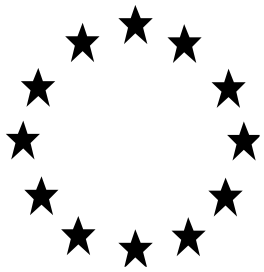
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



Insect Shocker

Product type(s) 18

Decanoic acid, Octanoic acid as included in the Union list of approved active substances

Case Number in R4BP: BC-HP019680-32

Evaluating Competent Authority: Spain

Date: March 2021

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1 CONCLUSION

The biocidal product INSECT SHOCKER contains 2.7 %w/w Decanoic acid & 0.7 %w/w Octanoic acid and given the nature of the formulation it is not considered explosive, oxidizing, highly flammable or auto-flammable. Therefore, there are not health hazards associated with the physico-chemical properties of the product under normal conditions of use.

There are not substances of concern in the biocidal product from the point of view of physical hazards according to Regulation (EC) No 1272/2008. Hence INSECT SHOCKER is not classified with regard to physico-chemical properties.

The product is stable after accelerated storage studies. The shelf life can be deemed as 2 years taking into account the results obtained from the accelerated storage studies. The authorization is conditioned to the subimission of the complete long term storage study. The label sentence 'protect from frost' must be included in the label.

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

In addition to the active substances, no other substances of concern for human health have been identified. The risk assessment of human health effects was carried out considering only the active substances. The risk is considered acceptable for non-professional users (general public).

According to the CAR for decanoic acid and octanoic acid, there is no indication for endocrine disrupting properties of active substances.

After reviewing the potential ED properties of co-formulants, three substances have been identified as having potential endocrine disrupting properties. If these substances are identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

The efficacy data of INSECT SHOCKER, submitted to support the authorisation of the intended uses, have demonstrated the efficacy of the biocidal product against cat fleas (*Ctenocephalides felis*) on infested textiles in households/private areas. Please find more information on the efficacy of the product in the correspondent section 2.2.5.

Environment

The use of INSECT SHOCKER was assessed in an indoor scenario assuming the application against cat fleas by hand-held spraying on household textiles not frequently wet washed such as pets' beds, pillows, sofas, carpets, etc. Emissions to the sewer are expected by the cleaning of surrounding floor surfaces and the washing of clothes of the applicator (non-professional user). This use poses acceptable risks to the environment.

The field of use in the authorisation must be: Textiles in households which are not wet washed (indoors).

A restriction must be included on the SPC and product label such as the following RMM: "Do not apply to washable home textiles".

Overall Conclusion

ES CA is of the opinion that an authorisation for INSECT SHOCKER can be granted pending on the long term storage study. This study mus be submitted by the applicant at least 2 years after the biocidal product authorization.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier	**Country (if relevant)**
Insect Shocker Amigard Stop Pulgas	**Spain**

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	SolNova s.r.l.
	Address	Sandro Gallo, 12 CP 30126 Venezia Lido (Veneto) Italy
Authorisation number	ES/APP(NA)-2021-18-00739	
Date of the authorisation	09-03-2021	
Expiry date of the authorisation	31-08-2025	

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	Amigard GmbH
Address of manufacturer	Binderstr. 62 CH-8702 Zollikon Switzerland
Location of manufacturing sites	AT-Chemie GmbH, Grafenweg 33, AT-6971 Hard (currently active) Further sites: Packaging Imolese s.p.a., Via Turati, 22- IT-40026 Imola (BO) ITALY VPS Group srl, via S. Vitale Ovest, 2901, IT-40059 VILLAFONTANA di Mediciana – Bologna – Italy PharmaMillennium srl, Via Petrarca, 49 – Zona Industriale, IT- 22070 Rovello Porro (CO) Betafarma Spa, Via E.de Nicola, 10, IT-20090 Cesano Boscone (MI) Sarem Cosmetics GmbH, Herderstrasse 94, F-40237 Düsseldorf Frike Chemicals AG, Motorenstr. 2A, CH-8623 Wetzikon Link Chemie AG, Dürrwiesen 16, D-73614 Schorndorf

2.1.1.4 Manufacturer(s) of the active substances

Active substance	Decanoic acid
Name of manufacturer	SolNova Vet S.L.
Address of manufacturer	C Juan Bravo, 3 Portal A 28006 Madrid

	Spain
Location of manufacturing sites	BASF Personal Care And Nutrition Gmbh Henkelstrasse 67, D-40551 Düsseldorf Germany

Active substance	Octanoic acid
Name of manufacturer	SolNova Vet S.L.
Address of manufacturer	C Juan Bravo, 3 Portal A 28006 Madrid Spain
Location of manufacturing sites	BASF Personal Care And Nutrition Gmbh Henkelstrasse 67, D-40551 Düsseldorf Germany

2.1.2 Product composition and formulation

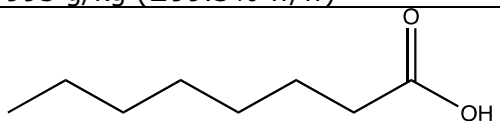
NB: the full composition of the product has been be provided in the confidential annex.

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	decanoic acid
IUPAC or EC name	n-decanoic acid
EC number	206-376-4
CAS number	334-48-5
Index number in Annex VI of CLP	607-709-00-X
Minimum purity / content	985 g/kg (≥98.5% w/w)
Structural formula	

Main constituent(s)	
ISO name	octanoic acid
IUPAC or EC name	n-octanoic acid
EC number	204-677-5
CAS number	124-07-2
Index number in Annex VI of CLP	607-708-00-4
Minimum purity / content	993 g/kg (≥99.3% w/w)
Structural formula	

2.1.2.2 Candidate(s) for substitution

There are no indications that n-decanoic acid and n-octanoic acid would fulfil the exclusion criteria specified in article 5(1), nor the substitution criteria specified in Article 10 (1) of Regulation (EU) No 528/2012.

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
decanoic acid	n-decanoic acid	Active substance	334-48-5	206-376-4	2.7 (tech.) 2.6595 (pure)
octanoic acid	n-octanoic acid	Active substance	124-07-2	204-677-5	0.7 (tech.) 0.6951 (pure)

Details of the product composition and **information on the co-formulants are confidential** and are presented in the confidential Annex (PAR confidential).

2.1.2.4 Information on technical equivalence

Not required. SolNova s.r.l. is listed as supplier in the art 95 List of active biocidal substance and product suppliers. SolNova s.r.l. has a quality assurance program monitoring that the used quality corresponds to the specifications of the authorisation.

2.1.2.5 Information on the substance(s) of concern

According to Annex A of *Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) (Version 4.0 December 2017)*, the biocidal product contains no substances of concern.

2.1.2.6 Type of formulation

EW – oil in water (RTU)

2.1.3 Hazard and precautionary statements

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

According to the rules of the CLP REGULATION (EC) No 1272/2008, the biocidal product is classified for health hazards based on the concentration of its components.

Classification	
Hazard category	Not applicable
Hazard statement	Not applicable
Labelling	
Signal words	Not applicable
GHS Pictograms	Not applicable
Hazard statements	Not applicable
Precautionary statements	Not applicable

2.1.4 Authorised uses

2.1.4.1 Use description 1

Table 1. Use # 1 – **Insecticide against cat fleas. Non-professional users. Indoors**

Product Type	18 (Insecticide)
Where relevant, an exact description of the authorised use	Insecticide to control cat fleas. Ready-to-use product containing octanoic acid (0.7%) / decanoic acid (2.7%) as active ingredients.
Target organism (including development stage)	Cat flea (*Ctenocephalides felis*) (adults, larvae)
Field of use	Indoors. Textiles in households (e.g. pets' beds, pillows, sofas, carpets, etc.) which are not wet washed.
Application method(s)	Ready-to-use formulation in a manual pump spray can. After vacuuming of infested textiles, apply the product by direct spraying on infested household textiles
Application rate(s) and frequency	Application rate: 12 g/m^2, this is 2 spray pumps (1.28 g) at each application point from a distance of 60 cm. Application frequency: No preventive application is recommended. Spray on the textile when an infestation is detected. After 1 week, a new application is recommended when the infestation persists.
Category(ies) of users	General public (non-professional users)
Pack sizes and packaging material	Bottle of 250 and 500 mL Bottle and spray trigger made of LDPE

2.1.4.2 Use-specific instructions for use

See section 2.1.5.1

2.1.4.3 Use-specific risk mitigation measures

See section 2.1.5.2

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

See section 2.1.5.3

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

See section 2.1.5.4

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

See section 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

INSECT SHOCKER is a ready-for-use product. No dilution is required. Shake the bottle well before use.
INSECT SHOCKER is an insecticide against cat fleas (*Ctenocephalides felis*) infesting household textiles particularly where pets usually dwell (e.g. pets' beds, pillows, sofas, carpets, etc.)
INSECT SHOCKER produces knockdown of fleas in several minutes. Fleas will be killed after 3 days. Adults, larvae and eggs will be affected.
INSECT SHOCKER must be applied only on the infested textiles by spraying when an infestation is detected. The direction of the spray must be away from the applicator.
Dose: 12 g/m^2.
Spray 2 (1.28 g) pumps at each application point, from a distance of around 60 cm. Each spray pump covers a round surface with diameter of ca. 33 cm .
Around 18 sprays are needed to treat 1 m^2 of an infested textile.
Use the product only in case of infestation.
No preventive application is recommended. After 1 week, when the infestation persists, a new application is recommended.
Do not apply INSECT SHOCKER directly on pets. Adult fleas spend most of their life on the host (humans, animals), therefore to control an infestation it is necessary to treat also the host to avoid re-infestations. Contact your Veterinarian for the adequate product. Larvae and eggs of fleas live on textiles where companion animals rest.

2.1.5.2 Risk mitigation measures

Do not apply directly on persons or animals. Wash contaminated spots with a mild household detergent.
Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed and drinks.
Do not apply on clothes or textiles intended to be used in direct contact with the skin
Treated mattresses must be enclosed in a protective cover before using them in order to avoid dermal contact with the product.
The product contains water; therefore it should not be used to treat crevices around sockets or power cables strips.
Do not apply to washable home textiles.

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

Basic First aid procedures:

- If contact in eyes, rinse with plenty of water for at least 15 minutes. Do NOT forget to remove the contact lenses
- If contact on skin, wash with soap and plenty of water, without rubbing
- If necessary take person to a hospital and show the label or packaging when possible.

DO NOT LEAVE POISONED PERSON ALONE.

Medical advice for doctors and sanitary staff

- Symptomatic and supportive treatment

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER
Phone 91 562 04 20
To incorporate this phone into the label you must make the corresponding notification to the INTCF according to the procedure established in Order JUS/909/2017

2.1.5.4 Instructions for safe disposal of the product and its packaging

Product must be disposed of according to the local rules for biocidal products.
In Spain:
Empty containers should be deposited in separate collection containers according to the material of the containers.
Unused product and other waste generated during the treatment must be deposited in the residual fraction or in the collecting facilities.

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

Shelf life: 2 years.
Protect from frost.
Store at a dry place at room temperature.
Avoid prolonged exposition to direct sun.
Keep at ambient temperature

2.1.6 Other information

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

The authorization is conditioned to the subimission of the complete long term storage study.

2.1.7 Packaging of the biocidal product

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

					materials (Yes/No)
Manual pump spray bottle	250 mL 500 mL	LDPE	None	Non-professional	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data on the active substance itself or on the substances of concern has been submitted in function of this product application. All new information relates to the biocidal product described within this application.
The reference list (including updates) for the studies submitted in support of the BPD dossier has been included in Annex 3 whilst the reference list for the studies considered confidential has been included in the confidential Annex.

2.1.8.2 Access to documentation

The applicant is owner of the data submitted in function of this product application. Additionally, the applicant is also owner of all the data described in the active substance dossier as the applicant was participant in the review program. Consequently, the applicant is listed as an approved supplier on the Art. 95 list. A letter of access is therefore not applicable.

2.2 Assessment of the biocidal product

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

No application for a product family at this time.

Table 2. Intended use # 1 – name of the use

Product Type(s)	PT 18 Insecticide– Name: Amigard Floh Stop and Amigard Stop Pulgas
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Cat flea: *Ctenophalides felis*, which is also representative for dog flea; adults, larve, eggs.
Field of use	General public, private use in house.
Application method(s)	Direct application on the infested surfaces by spraying with a manual pump spray bottle.
Application rate(s) and frequency	In case of infestation one-time-application up to a maximum once a week. No preventive application.
Category(ies) of user(s)	Non-professional
Pack sizes and packaging material	500 mL, 250 mL LDPE

Product Type(s)	PT 18 Insecticide – Name: Amigard Milbenfrei and Amigard No Acaros
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	House dust mites: *Dermatophagoides pteronyssinus* (population containing late nymphal and adult stages).
Field of use	General public, private use in house.
Application method(s)	Direct application on the infested surfaces by spraying with a manual pump spray bottle.
Application rate(s) and frequency	In case of infestation one-time-application up to a maximum once a week. No preventive application.
Category(ies) of user(s)	Non-professional
Pack sizes and packaging material	500 mL, 250 mL LDPE

