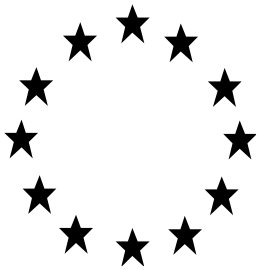
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



SZUKU szúnyog- és kullancsriasztó gél

SZUKU mosquito- and tick repellent gel

Product type 19

DEET (N,N-dietil-m-toluamid) 24.8% w/w

Current case No in R4BP: BC-NF068578-24

Previous authorization No: HU-2014-PA-19-00092-0000

Evaluating Competent Authority: Hungary

Date: 30 June 2022

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1 CONCLUSION

Szuku Mosquito- and Tick Repellent Gel is a ready-for-use cream containing 24.8% N,N-diethyl-meta-toluamide (DEET) as active substance. The product is used as a repellent by general public for the control of mosquitoes, and ticks.
In 2014 the first authorisation of the product was granted by Hungary, with authorisation number HU-2014-PA-19-00092-0000.
As the applicant did not submit the renewal of the product authorisation within the requested deadline, the product authorisation could not be granted under the RNL procedure.
The authorisation resulting from this procedure is considered as a new national authorisation.

Approval of the active substance:
The active substance DEET is included in the Union list of approved active substances, the approval of DEET for use in biocidal products of product-type 19 will expire on 31 July 2022. The expiry date of approval of DEET for use in biocidal products of product type 19 was postponed to 31 January 2025 by Decision (EU) 2021/2146.

The overall conclusion of the evaluation is that Szuku Mosquito- and Tick Repellent Gel meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore can be authorised for the use as repellent against mosquitoese and ticks used by general public The detailed grounds for the overall conclusion are described in this Product Assessment Report.

Composition
The composition of the product has been changed, the fragrance (0.5% pine scent) has been completely removed from it, concentration of water was increased accordingly.
The concentration of the active ingredient and all other components remain unchanged.

Physical hazard and physico-chemical properties
No physical hazard is identified.

Information and data submitted allow assessment of the physico-chemical properties of biocidal product, they are deemed acceptable for the appropriate use.
The Hungarian authority is of the opinion that the GLP stability studies with the old formulation are acceptable, as the omission of fragrances has a positive impact on shelf life. The shelf life of the product is two years under unchanged storage conditions.

Methods for detection and identification
A validated analytical method for the determination of the concentration of the active substance is available

Human health

The risk to non-professionals is acceptable with some risk management measures.

- For adults: one application per day is considered safe with standard use pattern: the product is applied to the face, neck, shoulders, upper and lower arms, hands, upper and lower legs, feet.

- For children between 2 and 6 years: Use of product once per day is safe. However, when we take into account the possibility of hand-to-mouth behaviour, an unacceptable risk is identified. Additional RMMs are requested, as adding a bittering agent (Bitrex) to the product to reduce ingestion and the repellent must be labelled according to the following: it must be applied only by adults; do not apply to children's palms; keep out of reach of children. In addition, the label should direct adults to wash their hands following application.

- For children more than 6 years of age: use of the Szuku Mosquito- and Tick Repellent Gel once per day is considered safe.

Efficacy

New efficacy reports were presented for the evaluation of the current formulation against *Aedes aegypti* and *Ixodes ricinus*.
It can be concluded from the test results that Szuku Mosquito- and Tick Repellent gel effectively repels mosquitoes for 5.5 hours and ticks for 3 hours when used according to the instructions.

Environment

In conclusion for the environment, the risk is expected to be unacceptable from indirect emission to groundwater from the use of Szuku mosquito- and tick repellent gel. The following risk mitigation measure is proposed to reduce the risk to an acceptable level:

- *„Preferably wear long-legged trousers and a long-sleeved shirt to reduce the amount of product needed for protection*."

It can be concluded that the conditions of article 19 of regulation (EU) no. 528/2012 are fulfilled and that the product may be authorised.

The biocidal product will be authorised for a period of 10 years in accordance with Article 17(4) of Regulation (EU) No 528/2012.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country (if relevant)**
SZUKU mosquito- and tick repellent gel	Hungary
SZUKU szúnyog- és kullancsriasztó gél	Hungary

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	**METATOX** Peszticid Gyártó- és Forgalmazó Kft.
	Address	H-5520 Szeghalom, Kossuth str. 8. HUNGARY
Authorisation number	HU-2022-PA-19-00399-0000	
Date of the authorisation	08/07/2022	
Expiry date of the authorisation	08/07/2032	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	METATOX Peszticid Gyártó- és Forgalmazó Kft.
Address of manufacturer	H-5520 Szeghalom, Kossuth str. 8. HUNGARY
Location of manufacturing sites	H-5520 Szeghalom, Kossuth str. 8. HUNGARY

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

Active substance	N,N-diethyl-m-toluamide (DEET)
Name of manufacturer	Vertellus Chemicals SA (acting for Vertellus LLC (United States) Avenue du Port 86 C BP 204 1000, Bruxelles Belgium
Address of manufacturer	201 N. Illinois Street, Suite 1800, IN 46204 Indianapolis, USA
Location of manufacturing sites	2110 High Point Road, Greensboro NC 27403, USA

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

2.1.2 Product composition and formulation

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

Yes ☐
No ☑

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	**DEET**
IUPAC or EC name	N,N-diethyl-meta-toluamide
EC number	205-149-7
CAS number	134-62-3
Index number in Annex VI of CLP	616-018-00-2
Minimum purity / content	min. 97.0 w/w % (970 g/kg)
Structural formula	

2.1.2.2 Candidate(s) for substitution

DEET is not a candidate for substitution in accordance of Article 10 of Reg. (EU) 528/2012 and its modifications.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product[2]

Common name	**IUPAC name**	**Function**	**CAS number**	**EC number**	**Content (w/w%)**
DEET, tech	N,N-diethyl-m-toluamide	Active substance	134-62-3	205-149-7	24.80
Stearyl alcohol, ethoxylated, <2.5 EO	octadecane-1-ol, ethoxlated (<2.5 mol EO)	emulsifier	9005-00-9	500-017-8	3.80

Please see the confidential annex for full composition.

