Product Assessment Report

ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS

June 2016

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Internal registration/file no:	
Authorisation/Registration no:	ES/APP(NA)-2016-19-00379
Granting date/entry into force of authorisation/ registration:	
Expiry date of authorisation/ registration:	31 July 2022
Active ingredient:	DEET
Product type:	19

Biocidal product assessment report related to product authorisation under Directive 98/8/EC

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1 General information about the product application

1.1 Applicant

Company Name:	GRUPO AC MARCA (LABORATORIOS GENESSE, S.L.)
Address:	Avda. Carrilet, 293-299
City:	Barcelona
Postal Code:	08907
Country:	Spain
Telephone:	+34 932606800
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E-mail address:	biocidas@grupoacmarca.com

1.1.1 Person authorised for communication on behalf of the applicant

Name:	Mrs. Nuria Floriach Gual
Function:	Technical Manager
Address:	Avda. Carrilet, 293-299
City:	Barcelona
Postal Code:	08907
Country:	Spain
Telephone:	+34 932606800
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E-mail address:	biocidas@grupoacmarca.com

1.2 Current authorisation holder[1]

Company Name:	GRUPO AC MARCA (LABORATORIOS GENESSE, S.L.)
Address:	Avda. Carrilet, 293-299
City:	Barcelona
Postal Code:	08907
Country:	Spain
Telephone:	+34 932606800
Fax:	+34 932606810
E-mail address:	biocidas@grupoacmarca.com
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	

[1] Applies only to existing authorisations

1.3 Proposed authorisation holder

Company Name:	GRUPO AC MARCA (LABORATORIOS GENESSE, S.L.)
Address:	Avda. Carrilet, 293-299
City:	Barcelona
Postal Code:	08907
Country:	Spain
Telephone:	+34 932606800
Fax:	+34 932606810
E-mail address:	biocidas@grupoacmarca.com
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	

1.4 Information about the product application

Application received:	31/07/2012
Application reported complete:	-
Type of application:	authorisation
Further information:	ES has ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS currently authorised under national legislation for use as repellent (PT19). The current application is for PT19 use and that will be assessed and authorised under 98/8/EC.

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS
Manufacturer's development code number(s), if appropriate:	-
Product type:	19
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	20% DEET (N,N-diethyl-m-toluamide)
Formulation type:	Spray
Ready-to-use product (yes/no):	Yes
Is the product the very same (identity and content) to another product already	No

authorised under the regime of directive 98/8/EC (yes/no); **If yes: authorisation/registration no. and product name:** **or** **Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):**	

1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	Apply the product sparingly and carefully to parts of the body that are not covered. Do not apply on clothing; divide the product evenly over the skin. The biocidal product is to be applied only once a day for adults and children over 2 years of age. The biocidal product is not for use on children under 2 years of age.
Target organisms:	Mosquito, tiger mosquito: *Aedes aegypti* , *Aedes albopictus* and *Culex spp* Ticks: *Ixodes ricinus* Black flies: *Odagmia ornate*
Category of users:	Non-professional user (general public)
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/feedingstuff (yes/no)	No
Proposed Label:	See the authorisation
Use Restrictions:	See the authorisation

1.5.3 Information on active substance(s)[2]

Active substance chemical name:	DEET (N,N-diethyl-m-toluamide)
CAS No:	134-62-3
EC No:	205-149-7

[2] Please insert additional columns as necessary

Purity (minimum, g/kg or g/l):	970 g/kg
Inclusion directive:	Directive 2010/51/EU
Date of inclusion:	1 August 2012
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes
Manufacturer of active substance(s) used in the biocidal product:	Vertellus Performance Materials Inc. (formerly Morflex, Inc.)
Company Name:	Vertellus Performance Materials Inc.
Address:	2110 High Point Road
City:	Greensboro (NC)
Postal Code:	NC 27403
Country:	USA
Telephone:	336 292 1781
Fax:	336 854 4058
E-mail address:	www.vertellus.com

1.5.4 Information on the substance(s) of concern[3]

Substance chemical name	2-Phenoxyethanol
CAS No:	122-99-6
EC No :	204-589-7
Purity (minimum, g/kg or g/l):	-
Typical concentration (minimum and maximum, g/kg, or g/l):	Please, see information in the confidential annex of this document about the composition of the biocidal product
Relevant toxicological/ecotoxicological information:	-
Original ingredient (trade name):	-

Based on Guidance for SoC, 2-phenoxyethanol was identified as substance of concern because the substance was notified for the product type 6 as preservative according to the biocides review programme. The substance has a harmonised classification with H302 and H319 but, nevertheless, the substance does not contribute to the classification because of the low concentration in the biocidal product.

1.6 Documentation

1.6.1 Data submitted in relation to product application

The applicant has not sent new data about the active substance regarding physico/chemical properties, analytical methods and human health in order to support the product authorisation.

[3] Please insert additional columns as necessary

According to the applicant, the formulation of DEET in ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS has no impact on the route or rate of degradation of the active substance DEET in the environment. So it was concluded that no additional studies involving the formulated product are required. The biocidal product contains three compounds different from the active substance (20% DEET) classifying as dangerous for the environment. These compounds are denatonium benzoate and perfume. Denatonium benzoate and perfume should not be considered of concern due to the low percentages in which they are present in the biocidal product.

Furthermore, VITALET, perfume, which is a mixture used in this biocidal product that contains Disodium Lauriminodipropionate Tocopheryl Phosphates, classifies as a mixture as R51 and R53. According to the document attached by the applicant "National Industrial Chemicals Notification and Assessment Scheme (NICNAS, 2006) in which an environmental risk assessment is developed, the conclusions are that on the basis of the PEC/PNEC ratio for this substance, the chemical is not considered to pose a risk to the environment based on the reported use pattern developed.

For the human exposure assessment, only calculations for one application per day are shown. This is because for two applications per day a scenario of concern was obtained.

The biocidal product is a spray to dermal use ready-to-use.

1.6.2 Access to documentation

The applicant has submitted the following letter of access:

- a letter of access from Vertellus Performance Materials Inc. (formerly Morflex, Inc.) to all the documents about the active substance DEET associated to the Annex I listing. Vertellus has access to the data used and submitted for the inclusion of DEET into Annex I of Directive 98/8/EC.

  Vertellus Performance Materials Inc. (formerly Morflex, Inc.) was considered as a new source and the technical equivalence was carried out by SE. The RMS considered that the DEET material manufactured by the different sources to be equivalent and it was hence acceptable for the manufacturers to join one task-force.

All substances data sheets are included in the dossier.

2 Summary of the product assessment

2.1 Identity related issues

The active substance DEET (N, N-diethyl-meta-toluamide) was included in the Annex I of Directive 98/8/EC (Commission Directive 2010/51/EC of 11 August 2010).

The formulation includes several components. The biocidal product contains some substances of concern according to the Technical Notes for Guidance on data requirements (please, see section 1.5.4). Information on the full composition of the product and assessment are detailed in additional confidential annex of this document.

According to article 19(9) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, the non-active substances of the biocidal product are included pursuant to Regulation (EC) No 1223/2009 (Commission Decision of 9 February 2006 amending Decision 96/335/EC

establishing an inventory and a common nomenclature of ingredients employed in cosmetic products).

2.2 Classification, labelling and packaging

2.2.1 Harmonised classification and labelling of the biocidal product

According to Regulation 1272/2008 (Until 1 June 2015, mixtures shall be classified, labelled and packaged in accordance with Directive 1999/45/EC):

GHS Pictograms		
Signal Word	Warning	
Classification	Hazard class and category: Hazard statement	Eye irrit. 2 H319: Causes serious eye irritation EUH 208: "Contains benzyl salicylate, butylphenyl methylpropional, cinnamyl alcohol, citronellol, linalool and alpha-isomethyl ionone. May produce an allergic reaction"
General precautionary statement	P102: Keep out of reach of children P103: Read label before use	
Prevention precautionary statement	P264: Wash … thoroughly after handling	
Response precautionary statements	-	
Storage precautionary statements	-	
Disposal precautionary statements	P501: Dispose of content and / or its container as hazardous waste according to the regulations in force.	

According to article 19(1) of Regulation (EC) Nº 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, the following substances must be mentioned in the labelling: Coumarin, geraniol, linalool, citronellol, cinnamyl alcohol, benzyl salicylate, butylphenylmethylpropional and alpha-isomethyl ionone.

2.2.2 Packaging of the biocidal product

The biocidal product is packaged in HDPE bottles of sprays of 100 and 200ml.

The packaging of the product placed on the market has to be limited to a maximum size of 200ml.

2.3 Physico/chemical properties and analytical methods

2.3.1 Physico-chemical properties

Regarding the active substance DEET the table has not been filled in because the letters of access have been submitted.

Regarding the biocidal product, these are the physico-chemical properties:

Table 1: Physico-chemical properties of the biocidal product:

	Method	Purity/Specification	Results	Reference
Physical state and nature	Visual	20%	Liquid	B.3.1.1
Colour			White	B.3.1.2
Odour			Characteristic	B.3.1.3
Explosive properties			None of the components are classified as explosive	B.3.2
Oxidizing properties			None of the components are classified as oxidant	B.3.3
Flash point			n.a.	
Autoflammability				
Auto-ignition Temperature				
Acidity / Alkalinity	Internal procedure		Initial pH:5.87 12 months storage pH:5.85 24 months storage pH:5.79 36 months storage pH:5.55	B.3.5
Relative density / bulk density	Internal procedure DEN 30-PX-01 (20ºC, 1 atm)		0.998 g/ml	B.3.6
Storage stability – stability and shelf life	CIPAC MT 46.3 In compliance with Monograph nº 17. FAO & WHO Specifications for Pesticides		Accelerated study: At t=0 the content of a.s.is 19.8% and At t=2 weeks at 54ºC the content of a.s. is 19.6% The difference in the content after and before the study is 1.01% At ambient T: t=0, 20% of DEET and t=36months, 18.98% of DEET .The product ECRAN REPEL & CARE REPELENTE DE MOSQUITOS is stable for 3 years, since the difference between initial and final concentration is 5.1%	B.3.7
Effects of temperature			n.a	
Effects of light			n.a	
Reactivity towards container material				
Technical characteristics in dependence of the formulation type			The product is ready to use	
Compatibility with other products			The product is ready to use	

	Method	Purity/Specification	Results	Reference
Surface tension			n.a	
Viscosity			n.a	
Particle size distribution			n.a	

n.a = not available

2.3.2 Analytical methods

	Principle of method
Technical active substance as manufactured:	GC-FID
Impurities in technical active substance:	GC-FID
Active substance in the formulation:	GC-FID

2.4 Risk assessment for Physico-chemical properties

The active substance DEET is not highly flammable, auto-flammable, explosive or oxidizing and should thus not be classified based on its physic-chemical properties.

The biocidal product ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS contains 20 %w/w DEET and given the nature of the formulation it is not considered explosive, oxidizing or auto- flammable.

2.5 Effectiveness against target organisms

2.5.1 Dose / mode of action / known limitations / resistance

Mode of action including time delay

DEET was historically believed to work by blocking insect olfactory receptors for 1-octen-3-ol, a volatile substance that is contained in human sweat and breath. The prevailing theory was that DEET effectively "blinds" the insect's senses so that the biting/feeding instinct is not triggered by humans or other animals which produce these chemicals. DEET does not appear to affect the insect's ability to smell carbon dioxide, as had been suspected earlier (Ditzen et al., 2008).

However, more recent evidence showed that DEET serves as a true repellent in that mosquitoes intensely dislike the smell of the chemical repellent (Syed and Leal, 2008) A type of olfactory receptor neuron in special antennal sensilla of mosquitoes that is activated by DEET as well as other known insect repellents such as eucalyptol, linalool, and thujone has been identified. Moreover, in a behavioral test DEET had a strong repellent activity in the absence of body odor attractants such as 1-octen-3-ol, lactic acid, or carbon dioxide. Female and male mosquitoes showed the same (Syed and Leal, 2008).

A recent structural study revealed that DEET binds to *Anopheles gambiae* Odorant binding protein 1 (AgamOBP1) with high shape complementarity, suggesting that AgamOBP1 is a molecular target of DEET and perhaps other repellents (Tsitsanou, 2011).

There is not a delay in time in efficacy after application.

The product has efficacy during at least the first 6 hours after application. This is supported by the

efficacy assays developed for our b.p in which more than 6 hours efficacy is observed.

Efficacy assay	Efficacy observed
Report number 25855 from CIDEMCO TECNALIA against *Aedes aegypti*	100% efficacy during the first 7 hours after application.
Report study number 1459f-PIR/0711 from TEC against *Culex spp*	100% efficacy during the first 8 hours after application.
Report study number 1459g-PIR/0711 from TEC against *Aedes albopictus*	showed 100% efficacy during the first 8 hours after
Report study number 111091 from National Institute of Public Health CEM Laboratory NRL for Disinfection and Public Health Pest Control against *Ixodes ricinus and Odagmia ornate*	Efficacy during the first 6 hours (*Ixodes ricinus*) and 4 hours (*Odagmia ornate*)

Dose:

According to the amount of product used for efficacy assays dosage for biocidal product should be 1.08 mg/cm^2.

DEET properties avoid the interaction between insects and human skin. Re-application is not permitted due to the risk assessment.

Known limitations:

Not other limitations in efficacy except the lasting time of the repellence effect are known.

Resistance:

This active ingredient had not been described as generator of resistance in natural mosquitos', ticks and blackflies populations.