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual	Insect Shocker Batch: 0K1251 Purity: As identified in section 2.1.2.3 Amigard Bio Insect Shocker Batch:1I1251 Purity: As identified in section 2.1.2.3 Amigard Bio Insect Shocker Batch:1E2151 Purity: As identified in section 2.1.2.3 (with preservative)	<u>Initially:</u> Liquid <u>After 2 weeks at 40ºC:</u> Liquid <u>After 3 months at 15-30ºC:</u> Liquid	See confidential Annex.
		Insect Shocker Batch: 0H13W (HDPE bottles) 0H13S (glass bottles) Purity: As identified in section 2.1.2.3 (without preservative)	<u>Initially and after 2 weeks at 54ºC:</u> Liquid	See confidential Annex.
Colour at 20 °C and 101.3 kPa	Visual	Insect Shocker Batch: 0K1251 Purity: As identified in section 2.1.2.3 Amigard Bio Insect Shocker Batch:1I1251 Purity: As identified in section 2.1.2.3 Amigard Bio Insect Shocker Batch:1E2151 Purity: As identified in section 2.1.2.3 (with preservative)	<u>Initially:</u> Milky white <u>After 2 weeks at 40ºC:</u> Milky white <u>After 3 months at 15-30ºC:</u> Milky white	See confidential Annex.
		Insect Shocker Batch: 0H13W (HDPE bottles) 0H13S (glass bottles) Purity: As identified in section 2.1.2.3 (without preservative)	<u>Initially and after 2 weeks at 54ºC:</u> Milky white.	See confidential Annex.
Odour at 20 °C and 101.3 kPa	Olfactory	Amigard Bio Insect Shocker Batch: 0K1251 Purity: As identified in section 2.1.2.3	<u>Initially:</u> Buttery-rancid characteristic	See confidential Annex.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
		Amigard Bio Insect Shocker Batch:1I1251 Purity: As identified in section 2.1.2.3 Amigard Bio Insect Shocker Batch:1E2151 Purity: As identified in section 2.1.2.3 (with preservative)	<u>After 2 weeks at 40ºC:</u> Slightly rancid <u>After 3 months at 15-30ºC:</u> Slightly rancid	
		Insect Shocker Batch: 0H13W (HDPE bottles) 0H13S (glass bottles) Purity: As identified in section 2.1.2.3 (without preservative)	<u>Initially and after 2 weeks at 54ºC:</u> Neutral	See confidential Annex.
Acidity / alkalinity	DIN 53785	Insect Shocker Batch: 0K1251 Purity: As identified in section 2.1.2.3 (with preservative)	<u>Initially:</u> pH of 4.30 @ 22°C.	See confidential Annex.
		Amigard Bio Insect Shocker Batch:1I1251 Purity: As identified in section 2.1.2.3 Amigard Bio Insect Shocker Batch:1E2151 Purity: As identified in section 2.1.2.3 (with preservative)	<u>After 2 weeks at 40ºC:</u> pH of 4.3 @ 23.9ºC. <u>After 3 months at 15-30ºC:</u> pH of 4.3 @ 23.9ºC.	See confidential Annex.
	DIN 53785	Insect Shocker Batch: 0H13W (HDPE bottles) Purity: As identified in section 2.1.2.3 (without preservative)	<u>Initially and after 2 weeks at 54ºC:</u> pH of 4.4 @ 20°C.	See confidential Annex.
		Insect Shocker Batch: 0H13S (glass bottles) Purity: As identified in section 2.1.2.3 (without preservative)	<u>Initially and after 2 weeks at 40ºC:</u> pH of 4.2 @ 20°C.	
Relative density / bulk density	DIN 53 217 (aerometer)	Insect Shocker Batch: 0K1251 Purity: As identified in section 2.1.2.3 (with preservative)	0.995 g/mL @ 20ºC	See confidential Annex.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
	DIN 53 217 (pycnometer)	Insect Shocker Batch: 0H13W (HDPE bottles) 0H13S (glass bottles) Purity: As identified in section 2.1.2.3 (without preservative)	Initially and after 2 weeks at 54ºC: 1 g/mL @ 20ºC.	See confidential Annex.
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Amigard Bio Insect Shocker Batch:1I1251 Purity: As identified in section 2.1.2.3 (with preservative)	Stable: ≤ 10%	See confidential Annex.
Active Substance content:				
decanoic acid			Initially: **2.7 % w/w** After 2 weeks at 40ºC: **not available** Difference: -- %	
octanoic acid			Initially: **0.7 % w/w** After 2 weeks at 40ºC: **not available** Difference: -- %	
Homogeneity of application			not available	
Appearance and stability of the package			Not changes were observed	
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Insect Shocker Batch: 0H13W (HDPE bottles) Purity: As identified in section 2.1.2.3 (without preservative)	Stable: ≤ 10%	See confidential Annex.
Active Substance content:				
decanoic acid			Initially: **2.82 % w/w** After 14 days at 55ºC: **2.59 % w/w** Difference: -8.16 %	
octanoic acid			Initially: **0.75 % w/w** After 14 days at 55ºC: **0.72 % w/w**	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			Difference: -4.00 %	
Homogeneity of application			not available	
Appearance and stability of the package			Not changes were observed	
Storage stability test – **accelerated storage**	CIPAC MT 46.3	Insect Shocker Batch: 0H13S (glass bottles) Purity: As identified in section 2.1.2.3 (without preservative)	Stable: ≤ 10%	
Active Substance content:				
decanoic acid			Initially: **2.81 % w/w** After 16 daysat 55ºC: **2.58 % w/w** Difference: -8.19 %	
octanoic acid			Initially: **0.77 % w/w** After 16 days at 55ºC: **0.71 % w/w** Difference: -7.79 %	
Homogeneity of application			not available	
Appearance and stability of the package			Not changes were observed	
Storage stability test – **long term storage at ambient temperature**	OECD DRAFT GUIDANCE DOCUMENT FOR STORAGE STABILITY TESTING OF PLANT PROTECTION AND BIOCIDAL PRODUCTS	Amigard Bio Insect Shocker (with preservative)	Stable: ≤ 10% DA: 5.6% OA: 7.1%	
Active Substance content:				
decanoic acid		Batch:1E2151 Purity: As identified in section 2.1.2.3	Initially: **2.7 % w/w** After 3 months at 15-30ºC:	See confidential Annex.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
			not available Difference: -- %	
		Batch: L506131 Purity: As identified in section 2.1.2.3	Initially: **2.7 % w/w** After 2 years at 25ºC: **2.56 % w/w** Difference: -5.2 %	See confidential Annex.
		Batch: L506148 Purity: As identified in section 2.1.2.3	Initially: **2.7 % w/w** After 2 years at 25ºC: **2.55 % w/w** Difference: -5.6 %	
octanoic acid		Batch:1E2151 Purity: As identified in section 2.1.2.3	Initially: **0.7 % w/w** After 3 months at 15-30ºC: **not available** Difference: -- %	See confidential Annex.
		Batch: L506131 Purity: As identified in section 2.1.2.3	Initially: **0.7 % w/w** After 2 years at 25ºC: **0.68 % w/w** Difference: -2.9 %	See confidential Annex.
		Batch: L506148 Purity: As identified in section 2.1.2.3	Initially: **0.7 % w/w** After 2 years at 25ºC: **0.65 % w/w** Difference: -7.1 %	
Homogeneity of application			Not available	
Appearance and stability of the package			Not changes were observed after 3 months.	See confidential Annex.
Storage stability test – **low temperature stability test for liquids**			Not available	
Effects on content of the active substance and technical characteristics of			Not relevant.	See confidential Annex.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
the biocidal product - **light**				
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			No significant changes	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			No significant changes	
Wettability			Not appl.	
Suspensibility, spontaneity and dispersion stability			Not appl.	
Wet sieve analysis and dry sieve test			Not appl.	
Emulsifiability, re-emulsifiability and emulsion stability			Not changes were oberved	
Disintegration time			Not appl.	
Particle size distribution, content of dust/fines, attrition, friability	Laser diffraction principle (internal method)		Average size 160 µm.	See confidential Annex.
Persistent foaming			Not foaming is observed	
Flowability/Pourability/Dustability			Not relevant	
Burning rate — smoke generators			Not appl.	
Burning completeness — smoke generators			Not appl.	

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Composition of smoke — smoke generators			Not appl.	
Spraying pattern — aerosols, trigger spray			Spray pattern diameter at distance 20 cm = 17.0+3.0 cm Droplet size mean = 160 µm The spray pattern show only droplets > 10 µm	See confidential Annex.
Physical compatibility			Not appl.	
Chemical compatibility			Not appl.	
Degree of dissolution and dilution stability			Not appl.	
Surface tension	DIN EN 14370:2004	Amigard Bio Insect Shocker Batch: 15320A (with preservative)	26.46±0.04 mN/m at 25,0±0.5°C	See confidential Annex.
Viscosity	DIN 53019	Amigard Bio Insect Shocker Batch: 0K1251 Purity: As identified in section 2.1.2.3 Amigard Bio Insect Shocker Batch:1I1251 Purity: As identified in section 2.1.2.3 Amigard Bio Insect Shocker Batch:1E2151 Purity: As identified in section 2.1.2.3	Initially: 3.1 mPa.s @ 23ºC After 2 weeks at 40ºC: 3.1 mPa*s @ 23.9ºC. After 3 months at 15-30ºC: 3.01 mPa*s @ 23.9ºC.	See confidential Annex.
	DIN 53019	Amigard Bio Insect Shocker Batch: not available Purity: not available (with preservative)	3.1 mPa.s @ 23ºC	See confidential Annex.
		Insect Shocker Batch: 0H13W (HDPE bottles) 0H13S (glass bottles) Purity: As identified in section 2.1.2.3 (without preservative)	Initially and after 2 weeks at 54ºC: 3.3 mPa*s @ 23ºC.	See confidential Annex.

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

Notes:
The applicant has modified the original composition to eliminate the preservative of the final formulation.

- Insect Socker and Amigar Bio Insect shocker (formulations with preservative until July 2020 – the b.p. is on the market)
- Insect Shocker (formulation without preservative from July 2020 – not commercially available)

This change does not affect to the final conclusion of this section.

Appearance
White milky emulsion in ready to use bottle.

Acidity / alkalinity
The pH value of the b.p. is 4.4 @ 20ºC before and after 2 weeks at 54ºC.
The biocidal product is a ready to use application and does not require manipulation like dilution or mixing before use. Therefore the pH value of the 1 % aqueous solution is not relevant.

Accelerated storage
The original plastic (HDPE) and glass bottles were stored under controlled conditions for a defined period of time and the product was then tested for changes in properties. The results show that the product is stable at 54ºC during 14 days.

Long term storage at ambient temperature
The study is ogoing.

Low temperature stability test for liquids
If the low temperature storage does not perform, a phrase like 'protect from frost' must be included in the label.

Effects of light
The actives and the other ingredients have no significant chromophores and absorptions in the UV/VIS spectrum.
The bottles were not exposed to direct sun light.

Effects of temperature and humidity
The product is a water-based micro emulsion containing an approximative water content of 90% w/w. The product efficacy is therefore not affected by exposure to humidity as this is not expected to change the chemical composition of the product or chemical environment of the active ingredient.

Effects on content of the active substance and technical characteristics of the biocidal product - reactivity towards container material
Tested for shelflife. No changes were observed in the storage studies submitted.

Technical characteristics of the biocidal –particle size distribution, persisten foam, emulsifiability, re-emulsifiability, emulsion stability, pourability-
The biocidal product is a ready to use application and does not require manipulation like dilution or mixing before use
Persistent foaming: the study is not required because during use, coarse but fine droplets are leaving the nozzle (average size 160 µm) while no foaming is observed.

Emulsifiability, re-emulsifiability, emulsion stability: the study is not required because the emulsion is stable over time (see shelf life).
Particle size distribution: the type 805-RB0B0 trigger sprayer has a nozzle producing a droplet size with will not enter the lungs.

Spraying pattern
The bottles and the spraying trigger were chosen carefully for the application and biocidal product. The trigger spray, optimized for this product, generates droplets that move in a highly directional way at high velocity to the target area.

Physical and chemical compatibility with other products
"Compatibility with other products" are not applicable to the product Insect Shocker as it is not intended to be used together with other products.
The biocidal product is sold in ready to use bottle and contains mostly water (> 80%). Mixing with other products or materials are not allowed.

Surface Tension
The surface tension is lower than 60 mN/m under the conditions of the plate method, therefore the biocidal product should be regarded as a surface-active material.

Viscosity
The biocidal product is a ready to use application and does not require manipulation like dilution or mixing before use. In addition, the use of viscosity is mainly for hazard classification of the aspiration hazard (H304). A ready-to-use emulsion does certainly not have such a hazard.

Conclusions
INSECT SHOCKER is a heterogeneous formulation consisting of an emulsion of pesticide in an organic liquid dispersed as fine globules in a continuous water phase. The formulation of the test item is a white milky emulsion in ready to use bottle.
The mean pH-value and relative density were determined to 4.3 and 0.995 g/cc at start, respectively.
One viscosity measurement at 23ºC determined the viscosity to a mean value of 3.1 mPa*s and two surface tension measurements at 25ºC determined the surface tension to a mean of 26.46 mN/m at test time start.
On the samples tested no significant change in properties could be detected. All samples passed the QS tests used to release the product after production, indicating that the samples maintained their original properties. The intermediate results indicate a good potential for stability (shelf life = 2 years @ 25ºC), the study will be continued over a prolonged period to give more reliable long term results.
The phrase 'protect from frost' must be included in the label because the low temperature stability test has not been submitted by the applicant.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Explosives	Expert-statement		The biocidal product is not explosive.	See confidential Annex.

Property	Guideline and Method	Purity of the test substance (% w/w)	Results	Reference
Flammable gases			Not appl.	
Flammable aerosols			Not appl.	
Oxidising gases			Not appl.	
Gases under pressure			Not appl.	
Flammable liquids	Expert-statement		The biocidal product is not flammable.	See confidential Annex.
Flammable solids			Not appl.	
Self-reactive substances and mixtures			Not appl.	
Pyrophoric liquids			Not appl.	
Pyrophoric solids			Not appl.	
Self-heating substances and mixtures			Not appl.	
Substances and mixtures which in contact with water emit flammable gases	Expert-statement		The product is water based, therefore it is not expected that in contact with water, release flammable gas.	See confidential Annex.
Oxidising liquids	Expert-statement		The biocidal product has not oxidising properties.	See confidential Annex.
Oxidising solids			Not appl.	
Organic peroxides			Not appl.	
Corrosive to metals			Not appl.	
Auto-ignition temperatures of products (liquids and gases)	Expert-statement		Auto-ignition is not foreseen.	See confidential Annex.
Relative self-ignition temperature for solids			Not appl.	
Dust explosion hazard			Not appl.	

Conclusion on the physical hazards and respective characteristics of the product

Note:
The applicant has modified the original composition to eliminate the preservative of the final formulation.

- Insect Socker and Amigar Bio Insect shocker (formulations with preservative until July 2020 – the b.p. is on the market)
- Insect Shocker (formulation without preservative from July 2020 – not commercially available)

This change does not affect to the final conclusion of this section.

Explosiveness
The biocidal product ingredients do not have explosive properties. Therefore, it is unlikely that the biocidal product Insect Shocker is explosive

Flammability
The biocidal product is a ready-to-use emulsion with more than 88% water content and no ingredient is flammable.

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

Auto-ignition temperature (liquids and gases)
Insect Shocker is a ready-to-use emulsion. From the aqueous nature of the product and physical properties of the ingredients it can safely be stated that Insect Shocker does not auto ignite.

Conclusions
The product is a ready-to-use emulsion, not under pressure. None of the above listed properties are present.
Hazards linked to explosive, oxidizing or flammable properties should not be considered because it does not contain ingredients with these properties.
This product does not classify as a consequence of its physico-chemical properties therefore there is no risk associated on it. The uses of this product do not consider its combination with any other product therefore cross reactivity is not expected.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Decanoic acid	GLC-FID	60, 80, 100, 120, 140 µg/L n=2	From 60 µg/mL to 140 µg/mL for octanoic acid n=3 r^2 = 0.99994	None		99.6 ± 0.5 %		8.3 µg/L	CAR & AR (2013)
Octanoic acid	GLC-FID	60, 80, 100, 120, 140 µg/L n=2	From 60 µg/mL to 140 µg/mL for octanoic acid n=3 r^2 = 0.99932	None		99.6 ± 0.5 %		6.9 µg/L	CAR & AR (2013)
Decanoic acid	GC-FID	1.0 to 10.0 % w/w n=2	10.04-40.15 µg/mL n=5 r^2 = 0.99576	All peaks are well separated and there is no evidence of interferences with the test item peaks.	98.45 – 102.36	100.3	1.89	3.268 mg/kg	See confidential annex
Octanoic acid	GC-FID	0.1 to 1.0 % w/w n=2	r^2 = 0.99765 n=5 4.46-17.86 µg/mL	All peaks are well separated and there is no evidence of interferences with the	97.40 – 102.89	100.0	1.64	0.854 mg/kg	See confidential annex

				test item peaks.					

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Decanoic acid	GC/MS	0.1 µg/L (n=2)	0-5 µg/L	71.6%	111.5-78.3 %			0.1 µg/L	CAR & AR (2013)

		1 µg/L (n=2) 2.5 µg/L (n=2)	y = 0,333x + 0,0119 R2 = 0,9994 r^2 = 0.9994 n= 7		91.5-100.4 % 95.9-101.9 %				
Octanoic acid	GC/MS	0.1 µg/L (n=2) 1 µg/L (n=2) 2.5 µg/L (n=2)	0-5 µg/L y = 0,4781x + 0,0469 R2 = 0,9994 r^2 = 0.9994 n=7	74.24%	112.5-88.2 % 93-89.6 % 101-101.1 %			0.1 µg/L	CAR & AR (2013)

Analytical methods for animal and human body fluids and tissues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		

Conclusion on the methods for detection and identification of the product

Note:

The applicant has modified the original composition to eliminate the preservative of the final formulation.

