Product Assessment Report

AROX na komary, kleszcze i meszki

Biocidal product assessment report related to national authorisation under Biocidal Product Regulation 528/2012

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1 General information about the product application

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1.1.1 Person authorised for communication on behalf of the applicant

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1.2 Information about the product application

Application received:	30 July 2012
Application reported complete:	09 May 2013
Type of application:	Application for national authorisation
Further information:	n.a.

1.3 Information about the biocidal product

1.3.1 General information

Trade names:	*AROX na komary, kleszcze i meszki*

	AROX na komary, kleszcze i meszki STANDARD *AROX na komary STANDARD* *AROX na kleszcze STANDARD* *AROX na meszki STANDARD* *Insekt Stop* *Komar Stop* *Insekt Blok* *Bug Block* *Mosquito Block* *Tick Block* *Black flies block* *Bite Block* *Komar-Blok* *Meszka-Blok* *Kleszcz-Blok* *Insect Block* *bzzzSTOP* *Magic Repellent* *Lotion Shake-off* *Bug-off-Lotion* *Skin guard* *TAMER na komary kleszcze i meszki* *CIOS na komary kleszcze i meszki*
Manufacturer's development code number(s), if appropriate:	No code assigned
Product type:	19 (Repellents and attractants)
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	DEET 19.5% Ethanol 8.33%
Formulation type:	Lotion
Ready to use product (yes/no):	Yes
Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); **If yes: authorisation/registration no. and product name:** **or** **Has the product the same identity and composition like the product evaluated in connection with the**	No

approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):	

1.3.2 Information on the intended use

Overall use pattern (manner and area of use):	outdoor (against ticks and black flies) indoor (against mosquitoes and black flies)
Target organisms:	Mosquitoes (*Culicidae*), Ticks (*Ixodidae*) Black flies (*Simulidae)*
Category of users:	Non-professional
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	Ready to use product intended to use on skin
Potential for release into the environment (yes/no):	Yes
Potential for contamination of food/ feedingstuff (yes/no)	No
Use Restrictions:	Please refer to section 2.9

1.3.3 Information on active substance

Active substance chemical name:	N,N-diethyl-m-toluamide (DEET)
CAS No:	134-62-3
EC No:	205-149-7
Purity (minimum, g/kg or g/l):	970 g/kg
Inclusion directive:	2010/51/EU
Date of inclusion:	01.08.2012
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes

Manufacturer of active substance used in the biocidal product

Company Name:	Vertellus Specialties Inc.
Address:	201 N Illinois Street, Suite 1800
City:	Indianapolis
Postal Code:	IN 46204

Country:	USA
Telephone:	317 248 65 48
Fax:	-
E-mail address:	hschwab@vertellus.com
Address of manufacturing site	Vertellus Performance Materials Inc 2110 West Gate City Blvd Greensboro, NC 27403 USA

1.3.4 Information on the substance(s) of concern

Substance chemical name	Ethanol
CAS No:	64-17-5
EC No :	200-578-6
Purity (minimum, g/kg or g/l):	960 g/kg
Typical concentration (minimum and maximum, g/kg, or g/l):	83.30 g/kg
Relevant toxicological/ecotoxicological information:	-
Original ingredient (trade name):	-

1.4 Documentation

1.4.1 Data submitted in relation to product application

Please see Annex 2.

1.4.2 Access to documentation

„Agrecol" Sp. z o.o. has letter of access to data held by Vertellus Specialties Inc., which was used to support the Annex I listing of the active substance DEET according to Directive 98/8/EC.

2 Summary of the product assessment

2.1 Identity related issues

The biocidal product *AROX na komary, kleszcze i meszki* contains 19.5% of the active substance N,N-diethyl-m-toluamide, DEET (purity > 970 g/kg).

Product contains ethanol which should be treated as substance of concern.

The source of active substance used in the biocidal product is identical to the source of active substance listed in a Union list of approved active substances.

2.2 Classification, labelling and packaging

2.2.1 Classification and labelling according to the CLP Regulation 1272/2008/EC

Signal word and pictogram	Hazard Statement	
	**H226**	Flammable liquid and vapour
	**H318**	Causes serious eye damage

EUH208	Contains d-limonene and citral. May produce an allergic reaction

Precautionary Statements:	**P102**	Keep out of reach of children
	P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
	P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing
	P310	Immediately call a POISON CENTER or doctor

2.2.2 Packaging of the biocidal product

The packaging details for the biocidal product, *AROX na komary, kleszcze i meszki*, for non-professional users are outlined in table below.

Packing type	Pack sizes for non-professional users
plastic pump bottle	50 ml (50g)

plastic pump bottle	75 ml (75g)
plastic pump bottle	100 ml (100g)
plastic pump bottle	150 ml (150g)
plastic pump bottle	200 ml (200g)
plastic pump bottle	250 ml (250g)

2.3 Physical-chemical properties and analytical methods

2.3.1 Physical-chemical properties

Physical-chemical properties of the active substance:

The letter of access from Vertellus Specialties Inc., granted to „Agrecol Sp. z o.o.”., has been submitted for the active substance therefore no additional information for this point is needed.

Physical-chemical properties of the biocidal product:

The product *AROX na komary, kleszcze i meszki* is ready-to-use lotion repellent containing DEET as the active substance. The product *AROX na komary, kleszcze i meszki* is creamy, viscous, white liquid with a lemon odour. Since none of the components are classified as explosive or oxidizing, it can be anticipated that *AROX na komary, kleszcze i meszki* has neither explosive nor oxidizing properties (also confirmed by structural analysis of individual ingredients). The flash-point of the product was determined and is equal to 57°C. Taking into consideration this fact and also information that one of the components of the product is classified as flammable liquid category 2 (ethanol 8.33 %), the product *AROX na komary, kleszcze i meszki* should be classified as flammable liquid category 3.

For this product the relative density (D^{20}_4) was equal to 1.005 and it pH = 5.8. It is characterized by kinematic viscosity equal to 5721 mm^2/sec in 20°C.

Because the product is all ready to use, no data on technical properties is considered required.

The active substance content decreased from 19.4 $\pm$ 0.1 %, to 19.3 $\pm$ 0.1 % after accelerated storage stability test (8 weeks in temperature 40°C). According to the study report, the product was stored in commercial packaging but it was no described precisely. In the real-time stability test the active substance content decreased from 19.4 $\pm$ 0.1 %, to 18.9 $\pm$ 0.1 % after 36 month. The loss of 0.51% is acceptable taking into consideration formulation type. The physical state, colour, odour, visual inspection of container (plastic pump bottle) and pH measurement were conducted. No changes of product after storage during 36 months were observed.

Taking into consideration results from above storage stability tests, the shelf life of the product is considered acceptable up to three years in ambient conditions.

	Method	Purity/ Specification	Results	Reference
Physical state and nature	EPA OPPTS 830.6303 Physical State	Mosquito and Tick Repellent Lotion, 19.6% DEET batch no (lot No.) KI/83066	creamy, viscous liquid	484.191.3734
Colour	EPA OPPTS 830.6302 Colour	Mosquito and Tick Repellent Lotion, 19.6% DEET batch no (lot No.)	White	484.191.3734

		KI/83066		
Odour	EPA OPPTS 830.6304 Odor	Mosquito and Tick Repellent Lotion, 19.6% DEET batch no (lot No.) KI/83066	Lemon	484.191.3734
Explosive properties	n.a	n.a	Due to the properties of components it can be assumed that *AROX Lotion for mosquitoes ticks and black flies* does not possess explosive properties.	n.a
Oxidizing properties	n.a	n.a	Due to the properties of components it can be assumed that *AROX Lotion for mosquitoes ticks and black flies* does not possess oxidizing properties.	n.a
Flash point	ASTM D7094-04	Mosquito and Tick Repellent Lotion Filling Solution 19.6% DEET batch no (lot No.) 110313/2012	Flash point at 57 °C	484.191.4186
Sustained Combustibility	Manual of Tests and Criteria, L.2, Part III, section 32; United Nations, 2009	Mosquito and Tick Repellent Lotion without Fragrance 20.4% DEET	Mosquito and Tick Repellent Lotion without Fragrance is not sustaining combustion.	484.191.4487
Autoflammability	n.a	n.a	The self-ignition none of individual components occurs so it can be assumed that *AROX Lotion for mosquitoes ticks and black flies* is not autoflammable.	n.a
Other indications of flammability	n.a.	n.a.	n.a.	n.a.

Acidity / Alkalinity	CIPAC MT 191	Mosquito and Tick Repellent Lotion Filling Solution 19.6% DEET batch no (lot No.) 110313/2012	pH: 5.8 at 20°C	484.191.3736
Relative density / bulk density	A3 (EC) No. 440/2008 - OECD 109 - CIPAC MT3 - OPPTS 830.730 EPA 712-C-96-035	Mosquito and Tick Repellent Aerosol, 19.6% DEET batch no (lot No.) 110313/2012	D^{20}_4= 1.005	484.105.3735
Storage stability – stability and shelf life	CIPAC MT 46 (8 weeks 40 °C)	Mosquito and Tick Repellent Lotion, 19.6% DEET batch no (lot No.) KI/83066	DEET content: at start: 19.4 ± 0.1 %, at the end: 19.3± 0.1 %	484.105.3733
	Stability test in commercial packaging. The sample was stored for 3 years	Mosquito and Tick Repellent Lotion, 19.6% DEET batch no (lot No.) KI/83066	DEET content: at start: 19.4 ± 0.1 %, at the end: 18.9± 0.1 %	484.105.3733
Effects of temperature	CIPAC MT 46	Mosquito and Tick Repellent Lotion, 19.6% DEET batch no (lot No.) KI/83066	Mosquito and Tick Repellent Lotion is stable for eight weeks at 40 °C	484.105.3733
Reactivity towards container material	Stability test in commercial packaging. The sample was stored for 3 years	Mosquito and Tick Repellent Lotion, 19.6% DEET batch no (lot No.) KI/83066	Intact package and label, dispenser works properly.	484.105.3733
Technical characteristics	n.a.	n.a.	n.a.	n.a.

in dependence of the formulation type				
Compatibility with other products	n.a.	n.a.	Mosquito and Tick Repellent Lotion is not intended for mixtures with any other products.	n.a.
Surface tension	n.a.	n.a.	Based on TNsG on Product Evaluation (2008) the justification of non-submission was submitted to RMS.	n.a.
Viscosity	OECD 114	Mosquito and Tick Repellent Lotion Filling Solution batch no (lot No.) 110313/2012	**At 20°C** (dynamic): 5750 mPa*sec (kinematic): 5721 mm^2/sec **at 40°C** (dynamic): 2630 mPa*sec (kinematic): 2640 mm^2/sec	484.191.3737
Particle size distribution	n.a.	n.a.	n.a.	n.a.

2.3.2 Analytical methods

Analytical method for determination of the active substance in the biocidal product

For the product, a GC-FID method was provided, which was used for all products. The validation includes the "AROX DEET Lotion 19,5%" (Laboratorium Z.Ch. Organika-Azot S.A. w Jaworznie, 2014).