2.1.2.4 Information on technical equivalence

There are no issues raised regarding the technical equivalence of the active substance. Metatox Kft. has a letter of access to the complete DEET dossier from Vertellus Chemicals SA (acting for Vertellus LLC (United States)) who is on the Article 95 list as RP participant

2.1.2.5 Information on the substance(s) of concern

The product contains stearyl alcohol, etoxylated <2.5 EO, which is classified into environmental hazard classes: Aquatic Acute 1 with M factor: 1 and Aquatic Chronic 2.
The classification is taken from the most recent safety data sheet of the component, earlier safety data sheet does not classify the substance as an environmentally hazardous substance.
Due to the concentration of stearyl alcohol, etoxylated <2.5 EO the product itself has long-term (chronic) hazard and should be classified as Aquatic Chronic 3 according to Table 4.1.3. of Reg. EC No. 1272/2008.
On the basis of the above, stearyl alcohol, etoxylated <2.5 EO shall be considered a substance of concern (SoC) in this biocidal product.

2.1.2.6 Type of formulation

EW – emulsion, oil in water (ready-to-use product)

2.1.3 Hazard and precautionary statements

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

Classification	
Hazard class/category	**Eye Irrit. 2** Serious Eye Damage/eye irritation - Category 2 **Aquatic Chronic 3** Long term (chronic) Aquatic Hazard – Category 3
Hazard statements	H319 Causes serious eye irritation. H412 Harmful to aquatic life with long lasting effects.
Labelling	
Signal words	WARNING
Pictogram	 GHS07
Hazard statements	H319 Causes serious eye irritation. H412 Harmful to aquatic life with long lasting effects
Precautionary statements	P102 Keep out of reach of children. P273 Avoid release to the environment. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313 If eye irritation persists: Get medical advice/attention. P501 Dispose of contents/container to national regulations.
Note	None of the packaging units of the product is larger than 125 ml, so the hazard and precautionary statements can be omitted from the label.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Ready-to-use mosquito- and tick repellent gel for amateur use

Product Type	PT19 (repellents and attractants)
Where relevant, an exact description of the authorised use	Repellent for outdoor use to be applied on the skin exposed to mosquito and tick bites. The formulation is not suitable for the use on cloth and hair. The product should be applied by an adult on children under 12 years old. Adults or children should not use the product more than once a day.
Target organism (including	**Culicidae (mosquitoes)** Stage: adults

development stage)	**Ixodidae (hard ticks)** Stages: Adults, nymphs
Field of use	Outdoor use
Application method(s)	Manual application, spreading evenly on the skin.
Application rate(s) and frequency	Once a day 1 g / 600 cm^2 (600 cm^2 is approximately equal to the skin area of the forearm of an average adult.) The product repels mosquitoes for 5.5 hours (330 minutes) and repels ticks for 3 hours.
Category(ies) of users	Non-professionals / general public
Pack sizes and packaging material	see Section 2.1.7. PE/PP cream jar with a screw-on cap with, 40 g, 50 g, 60 g, 80 g and 100 g filling weight.

2.1.4.2 Use-specific instructions for use

See general instructions

2.1.4.3 Use-specific risk mitigation measures

See 2.1.5.3.

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

See 2.1.5.4

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

See 2.1.5.5.

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

See 2.1.5.6.

2.1.5 General directions for use

2.1.5.1 Instructions for use

Spread the gel evenly over the skin surface to be protected.
When using on face, apply the repellent to the palms first then spread the product on the face avoiding contact with the eyes and the mouth.
The product should be applied by an adult on children under 12 years old. Adults or children should not use the product more than once a day. Do not apply the product to children's palms.

Do not apply to sunburned or scarred skin, avoid contact with open wounds.
Users with known allergies or sensible skin should use the product with special care, i.e. treat only a small area of skin for the first time. Should allergic symptoms (such as rubefaction, rash, etc.) appear on the skin as a result of the use of the product, immediately remove by washing with plenty of water and soap. Once protection against insect bites is not needed any more, wash treated skin with soap and water.
The product may damage certain synthetic fibres, imitation leather, plastics, watch glass, painted and varnished surfaces.

2.1.5.2 Risk mitigation measures

Use according to the instructions.
Use only outdoors.
Preferably wear long-legged trousers and a long-sleeved shirt to reduce the amount of product needed for protection.
Wash hands thoroughly with soap and water after use and before eating.
The product contains a bitter taste (Bitrex) that prevents accidental human consumption.
Make sure that the product does not get on cutlery, food or feed.
Store locked up.
Manufacturer's recommendation: pregnant and lactating women should avoid using the product if possible.

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

Contact with eyes: wash immediately with plenty of water. If there are contact lenses in the eyes, remove them and continue rinsing for a few minutes. Consult eye-specialist in case of irritation or impaired vision persists.
Contact with skin: in case of allergic symptoms, wash affected area with plenty of water. Consult a specialist if you have persistent complaint.
Inhalation: move to fresh air.
Ingestion: Get immediate medical advice and show the label to the doctor.

Use caution when using the product to minimize the risk of splashing, dripping, and / or scattering on the ground.

2.1.5.4 Instructions for safe disposal of the product and its packaging

Dispose of waste in accordance with local, national regulations. Do not re-use container for any purpose.
Prevent entry into drains or water-bodies.