Test substance	**Test organisms**	**Test system/concentrations applied/ exposure time**	**Test conditions**	**Test results: effects, mode of**	**Reference**
DEET	*Culex spp*	Arm in cage 1,08 mg/cm^2 3 minutes each hour	**Criteria - Details** Substrate: s*kin of the volunteer* Incubation temperature: *25ºC±2ºC* Moisture: *65%±5%* Aeration *smooth ventilation (30 m^3/h)* Method of exposure: *Exposure of volunteer's forearms during 3 minutes each hour until the 9th one.* Aging of samples: *Less than 3 months*	100% repellence during 8 hours	TNG: Insecticides, acaricides and products to control other arthropods (PT18) and Repellents and attractants (only concerning arthropods) (PT19). Draft guidance document to replace part of Appendices to chapter 7 (page 187 to 200) of the TNsG on Product evaluation. Test system based on MS 1497 (2000) and WHO/HTM/NTD/ WHOPES/2009.4; GUIDELINES FOR EFFICAY TESTING OF MOSQUITO REPELLENTS FOR HUMAN SKIN
DEET	*Aedes albopictus (Tiger mosquito)*	Arm in cage 1,08 mg/cm^2 3 minutes each hour	**Criteria - Details** Substrate *Skin of the volunteer* Incubation temperature: *25ºC±2ºC* Moisture: *65%±5%*	100% repellence during 8 hours	TNG: Insecticides, acaricides and products to control other arthropods (PT18) and Repellents and attractants (only concerning arthropods) (PT19). Draft guidance document to replace part of Appendices to chapter 7 (page 187 to 200) of the TNsG on Product evaluation. Test system based on MS 1497 (2000)
			Aeration: *smooth ventilation (30 m3/h)* Method of exposure: *Exposure of volunteer's forearms during 3 minutes each hour until the 9th one.* Aging of samples: *Less than 3 months*		and WHO/HTM/NTD/WHOPES/2009.4; GUIDELINES FOR EFFICAY TESTING OF MOSQUITO REPELLENTS FOR HUMAN SKIN

DEET	*Aedes aegypty*	Arm in cage 1,08 mg/cm^2 3 minutes each hour	**Criteria - Details** Substrate: *Skin of the volunteer* Incubation temperature: *22±2ºC* Moisture: *50±10%* Aeration: *no* Method of exposure *Individual exposure months* Aging of samples *Less than 3 months*	100% repellence during 8 hours	TNG: Insecticides, acaricides and products to control other arthropods (PT18) and Repellents and attractants (only concerning arthropods) (PT19). Draft guidance document to replace part of Appendices to chapter 7 (page 187 to 200) of the TNsG on Product evaluation. Test system based on MS 1497 (2000) and WHO/HTM/NTD/WHOPES/2009.4; GUIDELINES FOR EFFICAY TESTING OF MOSQUITO REPELLENTS FOR HUMAN SKIN
DEET	*Ixodes ricinus*	Skin from volunteers	**Criteria - Details**	100% repellence during 6 hours	TNG: Insecticides, acaricides and products to control other arthropods (PT18) and Repellents and attractants
		1,00 mg/cm^2 1,5 mg/cm^2 2,0 mg/cm^2	Substrate - *Skin of the volunteer* Incubation temperature: *25ºC* Moisture: 35-45% Aeration: No Method of exposure: *Individual exposure* Aging of samples: Less than 3 months		(only concerning arthropods) (PT19). Draft guidance document to replace part of Appendices to chapter 7 (page 187 to 200) of the TNsG on Product evaluation.
DEET	*Odagmia ornata*	0,8 mg/cm^2 1,5 mg/cm^2	**Criteria - Details** Substrate *Skin of the volunteer* Method of exposure: *Individual exposure* Aging of samples: *Less than 3 months*	100% repellence during 4 hours	TNG: Insecticides, acaricides and products to control other arthropods (PT18) and Repellents and attractants (only concerning arthropods) (PT19). Draft guidance document to replace part of Appendices to chapter 7 (page 187 to 200) of the TNsG on Product evaluation. The method is based in the approved methodology of the Chief Hygienist published in HEM-281-5.11.97/41038, and in Acta hygienic, epidemiologica et microbiologica, Appendix No 1/1998

		1,00 mg/cm^2 1,5 mg/cm^2 2,0 mg/cm^2	Substrate *Skin of the volunteer* Incubation temperature: *25ºC* Moisture: *35-45%* Aeration: *No* Method of exposure: *Individual exposure* Aging of samples: *Less than 3 months*		(only concerning arthropods) (PT19). Draft guidance document to replace part of Appendices to chapter 7 (page 187 to 200) of the TNsG on Product evaluation.
DEET	*Odagmia ornata*	0,8 mg/cm^2 1,5 mg/cm^2	**Criteria - Details** Subst *Skin of the volunteer* Method of exposure: *Individual exposure* Aging of samples *Less than 3 months*	100% repellence during 4 hours	TNG: Insecticides, acaricides and products to control other arthropods (PT18) and Repellents and attractants (only concerning arthropods) (PT19). Draft guidance document to replace part of Appendices to chapter 7 (page 187 to 200) of the TNsG on Product evaluation. The method is based in the approved methodology of the Chief Hygienist published in HEM-281-5.11.97/41038, and in Acta hygienic, epidemiologica et microbiologica, Appendix No 1/1998
DEET	*Ixodes ricinus*	Skin from volunteers	**Criteria - Details**	100% repellence during 6 hours	TNG: Insecticides, acaricides and products to control other arthropods (PT18) and Repellents and attractants
		1,00 mg/cm^2 1,5 mg/cm^2 2,0 mg/cm^2	Substrate *Skin of the volunteer* Incubation temperature: *25ºC* Moisture *35-45%* Aeration *No* Method of exposure: *Individual exposure* Aging of samples: *Less than 3 months*		(only concerning arthropods) (PT19). Draft guidance document to replace part of Appendices to chapter 7 (page 187 to 200) of the TNsG on Product evaluation.

DEET	*Odagmia ornata*	0,8 mg/cm^2 1,5 mg/cm^2	**Criteria - Details** Substrate *Skin of the volunteer* Method of exposure *Individual exposure* Aging of samples *Less than 3 months*	100% repellence during 4 hours	TNG: Insecticides, acaricides and products to control other arthropods (PT18) and Repellents and attractants (only concerning arthropods) (PT19). Draft guidance document to replace part of Appendices to chapter 7 (page 187 to 200) of the TNsG on Product evaluation. The method is based in the approved methodology of the Chief Hygienist published in HEM-281-5.11.97/41038, and in Acta hygienic, epidemiologica et microbiologica, Appendix No 1/1998
		1,00 mg/cm^2 1,5 mg/cm^2 2,0 mg/cm^2	Substrate *Skin of the volunteer* Incubation temperature: *25ºC* Moisture: *35-45%* Aeration: *No* Method of exposure: *Individual exposure* Aging of samples: *Less than 3 months*		(only concerning arthropods) (PT19). Draft guidance document to replace part of Appendices to chapter 7 (page 187 to 200) of the TNsG on Product evaluation.
DEET	*Odagmia ornata*	0,8 mg/cm^2 1,5 mg/cm^2	**Criteria - Details** Substrate *Skin of the volunteer* Method of exposure: *Individual exposure* Aging of samples: *Less than 3 months*	100% repellence during 4 hours	TNG: Insecticides, acaricides and products to control other arthropods (PT18) and Repellents and attractants (only concerning arthropods) (PT19). Draft guidance document to replace part of Appendices to chapter 7 (page 187 to 200) of the TNsG on Product evaluation. The method is based in the approved methodology of the Chief Hygienist published in HEM-281-5.11.97/41038, and in Acta hygienic, epidemiologica et microbiologica, Appendix No 1/1998

The product has efficacy during at least the first 6 hours after application. This is supported by the efficacy against *Aedes aegypti* during the first 7 hours after application, against *Aedes albopictus* efficacy during the first 8 hours after, against *Culex spp* during the first 8 hours after application, against *Ixodes ricinus* during the first 6 hours and against *Odagmia ornate* during 4 hours. Re-application is not permitted due to the risk assessment.

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

The biocidal product ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS is a ready-to-use spray for non-professional / general public use which contains 20% DEET (N,N-diethyl-m-toluamide). The biocidal product is applied by spray on the body areas to be protected.

2.6.2 Assessment of exposure to humans and the environment

Regarding human health, no new information was submitted.

Regarding environment assessment, please, see section 2.8

2.7 Risk assessment for human health

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

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

2.7.1.2 Toxicology of the substance(s) of concern

Substance chemical name	2-Phenoxyethanol
CAS No:	122-99-6
EC No :	204-589-7
Purity (minimum, g/kg or g/l):	-
Typical concentration (minimum and maximum, g/kg, or g/l):	Please, see information in the confidential annex of this document about the composition of the biocidal product
Relevant toxicological/ecotoxicological information:	-
Original ingredient (trade name):	-

Based on Guidance for SoC, 2-phenoxyethanol was identified as substance of concern because the substance was notified for the product type 6 as preservative according to the biocides review programme. The substance has a harmonised classification with H302 and H319 but, nevertheless, the substance does not contribute to the classification because of the low concentration in the biocidal product.

2.7.1.3 Toxicology of the biocidal product

The toxicology of the biocidal product ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS was examined appropriately according to standard requirements. The product was not a dummy product in the EU- review program for inclusion of the active substances. Justification for non-submission of data has been submitted for acute oral, dermal, inhalation toxicity and skin sensitisation. Eye and skin irritation studies were submitted. In addition, the information derived from existing data on the active substance DEET and co-formulants has been used, in order to minimise animal testing.

A MIC was sent in 2018 which delete a substance with sensiting properties (2-methyl-2H-isothiazol-3-one) of the composition.

Dermal Absorption:

No study was submitted with the biocidal product. Therefore, taking into account the EFSA or OECD guidance on dermal absorption, a default dermal absorption value of 25% will be applied because the biocidal product contains >5% active substance.

Acute toxicity:

No studies were submitted for the biocidal product. Justification for non-submission of data has been submitted for acute oral, dermal and inhalation toxicity. The Spanish CA accepts the applicant's justification and the data package.

The active substance DEET is classified as dangerous substances by oral acute toxicity but it does not exist in concentration that contributes to the classification of the product. In addition, according to CLP Regulation, where the mixture itself has not been tested to determine its acute toxicity, but there are sufficient data on the individual ingredients and similar tested mixtures to adequately characterise the hazards of the mixture, these data shall be used in accordance with the bridging rules. The acute toxicity estimate (ATE_{mix}) of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula for oral, dermal or inhalation toxicity:

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

where:

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

Considering the LD_{50} (oral) value and concentration of DEET and other possible components of the biocidal product, the ATE_{mix} is 9041 mg/kg and the biocidal product is not classified by oral acute toxicity according to CLP Regulation, table 3.1.1.

In addition, the biocidal product ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS does not contain any dangerous substance classified by dermal acute toxicity. About

inhalation acute toxicity, after a data research and an evaluation of every single co-formulants, there are not any substance as dangerous by inhalation route. In addition, the study of acute inhalation toxicity was waived because the inhalation route is excluded due to the use outdoor, and because the use indoor only takes place in summer, in situations where there is a high ventilation rate. Furthermore, as reported in the CAR of DEET, the active substance is a low volatile compound that has not and high distribution in air compartment. In conclusion, the biocidal product is not classified by dermal and inhalation acute toxicity.

Irritation and corrosivity:

Skin irritation

The active susbtance was considered to be skin irritant. In addition, there is a study performed with the biocidal product. Considering the study, the biocidal product is not classified as irritant to skin. A summary of the study is given below:

Species	**Method**	**Average score (24, 48, 72h)**		**Result**	**Remark**	**Reference**
		Erythema	Oedema			
Rabbit	OECD 404 GLP	0 (0-0-0)	0 (0-0-0)	Completely reversible	Not irritating	B6.2

Eye irritation

The active substance DEET was classified in the CAR as irritant to eyes according to Directive 1999/45/EC and according to CLP Regulation, Annex VI. In addition, there is a study performed with the biocidal product:

Species	**Method**	**Average Score**				**Reversibility Yes/No**	**Result**	**Reference**
		Cornea	*Iris*	*Conjunctiva*				
				Inflammation	*Redness*			
Rabbit	OECD 405 GLP	1.33	0	0.66	1.44	Yes	Irritating	B6.2

On the basis of the above data, the biocidal product ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS is irritating to the skin or eyes. According to CLP Regulation (corneal opacity ≥ 1), the biocidal product is classified as Eye Irrit.2 with the hazard statement H319 (Causes serious eye irritation).

Sensitization:

No study was submitted with the biocidal product. Nevertheless, some substances included in the biocidal product could produce an allergic reaction. These substances (fragances) and soothing are not present in the biocidal product at sufficient concentration(s) to trigger a human health classification but, according to the Regulation 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (section 2.8, Annex II), the label on the packaging of mixtures not classified as sensitising but containing at least one substance classified as sensitising and present in a concentration equal to or greater than that specified in Table 3.4.6 of Annex I, of this regulation, shall bear the statement:

EUH208 — "Contains (name of sensitising substance). May produce an allergic reaction".

For this reason, the label of ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS will include the statement: EUH 208: "Contains benzyl salicylate, butylphenyl mehtylpropional, cinnamyl alcohol, citronellol, linalool and alpha-isomethyl ionone. May produce an allergic reaction" according to CLP Regulation.

2.7.2 Exposure

The exposure of the biocidal products containing DEET has been re-assessed in line with the Commission implementing Decision (EU) 2018/1477 of 2 October 2018 on the terms and conditions of the authorisations of biocidal products containing ethyl butylacetylaminopropionate applicable to DEET.

There is a discrepancy between the application rate obtained from the efficacy studies and the application rate used in the exposure assessment. The application rate proven efficacious should be considered to assess the exposure (Article 19(1)(b)(i) of Regulation (EU) No 528/2012), even though it is acknowledged that it may lead to an unacceptable risk for human health with regard to a number of the intended uses (Article 19(1)(b)(iii)).

Until a consensus on how to generate efficacy for insect repellents data is reached, the human health risk assessment should contemplate the efficacy doses. Therefore the RMS has re-calculated the exposure with the dose that has proven to be efficient. Hence, the dose proven efficacious (1.15 g/600 cm2) has been considered in line with the Commission implementing Decision (EU) 2018/1477.

The product ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS is a ready-to-use spray containing DEET at a concentration of 20 %. Only the active substance DEET is considered in this exposure and risk assessment.

The biocidal product is is supplied in HDPE bottles of 100 and 200 ml (see section 2.2.2). It is applied onto the body areas to be protected. The biocidal product will be used by non-professional users. Primary exposure is expected in adults and children over 2 years of age. The use of DEET products is not allowed for children of less than 2 years of age (DEET CAR).

The main paths of human exposure towards active substance from its use in biocidal product are:

Table 2.7.2- 1 Summary of main paths of human exposure

Exposure route	Industrial use	Professional use	General public	Through the environment
Inhalation	NA	NA	Insignificant	Insignificant
Dermal	NA	NA	Main route	Insignificant
Oral	NA	NA	Significant	Insignificant

The product is intended to be used per dermal route. The exposure assessment is performed assuming a frequency of application of 1 time per day although the number of applications indicated by the applicant was **one or two per day .**This is because for two applications per day a scenario of concern was obtained. Dermal route is the main path of exposure

Exposure by inhalation is considered to be negligible according with the "Technical Notes for Guidance - Human Exposure to Biocidal Products - Guidance on Exposure Estimation" (European Commission, 2002, part 2) that, in section 5.2, with respect to insect repellents, states: "The inhalation route is excluded due to the use outdoors, and because use indoors takes place in the summer in situations where there is a high ventilation rate". This extreme was admitted for the assessment of the active substance (DEET CAR) and the inhalation exposure was not assessed. However, since the inhalation exposure cannot be completely ruled out a recommendation for adequate ventilation has been included on the product label.

Oral exposure by hand-to-mouth transfer is not considered to be a significant route of exposure since due to its smell and taste the DEET acts as a shelf-deterrent. More importantly, all the products of this family contain an ingredient that acts as a strong deterrent for ingestion (Bitrex). However, it should be noticed that Bitrex may not be effective in preventing ingestion in all age groups, in particular children < 12 years old (Technical Meeting Agreement) the oral route is considered possible and therefore the calculations for hand to mouth exposure have been included in a worst case exposure calculations.

2.7.2.1 Exposure of professional users

The product is not intended for professional use.

2.7.2.2 Exposure of non-professional users and the general public

The exposure calculations are based on the Recommendation 11 Ad hoc Working Group Human Exposure "proposal for harmonizing the assessment of human exposure to repellents (PT19)" as well as on Biocides Human Health Exposure Methodology (ECHA, 2015).

The assessment of the systemic effects has been carried out using the UK proforma approach which is based on the application rates supported by efficacy data. The Proforma method defines a maximun skin area that can be treated safely using a reverse referece scenario. The risk calculations are based on the toxicologically determined AEL for the active substance. Consequently, the potential exposure of the biocidal product is calculated by determining the maximum dose that can be applied onto a person without exceeding the AEL.

The daily exposure has been calculated for adults, children from 12 to < 18 years of age; children from 6 to < 12 years of age; and children from 2 to < 6 years of age. It is agreed that the Recommendation 14 of the Ad hoc working group human exposure does not cover the ages from 12 to 18 years old. In order to simplify the re-assessment, it is assumed that the exposure of adults covers the population of children from 12 to <18 years of age in a worst-case basis.

The default values fo body weight and surface area described at the Recommendation 14 of ad hoc working group human exposure are used for exposure assessment. The biocidal product is applied directly onto the body areas to be protected. For adults and children, the head, arms, legs, trunk and feet could be treated according to US EPA Child-Specific Exposure Factors Handbook, 2002. In addition, since the product can be used in people wearing swimming suits and therefore with the trunk exposed, the trunk has been included as a possible body part to spray on.