- Insect Socker and Amigar Bio Insect shocker (formulation with preservative until July 2020 – the b.p. is on the market)
- Insect Shocker (formulation without preservative from July 2020 – not commercially available)

This change does not affect to the final conclusion of this section.

The applicant also confirm that the analytical mehotd submitted to determine quantitatively the contents of decanoic and octanoic acid in the product Amigard Bio Insect Shocker can be used with the Insect Shocker product without modifications.

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

The active substances, impurities and residues are all fatty acids which are naturally present in all living cells and tissues. The analytical method is a reference method from literature which has been verified and adapted to cover the requirements of the BPR.

The original evaluation of the Rapporteur Member State confirmed the method which is, however, not fully included in the CAR.

In addition, a new method taking the SANCO/3030/99 rev.4 guideline into account is added.

The method is considered to fulfils all requirements to determine precisely and accurately the active substances content and can easily adapted to different situations. Because of the internal standard even extraction methods could be developed when needed.

The method is not suitable to distinguish between naturally present octanoic/decanoic acid and added octanoic/decanoic acid.

Analytical methods for soil

Based on the use of the A.S. in CIP or indoor, there is inherently only a negligible emission to the environment, therefore development of an analytical method for soil is not necessary.

If contamination of soil would happen, an analytical method is described in the adsorption/desorption screening test (see CAR).

The adsorption/desorption screening test described in CAR shows that decanoic acid is very fast degraded in soil (DT_{50} < 2 days) it is very unlikely that significant amounts would be found in soil.

Analytical methods for air

Based on the use of the A.S. in CIP or indoor, there is inherently negligible emission to the environment, therefore development of an analytical method for air is not necessary. The vapour pressure of decanoic acid is low, therefore no significant concentrations of decanoic acid air will occur. The vapour pressure of octanoic acid is low, therefore no significant concentrations of octanoic acid in air will occur.

Analytical methods for water

The active substances have been found to occur naturally in low concentrations in water. Although the degradation of the active substances applied to water happens rapidly (see CAR) an analytical method was developed and validated for the quantitative analysis of the active substances from aqueous solution.

Analytical methods for animal and human body fluids and tisues
As the active substances are not classified as toxic or very toxic an analytical method for the determination of residues in animal and human body fluids and tissues is not required.

Analytical methods for monitoring of active substances and residues in food and feeding stuff
No analytical method for the determination of the active substances in food/feedstuffs is presented, because no direct contact of food and feedstuffs with the active substances is expected due to the mode of use.

Conclusion
A method for the measurement of the content of the active susbtances in the formulation is available. The method has been successfully validated and is considered acceptable.

Validated analytical methods are also available for the determination of the active substance in water matrices because the applicant has showed that they have access rights to the analytical methods studies contained in the CAR. Other analytical methods are not required.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

INSECT SHOCKER is a biocidal product belonging to the Main Group 03: Pest control; Product Type 18: Insecticides, acaricides and products to control other arthropods.

INSECT SHOCKER is a ready-to-use emulsion containing two active substances, octanoic acid (0.7%) and decanoic acid (2.7%). This formulation is presented as an insecticide to control cat fleas and house dust mites. The intended users are non-professionals in private houses. The field of use is indoors in private houses.

The product is marketed in a trigger spray plastic bottle to be manually applied directly on the target organisms or sprayed on indoor surfaces where the target organisms spend part of their lives, such as household textiles (e.g. pets' beds, pillows, sofas, carpets).

It should be noted that INSECT SHOCKER is not presented for protection of pets or humans by direct application onto their bodies.

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

INSECT SHOCKER is an insecticide for the control of the following organisms:

- Cat fleas (*Ctenophalides felis*), which is also representative for dog fleas. Both fleas' species are the most common in-home pests in the EU (Adults, larvae and eggs)
- House dust mites (*Dermatophagoides pteronyssinus*) (Adults, nymphs and eggs)

The product is presented for the control of these pests which affect the mascots and humans.

Adult fleas live in the hosts' fur and skin most of their life. They feed on blood from their hosts by biting them. This may produce irritation, papules, crusts, excoriations and

erythema in the skin. Fleas can also be a source of pathogenic infections and anaemia. The female flea produces the eggs, which, once laid, fall off the host and develop in the areas where the animal spends its time (usually the pet beds, fibres of carpets and other household fabrics, cracks in the floor, or crevices in furniture and furnishings). After hatching, flea eggs develop into larvae. Larvae remain hidden in carpet fibres and in other protected areas. Before becoming adult fleas, the larvae transform into pupae within a silk-like cocoon. Pupae develop into adult stage. Newly emerged adult fleas immediately seek a host and jump to reach its body where the flea will spend the rest of its life.

It should be noted that according to its life cycle, adult fleas can be better controlled directly on the host. However INSECT SHOCKER should not be used on the host. Hosts should be treated with other products covered by the legislation on Veterinary Medical Products or a biocidal of product type 19 Repellent authorized specifically to repel cat fleas.

House dust mites are widespread in human habitation. They live generally in mattresses, carpets, furniture and bedding. They can cause asthma and allergic symptoms in humans and mascots.

2.2.5.3 Effects on target organisms, including unacceptable suffering

INSECT SHOCKER produces knockdown and mortality of adult cat fleas (adulticide). Knockdown will take 2 minutes, while mortality will be complete in 24 hours, after the fleas come into contact with the insecticide. Eggs and larvae in contact with the product will not develop to the adult stage (larvicide/ovicide). These effects were seen when the biocidal product is sprayed directly onto the organisms or sprayed onto the surfaces where the insects live by contacting with treated materials. However the application on surfaces is not as efficacious as the use directly on the fleas.

INSECT SHOCKER produces mortality of house dust mites including adults, nymphs and eggs (adulticide/larvicide/ovicide). Depending on the treated surface type, mortality will take longer. When the product is sprayed onto wool fabric and glazed tiles complete mortality will take 3 days; when sprayed onto (porous) plywood tiles, mortality will take 4 days. However the TNsG requires a higher level of efficacy.

2.2.5.4 Mode of action, including time delay

INSECT SHOCKER is a formulation containing two active substances, octanoic acid (0.7%) and decanoic acid (2.7%). The active substances are linear saturated fatty acids naturally present in some animal fats and certain vegetable oils. Even if fatty acids are naturally occurring substances, they produce local irritation/corrosive effects in skin and eyes of mammals at high concentrations.

According to the CAR of the active substances, the mode of action is unknown. It is speculated that the a.s. may damage the chitin cuticle of arthropods leading to desiccation. The Applicant indicated that studies in the scientific literature discussed that fatty acids may enter the tracheae and the known local corrosive/irritation effects cause loss of water.

In the efficacy studies against cat fleas and house dust mites, INSECT SHOCKER produces knockdown and mortality after direct spray on pests (direct efficacy) and after contact with treated surfaces (residual efficacy). In test systems with cat fleas knockdown took 1-2 minutes and mortality took 24h after direct treatment and 2-3 days after contact with

treated surfaces. In test systems with mites, they were killed in 3-4 days after contact with treated surfaces.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Insecticide	Household textiles	Insect Shocker formulation containing 0.7% octanoic acid & 2.7% decanoic acid	Cat flea *(Ctenocephalides felis)* Mixed-sex adults. 10 fleas/replicate 5 replicates/treatment Untreated controls included.	TNsG PT18-19 Laboratory non-choice test Direct spray effect on insects Observations: knockdown (up to 2h or 100% KD) and mortality after 24h.	Direct spray on animals placed on paper tissues inside a glass ring (diameter of 9.5 cm). Starvation for 5 days. 22ºC and 46% RH[1] Hand-held sprayer delivering 2 pumps at 60 cm (mean measured 1.25 g) on fleas. Exposure: continuous during 24h	Treated samples: -100% knockdown in 1'27'' -100% mortality in 24h. Controls: -0% knockdown in 2h -0% mortality in 24h. Conclusion: TNsG requires for adulticial products, 100% knockdown within 24h and ≥90% mortality within 48h; therefore this study is acceptable.	[redacted] BIO104d-15
			Cat flea *(Ctenocephalides felis)* (adults and 2nd instar larvae, separately) 10 fleas/ replicate 5 replicates/treatment Untreated controls included.	TNsG PT18-19 Simulated-use non-choice test Residual effect in representative surfaces (textile fabric). Animals exposed 1d after treatment of carpet samples. Observations: mortality up to 100% is achieved.	Spray on carpet samples (15x15 cm) made of polyamide fibres of 6.6 cm height. Starvation (adults) for 5 days. 25-27ºC and 58-63% RH Hand-held spray, delivering 4 pumps at 60 cm. Dose: 5.6 g/m^2 Exposure: 6h for adults; continuous for larvae.	Treated samples: - 88% mortality after 48h (adults), range 80-90%; - 88% mortality, after 24h (larvae). Controls: 0% mortality within 24h. Conclusion: TNsG requires ≥90% mean mortality of adults within 48h and ≥80% mean inhibition of larvae during the claimed duration; therefore this study is not acceptable to support the adulticidal use. The applied dose was confusing.	[redacted] BIO129d-15
			Cat flea	TNsG PT 18-19.	Spray on carpet samples (33x33 cm (1089 cm^2)	Treated samples: 0% eggs developed into adults after 39d	[redacted]

[1] RH = Relative Humidity

			(Ctenocephalides felis) (eggs) 5 replicates/treatment 20 eggs/replicate Untreated controls included.	Simulated-use non-choice test Direct spray on eggs placed on beakers covered with carpet tiles at the bottom and then beakers placed on carpet tiles. Observations: inhibition of development to adults for 39 days.	made of polypropylene and polyamide fibres of 9.5 cm height. 23-26ºC and 50-66% RH Hand-held spray, delivering 2 pumps at 60 cm (1.28g). Dose: 11.7 g/m^2. Exposure: continuous during 39d (5w).	Controls: 82% eggs (range:75-90%) developed into adults after 39d Conclusion: TNsG requires ≥80% inhibition of development of eggs into adult fleas. The study is considered acceptable to support the ovicidal effect.	BIO063b-16
			Cat flea *(Ctenocephalides felis)* (larvae) 5 replicates/treatment 20 larvae/replicate Untreated controls included.	TNsG PT 18-19. Simulated-use non-choice test Direct effect on larvae placed on beakers covered with carpet tiles at the bottom and then beakers placed on carpet tiles. Observations: inhibition of development to adults for 39 days.	Spray on carpet samples (33x33 cm (1089 cm^2) made of polypropylene and polyamide fibres of 9.5 cm height. 26ºC and 60-66% RH Hand-held spray, delivering 2 pumps at 60 cm (1.28g). Dose: 11.7 g/m^2. Exposure: continuous during 39d.	Treated samples: 0% larvae developed into adults after 39d Controls: 75% larvae (range 70-80%) developed into adults after 39d Conclusion: TNsG requires ≥80% inhibition of development of eggs into adult fleas. The study is considered acceptable to support the larvicidal effect.	[redacted] BIO 062c-16
Acaricide	Household fabric, plywood and glazed tiles		House dust mites *(Dermatophagoides pteronyssinus)* Mixed adults, nymphs and eggs. 50 mites/replicate 5 replicates/treatment Untreated controls included.	TNsG PT 18-19; Laboratory non-choice test Residual efficacy with representative surfaces: fabric, plywood and glazed tiles. Observations: knockdown (up to 2h or 100% KD) and mortality after 24h and up to 7 days.	Manual spray on porous fabric (wool), non-porous glazed, porous plywood tiles of 15x15 cm 25ºC and 65% RH Mites were fed on dry fish food Exposure: surface was dried for 1 day before exposure; then continuous exposure for 7d. Applied dose: 11.20 g/m^2 (number of applied pumps not indicated)	Treated samples: - Glazed tiles: 60-80% mortality in 24h - Plywood tiles: 0-10% mortality in 24h - Fabric tiles: 70-80% mortality in 24h 100% mortality was reached within 3d in fabric and glazed tiles and within 4d in plywood. Controls: 0% mortality in 7d, in all surface types. Conclusion: TNsG requires ≥90% mortality in 24h, therefore this study does not prove efficacy against mites.	[redacted] BIO130c-15

Conclusion on the efficacy of the product

The efficacy studies submitted by the Applicant demonstrated the efficacy of INSECT SHOCKER against cat fleas (*Ctenocephalides felis*).

The preservative 2-methylisothiazol-3(2H)-one (MIT) was present in the original formulation in which efficacy test were performed with a concentration of 0.1% (w/w).
The biocidal profile of MIT is only in the area of (anti-)microbial effects as the determined efficacy of MIT is for the product-types 6, 11, 12 and 13, which all belong to the protection against microbial impact. Available information and the low general toxicity indicate, that MIT is not an insecticide. Therefore, removal of this constituent does not change the efficacy of the product.

The direct effect on cat fleas of INSECT SHOCKER was tested in a laboratory study against adult fleas at the dosage of 2 pumps (1.25 g) at a distance of 60 cm on paper tissues, resulting in 100% knockdown after <2 minutes and in 100% mortality after 24 hours. This demonstrates the intrinsic effect of the product on adult fleas.

There were three simulated-use studies on cat fleas. A test with adult and larvae fleas exposed to treated carpet discs the day before at a dosage of 4 pumps (corresponding to 5.6 g/m^2), resulted in 88% mortality of adults after 48h and 98% mortality of larvae after 24h; 100% mortality of both was achieved after 3 days. However the dose is different than recommended. Moreover the effect on adults did not reach the level required by the guidance. ES CA considers this study is not acceptable to support the adulticidal use. However it should be noted that adult fleas are not usually found far from the hosts (dogs, cats, humans, etc.), therefore the use against adult fleas on surfaces is not essential to control infestations. Additional treatment of the animal with an appropriate veterinary product should be warranted to control infestations and to prevent resistance.

Two simulated-use studies tested the effect during 5 weeks on the development to adults of eggs and larvae of a dosage of 2 pumps (1.28 g or 11.7 g/m^2) sprayed on carpet discs. After 5 weeks, 0% of the eggs and larvae developed to adults, while controls showed 75% and 82% of the flea larvae and eggs, respectively, converted into adults. It should be noted that the dose is different than recommended. However the results fulfil the guidance requirements.

A laboratory study of the product against house dust mites (Dermatophagoides pteronyssinus) (adults, late nymphs and eggs) tested the mortality effect of a dosage of 11.20 g/m^2 sprayed on three representative surfaces, i.e. fabric (wool), plywood and glazed tiles. The amount of product applied was not confirmed by measurements and the number of pumps was not reported. The report indicated the study was a simulated-use test. The study was not a choice test, as required by the Guidance, for simulated-use trials.
100% mortality was obtained within 3 days in fabric and glazed tiles and within 4 days in plywood tiles. For laboratory studies the TNsG requires ≥90% mortality of mites in 24h, but this was not achieved. An average (all types of surfaces) mortality level of 72% was obtained after 24h of exposure. In glazed tiles, after 24h mortality was 60-80%. In plywood tiles, after 24h mortality was 0-10%. In fabric tiles, mortality was 70-80% after 24h. This does not support the efficacy of the product against mites. ES CA requested the App. simulated-use studies in order to support the label claim as 'acaricide', but he did not submit any other studies. Hence, the claims against mites are not authorised by the ES CA.

