"Minimum pure" AS content (%)	5.58%

2.1.2.2 Candidate(s) for substitution

There is no indication that alpha-cypermethrin would fulfil the exclusion criteria specified in article 5(1), nor the substitution criteria specified in Article 10 (1) of Regulation (EU) No 528/2012.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Alpha-cypermethrin	Reaction mass of (S)-α-cyano-3-phenoxybenzyl-(1R,3R)-3-(2,2 dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (R)-α-cyano-3-phenoxybenzyl-(1S,3S)-3-(2,2-dichlorovinyl)-2,2 imethylcyclopropanecarboxylate (1:1)	Active substance	67375-30-8	Not available*	6.00
Phenylsulfonat Ca	-	Emulsifying agent	Mix	Mix	3.58
	Benzenesulfonic acid, mono-C11-13-branched alkyl derivs., calcium salts		68953-96-8	273-234-6	2.51
	2-methylpropan-1-ol		78-83-1	201-148-0	1.07
Aromatic hydrocarbon solvent	Hydrocarbons, C9, aromatics (Solvent naphtha (petroleum), light arom)	Solvent	Related CAS Nº: 64742-95-6	Reach Registration provisional EC Nº: 918-668-5	86.839

2.1.2.4 Information on technical equivalence

The source of active substance Alpha-cypermethrin included in biocidal product ZENITRIN EC is supplied by applicant Sharda Cropchem España S.L.. This source was approved positive by technical equivalence (Asset num. EU-0012468-0000 and Decision num: TAP-D-1192779-14-00/F). As well, Sharda Cropchem España S.L..Spain, is included in Article 95 list acting as representative EU for Sharda Cropchem Limited (India)).

2.1.2.5 Information on the substances of concern

According to the Guidance on the BPR, Volume III Human Health - Assessment & Evaluation (Parts B+C), Version 4.0, December 2017, three substances of concern were identified: solvent naphta (petroleum light arom.), 2-methylpropan-1-ol and benzenesulfonic acid, mono-C11-13-branched alkyl derivs., calcium salts.

The biocidal product contains two compounds considered as substances of concern with regards to the environment different from the active substance, apha-cypermethrin.

Please see the confidential annex for further details.

2.1.2.6 Type of formulation

EC – Emulsifiable concentrate

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard category	Acute toxicity (oral), category 4 Aspiration hazard, category 1 Serious eye damage, category 1 Specific target organ toxicity — single exposure, category 3 Aquatic acute, category 1 Aquatic chronic, category 1
Hazard statement	H302 Harmful if swallowed. H304 May be fatal if swallowed and enters airways. H318 Causes serious eye damage. H335 May cause respiratory irritation. H336 May cause drowsiness or dizziness. H400 Very toxic to aquatic life. H410 Very toxic to aquatic life with long lasting effects.
Labelling	
Pictograms	 GHS05 GHS07 GHS08 GHS09
Signal words	Danger
Hazard statements	H302 Harmful if swallowed. H304 May be fatal if swallowed and enters airways. H318 Causes serious eye damage. H335 May cause respiratory irritation. H336 May cause drowsiness or dizziness. H410 Very toxic to aquatic life with long lasting effects. EUH066 Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P264 Wash … thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or in a well-ventilated area. P273 Avoid release to the environment. P280 Wear protective gloves/ protective clothing/eye protection/face protection/ hearing protection/… P301+P310+P331 IF SWALLOWED: Immediately call a POISON CENTER/doctor/…Do NOT induce vomiting. P330 Rinse mouth. P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310 Immediately call a POISON CENTER/doctor/… P391 Collect spillage. P403+P233 Store in a well-ventilated place. Keep container tightly closed. P405 Store locked up. P501 Dispose of contents/container as hazardous waste to a registered establishment or undertaking, in accordance with current regulations.

Note	The following P-statements were triggered by the included H-statements, but not assigned: • P301+P312 is triggered by H302, but it is not assigned as considered covered by P301+P330+P331 triggered by H304. • P312 is triggered by H335 and H336, but it is not assigned as considered covered by P310 triggered by H318.

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

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Surface treatment by spraying including cracks and crevices against crawling insects, indoor in household and commercial environments by professional users.

Product Type	PT18- Insecticides, acaricides and products to control other arthropods (Pest control).
Where relevant, an exact description of the authorised use	Insecticide against crawling insects.
Target organism (including development stage)	Blattelidae: Cockroaches *(Blattela germanica, Blatta orientalis)*- Adults Formicinae: Ants *(Lasius niger)*- Adults Tenebrionidae: Litter beetle *(Alphitobius diaperinus)*-Adults Dermanyssidae: Poultry red mites *(Dermanyssus gallinae)*- Adults
Field of use	Indoor Indoor use in private, commercial and public buildings.
Application method	Spraying on insect paths or places where insects may hide, rest, lay or settle with low-pressure sprayer in private houses or commercial and public use buildings.
Application rate and frequency	Dilute 25 mL of product in 5L of water. Apply 1L of in use solution to treat 20 m^2 surface – 0.5% Maximum 2 applications/year.
Category of user	Professional users*
Pack sizes and packaging material	Please see the relevant section.

* The user category in Spain corresponds to Trained Professional Users and (non-trained) Professional Users according to Royal Decree 830/2010.

2.1.4.1.1 Use-specific instructions for use

Dilute 25ml product in 5 litres of water and apply 1 litre diluted product per 20m^2 surface.
Spray on insect paths or places where insects may hide, rest, lay or settle with low pressure sprayer in private houses or commercial and public use buildings.
Do not apply in surfaces likely to be subjected to wet cleaning.
Do not use the product more than 2 times per year.

2.1.4.1.2 Use-specific risk mitigation measures

Only for treat maximum 5.9 and 27 m^2 of surface in household and commercial building. 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 crawling insects.

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

See section 2.1.5.3

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

See section 2.1.5.4

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

See section 2.1.5.5

2.1.4.2 Use description

Table 2. Use # 2 – Surface treatment by spraying including crack and crevices against crawling insects, indoor in livestock and breeding premises by professional users.

Product Type	PT18- Insecticides, acaricides and products to control other arthropods (Pest control).
Where relevant, an exact description of the authorised use	Insecticide against crawling insects.
Target organism (including development stage)	Blattelidae: Cockroaches *(Blattela germanica, Blatta orientalis)*- Adults Formicinae: Ants *(Lasius niger)*- Adults Tenebrionidae: Litter beetle *(Alphitobius diaperinus)*-Adults Dermanyssidae: Poultry red mites *(Dermanyssus gallinae)*- Adults
Field of use	Indoor Indoor use in livestock and breeding premises.
Application method(s)	Spraying - Apply at the normal rate after clean out and before the animals enter the house. Spray the entire surfaces of cages, or spots in boxes, percheries, joists, window ledges, pipes and floors where appropriate. Pay particular attention to corners, cracks and crevices, which may harbour insects or where insects may lay. The product can be applied in all the following animal house categories: Dairy Cattle Beef Cattle & Veal Calves

	Pigs Chicken (free range or battery cages) Non chicken poultry (turkeys, ducks and geese)
Application rate(s) and frequency	Dilute 25 ml product in 5 litres of water, then apply 1 litre diluted product per 20 m^2 surface. - 0.5 % Maximum 4 applications/year.
Category(ies) of users	Professional users*.
Pack sizes and packaging material	Please see the relevant section.

* The user category in Spain corresponds to Trained Professional Users and (non-trained) Professional Users according to Royal Decree 830/2010.

2.1.4.2.1 Use-specific instructions for use

Dilute 25 mL of product in 5L of water, then apply 1L of diluted product per 20 m^2 surface.

Apply at the normal rate after clean out and before the animals enter the house. Spray the entire surfaces of cages, boxes, percheries, joists, window ledges, pipes and floors where appropriate. Pay particular attention to corners, cracks and crevices which may harbour insects.

Do not apply in surfaces likely to be subjected to wet cleaning.

2.1.4.2.2 Use-specific risk mitigation measures

Avoid product application in presence of animals. When possible, remove animals from the treated premises before treatment or cover animal cages with a plastic.

Avoid as much as possible contact of animals with treated surfaces.

Cover water tanks, feed, troughs and other surfaces or equipment that may enter in contact with animal feed/foodstuffs before treatment to avoid any contamination.

Do not use in animal housings where exposure to a STP and/ or direct emission to surface water cannot be prevented.

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

Table 3. Use # 3 – Surface treatment by spraying against stable flies, wasps and mosquitoes, indoor in livestock and breeding premises by professional users.

Product Type	PT18- Insecticides, acaricides and products to control other arthropods (Pest control).
Where relevant, an exact description of the authorised use	Insecticide against stable flies, wasps and mosquitoes.
Target organism (including development stage)	Muscidae:-Stable fly *(Stomoxys calcitrans)*- Adults Culicidae: Mosquitoes *(Culex quinquefasciatus)*- Adults Hymenoptera: Vespinae: Wasps *(Vespula velutina)*- Adults
Field of use	Indoor Indoor use in livestock and breeding premises.
Application method	Spraying - Apply at the normal rate after clean out and before the animals enter the house. Spray the entire surfaces of cages, or spots in boxes, percheries, joists, window ledges, pipes and floors where appropriate. Pay particular attention to corners, cracks and crevices, which may harbour insects or where insects may lay. The product can be applied in all the following animal house categories: Dairy Cattle Beef Cattle & Veal Calves Pigs Chicken (free range or battery cages) Non chicken poultry (turkeys, ducks and geese)
Application rate and frequency	Dilute 25 ml product in 5 litres of water, then apply 1 litre diluted product per 20 m2 surface. - 0.5 % Maximum 4 applications/year.
Category of user	Professional users*.
Pack sizes and packaging material	Please see the relevant section.

* The user category in Spain corresponds to Trained Professional Users and (non-trained) Professional Users according to Royal Decree 830/2010.

2.1.4.3.1 Use-specific instructions for use

Dilute 25 mL of product in 5L of water, then apply 1L of diluted product per 20 m^2 surface.

Apply at the normal rate after clean out and before the animals enter the house. Spray the entire surfaces of cages, boxes, percheries, joists, window ledges, pipes and floors where appropriate. Pay particular attention to corners, cracks and crevices which may harbour insects.

Do not apply in surfaces likely to be subjected to wet cleaning.

2.1.4.3.2 Use-specific risk mitigation measures

Avoid product application in presence of animals. When possible, remove animals from the treated premises before treatment or cover animal cages with a plastic.

Avoid as much as possible contact of animals with treated surfaces.

Cover water tanks, feed, troughs and other surfaces or equipment that may enter in contact with animal feed/foodstuffs before treatment to avoid any contamination.

Do not use in animal housings where exposure to a STP and/or direct emission to surface water cannot be prevented.

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.
Dilute 25 mL of product in 5L of water. Apply 1L of in use solution to treat 20m^2 surface.
The in-use dilution will be applied through a low-pressure sprayer (hand-held or knapsack sprayer). Application must be performed to a band of 0.1 m width on the treated surfaces.
Do not apply in surfaces likely to be subjected to wet cleaning.

2.1.5.2 Risk mitigation measures

Wear protective chemical resistant gloves (penetration 10%), clothing (penetration 20%) and face protection during product dilution and application (gloves and clothing materials to be specified by the authorisation holder within the product information).
Avoid contact with skin and eyes.
Avoid breathing vapours/spays.
Do not eat or drink or smoke while using this product.
Use only in a well ventilated area.
Ensure adequate ventilation during and after use.
Wash hands thoroughly after handling.
Keep uninvolved persons, children and pets away from treated surfaces/areas until dried.
Ensure adequate ventilation before re-entry in treated premises.
Remove or cover terrariums, aquariums and animal cages before application. Turn off aquarium air-filter while spraying.
Keep cats away from treated surfaces. Due to their particular sensitivity to (name of the pyrethroid or pyrethrin), the product can cause severe adverse reactions in cats.
Contains α-cypermethrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms).
Do not apply in rooms where fish tanks and/or terrariums are present.

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

Do not spray directly on people, animals or bedding.

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

Remove all food, feed and drinks prior to treatment.

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

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

Avoid any unnecessary contact with the product. Misuse can cause damage to one's health and the environment.

Check the efficacy of the product on site: if need be, cause of reduced efficacy must be investigated to ensure that there is no resistance or to identify potential resistance.

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

Inform the authorisation holder if the treatment is ineffective.

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

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Inmediately call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.
Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

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

IF MEDICAL ADVICE IS NEEDED, HAVE PRODUCT CONTAINER OR LABEL AT HAND

Emergency measures to protect the environment:
Precautions: Prevent product from entering the environment (surface and ground water), sewerage, drainage, etc. with the construction of protective barriers and closing drains. Communicate to the competent authorities or tipping leaks into waterways, drains, sewers ...

2.1.5.4 Instructions for safe disposal of the product and its packaging

Empty containers, unused product, washing water, containers and other waste generated during application are considered hazardous waste. Deposit packaging waste at the established collection points or deliver it to a registered hazardous waste operator as agreed with the extended producer responsibility system. Deliver the other wastes to a

registered establishment or undertaking for hazardous waste, in accordance with current regulations.

Code the waste according to Decision 2014/955 / EU.

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

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

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

The product should be stored in tightly closed containers in a cool, dry, well-ventilated area.

Avoid high temperatures and direct action of sunlight.

Protect from moisture.

The containers must be placed in such a way as to allow free air circulation.

Do not store with oxidizers, alkalis (caustic solutions), or acids.

Keep away from foodstuffs, beverages and feed.

Check stocks regularly for damage.

Shelf-life: 2 years

2.1.6 Other information

Additional information (only relevant in Spain):

Following the provisions of BPR art. 37(1), the Spanish Competent Authority (ES CA) will modify the conditions of the Authorisation of this b.p. in the Spanish market in order to adapt the User categories to our national legal requirements (i.e. Royal Decree 830/2010).

The conclusions reached in this PAR are regarded as applicable to the Spanish categories of **TRAINED PROFESSIONALS** and **PROFESSIONALS**.

- **TRAINED PROFESSIONALS**: pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
- **PROFESSIONALS**: User applying biocidal products in the workplace. This user has some knowledge and skills in the handling of chemicals, and is able to correctly use personal protective equipment (PPE) if necessary.

In that context, the exposure assessment will be the same for professionals and trained professional users and the difference between the two will depend on the expert judgment following "limiting criteria" below:

1. The hazardousness of the product under evaluation.
2. The use being requested.
3. The frequency of use.
4. Complexity of control measures.

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	100, 250, 500, 750, 1000, 2000 and 5000 ml	Plastic (COEX)	Screw cap	Professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

New data submitted in support of the evaluation of the biocidal product and the active substance third party dossier are listed in Annex 3.1.

2.1.8.2 Access to documentation

The applicant has submitted a third party dossier in support of their source of alpha-cypermethrin, therefore the applicant is the owner od data dossier active substance and it is not need the Letter of access.

2.2 Assessment of the biocidal product

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

Table 2. Use 1 – Indoor crack and crevice treatment in household and commercial environments

Product Type(s)	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide against crawling and flying insects
Target organism (including development stage)	Muscidae:-House fly-Adults Muscidae:-Stable flies-Adults Culicidae:-Mosquitoes-Adults Hymenoptera: Vespinae:-Wasps-Adults Blattellidae:-Cockroaches-Adults Formicinae:-Ants-Adults Cimicidae:-Bed bug-Adults Arachnida: Acari:-Ticks-Adults
Field of use	Indoor Indoor use in private houses and commercial and public buildings.
Application method(s)	Spraying - Applications in crack and crevices and insect paths or places where insects may hide, rest, lay or settle with low pressure sprayer in private houses or commercial and public use buildings.
Application rate(s) and frequency	25 ml of product in 5L of water. 1 l of in-use solution to treat 20 m^2 surface - 0.5 %- Maximum 2 applications/year with minimum 2 months interval between applications.
Category(ies) of user(s)	Professional Trained professional (PCOs)
Pack sizes and packaging material	Bottle - Plastic: COEX - 100, 250, 500, 750, 1000, 2000 and 5000 ml

Table 2. Use 2 – Indoor crack and crevice treatment in livestock and breeding premises by professional users.

Product Type	PT18 - Insecticides, acaricides and products to control other arthropods (Pest control)
Where relevant, an exact description of the authorised use	Insecticide against crawling and flying insects
Target organism (including development stage)	Muscidae:-House fly-Adults Muscidae:-Stable flies-Adults Culicidae:-Mosquitoes-Adults Hymenoptera: Vespinae:-Wasps-Adults Blattellidae:-Cockroaches-Adults Formicinae:-Ants-Adults Cimicidae:-Bed bug-Adults Arachnida: Acari:-Ticks-Adults Tenebrionidae:-Lesser mealworm-Adults Dermanyssidae:-Poultry red mite-Adults
Field of use	Indoor Indoor use in livestock and breeding premises
Application method(s)	Spraying - Apply at the normal rate after clean out and before the animals enter the house. Spray the entire surfaces of cages, or in boxes, percheries, joists, window ledges, pipes and floors where appropriate. Pay particular attention to corners, cracks and crevices which may harbour insects or where insects may lay.
Application rate(s) and frequency	Dilute 25 ml product in 5 litres of water, then apply 1 litre diluted product per 20 m^2 surface. - 0.5 % - Maximum 4 applications/year with minimum 3 months interval between applications
Category(ies) of users	Professional (farmers) Trained professional (PCOs)
Pack sizes and packaging material	Bottle - Plastic: COEX - 100, 250, 500, 750, 1000, 2000 and 5000 ml

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Physical state at 20 °C and 101.3 kPa	EPA OPPTS 830.6303	Alpha-cypermethrin 6% EC (Batch SCL-74560)	Liquid	Gunasekar, D. 2020 – 6475/2019
Colour at 20 °C and 101.3 kPa	EPA OPPTS 830.6302	Alpha-cypermethrin 6% EC (Batch SCL-74560)	Yellow	Gunasekar, D. 2020 – 6475/2019
Odour at 20 °C and 101.3 kPa	EPA OPPTS 8306304	Alpha-cypermethrin 6% EC (Batch SCL-74560)	Pungent	Gunasekar, D. 2020 – 6475/2019
Acidity / alkalinity	CIPAC MT 75.3	Alpha-cypermethrin 6% EC (Batch SCL-74560)	pH (1%) = 7	Gunasekar, D. 2020 – 6475/2019

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Relative density / bulk density	EU Method A.3	Alpha-cypermethrin 6% EC (Batch SCL-74560)	δ = 0.89263 Kg/m^3 at 20°C	Gunasekar, D. 2020 – 6469/2019
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Alpha-cypermethrin 6% EC (Batch SCL-74560)	T^a = 54°C Time = 14 days Packaging – HDPE COEX bottle $[C]_0$ = 6.00% $[C]_f$ = 6.00% Δ = 0% Appearance – No changes were found. pH_0 (1%) = 7.00 pH_f (1%) = 7.01 Emulsion stability and re-Emulsification – No free oil, solid matter or creamy layer were observed and no changes were found after storing. Packaging – No cracks, colour changes, weight changes and shape changes were observed. <u>Conclusion</u>: The results obtained fulfil the Guidance criteria and therefore it can be stated that the biocidal product is not affected by high temperatures.	Gunasekar, D. 2020 – 6475/2019
Storage stability test – **long term storage at ambient temperature**	SANCO 3030/99 Rev. 5 and OPPTS 830.6317	Alpha-cypermethrin 6% EC	During the development of this study there have been no changes or deviations in such an analytical process. Regarding the results, the values remain within the values specified during the 24 months. **<u>Initial ('0' day)</u>** <u>Physical state:</u> liquid	Gunasekar, D. 2022 – 6476/2019

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
			Colour: yellow Odour: pungent pH (1% w/v): 7,02 Emulsion stability and re-emulsification: Uniform emulsion, no free oil, no solid matter and no cream were observed. Alphacypermethrin content (%, w/w): 6,0154 **6th month** Physical state: liquid Colour: yellow Odour: pungent pH (1% w/v): 7,02 Emulsion stability and re-emulsification: Uniform emulsion, no free oil, no solid matter and no cream were observed. Alphacypermethrin content (%, w/w): 5,9965 → Δ= 0,31% **12th month** Physical state: liquid Colour: yellow Odour: pungent pH (1% w/v): 7,02 Emulsion stability and re-emulsification: Uniform emulsion, no free oil, no solid matter and no cream were observed. Alphacypermethrin content (%, w/w): 5,9675 → Δ= 0,80% **24th month** Physical state: liquid Colour: yellow Odour: pungent pH (1% w/v): 7,01 Emulsion stability and re-emulsification: Uniform emulsion, no free oil, no solid matter and no cream were observed. Alphacypermethrin content (%, w/w): 5,9311 → Δ= 1,40%	

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
Storage stability test – **low temperature stability test for liquids**	CIPAC MT 39.3	Alpha-cypermethrin 6% EC (Batch SCL-74560)	T^a = 0°C Time = 7 days Appearance after 1 h at 0ºC: Test substance was homogeneous in nature, with no layer separation observed. Appearance after 7 days at 0ºC: Test substance was homogeneous in nature, with no layer separation observed. After centrifugation: No free oil, froth, solid matter and creamy layer were observed at the top or bottom of the emulsion tube.	Gunasekar, D. 2020 – 6474/2019
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	-	-	-	Not relevant. Opaque packaging.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	-	According to use experience and based on the accelerated storage stability test no effects from temperature or humidity are expected if the product is stored according to label recommendations.
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Visual examination	Alpha-cypermethrin 6% EC (Batch SCL-74560)	No cracks, colour changes, weight changes and shape changes were observed after accelerated storage test (54ºC, 14 days).	6475/2019 D. Gunasekar, 2020
Wettability	-	-	-	Not required. Relevant only for solid

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
				formulations to be dispersed in water.
Suspensibility, spontaneity and dispersion stability	-	-	-	Not relevant. The formulation is an Emulsifiable concentrate.
Wet sieve analysis and dry sieve test	-	-	-	Not relevant. The formulation is an Emulsifiable concentrate.
Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36.3	Alpha-cypermethrin 6% EC (Batch SCL-74560)	Water A and Water D at [C] = 0.37% and [C] = 1.5% **Initial emulsification** – No free oil, froth, solid matter and creamy layer were observed. **Emulsion stability on standing (30 min, 2 h, 24h)** – No free oil, froth, solid matter and creamy layer were observed at the top or bottom of the emulsion tube. **Re-emulsification after standing for 24h** – No free oil, frith, solid matter and creamy layer were observed at the top or bottom of the emulsion tube even after re-emulsification after standing 24h **Final emulsion stability (30 min after 24 h)** – No free oil, froth, solid matter and creamy layer were observed at the top or bottom of the emulsion tube.	Gunasekar, D. 2020 – 6475/2019
Disintegration time	-	-	-	Not relevant. Formulation

Property	Guideline and Method	Purity of the test substance (% (w/w))	Results	Reference
				is an emulsion concentrate and is not intended for disintegration when applied.
Particle size distribution, content of dust/fines, attrition, friability	-	-	-	Not relevant. The formulation is an Emulsifiable concentrate.
Persistent foaming	CIPAC MT 47.3	Alpha-cypermethrin 6% EC (Batch SCL-74560)	Amount of foam in the sample: Initial = 21.933 mL After 1 min = 20.733 mL After 12 min = 12.067 mL The results fulfil the Guidance criteria since they are lower than 60mL after 1 min.	Gunasekar, D. 2020 – 6468/2019
Flowability/Pourability/Dustability	-	-	-	Not relevant. The formulation is an Emulsifiable concentrate.
Burning rate — smoke generators	-	-	-	Not relevant, the product is not a smoke generator.
Burning completeness — smoke generators	-	-	-	Not relevant, the product is not a smoke generator.
Composition of smoke — smoke generators	-	-	-	Not relevant, the product is not a smoke generator.
Spraying pattern — aerosols	-	-	-	Not relevant, the product is not an aerosol.
Physical compatibility	-	-	-	Not relevant. The product is not intended to

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w))</th><th>Results</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td></td><td>be used in combination with other biocidal products.</td></tr>
<tr><td>Chemical compatibility</td><td>-</td><td>-</td><td>-</td><td>Not relevant. The product is not intended to be used in combination with other biocidal products.</td></tr>
<tr><td>Degree of dissolution and dilution stability</td><td>-</td><td>-</td><td>-</td><td>Not relevant because the product is an emulsifiable concentrate that is not soluble in water.</td></tr>
<tr><td>Surface tension</td><td>EU Method A.5
OECD 115</td><td>Alpha-cypermethrin 6% EC (Batch SCL-74560)</td><td>39.3663 mN/m (0.09% test solution) and 43.3063 mN/m (neat formulation) at 25.1ºC</td><td>6470/2019 D. Gunasekar, 2020</td></tr>
<tr><td>Viscosity</td><td>OECD 114</td><td>Alpha-cypermethrin 6% EC</td><td>At 20°C – dynamic viscosity
<table><tr><td>Speed (rpm)</td><td>Result (cP)</td></tr><tr><td>20</td><td>3.84</td></tr><tr><td>30</td><td>3.10</td></tr><tr><td>50</td><td>1.92</td></tr><tr><td>60</td><td>1.54</td></tr></table>At 40°C – dynamic viscosity
<table><tr><td>Speed (rpm)</td><td>Result (cP)</td></tr><tr><td>20</td><td>1.17</td></tr><tr><td>30</td><td>1.11</td></tr><tr><td>50</td><td>1.07</td></tr><tr><td>60</td><td>0.96</td></tr></table>The value varies with the speed – Non-newtonian liquid.</td><td>Gunasekar, D. 2020 – 6473/2019</td></tr>
</table>

Conclusion on the physical, chemical and technical properties of the product
"ZENITRIN EC" (Alpha-cypermethrin 6% EC) is a yellow liquid (emulsion) with a pungent odour. The pH value of a 1% aqueous dispersion of test item ir 7.00. The relative density resulted in 0.89263 g/mL. The formulation exhibited stability under accelerated, long-term and at low temperature

storage. Alpha-cypermethrin 6% EC exhibited complete initial emulsification as well as complete reEmulsification after 24 hours after mixing by inversion. The results of a persistent foam test indicated production of 12.067 mL of
foam/froth after 12 minutes, which is within the acceptable limits required. The viscosity is variable with the spindle speed, indicating the non-newtonian behavior of the test item. Dynamic viscosity values converted into kinematic leads to classification as Asp. Tox. Cat 1. The mean surface tension for the neat formulation is 43.3063 mN/m.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Method A.14	Alpha-cypermethrin 6% EC (Batch SCL-74560)	**Thermal sensitivity** – No fragmentation was observed for 6 mm and 2 mm diameter orifice plates. **Shock Impact test** – No sparks, fumes and bursting were observed Based on the results obtained it can be concluded that the biocidad product is non-explosive.	Gunasekar, D. 2020 – 6467/2019
Flammable gases	-	-	-	Not relevant. Formulation is not a gas.
Flammable aerosols	-	-	-	Not relevant. The product is not supplied as a pressurized aerosol.
Oxidising gases	-	-	-	Not relevant. Formulation is not a gas.
Gases under pressure	-	-	-	Not relevant. Formulation is not a gas.
Flammable liquids	Method A.9 CIPAC MT 12.3	Alpha-cypermethrin 6% EC (Batch SCL-74560)	Flash point = 97.3°C Non-flammable.	Gunasekar, D. 2020 – 6466/2019
Flammable solids	-	-	-	Not relevant. Formulation is not a solid.
Self-reactive substances and mixtures	-	-	-	There are no ingredients with explosive or self-reactive properties present in the biocidal product.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
				Therefore, the formulation is not self-reactive.
Pyrophoric liquids	-	-	-	Pyrophoric properties are not expected based on the experience in handling and use an the chemical structure of the product.
Pyrophoric solids	-	-	-	Not relevant. Formulation is not a solid.
Self-heating substances and mixtures	-	-	-	Not relevant. According to experience of use the product does not react with ambiental moisture or water.
Substances and mixtures which in contact with water emit flammable gases	-	-	-	Not relevant. According to experience of use the product does not react with ambiental moisture or water.
Oxidising liquids	EU Method A.21	Alpha-cypermethrin 6% EC (Batch SCL-74560)	Based on the mean pressure raise after contact with cellulose powder, the test item in non-oxidizing.	Gunasekar, D. 2020 – 6471/2019
Oxidising solids	-	-	-	Not relevant. Formulation is not a solid.
Organic peroxides	-	-	-	Not relevant. Formulation is not a solid.
Corrosive to metals	UN Test C.1 Criteria	Alpha-cypermethrin 6% EC	The corrosion rate of aluminium and steel in ZENITRIN EC ECO at 55ºC after 7 days are below the threshold of 6.25 mm/year (13,5%), since the greatest mass loss was of 0.004% and 0.001% respectively.	Marek Petryka, M.Sc. BC-22/22

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Auto-ignition temperatures of products (liquids and gases)	ASTM E659-78	Alpha-cypermethrin 6% EC (Batch SCL-74560)	T^a > 350°C	Gunasekar, D. 2020 – 6472/2019
Relative self-ignition temperature for solids	Not relevant			
Dust explosion hazard	Not relevant			

Conclusion on the physical hazards and respective characteristics of the product
According to the results obtained in the tests carried out, the biocidal product ZENITRIN EC is not explosive nor oxidising nor corrosive to metals. The auto-ignition temperature of the product is higher than 350ºC. The formulation has been determined to have a flash point of 97.3ºC so according to CLP Regulation it is categorized as non-flammable.