The parameters considered to calculate are:Parameters	Value
DEET $AEL_{repeated}$ (acceptable exposure limit a.s.)	8.2 mg a.s./kg bw/day
Number of applications	One per day (applicant)
Concentration of DEET in the product (AS)	20 %
Dermal absorption for DEET (DA) [1]	25 %
Oral absorption for DEET (AA)	100 % (worst-case approach)
Amount of BP [2]	100 ml and 200 ml net
Efficacy (g DEET/cm^2 skin)	0.65 g/600 cm^2 (0.0011 g/cm^2)
Amount of the product applied that expected to be ingested [3]	
Adults	4 % applied dose (product on fingers)
Children	8 % applied dose (product on hands)

The parameters considered to calculate are:Parameters	Value
Transfer coefficient[4]	100 %
Area of skin that can be treated (head, trunk, arms, legs, trunk and feet) [5]	
Adults/ Child > 12 years	16600 cm^2
Child 6 to < 12 years	9200 cm^2
Child 2 to < 6 years	6800 cm^2
Body weight [6]	
Adults/ Child > 12 years	60 Kg
Child 6 to < 12 years	23.9 Kg
Child 2 to < 6 years	15.6 Kg

[2] Guidance on absorption dermal. EFSA journal.
[2] (see section 2.2.2)
[3]Amount of product ingested (mg/Kg/day), assuming that a % of the amount deposited is available orally with a transfer coefficient of 100% (Recommendation 11 Ad hoc WGHE);
[4] Recommendation 11 Ad hoc WGHE;
[5,65] Recommendation 14 ad hoc WGHE.

Both dermal and oral exposures have been considered in a worst-case basis.

According to Recommendation 11th of the Ad hoc working group on human exposure, adults will ingest the amount applied to fingers. The surface of the fingers is approximately 4% of the treated body surface. The oral exposures are for the age groups < 12 years is calculated for the whole hands, i.e. approximately 8% of the treated body surface (head, arms, hands, legs and feet according to US EPA Child-Specific Exposure Factors Handbook, 2002) , with a 100 % of transfer coefficient..

In this scenario where the biocidal product is applied directly on the body areas, the exposure is expected to happen per dermal and oral route.

The following calculations model a scenario where the biocidal product is lodged onto the skin, leading to both dermal absorption due to direct contact with the skin after spraying; and oral absorption by hand-to-mouth transfer. The RMS acknowledges, that, since both procedures might take place at the same time, the calculation should take into account, out of the total amount of biocide product applied on the skin, that the quantity absorbed per dermal route will not be available to be in-taken per oral route and vice versa.

The amount of active substance absorbed per dermal and oral route has been calculated based on the following formulas:

Internal dermal dose a.s. = External dermal dose product × (content a.s.) × (% dermal absorption)

Internal oral dose a.s. = External oral dose product × (content a.s.) × (% oral absorption)

Total dose a.s. = Internal dermal dose a.s. + Internal oral dose a.s.

Where,

External dermal dose product = amount of applied biocidal product that will be lodged over the skin (mg).
External oral dose product = amount of the biocidal product will be ingested (mg)
Content a.s. = concentration of the active substance (mg/100mg)
% dermal absorption = fraction
% oral absorption = fraction

In line with the reverse scenario proposed by UK Proforma, the amount of product (external dose) that can be applied to a person without exceeding the AELrepeated is:

mg Biocidal product (external dose) = AELa.s. / Total dose a.s. (calculated)

The complexity lies in the fact that the quantity absorbed by the dermal route will not be available to be ingested; and on the contrary.

For adults, the ratio mg active substance/ mg biocidal product has been calculated assuming i.e. that an adult intakes the entire amount of product rubbed onto their fingers, which assuming a linear relation, is the 4% of total amount. Therefore, a 96% of the product will be left on the skin, available for dermal absorption.

AELrepeated a.s = 96 % dermal route + 4% oral route

If 1 mg of ECRAN REPEL & CARE REPELENTE DE MOSQUITOS is applied, the latter proportion would imply that 0.96 mg of the biocide product will be lodged over the skin, whilst 0.04 mg of the biocide product will be ingested by the adult.

1 mg Biocidal product = 0.96 mg per dermal route + 0.04 mg per oral route

Considering the concentration of DEET is 20 %, a default dermal absorption of 25 % and an oral absorption of 100 % the corresponding total internal dose is calculated as follows:

Dermal route

0.96 mg Biocidal product x (20 mg DEET/100 mg Biocidal product) x (25 mg DEET/100 mg DEET) = 0.0480 mg DEET internal

Oral route

0.04 mg Biocidal product x (20 mg DEET/100 mg Biocidal product) x (100 mg DEET/100 mg DEET) = 0.0080 mg DEET internal

Total dose DEET

0.0480 mg internal DEET per dermal route + 0.0080 mg internal DEET per oral route =
0.0560 mg internal DEET / mg of ECRAN REPEL & CARE REPELENTE DE MOSQUITOS

For every mg of ECRAN REPEL & CARE REPELENTE DE MOSQUITOS applied on an adult's skin, considering both oral and dermal exposures (since none of the exposures could occur separately) **0.0560** mg of DEET would be absorbed.

Considering an AEL of 8.2 mg/kg bw/day, the amount of product that can be applied on an adult without exceeding the AEL is:

8.2 mg DEET/kg bw/day x 1 mg Biocidal product/0.0560 mg DEET = 146 mg of Biocidal product/kg bw/day

That implies that **146 mg/Kg bw/day** of ECRAN REPEL & CARE REPELENTE DE MOSQUITOS can be applied on adult skin before reaching the AEL (limit dose).

For **children**, the ratio *mg active substance/ mg biocidal product* has been calculated assuming i.e. that a child intakes the entire amount of the product rubbed onto their hands, which assuming a linear relation, is the 8% of total amount. Therefore, a 92% of the product will be left on the skin, available for dermal absorption.

AELrepeated a.s = 92 % dermal route + 8% oral route

For children, If 1 mg of ECRAN REPEL & CARE REPELENTE DE MOSQUITOS is applied, this proportion would imply that 0.92 mg of the biocide product will be lodged over the skin, whilst 0.08 mg of the biocide product will be ingested by the child.

1 mg Biocidal product = 0.92 mg per dermal route + 0.08 mg per oral route

Dermal route

0.92 mg Biocidal product x (20 mg DEET/100 mg Biocidal product) x (25 mg DEET/100 mg DEET) = 0.0460 mg DEET internal

Oral route

0.08 mg Biocidal product x (20 mg DEET/100 mg Biocidal product) x (100 mg DEET/100 mg DEET) = 0.0160 mg DEET internal

Total dose DEET

0.0460 mg internal DEET per dermal route + 0.0160 mg internal DEET per oral route =
0.0620 mg internal DEET / mg ECRAN REPEL & CARE REPELENTE DE MOSQUITOS

For children, for every mg of ECRAN REPEL & CARE REPELENTE DE MOSQUITOS applied on the skin of a child, considering both oral and dermal exposures (since none of the exposures could occur separately) **0.0620** mg of DEET would be absorbed.

Considering the value of the AEL 8.2 mg/kg bw/day, the amount of product that can be applied on a child in order not to exceed the AEL is:

8.2 mg DEET/kg bw/day x 1 mg Biocidal product/0.0620mg DEET = 132 mg of Biocidal product/kg bw/day

That implies that **132 mg/Kg bw/day** of ECRAN REPEL & CARE REPELENTE DE MOSQUITOS PLUS can be applied on child skin before reaching the AEL (limit dose).

The number of applications and the maximum area of skin (cm^2) that can be treated in one day with the biocide product ”limit dose” so that the AEL is not exceded has been calculated (Table 2.7.2.2-1). The calculation taking into account the efficacy of the product as is recommended by the implementing decision (EU) 2018/1477. As worst case, the efficacy of product ECRAN REPEL & CARE REPELENTE DE MOSQUITOS (0.65 g product/600 cm^2 of skin) has been used for calculation.

The surface areas from the Recommendation 14 of the Ad hoc working group human exposure are used for exposure calculations,assuming that the head, trunk, arms, hands, legs and feet are treated. The trunk has been included by the RMS in the worst case exposure calculation, as a possible body part to spray on, since the product can be used person in wearing swimming suits and therefore with the trunk exposed,

In addition, as the product ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS is a ready-to-use spray of 100 and 200 ml net (see section 2.2.2~~),~~ the number of applications and the maximum skin area that can be treated in one day (so called ”limit dose”) have been calculated.

Table 2.7.2.2-1. Number of applications, amount product “limit dose” and area of skin treated with product “limit dose

Scenario	Adults/Child > 12 years	Child 6 to < 12 years	Child 2 to < 6 years

Scenario	Adults/Child > 12 years	Child 6 to < 12 years	Child 2 to < 6 years
nº application/day	1	1	1
Concentration DEET (% w/w)	20	20	20
AELdermal (mg a.s./kg bw/day) = Application rate "safely"	8,2	8,2	8,2
Body weight (kg)	60	23,9	15,6
Dermal absorption (%)	25	25	25
Oral absorption (%)	100	100	100
Amount of PRODUCT applied to reach repeated AEL (mg product /Kg/day)	146	132	132
Amount of PRODUCT applied to reach repeated AEL (mg product /day)	8786	3161	2063
Efficacy (0.65 g/600 cm^2)	0.0011	0.0011	0.0011
Area of skin that can be treated with product in one day [cm^2]	8110	2918	1905
Body surface (cm^2)	16600	9200	6800
Number of applications / day	0.5	0.3	0.3
% skin that can be treated in a day	49	32	28

2.7.2.3 Exposure to residues in food

Not relevant, as no contamination of food is expected if users follow the label instructions.

2.7.3 Risk Characterisation

ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS is a ready-to-use spray containing 20% DEET. There are no ingredients considered as substances of concern. Therefore, only DEET is included in the risk characterisation.

2.7.3.1 Risk for Professional Users

The product is not intended for professional use.

2.7.3.2 Risk for non-professional users and the general public

The exposure assessment for ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS expressed as the estimated amount product “limit dose” to reach the AEL of 8.2 mg/kg bw/day and the area of skin treated with product “limit dose” after dermal for adults, children 2 to < 6 years and child 6 to < 12 years are presented in Table 2.7.3.2-1.

As a worst-case approach, the oral exposure has also been performed the assessment, considering potential ingestion of a 4% out of the total applied product by adults (amount on fingers) and a potential ingestion of the 8% out of the total applied product by children

Table 2.7.3.2-1. Amount product “limit dose” and area of skin treated with product “limit dose”.

Scenario	Adults/Child > 12 years	Child 6 to < 12 years	Child 2 to < 6 years

Scenario	Adults/Child > 12 years	Child 6 to < 12 years	Child 2 to < 6 years
Amount of PRODUCT applied to reach repeted AEL (mg product /Kg/day)	146	132	132
Amount of PRODUCT applied to reach repeted AEL (mg product /day)	8786	3161	2063
Efficacy (0.65 g/600 cm^2)	0.0011	0.0011	0.0011
Area of skin that can be treated with product in one day [cm^2]	8110	2918	1905
Superficie cuerpo (cm^2)	16600	9200	6800
Number of applications / day	0.5	0.3	0.3
% skin that can be treated in a day	49	32	28

The recommended maximum skin area to be treated in one day to reduce exposure is show below. The default values for the body surfaces are based in the Recommendation 14 Ad Hoc working group human exposure.

There are different ways of phrasing the maximum dose recommendation. For clarification purposes, the following wording has been decided:

-An adult can be treated a maximum of 8110 cm^2 of area of skin. Apply in a uniform manner on face, arms, back hands and legs (8270 cm^2).

-Children of 6 to < 12 years can be treated a maximum of 2918 cm^2 of area of skin. Apply in a uniform manner on face, arms, lower legs and upper feet (2928 cm2).

-Children of 2 to < 6 years can be treated a maximum of 1905 cm^2 area of skin. Apply in a uniform manner on face, arms and lower legs (1955 cm^2)."

The reverse dose calculations for exposure show that the 85 to 74 % of the estimated internal dose per application (8.2 mg product/kg/d) of use for adults and children < 12 years respectively, can be absorbed on skin and the 13 to 23 % can be ingered before an AELrepeted is exceeded.

Although considering the oral exposure represents the worst-case determines that the oral exposure should not be overruled especially on children < 12 years old. However, acoording to the CAR of DEET it was concluded that the oral dose is likely to be largely overestimated given the DEET short half-life after oral exposure in dogs and rats and the rapid achievement of Cmax. The hand to mouth behaviour is more frequent in small children and taking into account that Bitrex may not be sufficiently effective protect small children from ingestion of product, an age limit of 2 years has been proposed together with the recommendation "restrict the use on children between three and twelve years old".

The maximum skin area that can be applied a person without exceeding the AEL is compared to treated area surface to show how many applications/day will be acceptable before the AEL (Table 2.7.3.2-2).

Table 2.7.3.2-2. Risk indicator value

Scenarios	Adults/Child > 12 years	Child 2 to < 6 years	Child 6 to < 12 years

Scenarios	Adults/Child > 12 years	Child 2 to < 6 years	Child 6 to < 12 years
Skin treated in one day (%)	49	32	28
Nº applications/day	0.5	0.3	0.3
Body areas which can be treated	face, arms, back hands and legs	face, arms, lower legs and upper feet	face, arms and lower legs

Therefore, for adults, children < 12 years of age and children > 12 years of age the number of applications/day is 0.5. 0.3 and 0.3 respectivaly. The number of applications per day does not cover the area that needs to be treated for adults, children 2 to <6 years and children 6 to <12 years.

For adults, the number of applications covers the 49 % of the area that could be treated; and for children approximately the 32-28 % of the area that could be treated.
The CAR of DEET requires the inclusion of a recommendation on maximum skin areas to be treated to reduce exposure

In summary, the risk characterization performed, considering both dermal and oral routes concludes that there is risk for each subpopulation (adults, children < 12 years of age, and children > 12 years of age). The product can be used once per day, on adultsand children over 2 years of age. Children's hands must not be treated with this product. Children under 2 years must not be treated with this product.

The RMS is in the opinion that not authorizing ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS would result in disproportionate negative impacts for society when compared to the risks to human health. It should be taken into account that insect repellents are essential to prevent vector borne diseases. Also, the availability of insect repellents containing different active substances is necessary to minimize the occurrence of resistance in the target harmful organisms. There is an immediate need to maintain a number of insect repellent products containing DEET on the market in order to protect human health.

In consequence, the RMS is in the opinion that ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS must be authorized on the grounds of Article 19(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the market and use of biocidal products.

This authorization is granted under the following conditions:

Once a consensus is reached and the efficacy methods are refined, the applicant commits to provide new efficacy data. At that point, the competent authorities will re-evaluate the human health risk assessment, and will take the appropriate regulatory measures, if necessary. Until then, the existence of risk for human health cannot be overruled.

ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS must not be used by children younger than two years old

Children must not handle or apply the product by themselves.

The application for adults, children < 12 years of age and children > 12 years of age must be restricted to one application a day and the area of skin that can be treated safely with the product should be taken into account.

2.7.3.3 Risk for consumers via residues

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.

2.8 Risk assessment for the environment

The following environmental risk assessment has been submitted by the applicant and reviewed by the ES CA.

2.8.1 Fate and distribution in the environment

The environmental fate and behaviour of the active substance DEET has been fully evaluated during the assessment for Annex I inclusion. A summary of the fate and distribution of DEET is presented in Section 2.2.2.1 of the final Assessment Report (11 March 2010), and the relevant endpoints appear in the EU List of Endpoints.

DEET is considered to be ready biodegradable and no major (>10%) transformation products were formed in studies of hydrolysis and aquatic phototransformation. DEET is extensively metabolised and excreted through the urine in all assessed mammals, and because the parent structure is ready biodegradable, and the metabolite structures found in urine do not differ significantly from the parent structure it is likely that they are also ready biodegradable. It causes only minor inhibitory effects on (STP) microbial activity.

