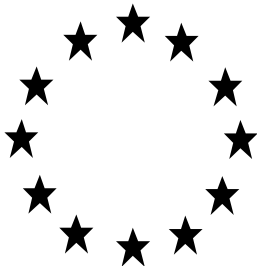
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



SANITERPEN INSECTICIDE DK

Product type 18

Deltamethrin

BC-CY001361-35

France

September 2016

Contents

1 GENERAL INFORMATION ABOUT THE PRODUCT APPLICATION

1.1 Applicant

Company Name:	ACTION PIN
Address:	Z.I. de Cazalieu 1078, route André Dupuy BP 30
City:	Castets
Postal Code:	40 260
Country:	France
Telephone:	+33.5.5855.0700
Fax:	+33.5.5855.0707
E-mail address:	Antoine.Andrieux@action-pin.fr

1.1.1 Person authorised for communication on behalf of the applicant

Name:	Antoine ANDRIEUX, Nicolas HUGUET
Function:	
Address:	Z.I. de Cazalieu – CS 60030
City:	Castets
Postal Code:	40 260
Country:	France
Telephone:	+33.5.5855.0704
Fax:	+33.5.5855.0707
E-mail address:	Antoine.Andrieux@action-pin.fr Nicolas.huguet@action-pin.fr

1.2 Proposed authorisation holder

Company Name:	ACTION PIN
Address:	Z.I. de Cazalieu 1078, route André Dupuy BP 30
City:	Castets
Postal Code:	40 260
Country:	France
Telephone:	+33.5.5855.0700
Fax:	+33.5.5855.0707
E-mail address:	Antoine.Andrieux@action-pin.fr
Letter of appointment for the applicant to represent the authorisation holder	no

provided (yes/no):	

1.3 Information about the product application

Application received:	27/09/2013
Application reported complete:	23/01/2014
Type of application:	Application for national authorisation (NA-APP)
Further information:	-

1.4 Information about the biocidal product

1.4.1 General information

Trade name:	SANITERPEN INSECTICIDE DK
Manufacturer's development code number(s), if appropriate:	Development name: Saniterpen 1 Development code: 27152-B1
Product type:	18
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	Deltamethrin technical: 2 % Deltamethrin pure: 0.21 %
Formulation type:	Emulsifiable concentrate (EC)
Ready to use product (yes/no):	No
Is the product the very same (identity and content) to another product already authorised under the regime of Directive 98/8/EC (yes/no); **If yes: authorisation/registration no. and product name:** **or** **Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to Directive 98/8/EC (yes/no):**	No No

1.4.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	Insecticide and acaricide for animals' houses and shelters. IV.1 Indoor use IV.1.3.4 Animal houses/shelters The product is used indoors, in empty animals' houses and shelters (animals not intented for human consumption).
Target organisms / stages:	Scientific name: *Dermanyssidae*: *Dermanyssus gallinae*, common name: poultry red mite, development stage: all. Scientific name: *Culicidae*: *Culex pipiens*, *Aedes aegypti*, common name: mosquitoes, development stage: adults.

	Scientific name: *Muscidae*: *Musca domestica*, common name: house fly, development stage: adults. Scientific name: *Muscidae*: *Stomoxys calcitrans*, common name: stable fly, development stage: adults. Scientific name: *Ceratopogonidae*: *Phlebotomus* sp., common name: sandflies, development stage: adults. Scientific name: *Pulicidae*:, common name: fleas, development stage: larvae (and adults).
Category of users:	Professional
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	**Method of application:** spraying **Detailed description of the method:** The product is sprayed on the ground, walls, ceiling, and around windows and doors to control flies and mosquitoes, or on walls and floor to control fleas or red mites. The product is designed to be first diluted in water in a knapsack sprayer (10% v/v) then it is sprayed on relevant surfaces using the handheld trigger of the sprayer on the surfaces. After application the surfaces shall not be cleaned as the product is able to control the insect infestation for a 3-months period. Cleaning should only be done before the next application. Dry cleaning shall be considered and dusts shall be collected and treated as a waste. Relevant dose is 5 mL of un-diluted product for 1 m^2. It means 50 mL of diluted product for 1 m^2. Surface to be treated must be calculated before using the product. **The application rate is** 50 mL/m² **for the dilution** 10% v/v**.** **Number and timing of application:** One application is sufficient to control the populations for a 3-month period. The product can be applied maximum 3 times a year. Maximum 350 m^2 of surface can be treated per application. If the infestation requires a treatment for a surface above this limit, another option shall be considered.
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/feedingstuff (yes/no)	No
Proposed Label:	Refer to doc III-B12
Use Restrictions:	Do not apply more than 3 times per year. Maximum 350 m^2 of surface can be treated per application. If the infestation requires a treatment for a surface above this limit, another option shall be considered. After application the surfaces shall not be cleaned as the product is able to control the insect infestation for a 3-months period. Cleaning should only be done before the next application. Dry cleaning shall be considered and dusts shall be collected and treated as a waste. Housing of animals which are destinated to food consumption shall not be treated. The product only is designed to protect pets (animals not destinated to food consumption). The product shall not be used inside houses for human habitat.

For full details of the intended uses claimed by the applicant, please see annex 0a.

1.4.3 Information on active substance

Active substance chemical name:	Deltamethrin (S)-α-cyano-3-phenoxybenzyl (1R, 3R)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate
CAS No:	52918-63-5
EC No:	258-256-6
Purity (minimum, g/kg or g/l):	Deltamethrin technical :10.40 % (mixture) 98.5 % purity
Inclusion directive:	Commission Directive 2011/81/EU
Date of inclusion:	20/12/2011
Is the active substance equivalent to the active substance listed in Annex I to Directive 98/8/EC (yes/no):	Yes
Manufacturer of active substance(s) used in the biocidal product:	BAYER SAS, Environmental Science
Company Name:	SBM Formulation - Béziers
Address:	CS 621 ZI avenue Jean Foucault
City:	Béziers
Postal Code:	34535
Country:	France
Contact:	
Telephone:	
Fax:	
E-mail address;	

1.4.4 Information on the substance(s) of concern

The product contains no substance of concern.

1.5 Documentation

1.5.1 Data submitted in relation to product application

Identity, physico-chemical and analytical method data

Physico-chemical properties studies and analytical methods on the biocidal product SANITERPEN INSECTICIDE DK were provided by Action Pin.

Action Pin has access to physico-chemical properties studies and analytical methods on the active substance with a Letter of Access of Bayer.

Efficacy data

- Laboratory study according to CEB N°135[1] method with the product SANITERPEN INSECTICIDE DK on *Musca domestica* (house fly), *Culex pipiens* (mosquito), *Ctenocephalides felis* (cat flea) and *Demanyssus gallinae* (poultry red mite).
- Laboratory study according to internal method with the product SANITERPEN INSECTICIDE DK on Stomoxys calcitrans (stable fly).
- Laboratory study according to CEB n° 135 method with the product SANITERPEN INSECTICIDE DK on on *Musca domestica* (house fly) and *Aedes* aegypti (mosquito).
- Semi-field tests conducted in laboratory according to BSI 4172[2] with the product SANITERPEN INSECTICIDE DK on *Aedes aegypti, Culex pipiens* (mosquitoes) and *Ctenocephalides felis* (cat fleas).
- Field test conducted in breeding premises according to CEB N°107[3] method with the product SANITERPEN INSECTICIDE DK on *Musca domestica* (house fly).

Toxicology data

Studies on the product were submitted: acute oral and dermal studies, dermal and ocular irritation studies and skin sensitisation assays.

Residue data

No studies were provided.

Ecotoxicology data

Studies on the product were submitted: acute toxicity studies to Rainbow Trout and *Daphnia magna*.

1.5.2 Access to documentation

BAYER SAS, Environmental Science granted a letter of access to the active substance dossier (part A) to Action Pin for the product SANITERPEN INSECTICIDE DK.

Please refer to Annex 2 for the complete list of studies for which access has been granted.

2 SUMMARY OF THE PRODUCT ASSESSMENT

2.1 Identity related issues

The source of the active substance used in the biocidal product SANITERPEN INSECTICIDE DK is same as the the source used for Annex I inclusion to Directive 98/8/EC.

It has to be noted that the product SANITERPEN INSECTICIDE DK contains a substance (terpineol, CAS: 8000-41-7) that is listed on the annex I of the regulation (EU) 1451/2007[4] as an existing active substance, although it is presented as a solvent in the product SANITERPEN INSECTICIDE DK. No active substance dossier has been submitted to support the approval of this substance on the list of the active substances of the Union.

The laboratory study n°1948c/0615, 2015/11 was conducted with the products SANITERPEN INSECTICIDE DK PAE, (0.02 % w/w deltamethrin) and SANITERPEN INSECTICIDE DK PAE without deltamethrine. Based on the results, It can be concluded that the product without active substance presents no efficacy on its own at

[1] CEB n°135 method: « Efficacy trial method for acaricide / insecticide products intended for surface treatment of storage facilities, processing and marketing if industrial animal or vegetal products»
[2] BS 4172-2:1993 Hand-held pressurized aerosol dispensers against houseflies. Method for determination of insecticidal efficiency
[3] CEB n°107 method : « Efficacy trial method for insecticide products intended to control stable flies in breeding buildings »
4 Regulation of the European Comission of 4 December 2007 in the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98//8 EC of the European Parliament of the Council concerning the placing of biocidal products on the market.

the recommended application rate and that terpineol is a co-formulant that has no insecticide properties in this product. More details are presented at the section 2.5)

2.2 Classification, labelling and packaging

2.2.1 Harmonised classification of the active substance deltamethrin

Classification - Regulation (EC) 1272/2008	
Class of danger	Acute tox. 3* Aquatic acute 1 Aquatic chronic 1
Hazard statements	H331: Toxic if inhaled. H301: Toxic if swallowed. H400: Very toxic to aquatic life (M=1000000). H410: Very toxic to aquatic life with long lasting effects (M=1000000).

2.2.2 Classification of the biocidal product SANITERPEN INSECTICIDE DK

Classification - Regulation (EC) 1272/2008	
Class of danger	Eye Irrit.2 Skin Sens.1 Aquatic acute 1 Aquatic chronic 1
Hazard statements	H319: Causes serious eye irritation. H317:May cause an allergic skin reaction. H400: Very toxic to aquatic life. H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P261: Avoid breathing dust/fume/ gas/mist/vapours/spray. P264: Wash … thoroughly after handling. P272: Contaminated work clothing should not be allowed out of the workplace. P280: Wear protective gloves/protective clothing/eye protection/face protection. P302 + P352: IF ON SKIN: Wash with plenty of water/… P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. P333 + P313: If skin irritation or a rash occurs: Get medical advice/attention. P337 + P313: If eye irritation persists get medical advice/attention. P321: Specific treatment (see … on this label). P363: Wash contaminated clothing before reuse.

	P273: Avoid release to the environment P391: Collect spillage. P501: Dispose of this material and its container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.2.3 Labelling of the biocidal product

The proposed labelling according to the CLP regulation is:

Pictograms	
Signal words	Warning
Class of danger	Eye Irrit. 2 Skin Sens.1 Aquatic chronic 1
Hazard statements	H319: Causes serious eye irritation. H317:May cause an allergic skin reaction. H410: Very toxic to aquatic life with long lasting effects.
Precautionary statements	P261: Avoid breathing dust/fume/ gas/mist/vapours/spray. P264: Wash … thoroughly after handling. P272: Contaminated work clothing should not be allowed out of the workplace. P280: Wear protective gloves/protective clothing/eye protection/face protection. P302 + P352: IF ON SKIN: Wash with plenty of water/… P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. P333 + P313:If skin irritation or a rash occurs: Get medical advice/attention. P337 + P313: If eye irritation persists get medical advice/attention. P321: Specific treatment (see … on this label). P363: Wash contaminated clothing before reuse. P273: Avoid release to the environment. P391: Collect spillage. P501: Dispose of this material and its container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.2.4 Packaging of the biocidal product

The packagings of the biocidal product as claimed by the applicant are:

- 60 mL individual in Polyethylene terephthalate (PET) bags,
- 1 L PET bottles with polypropylene (PP) and aluminium closure system,
- 5 L fluorated High density polyethylene (HDPE) cans with PP and aluminium closure system (confirmatory data is required in post-authorisation)

2.3 Physico/chemical properties and analytical methods

2.3.1 Active ingredient

2.3.1.1 Identity, origin of active ingredient

The source of the active substance used in the biocidal product SANITERPEN INSECTICIDE DK is the same as the source used for Annex I inclusion to Directive 98/8/EC.

Manufacturer of the active substance:

Name:	**Bayer CropScience AG**
Address:	Alfred-Nobel Strasse 50
	40789 Monheim am Rhein
	Germany
Contact person:	Laurent Patty
Telephone:	+33 (0)472 85 46 85
Fax number:	+33 (0)472 85 47 75
E-mail address:	laurent.patty@bayercropscience.com

Manufacturing site: confidential data, please refer to confidential PAR.

2.3.1.2 Physico-chemical properties

Physico-chemical properties of the active substance Deltamethrin have already been evaluated at EU level and are presented in the Competent Authority Report (CAR, 2011). The applicant Action Pin has a letter of access to these data.

2.3.1.3 Analytical method for determination of active ingredient and impurities in the technical active ingredient

Analytical method(s) for the determination of pure active substance Deltamethrin in the technical active substance as manufactured has already been performed and validated at EU level in the CAR (2011). The applicant Action Pin has a letter of access to these data.

Summary:

	Principle of method
Technical active substance as manufactured:	HPLC-UV and chiral HPLC-UV
Impurities in technical active substance:	-

2.3.1.4 Analytical method for determining relevant components and/or residues in different matrices

Analytical methods for the determination of residues of the active substance Deltamethrin in the different matrices have already been performed and validated at EU level in the CAR (2011). The applicant Action Pin has a letter of access to these data. Please refer to Annex 3 of this document.

Summary:

Soil (principle of method and LOQ)	LC-MS/MS using 1 transition **LOQ 0.1 µg/kg**
Air (principle of method and LOQ)	GC-ECD for quantification and GC-MS for confirmation **LOQ 0.27 µg/m^3**
Water (principle of method and LOQ)	Drinking water GC-ECD for quantification and confirmation **LOQ 0.05 µg/L** LC-MS/MS using 1 transition **LOQ 5.9 ng/L** GC-ECD for quantification and GC-MS/MS for confirmation **LOQ 3 ng/L** Surface water GC-ECD for quantification and GC-MS/MS for confirmation **LOQ 3 ng/L**
Body fluids and tissues (principle of method and LOQ)	Tissues GC-ECD for quantification and confirmation **LOQ 0.02 mg/kg** for milk, eggs, meat, fat, liver and kidney Fluids GC-MS for quantification and confirmation **LOQ 200 µg/l** for whole blood GC-MS multi-method for pyrethroids for quantification **LOQ 20 ng/L** for whole blood
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Not required as the intended uses will not result in significant residues when the label instruction is followed. However two methods are provided which can be used in case of suspected contamination: GC-ECD for quantification **LOQ 0.02 mg/kg** for rice, flour, bread, meat, candy, butter, banana cream pie and lettuce LC-MS/MS **LOQ 0.01 mg/kg** for edible materials **LOQ 0.05 mg/kg** for non-edible materials for barley, broccoli, corn, melon, lettuce, olive, pepper, sugar beet, tobacco, tomato, wheat and zucchini
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	GC-ECD for quantification and confirmation **LOQ 0.02 mg/kg** for milk, eggs, meat, fat, liver and kidney

2.3.2 Biocidal product

2.3.2.1 Identity, composition of the biocidal product, packaging

The biocidal product is not the same as the one assessed for the inclusion of the active substance in Annex I of Directive 98/8/EC.

The identification of the biocidal product is given in the table below:

Trade Name	SANITERPEN INSECTICIDE DK	
Manufacturer's development code number	Development code: 27152-B1 Development name: Saniterpen 1	
Ingredient of preparation	Function	Content (% w/w)
Deltamethrin (CAS No.52918-63-5)	Active substance (pure)	0.2
Formulants	Details on the composition of the product are included in the Confidential Annex	
Physical state of preparation	Liquid	
Nature of the preparation	EC, Emulsifiable concentrate	

Manufacturer of the biocidal product:

Name:	**Action PIN**
Address:	Z.I. de Cazalieu 1078, route André Dupuy 40260 Castets France
Contact person:	Nicolas Huguet
Telephone:	+33 (0)558 55 07 00
E-mail address:	Nicolas.huguet@action-pin.fr

Plant location:

Address:	448 route de l'océan 40560 Vielle Saint Girons France
Contact person:	Antoine Andrieux
Telephone:	+33 (0)558 55 07 00
E-mail address:	antoine.andrieux@action-pin.fr

2.3.2.2 Physico-chemical properties

The tested product SANITERPEN INSECTICIDE DK is an Emulsifiable concentrate (EC).

The content of Deltamethrin in tested product is:

- 0.173 % w/w in the Batch 27152-B1/95002
- 0.188 % w/w in the Batch 27152-B1/12003

For spraying utilisation, biocidal product is diluted at 10 % v/v in water (50 mL of diluted product to treat 1 m²).

Table 1: Physico-chemical properties of the biocidal product

Properties	Method	Purity/ Specification	Results	Reference	Acceptable
B3 – Physical, chemical and technical properties					
B3.1 Appearance					
B3.1.1 – Physical state and nature **B3.1.2 – Colour** **B3.1.3 – Odour**	Visual examination Organoleptic determination	Batch 27152-B1/95002	Homogeneous slightly yellow and limpid solution	B3.1 – Da Costa C., Demangel B. 2010 Study No. 09-901011-002 GLP	**Acceptable**
		Batch 27152-B1/95002	Homogeneous coulourless to very slightly yellow and limpid liquid	B3.2 – Demangel B. 2011 Study No. 09-901011-003 GLP	**Acceptable**
		Batch 27152-B1/12003	A slightly yellow liquid with a strong terpenic odour	B3.3 – Demangel B. 2013 Study No. 13-901011-013 No GLP	**Acceptable**
B3.2 Acidity/alkalinity					
pH 1% dilution	CIPAC MT 75.3	Batch 27152-B1/95002	Test item at 1% w/v in standard water D : After 1 min pH value 5.48 at 20°C After 10 min pH value 6.08 at 20°C	B3.1 – Da Costa C., Demangel B. 2010 Study No. 09-901011-002 GLP	**Acceptable**
B3.3 Relative density and bulk, tap density					
Relative density	EC Method A3 OECD No. 109 method	Batch 27152-B1/95002	Pycnometric method: $D_{(21.8°C / 4.0°C)}$ = 0.947 ± 0.001	B3.4 – Da Costa C. 2009 Study No. 09-901011-001 GLP	**Acceptable**
B3.4 Storage stability, stability and shelf-life					
B3.4.1 Storage stability tests					
B3.4.1.1 – Accelerated storage study (2 weeks at 54°C)	CIPAC MT 46.3 Visual examination HPLC/UV method for deltamethrin CIPAC MT 75.3 CIPAC MT 41	Batch 27152-B1/95002	**Initial** / **After storage 14 days at 54 ±2 °C in glass flask** **Appearance**: Homogeneous slightly yellow and limpid solution. The aspect was considered to be stable after storage, no significant change of weight was observed. **A.s. content** deltamethrin: 0.173 % w/v / 0.170 % w/v	B3.1 – Da Costa C., Demangel B. 2010 Study No. 09-901011-002 GLP	**Acceptable** The product was considered stable after 14 days at 54°C in glass flask, in PE/EVOH and in PET flask. The HPLC-UV

Properties	Method	Purity/ Specification	Results			Reference	Acceptable
			pH 1% w/v after 1 min after 10 min	 5.48 at 20°C 6.08 at 20°C	 5.47 at 20°C 6.13 at 20°C		method, used for the determination of deltamethrin content was validated in this report (part 2.3.2.3). The emulsion tests performed at 2% are not relevant as only concentration of use deposited is 10%
			Dilution stability	**2 % v/v in CIPAC water D at 20°C**			
			At T0	Homogeneous white and opaque liquid	Homogeneous white and opaque liquid with a white foam ring (about 3 mL)		
			At T18h	White and opaque liquid with a more opaque white higher phase (about 3 mL)	Off-white and opaque liquid with a white and creamy higher phase (about 3 mL)		
	CIPAC MT 46.3 Visual examination CIPAC MT 36.3	Batch 27152-B1/12003		**Initial**	**After storage 14 days at 54 ±2 °C in PE/EVOH flask**	B3.5 –Demangel B. 2013b Study No. 13-901011-008 GLP	
			Appearance	slight yellow limpid liquid. The aspect was considered to be stable after storage, no significant change of weight was observed. The packaging material was considered to be stable.			
			Emulsion stability	**2 % v/v in CIPAC water A at 30°C**			
			After 30s After 30 min After 24h	Homogeneous Homogeneous 1 mL of white cream	Homogeneous Homogeneous Whitish cloudy liquid (0-10mL), liquid with 2 mL of cream (10-98mL) and white cream (98-100mL)		
			Re-emulsification After 30 min	Homogeneous Homogeneous	Homogeneous Homogeneous		
			Emulsion stability	**2 % v/v in CIPAC water D at 30°C**			

Properties	Method	Purity/ Specification	Results			Reference	Acceptable
			After 30s After 30 min After 24h	Homogeneous Homogeneous 1 mL of white foam	Homogeneous Homogeneous Oily ring on the top		
			Re-emulsification After 30 min	Homogeneous Homogeneous	Homogeneous Homogeneous		
	CIPAC MT 46.3 Visual examination CIPAC MT 36.3	Batch 14008		**Initial**	**After storage 14 days at 54 ±2 °C in PET flask**	B3.6 –Demangel B., Ricau H. 2014 Study No. 14-901011-017 GLP	
			Appearance	slight yellow limpid liquid. The aspect was considered to be stable after storage, no significant change of weight was observed. Even if the packaging inflated, the packaging material was considered to be stable.			
			Emulsion stability	**2 % v/v in CIPAC water A at 30°C**			
			After 30s After 30 min After 24h	Homogeneous Ring of white cream Ring of white cream	Homogeneous Ring of white cream 2 mL of white cream		
			Re-emulsification After 30 min	Homogeneous Homogeneous	Homogeneous Homogeneous		
			Emulsion stability	**2 % v/v in CIPAC water D at 30°C**			
			After 30s After 30 min After 24h	Homogeneous Ring of white cream 2 mL of white cream	Homogeneous Ring of white cream 2 mL of white cream		
			Re-emulsification After 30 min	Homogeneous Homogeneous	Homogeneous Homogeneous		

Properties	Method	Purity/ Specification	Results			Reference	Acceptable
			Emulsion stability	**10 % v/v in CIPAC water A at 30°C**			
			After 30s After 30 min After 24h	Homogeneous Ring of white cream 13 mL of white cream	Homogeneous Ring of white cream 16 mL of white cream		
			Re-emulsification After 30 min	Homogeneous Homogeneous	Homogeneous Homogeneous		
			Emulsion stability	**10 % v/v in CIPAC water D at 30°C**			
			After 30s After 30 min After 24h	Homogeneous Ring of white cream 8 mL of white cream / 1 mL of oil	Homogeneous Ring of white cream 6 mL of white cream / 2 mL of oil		
			Re-emulsification After 30 min	Homogeneous Homogeneous	Homogeneous Homogeneous		
			Persistent foaming	**10 % v/v in CIPAC water D at 20°C**			
			After 10s 1 min 3 min 12 min	0 mL 0 mL 0 mL 0 mL	4 mL 2 mL 0 mL 0 mL		
B3.4.1.2 – Ambient shelf life study	GIFAP No. 17 Visual examination HPLC/UV method for deltamethrin CIPAC MT 75.3 CIPAC MT 41	Batch 27152-B1/95002		**Initial**	**After storage 2 years at 20 ±2 °C in semi opaque white plastic flask**	B3.2 – Demangel B. 2011 Study No. 09-901011-003 GLP	**Acceptable** The product was considered stable after 2 years at 20°C in PE-EVOH flask. The HPLC-UV method, used for the determination of deltamethrin content
			Appearance	Homogeneous colourless to slightly yellow and limpid solution. The aspect was considered to be stable after storage, no significant change of weight was observed. The packaging material was considered to be stable.			