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		
Alpha-cypermethrin	HPLC	6 measurements in duplicate From 2 to 12 mg/L	Y= 1486.7 x + 283.33 R^2= 0.9997	The method is specific (No interferences)	99.0708 – 100.4026	99.7094	0.0452-0.1517	LOQ= 0.2048 mg/L LOD= 0.0996 mg/L	Gunasekar, D. 2020 – 6475/2019

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

Monitoring methods were reported in the Alpha-cypermethrin CAR. Methods in soil, air, water and body fluids and tissues were submitted and deemed acceptable. No methods for detecting alpha-cypermethrin in food and feeding stuffs of plant and animal origin were provided as the intended uses will not result in significant residues in those matrices when the label instruction is followed.

Conclusion on the methods for detection and identificationof the product
The method was validated according to the requirements of the SANCO 3030/99 rev.4 guidelines. Based on the results obtained, the method can be considered valid (specific, linear and precise) for the determination of Alpha-cypermethrin.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Main group 03: Pest control.
ZENITRIN EC is an insecticide, PT 18; Insecticides, acaricides and products to control other arthropods. The product is for use indoors by professional. The product is for use in domestic, public and commercial premises and in livestock facilities.

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

ZENITRIN EC is used to control flying and crawling insects.

2.2.5.3 Effects on target organisms, including unacceptable suffering

ZENITRIN EC is formulated with the active substance alpha-cypermethrin, a synthetic pyrethroid. According to the CAR, Alpha-cypermethrin intoxication results in a rapid knockdown and resultant mortality. The affected insect shows uncoordinated movements and finally dies. It is not possible to assess unacceptable suffering.

2.2.5.4 Mode of action, including time delay

ZENITRIN EC is based on alpha-cypermethrin as active substance. Alphacypermethrin is a synthetic pyrethroid. It acts by preventing the transmission of impulses along nerves on adult insects by blocking the passage of positive sodium ions through sodium channels in nerver membranes, thus preventing action potentials passing down axons. This effect results in a rapid knockdown and mortality of the insects. The affected insects show uncoordinated movements and dead eventually.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)					
Function and field of use envisaged	**Test substance**	**Test organism(s)**	**Test method Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide. For use as surface treatment including crack and crevice treatment against crawling and flying insects, including livestock premises	Alpha-cypermethrin 6% SC (Read across product)	*Vespula vulgaris, Dermanyssus gallinae, Ixodes ricinus*	Laboratory trial against wasps, poultry red mites and ticks. CEB 135/159 The test was performed in 60 m^3 closed room with temperature between 24-26 °C. The product was applied at rate of 25 ml in 5 L of water to treat 100 m^2 porous and non-porous surfaces. 4 replicates were conducted per each species for treatment and untreated control. Total surface area treated was 1 m^2. Insects were forced to stay in the treated	**Direct spray trial:** 100% knockdown effect 30 seconds to 1 minute. Mortality after 24 hours was 100%. **Surface treatment trial:** Knockdown was recorded at least during 1 hour for fresh and 4 weeks aged surfaces. Final mortality (no recovery after 24 h) up to 12 weeks after treatment except ticks on porous surfaces where 100% mortality was recorded 48 h after	[redacted] Study No.2008 ALFASECT-LAB/1015

			surfaces during 1 hour (no choice test). Direct spray test was also conducted. 10 wasps, 50 poultry red mites and 25 ticks per replicate were treated with the product. Knockdown during 1 hour of exposure and mortality during 24 and 48 hours after insects exposure to the treated surfaces.	treatment. Faster results (100% mortality after 24 h) were achieved on non-porous surfaces.	
	Alpha-cypermethrin 6% SC (Read across product)	*Musca domestica, Cimex lectularius, Ixodes ricinus, Dermanyssus gallinae*	Simulated use test against various pests. Choice test. Residual efficacy assesed after 8 weeks. The test was conducted in four test chambers of 12 m^3 with temperature of 22°C +/- 1 °C, relative humidity of 60% +/- 5%, smooth ventilation and 8 hours of light per day (800 lux). Test chambers walls were made of non-sorbent panels and the floor was made of ceramic tiles. Panels were treated with the product and were made of ceramic tile (non-porous) and cement (porous). Food and water sources were not on the treated surfaces. The product was applied at rate of 25 ml in 5 L of water to treat 100 m^2 porous and non-porous surfaces. Total number of 250 flies, 250 bed bugs, 250 poultry red mites and 125 ticks were exposed to the product and the same number of pests were used as untreated control. Mortality after 24 hours of exposure and 8 weeks after was recorded.	The mean percentage mortality of 100% was recorded after 24 hours and 8 weeks later for all treated pests.	[redacted] Trial No. 2008-ALFASECT-SIM/0515
	Alpha-cypermethrin 6% SC	*Blattella germanica, Musca*	Field trial against German cockroaches,	B. germanica: 98.2% reduction of population 2 weeks	[redacted]

	(Read across product)	*domestica, Lasius niger and Culex quinquefasciatus*	house flies and black ants. Simulated use trial against mosquitoes. 4 replicates for each treatment were conducted for mosquitoes. 3 replicates for German cockroaches and house flies, 4 for black ants. Monitoring traps were used to assess the population of target species before and after the treatment. The product was applied at a rate of 25 ml in 5 L of water to treat 100 m^2. Assessments were performed at 2-weekly intervals for a total of 8 weeks after treatment (cockroaches); at 2, 4, 7, 14 and 21 days after treatment (flies) and at 2, 7, 14 and 21 days after treatment (ants). Mosquitoes were assessed at intervals: 15, 30, 45, 60 minutes and 2,4 and 24 hours after exposure.	after treatment, 84.7% after 8 weeks. M. domestica: 81.3% population reduction over a 21 days period L. niger: 99.9% reduction over a 21 days Culex quinquefasciatus: 92.9% knocked down and dead mosquitoes over a 24 h after treatment	Study Code 14/300
	Alpha-cypermethrin 6% SC (Read across product)	*Stomoxys calcitrans*	Field trial against stable flies. CEB Nº107 The trial was performed in naturally infested breeding premises. 5 replicates. Sticky traps were used to assess the population of stable flies before and after the treatment. The product was applied at a rate of 25 ml in 5 L of water to treat 100 m^2 and applied in areas preferred by flies to rest. Assessments were performed on 7, 14, 28 and 56 days (8 weeks) after treatment.	>90% population reduction of the stable flies until 8 weeks after application.	[redacted] Trial No. 2008-ALFASECT- FLY-FIELD/1015
	Alpha-cypermethrin 6% SC	*Alphitobius diaperinus*	Fiel trial against litter/darkling beetle.	>90% population reduction of the litter/darkling	[redacted]

	(Read across product)		CEB Nº107 (adapted to litter beetle). The trial was performed in naturally infested breeding premises and efficacy was calculated comparing the insects counts before and after treatment, in treated and untreated buildings. 5 replicates. Sticky traps were used assess the population of litter/darkling beetle before and after the treatment. The counts of trapped litter beetles were done 24 hours after setting, one and two weeks before treatment. The product was applied at a rate of 25 ml in 5 L of water to treat 100 m^2 preferred in the bottom of walls and doors and close to manure/litter. Assessments were performed on 7, 14, 28 and 56 days (8 weeks) after treatment.	beetle until 8 weeks after application.	Trial No. 2008-ALFASECT-LB-FIELD/1015
	Alpha-cypermethrin 6% SC (Read across product)	*Blatta orientalis*	A field trial against oriental cockroaches. CEB Nº249 Residual treatment. 5 sites were treated and 5 sites were used as untreated control. Cockroach populations were evaluated by sticky trapping before and after the treatment in naturally infested public buildings. 5 sticky traps were settled per site. The product was applied at a rate of 25 ml in 5 L of water to treat 100 m^2. Assessments were performed on 1, 7, 14, 28 and 56 days after treatment.	>90% population reduction of oriental cockroaches until 8 weeks after application.	[redacted] Study No. 2008-ALFASEC-CO-FIELD/1015
	Alpha-cypermethrin 6% SC & EC	*Blatella germanica* and *Blatta orientalis*	Laboratory trial against cockroaches (*B. germanica and B. orientalis*) to assess and compare the efficacy of	**Porous Surface:** <u>Knock down:</u> 100% after zero day and	[redacted] Study code: 368IAMG4667/R0

			two formulations containing 6% alphacypermethrin in SC and EC formulation. The test was conducted by surface application on one porous (cement) and non-propus (tile) surfaces. The products were applied at rate of 0.5% in water. 50 ml of this dilution was used to treat 1 m^2 of surface. Surfaces were cleaned and test ítem sprayed uniformly with separate atomizers. After spraying the surfaces were allowed to air dry and then the insects were released. 20 insects per replicate Three replicates were conducted for test ítem along with untreated controls. The treated surfaces were stored for ageing and the same test were repeated after 8 weeks on the same surfaces. Assessment for Knock down at 1hr and mortality after 24 hr of exposure. Surfaces were tested and stored at 25-30ºC with a relative humidity of 60-75%	after 8 weeks for both formulations. Mortality: 100% after zero day and 91-95% mortality after 8 weeks for both formulations. **Non-porous Surface:** Knock down: 100% after zero day and after 8 weeks for both formulations. Mortality: 100% after zero day and 95-98% mortality after 8 weeks for both formulations.	
	Alpha-cypermethrin 6% SC & EC	*Culex spp*	Laboratory trial against mosquitoes (*Culex quinquefasciatus*) to assess and compare the efficacy of two formulations cotaining 6% alphacypermethrin in SC and EC formulation. The test was conducted by surface application on one porous (cement) and non-propus (tile) surfaces. WHO guidelines. The products were applied at rate of 0.5% in water. 50 ml of this dilution was used to treat 1 m^2 of surface.	**Porous Surface:** Knock down: 92% (SC formulation) and 95% (EC formulation) after zero day Efficacies after 8 weeks were 83% (SC formulation) and 87% (EC formulation) Mortality: 100% after zero day for both formulations Efficacies after 8 weeks were 94% (SC formulation) and 97% (EC formulation)	[redacted] Study Code: 368IAMG4669/ R0

			Surfaces were cleaned and test ítem sprayed uniformly with separate atomizers. After spraying the surfaces were allowed to air dry and then the insects were released. 15 insects per replicate Three replicates were conducted for test ítem along with untreated controls. The treated surfaces were stored for ageing and the same test were repeated after 8 weeks on the same surfaces. Assessment for Knock down at 1hr and mortality after 24 hr of exposure. Surfaces were tested and stored at 25-30ºC with a relative humidity of 60-75%	**Non-porous Surface:** Knock down: 100% (SC) and 94% (EC) after zero day and 87-88% after 8 weeks for both formulations. Mortality: 100% after zero day and 93-95% mortality after 8 weeks for both formulations	
	Alpha-cypermethrin 6% SC & EC	*Alphitobius diaperinus*	Laboratory trial against litter beetle (*Alphitobius diaperinus*) to assess and compare the efficacy of two formulations cotaining 6% alphacypermethrin in SC and EC formulation. The test was conducted by surface application on one porous (cement) and non-propus (tile) surfaces. The products were applied at rate of 0.5% in water. 50 ml of this dilution was used to treat 1 m^2 of Surface. Surfaces were cleaned and test ítem sprayed uniformly with separate atomizers. After spraying the surfaces were allowed to air dry and then the insects were released. 25 insects per replicate Three replicates were conducted for test ítem along with untreated controls. The treated surfaces were stored for	**Porous Surface:** Knock down: 69% (SC formulation) and 74% (EC formulation) after zero day Efficacies after 8 weeks were 62% (SC formulation) and 50% (EC formulation) Mortality: 100% after zero day for both formulations Efficacies after 8 weeks were 97-98% for both formulations. **Non-porous Surface:** Knock down: 67% (SC) and 90% (EC) after zero day and 70% (SC) and 60% (EC) after 8 weeks. Mortality: 100% after zero day and 98-99% mortality after 8 weeks for both formulations.	[redacted] Study Code: 368IAMG4670/ R0

			ageing and the same test were repeated after 8 weeks on the same surfaces. Assessment for Knock down at 1hr and mortality after 24 hr of exposure. Surfaces were tested and stored at 25-30ºC with a relative humidity of 60-75%		
	Alpha-cypermethrin 6% SC & EC	*Lasius niger*	Laboratory trial against black ants (*Lasius niger*) to assess and compare the efficacy of two formulations cotaining 6% alphacypermethrin in SC and EC formulation. The test was conducted by Surface application on one porous (cement) and non-porous (tile) surfaces. The products were applied at rate of 0.5% in water. 50 ml of this dilution was used to treat 1 m^2 of surface. Surfaces were cleaned and test ítem sprayed uniformly with separate atomizers. After spraying the surfaces were allowed to air dry and then the insects were released and confined in the surfaces by using WHO cones. 20 insects per replicate Three replicates were conducted for test ítem along with untreated controls. The treated surfaces were stored for ageing and the same test were repeated after 8 weeks on the same surfaces. Assessment for Knock down at 1hr and mortality after 24 hr of exposure. Surfaces were tested and stored at 25-30ºC with a relative humidity of 60-75%	**Porous Surface:** <u>Knock down:</u> 100% (for both formualtions after zero day Efficacies after 8 weeks were 67% (SC formulation) and 100% (EC formulation) <u>Mortality:</u> 100% after zero day for both formulations Efficacies after 8 weeks were 99-100% for both formulations. **Non-porous Surface:** <u>Knock down:</u> 100% for both formulations after zero day and 88% (SC) and 100% (EC) after 8 weeks. <u>Mortality:</u> 100% after zero day and 99-100% mortality after 8 weeks for both formulations.	[redacted] Study Code 368IAMG4668/R0

	Alpha-cypermethrin 6% EC	*Stomoxys Calcitrans*	Laboratory test against stablefly (*Stomoxys calcitrans*) to assess the efficacy of alpha-Cypermethrin 6% in EC formulation. The test was carried out in petridishes 20 cm dia in which stable flies were treated to a range of concentrations of the biocidal product. 20 stable flies per treatment were tested, in four replicates As control was used distilled water at the same procedure that all the replicates. The treated petridishes were stored 8 weeks for ageing and assessment was repeated after 1, 2, 4, 6 and 8 weeks. The knockdown and percentage of mortality was recorded after 24 h. Tª= 28.3-31.4ºC RH= 65-77%	The bioefficacy and persistence of alpha-Cypermethrin 6% in EC formulation against stable flies (*Stomoxys calcitrans*) on the petridishes with different time intervals showed high mortality (100%), when compared to the reference item	[redacted] Study Nº 10151/2021
	Alpha-cypermethrin 6% EC	*Stomoxys Calcitrans*	Field test against stablefly (*Stomoxys calcitrans*) to assess the efficacy of alpha-Cypermethrin 6% in EC formulation. The test was carried out in cattle farms during spring and beginning of summer in porous concrete, floors, walls and beams. The product was applied by spraying directly on racks, beams, window sills, pipes and floors. The application rate was 1L per 20m^2. Three replicates for the selected rate dose were used. A control with water only was used as reference item. Observations were recorded after 24 h.	The bioefficacy of alpha-Cypermethrin 6% in EC formulation against stable flies (*Stomoxys calcitrans*) in field condition showed high mortality in 50mL/5L concentration when compared to the reference item. It has been observed a high percentage of population reduction (>95%) in contrast to reference item/control (<5%).	[redacted] Study Nº 11925/2022

Conclusion on the efficacy of the product

No specific efficacy trials were performed with the formulation Alpha-cypermethrin 6% EC (Zenitrin EC) but with a similar formulation Alpha-cypermethrin 6% SC containing the same concentration of active substance and applied at the same application rate (including previous dilution) than Zenitrin EC. The extrapolation between formulations is considered valid because the products are applied at the same rate in terms of active substance, following the same application instructions and against the same target organisms. In addition neither the SC nor EC formulations contain any ingredient intended to enhance the effect of the active substance or to attract or serve as nutrient to improve the ingestion of the product. A composition certificate in order to demonstrate the read accross between both formulation is included in the confidential annex.

Zenitrin EC is an insecticidal product in the form of suspension concentrate for surface treatment including crack and crevice treatment against crawling and flying insects. Laboratory trial, simulated use test and field trials were performed in a read across product to assess the efficacy of the product applied at a rate of 25 ml in 5 L of water to treat 100 m^2.

With both formulations (SC and EC), four trials have been submitted and the efficacy for both products have been similar.

Laboratory trials against cockroaches (*B. germánica and B. orientalis*) have resulted in an efficacy of 100% for knockdown and mortality for both formulations at time zero and efficacy between 90-100% after 8 weeks in porous (cement) and non-porous (tiles) surfaces. Efficacy of the SC and EC formulations have no significative differences.

Laboratory trials against mosquitoes (*Culex quinquefasciatus*) have resulted in an efficacy of 90-100% for knockdown and mortality for both formulations at time zero and efficacy between 83-97% after 8 weeks in porous (cement) and non-porous (tiles) surfaces. Efficacy of the SC and EC formulations have no significative differences.

Laboratory trials against litter beetle (*Alphitobius diaperinus*) have resulted in an efficacy of 90-100% for knockdown and mortality for both formulations at time zero and efficacy between 83-97% after 8 weeks in porous (cement) and non-porous (tiles) surfaces. Efficacy of the SC and EC formulations have no significative differences.

Laboratory trials against black ants (*Lasius niger*) have resulted in an efficacy of 100% for knock down and mortality for both formulations at time zero and efficacy between 88-100% after 8 weeks in porous (cement) and non-porous (tiles) surfaces. Efficacy of the SC and EC formulations have no significative differences.

Therefore, these four laboratory trials show that efficacy of both formulations are similar and trials with one formulation can be used for the assessment of the other formulation.

With alphacypermethrin 6% SC seven trials have been submitted.

Laboratory trial against wasps (*Vespula vulgaris*), poultry red mites (*Dermanyssus gallinae*) and ticks (*Ixodes ricinus*) as a residual spray treatment proved a very good effectivness with a fast knockdown and a complete mortality and a residual efficacy at least 12 weeks after treatment on various materials. Faster results were recorded on non-porous materials. Direct spray application on all tested insects showed fast knockdown effect (30 seconds to 1 minute) and 100% mortality after 24 h of exposure.

A simulated use test proved a very good control against various pests (*Musca domestica, Cimex lectularius, Ixodes ricinus, Dermanyssus gallinae*) until 8 weeks after application (mortality of 100% was recorded after 24 hours and 8 weeks later for all treated pests).

Two different field trials were performed in support of the efficacy of Alfasect against houseflies and stable flies. The field study against houseflies was performed in different animal housing premises (horses, hens and pigs) and cattle milking rooms. The population reduction was assessed at each testing site at regular periods of time until 21 days. The population reduction after 21 days was good (81%). In the case of stable flies (*S. calcitrans*) the test was performed in different animal breeding

premises (sheep and cow/veal stables). The results were very good even 8 weeks after the treatment (>95%)

For cockroaches, the product was tested in two different field trials against german and oriental cockroaches for up to 8 weeks. Results against german cockroaches were very good 2 and 4 weeks after application, however the population of cockroaches slightly increased in the weeks 6 and 8. This effect can be consequence of re-infestation from adjacent sites. Oriental cockroaches were also tested and the population reduction was very good even 8 weeks after application (up to 99%).

A field trial performed against black ants (*Lasius niger*) showed very good performance of the product with complete population reduction (99%) over 3 weeks after treatment. In a simulated use trial over 90% mosquitoes (*Culex quinquefasciatus*) were affected (knockdown and mortality) over a 24 hour experimental period.

Results of field trials against stable flies (*Stomoxys calcitrans*), litter/darkling beetle (*Alphitobius diaperinus*) and oriental cockroaches (*Blatta orientalis*) showed a very good control until 8 weeks after application (>90% population reduction).

Therefore, according to the results obtained from the efficacy trials performed in a read across product, it can be concluded that Zenitrin EC is effective against crawling (cockroaches, ants, poultry mites and litter beetles) and also against flying insects (wasps, mosquitoes and flies) and the label claims requested are supported with the relevant efficacy data.

According to the evaluation of the results of the efficacy table, the eCA concludes that:

Wasps (*Vespula vulgaris*): The applicant has submitted a laboratory test, as a residual spray treatment proved a very good effectiveness with a fast knockdown and a complete mortality and a residual efficacy at least 12 weeks after treatment on various materials. Direct spray application on all tested insects showed fast knockdown effect (30 seconds to 1 minute) and 100% mortality after 24 h of exposure.
The product is intended for the control of flying wasps so the requirement is a laboratory test. Wasps are approved for all intended uses.

Flies (*Musca domestica*): A simulated use test proved a very good control against (*Musca domestica)* until 8 weeks after application (mortality of 100% was recorded after 24 hours and 8 weeks later). The product is intended for the control of flying flies so the requirement is a simulated test. Flies are approved for general surface treatment.

The field study against houseflies was performed in different animal housing premises (horses, hens and pigs) and cattle milking rooms. The population reduction was assessed at each testing site at regular periods of time until 21 days. The population reduction after 21 days was 81% but the natural population was reducted too (26% in the control). We consider that this test is not enough robust to conclude that the claim for flies can be approved in stables and waste dumps.

Mosquitoes (*Culex quinquefasciatuss*):
Laboratory trials against mosquitoes (*Culex quinquefasciatus*) have resulted in an efficacy of 90-100% for knockdown and mortality for at time zero and efficacy between 83-97% after 8 weeks in porous (cement) and non-porous (tiles) surfaces.

In a simulated use trial over 90% mosquitoes (*Culex quinquefasciatus*) were affected (knockdown and mortality) over a 24 hour experimental period.

Mosquitoes are approved for the intended uses as general surface treatment and for Flying insects.

Cockroaches *(Blatta orientalis, Blatella germanica):* For cockroaches, the product was tested in two different field trials against german and oriental cockroaches for up to 8 weeks. Results against german cockroaches were very good 2 and 4 weeks after application, however the population of

cockroaches slightly increased in the weeks 6 and 8. This effect can be consequence of re-infestation from adjacent sites. Oriental cockroaches were also tested and the population reduction was very good even 8 weeks after application (up to 99%).

Ants (*Lasius niger*): Laboratory trials against black ants (*Lasius niger*) have resulted in an efficacy of 100% for knock down and mortality at time zero and efficacy between 88-100% after 8 weeks in porous (cement) and non-porous (tiles) surfaces.

A field trial performed against black ants (*Lasius niger*) showed very good performance of the product with complete population reduction (99%) over 3 weeks after treatment.
Ants are approved for the intended use.

Poultry red mites *(Dermanyssus gallinae):*
Laboratory trial against poultry red mites (*Dermanyssus gallinae*) as a residual spray treatment, proved a very good effectivness with a fast knockdown and a complete mortality and a residual efficacy at least 12 weeks after treatment on various materials. Faster results were recorded on non-porous materials. Direct spray application showed fast knockdown effect (1 minute) and 100% mortality after 24 h of exposure.

A simulated use test proved a very good control against poultry red mites *(Dermanyssus gallinae*) until 8 weeks after application (mortality of 100% was recorded after 24 hours and 8 weeks later).

Poultry red mites are approved for the intended uses.

Litter beetle *(Alphitobius diaperinus):*
Laboratory trial against litter beetle (*Alphitobius diaperinus*) have resulted in an efficacy of 90-100% for knockdown and mortality at time zero and efficacy between 83-97% after 8 weeks in porous (cement) and non-porous (tiles) surfaces.

Results of field trial against litter/darkling beetle (*Alphitobius diaperinus*) showed a very good control until 8 weeks after application (>90% population reduction).

Litter beetles are approved for the intended uses.

Stable flies *(Stomoxis calcitrans)*: Specific efficacy tests were performed with the formulation Alpha-cypermethrin 6% EC (ZENITRIN EC) to prove the efficacy against stable flies (*Stomoxys calcitrans*). The applicant has submitted a laboratory and a field test, obtaining good results of efficacy in both: >95% of percentage of mortality of stable flies, showing a reduction of amount of these insects in contrast to the control situation.

All in all, the use of ZENITRIN EC for the control of stable flies (*Stomoxys calcitrans*) in livestock and breeding premises is covered, and based on the data obtained in laboratory and field tests, ZENITRIN EC has a good effect when applied by spraying directly on the surfaces at the doses tested up to 8 weeks.

Stable flies are approved for the intended use in livestock and breeding premises. However, a general claim against flies cannot be authorised because the field test against houseflies is not enough robust to conclude the claim for flies can be approved in stables.

It is important to note that, according to a further clarification submitted by applicant in march 2023, the field test was carried out in different livestock farms built in concrete, floors, walls and beams in absence of animals, which were reintroduced after the treatment was completed.

The requirements and criteria of the TNsG on product evaluation for PT18 (2012) are not met for:

Ticks (*Ixodes ricinus*): The applicant has submitted a laboratory test, as a residual spray treatment proved a very good effectiveness with a fast knockdown and a complete mortality and a residual efficacy at least 12 weeks after treatment on various materials. A simulated use test has been submitted too, but following TNsG: 'with ticks it has to be established that thicks are knocked down or killed before they can attack to the skin and start feeding. This is compared to a control test'. That is missed on the simulated test submitted, so efficacy data are insufficient to conclude on *Ixodes ricinus.*

House flies *(Musca domestica)*: The field study against houseflies was performed in different animal housing premises (horses, hens and pigs) and cattle milking rooms. The population reduction was assessed at each testing site at regular periods of time until 21 days. The population reduction after 21 days was 81% but the natural population was reducted too (26% in the control). We consider that this test is not enough robust to conclude that the claim for flies can be approved in stables and waste dumps.
The efficacy against *Musca domestica* was not fully demonstrated for the use in livestock and breeding premises, since the population reduction observed in the field test (81%) is not much high in contrast to the natural reduction of flies population (26%) for conclude that the biocidal product has a good efficacy to reduce this population at negliglible levels.
It is important to clarify that a general claim against flies both the housefly and the stable fly (*S. calcitrans*) cannot be authorised because the field test against houseflies is not enough robust to conclude the claim for flies can be approved in stables. Therefore, the label of the product should indicate clearly that the biocidal product ZENITRIN EC has been authorised for its use in livestock and breeding premises only against stable flies (*S. calcitrans*).

Bedbugs *(Cimex Lectularius):* The applicant have submitted only a simulated use test against bed bugs (Cimex lectularius), it is a choice test and shows residual efficacy of 8 weeks, showing good efficacy on 2 types of surfaces porous (cement)) and non-porous (ceramic tile). But, typical surfaces like for example textile fabrics would have been relevant to test considering the infestation areas of this kind of insects.
Moreover, in order to be used by professionals users a laboratory test and a field test have to be submitted. The simulated-use test was not considered as sufficient to prove efficacy against bedbugs. So, considering the whole data set, it is concluded that efficacy of this product against bed bugs has not been sufficiently demonstrated.

The use against flying insects in domestic, public and commercial premises has not been authorised due to MA restrictions.

2.2.5.6 Occurrence of resistance and resistance management

Development of resistance against alpha-cypermethrin is possible. Cross resistance is possible due to common mode of action. So far, resistance has been only observed in agricultural use of alpha-cypermethrin. Biocidal treatments are of limited extension and resistance is not likely if good treatment practices are followed (alteration of insecticides with different modes of action, mixtures of insecticides with different modes of action and avoidance of frequent and repeated use).
According to the CAR, development of resistance against alpha-cypermethrin is in principle possible in a wide range of insect taxa. Due to the common mode of action of pyrethroids cross-resistance may be of importance. However, actual resistance (including cross-resistance) has to date only been observed in agricultural pest insects, which are the targets of large-scale applications of insecticides, thus increasing the likelihood of resistance development. Biocidal treatments, in contrast, are typically targeted on relatively small populations of pest insects forming more or less closed populations. Good treatment practice will most likely results in high control levels which in turn reduces the likelihood of resistance development. In the literature search, *Blattela germanica* is identified as susceptible to

alphacypermethrin, with no indications of resistance. Any records related to *Periplaneta americana* or to fleas (Siphonaptera) were not identified by the literature search. This suggests that both the American cockroach and the whole order of fleas (Siphonaptera) resistance has to date not been detected.