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

Shelf life of the products is 2 years. Store the product in the original container in a dry and cool place away from heat and direct sunlight. Protect from frost, do not store at temperatures below 0°C. Store at temperature no greater than 35°C Keep out of reach of children. Keep away from food, drink and animal feeding stuffs.

2.1.6 Other information

not available

2.1.7 Packaging of the biocidal product

Type of packaging	**Size/volume of the packaging**	**Material of the packaging**	**Type and material of closure(s)**	**Intended user (e.g. professional, non-professional)**	**Compatibility of the product with the proposed packaging materials (Yes/No)**
Ready-to-use mosquito- and tick repellent gel placed into a PE or PP cream jar	40 g	PE or PP plastic cream jar	Cream jar close with PE/PP screw-on closer-cap	non-professional (amateur use)	Yes
Ready-to-use mosquito- and tick repellent gel placed into a PE or PP cream jar	50 g	PE or PP plastic cream jar	Cream jar close with PE/PP screw-on closer-cap	non-professional (amateur use)	Yes
Ready-to-use mosquito- and tick repellent gel placed into a PE or PP cream jar	60 g	PE or PP plastic cream jar	Cream jar close with PE/PP screw-on closer-cap	non-professional (amateur use)	Yes
Ready-to-use mosquito- and tick repellent gel placed into a PE or PP	80 g	PE or PP plastic cream jar	Cream jar close with PE/PP screw-on closer-cap	non-professional (amateur use)	Yes

cream jar.					
Ready-to-use mosquito- and tick repellent gel placed into a PE or PP cream jar	100 g	PE or PP plastic cream jar	Cream jar close with PE/PP screw-on closer-cap	non-professional (amateur use)	Yes

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

Data on the active substance are available through Letter of access.
Data on the product are available in the IUCLID dossier.

2.1.8.2 Access to documentation

In support of the biocidal product authorization of DEET containing products in Hungary Vertellus Chemicals SA (acting for Vertellus LLC United States) granted the Metatox Kft. access to the data of the active ingredient DEET.

2.2 Assessment of the biocidal product (family)

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

Table 2. Intended use # 1

Product Type(s)	PT19 (repellents and attractants)
Where relevant, an exact description of the authorised use	The amateur users will use the repellent gel outdoor. Certain risk mitigation measures that reduce the exposure in children are necessary. These mitigation measures include: Children under 12 years old should not apply the product themselves, only with help from an adult. Do not use on unsuitable exposure areas i.e. palms and around eyes and mouth.
Target organism (including development stage)	**Culicidae (mosquitoes)** Stage: adults **Ixodidae (hard ticks)** Stages: Adults, nymphs
Field of use	Outdoor use
Application method(s)	Manual application, spreading evenly on the skin.
Application rate(s) and frequency	Once a day 1 g / 600 cm^2 (600 cm^2 is approximately equal to the skin area of the forearm of an average adult.) The product repels mosquitoes for 5.5 hours (330 minutes) and repels ticks for 3 hours.
Category(ies) of user(s)	Non-professionals / general public
Pack sizes and packaging material	see Section 2.1.7. PE/PP cream jar with a screw-on cap with, 40 g, 50 g, 60 g, 80 g and 100 g filling weight.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20°C and 101.3 kPa	visual inspection	Batch No.: 20220330/1	highly viscous creamy fluid	Metatox in house results on physical state, colour and odour by sensorial, organoleptic methods; 20 April 2022.
Colour at 20°C and 101.3 kPa	visual inspection	Batch No.: 20220330/1	white	
Odour at 20°C and 101.3 kPa	olfactory characterisation	20220230/1	no odour	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Taste	Bitter taste due to denatonium benzoate content. Detection threshold is 0.05 ppm ($5x10^{-6}$%) of denatonium benzoate. Product contains $5x10^{-4}$% denatonium benzoate, which is a 100-times higher concentration than the detection threshold.			U.S. consumer Products Safety Commission: Study of Aversive Agents, 1992
Acidity / alkalinity pH	CIPAC MT 191	Batch No.: 20130702/1	No need because pH is between 4 – 10 pH: 5.2 (20°C)	Study no: 671.191.4443 (GLP)
Relative density / bulk density	A3	Batch No.: 20130702/1	0.991 at 20°C	Study no: 671.191.4441 (GLP)
Storage stability test – **accelerated storage**	GIFAP, GC/FID	Samples in commercial packaging were kept 8 weeks at 40±2°C	Mean of DEET concentration: Start:25.8±0.2% End: 26.4±0.2%	Accelerated Storage stability test: GLP Study no: 671.105.4449 (GLP)
Storage stability test – **long term storage at ambient temperature**	GIFAP Technical Monograph N°17, Guidelines for Specifying the Shelf Life of Plant Protection Products, 2nd Edition, June 2009 GC/FID	Szuku gél Batch No: 20130702/1 Appearance: Highly viscous, white, creamy fluid with mild pine scent	No significant change after 6, 12 and 24months storage at 20°C: **DEET conc.:** Start: 25.8±0.2% 6 months: 25.5±0.1% 12 months: 26.7±0.2% 24 months: 26.1±0.2% **pH at 20°C** Start: 5.3 6 months:5.6 12 months: 5.5 24 months: 5.5 **Appearance:** does not change during the study **Container:** intact package and label during the whole study, in each timepoint.	Determination of Storage Stability of Szuku gél: GLP Study no: 671-105-4449 (GLP). Start: July 2013 End: Sept. 2015
Storage stability test – **low temperature stability test for liquids**	No study		Waived. As on the label must appear: keep away from frost. Storage	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			temperature must not fall below 0°C.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			The package precludes the effect of light to be considered.	
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**			See the storage stability tests.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**			Assessed as part of long-term storage stability test.	
Wettability	waived		Not required as the product is RTU	
Suspensibility, spontaneity and dispersion stability	waived		Not required as the product is RTU	
Wet sieve analysis and dry sieve test	waived		Not required as the product is RTU	
Emulsifiability, re-emulsifiability and emulsion stability	waived		Not required as the product is RTU	
Disintegration time	waived		Not required as the product is RTU	
Particle size distribution, content of dust/fines, attrition, friability	waived		Not required as the product is RTU	
Persistent foaming	waived		Not required as the product is RTU	
Flowability/Pourability/Dustability	waived		Not required as the product is RTU	
Burning rate — smoke generators	waived		Not required as the product is RTU	
Burning completeness — smoke generators	waived		Not required as the product is RTU	
Composition of smoke — smoke generators	waived		Not required as the product is RTU	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Spraying pattern — aerosols	waived		Not required as the product is RTU	
Physical compatibility	Not relevant as the product is not intended to be mixed with other substances, products.		The product should not be applied with other substances, mixtures.	
Chemical compatibility	Not relevant as the product is not intended to be mixed with other substances, products.		The product should not be applied with other substances, mixtures.	
Degree of dissolution and dilution stability	waived		Not required as the product is RTU	
Surface tension	Surface tension was not determined. justification was provided instead.		The value of the surface tension of the product has no influence on the hazards of the product and has no influence on the efficacy.	Accepted.
Viscosity	OECD 114	Batch No.: 20130702/1 A constant viscosity cannot be specified, because of the non-Newtonian behaviour of the product.	at 20°C dynamic: >75000 mPas kinematic: >75000 mm^2/s at 40°C dynamic: 1000–2000 mPas kinematic: 1000–2000 mm^2/s	Study no: 671.191.4447 (GLP)