DEET is moderately volatile and absorbs UV in the region 200-250 nm. The substance is predicted to have an atmospheric half-life of 0.63 days (15.2 hours). Thus an extensive accumulation of DEET in air and long range transport is unlikely. DEET is a liquid at room temperature, and it has a water solubility of 11.2 g/l and its log Pow is 2.4. It is hydrolytically stable under acidic, basic and neutral conditions, and photolytically stable in sterile distilled water.

Based on the calculated BCFs for aquatic and terrestrial organisms, DEET is considered to have very little or no potential to bioaccumulate.

DEET has a Koc of 43.3, suggesting that it is very mobile in soil and therefore could leach to the groundwater. However, DEET will not be directly emitted to soil and exposure is expected to be negligible.

The following statement appeared in Section 3.4 (Requirement for Further Information) of the final Assessment Report (11 March 2010);

"It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, ands permit the proposal for the inclusion of N,N-diethyl-meta-toluamide (DEET) in Annex I to Directive 98/8/EC.

However, further validation data to prove the applicability of the proposed analytical method for the water compartment is considered needed (The applicant has stated that further validation work is underway and the data will be submitted as soon as possible)."

According to verbal information: The CAR request was completed and submitted to the KEMI, who is the CA for DEET. They accepted the method with no questions.

The formulation of DEET in ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS has no impact on the route or rate of degradation of the active substance DEET in the environment. So it was concluded that no additional studies involving the formulated product are required.

The environmental exposure of DEET was assessed by Applicant in accordance with the Technical Guidance Document (TGD) on Risk Assessment (ECB Part II, 2003). In accordance with the 1998 Biocide Directive, the life cycle of the product is incorporated into the risk assessment. With regard to waste disposal of ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS, this remains outside of the remit of PT19 substances under Directive 98/8/EC and would be covered by the Hazardous Waste Directive if national concerns were raised regarding the disposal of this

product. Since at the time of preparation of the biocide product dossier for ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS no Emission Scenario Document (ESD) was available for repellents (PT19), environmental exposure assessments have been performed by the Applicant using the EU TGD Worksheet and EUSES program, considering the annual tonnage of the product. Regional and local emissions were calculated according to Industrial category IC5Personal/Domestic and Use category US15 cosmetic.

ES CA agrees with the comment made by the applicant that no additional studies involving the formulated product are required. Since an ESD has been published for repellents (PT19) on June 2015, ES CA has used it for calculation of releases of DEET to the environment instead of the annual tonnage of the product..

2.8.2 Effects on environmental organisms

In Doc II-A of DEET CAR, section 4.2.1, calculations of PNEC values for surface water (freshwater) are presented. Values are presented below for organisms of three trophic levels.

LC_{50} fish = 97 mg/l

LC_{50} invertebrates = 75 mg/l

E_rC_{50} algae = 43 mg/l

No marine species were tested and the applicant argues that these are not necessary based on the presence of studies performed on freshwater species, all suggesting low toxicity, and DEET will not be used or released in marine environments in considerable amounts. The effect of DEET on microbial activity in water was assessed by determining the level of inhibition of respiration of microorganisms present in activated sludge. DEET had only a minor inhibitory effect on aquatic microbial activity (26.8% inhibition at the highest tested concentration, 1000 mg/l).

The PNEC values for the water compartment and microorganisms can be calculated from toxicity data by using recommended assessment factors. Because only three acute aquatic tests were performed, all on freshwater species, the assessment factor for the freshwater compartment will be 1000 and for the marine water compartment 10 000 (assuming a greater species sensitivity distribution and thus greater uncertainties in extrapolation of data from the freshwater to the marine environment; or lower species diversity resulting in high ecosystem dependency).

For the sediment and soil compartments, there are no toxicity data available. The low Koc value indicates that sorption to sediment and soil is not likely. Nevertheless, PNEC values have been calculated based on equilibrium partitioning theory (Eq.P.) and $PNEC_{water}$. The formulas used assume uptake from the water phase only. This assumption is accepted for DEET, because of its low log P_{OW} and K_{OC} values. No quantitative estimation of $PNEC_{marine\ sediment}$ is necessary because the PEC values for the marine sediment compartment will be based on EqP and the same P_{OW} and K_{oc} values. The PEC/PNEC ratios for the marine sediment compartment will therefore be the same as for the corresponding water compartment.

PNECs were not calculated for the air compartment, as there are no data on biotic effects in the atmosphere. Furthermore, DEET is not expected to be subject to long range air transport (half life is less than 2d)**,** or contribute to global warming (although the substance has a vapour pressure higher than 0.01 Pa, the Henry´s law constant is low and DT_{50} is less than 2d; cf the TNsG on Annex I inclusion), ozone depletion in the stratosphere (atmospheric lifetime is <<1year, and it does not contain Cl, Br or F substituents) or acidification (the AP, Acidification Potential is low).

The log P_{OW} is 2.4, suggesting a low bioaccumulation potential (BCF estimates range between 3.85 and 63.1), see doc II-A 4.1.4. The risk of secondary poisoning is therefore expected to be low via ingestion of potentially contaminated food (e.g., fish) by birds or mammals. The risk for secondary poisoning via intake of terrestrial organisms such as earthworms is considered unlikely also because exposure to earthworms is expected to be negligible. No avian dietary tests were therefore required. The available avian acute lethality data are not appropriate for extrapolation to chronic dietary

uptake conditions (cf TGD II3.8.3.5). PNECs were therefore not calculated for oral uptake from the food chain (to quantify the risk of secondary poisoning).

According to DEET CAR the effects assessment is summarized in the following table:

DEET PNECs for the environmental compartments

Compartment	Available data	Assessment factor/Eq P	Remark	PNEC
Freshwater	$LC_{50dapnia}$: 75 mg/l LC_{50fish}: 97 mg/l $EC_{50algae}$: 43 mg/l	**1000**	No chronic data available (except for NOEC algae)	43/1000= 0.043 mg/l
Saltwater	$LC_{50daphnia}$: 75 mg/l LC_{50fish}:97 mg/l $EC_{50algae}$: 43 mg/l	**10.000** (TGD II4.3.1.3)	No chronic data available (except for NOEC algae), and no additional marine data	43/10000= 0.0043 mg/l
STP microorganisms	EC50: >1000 mg/l NOEC: 300 mg/l	For EC50: 100 For NOEC: 10	At the highest test concentration (1000 mg/l) there was 26.8% inhibition. At NOEC, there was 13% simulation rather than inhibition.	>1000/100 = >10 mg/l
Sediment, freshwater	Measured Koc: 43.3 Default assumptions: RHOwater: 1000 kg/m^3 $Fwater_{susp}$: 0.9 $Fsolid_{susp}$:0.1 RHOsolid: 2500 kg/m^3 Foc_{susp}: 0.1 (TGD II 2.3.4 table 5)	PNECsed: 1000*PNECwater*(K_{susp}-water/RHO_{susp}) (TGD II 3.5.3 eq70) Where: RHO_{susp}: $Fsolid_{susp}$*RHOsolid+$Fwater_{susp}$*RHOwater And Ksusp-water: Fwatersusp + Fsolidsusp*RHOsolid*(FOCsusp*Koc)/1000	RHO_{susp}=0.1*2500+0.9*1000=1150 kg/m^3 $K_{susp-water}$= 0.9+0.1*(0.1*43.3*(1.98/1150) =0,0741 mg/kg ww	1000*0.043*(1.98/1150)=0.074 mg/kg ww
Soil	Measured Koc: 43.3 Henry´s law constant: 3.93E-03 Pa*m^3/mol Default assumptions: R (gas constant)= 8.314 Pa*m^3/(mol*K) Temp:285 $Fair_{soil}$:0.2 $Fwater_{soil}$:0.2 $Fsolid_{soil}$: 0.6 Foc_{soil}: 0.02 RHOair: 1.3 kg/m^3 RHO_{solid}: 2500 kg/m^3 RHOwater: 1000 kg/m^3 (TGD II 2.3.4. and 2.3.5.2)	PNECsoil: 1000*PNECwater*($K_{soil-water}$/RHO_{soil}) (TGD II3.6.2.1) where: RHO_{soil}: $Fsolid_{soil}$*RHO_{solid}+$Fwater_{soil}$*RHOwater+$Fair_{soil}$*RHOair $K_{soil-water}$: $Fair_{soil}$*Kairwater+$Fwater_{soil}$+ $Fsolid_{soil}$*(Kp_{soil}/1000)*RHOsolid and Kp_{soil}=Foc_{soil}*Koc and: Kair-water=HENRY/(R*temp)	RHOsoil= 0.6*2500+0.2*1000+0.2*1.3=1700 kg/m^3 Kair-water: 3.93E-03/(8.314*285)=1,66E-06 Kpsoil: 0.02*43.3=0.866l/Kg ksoil-water= 0.2[3,93E-03/(8.314*285)]+0.2+0.6*[0.866/1000]*2500=1.499	1000*0.043*(1.499/1700)= 0.0379 mg/kg ww

2.8.3 Environmental exposure assessment

The environmental risk has been assessed for the DEET at 20%. It is assumed that the risk assessment for these substances also covers risks for their metabolites.

The expected use of this biocidal product is only for private users or consumers both in indoor and outdoor application. The application is by spraying the product directly on the skin. However, the main route into the environment is assumed to be indirect by reaching the water compartment via STP effluents, derived from public bathering or showering after product application.

A simple emission scenario for the release of biocidal product in the environment has been considered. This scenario assumes that the only environmental compartment affected is water.
Environmental risk assessment has been done following the Technical Guidance Document on Risk Assessment and EUSES program considering the annual tonnage of the product. Regional and local emissions were calculated according to Industrial category IC5Personal/Domestic and Use category US15 cosmetic.

ES CA does not agree with the applicant. Final CAR for DEET did not include direct emission to surface water, but at the Technical Meeting I 2009, several Member States had questions about possible direct emissions due to swimming for this kind of products. Finally, this swimming scenario was included in the ESD for PT19 on June 2015.

Predicted Environmental Concentrations (PEC) in STP, surface water, sediment, soil and groundwater were considered following PT19 Scenario (Repellents and Attractants) and the Guidance on the Biocidal Products Regulation (Volume IV Environment – Part B Risk Assessment (active substances) Version 1, April 2015.

According to Scenario PT19 emissions to the environment can take place during the application of the product on human skin. A fraction can be released to the floor when repellents are applied indoors or to paved or unpaved ground during outdoor applications. However, according to TM IV/2013, emissions resulting from the stage of application on human skin are of minor importance since they take place non-repeatedly on a very limited area and are therefore not considered within this ESD.

The main emissions of this use to the environment occur during the removal phase of the insect repellent. Removal of the product from human skin can either take place:

- Through showering or bathing of humans who have used an insect repellent. Sewage treatment plants are the primary compartment for emissions whereas surface water bodies (including sediment) as well as the soil compartment (including groundwater) are secondary exposed compartments for remnants via sewage treatment plant effluents and sewage sludge applications, respectively. Major emissions from the application of mosquito and tick repellents result from indoor showering or bathing with emission via the STP to surface water and sediment (waste phase).

- Through direct release to surface water if people with treated skin go swimming in outdoor surface waters (only for human skin repellents).

The water compartment is therefore expected to be exposed to DEET, and because of the physiochemical character of the substance, the emissions will continue to primarily remain in this compartment (supported by level III fugacity modelling). Additionally, secondary exposure of DEET to soil and groundwater were considered following application of sewage sludge to land. Emission to fresh water is expected to be worst case. Therefore risk for the marine environment is considered covered by the freshwater risk assessment.

2.8.3.1 PEC in surface water, sewage treatment plant and sediment

In view that an ESD has been published for repellents (PT19) on June 2015, ES CA has used it for calculation of releases to the environment. It can be distinguished between indirect release to surface water, when another environmental compartment (e.g. STP) is exposed before or direct release, when surface water is the first receiving environmental compartment.

PEC Sewage Treatment plant for indirect emission through showering and bathing of humans

The emission scenario for calculating the release of repellents used on human skin is based on the average consumption. According to the Applicant the average percentage of active substance in the product is 20 % w/w. The product is applied 1 times per day directly to skin.

The local scenario was assessed for indirect emission pathway, considering that the product can be applied only on human skin. PECs for the local scenario were calculated using ESD for PT19 and equations in the BPR guidance

$Elocal_{water}$ value (Emission rate to wastewater [standard STP], kg/d), i.e. the inflow of DEET to an STP during an emission episode, can be calculated from the formula below following the Scenario PT19; meanwhile the respective PECstp values have been obtained following the BPR Guidance.

$Elocal_{water}$= Nlocal * N_{appl} * $Qform_{appl}$ * $AREA_{skin}$ * $Cform_{weight}$ * F_{inh} * F_{water} * F_{penetr} * 10^{-9}
eq (3.8) ESD PT19

Table 2.8.3.1-1. Inputs for Elocalwater calculation according to Scenario PT19

INPUTS		**Value**	**Unit**	**Origin**
Number inhabitants feeding one sewage treatment plant	Nlocal	10000	cap	D
Active substance in the product	$Cform_{weight}$	200	$g.kg^{-1}$	S
Consumption per application	$Qform_{appl}$	1.08	$mg.cm^{-2}$ skin	D/S
Number of applications per day	N_{appl}	1	d^{-1}	D
Treated area of human skin	$AREA_{skin}$	16600	cm^2	P
Fraction released to air	F_{air}	0	-	D
Fraction dermally absorbed	F_{skin}	0	-	D
Fraction released to wastewater	F_{water}	1	-	D/O
Fraction of inhabitants using a repellent product	F_{inh}	0.2	-	P
Market share of repellent	F_{penetr}	0.5	-	D
Specific density of the product	RHOform	1000	$kg.m^{-3}$	D

Intermediate calculation: $F_{water} = 1 - (F_{air} + F_{skin}) = 1$

Table 2.8.3.1-2. Elocalwater according to Scenario PT19

OUTPUT				
Local emission rate to wastewater	**$Elocal_{water}$**	2.302	$kg.d^{-1}$	O

PEC value is calculated according to the BPR Guidance. Following calculations done in the DEET CAR $Clocal_{eff}$ is used for PEC_{stp} calculation:

$Clocal_{inf} = Elocal_{water} * 10^6 / EFFLUENT_{STP}$

$EFFLUENT_{STP} = CAPACITY_{STP} * WASTEW_{inhab}$ = 2000000 L/d.