The continued threat of resistance must be managed in order to prevent its manifestation in species where it has already developed and in order to minimize the risk of resistance developing in species which have not yet developed resistance to the synthetic pyrethroids. For this reason, strategies such as alteration of insecticides with different modes of action, mixtures of insecticides with different modes of action and avoidance of frequent and repeated use are standard practice.

The proposed resistance management strategy includes the following actions:

- The incorporation of a label warning: 'Use products at recommended doses and intervals'.
- To avoid the potential for insect resistance, the product should be used in alternation with other products not containing the same a.s. to avoid resistant populations.
- If resistance is confirmed, stop the use of the product and rotate to an insecticide with alternative mode of action.
- The authorisation holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.2.5.7 Known limitations

There are no known limitations to consider for the product.

2.2.5.8 Evaluation of the label claims

In conclusion, the following claimed uses are compliant with the requirements of the TNsG on product evaluation for PT18:

- Use against flying insects, house fly (*Musca domestica*), mosquitoes (*Culex quinque fasciatus*, adults), wasps (*Vespula velutina*, adults) as surface treatment by spraying for professionals (indoor use in private and commercial and public buildings). Application rate: 1L of in use solution to treat 20 m^2 surface (0.5%).

  The use against flying insects in domestic, public and commercial premises has not been authorised due to MA restrictions.

- Use against crawling insects, cockroaches (*B. germanica* and *B. orientalis,* adults*),* ants (*L. niger,* adults), litter beetle (*Alphitobius diaperinus,* adults) and poultry red mites (*Dermanyssus gallinae*, adults) as surface treatment by spraying (including crack and crevices) for professionals (indoor use in private and commercial and public buildings). Application rate: 1L of in use solution to treat 20 m^2 surface (0.5%).

- Use against crawling insects, cockroaches (*B. germanica* and *B. orientalis,* adults*),* ants (*L. niger,* adults), litter beetle (*Alphitobius diaperinus,* adults) and poultry red mites (*Dermanyssus gallinae*, adults) as surface treatment by spraying (including crack and crevices) for professionals (indoor use in livestock and breeding premisses). Application rate: 1L of in use solution to treat 20 m^2 surface (0.5%).

- Use against stable fly (*Stomoxys calcitrans*, adults), mosquitoes (*Culex quinque fasciatus*, adults), wasps (*Vespula velutina*, adults) as surface treatment by spraying for professionals (indoor use in livestock and breeding premisses). Application rate: 1L of in use solution to treat 20 m^2 surface (0.5%).

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

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

2.2.6 Risk assessment for human health

ZENITRIN EC is a dustable powder containing 6 % alpha-cypermethrin.

No animal or human data on toxicological properties have been generated, but a calculation of toxicological properties according to CLP criteria has been carried out, taking into account the amount of each ingredient in the product. Active substance effects and critical concentrations are described in the alpha-cypermethrin assessment report. Information on co-formulants are found on the ECHA dissemination website and in the SDSs submitted. Therefore, new studies with the biocidal product are scientifically not justified.

The full composition of the product ZENITRIN EC has been provided in the confidential annex

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	ZENITRIN EC is neither irritant nor corrosive to the skin.
Justification for the value/conclusion	Based on the classification of alpha-cypermethrin and the different co-formulants and their respective content in the final formulation. The product contains 3.58% of Phenylsulfonat CA that is classified as skin irritant, category 2; H315. Other substance is classified as skin irritation, but it is below the specific cut-off values established in Regulation (EC) No 1272/2008 (CLP Regulation). Hence, according to the classification criteria of the CLP Regulation, ZENITRIN EC is not classified as corrosive or irritant to skin. However, due to the content of the aromatic hydrocarbon solvent in the biocidal product, the supplemental hazard statement EUH066 must be assigned.
Classification of the product according to CLP	ZENITRIN EC is not classified as skin irritant, however the supplemental hazard statement EUH066 must be assigned.

Data waiving	
Information requirement	Skin corrosion/irritation study
Justification	The composition of the product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Serious eye damage
Justification for the value/conclusion	Based on the classification of alpha-cypermethrin and the different co-formulants and their respective content in the final formulation.

	The product contains 3.58% of Phenylsulfonat CA that is classified as eye damage, category 1; H318. Hence, according to the classification criteria of the CLP Regulation, ZENITRIN EC must be classified as eye damage, category 1, H318.
Classification of the product according to CLP	ZENITRIN EC is classified as eye damage category 1, H318.

Data waiving	
Information requirement	Eye irritation study
Justification	The composition of the product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/conclusion	Causes respiratory irritation.
Justification for the conclusion	Based on the classification of alpha-cypermethrin and the different co-formulants and their respective content in the final formulation. The active substance, alpha-cypermethrin, and two co-formulants (aromatic hydrocarbon solvent and Phenylsulfonat CA) are classified as STOT SE 3. Taking all substances into account, the product contains more than 20% of co-formulants classified for its specific target organ toxicity after single exposure, category 3; H335. Therefore, it can be concluded that the product ZENITRIN EC is classified with regards to respiratory tract irritation according to the criteria set out in the Regulation (EC) Nº 1272/2008 (CLP Regulation).
Classification of the product according to CLP	STOT SE 3; H335: May cause respiratory irritation.

Data waiving	
Information requirement	Respiratory tract irritation data.
Justification	No data on respiratory tract irritation have been submitted. Furthermore, this data is not required under Biocides Regulation. However, the composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) Nº 1272/2008 (CLP Regulation).

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	ZENITRIN EC is not a skin sensitiser.
Justification for the value/conclusion	Based on the classification of the alpha-cypermethrin and the co-formulants and their final content in the formulation. None of the components of the product is classified for skin sensitisation. Therefore,

	the product does not meet the criteria for classification for skin sensitisation according to Regulation (EC) Nº 1272/2008.
Classification of the product according to CLP	No classification required according to CLP.

Data waiving	
Information requirement	Skin sensitization study
Justification	The composition of the product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Respiratory sensitization (ADS)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	ZENITRIN EC is not respiratory sensitizer.
Justification for the value/conclusion	Based on the classification of alpha-cypermethrin and the different co-formulants and, their respective final content in the formulation. None of the components of the product are classified for respiratory sensitization. Therefore, the product does not meet the criteria for classification for respiratory sensitization according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification required according to CLP.

Data waiving	
Information requirement	Respiratory sensitization data
Justification	The composition of the product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Acute toxicity

The assessment of the acute toxicological properties of ZENITRIN EC is derived from the classification of the active substance and co-formulants as agreed in the Annex VI of the CLP regulation or, when not available, as agreed in the Classification and Labelling notification at ECHA. This information is included in their safety data sheets. For confidentiality reasons, the names and percentages of co-formulants are disclosed in PAR confidential annex document.

According to Regulation (EC) No 1272/2008 classification of mixtures based on ingredients of the mixture is determined by calculation from the ATE values (ATE_{mix}):

$$\frac{100}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

or

$$\frac{100 - (\sum C_{unknown} if > 10\%)}{ATE_{mix}} = \sum_{r} \frac{C_i}{ATE_i}$$

where:

C_i = concentration of ingredient i (% w/w or % v/v)
i = the individual ingredient from 1 to n
n = the number of ingredients
ATE_i = Acute Toxicity Estimate of ingredient i.

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	ATE_{mix}:300 < ATE ≤2000
Justification for the selected value	The classification of the biocidal product was conducted using endpoints included in the Assessment Report (PT18) of alpha-cypermethrin. No other components of the product are classified for acute oral toxicity. According to Assessment Report, the worst case acute oral LD50 for alpha-cypermethrin is 57 mg/kg bw. The calculated oral ATE for ZENITRIN EC is 950 mg/kg bw. Therefore the product meets the criteria for classification for acute oral toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	Acute oral toxicity Category 4; H302: Harmful if swallowed.

Data waiving	
Information requirement	Acute oral toxicity study.
Justification	The composition of the product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	ZENITRIN EC is not harmful by inhalation route.
Justification for the selected value	Based on the classification of alpha-cypermethrin and the different co-formulants and, their respective final content in the formulation. None of the components of the product is classified as harmful by inhalation route. Therefore, the product does not meet the criteria for classification for acute inhalation toxicity according to Regulation (EC) No 1272/2008.
Classification of the product according to CLP	No classification required according to CLP.

Data waiving	
Information requirement	Acute inhaltion toxicity study.

Justification	The composition of the product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	ATE_{mix}>2000 mg/Kg bw
Justification for the selected value	Based on the classification of alpha-cypermethrin and the different co-formulants and their respective final content in the formulation. One co-formulant is classified with regards to their acute toxic properties by dermal route as acute toxicity, category.4; H312. According to CLP Regulation, calculation of ATEmix for oral toxicity results in 30726 mg/Kg bw and no classification is triggered.
Classification of the product according to CLP	No classification required according to CLP.

Data waiving	
Information requirement	Acute dermal toxicity study.
Justification	The composition of the product is known. Sufficient data on the intrinsic properties are available through safety data sheets and other information for each of the individual components in the product. In addition, synergistic effects between any of the components are not expected. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008, therefore this study does not need to be conducted.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption		
Substance	Alpha-cypermethrin	
Value(s)*	25% (Concentrate)	70% (Dilution)
Justification for the selected value(s)	Default value from EFSA guidance on dermal absorption for organic solvent-based formulations (EFSA Journal 2017; 15(6):4873).	

Data waiving	
Information requirement	Dermal absorption study
Justification	There is no experimental data available on the dermal absorption of ZENITRIN EC 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, 2017;15(6):4873) using a default value of 70% dermal absorption for this product.

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

Three ingredients contained in the product ZENITRIN EC are regarded as substances of concern according to definition in BPR Regulation Art. 3(1):

- Hydrocarbons, C9, aromatics (Solvent naphtha (petroleum), light arom).
- Benzenesulfonic acid, mono-C11-13-branched alkyl derivs., calcium salts.
- 2-methylpropan-1-ol

Aromatic hydrocarbon solvent is classified, among other hazard classes, as aspiration hazard, Category 1 with the hazard statement H304, specific target organ toxicity (respiratory irritant), single exposure, category 3: H335 and specific target organ toxicity (central nervous system), single exposure, category 3: H336 Also, skin defatting statement: EUH066 is included This co-formulant is present in the product in such proportion as to lead to classification of the product as Asp. Tox. 1 (H304) and STOT SE 3 (H335 and H336).

Benzenesulfonic acid, mono-C11-13-branched alkyl derivs., calcium salts is classified as H312 (Acute tox 4), H315 (Skin irrit 2) and H318 (Eye damage 1). Isobutanol is classified as H226 (Flam liq 3), H315 (Skin irrit 2), H318 (Eye damage 1)., H335 (STOT SE 3) and H336 (STOT SE 3). Both co-formulants are components of Phenylsulphonat CA. These two co-formulants contribute, by additivity, to the classification of the biocidal product as Eye damage 1; H318 (Causes serious eye damage). Therefore, they should have been considered as substances of concern.

For further details, please refer to the Confidential Annex.

Available toxicological data relating to a mixture

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

Other

Specific target organ toxicity (respiratory irritant), single exposure (STOT SE)

Value used in the Risk Assessment – STOT SE	
Value/conclusion	STOT SE; H335
Justification	According to its SDS the aromatic hydrocarbon solvent is classified as STOT SE 3; H335. No specific concentration limits are given for this ingredient, so the generic concentration limits of the CLP apply (point 3.8.3.4.5. of CLP Regulation ≥ 20%). Since its concentration is above the generic concentration value, it triggers the classification of the product.
Classification of the products according to CLP	Classification as STOT SE 3; H335: *"May cause respiratory irritation"* is required.

Specific target organ toxicity (central nervous system), single exposure (STOT SE)

Value used in the Risk Assessment – STOT SE	
Value/conclusion	STOT SE; H336
Justification	According to its SDS the aromatic hydrocarbon solvent is classified as STOT SE 3; H336. No specific concentration limits are given for this ingredient in Annex VI of CLP, so the generic concentration limits of the CLP apply (point 3.8.3.4.5. of CLP Regulation ≥ 20%). Since its concentration is above the generic concentration value, it triggers the classification of the product.

Classification of the products according to CLP	Classification as STOT SE 3; H336: *"may cause drowsiness or dizziness"* is required.

Specific target organ toxicity, repeated exposure (STOT RE)

Value used in the Risk Assessment – STOT RE	
Value	The product does not cause organ damage through prolonged or repeated exposure.
Justification for the selected value	The active substance Alpha-cypermethrin may cause damage to the Central Nervous System (CNS) through prolonged or repeated exposure (STOT RE 2) whilst the co-formulants do not have this classification. However, the concentration of the active substance in the preparation is below of the classification limit (10%) set in Regulation (EC) Nº 1272/2008. Therefore, the biocidal product does not meet the criteria for classification as a specific target organ toxicant.
Classification of the product according to CLP	No classification required according to CLP.

Aspiration harard (Asp tox 1)

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	May pose an aspiration toxicity hazard
Justification for the value/conclusion	Based on intrinsic properties of individual components of the biocidal product ZENITRIN EC. The SoC "Hydrocarbons, C9, aromatics (Solvent naphtha (petroleum), light arom)" is a hydrocarbon and has a kinematic viscosity as provided in the SDS of 0.8 mm²/s at 40°C. The concentration of the SoC in ZENITRIN EC is above the concentration limit of ≥ 10% for classification with Aspiration toxicity Category 1. Thus, ZENITRIN EC needs to be classified with respect to aspiration toxicity hazard.
Classification of the product according to CLP	H304: May be fatal if swallowed and enters airways

Endocrine disruption

Endocrine disrupting properties assessment of active substance and co-formulants is mandatory from 7 June 2018, date when the Regulation (EU) 2017/2100 came into force, according to the article 19 of BPR.

Assessment of the ED properties of the active substances:

The biocidal product contains only one active substance. Assessment report of alpha-cypermethrin (Belgium, 2014) indicates that active substance is not classified as Carc. 2 or Repr. 2 and has not been identified as having endocrine disrupting properties. However, a comprehensive ED-assessment of the active substance and its metabolites according to Regulation (EU) 2017/2100 and the "Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption" will need to be performed at the renewal stage.

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

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

Overall conclusion on the biocidal product regarding ED properties:

Based on the existing knowledge and the data provided in alpha-cypermethrin assessment report, there is no indication of concern regarding the ED properties of the substances used in the ZENITRIN EC biocidal product.

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

2.2.6.2 Exposure assessment

ZENITRIN EC is intended for trained professionals and farmers applying the product in livestock facilities.

Additional information (only relevant in Spain):

Following the provisions of BPR art. 37(1), the Spanish Competent Authority (ES CA) will modify the conditions of the Authorisation of this b.p. in the Spanish market in order to adapt the User categories to our national legal requirements.
Royal Decree 830/2010 stipulates the specific training and skills for Trained Professional users of biocides. It follows that in Spain there are three User categories regarding the application of biocides, namely:

- *Trained Professional users* (TP): professionals whose daily work is related to the application of biocides (e.g. Pest Control Operators). They should have received specific training on the safe use of biocides including correct use of Personal Protection Equipment (PPE), and should have a formal professional certificate.
- *Professional users* (P): non-trained professionals which may use biocides in the context of their working activities, but not as a normal activity. It is unlikely that they have received specific training on the safe use of biocides. However it can be expected that they have some knowledge and skills on the handling of chemicals, according to the national legislation on occupational risks prevention, so that they are able to use correctly some kind of PPE if necessary.
- *Non-professional users* (NP) (General public): users of biocides in domestic areas in the context of their private life activities, who are not professionals.

The conclusions reached in this PAR are regarded as applicable to the Spanish categories of **Trained Professionals and Professionals**.

At the same time, there are also some restrictions of packaging in relation to those user categories and product types. In this case, for professional users the maximum size that can be authorized is 1 kg.
In that context, the exposure assessment will be the same for professionals and trained professional users and the difference between the two will depend on the expert judgment following "limiting criteria" below:

1. The hazardousness of the product under evaluation.
2. The use being requested.
3. The frequency of use.
4. Complexixy of control measures.

ZENITRIN EC contains Alpha-cypermethrin as the only active substance. Users may be primarily exposed to ZENITRIN EC when mixing, loading and applying the product indoors via spray application and when

cleaning the spray equipment. Secondary exposure may affect to toddlers when accidentally entering in contact with treated surfaces and adults during laundering/disposing of working clothes.

The product is applied at a rate of 25 ml of product in 5L of water for 100 m^2 floor surface.

The risk assessment for human healt has been conducted following the *Guidance on the Biocidal Products Regulation*. *Volume III Human Health – Part B Risk Assessment* and relevant HEEG and AdHoc documents for each relevant population group.

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**		
	Professionals[(1)]	**Non professionals**	**Professionals[(1)]**	**General public**	**Via food**
Inhalation	Yes	n.a.	n.a	Yes	No
Dermal	Yes	n.a	n.a	Yes	No
Oral	No	n.a	n.a	Yes (infants)	No

[(1)] Pest Control Operators and Farmers trained in the use of biocides

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Mixing and loading Application Cleaning spray equipment – Household, commercial and public areas	Primary exposure During application trained professional users are exposed to alpha-cypermethrin and relevant SoC during the different stages of the application process: mixing and loading the product in the application device, product application and cleaning of application devices.	Professionals
2.	Mixing and loading Application Cleaning spray equipment – Livestock and breeding premises	Primary exposure During application trained professional users are exposed to alpha-cypermethrin and relevant SoC during the different stages of the application process: mixing and loading the product in the application device, product application and cleaning of application devices.	Professionals
3.	Adults and toddler re-entering in a treated room	Secondary exposure Exposure to adults and toddler after treatment application indoors	Bystanders
4.	Laundering	Secondary exposure Exposure to persons laundering contaminated work clothing	Bystanders

See calculations in Annex 3.2.

Professional exposure

Only for Spain:
According to national legislation, in Spain there are until three user categories:

- Trained professional users (TP): pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
- Professional users (NTP): professionals that use the biocidal products in the context of his profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.
- Non-professional users (NP): users who are not professionals and that apply the biocidal product is in his private life.

At the same time, there are also some restrictions of packaging in relation to those user categories and product types.
In that context, the exposure assessment will be the same for professionals and trained professional users and the difference between the two will depend on the expert judgment following "limiting criteria" below:

5. The hazardousness of the product under evaluation.
6. The use being requested.
7. The frequency of use.
8. Complexixy of control measures.

ZENITRIN EC is intended for its application in household, commercial and public areas and in livestock premises such as dairy farms, stables or poultry.

Scenario 1 – Professional application in household, commercial and public areas

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

Description of Scenario 1

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

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

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

	Parameters	Value
Tier 1	Spray concentration:	2.68×10^{-4} mg a.s./mg dilution
	Application rate:	13.4 mg a.s./m^2
	Water rate:	1 l spray solution per 20 m^2
	Time of mix/loading and application:	120 min per day
	Work rate:	108 L spray per day**
	Operator body weight:	60 kg
	Dermal absorption:	25% concentrate 70% dilution***
	Inhalation absorption:	100%
	Hands exposure values (no gloves) (indicative 75th percentile):	181 mg dilution/min
	Rest of body exposure values (indicative 75th percentile):	92 mg dilution/min
	Inhalation exposure values (indicative 75th percentile):	104 mg dilution/m^3
Tier 2	Gloves	From the model
	Clothing penetration	20%
	RPE factor	10%

* The exposure model considers exposure to the in use spray. Therefore, the application which covers the highest in use spray concentration (i.e. application to impermeable surfaces) represents the worst case.

**The value of 120 minutes was assumed for time of actual spraying in the estimate of operator exposure. For hand held application with hydraulic nozzles an average flow rate of about 0.9 l/minute can be assumed. For work rate the amount of 108 l spray applied per day (=2160 m^2) was assumed. This value is conservative as the area treated is considered 2 m^2 per house and 9.3 m^2 per large building.

*** Default values for dermal absorption have been considered according to the EFSA Guidance on Dermal Absorption (EFSA Journal 2017; 15(6):4873).

Calculations for Scenario 1

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

Exposure description	**Tier 1** **Without PPE**	**Tier 2** **Gloves + Coated coverall**
Mixing/loading and application. Spray model 1		
Potential Hand		
Indicative value (rate of deposition of product)	181 mg dilution/min	10.7 mg dilution/min
Task duration (default value)	120 min/day	120 min/day
Spray concentration	$2.68x10^{-4}$ mg a.s./mg dilution	$2.68x10^{-4}$ mg a.s./mg dilution
Active substance on hands	5.816 mg a.s. /day	0.344 mg a.s. /day
Rest of body potential dermal exposure		
Indicative value (rate of deposition of product):	92 mg dilution/min	92 mg dilution/min
Task duration (default value)	120 min/day	120 min/day
Spray concentration	$2.68x10^{-4}$ mg a.s./mg dilution	$2.68x10^{-4}$ mg a.s./mg dilution
Potential amount of product on rest of body	2.956 mg a.s. /day	2.956 mg a.s. /day
Clothing penetration (default value)	100 %	20 % (coated coverall)
Actual dermal deposit of product on rest of body	2.956 mg a.s. /day	0.591 mg a.s. /day
Total dermal exposure		
Total actual dermal exposure to product via hands and body	8.773 mg a.s. /day	0.935 mg a.s. /day
Skin penetration	70%	70%
Total dermal systemic exposure to a.s. via hands and body for a 60 kg adult	**0.10235 mg a.s./kg bw/day**	**0.0109 mg a.s./kg bw/day**
Inhalation exposure		
Indicative value (exposure to product via inhalation)	104 mg dilution/m^3	104 mg dilution/m^3
Breathing rate (default value)	1.25 m^3/h	1.25 m^3/h
Task duration(default value)	120 min/day	120 min/day
Spray concentration	$2.68x10^{-4}$ mg a.s./mg dilution	$2.68x10^{-4}$ mg a.s./mg dilution
RPE factor	-	10%
Total inhalation exposure to a.s.	**0.00116 mg a.s./kg bw/day**	**0.000116 mg a.s./kg bw/day**
Cleaning application equipment. Recommendation No 4 of the BPC Ad Hoc Working Group on Human Expossure		
Potential Hand		
Indicative value (rate of deposition of product)	35.87 µl in-use product/min	
Task duration (default value)	20 min/day	
Product on hands	717.4 µl/day	

Rest of body potential dermal exposure		
Indicative value (rate of deposition of product):	19.28 µl in-use product/min	
Task duration (default value)	20 min/day	
Potential amount of product on rest of body	385.6 µl/day	
Clothing penetration (default value)	100 %	
Actual dermal deposit of product on rest of body	385.6 µl/day	
Total dermal exposure to product via hands and body	1.103 ml/day	
Spray concentration	$2.68x10^{-4}$ mg a.s./mg dilution	
Total dermal exposure to a.s. via hands and body	0.310 mg	
Skin penetration	70%	
Total dermal systemic exposure to a.s. via hands and body for a 60 kg adult	**0.00034 mg a.s./kg bw/day**	
Total exposure		
Total systemic exposure via skin and inhalation to a.s.	**0.103851 mg a.s./kg bw/day**	**0.01241 mg a.s./kg bw/day**
Total systemic exposure as % of systemic AEL*	**649 %**	**77.6 %**

* AELsystemic= 0.016 mg/kg bw/day (occupational $AEL_{mid\text{-}term}$)

The estimated systemic exposure of trainded professional users **accounts for 649%** of the proposed systemic AEL when not considering PPE (proposed systemic AEL=0.016 mg/kg bw/day for occupational exposure as defined in the CAR document). When using gloves (PENETRATION 10%), and coverall (PENETRATION 20%) the estimated systemic exposure **accounts for 77.6%** of the proposed systemic AEL.

Conclusion

The estimated systemic exposure of trained professionals mixing and loading, applying and cleaning the applying equipments accounts for 649% of the proposed occupational AEL (0.016 mg/kg bw/day) when not considering PPE and 77.6% when using gloves and coverall.

Based on these calculations there is unacceptable risk anticipated for professional users when not using PPE according to systemic effects caused by alpha-cypermethrin.

Risk mitigation measures are required to protect trained professional operators from excesive exposure to alpha-cypermethrin. Furhtermore, trained professional operators typically use both dermal protection equipment (at least gloves PF10 and protective clothing) when applying insecticides by spraying.

Summary table: estimated exposure from trained professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake (mg/Kg bw/day)**	**Estimated dermal uptake (mg/Kg bw/day)**	**Estimated oral uptake (mg/Kg bw/day)**	**Estimated total uptake (mg/Kg bw/day)**
Scenario 1	1/No PPE	0.00116	0.10269	-	0.10385
	2/Gloves + coated cloting	0.00116	0.01125	-	0.01241
	3/ Gloves + coated cloting + RPE	0.00112	0.01125		0.01137

Further information and considerations on Scenario 1

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

According to the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), the product classification triggered by the solvent naphtha (petroleum) is included in Band A, and the classification triggered by Phenylsulfonat CA (benzenesulfonic acid and isobutanol) is included in Band B.

Component	Effects	Classification	Band
Phenylsulfonat CA	Severe eye irritant	Eye Dam 1 (H318)	A
Hydrocarbons, C9 aromatics	Irritant to respiratory track May cause drowsiness or dizziness Causes skin dryness	STOT SE 3 (H335) STOT SE 3 (H336) EUH066	B

Foolowing the anding evaluation scheme for classified SoCs leading to the classification of the biocidal product:

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

It must be noted the risks defined above are referred to the straight product. The product is diluted in a rate of 1:200 in water when sprayed. When the product is diluted it is not expected that the concentration of the individual ingredients lead to classification of the dilution and therefore no risk for local effects are expected when the product is applied or the application devices are cleaned (for instance, the dilution at a rate of 1:200 leads to a concentration of the ingredient(s) responsible of Severe eye damage Category 1 200 times lower, which is well below the threshold value setting classification with regard to irritant or corrosive effects to eye or to specific organ toxicity. Therefore the only relevant stage for local effects is during mixing and loading the product in the application system. This stage is usually of short duration (several seconds or a few minutes) and low volumes of product are used (typically 25-50 mL/day). Therefore, if the risk mitigation measures reported above are followed, no risk to trained professional operators derived from local effects is expected. In any case, the use of PPE and risk mitigation measures is recommended during the whole cycle of use of the product.

Qualitative Risk Assessment fo local effects:

Hazard categoty	**Relevant local effect**	**CLP hazard classification assigned to the biocidal product and/or its in-use solution**
High	Severe eye irritant	Eye Dam 1 (H318)
Low	Irritant to respiratory track May cause drowsiness ot dizziness Causes skin dryness	STOT SE 3 (H335) STOT SE 3 (H336) EUH066

Hazard		Exposure information		
Hazard category	**Effects**	**Frecuency and duration of potential exposure**	**Degree of potential exposure under best practice conditions**	**Relevant RMMs (PPE not relevant)**
High	Eye Dam 1 (H318)	Mixing and loading the product. Short duration (seconds or few minutes) Low volumes used (25-50 ml/day)	Practically no exposure (use of gloves)	- Wash hands thoroughly after handling - Do not eat, drink or smoke when using this product. - Avoid breathing vapours/spray. - Use only in a well ventilated area (ensure good ventilation during use). - Wear protective gloves, clothing and face protection.
Low	STOT (H335) STOT (H336) EUH066			

Scenario 2 – Professional application in livestock and breeding premises

Similar conditions of use as in household, commercial and public areas are expected (the product is applied upwards and downwards with a low pressure spraying equipment during approx. 120 minutes, preliminary mixing/loading operations are required). The assessment of the risk to professional operators when using ZENITRIN EC in livestock and breeding areas is similar than the risk associate to professional operators when treating household, commercial and public areas.

Non-professional exposure

Not relevant.

Exposure of the general public

The general population may be exposed to the product without being aware of it. Exposure to ZENITRIN EC is likely by contact with treated surfaces or by cleaning the product residues after application. Due to the mode of application of the product in crack and crevice, this exposure is limited in time and extension and can be considered an acute exposure. The general public is divided in four representative populations: adult, children, toddler and infant.