Conclusion on the physical, chemical and technical properties of the product
Data and information submitted allow reliable assessment of the physical-chemical properties of Szuku Mosquito- and Tick Repellent Gel. No physical-chemical hazard occurs. Consideration of the physical-chemical properties of the product does not suggest any explosive, oxidising, flammable potential. Storage stability study (GLP) at ambient temperature was performed with the composition containing 0.5% pine scent (old formulation), read-across of these results are acceptable as the concentration of DEET and all other components except water remain the same and absence of fragrance is beneficial for shelf life. The water concentration is increased by 0.5%.

Shelf life of the product is 2 years.
Store in the original container in a dry and cool place away from heat and direct sunlight.
Protect from frost, do not store at temperatures below 0°C.
Store at temperature no greater than 35°C.

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Justification of no submission data		Consideration of structure and physical-chemical properties of the components does not suggest any explosive, oxidising potential. Widespread experiments over many years have not shown any evidence of explosiveness.	
Flammable gases	waived		Not relevant. The product is emulsion	
Flammable aerosols	waived		Not relevant as the product is not an aerosol	
Oxidising gases	waived		Not relevant. The product is emulsion	
Gases under pressure	waived		Not relevant. The product is emulsion	
Flammable liquids	Justification of no submission data		Not relevant. The product is creamy gel, therefore flash point is not applicable. None of the components are classified as flammable.	
Flammable solids	waived		Not relevant. The product is emulsion	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Self-reactive substances and mixtures	waived		There are no chemical groups present in the molecules of ingredients associated with self-reactive properties according to tables in Appendix 6 of the UN RTDG Manual.	
Pyrophoric liquids	waived		During production, handling and storage no experience has shown evidence that the porduct ignites spontaneously on coming into contact with air.	
Pyrophoric solids	waived		Not relevant. The product is not solid.	
Self-heating substances and mixtures	waived		Not relevant the product is not a solid. None of the components are classified as self-heating.	
Substances and mixtures which in contact with water emit flammable gases	waived		None of the components of the product contain metals or metalloids and experience in handling, producing and storage shows the product does not react with water.	
Oxidising liquids	waived		Consideration of structure and physical-chemical properties of the components does not suggest any	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			oxidising potential. Widespread experiments and commercial use over many years has not shown any evidence of oxidizing hazard.	
Oxidising solids	waived		Not relevant. The product is not solid.	
Organic peroxides	waived		Not relevant. No organic peroxide is among the components.	
Corrosive to metals	waived	The acidity or alkalinity test is not needed, because the pH of the product is between the values of 4 and 10. Moreover, according to the results of the OECD 404 test, the product should not be classified as skin corrosive or skin irritant.	There are no strongly acidic/basic substances in such concentrations that would cause considerable acidity/ alkalinity and initiate the corrosion process. Despite the sodium hydroxide content of the product, the pH of it is 5.2	
Auto-ignition temperatures of products (liquids and gases)	waived		For a highly viscous gel, more than 65% water content auto-ignition potential is not expected. Spontaneous combustion is excluded.	
Relative self-ignition temperature for solids	waived		Not relevant. The product is not solid.	
Dust explosion hazard	waived		Not relevant. The product is not solid.	

Conclusion on the physical hazards and respective characteristics of the product
Explosive, oxidising, flammable and corrosive properties are not expected according to available data and information. The product is not classified into physical hazard classes based on its physical-chemical properties.

2.2.4 Methods for detection and identification

Method has been developed and validated for the determination of DEET content of product named: SZUKU mosquito- and tick repellent gel (nominal content: 24.8%)
Validation data demonstrate that this method is suitable for the determination of the active substance content in the product.