PEC_{stp} = $Clocal_{eff}$ (Continuous release) = $Clocal_{inf}$ * $Fstp_{water}$ eq (33) BPR Guidance

Table 2.8.3.1-3. PEC_{stp} calculation

INPUTS		**Value**	**Unit**	**Origin**
Concentration in untreated wastewater (skin)	$Clocal_{inf}$	1.151	$mg.L^{-1}$	BPR Guidance
Fraction of emission directed to water by STP	$Fstp_{water}$	0.126	-	EUSES/D TGD
OUTPUT				
PEC_{stp} =	**$Clocal_{eff}$**	**0.145**	$mg.L^{-1}$	O

PEC in surface water and sediment for indirect emission through showering and bathing of humans

In this section, the local concentration in surface water during emission episode is derived.
According to the BPR Guidance:

$PEClocal_{water} = Clocal_{water} = Clocal_{eff} / [(1 + kp_{susp} * SUSP_{water} * 10^{-6}) * DILUTION]$
(45 BPR Guidance)

Where,

$K_{p,susp} = Foc_{susp} * K_{oc}$ eq (23) BPR Guidance

Table 2.8.3.1-5. Inputs for $K_{p,susp}$ calculation

Weight fraction organic carbon in suspended matter (Foc_{susp})	0.1	$kg.kg^{-1}$	BPR table 5
Part.coef. Carbon-water	43.3	$l.kg^{-1}$	S

Table 2.8.3.1-4. Model inputs and outputs for $PEClocal_{water}$ calculation

INPUTS		**Value**	**Unit**	**Origin**
Concentration of the substance in the STP effluent	$Clocal_{eff}$	0.145	$mg.L^{-1}$	BPR Guidance
solids-water partitioning coefficient of suspended matter	$K_{p,susp}$	4.33	$l.kg^{-1}$	BPR Guidance
Concentration of suspended matter in the river	SUSPwater	15	$mg.L^{-1}$	D
Dilution factor	DILUTION	10	-	D
OUTPUT				
$PEClocal_{water}$ =	**$Clocal_{water}$**	**0.0145**	$mg.L^{-1}$	O

In order to estimate the $PEClocal_{sed}$, equation no. 50 of the BPR Guidance is applied:

$PEClocal_{sed} = (K_{susp\text{-}water} / RHO_{susp}) * PEClocal_{water} * 1000$

Where,

$K_{susp\text{-}water} = Fwater_{susp} + [Fsolid_{susp} * (Kp_{susp} / 1000) * RHOsolid]$ (24) BPR Guidance

Table 2.8.3.1-5. Input for Ksusp-water calculation

Fraction water in susp.matter	0.9	$m^3.m^{-3}$	Table 5 BPR Guidance
Fraction solids in susp.matter	0.1	$m^3.m^{-3}$	Table 5 BPR Guidance
solids-water part. Coef. of susp	4.33	$l.kg^{-1}$	eq. (23) BPR Guidance
Density of the solid phase	2500	$kg.m^{-3}$	D

Table 2.8.3.1-6. Input table for $PEClocal_{sediment}$ calculation

Concentration in surface water during emission episode	$PEClocal_{water}$	0.0145	$mg.L^{-1}$	eq. (45) BPR Guidance
Suspended matter-water partitioning coefficient	$K_{susp-water}$	1.9825	$m^3.m^{-3}$	eq. (24) BPR Guidance
Bulk density of suspended matter	RHO_{susp}	1150	$kg.m^{-3}$	eq. (18) BPR Guidance
OUTPUT				
$PEClocal_{sed}$ =		**0.025**	$mg.kg^{-1}$	O

PEC in surface water and sediment for direct emission through swimming

The estimation of the local PECs for the aquatic compartment only includes surface water and sediment for the swimming-pathway because of direct entry of b.p. in the environment. Only DEET releases are considered below.

According to ESD PT19, the local emission rate to surface water body ($Elocal_{water}$) can be calculated from the formula (Table 3-7 [3.12]):

$$Elocal_{water} = N_{swimmer} * N_{appl} * Qforma_{ppl} * AREA_{skin} * Cform_{weight} * F_{swim} * F_{waterbody} * 10^{-9}$$

Table 2.8.3.1-7. Input values used to estimate $Elocal_{water}$

Input parameters (abbrev)	Inputs	Value	Unit	Remarks
$N_{swimmers}$	Daily number of swimmers	1500	-	Set per default (see Appendix 6.3. ESD PT19).
F_{swim}	Fraction of swimmers using the repellent product	0.1	-	As a best guess it is assumed, that 2% of the swimmers use an insect repellent before entering the surface water body. This value of 0.02 for F_{swim} should be used as default value for active substance approval. However, for product authorisation a higher value (0.1) can be appropriate, to cover areas with higher insect infestation.
N_{appl}	Number of applications per day	1	d^{-1}	According to Schets et al. (2011) visits of swimmers at Dutch fresh- and seawater sites lasted 41-79 minutes per occasion in 2007 and 2009. It can be expected that during this time period, treatment with a repellent will take place only once.
$F_{waterbody}$	Fraction released to surface water body	1	-	Set per default.
$Cform_{weight}$	Active substance in the product	200	$g.kg^{-1}$	20% (information submitted by the applicant).
$Qform_{appl}$	Consumption per application	1.08	$mg.cm^{-2}$ skin	According to the amount of the product used for efficacy assays.
$AREA_{skin}$	Treated area of human skin	16600	cm^2	Set per default (see Table 3-3 ESD PT19).
RHOform	Specific density of the product	1000	$kg.m^{-3}$	Set per default.

If using this input values, $Elocal_{water}$ is 0.537 kg/d.

The surface water concentrations following swimming of humans having used an insect repellent on their skin are calculated with these equations:

$$Clocal_{water,1d} = Elocal_{water} * 10^3 * T_{emission,1d} / V_{waterbody}$$ (3.13) ESD PT19

$$Clocal_{water,91d} = Elocal_{water} * 10^3 * T_{emission,91d} / V_{waterbody}$$ (3.14) ESD PT19

$$Clocal_{water,91d-ref} = Clocal_{water,1d}[1-(e^{-kdegwater_*Temission,1d})^{Nemission,91d} / 1-e^{-kdegwater_*Temission,1d}]$$ (3.15) ESD PT19

Table 2.8.3.1-8. Input values used to estimate $PEClocal_{water}$

Input parameters (abbrev)	Inputs	Value	Unit	Remarks
$Elocal_{water}$	Local emission rate to surface water	0.537	$kg.d^{-1}$	-
$V_{waterbody}$	Volume of waterbody	435000	m^3	Set per default (see Appendix 6.3. ESD PT19).
$Kdeg_{water}$	1st order rate constant for biodegradation in surface water	0.047	d^{-1}	The rate constant for biodegradation in surface water for readily biodegradable substances can be taken from Table 7 of the Technical Guidance Document (k = 0.047 d^{-1}; EC, 2003).
$T_{emission,1d}$	Number of emission days	1	d	Concentrations of the repellent have to be calculated for emission periods of 1 day and 91 days.
$T_{emission,91d}$	Number of emission days	91	d	Concentrations of the repellent have to be calculated for emission periods of 1 day and 91 days.
$N_{emission,91d}$	Number of emission events	91	-	-

As a first tier approach, the $PEClocal_{water}$ corresponds to $Clocal_{water,91d}$ from equation 3.14 and should be used for the risk assessment, representing the worst-case situation. Therefore, **$PEClocal_{water,91d}$** is **0.1125 mg/L**.

Calculation of $PEClocal_{water}$ according to $Clocal_{water,91d\text{-}ref}$ (equation 3.15) provides a refinement option considering degradation processes in the water body. This approach is based on equations 4, 7 and 8 of the ESD for PT 18 (OECD ESD No. 14 (insecticides for stables and manure storage systems); OECD, 2006). Therefore, **$PEClocal_{water,91d\text{-}ref}$** is **0.0265 mg/L**.

In order to estimate the $PEClocal_{sed}$, equation no. 50 of the BPR Guidance is applied:

$PEClocal_{sed} = (K_{susp\text{-}water} / RHO_{susp}) * PEClocal_{water} * 1000$

The input values are:

Table 2.8.3.1-9. Input values to estimate $PEClocal_{sed}$

Input parameters (abbrev)	Inputs	Value	Unit	Remarks
$PEClocal_{water,91d}$	Concentration in surface water during emission episode (1st Tier)	0.1125	$mg.L^{-1}$	(3.14) ESD PT19
$PEClocal_{water,91d-ref}$	Concentration in surface water during emission episode (2nd Tier)	0.0265	$mg.L^{-1}$	(3.15) ESD PT19
$K_{susp-water}$	Suspended matter-water partitioning coefficient	1.9825	$m^3.m^{-3}$	(24) BPR Guidance
RHO_{susp}	Bulk density of suspended matter	1150	$kg.m^{-3}$	(18) BPR Guidance

$K_{susp-water}$ is calculated with equation no. 24 of the BPR Guidance:

$K_{susp-water} = Fwater_{susp} + [Fsolid_{susp} * (Kp_{susp} / 1000) * RHOsolid]$, where:

Table 2.8.3.1-10.

Input parameters (abbrev)	Inputs	Value	Unit	Remarks
$Fwater_{susp}$	Fraction water in suspended matter	0.9	$m^3.m^{-3}$	Table 5 BPR Guidance
$Fsolid_{susp}$	Fraction solids in suspended matter	0.1	$m^3.m^{-3}$	Table 5 BPR Guidance
Kp_{susp}	solids-water partitioning coeff. in suspended matter	4.33	$l.kg^{-1}$	eq. (23)
RHOsolid	Density of the solid phase	2500	$kg.m^{-3}$	Set per default

Kp_{susp} is calculated with equation no. 23 of the BPR Guidance:

$Kp_{susp} = Foc_{susp} * Koc$, where:

Table 2.8.3.1-11.

Input parameters (abbrev)	Inputs	Value	Unit	Remarks
Foc_{susp}	Fraction water in suspended matter	0.1	$kg.kg^{-1}$	Table 5 BPR Guidance
Koc	Fraction solids in suspended matter	43.3	$l.kg^{-1}$	-

Therefore, **$PEClocal_{sed,91d}$** is **0.193 mg/L**, as a first tier approach representing the worst-case situation. Calculation of $PEClocal_{sed,91d-ref}$ provides a refinement option; thus, **$PEClocal_{sed,91d-ref}$ = 0.045 mg/L**.

2.8.3.2 PEC in air

No information for this end-point is available for the biocidal product. Effects on the atmospheric compartment have not been considered as being of concern for the active substance.

ES CA agrees with the applicant. DEET has a vapour pressure of 0.23 Pa (25°C) /EU Endpoint List/ and a Henry's law constant of 3.93E-03 Pa*m3/mol /EU Endpoint List/. The substance is predicted to have an atmospheric half-life of 0.63 days (15.2 hours) /EU Endpoint List/. Thus an accumulation of DEET in air and long range transport is unlikely. As the substance unlikely shows significant

long-range transport, it is considered of no concern for ozone depletion. According to the TGD II, in IC5, UC36 (cosmetic odour agents; p 226), 5% of the applied amount (for substances having vapour pressure below 100 Pa) is assumed to be emitted to the air. However the half life is below the trigger value of < 2 days that is used as cut-off value to identify chemicals that could be of potential concern. The PEC of DEET in air is therefore considered to be negligible and the substance will not pose a risk to the atmospheric environment. Furthermore, according to ESD for PT19, air emissions resulting from the stage of application on human skin or garment are of minor importance since they take place non-repeatedly on a very limited area and are therefore not considered within the ESD.

2.8.3.3 PEC in soil

PEC in agricultural soils is used for risk characterisation of terrestrial ecosystems. According to the BPR Guidance section 2.3.8.5 it can be distinguished between indirect releases (i.e.: release via sewage sludge application from a STP) or direct releases when soil is the first receiving environmental compartment. However, most relevant direct emissions result from outdoor swimming and bathing after application of the product, important direct emissions to soil are therefore not expected. Besides, scenario PT 19 does not contemplate direct emissions to soil.

Indirect release

Exposure to soil via the sewer system can occur through application of sewage sludge from a STP, which can be used as a fertiliser or soil improver. The concentrations in soil arising from such application of sewage sludge will depend on the concentration of DEET in sludge, the amount of sludge applied to soil, and the volume of soil mixed with the sewage sludge

In this section the following endpoints and underlying parameters are derived:

- Local concentration in soil (averaged for a certain time period)
- Local concentration in agricultural soil (averaged over a certain time period)
- Local concentration in grassland (averaged over a certain time period)

The concentration at the regional scale is used as background concentration for the local scale and refers to the concentration in unpolluted soil resulting from deposition only. But as deposition is not considered to be a relevant exposure process the Predicted Environmental Concentration for local soils (PEClocal) is equal to the Clocal for soils.

$$\mathbf{PEClocal_{soil} = Clocal_{soil} = (1/kT) \times C_{soil\ 10}(0) * (1 - e^{-kT})}$$ Eq (66) (55) BPR Guidance

Table 2.8.3.3-1. Inputs and outputs for $PEClocal_{soil}$ calculation

INPUTS		**Value**	**Unit**	**Origin**
Averaging time	T	30	d	Table 11
First order rate constant for removal from top soil	k	0.0254	d^{-1}	eq. (56)
Initial concentration after 10 years (skin)	$C_{soil\ 10,\ skin}$ (0)	0.0216	$mg.kg^{-1}$	eq. (63)
OUTPUTS				
$PEClocal_{soil}$ =	**$Clocal_{soil}$**	**0.0135**	$mg.kg^{-1}$	O

For $PEClocal_{soil}$ air emissions are not considered because an extensive accumulation of DEET in air and long range transport is unlikely. A series of equations must be solved before obtaining this PEC value.

Constant k is obtained by applying the following formula:

$k = k_{volat} + k_{leach} + kbio_{soil}$ eq (56) BPR Guidance

Table 2.8.3.3-2. Inputs and outputs for k calculation

INPUT			
k_{volat}	0.0007	d^{-1}	eq (57)
k_{leach}	0.0016	d^{-1}	eq (58)
$kbio_{soil}$	0.0231	d^{-1}	eq (29)
OUTPUT			
k	0.0254	d^{-1}	eq (56)

The rest of the values are obtained following this step-wise procedure. In accordance with BPR Guidance the initial concentration in year 10 is:

$C_{soil10}(0) = Csludge_{soil\,10}(0) = Csludge_{soil\,1}(0) * [1 + \sum^{9}_{n=1} Facc^{n}] + Cdep_{soil10}$
eq (62/63) BPR Guidance

Table 2.8.3.3-3. Inputs and outputs for C_{soil10} (0) calculation

INPUTS		**Value**	**Unit**	**Origin**
Concentration in soil due to sludge in first year at t=0	$Csludge_{soil\,1}(0)$	0.0194	$mg.kg^{-1}$	eq (60)
Fraction accumulation in one year	Facc	9.516E-05	-	eq (61)
OUTPUT				
$C_{soil\,10}$ (0) =	$C_{sludgesoil\,10}$ (0)	0.0216	$mg.kg^{-1}$	O

Since the fraction of accumulation equals to 0, Csoil 10 (0) = Csludge 1 (0)

The concentration of DEET in soil, just after the first year of sludge application, is estimated in the following way:

$$Csludge_{soil\,1}(0) = \frac{C_{sludge} * Appl_{sludge}}{DEPTH_{soil} * RHO_{sludge}}$$ eq (60) BPR Guidance

Table 2.8.3.3-4. Inputs and outputs for $Csludge_{soil\,1}$(0) calculation

INPUTS		**Value**	**Unit**	**Origin**
Concentration in dry sewage sludge	C_{sludge}	13.199	$mg.kg^{-1}$	eq (36)
Dry sludge application rate	$APPL_{sludge}$	0.5	$kg.m^{-2}.yr^{-1}$	Table 11
Mixing depth of soil	$DEPTH_{soil}$	0.2	m	Table 11
Bulk density of soil	RHO_{soil}	1700	$kg.m^{-3}$	eq (18)
OUTPUT				
$Csludge_{soil\,1}(0)$		0.0194	$mg.kg^{-1}$	O

Where C_{sludge} (concentration in sewage sludge) is:

$$Csludge = \frac{Fstp_{sludge} * Elocal_{water} * 10^{6}}{SLUDGERATE}$$ eq (36) BPR Guidance

Table 2.8.3.3-5. Inputs and outputs for Csludge calculation

INPUTS	**Value**	**Unit**	**Origin**
Fraction of emission to sludge by STP	0.00407	-	EUSES
Local emission rate to water during episode	2.302	$kg.d^{-1}$	PT-19
Rate of sewage sludge production (SLUDGERATE)	710	$kg.d^{-1}$	eq (37)
OUTPUT			
Concentration in dry sewage sludge	13.1991	$mg.kg^{-1}$	eq (36)

Where:

$SLUDGERATE = 2/3 * SUSPCONC_{inf} * EFFLUENT_{stp} + SURPLUSsludge * CAPACITY_{stp}$
eq (37) BPR Guidance

Table 2.8.3.3-6. Inputs and outputs for SLUDGERATE calculation

INPUTS	**Value**	**Unit**	**Origin**
Concentration of suspended matter in STP influent	0.45	$kg.m^{-3}$	Table 9
Effluent discharge rate of STP	2000	$m3.d^{-1}$	eq (34)
Surplus sludge per inhabitant equivalent	0.011	$kg.d\text{-}1.eq^{-1}$	Table 9
Capacity of the STP	10000	eq	Table 9
OUTPUT			
SLUDGERATE	710	$kg.d^{-1}$	eq (37)

PEC calculations for agriculture and grassland are obtained using the same formulas but varying the depth of soil and average time (see table 11 BPR Guidance).