Scenario 3 - Secondary exposure after application indoors

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

The choice of secondary exposure parameters and calculation method has been made using the HEEG oppinioin No 7. In this document developed for PT 2, 3 and 4 product types, but valid for PT18 biocides different routes of exposure are defined:

Secondary exposure as a result of use of ZENITRIN EC may occur via the dermal route (transfer of surface bound residues to the skin) and by inhalation (while aerosol particles settle during the acute phase of the secondary exposure). However inhalation exposure (secondary) as a result of use of alpha-

cypermethrin in the biocidal product is considered to be not relevant since the application must be performed in absence of persons (other than the person applying the product, already covered by the assessment during application stage) and re-etnering in treated sites is restricted until spray residues are settled and dried. Besides, vapour pressure of alpha-cypermethrin is low ($2.51x10^{-5}$ Pa; 20ºC; according to Council Directive 1999/13/EC, a substance should be considered volatile when the vapour pressure >0.01 kPa at 20ºC). Thus, secondary exposure is considered predominantly via the dermal route (transfer of surface bound residues to the skin). The transfer of residues to the skin depends on:

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

The calculation of the secondary exposure is based in the following equations:

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

And

$$E_{dermal} = D \times \text{Dermal absorption} / \text{Body weight}$$

3
In the case of toddlers, hand-to-mouth transfer is possible. It is assumed that 10% of the external dermal dose is absorbed by oral route. The calculation is conducted as follows:

$$E_{oral} = D \times \text{Hand to mouth transfer} \times \text{Oral absorption} \div \text{Body weight}$$

The assumptions/considerations to calculate secondary exposure to ZENITRIN EC are summarised below:

Secondary exposure after application indoors	
Maximum application rate (considering the density of the product as 0.89263 g/mL)	233 mg product/m^2 (13.4 mg a.s./m^2)
Surface residues (SR):	0.000402 mg a.s./cm^2* (=13.4 mg/m^2 * 30% dislodgable fraction)
Transfer Coefficient (TC):	7200 cm2 per hour (Adult)** 2000 cm2 per hour (child, toddler)**
Surface Area Transferable Residues (TR):	10% of the residues present on the surface***
Exposure Period (EP):	1 hour per day
Hand to mouth transfer coefficient	10%
Dermal absorption	70%
Oral Absorption	43% (According to CAR document)
Body weight	60 Kg (adult) 10 kg (toddler)

* To be consistent with the proposed transfer coefficient, in a conservative approach it is assumed that "virtually" the residues are distributed to the whole surface in the room.
** According to AdHoc Recommendation No 12
*** The product is not extensively applied in the surfaces, but in crack and crevices, where treated surfaces are usually out from the reach of person. Therefore a reduction in the effective contact area is applied.
**** CAR Report for Alpha-cypermethrin

The secondary exposure after indoor crack and crevice application is summarised below:

Summary table: estimated secondary exposure				
Population	**Estimated dermal uptake (mg/Kg bw/day)**	**Estimated oral uptake (mg/Kg bw/day)**	**Estimated total uptake (mg/Kg bw/day)**	**% AEL**
Adult	0.00337	0.00019	0.00357	**19.8**
Toddler	0.00562	0.00035	0.00597	**33.2**

AEL_{acute} = 0.018 mg/Kg bw/d has been used as reference. The secondary exposure to general population does not take place during a long period of time and is of low frequency. Therefore this parameter is taken as reliabel reference value for safe use.

Conclusion
The estimated systemic exposure of the toddler is the worst case when considering secondary poisoning for general population and accounts for 32.2%. Risk to adults indirectly exposed to the product residues in the surfaces when entering in treated areas is also acceptable accounting for 19.8% of the acute AEL. Based on these calculations there is no unacceptable risk anticipated for persons being secondary exposed after the application of ZENITRIN EC indoors.

Further information and considerations on scenario 3
Although the product is classified for other local effects due to the presence of SoCs , these risks are expected to be negligible when product is diluted and dried.
In addition, in order reduce the possibility of exposure to bystanders when re-entry in treated premises immediately after application, the following recommendations are proposed:

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

Scenario 4 - Secondary exposure to persons laundering contaminated work clothing

This scenario only affects to non-PCOs where washable workwear is used. In the case of PCOs the coverall is disposable and therefore no laundry operations are envisaged.

In general this approach assumes that the laundering is undertaken in a domestic, automatic washing machine. Therefore, exposure will be by the dermal route, via the hands, from handling the contaminated clothing prior to and during introduction of the clothing into the washing machine. It is considered that laundering is undertaken after the use of the clothes (non-PCOs only apply the product sporadically and it is assumed that the workwear used during product application is washed off just after the application of the product): hence the total amount of active substance present on the work clothing after one day of working is assumed to be the actual dermal deposit on the rest of the body as per Scenario 1 = 2.956 mg a.s./day) present on the work clothing as a wost case. The area of a medium-sized coverall is 22700 cm^2.

Therefore, expressed as mg alpha-cypermethrin/cm^2, the accumulated residues in the workwear after one application are 0.00013 mg/cm^2.

The total area of the palms and backs of both hands for an adult is 820 cm^2, the transfer coefficient for contamination (of dried fluid) from cotton or knitwear to wet hands is 30% (Technical notes for guidance; Human exposure risk assessment to biocidal products, Guidance on exposure estimation, June 2002") and using the dermal penetration figure of 70%, the systemic dose for a 60 kg adult can be calculated as:

Systemic dose when laundering = a.s. residues on coverall x surface area of both hands x transfer coefficient x dermal absorption/body weight

Systemic dose when laundering = 0.00013 mg a.s./cm^2 x 820 m^2 x 0.3 x 0.7 / 60 = 0.000374 mg/kg bw/day

As the work clothes are supposed to be laundering after one week of work, 5 days, the systemic dermal dose from **laundering** the contaminated work clothing is **0.00187mg a.s./kg bw/day** (= **10.4 %** of AEL_{acute}).

Conclusion
The estimated secondary dermal exposure of persons laundering contaminated work clothing at home accounts for 10.4 % of the proposed systemic AEL (proposed systemic AEL=0.018 mg/kg bw/day).
Based on these calculations there is no unacceptable risk anticipated for persons laundering contaminated work clothing.

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

Combined scenarios

No combined scenarios are expected for professional users since their work clothes must be disposable or laundered in company laundery services.

Only for Spain:

- Professional users (NTP): professionals that use the biocidal products in the context of his profession, that is not pest control operator, and that are unlikely to have received any specific training in biocidal product use according to the national legislation in force. It can be expected that they have some knowledge and skills handling chemicals (if they must use it in their job) and they are able to use correctly some kind of PPE if necessary.

Combined scenarios:

The combined exposure to non-PCO users when applying the product, re-entering in treated areas and laundering the work clothes (Scenarios 1+3+4). Considering the non-continuous use of the product, and the short period of time that professional (farmer)/amateur users are in contact with the product, the reference systemic AEL of 0.018 mg/Kg bw/d for acute effects is taken as reference value triggering safe use.

Combined exposure to alpha-cypermethrin after the use of ZENITRIN EC			
Scenarios	**Exposure estimation (Aggregated) [mg/kg bw/day]**	**AEL [mg/Kg bw/d]**	**% of AEL**
1.2+3.2+4	0.01785	0.018	99.2

Taking into account that professionals don't use the product during the entire workday but only occasionally, the risk is considered acceptable.

Conclusion:
The estimated combined exposure of the trained professional user when no PPE are worn is well above of the limit value, resulting in 649 % of the AEL for occupational exposure (0.016 mg/Kg bw/d). When PPE (gloves, coverall) are worn, the exposure is considerably reduced up to the 77.6% of the occupational AEL, resulting in a safe use of the product for professionals.

Monitoring data
Not applicable.

Dietary exposure

Biocidal products may enter into contact with animals and products from animal origin when they are applied into animal livestock/breeding premises or other places such as milking parlors, food/feed storage premises, etc. After exposure, chemicals of concern may enter into animal organism, suffering typical metabolic processes and being transferred into humans by means of diet consumption leading to human health concerns. For this reason a safety assessment to determine the dietary risk to humans shall be performed.

The assessment is performed in a stepwise approach according to the "*Draft Proposal for the Guidance on Estimating Livestock Exposure to Biocidal active Substances*" – CA-Sept-Doc.6.3.b and the "*Guideline on risk characterization and assessment of maximum residue limits (MRL) for biocides*" EMA/CVMP/SWP/90250/2010. This assessment comprises the following tiers:

1- Evaluation of the external exposure of animals over all routes (dermal, inhalation and oral) and comparison against a trigger value (4 µg/Kg bw/day as conservative value of external exposure of food producing animals according to Annex I of EMA guidance (EMA/CVMP/SWP90250/2010)). If external exposure is below trigger value assessment can be finished in this stage. This first tier is a screening stage where it is assumed that all the applied product is transferred in some or other way to the animals
2- After the screening stage, and if positive results are not achieved, realistic worst case estimations for external exposure must be assessed. These estimatios come from different scenarios relevant for the application mode, assessing the external exposure by different routes (oral, dermal and inhalation). These scenarios can be further refined.
3- Starting with the external exposure estimation for exposed livestock animals, biocide residues in animal tissues can be estimated taking into account product and active substance specific information. The estimated values are used to calculate consumer exposure (Using EMA Food Basket). Based on these residues in animals tissues the Worst Case Consumer Exposure (WCCE) is estimated. Comparison of WCCE with ADI (If no ADI has been derived for the relevant substance, then AEL is usually taken as reference value). If consumer exposure is below 30% of ADI the assessment can be concluded at this stage. Additional refinements can be performed at this stage by considering mitigation measures or by performing residue tests in order to have more realistic sight of actual exposure (dislodgeable residues, actual concentration of chemical in insects, etc…)
4- If any of the assessments described above fits to regulatory limit values then a MRL derivation process needs to be performed and residue data needs to be provided and an extensive dietary risk assessment should be performed.

Residue definitions
No residue definitions were reported in the CAR for Alpha-cypermethrin, however, the Draft Assessment Report of the same substance for Plant Protection Products has agreed the residue definition as Alpha-cypermethrin. Alpha-cypermethrin is an isomer of Cypermethrin and the reference MRLs are obtained from cypermethrin, including its isomer alpha-cypermethrin and other constituent isomers.

List of scenarios

Summary table of main representative dietary exposure scenarios			
Scenario number	**Type of use**	**Description of scenario**	**Subject of exposure**
5	Professional use in animal husbandry	Application of ZENITRIN EC in livestock premises by trained professionals and professional (farmers) users.	1- General assessment to all animals defined in the Guidance on Estimating livestock Exposure to Biocidal Active substances 2- Assessment of WCCE against ADI for food commodities (egg, milk, meat, fat and offal)

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.	PPP	Insecticide	MRL*

*Reg. (EC) No 149/2008; Reg (EC) No 839/2008; Reg (EC) No 459/2010; Reg (EC) No 520/2011

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Description of Scenario 5		
ZENITRIN EC is applied in livestock premises by spraying of surfaces (crack and crevice treatment). As consequence of the use of the product animals can be exposed to alpha-cypermethrin in different ways that must be assessed in a tier approach. Relevant guidelines for assessing the consumer exposure of biocidal products when they are used in livestock premises is still under development by the ARTFood Working Group, however, in the meanwhile a tiered approach is recommended as described in the "Guideline on Risk Characterisation and Assessment of Maximum Residue Limits (MRL) fro Biocides" (EMA, January 2015). TIER 1: The first tier is a rough assessment stage. The external dose is calculated and compared with the threshold value (4 µg a.s./Kg bw/day) TIER 2: This tier is a realistic worst case estimation of the external burden of the active substance on animals based in different exposure scenarios. TIER 3: The external exposure calculated in the tier 2 is converted into systemic values by the application of the different absorption coefficients. Afterwards, the adsorbed doses are converted into the worst case consumer estimates (WCCE) and compared with the MRLs set, which later will be comared with the ADI. If the WCCE > 30% of ADI the assessment will be negative and severe Risk Mitigation Measures will be proposed		
	Parameters[1]	Value
Tier 1 – Assessment of external exposure (Screening) (1)	Concentration of the a.s. in the product	60000 mg/Kg
	Maximum application rate of a.s. (AR)	13.4 mg/m^2
	Screening Scenario	Surface treatment of animal housing (wall only)
	Wall area per stable (A)	Refer to Table 2 in Annex 3.7
	Number of animals per stable (No_{animal})	Refer to Table 2 in Annex 3.7
	Body weight of animals (bw)	Refer to Table 1 in Annex 3.7
Tier 2 – Assessment of external exposure (Realistic worst case)	Oral: Animal licking surfaces	
	Maximum application rate of a.s. (AR)	13.4 mg/m^2
	Area of tongue (A_{tongue})	0.008 m^2 (Refer to Table 2 in Annex 3.7)
	Number of licks (L)	10 (Refer to Table 2 in Annex 3.7)
	Body weight of animals (bw)	Refer to Table 1 in Annex 3.7
	Refinement factor (RF)	0.85 (2)
	Oral: Uptake of feed contaminated in trough	
	Maximum application rate of a.s. (AR)	13.4 mg/m^2

	Emission factor: Fraction emitted to floor during application (EF)	0.11 (2)
	Area of trough exposed ($A_{feed\ surf}$)	Refer to Table 2 in Annex 3.7
	Body weight of animals (bw)	Refer to Table 1 in Annex 3.7
	Refinement factor (RF)	30% dislodgeable factor(3)
	Oral: Ingestion of dead insects	
	Concentration of active substance in the product (C)	6%
	Daily consumption of biocidal product by flies (D_{con})	3.5 mg b.p. (Refer to Table 3 in Annex 3.7)
	Application rate (AR = C x D_{con})	0.21 mg a.s./fly/day
	Number of flies consumed (No_{fly})	10 flies/day (Refer to Table 3 in Annex 3.7)
	Body weight of animals (bw)	Refer to Table 1 in Annex 3.7
	Refinement factor (RF)	1 (default)
	Dermal: Rubbing against treated surfaces	
	Maximum application rate of a.s. (AR)	13.4 mg/m^2
	Animal surface area in contact with the treated surface ($BSA_{cont.}$)	Refer to Table 1 in Annex 3.7
	Body weight of animals (bw)	Refer to Table 1 in Annex 3.7
	Refinement factor (RF)	0.85 (2)
	Dermal: Direct exposure through spray treatment	
	Maximum application rate of a.s. (AR)	13.4 mg/m^2
	Wall area per stable (A_{wall})	Refer to Table 2 in Annex 3.7
	Emission factor: Fraction emitted to floor during application (EF)	0.11(2)
	Fraction of floor area covered by animals ($F_{covered}$)	0.5 (Refer to Table 3 in Annex 3.7)
	Number of animals per stable (No_{animal})	Refer to Table 2 in Annex 3.7
	Body weight of animals (bw)	Refer to Table 1 in Annex 3.7
	Refinement factor (RF)	1 (default)
	Inhalation: Spray inhalation during surface spray treatment	
	Indicative value (exposure to product via inhalation)	104 µl in-use product/m^3 (4)
	Concentration of in-use solution	0.0003 mg/µl
	Cocentration of active substance in air (C_{air})	0.0312 mg a.s./m^3
	Alveolar ventilation rate (AVR) (in m^3/day)	Refer to Table 1 in Annex 3.7
	Exposure time (T)	2 hours/day
	Body weight of animals (bw)	Refer to Table 1 in Annex 3.7

Tier 3 – Calculation of WCCE	Oral absorption	0.43 (5)
	Dermal Absorption	0.7 (EFSA Guidelines default)
	Transfer factor of internal exposure to food commodities	Refer to Table 4 in Annex 3.7
	Theoretical daily intake for consumers to relevant food commodities	Refer to Table 4 in Annex 3.7

(1) Relevant external exposures were calculated using the Excel template published by BfR "Livestock exposure Calculator". Output of the assessment is reported in the Annex 3.2.
(2) Emission factors according to the OECD ESD PT18.
(3) HEEG Opinion No 7
(4) Indicative value for inhalation exposure during treatment to professional operator (Spray Model 1)
(5) CAR Report for Alpha-cypermethrin

TIER 1: Assessment of external exposure (Screening)
The external exposure of animals (E) during the screening stage is calculated as follows:

$$E = (AR \times A) \div (No_{anim} \times bw)$$

The wall area per stable is calculated by the substraction of the floor area from the total area (wall and roof) of the stable. For this scenario, the following results were obtained:

Animal Species	**External Exposure (mg/Kg bw)**
Beef cattle	0.1351
Dairy cattle	0.1031
Calf	0.1424
Fattening pig	0.1240
Breeding pig individual housing	0.1367
Breeding pig group housing	0.1757
Sheep	
Lamb	
Slaughter goat (= goat kids)	
Lactating goat	
Broilers (free range, litter floor)	0.1931
Broilers (parent broilers, free range, grating floor)	0.2365
Broilers (parent broilers in rearing, free range, grating floor)	0.2190
Laying hen (battery)	0.1175
Laying hen (free range, litter floor)	0.4232
Laying hen (free range, grating floor)	0.1947
Turkey	
Horse	
Rabbit	0.6432

This screening stage takes into account that all the product applied is received by the animals. In all the cases, the external exposure of the relevant animals for the scenario "treatment of walls" exceeds the threshold value of 0.004 mg/Kg bw, so further refinement is required.

TIER 2: Assessment of external exposure (Realistic worst case)

The Tier 2 assessment takes into account different scenarios and different exposure routes:

- Oral route:
  Animal licking surfaces:

$$E = (AR \times A_{tongue} \times L \div bw) \times RF$$

  Uptake of feed contaminated in trough:

$$E = (AR \times EF \times A_{feed.\ surf} \div bw) \times RF$$

  Ingestion of dead insects:

$$E = (AR \times No_{flies} \div bw) \times RF$$

Thus, the oral exposure to ZENITRIN EC after spray treatment of surfaces is the sum of each assessment for each individual animal (see Annex 3.2 for more details)

Animal Species	**Animal licking surfaces (mg/Kg bw)**	**Uptake of feed contaminated in trough (mg/Kg bw)**	**Ingestion of dead insects (mg/Kg bw)**	**Total external exposure by oral route (mg/Kg bw)**
Beef cattle	0.0021	0.0021		**0.0042**
Dairy cattle	0.0016	**0.0066**		**0.0082**
Calf	**0.0054**	0.0037		**0.0090**
Fattening pig	**0.0107**	**0.0059**		**0.0166**
Breeding pig individual housing	**0.0041**	**0.0216**		**0.0257**
Breeding pig group housing	**0.0041**	**0.0255**		**0.0297**
Sheep	**0.0143**			**0.0143**
Lamb	**0.0268**			**0.0268**
Slaughter goat (= goat kids)	**0.0825**			**0.0825**
Lactating goat	**0.0153**			**0.0153**
Broilers (free range, litter floor)			**1.2353**	**1.2353**
Broilers (parent broilers, free range, grating floor)			**1.2353**	**1.2353**
Broilers (parent broilers in rearing, free range, grating floor)			**1.2353**	**1.2353**
Laying hen (battery)		**0.0078**	**1.1053**	**1.1130**
Laying hen (free range, litter floor)		**0.0078**	**1.1053**	**1.1130**
Laying hen (free range, grating floor)		**0.0078**	**1.1053**	**1.1130**
Turkey			**0.3000**	**0.3000**
Horse				
Rabbit				

- Dermal route:
  Rubbing against treated surfaces:

$$E = (AR \times BSA_{cont} \div bw) \times RF$$

  Direct exposure through spray treatment:

$$E = (AR \times EF \times A_{wall} \times F_{covered} \div bw \times No_{anim}) \times RF$$

The dermal exposure to livestock animals is summarized below:

Animal Species	**Animal rubbing against treated surfaces (mg/Kg bw)**	**Direct exposure through spray treatment (mg/Kg bw)**	**Total external exposure by dermal route (mg/Kg bw)**
Beef cattle	**0.03859**		**0.03859**

Dairy cattle	**0.03463**		**0.03463**
Calf	**0.05829**		**0.05829**
Fattening pig	**0.06030**		**0.06030**
Breeding pig individual housing	**0.04329**		**0.04329**
Breeding pig group housing	**0.04329**		**0.04329**
Sheep			
Lamb			
Slaughter goat (= goat kids)	**0.15462**		**0.15462**
Lactating goat	**0.08614**		**0.08614**
Broilers (free range, litter floor)		**0.01062**	**0.01062**
Broilers (parent broilers, free range, grating floor)		**0.01301**	**0.01301**
Broilers (parent broilers in rearing, free range, grating floor)		**0.01204**	**0.01204**
Laying hen (battery)		**0.00646**	**0.00646**
Laying hen (free range, litter floor)		**0.02327**	**0.02327**
Laying hen (free range, grating floor)		**0.01071**	**0.01071**
Turkey			
Horse	**0.05427**		**0.05427**
Rabbit			

- Inhalation route:
  Direct exposure through spray treatment:

$$E = (C_{air} \times AVR \times T \div bw \times 24) \times RF$$

The inhalation exposure as consequence of spray drift during application is:

Animal Species	**Total external exposure by inhalation route (mg/Kg bw)**
Beef cattle	0.00023
Dairy cattle	0.00022
Calf	0.00029
Fattening pig	0.00033
Breeding pig individual housing	0.00027
Breeding pig group housing	0.00027
Sheep	0.00037
Lamb	0.00041
Slaughter goat (= goat kids)	0.00054
Lactating goat	0.00036
Broilers (free range, litter floor)	0.00027
Broilers (parent broilers, free range, grating floor)	0.00027
Broilers (parent broilers in rearing, free range, grating floor)	0.00027
Laying hen (battery)	0.00024
Laying hen (free range, litter floor)	0.00024
Laying hen (free range, grating floor)	0.00024
Turkey	0.00020
Horse	0.00025
Rabbit	0.00084

Thus the total external exposure for the realistic worst case scenarios is:

Animal Species	Total external exposure by oral route (mg/Kg bw)	Total external exposure by dermal route (mg/Kg bw)	Total external exposure by inhalation route (mg/Kg bw)	Total external exposure (mg/Kg bw)
Beef cattle	**0.0042**	**0.03859**	0.00023	**0.04303**
Dairy cattle	**0.0082**	**0.03463**	0.00022	**0.04308**
Calf	**0.0090**	**0.05829**	0.00029	**0.06763**
Fattening pig	**0.0166**	**0.06030**	0.00033	**0.07724**
Breeding pig individual housing	**0.0257**	**0.04329**	0.00027	**0.06930**
Breeding pig group housing	**0.0297**	**0.04329**	0.00027	**0.07323**
Sheep	**0.0143**		0.00037	**0.01466**
Lamb	**0.0268**		0.00041	**0.02721**
Slaughter goat (= goat kids)	**0.0825**	**0.15462**	0.00054	**0.23761**
Lactating goat	**0.0153**	**0.08614**	0.00036	**0.10182**
Broilers (free range, litter floor)	**1.2353**	**0.01062**	0.00027	**1.24619**
Broilers (parent broilers, free range, grating floor)	**1.2353**	**0.01301**	0.00027	**1.24857**
Broilers (parent broilers in rearing, free range, grating floor)	**1.2353**	**0.01204**	0.00027	**1.24761**
Laying hen (battery)	**1.1130**	**0.00646**	0.00024	**1.11973**
Laying hen (free range, litter floor)	**1.1130**	**0.02327**	0.00024	**1.13654**
Laying hen (free range, grating floor)	**1.1130**	**0.01071**	0.00024	**1.12397**
Turkey	**0.3000**		0.00020	**0.30020**
Horse		**0.05427**	0.00025	**0.05452**
Rabbit			0.00084	0.00084

For almost all the estudied animals, the total exposure is more than 0.004 mg a.s./Kg animal, so further refinement is required. This refinement consists in the calculation of the absorbed dose by animals and its transfer into different food commodities (eggs, milk, meat, fat and offal) as defined by EMA and its comparison against the ADI. If the estimated Worst Case Consumer Exposure (WCCE) is below the 30% of the ADI, then the risk is acceptable. If not, a MRL assessment must be performed.

The external exposure of animals to alpha-cypermethrin can be converted into internal (systemic) exposure by applying agreed absorption parameters (43% oral and 70% dermal). Although this is a rough estimation, this assumption is applicable in most of the cases. Furthermore, the safety margin (30% of ADI) supports the use of adsorption factors inter and intra species.

Animal Species	Total internal exposure by oral route (mg/Kg bw)	Total internal exposure by dermal route (mg/Kg bw)	Total internal exposure by inhalation route (mg/Kg bw)	Total internal exposure (mg/Kg bw)
Beef cattle	0.0018	0.0270	0.00023	0.0291
Dairy cattle	0.0035	0.0242	0.00022	0.0280
Calf	0.0039	0.0408	0.00029	0.0450
Fattening pig	0.0071	0.0422	0.00033	0.0497

Breeding pig individual housing	0.0111	0.0303	0.00027	0.0416
Breeding pig group housing	0.0128	0.0303	0.00027	0.0433
Sheep	0.0061		0.00037	
Lamb	0.0115		0.00041	
Slaughter goat (= goat kids)	0.0355	0.1082	0.00054	0.1088
Lactating goat	0.0066	0.0603	0.00036	0.0607
Broilers (free range, litter floor)	0.5312	0.0074	0.00027	0.5314
Broilers (parent broilers, free range, grating floor)	0.5312	0.0091	0.00027	0.5314
Broilers (parent broilers in rearing, free range, grating floor)	0.5312	0.0084	0.00027	0.5314
Laying hen (battery)	0.4786	0.0045	0.00024	0.4788
Laying hen (free range, litter floor)	0.4786	0.0163	0.00024	0.4788
Laying hen (free range, grating floor)	0.4786	0.0075	0.00024	0.4788
Turkey	0.1290		0.00020	0.1292
Horse		0.0380	0.00025	0.0382
Rabbit			0.00084	0.00084

The calculation of the WCCE has been performed for each animal group taking into account the relevant food commodity for each of them as defined by the standard food basket intake and transfer factors as reported in the Annex 2 of the EMA guidance EMA/CVPM/SWP/90250/2010 of 15 of January 2015 "*Guideline on risk characterisation and assessment of maximum residue limits (MRL) for biocides*":

Commodity	Transfer factor	Standard food basket intake (Kg)
Eggs	1.60	0.10
Milk	0.52	1.50
Meat	0.33	0.30
Fat	30.00	0.05
Liver	2.62	0.10
Kidney	2.62	0.05

The WCCE is calculated as follows:

WCCE = Total internal exposure x Transfer Factor x Food basket calculation ÷ bw (adult)

The estimated daily intake is calculated for each individual commodity and the WCCE is the sum all the relevant food commodities for each animal

Calculation of WWCE				
Animal Species	**Total internal exposure (mg/Kg bw)**	**Relevant food commodity**	**WCCE (mg/Kg bw)**	**% ADI**
Beef cattle	0.0291	Meat, fat, liver, kidney	0.0010	6.4
Dairy cattle	0.0280	Milk	0.0004	2.4
Calf	0.0450	Meat, fat, liver, kidney	0.0015	9.9
Fattening pig	0.0497	Meat, fat, liver, kidney	0.0016	11.0
Breeding pig individual housing	0.0416	Meat, fat, liver, kidney	0.0014	9.2
Breeding pig group housing	0.0433	Meat, fat, liver, kidney	0.0014	9.6

Sheep	0.0065	Milk, meat, fat, liver, kidney	0.0003	2.0
Lamb	0.0119	Meat, fat, liver, kidney	0.0004	2.6
Slaughter goat (= goat kids)	0.1088	Meat, fat, liver, kidney	0.0048	**31.9**
Lactating goat	0.0607	Meat, fat, liver, kidney	0.0022	14.9
Broilers (free range, litter floor)	0.5314	Meat, fat, liver, kidney	0.0179	**119.2**
Broilers (parent broilers, free range, grating floor)	0.5314	Meat, fat, liver, kidney	0.0179	**119.5**
Broilers (parent broilers in rearing, free range, grating floor)	0.5314	Meat, fat, liver, kidney	0.0179	**119.4**
Laying hen (battery)	0.4788	Eggs	0.0013	8.6
Laying hen (free range, litter floor)	0.4788	Eggs	0.0013	8.8
Laying hen (free range, grating floor)	0.4788	Eggs	0.0013	8.6
Turkey	0.1292	Meat, fat, liver, kidney	0.0043	28.6
Horse	0.0382	Meat, fat, liver, kidney	0.0013	8.5
Rabbit	0.00084	Meat, fat, liver, kidney	0.00003	0.2

In the table above can be found all the worst case consumer estimates after the exposure of each individual type of animal in its livestock premise. When these values are compared with the ADI for alpha-cypermethrin (defined in the SANCO Document SANCO/4335/2000 fina of 13th of February 2004). For alpha-cypermethrin, this ADI was derived from a dog 90 days toxicity study using a safety factor of 100, resuting in 0.016 mg/Kg bw/day. In all the examples studied, except for broilers, hens and turkeys, the WCCE is below the 30% of the ADI (0.0048 mg/Kg bw/day) indicating a safe use of ZENITRIN EC ECOwith regards to the consumer. In the case of broilers, hens and turkey the high WWCE is derived mainly from the high external exposure assumed when broilers eat contaminated flies, followed by the high accumulation in fat of the contaminant according to the transfer factors defined in the EMA Guidance. According to the CAR of Alpha-cypermethrin, this substance has high potential of bioaccumulation in fat and skin, but it is also rapidly excreted in urine (*ca.* 50%) and in faeces (*ca.* 40%). In addition, the external burden of alpha-cypermethrin in the affected animals comes mainly determined by the ingestion of contaminated flies, which is clearly an overestimation. For this reason, it is considered that the use of ZENITRIN EC ECOis safe with regards to the consumer exposure after ingesting food commodities from animals that may be in contact with the product during and after the treatment of livestock premises.