Properties	Method	Purity/ Specification	Results			Reference	Acceptable
			A.s. content deltamethrin	 0.173 % w/v	 0.173 % w/v		was validated in this report (part 2.3.2.3). The emulsion and dilutions tests performed at 2% are not relevant as only concentration of use deposited is 10%
			pH 1% w/v after 1 min after 10 min	 5.48 at 20°C 6.08 at 20°C	 5.15 at 20°C 5.16 at 20°C		
			Dilution stability	**2 % v/v in CIPAC water D at 20°C**			
			At T0	Homogeneous white and opaque liquid	Homogeneous white and opaque liquid solution		
			At T18h	White and opaque liquid with a more opaque white higher phase (about 3 mL)	White opaque liquid with about 2 mL of creamy white upper phase		
	GIFAP No. 17 HPLC/UV method for deltamethrin CIPAC MT 36.3	Batch 27152-B1/12003		**Initial**	**After storage 2 years at 20 ±2 °C in PE-EVOH flask**	B3.5 –Demangel B. 2013b Study No. 13-901011-008 GLP	
			A.s. content deltamethrin	 0.188 % w/v	 0.186 % w/v		
			Emulsion stability	**2 % v/v in CIPAC water A at 30°C**			
			After 30s After 30 min After 24h	Homogeneous Homogeneous 1 mL of white cream	Foam ring Foam ring 3 mL of cream at the top		
			Re-emulsification After 30 min	Homogeneous Homogeneous	3 mL of cream at the top 5 mL of cream at the top		
			Emulsion stability	**2 % v/v in CIPAC water D at 30°C**			
			After 30s After 30 min After 24h	Homogeneous Homogeneous 1 mL of white foam	Homogeneous Homogeneous 1 mL oil on the top		
			Re-	Homogeneous	Homogeneous		

Properties	Method	Purity/ Specification	Results	Reference	Acceptable
			emulsification / After 30 min / Homogeneous / 1 mL oil on the top		
B3.4.1.3 – Low temperatures stability test (liquids)	CIPAC MT 39.3	Batch 27152-B1/95002	At the start of the test, the test item was a homogeneous yellow and limpid liquid. After 7 days of cooling at 0 ±2 °C, no change was observed in the test item aspect.	B3.4 – Da Costa C. 2009 Study No. 09-901011-001 GLP	**Acceptable** The product was considered stable after 7 days at 0°C.
B3.4.2 Effects on content of the active substance and technical characteristics of the biocidal product					
B3.4.2.1 – Light	-	-	Not required as the biocidal product is packaged in light protectant container	-	**Acceptable**
B3.4.2.2 – Temperature and humidity	-	-		-	**Acceptable**
B3.4.2.3 – Reactivity towards container material	-	-		-	**Acceptable**
B3.5 Technical characteristics of the biocidal product					
B3.5.1 – Wettability	-	-	Not required as the product is emulsifiable concentrate (EC)	-	**Acceptable**
B3.5.2 – Suspensibility, spontaneity and dispersion stability	-	-	Not required as the product is emulsifiable concentrate (EC)	-	**Acceptable**
B3.5.3 – Wet sieve analysis and dry sieve test	-	-	Not required as the product is emulsifiable concentrate (EC)	-	**Acceptable**

Properties	Method	Purity/ Specification	Results	Reference	Acceptable
B3.5.4 – Emulsifiability, re-emulsifiability and emulsion stability	CIPAC MT 36.3	Batch 27152-B1/12003 Batch 27152-B1/15001	**In 2 % v/v in CIPAC water A at 30°C:** After 30s: Homogeneous white opaque liquid After 30 min: Homogeneous white opaque liquid After 24h: Homogeneous white opaque liquid with 2 mL of white creamy phase Re-emulsification (after 30s): Homogeneous white opaque liquid After 30 min: Homogeneous white opaque liquid **In 2 % v/v in CIPAC water D at 30°C:** After 30s: Homogeneous white opaque liquid After 30 min: Homogeneous white opaque liquid After 24h: Homogeneous white opaque liquid with 2 mL of white foam Re-emulsification (after 30s): Homogeneous white opaque liquid After 30 min: Homogeneous white opaque liquid	B3.5 –Demangel B. 2013b Study No. 13-901011-008 GLP	**Acceptable at 10% dilution (2% dilution is not in deposited concentration of use)**
	CIPAC MT 36.3	Batch 14008	**In 2 % v/v in CIPAC water A at 30°C:** After 30s: Homogeneous white opaque liquid After 30 min: Homogeneous white opaque liquid with a ring of white cream at the top After 24h: Homogeneous white opaque liquid with 2 mL of white cream at the top. The solution was white opaque fading to whitish cloudy at the bottom Re-emulsification (after 30s): Homogeneous white opaque liquid After 30 min: Homogeneous white opaque liquid **In 2 % v/v in CIPAC water D at 30°C:** After 30s: Homogeneous white opaque liquid After 30 min: Homogeneous white opaque liquid with a ring of white cream at the top After 24h: Homogeneous white opaque liquid with a ring of white cream at the top Re-emulsification (after 30s): Homogeneous white opaque liquid After 30 min: Homogeneous white opaque liquid **In 10 % v/v in CIPAC water A at 30°C:** After 30s: Homogeneous white opaque liquid After 30 min: Homogeneous white opaque liquid with a ring of	B3.6 –Demangel B., Ricau H. 2014 Study No. 14-901011-017 GLP	

Properties	Method	Purity/ Specification	Results	Reference	Acceptable
			white cream at the top After 24h: Homogeneous white opaque liquid with 13 mL of white cream at the top. The solution was white opaque fading to colourless cloudy at the bottom Re-emulsification (after 30s): Homogeneous white opaque liquid After 30 min: Homogeneous white opaque liquid **In 10 % v/v in CIPAC water D at 30°C:** After 30s: Homogeneous white opaque liquid After 30 min: Homogeneous white opaque liquid with a ring of white cream at the top After 24h: Homogeneous white opaque liquid with 8 mL of white cream under 1 mL of colourless oil at the top Re-emulsification (after 30s): Homogeneous white opaque liquid After 30 min: Homogeneous white opaque liquid		
B3.5.5 – Disintegration tima	-	-	Not required as the product is emulsifiable concentrate (EC)	-	**Acceptable**
B3.5.6 – Particle size distribution, content of dust/ fines attrition, friability	-	-	Not required as the product is emulsifiable concentrate (EC)	-	**Acceptable**
B3.5.7 – Persistent foaming	CIPAC MT 47.2	Batch 27152-B1/95002	**In 2 % v/v in CIPAC water D at 20°C:** After 10 s: 5 mL After 1 min: 4 mL After 3 min: 2.5 mL After 12 min: 1 mL	B3.4 – Da Costa C. 2009 Study No. 09-901011-001 GLP	**Acceptable**
	CIPAC MT 47.2	Batch 14008	**In 10 % v/v in CIPAC water D at 20°C:** After 10 s: 0 mL After 1 min: 0 mL After 3 min: 0 mL After 12 min: 0 mL	B3.6 –Demangel B., Ricau H. 2014 Study No. 14-901011-017 GLP	
B3.5.8 – Flowability/ Pourability/ Dustability	-	-	Not required as the product is emulsifiable concentrate (EC)	-	**Acceptable**
B3.5.9 – Burning rate – smoke generators	-	-	Not required as the formulation is not intended to be used with a smoke generator	-	**Acceptable**
B3.5.10 – Burning	-	-	Not required as the formulation is not intended to be used with a	-	**Acceptable**

Properties	Method	Purity/ Specification	Results	Reference	Acceptable
completeness – smoke generators			smoke generator		
B3.5.11 – Composition of smoke – smoke generator	-	-	Not required as the formulation is not intended to be used with a smoke generator	-	**Acceptable**
B3.5.12 –Spraying pattern - aerosols	-	-	Not required as the formulation is not an aerosols	-	**Acceptable**
B3.5.13 – Other technical characteristics	-	-	-	-	**Acceptable**
B3.6 Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised					
B3.6.1 – Physical compatibility	-	-	Not applicable. The product is intended to be diluted only in water before use.		**Acceptable**
B3.6.1 –Chemical compatibility	-	-	Not applicable. The product is intended to be diluted only in water before use.		**Acceptable**
B3.7 Degree of dissolution and dilution stability					
Dilution stability	CIPAC MT 41	Batch 27152-B1/95002	**In 2 % v/v in CIPAC water D at 20°C:** At T0: Homogeneous white and opaque liquid After 18h: White and opaque liquid with a more opaque white higher phase (about 3 mL)	B3.1 – Da Costa C., Demangel B. 2010 Study No. 09-901011-002 GLP	**Acceptable**
B3.8 Surface tension					
Surface tension	EC Method A5	Batch 27152-B1/95002	The mean surface tension at 20.4 °C of the pure test item was: 31.5 ± 0.2 mN/m (corrected value). The test item was considered as surface-active in our experimental conditions.	B3.4 – Da Costa C. 2009 Study No. 09-901011-001 GLP	**Acceptable** The product is considered as surface-active.
B3.9 Viscosity					
Viscosity	OECD No. 114	Batch 27152-B1/95002	At 20°C (shear rate 4.65 s^{-1}): 158.4 mPa.s (increasing rotation speed) 133.1 mPa.s (decreasing rotation speed) At 20°C (shear rate 46.5 s^{-1}): 87.5 mPa.s (increasing rotation speed) 91.1 mPa.s (decreasing rotation speed) At 40°C (shear rate 9.30 s^{-1}): 51.6 mPa.s (increasing rotation speed)	B3.4 – Da Costa C. 2009 Study No. 09-901011-001 GLP	**Acceptable** The product is considered as a non-newtonian liquid.

Properties	Method	Purity/ Specification	Results	Reference	Acceptable
			38.4 mPa.s (decreasing rotation speed) At 40°C (shear rate 139.5 s^{-1}): 26.6 mPa.s (increasing rotation speed) 24.0 mPa.s (decreasing rotation speed) Taking into account the results obtained at 20.0 and 40.0 °C, the test item was considered to have non-newtonian properties in our experimental conditions.		
B4 – Physical hazards and respective characteristics					
B4.1 – Explosives	EC Method A14	Batch 27152-B1/95002	**Mechanical sensitivity (shock) :** Impact energy = 40 joules No signs of ignition or explosion on impact. When the test assembly was dismantled after the trial, there were no signs of decomposition. **Thermal sensitivity :** No explosions were observed using either the 6mm or the 2mm orifice plates. The test item was not considered to have explosive properties in experimental conditions.	B3.4 – Da Costa C. 2009 Study No. 09-901011-001 GLP	**Acceptable** The product is not expected to have explosive properties.
B4.2 – Flammable gases	-	-	Not required as the product is emulsifiable concentrate (EC)	-	**Acceptable**
B4.3 – Flammable aerosols	-	-	Not required as the product is emulsifiable concentrate (EC)	-	**Acceptable**
B4.4 – Oxidising gases	-	-	Not required as the product is emulsifiable concentrate (EC)	-	**Acceptable**
B4.5 – Gases under pressure	-	-	Not required as the product is emulsifiable concentrate (EC)	-	**Acceptable**
B4.6 – Flammable liquids	EC Method A9	Batch 27152-B1/95002	Automatic Setaflash closed tester: The flash point of the test item was: 84.0 ± 0.5 °C (corrected value).	B3.4 – Da Costa C. 2009 Study No. 09-901011-001 GLP	**Acceptable** The product is not flammable.
B4.7 – Flammable solids	-	-	Not required as the product is emulsifiable concentrate (EC)	-	**Acceptable**
B4.8 – Self-reactive substances and mixtures	-	-	Not required as the product is not explosive according to EC method A.14 and not flammable according to EC method A.9.	-	**Acceptable**
B4.9 – Pyrophoric	-	-	Not required as experience in manufacture and handling shows	-	**Acceptable**

Properties	Method	Purity/ Specification	Results	Reference	Acceptable
liquids			that the product does not ignite spontaneously on coming into contact with air at normal temperature..		
B4.10 – Pyrophoric solids	-	-	Not required as the product is emulsifiable concentrate (EC)	-	**Acceptable**
B4.11 – Self heating substances and mixtures	-	-	Not required as the product is not explosive according to EC method A.14 and not flammable according to EC method A.9.	-	**Acceptable**
B4.12 – Substances and mixtures which in contact with water emit flammable	-	-	Not required as experience in handling and use shows that the product does not react with water.	-	**Acceptable**
B4.13 – Oxidising liquids	EC Method A21	Batch 27152-B1/95002	The test mixtures produced pressure rise times (12.8s) well above the 3.6 s average for the 65% aqueous nitric/cellulose reference mixtures. The test item was not considered to have oxidizing properties in experimental conditions.	B3.4 – Da Costa C. 2009 Study No. 09-901011-001 GLP	**Acceptable** The formulation is not expected to have oxidising properties.
B4.14 – Oxidising solids	-	-	Not required as the product is emulsifiable concentrate (EC)	-	**Acceptable**
B4.15 – Organic peroxides	-	-	Not required as the product not contains organic peroxide	-	**Acceptable**
B4.16 – Corrosive to metals	-	-	Not required as the product has not a low or high pH value (pH = 5.5) and does not contain halogens.	-	**Acceptable**
B4.17 Additionnal physical indications of hazard					
B4.17.1 – Auto-ignition temperatures of products (liquids and gases)	EC Method A15	Batch 27152-B1/95002	The mean self ignition temperature of the test item was: 265 ± 4 °C (corrected value).	B3.4 – Da Costa C. 2009 Study No. 09-901011-001 GLP	**Acceptable** The product is not expected to have self-ignition properties at ambient temperature.
B4.17.2 – Relative self-ignition temperature for solids	-	-	Not required as the formulation is emulsifiable concentrate (EC)	-	**Acceptable**
B4.17.3 – Dust explosion hzard	-	-	Not required as the formulation is emulsifiable concentrate (EC)	-	**Acceptable**

Conclusion:

The biocidal product SANITERPEN INSECTICIDE DK is a homogeneous slightly yellow and limpid liquid with a strong terpenic odour. The product has not explosive properties, nor oxidising properties. It is not flammable (flash point is 84± 0.5°C) and not auto-flammable at ambient temperature (self-ignition temperature is 265 ± 4°C). The pH of the product in aqueous dilution (1% w/v standard water D) is about 6.8 at 20°C and the density of the product is 0.947. The product is considered as surface-active (mean surface tension at 20.4°C of the pure test item is 31.5 ± 0.2 mN/m) and has non-Newtonian properties at 20.0°C and 40.0°C.

After the accelerated storage procedure (14 days at 54 ± 2°C), no significant change of the product was observed, regarding the deltamethrin content, the aspect of the product and the pH. The product SANITERPEN INSECTICIDE DK is considered stable after the accelerated storage during 14 days at 54 ± 2°C.

After the long term storage procedure (2 years at ambient temperature), no significant change of the product was observed, regarding deltamethrin content, aspect of the product and its commercial packaging material (semi opaque white plastic flask hermetically closed and PE-EVOH) and pH. No change of deltamethrin content in the product was observed after 2 years at 20 ± 2°C. The product SANITERPEN INSECTICIDE DK is considered stable after the long term storage during 2 years at 20 ± 2°C.

Considering the nature of product (emulsion concentrate), the results of the shelf life study obtained for the PE-EVOH packaging are not transposable to fluorinated HDPE packaging andto PET bags or PET bottles. Nevertheless an accelerated storage study has been provided for PET packaging and considered acceptable.

Consequently, a compatibility study of product with the fluorinated HDPE packaging (monitoring of the deformation and mass of the packaging during a study of storage) should be provided in post-autorization.

After storage of the product for 7 days at 0 ± 2°C, no change was observed in the test item aspect. The product is considered to be stable after 7 days at 0°C.

The emulsions were considered to be stable (10% v/v in standard water A and D at 30 ± 2°C) before and after storage. The mean volume of foam produced after several inversions of the test item in standard water D at 20 ± 2°C is 0 mL at 10% v/v after 1 min.

2.3.2.3 Analytical method for determining the active substance and relevant component in the biocidal product

An analytical method for the determination of the active substance deltamethrin in the formulation SANITERPEN INSECTICIDE DK has been developed. The following analytical method for the determination of the active substance in the formulation performed on SANITERPEN INSECTICIDE DK has not previously been reviewed and is provided in support of this assessment.

Report:	**B5.1 – RICAU H., 2010**
Title:	Validation of the analytical method for the determination of deltamethrin in SANITERPEN INSECTICIDE DK
Document No:	Defitraces, Report No. 09-901011-004
GLP	Yes

Principle of the method

A quantity of about 1.0 g (to the nearest 0.1 mg) of the test item was weighed into a 100-mL volumetric flask, and the volume was made with acetonitrile. Deltamethrin was analyzed by liquid chromatography using an UV detector (225nm).

Specificity

To define the specificity of the analytical method, the following solutions were analyzed: solvent, blank formulation, reference item and test item.

In the reference item and in the test item, the peak at the retention time around 21 min represents deltamethrin. Three impurities are present in the blank formulation but their areas represent less than 3% of active substance area peak, then the specificity was therefore defined for deltamethrin.

Representative chromatograms of standard solution, sample solution of formulation and formulation blank were provided.

Linearity

For the calibration of deltamethrin, a calibration curve based on one injection per dilution was generated. The results were used to calculate the calibration curves to verify the linearity of detector response.

The analytical system gave a linear response (n=5) between 0.01 g/L and 0.030 g/L of Deltamethrin. The linear correlation coefficient for the calibration range was found to be > 0.99.

equation of the calibration line: $Y = 4.90*10^{8} X + 2.78*10^{5}$

correlation coefficient: $r^2 = 0.9984$

Accuracy

For accuracy 100%: A quantity of about 99.8 mg (to the nearest 0.1 mg) of blank formulation was weighed into a 10-mL volumetric flask a volume of 2-mL of the REF02 Delta was added and the volume was made up with acetonitrile (EXACT 1 100%). An identical solution was prepared with REF03 Delta (EXACT 2 100%).

For accuracy 50%: A quantity of about 49.9 mg (to the nearest 0.1 mg) of blank formulation was weighed into a 10-mL volumetric flask a volume of 1-mL of the REF02 Delta was added and the volume was made up with acetonitrile (EXACT 1 50%). An identical solution was prepared with REF03 Delta (EXACT 2 50%).

	Fortification Level [mg/L]	Number of Analyses	Mean Recovery [%]
Accuracy 100%	20.6	2	96.9
	20.8	2	96.2
Accuracy 50%	10.3	2	101.8
	10.4	2	95.1

Repeatability

The precision was determined by analyzing twice five specimen samplings. The content of deltamethrin for each analysis was calculated with the average value of the response factor of the two calibration solutions. Then, the average value of the content, the standard deviation and the Relative Standard Deviation (R.S.D.) were calculated.

The acceptability of the precision was based on the following modified Horwitz equation.

Precision results for Pyrimethanil

Mean Fortification Level [% w/w]	Number of Analyses	RSD [%]	RSD Horwitz [%]
0.193	10	2.89	3.44

Conclusion

Specificity, linearity, precision and recovery were provided and found acceptable for Deltamethrin.

Analytical methods using HPLC/UV (RICAU H., 2010, report No. 09-901011-004) for the determination of deltamethrin in the formulation (Saniterpen DK) as manufactured has been performed and validated in accordance to guidance of Regulation (EU) No 528/2012.

2.3.2.4 Analytical methods for determining relevant components and/or residues in different matrices

Analytical methods for deltamethrin residues in soil, air, water (including drinking water) and sediment, animal and human body fluids and tissues and deltamethrin residues in food/feed of plant and animal origin are available in Assessment Report Deltamethrin Product-type 18 (insecticides), May 2011.

A Letter of Access from Bayer has been provided.

2.4 Risk assessment for Physico-chemical properties

SANITERPEN INSECTICIDE DK is an emulsion concentrate product containing deltamethrin (0.2 % (w/w)) for spray application. It is not highly flammable, not auto-flammable, not explosive and does not have oxidizing properties.

The product is stable for 14 days at 54°C and 2 years at ambient temperature.

The product SANITERPEN INSECTICIDE DK is compatible with PE/EVOH, PET and fluorated HDPE, packages.

Risk mitigation measures linked to risk assessment for physico-chemical properties

None.

Disposal considerations

None.

Required information linked to risk assessment for physico-chemical properties

A compatibility study of product with the fluorinated HDPE packaging (monitoring of the deformation and mass of the packaging during a study of storage) is neede post-authorization.

2.5 Effectiveness against target organisms

2.5.1 Function

MG 03: Pest Control

Product Type 18: Insecticides, acaricides and products to control other arthropods.

SANITERPEN INSECTICIDE DK is an emulsion concentrate. It is applied diluted in water.

The formulation contains 0.2 % w/w of the insecticidal active substance, deltamethrin.

The biocidal product SANITERPEN INSECTICIDE DK is used by professional, for the control of poultry red mites, mosquitoes, flies, fleas and sand flies in empty animal's houses and shelters.

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

According to the uses claimed by the applicant, the product SANITERPEN INSECTICIDE DK is intended to be used to control poultry red mites (eggs, larvae and adults), mosquitoes adults, flies adults, fleas adults and sandflies adults.

The specific target organisms to be controlled are:

- Poultry red mites: *Dermanyssus gallinae*
- Mosquitoes*: Culex spp*, and *Aedes spp* genus
- House fly: *Musca domestica* and Stable fly *Stomoxys calcitrans*
- Fleas: *Pulicidae spp*
- Sandflies*: Phlebotomus spp.*

The solution must be sprayed on the floor, walls, ceiling, and around windows and doors to control flies and mosquitoes, or applied on the floor and walls to control fleas and red mites. Application equipment which shall be used is a knapsack sprayer with handheld trigger.

The application rates recommended by the applicant are the following:

The recommended application rate (porous and non-porous surfaces) is 10 % v/v, with an application rate recommended of 50 mL of diluted product per m².

The product is claimed as efficient during 3 months.

Animals, textiles, animal food and sources of water shall be cleared off the treated areas before using the product. They can be reintroduced only when the treated surfaces are dried. A default time of 24H shall be considered.

2.5.3 Effect on target organisms and efficacy

The products SANITERPEN INSECTICIDE DK (0.2% deltamethrin) and SANITERPEN INSECTICIDE DK PAE (0.02% deltamethrin) contain terpineol, used as solvent. The differences of composition between Saniterpen Insecticide DK and Saniterpen Insecticide DK PAE are described in document C4-Bridging data. The component ternineol is identified in annex 1 of Commission Regulation 1451/2007/CE of 4 th december 2007, and is also known in the litterature as having potential insecticide effects. In order to demonstrate that "Terpineol" doesn't have any insecticidal properties in these formulations, a laboratory study has been carried out with SANITERPEN INSECTICIDE DK PAE (0.02% deltamethrin). This product covers Saniterpen Insecticide DK at its recommended dilution dose.

The laboratory study n°1948c/0615, 2015/11 was conducted with the products SANITERPEN INSECTICIDE DK PAE, (0.02 % w/w deltamethrin) and SANITERPEN INSECTICIDE DK PAE without deltamethrine, on *Musca domestica* (house fly, adults), *Stomoxys calcitrans* (Stable fly, adults), *Phlebotomus duboscqi (*sandfly, adults), *Culex pipiens* and *Aedes aegypti* (mosquitoes, adults), *Ctenocephalides felis* (cat flea, adults and

larvae) and *Dermanyssus gallinae* (poultry red mite, adults and larvae) according to a methodology adapted from the standard ASTM E 654-96 (Reapproved 2009): "Standard test method for effectiveness of aerosol and pressurized spray Insecticides against cockroaches".

The products were sprayed directly at the claimed application rate of 50 mL of product per m² on the arthropods. After the spraying, different parameters were measured, including the KD1 hour, KT100 and mortality after 1 day and 3 days. Four replicates were made for each species.