The analytical method is based on dilution with acetone, using an amount of 3 g lotion product (placed to warm water bath to evaporated volatile ingredients), diluted in 50 ml acetone, transferred of 10 mL sample into a flask, added of 10 ml internal standard (1.25g heptadecane diluted in 250 ml acetone), refilled acetone to 25 ml and injected into the GC system.

Specificity

No interference based on representative chromatograms.

Linearity

r=0,9987; y=1.2699x+0,0193 (for representative calibration curve), n=3x5 (5 sets of 3 measurements), range 65-130% of the theoretical concentration (100% = 2.4 mg/mL).

Accuracy

Mean recovery 101,5%

Precision

1,5% SD; 0,3% RSD

	Principle of method
Technical active substance as manufactured:	The letter of access from Vertellus Specialties Inc., granted to „Agrecol Sp. z o.o.”., has been submitted for the active substance therefore no additional information for this point is needed
Impurities in technical active substance:	The letter of access from Vertellus Specialties Inc., granted to „Agrecol Sp. z o.o.”., has been submitted for the active substance therefore no additional information for this point is needed
Active substance in the formulation:	GC-FID method was provided.

Residue analytical method in air

The method for identification of DEET was not submitted during the evaluation process for active substance. Due to the fact that the active substance’s vapour pressure is higher than borderline value 0.01 Pa the method for identification residues in air was needed. Applicant has been submitted new method which was developed and validated according to requirements (SANCO/825/00 rev 8.1).

Method description

Air is drawn through a Tenax cartridge for 6 hours at 1L/min (360L air) at 35°C and 80%RH and at 20°C and 30%RH, followed by desorption with acetone and dilution in methanol,followed by analysis by HPLC-MS/MS with external standardisation.

The LC-MS/MS method submitted is acceptable and complies with SANCO/825/00 rev 8.1 and TNsG validation requirements. The required LOQ of 0.225mg/m3, based on the lowest AELacute of 0.75 mg/kg bw/day, is met.

Target analyte	Method /equipment	Specificity	Linearity	Accuracy (min-max (mean)) [%]		Repeatability [% RSD]
DEET	LC-MS/MS 192->119 m/z 35°C, 80%RH	No interference	0.2 – 5ng/L, n=9 r^2 = 0.9994 y=799154x+ 54527.8	Control (n=2)	Not detected	-
				0.225mg/m^3	101 - 105 (103)	1.7 (n=5)
				2.25mg/m^3	87 – 93 (90)	3.3 (n=5)
	LC-MS/MS 192->119 6.0 (n=5) m/z 20°C, 30%RH			Control (n=2)	Not detected	-
				0.225mg/m^3	94 – 110 (101)	6.0 (n=5)
				2.25mg/m^3	97 – 105 (101)	2.8 (n=5)

2.4 Risk assessment for physical-chemical properties

Based on the properties of the components of the formulation, the product *AROX na komary, kleszcze i meszki* is not considered explosive or oxidizing or auto-flammable. However, due to the content of ethanol and the result of flash point test (57°C) the product should be classified as flammable liquids category 3. Based on the results from the study on "Mosquito and Tick Repellent Lotion without Fragrance" it is not sustaining combustion.

Taking into consideration results from the accelerated storage stability test and 36 months storage stability test, the shelf life of the product is considered acceptable up to three years in ambient conditions.

It should be kept away from heat/sparks/open flames/hotsurfaces.

The physico-chemical properties of the formulation indicate that no particular problems are to be expected when it is handled and stored as recommended.

2.5 Effectiveness against target organisms

2.5.1 Function

The biocidal product *AROX na komary, kleszcze i meszki* is ready-to-use, insect repellent (PT19) based on 19.5% (w/w) DEET. The product is intended to use by non-professional users.

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

The biocidal product *AROX na komary, kleszcze i meszki* is intended to repel biting insects – mosquitoes (*Culicidae*), ticks (*Ixodidae*) and black flies (*Simulidae*), thereby could protect humans from pathogens transmitted by these insects.

With the purpose to protect humans against mosquitoes (indoor application in well ventilated areas only), ticks (outdoor application only) and black flies (indoor and outdoor application) the product should be applied on uncovered skin.

2.5.3 Effects on target organisms

The *AROX na komary, kleszcze i meszki* is applied directly on the human skin. The active substance DEET evaporates from the skin surface into air surrounding the skin. The target organisms sense the repellent and refrain from landing on the skin and next from biting.

2.5.4 Mode of action

The mechanism of action of insect repellent active substances is not relevant yet. This effect could be based on olfactory and gustatory processes. The repellent actions starts directly after application.

2.5.5 Occurrence of resistance

Resistance to the product isn't known and not expected. There is only low selection pressure because the insects which are repelled do not die, and there are many other food sources available for these insects. Therefore, it is considered unnecessary to take actions to prevent development of resistance by target organisms.

2.5.6 Evaluation of the label claims

The following studies are available for the evaluation of label claims:

- laboratory study to determine the efficacy of 19.5% DEET Lotion Repellent against mosquitoes, *Aedes albopictus* and *Culex quinquefasciatus* and ticks, *Ixodes* (Test IIIB5.10/01; Test IIIB5.10/02; Test IIIB5.10/03);

- laboratory study to determine the efficacy of 19.5% DEET l Lotion Repellent against ticks, (Test IIIB5.10/04);
- laboratory study to determine the efficacy of 19.5% DEET Lotion Repellent against black flies, *Simulium spp.* (Test IIIB5.10/05);
- field study to determine the efficacy of 19.5% DEET Lotion Repellent against black flies, *Simulium spp.*(Test IIIB5.10/06).

A summary of these efficacy studies can be found in Table 2.1.

Based on submitted studies, Polish CA can accept efficacy against:

- mosquitoes for 4.5 h after application (indoor application in well ventilated areas only);
- ticks for 2.0 h after application (outdoor application only);
- black flies for 5 h after application (indoor and outdoor application).

Studies on *Aedes albopictus* and *Culex quinquefasciatus*

According to the TNsG[1] for PT 18 and PT 19 testing of repellents against mosquitoes should be performed on a mosquitoes of *Culex* and *Aedes* genus. Applicant submitted study performed under laboratory conditions on mosquitoes of species *Aedes albopictus* and *Culex quinquefasciatus*.

In case of mosquitoes of the species *Aedes albopictus* (Test IIIB5.10/01) repellency greater than 95% is shown for 4.5 h after the application and complete protection time (CPT) is 250 min. These data support the efficacy of the product against mosquitoes of the species *Aedes albopictus* for 4.5 h after the application. In case of mosquitoes of the species *Culex quinquefasciatus* (Test IIIB5.10/02) repellency greater than 95% was maintained for 4.5 h after the application and complete protection time (CPT) after 270 min. These data support the efficacy of this product against mosquitoes of the species *Culex quinquefasciatus* for 4.5 h after the application.

Basis on both studies it can be accepted that product is efficacy against mosquitoes for 4.5 hours after application.

[1] BPD 98/8/EC: Technical Notes of Guidance: TNsG on Product Evaluation, Product type 18-Insecticides, acaricides and products to control other arthropods and Product type 19 – repellents and attractants (only concerning arthropods); CA-Dec12-Doc.6.2.a-Final

The TNsG on PT18 and PT 19 states that to show efficacy of products intended for use as repellent on skin against mosquitoes, both simulated-use test (arm in cage) and field study showing repellence in the field need to be provided. The applicant submitted study performed only on laboratory conditions only, therefore there is no evidence for efficacy against mosquitoes outdoor. Taking into account information above, it can be concluded that product *AROX na komary, kleszcze i meszki* provides sufficient protections against mosquitoes indoor only.

Studies on *Ixodes ricinus* and *Dermacentor spp.*

According to the TNsG for PT 18 and PT 19 testing of repellents against ticks should be performed on ticks of *Ixodes* or *Dermacentor* genus. Applicant submitted two efficacy studies, performed under laboratory conditions. One study was performed on ticks of the species *Ixodes ricinus* and the second study – on ticks *Dermacentor spp.*

According to the TNsG repellency should be ≥ 90% during the claimed efficacy period. Repellency against ticks of the species *Ixodes ricinus* (Test IIIB5.10/03) was too low (only 78.8% after 0.5 hour of application), moreover there was no repellency against ticks ≥90% for the duration of the experiment. Therefore based on this study it cannot be accepted efficacy of the product against ticks. However in other laboratory study (Test IIIB5.10/04) performed on ticks *Dermacentor spp*. 90% repellency was shown for 2.0 h after application. Basis on this study can be accepted that efficacy of the product against ticks for 2.0 h after application.

The TNsG on PT 18 and PT 19 states that to show efficacy of products intended for use as repellent against ticks only laboratory test need to be provided. Consequently, based on studies carried out on ticks *Dermacentor spp.* it can be concluded that product provide sufficient protection against ticks for 2.0 h after outdoor application.

Studies on black flies of *Simulium spp.*

Applicant submitted efficacy study, which was performed under laboratory and field conditions on black flies of species *Simulium spp.* On the basis of laboratory study (Test IIIB5.10/05) it can be accepted that product is efficacy against black flies for 0.5 hours after application (repellency greater than 90%). Data from field study (Test IIIB5.10/06) support the efficacy of this product outdoor against black flies of the species *Simulium costatum* and *Odagmia ornata* for 5h after the application. Basis on the field study is possible to accept efficacy of the product against black flies outdoor. Moreover according to the Polish CA the product effectively repels black flies also during indoor application.