Further information and considerations on scenario 1

In order to assure a safe use of the product, and trying to minimise the likely exposure of the animals with the product, the following risk mitigation measures are proposed:

- Avoid product application in presence of animals. When possible, remove animals from the treated premises before treatment or cover animal cages with a plastic.
- Avoid as much as possible contact of animals with treated surfaces.
- When possible, cover the floor and non-intended adjacent surfaces with a plastic sheet to reduce as much as possible splits during application.
- Cover water tanks, feed, troughs and other surfaces or equipment that may enter in contact with animal feed/foodstuffs before treatment to avoid any contamination

Summary of exposure assessment

Scenarios and values to be used in risk assessment					
Scenario	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/Kg bw/d)**	**AEL (mg/Kg bw/d)**	**(%)**
1	Professionals – Household, commercial and public areas	Tier 1/No PPE Tier 2/Gloves, coveral	0.10385 0.01241	0.016	649.1 77.6
2	Professionals – Livestock and breeding premises	Extrapolated from Scenario 1.	Same as Scenario 1.		
3	General population – Re-entry in treated sites - Adult - Toddler	Tier 1/No PPE	0.00597 0.00357	0.018	33.2 19.8
4	General population (Adult) – Laundering working clothes	Tier 1/No PPE	0.00187	0.018	10.4
Only for Spain 1.2+3.2+4	Professional – Product application + re-entering treated sites + Laundering	Tier 1/No PPE.	0.01785	0.018	99.2

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Substance	Reference	Study	NOAEL (LOAEL)	AF	Correction for oral absorption	Value (mg/Kg bw/d)
Alpha-cypermethrin	$AEL_{short-term}$	CAR document	4 mg/Kg bw/d	100	0.45	0.018
	$AEL_{medium-term}$	CAR document	3.5 mg/Kg bw/d	100	0.45	0.016
	$AEL_{long-term}$	CAR document	2 mg/Kg bw/d	100	0.45	0.009
	ARfD					Not derived
	ADI					Not derived

Following the CAR of alpha-cypermethrin, the exposure levels for the professional users are compared with the medium-term AEL (occupational).

Risk for industrial users

Not applicable as not proposed for industrial use.

Risk for professional users

Systemic effects

Scenarios and values to be used in risk assessment					
Scenario	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/Kg bw/d)**	**AEL (mg/Kg bw/d)**	**ADI (%)**
1	Trained professionals – Household, commercial and public areas	Tier 1/No PPE Tier 2/Gloves, coveral	0.10385 0.01241	0.016	649 77.6
2	Trained professionals – Livestock and breeding premises	Extrapolated from Scenario 1.	Same as Scenario 1.		

Combined scenarios

Scenarios and values to be used in risk assessment					
Scenario	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/Kg bw/d)**	**AEL (mg/Kg bw/d)**	**ADI (%)**
Only for Spain 1.2+3.2+4	Professional – Product application + re-entering treated sites + Laundering	Tier 1/No PPE.	0.01785	0.018	99.2

Local effects

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

According to the Guidance on the BPR Volume III Human Health- Assessment & Evaluation– Part B and C Risk Assessment (Version 4.0 December 2017), the product classification triggered by the solvent

naphtha (petroleum) is included in Band A, and the classification triggered by Phenylsulfonat CA (benzenesulfonic acid and isobutanol) is included in Band B.

Component	Effects	Classification	Band
Phenylsulfonat CA	Severe eye irritant	Eye Dam 1 (H318)	A
Hydrocarbons, C9 aromatics	Irritant to respiratory track May cause drowsiness or dizziness Causes skin dryness	STOT SE 3 (H335) STOT SE 3 (H336) EUH066	B

Foolowing the anding evaluation scheme for classified SoCs leading to the classification of the biocidal product:

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

It must be noted the risks defined above are referred to the straight product. The product is diluted in a rate of 1:200 in water when sprayed. When the product is diluted it is not expected that the concentration of the individual ingredients lead to classification of the dilution and therefore no risk for local effects are expected when the product is applied or the application devices are cleaned (for instance, the dilution at a rate of 1:200 leads to a concentration of the ingredient(s) responsible of Severe eye damage Category 1 200 times lower, which is well below the threshold value setting classification with regard to irritant or corrosive effects to eye or to specific organ toxicity. Therefore the only relevant stage for local effects is during mixing and loading the product in the application system. This stage is usually of short duration (several seconds or a few minutes) and low volumes of product are used (typically 25-50 mL/day). Therefore, if the risk mitigation measures reported above are followed, no risk to trained professional operators derived from local effects is expected. In any case, the use of PPE and risk mitigation measures is recommended during the whole cycle of use of the product.

Qualitative Risk Assessment fo local effects:

Hazard category	**Relevant local effect**	**CLP hazard classification assigned to the biocidal product and/or its in-use solution**
High	Severe eye irritant	Eye Dam 1 (H318)
Low	Irritant to respiratory track May cause drowsiness ot dizziness Causes skin dryness	STOT SE 3 (H335) STOT SE 3 (H336) EUH066

Hazard		**Exposure information**		
Hazard category	**Effects**	**Frecuency and duration**	**Degree of potential exposure**	**Relevant RMMs (PPE not relevant)**

		of potential exposure	**under best practice conditions**	
High	Eye Dam 1 (H318)	Mixing and loading the product. Short duration (seconds or few minutes) Low volumes used (25-50 ml/day)	Practically no exposure (use of gloves)	- Wash hands thoroughly after handling - Do not eat, drink or smoke when using this product. - Avoid breathing vapours/spray. - Use only in a well ventilated area (ensure good ventilation during use). - Wear protective gloves, clothing and face protection.
Low	STOT (H335) STOT (H336) EUH066			

Conclusion

Risk mitigation measures are required to protect Professional operators from excesive exposure to alpha-cypermethrin. Use of PPE are required. The use of ZENITRIN EC by professionals is safe when gloves and protective clothes (coated coverall PF 80%) are worn.

In addition the following risk mitigation measures and safety precautions are recommended in order to reduce the risk during the use of the product to professional users:

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

Risk for the general public

Systemic effects

Scenarios and values to be used in risk assessment					
Scenario	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake (mg/Kg bw/d)**	**AEL (mg/Kg bw/d)**	**ADI (%)**
3	General population – Re-entry in treated sites - Adult - Toddler	Tier 1/No PPE	 0.00597 0.00357	0.018	 33.2 19.8
4	General population (Adult) – Laundering working clothes	Tier 1/No PPE	0.00187	0.018	10.4

Combined scenarios

Not relevant

Local effects

Not relevant

Conclusion

The use of ZENITRIN EC is within acceptable limits with regards to general population re-entering in treated areas or laundering working clothes contaminated with the product.

Risk for consumers via residues in food

The product ZENITRIN EC can be applied in livestock premises and the different animals housed may enter into contact with the product and subsequently reach the food chain as residues in tissues and food commodities. For this reason an assessment of the exposure to consumers via residues in food is necessary.

The assessment has been performed following the EMA Guidance "*Guideline on risk characterization and assessment of maximum residue limits (MRL) for biocides"* where a tiered approach is recommended.

The first part of the assessment involves the assessment of the external dose received by the animals as consequence of the application of the product. This external doses must not exceed the conservative threshold value of 0.004 mg/Kg bw. In all the scenarios assessed the external exposure is above this threshold value.
The second part of the assessment considers the Worst Case Consumer Exposure (systemic exposure), which is compared with the ADI of Alpha-cypermethrin. In all the scenarios assessed (except for broilers) the estimated daily intake of alpha-cypermethrin as consequence of the a.s. transfer into food commodities is below the 30% of the ADI indicating safe use of the product except in the case of broilers. However, and in order to assure the maximum safety for the consumer, the following Risk Mitigation Measures are proposed:

- The product should be applied away from animals. When possible, remove animals from the treated premises before treatment or cover animal cages with a plastic. DO NOT apply directly to animals.
- Avoid as much as possible contact of animals with treated surfaces.
- Cover water tanks, feed, troughs and other surfaces or equipment that may enter in contact with animal feed/foodstuffs before treatment to avoid any contamination

These RMM considerably reduce the exposure of animals when re-entering in treated sites, reducing and minimising possible exposure of consumers to Alpha-cypermethrin as consequence of the use of ZENITRIN EC in livestock premises (except broilers).

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

Not relevant.

2.2.7 Risk assessment for animal health

No additional studies (i.e. residues) have been performed to assess the risk for animal health.

2.2.8 Risk assessment for the environment

The uses of ZENITRIN EC have not been evaluated in the the alpha-cypermethrin assessment report. The product is intended for professional users only in indoor treatments in household, commercial and public sites and for the use in animal housing premises.

ZENITRIN EC is an insecticidal emulsifiable concentrate for professional use that is diluted in water prior to use and intented to be applied by spraying in surface treatments against flying and crawling insects (crack and crevices). The product contains 60 g/Kg alpha-cypermethrin and it is applied at a rate of 0.25 ml of product per m2 of floor.

Active substance data is supported with the data relied upon original data submitted by the review programme participant (BASF AGRO B.V.) for which the applicant has obtained a LoA.

2.2.8.1 Effects assessment on the environment

Data for environmental fate and ecotoxicological properties have been obtained from the original data submitted during the active substance evaluation process following the same approach as reported in the CAR document for Alphacypermethrin.

The biocidal product ZENITRIN EC contains 6% w/w alpha-cypermethrin as active substance (a.s.). This a.s. is classified as Aquatic Acute 1 M=1000, Aquatic Chronic 1 M=1000 according to their entry in Annex VI of Regulation (EC) No. 1272/2008. 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 ZENITRIN EC is classified as Aquatic Acute Category 1, Aquatic Chronic Category 1 with the hazard statement H410.

However, two of the coformulants contained in the product ZENITRIN EC, are substances classified as dangerous / hazardous or that meet the criteria for classification as dangerous / hazardous according to Regulation (EC) No 1272/2008, and they are present in the biocidal product at a concentration which leads the product to be regarded as dangerous / hazardous. Therefore Solvesso 100 and Benzenesulfonic acid should be considered as Substances of Concern (SoC) for the environment in the product ZENITRIN EC. Nevertheless, exemptions are possible if the substances are contributing only to a very limited extent to the overall toxicity of the mixture and are neither EDs nor PBT - or vPvB-substances.

A qualitative risk assessment has been performed in the confidential PAR with the SoCs for the environment Solvesso 100 and Benzenesulfonic acid. That evaluation has confirmed that the only relevant substance for the risk assessment is the a.s. alpha-cypermethrin.

Based on that evaluation it has been concluded that only the active substance should be regarded as relevant and no mixture assessment is needed. Therefore, only the environmental risk assessment for the a.s. alpha-cypermethrin is presented in this document.

Further Ecotoxicological studies

The following data have been obtained from the active substance's CAR for the different compartments:

Summary table - Further ecotoxicological studies (CAR alpha-cypermethrin)

Summary table of further ecotoxicological studies Alpha-cypermethrin			
Species	**Time-scale**	**Endpoint**	**Toxicity**
Fish			
Pimephales promelas	96 h	Mortality (LC_{50})	0.93 µg/L (measured)

Pimephales promelas	34 d	Overall mortality across development stages (NOEC)	0.03 µg/L (measured)
Invertebrates			
Daphnia magna	48 h	Immobilization (EC_{50})	0.3 µg/L (nominal)
Daphnia magna	21 d	Reproduction (NOEC)	0.03 µg/L (nominal)
Algae			
Pseudokirchneriella subcapitata	72 h	Cell multiplication inhibition (E_rC_{50})	>1.0 mg/L (nominal)
Microorganisms			
Activated sludge micro-organisms	3 h	Respiration inhibition (EC_{50})	>1000 mg/L (nominal)
Long term effects on the aquatic environment			
Chironomus (Larvae)	28 d	NOEC	0.024 µg/L
Aquatic and benthic invertebrates and algaes (mesocosm studies)	126 d	EAC	0.015 µg/L
Chironomus riparius		NOEC development rate	0.0225 mg/Kg dwt
Effects on soil micro-organisms			
Nitrogen mineralization	28 d	EC50	>100 mg/Kg
	28d	NOEC	>100 mg/Kg
Carbon mineralization	28d	EC50	>100 mg/Kg
	28d	NOEC	>100 mg/Kg
Mammals, toxicity			
Dogs	1 year.	NOAEL, chronic toxicity, Irritation secondaryto systemic toxicity	60 ppm, equivalent to 2.0 mg/Kg bw/day
Birds, toxicity			
Colinus virginianus	22 weeks	NOEC Reproductive toxicity	150 mg a.s./Kg feed

According to active substance's CAR, the table below shows the toxicity data for aquatic species exposed to major metabolites from alpha-cypermethrin.

Summary table of further ecotoxicological studies (3-phenoxybenzoic acid, 3-PBA; CL 206128)			
Species	**Time-scale**	**Endpoint**	**Toxicity**
Fish			
Lepomis macrochyrus	96 h	Mortality (LC_{50})	>103.2 mg/L (measured)
Invertebrates			
Daphnia magna	48 h	Immobilization (EC_{50})	39 mg/L (nominal)
		NOEC	12.5 mg/L (nominal)
Algae			
Pseudokirchneriella subcapitata	72 h	(E_rC_{50})	85 mg/L (nominal)
		(E_bC_{50})	38.1 mg/L (nominal)

Summary table of further ecotoxicological studies (Cis-DVCA, CL 912554)			
Species	**Time-scale**	**Endpoint**	**Toxicity**
Fish			
Lepomis macrochyrus	96 h	Mortality (LC_{50})	>102.8 mg/L (measured)
Invertebrates			
Daphnia magna	48 h	Immobilization (EC_{50})	61.9 mg/L (nominal)
		NOEC	25 mg/L (nominal)
Algae			

Pseudokirchneriella subcapitata	72 h	(E_rC_{50})	70 mg/L (nominal)
		(E_bC_{50})	31.6 mg/L (nominal)

Summary table of further ecotoxicological studies (3-phenoxybenzaldehyde, CL 206969)			
Species	**Time-scale**	**Endpoint**	**Toxicity**
Invertebrates			
Daphnia magna	48 h	Immobilization (EC_{50})	0.8 mg/L (measured)
		NOEC	0.286 mg/L (measured)

Conclusion used in Risk Assessment – Further ecotoxicological studies

Based on the lowest endpoints listed above, the PNEC have been established in the following values:

$PNEC_{STP}$: 100 mg/L based on EC_{50} > 1000 mg/L in microbial respiration in active sludge test and an assessment factor of 10
$PNEC_{surface\ water}$: 4.8×10^{-6} mg/L based on the lowest NOEC value from a 28-days toxicity to sediment dwelling organisms (*Chironomus riparius*) of 2.4×10^{-5} mg/L and an assessment factor of 5 taking into account the additional data from a mesocosm study with data for the same organism.
$PNEC_{sediment}$: 4.5×10^{-3} mg/Kg dwt (**$9.78x10^{-4}$ mg/Kg wwt** using a conversion factor of 4.6) based on the lowest available NOEC value from toxicity test with *Chironomus riparius* (0.0225 mg/Kg dwt) and an assessment factor of 5.
$PNEC_{soil}$: 0.882 mg/Kg wwt based on the lowest NOEC values derived from two long-term studies on soil microorganism C- and N- transformation (NOEC>100 mg/Kg drysoil), the PNECsoil after converting the NOEC related to dry soil to an effect values for naturally wet soil and applying am assessment factor of 100, the PNEC for the terrestrial compartment has been determined to be >0.882 mg/Kg wwt
$PNEC_{secondary\ poisoning}$: Mammal - 2.67 mg/Kg food based on 1 year NOAEL in dogs (2.0 mg/Kg bw/day) converted into NOEC applying a conversion factor of 40 and to PNEC by an assessment factor of 30 according to the Guidance on the Biocidal Products Regulation Vol. IV Part B. **Bird – 5.00 mg/Kg food** based on the dietary long term NOEC of 150 mg/kg diet, applying an assessment factor of 30 according to the Guidance on the Biocidal Products Regulation Vol. IV Part B.

Degradation of alpha-cypermethrin in the different environmental compartments

<u>*Degradation of alpha-cypermethrin in the aquatic compartment (including sediment)*</u>
Alpha-cypermethrin has been shown to be stable at pH 4 and hydrolyse very slowly under environmental temperature of 12°C and pH 7 with predicted DT_{50} of 564.4 days. Whereas, at more alkaline pH (pH 9) alpha-cypermethrin showed a DT_{50} of 9.9 days (Van Dijk, 1993). A major metabolite was identified as 3-phenoxybenzaldehyde (CAS-no. 39515-51-0). Photolysis will contribute to degradation of alpha-cypermethrin with a DT_{50} of 4.85 days predicted from the available data after adjustment for natural sunlight (Concha *et al*., 2001). Alpha-cypermethrin is not readily biodegradable according to OECD 301 B and D guidelines (Stone and Watkinson, 1983).

In the water-sediment degradation studies using samples from natural aquatic systems, alpha-cypermethrin incubated in the dark disappeared rapidly from the water phase due to strong adsorption to the sediment and metabolisation. Alpha-cypermethrin was also readily eliminated in the sediment phase, by metabolisation and formation of bound residues. Alpha-cypermethrin quickly moves from the water phase into the sediment with DT_{50} in water ranging between 0.8 and 4 days, and in sediment between 12 and 67 days. BE CA recalculated DT_{50} water of 2.22 days and DT_{50} sediment of 28.13 days at 12 °C (TGD, Part B, , formula 25).

The main degradation products formed were cis-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers (CL 912554) and 3-phenoxybenzoic acid (CL 206128), both of which underwent further degradation to $^{14}CO_2$. The DT_{50} of CL 912554 in the total system ranged between 27 and 70 days, and the DT_{50} of CL 206128 ranged between 4 and 6 days.

Although there is no direct exposure, surface water and sediment are assessed for the environmental risk and PEC values calculated to cover the effects of alpha-cypermethrin residues in the STP effluent.

Information on the metabolites is available in the Assessment Report. The ecotoxicity data show that the metabolites are far less toxic to aquatic organisms compared to parent alpha-cypermethrin:

- The 48 h EC_{50} (immobilisation) of cis-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers (CL 912554) towards invertebrates *(Daphnia magna)* is 62 mg/L.
- The 48 h EC_{50} (immobilisation) of 3-phenoxybenzoic acid (CL 206128) towards invertebrates *(Daphnia magna)* is 39 mg/L.
- The 48 h EC_{50} (immobilisation) of 3-phenoxybenzaldehyde CL 206969 towards invertebrates *(Daphnia magna)* is 0.8 mg/L.

While the 48 h EC_{50} (immobilisation) of alpha-cypermethrin (also *Daphnia magna*) is much lower (0.3 µg/L).

Mobility of alpha-cypermethrin metabolites was shown to be minimal in laboratory leaching studies with alpha-cypermethrin.

Thus, it is demonstrated that the aqueous metabolites of alpha-cypermethrin are of less ecotoxicological significance than the parent compound with respect to invertebrate toxicity.

<u>*Degradation of alpha-cypermethrin in soils*</u>
Degradation of alpha-cypermethrin was investigated under aerobic conditions in a sandy loam soil (Gedik and Keirs, 2001). Alpha-cypermethrin seems to degrade in this type of soil with DT_{50} of 39.1 days at 12°C with CO_2 as the principal degradation product (~35% at 12°C). Four minor degradation products, including 3-phenoxybenzoic acid (CL 206128) (≤5.44% AR) and three unknowns, as well as polar materials, were also extracted from the soil (<9% of AR).

In addition to laboratory studies, field soil dissipation studies were also conducted (Doc. III-A7.2.2.2/01-09). Alpha-cypermethrin degradation was followed during three years with one application of EC alpha-cypermethrin formulation (0.5 kg a.s./ha). DT_{50} values ranged from <14 to 112 days. In all of these studies, 90% of the dissipation occurred within a year. The degradation product, 3-phenoxybenzoic acid (CL 206128), is degraded more rapidly than the parent compound.

Based on reliable adsorption/desorption data (Hill, 1993) it can be concluded that alpha-cypermethrin is strongly adsorbed in soil (Koc range 26492 to 144652, mean 76344ml/g, n = 12). Based on common mobility classification schemes (McCall *et al*., 1983; Fate of Chemicals in the Environment, ACS, pp. 105-123) alpha-cypermethrin is classified as immobile in soil (Koc > 5000).

A further study of the effect of sunlight on a soil surface indicated that alpha-cypermethrin is not rapidly degraded through photodegradation on soil surfaces with DT_{50} of 113.5 days at 12°C. The major product of photodegradation is 3-phenoxybenzoic acid (CL 206128) (16.4% AR) and 3-phenoxybenzaldehyde (CL 206969) is a minor degradation product (<3%).

<u>*Degradation of alpha-cypermethrin in the atmosphere*</u>
Based on the vapour pressure (3.4×10^{-7} Pa at 25°C) and the Henry's law constant (0.069 Pa×m³/mol at 25°C), volatilisation of alpha-cypermethrin is negligible. The fate of alpha-cypermethrin in air was investigated using the quantitative structure activity relationship estimation method (QSAR; TGD, 2003) (Mangels, 1995), which considers the reaction with the daily air concentrations of hydroxyl radicals (OH•) and with the help of the software AOPWIN. The half-life was calculated at 3.47 hours. Therefore, alpha-cypermethrin is rapidly degraded by photochemical processes and due to its low vapour pressure alpha-cypermethrin is not considered as volatile. The air compartment is thus not considered further within the following exposure assessment.

* Taking together all this information, it is justified to **disregard the metabolites in the environmental exposure and risk assessment and to base the assessment solely on alpha-cypermethrin**.

Endocrine disruption activity of non-active substances

The Commission Delegated Regulation (EU) 2017/2100 specifying the scientific criteria for the determination of endocrine-disrupting properties (ED criteria) under Regulation (EU) No 528/2012 (BPR) establishes that the ED criteria become applicable by 7 June 2018 for biocides.

No further ecotoxicological studies are available for ZENITRIN EC. The product was not tested for potential endocrine disruption properties. ZENITRIN EC contains the active substance Alpha-Cypermethrin and various co-formulants (see confidential PAR).

For the active substance, no ED assessment is required because for active substances which have been approved, the EU assessment should be followed.

For the co-formulants a screening was performed by consulting:
• ECHA data for identification of ED and PBT, under REACH, BPR or CLP
• Identified as ED by United States EPA (https://comptox.epa.gov/dashboard/)
• Identified as ED by the United Nations Environment (July 2017) Programme(http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y
and
https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)

During screening performance none of the co-formulant triggered an alert for ED property thus, ES CA considered that there is no concerned regarding the ED properties of this coformulants.

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

Please, refer to "Further ecotoxicological studies" above.

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

No additional trials to assess risk to non-target organisms under field conditions have been conducted.

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

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

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

Not relevant.

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

ZENITRIN EC is applied indoors in household, commercial and public environments and in animal housing buildings. Depending on the use, different routes of exposure to the environment are likely.

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

Different release pathways are envisaged depending on the mode of application of the product according to the *Guidance on the Biocidal Products Regulations, Vol. IV Environment – Part B Risk Assessment* (Version 2.0, October 2017). The *Emission Scenario Document for Insecticides, Acaricides and Products to Control other Arthropods for Household and Professional Users* (*OECD Series of Emission Scenario Documents No.18*) defines the release pathways when the product is applied in household, commercial and public buildings, whilst the *Emission Scenario Document for Insecticides for Stables and Manure Storage Systems* (*OECD Series of Emission Scenario Documents No.14)* describes the relevant emission pathways when the product is applied in animal housing buildings.

According to the Exposure scenario document and the Guidance on Risk Assessment of Biocidal products, indoor application in household, commercial and public buildings may result in indirect environmental exposure via the sewage system (i.e. during a cleaning operation following treatment). This poses a risk of the product entering sewage treatment plants (STPs) and subsequently being released via effluent into surface water.
Depending on product properties, during mixing/loading and application stages, the product can be released to air, targeted surfaces, and floor. These releases can be washed-off after wet cleaning operations in the treated premises, reaching sewer systems, and ending up in STPs, where the active substance is released to different environmental compartments: surface water after effluent emission and soil after sludge application, and subsequently groundwater.

Due to a low vapour pressure of the active substance (2.51×10^{-5} Pa at 20 ºC) it is not expected that any volatile losses of alpha-cypermethrin to the air compartment would occur either before, during, or after application of ZENITRIN EC. This is also consistent with the guidance presented in the ESD which states that the exposure of the air compartment is limited in time and restricted to the local scale and that F_{air} may be considered negligible from an environmental point of view (OECD, 2008).

When an insecticidal product is used in animal housing buildings, different release pathways are envisaged depending on the type of animal housing and the manure storage system. ZENITRIN EC is not applied directly in manure, but it can reach manure storage systems after application on surfaces.

According to Emission Scenario Document for Insecticides for Stables and Manure, the final destination of insecticides applied in animal housings (stables, barns, etc.) is the manure which is applied to land afterwards, however, depending on the manure storage system of the facility, other environmental compartments can be affected:

- Wet storage system (slurry). The whole amount of biocide is released to agricultural soil. It can be leached afterwards to groundwater. Release to air after spray application or due to evaporation of the active substances is considered negligible.
- Dry Storage systems. Usually the whole biocide is released to agriculture soil and consequently to groundwater after leaching. However can be situations where liquid phase collected during manure storage can be released to private Waste Water Treatment Plant (WWTP) or STP. In these cases the release pathways follows the typical route (Release to WWTP/STP where the chemical is distributed between water and sludge) and the remaining dry manure collected is directly released to agricultural soil.

Different stages are involved during the whole use of the product ZENITRIN EC indoors: Loading the product in the application equipment, product application and cleaning operations of treated surfaces/articles. Depending on the product properties, during mixing/loading and application stages, the product can be released to air, target surfaces/objects and floor (and manure if the product is applied in livestock premises).

Releases reaching STP or WWTP may reach different environmental compartments: surface water after effluent emission and soil after sludge application and subsequently ground water. Releases ending up

in dry manure (either directly or under a separation stage) are directly released to soil and may subsequently reach groundwater. For this later application degradation of the chemical during manure storage is not considered as a worst case estimation.

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

No further studies on fate and behaviour of alpha-cypermethrin in the environment have been performed. The values have been extracted from the CAR of alphacypermethrin.

Leaching behaviour (ADS)

Not relevant.

Testing for distribution and dissipation in soil (ADS)

Additional data on distribution and dissipation in soil of the a.s. or the biocidal product are not necessary. New data are not available.

The data on the distribution and dissipation of the a.s. gives sufficient information and there are no indications of risk due to specific properties of the b.p.

The emissions to soil exclusively occur via sewage sludge or slurry/manure applications. Several field and laboratory degradation studies in soil are available for alpha-cypermethrin, showing aerobic degradation of the a.s. with half-lives ranging from < 14 to 112 days (12°C). CO2 was the only detected major metabolite. All other metabolites formed were minor metabolites (formed in amounts < 10%). In all of the studies, 90 % of dissipation occurred within a year. Alpha-cypermethrin will therefore not persist in soil. Furthermore, the components of the biocidal product do not influence the distribution characteristics of the a.s. The formulation types are not expected to change the model of action of the a.s or its bioavailability. Further testing for distribution and dissipation in the environment is therefore not deemed reasonable.

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

Additional data on distribution and dissipation in water and sediment of the a.s. or the biocidal product are not necessary. New data are not available.

The data on the distribution and dissipation of the a.s. gives sufficient information and there are no indications of risk due to specific properties of the b.p.