The Applicant did not include a residual activity claim for a particular time period. On the contrary the Applicant does not recommend the use of this product to prevent infestations.

In addition, the efficacy tests included different life-cycle stages of fleas to show the effect as adulticide and larvicide/ovicide. It should be noted that the stage of pupae of fleas was not included in any efficacy study. Flea pupae are considered the most resistant stage of the flea life cycle. This is important for non-professional users since this product has not demonstrated its ability to control the entire infestation. In this sense, the eCA considers it is important to add some information for the consumer to be aware that infested pets should also be treated by a dedicated veterinary product in order to achieve the full control of fleas' infestations.

2.2.5.6 Occurrence of resistance and resistance management

The Applicant states that resistance to the biocidal product or its active substance has not been observed or reported so far. The active substances are part of the triglyceride pathway which is present in all living cells. The mode of action can only be based on the irritation/corrosive properties of the active substance(s) therefore the development of resistance is very unlikely as no mechanisms are known to develop protection against irritation damage.

The eCA has searched in the literature and found that both fleas and mites are known to develop resistance to classical insecticides such as DDT and other pyrethroids (Saleh et al. 1991[2]; Coles & Dryden 2014[3]). However studies addressing resistance of these organisms to octanoic and decanoic acids were not found.

In addition the Applicant states that occurrence of resistance is not likely because the product is not intended to be applied regularly over long periods. The product label includes the text: To be used in case of infestation, not as preventive application. This is accepted by the eCA.

However fleas and mites may be very difficult to control, especially when pets are also infested which may produce re-infestations. Re-infestations may be the reason why consumers could use the product several times, leading to resistance of the pests. The use of a control program that targets both adult and environmental flea life stages may decrease the rate of resistance development. This involves treating also the pets with different veterinarian products. This information should be included in the label.

2.2.5.7 Known limitations

Considering the life-cycle of cat fleas infesting in-home pets, it should be noted that adult fleas remain on the host for the rest of their lives. Therefore a limitation of the efficacy of

[2] S.M. Saleh, N.L. Kelada, N. Shaker. Control of European house dust mite *Dermatophagoides pteronyssinus* (Trouessart) with Bacillus spp. Acarologia, t. XXXII, fasc. 3, 1991.

[3] Coles TB, Dryden MW. Insecticide/acaricide resistance in fleas and ticks infesting dogs and cats. Parasites & Vectors, 7:8; 2014.

Insect Shocker would be related with the lack of treatment of in-home pests, since adult fleas will continue to produce eggs which will re-infest the treated surfaces and the host. In order to stop re-infection the pets should be treated with another specific product.

INSECT SHOCKER should not be used to directly treat the pets, as this use is considered to be covered by legislation on Veterinary Medical Products and therefore this assessment does not include this use.

2.2.5.8 Evaluation of the label claims

The following label claims were evaluated:

- Use as an insecticide against cat fleas (adulticide/larvicide/ovicide)

The laboratory and simulated-use efficacy studies demonstrated the required effect (mortality/knockdown) on adult fleas, treated by direct spray onto the insects and by contact with treated household textiles (carpet discs as representative surfaces). However the application on surfaces did not reach the minimum level of efficacy. Nevertheless adult fleas are mainly found on the hosts (pets, humans, etc.) and not on the surfaces to be treated with this product.

In addition, the effect on the larvae and eggs was also demonstrated in dedicated studies. The effect as larvicide and ovicide should be observed as inhibition of the larvae and eggs to develop to adults.

It should be noted that the flea life cycle stage of pupae was not included in the efficacy studies. Pupae are considered the most resistant stages of the flea life cycle. This is an important issue for the consumer since this product has not demonstrated its ability to control all the life cycle stages. After the treatment of textiles, pupae could be alive. Pupae may therefore develop to adults, and adults may hide on the pets' fur to start their reproduction cycle. In this sense, the eCA considers it is important to add some information for the consumer to be aware that infested pets should also be treated by a dedicated veterinary product in order to achieve the full control of fleas' infestations.

Even with an additional treatment of the hosts, pupae could still be alive. Therefore the Applicant's recommendation of repeating the application of the product in case of necessity one week after the first application is acceptable for the eCA.

- Use as an acaricide against house dust mites (adulticide/larvicide/ovicide).

The laboratory study demonstrated an effect (mortality) on adult, nymph and egg mites, by contact with treated household surfaces (carpet, glazed ceramic and plywood tiles as representative surfaces). However the level of effect was below the requirement of the TNsG. The dose applied was not clearly reported.

Since the Applicant submitted only one non-compliant study with only one mite species, INSECT SHOCKER cannot be authorised for its use against house dust mites as `acaricide´ and as secondary pest.

- Dose rates

The Applicant proposed a dose rate of 6-11 g/m^2. However in the efficacy studies these doses where not confirmed.
The efficacy studies confirmed that the dosage of 2 spray pumps delivered on the same spot at a distance of 60 cm was efficacious to achieve the mortality effect on cat fleas (2 spray pumps contain ca. 1.28 g of product; spray pattern is a round surface with a diameter of ca. 33 cm (Report BIO063b-16); thus dose is ≈11.7 g/m^2)
Thus treating a 1-m^2 surface would involve 18 spray pumps on textiles. This indication should be included in the authorisation.

- Use as spray onto representative surfaces

The simulated-use efficacy studies were conducted on representative surfaces as explained before. For cat fleas, these are mainly household textiles where pets usually dwell. The efficacy studies were conducted with such representative surfaces, i.e. carpets made of polyamide and wool.

The Applicant proposed the use as direct spray onto insects located in textiles. Residual efficacy was not adequately confirmed; only direct application onto fleas was proved. Therefore preventive use will not be authorised. The use on textiles when an infestation is detected can be authorised.

- Duration of effect (residuality)

The formulation does not provide residual efficacy. The effect is limited to the direct spray application onto cat fleas and the contact of these organisms with recently treated surfaces.

The Applicant did not propose the use of this product for prevention of infestations. The product must be used when an infestation exists.

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

INSECT SHOCKER is not intended to be authorised for use with other biocidal product(s).

2.2.6 Risk assessment for human health

INSECT SHOCKER contains two active substances, i.e. Decanoic acid (2.7% w/w) and Octanoic acid (0.7% w/w) and other co-formulants.

No studies on the effects of INSECT SHOCKER on human health have been submitted. However there are valid data available on each of the components in the mixture sufficient to allow the classification of the mixture according to the rules laid down in Regulation (EC) No. 1272/2008. Therefore new studies with the biocidal product are scientifically not justified. Hence ES CA has not requested the Applicant new studies.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	INSECT SHOCKER is neither corrosive nor irritating to skin
Justification for the value/conclusion	The product contains two active substances and co-formulants classified as as irritating or corrosive to the skin. However these substances are present at a concentration below their generic cut-off value and thus they do not trigger the classification of INSECT SHOCKER.
Classification of the product according to CLP	No classification is required.

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

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	INSECT SHOCKER is not irritating to eyes
Justification for the value/conclusion	The product contains several substances classified as eye irritant or serious eye damage. However these substances are present at a concentration below their generic cut-off value and thus they do not trigger the classification of INSECT SHOCKER.
Classification of the product according to CLP	No classification is required.

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

Respiratory tract irritation

Conclusion used in Risk Assessment – Respiratory tract irritation	
Value/conclusion	INSECT SHOCKER is not irritant to the respiratory tract.
Justification for the value/conclusion	None of the components of INSECT SHOCKER is classified as STOT – single exposure, category 3 (May cause respiratory irritation). Therefore the product is not considered irritanting to the respiratory tract.
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Data on respiratory tract irritation of the biocidal product.
Justification	No experimental data on respiratory tract irritation of the biocidal product is available. However, the composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitization	
Value/conclusion	INSECT SHOCKER is not sensitising to skin
Justification for the value/conclusion	The biocidal product contains several co-formulants classified as skin sensitizer. However, the concentration of these substances is below their generic concentration limits cut-off value and thus they do not trigger the classification of INSECT SHOCKER.
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Skin sensitization study
Justification	A study with the product is not scientifically justified. The composition of the product is known. Sufficient data on the intrinsic properties are

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

Respiratory sensitization

Conclusion used in Risk Assessment – Skin sensitization	
Value/conclusion	INSECT SHOCKER is not a respiratory sensitiser
Justification for the value/conclusion	None of the components of INSECT SHOCKER is classified as respiratory sensitiser. Therefore the product is not considered a respiratory sensitiser.
Classification of the product according to CLP	No classification is required

Data waiving	
Information requirement	Data on respiratory sensitization of the biocidal product.
Justification	For the biocidal product the composition is known. Sufficient data on the intrinsic properties of the components are available from safety data sheets and other information for each of the individual components in the product. Consequently, classification of the mixture can be made according to the rules laid down in Regulation (EC) No 1272/2008. None of the ingredients are classified as respiratory sensitizers, so the product is not classified.

Acute toxicity

Acute toxicity by oral route

Conclusion used in Risk Assessment – Acute oral toxicity	
Value/conclusion	INSECT SHOCKER is not classified for acute oral toxicity
Justification for the value/conclusion	None of the components of INSECT SHOCKER is classified for acute oral toxicity. Therefore the product is not considered acutely toxic.
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Acute oral toxicity study.
Justification	A study with the product is not scientifically justified. No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid

	down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted.

Acute toxicity by inhalation

Conclusion used in Risk Assessment – Acute inhalation toxicity	
Value/conclusion	INSECT SHOCKER is not classified for acute inhalation toxicity
Justification for the value/conclusion	None of the components of INSECT SHOCKER is classified for acute inhalation toxicity. Therefore the product is not considered acutely toxic.
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Acute inhalation toxicity study.
Justification	A study with the product is not scientifically justified. No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted.

Acute toxicity by dermal route

Conclusion used in Risk Assessment – Acute dermal toxicity	
Value/conclusion	INSECT SHOCKER is not classified for acute dermal toxicity
Justification for the value/conclusion	None of the components of INSECT SHOCKER is classified for acute dermal toxicity. Therefore the product is not considered acutely toxic.
Classification of the product according to CLP	No classification is required.

Data waiving	
Information requirement	Acute dermal toxicity study.
Justification	A study with the product is not scientifically justified. No studies have been performed with the biocidal product in order to avoid unnecessary testing with vertebrates. The composition of the product is known and there are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP Regulation), and synergistic effects between any of the components are not expected Therefore, this study does not need to be conducted.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substances	Decanoic acid and octanoic acid
Value(s)*	Dermal absorption values considered are: - 100% of dermal absorption of Octanoic acid. - 100% of dermal absorption of Decanoic acid.
Justification for the selected value(s)	There are not experimental studies available on the dermal absorption of INSECT SHOCKER. In the CARs of the active substances studies on dermal absorption are not available. Due to the lipophilicity of (undissociated) Octanoic acid (log P_{OW} of 3.03) and Decanoic acid (log P_{OW} of 4.09), it is expected they easily penetrate and cross cell membranes. As it was found with absorption from the gut, it is appropriate to assume that the permeation through skin is easy. Also the skin irritating effects of the C8 and C10 fatty acids would support dermal absorption. On the other hand the low water solubility would limit dermal absorption. However after skin contact, the formation of a reservoir of the active substance in the stratum corneum and desquamation of the stratum corneum in time will result in less than 100% systemic availability. Nevertheless in the absence of a dermal uptake study for the purpose of risk assessment 100% absorption of C8 and C10 fatty acids through the skin should be assumed.

Data waiving	
Information requirement	Study with the product is scientifically unjustified.
Justification	A dermal absorption study with the biocidal product was not performed. The risk assessment of INSECT SHOCKER will be based on a qualitative risk assessment for local effects. Therefore additional information on dermal absorption of the product is not necessary.

Endocrine disrupting properties

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

According to the CAR for decanoic acid and octanoic acid, there is no indication for endocrine disrupting properties of active substances. However, a comprehensive ED-assessment for the active substance and its metabolites according to Regulation (EU) 2017/2100 and the "Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption" will need to be performed at the renewal stage.

After reviewing the potential ED properties of co-formulants, three substances have been identified as having potential endocrine disrupting properties. If these substances are

identified as having ED properties in the future, the conditions for granting the biocidal product authorisation will be revised.

For the assessment of endocrine-disrupting properties of co-formulant(s), please refer to the respective section of the confidential annex to the PAR.

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

The biocidal product INSECT SHOCKER contains two active substances and other co-formulants. The active substances are decanoic acid (2.7% w/w) and octanoic acid (0.7% w/w).

Most of the co-formulants present are not classified for any hazards. However one co-formulant in the form of premix are classified for human health hazards. Due to the low concentration of most of these components in the biocidal product, they do not trigger the classification of the product.

Available toxicological data relating to a mixture

Not applicable.

Other

Additional tests relating to the exposure of the active substances or the formulated product INSECT SHOCKER are not considered necessary.

2.2.6.2 Exposure assessment

INSECT SHOCKER is an insecticide against mites and cat and dog fleas and a ready to use trigger spray can in accordance with the request of the applicant. The biocidal product is not sold for professional use.

INSECT SHOCKER is a product to be used in case of infestion, not as a preventive application. In case of infestation one time application up to a maximum once a week. No preventive application is recommended on the label.

Application method: direct spraying on the infested places. The type 805-RB0B0 trigger sprayer has a nozzle producing a droplet size with will not enter the lungs.
The application dose (no dilution) of active substances in the biocidal product in treated article or system is 18 trigger sprays/m^2 (12 g/m^2) for using against cat fleas, according to the section 2.2.5.
Application aim: control, curative and health protection.

INSECT SHOCKER contains two active substances: Decanoic acid (2.7% w/w) and octanoic acid (0.7% w/w) and several coformulants detailed in the confidential annex.
The rapporteur of the active substances dossier considered only the local irritation hazards as relevant.

The eCA has only considered the local irritation hazards as relevant as indicated in the active substances dossier.

According the annex A of the document "Guidance on the Biocidal Products Regulation Volume III Human Health - Assessment & Evaluation (Parts B+C) Version 2.1 February 2017" : a qualitative exposure and risk assessment should be done in order to determine whether S-phrases/P-statements normally associated with concerned R-phrases/H statements are sufficient or whether other risk mitigation measures should be applied. The qualitative risk assessment can be found in the Risk characterization for human health section.

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

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation[1]	N.a.	N.a.	Yes	N.a.	N.a.	Yes	No
Dermal	N.a.	N.a.	Yes	N.a.	N.a.	Yes	No.
Oral	N.a.	N.a.	Yes	N.a.	N.a.	Yes	No

[1] exposure via inhalation route is not considered negligible due to the vapour pressure of several coformulants. See confirdential annex for additional data.
n.a. = not applicable.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Insecticide treatment	**Primary exposure**: direct application of the INSECT SHOCKER	Non-professionals
2.	Using treated surface	**Secondary exposure**: with correct application, only occurs through contact with the treated surface	Non-professionals
3.	Cleaning	**Secondary exposure**: The treated surfaces may be cleaned using a vacuum cleaner to remove mites/fleas and product residues.	Non-professionals
4.	Inhalation volatized residues	**Secondary exposure** : General public - Inhalation volatized residues indoors (chronic exposure)	General public Adult, child, toddler, infant

Industrial exposure

Not applicable.

Professional exposure

Not applicable.