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
DEET	GC-FID	100% of the nominal conc. of DEET//5 replicates two series	0.8 - 2 mg DEET/mL 6 conc. levels /3parallel each – four series r^2: 0.994 – 1.000	no interfering peak	22.9 – 26.2	97	0.2	0.8 mg DEET /mL	GLP*:

* Validation of the Analytical Method for Determination of the Active Ingredient Content of SZUKU gel (GLP) Toxi-Coop Zrt., Study no.: 671.199.4451, 14 August 2013

Analytical methods for monitoring									
Analyte	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
DEET									*

* Refer to Letter of Access obtained from the manufacturer of the active substance and refer to the CAR of the active substance

Analytical methods for soil									
Analyte	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
DEET	LC-MS/MS							0.01 mg/kg	*

* Refer to Letter of Access obtained from the manufacturer of the active substance and refer to the CAR of the active substance

Analytical methods for air									
Analyte	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
DEET	LC-MS/MS,							0.225 µg/m^3	*

* Post Annex data: A residue analytical method of DEET in air (22 July 2013) owned by Vertellus was developed: Validation of Methodology for the Determination of Residues in Air (Huntingdon Life Sciences: RQN0001).

Analytical methods for water									
Analyte	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
DEET	HPLC-MS/MS							1 ng/L for ground and drinking water 0.1 µg/L for surface water	*

* Refer to Letter of Access obtained from the manufacturer of the active substance and refer to the CAR of the active substance

Analytical methods for animal and human body fluids and tissues									
Analyte	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
DEET	HPLC/ UV							Blood plasma 49.4 µg/L	*

* Refer to Letter of Access obtained from the manufacturer of the active substance and refer to the CAR of the active substance

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

* Not required, as the use patterns of DEET, will not result in any contact with food and feedstuffs of plant origin. Refer to Letter of Access obtained from the manufacturer of the active substance and refer to the CAR of the active substance

According to TAB analytical methods are not required for SoCs that are not formed during the storage and their concentration remains unchanged, so analytical method for stearyl alcohol, ethoxylated, <2.5 EO is not provided as its concentration is unlikely to change during the storage period.

Conclusion on the methods for detection and identification of the product
A GC-FID method for determination of the DEET in the product has been satisfactorily validated against the criteria given in the ECHA Guidance of the BPR Vol I, Parts A+B+C. All validation parameters meet the acceptance criteria. Monitoring analytical methods in soil, air, water and animal and human body fluid and tissues are covered by the data and information submitted during the active substance approval and deemed acceptable at EU level.

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

Main group: 3 – Pest control
Product type (PT): 19 (Repellents and attractants)
Function: Repellent

The formulation of SZUKU Mosquito and Tick Repellent Gel will be used to repel mosquitoes and ticks. The amateur user will use the repellent cream outdoors.

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

Culicidae (mosquitoes)
Stage: Imagines (adults)
Ixodidae (hard ticks)
Stages: Adults, nymphs

2.2.5.3 Effects on target organisms, including unacceptable suffering

Szuku Mosquito- and Tick Repellent Gel repels blood sucking arthropods (e.g. mosquitoes) upon direct contact with the product. When applied to the skin, it vaporizes to discourage the approach of insects and ticks and consequently protects the skin from bites.

According to chapter 5.6.5.1.3.8. of the Technical Notes on Guidance (Efficacy) v4.1. 2022 February, non-insecticidal effect of the repellent product should be investigated. This product contains DEET, which is only approved in PT 19. Therefore a literature search was performed in the browser with keywords "N, N-diethyl-m-toluamide" or "DEET", and "insecticide" or "insecticidal" or "effect" or "mode of action".

Some studies shown that DEET exerts an insecticidal effect to mosquitoes when sprayed on walls [1.] and on filter paper laboratory assays [2.]. An insecticidal effect was also observed for I. ricinus ticks and mosquitoes when they were in contact with DEET-impregnated bed nets [3.]. However, in the submitted efficacy tests, no other adverse effect was reported besides repellence.
In the referred studies, insects contacted the treated surfaces for prolonged periods. We think that the insecticidal mode of action of DEET in this product is irrelevant, because the product is used outdoors, and as seen in the efficacy studies, during the effective period, mosquitoes may only land for a second on the skin and ticks choose not to crawl on the treated skin. Therefore, there is not enough contact time with the substance to reach an effective insecticidal dose in the insects and ticks. Furthermore, effectiveness of DEET in topical repellents was tested in many product formulations for decades without any observed evidence of insecticidal effect. Therefore, we conclude that the insecticidal effect of this product, when used according to the instructions, can be excluded.

*[1.] Kitau, J., Oxborough, R., Matowo, J. et al. Indoor residual spraying with microencapsulated DEET repellent (N, N-diethyl-m-toluamide) for control of Anopheles arabiensis and Culex quinquefasciatus. Parasites Vectors **7,** 446 (2014).* https://doi.org/10.1186/1756-3305-7-446

[2.] Licciardi S, Herve JP, Darriet F, Hougard JM, Corbel V. Lethal and behavioural effects of three synthetic repellents (DEET, IR3535 and KBR 3023) on Aedes aegypti mosquitoes in laboratory assays. Med Vet Entomol. 2006 Sep;20(3):288-93. doi: 10.1111/j.1365-2915.2006.00630.x. PMID: 17044879.

[3.] Faulde MK, Albiez G, Nehring O. Insecticidal, acaricidal and repellent effects of DEET- and IR3535-impregnated bed nets using a novel long-lasting polymer-coating technique. Parasitol Res. 2010 Mar;106(4):957-65. doi: 10.1007/s00436-010-1749-6. Epub 2010 Feb 17. PMID: 20162432.

2.2.5.4 Mode of action, including time delay

The product repels arthropods upon direct contact; the exact mode of action is still not completely clarified. A theory suggests that DEET interferes with and masks the olfactory system of target organisms. Some results show that repellency is a matter of direct detection leading to mosquitoes smelling and avoiding DEET (Syed and Leal 2008). The mode of action of DEET is still under discussion. Direct toxic effects on target organisms could not be observed. There is no time delay for effectiveness after application, the product provides protection instantly.