The emissions to sediment exclusively occur via sewage sludge or slurry/manure applications. Higher tier water-sediment degradation studies are available for alpha-cypermethrin showing that alpha-cypermethrin moved rapidly from the water phase to the sediment phase with a DT50 in the water phase of between 0.88 and 4 days and in sediment between 12 and 67 days (12°C). The main degradation products formed were cis-2,2-dimethyl-3-(2',2'-dichlorovinyl)cyclopropane carboxylic acid isomers (DT50 27-70 days) and 3-phenoxybenzoic acid (DT50 4-6 days), both of which underwent further degradation to CO2, showing aerobic degradation of the a.s. with half-lives ranging from < 14 to 112 days (12°C). Alpha-cypermethrin will therefore not persist in sediment. Furthermore, the components of the product do not influence the distribution characteristics of the a.s. Further testing for distribution and dissipation in the environment is therefore not deemed reasonable.

Testing for distribution and dissipation in air (ADS)

Additional data on distribution and dissipation in air of the a.s. or the biocidal product are not necessary. New data are not available.

Volatilisation to the atmosphere following normal biocidal use of the b.p. is limited due to the very low vapour pressure (3.4 x 10-7 Pa at room temperature). Accumulation in air does not occur due to the low air photolysis DT50 of 10.4 h. Thus, accumulation and transport in air can be excluded and further testing is not deemed reasonable.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not relevant.

Estimated aquatic bioconcentration

Conclusion used in Risk Assessment –Aquatic bioconcentration	
Value/conclusion	BCFfish = 910 L/Kg
Justification for the value/conclusion	BCF value used in the assessment is based in the BCF value of the alphacypermethrin in CAR.

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)

Not applicable.

2.2.8.2 Exposure assessment

The biocidal product (b.p.) ZENITRIN EC is a emulsifiable concentrate containing 6 % (w/w) of the active substance alpha-cypermethrin . The b.p. is to be used to control crawling (ants, cockroaches, acari) and flying (flies, mosquitoes, wasps) in domestic premises and public or commercial buildings and in livestock and breeding premises. ZENITRIN EC is intended to be used indoors by professionals. For the biocidal product three different application patterns are foreseen:

(1) Indoor surface spray treatment (including crack and crevice) in private houses and commercial buildings against crawling insects.
(2) Indoor surface spray treatment in private houses and commercial buildings against flying insects.
(3) Indoor surface spray treatment in livestock and breeding premises against flying and crawling insects.

The predicted environmental concentrations (PECs) for each compartment and active substance are assessed applying the EU Guidance on the Biocidal Products Regulation (BPR) on Volume IV Environment (2007) chapter 2.3.7 and the emission scenario description is based on the Emission Scenario Document for insecticides, acaricides and products to control other arthropods for household and professional uses (OECD ESD PT 18 No. 18, 2008) for Scenario 1 and the Emission Scenario Document for insecticides for Stables and Manure storage systems (OECD ESD PT 18 No. 14, 2006) for Scenario 2.

When performing the environmental evaluation of indoor use in private houses and commercial buildings the following points have been taken into account:

- The efficacy for applying the product to a targeted the area of application has not been demonstrated, this makes that the reduction of the cleaning factor from 0.5 to 0.25 could not be considered in the environmental assessment evaluation for ZENITRIN.
- Nor have there been any studies that can support the efficacy of a spot treatment.
- Taking into account the application method specified in the product by the applicant, the areas of 5.9 and 27 m2 for private houses and commercial buildings respectively have been considered suitable for the environmental risk assessment.

General information

]

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Surface spray application by professional users in private houses and large buildings. Indoor. Scenario 2: Surface spray application by professional users in livestock and breeding premises. Indoor.
ESD(s) used	Emission Scenario Document for Product Type 18: Insecticides, acaricides and products to control other arthropods for households and professional uses (OECD, 2008) Emission Scenario Document for Product Type 18: Insecticides for Stables and Manure storage systems (OECD, 2006)
Approach	Scenario 1: Average consumption. Application of the recommended dosis of product as a surface treatment in private houses and commercial buildings, 2 applications per year. Indoor. Scenario 2: Average consumption. Application of the recommended dosis of product as surface treatment in private houses and commercial buildings, 4 applications per year. Indoor. Several sub-scenarios are assessed for this scenario: • Dairy cows • Beef cattle • Veal Calves • Sows in individual pens • Sows in groups • Fattening pigs • Laying hens in battery cages without treatment • Laying hens in battery cages with aeration (Belt drying) • Laying hens battery cages with force drying • Laying hens compact battery cages • Laying hens in free range with litter floor • Broilers in free range with litter floor • Laying hens in free range with grating floor (aviary system) • Parent broilers in free range with grating floor • Parent broilers in rearing with grating floor • Turkeys in free range with litter floor • Ducks in free range with litter floor • Geese in free range with litter floor
Distribution in the environment	Calculated based on : Guidance on the Biocidal Products Regulation, Volume IV Environment, Parts B+C Risk Assessment and Evaluation (active substances) (version 2.0 October 2017). Technical Agreements for Biocides Environment (ENV) October 2022
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Production: No, as the active substance alpha-cypermethrin is manufactured outside the EU.

	Formulation: No, as the formulation process takes place in closed systems and with appropriate control measurements in place to exclude release of the active substance to the environment during formulation of the product. Use: Yes, Scenarios 1 and 2 following the ESD Service Life: Yes, Scenarios 1 and 2 following the ESD
Remarks	None

In order to obtain the PEC values, basic properties of the active substances have to be considered. All of the properties are taken from the Product Assessment Report for the active substance alpha-cypermethrin.

Active substance properties for calculating the fate and distribution in the environment			
Property	**Value**	**Unit**	**Source**
Molecular weight	416.3	g/mol	-
Melting point	82.3	°C	CAR alphacypermethrin
Boiling point	None (decompose before boiling)	°C	CAR alphacypermethrin
Vapour pressure (at 20ºC)	$2.5x10^{-7}$	Pa	CAR alphacypermethrin
Water solubility (at 20°C)	$5.8x10^{-3}$ (pH 7)	mg/l	CAR alphacypermethrin
Log Octanol/water partition coefficient	5.5	Log 10	CAR alphacypermethrin
Organic carbon/water partition coefficient (Koc)	76344	l/kg	CAR alphacypermethrin
Henry's Law Constant	0.069	$Pa/m^3/mol$	CAR alphacypermethrin
Biodegradability	Not readily biodegradable	-	CAR alphacypermethrin
DT_{50} for degradation in soil	112	d (at 12ºC)	CAR alphacypermethrin
BCF fish	910	L/Kg	CAR alphacypermethrin
BCF earthworm	3796	L/Kg	CAR alphacypermethrin

According with these data of the active substance alphacypermethrin the fate and distribution in the STP has been calculated according to the model SimpleTreat 4.1 obtained by EUSES:

Calculated fate and distribution in the STP	
	euses
Compartment	Percentage (%)
	Alphacypermethrin
Air	0.00842%
Water	14.86%
Sludge	85.13%
Degraded in STP	0

Emission estimation

In the following environmental exposure assessment for the product ZENITRIN EC, emissions of the active substance alpha-cypermethrin were taken into consideration.

ZENITRIN EC is an insecticide intended for indoor use for the control of flying insects and for crawling insects. The product solution shall be applied in cracks and crevices, corners, behind and under furniture and in other areas where insects usually hide.

Two scenarios (supported by the efficacy studies against target organisms) in the environmental risk assessment are considered:
Scenario 1: Surface application by professional users in private houses and larger buildings.
Scenario 2: Surface application by professional users in livestock facilities.

ZENITRIN EC is an emusifiable concentrate formulation containing the active substance alpha-cypermethrin at a concentration of 60 g/Kg; 25 mL of the product are diluted with water to obtain 5 L of working solution for all intended uses and target organisms. The product is applied as a spray using a suitable handheld or a knapsack sprayer capable of producing a coarse spray at a rate of 5 L per 100 m^2 (1 L for treating 20 m^2). The target application rate is 13.4 mg alpha-cypermethrin/m^2 when considering a density of the product of 0.89263 g/mL.

Since production and formulation of ZENITRIN EC is not regulated under the BPR No. 528/2012 it has not been considered in the environmental exposure assessment.

For the waste disposal stage of the product life cycle, it is considered that exposure to the wastewater compartment by washing application equipment or by illegal disposal should not occur. It should be noted that disposal of insecticide residues to wastewater is not recognized as a potential exposure pathway in the ESD for household and professional uses of insecticides (PT18; OECD, 2008). In addition, it is not expected that the disposal of empty product packaging to a landfill will contribute significantly to the overall environmental exposure in comparison to the emissions from other parts of the life-cycle of the substance (e.g. preparation, application and cleaning stages). Therefore, based on the recommendations made in the BPR Guidance Vol. IV Parts B + C (2017) it is proposed that waste considerations can be excluded from the assessment process, since general risk management measures based on EU waste legislation should be sufficient.

Scenario 1: Surface application by professional users in private houses and large buildings

Potential emissions to the environment as a result of indoor use of ZENITRIN EC in private houses and/or large buildings are possible during the following steps:

- Mixing and loading
- Application
- Cleaning

During the mixing and loading step releases to the environment may occur. For indoor applications it is assumed that preparation is always carried out indoors. During preparation a fraction of the commercial product is released to air, another fraction may contaminate the applicator and another portion might be released to the floor.

For the application step, there is no relationship between the room size and the quantity of product applied. The sprayed product ends up on the object and on the floor around it.

The ESD for PT 18 considers that the treatment and cleaning steps take place on the same day. Emissions due to both steps are added to estimate the final releases into the environment. In addition, in the treatment step, degradation of the product is not taken into account.

ZENITRIN EC is applied by professionals in private houses and/or large buildings. In compliance with the ESD for insecticides, (OECD ESD for PT 18, 2008) and TAB (2022), emission estimations use the default areas for typical application in domestic households and larger buildings.

As stated before, for the environmental evaluation of indoor use in private houses and commercial buildings the following points have been taken into account:

- The reduction of the cleaning efficiency from 0.5 to 0.25 (ENV TAB 149), could not be considered in the environmental assessment evaluation for ZENITRIN because the efficacy of an attached extension to target the area of product application has not been adequately demonstrate.
- Taking into account the application method specified in the product by the applicant, the treated areas of 5.9 and 27 m2 for private houses and commercial buildings respectively have been considered for the environmental risk assessment.

Input parameters for calculating the local emission				
Scenario 1. Surface treatment in houses and larger buildings				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Application rate	-	0.25	ml/m^2	-
Density	-	0.89263	g/ml	As per study
Quantity of commercial product applied	Q_{prod}	0.2232	g/m^2	Product weight after density correction

Calculations for Scenario 1

Emission estimation for mixing/loading step

Input parameters for calculating the local emission					
Scenario 1. Mixing and loading step					
Input	**Symbol**	**Value**	**Unit**	**Remarks**	**Input**
Quantity of commercial product used for the preparation per building	$Q_{prod,prep}$	House Larger building	1.32 6.03	g	Result of the product applied and the treated area.
Fraction of active substance in the commercial product	F_{AI}		0.06	-	-
Number of preparations per day	N_{prep}	House Larger building	1 3	d^{-1}	D*
Fraction emitted to floor during preparation step	$F_{prep,floor}$		0.0004	-	D*
Fraction emitted to the applicator during preparation step	$F_{prep,\ applicator}$		0.0012	-	D*
Fraction emitted to the air during preparation step	$F_{prep,\ air}$		0	-	D*

* Default values from ESD PT 18 (OECD, 2008)

The product is an emulsifiable concentrate for dilution. The mixing/loading step is considered relevant. The following equation is used for the estimation:

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

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

The product is a liquid and the active substance shows a very low vapour pressure, the fraction emited to air during the mixing/loading step is 0, and the emission to air doesn't need to be taken into consideration.

Emission estimation for application step

Input parameters for calculating the local emission				
Scenario 1. Application step				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Number of applications per day per building	$N_{appl,\ building}$	1	d^{-1}	D*
Area treated with the product	$AREA_{treated}$	House 5.9 Larger building 27	m^2	D*
Fraction emitted to air during the application	$F_{appl.air}$	0.02	-	D*
Fraction emitted to treated surface during the application	$F_{appl.treated}$	0.85	-	
Fraction emitted to floor during the application	$F_{appl,floor}$	0.11	-	
Fraction emitted to the applicator during the application	$F_{appl,applicator}$	0.02	-	

* Default values from ESD PT 18 (OECD, 2008)

According to the chapter 3.4.3.2 of OECD ESD No.18 (2008), the following equations are used for the estimation:

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

Emission estimation for cleaning step

Input parameters for calculating the local emission				
Scenario 1. Cleaning step				
Input	**Symbol**	**Value**	**Unit**	**Remarks**
Fraction emitted to waste water by the applicator during the cleaning step	$F_{applicator,ww}$	1	-	D*
	F_{CE}			

Cleaning efficiency		Spray surface treatment 0.5	-	D*
Number of buildings	$N_{buildings}$	House 4000 Larger building 300	-	D**
Simultaneity factor	$F_{simultaneity}$	0.00204***	-	D*

* Default values from ESD PT 18 (OECD, 2008)
** Technical agreements for biocides ENV 117
*** values from ESD PT 18 (OECD, 2008) from calculation for 1-2 applications per year (37.82 x 0.54)/100 =0.2042%

During the cleaning step two cases are considered:
- Cleaning event results only in emissions to wastes: 100% of the treated surface is cleaned by vacuum/broom and the clothes of the applicant are disposable;
- Cleaning step results only in emissions to wastewater: 100% of the treated surface is washed (F_{ww} = 1) and the clothes of the applicant are washed ($F_{applicator, ww}$ = 1).

The first case (emission as solid waste) is not considered further in the risk assessment because this risk route of exposure is much less likely to be of concern when compared to the direct exposure via the STP compartment. In addition, the effect of its dilution with other wastes, biodegradation of the active substance and the significant containment measures at landfill sites according to European Union waste regulations (EU Directive 99/31/EC) reduce any further concerns.

In the second case (emissions to wastewater) for products applied by spraying the ENV TAB 149 proposes the default factor for cleaning efficiency: F_{CE} = 0.5 for surface treatment.

As releases to wastewater, emissions are evaluated using the following equations according to the chapter 3.5 of OECD ESD No.18 (2008):

$$E_{applicator,ww} = (E_{appl,applicator} + E_{prep,applicator}) \times F_{applicator,ww}$$
$$E_{treated,ww} = (E_{prep,floor} + E_{appl,floor} + E_{appl,treated}) \times F_{ww} \times F_{CE}$$
$$E_{local,ww} = \left(E_{treated,ww} + E_{applicator,ww}\right)$$

It is also supposed that residues removed through wet cleaning may potentially be emitted to the sewer and subsequently to the sewage treatment plant (STP), as it is one of the main receiving compartments in which insecticides are released through cleaning events. According to the chapter 2.7 of OECD ESD No.18 (2008), in order to take into account the simultaneity of the treatment, the emission rates have to be multiplied by the number of houses and the simultaneity factor:

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

Taking all of the equations and the input parameters into account, the emission rates are shown in the following table:

Resulting local emission to relevant environmental compartments			
Step	**Compartment**	**Local emission ($E_{STPcompartment}$) [kg/d]**	
		Surface treatment	
		House	**Large building**
Mixing/loading	Applicator	9,48E-08	1,30E-06

	Floor	3,16E-08	4,34E-07
Application	Air	1,58E-06	7,23E-06
	Treated	6,72E-05	3,07E-04
	Floor	8,69E-06	3,98E-05
	Applicator	1,58E-06	7,23E-06
Releases to wastewater	Applicator	1,68E-06	8,53E-06
	Treated	3,79E-05	1,74E-04
	Local	3,96E-05	1,82E-04
Accumulated releases to STP	Local	3,24E-04	1,12E-04
Combined releases to STP	Local	**4,35E-04**	

Total emissions are estimated as a sum of the releases to STP for houses and larger buildings.

The estimations considering both house and large building applications combined are 4.35×10^{-4} kg/d for surface treatment.

Fate and distribution in exposed environmental compartments for Scenario 1

The identification of the exposed compartments is needed for the characterisation of the hazard and next estimation of the predicted environmental concentration (PEC).

Identification of relevant receiving compartments based on the exposure pathway						
Aquatic compartment			Terrestrial compartment			Secondary poisoning
STP	Surface water	Sediment	Soil	Air	Groundwater	
yes	yes	yes	yes	-	yes	yes

All compartments are taken into account, except air.

PEC estimation for the aquatic compartment

According to the Guidance on the Biocidal Products Regulation, Vol. IV (2017), the predicted environmental concentrations on the aquatic compartment are the STP concentration for inhibition to microorganisms (PEC_{STP}), the concentration in surface water during the emission episode (PEC_{water}) and the concentration in seciment (PEC_{sed}).

As stated on the chapter 2.3.7, the next equations are used in the calculation of PECs:

$$C_{local\ inf.} = \frac{E_{local\ water} \times 10^6}{EFFLUENT_{STP}}$$

$$C_{local\ eff.} = PEC_{STP} = C_{local\ inf.} \times F_{STP\ water}$$

$$C_{local\ water} = PEC_{water} = \frac{C_{local\ eff.}}{(1 + K_{susp.} \times SUSP_{water} \times 10^{-6}) \times DILUTION}$$

$$PEC_{sed} = \frac{K_{susp.}}{RHO_{susp}} \times PEC_{water} \times 1000$$

$C_{local\ inf.}$ represents the concentration in untreated wastewater. It is calculated using $EFFLUENT_{STP}$ (effluent discharge rate of STP, 2000000 L/d default) and the local emission rate to wastewater estimated previously.

$C_{local\ eff.}$ (=PEC_{STP}) represents the concentration of substance in the STP effluent and can be estimated with the $C_{local\ inf.}$ and the $F_{STP\ water}$, the fraction of emission directed to water by STP (estimated with EUSES/Simple Treat for each active substance).

$C_{local\ water}$ (=PEC_{water}) represents the concentration in surface water during the emission episode. It is calculated with the $C_{local\ eff.}$ previously estimated; SUSPwater, the concentration of suspended matter in the river (15 mg/l by default); DILUTION, the dilution factor (10 by default) and $K_{susp.}$, the solids-water partition coefficient of suspended matter, caulculated with the following equation:

$$K_{susp} = Foc_{susp} \times Koc$$

Where Foc_{susp} is the weight fraction of organic carbon in susp. solids (0.1 kg_{oc}/kg_{solid} by default) and Koc is the partition coefficient organic carbon-water of the active substance, in l/kg.

PEC_{sed} represents the predicted environmental concentration in sediment and is estimated with the PEC_{water} previously calculated, $K_{susp\text{-}water.}$ and RHO_{susp}, the bulk density of suspended matter (1150 kg/m^3 by default).

PEC estimation for the terrestrial compartment

According to the Guidance on the Biocidal Products Regulation, Vol. IV (2017), the predicted environmental concentrations on the soil compartment as a result of the treatment where wastewater is generated and released to STP system, can be considered as coming indirectly via the application of sewage sludge to land. Different PECs are calculated, depending on the soil and averaging time.

The concentration of active substance in dry sewage sludge can be calculated using equations (36 and 37) taken from the ECHA guidance on ERA plus default parameters presented in the same guidance document:

$$C_{sludge} = \frac{f_{STP,sludge} \times E_{local\ water} \times 10^6}{SLUDGE_{rate}}$$

C_{sludge} represents concentration on the sludge and is calculated with $f_{STP,\ sludge}$ the fraction of emission directed to sludge by STP (estimated with EUSES/Simple Treat for each active substance); $E_{local\ water}$, the local emission previously viewed and the SLUDGERATE, the rate of sewage production (set to 790 kg/d from default values).

$$SLUDGERATE = \frac{2}{3} \times SUSPCONC_{inf} \times EFFLUENT_{STP} + SURPLUS_{sludge} \times CAPACITY_{STP}$$

$$EFFLUENT_{STP} = CAPACITY_{STP} \times WASTEWAT_{inhab}$$

Input values for calculating the fate and distribution in the environment			
Input	**Unit**	**Value**	**Remarks**
Koc	L/kg	76344	(S) PAR active substance
$F_{STPwater}$	-	0.1486	(O) EUSES
$F_{STPsludge}$	-	0.8513	(O) EUSES
K_{susp}	L/kg	7634.4	(O) BPR Guidance Vol. IV- Eq 26, page 57 Ksusp = Focsusp x Koc = 0.1 x 76344 =**7634.4**
$K_{susp\text{-}water}$	m^3/m^3	1909.5	(O) BPR Guidance Vol. IV – Eq 27, page 58 Ksusp water =Fwater susp + Fsolid susp x (Kp susp/1000) x RHOsolid = 0.9 + 0.1 x (7634.4/1000)x2500 =**1909.5**

$K_{soil\text{-}water}$	m^3/m^3	2290.52	(O) BPR Guidance Vol. IV - eq 27, page 58 Ksoil water = Fair soil x Kair water +Fwater soil + Fsolid soil x (Kp soil/1000) x RHOsolid = 0.2 x 2.912E-5 + 0.2 + 0.6x(1526.88/1000)x2500 =**2290.52** Kairwater=H/RT =0.069/(8.314x285)=2.912E-5 Kp soil=Focsoil x Koc =0.02 x 76344 =1526.88
$K_{p\ soil}$	L/kg	1526.88	(O) BPR Guidance Vol. IV - eq 26, page 57 Kp soil=Focsoil x Koc =0.02 x 76344 =**1526.88**
$EFFLUENT_{STP}$	L/d	2000000	(D) BPR Guidance Vol. IV
SUSPwater	mg/L	15	(D) BPR Guidance Vol. IV
DILUTION	-	10	(D) BPR Guidance Vol. IV
RHO_{susp}	kg/m3	1150	(D) BPR Guidance Vol. IV
RHO_{soil}	kg/m3	1700	(D) BPR Guidance Vol. IV
$SLUDGE_{rate}$	kg/d	790	(O) Calculated from default values, BPR Guidance Vol. IV
$APPL_{sludge}$	$kg/m^2/yr$	0.5	(P) BPR Guidance Vol. IV for arable soil
$DEPHT_{soil}$	m	0.2	(P) BPR Guidance Vol. IV for arable soil

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

$$C_{soil}(0) = \frac{C_{sludge} \times APPL_{sludge}}{DEPHT_{soil} \times RHO_{soil}}$$

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

Where sewage sludge is applied to agricultural soil, an application rate of 5000 kg/ha per year has been assumed (based on typical application rates across the EU) whilst the rate for grassland is assumed to be lower at 1000 kg/ha yr - these applications are considered to occur once per year. As alpha-cypermethrin is not readily biodegradable, there is potential for accumulation of the compound when sewage sludge is applied over consecutive years (as a realistic worst case, it is generally assumed that sludge is applied annually for 10 years).
Being the degradation rate 83.5 days, if removal of active substance via volatilisation and leaching from topsoil are ignored as being minor processes, losses would solely be as a result of soil degradation, then the pseudo-first order rate constant k (represented by $Kbio_{soil}$) can be derived from the following equation:

$$K_{soil} = \frac{\ln 2}{DT_{50\ soil}}$$

Where $DT_{50,\ soil}$ is the half-life for (bio) degradation in aerobic soil.

At the end of each year, a fraction of the initial concentration (Facc) may potentially remain in the top soil layer and this can be determined by use of the equation stating:

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

Facc representing the fraction accumulation in 1 year and k the first order rate constant for removal from top soil via degradation, volatilisation and leaching.

In the case of alpha-cypermethrin, Facc = 1.04 x 10^{-1} and soil accumulation is not expected to occur in high extent.

For the indirect release, the PEC for local soil (referred to as $Clocal_{soil}$) is calculated as the average concentration in soil over T days, using the following equation taken from the ECHA guidance on ERA (equation 55), considering the aerial deposition flux per kg of soil (D_{air}) as zero:

$$PEC_{soil,T} = Clocal_{soil} = \frac{C_{soil,T}(0)}{K \times T} \times (1 - e^{-KT})$$

Where k is a constant calculated as $\ln(2)/DT_{50soil}$, T is the period and $C_{soil,T}$ (0) is the initial concentration in soil in year T

Considering 1 release per year, $C_{soil,\ 10}$ (0) is the concentration released on year 10 plus the accumulation from the previous years, estimated with the fraction of accumulation in 1 year:

$$C_{soil,10}(0) = C_{soil}(0) \times \left(1 + \sum_{n=1}^{n=9} Facc^n\right)$$

The average period of 180 days for agricultural soil and grassland is also the relevant period for the derivation of porewater concentration. Using the same accumulation factor the $PEC_{groundwater}$ is estimated as:

$$PEC_{groundwater} = \frac{PEC_{soil,T} \times RHO_{soil}}{K_{soil-water} \times 1000}$$

With $K_{soil\text{-}water}$ being the soil-water partition coefficient.

For the direct release, the equations are the same except for the initial concentration on the grassland. In this case, the concentration is equal to the concentration released during application of the product only being released to grass:

$C_{sludge,grass} = C_{spot,soil}$

And the averaging period of 180 days represents a reasonable assumption for the period that cattle are grazing on the field.

Calculated PEC values Scenario 1

Summary table on calculated PEC values for Scenario 1					
Scenario 1	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**	**PEC_{GW}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg]	[µg/l]
Surface treatment CFV=0.50	3.23E-5	2.90E-6	4.82E-3	4.64E-4	3.45E-4

Primary and secondary poisoning

According to BPR Guidance, Vol. IV, a substance is considered bioaccumulable if, between other criteria, has a log Kow > 3, and it is also considered for possible secondary poisoning if log Kow >4.5. Calculated log Pow for Alpha-cypermethrin was determined on 6.82 According to the application pattern and, mode of use and product properties primary poisoning to animals is not likely. Secondary poisoning is assessed for alpha-cypermethrin following the approach described in the BPR Guidance, Vol IV. Thus, an estimation of the theoretical exposure of top predators via the aquatic and terrestrial food chain has been performed and is presented in the following tables.

<u>BPR Guidance approach</u>

Primary poisoning sticks to the direct oral route on aquatic and terrestrial organisms, represented by fish and earthworm respectively. Following the BPR Guidance, Vol. IV, Chapter 3.8, PECs can be estimated with the following equations:

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

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Predicted Environmental Concentration in fish-eating predators	$PEC_{oral,\ fish\text{-}eating\ predator}$	[$mg.kg_{wet\ fish}^{-1}$]	-	Output
Predicted Environmental Concentration in surface water	$PEC_{\ surface\ water}$	[$mg.L^{-1}$]	[1]	Input
Bioconcentration Factor for fish on wet weight basis	BCF_{fish}	[$L.kg_{wet\ fish}^{-1}$]	910	Input
Biomagnification factor in fish	*BMF*	[-]	1	Default

[1]PECwater for the different scenarios.

BCFfish According to alpha-cypermethrin CAR.

BMF According to alpha-cypermethrin CAR and Table 23 of ECHA Guidance on the BPR (Volume IV Environment –Version 2.0, October 2017)

$$PEC_{oral,earthworm} = \frac{BCF_{earthworm} \times C_{groundwater} + C_{soil} \times F_{gut} \times CONV_{soil}}{1 + F_{gut} \times CONV_{soil}}$$

Where:

Variable/parameter (unit)	Symbol	Unit	Value	Source
Predicted Environmental Concentration in earthworm-eating predators	$PEC_{oral,\ earthworm\text{-}eating\ predator}$	[$mg.kg_{wet\ earthworm}^{-1}$]	-	Output
Concentration in earthworm on wet weight basis	$C_{earthworm}$	[$mg.kg_{wet\ earthworm}^{-1}$]	-	Output
Bioconcentration Factor for earthworms on wet weight basis	$BCF_{earthworm}$	[$mg.kg_{wet\ earthworm}^{-1}$]	3796	Input
Concentration in porewater	$C_{porewater}$	[$mg.L^{-1}$]	[2]	Input
Concentration in soil	C_{soil}	[$mg.kg_{\ wwt}^{-1}$]	[3]	Input
Fraction of gut loading in worm	F_{gut}	[$kg_{dwt}.kg_{wwt}^{-1}$]	0.1 [4]	Default
Conversion factor for soil concentration wet-dry weight soil	$CONV_{soil}$	[$kg_{wwt}.kg_{dwt}^{-1}$]	1.13 [4]	Default

BCFearthworm According to alpha- cypermethrin CAR.

[2] PECporewater for the different scenarios.

[3] 180 days PECsoil for the different scenarios.

[4] Default values were obtained from ECHA Guidance on the BPR (October 2017).