Non-professional exposure

Primary exposure

Scenario [1] Insecticide treatment

Description of Scenario [1]		
Direct spray application • Cat fleas: Shake bottle well before use. Treat the infested surface by spraying on the dwelling areas of the companion animals, e.g. pets' beds, pillows, sofas or carpets. Apply one spray at a distance of approx. 60 cm which treats a round surface with a diameter of 30 cm, leaving it visibly wet. This corresponds to a dosage of 12 g/m^2 (18 sprays). Apply the product in this way on the entire surface to be treated. If necessary, repeat the application next week.		
	Parameters	Value
Tier 1	% of active substance in the biocidal product Decanoic acid (DA) Octanoic acid (OA)	 2.7% 0.7%
	Application distance	60 cm
	Application dose	12 g/m^2
	Round surface treated in 1 spray	33 cm
	surface treated in 1 spray	0.06 m^2
	Amount of biocidal product in treated surface	0.72 g
	Amount of active substances in treated surface	19.4 mg DA 5 mg OA
	Dermal & Oral absorption[1]:	100%
	Body weight	60 kg

[1] *CARs*

Calculations Local exposure for Scenario 1 – Spraying systems at low pressure

No calculations are needed. Direct oral and dermal contact to the biocidal product is possible for normal work practice. However, the biocidal product has been reformulated lowering the concentration of octanoic acid to address the skin and eye irritation properties of the active substances.

Accidental spillages to the bare skin would be washed off and the contaminated skin rinsed with water, if this happens.

As a result of their low concentration in the product, the active substances are not expected to lead to substantial inhalation exposure levels.
With regard to the other ingredients, several coformulants are identified with high vapour pressure. This issue is addressed in the Scenario 4.

Further information and considerations on scenario [1]

Not applicable

Combined scenarios
Not applicable

Secondary exposure

Scenario [2] using treated surface

Description of Scenario [2]		
Post-application • Cat fleas: Shake bottle well before use. Treat the infested surface by spraying on the dwelling areas of the companion animals, e.g. pets' beds, pillows, sofas or carpets. Apply one spray at a distance of approx. 60 cm which treats a round surface with a diameter of 30 cm, leaving it visibly wet. This corresponds to a dosage of 12 g/m^2 (18 sprays). Apply the product in this way on the entire surface to be treated. If necessary, repeat the application next week.		
	Parameters	Value
Tier 1	% of active substance in the biocidal product Decanoic acid Octanoic acid	 2.7% 0.7%
	Application distance	60 cm
	Application dose	12 g/m^2
	Round surface treated in 1 spray	33 cm
	Surface treated in 1 spray	0.06 m^2
	Amount of biocidal product in treated surface	0.72 g
	Amount of active substances in treated surface	19.4 mg DA 5 mg OA
	Dermal & Oral absorption[1]:	100%
	Body weight	60 kg

[1] *CARs*

Calculations Local exposure for Scenario 2 – use of treated surfaces

No calculations are needed. Indirect oral and dermal contact to the biocidal product is possible for the general public living in places where the product has been used to treat the infestation.

As a result of their low concentration in the product, the active substances are not expected to lead to substantial inhalation exposure levels.
With regard to the other ingredients, several coformulants are identified with high vapour pressure. This issue is addressed in the Scenario 4.

Further information and considerations on scenario [2]
Not applicable

Combined scenarios
Not applicable

Scenario [3] cleaning treated surface

Description of Scenario [3]		
Post-application • Cat fleas: The treated surfaces may be cleaned after one day after application using a vacuum cleaner to remove fleas and product residues.		
	Parameters	Value
Tier 1	% of active substance in the biocidal product Decanoic acid Octanoic acid	 2.7% 0.7%
	Application distance	60 cm
	Application dose	12 g/m^2
	Round surface treated in 1 spray	33 cm
	surface treated in 1 spray	0.06 m^2
	Amount of biocidal product in treated surface	0.72 g
	Amount of active substances in treated surface	19.4 mg DA 5 mg OA
	Dermal & Oral absorption[1]:	100%
	Body weight	60 kg

[1] *CARs*

Calculations Local exposure for Scenario 3 – cleaning

No calculations are needed. No exposure is foreseen during the cleaning procedure using vaccum cleaner.

Further information and considerations on scenario [3]
Not applicable

Combined scenarios
Not applicable

Scenario 4 – Inhalation of volatilised residues indoors (chronic exposure)

Non-Professional and general public may be exposed to volatilised residues from treated textiles in households. However, based on the document, HEEG opinion 13 on Assessment of Inhalation Exposure of volatilised biocide active substance, it might not be necessary to calculate the exposure to volatilised residues if the relation between the SVC (saturated vapour concentration) and $AEC_{long\text{-}term}$ (acceptable exposure concentration at long term) is measured:

- For active substances (DA & OA):

$$\frac{0.410\,.mw\,.vp}{AEC_{long-term}} = \frac{0.410 * mw * vp}{no\ hazard\ identified}$$

- For coformulant 1:

$$\frac{0.410\,.mw\,.vp}{AEC_{long-term}} \leq 1$$

- For coformulant 2:

$$\frac{0.410\,.mw\,.vp}{AEC_{long-term}} = \frac{0.410 * mw * vp}{no\ hazard\ identified}$$

- For coformulant 3:

$$\frac{0.410\,.mw\,.vp}{AEC_{long-term}} > 1$$

- For coformulant 4:

$$\frac{0.410\,.mw\,.vp}{AEC_{long-term}} = \frac{0.410 * mw * vp}{no\ hazard\ identified}$$

- For coformulant 5:

$$\frac{0.410\,.mw\,.vp}{AEC_{long-term}} = \frac{0.410 * mw * vp}{no\ hazard\ identified}$$

Remark: the mw (molecular weight), vp (vapour pressure) and $AEC_{long\text{-}term}$ for local effects in general population come from the ECHA and PubChem databases.

The result of this equation is not possible because no hazard has been identified for the active susbtances and several coformulants. Therefore, the **exposure to volatilised residues indoor** can be considered **negligible** due to their low vapour pressures for non-professional (general public).

The result of this equation is lower than 1 for coformulant 1. The **exposure to volatilised residues indoor** can be considered **negligible** for non-professional (general public) for this substance.

The result of this equation is higher than 1 for coformulant 3. The **exposure to volatilised residues** indoor cannot be considered negligible for non-professional (general public) for this substance. This exposure is therefore considered into the scenarios **for coformulant 3 only but** due to the low concentration of this component in the biocidal product, **coformulant 3 do not trigger the classification of the product**.
.

See confidential annex for additional information about this section.

Description of Scenario 4 – Inhalation of volatized residues indoors		
For decanoic acid, octanoic acid and several coformulants: exposure to volatilized residues indoor can be considered negligible based on HEEG opinion 13 (see above). However, for several coformulants, based on HHEG opinion 13, exposure to volatilized residues indoor can not be considered negligible and have been calculated. A model for inhalation of volatilised residue from treated textiles in households has been provided in the TNsG (Part 3, p.50). The model assumes that the room is moderately ventilated, that 1% of the saturated vapour concentration (SVC) will be available for inhalation and that residence time is 18 hours per day. The model has been superseded by HEEG Opinion 13, MOTA Version 5 (published 2013) which stipulates that a 24 hour exposure period and no ventilation rate (100% SVC available for inhalation) are assumed as part of the first tier assessment. The body weight and inhalation rate have been updated according Biocide Human Health Exposure Methodology, October 2015.		
	Parameters	Value
Tier 1 No PPE	Vapour pressure[1]	See confidental annex
	Molecular weight[1]	See confidental annex
	Gas constant	8.314 J/mol/K
	Temperature (degrees Kelvin)	298 K
	Saturated vapour concentration (SVC)	See confidential annex
	Body weight[2]	Adult: 60 kg Child: 23.9 kg Toddler: 10 kg Infant : 8 kg
	Inhalation rate[2]	Adult: 1.25 m^3 air/h Child: 1.32 m^3 air/h Toddler: 1.26 m^3 air/h Infant : 0.84 m^3 air/h
	Duration	24 hours

[1] ECHA database.
[2] Biocides Human Health Exposure Methodology, Oct 2015.

Further information and considerations on scenario [4]
Not applicable

Combined scenarios
Not applicable

Monitoring data
Not applicable

Dietary exposure
The only possibility of secondary exposure as a result of use of BP is when a consumer use a treated surface or system which may be not cleaned using a vacuum cleaner to remove cat fleas and product residues. The possible residues are only a small fraction compared to the natural presence.

For octanoic and decanoic acid no ADI or ARfD are set, and no specific MRL's are set or required yet according to Leg (EU) 2015/1608 (Annex IV).
As no specific MRL exists for octanoic and decanoic acid, a default MRL value of 0.01 mg/kg food could be applied. However, as no specific reference values can be derived due to the lack of systemic adverse effects (no systemic AELs, ADI, ARfD) no assessment is deemed needed. In addition, according to the CARs the daily human uptake of fatty acids as natural food contents is, e.g. according to Henderson et al 2003 already about 900 mg/kg bw day. The consumer exposure to the active substances (without systemic hazards identified, without derived reference values) linked to use as a biocidal product is considered as negligible compared to other uses in the food chain.
In conclusion, no exposure is foreseen as regards to the intended use of the product.

Information of non-biocidal use of the active substance

Summary table of other (non-biocidal) uses of decanoic acid			
	Sector of use [1]	**Intended use**	**Reference value(s) [2]**
1.	Plant protection product	Paths and open areas with tree growth, woody ornamentals, Decorative lawns, turf, vegetables, berry fruit, pome fruit and azalea. [3] Date of approval: 01/09/2009 Expiration of approval: 31/08/2020.	MRL[4]
2.	Flavouring agents	Flavouring agent or adjuvant	EU Food Improvement Agents[5], Flavor and Extract Manufacturers Association (FEMA)[6], FDA Center for Food Safety and Applied Nutrition (CFSAN)[7]
3.	Food Additives	Antifoaming agent	FAO/WHO Food Additive Evaluations (JECFA)[8]
Summary table of other (non-biocidal) uses of octanoic acid			
	Sector of use [1]	**Intended use**	**Reference value(s) [2]**
1.	Plant protection product	Paths and open areas with tree growth, woody ornamentals, Decorative lawns, turf, vegetables, berry fruit, pome fruit and azalea.[3] Date of approval: 01/09/2009 Expiration of approval: 31/08/2020.	MRL[4]
2.	Flavouring agents	Flavouring agent or adjuvant	EU Food Improvement Agents[5], Flavor and Extract Manufacturers Association (FEMA)[9], FDA Center for Food Safety and Applied Nutrition (CFSAN)[10]
3.	Food Additives	Antifoaming agent	FAO/WHO Food Additive Evaluations (JECFA)[11]

[1] e.g. plant protection products, veterinary use, food or feed additives
[2] e.g.: MRL: maximum residues levels
[3] SANCO/2611/08 – rev. 2.
[4] Reg. (EC) No 839/2008.
[5] Regulation (EU) No 872/2012;
[6] GRAS Reference 2364.
[7] Document Number (21 CFR): 172.210, 172.860, 173.340, 178.1010.
[8] TRS 884-JECFA 49/29.
[9] GRAS Reference 2799.
[10] TRS 1000-JECFA 82/84.
[11] Document Number (21 CFR): 172.210, 172.860, 173.315, 173.340, 173.370, 178.1010, 184.1025.

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

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

Aggregated exposure

Not applicable

Summary of exposure assessment

The Assessment Report for decanoic acid and octanoic acid states "The only toxicological concern evident is the severely irritating property of the medium chain fatty acids." As this concern is concentration dependent, the biocidal product has been reformulated and the concentration of octanoic acid has been lowered.
Based on the fact that the biocidal product can be considered as having no harmful effects neither on the skin nor on the eyes, it can be concluded that no risk from use exists.

2.2.6.3 Risk characterisation for human health

The derivation of a systemic AEL is considered inappropriate. Risk assessment is focused on risk for local effects. However, the available data for the active substances are insufficient for the derivation of local oral, local dermal and local inhalation acceptable exposure concentrations (AEC)s.
In conclusion, a qualitative risk assessment of the potential local effects is made.

This, according to the CAR's of the active substances octanoic acid and decanoic acid:
As summarized in Doc IIA.5 the publications from Webb 1993, Harkins 1968, Traul et al. 2000 for medium chain triglycerides (MCTs) as well as the publications from Mori 1953 and WHO/IPCS 1998 for the free fatty acids do not indicate any adverse systemic effect and support NOAELs above 1000 mg/kg bw/d. Daily human uptake of fatty acids as food contents is, e.g. according to Henderson et al 2003 about 900 mg/kg bw day and the metabolic pathways are similar for all fatty acids, that is complete catabolism for energy supply or conversion to fat suitable for storage (see also Doc II-A 3.1). Therefore, the derivation of a systemic AEL is considered unnecessary. Risk assessment is focused on risk for local effects. The available data for the active substances is insufficient for the derivation of local oral, local dermal and local inhalation acceptable exposure concentrations (AECs). In any case the data for the active substances would be inadequate for the assessment of the biocidal products that are different with regard to pH, solvents and other ingredients.

Absorption of the active substance and other non-active ingredients:

- Oral absorption: 100%
- Dermal absorption: 100%
- Inhalation absorption: 100%

As there are no dermal absorption studies available for the biocidal product, 100% absorption is assumed to be a conservative estimate.

The following steps were taken during this qualitative risk assessment:

- Step 1: Description of the local hazards
- Step 2: Assignment of hazard categories
- Step 3: Identification of the exposure scenarios
- Step 4: Acceptability or non-acceptability of the risks
- Step 5: Concluding qualitatively on the acceptability of risk

Risk From Substances of concern:
Not relevant because no SoC were deemed.

Risk for industrial users

Manufacturing of active substance and formulation of products is not covered by BPR, otherwise the product is not used in an industrial way.

Risk for professional users

Systemic effects
Not relevant

Local effects
Not relevant

Risk for non-professional users (general public)

Systemic effects
Not relevant

Local effects
The product INSECT SHOCKER being not classified, no hazard has been identified.
Therefore, no local risk assessment is required.

Conclusion

The risk is considered acceptable for non-professional users (general public).

Risk for consumers via residues in food

The only possibility of secondary exposure as a result of use of BP is when a consumer use a treated surface or system which may be not cleaned using a vacuum cleaner to remove fleas/mites and product residues or a suitable carpet shampoo solution. The contribution of these residues originating from parts not cleaned is considered to be not relevant regarding the low concentrations possible in e.g.: pets' beds, pillows, mattresses, sofas, carpets. The possible residues are only a small fraction compared to the natural presence.
For the C8 and C10 acids the derivation of systemic AELs were considered unnecessary. Risk assessment is focused on risk for local effects.
For octanoic and decanoic acid no ADI or ARfD are set, and no specific MRL’s are set or required yet according to Leg (EU) 2015/1608 (Annex IV).

As no specific MRL exists for octanoic and decanoic acid, a default MRL value of 0.01 mg/kg food could be applied. However, as no specific reference values can be derived due to the lack of systemic adverse effects (no systemic AELs, ADI, ARfD) no assessment is deemed needed. In addition, according to the CARs the daily human uptake of fatty acids as natural food contents is, e.g. according to Henderson et al 2003 already about 900 mg/kg bw day. The consumer exposure to the active substances (without systemic hazards identified, without derived reference values) linked to use as a biocidal product is considered as negligible compared to other uses in the food chain.
In conclusion, no exposure is foreseen as regards to the intended use of the product.

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

Not applicable. This local risk assessment covers all active substances and 'substance(s) of concern'.