The mode of action is determined by the active substance DEET. The incorporation of the active substance into the biocidal product does not alter the mode of action or time delay. Thus, these items are covered by Doc II-A, Section 2.4 of the Competent Authority Report (CAR) on DEET (PT 19) prepared according to Art. 11(2) of Directive 98/8/EC by the Rapporteur Member State Sweden.

2.2.5.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
repellent	*topical application on skin*	*SZUKU mosquito- and tick repellent gel*	*(Aedes eagypti L.)* *Laboratory-bred wild strain (5-9 days old adult females)*	*Laboratory test. Repellence test.* *Application of the test item: Test area of the volunteer's arm washed with soap and rinsed with water, then dried with and uncontaminated cloth towel. A latex glove protected the hands of test subjects.* *Observation period: after application of the test item, treated arm was inserted into the cage and was exposed for 5 minutes to determined landing and / or probing. All such activities recorded. Attempted biting on the latex glove was excluded from the test. This procedure was repeated at 30 minutes intervals.*	*Duration: exposure for a 7-hour period; subjects exposed for 5 minutes every 30 minutes.* *Concentration applied: 1 g product / 600 cm2 of exposed area.* *Conditioning period: mosquitoes were reared under optimal conditions (26°C ±2°C, 80% relative humidity, 16:8 light:dark photoperiod)*	*The first confirmed events occurred at 6 hours for 5 of the volunteers.*	*MATE Hungarian University of Agriculture and Life Sciences, Department of Ecotoxicology, Agro-environmental Research Centre, Institute of Environmental Science* *Data owner: METATOX Kft.*
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
repellent	*topical application on skin*	*SZUKU mosquito- and tick repellent gel*	*field-collected ticks, unfed adult females and*	*Laboratory test. Repellence test.*	*Duration: 8-hour period; subjects exposed for 5 minutes every*	*The SZUKU mosquito- and tick-repellent gel (24,8%*	*MATE Hungarian University of Agriculture and Life*

			nymphs mixed.	*Application of the test item: Test area of the volunteer's arm washed with soap and rinsed with water, then dried with and uncontaminated cloth towel. A latex glove protected the hands of test subjects.* *Ticks were placed on the untreated control arm then 5 ticks showing questing activity were used for each observation period on the treated arm of the volunteer.*	*hour.* *Concentration applied: 1 g product / 600 cm2 of exposed area.* *Temperature: 22.1 °C – 24.8 °C* *relative humidity: 60-72 %*	*DEET) was effective in an average of 94.6% and 86.4% of tick tests within 3 and 5 hours, respectively*	*Sciences, Department of Ecotoxicology, Agro-environmental Research Centre, Institute of Environmental Science* *Data owner: METATOX Kft.*

[Please insert/delete rows according to the number of studies.]

Conclusion on the efficacy of the product

conclusion by HUCA:
We are aware that the submitted arm-in-cage study against mosquitoes does not meet all requirements of the Technical Notes on Guidance (Efficacy) v4.1. 2022 February. The product was tested for only 1 representative species of mosquitoes.

Taking into consideration document CA-July12-Doc.6.2d – Final, "In the case of an application for a first authorisation, the default cut-off date should be the two years before the date of submission of the application." The application was submitted in July 2021, months before the issue of the guidance, therefore we do not require the applicant to comply with the 2022 guidance. We performed this evaluation according to the principles of the 2018 v3.0 guidance. However, for the future renewal of the authorisation, we will re-evaluate the compliance to subsequent guidances.

The studies have demonstrated that the product effectively repels mosquitoes for 330 minutes = 5.5 hours (Complete Protection Time against mosquitoes: 5.5 hours).

The test against Ixodes ricinus reported effectiveness in an average of 94.6% and 86.4% within 3 and 5 hours, respectively. We calculated the protection time (CPT) of 1-4 hours for the volunteers separately. No outliers were excluded. We tested the dataset for all 10 volunteers' individual CPTs for normal distribution. The Kolmogorov-Smirnov test and the D'Agostino-Pearson test was performed with a significance level set to 0.05. None of the two tests indicated a significant difference from the normal distribution. Therefore we accept the median CPT (3 hours) as a result. (For further information, calculation tables are embedded in the confidential annex) **The product repels ticks for 3 hours.**

2.2.5.6 Occurrence of resistance and resistance management

Resistance to the product is not known and not expected, since there is only low selection pressure; the arthropods are repelled but not killed (ie. in case of insecticides the survivals pass the resistance genes).
There are many other host species available for these arthropods.
Furthermore, for mosquitoes, due to the continental climate, the breeding season is relatively short which means a smaller number of generations and less potential of inheritance of any genetic modifications.
European and international literature gives no scientific evidence on resistance in spite of a fact, that DEET compositions are in use since the past 50 years.
Therefore, it is considered unnecessary to take actions to prevent development of resistance by target organisms.
Prevention of resistance: there are not known cases of resistance in the environment.

2.2.5.7 Known limitations

To reduce exposure, if possible, wear long-legged trousers and long-sleeved outerwear in outdoors.
Only treat skin surfaces exposed to insect bites that are not covered by clothing.
Pregnant and lactating women should avoid using the product if possible.

2.2.5.8 Evaluation of the label claims

The following label claims were accepted by HUCA:
The product may be used by members of the general public outdoors in order to repel mosquitoes and ticks.
The recommended dose is 1g product / 600 cm^2 of skin.
The product provides a 5.5 hour (330 minutes) protection time against mosquitoes and a 3 hour protection time against ticks.

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

The product is not to be used with other (biocidal) products.