BCF represents the bioconcentration factor for each organism. For fishes, PEC_{water} was already estimated and BMF_{fish} is a biomagnification factor depending on BCF_{fish}. For earthworms, $C_{groundwater}$ and C_{soil} were already estimated too, while F_{gut} and $CONV_{soil}$ are the fraction of gut loading in worm and the conversion factor for soil concentration, 0.1 kg dw/kg wwt and 1.13 kg wwt/kg dw respectively.

BCF values are usually stated on the CAR of the active substance.

According the CAR of the alphacypermethrin, the BCF values were 910 l/kg fish and 3796 l/kg earthworm for alpha-cypermethrin.

The summary of the PEC for secondary poisoning are presented in the following table:

Summary table on secondary poisoning via the aquatic food chain	
Scenario 1- Surface y crack Alpha-cypermethrin	***PEC*$_{oral,\ fish\text{-}eating\ predator}$**
Surface	2,64E-03
Summary table on secondary poisoning via the terrestrial food chain	
Scenario 1- Surface y crack Alpha-cypermethrin	***PEC*$_{oral,\ earthworm\text{-}eating\ predator}$**
Surface	1,22E-03

Scenario 2: Surface spray application by professional users in livestock and breeding premises

ZENITRIN EC is intended for surface spray application by professional users in livestock and breeding premises in areas where insects may lay (flying insects), hide or crawl (crawling insects). It is recommended for its application at a rate of 25 ml of product diluted in 5 l of water for treating 100 m^2. ZENITRIN EC contains a nominal amount of alpha-cypermethrin of 6 g per 100 g of product.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 2. Application in animal housing			
Amount of biocidal product (concentrate) prescribed to be used for area specified for application	0.2232	g/m^2	Product of the application rate and the product density
Concentration of active substance in the product	6	%	
Active substance concentration per treated m^2	13.4	mg/m^2	app_rate

The final release and fate of insecticides applied in animal housing will be determined by the following factors:

1- the type of animal housing and manure storage system (number of animals, manure generation, size of stables and manure storage systems…)
2- the type of insecticide (adulticide, larvicide…)
3- the way of application (spraying, painting, bait application…) and
4- the stream where the biocide is applied (manure, wastewater, slurry).

The stream where the biocide is applied in animal housing will depend on the manure storage system in the specific animal housing:

- Insecticide can be applied in some housing sites where the manure is stored in dry storage systems (typically poultry). In this case, the fraction of insecticide reaching dry manure will be stored in the dry manure storage system and eventually released to soil. From soil the biocide may reach other different compartments such as groundwater and surface water/sediment. This scenario is defined as *manure*.
- When the animal housing presents a wet manure storage system (slurry), insecticide residues may reach the manure storage system, being released to the land eventually. This scenario is defined as *slurry*.

- The last scenario is when wastewater is directly released to a WWTP or a STP. This scenario is defined as *wastewater*.

ZENITRIN EC is applied by spraying against adult insects. Other factors are used to calculate the release to the relevant compartments (manure, slurry and/or wastewater). Those factors depend on the type of animal housing considered, and also the type of manure storage system of the animal housing. The following animal housing premises are considered in this assessment following the Categories and sub-categories described in the ESD No 14 for insecticides in stables and manure:

1- Dairy cows (Slurry)
2- Beef cattle (Slurry)
3- Veal calves (Slurry)
4- Sows in individual pens (Slurry)
5- Sows in groups (Slurry)
6- Fatterning pigs (Slurry)
7- Laying hens in battery cages without treatment (Slurry)
8.1- Laying hens in battery cages with aeration (belt drying) (Slurry)
8.2- Laying hens in battery cages with aeration (belt drying) (Wastewater)
9- Laying hens in battery cages with forced drying (Manure)
10- Laying hens in compact battery cages (Slurry)
11.1- Laying hens in free range with litter floor (Wastewater)
11.2- Laying hens in free range with litter floor (Manure)
12.1- Broilers in free range with litter floor (Wastewater)
12.2- Broilers in free range with litter floor (Manure)
13- Laying hens in free range with grating floor (Slurry)
14- Parent broilers in free range with grating floor (Slurry)
15- Parent broilers in rearing with grating floor (Slurry)
16.1- Turkeys in free range with litter floor (Wastewater)
16.2- Turkeys in free range with litter floor (Manure)
17.1- Ducks in free range with litter floor (Wastewater)
17.2- Ducks in free range with litter floor (Manure)
18.1- Geese in free range with litter floor (Wastewater)
18.2- Geese in free range with litter floor (Manure)

Fate and distribution in exposed environmental compartments for Scenario 2

The identification of the exposed compartments is needed for the characterisation of the hazard and next estimation of the predicted environmental concentration (PEC).

Different approaches are used when determining the releases to the environmental compartments depending on the type of the manure storage system.
As ZENITRIN EC is intended to be used as insecticide in all breeding areas, the emission calculation was conducted for all of relevant categories and subcategories. In dependence on the relevant emission streams different exposure pathway scenarios exist.

In case of livestock, the relevant emission stream is only slurry. Contrary, the relevant emission stream of housing systems for poultry is depicted by:

- discharge of stable cleaning water to the municipal STP and slurry (battery cages with aeration)
- manure and liquid waste (free-range system with litter floor)
- solely slurry (free-range with grating floor, battery cages without treatment and compact battery cages) and
- solely manure (battery cages with forced drying).

In case that the poultry housing system is not connected to the local sewer system, the waste water from the housing would remain on site and be stored in a specific collection tank. Then, waste water will be mixed with slurry/manure and will commonly be applied to agricultural land.

In case that the animal housing is connected to the local sewer system, a fraction of a.s. could be released with waste water to the local STP whilst another fraction of a.s. could be applied to agricultural land after a period of storage in manure/slurry. Thus, two different scenarios must be assessed for the receiving as well as secondarily affected environmental compartments for the life cycle stage 'professional use phase' according to the ESD PT3 (2011). In the following table both scenarios, poultry housing connected to the local sewer system ("via STP") and cattle, swine and poultry housing which not connected to the local sewer system ("via manure/slurry"), with the relevant receiving compartments are summarised.

Therefore, separated calculations are considered for manure/slurry scenarios (direct application on soil) and for wastewater scenarios (direct release to STP).

Identification of relevant receiving compartments based on the exposure pathway						
	Wastewater (STP)	**Surface water**	**Sediment**	**Soil**	**Groundwater**	**Air**
via STP	Yes	Yes (indirect)	Yes (indirect)	Yes (indirect)	Yes (indirect)	n.r.
via manure/ slurry	No	Yes (indirect)	Yes (indirect)	Yes (direct)	Yes (direct)	n.r.

All compartments are taken into account, except air.

Therefore, the emissions of alpha-cypermethrin from the use of Zenitrin EC to the relevant waste stream must be calculated according to the applicable guidance. The scenario configuration and calculation parameters are specific to each application per animal housing type. A summary of the input parameters for treatments against flies and wasps (i2=1), bloodsucking pests (mosquitoes) (i2=2) and other insects (not affecting livestock; crawling insects) (i2=4) where emission to the environment is via land application of contaminated manure/slurry and via the STP can be found in the tables below, along with intermediate output values.

For the sake of clarity and interpretation of this document, only the evaluation for treatments against flies and wasps (i2=1) is shown since for the scenario 2, this is the worst case for fractions of a.s. released to relevant streams.

The number of applications considered for the exposure assessment are, as applied by the applicant, Napp-bioc = 4 applications per year, Tbioc-int: 91 days.

Default values regarding e.g. number of animals in housing (ESD PT18 stables, table 5.2), the fractions of a.s. released to the relevant streams (ESD PT18 stables, table 5.4 and TAB ENV 233), were directly used in accordance with the ESD No.14 (2006) and associated documents. The treated area in the stables, which is used for calculations, is the total area of the housing (floor, walls and roof).

The calculations were performed following the Emission Scenario Document for PT 18 (OECD ESD No 14), Guidance on the BPR, Volume IV Environment – Assessments and Evaluation (Parts B+C), Technical Agreement for Biocides TAB – ENV and changes implemented in the Addendum to OECD Series on emission scenario documents, Number 14 (TAB 212). All calculations were performed using the ECHA calculation tool.

The calculations considering the emission via STP were performed using the SimpleTreat model 4.1.

Phosphorous immission standards were not considered in the current assessment since they are unique in the Netherlands and therefore not applicable EU wide. It was decided to use the Nitrogen immission standards from the EC Nitrates Directive (91/676/EEC) of 170 kg N $ha^{-1}.yr^{-1}$ for all soils (arable land and grassland) (ENV TAB 160).

Input parameters for use against flies (i2=1)[1], bloodsucking pest (i2=2) and other insects not affecting livestock (i2=4)

Parameter	Symbol	S / D / O / P	Unit	Value
Biocidal product parameters				
Way of application	appway	S/P	-	Spraying / foaming
Amount of diluted b.p. prescribed to be used per m²	Qprod	S	L diluted b.p./m²	0,05
Dilution factor	Fdil	S	-	0,005
Purity of the active substance	-	S	%	100
Content of active substance in b.p.	Fbioc	S	% (w/w)	6
Biocidal product density	-	S	g /mL	1
Application rate	app_rate	O	g a.s./m²	0,0134
Scenario related parameters				
Number of land applications for grassland	Nlapp-gr	D	-	4
Number of applications for arable land	Nladd-ar	D	-	1
Number of applications for arable land in 10 years	Nlapp-ar, 10	O/D	-	10
Number of (repeated) b.p. applications in animal housing	Napp-bioc	S	1/years	4
Manure storage time for arable land scenario	Tar-int	D	d	212
B.p. application interval	Tbioc-int	S	d	91
Land application interval for manure application on grassland	Tgr-int	D	d	53
Land application interval for manure application on arable land	Tar-int, 10	D	d	365
Density of wet bulk soil	RHOsoil wet	D	kg (wwt)/m³	1700
Bulk density of wet suspended matter	RHOsusp wet	D	kg (wwt)/m³	1150
Soil water partition coefficient	Ksoil-water	S	m³/m³	2290.5 B)
Solids-water partitioning coefficient of suspended matter	Kp,susp	S	L/kg	7634.4 B)
Suspended matter-water partition coefficient	Ksusp-water	S	m³/m³	1909.5 B)
Concentration of suspended matter in river	SUSPwater	D	mg/L	15
Dilution	DILUTION run-off	D	-	10
Standard concentration in air at 100 m from source for a source strength of 1 kg / d	Cstd, air	D	mg/m³	2.78E-04
Source strength	Source strength	D	kg/d	1
Number of emission days per year	Temission	D	d/year	365
Further input parameters for grassland				

Mixing depth in soil, grassland	DEPTH grassland	D	m	0.05
Half-life time for biodegradation in soil, grassland, at 12°C	DT50bio soil_gr	S	d	112
First order rate constant for volatilisation from soil, grassland	kvolat_gr	S	1/d	0 C)
First order rate constant for leaching from top soil, grassland	kleach_gr	S	1/d	4.19E-06
First order rate constant for degradation in bulk soil, grassland	kdegr_gr	O	1/d	6.19E-03
Overall removal rate constant in soil, grassland	k_gr	O	1/d	6.19E-03
Nitrogen immision standard for one year on grassland	Q N, grassland	D	kg/ha	170
Further input parameters for arable land				
Mixing depth in soil, arable land	DEPTH arable land	D	m	0.20
Half-life time for biodegradation in soil, arable land, at 12°C	DT50bio soil_ar	S	d	112
First order rate constant for volatilisation from soil, arable land	kvolat_ar	S	1/d	0 C)
First order rate constant for leaching from top soil, arable land	kleach_ar	S	1/d	1.05E-06
First order rate constant for degradation in bulk soil, arable land	kdegr_ar	O	1/d	6.19E-03
Overall removal rate constant in soil, arable land	k_ar	O	1/d	6.19E-03
Nitrogen immision standard for one year on arable land	Q N, arable land	D	kg/ha	170

A) S: data set; D: default; O: output; P: pick list

B) Calculated according to Guidance on Biocidal Products Regulation: Volume IV Environment – Assessment and Evaluation (Parts B+C), Version 2.0, October 2017

C) Alpha cypermethrin is considered to be non-volatile.

1) Worst case for fractions of a.s. released to the relevant streams

Calculation of emissions in animal housing premises where direct emissions to manure are envisaged

Relevant scenarios for this type of environmental release are:

1- Dairy cows (Slurry)
2- Beef cattle (Slurry)
3- Veal calves (Slurry)
4- Sows in individual pens (Slurry)
5- Sows in groups (Slurry)
6- Fatterning pigs (Slurry)
7- Laying hens in battery cages without treatment (Slurry)
8.1- Laying hens in battery cages with aeration (belt drying) (Slurry)
9- Laying hens in battery cages with forced drying (Manure)
10- Laying hens in compact battery cages (Slurry)
11.2- Laying hens in free range with litter floor (Manure)
12.2- Broilers in free range with litter floor (Manure)
13- Laying hens in free range with grating floor (Slurry)
14- Parent broilers in free range with grating floor (Slurry)
15- Parent broilers in rearing with grating floor (Slurry)

16.2- Turkeys in free range with litter floor (Manure)
17.2- Ducks in free range with litter floor (Manure)
18.2- Geese in free range with litter floor (Manure)

When the product is applied in the surfaces of animal housing facilities where direct manure application is envisaged or where releases to the slurry (liquid + manure) may occur, the active substance is potentially collected along with the manure and stored following normal farming practices. The stored manure is eventually released to agricultural/grassland soil. The amount of manure that is permitted to be applied to land is controlled by the nitrogen and/or phosphate content of the manure. However, at the product authorisation level the N-standards are taken into consideration. No data about degradation in manure is available, so no degradation of the active ingredient during manure storage period is considered.

The scenario configuration and calculation parameters for animal housing premises use against flies (i2=1) (worts case for scenario 2), are included in the following table:

Type of housing		Fraction to the manure	Area	Nitrogen production/animal
		Fslurry/manure		Qnitrog
		(-)	m2	kg
1	Dairy cows	0,5	2840	3,39E-01
2	Beef cattle	0,5	1370	2,88E-01
3	Veal calves	0,5	490	2,38E-02
4	Sows, in individual pens	0,5	1470	7,11E-02
5	Sows in groups	0,5	1870	7,11E-02
6	Fattening pigs	0,5	1570	3,04E-02
7	Laying hens in battery cages without treatment	0,5	1850	2,02E-03
8.1	Laying hens in battery cages with aeration (belt drying)	0,3	1850	1,81E-03
9	Laying hens in batters cages with forced drying (deep pit, high rise)	0,8	1850	1,81E-03
10	Laying hens in compact battery cages	0,5	1850	1,81E-03
11.2	Laying hens in free range with litter floor (partly litter floor, partly slatted)	0,3	3460	1,71E-03
12.2	Broilers in free range with litter floor	0,3	2710	1,56E-03
13	Laying hens in free range with grating floor (aviary system)	0,5	3092	1,71E-03
14	Parent broilers in free range with grating floor	0,5	990	2,98E-03
15	Parent broilers in rearing with grating floor	0,5	1250	1,37E-03
16.2	Turkeys in free range with litter floor	0,3	7980	4,82E-03
17.2	Ducks in free range with litter floor	0,3	4820	2,74E-03
18.2	Geese in free range with litter floor	0,3	6000	4,82E-03

Type of housing		Number of biocides application during manure storage period		Number of prescribed maximum repeated treatments according to information given by the applicant	Amount of active ingredient to be used in housing or manure storage for one application
		Napp-manure		Napp-prescr	Qai_prescri
		(-)		(-)	kg
		grass	arable		
1	Dairy cows	0,58	1	4	3,80E-02
2	Beef cattle	0,58	1	4	1,83E-02
3	Veal calves	0,58	1	4	6,56E-03
4	Sows, in individual pens	0,58	1	4	1,97E-02
5	Sows in groups	0,58	1	4	2,50E-02
6	Fattening pigs	0,58	1	4	2,10E-02
7	Laying hens in battery cages without treatment	0,58	1	4	2,48E-02
8.1	Laying hens in battery cages with aeration (belt drying)	0,58	1	4	2,48E-02
9	Laying hens in batters cages with forced drying (deep pit, high rise)	0,58	1	4	2,48E-02
10	Laying hens in compact battery cages	0,58	1	4	2,48E-02
11.2	Laying hens in free range with litter floor (partly litter floor, partly slatted)	0,58	1	4	4,63E-02
12.2	Broilers in free range with litter floor	0,58	1	4	3,63E-02
13	Laying hens in free range with grating floor (aviary system)	0,58	1	4	4,14E-02
14	Parent broilers in free range with grating floor	0,58	1	4	1,33E-02
15	Parent broilers in rearing with grating floor	0,58	1	4	1,67E-02
16.2	Turkeys in free range with litter floor	0,58	1	4	1,07E-01
17.2	Ducks in free range with litter floor	0,58	1	4	6,45E-02
18.2	Geese in free range with litter floor	0,58	1	4	8,03E-02

Type of housing		Amount of active ingredient in relevant stream	Amount (maximum) of biocide in manure at the end of storage periodof active ingredient in relevant stream		Nitrogen production during the manure storage period	
		Qai	Qai-grasland	Qai-arable	Qnitrog-grass	Qnitrog-arable
		kg	kg	kg	kg	kg
1	Dairy cows	1,90E-02	1,11E-02	1,90E-02	1,80E+03	3,08E+03
2	Beef cattle	9,17E-03	5,34E-03	9,17E-03	1,91E+03	3,28E+03
3	Veal calves	3,28E-03	1,91E-03	3,28E-03	1,01E+02	1,73E+02
4	Sows, in individual pens	9,84E-03	5,73E-03	9,84E-03	4,97E+02	8,54E+02
5	Sows in groups	1,25E-02	7,29E-03	1,25E-02	4,97E+02	8,54E+02
6	Fattening pigs	1,05E-02	6,12E-03	1,05E-02	6,45E+02	1,11E+03
7	Laying hens in battery cages without treatment	1,24E-02	7,21E-03	1,24E-02	2,25E+03	3,86E+03
8.1	Laying hens in battery cages with aeration (belt drying)	7,43E-03	4,33E-03	7,43E-03	2,01E+03	3,46E+03
9	Laying hens in batters cages with forced drying (deep pit, high rise)	1,98E-02	1,15E-02	1,98E-02	2,01E+03	3,46E+03
10	Laying hens in compact battery cages	1,24E-02	7,21E-03	1,24E-02	2,01E+03	3,46E+03
11.2	Laying hens in free range with litter floor (partly litter floor, partly slatted)	1,39E-02	8,09E-03	1,39E-02	9,06E+02	1,56E+03
12.2	Broilers in free range with litter floor	1,09E-02	6,34E-03	1,09E-02	1,65E+03	2,84E+03
13	Laying hens in free range with grating floor (aviary system)	2,07E-02	1,21E-02	2,07E-02	1,81E+03	3,11E+03
14	Parent broilers in free range with grating floor	6,63E-03	3,86E-03	6,63E-03	1,11E+03	1,90E+03
15	Parent broilers in rearing with grating floor	8,37E-03	4,87E-03	8,37E-03	6,53E+02	1,12E+03
16.2	Turkeys in free range with litter floor	3,21E-02	1,87E-02	3,21E-02	2,55E+03	4,39E+03
17.2	Ducks in free range with litter floor	1,94E-02	1,13E-02	1,94E-02	1,45E+03	2,49E+03
18.2	Geese in free range with litter floor	2,41E-02	1,40E-02	2,41E-02	2,55E+03	4,39E+03

The summary of the PEC for the different compartments are summarized in the table below:

Scenario 2 (Animal housing- Emission pathway via manure / slurry)									
Type of housing		PIECsoil after 10 year consecutive application, degradation in soil included TAB ENV 212):		PECgroundwater (ESD Addendum, eq. 40, TAB ENV 212):		PEC surface water ESD Addendum, eq. 41, TAB ENV 212):		PEC sediment (Eq. 53 BPR Guidance, v. 2.0-Oct. 2017):	
		based on nitrogen immission standards							
		PIEC (mg/kg wwt)		PEC_{gw} (µg/l)		PEC_{sw} (mg/l)		PEC_{sed} (mg/kg dwt)	
		Grass	Arable	Grass	Arable	Grass	Arable	Grass	Arable
1	Dairy cows	8,99E-04	3,44E-04	4,02E-04	1,54E-04	6,09E-08	2,33E-08	1,01E-04	3,87E-05
2	Beef cattle	4,08E-04	1,56E-04	1,83E-04	6,99E-05	2,76E-08	1,06E-08	4,59E-05	1,76E-05
3	Veal calves	2,76E-03	1,06E-03	1,23E-03	4,73E-04	1,87E-07	7,15E-08	3,10E-04	1,19E-04
4	Sows, in individual pens	1,68E-03	6,44E-04	7,52E-04	2,88E-04	1,14E-07	4,36E-08	1,89E-04	7,24E-05
5	Sows in groups	2,14E-03	8,19E-04	9,57E-04	3,66E-04	1,45E-07	5,55E-08	2,41E-04	9,21E-05
6	Fattening pigs	1,38E-03	5,30E-04	6,19E-04	2,37E-04	9,37E-08	3,59E-08	1,56E-04	5,96E-05
7	Laying hens in battery cages without treatment	4,68E-04	1,79E-04	2,09E-04	8,02E-05	3,17E-08	1,21E-08	5,26E-05	2,01E-05
8.1	Laying hens in battery cages with aeration (belt drying)	5,22E-04	2,00E-04	2,34E-04	8,95E-05	3,54E-08	1,35E-08	5,87E-05	2,25E-05
9	Laying hens in batters cages with forced drying (deep pit, high rise)	8,35E-04	3,20E-04	3,74E-04	1,43E-04	5,66E-08	2,17E-08	9,40E-05	3,60E-05
10	Laying hens in compact battery cages	5,22E-04	2,00E-04	2,34E-04	8,95E-05	3,54E-08	1,35E-08	5,87E-05	2,25E-05
11.2	Laying hens in free range with litter floor (partly litter floor, partly slatted)	2,17E-03	8,31E-04	9,71E-04	3,72E-04	1,47E-07	5,63E-08	2,44E-04	9,35E-05
12.2	Broilers in free range with litter floor	9,32E-04	3,57E-04	4,17E-04	1,60E-04	6,31E-08	2,42E-08	1,05E-04	4,01E-05
13	Laying hens in free range with grating floor (aviary system)	9,70E-04	3,71E-04	4,34E-04	1,66E-04	6,57E-08	2,52E-08	1,09E-04	4,18E-05
14	Parent broilers in free range with grating floor	5,09E-04	1,95E-04	2,28E-04	8,72E-05	3,45E-08	1,32E-08	5,73E-05	2,19E-05
15	Parent broilers in rearing with grating floor	1,09E-03	4,16E-04	4,87E-04	1,86E-04	7,37E-08	2,82E-08	1,22E-04	4,68E-05
16.2	Turkeys in free range with litter floor	1,78E-03	6,80E-04	7,95E-04	3,04E-04	1,20E-07	4,61E-08	2,00E-04	7,65E-05
17.2	Ducks in free range with litter floor	1,89E-03	7,23E-04	8,44E-04	3,23E-04	1,28E-07	4,89E-08	2,12E-04	8,13E-05
18.2	Geese in free range with litter floor	1,34E-03	5,11E-04	5,98E-04	2,29E-04	9,05E-08	3,46E-08	1,50E-04	5,75E-05

Calculation of emissions in animal housing premises where emissions to the environment through STP or WWTP systems are envisaged

Relevant scenarios for this type of environmental release are:

8.2- Laying hens in battery cages with aeration (belt drying) (Wastewater)
11.1- Laying hens in free range with litter floor (Wastewater)
12.1- Broilers in free range with litter floor (Wastewater)
16.1- Turkeys in free range with litter floor (Wastewater)
17.1- Ducks in free range with litter floor (Wastewater)
18.1- Geese in free range with litter floor (Wastewater)

Calculation of PEC values for aquatic compartment

After empying the housing, cleaning operations are performed. Liquid waste is collected in tanks and discharged to the sewer, which is conneted to a STP. For this type of scenario, PEC values are calculated following the ESD when releases are discharged to STP (OECD Scenario No 18: Insecticides, acaricides and products to control other arthropods for household and professional uses.

Following application of ZENITRIN EC in livestock facilities, the amount of active substance reaching the standard STP is calculated using the ECHA calculation tool as stated previously. The scenario configuration and calculation parameters for animal housing premises use against flies (i2=1) (worts case for scenario 2), are included in the following table:

Type of housing		Fraction to STP	Amount of active ingredient to be used in m2 of area for one application	Amount of active ingredient reaching STP	Effluent discharge rate of STP	Concentration in untreated wastewater
		Fwastewater	Qai_prescri	Qai-STP	Effluent $_{STP}$	Clocal inf
		(-)	kg	kg	l.d-1	mg.l-1
8.2	Laying hens in battery cages with aeration (belt drying)	0,2	2,48E-02	4,95E-03	2,00E+06	2,48E-03
11.1	Laying hens in free range with litter floor (partly litter floor, partly slatted)	0,2	4,63E-02	9,27E-03		4,63E-03
12.1	Broilers in free range with litter floor	0,2	3,63E-02	7,26E-03		3,63E-03
16.1	Turkeys in free range with litter floor	0,2	1,07E-01	2,14E-02		1,07E-02
17.1	Ducks in free range with litter floor	0,2	6,45E-02	1,29E-02		6,45E-03
18.1	Geese in free range with litter floor	0,2	8,03E-02	1,61E-02		1,07E-02

From the STP system, the active ingredient is released to surface water and sediment.

The summary of the PEC for the aquatic compartment are summarized in the table below:

Determination of PEC_{STP}, PEC_{SW} and PEC_{sed} for the relevant scenarios with wastewater emissions for the aquatic compartment				
Scenario 2 (Animal housing- Emission pathway via STP)		**PEC_{STP} (mg/L)**	**PEC_{SW} (mg/L)**	**PEC_{sed} (mg/kg wwt)**
8.2	Laying hens in battery cages with aeration (belt drying)	3,68E-04	3,30E-05	5,48E-02
11.1	Laying hens in free range with litter floor	6,88E-04	6,18E-05	1,03E-01
12.1	Broilers in free range with litter floor	5,39E-04	4,84E-05	8,03E-02
16.1	Turkeys in free range with litter floor	1,59E-03	1,42E-04	2,37E-01
17.1	Ducks in free range with litter floor	9,59E-04	8,60E-05	1,43E-01
18.1	Geese in free range with litter floor	1,19E-03	1,07E-04	1,78E-01

Calculation of PEC values for soil compartment

Exposure of active substances to the soil compartment as a result of the treatment in poutry facilities where wastewater is generated and released to STP system, can be considered as coming indirectly via the application of sewage sludge to land.

The summary of the PEC for the soil compartment are summarized in the table below:

Determination of PEC_{soil} and $PEC_{groundwater}$ for the relevant scenarios with wastewater emissions for the aquatic compartment			
Scenario 2 (Animal housing- Emission pathway via STP)		**PEC_{soil} (mg/kg wwt)**	**PEC_{GW} (mg/L)**
8.2	Laying hens in battery cages with aeration (belt drying)	5,29E-03	3,92E-03
11.1	Laying hens in free range with litter floor	9,89E-03	7,34E-03
12.1	Broilers in free range with litter floor	7,74E-03	5,75E-03
16.1	Turkeys in free range with litter floor	2,28E-02	1,69E-02
17.1	Ducks in free range with litter floor	1,38E-02	1,02E-02
18.1	Geese in free range with litter floor	1,71E-02	1,27E-02

Primary and secondary poisoning:

In a similar way to what was performed previously in scenario 1 for primary and secondary poisoning, following the BPR Guidance, Vol. IV, Chapter 3.8, PECs can be estimated with the following equations:

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

$$PEC_{oral,earthworm} = \frac{BCF_{earthworm} \times C_{groundwater} + C_{soil} \times F_{gut} \times CONV_{soil}}{1 + F_{gut} \times CONV_{soil}}$$

The summary of the PEC for secondary poisoning are presented in the following tables.