2.2.7 Risk assessment for animal health

An scenario could be presented here where companion animal comes into contact with the applied product after trigger spray application and ingests the residue licking the treated surface. This will be a short-term oral exposure scenario. However, taking into account the application process, including clean step, of the biocidal product, the exposure of companion animals is not foreseen.

2.2.8 Risk assessment for the environment

ES CA:
The risk assessment for the environment is reported as submitted by the Applicant. The ES CA assessment is presented in separate boxes on a green background.

The Assessment Report for decanoic acid and octanoic acid concludes that these substances are neither a vPvB, nor a PBT substance and are no candidates for substitution. In the environmental risk assessment no risk is identified for the air compartment, for the aquatic compartment including sediment, for the soil compartment including groundwater and for secondary poisoning.

There is no indication of an endocrine potential.

None of the other biocidal product ingredients of the Insect Shocker are considered as hazardous to the environment alone or in combination, at the concentrations used.

For that reason only the EUSES has been recalculated for a new environmental risk assessment and has not yielded new concerns or risks. The applicant follows the risk assessment of the Assessment Report especially as the use is foreseen only inside the house.

As recommended all information outside the scope of use of the biocidal product has been removed from the environmental risk assessment part.

ES CA:

INSECT SHOCKER is a ready-to-use emulsion marketed in plastic hand-held trigger spray bottles. The product is an insecticide against cat fleas (*Ctenocephalides felis*) for use by non-professional users on household textiles, particularly where pets usually dwell (e.g. pets' beds, pillows, sofas, carpets, etc.).

INSECT SHOCKER is a ready-to-use emulsion containing two active substances (a.s.), i.e. Decanoic acid (2.7% w/w) and Octanoic acid (0.7% w/w). These a.s. are classified as Aquatic Chronic 3 according to their entry in Annex VI of Regulation (EC) No. 1272/2008.

INSECT SHOCKER has several other co-formulants in the formulation. ES CA analised the information available on the co-formulants (i.e. Safety Data Sheets, C&L Inventory, REACH Registration dossiers, REACH Evaluation Reports and CARs of approved biocidal active substances). Some of the co-formulants are not classified for environmental hazards and therefore do not contribute to the classification or possible risks of the mixture. But other co-formulants carry environmental hazard classification. Most of them are however below the concentration limits specified in Regulation (EC) No. 1272/2008 leading the product to be regarded as hazardous. Therefore they do not contribute to the classification of the biocidal product for environmental hazards.

Therefore the biocidal product INSECT SHOCKER does not contain Substances of Concern for the environment. Consequently, all the information concerning the environmental risk assessment for this product is based on data of the actives substances as included in the Assessment Reports of PT18 uses (final CAR of December 2013).

The Applicant submitted initially an application for National Authorisation of an insecticidal/acaricidal product against dust mites and cat fleas. The product was intended to be used on infested surfaces.

During the evaluation of the efficacy of INSECT SHOCKER, ES CA has concluded that only the use against fleas can be authorised. The type of surfaces representative for use against cat fleas in private houses are household textiles susceptible of harbour these target organisms. According to the product label INSECT SHOCKER should be used on textiles such as pets' beds, pillows, sofas, carpets, etc.

The application of INSECT SHOCKER on the infested textiles is by spraying at the dose rate of 12 g/m^2. The product is not for preventive use but for curative use (i.e. it is applied only in case of infestation). After 1 week, when the infestation persists, a new application is recommended.

According to the instructions for use, treated surfaces (textiles) may be cleaned one day after application using a vacuum cleaner to remove dead insects and product residues.

2.2.8.1 Effects assessment on the environment

ES CA:

The studies supporting environmental fate and toxicity properties of the product INSECT SHOCKER are based on information of the active substances Decanoic acid and Octanoic acid as provided in the Competent Authority Assessment Reports of PT18 uses (final CAR of December 2013).

Decanoic acid and Octanoic acids are linear saturated fatty acids differing only in the chain length (10 or 8 C-atoms). Fatty acids like Octanoic and Decanoic acid are ubiquitously present in all living species and are part of the fatty acid metabolism. They have mainly irritating properties, which are the basis of their effects on insects and arachnids.

As explained above, no Substances of Concern regarding the environment are contained in the biocidal product in such quantity as to lead to classification and therefore this assessment is based only on the properties of the active substances as reported in the CARs, as well as specific characteristics related with the product application.

The following PNEC values were derived in the Assessment Reports of the active substances:

Environmental compartment	**PNEC values**	
	Decanoic acid	**Octanoic acid**
$PNEC_{water}$	5.7E-03 mg a.s./L	4.7E-03 mg a.s./L
$PNEC_{sed}$	3.7E-02 mg a.s./kg_{wwt}	1.2E-02 mg a.s./ kg_{wwt}
$PNEC_{microorganisms}$	100 mg a.s./L	8.37E+01 mg a.s./L
$PNEC_{soil}$	2.7E-02 mg a.s./$kg_{wwt\ soil}$	7.5E-03 mg a.s./ $kg_{wwt\ soil}$
$PNEC_{oral}$ (birds)	3.3E-01 mg a.s./kg_{diet}	3.3E-01 mg a.s./ kg_{diet}

$PNEC_{oral}$ (mammals)	1.56E+03 mg a.s./ kg_{diet}	1.56E+03 mg a.s./ kg_{diet}

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

The recalculation with EUSES is provided to the CA as addendum.

ES CA:

The active substances, Decanoic acid (2.7% w/w) and Octanoic acid (0.7% w/w), have a Harmonised Classification & Labelling assigned as Aquatic Chronic 3, according to their entries in Annex VI of Regulation (EC) No. 1272/2008.

INSECT SHOCKER has several other co-formulants in the formulation. Most of them are not classified for environmental hazards and therefore they do not contribute to the classification of the mixture.

However other co-formulants carry environmental hazard classification. A few components are classified as Aquatic Acute 1.

All these classified co-formulants are present in concentrations below 0.1% in the biocidal product. ES CA followed the summation method according to Regulation (EC) No. 1272/2008 and concluded that the product is not classified as Acute 1.

Some components are classified as Chronic 1. Others as Chronic 2 and also some components, in addition to the a.s., are classified as Chronic 3. They are all in very low concentrations in the product, except the a.s. Based on the summation of the concentrations of classified components, according to Regulation (EC) No. 1272/2008, INSECT SHOCKER is not classified for long-term hazards.

ES CA:

Endocrine disruption activity of non-active substances

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

No further ecotoxicological studies are available for INSECT SHOCKER. The product was not tested for potential endocrine disruption properties. INSECT SHOCKER contains the active substances Decanoic acid (2.7% w/w) and Octanoic acid (0.7% w/w) and various co-formulants (see confidential PAR).

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

For the co-formulants a screening was performed by consulting:
• ECHA data for identification of ED and PBT, under REACH, BPR or CLP

• Identified as ED by United States EPA (https://comptox.epa.gov/dashboard/)
• Identified as ED by the United Nations Environment (July 2017) Programme (http://wedocs.unep.org/bitstream/handle/20.500.11822/25634/edc_report2.pdf?sequence=1&isAllowed=y and https://wedocs.unep.org/bitstream/handle/20.500.11822/25635/edc_report2_factsheet.pdf?sequence=1&isAllowed=y)

During screening performance, three substances have been identified as having potential endocrine disruptive properties. One co-formulant is currently being evaluated in the frame of REACH for its potential ED properties and two other co-formulants have shown significant estrogen Receptor activity in U.S. EPA Endocrine Disruptor Screening Program (EDSP). Hence, it is not possible to conclude whether these co-formulants should be considered to have ED properties or not before the end of the assessment. In case any co-formulants are finally identified as ED, the biocidal product will be considered as ED and authorisation will have to be revised accordingly.

Further Ecotoxicological studies
None available for the biocidal product.

Data waiving	
Information requirement	The concentration and hazard of each ingredient is known. Application of the rules of Regulation (EC) No 1272/2008 (CLP) results in no classification.
Justification	Testing on the product/mixture is not needed because valid data are available on each of the components in the mixture allowing classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No 1272/2008 (CLP), and synergistic effects between any of the components are not expected.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)
None available for the biocidal product. As the use is exclusively inside the house, it is not applicable.

ES CA:
No further data are available. Ecotoxicological data have been extrapolated from the active substances as reported in the CARs.

Supervised trials to assess risks to non-target organisms under field conditions
None available for the biocidal product. As the use is exclusively inside the house, it is not applicable.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk
None available for the biocidal product. Based on the intrinsic properties of all ingredients it is not considered as relevant.

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

None available for the biocidal product. As the use is exclusively inside the house, it is not applicable.

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

Use is exclusively inside the house. The most likely removal is through evaporation and cleaning of the surface on which the biocidal product has been applied. That view was accepted in the Assessment Report.

ES CA:

The biocidal product belongs to Product Type 18 (Insecticides, acaricides and other biocidal products against arthropods). It is intended to be used indoors by non-professional users against cat fleas in order to protect human and animal (pets) health.

The product is applied by spraying at a rate of 12 g/m2 on household textiles, particularly where pets usually dwell (e.g. pets' beds, pillows, sofas, carpets, etc.). The product is for application only in case of infestation. After 1 week, if the infestation persists, a new application is recommended.

According to the instructions for use, treated surfaces may be cleaned one day after application using a vacuum cleaner to remove dead insects and product residues.

Exposure to the receiving environmental compartments such as soil, water and air depends on the physical-chemical properties of the active substances as well as its formulation type, mode of application, use and disposal. For the environmental risk assessment, the relevant compartments for emissions have to be defined and a numerical assessment of the potential residues in each area of importance has to be conducted.

The emission scenario document (ESD) for PT18 provides models to calculate emissions of the a.s. to the environment and related concentrations in the receiving compartment at a local scale. The ESD for PT18 covers the following life-cycle steps as being potentially relevant for the environmental emissions:

- Mixing/loading
- Application
- Releases from indoor treated surfaces by cleaning.

INSECT SHOCKER is a ready-to-use product, thus, emissions from the step of 'mixing and loading' are not expected and therefore not assessed.

The product can be released to air, the target surfaces, the applicator (consumer) and the surrounding floor during the application stage. Therefore, the intermediate receiving compartments consist of indoor air, floors, applicator, treated surfaces (textiles), and wastewaters.

According to ESD for PT18 and the Guidance on the Biocidal Products Regulation, indoor application may result in indirect environmental exposure via the sewage system (i.e. during a cleaning operation following treatment). This poses a risk of the product entering the sewage treatment plant (STP) and subsequently being released via effluents into surface

water. Consequently, the final receiving compartments in the environment are outdoor air (atmosphere), STP, surface water (after effluent emission), soil (after sludge application) and groundwater (after leaching from agricultural soil).

Emissions to these environmental compartments result from the cumulative emissions from the application and cleaning steps indoors following the treatment of infestations with INSECT SHOCKER.

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

ES CA:
New environmental fate and behaviour on the a.s. or product specific data are not available as they are not considered necessary. All agreed endpoints have been taken from the CAR of the a.s. in PT 18. The co-formulants are not considered Substances of Concern.

Leaching behaviour (ADS)

ES CA:
Additional data on leaching behaviour of the a.s. or the biocidal product are not necessary. New data are not available.

Testing for distribution and dissipation in soil (ADS)

None available for the biocidal product. As the use is exclusively inside the house, it is not applicable.

None of the other biocidal product ingredients of the Insect Shocker are considered as hazardous to the environment alone or in combination with the other substances at the concentrations used.

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

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

None available for the biocidal product. As the use is exclusively inside the house, it is not applicable.

None of the other biocidal product ingredients of the Insect Shocker are considered as hazardous to the environment alone or in combination with the other substances at the concentrations used.

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

It should be noted that in the final CARs of the active substances an indication was given for the Member States to be taken into account during the stage of authorization of biocidal products containing these active substances.

'For product authorisation additional information is required, concerning the degradation rates of the active substance during pre-treatment and/or in a waste water treatment plant (e.g. preferably monitoring of STP influent and effluent concentrations, or by means of simulations tests).'

This condition was related to the fact that the concentration of the fatty acids in surface water ($PEC_{surface\ water}$) was estimated to be slighty above the threshold value of 0.1 µg/L for organic pesticides as set in the drinking water Directive 98/83/EC. However, as indicated in the CAR, it should be noted that the $PEC_{surface\ water}$ does not correspond with the exposure concentration at the water abstraction point. The standard calculations do not take into account the degradation of the fatty acids in water and dilution in surface water.

ES CA requested the Applicant information on this regard. The Applicant assumed that the condition mentioned in the CAR of PT18 was related only to emissions from the uses of PT4 products. The Applicant informed that for the approval of the a.s. in PT4 products, measurements on the removal decanoic acid and octanoic acid in the effluents of a brewery plant were made in response to the request of the eCA. The measurements showed that the reduction of the a.s. in the on-site STP effluents is much greater than predicted by EUSES.

The Applicant has also argued that the monitoring in a public STP of the fatty acids emitted from PT18 products does not make sense from a technical and scientifical point of view, as no analytical method can distinguish between the fatty acids coming from biocidal products and the ones from other naturally (or anthropogenical) occurring sources. In case of PT4 products, the emissions of fatty acids are clearly localised and can be determined in the effluents of a brewery plant.

ES CA does not agree with the Applicant because simulation tests can be made to study the degradation of the fatty acids. However additional data have not been requested to the Applicant, although $PEC_{surface\ water}$ is slightly above the threshold value of 0.1 µg/L for organic pesticides as set in the drinking water Directive 98/83/EC, because as stated in the CAR, the $PEC_{surface\ water}$ does not correspond with the exposure concentration at the water abstraction point. Nevertheless, we agree with the Applicants' view that the estimation of the degraded fraction of fatty acids in the urban STP is largely overestimated with EUSES and represents a worst case, most likely irrealistic.

Testing for distribution and dissipation in air (ADS)

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

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

Not relevant for INSECT SHOCKER.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be

required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not relevant for INSECT SHOCKER.

2.2.8.2 Exposure assessment

ES CA:

The applicant, SolNova Vet S.L., is the manufacturer of the active substances approved at EU level and included in Annex I of Directive 98/8/EC.

The Annex I assessment of these active substances, Decanoic acid and Octanoic acid, was supported by the representative formulation INSECT SHOCKER FL (1.5% w/w Decanoic acid or 1.5% w/w Octanoic acid). The application of INSECT SHOCKER FL was by spraying directly on infested objects and the surrounding floor by non-professional users. The typical size of application area was around 1 m² according to the intended use. Therefore, the eCA chose the targeted spot applications scenario for houses according to the ESD for PT18. An application area of 2 m² was taken as worst case by the eCA. The fractions of a.s. emitted to air, the treated area, the surrounding floor and the applicator were based on default values of the ESD for targeted spot applications by hand-held spraying. The cleaning efficiency was 50% of the treated area and the surrounding floor.

According to the Applicant, the exposure assessment of INSECT SHOCKER (2.7% w/w Decanoic acid and 0.7% w/w Octanoic acid) presented in this PAR follows the same scenario as considered for INSECT SHOCKER FL in the CARs of the a.s. However the EUSES reports submitted do not show the same conditions. The Applicant has not explained further how he did the assessment when ES CA has requested additional information on the exposure scenarios.