Table 2.1 Effectiveness of the biocidal product against target organism

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test conditions	Test results: effects, mode of action, resistance	Reference	Comments from Polish CA
Mosquito and Tick Repellent 19,5% DEET Lotion Repellent 195 g/kg DEET (19.5%) Batch No: KI/83066 Study No: 12/150B	Mosquito (*Aedes albopictus*) 100 female adult/cage.	Repellence test - laboratory test/ 1 g product per 600 cm^2/ 5 minutes exposure time at 30 minutes intervals	Pre-conditioning: The mosquitoes was starved for 12 hours. During test: During testing, cages was held at 23.9 – 28.2%, > 60 % relative humidity. Observation period: After 30 minutes untreated arm was inserted into the cage and was exposed for 5 minutes to determine landing and/or probing. This procedure was repeated at 1 hour intervals for a maximum of 5.5 hours.	Complete protection time (CPT): 250 min (± 40) Repellency during 4.5 hour of application was over the 95%.	I2LResearch Ltd Test IIIB5.10/01	According to submitted documentation acceptable biting protection time against mosquitoes (species *Aedes albopictus*) is 4.5 h
Mosquito and Tick Repellent 19,5% DEET Lotion Repellent 195 g/kg DEET (19.5%) Batch No: KI/83066 Study No: 12/150B	Mosquito (*Culex quinquefasciatus*)	Repellence test - laboratory test/ 1 g product per 600 cm2/ 5 minutes exposure time at 30 minutes intervals	Pre-conditioning: The mosquitoes was starved for 12 hours. During test: During testing, cages was held at 23.9 – 28.2%, > 60 % relative humidity. Observation period: After 30 minutes untreated arm was inserted into the cage and was exposed for 5 minutes to determine landing and/or probing. This procedure was	Complete protection time (CPT): 270 min (+ 69.3) Repellency (taking into account the standard errors) greater than 95% is shown for 4.5 h after the application.	I2LResearch Ltd Test IIIB5.10/02	According to submitted documentation acceptable biting protection time against mosquitoes (species *Culex quinquefasciatus*) is 4.5 h

			repeated at 1 hour intervals for a maximum of 6.5 hours			
Mosquo and Tick Repellent 19,5% DEET Lotion Repellent 195 g/kg DEET (19.5%) Batch No: KI/83066 Study No: 12/150	Tick (*Ixodes ricinus*) 40 nymph adult/cage)	Repellence test - laboratory test/ 1 g product per 600 cm^2/ 3 minutes exposure time at 30 minutes intervals	Condition during test: During testing, cages was held at 23.8-25.3 °C, 62.7-80.4% relative humidity. Observation period: 30 min after product application. This process was repeated at 1 hour intervals for a maximum of 3.5 hours.	Complete protection time (CPT): 48.8 min (+ 9.7) Repellency after 0.5 hour of application was only 78.8%; it was too low.	I2LResearch Ltd Test IIIB5.10/03	Submitted study can not be accepted
19.5% DEET Lotion Repellent 195 g/kg DEET (19.5 %) Study No: Procedure Zm-22-HS dated 22.01.2015 and addendum dated 13.02.2015	Tick (*Dermacentor* spp.) 40 nymph adult/test	Repellence test – laboratory test/ 200 mg product per 30-40 cm2/ 1 minute exposure time at 30 minutes and 1 hours intervals	Condition during test: During testing, cages was held at: 21 °C, 61% relative humidity. Observation period: 10 min after product application. This process was repeated at 1 hour intervals (one measurement after 1.5 h) for a maximum of 4 hours.	Repellency during 2.0 hour of application was at least 90%.	National Institute of Public Health Test IIIB5.10/04	According to submitted documentation acceptable biting protection time against ticks is 2.0 h.
Mosquito and Tick Repellent 19,5% DEET Lotion Repellent 195 g/kg DEET (19.5%) Batch No: KI/83066 Study No: 12/151B	Black fly (*Simulium* spp) 50 female adult/cage.	Repellence test – laboratory test/ 1 g product per 600 cm^2/ 5 minutes exposure time at 30 or 60 minutes intervals	Condition during test: During testing, cages were held at 25.2-26.5 °C, 62-76 % relative humidity. Observation period: 30 min. after treatment, repeated at 1 hour intervals for a maximum of 3.5 hours.	Complete protection time (CPT): 110 min (+ 52.9) Repellency: duration 0.5 hour post treatment with over the 95% repellency	I2LResearch Ltd Test IIIB5.10/05	According to submitted documentation acceptable biting protection time against *Simulium* spp. Is 0.5 hour

Mosquito and Tick Repellent 19,5% DEET Aerosol Repellent 195 g/kg DEET (19.5 %) Batch No: KI/83066 *Study No:* 12/152B	Black fly (*Simulium spp*) wild species	Repellence test – field test/ 1 g product per 600 cm^2/ 5 minutes exposure time at 1 hour intervals	Condition during test: The weather conditions were: 10.3 - 22.5 °C, 71.1 - 91.2 % relative humidity, 8-377 lux light intensity and 0-2.2 km/h wind speed. Observation period: 2 hours after treatment, repeated at 1 hour intervals for a maximum of 7 hours.	Complete protection time (CPT): 360 min (+ 0) Repellency: duration 5 hour post treatment with over the 95% repellency	I2LResearch Ltd Test IIIB5.10/06	According to submitted documentation acceptable biting protection time against *Simulium* spp. is 5 hours

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

AROX na komary kleszcze i meszki is used in Product Type 19 "Repellents and Attractants", as an insect repellent and is applied directly on human skin. Mosquitoes, ticks and black flies are the target organisms. The pattern of use is similar for applications against all parasites and exposure calculations presented here are therefore valid for use scenarios of each of the target organisms. The product is for non-professional use.

The product *AROX na komary kleszcze i meszki* is a lotion repllent containing DEET at a concentration of 19.5%. It contains one substance of toxicological concern – ethanol at concentration 8.3%. Therefore, both – the active substance DEET and substance of concern – ethanol are considered in this exposure and risk assessment. The detailed composition of the product is provided in the document IIIB2.

From the risk assessment for human health described in chapter 2.7, it is concluded that for adults as well as for children over 12 years, an application twice a day is possible without restrictions. Children under 12 years must not be treated with *AROX na komary kleszcze i meszki*. To avoid accidental oral uptake, recommendation “Wash hands after application” is necessary.

Table 2.2 Summary of intended uses

PT	Field of use envisaged	Substance concentration
Group 19: Insect repellent	Direct application onto the skin Application outdoor (against ticks and black flies) or well ventilated area (against mosquitoes and black flies)	19.5 % DEET

2.6.2 Assessment of exposure to humans and the environment

General information - toxicology

The applicant has submitted an effect and exposure assessment for the product *AROX na komary kleszcze i meszki*. The human health exposure and risk assessment of the product *AROX na komary kleszcze i meszki* were examined by the PL CA appropriately according to standard requirements. Studies with product have been provided. No new studies have been provided concerning the active substance and human health exposure. The product was not reference product in the EU-review program for inclusion of the active substance in Annex I of Directive 98/8/EC. The PL CA has revised this risk assessment for the human health aspect.

The direct exposure of humans to the active ingredient DEET from biocidal uses of *AROX na komary kleszcze i meszki* has been estimated using valid exposure models and approaches as described in Document IIB, Chapter 8.2 of the Competent Authority Report on DEET[2]. The indirect and secondary exposures are not relevant.

The evaluation of professional exposure is not relevant since the product *AROX na komary kleszcze i meszki* is intended for non-professional use only.

For more details see section 2.7 of Product Assessment Report.

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 in the review program under directive 98/8/EC. The results of this

[2] Competent Authority Report available at https://circabc.europa.eu

toxicological assessment can be found in the CAR. The assessment report, including the List of End-Points for the substance, can be found on CIRCA.

2.7.1.2 Toxicology of the substance(s) of concern

AROX na komary kleszcze i meszki contains ethanol as a substance of concern. The content of ethanol in the formulation is 8.33%.

Ethanol is notified according to the biocides review program (for PT1, 2 and 4). A draft CA-report is available, although not discussed in the Working Groups.

List of Endpoints[3]

Ethanol is readily absorbed by the oral and inhalation routes and subsequently, metabolized and excreted in humans. At exposures relevant to occupational and consumer exposure during manufacture and use of ethanol containing products, the alcohol dehydrogenase metabolic route in the liver dominates and does not become saturated. This mechanism follows first order kinetics. The first step of the metabolic path is the rate-determining step; concentrations of the intermediate metabolite acetaldehyde are very low. Ethanol is not accumulated in the body. Dermal uptake of ethanol is very low. Ethanol has a low order of acute toxicity by all routes of exposure. Lowest robust reported values are an inhalation LC_{50} of >60,000 ppm (114,000 mg/m^3, 1 hour, mouse), and an oral LD_{50} of 8300 mg/kg bw (mouse). Ethanol is a moderate eye irritant but is neither a skin irritant nor a sensitizer. For repeat dose effects, the lowest reported NOAEL is approximately 2400 mg/kg bw/day from a dietary study with rats. At higher doses, male rats showed minor changes to organ weights and haematology/biochemistry; female rats showed minor biochemistry changes and increased length of oestrus cycle along with liver nodules; adverse liver effects were observed at concentrations of 3600 mg/kg bw/day and above. The balance of evidence is that ethanol is not genotoxic. Negative results from a number of bacterial mutation assays appear to be reliable. Of the mammalian cell mutation assays a weak mutagenic effect in mouse lymphoma cells occurred only at very high ethanol concentrations. *In-vivo* tests for chromosome aberrations in both rats and Chinese hamsters have given negative results. There is very little evidence to suggest that ethanol is genotoxic in somatic cells and it may have a very limited capacity to induce genetic changes *in-vivo* but under very specific circumstances and at very high doses achievable in humans only by deliberate oral ingestion.

[3] OECD SIDS ETHANOL Initial Assessment Report For SIAM 19 Berlin, Germany, 19 – 22 October 2004

Evidence of the carcinogenicity of ethanol is confined to epidemiological studies assessing the impact of alcoholic beverage consumption. These do not indicate any such hazard exists from potential exposure to ethanol in the work place or from the use of ethanol in consumer products.

No fertility or developmental effects were seen at inhalation exposures up to 16000 ppm (30,400 mg/m^3). The lowest reported NOAEL for fertility by the oral route was 2000 mg/kg bw in rats, equivalent to a blood alcohol concentration of 1320 mg/L, although this was based on a significant increase in the number of small pups rather than a direct effect on fertility; such direct effects are not seen until much higher doses. Many studies exist examining the developmental end point for ethanol. However, most use very high doses and few are individually robust enough to allow a NOAEL to be established. However, the collective weight of evidence is that the NOAEL for developmental effects in animals is high, typically >=6400 mg/kg bw, compared to maternally toxic effects at 3600 mg/kg bw. The potential for reproductive and developmental toxicity exists in humans from deliberate over-consumption of ethanol. Blood ethanol concentrations resulting from ethanol exposure by any other route are unlikely to produce reproductive or developmental effects.

According to OECD SIDS publication most data available on ethanol is via the oral route of exposure. Much is at high doses which limits its value to risk assessment of ethanol as a chemical substance. From the data available, it is possible to surmise that ethanol is of repeat dose low toxicity by the oral route, with a lowest reported NOAEL in animals of 2400 mg/kg for rats. Taking into account study in rats for which the NOAEL was 2400 mg/kg bw per day using an uncertainty factor of 100, Acceptable Exposure Level (AEL) for ethanol is 24 mg/kg bw/day. This value has been assumed as overall systemic limit value for the human population.

Dermal absorption percentage of ethanol is unknown. The EFSA Guidance[4] on dermal absorption recommends a value of 25% for formulations containing >5% substance. Therefore the RMS has performed calculations by considering 25% value for dermal uptake fraction of ethanol. The resulting systemic exposure estimate was compared with AEL of 24 mg/kg bw/day.

[4] EFSA Guidance on dermal absorption. EFSA Journal 2012;10(4):2665

2.7.1.3 Toxicology of the biocidal product

The toxicology of the biocidal product *AROX na komary kleszcze i meszki* was examined appropriately according to standard requirements. The product was not a representative product in the EU-review program for inclusion of the active substance in Annex I of Directive 98/8/EC.

GLP-compliant studies with the product have been submitted by the applicant to address skin and eye irritation, skin sensitization and dermal absorption. The results of these studies are presented below.