2.2.6 Risk assessment for human health

(The following data are based on the Annex I inclusion dossier of DEET)

The absorption, distribution, metabolism, and excretion studies (ADME) in rats show that orally administered DEET is absorbed almost completely, and 74-91% of it was excreted in the urine and 3-7% in the faces. DEET showed no evidence for accumulation. The dermal absorption of DEET occurred at a slower rate than oral absorption (peak plasma concentration ≥4 hr vs. <1 hr, respectively). 74-78% of the administered radioactivity was excreted via urine and about 3-7% was excreted via the faeces. DEET was metabolised completely in all oral and dermal treatment groups with little or no parent compound excreted in the urine. DEET is extensively metabolized to 2 major metabolites, m-[(N,N-diethylamino)carbonyl] benzoic acid and m-[(ethylamino)carbonyl] benzoic acid. Penetration through human skin is much slower and less extensive (peak plasma

concentration ≥8 hr), it is metabolised completely, and excreted rapidly when applied to human skin. Less than 20% (when corrected for total recovery) of a dermally applied dose of DEET as a 15% (w/w) solution in ethanol is absorbed through the skin during an 8-hour exposure period. Dermal absorption is 11% for the undiluted technical grade material.

The acute toxicity studies show that the oral LD_{50} for DEET warrants a classification as H302, harmful if swallowed. The rabbit acute dermal LD_{50} of DEET is greater than 2000 mg/kg and the rodent acute dermal LD_{50} is > 5000 mg/kg. The acute inhalation LD_{50} of DEET is greater than 2.02 mg/L (the highest concentration tested), which is lower than the upper EU classification limit acute toxicity category 4 according to GHS and the recommended highest dose according to the OECD guideline. However, in light of animal welfare consideration, testing of animals at higher doses was not considered warranted since inhalation exposure to the product is considered negligible. Even if no mortality was observed at the limit dose tested (2.02 mg/l/4h), it can not be fully ensured that the LC_{50} would be > 5mg/l/4h. The classification into acute inhalation hazard class can therefore not be fully ruled out based on this test.

DEET is slightly irritating to the skin. However, repeated dose studies (dermal) in pigs and rats showed that repeated dermal dosing resulted in dermal irritation at all doses tested and remained at study end. A classification as Eye irrit 2 irritating to eyes is not warranted based on the results in the eye irritation test. However, the mean score for corneal opacity is 1 for three animals at 24, 48 h and 72 h, and warrants a classification as Eye Irrit 2 – H319 according to the GHS.

DEET did not result in a skin sensitisation response in the Buehler test.

Several repeated dose toxicity studies for the oral and dermal route have been submitted for DEET. Male rats were the more sensitive gender to DEET for repeated dose effects. Male rats developed alpha2µ-globulin nephropathy that is considered gender and species specific. This effect was not considered relevant for risk assessment. Clinical signs of neurotoxicity also occurred in dogs shortly after oral dosing. In both rats and dogs decreased body weight was observed after oral dosing with DEET. Dermal application of DEET to rats and minipigs resulted mainly in skin irritation but no systemic toxicity or pathological findings.

DEET showed no genotoxic potential in a battery of *in vitro* tests in bacteria and mammalian cells. DEET did not result in an increase in tumours in rats and mice and was not considered oncogenic in the carcinogenicity studies.

The teratogenicity of DEET was investigated in two species, rat and rabbit. The studies were performed according to the OECD 414 guideline and both studies were preceded by dose finding studies. However, the studies were performed prior to the latest revision of the OECD guideline in 2001 and have therefore some discrepancies compared to the current guideline. The females were treated only during the organogenesis and not until scheduled sacrifice. The studies therefore have some limitations in assessing potential effects during later stages of embryonal development. However, considered that the 2-generation study in rats gave no further indications of embryotoxic or teratogenic effects at comparable doses, these studies are considered acceptable for risk assessment purposes. There were no teratogenic effects observed in the studies up to maternally toxic doses, embryotoxicity was only expressed as decreased foetal body weight (rats).

There were no effects on reproduction in a 2-generation study in rats. Parental males were the more sensitive gender based on kidney effects that were considered species specific and irrelevant for risk assessment to humans. There were no effects on reproduction. The

effects observed in females and offspring were reduced body weight, in offspring during later parts of the lactation period.

DEET is used as an arthropod repellent directly applied to the skin. For risk assessment in consumers an $AEL_{repeated}$ of 8.2 mg/kg bw/day is set based on the 90-day dermal study in rats with a NOAEL of 1000 mg/kg bw/day, the highest achievable dose, and using a standard assessment factor of 100 and correction of a dermal absorption of approximately 82% in the rat. It was decided at TM II 2009 to use the dermal study in rats, even though the rat was clearly not the most sensitive species with respect to neurotoxic effects. It was discussed to use an additional factor for correcting for the difference in species sensitivity. At the same time, it was also discussed that the assessment factor could be reduced due to the availability of human plasma data and plasma data in both rats and dogs, as well as metabolism data in humans and rats. The use of a standard assessment factor of 100 was therefore considered appropriate.

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation
The product contains 24.8% DEET. The other components in the product are either not irritating or present in such a low concentration that they do not have an irritating effect.

An acute skin irritation study of the test item Szuku Mosquito- and Tick Repellent Gel was performed in New Zealand White rabbits according to OECD method 404. At 1 hour after exposure very slight erythema (score 1) was observed on all animals. At 24, 48 and 72 hours after exposure rabbits were free of symptoms.

Based on the scores obtained for erythema and oedema, the reversibility of symptoms and taking into account the provisions of CLP; criteria, classification of the test item Szuku mosquito- and tick repellent gel for skin irritation and corrosivity is not required.

Summary table of animal data on skin irritation						
Species	**Method, Guideline**	**Average score 24, 48, 72 h**		**Reversibility (yes/no)**	**Remark**	**Reference**
		Erythema	Oedema			
Rabbit NZW 3 males	OECD 404 GLP	0.00 (0.00-0.00-0.00)	0.00 (0.00-0.00-0.00)	Yes 24h after patch removal all animals were free of symptoms	Not irritating	Toxi-Coop Zrt., Piroska Mácsai Kuthy, Acute Skin Irritation Study of Test Item Szuku Gél in Rabbits;2012

No human data are available.