The untreated controls demonstrated the validity of the test, with less than 5 % of mortality. The product SANITERPEN INSECTICIDE DK with active substance showed total efficacy against all tested target organisms. The product without active substance gave no significant efficacy (<10% mortality witin 72 hours).

It can be concluded that the product without active substance presents no efficacy on its own at the recommended application rate and that terpineol is a co-formulant that has no insecticide properties in this product.

The studies submitted to demonstrate the efficacy of the product SANITERPEN INSECTICIDE DK, according to the uses and doses claimed, are described below. These studies were carried out with the product SANITERPEN INSECTICIDE DK (0.2 % w/w deltamethrin).

Only laboratory test has been submitted for sand flies during the evaluation. As this target organism was not present initially and as no field test has been provided to support the efficacy against this target, FR not considered this claim in the evalution of the dossier.

1) **Laboratory study n°1558b/1112R, 2013/04 conducted with the product SANITERPEN INSECTICIDE DK, (0.2 % w/w deltamethrin) on *Musca domestica* (house fly, eggs and larvae), *Culex pipiens* (mosquito, adults), *Ctenocephalides felis* (cat flea, adults and larvae) and *Dermanyssus gallinae* (poultry red mite, adults and larvae) according to CEB N°135 method**

The product was sprayed at the dose of 10 % v/v, at the rate of 50 mL of diluted product per m² on 4 representative surfaces (concrete, wood, plaster and ceramic tiles) and the arthropods were placed in contact with these surfaces for an exposure time of 4 hours. The same test was done with treated surfaces after 1, 2 and 3 months of storage. Four replicates were made for each test condition (surface*treatment*storage*arthropod).

The untreated controls demonstrated the validity of the test, with less than 5 % of mortality. The product SANITERPEN INSECTICIDE DK showed total efficacy against flies (eggs and larvae), fleas (adults and larvae), mosquitoes (adults) and poultry red mites (adults and larvae), on both porous and non-porous surfaces. This efficacy lasted for at least 3 months after application.

2) **Laboratory study n°4678, 2013/09/09 conducted with the product SANITERPEN INSECTICIDE DK, (0.2 % w/w deltamethrin) on *Stomoxys calcitrans* (stable fly, adults), according to an internal method**

The product was sprayed at the dose of 10 % v/v, at the rate of 50 mL of diluted product per m² on four representative surfaces (plywood, glazed tiles, concrete, plaster) and the stable flies (*Stomoxys calcitrans*) were placed in contact with these surfaces, one day and two months after treatment for an exposure time of 4 hours. Five replicates were made for each test condition (surface*treatment*storage).

The untreated controls demonstrate the validity of the test, with less than 5 % of mortality. The product SANITERPEN INSECTICIDE DK showed 100 % of efficacy until 24 hours for all the representative surfaces except for plywood, where the efficacy demonstrated is 90 % at 24 hours.

2 months after the treatment, the residual efficacy of the product is 100 % only for the non-porous glazed tiles but is much weaker for the others surfaces (between 12 and 54 %), then is considered as not sufficient.

3) **Laboratory study n°1826a/0914R, 2014/12 conducted with the product SANITERPEN INSECTICIDE DK, (0.2 % w/w deltamethrin) on *Musca domestica* (house fly, adults) and *Aedes aegypti* (mosquito, adults) according to CEB N°135 method**

The product was sprayed at the dose of 10 % v/v, at the rate of 50 mL of diluted product per m² on 2 representative surfaces (concrete and ceramic tiles) and the arthropods were placed in contact with these surfaces for an exposure time of 1 hour. The same test was done with treated surfaces after 1, 2 and 3 months of storage. Four replicates were made for each test condition (surface*treatment*storage*arthropod).

The untreated controls demonstrated the validity of the test, with less than 4 % of mortality. The product SANITERPEN INSECTICIDE DK showed a knock-down effect within 5 minutes and a total efficacy against flies (adults) and mosquitoes (adults) within 24 hours, on both porous and non-porous surfaces. This efficacy lasted for at least 3 months after application.

4) **Semi-field tests n°1826a/0914, 2014/11 conducted with the product SANITERPEN INSECTICIDE DK, (0. 2 % w/w deltamethrin) on *Aedes aegypti*, *Culex pipiens* (mosquitoes) and *Ctenocephalides felis* (fleas), according to BSI 4172 method**

The product was sprayed at the dose of 10 % v/v, at the rate of 50 ml of the diluted product /m² in a test chamber (30 m^3 with 12 m² floor). The treated surface (ceramic tiles) is half of the test chamber (6 m²). To simulate what happens in premises, some panels of polystyrene blocks and cardboards are set into the test chamber to be harbourages and a water+food sources (these ones are not treated). The insects are able to reach water and food sources without being in contact with the insecticide and they have the choice not to be in contact with the product.

Three replicates were made for each species.

The untreated controls demonstrated the validity of the test, with less than 10 % of mortality for each species. The product SANITERPEN INSECTICIDE DK showed total efficacy 7 days after the application.

Nevertheless it shall be noted that experimental conditions described in this simulated test are different from the real conditions observed in breeding premises (behaviour of insect's populations more complex, nature of building materials, variability of parameters such as temperature, humidity and light not taken into account).

Moreover, residual activity of the product until 3 months was not assessed.

It shall be also noted that these semi-field tests were performed only with adult's insects whereas larvae stage were also claimed for fleas.

5) **Field test n° 1527/0712R, 2012/11 conducted in breeding premises with the product SANITERPEN INSECTICIDE DK, on *Musca domestica* (house fly), according to CEB n° 107 method**

After confirmation and evaluation of the initial infestation level with sticky traps, the product was diluted in water (10 % v/v) and applied by spraying on vertical surfaces, at the application rate of the diluted product of 50 ml per m². The reduction of the insect's population was assessed after 7, 14, 30, 60 and 90 days, by counting flies trapped on sticky traps let for 24 hours in the premises.

A reference product is included and three premises are treated with each product.

The population decreased in the treated breeding premises until 85 % from the first week and 91 % from two weeks after treatment and still of 98.4 % after 3 months. The test product gave results similar to the reference product.

Conclusion

All efficacy studies are presented in Annex 9.

In conclusion, in accordance with the tests submitted and the requirements of the TNsG on PT18, the product SANITERPEN INSECTICIDE DK is efficient against domestic flies (*Musca domestica*, adults) but the efficacy against stable flies (*Stomoxys calcitrans*, adults) and poultry red mites (*Dermanyssus gallinae*) is not proved as no field test has been provided for this target organism.

Semi-field tests are submitted for mosquitoes and fleas but experimental conditions are a bit far from the field and therefore not sufficiently reliable. So, in the absence of sufficient supporting data on mosquitoes (genus *Culex* and *Aedes)* and fleas *(Pulicidae)*, suitable information (as semi-field or field tests) demonstrating the

efficacy of SANITERPEN INSECTICIDE DK against these target organisms, will need to be provided in support of the authorisation, within one year.

Target Organismes	Rates and uses acceptable	Method of application	Time delay of the biocidal product
House flies, adults (*Musca domestica*) Mosquito, adults (*genus Culex, genus Aedes*) Fleas (*Pulicidae*), adults	10 % v/v The product is diluted in water Application rate : 50 ml of diluted product /m²	Surface treatment (spraying using knapsack sprayer) Porous and non porous surfaces	After a few hours

Based on these efficacy data, the product SANITERPEN INSECTICIDE DK (0.2 % w/w deltamethrin), formulated as liquid concentrate, at a rate of 10 % v/v, showed an efficacy against house flies (*Musca domestica,* adults*)*, mosquitoes (genus *Culex* and *Aedes,* adults*)* and fleas (*Pulicidae*, adults) over a 3 months period.

In laboratory tests, the effect began a few hours after application.

2.5.4 Mode of action including time delay

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

Pyrethroids impair ion transport through the membrane of nerve axons, causing muscular paralysis in the insect; death seems to follow a nervous system impairment that occurs a few minutes to several hours after pesticide absorption. The primary site of activity of deltamethrin is the voltage sensitive sodium channel in nerve membrane. Deltamethrin prolongs the opening of the sodium channels (i.e. the channels directly responsible for generating nerve action potentials) leading to neuronal hyper excitability.

The effect begins around a few hours after contact of the product in the laboratory trials submitted by the applicant.

2.5.5 Occurrence of resistance - resistance management / unacceptable effect

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

Resistant populations of house flies (*Musca domestica*) have been identified in the whole world (Asia, Europe, and America). Several mechanisms are involved in resistance to pyrethroïds in house fly. This includes detoxification of the active substances, knockdown resistance (also called “kdr”), correlated with decrease nerve sensitivity, and decrease in the rate of penetration of the products. These mechanisms can co-exist in a resistant strain[5]. Cross-resistance also exists in resistant strains, among pyrethroïds, but also other insecticide types (chlorpyrifos and imadacloprid).

[5] Nannan L, Xin Y. Insecticide resistance and cross-resistance in the house fly (Diptera:Muscidae).J. Econ. Entomol. 93(4):1269-1275 (2000).

A recent French study with two populations of stable fly (*Stomoxys calcitrans*) concluded that the population from the "conventional" farm, with cattle and stable walls frequently treated with deltamethrin, was resistant to the five tested pyrethroïds, including deltamethrin[6].

Concerning *Culex pipiens* (or *C.quinquefasciatus*, very close species), deltamethrin resistant populations have been identified in many part of the world, including North and West Africa and Asia[7]. Resistant populations have not been identified in Europe yet.

Populations of fleas (*Ctenocephalides felis)* resistant to deltamethrin have not been identified in Europe yet. Resistance to insecticide is difficult to identify in fleas, because of important intra-population variability[8].

Concerning poultry red mites (*Dermanyssus gallinae*), populations resistant to permethrin, another pyrethroïds active substance, have been identified in France and other European countries. However, resistance to deltamethrin is not reported in the scientific literature[9].

To ensure a satisfactory level of efficacy and avoid the development of resistance in susceptible insect populations, the following recommendations have to be implemented:

- Always read the label or leaflet before use and respect follow all the instructions provided.
- 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).
- Alternate products containing active substances with different mode of action, (to remove resistant individuals from the population).
- Establish a baseline and monitor levels of effectiveness on populations in key areas (at least one survey per year) in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.
- The users should inform if the treatment is ineffective and report straightforward to the registration holder.
- The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

2.5.6 Evaluation of the label claim

French competent authorities (FR CA) assessed that the product SANITERPEN INSECTICIDE DK, as a liquid concentrate, diluted in water at 10 % v/v, at an application rate of 50 ml of diluted product per m², has shown a sufficient efficacy for the control of domestic flies (*Musca domestica*), mosquitoes (genus *Culex spp* and *Aedes spp*) and fleas (*Pulicidae*), up to 3 months.

The product is applied indoor on the porous and non-porous surfaces in empty animals' housing (animals not intended for food consumption).

As only efficacy has been demonstrated against adult's insects, treatment with the product SANITERPEN INSECTICIDE DK shall be completed with a product efficient on larvae stages.

[6] Salem A, Bouhsira E, Liénard E, Bousquet Melou A, Jacquiet P, Franc M. Susceptibility of two European strains of *Stomoxys calcitrans* (L.) to Cypermethrin, Deltamethrin, Fenvalerate, ƛ-cyalothrin, Permethrin and Phoxim. Intern J Appl Res Vet Med. Vol. 10, N°.3, 2012.

[7] Tahir HM, Butt A, Khan SY. Response of *Culex quinquefasciatus* to deltamethrin in Lahore district. Journal of Parasitology and Vector Biology Vol. 1 (3) pp. 019-024, October, 2009

[8] Bossard RL, Hinkle NC, Rust MK. Review of insecticide resisitance in cat fleas (Siphonatera : Pulicidae). J. Med. Entomol. 35(4):415-422 (1998)

[9] Marangi M, Cafiero MA, Capelli G, Camarda A, Sparagano OAE, Giangaspero A. Evaluation of the poultry red mite, *Dermanyssus gallinae* 'Acari:Dermanyssidae) susceptibility to some acaricides in field populations from Italy. Exp Appl Acarol (2009) 48:11-18.

2.5.7 Summary of efficacy assessment

The efficacy level of the product SANITERPEN INSECTICIDE DK (0.2 % w/w deltamethrin) is satisfactory for the uses proposed in Table 2 below.

Conditions of use linked to efficacy assessment

To ensure a satisfactory level of efficacy and avoid the development of resistance in susceptible insect populations, the following recommendations have to be implemented:

- Always read the label or leaflet before use and respect follow all the instructions provided.
- 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).
- Alternate products containing active substances with different mode of action, (to remove resistant individuals from the population).
- The users should inform if the treatment is ineffective and report straightforward to the registration holder

Recommendations to be taken into account by the authorisation holder

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

Required information linked to efficacy assessment

- Suitable information (as semi-field or field tests in the real use conditions) demonstrating the efficacy of SANITERPEN INSECTICIDE DK against target organisms mosquitoes (genus *Culex* and *Aedes)* and fleas *(Pulicidae)*, will need to be provided in support of the authorisation, within one year.
- Establish a baseline and monitor levels of effectiveness on populations in key areas (at least one survey per year) in order to detect any significant changes in susceptibility to active substance. Information from resistance monitoring programs allows early detection of problems and gives information for correct decision making.

2.6 Description of the intended use(s)

Table 2: Summary of intended uses

MG/PT	Field of uses envisaged	Likely concentrations at which product will be used
Main Group 03; Pest Control PT18: insecticides, acaricides and products to control other arthropods	Professional uses	
	Insecticide for use against house flies, mosquitoes and fleas infestations (adult stage) indoor in empty animals' housing (animals not intended for human consumption).	10 % v/v 5 ml of product is diluted in 45 ml of water and is applied with a knapsack sprayer) Application rate : 50 ml of diluted product/m²

2.7 Risk assessment for human health

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

The toxicology of the active substance was examined extensively according to standard requirements. The results of this toxicological assessment can be found in the CAR. The threshold limits and labelling regarding human health risks listed in Annex 4 „Toxicology and metabolism" must be taken into consideration.

The following corresponds to the summary of the effect assessment available in the assessment report of Deltamethrine.

Absorption, distribution, metabolism and excretion

The rate of oral absorption of deltamethrin was approximately 75%, this based on urinary and biliary excretion data in rats. Deltamethrin was rapidly absorbed when orally administered to rats (the majority of the radioactivity was eliminated within 24 hrs after dosing, 19-47% with the urine; 32-55% in faeces) and distributed to most tissues. Residues in tissues and carcass were low. The highest residues were found in fat. There was no indication of accumulation, although the residue of deltamethrin in adipose tissue eliminated with a half-life of >24 hrs.

Deltamethrin was rapidly excreted in both urine and faeces. 7 days postdose, 31% to 56% of the oral dose was excreted with the urine and 36% to 59% in faeces. No 14CO2 was formed according to data from the open literature. Deltamethrin was rapidly and extensively metabolised in rats. The main route of metabolism was via cleavage of the ester bond with or without hydroxylation at the 4' position of the alcohol moiety. The acid moiety and alcohol moiety were further transformed and excreted in urine in free forms and as conjugated metabolites. Unchanged deltamethrin was the major compound in faeces.

No studies were located regarding absorption rate following inhalation exposure to animals. Consequently a default absorption value by inhalation was considered in the risk assessment.

Dermal absorption

Dermal penetration studies have been conducted in vitro in rats with deltamethrin as an oil/water emulsion (EW) and as an emulsifiable concentrate (EC) in rat and human skin and in an in vivo study in rats. The results of these studies indicated that dermal absorption was somewhat lower for the EW 15 than for the EC 25. The Decis EC 25 formulation may be considered to be a worst case with regard to K-Othrine formulations. The main difference which is relevant to skin absorption is the solvent (water in K-Othrine SC formulations versus light aromatic solvent in Decis EC 25). The content of aromatic solvent is expected to enhance the degree of dermal absorption in comparison with K-Othrine formulations. For the solid formulations of deltamethrin a lower dermal absorption is expected since water and certain solvents favour.

Using data obtained in the dermal absorption studies on Decis EC 25 formulation, the dermal absorption of deltamethrin in man was estimated to 1.19% for the concentrate and 1.89% for the a.s. when diluted in the spray solution. The value of 2% (maximum dermal absorption) was used in the risk assessment.

Acute toxicity, irritation and corrosivity, sensitisation

Deltamethrin was considered of high acute toxicity by the oral and inhalation route (LD_{50} rat: 87 mg/kg bw; LC_{50} rat: 0.6 mg/L), while the acute dermal toxicity of deltamethrin was low (LD_{50} rat: >2000 mg/kg bw). Clinical signs of systemic toxicity, poor condition and neurotoxicity were observed in rats after oral and inhalation administration. Skin and eye irritation and pathological changes (enlarged inguinal and mandibular lymph nodes, and pulmonary congestion) were noted in addition after administration via the inhalation route. No clinical signs were noted in rats after dermal application.

The vehicle has a great influence on the LD_{50}. Sesame oil as vehicle shows less toxicity than polyethylene glycol. Aqueous suspensions are significantly less toxic than formulations in oils.

Deltamethrin was not irritating according to skin- and eye irritation studies in rabbits, and no sensitising potential was found in tests according to GPMT (Guinea Pig Maximisation Test) or Buehler.

Repeated dose toxicity (short-term toxicity)

The short-term oral toxicity of deltamethrin was investigated in rats (90-day studies) and dogs (90-day studies; one-year study). In both species, the nervous system was the main target organ. Reduced bodyweight gain was also noted in both species.

The lowest relevant NOAEL for short-term toxicity was 1 mg/kg bw/day obtained in the 90-day (gelatine capsules, vehicle: PEG 200) and 1-year oral (gelatine capsules, vehicle: none) toxicity studies in dogs based on clinical signs of neurotoxicity noted in both sexes at the dose level of ≥ 2.5 mg/kg bw/day.

In addition, the repeated dose toxicity was investigated in rats after dermal exposure (21-day toxicity study in rats) where dermal irritation was noted, and inhalation exposure (14-day toxicity study in rats) where clinical signs (irritative and neurotoxic) and reduced bodyweight gain were noted. Scratching was noted in all treated groups in the inhalation toxicity study. This effect was considered to be related to the irritant nature of deltamethrin but may also be due to the neurotoxic nature of the substance (an indirect consequence of parasthesia).

Genotoxicity

The genotoxic potential of deltamethrin was investigated in a battery of tests in vitro (assays for gene mutations, chromosomal aberrations and DNA effects). All tests were negative.

Based on the weight of evidence from this full in vitro package and the results of the carcinogenicity studies, it was concluded that deltamethrin is not mutagenic.

Chronic toxicity (long-term toxicity) and carcinogenicity

The long term toxicity of deltamethrin was studied in rats and mice. No evidence of carcinogenic potential of deltamethrin was found in the rat or the mouse. In both species the nervous system was the target organ. The liver was another target organ in the rat.

Lowest relevant NOAEL for long-term toxicity was 1 mg/kg bw/day obtained in the 2-year chronic toxicity/carcinogenicity (feeding) study in the rat based on liver effects (histopathological changes) noted at the dose level of 5 mg/kg bw/day and above. In addition clinical signs of neurotoxicity were noted at higher doses.

Reproductive toxicity

Reproductive toxicity of deltamethrin was investigated in a two-generation study in rats. Developmental toxicity was investigated in rats, mice and rabbits. The mouse study was considered acceptable but of restricted quality due to low number of pregnant animals used in each test groups.

No effect on mating performance or fertility was noted in the rat two-generation (feeding) study. Clinical signs (indicating neurotoxic effects), reduced body growth and histopathological changes (gastric erosions) were noted in adult rats. In offsprings reduced pup body weights, increased pup deaths (F1 generation) and reduced lactation index (F1 generation) were noted at maternal toxic doses.

No developmental toxicity was noted in rats or rabbits at maternal toxic doses. Increased incidence of supernumerary ribs was noted in the offspring of mouse at doses with maternal toxicity.

Lowest relevant developmental LOAEL was 3 mg/kg bw/day based on a statistically significant increase in the occurrence of supernumerary ribs noted in mice at ≥ 3 mg/kg bw/day.

Neurotoxicity

The neurotoxicity of deltamethrin was investigated in standard toxicity studies with the rat (acute neurotoxicity study; subchronic neurotoxicity study; developmental neurotoxicity (DNT) study) and in experimental (non GLP) studies in rats and mice. No studies on acute delayed neurotoxicity were submitted (not required).

The NOAEL for acute neurotoxicity in adult CD-rats was 5 mg/kg bw, while the NOAEL for subchronic neurotoxicity in adult CD rats was 4 mg/kg bw/day. In both studies the NOAEL was based on signs of neurotoxicity noted at 15 mg/kg bw/day and above, and mortalities and reduced bodyweight gain noted at higher dose levels.

The NOAEL for developmental neurotoxicity in Wistar rats was 6.78 mg/kg bw/day based on reduced bodyweight gain, increased incidence of vocalizations with handling (males only) and delayed balanopreputial separation noted in offsprings at a dose with maternal toxicity (16.1 mg/kg bw/day).

The DNT study follows the OECD guideline no. 426 in that way that some exposure to the pups was demonstrated in the pilot study. However, the view of RMS is that there might be some uncertainty in the DNT study protocol in those cases where direct dosing of pups has not been considered and the exposure level in offspring is not clear. No blood analyses were taken and the offspring dose level might be very low. The effects noted in the pups of the high dose group (decreased body weight and body weight gain, delayed sexual maturation in males) are not sufficient evidence to support exposure to the pups during the brain growth spurt period since these effects in the offspring could be due to maternal toxicity or exposure in utero. Furthermore, there is a concern for the lack of data for the most sensitive strain. Comparing data from standard neurotoxicity studies the Wistar rat used in the DNT study seems to be a less sensitive strain with regard to neurotoxicity of deltamethrin. There were no clinical signs of neurotoxicity reported for adult Wistar rats administered deltamethrin via the diet at doses up to 16.1 mg/kg bw/day (noted in the DNT study), whereas clinical signs of neurotoxicity were evident in the CD rat at a dose level of 14 mg/kg bw/day (noted in the 13-week neurotoxicity study). The choice of strain used in the deltamethrin DNT study might therefore be questioned.

Due to the uncertainties mentioned above the RMS originally proposed (draft CAR) to use an extra safety factor of 3 in the risk assessment of deltamethrin. The Technical Meeting I in 2010 reached an agreement that where uncertainties are perceived by the RMS of a pyrethroid on the DNT studies (especially negative studies), these uncertainties should be formally expressed in the CAR. The TM also agreed that the currently available evidence does not support the use of an extra assessment factor to cover for the perceived uncertainties on DNT in the dossier of deltamethrin.

During the Technical Meeting II in 2010, it was decided to use the document on survey of DNT studies for pyrethroids prepared by the Netherlands as basis for the assessment of this category of substances. The conclusions of this survey were:

- Possible DNT effects induced by pyrethroids are covered by the AELs set on neurotoxicity in the acute neurotoxicity and medium-term studies since DNT effects from acceptable OECD TG 426 performed studies are taking place at higher LOAELs than other neurotoxicological effects.

- The DNT effects are also covered by the AELs set for long-term exposure (based on neurotoxic or other critical endpoints).

- As neurotoxic effects are critical effects after acute or medium-term exposure and the available data indicate that DNT effects are induced at higher LOAELs, it is unlikely that, in the absence of DNT studies, the potential DNT effects are not covered by AELs set on neurotoxic effects observed in acute and medium-term studies. It was concluded that additional DNT studies according to OECD TG 426, if such a study is not present, is not necessary.

The RMS respects the decision of TM although the view of RMS is still that there might be some uncertainty in the DNT study protocol and the most sensitive strain has not been used in the DNT study.

Medical data

Medical data from manufacturing, formulating and packaging plants indicate that transitory skin sensations were the most prevalent finding (paraesthesia, transient local burning, tingling, pickling sensations, itching, numbness of the facial skin – erythema in some cases). Cases of intoxications (mostly occupational due to inappropriate handling of products) have been reported. Two cases of occupational acute deltamethrin poisoning died of convulsions and another died of pulmonary oedema. No late sequeala of pyrethroid poisoning have been described in the scientific literature. There is no specific antidote for pyrethroids. Any treatment can only be symptomatic.