All toxicology tests were conducted on products with code names: Mosquito &Tick Repellent Lotion an 19.5% DEET Repellent Lotion, which have been confirmed to be identical as *AROX na komary kleszcze i meszki*.

Acute toxicity

Acute oral, dermal and inhalation toxicity

According to Regulation (EU) No. 528/2012 "*testing on the product/mixture does not need to be conducted if there are valid data available on each of the components in the mixture to allow classification of the mixture according to the rules laid down in Directive 1999/45/EC and Regulation (EC) No. 1272/2008 (CLP), and synergistic effects between any of the components are not expected*". The acute oral toxicity of *AROX na komary kleszcze i meszki* can be derived from the product component data. Besides DEET, there are no other components in the product which are classified with respect to acute oral toxicity. Therefore, a study on the acute oral toxicity of the biocidal product is considered scientifically unjustified and has been waived for animal welfare reasons. *AROX na komary kleszcze I meszki* does not have to be classified, neither according to Directive 1999/45/EC nor to CLP Regulation.

Justification for non-submission of data has been submitted also for acute dermal and inhalation toxicity study. Neither DEET nor any of the other ingredients of the product are classified for the acute dermal and inhalative toxicity. Taking into consideration the estimated acute dermal LD_{50} and acute inhalation LC_{50} of the formulated product *AROX na komary kleszcze i meszki* does not require classification and any phrase are considered necessary.

Irritation and Corrosivity

Acute dermal irritation (in-vitro)

The test item Mosquito and Tick Repellent Lotion was applied, as supplied, at the dose of 20 µL (or a sufficient amount to cover uniformly the entire skin surface) evenly to the epidermal surface of each of the three test EPISKIN model units. The experimental protocol was compliant with the OECD method 439 and the REACH ANNEX III, test method EC B.46.

The test item showed reduced cell viability in comparison to the negative control (mean value: 62%). However, all test item results were above 50% of the mean negative control value and therefore the test item was considered to be non-irritant to the skin.

Positive and negative controls showed the expected cell viability values within acceptable limits. The experiment was considered to be valid.

The results obtained, under these experimental conditions, enable to conclude that the test item Mosquito and Tick Repellent Lotion must not be classified, according to the criteria for classification, packaging and labelling of dangerous substances and preparations in compliance with the EEC Directives 67/548, 2001/59 and 99/45. No symbol or risk phrase is required.

In accordance with the Regulation (EC) No. 1272/2008, the test item must not be classified. No signal word or hazard statement is required.

Acute eye irritation

The *in-vitro* eye corrosives and severe irritants study, using the Isolated Chicken Eye model with Mosquito and Tick Repellent Lotion was submitted as a part of testing strategy for eye irritation. The endpoints evaluated were corneal opacity, swelling, fluorescein retention and morphological effects (e.g. pitting or loosening of the epithelium). No ocular corrosion or severe irritation potential was observed. Thus, according to the guideline OECD 438 the biocidal product cannot be classified as an ocular corrosive or severe eye irritant. Furthermore, the results suggested that the test item was moderately irritating. However, to obtain a definitive classification in relation to the irritation potential, a further *in-vivo* rabbit study was required.

The second study with the test item Mosquito and Tick Repellent Lotion was performed compliant with the OECD guideline No. 405 using 3 males New Zealand white rabbits at the dose of 0.1 mL. The eyes were examined at 1, 24, 48 and 72 hours then 1, 2 and 3 weeks after the application. The duration of the observation period was sufficient for

the statement of reversibility or irreversibility of changes. Individual reactions of animal were recorded at each observation time.

In accordance with the Regulation (EC) No. 1272/2008, the test item should be classified into Category 1 ("irreversible effects on the eye/serious damage to eyes"), because effects on the cornea was not expected to reverse within an observation period of 21 days in all animal. The signal word "Danger" and hazard statement H318 "Causes serious eye damage" are required.

Skin sensitization

The potential allergenicity of Mosquito and Tick Repellent Lotion was tested at the maximum concentration of 100% as the undiluted test item and at concentrations of 50%, 25% and 10% as formulations in an appropriate vehicle (Acetone: Olive oil 4:1 (v/v) mixture) and was experimentally investigated using a murine Local Lymph Node Assay (LLNA). Results showed that the product is not regarded as a potential skin sensitizer in the test. Thus, the biocidal product does not have to be classified and labelled with respect to skin sensitisation.

Dermal absorption

Percutaneous absorption *in-vitro* of radiolabelled active substance DEET in a product *AROX na komary kleszcze i meszki* was conducted according to the OECD Guideline 428 and OECD 28.

[14C] DEET in the test preparation was topically applied to human skin *in-vitro*. Under the experimental conditions for [14C] DEET in the test preparation, the absorbed dose and dermal delivery of [14C] DEET were 28.98% (60.37 µg equiv/cm^2) and 31.65% (65.94 µg equiv/cm^2) of the applied dose, respectively. The majority of the applied dose was removed by washing the skin; the total dislodgeable dose was 63.87% of the applied dose. The mass balance was complete with 96.68% of the applied dose recovered.

However, according to applicant this value can be overestimated. The results above are the measurements made in 24 hour post dose. The Guidance for conduct of skin absorption studies, OECD 2004 states that exposure period should reflect the occupational exposure of the product. In case of repellents the most appropriate exposure period would be 8 hours. Mean absorption of DEET in test preparation after 8 hours would be about 16%, but applicant proposed to use value 20% as worst case. Therefore, in the exposure assessment the 20% dermal absorption value will be used.

The relevant data for the health assessment of the biocidal product is laid out in Annex 5 "Toxicology - biocidal product" of this document.

2.7.2 Exposure

AROX na komary kleszcze i meszki is intended for non-professional application, where the route of exposure is mainly dermal. Product is applied directly on human skin. The exposure assessment is based on an application frequency of 1-2 times per day. The product is a 19.5% DEET lotion formulation.

Oral exposure by hand-to-mouth transfer is not considered to be a significant route of exposure because of the bitter taste of DEET and the content of the bitter agent. However, the efficacy of Bitrex was discussed at a Technical Meeting where it was concluded that Bitrex may not be effective in preventing ingestion in all age groups, in particular children <12 years old. Therefore the oral route is still considered to be possible and the calculations for hand-to- mouth transfer are included by the RMS in the worst case exposure calculations. A reverse reference scenario for oral ingestion was considered by RMS for exposure assessment.

Because of the formulation type (the biocidal product is neither a gas nor a volatile liquid, nor a powder) and the application method (it does not generate the aerosol, particles or droplets in an inhalable size range, MMAD <50 μm) in PL CA point of view the inhalation exposure to product *AROX na komary kleszcze i meszki* is considered to be not likely. Similarly, for non-users, the risk of inhalation exposure to residues during or after application via the environment is considered to be not likely.

Table 2.3 Summary of main paths of human exposure

Exposure path	Industrial use	Professional use	General public	Via the environment
Inhalation	Not applicable	Not applicable	Not likely	Not applicable
Dermal	Not applicable	Not applicable	Potentially significant	Not applicable
Oral	Not applicable	Not applicable	Negligible	Not applicable

2.7.2.1 Exposure of professional users

Not relevant. The product is intended for use by amateurs.

2.7.2.2 Exposure of non-professional users and the general public

In Annex 7 "Safety for non-professional operators and the general public", the results of the exposure calculations for the active substance and the substance of concern for the non-professional user and the general public are laid out.

Acive substance DEET

AROX na komary kleszcze i meszki is intended for consumer application, where the route of exposure is mainly dermal. DEET is applied directly on human skin. Exposure has been estimated using 2 different methods based on the TNsG proposal using ConsExpo 4.1 (**Tier 1**) and refinement by using exposure data on amount applied to skin from a usage study for the 75th percentile (Boomsma and Parthasarathy, 1990) (**Tier 2**). The exposure assessment is based on an application frequency of 1-2 times per day. Calculations were performed for adults, 2 years children and 12.5 years children.

Tier 1

According to the TNsG, the dermal exposure can be calculated by a fixed volume model: The data are based on the US-EPA, 1998 assessment of DEET and assumes an average of between 1.0 and 1.3 g of active ingredient per application. It is also stated that children fall within this range. However, according to the TNsG, the concentration of DEET contained in the formulation is not stated. The default values proposed in the TNsG were not based on these insect repellent data but were instead based on the use of suntan creams and body lotions. The default values for amounts of suntan creams and body lotion applied, given in the "Cosmetics fact sheet" are 10 g and 8 g per application (Bremmer et al., 2002, in preparation). For both products, almost all of the skin is treated. Insect repellents are applied on the uncovered skin: on the head, hands, arms, legs and feet. The surface of these body parts is 64% of the total body surface (Bremmer and van Veen, 2000). If the use

of repellents is comparable to that of suntan creams and body lotions, 5 to 6 g is used per application. Based on the above, the default value and the amount of repellent per application is set at 6 g for adults. The total body surface of an adult is 1.75 m^2 (Bremmer and van Veen, 2000). If it is assumed that there is a linear relationship between the body surface and the amount of repellent used, the amount of repellent used for a child of 2 years would be 1.81 grams per application and for a child of 12.5 years would be 4.49 grams per application. Default values of body weight and body surface of 2 years (based on average values for children 1.5 years and 2.5 years old) and 12.5 years children are assumed based on "General Fact Sheet Limiting conditions and reliability, ventilation, room size, body surface area" (RIVM report 320104002/2006). Exposure due to hand-to-mouth transfer has also been included in the calculations as a worst-case approach. According to TNsG on Human Exposure, 2002 for infants 10.5 months of age, the surface of the hands is approximately 10% of the total treated body surface (head, hands, arms, legs and feet), and this value is applicable for children in all age groups; for adults it is proposes that 4% (the amount on fingers only) of 6 g is taken in by hand-to-mounth contact. Two applications are assumed per day for a 19.5% product and dermal absorption value of 20% was used to calculate internal exposure in humans according to CAR for active substance DEET. Body weights of 60 kg are assumed for adults, both males and females and a body weight of 11.2 kg was assumed for 2 years child and 39.3 kg for 12.5 years children.

Tier 2

A user survey study has been performed in the USA involving human use and exposure to insect repellents containing DEET (Boomsma and Parthasarathy,1990). The 75th percentile is considered acceptable since the user study had a large number of study subjects. The study involved a total of 540 subjects who were portioned into analyzable subsamples both of adult males and females and children (age: 13-17 years, 12 years and younger). Detailed information have been described in Confidential Annex 9.

Taking into account the endorsed HEEG default factors (2013) for toddler and children the surface of the hands is approximately 8% of the total particular treated body surface (head, hands, arms, legs and feet). For adults, the surface of hands is approximately 8% of the total particular treated body surface too but adults will ingest the amount on their fingers only so the factor of 4% of the total treated body surface was used for internal oral dose calculation.