Agric. Soil: $PEClocal_{agr.soil} = Clocal_{agr.soil} = (1/kT) * C_{agr.soil\ 10}(0) * (1 - e^{-kT})$
eq (66) (55) BPR Guidance

Table 2.8.3.3-7. Inputs and outputs for $PEClocal_{agr.soil}$ calculation

INPUTS		**Value**	**Unit**	**Origin**
Averaging time	T	180	d	Table 11
First order rate constant for removal from top soil	k	0.0254	d^{-1}	eq. (56)
Initial concentration after 10 years (skin)	$C_{agr.soil\ 10}(0)$	0.0194	$mg.kg^{-1}$	eq. (63)
OUTPUT				
$PEClocal_{agr.soil}$ =	**$Clocal_{agr.soil}$**	**0.0042**	$mg.kg^{-1}$	O

Grassland: $PEClocal_{grassland} = Clocal_{grassland} = (1/kT) \times C_{grassland}(0) \times (1 - e^{-kT})$
eq (66) (55) BPR Guidance

Table 2.8.3.3-7. Inputs and outputs for $PEClocal_{grassland}$ calculation

INPUTS		**Value**	**Unit**	**Origin**
Averaging time	T	180	d	Table 11
First order rate constant for removal from top soil	k	0.0269	d^{-1}	eq. (56)
Initial concentration after 10 years (skin)	$C_{grassland\ 10,\ skin}(0)$	0.0077	$mg.kg^{-1}$	eq. (63)
OUTPUTS				
$PEClocal_{grassland}$ =	**$Clocal_{grassland}$**	**0.00158**	$mg.kg^{-1}$	O

2.8.3.4 PEC in groundwater

In order to confirm if the product leaches into groundwater an evaluation was conducted.
In accordance with the BPR Guidance, the concentration of the a.s. in soil porewater has been calculated to provide an indication for potential groundwater levels. It should be noted that this is a worst-case assumption, neglecting transformation and dilution in deeper soil layers.

Thus, the predicted environmental concentration in groundwater ($PEC_{localgroundwater}$) is equal to the predicted environmental concentration in porewater ($PEC_{localsoil,\ porew}$). In order to calculate the concentration of the a.s. in porewater, a number of partition coefficients are derived from the following equations:

$K_{soil\text{-}water} = Fair_{soil} * K_{air\text{-}water} + Fwater_{soil} + [Fsolid_{soil} * (Kp_{soil} / 1000) * RHOsolid]$
eq (24) BPR Guidance

Table 2.8.3.4-1. Inputs and outputs for $K_{soil\text{-}water}$ calculation

INPUTS	**Value**	**Unit**	**Origin**
Fraction air in soil	0.2	$m^3.m^{-3}$	Table 5 BPR Guidance
K Air-water partitioning coefficient	1.6586E-06	-	eq. (22)
Fraction water in soil	0.2	$m^3.m^{-3}$	Table 5 BPR Guidance
Fraction solids in soil	0.6	$m^3.m^{-3}$	Table 5 BPR Guidance
K solids-water partitioning coefficient of soil	0.866	$l.kg^{-1}$	eq (23)
Density of the solid phase	2500	$kg.m^{-3}$	D
$K_{air\text{-}water}$ = HENRY / R x TEMP (22) BPR Guidance			
Henry's law constant	0.0039	$Pa.m^3.mol^{-1}$	S
Gas constant	8.314	$Pa.m^3.mol^{-1}.k^{-1}$	D
Temperature air-water interface	285	k	D
$Kp_{soil} = F_{oc,soil}$ x K_{oc} (23) BPR Guidance			
Weight fraction of org.carbon in soil	0.02	$kg.kg^{-1}$	Table 5
Partition coeff. Org.carbon-water	43.3	$l.kg^{-1}$	S

Solving the equations for $PEC_{localgrw}$ the following results are obtained.

$PEClocal_{grw} = PEClocal_{agr.soil, porewater} = (PEClocal_{agr.soil} * RHO_{soil}) / (K_{soil-water} * 1000)$
eq (68)(67) BPR Guidance

Table 2.8.3.4-2. Inputs and outputs for $PEClocal_{agr.soil, porewater}$ calculation

INPUTS		Value	Unit	Origin
Predicted environmental conc. in soil	$PEClocal_{agr.soil}$	0.0042	$mg.kg^{-1}$	eq. (66)(55)
Soil-water partitioning coefficient	$K_{soil-water}$	1.499	$m^3.m^{-3}$	eq. (24)
Bulk density of wet soil	RHO_{soil}	1700	$kg.m^{-3}$	eq. (18)
OUTPUT				
$PEClocal_{grw}$ =	**$PEClocal_{agr.soil,porewater}$**	**0.00477**	$mg.L^{-1}$	O

$PEClocal_{grw} = PEClocal_{grassland, porewater} = (PEClocal_{grassland} \times RHO_{soil}) / (K_{soil-water} \times 1000)$
eq (68)(67) BPR Guidance

Table 2.8.3.4-3. Inputs and outputs for $PEClocal_{grassland, porewater}$ calculation

INPUTS		Value	Unit	Origin
Predicted environmental conc. in soil (skin)	$PEClocal_{soil,skin}$	0.0135	$mg.kg^{-1}$	eq (66) (55)
Soil-water partitioning coefficient	$K_{soil-water}$	1.499	$m^3.m^{-3}$	eq (24)
Bulk density of wet soil	RHO_{soil}	1700	$kg.m^{-3}$	eq (18)
OUTPUT				
$PEClocal_{grw}$ =	**$PEClocal_{grassland, porewater}$**	**0.0154**	$mg.L^{-1}$	O

The concentration in groundwater should be <0.1 µg/L for active substance, relevant metabolites or breakdown/reaction products and substances of concern. Since the values obtained are aboved this value PEC_{grw} was further refined using the nine FOCUS groundwater scenarios, as developed for plant protection products (see table 2.8.4.3-4).

2.8.3.5 Non compartment specific exposure relevant to the food chain (secondary poisoning)

No information for this end-point is available for the biocidal product. The low BCF values suggest that DEET has a low bioaccumulation potential. Therefore, no risk of secondary poisoning via ingestion of potentially contaminated food (e g earthworms or fish) by birds or mammals was identified. The product is used as a direct application skin repellent. The potential for secondary exposure from use is therefore negligible.

ES CA agrees with the applicant. Non-target animals are potentially at risk of secondary poisoning via:

(i) consumption of worms from contaminated soil
(ii) consumption of contaminated fish
(iii) consumption of contaminated vegetation, and
eating treated insects that have accumulated the poison

The use pattern of products that contain DEET ensures that the contamination of soil and ground water are negligible, has very low hazard to surface water therefore the potential for secondary poisoning is negligible.

Bioconcentration
As the log K_{ow} is < 3 (2.4), a risk for bioconcentration and biomagnification is not expected (conform the biomagnification trigger value proposed for K_{ow} in the TGD). The low BCF values also suggest that DEET has a low bioaccumulation potential. The risk for bioconcentration in the proposed use is therefore considered not relevant.

Primary and secondary poisoning of birds and mammals
As DEET has low bioaccumulation potential and due to the use pattern no risk of secondary poisoning via ingestion of potentially contaminated food (e g earthworms or fish) by birds or mammals was identified. For the terrestrial compartment, the expected negligible exposure adds to this conclusion. No avian dietary tests were required. However, acute oral avian toxicity was investigated and LD50 was determined to 1375 mg/kg bw. As DEET is not bioaccumulative and the concentrations in surface water are low, the risk for the primary and secondary poisoning is considered acceptable.

2.8.4 Risk characterisation for the environment

The risk characterisation for the environment is the comparison of the exposure estimates to the toxicity of the substance. Both aspects were already discussed in sections 2.8.2 and 2.8.3, respectively, and only the relevant values are summarised below. The environmental risk has been assessed both for the active substance (DEET)

2.8.4.1 Aquatic compartment (incl. sediment)

Even when making worst case assumptions for the local environment none of the PEC/PNEC ratios exceed 1, see tables 2.8.4.1-3 and 2.8.4.1-4.

Risk assessment for indirect emission via STP through showering and bathing of humans

Two local scenarios were assessed for indirect emission pathway, considering that the product can be applied on human skin. PECs for the local scenario were calculated using ESD for PT19 and equations in the BPR guidance, and

Estimated local PECs for microorganism (in STP), fresh surface water and sediment were almost identical in both approaches. As shown below, none of the PEC/PNEC ratios for DEET exceed 1, even if based on worst case local PEC values (Table 2.8.4.1-1).

Note that emission to surface water is expected to be worst case. Therefore risk for the marine environment is considered covered by the surface water risk assessment. Furthermore, no quantitative estimation of $PNEC_{marine\ sediment}$ is necessary because the PEC values for the marine sediment compartment will be based on EqP and the same P_{OW} and K_{oc} values. The PEC/PNEC ratios for the marine sediment compartment will therefore be the same as for the corresponding water compartment.

Table 2.8.4.1-1. PEC/PNEC ratios for the worst case local scenario for the aquatic compartments during an indirect emission episode (DEET).

Aquatic Compartment	PEC	PNEC	PEC/PNEC
Microorganisms (STP) (mg/l)	0.145	> 10	< 0.0145
Surface water (mg/l)	0.0145	0.043	0.337
Surface water sediment (mg/kg)	0.025	0.0741	0.337

Risk assessment for direct emission through swimming

In table 2.8.4.1-4 the PEC/PNEC ratios for direct emission to surface water and sediment due to swimming are indicated. The PECs were calculated using ESD PT19 The PEC/PNEC ratios for both surface water and sediment are < 1.

Table 2.8.4.1-4. PEC/PNEC ratios for the worst case local scenario for the aquatic compartments during a direct emission episode

Aquatic Compartment	PEC	PNEC	PEC/PNEC
Surface water,91d (mg/l)	0.1125	0.043	2.62
Surface water,91d-ref (mg/l)	0.0265	0.043	0.62
Sediment, 91d (mg/kg)	0.193	0.0741	2.61
Sediment, 91d-ref (mg/kg)	0.045	0.0741	0.61

2.8.4.2 Atmosphere

DEET has a vapour pressure of 0.23 Pa (25°C) /EU Endpoint List/ and a Henry's law constant of 3.93E-03 Pa*m3/mol /EU Endpoint List/. The substance is predicted to have an atmospheric half-life of 0.63 days (15.2 hours) /EU Endpoint List/. Thus an accumulation of DEET in air and long range transport is unlikely. As the substance unlikely shows significant long-range transport, it is considered of no concern for ozone depletion. According to the TGD II, in IC5, UC36 (cosmetic odour agents; p 226), 5% of the applied amount (for substances having vapour pressure below 100 Pa) is assumed to be emitted to the air. However the half life is below the trigger value of < 2 days that is used as cut-off value to identify chemicals that could be of potential concern. The PEC of DEET in air is therefore considered to be negligible and the substance will not pose a risk to the atmospheric environment. Therefore no risk assessment is performed for the atmosphere.

2.8.4.3 Terrestrial compartment

In the scenario for the swimming pathway (direct emission), the terrestrial compartment is not exposed and therefore is not assessed.

Risk assessment for indirect emission via STP through showering and bathing of humans

Exposure to soil via the sewer system can occur through application of sewage sludge from a STP, which can be used as a fertilizer or soil improver. PECs for the local scenario were calculated using ESD for PT19 and equations in the BPR guidance, and

For risk assessment purposes, the **PEC soil** values calculated using ESD for PT19 were selected as worst case scenarios. None of the PEC/PNEC ratios exceed 1 (See table 2.8.4.3-1).

Table 2.8.4.3-1. PEC/PNEC ratios for the terrestrial compartments during an indirect emission episode (PEC soil values calculated using ESD for PT19).

Terrestrial Compartment	PEC (mg/kg)	PNEC (mg/kg)	PEC/PNEC
Soil	0.0135	0.0379	0.4356
Agricultural soil	0.0042	0.0379	0.1108
Grassland	0.0158	0.0379	0.0416

Concerning the **PECs for groundwater**, estimations on porewater agricultural soil and porewater grassland using ESD for PT19 were the worst case in human skin scenario (See Table 2.8.4.3-2).

Table 2.8.4.3-2. PECs for groundwater for indirect emission to groundwater

PECporewater agr. Soil (µg/L)	PECporewater grassland (µg/L)
4.77	1.801

Considering that the calculated PECs for porewater exceed the drinking water limit for groundwater of 0.1 µg/L, PEC_{gw} for the nine FOCUS groundwater scenarios, as developed for plant protection products, were calculated. Model used, input data and assumptions are shown in table 2.8.4.3-3, assuming that the only exposure route to groundwater is via the application of sludge from STPs.

Input parameter	**Unit**	**Value**	**Reference**
Product name : ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS			
Substance active: DEET			
		DEET	**References**
Physicochemical parameters			
Molecular weight	$g.mol^{-1}$	191.27	**AR**
Water solubility (25 °C)	$mg.L^{-1}$	11200	AR
Molar enthalpy of dissolution	$kJ.mol^{-1}$	95	Default
Saturated vapour pressure (25 °C)	Pa	0.11	AR
Molar enthalpy of vaporisation	$kJ.mol^{-1}$	95	Default
Diffusion coefficient in water (20 °C)	$m^2.d^{-1}$	4.3×10^{-5}	Default
Diffusion coefficient in air (20 °C)	$m^2.d^{-1}$	0.43	Default
Degradation parameters			
Half-life (20°C, pF2)	d	30	AR
Arrhenius activation energy	$kJ.mol^{-1}$	65.4	Default
Exponent of moisture correction function	-	0.7	Default
Sorption parameters			
K_{oc} value	$L.kg^{-1}$	4609	AR
K_{om}value (20°C)	$mL.g^{-1}$	25.1E+03	AR
Freundlich exponent 1/n	-	0.9	Default
Method of subroutine description	-	pH independent	-
Crop related parameters			
Crop uptake factor	-	0	Default
Application Schemes			
Dosage	$Kg.ha^{-1}$	0.102	
Application type	-	Incorporation	
Depth	m	0.10 (alfalfa); 0.20 (maize)	
Repeat interval for years	-	1	
Date	Alfalfa	01/10/1901	
	Maize	20 days before emerging	
Crops Application			
Crop(s)	-	Grassland	
Selected Locations		CHATEAUDUN	
		HAMBURG	
		JOIKIONEN	
		KREMSMUENSTER	
		OKEHAMPTON	
		PIACENZA	

		PORTO
		SEVILLA
		THIVA

The resulting PEC_{GW} are shown in the following tables.