Other test(s) related to the exposure of humans The trans-deltamethrin isomer has been tested for oral acute toxicity and mutagenicity (Ames test). The results of these studies showed that the acute oral toxicity of the

trans-deltamethrin does not exceed the acute oral toxicity of the parent compound cis deltamethrin and no genotoxicity potential was found according to the Ames test.

In a study where food commodities (covered and uncovered) were exposed to an environment in which a deltamethrin based product was applied as a general surface treatment showed that the use of deltamethrin products will not contaminate food stuffs when spray is applied downwards. Spraying overhead or direct transfer of residues from treated spaces was not investigated in this study. However, no exposure of food stuffs is expected during and after crack and crevice treatment of food handling areas with the deltamethrin product when label instructions are followed.

Biocidal products

The acute toxicity of K-Othrine SC 26.25, SC 7.5 and DP 0.05 by oral, dermal and inhalation exposure is low. The acute toxicity of K-Othrine WG 250 by oral and dermal route is low, whereas the acute toxicity by inhalation route is moderately; therefore K-Othrine WG 250 should be classified as “Harmful” and assigned the risk phrase R20 (“Harmful by inhalation”).

The products are not irritating to skin or eyes, and are not sensitising to skin.

Tolerable exposure

The reference values, (acute/medium term and long term AELs) derived for deltamethrin were obtained from studies in dogs since the data submitted demonstrated that the dog was the most sensitive species to the toxicity of deltamethrin. In addition a safety factor of 100 was applied taking into account a factor for inter- and intraspecies differences of 100 (10 x 10).

Acceptable daily intake (ADI)

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

Acute reference dose (ARfD)

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

Acceptable exposure levels (AELs)

AEL (acute): An AEL of 0.0075 mg/kg bw/day was derived based on the NOAEL (1 mg/kg bw/day) obtained in a 13-week dog study after taking an oral absorption of 75% and a safety factor of 100 into account. In the study neurotoxic effects occurred early after dosing.

AEL (medium-term): An AEL of 0.0075 mg/kg bw/day was derived based on the NOAEL (1 mg/kg bw/day) obtained in the 13-week and 1-year dog studies after taking an oral absorption of 75% and a safety factor of 100 into account.

AEL (long-term): An AEL of 0.0075 mg/kg bw/day was derived based on the NOAEL (1 mg/kg bw/day) obtained in the 1-year dog study after taking an oral absorption of 75% and a safety factor of 100 into account.

Maximum acceptable concentration in drinking water

According to Council Directive 98/83/EC relating to the quality of water intended for human consumption, the maximum admissible concentration for pesticides in drinking water is 0.1µg/l for substances considered separately.

2.7.1.2 Toxicology of the substance(s) of concern

The biocidal product contains no substance of concern.

2.7.1.3 Toxicology of the biocidal product

Toxicological data have been submitted on the product SANITERPEN INSECTICIDE DK.

The basis for the health assessment of the biocidal product is laid out in Annex 5 ”Toxicology – biocidal product”

2.7.1.3.1 Percutaneous absorption

A default dermal absorption value of 10% has been used for risk assessment considering the physico-chemical properties of the active substance (log Pow > 4 and molecular weight > 500 g/mol), in accordance with the recommandations of EFSA guidance on dermal absorption[10].

2.7.1.3.2 Acute toxicity

Acute oral and acute dermal toxicity of the product was tested.

In the acute oral toxicity study (OECD 423), rats were exposed to a single dose of 2000 mg/kg bw.

No mortality was observed during the test.

A decrease of the spontaneous activity (6/6) and the muscle tone (4/6), associated with a decrease of the righting reflex (2/6) and a piloerection (5/6), was registered from 30 minutes after the test item administration. The animals recovered a normal activity 24 hours after the test item administration.

The macroscopic examination of the animals at the end of the study did not reveal treatment related changes.

The LD50 of the test item SANITERPEN INSECTICIDE DK is higher than 2000 mg/kg body weight by oral route in the rat.

In the dermal acute toxicity study (OECD 402), rats were exposed to a single dose of 2000 mg/kg bw.

No mortality occurred during the study. Neither cutaneous reactions nor systemic clinical signs related to the administration of the test item were observed.

The macroscopic examination of the animals at the end of the study did not reveal treatment-related changes.

The dermal LD_{50} of the test article SANITERPEN INSECTICIDE DK is higher than 2000 mg/kg bw in rats.

Based on the results, no classification is required for SANITERPEN INSECTICIDE DK.

No acute inhalation toxicity study was generated for SANITERPEN INSECTICIDE DK. The product SANITERPEN INSECTICIDE DK does not contain ingredient classified for health effects resulting from an acute exposure by inhalation. Therefore, according to the classification rules in Directive 1999/45/EC, no classification regarding acute inhalation toxicity is warranted for the product SANITERPEN INSECTICIDE DK.

[10] Guidance on dermal absorption, EFSA, 2012

2.7.1.3.3 Irritation and corrosivity

In the skin irritation study (OECD 404) in rabbits (3 animals), a well-defined to moderate erythema (score 1.0/2.0/3.0) and a slight to moderate oedema (score 1.7/2.0/2.0) was noted on the treated area of the three animals, mean at 24h-48h-72h.

The erythematous reactions were totally reversible between D2 and D4. The oedematous reactions were totally reversible between D3 and D4.

A slight dryness was noted in two animals and a roughness in the last one, since D2. The skin recovered a normal aspect between D8 and D10.

Based on the results, classification as **Xi, R38 "irritating to skin"** is required for SANITERPEN INSECTICIDE DK according to the directives 67/548/CE and 2001/59/CE criteria. No classification is required according to the CLP regulation criteria.

In the eye irritation study (OECD 405) in rabbits (3 animals), the observed ocular reactions have been moderate and totally reversible in the three animals.

A moderate redness of the conjunctiva (score 2.0/2.7/3.0) was noted in the 3 rabbits respectively, mean at 24h-48h-72h and totally reversible between D7 and D10.

An important chemosis (score 3.0/2.7/3.7) was noted in the 3 rabbits respectively, mean at 24h-48h-72h and totally reversible between D8 and D10.

A moderate corneal opacity (score 2.0/2.0/2.0) was noted in the 3 rabbits respectively, mean at 24h-48h-72h and totally reversible between D5 and D7.

A congestion of the iris (score 0.7/1.0/1.0) was noted in the 3 rabbits respectively, mean at 24h-48h-72h and totally reversible between D3 and D7.

A whitish secretion requiring a physiological saline rinse was noted at D2 in two animals.

Based on the results, classification as **Eye Irrit.2 – H319** is required for SANITERPEN INSECTICIDE DK, according to the CLP regulation criteria.

2.7.1.3.4 Sensitisation

Two LLNA studies (with cell counting) in mice were submitted.

Positive skin reactions were observed under the experimental conditions.

In the first study, no mortality and no signs of systemic toxicity were noted in the test and control animals during the test.

A Stimulation Index of more than 1.4 was recorded for the three concentrations of the test item.

The Stimulation Index (**SI**) calculated by pooled approach was respectively **2.17, 2.69** and **2.59** for the treated groups at **25%, 50%** and **100%**.

A slight dryness was noted at the concentrations of 25% and 50% on day 6. A slight dryness to dryness was noted at the concentration of 100% on day 5 and day 6.

An increase in ear thickness (+28.0%, +27.1%, +35.3%) and in ear weight (+13.9%, +33.7%, +50.1%) was recorded at the concentration of 25%, 50% and 100% respectively.

Therefore, the test item must be considered “slightly-irritant” at the concentrations of 25% and 50%, and "irritant" at the concentration of 100%.

In the second study, no mortality and no signs of systemic toxicity were noted in the test and control animals during the test.

A Stimulation Index of more than 1.4 was recorded for the two highest concentrations.

The Stimulation Index (**SI**) calculated by pooled approach was respectively **1.26, 1.44** and **1.60** for the treated groups at **2.5%, 5%** and **10%**. The EC1.4 determined by linear regression was 4.44%.

Slight dryness was noted on day 6 in all animals treated at 10% (4/4). No significant increase in ear thickness and in ear weight was noted in animals treated at 2.5%, 5% and 10%.

Based on these results, SANITERPEN INSECTICIDE DK must be considered a skin sensitizer.

However, the non radioactive cell count LLNA is not currently validated and no guideline is available. The EC determination is not possible.

Although the method used is not currently validated, the test has been accepted since positive results were observed.

SANITERPEN INSECTICIDE DK must be classified **Skin Sens. Cat 1 – H317** according to the CLP regulation criteria.

2.7.2 Human exposure assessment

SANITERPEN INSECTICIDE DK is an insecticide and acaricide containing 0.2% (w/w) deltamethrine as active substance. It is intended to be used by professional only to control flying and crawling insects and mites.

The product is applied by spraying after a dilution at 10% (v/v), only indoors in animal houses and shelters (animals not intended for human consumption).

The application rate is claimed to be 50 mL of diluted product/m^2, i.e. 10 mg a.s./m^2..

2.7.2.1 Identification of main paths of human exposure towards active substance from its use in biocidal product

Table 3: Main paths of human exposure

Exposure path	Industrial use	Professional use	General public	*via* the environment
Inhalation	na	yes	yes	na
Dermal	na	yes	yes	na
Oral	na	na	na	na

na: not applicable

2.7.2.2 Direct exposure as a result of use of the active substance in biocidal product

2.7.2.2.1 Exposure of professional users

SANITERPEN INSECTICIDE DK is an emulsifiable concentrate that is diluted with water before use (50 mL of product in 450mL of water), therefore dermal and inhalation exposure can occur during mixing and loading and application phases. Moreover, the product is applied with a knapsack sprayer (with hand held trigger), this equipment requires a cleaning phase after use.

Professional exposure during the mixing and loading and the application phases has been assessed using the Spraying model 1 from TNsG 2002[11].

Exposure during the cleaning of equipment has been assessed with the BEAT scenario "*Cleaning of spray equipment*" taken from TNsG second version of 2007[12].

The following parameters have been used:

- Concentration of active substance in the product after dilution: 0.02%;
- Application duration: 120 min (TNsG 2002);
- Cleaning duration (equipment): 10 min (TNsG 2007);
- Dermal absorption value: 10% (EFSA);
- Inhalation absorption value: 100% (default);
- $AEL_{long\text{-}term}$ = 0.0075 mg/kg bw/d;
- Protection factor of the gloves: 90%.

Table 4: Exposure assessment for professional users

Tier	Inhalation exposure	Dermal exposure	Total exposure
PPE	Systemic dose	Systemic dose	Systemic dose
	mg a.i. / kg bw /day	mg a.i. / kg bw /day	mg a.i. / kg bw /day
Task – time frame:	**Mixing / Loading and application – 120 minutes daily**		
Tier 1: Without PPE	8.7×10^{-4}	0.01	0.01
Tier 2 With gloves	8.7×10^{-4}	4.1×10^{-3}	5×10^{-3}
Task – time frame:	**Cleaning equipment – 10 minutes daily**		
Tier 1: Without PPE	negligible	6.3×10^{-4}	6.3×10^{-4}
Tier 2 With gloves	negligible	1.9×10^{-4}	1.9×10^{-4}

[11] Technical Notes for Guidance on Human Exposure to biocidal products, part. 2, 2002.
[12] Technical Notes for Guidance Human exposure to biocidal products, january 2008 (adopted during CA meeting of 19-20 june of 2007)

2.7.2.2.2 Exposure of non-professional users

SANITERPEN INSECTICIDE DK is for professional use only.

2.7.2.3 Indirect exposure as a result of use of the active substance in biocidal product

The general public (adult, child and infant) can be potentially exposed to SANITERPEN INSECTICIDE DK *via* the oral, dermal and inhalation routes. Nevertheless, as SANITERPEN INSECTICIDE DK is applied by professionals in animal houses and shelters, infants should not come into contact with freshly treated surfaces, so exposure is not calculated.

The exposure estimation values have been calculated on the basis of these scenarios:

- Adult and child – Inhalation of volatilised residues, indoor (chronic);
- Adult and child – Dermal exposure to treated surfaces (chronic).

For the scenario “Inhalation of volatilised residues by an adult” the saturated Vapour Concentration (SVC) has been calculated using the following parameters:

- Vapour pressure of deltamethrin: 1.24×10^{-8} Pa;
- The gas constant R: 8.31 $J.K.mol^{-1}$;
- Temperature: 293 K;
- Molecular Weight of deltamethrin: 505.2 g/mol;
- Body weight: 60kg (adult) and 23.9 kg (child) (HEEG opinion on default human factor values)[13];
- Inhalation rate: 16 m^3/24h (adult) and 12 m^3/24h (child) (HEEG opinion on default human factor values).

For the scenario “Dermal exposure of an adult to treated surfaces”, the dermal exposure value has been calculated using the following parameters:

- Concentration of active substance in the product after dilution: 0.02%;
- Application rate: 50 mL/m^2;
- Density of the product: 0.947;
- Transfer coefficient of dislogebable residues (dried fluids on various type of surface): 18% (TNsG on Human exposure, 2008);
- Hand surface (only palms of both hands): 410 cm^2(adult) and 213.9 cm^2 (child) (HEEG opinion on default human factor values);
- Dermal absorption value: 10% (EFSA).

[13] HEEG opinion on default human factor values for use in exposure assessemnts for biocidal product, endorsed at TM II 2013.

Table 5: Secondary exposure assessment

Scenario	Inhalation exposure	Dermal exposure	Oral exposure	Total exposure
	Systemic dose	Systemic dose	Systemic dose	Systemic dose
	mg a.i. / kg bw /day	mg a.i. / kg bw /day	mg a.i. / kg bw /day	mg a.i. / kg bw /day
Chronic exposure				
Adult – Inhalation of volatilised residues, indoor	6.9×10^{-7}	na	na	6.9×10^{-7}
Child – Inhalation of volatilised residues, indoor	1.3×10^{-6}	na	na	1.3×10^{-6}
Adult – Dermal exposure with treated surface, indoor	na	1.2×10^{-4}	na	1.2×10^{-4}
Child – Dermal exposure with treated surface, indoor	na	$1,5 \times 10^{-4}$	na	1.5×10^{-4}

2.7.2.4 Indirect exposure via residues in food

SANITERPEN INSECTICIDE DK is intended to be used only in empty animals' houses and shelters excluding thoses used by animals for human consumption. So as housing or transport vehicles used for livestock will not be treated, exposure of livestock and human exposure via food of animal origin was not assessed in this report.

2.7.3 Risk characterisation for human health

The estimated exposures for the professional users are compared to the systemic AEL of deltamethrine set in the Assessment Report (0.0075 mg/kg bw/day for short, medium and long-term exposures).

2.7.3.1 Risk for direct exposure

2.7.3.1.1 Professional users

Based on the risk assessment of the active substance, the risk for professional users resulting from the intended use is acceptable for SANITERPEN INSECTICIDE DK, when PPE are worn (%AEL < 100% for M&L/application and cleaning phases).

Table 6: Summary of risk characterisation for professionals

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
Mixing / Loading and application – 120 minutes daily				
Tier 1 Without EPI	0.0075	0.01	157	**Unacceptable**
Tier 2 With gloves	0.0075	5×10^{-3}	66	Acceptable
Cleaning equipment – 10 minutes daily				
Tier 1 Without EPI	0.0075	6.3×10^{-4}	8	Acceptable
Tier 2 With gloves, coverall and RPE	0.0075	1.9×10^{-4}	2.5	Acceptable

2.7.3.1.2 Non-professional users

The product is for professional use only.

2.7.3.2 Risk for indirect exposure

Based on the risk assessment of the active substance, no unacceptable risk has been identified for every indirect exposure considered scenarios. For details, see Excel document in separate appendix.

Table 7: Summary of risk characterisation for general public

Scénario	AEL (mg/kg bw/d)	Exposure (mg/kg bw/d)	%AEL	Risk
Chronic exposure				
Adult – Inhalation of volatilised residues, indoor	0.0075	6.9×10^{-7}	0.01	Acceptable
Child – Inhalation of volatilised residues, indoor	0.0075	1.3×10^{-6}	0.02	Acceptable
Adult – Dermal exposure with treated surface, indoor	0.0075	1.2×10^{-4}	1,6	Acceptable
Child – Dermal exposure with treated surface, indoor	0.0075	1.5×10^{-4}	2.03	Acceptable

2.7.3.3 Risk for consumers via residues

SANITERPEN INSECTICIDE DK is intended to be used only in empty animals' houses and shelters excluding thoses used by animals for human consumption. So as housing or transport vehicles used for livestock will not

be treated, exposure of livestock and human exposure via food of animal origin was not assessed in this report.

2.7.4 Conclusions for human health

Risks related to the use of SANITERPEN INSECTICIDE DK by professionals are considered acceptable during spray application when gloves are worn. Risk related to secondary exposure is also considered acceptable.

Regarding the intended used, exposure of livestock and human exposure via food of animal origin are not expected. Therefore, a dietary risk assessment is not required.

Risk mitigation measures linked to risk assessment for human health

- Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during the product handling phase .
- Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product;
- Keep out of the reach of children.

Risk mitigation measures linked to risk assessment for consumers

- Do not use on surfaces likely to be in direct contact with animals intended for food consumption, food, feed or drinks.

Required information linked to risk assessment for human health and consumers

None.

Emergency (not assessed by Anses)

- **Inhalation**: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur, show this container or label.
- **Skin contact:** Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Get medical attention if symptoms occur.
- **Eye contact**: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse with warm water for at least 10 minutes. Get medical attention if irritation or vision impairment occur.
- **Ingestion:** Wash out mouth with water. Get medical attention if symptoms occur, show this container or label.Do not drink or induce vomiting in case of consciousness alteration.
- **Note to physician**: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

2.8 Risk assessment for the environment

The summary of information on the active substance properties is carried out with the data from the Competent Authority Report (CAR) of deltamethrin supplied by Bayer Environmental Science SAS. (Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, deltamethrin CAS 52918-63-5, Product Type 18 (Insecticides, acaricides and products to control other arthropods), RMS Sweden, May 2011).

2.8.1 Fate and distribution in the environment of the active substance deltamethrin

2.8.1.1 Degradation

2.8.1.1.1 Abiotic degradation

2.8.1.1.1.1 Hydrolysis in function of pH

For the active substance deltamethrin, no significant hydrolysis was observed at pH 5 and 7. At pH 9, however, the hydrolysis was significant with a half-life of 2.5 days at 25°C (7 days at 12°C). At pH 8, half-life was 31 days at 23°C (75 days at 12°C).

2.8.1.1.1.2 Photolysis in water

Direct photochemical reactions do not occur at a rate that makes this a significant route of degradation of deltamethrin under natural conditions in water.

2.8.1.1.1.3 Photolysis in soil

In soil, direct and indirect photochemical reactions may contribute to the degradation of deltamethrin, but other routes of transformation account for the major loss of parent compound.

2.8.1.1.1.4 Photodegradation in air

The photo-oxidative degradation of deltamethrin in air was estimated by a structural activity relationship (QSAR) method using the Atmospheric Oxidation Program v1.91 (AOPWIN). Half-life for reaction with OH-radicals was calculated to 16.4 hours.

2.8.1.1.2 Biotic degradation

2.8.1.1.2.1 Aquatic compartment

- Ready biodegradation / inherent biodegradation

Deltamethrin is not readily biodegradable under OECD 301F Test (degradation of 0% after 28 days).

- Degradation in water/sediment system

A higher tier water/sediment simulation study in two different water/sediment systems has been conducted and provides information on aerobic aquatic degradation of deltamethrin. 60% of the applied radioactivity was found in the sediments immediately after application. The total system degradation DT_{50} of deltamethrin in two different water/sediment systems was estimated to 85 and 267 days at 12°C, and the dissipation DT_{50} in sediment to 104 and 253 days at 12°C. The difference in degradation rate between the two systems probably reflects difference in amount of fine-textured material and amount of organic matter.

2.8.1.1.2.2 Degradation in STP

No study on the degradation of the active substance in STP has been submitted in the CAR of deltamethrin.

2.8.1.1.2.3 Terrestrial compartment

- Aerobic degradation

Four laboratory studies on degradation in soils have been submitted in the CAR of deltamethrin, and one further study presented calculations of rate of degradation for the relevant metabolite Br_2CA (> 10%) based on data from the four laboratory studies. In one additional study the rate of degradation for deltamethrin and its relevant metabolite were re-calculated using more appropriate approaches than in the original studies.

Deltamethrin is relatively rapidly degraded in soil, with a geometric mean DT_{50} value of 48 days at 12°C. The main metabolite of deltamethrin was Br_2CA. It was detected in available studies, up to 23% of applied radioactivity after about 2 weeks of incubation. No other metabolites were detected at levels of > 10% of applied radioactivity. When normalised to 12°C, the geometric mean of DT_{50} value for Br_2CA was 5.6 days.

- Anaerobic degradation

No study on the anaerobic degradation of deltamethrin in soil has been submitted in the CAR.

2.8.1.2 Distribution

Deltamethrin is very strongly adsorbed to soil and other organic matter, with an arithmetic mean Koc value of 408 250 $L.kg^{-1}$. The relevant metabolite is more mobile with an arithmetic mean Koc value of 25.6 $L.Kg^{-1}$.

2.8.1.3 Accumulation

The bioaccumulation of ^{14}C-deltamethrin was investigated in bluegill sunfish (*Lepomis macrochirus*). The BCF_{fish} values obtained were 310, 2800 and 1400 $L.Kg^{-1}$ for edible, non-edible and whole body tissue, respectively. After the 14-day depuration period 70, 75 and 76% of the ^{14}C-residues had been eliminated from the edible, non-edible and whole body tissue, respectively. The biological half-life was 4.3 days for whole body tissue.

No experimental data are available for terrestrial bioconcentration. Therefore, the terrestrial BCF have been estimated using a linear Quantitative Structure Activity Relationship (QSAR) model and the log P_{ow} of deltamethrin of 4.6 at 25°C. The $BCF_{earthworm}$ was 483 $L.kg^{-1}$ (according to TGDII Equation 82d).

2.8.1.4 Behaviour in air

Due to its low vapour pressure, deltamethrin is not expected to volatilise to air from plants and soil at significant levels, which was confirmed in a wind tunnel study. However, the calculated Henry's law constant is 1.252×10^{-3} $Pa.m^3.mole^{-1}$, indicating that deltamethrin has a tendency to volatilise from water. If present in air, the data on indirect photo-oxidation indicate a rapid degradation when reacting with hydroxyl radicals.

2.8.2 Effects on environmental organisms for active substance deltamethrin

No new ecotoxicological information on the active substance deltamethrin has been submitted in the product dossier compared to the CAR.

2.8.2.1 Aquatic compartment (including water, sediment and STP)

2.8.2.1.1 Aquatic organisms

The table below summarises all the data available for the active substance deltamethrin. The metabolite Br2CA is considered not relevant for the aquatic compartment. Moreover it has been demonstrated in the CAR that the risk assessment for the metabolite, Br2CA was covered by the risk assessment for deltamethrin.