The internal dermal exposure has been calculated according to the following formula:

External dermal dose a.s. = ((number of applications) × (amount of a.s. (75th percentile based on survey data) × (content a.s. / content a.s. based on survey data)) / body weight based on survey data

Internal dermal dose a.s.= (external dermal dose a.s.) x (% dermal absorption)

The internal oral exposure has been calculated based on the following formula:

Internal oral dose a.s. = ((number of applications) × (amount of a.s. (75th percentile based on survey data) × (content a.s. / content a.s. based on survey data) × (% ingested amount)) / body weight based on survey data

The number of applications is considered to be two or one per day. For dermal absorption the value of 20% is used. Oral absorption is considered to be 100% as a worst-case approach.

Ethanol

The content of ethanol in the formulation is 8.33 %. Additional exposure assessment on ethanol for 2 years and 12.5 years children was carried out using ConsExpo 4.1. Exposure calculations based on default values (Tier 1) were performed in the same manner as for the active substance.

2.7.2.3 Exposure to residues in food

The application of *AROX na komary kleszcze i meszki* does not result in residues to which consumers might become exposed.

2.7.3 Risk Characterisation

2.7.3.1 Risk for Professional Users

Not relevant, as *AROX na komary kleszcze i meszki* is intended only for consumer use.

2.7.3.2 Risk for non-professional users and the general public

Active substance DEET

Two approaches have been taken to risk characterisation based on traditional method comparing the estimated exposure with an AEL: based on default values (Tier 1) and based on using the 75th percentile of human dermal exposure based on the USA survey study (Tier 2). The main exposure route is dermal; however there is a possibility of minimal oral

exposure via hand-to-mounth behaviour if the product is applied on hands. As a worst-case approach, the RMS has also performed the assessment of the oral exposure. The resulting oral exposure estimates were compared with $AEL_{acute\ oral}$ of 0.75 mg/kg bw/day and dermal exposure estimates were compared with $AEL_{repeated\ dermal}$ of 8.2 mg/kg bw/day.

Both systemic dermal and systemic oral exposure to DEET of non-professional users applying *AROX na komary kleszcze i meszki* on the skin was estimated.

was decided at TM I and II 2009 that risk characterisation for DEET products should be performed for two daily applications and by using the 75th percentile of human dermal exposure based on the USA survey study. Taking into account only dermal exposure in Tier 2, the use of the product with 19.5% DEET, 2 times per day is considered acceptable for adults and children >12 years old. Oral exposure by hand-to-mounth transfer is considered by RMS to be a less significant route of exposure because according to CAR of DEET the smell and taste of DEET act as a self deterrent against this type of activity. Additionally product contains denatonium benzoate which acts as strong deterrents for ingestion. Moreover according to CAR of DEET it was concluded that the oral dose is likely to be largely overestimated given the short half life after oral exposure in dogs and rats and the rapid achievement of C_{max}. The risk by oral route have been included to present worst case calculation. Taking into account exposure by oral route the risk for adult and children is exceeded. The hand-to-mouth behaviour is more frequent in small children. Recommendation "wash hands after application" should be included on product label in order to limit the potential oral exposure. For adult and children over 12 years it might be a suitable risk mitigation measure to prevent oral ingestion due to hand-to-mounth contact.

For children <12 years old the application of product containing 19.5% DEET twice per day is not considered acceptable. The phrase "Do not use on children < 2 years old needs to be put on the label of the product in accordance with the inclusion directive of DEET in Annex I of Directive 98/8/EC (Commission Directive 2010/51/EU). However, there is no need for this restriction on the label due to the phrase- „Do not use on children <12 years old".

Ethanol

AROX na komary kleszcze i meszki contains ethanol as a substance of concern. The content of ethanol in the formulation is 8.33%. In summary risk characterisation of non-professionals users to the biocidal products containing 19.5% DEET as active substance is considered acceptable, if the biocidal product is used by adults and children over 12 years. Accordingly additional risk characterisation of ethanol was carried out for 12.5 years children using

ConsExpo 4.1. Exposure calculations based on default values (Tier 1) were performed in the same manner as for the active substance. Dermal absorption percentage of ethanol is unknown. The EFSA Guidance on dermal absorption recommends a value of 25% for formulations containing >5% substance. Therefore the RMS has performed calculations by considering 25% value for dermal uptake fraction of ethanol. The resulting systemic exposure estimate was compared with AEL of 24 mg/kg bw/day. Based on these results the RMS PL concludes that no unacceptable risk results from the presence of ethanol as a substance of concern in the formulation for >12 years children and thereby adults.

Conclusions

Based on the calculations above there is no concern for adults and children over 12 years using the biocidal product (lotion formulation containing 19.5% DEET as a repellent), when used twice a day. Do not use more than twice a day. For children <12 years old, the exposure after dermal application exceeds the $AEL_{repeated}$ when applied one and twice per day. It is therefore considered necessary not to apply in children <12 years old. For facial application, distribute the product on your hands and rub the product over the face. Avoid contact with eyes and areas around eyes, mucous membranes and damaged skin. Keep this product away from children. Wash hands after application.

2.7.3.3 Risk for consumers via residues

Not relevant because no contamination of food is expected.

2.8 Environmental exposure

2.8.1 Exposure assessment

The biocidal product *AROX na komary, kleszcze i meszki* contains 195g/kg of the active substance DEET and is intended to use by non-professional users to repel biting insects mosquitoes, ticks and black flies. Biocidal product is ready-to-use spray applied on uncovered skin two times per day.

The major emissions of biocidal product to the environment result from removal phase of the insect repellent. Removal of the biocidal product from human skin can either take place:

- during showering or bathing of human who have used an insect repellent, this results in indirect emission via STP to surface water;
- showering or bathing (swimming) outdoor after application of product on skin, this results in direct release to surface water and sediment.

The product *AROX na komary kleszcze i meszki* contains three potential substances of concern (lemon fragrance, denatonium benzoate and Carbopol Ultrez 10) classified and labelled under CLP regulation 1272/2008. However concentrations of these substances in biocidal product are very low (1%, 0.001%, 0.25% respectively) and do not affect overall classification of the product. Therefore only active substance DEET was considered as of concern for environment and the risk characterisation was performed for this substance.
No studies were submitted on environmental fate and behavior of the biocidal product *AROX na komary, kleszcze i meszki.* However as stated above only active substance DEET was considered as of concern for environment. Therefore it was assumed that fate and distribution in the environment of the product can be based on data for active substance.

Due to the lack of a specific document or guidance for products type (PT) 19, environmental exposure assessment was performed using the *ESD* for PT1[5], *TGD*[6] and German Competent Authority scenario[7].
Emission scenario for PT1 was chosen to estimate diffuse emission to the environment due to showering and bathing of the public. German CA scenario for swimming – to estimate direct emission to lakes due to swimming of people who applied on skin the biocidal product *AROX na komary kleszcze i meszki*.
The scenario for PT1 describes 2 different ways to calculate emissions – based on the tonnage and based on the average consumption. However tonnage scenario is not applicable for evaluation of individual products. Therefore Polish Competent Authority performed the environmental exposure assessment only with use of consumption scenario.

[5] *Environmental Emission Scenarios for biocides used as human hygiene biocidal products (Product type 1), European Commission DG ENV/RIVM, January 2004*
[6] *Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances. Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market*. Part II. Published
[7] DE Proposal for an emission scenario taking into account direct releases to surface water when repellents (PT19) applied to human skin (TM2011-Env-item5c-DE proposal for swimming scenario)

The risk assessment was performed by comparing the Predicted Environmental Concentration (PEC) with the Predicted No Effect Concentration (PNEC). The PNEC values have been derived from Assessment Report for which company Agrecol Sp. z o.o. submitted a letter of access.

Endpoints necessary to estimate fate and behaviour in environment was derived from the CAR for DEET.

Indirect emission

Major emissions from the application of *AROX na komary kleszcze i meszki* result from indoor showering, bathing or laundry with emission via the STP to surface water and sediment (waste phase).

The water compartment (both inland and marine) is expected to be indirectly exposed to DEET mainly from STP effluents and because of the physiochemical character of the substance the emissions will continue to primarily remain in this compartment. The most relevant environmental compartment of concern for DEET is therefore the aquatic.

Final environmental exposure will to a large extent depend on whether households are connected to STPs equipped with at least secondary (biological) treatment. Other efficient treatment processes include ozonation and PAC (Powdered Activated Carbon) addition, although these are more common in drinking water treatment.

In the following sections, PECs are derived by using the ESD for PT 1 and equations from the *TGD*. These calculations are based on amount of product consumed by individuals.

Direct emission

Direct emission to surface water and sediment can result from outdoor showering or bathing (swimming) after application of the product on the skin.

In the following sections, PECs were derived by using the German CA scenario for swimming and equations in the *TGD.* These calculations are based on amount of product consumed by individuals.

2.8.1.1 PEC_{STP}, $PEC_{surface\ water}$ and $PEC_{sediment}$ – indirect emission

Indirect emission to surface water take place via showering/bathing of humans who have used biocidal product *AROX na komary kleszcze i meszki*.

Sewage treatment plants are the primary compartment for emissions whereas surface water bodies (including sediment) as well as the soil compartment are secondary exposed compartments via STP effluents and sewage sludge applications, respectively.

During outdoor use, applications on paved ground and subsequent transport of DEET to environmental compartments via STPs are evaluated to be negligible compared to emissions entering STPs via showering/bathing of human.

The calculation of environmental emissions of DEET due to showering/bathing after application of *AROX na komary kleszcze i meszki* performed using the average consumption of the product.

Local emission rate to wastewater calculated using formula presented below:

$$Elocal_{water} = N_{local} \times N_{appl} \times F_{inh} \times F_{water} \times Qform_{appl} \times Cform_{weight} \times F_{penetr} \times 10^{-6}$$

However, due to the fact that certain value (for which the applicant did not confirm the access) was used in the calculation by RMS, full calculations were placed in Annex 9 as a confidential.

Predicted Environmental Concentration (PEC) in the receiving environmental compartments (water, sediment and sewage treatment plants) were calculated according to the TGD. The calculations were made with the model EUSES[8] using input parameters presented in Table 2.1. Calculated in confidential Annex 9, $Elocal_{water}$ value was used as output from the PT 1 scenario.

Table 2.4 Input parameters for DEET used in EUSES 2.1.2 model

Parameter	Value	Unit
Molecular weight	191.27	g/mol
Melting point	-20	^{o}C
Boiling point	284.2	^{o}C
Vapour pressure at 25^{o}C	0.23	Pa
Solubility in water at 25^{o}C	11 200	mg/l
K_{ow}	2.4	-

The calculated PEC_{water}, $PEC_{sediment}$, and PEC_{STP} values for indirect emission to water, sediment and STP due to body cleaning presented in Table 2.2.

[8] EUSES version 2.1.1 (European Union System for the Evaluation of Substances)

Table 2.5 PEC values for indirect emission to surface water and sediment via the STP due to body cleaning

PEC_{STP} [mg/l]	$PEC_{surface\ water}$ [mg/l]	$PEC_{sediment}$ [mg/kg_{wwt}]
0.139	0.0139	0.0242

2.8.1.2 $PEC_{surface\ water}$ and $PEC_{sediment}$ – direct emission

Document developed by German CA proposed to calculate the local concentration in water and sediment resulting from outdoor showering or bathing (swimming) after application of the product on skin.