Summary table on secondary poisoning via the aquatic food chain			
Scenario 2- via Slurry/manure		$PEC_{oral,\ fish\text{-}eating\ predator}$	
		Grass	***Arable***
1	Dairy cows	5,54E-05	2,12E-05
2	Beef cattle	2,51E-05	9,63E-06
3	Veal calves	1,70E-04	6,51E-05
4	Sows, in individual pens	1,04E-04	3,97E-05
5	Sows in groups	1,32E-04	5,05E-05
6	Fattening pigs	8,53E-05	3,27E-05
7	Laying hens in battery cages without treatment	2,88E-05	1,10E-05
8.1	Laying hens in battery cages with aeration (belt drying)	3,22E-05	1,23E-05
9	Laying hens in batters cages with forced drying (deep pit, high rise)	5,15E-05	1,97E-05
10	Laying hens in compact battery cages	3,22E-05	1,23E-05
11.2	Laying hens in free range with litter floor (partly litter floor, partly slatted)	1,34E-04	5,12E-05
12.2	Broilers in free range with litter floor	5,74E-05	2,20E-05
13	Laying hens in free range with grating floor (aviary system)	6,54E-03	1,64E-03
14	Parent broilers in free range with grating floor	1,20E-03	3,01E-04
15	Parent broilers in rearing with grating floor	1,87E-01	4,67E-02
16.2	Turkeys in free range with litter floor	3,43E-02	8,59E-03
17.2	Ducks in free range with litter floor	2,52E-01	6,31E-02
18.2	Geese in free range with litter floor	4,63E-02	1,16E-02

Summary table on secondary poisoning via the terrestrial food chain			
Scenario 2- via Slurry/manure		$PEC_{oral,\ earthworm\text{-}eating\ predator}$	
		Grass	***Arable***
1	Dairy cows	1,46E-03	5,60E-04
2	Beef cattle	6,64E-04	2,54E-04
3	Veal calves	4,49E-03	1,72E-03
4	Sows, in individual pens	2,74E-03	1,05E-03
5	Sows in groups	3,48E-03	1,33E-03
6	Fattening pigs	2,25E-03	8,62E-04
7	Laying hens in battery cages without treatment	7,61E-04	2,92E-04
8.1	Laying hens in battery cages with aeration (belt drying)	8,50E-04	3,25E-04
9	Laying hens in batters cages with forced drying (deep pit, high rise)	1,36E-03	5,21E-04
10	Laying hens in compact battery cages	8,50E-04	3,25E-04
11.2	Laying hens in free range with litter floor (partly litter floor, partly slatted)	3,53E-03	1,35E-03
12.2	Broilers in free range with litter floor	1,52E-03	5,81E-04
13	Laying hens in free range with grating floor (aviary system)	1,58E-03	6,04E-04

Summary table on secondary poisoning via the terrestrial food chain			
Scenario 2- via Slurry/manure		$PEC_{oral,\ earthworm\text{-}eating\ predator}$	
		Grass	***Arable***
14	Parent broilers in free range with grating floor	8,29E-04	3,17E-04
15	Parent broilers in rearing with grating floor	1,77E-03	6,78E-04
16.2	Turkeys in free range with litter floor	2,89E-03	1,11E-03
17.2	Ducks in free range with litter floor	3,07E-03	1,18E-03
18.2	Geese in free range with litter floor	2,17E-03	8,32E-04

Summary table on secondary poisoning via the aquatic food chain		
Scenario 2- via STP		$PEC_{oral,\ fish\text{-}eating\ predator}$
8.2	Laying hens in battery cages with aeration (belt drying)	3,01E-02
11.1	Laying hens in free range with litter floor (partly litter floor, partly slatted)	5,62E-02
12.1	Broilers in free range with litter floor	4,40E-02
16.1	Turkeys in free range with litter floor	1,30E-01
17.1	Ducks in free range with litter floor	7,83E-02
18.1	Geese in free range with litter floor	9,75E-02

Summary table on secondary poisoning via the terrestrial food chain		
Scenario 2-via STP		$PEC_{oral,\ earthworm\text{-}eating\ predator}$
8.2	Laying hens in battery cages with aeration (belt drying)	1,39E-02
11.1	Laying hens in free range with litter floor (partly litter floor, partly slatted)	2,60E-02
12.1	Broilers in free range with litter floor	2,04E-02
16.1	Turkeys in free range with litter floor	6,00E-02
17.1	Ducks in free range with litter floor	3,63E-02
18.1	Geese in free range with litter floor	4,51E-02

2.2.8.3 Risk characterisation

The compartison of the PEC estimated with the PNEC values is done with the Risk Characterization Ratio (RCR), the ratio of the PEC/PNEC.

The PNEC values can either be estimated with the toxicity data for each active substance or directly be taken from the Product Assessment Report.

For the groundwater PNEC the limit is stablished by the Drinking Water Directive to 0.1 µg/l.

For primary and secondary poisoning, the PNEC values are extrapolated from toxicity tests on bird and mammals. For that reason, the PEC values for fish and earthworms have to be considered as food intake (mg/kg_{food}).

Summary table on PNEC values		
$PNEC_{STP}$	100	mg/l
$PNEC_{water}$	$4.8x10^{-6}$	mg/l
$PNED_{sed}$	$9.78x10^{-4}$	mg/kg_{wwt}
$PNEC_{soil}$	0.882	mg/kg
$PNEC_{GW}$	0.1	µg/l
$PNEC_{bird}$	5	mg/kg_{food}
$PNEC_{mammal}$	2.67	mg/kg_{food}

If PEC/PNEC is greater than 1, the risk is considered unacceptable.

Scenario 1: Indoor surface treatment in private houses and commercial buildings, 1-2 applications/year

Summary table on calculated PEC/PNEC values for Scenario 1		
Compartment		**Surface treatment PEC/PNEC**
Aquatic	STP	3,23E-07
	Surface water	6,05E-01
	Sediment	**4,93E+00**
Terrestrial	Soil	5,27E-04
	Groundwater	3,45E-04

Values on red bold are considered above the trigger value 1.

Conclusion: When the product is applied by professional users in private houses and commercial buildings 1-2 times per year as a surface treatment, unacceptable risk to sediment in the aquatic compartment is predicted for both flying and crawling insects.

On the basis of the efficacy evaluation and taking into account the life habits of the insects, the application of the product could restricted to locations not regularly cleaned, i.e. behind or under the fridge, under the oven or the water heater, for crawling insects, and when this happens the risk in the aquatic compartment is reduced to acceptable levels. No risks to other environmental compartments are predicted. Therefore, authorisation of ZENITRIN

against crawling insects as a surface treatment indoors may be granted subject to the following conditions:

The following instructions must be included on the label:

Do not use the product more than 2 times per year.

The following risk mitigation measure must be implemented:

Only for treat maximum 5.9 and 27 m2 of surface in household and commercial building.

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 crawling insects.

Scenario 2: Indoor crack and crevice treatment in livestock facilities, 4 applications/year

For Scenario 2, the risk characterisation will be done separatedly for premises where emissions to the environment are done through STP and for direct emissions to manure.

Calculation of emissions in animal housing premises where direct emissions to manure are envisaged

For direct emissions to manure the risk characterisation is similar to the other evaluations. In this case, only soil, groundwater, surface water and sediment are reviewed for eighteen different scenarios:

1- Dairy cows (Slurry)
2- Beef cattle (Slurry)
3- Veal calves (Slurry)
4- Sows in individual pens (Slurry)
5- Sows in groups (Slurry)
6- Fatterning pigs (Slurry)
7- Laying hens in battery cages without treatment (Slurry)
8.1- Laying hens in battery cages with aeration (belt drying) (Slurry)
9- Laying hens in battery cages with forced drying (Manure)
10- Laying hens in compact battery cages (Slurry)
11.2- Laying hens in free range with litter floor (Manure)
12.2- Broilers in free range with litter floor (Manure)
13- Laying hens in free range with grating floor (Slurry)
14- Parent broilers in free range with grating floor (Slurry)
15- Parent broilers in rearing with grating floor (Slurry)
16.2- Turkeys in free range with litter floor (Manure)
17.2- Ducks in free range with litter floor (Manure)
18.2- Geese in free range with litter floor (Manure)

Each scenario will be evaluated for two different kinds of soil, arable and grassland, and 4 applications per year (as stated previously).

Scenario 2 (Animal housing- Emission pathway via manure / slurry)														
Type of housing	PIECsoil after 10 year consecutive application, degradation in soil included TAB ENV 212):				PECgroundwater (ESD Addendum, eq. 40, TAB ENV 212):		PEC surface water ESD Addendum, eq. 41, TAB ENV 212):				PEC sediment (Eq. 53 BPR Guidance, v. 2.0-Oct. 2017):			
	based on nitrogen immission standards													
	PIEC (mg/kg wwt)		Risk Ratio Soil		PEC_{gw} (µg/l)		PEC_{sw} (mg/l)		Risk Ratio Surfacewater		PEC_{sed} (mg/kg dwt)		Risk Ratio Sediment	
	Grass	Arable	Grass	Arable	Grass	Arable	Grass	Arable	Grass	Arable	Grass	Arable	Grass	Arable
1	8,99E-04	3,44E-04	1,02E-03	3,90E-04	4,02E-04	1,54E-04	6,09E-08	2,33E-08	1,27E-02	4,86E-03	1,01E-04	3,87E-05	1,03E-01	3,96E-02
2	4,08E-04	1,56E-04	4,63E-04	1,77E-04	1,83E-04	6,99E-05	2,76E-08	1,06E-08	5,76E-03	2,20E-03	4,59E-05	1,76E-05	4,69E-02	1,80E-02
3	2,76E-03	1,06E-03	3,13E-03	1,20E-03	1,23E-03	4,73E-04	1,87E-07	7,15E-08	3,89E-02	1,49E-02	3,10E-04	1,19E-04	3,17E-01	1,21E-01
4	1,68E-03	6,44E-04	1,91E-03	7,30E-04	7,52E-04	2,88E-04	1,14E-07	4,36E-08	2,37E-02	9,08E-03	1,89E-04	7,24E-05	1,93E-01	7,40E-02
5	2,14E-03	8,19E-04	2,43E-03	9,28E-04	9,57E-04	3,66E-04	1,45E-07	5,55E-08	3,02E-02	1,16E-02	2,41E-04	9,21E-05	2,46E-01	9,42E-02
6	1,38E-03	5,30E-04	1,57E-03	6,01E-04	6,19E-04	2,37E-04	9,37E-08	3,59E-08	1,95E-02	7,48E-03	1,56E-04	5,96E-05	1,59E-01	6,09E-02
7	4,68E-04	1,79E-04	5,30E-04	2,03E-04	2,09E-04	8,02E-05	3,17E-08	1,21E-08	6,60E-03	2,53E-03	5,26E-05	2,01E-05	5,38E-02	2,06E-02
8.1	5,22E-04	2,00E-04	5,92E-04	2,27E-04	2,34E-04	8,95E-05	3,54E-08	1,35E-08	7,37E-03	2,82E-03	5,87E-05	2,25E-05	6,00E-02	2,30E-02
9	8,35E-04	3,20E-04	9,47E-04	3,63E-04	3,74E-04	1,43E-04	5,66E-08	2,17E-08	1,18E-02	4,51E-03	9,40E-05	3,60E-05	9,61E-02	3,68E-02
10	5,22E-04	2,00E-04	5,92E-04	2,27E-04	2,34E-04	8,95E-05	3,54E-08	1,35E-08	7,37E-03	2,82E-03	5,87E-05	2,25E-05	6,00E-02	2,30E-02
11.2	2,17E-03	8,31E-04	2,46E-03	9,42E-04	9,71E-04	3,72E-04	1,47E-07	5,63E-08	3,06E-02	1,17E-02	2,44E-04	9,35E-05	2,50E-01	9,56E-02
12.2	9,32E-04	3,57E-04	1,06E-03	4,04E-04	4,17E-04	1,60E-04	6,31E-08	2,42E-08	1,31E-02	5,03E-03	1,05E-04	4,01E-05	1,07E-01	4,10E-02
13	9,70E-04	3,71E-04	1,10E-03	4,21E-04	4,34E-04	1,66E-04	6,57E-08	2,52E-08	1,37E-02	5,24E-03	1,09E-04	4,18E-05	1,12E-01	4,27E-02
14	5,09E-04	1,95E-04	5,77E-04	2,21E-04	2,28E-04	8,72E-05	3,45E-08	1,32E-08	7,18E-03	2,75E-03	5,73E-05	2,19E-05	5,86E-02	2,24E-02
15	1,09E-03	4,16E-04	1,23E-03	4,72E-04	4,87E-04	1,86E-04	7,37E-08	2,82E-08	1,53E-02	5,88E-03	1,22E-04	4,68E-05	1,25E-01	4,79E-02
16.2	1,78E-03	6,80E-04	2,01E-03	7,71E-04	7,95E-04	3,04E-04	1,20E-07	4,61E-08	2,51E-02	9,60E-03	2,00E-04	7,65E-05	2,04E-01	7,82E-02

Scenario 2 (Animal housing- Emission pathway via manure / slurry)														
Type of housing	**PIECsoil after 10 year consecutive application, degradation in soil included TAB ENV 212):**				**PECgroundwater (ESD Addendum, eq. 40, TAB ENV 212):**		**PEC surface water ESD Addendum, eq. 41, TAB ENV 212):**				**PEC sediment (Eq. 53 BPR Guidance, v. 2.0-Oct. 2017):**			
	based on nitrogen immission standards													
	PIEC (mg/kg wwt)		**Risk Ratio Soil**		**PEC_{gw} (µg/l)**		**PEC_{sw} (mg/l)**		**Risk Ratio Surfacewater**		**PEC_{sed} (mg/kg dwt)**		**Risk Ratio Sediment**	
	Grass	**Arable**	**Grass**	**Arable**	**Grass**	**Arable**	**Grass**	**Arable**	**Grass**	**Arable**	**Grass**	**Arable**	**Grass**	**Arable**
17.2	1,89E-03	7,23E-04	2,14E-03	8,19E-04	8,44E-04	3,23E-04	1,28E-07	4,89E-08	2,66E-02	1,02E-02	2,12E-04	8,13E-05	2,17E-01	8,31E-02
18.2	1,34E-03	5,11E-04	1,51E-03	5,80E-04	5,98E-04	2,29E-04	9,05E-08	3,46E-08	1,88E-02	7,22E-03	1,50E-04	5,75E-05	1,54E-01	5,88E-02

Conclusion:

As the PEC/ PNEC values are less than 1, an acceptable level of risk to all the compartments is predicted for the scenario 2 where the emission pathway is via manure or slurry for all the types of animal housing.

Calculation of emissions in animal housing premises where emissions to the environment through STP or WWTP systems are envisaged

For emissions through STP or WWTP systems the risk characterisation is done as for Scenario 1. In this case, eight different scenarios are reviewed:

8.2- Laying hens in battery cages with aeration (belt drying) (Wastewater)
11.1- Laying hens in free range with litter floor (Wastewater)
12.1- Broilers in free range with litter floor (Wastewater)
16.1- Turkeys in free range with litter floor (Wastewater)
17.1- Ducks in free range with litter floor (Wastewater)
18.1- Geese in free range with litter floor (Wastewater)

Scenario 2 (Animal housing- Emission pathway via STP)									
Type of housing	**PEC STP**	**Risk ratio STP**	**PECsw**	**Risk ratio SW**	**PECsed**	**Risk ratio sed**	**PECsoil**	**Risk ratio soil**	**PECgw**
	mg.l-1		**mg.l-1**		**mg.kgdt**		**mg.kg-1**		**µg.l-1**
8.2	3,68E-04	3,68E-06	3,30E-05	**6,88E+00**	5,48E-02	**5,61E+01**	5,29E-03	5,99E-03	3,92E-03
11.1	6,88E-04	6,88E-06	6,18E-05	**1,29E+01**	1,03E-01	**1,05E+02**	9,89E-03	1,12E-02	7,34E-03
12.1	5,39E-04	5,39E-06	4,84E-05	**1,01E+01**	8,03E-02	**8,21E+01**	7,74E-03	8,78E-03	5,75E-03
16.1	1,59E-03	1,59E-05	1,42E-04	**2,97E+01**	2,37E-01	**2,42E+02**	2,28E-02	2,59E-02	1,69E-02
17.1	9,59E-04	9,59E-06	8,60E-05	**1,79E+01**	1,43E-01	**1,46E+02**	1,38E-02	1,56E-02	1,02E-02
18.1	1,19E-03	1,19E-05	1,07E-04	**2,23E+01**	1,78E-01	**1,82E+02**	1,71E-02	1,94E-02	1,27E-02

Values on red bold are considered above the trigger value 1.

Conclusion:

The assessment of scenario 2 where emissions through STP or WWTP systems are envisaged, showed unacceptable risks for surface water and sediment compartment. Therefore the following risk mitigation measure must appear on the label restricting the application:

1. Do not use in animal housings where exposure to a STP and/ or direct emission to surface water cannot be prevented

Primary and secondary poisoning

Primary poisoning

No primary poisoning is foreseeable according to the intended use pattern.

Secondary poisoning for Scenario 1

Summary table on secondary poisoning via the aquatic food chain		
Scenario 1	**PEC/PNECbirds**	**PEC/PNECmammals**
Surface	5,28E-04	9,89E-04
Summary table on secondary poisoning via the aquatic food chain		
Scenario 1	**PEC/PNECbirds**	**PEC/PNECmammals**
Surface	2,45E-04	4,58E-04

Conclusion:

In scenario 1, secondary poisoning of aquatic and terrestrial organisms does not result in a risk. The PEC/PNEC ratios are all below 1.

Secondary poisoning for Scenario 2

Summary table on secondary poisoning via the aquatic food chain					
Scenario 2- Slurry/manure		**PEC/PNECbirds**		**PEC/PNECmammals**	
		Grass	**Arable**	**Grass**	**Arable**
1	Dairy cows	1,11E-05	4,24E-06	2,08E-05	7,95E-06
2	Beef cattle	5,03E-06	1,93E-06	9,42E-06	3,61E-06
3	Veal calves	3,40E-05	1,30E-05	6,37E-05	2,44E-05
4	Sows, in individual pens	2,07E-05	7,94E-06	3,88E-05	1,49E-05
5	Sows in groups	2,64E-05	1,01E-05	4,94E-05	1,89E-05
6	Fattening pigs	1,71E-05	6,53E-06	3,19E-05	1,22E-05
7	Laying hens in battery cages without treatment	5,77E-06	2,21E-06	1,08E-05	4,14E-06
8.1	Laying hens in battery cages with aeration (belt drying)	6,44E-06	2,46E-06	1,21E-05	4,62E-06
9	Laying hens in batters cages with forced drying (deep pit, high rise)	1,03E-05	3,94E-06	1,93E-05	7,38E-06
10	Laying hens in compact battery cages	6,44E-06	2,46E-06	1,21E-05	4,62E-06
11.2	Laying hens in free range with litter floor (partly litter floor, partly slatted)	2,68E-05	1,02E-05	5,01E-05	1,92E-05
12.2	Broilers in free range with litter floor	1,15E-05	4,40E-06	2,15E-05	8,24E-06
13	Laying hens in free range with grating floor (aviary system)	1,31E-03	3,28E-04	2,45E-03	6,13E-04
14	Parent broilers in free range with grating floor	2,40E-04	6,02E-05	4,50E-04	1,13E-04
15	Parent broilers in rearing with grating floor	3,73E-02	9,35E-03	6,99E-02	1,75E-02
16.2	Turkeys in free range with litter floor	6,85E-03	1,72E-03	1,28E-02	3,22E-03
17.2	Ducks in free range with litter floor	5,04E-02	1,26E-02	9,44E-02	2,36E-02

18.2	Geese in free range with litter floor	9,26E-03	2,32E-03	1,73E-02	4,34E-03

Summary table on secondary poisoning via the terrestrial food chain					
Scenario 2- Slurry/manure		PEC/PNECbirds		PEC/PNECmammals	
		Grass	Arable	Grass	Arable
1	Dairy cows	2,93E-04	1,12E-04	5,48E-04	2,10E-04
2	Beef cattle	1,33E-04	5,08E-05	2,49E-04	9,52E-05
3	Veal calves	8,98E-04	3,44E-04	1,68E-03	6,44E-04
4	Sows, in individual pens	5,47E-04	2,10E-04	1,02E-03	3,92E-04
5	Sows in groups	6,96E-04	2,67E-04	1,30E-03	4,99E-04
6	Fattening pigs	4,50E-04	1,72E-04	8,43E-04	3,23E-04
7	Laying hens in battery cages without treatment	1,52E-04	5,83E-05	2,85E-04	1,09E-04
8.1	Laying hens in battery cages with aeration (belt drying)	1,70E-04	6,51E-05	3,18E-04	1,22E-04
9	Laying hens in batters cages with forced drying (deep pit, high rise)	2,72E-04	1,04E-04	5,09E-04	1,95E-04
10	Laying hens in compact battery cages	1,70E-04	6,51E-05	3,18E-04	1,22E-04
11.2	Laying hens in free range with litter floor (partly litter floor, partly slatted)	7,07E-04	2,71E-04	1,32E-03	5,07E-04
12.2	Broilers in free range with litter floor	3,03E-04	1,16E-04	5,68E-04	2,17E-04
13	Laying hens in free range with grating floor (aviary system)	3,16E-04	1,21E-04	5,91E-04	2,26E-04
14	Parent broilers in free range with grating floor	1,66E-04	6,35E-05	3,10E-04	1,19E-04
15	Parent broilers in rearing with grating floor	3,54E-04	1,36E-04	6,63E-04	2,54E-04
16.2	Turkeys in free range with litter floor	5,78E-04	2,21E-04	1,08E-03	4,15E-04
17.2	Ducks in free range with litter floor	6,14E-04	2,35E-04	1,15E-03	4,40E-04
18.2	Geese in free range with litter floor	4,35E-04	1,66E-04	8,14E-04	3,12E-04

Summary table on secondary poisoning via the aquatic food chain			
Scenario 2-STP		PEC/PNECbirds	PEC/PNECmammals
8	Laying hens in battery cages with aeration (belt drying)	6,01E-03	1,13E-02
11	Laying hens in free range with litter floor (partly litter floor, partly slatted)	1,12E-02	2,11E-02
12	Broilers in free range with litter floor	8,81E-03	1,65E-02
16	Turkeys in free range with litter floor	2,59E-02	4,86E-02
17	Ducks in free range with litter floor	1,57E-02	2,93E-02
18	Geese in free range with litter floor	1,95E-02	3,65E-02

Summary table on secondary poisoning via the terrestrial food chain			
Scenario 2-STP		PEC/PNECbirds	PEC/PNECmammals
8	Laying hens in battery cages with aeration (belt drying)	2,78E-03	5,21E-03
11	Laying hens in free range with litter floor (partly litter floor, partly slatted)	5,20E-03	9,75E-03
12	Broilers in free range with litter floor	4,08E-03	7,63E-03

Summary table on secondary poisoning via the terrestrial food chain			
Scenario 2-STP		**PEC/PNECbirds**	**PEC/PNECmammals**
16	Turkeys in free range with litter floor	1,20E-02	2,25E-02
17	Ducks in free range with litter floor	7,25E-03	1,36E-02
18	Geese in free range with litter floor	9,03E-03	1,69E-02

Conclusion:

In scenario 2, the assessment for secondary poisoning of aquatic and terrestrial organisms does not result in any risk. The PEC/PNEC ratios are far below 1 for both uses in all animal (sub-)categories.

Mixture toxicity

Not relevant. The product is not intended to be used in combination with other mixtures or biocidal products.

Aggregated exposure (combined for relevant emmission sources)

Not applicable as the product is only intended to be used as PT18.

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

Scenario 1:

The assessment of scenario 1 (indoor use, professional, flying and crawling insects) showed an unacceptable risk for sediment compartment.

However, this risk can be reduced to acceptable levels or prevented, only for crawling insects, by imposing the following conditios on the label:

Instrucction for use:

Do not use the product more than 2 times per year.

Risk mitigation measures:

Only for treat maximum 5.9 and 27 m2 of surface in household and commercial building.

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 crawling insects.

Therefore, these uses for crawling insects can be considered as acceptable.

Scenario 2:

Based on the calculated PEC/ PNEC ratios, acceptable level of risk to the environment is predicted for the application of the product in livestock and breeding premises except for those connected to STP or WWTP systems, and thus the risk mitigation measure must appear on the label restricting the application:

1. Do not use in animal housings where exposure to a STP and/ or direct emission to surface water cannot be prevented.

2.2.9 Measures to protect man, animals and the environment

See risk mitigation measures for authorized uses

2.2.10 Assessment of a combination of biocidal products

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

2.2.11 Comparative assessment

Not relevant.

3 ANNEXES

3.1 List of studies for the biocidal product

Author	Year	Title	Report no.	Owner company
[redacted]	[redacted]	Determination of density of Alpha-cypermethrin 6% EC	6469/2019	Bioscience research foundation
[redacted]	[redacted]	Accelerated storage stability of Alpha-cypermethrin 6% EC	6475/2019	Bioscience research foundation
[redacted]	[redacted]	Low temperature stability (0°C) of Alpha-cypermethrin 6% EC	6474/2019	Bioscience research foundation
[redacted]	[redacted]	Determination of persistent foam Alpha-cypermethrin 6% EC	6468/2019	Bioscience research foundation
[redacted]	[redacted]	Determination of surface tension of Alpha-cypermethrin 6% EC	6470/2019	Bioscience research foundation
[redacted]	[redacted]	Determination of viscosity of Alpha-cypermethrin 6% EC	6473/2019	Bioscience research foundation
[redacted]	[redacted]	Determination of explosive properties of Alpha-cypermethrin 6% EC	6467/2019	Bioscience research foundation
[redacted]	[redacted]	Test for determining the corrosive properties to metals	BC-22/22	Lukasiewicz Research Network
[redacted]	[redacted]	Determination of flash point of Alpha-cypermethrin 6% EC	6466/2019	Bioscience research foundation
[redacted]	[redacted]	Determination of chemical oxidizing properties of Alpha-cypermethrin 6% EC	6471/2019	Bioscience research foundation
[redacted]	[redacted]	Determination of auto-ignition temperature of Alpha-cypermethrin 6% EC	6472/2019	Bioscience research foundation
[redacted]	[redacted]	Laboratory trial to determine the efficacy of an alphacypermethrin 6% SC formulation against waso, ticks and poultry red mites.	Study No. 2008-ALFACECT-LAB/1015	Sharda CropChem Ltd.
[redacted]	[redacted]	Simulated use trial of alphacypermethrin 6% SC against various pests.	Trial No. 2008-ALFASECT-SIM/0515	Sharda CropChem Ltd.
[redacted]	[redacted]	Field trials to determine de efficacy of Alphacypermethrin 6% SC against four species.	Study Code 14/300	I2L Research Ltd.

[redacted]	[redacted]	Efficacy of alphacypermethrin 6% SCformulation against litter beetle (darkling beetle) under field conditions.	Trial No. 2008-ALFASECT-LB-FIELD/1015	Sharda CropChem Ltd.
[redacted]	[redacted]	Efficacy of alphacypermethrin 6% SC formulation against stable flies under field conditions.	Trial No. 2008-ALFASECT-FLY-FIELD/1015	Sharda CropChem Ltd.
[redacted]	[redacted]	Field trial of the efficacy of an insecticidal residual treatment to control oriental cockroaches.	Study No. 2008-ALFASEC-CO-FIELD/1015	Sharda CropChem Ltd.
[redacted]	[redacted]	Efficacy assessment of two products (Alphacypermethrin 6% SC and Alphacypermrthrin 6% EC) against cockroaches.	Study Code: 368IAMG4667/R0	Ross Lifescience Pvt. Ltd.
[redacted]	[redacted]	Efficacy assessment of two products (Alphacypermethrin 6% SC and Alphacypermethrin 6% EC) against Litter beetle, *Alphitobius diaperinus.*	Study Code: 368IAMG4670/R0	Ross Lifesciences Pvt. Ltd.
[redacted]	[redacted]	Efficacy assessment of two products (Alphacypermethrin 6% SC and alphacypermethrin 6% EC) against Mosquito *Culex quinquefasciatus.*	Study Code: 368IAMG4669/R0	Ross Lifescience Pvt. Ltd.
[redacted]	[redacted]	Efficacy assessment of two products (Alphacypermethrin 6% SC and alphacypermethrin 6% EC) against Black ants, *Lasius niger*.	Study Code 368IAMG4668/R0	Ross Lifescience Pvt. Ltd.
[redacted]	[redacted]	Bioefficacy of alphacypermethrin 6% EC against Stable fly (*Stomoxys calcitrans*) in field condition.	Study Nº 10151/2021	Bioscience research Foundation
[redacted]	[redacted]	Bioefficacy of alphacypermethrin 6% EC Stable fly in field condition.	Study Nº 11925/2022	Bioscience research Foundation

3.2 Output tables from exposure assessment tools


Zenitrin EC Human Exposure.xlsx


Zenitrin EC Dietary_exposure.xls

3.3 New information on the active substance

No new data has been submitted.

3.4 Residue behaviour

No new data has been submitted.

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[2]

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

3.6 Confidential annex

See confidential annex document.

3.7 Other

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