Alfalfa

LOCATION	**DEET**
CHATEAUDUN	0.0048
HAMBURG	0.043
KREMSMUENSTER	0.026
OKEHAMPTON	0.059
PIACENZA	0.016
PORTO	0.0018
SEVILLA	0.00003
THIVA	0.00047

Maize

LOCATION	**DEET**
CHATEAUDUN	0.0036
HAMBURG	0.0146
JOKIOINEN	0.0023
KREMSMUENSTER	0.0045
OKEHAMPTON	0.022
PIACENZA	0.014
PORTO	0.0020
SEVILLA	0.0001
THIVA	0.0001

The results show that the predicted groundwater concentration of DEET following the intended use of this substance are <0.1 µg/L for all FOCUS scenarios.
Please note that monitoring data presented in the CAR (Doc. IIC, section 13.1) from The Netherlands indicate that DEET may have a potential to leach to groundwater (1.6% of the samples analysed, contained >0.1 µg/L).

2.8.4.4 Non compartment specific exposure relevant to food chain (primary and secondary poisoning)

Overall, primary exposure of DEET to the environment is considered to occur to STPs (the user is expected to wash the repellent off the skin in the bathroom connected with the sewage system) and secondary exposure was considered for surface water and sediment from release of treated water from STPs. The water compartment is therefore expected to be exposed to DEET, and because of the physiochemical character of the substances, the emissions will continue to primarily remain in this compartment (supported by level III fugacity modelling). Additionally, secondary exposure of DEET to soil and groundwater were considered following application of sewage sludge to land. These additional secondary exposure scenarios are considered as supporting information, since exposure to these environmental compartments, based on proposed active substance content and product use pattern is highly unlikely and exposure concentrations are expected to be negligible.

There is no exposure to the soil for the proposed use. Exposure of soil organisms and non target arthropods can therefore be excluded.

As the log Kow is < 3 (2.4), a risk for bioconcentration and biomagnification is not expected (conform the biomagnification trigger value proposed for Kow in the TGD). The risk for bioconcentration in the proposed use is therefore considered not relevant. As both substances are not bioaccumulative and the concentrations in surface water are low, the risk for the primary and secondary poisoning is considered negligible. According to the risk assessment the risk on soil organisms are also negligible therefore DEET are not likely to present any unacceptable risk to the animals in the food chain.

Primary poisoning

Non-target animals such as wild and domestic animals will not come in contact with the product ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS as it is used in low amount on the human skin. The user is expected to wash the repellent off the skin in the bathroom connected with the sewage system.

Because of the smell and taste of DEET, it acts as a self deterrent against consumption by humans and animals. The ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS product contains an ingredient that acts as a strong deterrent for ingestion (Denatonium benzoate). Therefore, the oral routes are considered insignificant sources of exposure for the DEET.

Secondary poisoning

The available avian acute lethality data are not appropriate for extrapolation to chronic dietary uptake conditions (TGD II 3.8.3.5). PNECs were not calculated for oral uptake from the food chain (to quantify the risk of secondary poisoning). No further avian data were required, because DEET has a low potential for bioconcentration and bioaccumulation [log Kow <3; TGD II 3.8.2)] and because log Kow < 4.5, the primary uptake route into predators is assumed to be direct uptake from the water phase (TGD II 3.8.3.1). In addition, DEET is extensively metabolized and excreted through the urine in all assessed mammals.

In general non-target animals are potentially at risk of secondary poisoning via:

(i) consumption of worms from contaminated soil
(ii) consumption of contaminated fish
(iii) consumption of contaminated vegetation, and
eating insects that have accumulated the poison

From the above, the consumption of contaminated fish can have a negligible effect all the others are not very likely due to the following reasons:

The use pattern of products that contain DEET ensures that the contamination of soil and groundwater are negligible, has very low hazard to surface water therefore the potential for secondary poisoning is negligible. In surface waters and soil, DEET degrades at a moderate to rapid rate (its half-life is measured in days to weeks).

2.8.4.5 PBT assessment

PBT assessment is summarized in the N,N-diethyl-m-toluamide (DEET) CAR, Doc I section 2.2.2.3. PBT assessment. DEET does not meet any of the criteria for Persistent, Bioaccumulative and Toxic (PBT) substances or the very Persistent, very Bioaccumulative (vPvB) category.

2.9 Measures to protect man, animals and the environment

For the product ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS, no unacceptable risks were identified for the environment but the following risk mitigation measures are required:

Do not throw the product on the ground, into a water course, into the sink or down the drain and into the environment.

Prevent accidental exposure of the product to the environment.

In case of accedental exposure of the product to the environment: stop release, if possible without risk. Dike or contain release, if possible, and if immediate response can prevent further damage or danger. Isolate and control access to the release area. Take actions to reduce vapors. Collect substance into drums, etc. via drains, pumps, etc., if appropriate. Absorb with appropriate absorbent. Clean spill area of residues and absorbent.

For non-professional users:

- *P501: Remove the content and / or its container as hazardous waste according to the regulations in force Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations*
- *Do not release to soil, ground, surface water or any kind of sewer*
- Regarding the possibility of destruction or decontamination following release in or on the following: (a) Air, (b) Water, including drinking water, and (c) Soil:

a) The risk of release of the active ingredient or the product to atmosphere is negligible.

b) Leak/spill: Remove all sources of ignition. Use an inert absorbent material, and non-sparking tools. Ventilate area. Prevent from entering a watercourse.

Because of the smell and taste of DEET, it acts as a self deterrent against consumption by humans and animals. The ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS product contains an ingredient that acts as a strong deterrent for ingestion (denatonium benzoate). Therefore, the oral routes are considered insignificant sources of exposure for the DEET.

For the product ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS, no unacceptable risks were identified for the human health taking into account the following risk mitigation measures are required:

Apply the product sparingly and carefully to parts of the body that are not covered. Do not apply on clothing; divide the product evenly over the skin.

The biocidal product is to be applied only once a day, for adults and children over 2 years of age.

The biocidal product is not for use on children under 2 years of age.

Avoid contact with eyes, mucous membranes, nose, lips and damaged skin. Apply carefully to areas where skin folds normally occur.

Do not apply on young children´s hands. For other users, wash your hands thoroughly with soap and water before eating or drinking.

Do not mix with other chemical substances/mixtures.

When used in combination with sun block lotion, apply sun block first then wait 30 minutes before applying the biocidal product.

Wash the areas of skin that have been treated when protection is no longer needed or if side effects occur.

The biocidal product must not be applied where food, feeding stuffs or drinking water can become contaminated.

Apply hygiene measures: do not eat, drink or smoke during the applying of the product and wash hands after use.

Use only outdoors or in a well-ventilated area.

Do not inhale the product.

Keep this product away from children.

Avoid contact with plastics, synthetic-/leather clothing and painted surfaces.

Specific treatment in case of an accident, e.g. first aid measures, antidotes, medical treatment if available.

Poisoning may cause:

- Irritation of the eyes, skin, mucous membranes, respiratory and gastrointestinal tract.
- Allergic skin reaction (including anaphylaxis).
- Overuse and/or multiples dermal applications may cause neuronal disorders (behavioural disorders, ataxia, hypertonia, seizures, encephalopathy and coma).

Basic first aid procedures:

- Move the person away from the contaminated area and remove contaminated or spattered clothing
- If contact in eyes, rinse with plenty of water for 15 minutes. Do **NOT** forget to remove the contact lenses.
- If contact on skin, wash with soap and plenty of water, without rubbing. Remove the product from skin folds and from under fingernails.
- If swallowed, do **NOT** induce vomiting unless told to do so by poison control or a health care professional. Call immediately to a poison control center and if necessary take the person to a hospital and show the label or packaging whenever possible.
- Keep the patient at rest and maintain the body temperature.
- If the person in unconscious, turn the patient sideways with the head at lower than the rest of the body and the knees bended.
- If necessary take the person to a hospital and show the label or packaging whenever possible.

DO NOT LEAVE THE POISENED PERSON ALONE UNDER ANY CIRCUMSTANCE

Medical advice for doctors and sanitary staff:

- Gastrointestinal decontamination is not recommended.
- Contraindication: Syrup of Ipecac
- Symptomatic and supportive treatment.

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

3 Proposal for decision

ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS is a spray (ready-to-use) for non-professional / general public use for the purpose of spraying on the body areas to be protected that contains 20% (w/w) DEET (N, N-diethyl-meta-toluamide).

The physico-chemical properties have been evaluated and there are no hazards associated with the product under normal conditions of use.

The product has efficacy during at least the first 6 hours after application. This is supported by the efficacy against *Aedes aegypti* during the first 7 hours after application, against *Aedes albopictus* efficacy during the first 8 hours after, against *Culex spp* during the first 8 hours after application, against *Ixodes ricinus* during the first 6 hours and against *Odagmia ornate* during 4 hours.

Regarding the risk for human health of non-professional users it can be concluded that exposure to the biocidal product containing 20% DEET as active substance is considered acceptable, if the biocidal product is used as intended and all safety advices are followed: the product can be used once per day on adults and children over 2 years. Additionally, an age limit of 2 years is proposed as a cut-off for considering oral exposure in accordance with the approach used in the CAR of DEET.

The risk for the environment for the use of ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS has been evaluated when applied directly on uncovered human skin, on an application frequency of one a day. The product, containing 20 % (200 g/kg) DEET will be used to repel ticks, mosquitoes and flies. The overall conclusion is that the intended uses of ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS do not pose an unacceptable risk to the sewage treatment plant, soil, air, surface water, sediment, and groundwater compartments.

The Spanish CA authorises under certain conditions of use the biocidal product ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS as a repellent (PT19) for dermal use, against mosquito, tiger mosquito, ticks and blackflies by spraying on the body areas to be protected by non-professional users.

Particular Conditions

The biocidal product under PT19 (Repellent) ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS contains 20% (w/w) DEET (N, N-diethyl-meta-toluamide).

The active substance as manufactured shall have the following minimum purities:

DEET (N, N-diethyl-meta-toluamide): 970 g/kg

Only ready-to-use ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS product is authorised.

Read attached instructions before use.

The biocidal product acts against vector-borne topical diseases as for example yellow fever, zika virus, dengue fever or chikungunya.

The product is authorised only for use against *Aedes spp*. and *Culex spp* for on average 7 and 8 hours. The laboratory test with *Ixodes ricinus* shows that ticks are repelled for the first 6 hours and against the blackflies *Odagmia ornate* during 4 hours. Authorisation of this product does not allow use against non-target organisms.

The application for adults and children over 2 years of age must be restricted to one application a day.

The biocidal product is not for use on children under 2 years of age.

Apply the product sparingly and carefully to parts of the body that are not covered. Do not apply on clothing; divide the product evenly over the skin.

Keep the spray bottle at least 15 cm from the skin; do not spray directly on the face. To protect the face from insect bites, first spray or spread a small quantity of the product onto the palm of the hand and then spread on the face.

Avoid contact with eyes, mucous membranes, nose, lips and damaged skin. Apply carefully to areas where skin folds normally occur.

Do not apply on young children´s hands. For other users, wash your hands thoroughly with soap and water before eating or drinking.

The product contains an aversive or bittering agent.

Do not mix with other chemical substances/mixtures.

When used in combination with sun block lotion, apply sun block first then wait 30 minutes before applying the biocidal product.

Wash the areas of skin that have been treated when protection is no longer needed or if side effects occur.

The biocidal product must not be applied where food, feeding stuffs or drinking water can become contaminated.

Apply hygiene measures: do not eat, drink or smoke during the applying of the product and wash hands after use.

Use only outdoors or in a well-ventilated area.

Do not inhale the product.

Keep this product away from children.

Avoid contact with plastics, synthetic-/leather clothing and painted surfaces.

The packaging of the product placed on the market has to be limited to a maximum size of 200ml.

Do not throw the product on the ground, into a water course, into the sink or down the drain.

Dispose of contents/container as a hazardous waste at household waste recycling centres.

Remove the content and / or its container as hazardous waste according to the regulations in force.

Expiry Date of the Authorisation:

The authorisation of the product ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS expires on 31 July 2022, which is the expiry date of Annex I listing of the active substance DEET (N, N-diethyl-meta-toluamide).

Annex:

1. **Summary of product characteristics**
2. **List of studies reviewed**
3. **Analytical methods residues – active substance**
4. **Toxicology and metabolism –active substance**
5. **Toxicology – biocidal product**
6. **Safety for professional operators**
7. **Safety for non-professional operators and the general public**
8. **Residue behaviour**

Annnex 1: Summary of product characteristics for a biocidal product

Summary of product characteristics for a biocidal product

ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS

Product type(s) [19]

ES/APP(NA)-2016-19-00379

ES-0008886-0000

1. Administrative information

1.1. Trade name(s) of the product

Trade name(s)[4]	ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS

1.2. Authorisation holder

Name and address of the authorisation holder	**Name**	GRUPO AC MARCA (LABORATORIOS GENESSE, S.L.)
	Address	Avda. Carrilet, 293-299 08907 – Barcelona
Authorisation number	ES/APP(NA)-2016-19-00379	
Suffixes to the authorisation number linked to trade names[5]		
R4BP asset reference number	ES-0008886-0000	
Date of the authorisation	28/06/2016	
Expiry date of the authorisation	31 July 2022	

1.3. Manufacturer(s) of the product

Name of manufacturer 1	Marca CZ s.r.o.
Address of manufacturer	Prisimasy 124, 282 01 Cesky Brod, ICO 63668262 Czech Republic
Location of manufacturing sites	Prisimasy 124, 282 01 Cesky Brod, ICO 63668262 Czech Republic

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

Active substance	DEET (N,N-diethyl-m-toluamide)
Name of manufacturer	Vertellus Performance Materials Inc. (formerly Morflex, Inc.)
Address of manufacturer	Vertellus Performance Materials Inc. 2110 High Point Road Greensboro (NC) NC 27403 (USA)
Location of manufacturing sites	Vertellus Performance Materials Inc. 2110 High Point Road Greensboro (NC) NC 27403 (USA)

[4] In case the product would have more than one name, all names can be provided in this field.

[5] Where relevant for the Member State delivering a national authorisation. Insert rows as necessary.

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
DEET	N, N-diethyl-m-toluamide	Active substance	134-62-3	205-149-7	20
2-phenoxyethanol	-	Preservative	122-99-6	204-589-7	0.58
-	-	Non active substances	-	-	-

2.2. Type of formulation

Spray

3. Hazard and precautionary statements[6]

Hazard statements	H319: Causes serious eye irritation EUH208: "Contains benzyl salicylate, butylphenyl methylpropional, cinnamyl alcohol, citronellol, linalool and alpha-isomethyl ionone. May produce an allergic reaction"
Precautionary statements	P102: Keep out of reach of children P103: Read label before use P264: Wash … thoroughly after handling P501: Dispose of content and / or its container as hazardous waste in accordance with current regulations

4. Authorised use(s)

4.1. Use description[7]

Table 1. Use # 1 – Repellent – Mosquitoes, ticks and blackflies– Non-professional user (general public) – Adults and children over 2 years of age - Spray – Indoor and Outdoor use

Product Type	PT19, repellent
Where relevant, an exact description of the authorised use	Repellent against mosquitoes, ticks and blackflies for human hygiene
Target organism(s) (including development stage)	Mosquitoes: *Aedes albopictus, Aedes aegypti* and *Culex spp* Tick: *Ixodes ricinus* Blackfly: *Odagmia ornate*
Field(s) of use	Indoor and outdoor use in a well-ventilated area
Application method(s)	Topical application in human skin by spray

[6] According to Regulation (EC) 1272/2008, or where relevant, Directive 1999/45/EC. This section shall only include precautionary statements triggered by the CLP legislation. In accordance with paragraph 8 of document CA-May13-Doc.5.4, a precautionary statement that has been proven unnecessary in the risk assessment because of the intended use of the product should be left out of the SPC and of the label. For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

[7] Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a single biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

Application rate(s) and frequency	The product is to be applied once a day for adults and children over 2 years of age. The maximum time protection is during 6 hours for mosquitoes and ticks and during 4 hours for blackflies
Category(ies) of users	Non professional user (general public)
Pack sizes and packaging material	The biocidal product is packaged in HDPE bottles of sprays of 100 and 200ml.