Polish CA used German scenario with the following parameterization:

- The assumed volume of lake is set to 1 million m^3 (1 000 000 000 l) as a worst case. This is seen as representative for a medium quarry pond and for natural and other freshwater lakes for swimming.
- For the worst case estimation the average number of people swimming on the same day in one lake or pond while using the biocidal product is set to 20 (Fmainsource = 0.002; this corresponds to 20 persons out of 10 000 inhabitants).
- The fraction of the product which is emitted to the water ($F_{emission}$) is set by default to 1.
- The time of swimming during the year is limited by the temperature of the air and the water, therefore it was estimated that swimming will take place once a day on 150 days per year as a maximum limit. The time is set as T_{1d} and $T_{emission}$.

For $PEClocal_{water}$ three situation are calculated: concentration in STP influent ($Clocal_{inf}$), local concentration in water ($Clocal_{water}$) after 1 day and annual concentration in water ($Clocal_{water\_annual}$) after 150 days.

The $Qform_{appl}$, $Cform_{appl}$, N_{appl} values and the rate constant k have been adapted according to the documentations of biocidal product *AROX na komary kleszcze i meszki* and active substance DEET.

Local emission rate to water was calculated using formula presented below:

$$Elocal_{water} = N_{swimmer} \times N_{appl} \times Qform_{appl} \times Cform_{appl} \times F_{emission} \times 10^{-6}$$

The $Clocal_{inf}$ value was calculated according to the modified equation no. 32 of the TGD, where $EFFLUENT_{STP}$ value is replaced by the volume of the lake $V_{waterbody}$ = 1 000 000 000 L/d:

$$Clocal_{inf} = \frac{Elocal_{water}}{V_{waterbody}}$$

The $Clocal_{water}$ value was calculated according to the modified equation no. 7.16 from the OECD emission scenario document for PT 8 (wood preservatives) for the release into a static water body (input of active substance for 1 day):

$$Clocal_{water} = \frac{Elocal_{water}}{V_{waterbody} \times k} \times \left[1 - \frac{\left[1 - e^{(-T_{1d} \times k)}\right]}{T_{1d} \times k}\right]$$

The $Clocal_{water\_annual}$ was calculated according to the modified equation no. 7.16 from the OECD emission scenario document for PT 8 (wood preservatives) for the release into a static water body (continuous input of active substance for one season):

$$Clocal_{water\_ann} = \frac{Elocal_{water}}{V_{waterbody} \times k} \times \left[1 - \frac{\left[1 - e^{(-T_{emission} \times k)}\right]}{T_{emission} \times k}\right]$$

However, due to the fact that certain value (for which the applicant did not confirm the access) was used in the calculation by RMS, calculation of environmental emissions due release to water bodies via swimming were placed in Annex 9 as a confidential.

$PEClocal_{water}$ used for the risk assessment is selected by comparing the three local concentrations and choosing the highest value calculated $Clocal_{inf}$ or $Clocal_{water}$ or $Clocal_{water\_annual}$ values representing the worst-case situation.
Therefore:

$$\boldsymbol{PEClocal_{water} = 0.00088\ mg/l}$$

The $PEClocal_{sediment}$ was derived from the $PEClocal_{water}$ value considering the properties of suspended matters. The $PEClocal_{sediment}$ value was estimated according to the TGD (equation 50) as follows:

$$PEClocal_{sed} = \frac{K_{susp-water}}{RHO_{susp}} \times PEClocal_{water} \times 1000$$

Therefore:

$$\boldsymbol{PEClocal_{sed} = 6.98 \times 10^{-4}\ mg/kg}$$

2.8.1.3 PEC_{soil} and $PEC_{groundwater}$ – indirect emission

The estimation of the local PEC for soil and groundwater was performed in EUSES model. The $Elocal_{water}$ value, calculated in section 3.3.2.1 was used as output from the PT1 scenario.

The PEC_{soil} and $PEC_{groundawter}$ values for indirect emission to soil and groundwater from STP are presented in Table 2.3

Table 2.6 PEC values for indirect emission to soil and groundwater due to body cleaning

$PEC_{agricultural\ soil}$ 30d [mg/kg_{wwt}]	$PEC_{agricultural\ soil}$ 180d [mg/kg_{wwt}]	$PEC_{grassland}$ 180d [mg/kg_{wwt}]	$PEC_{porewater\ grassland}$ [µg/l]	$PEC_{porewater\ agricultural\ soil}$ [µg/l]
0.012	0.00376	0.00141	1.57	4.18

According to performed calculations concentrations of DEET in porewater under grassland and agricultural soil resulting from use of biocidal product *AROX na komary kleszcze i meszki* are respectively 1.57 µg/l and 4.18 µg/l. In accordance with Directive 98/83/EC on the quality of water intended for human consumption, maximum permissible concentration of biocides (as pesticides) cannot exceed 0.1 µg/l.

Estimated DEET concentration in groundwater exceeds the permissible level. Therefore Polish CA performed calculation using the FOCUS PEARL model.

$PEC_{groundwater}$ value for the nine FOCUS groundwater scenarios, as developed for plant protection products, were calculated. Values of input parameters of FOCUS Pearl groundwater model which are not listed in Table 2.4 were set to default values.

The overall assumption is that the only exposure route to groundwater is via the application of sludge from STPs.

Table 2.7 Summary of data used and assumptions made to calculate $PEC_{groundwater}$ for active substance DEET in FOCUS scenarios

Parameter	Value
Model used	FOCUS PEARL ver. 4.4.4.
Years of simulation	26 (including 6 yrs "warming-up" period)
Application rate	0.058 kg/h[1]
Date of application	1 October annually for 20 years[2]
Molar mass	191.27 g/mol
Vapour pressure	0.23 Pa (25°C)
Solubility in water	11 200 mg/l (25°C)
K_{om}	25.1 l/kg[3]
Freundlich sorption exponent 1/n	0.9 (FOCUS default)

DT_{50} soil	30 days (12^oC)[4]
Coefficient for uptake in plants	0

[1] Calculated form EUSES output concentration of DEET in dry sewage sludge of 11.6 mg/l and application of 5 000 kg dry sludge/ha and year to agricultural land (at a single event as suggested in the TGD, section 2.3.8.5)
[2] Autumn application assumed to represent a worst-case situation
[3] Calculated from K_{oc} as 43.3/1.724
[4] In accordance with TGD section 2.3.6.5, for ready biodegradable substances

The parameter „coefficient for uptake by plants "was set to zero as a worst case scenario. The data generates a value for the 80th percentile of levels of substance present in groundwater at a depth of 1 m as an annual average in µg/L. Therefore it is the potential concentration in groundwater. Values beyond 0.1µg/l are unacceptable according to the EU Drinking Water Directive.

The resulting $PEC_{groundwater}$ calculations are presented in Table 2.5.

Table 2.8 Potential concentrations of DEET in groundwater calculated using FOCUS Pearl scenarios, assuming application of sewage sludge form STP to agricultural land (no crop calendar)

Scenario	PECgrw [µg/l]
Chateaudun	0.002311
Hamburg	0.034653
Jokioinen	0.005377
Kremsmuenster	0.015264
Okehampton	0.050752
Piacenza	0.076553
Porto	0.037714
Sevilla	0.001029
Thiva	0.001868

The FOCUS Pearl groundwater simulation reports of DEET concentration - result of use of biocidal product *AROX na komary kleszcze i meszki* show no unacceptable risk. In all scenarios predicted groundwater concentrations do not exceed the limit value of 0.1 µg/l.

2.8.1.4 PEC_{soil} and $PEC_{groundwater}$ – direct emission

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

2.8.1.5 PEC_{air}

The active substance DEET has a vapour pressure of 0.23 Pa (25°C) and a Henry's law constant of 3.93×10^{-3} Pa×m^3/mol. The substance is predicted to have an atmospheric half-life of 0.63 days (15.2 hours). Thus an accumulation of DEET in air and long range transport is unlikely. Therefore DEET is not considered as substance of concern for ozone layer.

The PEC of DEET in air is therefore considered to be negligible and the substance will not pose a risk to the air.

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

The log K_{ow} value for DEET is equal 2.4 and indicates a low bioaccumulation potential (estimate BCF value 63.1). 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 of earthworms is expected to be negligible. No avian dietary tests were therefore required. However, acute avian toxicity was measured by oral intubation and there was a clear dose-response relationship regarding both lethality and sublethal effects. DEET was found to have only slight acute avian toxicity (LD_{50} 1365 mg/kg bw). Sublethal effects (behaviour, appearance and weight loss and reduced feed intake) appeared relatively soon after dosing, but signs of toxicity disappeared with time among the survivors.

As DEET is not bioaccumulative and the concentrations in surface water and soil are low, the risk for the primary and secondary poisoning is considered acceptable.

2.8.2 Risk assessment

2.8.2.1 Aquatic compartment (including sediment and STP)

Indirect emission

Exposure of surface water and sediment to DEET from biocidal product *AROX na komary kleszcze i meszki* in that case is result of emission from STP – via showering and/or bathing of humans who have used a biocidal product.

Predicted environmental concentrations of DEET in surface water (PEC_{water}), sediment (PEC_{sed}) and STP (PEC_{STP}) were calculated in Document IIB and were compared to $PNEC_{water}$ – 0.043 mg_{DEET}/l value, $PNEC_{sed}$ – 0.0741 mg_{DEET}/l value and $PNEC_{STP}$ – 10 mg_{DEET}/l value (according to *Assessment Report*). The calculated PEC/PNEC ratios for indirect emission of biocidal product to aquatic compartment are summarised in Table 2. 6.

Table 2.9 PEC/PNEC ratios for indirect emission to the aquatic environment via the STP due to body cleaning

Emission scenario	PEC_{STP} [mg/l]	$PNEC_{STP}$ [mg/l]	PEC/PNEC
showering/bathing scenario	0.139	10	0.01

Emission scenario	PEC_{water} [mg/l]	$PNEC_{water}$ [mg/l]	PEC/PNEC
showering/bathing scenario	0.0139	0.043	0.32

Emission scenario	PEC_{sed} [mg/l]	$PNEC_{sed}$ [mg/l]	PEC/PNEC
showering/bathing scenario	0.0242	0.0741	0.33

Direct emission

Exposure of surface water and sediment to DEET – active substance in *AROX na komary kleszcze i meszki* may also occur when product is used outdoor. Exposure of surface water arises through a direct contamination – via direct release to surface water if people with treated skin swim in outdoor surface water or take shower outdoor.

Predicted environmental concentration for surface water (PEC_{water}) and sediment (PEC_{sed}) for DEET were calculated in Document IIB and were compared to $PNEC_{water}$ – 0.043 mg_{DEET}/l value and $PNEC_{sed}$ – 0.0741 mg_{DEET}/l value (according to *Assessment Report*). The calculated PEC/PNEC ratios for direct emission of biocidal product to aquatic compartment are summarised in Table 2.7.