Table 8: Existing endpoints for aquatic organisms

Test item	Species	Guideline	Endpoints	Toxicity [µg.L^{-1}]	Reference
Fish					
Deltamethrin	*Onchorhynchus mykiss*	OECD 203	LC_{50} – 96h Flow-through conditions	0.26[1]	A.7.4.1.1/02
	Pimephales promelas	US EPA 72-5	NOEC – 260d	0.017[1]	A.7.4.3.2/02
Invertebrates					
Deltamethrin	*Gammarus fasciatus*	US EPA	LC_{50} – 96h Flow-through conditions	0.0003[1]	A.7.4.1.2/02
	Daphnia magna	OECD 211	NOEC – 21d Flow-through conditions	0.0041[1]	A.7.4.3.4/01
	Chironomus riparius	BBA 1995	NOEC – 28d	0.0035[1]	A.7.4.3.5.1/01
Algae					
Deltamethrin	*Chlorella vulgaris*	Brazilian method D.4.1	EbC_{50} – 96h ErC_{50} – 96h NOErC Static conditions	>0.47E03[1] >0.47 E03[1] 0.47 E03	A.7.4.1.3/02
Higher tier studies					
Deltamethrin	*water flea*	Mesocosm guidance[3]	NOEC Mesocosm conditions	0.0048[2]	A.7.4.3.5.3

[1] measured concentrations
[2] nominal concentrations
[3] OECD 2004 "Simulated Freshwater Lentic Field Tests (Outdoor Microcosms and Mesocosms)"

Additional endpoints: not relevant

Justification of $PNEC_{water}$

According to the TGD for Risk Assessment (2003), and using the lowest chronic laboratory NOEC value (3.5 ng.L^{-1}) and an assessment factor of 5 (considering that the test organism had been identified as the most sensitive), the $PNEC_{water}$ is 0.7 ng L^{-1}.

2.8.2.1.2 Sediment dwelling organisms

Justification of $PNEC_{sediment}$

The $PNEC_{sediment}$ is estimated from $PNEC_{water}$ in using the Equilibrium Partitioning Method (according to the TGD for Risk Assessment (2003)) with the mean Koc value for deltamethrin of 408 250 L.Kg^{-1}. The $PNEC_{sediment}$ is 6.2 µg kg_{wwt}^{-1}.

2.8.2.1.3 STP micro-organisms

The table below summarises the data available for the active substance deltamethrine.

Table 9: Existing endpoints for STP micro-organisms

Test item	Guideline	Species/ Inoculum	Exposure design	Exposure duration	Result [mg a.s.L^{-1}]			reference
					NOEC	EC_{50}	EC_{80}	
Deltamethrin	OECD 209	Activated sludge	Respiration inhibition	3h		>300	-	A.7.4.1.4/01
Deltamethrin	OECD 209	Activated sludge	Respiration inhibition	3h	>0.3	**>0.3**		A.7.4.1.4/02

Additional endpoints: not relevant

Justification of $PNEC_{STP\ micororganisms}$

According to the TGD for Risk Assessment (2003), and taking into account that deltamethrin had no significant effect at the highest tested concentration (NOEC ≥ 0.3 mg L^{-1}), an assessment factor of 10 can be applied. Thus, the $PNEC_{microorganisms}$ is 30 µg.L^{-1}.

2.8.2.2 Atmosphere

Significant exposure of the environment via air is not expected.

Due to its low vapour pressure, deltamethrin is not expected to volatilise to air from plants and soil at significant levels, which was confirmed in a wind tunnel study. However, the calculated Henry's law constant is 1.252 x 10^{-3} $Pa.m^3.mole^{-1}$, indicating that deltamethrin has a tendency to volatilise from water. If present in air, the data on indirect photo-oxidation indicate a rapid degradation when reacting with hydroxyl radicals (DT_{50} reaction with OH-radicals = 16.4 hours). It is thus considered that it is not likely that significant volatilisation will occur after use of deltamethrin.

2.8.2.3 Terrestrial compartment

The table below summarises all the data available for the active substance deltamethrin and its relevant metabolite, Br_2CA.

Table 10: Toxicity so soil organisms

Test item	Guideline/ Test method	Species inoculums	Endpoint / type of test	Exposure design duration	Results	Reference

Test item	Guideline/ Test method	Species inoculums	Endpoint / type of test	Exposure design duration	Results	Reference
ACUTE						
Deltamethrin	OCDE 207	*Eisenia fetida*	$LC50_{mortality}$	14d - Artificial soil	> 1290 mg/kg^{-1} $_{dw\ soil}$	A.7.5.1.2/01
CHRONIC						
Br_2CA	SECOFASE (1996)	*Hypoaspis aculeifer*	$NOEC_{mortality}$ Br_2CA mixed with LUFA 2.1 soil	14d	10 mg/kg^{-1} $_{dw\ soil}$	A.7.5.2.1/01
Deltamethrin	BBA VI 2-2	*Eisenia fetida*	$NOEC_{reproduction}$	56d - Artificial soil	0.78 mg/kg^{-1} $_{dw\ soil}$	A.7.5.2.1/02
	ISO 11267	*Folsomia candida*	$NOEC_{mortality}$	28d - Artificial soil	1.25 mg/kg^{-1} $_{dw\ soil}$	A.7.5.2.1/03
	Hypoaspis ring-test (SETAC, 2005)	*Hypoaspis aculeifer*	$NOEC_{mortality}$ and $NOEC_{reproduction}$	16d - Artificial soil	1.78 mg/kg^{-1} $_{dw\ soil}$	A.7.5.2.1/04
	BBA VI, 1-1	Microorganisms	NOEC- Effect on aerobic respiration in 2 soils	28/56-d	>0.50 mg/kg^{-1} $_{dw\ soil}$ equivalent to > 375 g/ha	A.7.5.1.1/01
	BBA VI, 1-1	Microorganisms	NOEC - Effect on N cycle in 2 soils	28d	>0.50 mg/kg^{-1} $_{dw\ soil}$ equivalent to > 375 g/ha	A.7.5.1.1/02

Additional endpoints: not relevant.

Justification of $PNEC_{soil}$

Due to the lack of effects in the tests on micro-organisms and chronic toxicity to earthworms, the PNEC is based on the NOEC from the reproduction test on springtails.

The results are converted to standard soil which is defined as a soil with an organic matter content of 3.4% using the following equation:

$NOEC_{standard} = NOEC_{exp} \times F_{om,\ soil\ standard} / F_{om,\ soil\ exp}$ (TGD, part II, Eq. 71)

With $NOEC_{exp} = 1.25\ mg.kg^{-1}$ dry soil

$F_{om,\ soil\ standard} = 3.4\ \%$

$F_{om,\ soil\ exp} = 5\ \%$

Then, $NOEC_{standard} = 0.85\ mg.kg^{-1}$ dry soil

An assessment factor of 10 can be applied. Thus, the following $PNEC_{soil}$ is derived:

$PNEC_{soil}$ = 85 µg.kg^{-1} dry soil (75 µg.kg^{-1} wet soil)

No $PNEC_{soil}$ was derived for the metabolite Br_2CA, since toxicity results show that the parent compound is more toxic and more persistent than this metabolite. Therefore the risk assessment of this metabolite is covered by the active substance for the soil compartment.

2.8.2.4 Effects on honeybees

No data, the exposure of deltamethrin to honeybees is expected to be very limited.

2.8.2.5 Non compartment specific effect relevant to the food chain

The table below summarises the data available for the active substance deltamethrin:

Table 11: Toxicity to birds and mammals

Test item	Guideline/Test method	Species	Test/ Duration		Results	reference
Birds						
Deltamethrin	US EPA FIFRA E 71-1	*Bobwhite quail (Colinus virginianus)*	Acute oral LD_{50}		>2250 $mg.kg^{-1}_{bw}$	A.7.5.3.1.1/01
	Conducted before an appropriate guideline	Mallard duck *(Anas platyrhynchos)*	Acute oral LD_{50}		> 4640 $mg.kg^{-1}_{bw}$	A.7.5.3.1.1/02
	US EPA 71-2 / OECD 205	*Bobwhite quail (Colinus virginianus)*	Dietary 5-day LC_{50}		> 5620 mg/kg^{-1}_{diet}	A.7.5.3.1.2/01
	US EPA 71-2 / OECD 205	Mallard duck *(Anas platyrhynchos)*	Dietary 5-day LC_{50}		8039 mg/kg^{-1}_{diet}	A.7.5.3.1.2/02
	US EPA 71-4; OECD 206	*Bobwhite quail (Colinus virginianus)*	Reproduction 22-week NOEC		> 450 mg/kg^{-1}_{diet} (55 $mg.kg^{-1}_{bw}\ d^{-1}$)	A.7.5.3.1.3/01
	US EPA 71-4; OECD 206	Mallard duck *(Anas platyrhynchos)*	Reproduction 22-week NOEC		> 450 mg/kg^{-1}_{diet} (70 $mg.kg^{-1}_{bw}\ d^{-1}$)	A.7.5.3.1.3/02
Mammals						
Deltamethrin	OECD 401	rat	LD_{50}	Oral	95 $mg.kg^{-1}_{bw}$ (males) 87 $mg.kg^{-1}_{bw}$ (females)	A6.1.1/01
	OECD 416	rat	NOAEL	Oral	80 ppm	A6.8.2/01

Justification of PNECoral,bird and PNECoral,mammal for secondary poisoning

The $PNEC_{bird}$ and the $PNEC_{mammals}$ calculations are based on a long-term toxicity / reproduction study with bird and on a 2 generation toxicity test on rat respectively. According to the TGD for Risk Assessment (2003), an assessment factor of 30 for bird and mammal can be applied. Thus, the following $PNEC_{oral}$ are derived:

$$\mathbf{PNEC_{oral,bird} = 15\ mg.kg^{-1}_{\ diet}}$$

$$\mathbf{PNEC_{oral,mammal} = 2.67\ mg.kg^{-1}_{\ diet}}$$

2.8.2.6 Summary of PNECs of the active substance deltamethrin

Table 12: Summary of PNECs of the active substance deltamethrin

Compartment	Species	Endpoint	Safety factor	PNEC
Surface water	*Chironomus riparius*	NOEC – 28d = 3.5 $n.gL^{-1}$	5	0.7 $ng.L^{-1}$
Sediment	6.2 $\mu g.kg^{-1}$ ww sediment (equilibrium partitioning)			
Microorganisms (STP)	Activated sludge	NOEC ≥ 0.3 mg L^{-1}	10	30 $\mu g.L^{-1}$
Soil	*Folsomia candida*	NOECstandard = 0.85 $mg.kg^{-1}_{\ dry\ soil}$	10	75 $\mu g.kg^{-1}$ wet soil
Bird	*Colinus virginianus* *Anas platyrhynchos*	NOEC > 450 $mg/kg^{-1}_{\ diet}$	30	15 $mg.kg^{-1}$ diet
Mammal	*Rat*	NOAEL = 80 ppm	30	2.67 $mg.kg^{-1}$ diet

2.8.2.7 PBT and ED Assessment

According to the PBT assessment in TGD, criteria for substance to be persistent (P) and very persistent (vP) are fulfilled when:

- T 1/2 in freshwater sediment > 120 days for P;
- T 1/2 in freshwater sediment > 180 days for vP.

Results of a simulation test on two different water/sediment systems show that deltamethrin partitions very rapidly to sediment. The degradation half-lives of deltamethrin in both systems were 85 and 267 days at 12°C (degradation in the whole water/sediment systems).

It can be concluded that in one system the DT_{50} normalised to 12°C exceeds the P- and the vP-criteria for freshwater sediment – while in the other system the DT_{50} normalised to 12°C does not exceed any of P / vP criteria. With one value below the criteria and one value above, it cannot be concluded whether deltamethrin should be classified as persistent in the sediment compartment or not.

Laboratory data from four different soils were available; the DT_{50}s ranged from 31 to 74 days (12°C). Hence, none of the half-lives for degradation in soil exceeds the P-criterion for soil (i.e. > 120 days). It is concluded that deltamethrin cannot be classified as persistent in the soil compartment.

Both environmental compartments for which there is adequate data available (i.e., sediment and soil) are considered to represent relevant environmental compartments since emissions may occur to both systems, via

release from STP or application of sludge. Based on the data above **it can be concluded that deltamethrin potentially fulfils the criteria for persistence**.

According to the PBT assessment in TGD, a substance is considered to fulfill the B criterion when the bioconcentration factor (BCF) exceeds a value of 2 000 L/kg. In a BCF study done with *Lepomis macrochirus*, the steady-state BCF for uptake of deltamethrin estimated in whole fish was 1400 L/kg. Considering this result, **deltamethrin is not selected according to the B criterion**.

According to the PBT assessment in TGD, the toxicity criterion is fulfilled when the chronic NOEC for aquatic organism is less than 0.01 $mg.L^{-1}$ or when the substance is toxic to mammals and classified as Very Toxic or Toxic after oral dosing. Based on ecotoxicity freshwater data on water flea, NOEC = 4.8 $ng.L^{-1}$, **T criterion is fulfilled**.

As the B criterion is not fulfilled and only the T criterion is clearly fulfilled, deltamethrin is not classified as a PBT.

2.8.3 Effects on environmental organisms for biocidal product SANITERPEN INSECTICIDE DK

The applicant provided acute ecotoxicological data about the biocidal product SANITERPEN INSECTICIDE DK. Nevertheless, the results of these new acute studies do not modify the PNEC values already stated for the active substance and do not bring elements to change the calculated classification. Therefore the risk assessment for the product is based on the data obtained from the active substance deltamethrin (Competent Authority Report According to Directive 98/8/EC, Active substance in Biocidal Products, deltamethrin CAS 52918-63-5, Product Type 18 (Insecticides, acaricides and products to control other arthropods), RMS Sweden, May 2011).

No classified compound other than the active substance is present in the biocidal product. Therefore, FR CA considered that the effects of deltamethrin outweigh those of the non-active components of the product and that the effects assessment for the product SANITERPEN INSECTICIDE DK can be extrapolated from the effects assessment of the active substance deltamethrin.

2.8.3.1 Aquatic compartment (including water, sediment and STP)

2.8.3.1.1 Aquatic organisms

Two studies, conducted on a product similar to SANITERPEN INSECTICIDE DK, are available. The results are presented in the following table but not used in the risk assessment.

Table 13: Additional endpoints on SANITERPEN INSECTICIDE DK

Test item	Species	Guideline	Endpoints	Toxicity (mg/L)	Reference
Fish					
SANITERPEN INSECTICIDE DK	*Onchorhynchus mykiss*	OECD 203	LC_{50} – 96h Semi-static conditions	3.18* 6.14E-03**	B9.2.1
Invertebrates					
Deltamethrin	*Daphnia magna*	OECD 202	EC_{50} – 48h Semi-static conditions	<1* <1.93E-03**	B9.2.2

* mg product/L (nominal concentrations)

** mg deltamethrine/L(nominal concentrations)

2.8.3.1.2 Sediment dwelling organisms

No additional data. Refer to section 2.8.2.1.2.

2.8.3.1.3 STP micro-organisms

No additional data. Refer to section 2.8.2.1.3.

2.8.3.2 Atmosphere

No additional data. Refer to section 2.8.2.2.

2.8.3.3 Terrestrial compartment

No additional data. Refer to section 2.8.2.3.

2.8.3.4 Non compartment specific effect relevant to the food chain

No additional data. Refer to section 2.8.2.5.

2.8.3.5 Summary of PNECs

No additional data. Refer to section 2.8.2.6.

2.8.4 Environmental exposure assessment

The product SANITERPEN INSECTICIDE DK contains 0.2% w/w of deltamethrin. It is used by professionals only. The product is applied after dilution by spraying and is intended to control insects and mites. SANITERPEN INSECTICIDE DK is applied only indoors in empty animal houses and shelters.

Targeted animal houses and shelters are small houses which are used in rural areas by farmers, hunters, agricultural workers, or houses and shelters used for small farming (dog farming, ornamental chicken farming), or by small associations working for the protection of the animals.

Animals which are intended to be protected with the product are not intended to be used for consumption. Only pets (i.e. horses, dogs, rabbits…) environment is intended to be treated. The product is not intended to be used in big animal farming or industrial farming. The packaging is not intended for such an activity (3 x 60mL, 1L, 5L).

The intended uses of SANITERPEN INSECTICIDE DK can be covered in one environmental exposure scenario as the profile of users and location of use are the same for all the pets' environment location which are treated with the product.

The recommended application dose is 5 mL $_{product}$ /m^2 or 10 mg $_{a.s.}$/m^2. The efficacy against target insects lasts for 3 months after application in field conditions. During winter there is no insect infestation due to climatic condition. The product shall be applied only 3 times per year maximum.

2.8.4.1 Assessment of exposure to the environment: Professional Use of SANITERPEN INSECTICIDE DK for treatment of pet's environment in rural areas

The environmental risk assessment is made according to the ESD n°18 "Emission scenario document for insecticides, acaricides and products to control other arthropods for household and professional uses" (2008). The ESD n°18 relates to consumer uses (in households) and professional uses (in other buildings). Non-professional users are excluded in the scenario presented below as the product is intended to be used by professionals only.

"Other buildings" shall be clearly defined in our case. Buildings which are treated are only:

- Animal housing in rural areas (for example horse shelter, ornamental chickens shelter, dog shelters);
- Animal shelters for small animal farming intended for pet production or pet protection (dog kennels, rabbit houses).

Another ESD on the use of insecticides is available: ESD n°14 "Emission scenario document for Stables and Manure Storage Systems" which covers insecticide applications in industrial farming (production of livestock, poultry…). It was considered that this ESD was not fully adapted for the uses of SANITERPEN INSECTICIDE DK described above (small animal housing, generally up to 10 pets).

Details on use of the product

Number of application and dose

Three applications per year every 3 months are required to manage insect infestation with SANITERPEN INSECTICIDE DK. The product is diluted at 10% (v/v) in water before use. The application dose is 50 $mL_{diluted\ product}/m^2$, corresponding to 10 mg $_{a.s.}/m^2$ (considering 0.2% deltamethrin in the product). During application, the surfaces are treated only once with the product.

Surface

The maximum surface to be treated per application is proposed by the applicant to be 350 m^2. This corresponds to the maximum use of the 5L packaging which can cover 1000 m^2. Considering 3 applications per year, the treated surface can be lowered to 333 m^2 per application. The value of 350 m^2 per building was therefore proposed and accepted for the assessment of these small animal housings and shelters.

No literature exists on the areas of specific type of building which is targeted by the product SANITERPEN INSECTICIDE DK but usual surfaces (floor, walls and ceilings) which are encountered in rural areas are:

- Approximately 200 m^2 for horse shelters
- Approximately 150 m^2 for kennels
- Approximately 90 m^2 for rabbits hutches
- Approximately 100 m^2 for chicken coops.

The product SANITERPEN INSECTICIDE DK is intended to be applied in small animal housing (generally up to 10 pets) and only for pets (no animal consumption). Considering this specific use and in comparison to the smallest area of farm animals housing proposed in the ESD n°14 "Emission scenario document for Stables and Manure Storage Systems" (490 m^2 for veal calves), it can be considered that the value of 350 m^2 covers all pets housings.

The product SANITERPEN INSECTICIDE DK is intended to be used by professionals only. Limitation of application to a maximum surface of 350 m^2 is a risk management measure clearly stated on the label of the product: "*SANITERPEN INSECTICIDE DK is designed to be used on a max. surface of 350 m^2 per application. If treatment requires a higher surface treatment, another solution shall be investigated*".

Equipment

The product SANITERPEN INSECTICIDE DK is intended to be diluted in a Lever-operated Knapsack sprayer with a handheld trigger only (see 2.4.1.3 of the ESD 18). Dilution may be done with a specific designed dilution

system in order to avoid any spill on the applicator or on the floor but this is not a mandatory requirement. Exposure assessment is carried out considering manual dilution.

Operating instructions

Different risk mitigations are proposed by the applicant before the use of the product. They are reported below in order to have a clear view of the operating instructions to include in the exposure assessment:

Before using SANITERPEN INSECTICIDE DK

- Buildings, houses and shelters shall be cleared from all animals, animal food and water. Textiles (pillows, blankets…) shall be taken away and washed thoroughly.
- Floor and walls, including previously treated surfaces, shall be mechanically cleaned from dusts using vacuum system or brush and dusts shall be collected and treated as a waste.
- Depending on the case, risk management measures regarding resistance (see section 6 of the IUCLID dossier) shall be considered.
- Surface to be treated shall be determined and calculated regarding specific cases (pets to be protected, insects to be controlled). In all case it should be limited to 350 m^2.

Preparation and application

- Dilution shall be performed on a waterproof surface directly in the application equipment. Only the quantity which is necessary for the treatment shall be prepared.
- Application shall be made according to the recommended equipment. Surfaces shall be treated only once during the application.

After application of SANITERPEN INSECTICIDE DK

- After application the sprayer equipment shall be rinsed 3 times with water and rinsing water shall be collected and treated as a waste.
- SANITERPEN INSECTICIDE DK must be kept inside the original packaging.
- In any case, never throw rinsing water or SANITERPEN INSECTICIDE DK in the waste water system or surface water.
- After application treated surfaces shall not be cleaned (cleaning will take place before the next application).
- Animals shall be re-introduced only when the surfaces are dried (max. 24hours). Textiles shall be reintroduced also only when animals are re-introduced.

Details on the Exposure assessment

In the calculations, default values (according to the TGD) and updated data from MOTA (Manual of Technical Agreements – version 6) were used, unless submitted data were available in the dossier. All deviations are detailed and justifications are provided below. Calculations are based on the maximum amount used per application as a worst-case scenario.

The assessment has been carried out for the **mixing/loading and application phase** and for the subsequent **cleaning phase**, as it is indicated by the applicant that the surface must be cleaned before a new application (but not between applications). In his proposal, the applicant carried out an environmental exposure assessment in considering specific operating instructions. The treated surfaces shall be mechanically cleaned using vacuum system or brush. And in any case, never throw rinsing water in the waste water system or surface. Consequently in the applicant evaluation, a release to wastewater was only taken into account from applicator emission. Nevertheless, in order to evaluate the relevance of these operating instructions, an exposure assessment with emission to wastewater from floor and treated surfaces has been added.

To complete the assessment, a potential emission into the environment *via* a potential **application of manure** (for example to cover horse manure application) on arable land and grassland has been taken into account. It should be noted that this scenario taken from the ESD n°14 “Emission scenario document for Stables and Manure Storage Systems” is considered as a very worst case approach as the emission calculations form this document cover industrial farming.

Release to STP via wastewater after cleaning of treatment surfaces

- ***Number of buildings per STP and simultaneity factor***

  The applicant proposed a value of 100 pets-housing per STP combined with a simultaneity factor of 0.82% (1 to 11 applications per year according to the ESD) considering the maximal intended application number of 3 per year. These proposals were considered acceptable. Nevertheless, this leads to less than one building cleaned per day, which is not realistic. Consequently, one building cleaned per day at the STP scale has been considered in the environmental exposure assessment for the use of the product SANITERPEN INSECTICIDE DK.

- ***Cleaning efficiency (Spray-Surface)***

  A cleaning efficiency of 50% was used as proposed for a spray-surface application in the ESD n°18 for household insecticides (Table 3.3-8).