4.1.1. Use-specific instructions for use[8]

See section 5.1

4.1.2 Use-specific risk mitigation measures

See section 5.2

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

See section 5.3

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

See section 5.4

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

See section 5.5

5. General directions for use[9]

5.1. Instructions for use[6]

Read attached instructions before use The biocidal product acts against vector-borne tropical diseases as for example yellow fever, zika virus, dengue fever or chikungunya. Apply the product sparingly and carefully to parts of the body that are not covered. Do not apply on clothing; divide the product evenly over the skin. Keep the spray bottle at least 15 cm from the skin; do not spray directly on the face. To

[8] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

[9] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

protect the face from insect bites, first spray or spread a small quantity of the product onto the palm of the hand and then spread on the face.

The biocidal product is to be applied only once day, for adults and children over 2 years of age.

The biocidal product is not for use on children under 2 years of age.

Do not throw the product on the ground, into a water course, into the sink or down the drain.

5.2. Risk mitigation measures

Avoid contact with eyes, mucous membranes, nose, lips and damaged skin. Apply carefully to areas where skin folds normally occur.

Do not apply on young children´s hands. For other users, wash your hands thoroughly with soap and water before eating or drinking.

The product contains an aversive or bittering agent.

Do not mix with other chemical substances/mixtures.

When used in combination with sun block lotion, apply sun block first then wait 30 minutes before applying the biocidal product.

Wash the areas of skin that have been treated when protection is no longer needed or if side effects occur.

The biocidal product must not be applied where food, feeding stuffs or drinking water can become contaminated.

Apply hygiene measures: do not eat, drink or smoke during the applying of the product and wash hands after use.

Use only outdoors or in a well-ventilated area.

Do not inhale the product.

Keep this product away from children.

Avoid contact with plastics, synthetic-/leather clothing and painted surfaces.

The packaging of the product placed on the market has to be limited to a maximum size of 200ml.

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

Poisoning may cause:

- Irritation of the eyes, skin, mucous membranes, respiratory and gastrointestinal tract.
- Allergic skin reaction (including anaphylaxis).
- Overuse and/or multiples dermal applications may cause neuronal disorders

(behavioural disorders, ataxia, hypertonia, seizures, encephalopathy and coma).

Basic first aid procedures:

- Move the person away from the contaminated area and remove contaminated or spattered clothing
- If contact in eyes, rinse with plenty of water for 15 minutes. Do **NOT** forget to remove the contact lenses.
- If contact on skin, wash with soap and plenty of water, without rubbing. Remove the product from skin folds and from under fingernails.
- If swallowed, do **NOT** induce vomiting unless told to do so by poison control or a health care professional. Call immediately to a poison control center and if necessary take the person to a hospital and show the label or packaging whenever possible.
- Keep the patient at rest and maintain the body temperature.
- If the person in unconscious, turn the patient sideways with the head at lower than the rest of the body and the knees bended.
- If necessary take the person to a hospital and show the label or packaging whenever possible.

DO NOT LEAVE THE POISENED PERSON ALONE UNDER ANY CIRCUMSTANCE

Medical advice for doctors and sanitary staff:

- Gastrointestinal decontamination is not recommended.
- Contraindication: Syrup of Ipecac
- Symptomatic and supportive treatment.

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

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

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

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

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

The product is stable for 3 years at ambient temperature

6. Other information

Definition of non-professional users (general public): users who are not professionals and that apply the biocidal product is in his private life.

Annex 2: List of studies reviewed

List of <u>new data</u>[10] submitted in support of the evaluation of the active substance

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No

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

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
B 3.7	Internal report	Lab. Genesse	2016	Ecran Repel & Care Repelente de Mosquitos . Estabilidad 1-2-3 Años	Laboratorios GENESSE (Grupo AC MARCA)		X	X	
B 4	Report nº 2012/580SA Mi	Meluso	2012	Set up and Validation of a GC Method for the Identification and Quantification of active ingredient DEET in the test product ECRAN Repel & Care Repelente de Mosquitos	Eurofins Biolab S.r.l.		X	X	
IIIB6.2	0147.01-12	R. Ferrer, A. Vila-Ferrán	2012	Dermal Irritation. Laboratory: MICROBIOS	Laboratorios GENESSE (Grupo AC MARCA)		x	x	
IIIB6.2	0147.01-12	R. Ferrer, A. Vila-Ferrán	2012	Ocular Irritation. Laboratory: MICROBIOS	Laboratorios GENESSE (Grupo AC MARCA)		x	x	

10 Data which have not been already submitted for the purpose of the Annex I inclusion.

Annex 3: Analytical methods residues – active substance

<Active Substance>

Matrix, action levels, relevant residue and reference

matrix	limit	relevant residue	reference or comment
plant products			Not required as the use pattern of DEET will not results in any contact with food or feeding stuffs
food of animal origin			Not required as the use pattern of DEET will not results in any contact with food or feeding stuffs
soil	LOQ 0.01 mg/Kg		LC-MS/MS
water	LOQ: 1.0 ng/L LOD:0.02 ng/mL (equivalent to 0.2 ng/L in water)		The UPLC-MS/MS method in ground and drinking water was demonstrated to be accurate, precise, sensitive and specific.
surface water	LOQ: 0.1 µg/L		UPLC-MS/MS
air			No method considered required based on the use pattern and properties of DEET
body fluids / tissues	LOQ 49.4µg/L	In blood plasma	HPLC-UV. No confirmatory method provided. No further data required as DEET is not classified as toxic or highly toxic.

Methods suitable for the determination of residues (monitoring methods)

Methods for products of plant origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner
				Not necessary, since the contemplated use of DEET does not involve contact with food or feed	

Methods for foodstuffs of animal origin

reference	matrix	LOQ (mg/kg)	principle	comment	owner
				Not necessary, since the contemplated use of DEET does not involve contact with food or feed	

Methods for soil

reference	LOQ (mg/kg)	principle	comment	owner
	0.01	LC-MS/MS		DEET - EUJV

Methods for drinking water and surface water

reference	matrix	LOQ (µg/l)	principle	comment	owner
	Drinking and ground water	1.0 ng/L	UPLC-MS/MS		DEET - EUJV
	Surface water	0.1µg/L			

Methods for air

reference	LOQ (µg/m3)	principle	comment	owner
			No method has been considered necessary, based on the contemplated use and properties of DEET, and the representative product.	

Methods for body fluids/tissue

reference	matrix	LOQ (mg/kg)	principle	comment	owner

reference	matrix	LOQ (mg/kg)	principle	comment	owner
	Blood plasma	49.4µg/L	HPLC-UV	No further data Required as DEET is not classified as toxic or highly toxic	DEET - EUJV

Annex 4: Toxicology and metabolism –active substance

<DEET>

This information can be consulted in the Assessment Reports of the active substance DEET (N,N-diethyl-m-toluamide)

Annex 5: Toxicology – biocidal product

<Biocidal Product>

General information

Formulation Type	emulsion (ready-to-use)
Active substance(s) (incl. content)	20% DEET
Category	

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)	
Rat LD50 oral (OECD 420)	Justification for non submission of data*
Rat LD50 dermal (OECD 402)	Justification for non submission of data*
Rat LC50 inhalation (OECD 403)	Justification for non submission of data*
Skin irritation (OECD 404)	No irritant
Eye irritation (OECD 405)	Irritant to eyes
Skin sensitisation (OECD 429; LLNA)	Justification for non submission of data*

***** Justification for non-submission of data has been submitted for acute oral, dermal, inhalation toxicity and skin sensitisation. Eye and skin irritation studies were submitted. In addition, the information derived from existing data on the active substance DEET and co-formulants has been used, in order to minimise animal testing.

Dermal Absorption:

No study was submitted with the biocidal product. Therefore, taking into account the EFSA or OECD guidance on dermal absorption, a default dermal absorption value of 25% will be applied because the biocidal product contains >5% active substance.

Acute toxicity:

No studies were submitted for the biocidal product. Justification for non-submission of data has been submitted for acute oral, dermal and inhalation toxicity. The Spanish CA accepts the applicant's justification and the data package.

The active substance DEET is classified as dangerous substances by oral acute toxicity but it does not exist in concentration that contributes to the classification of the product. In addition, according to CLP Regulation, where the mixture itself has not been tested to determine its acute toxicity, but there are sufficient data on the individual ingredients and similar tested mixtures to adequately characterise the hazards of the mixture, these data shall be used in accordance with the bridging rules. The acute toxicity estimate (ATE_{mix}) of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula for oral, dermal or inhalation toxicity:

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

where:

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

Considering the LD_{50} (oral) value and concentration of DEET and other possible components of the biocidal product, the ATE_{mix} is 9041 mg/kg and the biocidal product is not classified by oral acute toxicity according to CLP Regulation, table 3.1.1.

In addition, the biocidal product ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS does not contain any dangerous substance classified by dermal acute toxicity. About inhalation acute toxicity, after a data research and an evaluation of every single co-formulants, there are not any substance as dangerous by inhalation route. In addition, the study of acute inhalation toxicity was waived because the inhalation route is excluded due to the use outdoor, and because the use indoor only takes place in summer, in situations where there is a high ventilation rate. Furthermore, as reported in the CAR of DEET, the active substance is a low volatile compound that has not and high distribution in air compartment. In conclusion, the biocidal product is not classified by dermal and inhalation acute toxicity.

Irritation and corrosivity:

Skin irritation

The active susbtance was considered to be skin irritant. In addition, there is a study performed with the biocidal product. Considering the study, the biocidal product is not classified as irritant to skin. A summary of the study is given below:

Species	**Method**	**Average score (24, 48, 72h)**		**Result**	**Remark**	**Reference**
		Erythema	Oedema			
Rabbit	OECD 404 GLP	0 (0-0-0)	0 (0-0-0)	Completely reversible	Not irritating	B6.2

Eye irritation

The active substance DEET was classified in the CAR as irritant to eyes according to Directive 1999/45/EC and according to CLP Regulation, Annex VI. In addition, there is a study performed with the biocidal product:

Species	**Method**	**Average Score**				**Reversibility Yes/No**	**Result**	**Reference**
		Cornea	*Iris*	*Conjunctiva*				
				Inflammation	*Redness*			
Rabbit	OECD 405 GLP	1.33	0	0.66	1.44	Yes	Irritating	B6.2

On the basis of the above data, the biocidal product ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS is irritating to the skin or eyes. According to CLP Regulation (corneal opacity ≥ 1), the biocidal product is classified as Eye Irrit.2 with the hazard statement H319 (Causes serious eye irritation.

Skin sensitisation:

No study was submitted with the biocidal product. Nevertheless, some substances included in the biocidal product could produce an allergic reaction. These substances (fragances) and soothing are not present in the biocidal product at sufficient concentration(s) to trigger a human health classification but, according to the Regulation 286/2011 of 10 March 2011 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (section 2.8, Annex II), the label on the packaging of mixtures not classified as sensitising but

containing at least one substance classified as sensitising and present in a concentration equal to or greater than that specified in Table 3.4.6 of Annex I, of this regulation, shall bear the statement:

EUH208 — "Contains (name of sensitising substance). May produce an allergic reaction".

For this reason, the label of ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS will include the statement: EUH 208: "Contains benzyl salicylate, butylphenyl mehtylpropional, cinnamyl alcohol, citronellol, linalool and alpha-isomethyl ionone. May produce an allergic reaction" according to CLP Regulation.

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)
Short-term toxicity studies Toxicological data on active substance(s) (not tested with the preparation) Toxicological data on non-active substance(s) (not tested with the preparation) Further toxicological information

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Directive 1999/45/EC	
Regulation 1272/2008/EC	Eye irrit. 2 H319: Causes serious eye irritation EUH 208: "Contains benzyl salicylate, butylphenyl mehtylpropional, cinnamyl alcohol, citronellol, linalool and alpha-isomethyl ionone. May produce an allergic reaction"

Annex 6: Safety for professional operators

ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS

ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS is not intended for professional use.

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

ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS

General information	
Formulation Type	spray (ready-to-use)
Active substance(s) (incl. content)	20% DEET
Category	
Authorisation number	ES/APP(NA)-2016-19-00XXX

DEET (N,N-diethyl-m-toluamide)

Data base for exposure estimation	
according to	Appendix: Toxicology and metabolism – active substance/CAR and UK Proforma (reverse scenario

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

Conclusion:

Regarding the risk for human health of non-professional users it can be concluded that there is risk for each subpopulation (adults, children < 12 years old, and children > 12 years old): the product can be used once per day on adults and children over 2 years. Children's hands must not be treated with this product. Children under 2 years must not be treated with this product.

For reasons of public health, GOIBI ANTIMOSQUITO FAMILY SPRAY must be authorized on the grounds of Article 19(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2019 concerning the market and use of biocidal product.

Details for the exposure estimates:

Internal dermal dose a.s. = (Number of applications) × External dermal dose product × (content a.s.) × (% dermal absorption)

Internal oral dose a.s. = (Number of applications) × External oral dose product × (content a.s.) × (% ingested amount)

Total dose a.s.= Internal dermal dose a.s + Internal oral dose a.s

External dose (x mg/kg/d product) = AELrepeated / Internal dose (x mg/kg/d a.s.)

Number of sprays = External dose (x mg/kg/d product) /Amount of spray in a single spray spot (mg)

Area of skin (limit dose) = External dose (x mg/kg/d product) / Efficacy

Number of applications = Area of skin (limit dose)/Area could be treated

ECRAN REPEL & CARE SPRAY REPELENTE DE MOSQUITOS DEET 20%

Scenario	**Adult / Children >**	**Children 6 to < 12**	**Children 2 to < 6**

	12		
potential Dermal (applied)			
nº application/day	1	1	1
Concentration DEET (% w/w)	20	20	20
AELdermal (mg a.s./kg bw/day) = Application rate "saferty"	8,2	8,2	8,2
Body weight (kg)	60	23,9	15,6
Dermal absorption (%)	25	25	25
Oral absorption (%)	100	100	100
Dermal (0,96 mg product/Kg/day) / (1 mg product/Kg/day)	**0,96**	**0,92**	**0,92**
Oral (0,04 mg product/Kg/day) / (1 mg product/Kg/day)	**0,04**	**0,08**	**0,08**
Amount of a.s. (mg) per mg product (Dermal) = (mg a.s/Kg/day) / (mg product/Kg/day) INTERNAL DOSE A.S	**0,0480**	**0,0460**	**0,0460**
Amount of a.s. (mg) per mg product (Oral) = (mg a.s/Kg/day) / (mg product/Kg/day) INTERNAL DOSE A.S	**0,0080**	**0,0160**	**0,0160**
Amount of a.s. (mg) per mg product (dermal + oral) = (mg a.s/Kg/day) / (mg product/Kg/day) TOTAL DOSE A.S.	**0,0560**	**0,0620**	**0,0620**
Amount of PRODUCT applied to reach repeted AEL (mg product /Kg/day)	**146**	**132**	**132**
Amount of PRODUCT applied to reach repeted AEL (mg product /day)	**8786**	**3161**	**2063**
Efficacy (0,65 g/600 cm2)	0,0011	0,0011	0,0011
Area of skin that can be treated with product in one day [cm2]	**8110**	**2918**	**1905**
Body surface (cm2)	16660	9200	6800
Number of applications	**0,5**	**0,3**	**0,3**
% skin that can be treated	**49**	**32**	**28**

Annex 8: Residue behaviour

<Active Substance>

Intended Use (critical application)
Active substance(s):20% DEET
Formulation of biocidal product: emulsion (ready-to-use)
Place of treatment: Apply the spray on the body areas to be protected

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

The acute or chronic exposure to residues in food resulting from the intended uses is unlikely to cause a risk to consumers. Regarding consumer health protection, there are no objections against the intended uses.