Table 2.10 PEC/PNEC ratios for direct emission to the aquatic environment due to swimming

Emission scenario	PEC_{water} [mg/l]	$PNEC_{water}$ [mg/l]	PEC/PNEC
swimming scenario	8.80×10^{-4}	4.30×10^{-2}	0.02

Emission scenario	PEC_{sed} [mg/l]	$PNEC_{sed}$ [mg/l]	PEC/PNEC
swimming scenario	6.98×10^{-4}	7.41×10^{-2}	9.42×10^{-3}

Screening study

In 2010, SWECO Environment performed a screening study of DEET in a number of matrices and at one background locality financed by the Swedish Environmental Protection Agency[9]. The project was initiated because transnational and national studies had shown a high prevalence of DEET in both surface waters and ground waters in Europe, USA and Australia.

In the screening study measured the occurrence of DEET in matrices such as surface water, ground water and sewage water.

The active substance DEET was detected in water in STPs, surface waters downstream of STPs and in groundwater. In addition, DEET was found in water and sediments at recreational bathing sites. The results demonstrate that DEET does not occur in sewage sludge or in surface waters and sediments that are not influenced by STPs.

In risk assessment only DEET concentrations downstream of STPs were used. The main reason is that water samples taken in the close vicinity of bathers that has applied DEET to their skin cannot be viewed as representative of concentrations in the water of these lakes.

Risk characterisation ratios (RCRs) were estimated by calculating the ratio between Measured Environmental Concentration (MEC) and Predicted No Effect Concentration (PNEC) based on acute toxicity tests presented in Table 2.3.

Table 2.11 MEC/PNEC ratios for active substance DEET to the aquatic environment

MEC [ng/l]	**PNEC [ng/l]**	**RCRs**
200	47 000	0.0046

Presented above calculation suggest that DEET does not constitute an acute risk to the aquatic environment.

Conclusion: The calculated PEC/PNEC values and screening study indicate that there is no concern for the surface water, sediment and STP compartment as a result of use of biocidal product *AROX na komary kleszcze i meszki*.

[9] Screening of N,N-dietyl-m-toluamid (DEET), SWECO Environment, Screening Report, Client Swedish Environmental Protection Agency, Project number: 1270481000, Malmö 2011-07-06

2.8.2.2 Terrestrial compartment

Indirect emission

Exposure of soil to DEET from *AROX na komary kleszcze i meszki* is result of application of sludge from STP.

Predicted environmental concentration of DEET in soil (PEC_{soil}) was calculated in Document IIB and was compared to $PNEC_{soil}$ 0.0379 mg_{DEET}/kg_{wwt} value (according to *Assessment Report*). The calculated PEC/PNEC ratios for soil are summarised in Table 2.9.

Table 2.12 PEC/PNEC ratio for indirect emission to soil due to application of sludge from STP

Emission scenario	PEC_{soil} [mg/kg_{wwt}]	$PNEC_{soil}$ [mg/kg_{wwt}]	PEC/PNEC
showering/bathing scenario	0.012	0.0379	0.32

The calculated PEC/PNEC value indicates that there is no concern for the soil compartment as a result of use of *AROX na komary kleszcze i meszki* in indirect emission scenario.

Direct emission

In the scenario for the swimming pathway the terrestrial compartment is not exposed. Therefore the PEC/PNEC ratio was not calculated.

Conclusion: The calculated PEC/PNEC values are below 1 and indicate that there is no concern for soil compartment as a result of use of biocidal product *AROX na komary kleszcze i meszki*.

2.8.2.3 Groundwater compartment

Indirect emission

Exposure of groundwater to the active substance DEET derived from the product *AROX na komary kleszcze i meszki* was calculated in Document IIB.

In accordance with EU Drinking Water Directive (98/83/EC) maximum permissible concentration of biocides (as pesticides) cannot exceed 0.1 µg/l. According to the FOCUS Pearl groundwater simulation reports concentration of DEET in pore water in a depth of 1 m are below 0.1µg/l, so does not exceed the permissible level and does not posed unacceptable risk.

Direct emission

In the scenario for the swimming pathway the groundwater is not exposed. Therefore the PEC/PNEC ratio was not calculated and risk not assessed.

2.8.2.4 Atmosphere

The PEC/PNEC ratio was not calculated, the physiochemical properties of DEET do not suggest that this substance will pose a significant threat to air.

2.8.2.5 Primary poisoning and secondary poisoning (non compartment specific effects relevant to the food chain)

Primary poisoning of birds and mammals due to intake of the product is not expected to be relevant. Considering the low acute toxicity of DEET to birds (LD_{50} 1365 mg/kg bw) and the type of use intake by birds and mammals of the active substance via water is considered as negligible.

Although PEC/PNEC ratios could not be calculated, it can be concluded that no risk for secondary poisoning has been identified based on the low BCF value.

2.9 Measures to protect man, animals and the environment

1. Product should be stored in original, labelled and closed container, at room temperature, in dry place inaccessible to children and pets.
2. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
3. Package cannot be reused and be used for any other purpose.
4. Do not use on children <12 years old.
5. Do not use more than twice a day.
6. For facial application, distribute the product on your hands and rub the product over the face.
7. Causes serious eye damage.
8. Contains d-limonene and citral. May produce an allergic reaction.
9. Avoid contact with eyes and areas around eyes, mucous membranes and damaged skin.
10. Keep this product away from children.
11. Wash hands after application.
12. Use only outdoors or in a well-ventilated area.

13. The product is not to be used with other products (biocidal and suntan products).
14. Do not eat, drink or smoke when using this product.
15. Read label before use.
16. Dispose of contents/containers in accordance with the national regulations.
17. Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F

3 Proposal for decision

1. Product Formulation - active substance content	**% w/w**	**Manufacturer of active substance**
N,N-diethyl-m-toluamide (DEET)	19.5	Vertellus Specialties Inc. 201 N Illinois Street, Suite 1800, Indianapolis, IN 46204 USA

2. Formulation type	Lotion
3. Product type	PT19
4. User	non-professionals
5. Packaging	plastic pump bottle 50 ml (50g), 75 ml (75g), 100 ml (100g), 150 ml (150g), 200 ml (200g), 250 ml (250g)
6. Application	outdoor (against ticks and black flies) indoor in well ventilated area (against mosquitoes and black flies)
7. Application Method	applied on uncovered skin
8. Organism controlled	mosquitoes (*Culicidae*) ticks (*Ixodidae*) black flies (*Simulidae)*
9. Shelf life	up to 3 years
10. Expiry data of the authorisation	10 years from the date of granting the authorization
11. Any other specific conditions:	Please see section 2.9

Annex 1: Summary of product characteristics

Annex 2: List of studies reviewed

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
IIIB	3.1.1 3.1.2 3.1.3	Viktória Halász-Laky	2012	Determination of the Physical State of Mosquito and Tick Repellent Lotion Study no: 484.191.3734	DEET Lotion Repellent Task Force	☒	☐	☒	☐
IIIB	3.4	Viktória Halász-Laky	2013	Determination of the Flash Point of Mosquito and Tick Repellent Lotion Filling Solution Study no: 484.191.4186	DEET Lotion Repellent Task Force	☒	☐	☒	☐
IIIB	3.4	Viktória Halász-Laky	2013	Sustained Combustibility Test with Mosquito and Tick Repellent Lotion without Fragrance Study no: 484.191.4487	DEET Lotion Repellent Task Force	☒	☐	☒	☐
IIIB	3.5	Viktória Halász-Laky	2012	Determination of the pH and Acidity or Alkalinity of Mosquito and Tick Repellent Lotion Filling Solution Study no: 484.191.3736	DEET Lotion Repellent Task Force	☒	☐	☒	☐
IIIB	3.6	Viktória Halász-Laky	2012	Determination of the Relative Density of Mosquito and Tick Repellent Lotion Filling Solution Study no: 484.191.3735	DEET Lotion Repellent Task Force	☒	☐	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IIIB	3.7	Viktória Halász-Laky	2012	Determination of the Storage Stability of Mosquito and Tick Repellent Lotion Accelerated Storage Test Study no: 484.105.3733	DEET Aerosol Repellent Task Force	☒	☐	☒	☐
IIIB	3.10	Viktória Halász-Laky	2012	Determination of the Viscosity of Mosquito and Tick Repellent Lotion Filling Solution Study no: 484.191.3737	DEET Aerosol Repellent Task Force	☒	☐	☒	☐
IIIA	4.2(c)	Chris Miller	2013	DEET: Validation of Methodology for the Determination of Residues in Air Study no: RQN0001	Vertellus Specialties Inc	☒	☐	☒	☐
IIIB	4.1/01	Viktória Halász-Laky	2012	Validation of the Analytical Method for the Determination of the Active Ingredient Content of Mosquito and Tick Repellent Lotion Study no: 484.199.3732	DEET Aerosol Repellent Task Force	☒	☐	☒	☐
IIIB	4.1/02	Laboratorium Z.Ch. Organika-Azot S.A. w Jaworznie	2014	Validation of the Analytical Method for the Determination of DEET content of AROX Spray for mosquitoes ticks and black flies (Raport z walidacji metody analitycznej oznaczania DEET w preparacie przeciw komarom i kleszczom „Arox DEET Lotion 19.5%") Study no: 3/DEET/2014	Z.Ch. Organika-Azot S.A	☒	☐	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IIIB	5.10/01 5.10/02 5.10/03	Helena Heaven	2012	Laboratory study to determine the efficacy of 19.5% DEET Lotion Repellent against mosquitoes, *Aedes albopictus* and *Culex quinquefasciatus* and ticks, *Ixodes*, Study Code: 12/150B I2LResearch Ltd	DEET Aerosol Repellent Task Force	☒	☐	☒	☐
IIIB	5.10/04	Narodowy Instytut Zdrowia Publicznego PZH, Samodzielnia Pracownia Entomologii Medycznej i Zwalczania Szkodników	2014 and 2015	Sprawozdanie z badań labolatoryjnych preparatu "19,5% DEET Lotion Repellent" w zakresie działania odstraszającego na kleszcze, Procedure Nr.: Zm-22-HS. Date: 17.11.2014 and addendum dated on 21.01.2015 and 13.02.2015	Agrecol Sp. z o.o.	☐	☒	☒	c
IIIB	5.10/05	Helena Heaven	2012	Laboratory study to determine the efficacy of 19.5% DEET Lotion Repellent against black flies, *Simulium* spp, Study Code: 12/151B I2LResearch Ltd Report amendment no:1, Laboratory study to determine efficacy of two repellents against black flies. Study code: 12/151	DEET Lotion Repellent Task Force	☒	☐	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IIIB	5.10/06	Helena Heaven	2012	Field study to determine the efficacy of 19.5% DEET Lotion Repellent against black flies, *Simulium* spp, Study Code: 12/152B I2L Research Ltd. UK	DEET Lotion Repellent Task Force	☒	☐	☒	☐
IIIB	6.2.1 (01)	István Ágh	2012	In Vitro Skin Irritation Test with Mosquito and Tick Repellent Lotion Filling Solution in the EPISKIN Model Study no: 484.554.3759	DEET Lotion Repellent Task Force	☒	☐	☒	☐
IIIB	6.2.2 (1)	István Buda	2012	Mosquito and Tick Repellent Lotion Filling Solution In vitro test for eye corrosives and severe irritants in isolated chicken eyes Study no: 484.549.3761	DEET Lotion Repellent Task Force	☒	☐	☒	☐
IIIB	6.2.2 (2)	Piroska Mácsai Kuthy	2012	Acute eye irritation study Of test item mosquito and tick repellent Lotion filling solution in rabbits Study no: 484.551.3865	DEET Lotion Repellent Task Force	☒	☐	☒	☐
IIIB	6.3 (01)	Mária Pénzes	2012	Skin sensitization study: local lymph node assay of test item Mosquito and Tick Repellent Lotion without fragrance IN MICE (Pooled Treatment Group Approach) Study No: 484.553.4183	DEET Lotion Repellent Task Force	☒	☐	☒	☐

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IIIB	6.4	Charles River, Tranent	2013	The *In Vitro* Percutaneous Absorption of Radiolabelled N,N Diethyl-meta-toluamide (DEET) in a Lotion Repellent Test Facility Study No. 792508, Report No.33938	Agrecol Sp. z o.o	☐	☒	☒	☐

Annex 3: Analytical methods residues – active substance

<DEET>

New data was submitted for determination DEET in air.