Table 14: Release to wastewater for the mixing/loading and the cleaning phases

Parameter	*Symbol*	*Value*	*Unit*	*Source*
Product Information				
Product Name	(-)	Saniterpen insecticide Dk	(-)	(-)
Active Ingredient	(-)	Deltamethrin	(-)	(-)
Fraction of deltamethrin in product	Fai	0.002	(-)	Input
Application dose of Product	Q_{prod}	50	$mL.m^{-2}$	Input
Dilution rate in water (v/v) before use	DIL	10	%	Input
Treatment Rate of deltamethrin	Qai	0.01	$g_{as}.m^{-2}$	Output
Quantity of commercial product used for the preparation, building	$Q_{prod, prep}$	1.75E+04	g	Output
Product formulation and container type	(-)	Liquid 5 liters (D= 45/63 mm)	(-)	Pick-list
Treatment Sub-category	(-)	Surface spray / Total Surface	(-)	Pick-list
User Type	(-)	Professional	(-)	Pick-list
Area of treated surface, larger building	$AREA_{treated}$	350	m^2	Calculated
Indoor Mixing/Loading				
Fraction emitted to air	$F_{prep,air}$	0	(-)	Default
Fraction emitted to applicator	$F_{prep,applicator}$	0.0012	(-)	Default
Fraction emitted to floor	$F_{prep,floor}$	2.00E-05	(-)	Default
Emission to air	$E_{prep,air}$	0	$kg.d^{-1}$	Output
Emission to applicator	$E_{prep,applicator}$	4.20E-06	$Kg.d^{-1}$	Output
Emission to floor	$E_{prep,floor}$	7.00E-08	$Kg.d^{-1}$	Output
Indoor application by spraying - Application				
Number of applications per day, building	N_{appl}	1	(-)	Default
Fraction emitted to air	$F_{appli,air}$	0.02	(-)	Default
Fraction emitted to applicator	$F_{appli,applicator}$	0.006	(-)	Default
Fraction emitted to floor	$F_{appli,floor+treated}$	0.974	(-)	Output
Emission to air	$E_{application,air}$	7.00E-05	$Kg.d^{-1}$	Output
Emission to applicator	$E_{application,applicator}$	2.10E-05	$Kg.d^{-1}$	Output
Emission to floor	$E_{application,floor+treated}$	3.41E-03	$Kg.d^{-1}$	Output
Indoor application by spraying – Cleaning before the next application				
Fraction emitted to wastewater from applicator (washable coveralls)	$F_{applicator,ww}$	1	(-)	Default
Fraction emitted to wastewater from floor /	$F_{treated\ surface,ww}$	1	(-)	

Parameter	*Symbol*	*Value*	*Unit*	*Source*
treated surface during the cleaning step				
Number of animal housings per STP	$N_{buildings/STP}$	1	(-)	
Cleaning efficiency (Spray-Surface)	F_{CE}	0.5	(-)	Default
Release to waste water for one building and one application				
Emission from applicator to waste water	$E_{applicator,ww}$	2.52E-05	$Kg.d^{-1}$	Output
$E_{applicator,ww} = (E_{prep,applicator} + E_{application,applicator}) \times F_{applicator,ww}$				
Emission from floor/treated to waste water during the cleaning step	$E_{treated\ surface,\ ww}$	1.71E-03	$Kg.d^{-1}$	Output
$E_{treated,ww} = (E_{prep,floor} + E_{application,floor+treated}) \times F_{treated\ surface,ww} \times N_{buildings/STP} \times F_{CE}$				

Release to soil via application of manure

The emission estimation is based on the ESD n°14 “Emission scenario document for Stables and Manure Storage Systems”, which is considered as a very worst case approach as the emission calculations from this document cover industrial farming. The scenario is calculated for the worst case scenario “veal calves” described in the ESD, considering default values for this animal category. The input parameters and the results of the emission calculation are reported below, considering three applications per year maximum without taking into account of winter, as there is no insect infestation during winter due to climatic condition, which leads to a treatment interval of 3 months.

Table 15: Emissions to soil via manure spreading - Input parameters for the emission scenario PT18 - Disinfection of animal houses by spraying – professional use (veal calf)

Variable/parameter	Unit	Symbol	S/D/O	Value
INPUT				
Type of animal house	[-]	cat-subcat (i1)	D	Veal Calves
Type of application	[-]	appway (i3)	D	Spraying
Area of the housing : Wall and floor	[m^2]	AREA	D	330
Content of a.i. in product	[$g.L^{-1}$]	Fbioc	S	2
Amount of (undiluted) product prescribed to be used per m^2	[$L.m^{-2}$]	Vprod	S	5.00E-02
Dilution factor	[$g.L^{-1}$]	F_{dil}	D	0.10
Fraction of a.i. released	[-]	$F_{slurry/manure}$	D	0.5
OUTPUT				
Amount of a.i. to be used for one application	[kg]	Qai-prescr	O	3.30E-03
Amount of a.i. in slurry/manure after one application	[kg]	$Qai_{slurry/manure\ t0}$	O	1.65E-03
CALCULATIONS				
Emission to manure/ slurry :				
$Qai\text{-}prescr_{i1,i2,i3} = 10^{-3} * Fbioc * Vprod * F_{dil} * AREA_{i1}$				
$Qai_{manure} = Qai\text{-}prescr * F_{slurry/manure}$				
Number of disinfectant applications in one year	[-]	Napp-bioc	D	3
Biocide application interval	[d]	Tbioc-int	D/O	92
Number of manure applications - grassland	[-]	Nlapp-grass	D	4/1*

Variable/parameter	Unit	Symbol	S/D/O	Value
Number of manure applications - arable land	[-]	Nlapp-arab	D	1
Manure application time interval for grassland	[d]	Tgr-int	D	53
Manure application time interval for arable land	[d]	Tar-int	D	212
Number of animals	[-]	Nanimal $_{i1}$	D	80
Amount of nitrogen per animal	[kg.d^{-1}]	Qnitrog $_{i1}$	D	2.38E-02
IF NITROGEN IMMISSION STANDARDS ARE APPLIED				
Nitrogen immission standard for one year - grassland	[kg.ha^{-1}]	$Q_{N,grassland}$	D	170
Nitrogen immission standard for one year - arable land	[kg.ha^{-1}]	$Q_{N,arable\_land}$	D	170
Mixing depth with soil - grassland	[m]	$DEPTH_{grassland}$	D	0.05
Mixing depth with soil - arable land	[m]	$DEPTH_{arable\_land}$	D	0.2
Density of wet bulk soil	[kg.m^{-3}]	$RHO_{soilwet}$	D	1700
Intermediate Calculations				
Number of biocide applications - grassland	[-]	Napp-manure $_{grassland}$	O	1
Number of biocide applications - arable land	[-]	Napp-manure $_{arable\ land}$	O	3
Amount of active ingredient in manure - grassland	[kg]	Qai-grass$_{i1,i2,i3,i4}$	O	1.65E-03
Amount of active ingredient in manure - arable land	[kg]	Qai-arab$_{i1,i2,i3,i4}$	O	4.95E-03
Amount of nitrogen - grassland	[kg]	Qnitrog-grass$_{i1,i4}$	O	1.01E+02
Amount of nitrogen - arable land	[kg]	Qnitrog-arab$_{i1,i4}$	O	4.04E+02
OUTPUTS				
Soil exposure				
Initial concentration of a.i. in soil - nitrogen - grassland	[mg.kg$^{-1}_{wwt}$]	PIECgrs-N$_{i1,i2,i3,i4}$	O	3.27E-03 (1 appl) 8.17E-04 (4 appl.)
Initial concentration of a.i. in soil - nitrogen - arable land	[mg.kg$^{-1}_{wwt}$]	PIECars-N$_{i1,i2,i3,i4}$	O	6.13E-04
CALCULATIONS				
Intermediate Calculations				
Napp-manure *(for grassland and arable land)*:				
If Tbioc-int > Tgr/ar-int, then Napp-manure = 1				
If Tbioc-int < Tgr/ar-int, then Napp-manure = ROUND (Tgr/ar-int/Tbioc-int)				
Qai-grass$_{i1,i2,i3,i4}$ = Qai$_{manure\ (DEG)}$ * Napp-manure$_{gr}$				
Qai-arab$_{i1,i2,i3,i4}$ = Qai$_{manure\ (DEG)}$ * Napp-manure$_{ar}$				
Qnitrog-grass$_{i1,i4}$ = Nanimal$_{i1}$ * Qnitrog$_{i1}$ * Tgr-int$_{i2}$				
Qnitrog-arab$_{i1,i4}$ = Nanimal$_{i1}$ * Qnitrog$_{i1}$ * Tar-int$_{i2}$				
End calculations				
Soil exposure				
$PIECgrs-\ N_{i1,i2,i3,i4} = \frac{100 \times Qai-grass_{i1,i2,i3,i4} \times Q_{N,grassland}}{Qnitrog-grass_{i1,i4} \times Nl_{app-grass} \times DEPTH_{grassland} \times RHOsoil_{iwet}}$				
$PIECars-\ N_{i1,i2,i3,i4} = \frac{100 \times Qai-arab_{i1,i2,i3,i4} \times Q_{N,arable-land}}{Qnitrog-arab_{i1,i4} \times Nl_{app-arab} \times DEPTH_{arab-land} \times RHOsoil_{wet}}$				

* The ESD indicates applications on grassland in 4 times; nevertheless a worst case application in only one go was considered here for the soil contamination. For surface water contamination via run-off, it was deemed more realistic to take the PEC value after only one application on 4.

2.8.4.2 PEC calculations

Emission to the environment can occur either through release to STP, or through release to manure. These two ways of emission induce different environmental concentrations.

According to the deltamethrin dossier, the following distribution characteristics in the STP (determined from the SimpleTreat 3.1 Model) and the following physicochemical parameters have been used. Moreover calculations have been adjusted to consider a SLUDGE RATE value of 710 $kg.d^{-1}$ instead of 790 $kg.d^{-1}$ integrated in the EUSES program.

Table 16: Physico-chemical parameters used for PEC calculations

Fate	% of residue
to air	0.0
to water	9.6
to sludge	90.4
degraded	0.0
Total	100.0
Physico-chemical parameter	Value
Organic carbon-water partition coefficient	408 250 L kg-1
Henry's law constant	1.252 x 10-3 Pa.m3.mol-1
Rate constant for biodegradation in soil	1.44E-02 (12°C)

No PEC was derived for the relevant metabolite Br_2CA in the aquatic or terrestrial compartment, since toxicity results show that the parent compound is more toxic and more persistent than this metabolite. Nevertheless, predicted concentrations in porewater have been estimated for this metabolite, considering a Koc value of 25.61 $L.Kg^{-1}$ and a DT_{50} in soil at 12°C of 5.6 days.

2.8.4.2.1 Aquatic compartment (surface water, sediment, STP)

Two ways of aquatic contamination are foreseen after application and cleaning of SANITERPEN INSECTICIDE DK:

- via the STP, if the surfaces are cleaned with water,
- via the contaminated manure application on agricultural soil and potential run-off to waterbodies.

RELEASE VIA THE WASTE WATER (STP)

The concentrations of deltamethrin in the STP effluent, in surface water and in sediment are calculated according to the TGD equations considering the emissions to waste water calculated from indoor applications of SANITERPEN INSECTICIDE DK in empty animal houses and shelters.

Table 17: PECs in the aquatic compartment - Emission from applicator to STP

Symbol	Parameter	Value	Unit	Reference
$E_{applicator,ww}$	Emission from applicator to waste water	2.52E-05	[$kg.d^{-1}$]	Output

Symbol	Parameter	Value	Unit	Reference
PEC_{STP}	PEC in the treated wastewater	1.21E-06	[$mg.L^{-1}$]	TGD Eq. 33
$PEClocal_{water}$	PEC in water during emission episode	7.50E-08	[$mg.L^{-1}$]	TGD Eq. 45
$PEClocal_{sed}$	PEC in sediment during emission episode	6.66E-04	[$mg.kg^{-1}_{wwt}$]	TGD Eq. 50

Table 18: PECs in aquatic compartment - Emission from surface cleaning phase to STP

Symbol	Parameter	Value	Unit	Reference
$E_{treated\ surface,\ ww}$	Emission from floor/treated to waste water during the cleaning step	1.71E-03	[$kg.d^{-1}$]	Output
PEC_{STP}	PEC in the treated wastewater	8.23E-05	[$mg.L^{-1}$]	TGD Eq. 33
$PEClocal_{water}$	PEC in water during emission episode	5.10E-06	[$mg.L^{-1}$]	TGD Eq. 45
$PEClocal_{sed}$	PEC in sediment during emission episode	4.53E-02	[$mg.kg^{-1}_{wwt}$]	TGD Eq. 50

RELEASE VIA THE MANURE SPREADING

The $PEClocal_{water}$ following the run-off after manure/slurry spreading onto soil are calculated as shown below: PIEC grs-ars- surface water N = PIEC grs-ars- groundwater N / DILUTIONrun-off. A dilution factor of 10 was considered according to the ESD n°14. Result for the worst case scenario (housing of veal calves) is shown in the following table.

PEC soil values considered to carry out the calculation (initial PEC soil) are presented in Table 19. It is worth noting that for surface water contamination via run-off, it was deemed more realistic to take the PEC value after only one application for grassland.

Table 19: PECs in aquatic compartment - Emission from manure application and potential run-off

Symbol	Parameter	Value		Unit
Veal calves (Deltamethrin)		Grassland	Arable land	
$PEClocal_{water}$ Deltamethrin	PEC in water during emission episode	1.14E-08	8.54E-09	[$mg.L^{-1}$]

2.8.4.2.2 Atmospheric compartment

Significant exposure of the environment via air is not expected.

Due to its low vapour pressure, deltamethrin is not expected to volatilise to air from plants and soil at significant levels, which was confirmed in a wind tunnel study. However, the calculated Henry's law constant is 1.252×10^{-3} $Pa.m^3.mole^{-1}$, indicating that deltamethrin has a tendency to volatilise from water. If present in air, the data on indirect photo-oxidation indicate a rapid degradation when reacting with hydroxyl radicals (DT_{50} reaction with OH-radicals = 16.4 hours).

2.8.4.2.3 Terrestrial compartment (soil and groundwater)

RELEASE VIA THE WASTE WATER

The concentrations in agricultural soil, following the spreading of contaminated STP sludge, are calculated according to the TGD equations considering the emission rates to wastewater (E_{ww}). A degradation of deltamethrin in soil (DT_{50} value of 48 days at 12°C) is taken into account. To estimate PECs in porewater for the relevant metabolite Br_2CA, a Koc value of 25.61 $L.Kg^{-1}$ and a DT_{50} in soil at 12°C of 5.6 days have been considered. Initial concentrations of Br_2CA in soil following application of sewage sludge to land were estimated on the worst-case assumption that the metabolite is formed in the sludge at a quantity equivalent to 100% of the parent (adjusted to take into account the molecular weights of the compounds, F=0.59).

According to the TGD, PECs groundwater were derived from the twa value of PECs soil over 180 days.

Table 20: PECs in Terrestrial compartment – Release via the STP - Emission from applicator

Symbol	Parameter	Value	Unit	Reference
$E_{applicator,ww}$	Emission from applicator to waste water	2.52E-05	$Kg.d^{-1}$	Output
$PEC_{local\ soil}$	$PEC_{soil\ 30d}$	3.85E-05	$[mg.kg^{-1}_{wwt}]$	TGD Eq. 60
$PEC_{local\ soil\ porewater\ Deltamethrin}$	$PEC_{in\ porewater\ (agricultural.soil)\ 180d}$	2.34E-06	$[\mu g.L^{-1}]$	TGD Eq. 67
$PEC_{local\ soil\ porewater\ Br2CA}$		2.15E-03		

Table 21: PECs in Terrestrial compartment – Release via the STP - Emission from surface during cleaning phase

Symbol	Parameter	Value	Unit	Reference
$E_{treated\ surface,\ ww}$	Emission from floor/treated to waste water during the cleaning step	1.71E-03	$Kg.d^{-1}$	Output
$PEC_{local\ soil}$	$PEC_{soil\ 30d}$	2.62E-03	$[mg.kg^{-1}_{wwt}]$	TGD Eq. 60
$PEC_{local\ soil\ porewater\ Deltamethrin}$	$PEC_{in\ porewater\ (agricultural.soil)\ 180d}$	1.60E-04	$[\mu g.L^{-1}]$	TGD Eq. 67
$PEC_{local\ soil\ porewater\ Br2CA}$		1.46E-01		

RELEASE VIA THE MANURE SPREADING

Soils are exposed SANITERPEN INSECTICIDE DK by manure used in agriculture. The concentrations in soil in the case of an immission standard for nitrogen and land application on arable land or grassland ($PIECars\text{-}N_i$ / $PIECgrs\text{-}N_i$) are summarised in the table below for the worst case scenario, “housing of veal calves”.

Table 22: Overview on the calculated PEC for the soil compartment (intial and twa over 180d) – Manure/slurry spreading

Symbol	Parameter	Value		Unit	Reference
Emission from floor/treated to manure		**Grassland-N**	**Arable Land-N**		

$PIEC_{local\ soil}$ Deltamethrin	PEC soil initial	3.27E-03 8.17E-04*	6.13E-04	[$mg.kg^{-1}_{wwt}$]	TGD Eq. 60
$PIEC_{local\ soil}$ B_{r2CA}		1.93E-03 4.82E-04*	3.61E-04		
$PIEC_{local\ soil\ 180d}$ Deltamethrin	PEC in soil 180d	1.17E-03 2.92E-04*	2.19E-04	[$mg.kg^{-1}_{wwt}$]	TGD Eq. 67
$PEC_{local\ soil\ 180d}$ B_{r2CA}		8.64E-05 2.16E-05*	1.62E-05		

* For one application only on grassland

Application on soil of manure containing deltamethrin and Br_2CA can result in groundwater contamination. Therefore, PEC porewater values are derived based on PT 18 ESD calculations from concentrations of the active substance in soil based on the nitrogen immission standard for arable/grassland soil and leading to concentrations in porewater for soils. The time-weighted averaged PEC values (over 180 days) of deltamethrin and Br_2CA are used to define groundwater concentrations. The concentrations in porewater after application on arable land and grassland are summarised in the table below.

Table 23: Overview on the calculated PEC groundwater initial – Manure/slurry spreading

RELEASE VIA THE MANURE SPREADING	**$PEC_{local\ soil\ porewater}$ Grassland [$\mu g.L^{-1}$]**	**$PEC_{local\ soil\ porewater}$ Arable Land [$\mu g.L^{-1}$]**
Veal calves (Deltamethrin)	4.55E-04 1.14E-04*	8.54E-05
Veal calves (Br_2CA)	3.39 8.46E-01*	6.35E-01

* For one application only on grassland

Table 24: Overview on the calculated PEC groundwater 180 days – Manure/slurry spreading

RELEASE VIA THE MANURE SPREADING	**$PEC_{local\ soil\ porewater}$ Grassland [$\mu g.L^{-1}$]**	**$PEC_{local\ soil\ porewater}$ Arable Land [$\mu g.L^{-1}$]**
Veal calves (Deltamethrin)	1.63E-04	3.05E-05
Veal calves (Br_2CA)	**1.52E-01**	2.84E-02

2.8.4.2.4 Non-compartmental-specific exposure relevant to the food chain (secondary poisoning)

The product SANITERPEN INSECTICIDE DK is an insecticide applied only indoors.

Primary poisoning, i.e. the direct consumption of insecticide by non-target animals like birds, mammals or honeybees, is a topic only for outdoor uses. Consequently, risk of primary poisoning is not relevant and has not been assessed.

The concentration of deltamethrin in contaminated food is calculated in order to address the risk of secondary poisoning to top predators via the aquatic food chain (i.e. fish-eating birds and mammals). Biomagnification

may also occur via the terrestrial food chain and the risk concerning secondary poisoning for worm-eating birds and mammals is also assessed.

RELEASE VIA THE WASTE WATER

The PEC $_{oral,fish}$ value and the PEC $_{oral,earthworm}$ are presented in the Tables below.

Table 25: Overview on the calculated local PECoral $_{fish}$ and local PECoral $_{earthworm}$ – Release to waste water - Emission from applicator

Symbol	Parameter	Value	Unit	Reference
E $_{treated\ surface,\ ww}$	Emission from floor/treated to waste water during the cleaning step	2.52E-05	Kg.d^{-1}	Output
PEC$_{oral,\ predator}$	Predicted Environmental Concentration in food (fish)	5.25E-05	[mg.kg^{-1}]	TGD Eq. 76
PEC$_{oral,\ predator}$	Predicted Environmental Concentration in food (earthworm)	1.37E-06	[mg.kg^{-1}]	TGD Eq. 81

Table 26: Overview on the calculated local PECoral $_{fish}$ and local PECoral $_{earthworm}$ – Release to waste water - Emission from surface cleaning phase

Symbol	Parameter	Value	Unit	Reference
E $_{treated\ surface,\ ww}$	Emission from floor/treated to waste water during the cleaning step	1.71E-03	Kg.d^{-1}	Output
PEC$_{oral,\ predator}$	Predicted Environmental Concentration in food (fish)	3.56E-03	[mg.kg^{-1}]	TGD Eq. 76
PEC$_{oral,\ predator}$	Predicted Environmental Concentration in food (earthworm)	9.33E-05	[mg.kg^{-1}]	TGD Eq. 81

RELEASE VIA THE MANURE SPREADING

The PEC $_{oral,fish}$ value and the PEC $_{oral,earthworm}$ are presented in the Tables below for the worst case scenario, housing of veal calves.

Table 27: Overview on the calculated local PECoral $_{fish}$ and local PECoral $_{earthworm}$ – Release via the manure spreading

RELEASE VIA THE MANURE SPREADING	Grassland	Arable Land
Veal calves		
PEC $_{fish}$ [mg.kg^{-1}]	7.97E-06	5.98E-06
PEC $_{earthworm}$ [mg.kg^{-1}]	9.46E-05	1.77E-05

2.8.5 Risk characterisation for the environment

Risk characterization for the environment is done quantitatively by comparing predicted environmental concentrations (PEC) and the concentrations below which effects on organism will not occur (PNEC) according to the Technical Guidance Document (TGD, 2003) and Emission Scenario Documents for PT18. The environmental risk characterization has been carried out for deltamethrin. For indoor uses of SANITERPEN INSECTICIDE DK in empty animal houses and shelters, risks following indirect emissions via the STP and via manure applications on agricultural land are characterized for all compartments.

2.8.5.1 Professional Use of SANITERPEN INSECTICIDE DK for treatment of pet's environment in rural areas - INDOOR application in empty animal houses and shelters

Calculations are based on the maximum amount applied per day as a worst-case scenario, as detailed in the environmental exposure assessment section. The scenario includes the emission of active substance to environmental compartments when diluting, applying the product and during cleaning events. According to the intended use, the main route of entry into the environment is assumed to be indirect to the aquatic compartment, via STP effluents, during the preparation/application phase and the cleaning phase.

To complete the assessment, a potential emission into the environment *via* application of manure (for example to cover horse manure application) on arable land and grassland have been taking into account considering a maximum of 3 insecticide applications per year. It should be noted that this scenario taken from the ESD n°14 "Emission scenario document for Stables and Manure Storage Systems" is considered as a very worst case approach as the emission calculations form this document cover industrial farming.

RELEASE VIA THE WASTE WATER

The table below summarizes the PEC/PNEC ratios for the aquatic compartment (including STP, surface water and sediment) and terrestrial compartment (including soil and groundwater), the threshold values for groundwater being < 0.1 µg.L^{-1}.

Table 28: Risk characterization for indirect emissions (*via* the STP) - Indoor application in empty animal houses and shelters of SANITERPEN INSECTICIDE DK.

	PEC	PEC/PNEC	Risks
Emission from applicator			
STP [mg.L^{-1}]	$PNEC_{STEP\ microorganisms}$ = 3.00E-02 mg.L^{-1}		
	1.21E-06	4.03E-05	Acceptable
Surface water [mg.L^{-1}]	$PNEC_{surface\ water}$ = 0.70 ng L^{-1}		
	7.50E-08	1.07E-01	Acceptable
Sediment [mg.kg_{wwt}^{-1}]	$PNEC_{sediment}$ = 6.20 µg.$kg_{wwt\ sediment}^{-1}$		
	6.66E-04	1.07E-01	Acceptable
Soil [mg.kg_{wwt}^{-1}]	$PNEC_{soil}$ = 0.075 mg.$kg_{w\ soil}^{-1}$		
	3.85E-05	5.13E-04	Acceptable
Groundwater	Threshold value = 0.1 µg.L^{-1}		

	Deltamethrin	< 0.1 µg.L^{-1}	Acceptable
	BR_2CA	< 0.1 µg.L^{-1}	
Secondary Pois.	PNEC $_{oral\ mammal}$ 2.67 mg kg_{diet}^{-1}		
Terrestrial food chain [mg kg_{diet}^{-1}]	1.37E-06	5.13E-07	Acceptable
Aquatic food chain [mg kg_{diet}^{-1}]	5.25E-05	1.97E-05	Acceptable
Emission from surface cleaning phase			
STP [mg.L^{-1}]	$PNEC_{STEP\ microorganisms}$ = 3.00E-02 mg.L^{-1}		
	8.23E-05	2.74E-03	Acceptable
Surface water [mg.L^{-1}]	$PNEC_{surface\ water}$ = 0.70 ng L^{-1}		
	5.10E-06	**7.29E+00**	**Unacceptable**
Sediment [mg.kg_{wwt}^{-1}]	$PNEC_{sediment}$ = 6.20 µg.$kg_{wwt\ sediment}^{-1}$		
	4.53E-02	**7.31E+00**	**Unacceptable**
Soil [mg.kg_{wwt}^{-1}]	$PNEC_{soil}$ = 0.075 mg.$kg_{w\ soil}^{-1}$		
	2.62E-03	3.49E-02	Acceptable
Groundwater	Threshold value = 0.1 µg.L^{-1}		
	Deltamethrin	< 0.1 µg.L^{-1}	Acceptable
	BR_2CA	**> 0.1 µg.L^{-1}**	**Unacceptable**
Secondary Pois.	PNEC $_{oral\ mammal}$ 2.67 mg kg_{diet}^{-1}		
Terrestrial food chain [mg kg_{diet}^{-1}]	9.33E-05	3.49E-05	Acceptable
Aquatic food chain [mg kg_{diet}^{-1}]	3.56E-03	1.33E-03	Acceptable

RELEASE VIA THE MANURE SPREADING

The tables below summarize the PEC/PNEC ratios for terrestrial compartment (including soil and groundwater), the threshold values for groundwater being < 0.1 µg.L^{-1}.