ES CA does not agree with the Applicant's selection of the exposure scenario. The Technical Agreements for Biocides (TAB) (ECHA, 2018) includes a 'Scenario for spraying application to treat against cat fleas or bedbugs (indoor)' (ENV 147). This scenario was agreed in WG-IV-2017 for insecticides to treat against cat fleas applied as hand-held spray on soft furnishings and carpeted areas not expected to be subject to regular wet cleaning. It is assumed that a surface area of 22 m^2 in private houses would be treated in case of infestation (household textiles not frequently washed). An area of 5.9 m^2 is used to reflect the area wet cleaned surrounding the treated textiles (the floor). The default cleaning efficiency is 20 %. The fractions of a.s. emitted to the intermediate compartments are identical to the scenarios of the CARs of the a.s. The emissions to waste waters estimated with this scenario are higher than with the Applicant's scenario.

ES CA has concluded that INSECT SHOCKER has demonstrated sufficient efficacy as insecticide against cat fleas. The intended use of INSECT SHOCKER is by spraying on household textiles, particularly where pets usually dwell (e.g. pets' beds, pillows, sofas, carpets, etc.). Therefore ES CA believes the exposure scenario of TAB (Entry: ENV 147) represents adequately the use of INSECT SHOCKER.

ES CA has carried out the environmental exposure assessment for INSECT SHOCKER on the basis of the ECHA Guidance on the Biocidal Products Regulation (2015), the OECD PT18 emission scenario document (ESD) for household and professional uses (OECD Series on Emission Scenario Documents, Number 18 (ENV/JM/MONO(2008)14), and the TAB v.2 (ECHA, 2018).

The assessment conducted by ES CA is presented in green boxes.

General information

Assessed PT	PT 18
Assessed scenarios	Scenario 1: Direct spraying on target organism with manual trigger spray
ESD(s) used	EUSES emission Scenario for Product Type 18: Insecticides (18.2.1) Indoor, spray application S
Approach	Scenario 1: Average consumption Average consumption
Distribution in the environment	Calculated based on EUSES 2.1.2 Industry category: 15/0 Others Use category: 39 Biocides, non-agricultural Scenario choice for biocides: (18) Insecticides Additional scenario information: (18.2.1) Indoor, spray application
Groundwater simulation	No: The active substance degradate very fast resulting in the impossibility to determine adsorption desorption studies
Confidential Annexes	YES: In the confidential Annex 1 to Part B the tonnage based scenarios 2 and 3 are provided
Life cycle steps assessed	Scenario 1: Production: No Formulation No applicable Use: Yes Service life: No applicable
Remarks	The Assessment Report considered primary and secondary poisoning and aggregated exposure as not relevant

Emission estimation

Scenario [1]

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario 1: Direct spraying on the target organism with manual trigger spray			
Annual tonnage in the EU	-	-	Provided in the confidential Annex
Concentration of active substance decanoic acid in the product	2.7	%	

Concentration of active substance octanoic acid in the product	0.7	%	

Calculations for Scenario [*1*]

Resulting local emission to relevant environmental compartments (DA = decanoic acid, OA = octanoic acid)		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks DA = decanoic acid OA = ocanoic acid**
Freshwater	DA: No emissions to compartment OA: No emissions to compartment	
Freshwater sediment	DA: No emissions to compartment OA: No emissions to compartment	
Seawater	DA: No emissions to compartment OA: No emissions to compartment	
Seawater sediment	DA: No emissions to compartment OA: No emissions to compartment	
STP	DA: 0.0169 OA: 0.0169	From EUSES 2.1.2 Use in houses connected to STP
Air	DA: 0.0169 OA: 0.0169	From EUSES 2.1.2 Intermittent release
Soil Groundwater	DA: No emissions to compartment OA: No emissions to compartment DA: No emissions to compartment OA: No emissions to compartment	

The biocidal use is only inside private living spaces. The biocidal product is sprayed directly on the place of infestation. There will be evaporation especially of the water content of the product. Cleaning of the treated surfaces with water will result in emission via the sewersystem to the STP.

Fate and distribution in exposed environmental compartments

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	no	no	no	no	yes	yes	no.	no	no

ES CA:

As explained above, the use of an insecticide on infested textiles would lead to direct emissions of waste water to the STP and the indoor air. Indirect emissions to the other compartments as a result of the discharges to surface waters, the sludge and the air, are also considered.

Input parameters for calculating the fate and distribution in the environment (DA = decanoic acid; OA = octanoic acid)			
Input	Value	Unit	Remarks
Molecular weight	DA: 172.27 OA: 144.21	g/mol	-
Melting point	DA: 29.8 OA: 16.6	°C	-
Boiling point	DA: 237 OA: 146.8	°C	-
Vapour pressure (at 25°C)	DA: 2.17E-04 OA: 1.35E-02	Pa	-
Water solubility (at 20°C and pH 7)	DA: 1,843 OA: 2,970	mg/l	-
Log Octanol/water partition coefficient	DA: 4.09 OA: 3.03	Log 10	Estimated by QSAR
Organic carbon/water partition coefficient (Koc)	DA: 264 OA: 83.9	L/kg	Estimated by QSAR
Henry's Law Constant (at 25ºC)	DA: 4.72E-01 OA: 2.37E-01	Pa x m^3 x mol^{-1}	Estimated by QSAR
Biodegradability[1]	DA: Ready biodegradable OA: Ready biodegradable	-	-
Rate constant for STP	-	h^{-1}	Not available
DT_{50} for biodegradation in surface water	-	d or hr	Not available
DT_{50} for hydrolysis in surface water	-	d or hr	Hydrolytically stable
DT_{50} for photolysis in surface water	-	d or hr	Not susceptible to photolysis
DT_{50} for degradation in soil	-	d or hr (at 12ºC)	Not available
DT_{50} for degradation in air	DA: 34.5 OA: 46.1	hr hr	Estimation of indirect photochemical degradation
BCF_{fish}	DA: 598 OA: 75	L/kg	Estimated by QSAR
$BCF_{earthworm}$	DA: 148 OA: 14	L/kg	Estimated by QSAR

[1]Biodegradation: At the end of the 10-day window on day 11, 79% and 80% biodegradation (ThOD) were found for Decanoic acid and for the Octanoic acid the values were 66% and 73% biodegradation (ThOD). At the end

of the 28-day exposure period a mean degradation rate of 92% and 84% was calculated for the Decanoic acid and the Octanoic acid respectively.

ES CA:
The former input parameters were obtained by ES CA from the CAR of the active substances. The original values presented by the Applicant were not complete or correct.

Calculated PEC values

Summary table on calculated PEC values (DA = decanoic acid, OA = octanoic acid)								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}** [1]	**PEC_{air}**
	[mg/m^3]	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg/m^3]	[µg/l]	[mg/m^3]
Scenario 1	DA: OA:	DA: 8.57E-05 OA: 8.57E-05	DA: 5.59E-04 OA: 2.27E-04	DA: 1.17E-06 OA: 1.19E-06	DA: 5.59E-05 OA: 2.27E-05	DA: 4.44E-04 OA: 1.42E-04		DA: 6.44E-07 OA: 6.44E-07

[1] If the PEC_{GW} was calculated by using a simulation tool (e.g. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table.

ES CA:

The input parameters of the emission scenario according to ENV 147 of TAB are presented below. It is assumed that the ready-to-use product is applied by a non-professional user (consumer) on household textiles not frequently wet washed.

The default value for the Simultaneity Factor should be 5.52%, as indicated in the PT18 ESD for indoor applications of insecticides. This value would represent a daily application of the insecticide. However, the Applicant indicated that INSECT SHOCKER is not for preventive use but for curative use (i.e. it is applied only in case of infestation). After 1 week, when the infestation persists, a new application is recommended. Therefore ES CA considers that the default value is an irrealistic worst case. For weekly applications, the recalculated value following the equation provided in the PT18 ESD should be 2.75%.

In addition according to TAB entry ENV 145 (v. 2) for products that are specifically used against pet fleas only, the Simultaneity Factor can be refined as follows:

$$Fsim = 0.45 * Freq * Npets * Fpen$$

Where,
"0.45" comes from EU-wide data suggesting that 45% of households own cats and/or dogs (e.g. 'Facts and Figures 2016' report from the European Pet Food Industry Federation (FEDIAF));
Freq = frequency of use (e.g. for a product applied monthly, Freq = 1/30);

Npets = fraction of number of pets requiring treatment for fleas; default value = 0.5;
Fpen = market penetration value; default value = 0.5.

For INSECT SHOCKER, ES CA considers that frequency of use should be weekly in a worst case scenario, i.e. Freq = 4/30. The calculation of Fsim results in 0.015 (1.5%). ES CA has used this refined value in the following calculations of emissions to waste water

Input parameters for Scenario 1

Input	Value	Unit	Remarks
Scenario 2: Indoor spray application; surface treatment on household textiles			
Application rate of biocidal product	12	g/m^2	
Concentration of active substance in the product	DA: 27 OA: 7	*g/Kg*	
Application Step			
Number of applications per day	1	d^{-1}	
Fraction emitted to air during application	0.02	-	Default value
Fraction emitted to floor during application	0.11	-	Default value
Fraction emitted to treated surfaces during application	0.85	-	Default value
Fraction emitted to applicator during application	0.02	-	Default value
Area treated with the product	5.9	m^2	Default value for barrier treatment in houses
Cleaning step			
Fraction emitted to waste water during cleaning	1	-	Default value
Fraction emitted to waste water from applicator - washable coveralls	1	-	Default value
Fraction of cleaning efficiency of wet cleaning	0.2	-	Default value
Simultaneity factor	0.015	-	Refined value (i.e. use once a week)
Number of houses	4000	-	Default value

The following emissions were estimated:

Emission rates due to application of INSECT SHOCKER on targeted spots

Local emission rate to air $E_{application,\ air} = N_{appl,\ building} \times F_{application,\ air} \times Q_{prod} \times F_{AI} \times AREA_{treated}$	DA: 3.82E-05 kg.d^{-1} OA: 9.91E-06 kg.d^{-1}
Local emission rate to floor $E_{application,\ floor} = N_{appl,\ building} \times F_{application,\ floor} \times Q_{prod} \times F_{AI} \times AREA_{treated}$	DA: 2.10E-04 kg.d^{-1} OA: 5.45E-05 kg.d^{-1}
Local emission rate to treated area $E_{application,\ treated\ area} = N_{appl,\ building} \times F_{application,\ treated\ area} \times Q_{prod} \times F_{AI} \times AREA_{treated}$	DA: 1.62E-03 kg.d^{-1} OA: 4.21E-04 kg.d^{-1}
Local emission rate to applicator $E_{application,\ applicator} = N_{appl,\ building} \times F_{application,\ applicator} \times Q_{prod} \times F_{AI} \times AREA_{treated}$	DA: 3.82E-05 kg.d^{-1} OA: 9.91E-06 kg.d^{-1}
Emission rates due to cleaning of treated targeted spots	
Local emission rate to waste water from applicator $E_{applicator,\ ww} = E_{application,\ applicator} \times F_{applicator,\ ww}$	DA: 3.82E-05 kg.d^{-1} OA: 9.91E-06 kg.d^{-1}
Local emission rate to waste water from floor and treated area $E_{floor/treated\ area,\ ww} = (E_{application,\ floor} + E_{application,\ treated\ area} + E_{application,\ air}) \times F_{floor,\ ww} \times F_{CE}$	DA: 3.67E-04 kg.d^{-1} OA: 9.52E-05 kg.d^{-1}
Resulting local emissions to relevant environmental compartments	
STP	DA: 2.43E-02 kg.d^{-1} OA: 6.30E-03 kg.d^{-1}
Air	DA: 3.82E-05 kg.d^{-1} OA: 9.91E-06 kg.d^{-1}

According to EUSES, the estimated fate and distribution of the fatty acids in the standard urban STP is the following.

Calculated fate and distribution in the STP		
Fraction of emission directed by STP to compartment:	*DA (%)*	*OA (%)*
Air	0.095	0.049
Water	12.4	12.6
Sludge	2.4	0.78
Degraded in STP	85.2	86.6

It should be noted that these percentages would represent worst case values if information submitted by the Applicant is taken into account. This information includes a report containing monitoring data of the influents and effluents of an on-site STP which receives sewage of a brewery plant[4]. According to the data there is a 1033-fold reduction of decanoic

[4] Determination of fatty acids (octanoic and decanoic acids) residual concentration in the effluent of a brewery under real operational conditions following the OECD 314 guidelines. S. Verschaeve, SOPURA, Belgium; Report 10607. December 2012

acid and 3100-fold reduction of octanoic acid. The difference of the effluents' concentrations measured in the report compared to the concentrations estimated with EUSES fractions is 2-3 orders of magnitude.

ES CA accepts that EUSES estimations largely underestimate the fraction degraded in the urban STP. However the measured reduction of the fatty acids in an on-site industrial STP will not be used for refinement of emissions from the standard municipal STP, since the effectiveness of the adapted inoculum of an on-site industrial STP could not correspond to that of an urban STP.

The resulting PEC values estimated with EUSES are the following.

Summary table on calculated PEC values

	PEC_{STP}	PEC_{water} *	PEC_{sed}	$PEC_{soil,\ 30d,agri}$	$PEC_{soil,\ 180d,agri}$	$PEC_{soil,\ 180d,grass}$	PEC_{GW}	PEC_{air}
Scenario 1	[mg/L]	[mg/L]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/L]	[mg/m^3]
	DA: 1.50E-03 OA: 3.95E-04	DA: 1.50E-04 OA: 3.95E-05	DA: 9.79E-04 OA: 1.03E-04	DA: 7.73E-04 OA: 6.42E-05	DA: 2.46E-04 OA: 1.98E-05	DA: 9.37E-05 OA: 7.25E-06	DA: 5.14E-02 OA: 1.24E-02	DA: 1.75E-11 OA: 2.34E-12

*The final estimated concentration of Octanoic acid in surface water, after receiving the effluents of the urban STP, is above the parametric value of 0.1 µg/L, which is the maximum allowable level of organic pesticides in surface water according to Directive 98/83/EC. ES CA notes that the threshold mentioned in Directive 98/83/EC is meant for surface waters in or from the area of envisaged use intended for the abstraction of drinking water.
In adidition, as explained before, EUSES overestimates the emissions of the fatty acids from the urban STP. Therefore ES CA have not requested the Applicant additional information concerning the degradation rates of the a.s. during waste water pre-treatment and/or treatment in a urban STP

Primary and secondary poisoning

Not relevant; Assessment Report.

ES CA:

<u>Primary poisoning</u>

The possibility of primary poisoning of INSECT SHOCKER is very unlikely. INSECT SHOCKER is not a granular formulation and it is not applied with a food attractant. Therefore primary poisoning was not considered further.

<u>Secondary poisoning</u>

According to the guidance, it is accepted that values of log Kow ≥3 indicate that the substance may bioaccumulate. The low Kow of Decanoic and Octanoic acids are 4.09 and

3.03, respectively. Both substances are ready biodegradable, but the uptake rate may still be greater than the rate of the degradation processes, leading to high BCF values.

The BCF values of the a.s. were estimated by QSAR (EUSES). Aquatic BMF default values were derived from the BCF in fish. For Decanoic acid the calculated BCF values are >100 L/kg, thus they indicate the substance could be bioaccumulative. In addition there is no information on the degradation potential of the a.s. which could lead to preclude the bioaccumulation potential. Therefore the assessment of the fatty acids should consider secondary poisoning.

The following $PEC_{oral,predator}$ values for aquatic and terrestrial predators were estimated:

Concentration of a.s. in food (fish or earthworm) of predators		
	DA	**OA**
$PEC_{oral,fish}$	1.23E-04 $mg/kg_{wet\ fish}$	4.05E-06 $mg/kg_{wet\ fish}$
$C_{earthworm}$	3.43E-03 $mg/kg_{wet\ earthworm}$	7.90E-05 $mg/kg_{wet\ earthworm}$

Mixture toxicity

Not relevant: The biocidal product is not classified as hazardous for the environment.