Methods for air

Reference	LOQ (mg/m3)	Principle	Comment	Owner
Chris Miller (2013) "DEET: Validation of Methodology for the Determination of Residues in Air"	0.225	LC-MS/MS	-	Vertellus Specialties Inc

Annex 4: Toxicology and metabolism –active substance

<DEET>

No new data for the active substance was submitted. For datailed information please see the CAR for active substance DEET.

Annex 5: Toxicology – biocidal product

<AROX na komary kleszcze i meszki>

General information	
Formulation Type:	Lotion
Active substance(s) (incl. content)	19.5 % w/w DEET
Category	PT19 (Repellents and attractants)

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)	
Rat LD_{50} oral (OECD 420)	No study was submitted
Rat LD_{50} dermal (OECD 402)	No study was submitted
Rat LC_{50} inhalation (OECD 403)	No study was submitted
Skin irritation (OECD 439)	Not irritating
Eye irritation (OECD 438) (OECD 405)	Moderately irritating Risk of serious damage to eyes (R41) Causes serious eye demage (H318)
Skin sensitisation (OECD 429; LLNA)	Not a skin sensitizer

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)	
Short-term toxicity studies	Not required
Toxicological data on active substance(s) (not tested with the preparation)	For datailed information please see the CAR for active substance DEET.
Toxicological data on non-active substance(s) (not tested with the preparation)	The biocidal produkt contains ethanol as a substance of concern. The content of ethanol in the formulation is 8.33%. For datailed information please see chapter 2.7.1.2 of PAR.
Further toxicological information	The biocidal product *AROX na komary kleszcze i meszki* is not intended to be used in areas where food for human consumption is prepared, consumed or stored, or where feeding

	stuff for livestock is prepared, consumed or stored. Therefore, no additional toxicological information is considered necessary.

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
according to EC 1272/2008	
H318	Causes serious eye damage
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing
P310	Immediately call a POISON CENTER or doctor

Annex 6: Safety for professional operators

<AROX na komary kleszcze i meszki>

Product is not intended for professional use.

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

< Active substance DEET >

Estimated exposure based on default values for 2 years child using ConsExpo 4.1 is summarized in table below (Tier 1)

Dose	Lotion application [1 application/day]	Lotion application [2 applications/day]
Dermal		
Dermal external dose	31.5 mg/kg	31.5 mg/kg
Dermal acute (internal) dose	6.3 mg/kg	6.3 mg/kg
Dermal chronic (internal) dose	6.3 mg/kg/day	12.6 mg/kg/day
Oral		
Oral external dose	3.15 mg/kg	3.15 mg/kg
Oral acute (internal) dose	3.15 mg/kg	3.15 mg/kg
Oral chronic (internal) dose	3.15 mg/kg/day	6.31 mg/kg/day
Total		
Total external dose	34.7 mg/kg	34.7 mg/kg
Total acute dose (internal)	9.46 mg/kg	9.46 mg/kg
Total chronic dose (internal)	9.46 mg/kg/day	18.9 mg/kg/day

Estimated exposure based on default values for 12.5 years child using ConsExpo 4.1 is summarized in table below (Tier 1)

Dose	Lotion application [1 application/day]	Lotion application [2 applications/day]
Dermal		
Dermal external dose	22.3 mg/kg	22.3 mg/kg
Dermal acute (internal) dose	4.46 mg/kg	4.46 mg/kg
Dermal chronic (internal) dose	4.46 mg/kg/day	8.91 mg/kg/day
Oral		
Oral external dose	2.22 mg/kg	2.22 mg/kg
Oral acute (internal) dose	2.22 mg/kg	2.22 mg/kg
Oral chronic (internal) dose	2.22 mg/kg/day	4.45 mg/kg/day
Total		
Total external dose	24.5 mg/kg	24.5 mg/kg
Total acute dose (internal)	6.68 mg/kg	6.68 mg/kg
Total chronic dose (internal)	6.68 mg/kg/day	13.4 mg/kg/day

Estimated exposure based on default values for adult using ConsExpo 4.1 is summarized in table below (Tier 1)

Dose	Lotion application [1 application/day]	Lotion application [2 applications/day]
Dermal		
Dermal external dose	19.5 mg/kg	19.5 mg/kg
Dermal acute (internal) dose	3.9 mg/kg	3.9 mg/kg
Dermal chronic (internal) dose	3.9 mg/kg/day	7.8 mg/kg/day
Oral		
Oral external dose	0.778 mg/kg	0.778 mg/kg
Oral acute (internal) dose	0.778 mg/kg	0.778 mg/kg
Oral chronic (internal) dose	0.778 mg/kg/day	1.56 mg/kg/day
Total		
Total external dose	20.3 mg/kg	20.3 mg/kg
Total acute dose (internal)	4.68 mg/kg	4.68 mg/kg
Total chronic dose (internal)	4.68 mg/kg/day	9.36 mg/kg/day

Estimated exposure based on the 75th percentile of human use rate (Boomsma and Parthasarathy, 1990) (Tier 2)

Category of users	Dermal internal dose [mg/kg bw/day]		Oral internal dose [mg/kg bw/day]	
	1 application per day	2 applications per day	1 application per day	2 applications per day
<12 years child	8.3	16.6	3.3	6.6
>12 years child	3.9	7.9	1.6	3.2
Adult, female	2.5	5.0	0.5	1.0
Adult, male	3.2	6.4	0.6	1.3

Summary of risk for non-professional users

% AEL		*AROX na komary kleszcze i meszki*							
		Tier 1				**Tier 2**			
		1 application per day		**2 applications per day**		**1 application per day**		**2 applications per day**	
		Dermal	**Oral**	**Dermal**	**Oral**	**Dermal**	**Oral**	**Dermal**	**Oral**
<12 years child*		77	420	154	841	101	444	203	888
>12 years child		54	296	109	593	48	211	97	421
Adult	**Female**	48	104	95	208	30	66	61	133
	Male					39	85	78	171

*in Tier 1 %AEL for <12.5 years child has been presented as for 2 years child

Reverse reference scenario for 75th percentile of use

	External exposure per application [mg/kg bw/day]	**Internal dose (dermal only*) [mg/kg bw/day]**	**AEL_{acute}** / external exposure**	**$AEL_{repeated}$** / internal exposure (dermal only)**
children <12 years	41.6	8.3	0.018	0.988
children >12 years	19.7	3.9	0.038	2.103
adult males	16.0	3.2	0.047	2.562
adult females	12.4	2.5	0.060	3.280

*oral ingestion is not expected to give a significant contribution to the exposure with use of product containing Bitrex. **AEL_{acute}= 0.75 mg/kg bw/day based on the 5 day oral study in dogs.***$AEL_{repeated}$= 8.2 mg/kg bw/day, based on the dermal 90 day study in rats and a dermal absorption in rats of approximately 82%.

< Ethanol as substance of concern >

Estimated exposure based on default values for 2 years child using ConsExpo 4.1 is summarized in table below (Tier 1): 8.33% ethanol

Dose	Lotion application 1 application/day	Lotion application 2 applications/day
Dermal		
Dermal external dose	13.5 mg/kg	13.5 mg/kg
Dermal acute (internal) dose	3.37 mg/kg	3.37 mg/kg
Dermal chronic (internal) dose	3.37 mg/kg/day	6.73 mg/kg/day
Oral		
Oral external dose	1.35 mg/kg	1.35 mg/kg
Oral acute (internal) dose	1.35 mg/kg	1.35 mg/kg
Oral chronic (internal) dose	1.35 mg/kg/day	2.7 mg/kg/day
Total		
Total external dose	14.8 mg/kg	14.8 mg/kg
Total acute dose (internal)	4.72 mg/kg	4.72 mg/kg
Total chronic dose (internal)	4.72 mg/kg/day	9.44 mg/kg/day

Estimated exposure based on default values for 12.5 years child using ConsExpo 4.1 is summarized in table below (Tier 1): 8.33% ethanol

Dose	Lotion application [1 application/day]	Lotion application [2 applications/day]
Dermal		
Dermal external dose	9.52 mg/kg	9.52 mg/kg
Dermal acute (internal) dose	2.38 mg/kg	2.38 mg/kg
Dermal chronic (internal) dose	2.38 mg/kg/day	4.76 mg/kg/day
Oral		
Oral external dose	0.95 mg/kg	0.95 mg/kg
Oral acute (internal) dose	0.95 mg/kg	0.95 mg/kg
Oral chronic (internal) dose	0.95 mg/kg/day	1.9 mg/kg/day
Total		
Total external dose	10.5 mg/kg	10.5 mg/kg
Total acute dose (internal)	3.33 mg/kg	3.33 mg/kg
Total chronic dose (internal)	3.33 mg/kg/day	6.66 mg/kg/day

Summary of risk for non-professional users (8.33% ethanol)

12.5 years child	Oral chronic dose [mg/kg bw/day]	Dermal chronic dose [mg/kg bw/day]	%AEL*
1 application per day	0.95	2.38	9.9
2 applications per day	1.9	4.76	19.8

***** Taking into account only dermal exposure

Annex 8: 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.

Annex 9: Confidential information – ONLY FOR RMS INFORMATION, NOT FOR APPLICANT

This part of the Product Assessment Report contains data submitted NOT by applicant.

Applicant did not submitted the access for certain value which was used in the calculation by Polish Competent Authority, therefore **information contained in this Annex are NOT intended for the applicant but for the Member States only.**