Table 29: Risk characterization for terrestrial compartment - Indoor application in empty animal houses and shelters of SANITERPEN INSECTICIDE DK

Release via the manure spreading Veal calves	**PEC**	**PEC/PNEC**	**Risks**
Grassland			
Surface water [mg.L^{-1}]	PNEC$_{surface\ water}$ = 0.70 ng L^{-1}		
	1.14E-08	1.63E-02	Acceptable
Soil [mg.kg$_{wwt}^{-1}$]	PNECsoil = 0.075 mg.kgw soil^{-1}		
	3.27E-03	4.36E-02	Acceptable
Groundwater	Threshold value = 0.1 µg.L^{-1}		
	Deltamethrin	< 0.1 µg.L^{-1}	Acceptable
	BR_2CA	**> 0.1 µg.L^{-1} (0.152 µg.L^{-1})**	**Acceptable**
Secondary Pois.	PNEC $_{oral\ mammal}$ = 2.67 mg kg $_{diet}^{-1}$		
Terrestrial food chain [mg kg $_{diet}^{-1}$]	9.46E-05	3.54E-05	Acceptable
Aquatic food chain [mg kg $_{diet}^{-1}$]	7.97E-06	2.99E-06	Acceptable
Arable Land			
Surface water [mg.L^{-1}]	PNEC$_{surface\ water}$ = 0.70 ng L^{-1}		
	8.54E-09	1.22E-02	Acceptable
Soil [mg.kg$_{wwt}^{-1}$]	PNECsoil = 0.075 mg.kgw soil^{-1}		
	6.13E-04	8.17E-03	Acceptable
Groundwater	Threshold value = 0.1 µg.L^{-1}		
	Deltamethrin	< 0.1 µg.L^{-1}	Acceptable
	BR_2CA	< 0.1 µg.L^{-1}	Acceptable
Secondary Pois.	PNEC $_{oral\ mammal}$ = 2.67 mg kg $_{diet}^{-1}$		
Terrestrial food chain [mg kg $_{diet}^{-1}$]	1.77E-05	6.64E-06	Acceptable

Aquatic food chain [mg kg_{diet}^{-1}]	5.98E-06	2.24E-06	Acceptable

2.8.6 Conclusions for the environment

The product SANITERPEN INSECTICIDE DK is applied **by professionals only indoors in empty animal houses and shelters**.

Targeted animal houses and shelters are small houses which are used in rural areas by farmers, hunters, agricultural workers, or houses and shelters used for small farming (dog farming, ornamental chicken farming), or by small associations working for the protection of the animals.

The risk assessment has been carried out for the **mixing/loading and application phase** and for the subsequent **cleaning phase**, as it is indicated by the applicant that the surface must be cleaned before a new application (but not between applications). Consequently a release to wastewater from floor and treated surfaces was taken into account. To complete the assessment, a potential emission into the environment *via* a potential **application of manure** (for example to cover horse manure application) on arable land and grassland has been taken into account. It should be noted that this scenario taken from the ESD n°14 "Emission scenario document for Stables and Manure Storage Systems" is considered as a very worst case approach as the emission calculations form this document cover industrial farming.

Risks are acceptable for the **mixing/loading and application phases from the applicator** for all environmental compartments.

Concerning the **cleaning phase,** risks are acceptable for STP and soil compartments. On the other hand, risks are unacceptable for surface water, sediment and groundwater, taking into account the intended dose rate and a cleaning efficiency of 50% with water.

Considering a potential **application of manure** (for example to cover horse manure application) on arable land and grassland, risks are acceptable considering that the proposed scenario is a very worst case approach.

In conclusion, risks are acceptable taking into account the intended dose rate and with respect to the operating instructions proposed by the applicant and presented below leading to **no releases at all to the STP via the wastewater during the cleaning phase of the treated surfaces**:

Risk mitigation measures linked to risk assessment for environment

Before using SANITERPEN INSECTICIDE DK

- Floor and walls, including previously treated surfaces, shall be mechanically cleaned from dusts using vacuum system or brush and dusts shall be collected and treated as a waste.
- Surface to be treated shall be determined and calculated regarding specific cases (pets to be protected, insects to be controlled). In all case it should be limited to 350 m^2.

After application of SANITERPEN INSECTICIDE DK

- After application the sprayer equipment shall be rinsed 3 times with water and rinsing water shall be collected and treated as a waste.
- The product must be kept inside the original packaging.
- In any case, never throw rinsing water or the product in the waste water system or surface water.
- After application treated surfaces shall not be cleaned (dry cleaning will take place before the next application).

Disposal considerations

- Dispose of unused product, its packaging and all other waste in accordance with local regulations.
- Do not discharge unused product into water courses, into pipes (sink, toilets…) nor down the drains.

2.9 Risk assessment for companion and ornamental animals

The product is applied only indoors in animal houses and shelters to protect animals from target pests. Only animals not intented for human consumption are considered.

No data were submitted by the applicant to assess the risk for animals living in treated premises and few data in the CAR can be used to address this issue. Moreover, existing scenarios are designed to assess the exposure of animals intended for human consumption (assessment of dietary risk) and the exposure of wild animals (primary and secondary poisoning). No scenario and no guidance is available to assess the risks for companion animals and ornamental animals (pets).

However, some elements were considered to estimate the risk for these animals, based on guidance on the assessment of exposure of farm animals intended for human consumption and on extrapolation from method used for human risk assessment.

Exposure by ingestion (animals licking treated surfaces, grooming, ingestion of dead insects, ingestion of contaminated feed and drinks) and by dermal contact is considered.

2.9.1 Toxicological reference values

Deltamethrin is used in veterinary medicines authorised in EU. National and European databases were consulted. Roughly 10-12 medicines based on deltamethrin are authorised for dermal application. The doses are the following:

- 100 to 225 mg/animal for cattle;
- 75 mg/animal for adult sheeps;
- 25 mg/animal for young sheeps below 10 kg;
- 750 mg to 1 g in collars for dogs.

Moreover, on the basis of the studies assessed in the CAR, the following reference values were determined:

- Dogs: for human, an AEL of 0.0075 mg/kg bw/day was derived based on the NOAEL (1 mg/kg bw/day) obtained in the 1-year dog study, taking into account an oral absorption of 75% and a safety factor of 100. A specific AEL for dogs can be derived considering an intra-species assessment factor of 1, leading to an AEL for dog of 0.075 mg/kg bw/d.
- Rabbits: a $NOEL_{maternal}$ of 10 mg/kg bw/d has been observed in a developmental toxicity study in rabbits. This value can be used to derive a specific AEL for this species considering an intra-species assessment factor of 1 and an oral absorption of 75%. An AEL value of 0.75 mg/kg bw/d is calculated for rabbits.
- Birds: a PNEC of 15 mg/kg diet was derived from a study on *Colinus virginianus*, with a safety factor if 30.

2.9.2 Exposure assessment for horses, rabbits and birds

Exposure of animals has been evaluated on the basis of the draft “Guidance on estimating livestock exposure to active substances used in biocidal product” (version CA-Dec10-Doc.6.2.b). The calculator developed by BfR and available online has been used. The application rate of 10 mg deltamethrin/m² was used.

Step 1: Screening scenario:

- Hypothesis: the entire amount of biocidal product applied is taken up by animals regardless of the route of exposure;

- Default values are taken from the draft guidance document;
- Screening scenario: surface treatment of animal housing (floor and wall of stable without partitions);
- Animal are present in the premises during treatment.

Step 2 - realistic worst case:

Exposure can be refined considering each relevant route of exposure (oral-animal licking surfaces, oral-ingestion of dead insects (for poultry), dermal-rubbing against surfaces). Moreover, according to the applicant, animals are not present during application and all feed and toughs are taken out.

No exposure or negligible exposure is expected from licking surfaces, for horses and rabbits. Licking is also not relevant for birds.

Input values for realistic worst case scenario are reported in Table 30.

Results are reported in Table 31.

Table 30: Input values for realistic worst case scenario

Factor	Value (source: draft guidance document)
Oral exposure through ingestion of flies	
Fly consumption	10 flies/day (default value)
Consumption of B.P. (spray deposit) by flies	3.5 mg product/d
Concentration of a.s. in BP applied on surfaces	0.2 g/L
a.s. consumption by flies	0.0007 mg/fly/d
Feed intake	Broiler: 0.12 kg dry matter/d (default value) Turkey: 0.35 kg dry matter/d (default value)
Dermal exposure through rubbing against surfaces	
Emission factor for spraying	1 (worst case)
Body surface area in contact with surface	Horse: 1.62 m² (default value)
Body weight	Broiler: 1.7 kg (default value) Turkey: 7 kg (default value) Horse: 400 kg (default value) Rabbit: 2.5 kg (default value)

Table 31: Exposure of animals for surface treatment of animal housing (floor and wall of stable without partitions) – screening scenario and realistic worst case scenario

Animal Species		Exposure (mg a.s./kg bw/day)		
		Screening scenario	Oral - Ingestion of dead insects (poultry only)	Dermal - Rubbing against surfaces
Broilers		Nd	0.0412	Nd
Broilers	free range, litter floor	0.4706	Nd	Nd
Broilers	parent broilers, free range (grating floor)	0.5042	Nd	Nd
Broilers	parent broilers in rearing, free range	0.4902	Nd	Nd

	(grating floor)			
Laying hen		Nd	0.0368	Nd
Laying hen	battery	0.2757	Nd	Nd
Laying hen	free range (litter floor)	1.0684	Nd	Nd
Laying hen	free range (grating floor)	0.4795	Nd	Nd
Turkey		Nd	0.0100	Nd
Horse		Nd	Nd	0.04050
Rabbit		0.6720	Nd	Nd

Nd: not determined

It should be noted that these results are based on parameters relevant for farming of animals intended for human comsumption. They may be not representative of the conditions in companion animals breeding installations.

Estimates for the risk characterisation are presented in 32.

Table 32: Risk characterisation for horses, rabbits and birds

	Exposure (mg/kg bw/d)	AEL or PNEC	Risk ratio
Broiler	0,0041	15 mg/kg diet Corresponding to 1.8 mg/d or 1.1 mg/kg bw/d	0,004
Turkey	0,0010	15 mg/kg diet Corresponding to 5.25 mg/d or 0.75 mg/kg bw/d	0,001
Rabbits	0.6720	0.75 mg/kg bw/d	0.9
Horses	0.0405	No AEL	Not determined Exposure is higher than human AEL and lower than dog AEL. Exposure is also lower than medicinal doses for veterinary medicines for cattle and sheeps, within the same order of magnitude.

2.9.3 Exposure assessment and risk characterisation for dogs

Exposure by ingestion (animals licking treated surfaces) was assessed by reverse scenario, in order to determine the maximum treated surface area that a dog has to lick to reach the AEL.

The following parameters have been considered:

- Concentration of active substance in the diluted product (applied on surfaces): 0.02%;
- Application rate: 50 mL product/m^2;
- Density value: 0.947;
- Oral absorption value: 75%;
- Transfer coefficient : 100% (from TNsG 2008);
- Body weight of a puppy: 5 kg;
- AEL_{dog} = 0.075 mg/kg bw/d

A maximum surface area of 0.05 m^2 has to be licked by a puppy to reach the AEL. This value can be considered realistic, leading to an unacceptable risk.

2.9.4 Pharmacovigilance data

Veterinary pharmacovigilance available data in France cannot be used to determine hypersensitivity of a species to deltamethrin.

However, it could be noted that the most adverse effects have been reported for cats and equines (29 cases for cats and 17 for horses since 2002). The main clinical symptoms are:

- For cats: hypersalivation, vomiting, ataxia, tremors, and (likely related to overdosing) death;
- For horses: hyperthermia, itch and agitation.

Furthermore, bibliographic data reveal that cats are particularly sensitive to pyrethroids, due to a lack of glucuronide conjugation enzymes and other not yet elucidated reason(s)[14,15,16]. Although sensitivity to permethrin is more documented, without any further data, it is recommended that the product SANITERPEN INSECTICIDE DK is not used to treat premises were cats are housed, as well as other species that may display a particular sensitivity to deltamethrin.

2.9.5 Conclusions for companion and ornamental animals

In conclusion, secondary exposure to companion animals with treated surfaces cannot be precisely assessed. However, considering the presented estimations, this exposure cannot be considered negligible. In order to limit this exposure, the following instructions and risk mitigation measures must be respected.

Risk mitigation measures linked to risk assessment for animals

- Do not use in premises where cats or other animals with particular sensitivity to pyrethrinoïds are housed.
- Alternate products containing active substances with different mode of action than pyrethroïds.
- Apply only during a fallowing period in animal shelters/housings (empty premises).
- Do not apply on surfaces likely to be licked by animals.
- Prior treatment, remove the bowls, feeders, drinkers and textiles from animal sleeping areas. If they cannot be removed, empty and cover them with a plastic sheet for the duration of the treatment.
- Wait complete drying of the treated surfaces after the end of the treatment, before allowing animals to re-enter.
- .

[14] Gfeller, R.G., Messonnier, S.P., 2004. *Handbook of Small Animal Toxicology and Poisonings, second ed*. Mosby, St. Louis, MO, USA.
[15] Anadón A., Martínez-Larrañaga M.R., Martínez M.A., 2008. *Use and abuse of pyrethrins and synthetic pyrethroids in veterinary medicine*. The Veterinary Journal 182 (2009) 7–20.
[16] Beugnet F., Franc M., 2012. *Insecticide and acaricide molecules and/or combinations to prevent pet infestation by ectoparasites*. Trends in Parasitology, July 2012, Vol. 28, No. 7.

2.10 Measures to protect man, animals and the environment

See Summary of Product Characteristics (SPC)

3 PROPOSAL FOR DECISION

Conclusions of efficacy and risk assessment

Risk assessment for Physico-chemical properties

SANITERPEN INSECTICIDE DK is an emulsion concentrate product containing deltamethrin (0.2 % (w/w)) for spray application. It is not highly flammable, not auto-flammable, not explosive and does not have oxidizing properties.

The product is stable for 14 days at 54°C and 2 years at ambient temperature.

The product SANITERPEN INSECTICIDE DK is compatible with PE/EVOH, PET and fluorated HDPE, packages.

Summary of efficacy assessment

The efficacy level of the product SANITERPEN INSECTICIDE DK (0.2 % w/w deltamethrin) is satisfactory for the uses proposed in Annex 0b.

Summary of risks characterisation of the product for human health

Risks related to the use of SANITERPEN INSECTICIDE DK by professionals are considered acceptable during spray application when gloves are worn. Risk related to secondary exposure is also considered acceptable.

Summary of risks characterisation of the product for consumer

Regarding the intended used, exposure of livestock and human exposure via food of animal origin are not expected. Dietary risk assessment is not required.

Summary of risks characterisation of the product for the environment

Risks are acceptable for the mixing/loading and application phases from the applicator for all environmental compartments.

Concerning the cleaning phase, risks are acceptable for STP and soil compartments. On the other hand, risks are unacceptable for surface water, sediment and groundwater, taking into account the intended dose rate and a cleaning efficiency of 50% with water.

Considering a potential application of manure (for example to cover horse manure application) on arable land and grassland, risks are acceptable considering that the proposed scenario is a very worst case approach.

In conclusion, risks are acceptable taking into account the intended dose rate and with respect to the operating instructions proposed by the applicant and presented below leading to no releases at all to the STP via the wastewater during the cleaning phase of the treated surfaces:

Summary of risks characterisation of the product for companion and ornamental animals

Secondary exposure to companion animals with treated surfaces cannot be precisely assessed. However, considering the presented estimations, this exposure cannot be considered negligible. In order to limit this exposure, the following instructions and risk mitigation measures must be respected.

Risk mitigation measures and conditions of use

The uses proposed for authorization are detailed in annex 0B

Conditions of use linked to efficacy assessment

To ensure a satisfactory level of efficacy and avoid the development of resistance in susceptible insect populations, the following recommendations have to be implemented:

- Always read the label or leaflet before use and respect follow all the instructions provided.
- 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).
- Alternate products containing active substances with different mode of action, (to remove resistant individuals from the population).
- The users should inform if the treatment is ineffective and report straightforward to the registration holder.

Risk mitigation measures for human health and environment

- Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during the product handling phase.
- Apply strict hygiene measures: do not eat, drink or smoke during handling of the product and wash hands after use of the product;
- Keep out of the reach of children.
- Do not use on surfaces likely to be in direct contact with animals intended for food consumption, food, feed or drinks
- Floor and walls, including previously treated surfaces, shall be mechanically cleaned from dusts using vacuum system or brush and dusts shall be collected and treated as a waste.
- Surface to be treated shall be determined and calculated regarding specific cases (pets to be protected, insects to be controlled). In all case it should be limited to 350 m^2.
- After application the sprayer equipment shall be rinsed 3 times with water and rinsing water shall be collected and treated as a waste.
- The product must be kept inside the original packaging.
- In any case, never throw rinsing water or the product in the waste water system or surface water.
- After application treated surfaces shall not be cleaned (dry cleaning will take place before the next application).

Risk mitigation measures for animals

- Do not use in premises where cats or other animals with particular sensitivity to pyrethrinoïds are housed.
- Alternate products containing active substances with different mode of action than pyrethroïds.
- Apply only during a fallowing period in animal shelters/housings (empty premises).
- Do not apply on surfaces likely to be licked by animals.
- Prior treatment, remove the bowls, feeders, drinkers and textiles from animal sleeping areas. If they cannot be removed, empty and cover them with a plastic sheet for the duration of the treatment.
- Wait complete drying of the treated surfaces after the end of the treatment, before allowing animals to re-enter.

Emergency

- **Inhalation**: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur, show this container or label.
- **Skin contact:** Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Get medical attention if symptoms occur.
- **Eye contact**: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse with warm water for at least 10 minutes. Get medical attention if irritation or vision impairment occur.
- **Ingestion:** Wash out mouth with water. Get medical attention if symptoms occur, show this container or label.Do not drink or induce vomiting in case of consciousness alteration.
- **Note to physician**: Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Disposal

- Dispose of unused product, its packaging and all other waste in accordance with local regulations.
- Do not discharge unused product into water courses, into pipes (sink, toilets…) nor down the drains.

Recommendations to be taken into account by the authorisation holder

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

Information required post-authorisation

Required information linked to physical-chemical properties evaluation

- a compatibility study of product with the fluorinated HDPE packaging (monitoring of the deformation and mass of the packaging during a study of storage) is needed.

Required information linked to efficacy assessment

- Suitable information (as semi-field or field tests in the real use conditions) demonstrating the efficacy of SANITERPEN INSECTICIDE DK against target organisms mosquitoes (genus *Culex* and *Aedes)* and fleas *(Pulicidae)*, with different development stages, will need to be provided in support of the authorisation, within one year.
- Establish a baseline and monitor levels of effectiveness on populations in key areas (at least one survey per year) in order to detect any significant changes in susceptibility to active substance..

4 APPENDICES

Annex 0a: Practical use claimed by the applicant

Table 33: Practical use claimed by the applicant

Name of the product and type of formulation (gel, paste, spray, dust, powder, fumigation…)	Target organisms (common species and genus) and development stages (eggs, larvae, nymph, adults…)*	User category (professional/non professional)*	Application aim	Area of use (indoor, outdoor, and field of use)	Method of application	Application rate (expressed in g/m^3, g/m^2, ml/m^2…)Maximum and minimum dosage (if appropriate)	Mode of action including time delay (kill, knockdown…)	Time delay of residual efficacy if indirect or surface treatment (hours, days, weeks and months)	Time delay for human , food and animals reentrance after treatment (if appropriate)	Frequency and duration of application	Dosage and applications requirements (exposure time, ventilation, temperature,)	Package details : Individual packaging (yes/no)**	Primary packaging *** : type : bulk, individual wrapping…/ nature: bucket, bottle, sachet…/ material: paper, polyethylene…/ sizes	Secondary packaging	Accepted and authorized by the RMS (yes/no)
SANITERPEN INSECTICIDE DK Formulation: Emulsifiable concentrate	Dermanyssidae: *Dermanyssus gallinae* (Poultry red mite) Eggs, larvae and adults	Professional	To kill insect to protect health of animals and humans	To be used indoors only in empty Animal houses/shelters for surface treatment.	Spraying (using Knapsack sprayer) on surfaces after dilution 10% v/v	5mL/m2 of undiluted product. 350m2 max. per application	Knockdown + Residual efficacy of 3 months.	Residual efficacy of three months.	Animals can re-enter the treated areas when the surfaces are dried. 24hours per default.	One application every 3 months. Max 3 applications per year.	10% dilution, application with knapsack sprayer (with hand held trigger).	Yes	5 L HDPE bottle, 1L PET bottle, 3x60mL PET individual bags	-	

	Culicidae: *Culex pipiens, Aedes sp*. (Mosquitoes) Adults	Professional	To kill insect to protect health of animals and humans	To be used indoors only in empty Animal houses/shelters for surface treatment.	Spraying (using Knapsack sprayer) on surfaces after dilution 10% v/v	5mL/m2 of undiluted product. 350m2 max. per application	Knockdown + Residual efficacy of 3 months.	Residual efficacy of three months.	Animals can re-enter the treated areas when the surfaces are dried. 24hours per default.	One application every 3 months. Max 3 applications per year.	10% dilution, application with knapsack sprayer (with hand held trigger).	Yes	5 L HDPE bottle, 1L PET bottle, 3x60mL PET individual bags	-	
	Muscidae: *Musca domestica* (House fly) Adults	Professional	To kill insect to protect health of animals and humans	To be used indoors only in empty Animal houses/shelters for surface treatment.	Spraying (using Knapsack sprayer) on surfaces after dilution 10% v/v	5mL/m2 of undiluted product. 350m2 max. per application	Knockdown + Residual efficacy of 3 months.	Residual efficacy of three months.	Animals can re-enter the treated areas when the surfaces are dried. 24hours per default.	One application every 3 months. Max 3 applications per year.	10% dilution, application with knapsack sprayer (with hand held trigger).	Yes	5 L HDPE bottle, 1L PET bottle, 3x60mL PET individual bags	-	
	Pulicidae: (Fleas) Larvae and adults	Professional	To kill insect to protect health of animals and humans	To be used indoors only in empty Animal houses/shelters for surface treatment.	Spraying (using Knapsack sprayer) on surfaces after dilution 10% v/v	5mL/m2 of undiluted product. 350m2 max. per application	Knockdown + Residual efficacy of 3 months.	Residual efficacy of three months.	Animals can re-enter the treated areas when the surfaces are dried. 24hours per default.	One application every 3 months. Max 3 applications per year.	10% dilution, application with knapsack sprayer (with hand held trigger).	Yes	5 L HDPE bottle, 1L PET bottle, 3x60mL PET individual bags	-	

	Muscidae: *Stomoxys calcitrans* (Stable flies) Adults	Professional	To kill insect to protect health of animals and humans	To be used indoors only in empty Animal houses/shelters for surface treatment.	Spraying (using Knapsack sprayer) on surfaces after dilution 10% v/v	5mL/m2 of undiluted product. 350m2 max. per application	Knockdown + Residual efficacy of 3 months.	Residual efficacy of three months.	Animals can re-enter the treated areas when the surfaces are dried. 24hours per default.	One application every 3 months. Max 3 applications per year.	10% dilution, application with knapsack sprayer (with hand held trigger).	Yes	5 L HDPE bottle, 1L PET bottle, 3x60mL PET individual bags	-	

Annex 0b: Proposed uses for authorisation

Table 34: Proposed uses for authorisation

Name of the product and type of formulation (gel, paste, spray, dust, powder, fumigation…)	Target organism	Dosage validated	User category	Area of use	Methods of application	Primary packaging: type: bulk, individual wrapping…	Authori-sation
SANITERPEN INSECTICIDE DK Formulation: Emulsifiable concentrate	House flies, adults (*Musca domestica*) Mosquito, adults (*genus Culex genus Aedes*)* Fleas (*Pulicidae*)*, adults	10 % v/v The product is diluted in water Application rate : 50 ml of diluted product /m²	Professionals	Indoor in animals housing and shelters and transport units (animals not intended for human consumption) Porous and non porous surfaces	Surface treatment (spraying using knapsack sprayer)	60 mL individual PET bags, 1 L PET bottles with PP and aluminium closure system, 5 L fluorated HDPE cans with PP and aluminium closure system.	