ES CA:
Mixture toxicity is relevant for INSECT SHOCKER since two a.s. are present in the formulation. The co-formulants present in the biocidal product are however not considered relevant substances for mixture toxicity assessment. Please see below the resulting RCR estimated for the mixture of the two a.s.

Aggregated exposure (combined for relevant emission sources)

Not relevant; Assessment report.

Conclusion: Not relevant; only one application scenario.

ES CA:

The active substances Decanoic and Octanoic acids are registered under REACH Regulation in the annual tonnage band of 10,000−100,000 T/y. According to the CAR of the a.s. in Product Types 4, 18 and 19, the annual tonnage of the a.s. for use in biocidal products is less than 10% of total tonnage (all uses).

The uses of the representative biocidal products containing the a.s. are insecticides, repellelents for application on skin and disinfectants for food and feed areas. These uses produce emissions to the environment directly via the sewer to the urban STPs and indirectly to the remainder compartments.

According to the ECHA's database of registered substances, the other notified uses have a similar emission pattern. Hence the emission pattern is not specific for biocides. Therefore, the main emissions to the environment are already assessed in the context of REACH

procedures. As a consequence the aggregated exposure is not required for the biocidal product INSECT SHOCKER.

Overall conclusion on the risk assessment for the environment of the product
The recommended use of the ready to use biocidal product is inside private living spaces, results in limited environmental emission and exposure. The risk assessment demonstrates safe use.

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: Not relevant; Negligible emission.

ES CA:

Exposure of the atmospheric compartment to Decanoic and Octanoics acids is expected from the spray application of INSECT SHOCKER. However, exposure to the air is considered to be negligible since INSECT SHOCKER is applied indoors and, hence, it is unlikely that it produces significant levels in the air outside.

In addition, in case of emissions to the atmosphere, the a.s. are expected to degrade fastly in the air on the basis of the calculated half-lives of 34.5 h (DA) and 46.13 h (OA), (AOPWIN). Furthermore, evaporation or volatilisation is not likely to be a major route of entry into the atmospheric compartment based on the vapour pressure of 2.17E-04 (DA) and 1.35E-02 (OA) Pa at 25 °C and the Henry's Law Constants of 4.72E-01(DA) and 2.37E-01 (OA) Pa.m3/mol at 25°C.

Emissions to air have, however, been calculated with EUSES. PEC_{air} were estimated to be from 1.75E-11 (DA) and 2.34E-12 (OA) mg/m^3, indicating that emissions can be considered negligible.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1	DA: $6.93*10^{-5}$ OA: $6.93*10^{-5}$

Conclusion: The risk assessment demonstates safe use.

Aquatic compartment

Summary table on calculated PEC/PNEC values				
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**	**$PEC/PNEC_{seawater}$**	**$PEC/PNEC_{regionla}$**

Scenario 1	DA: 0.00739 OA: 0.00897	DA: 0.0739 OA: 0.0897	DA: 0.0739 OA: 0.00897	DA: $9.85*10^{-6}$ OA: $1.46*10^{-5}$

Conclusion: The risk assessment demonstates safe use.

Terrestrial compartment

Conclusion: Not relevant; only indoor use.

Groundwater

Not relevant; only indoor use. Reason: adsorption/desorption messurements were scientifically impossible because of the biodecgradation of decanoic acid or octanoic acid are so fast that the fatty acid could not determined in the soil. The outcome clearly shows that contamination of the groundwater will not occur.

Primary and secondary poisoning

Primary poisoning
Conclusion: Not relevant – Assessment report.

Secondary poisoning
Conclusion: Not relevant – Assessment report.

ES CA:
The following RCR were estimated.

	Decanoic acid	**Octanoic acid**
$PEC/PNEC_{STP}$	1.50E-05	4.72E-06
$PEC/PNEC_{water}$	2.63E-02	8.40E-03
$PEC/PNEC_{sed}$	2.65E-01*	8.58E-02*
$PEC/PNEC_{soil}$	3.44E-02*	8.56E-02*
PEC_{GW} [µg/L]	5.14E-02**	1.24E-02**
$PEC/PNEC_{mammal,aquatic}$	7.90E-08	2.60E-09
$PEC/PNEC_{bird,\ aquatic}$	3.72E-04	1.23E-05
$PEC/PNEC_{mammal,terrestrial}$	2.21E-06	5.08E-08
$PEC/PNEC_{bird,terrestrial}$	1.04E-02	2.39E-04

*An additional factor of 10 has been considered as PNECsed and PNECsoil were estimated using the EPM method and Log Kow is between 3 and 6.
**Below 0.1 µg/L (Drinking Water Level, Directive 98/83/EC).

Mixture toxicity

Not applicable. Not used in combination with other products.

ES CA:

Mixture toxicity is relevant for INSECT SHOCKER since two a.s. are present in the formulation. The results of mixture toxicity assessment are summarised in the following table.

Summary table on calculated ΣPEC/PNEC values				
ΣPEC/PNEC$_{STP}$	**ΣPEC/PNEC$_{water}$**	**ΣPEC/PNEC$_{sed}$**	**ΣPEC/PNEC$_{soil}$**	**ΣPEC$_{GW}$ (µg/L)**
1.97E-05	3.47E-02	3.50E-01	1.20E-01	6.38E-02

In conclusion, the RCR of the mixture are below 1 for all the compartments considered. Therefore, the use of INSECT SHOCKER can be considered acceptable for the environment according to the results of the risk assessment.

Overall conclusion on the risk assessment for the environment of the product
The risk assessment demonstrates no risk when used as recommended.

ES CA:
The use of INSECT SHOCKER can be considered acceptable for the environment according to the results of the risk assessment.

The use of INSECT SHOCKER was assessed in an indoor scenario assuming the application against cat fleas by hand-held spraying on household textiles not frequently wet washed such as pets' beds, pillows, sofas, carpets, etc. Emissions to the sewer are expected by the cleaning of surrounding floor surfaces and the washing of clothes of the applicator (non-professional user). This use poses acceptable risks to the environment.

The field of use in the authorisation decision of INSECT SHOCKER must be: Textiles in households which are not wet washed (indoors).

A restriction must be included on the SPC and product label such as the following RMM: "Do not apply to washable home textiles".

2.2.9 Measures to protect man, animals and the environment

Not relevant; Assessment report.

ES CA:
A restriction must be included on the SPC and product label to protect the environment such as the following RMM: "Do not apply to washable home textiles".

2.2.10 Assessment of a combination of biocidal products

Not relevant; not intented to be used in combination with other biocidal products.

2.2.11 Comparative assessment

Not relevant: The active substance are not a candidate for substitution.

3 ANNEXES

3.1 List of studies for the biocidal product

See confidential annex.

3.2 Output tables from exposure assessment tools

Scenario 4 – Inhalation of volatilised residues indoors (chronic exposure)

See confidential Annex for better information.

EUSES DA 20-1-2016-COMPACT.DOC
EUSES OA 20-1-2016-COMPACT.DOC

3.3 New information on the active substance

Not applicable

3.4 Residue behaviour

Not relevant

3.5 Summaries of the efficacy studies (B.5.10.1-xx)[5]

1. [redacted]. Efficacy after Direct Spray Treatment of Product "Insect Shocker" against Cat Fleas. Report no. BIO 104b-15. [redacted], Germany. 2015. (IUCLID/Efficacy#001)

A direct spray treatment test was conducted in laboratory conditions (22ºC and 46% Relative Humidity (RH)) against cat fleas (*Ctenocephalides felis*) kept on paper tissues inside glass rings (diameter of 9.5 cm). There were 5 replicates of the treatment and control, each one with 10 adult fleas (mixed sex). The formulation INSECT SHOCKER in a pump spray was inserted in a direct spray apparatus so that the spray struck vertically to the paper tissues at a distance of 60 cm. The dosage was 2 strokes per application point. This corresponds to an average amount of 1.25 g of Insect Shocker confirmed with weight measurements of the spray can (thus 1 stroke = 0.625 g). Glass rings were covered by a net to prevent the fleas from escape. During the following 24h the fleas were exposed to the product.

As a result 100% knockdown of the fleas was achieved after 1 minute and 27 seconds on average (range 1'21''-1'30''); after 2h knockdown remained unchanged, therefore no recovery of the fleas was noted. After 24h, 100% mortality was achieved. Controls showed no effect after 24h (i.e. 0% mortality). Intrinsic efficacy of the direct use against adult fleas can be considered acceptable.

2. [redacted] Residual Efficacy of product "Insect Shocker" against Cat Fleas. Report no. BIO 129d-15. [redacted], Germany. 2015. (IUCLID/Efficacy#002)

The efficacy of INSECT SHOCKER was tested in laboratory conditions (25-27ºC and 58-63% RH) against cat fleas (*C. felis*). There were 5 replicates of 10 individuals each (mixed sex adults and larvae of 2nd instar, tested separately). The adults and larvae were kept inside

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

glass rings (diameter 9.5 cm) and exposed to treated and non-treated (controls) carpet tiles (15 x 15 cm). The carpet samples were made of polyamide fibres of 6.6 cm height. The study was not a choice test but the fibres are long enough to allow the fleas harbour.
The samples were sprayed manually at 45º angle and 60-cm distance. The treated samples were dried for 1 day. The applied dose was 4 spray pumps, which according to the authors corresponds to a dose of 5.6 grams per square metre. This is not according to the claimed dosage for fleas in the project labels (i.e. for fleas 1 stroke should be equal to 6 g/m^2).
One day after treatment, the adult fleas were exposed to the treated carpet for 6h while the larvae were exposed continuously until 100% mortality was achieved. Knockdown was not reported. The mean mortality of adults after 48h was 88% (range was from 80% (1 repl.) to 90% (3 repl.)) and 100% mortality was observed after 3 days. TNsG requires ≥90% mean mortality of adult fleas within 48h which did not occurred. However in 4 out of 5 replicates mortality reached 90%. Controls were not affected (0% in each of the replicates).
For larvicidal products, TNsG requires ≥80% inhibition of the development of larvae into adult fleas during the claimed duration of action of the product. The App did not claim any duration. The results of effects towards larvae were reported as percentages of mortality. Mortality of the larvae was 88% after 24h and it achieved 100% after 4d; controls were not affected either. Therefore the results fulfilled the requirement of the guidance.
ES CA considers that this study is not acceptable to support the adulticidal use since mortality of adults did not reach the required level. However it should be noted that adult fleas are not usually found far from the hosts (dogs, cats, humans, etc.), therefore the use against adult fleas on surfaces is not essential to control infestations. Additional treatment of the animal with an appropriate veterinary product should be warranted to control infestations and to prevent resistance.

Furthermore the doses applied in this study are confusing in relation to those recommended by the Applicant (i.e. a dose of 5.6 g/m^2 should be obtained with 1 spray pump).

The Applicant submitted this test as a simulated-use study. The application of the product (identical nozzle and can; manual spraying), representative surfaces and exposure duration (only in case of larvae) are indeed designed to mimic the practical use situation. But the study is not a choice test and the doses in terms of the number of strokes are questionable. Therefore the ES CA requested additional efficacy studies focusing on stages of the life cycle other than the adults.

3. [redacted] Efficacy of product "Insect Shocker" against applied by direct spray treatment against flea eggs. Report no. BIO 063c-16[redacted], Germany. 2016. (IUCLID/Efficacy#001)

A simulated-use study with INSECT SHOCKER was conducted against cat flea eggs (*Ctenocephalides felis*). 5 replicates with 20 eggs each were used for the treatment and control test beakers. The product was directly sprayed on the eggs placed into a beaker covered with a carpet disc (made of polypropylene and polyamide fibres of 9.5 cm height). Food was added to the beakers. The beakers were placed on a carpet tile. The spraying was performed manually at a distance of 60 cm and perpendicularly onto 33 x 33 cm carpet tiles (1089 cm^2). According to the authors the spray pattern at 60-cm distance is a round surface with a diameter of ca. 33 cm. The application rate was 2 strokes which deposited on average 1.28g of product. This corresponds to a dose of 1.28 g / 1089 cm^2 = 11.7 g/m^2. This is not according to the claimed dosage for fleas in the project labels (i.e. 1 stroke or 6 g/m^2).

The treated carpet discs were left open for 48h to allow them to dry, and then covered and placed in an incubator at 23-26ºC and 50-66% of RH. Exposure to the product was continuous as it occurs in actual situations. The development of the eggs to adults was observed during 39 days. Controls yielded on average 82% of adult fleas after 39 days while

treated samples yielded no adults (i.e. 0%). Ovicidal efficacy at a dose of 11.7 g/m^2 can be considered acceptable since 100% hatching inhibition occurred after residual treatment. For ovicidal products, TNsG requires ≥80% inhibition of the development of eggs into adult fleas during the claimed duration of action of the product. The App did not claim any specific duration. ES CA considers the ovicidal effect of INSECT SHOCKER was proved.

4. [redacted] Efficacy of product "Insect Shocker" against applied by direct spray treatment against flea larvae. Report no. BIO 062c-16. [redacted], Germany. 2016. (IUCLID/Efficacy#001)

A simulated-use study with INSECT SHOCKER identical to the former study (i.e. Report no. BIO 063c-16) with flea eggs was conducted with flea larvae (*Ctenocephalides felis*). The applied dosage was 2 spray strokes (1.28 g of Insect Shocker) corresponding to 11.7 g/m^2. The development of the larvae to adults was observed during 39 days.

Controls achieved on average 75% of adult fleas after 39 days while treated samples yielded no adults (i.e. 0%). Larvicidal efficacy can be considered acceptable since 100% inhibition of development occurred after treatment.

5. [redacted] Residual Efficacy of product "Insect Shocker" against house dust mites – laboratory. BIO 130c-15. [redacted], Germany. 2015. (IUCLID/Efficacy#003)

INSECT SHOCKER was tested against house dust mites (*Dermatophagoides pteronyssinus*) in a laboratory non-choice test (not a simulated-use study as stated by the App.). The spraying was done manually and vertically onto porous textile fabric (wool), porous plywood and non-porous glazed surfaces (tiles 15 x 15 cm). The applied dosage was 11.20 g/m^2. However the number of applied pumps was not specified. The amount of applied product was neither measured nor reported. The treated tiles were left to dry for 1 day. After that the mites inside glass rings were exposed continuously in darkness to treated and non-treated tiles (controls). 5 replicates of ca. 50 individuals (mixed population containing adults, nymphs, and eggs) were considered. The mites were fed on dry fish food. Tests were conducted at 25ºC and 65% RH. Mortality (lack of movement and "shine" of bodies) was observed daily up to 7 days.

An average (all types of surfaces) mortality level of 72% was obtained after 1 day of exposure. In glazed tiles, after 24h mortality of mites was 60-80%. In plywood tiles, after 24h mortality of mites was 0-10%. In fabric tiles, after 24h mortality of mites was 70-80%. 100% mortality was achieved after 3 days in fabric and glazed tiles and 4 days in plywood tiles. Controls had 0% mortality at all samplings points up to 7 days and at all types of surfaces. The Guidance requires in general ≥90% mortality in 24 hours for laboratory tests, which was not fulfilled in this study.

ES CA requested more efficacy studies in order to prove the label claim as acaricide, but the Applicant did not submit any other data. Therefore ES CA will not authorise the use against house dust mites.