In the absence of sufficient supporting data on mosquitoes (genus Culex and Aedes) and fleas (Pulicidae), suitable information (as semi-field or field tests) demonstrating the efficacy of SANITERPEN INSECTICIDE DK against these target organisms, will need to be provided in support of the authorisation, within one year.

Annex 1: Summary of product characteristics

See separated file.

Annex 2: List of studies reviewed

Table 35: List of <u>new data</u> submitted in support of the evaluation of the biocidal product

Section No	Reference No	Author	Year	Title	Owner of data	Letter of access		Data protection claimed		Essential studies for evaluation	
						Yes	No	Yes	No	Yes	No
B3.1.1 B3.1.2 B3.2 B3.4.1.1 B3.7	B3.1	C. Da Costa, B. Demangel	2010	Accelerated storage procedure for 14 days at 54 ± 2°C and physico-chemical tests before and after storage on SANITERPEN INSECTICIDE DK, Défitraces, Report No.09-901011-002 GLP	Action Pin	☐	☒	☒	☐	☐	☐
B3.1.1 B3.1.2 B3.2 B3.4.1.2 B3.7	B3.2	B. Demangel	2011	Physico-chemical tests and chemical stability after a storage procedure for 2 years at 20 ± 2°C on SANITERPEN INSECTICIDE DK, Défitraces, Report No.09-901011-003 GLP	Action Pin	☐	☒	☒	☐	☐	☐
B3.1.3	B3.3	B. Demangel	2013a	SANITERPEN INSECTICIDE DK, Défitraces, Study No.13-901011-013 No GLP	Action Pin	☐	☒	☒	☐	☐	☐
B3.3 B3.4.1.3 B3.5.4 B3.5.7 B3.8 B3.9 B4.1 B4.6 B4.13 B4.17.1	B3.4	C. Da Costa	2009	Physico chemical tests on SANITERPEN INSECTICIDE DK, Défitraces, Report No.09-901011-001 GLP	Action Pin	☐	☒	☒	☐	☐	☐
B3.5.4	B3.5	B. Demangel	2013b	Emulsion characteristics and re-emulsification properties test and analyses of deltamethrin on specimens of	Action Pin	☐	☒	☒	☐	☐	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of access		Data protection claimed		Essential studies for evaluation	
						Yes	No	Yes	No	Yes	No
				SANITERPEN INSECTICIDE DK, Défitraces, Report No.13-901011-008 GLP							
B3.4.1.1 B3.5.4 B3.5.7	B3.6	B. Demangel, H. Ricau	2014	Chemical analyses and physico-chemical tests before and after an accelerated storage procedure at 54 °C ± 2 °C for 14 days on SANITERPEN INSECTICIDE DK Défitraces, Report No.14-901011-017 GLP	Action Pin	☐	☒	☒	☐	☐	☐
B5.1	B5.1	H. Ricau	2010	Validation of the analytical method for the determination of deltamethrin in SANITERPEN INSECTICIDE DK, in compliance with SANCO/3030/99 rev.4 EU, Défitraces, Report No.09-901011-004 GLP	Action Pin	☐	☒	☒	☐	☐	☐
B6.5	B6.5	N. Huguet	2013	Deltamethrin mode of action.	Action Pin	☐	☒	☒	☐	☒	☐
B6.7	B6.7/01	B. Serrano	2013	Laboratory measurement of the effectiveness of an insecticide speciality intended for the destruction of insects in farm buildings, animal accomodation, transport and farming equipement. TEC Laboratory. April 2013. Assay No. 1558b/1112.	Action Pin	☐	☒	☒	☐	☒	☐
B6.7	B6.7/02	K.H. Lüpkes	2013	Residual efficacy of Saniterpen Insecticide DK and Saniterpen Insecticide DK Extra against stable flies Stomoxys calcitrans on treated tiles. Biogenius GmbH, Biology. September 2013. Report No. Mo4678.	Action Pin	☐	☒	☒	☐	☐	☒
B6.7	B6.7/03	B. Serrano	2012	Field testing of an insecticide speciality intended to control flies in breeding premises. TEC Laboratory. November 2012. Assay No. 1527/0712.	Action Pin	☐	☒	☒	☐	☒	☐
B6.7	B6.7/04	N.Huguet	2013	Field tests waiving argumentation.	Action Pin	☐	☒	☐	☒	☐	☒
B6.7	B6.7/05	B. Serrano	2014	Laboratory measurement of the	Action Pin	☐	☒	☒	☐	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of access		Data protection claimed		Essential studies for evaluation	
						Yes	No	Yes	No	Yes	No
				effectiveness of an insecticide speciality intended for the control of insects in farm buidings, animal accomodation, transport and farming equipment. Efficacy against flies Musca domestica and mosquitoes Aedes aegypti. TEC Laboratory. November 2014. Assay No. 1826a/0914.							
B6.7	B6.7/06	B. Serrano	2014	Simulated use trial of the efficacy of insecticide products intended to control insects in breeding or good food storage premises - Trial against fleas and mosquitoes (Aedes sp. + Culex sp.) TEC Laboratory. November 2014. Assay No. 1826b/0914.	Action Pin	☐	☒	☒	☐	☒	☐
B6.7	B6.7/07	N.Huguet	2014	Study plan red mite simulate use	Action Pin	☐	☒	☐	☒	☐	☒
B6.7	B6.7/08	B. Serrano	2014	Laboratory emasurement of the effectiveness of an insecticide speciality intended for the control of insects in farm buildings, animal accomodation, transport and farming aquipment Efficacy against sandflies Phlebotomus perniciosus TEC Laboratory. July 2014. Assay No. 1782b/0514R.	Action Pin	☐	☒	☒	☐	☒	☐
B6.8	B6.8/01	N. Liu and X. Yue	2000	Insecticide resistance and cross-resistance in the house fly (Diptera: Muscidae). Journal of Economic Entomology, 93 (4): 1269-1275.	Public	☐	☒	☐	☒	☒	☐
B6.8	B6.8/02	Y.L. Konan, A.A. Koffi, J.M.C. Doannio and F. Darriet	2003	Résistance de *Culex quinquefasciatus* (Say, 1823) à la deltaméthrine et l'utilisation de la moustiquaire imprégnée en milieu urbain de Bouaké, Côte d'Ivoire. Bulletin de la Société de Pathologie Exotique, 92 (2): 128-129.	Public	☐	☒	☐	☒	☒	☐
B6.8	B6.8/03	H.F. Tahir, A. Butt and S.Y. Khan	2009	Response of *Culex quinquefasciatus* to deltamethrin in Lahore district. Journal of Parasitology and Vector Biology, 1 (3): 19-24.	Public	☐	☒	☐	☒	☒	☐
B6.8	B6.8/04	R.L. Bossard, N.C. Hinkle and M.K.	1998	Review of insecticide resistance in cat fleas (Siphonaptera: Pulicidae). Journal of	Public	☐	☒	☐	☒	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of access		Data protection claimed		Essential studies for evaluation	
						Yes	No	Yes	No	Yes	No
		Rust		Medical Entomology, 35 (4): 415-422.							
B6.8	B6.8/05	M. Marangi, M.A. Cafiero, G. Capelli, A. Camarda, O.A.E. Sparagano and A. Giangaspero	2009	Evaluation of the poultry red mite, *Dermanyssus gallinae* (Acari: Dermanyssidae) susceptbility to some acaricides in field populations from Italy. Experimental and Applied Acarology, 48: 11-18.	Public	☐	☒	☐	☒	☒	☐
B6.8	B6.8/06	F. Beugnet, C. Chauve M. Gauthey and L. Beert	1997	Resistance of the red poultry mite to pyrethroids in France. Veterinary Record, 140: 577-579.	Public	☐	☒	☐	☒	☒	☐
B8.1	B8.1	F. Richeux	2008	Saniterpen Insecticide DK: Assessment of acute dermal irritation.Phycher Bio Développement, Report number IC-OCDE-PH-07/0470	Action Pin	☐	☒	☒	☐	☒	☐
B8.2	B8.2	F. Richeux	2009	Saniterpen Insecticide DK: Eye irritation test in the rabbit.Phycher Bio Développement, Report number IO-OCDE-PH-09/0151	Action Pin	☐	☒	☒	☐	☒	☐
B8.3	B8.3-1	F. Richeux	2009	Saniterpen Insecticide DK, Local Lymph Node Assay in the mouse.Phycher Bio Développement, Report number LLNA-PH-09/0151	Action Pin	☐	☒	☒	☐	☒	☐
	B8.3-2	F. Richeux	2009	Saniterpen Insecticide DK, Assessment of the skin sensitisation potential in the mouse using the Local Lymph Node Assay (LLNA)Phycher Bio Développement, Report number LLNA-PH-12/0296	Action Pin	☐	☒	☒	☐	☒	☐
B8.5.1	B8.5.1	F. Richeux	2008	Saniterpen Insecticide DK: Assessment of acute oral toxicity in rats – Acute toxic class method.Phycher Bio Développement, Report number TAO423-PH-07/0470	Action Pin	☐	☒	☒	☐	☒	☐
B8.5.3	B8.5.3	F. Richeux	2009	Saniterpen Insecticide DK: Acute dermal toxicity in the rat.Phycher Bio Développement, Report number TAD-PH-09/0151	Action Pin	☐	☒	☒	☐	☒	☐
B9.2.1	B9.2.1	'A.Kley and	2012	Acute toxicity of Saniterpen Insecticide DK to Rainbow Trout (*Oncorhynchus mykiss*) in	Action Pin	☐	☒	☒	☐	☐	☒

Section No	Reference No	Author	Year	Title	Owner of data	Letter of access		Data protection claimed		Essential studies for evaluation	
						Yes	No	Yes	No	Yes	No
		T.Deierling		a 96-hour Semi Static Test, IBACON, IBACON Project 59702230							
B9.2.2	B9.2.2	’A.Kley and T.Deierling	2012	Acute Toxicity of Saniterpen Insecticide DK to Daphnia magna in a Semi Static 48-hour Immobilisation Test, IBACON, IBACON Project 59701220	Action Pin	☐	☒	☒	☐	☐	☒

Annex 3: Analytical methods residues – active substance

Deltamethrin

Date: 31/03/2015

Table 36: Matrix, action levels, relevant residue and reference

matrix	limit	relevant residue	reference or comment
plant products	-	deltamethrin	No exposure expected
food of animal origin	0.02 mg/kg	deltamethrin	Confirmatory method is required at AS reapproval
soil	0.1 µg/kg	deltamethrin	Confirmatory method is required at AS reapproval
drinking water	3 ng/L	deltamethrin	Confirmatory method is required at AS reapproval
surface water	3 ng/L	deltamethrin	Confirmatory method is required at AS reapproval
air	2.25 µg/m^3	deltamethrin	-
body fluids / tissues	20 ng/L	deltamethrin	Confirmatory method is required at AS reapproval

Table 37: Methods suitable for the determination of residues (monitoring methods)

Matrix	Method	Limit of quantification	Reference
Soil	LC-MS/MS	0.1 µg/kg***	*Brumhard, B. (2005a)*
Air	GC-ECD	0.27 µg/m^3	*Class, T. (2001a)*
Water	GC-ECD	3 ng/L***	*Class, T. (2001b)*
	LC-MS/MS	5 ng/L*	*Brumhard, B. (2005b)*
	GC-ECD	50 ng/L*	*Martens, R. (1999)*
Blood	GC-MS multi-method for pyrethroids	20 ng/L***	*Ramesh, A. & Ravi, P.E. (2004)*
	GC-MS	200 µg/L**	*Frenzel, T. et al (1998)* *Frenzel, T. et al (2000)* *Brennecke, R. (1998)*
Muscle, fat, liver/kidney, eggs	GC-ECD	0.02 mg/kg***	*Martens, R. (2000)*
Milk	GC-ECD	0.02 mg/L***	*Martens, R. (2000)*
Plants	GC-ECD	0.02 mg/kg for rice, flour, bread, meat, candy, butter, banana cream pie and lettuce	*Silvoy, J.J. (1993a)*
	LC-MS/MS	0.02 mg/kg for edible material for barley, broccoli, corn, melon, lettuce, olive, pepper, sugar beet, tobacco, tomato, wheat and zucchini	*Zimmer D. & Philipowski C. (2004)*
		0.05 mg/kg for non-edible materials for barley, broccoli, corn, melon, lettuce, olive, pepper, sugar beet, tobacco, tomato, wheat and zucchini	

* The LOQ is not low enough to cover the concentration having an effect on the most sensitive aquatic organisms (NOEC: 4.8 ng/L, from mesocosm study; see Doc II-A section 4).

** The LOQ (200 µg/l) is not in compliance with the general requirement in Regulation (EU) No 528/2012 (i.e. 50 µg/l).

*** Confirmatory methods is required to update this dossier at AS reapproval

Annex 4: Toxicology and metabolism –active substance

Deltamethrin

Threshold Limits and other Values for Human Health Risk Assessment

Date: 19/02/2015

Summary			
	Value	Study	SF
AEL long-term	0.0075 mg/kg bw/d	13-week dog study	100
AEL medium-term	0.0075 mg/kg bw/d	13-week and 1-year dog studies	100
AEL acute	0.0075 mg/kg bw/d	1-year dog study	100
ADI			
ARfD Not relevant			

Inhalative absorption	100%
Oral absorption	75%
Dermal absorption	2%

Classification	
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Acute tox. 3* - H301 Acute tox. 3* - H331 No specific limit concentrations

Annex 5: Toxicology – biocidal product

SANITERPEN INSECTICIDE DK

Date: 19/02/2015

General information	
Formulation Type	Emulsifiable concentrate
Active substance(s) (incl. content)	0.2% (w/w)
Category	

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)	
Rat LD50 oral (OECD 401)	>2000mg/kg bw/d
Rat LD50 dermal (OECD 402)	>2000mg/kg bw/d
Skin irritation (OECD 404)	Non irritant for skin
Eye irritation (OECD 405)	Irritant for eyes
Skin sensitisation (OECD 406; Buehler modified)	Skin sensitiser

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)	
Short-term toxicity studies	None
Toxicological data on active substance(s) (not tested with the preparation)	None
Toxicological data on non-active substance(s) (not tested with the preparation)	None
Further toxicological information	None

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Regulation 1272/2008/EC	Eye Irrit.2 – H319 Skin Sens.1 – H317

Annex 6: Safety for professional operators

SANITERPEN INSECTICIDE DK

Date: 19/02/2015

Exposure assessment

Exposure scenarios for intended uses (Annex IIIB, point 6.6)

Primary exposure of professionals

	Component	CAS	Actual Dermal Total [mg/kg/d]	Inhalation Exposure [mg/m³]	Model
Mixing / Loading and application					
Tier 1	Deltamethrine	52918-63-5	0.01	8.7×10^{-4}	Spraying model 1
Tier 2	Deltamethrine	52918-63-5	4.11×10^{-4}	8.7×10^{-4}	
Cleaning equipment					
Tier 1	Deltamethrine	52918-63-5	negligible	6.3×10^{-4}	Cleaning of spray equipment from BEAT
Tier 2	Deltamethrine	52918-63-5	negligible	1.9×10^{-4}	

Risk assessment

Component	CAS	AEL [mg/kg/d]	Absorption [%]		Total syst exposure [mg/kg bw/d]	% AEL	Risk
			inhalation	dermal			
Mixing / Loading and application							
Deltamethrine	52918-63-5	0.0075	100	10	0.01	157	Unacceptable
Deltamethrine	52918-63-5	0.0075	100	10	5×10^{-3}	66	Acceptable
Cleaning equipment							
Deltamethrine	52918-63-5	0.0075	100	10	6.3×10^{-4}	8	Acceptable
Deltamethrine	52918-63-5	0.0075	100	10	1.9×10^{-4}	2.5	Acceptable

Secondary exposure of general public

	Component	CAS	Inhalation Exposure [mg/m³]	Actual Dermal Total [mg/kg/d]	Oral exposure [mg/kg/d]
Chronic exposure					
Adult – Inhalation of volatilised residues, indoor	Deltamethrine	52918-63-5	6.9×10^{-7}	na	na
Child – Inhalation of volatilised residues, indoor	Deltamethrine	52918-63-5	1.3×10^{-6}	na	na
Adult – Dermal exposure with treated surface, indoor	Deltamethrine	52918-63-5	na	1.2×10^{-4}	na
Child – Dermal exposure with treated surface, indoor	Deltamethrine	52918-63-5	na	1.5×10^{-4}	na

Risk assessment

	Component	AEL [mg/kg/d]	Absorption [%]		Total syst exposure [mg/kg bw/d]	% AEL	Risk
			oral	dermal			
Chronic exposure							
Adult – Inhalation of volatilised residues, indoor	Deltamethrine	0.0075	75	10	6.9×10^{-7}	0.01	Acceptable
Child – Inhalation of volatilised residues, indoor	Deltamethrine	0.0075	75	10	$1.,3 \times 10^{-6}$	0.02	Acceptable
Adult – Dermal exposure with treated surface, indoor	Deltamethrine	0.0075	75	10	1.2×10^{-4}	1.6	Acceptable
Child – Dermal exposure with treated surface, indoor	Deltamethrine	0.0075	75	10	1.5×10^{-4}	2.03	Acceptable

Annex 7: Safety for non-professional operators and the general public

SANITERPEN INSECTICIDE DK

Date:19/02/2015

The product is for professional use only.

Annex 8: Residue behaviour

Deltamethrin

Date:19/02/2015

Regarding the intended used, exposure of livestock and human exposure via food of animal origin are not expected. Dietary risk assessment is not required.

Annex 9: Efficacy of the active substance from its use in the biocidal product

Table 38: Efficacy of the active susbstance from its use in the biocidal product

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	RI
SANITERPEN INSECTICIDE DK	House fly (*Musca domestica*) nymphs + eggs Mosquito (*Culex Pipiens) adults* Poultry red mite (*Dermanyssus gallinae)* nymphs + adults Cat flea (*Ctenocephalides felis*) Nymphs + adults	Laboratory test CEB n°135 4 hours of exposure 10 % v/v, 50 ml of diluted product /m²	Room of 60 m^3 Average conditions of a warehouse with typical surfaces treated measured 15 cm x 15 cm (concrete, untreated wood, plaster panel and ceramic tiles) Constant temperature between 20 et 25 °C Relative humidity 65% ± 5% Photoperiod: 16h light / 8 h darkness	100 % mortality was achieved within 24 hours. Residual activity up to 3 months after application on both porous and non-porous surfaces	Serrano (TEC) (2013) **1558b/1112R**	1
SANITERPEN INSECTICIDE DK	Stables fly (*Stomoxys calcitrans)* adults	Laboratory test Internal method 4 hours of exposure 10 % v/v, 50 ml of diluted product / m²	Four representatives surfaces measured 15 cm X 15 cm (porous plywood, non-porous glazed tiles, porous concrete, porous plaster). Constant temperature between 25 °C ± 2 Relative humidity 60% ± 10% Photoperiod: 16h light / 8 h darkness	Knock-down effect after one hour 100 % of mortality after 24H for all the representative surfaces excepted for plywood where 100 ù of mortality is demonstrated after 8 hours and 90 % after 24 hours. 2 months after the treatment, the remained efficacy is 100 % on the non-porous glized tiles but not sufficient for the others surfaces (16 % for porous concrete, 12 % for porous plaster and 54 % for plywood	K-H Lüpkes 2013 **MO 4678**	3

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	RI
SANITERPEN INSECTICIDE DK	<u>House fly</u> *(Musca domestica)* Adult <u>Mosquito</u> *(Aedes aegypti)* adult	Laboratory test CEB n°135 1 hour of exposure time 10 % v/v, 50 ml of diluted product/m²	Room of 60 m^3 Average conditions of a warehouse with typical surfaces treated measured 15 cm X 15 cm (concrete and ceramic tiles) Constant temperature between 20 et 25 °C Relative humidity 65% ± 5% Photoperiod: 16h light / 8 h dark	100 % mortality was achieved within 24 hours Residual activity up to 3 months after application on both porous and non-porous surfaces.	Serrano (TEC) (2014) **1826a/0914**	1
SANITERPEN INSECTICIDE DK	<u>Mosquitoes</u> (*Aedes aegypti and Culex pipiens*) adults <u>Cat flea</u> (*Ctenocephalides felis*) adults	Semi-field study BSI 4172 part 1&2 method 10 % v/v of diluted product, 50 ml /m²	Room of 30 m^3 (12 m² floor) 1 typical surface measured 6 cm² (ceramic tiles) Constant temperature 25 °C ± 2°C Relative humidity 65% ± 5% Dead insects are count 7 days after treatment	100 % of efficacy was achieved 7 days after the treatment.	Serrano (TEC) (2014) **1826a/0914R**	1

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	RI
SANITERPEN INSECTICIDE DK	House flies (*Musca domestica*) adults	Field study CEB n°107 10 % v/v of diluted product, 50 ml/m²	After a confirmation of the level of infestation, the product is applied on vertical surface by spraying. The reduction of insect's population was assessed after 7, 14, 30, 60 and 90 days. The assessment of the tested product is compared to a reference product.	The population decreased in the treated breeding premises until 85 % from the first week and 91 % 2 weeks after the treatment and still 98 % after 3 months. The efficacy demonstrated is similar to the reference product	Serrano (TEC) (2014) **1527/0712R**	1

Test substance	Test organisms	Test system / Concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	RI
SANITERPEN INSECTICIDE DK PAE (0.02% deltamethrin) SANITERPEN INSECTICIDE DK PAE Without deltamethrin	House fly (*Musca domestica*) Adults Stable fly (*Stomoxys calcitrans*) Adults Mosquitoes (*Culex Pipiens, Aedes aegypti*) Adults Sand fly (*Phlebotomus duboscqi*) Adults Poultry red mite (*Dermanyssus gallinae*) Adults + larvae Cat flea (*Ctenocephalides felis*) Adults + larvae	Laboratory test ASTM E 654-96 Direct spraying Dose: 1.57 ml on the 0.0314 m² test surface = 50 ml/m².	Room of 30 m3 (12 m² floor) Constant temperature 25°C +/- 2°C Relative humidity 65% +/- 5% Insects/mites were held into a glass ring of 20 cm diameter (0.0314 m²) and 10 cm height. A steel grid was placed on the top in case of flying insects. 4 replicates Expression of results: KT 100 = time of exposure to knockdown 100% of insects/mites. Mortality after 24 hours. Mortality after 72 hours. Results of both products are compared.	The untreated control gave a low mortality (< 10%), the trial is validated. The marketed product SANITERPEN INSECTICIDE DK PAE has proved a fast (KT100 < 15 min) and a complete insecticide efficacy (mortality 24 hours = 100%) against all the pests in testing; The same product but without deltamethrin gave no significant efficacy (<10%) against all the pests in testing;	Serrano, (TEC), (2015) 1948c/0615Ra	2