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating
Justification for the value/conclusion	Acute skin irritation study of test item by Toxi-Coop Zrt. (attached)
Classification of the product according to CLP	Not necessary

Eye irritation

An Isolated Chicken Eye Test (ICET) according to OECD method 438 was performed with Szuku Mosquito- and Tick Repellent Gel. The test compound was applied in a single dose onto the cornea of isolated chicken eyes in order to evaluate the corrosive and/or severe irritant potential of the substance. Based on the results of the study, the test item is moderately irritant and has no corrosive or severely irritant potential. As no *in vivo* rabbit eye test was submitted a definitive conclusion regarding eye irritating potential cannot be drawn. Consequently, based on the result of the ICE test and according to the criteria of CLP the product must be classified as H319 Causes serious eye irritation and pictogram GHS07 should be presented on its label.

Summary table of in vitro studies on serious eye damage and eye irritation

<table>
<tr><th>Species</th><th>Method</th><th>Score</th><th>Remark</th><th>Reference</th></tr>
<tr>
<td>Chicken eyes</td>
<td>OECD 438
GLP
Isolated Chicken Eye Test
ICET</td>
<td>
Test Item: Szuku Mosquito- and Tick Repellent Gel
<table>
<tr><th>Observation</th><th>Value</th><th>ICE Class1</th></tr>
<tr><td>Mean maximum corneal swelling at up to 75 min</td><td>1%</td><td>I</td></tr>
<tr><td>Mean maximum corneal swelling at up to 240 min</td><td>2%</td><td>I</td></tr>
<tr><td>Mean maximum corneal opacity</td><td>0.33</td><td>I</td></tr>
<tr><td>Mean fluorescein retention</td><td>2.83</td><td>IV</td></tr>
<tr><td>Other Observations</td><td colspan="2">None</td></tr>
<tr><td>Overall ICE Class</td><td colspan="2">2xI, 1xIV</td></tr>
</table>
Positive Control: Trichloracetic Acid
<table>
<tr><th>Observation</th><th>Value</th><th>ICE Class1</th></tr>
<tr><td>Mean maximum corneal swelling at up to 75 min</td><td>18%</td><td>IV</td></tr>
<tr><td>Mean maximum corneal swelling at up to 240 min</td><td>30%</td><td>IV</td></tr>
<tr><td>Mean maximum corneal opacity</td><td>4.00</td><td>IV</td></tr>
<tr><td>Mean fluorescein retention</td><td>2.83</td><td>IV</td></tr>
<tr><td>Other Observations</td><td colspan="2">The positive control was adhering to the comea surface after the post-treatment rinse. The comea surface was not cleared 240 min after the post-treatment rinse</td></tr>
<tr><td>Overall ICE Class</td><td colspan="2">1xIII, 2xIV</td></tr>
</table>
Negative Control: NaCl (9 g/L saline)
<table>
<tr><th>Observation</th><th>Value</th><th>ICE Class1</th></tr>
<tr><td>Mean maximum corneal swelling at up to 75 min</td><td>0%</td><td>I</td></tr>
<tr><td>Mean maximum corneal swelling at up to 240 min</td><td>3%</td><td>I</td></tr>
<tr><td>Mean maximum corneal opacity</td><td>0.00</td><td>I</td></tr>
</table>
</td>
<td>The test item was moderately irritating.</td>
<td>Toxi-Coop Zrt., István Buda, Szuku Mosquito- and Tick Repellent Gel - In vitro test for eye corrosives and severe irritants in isolated chicken eyes; 2012</td>
</tr>
</table>

Summary table of in vitro studies on serious eye damage and eye irritation				
		Mean fluorescein retention: 0.50 (I) Other Observations: None Overall ICE Class: 3xI I = none II = slight III = moderate IV = severe		

No human data are available.

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Causes serious eye irritation
Justification for the value/conclusion	Eye irritation Category 2
Classification of the product according to CLP	H319 Causes serious eye irritation GHS07

Respiratory tract irritation

Data waiving	
Information requirement	Study scientifically unjustified. No ingredients of the product are classified as STOT SE 3 (H335 - May cause respiratory irritation) in the applied concentration.
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Value/Conclusion	The product is not expected to be irritating to respiratory tract.
Justification for the conclusion	Estimation by calculation according Guidance on the Application of the CLP criteria (version 5, July 2017) when data are available for all ingredients or only for some ingredients of the mixture. Σ%Category 3 – Respiratory Irritation < 20%. Therefore the product not classified for respiratory irritation
Classification of the product according to CLP	No classification needed

Skin sensitization

Summary table of animal studies on skin sensitisation				
Species	**Method**	**Results**	**Remark**	**Reference**

Summary table of animal studies on skin sensitisation					
Mouse 4 animals / groups (28 animals)	OECD 429 GLP	Test groups / Stimulation Indices: vehicle control: 1 positive control (HCA in AOO): 12.3 untreated (negative) control: 1.0 100 %: 0.9 50 %: 3.4 25 %: 2.2 10 %: 4.0	Non-sensitising	Toxi-Coop Zrt., Mária Pénzes, Skin sensitization study: Local lymph node assay of test item Szuku mosquito- and tick repellent gel in mice	

No human data are available.

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	not sensitiser
Justification for the value/conclusion	Toxi-Coop Zrt., Mária Pénzes, Skin sensitization study: Local lymph node assay of test item Szuku mosquito- and tick repellent gel in mice
Classification of the product according to CLP and DSD	No classification needed

Respiratory sensitization (ADS)

Data waiving	
Information requirement	Study scientifically unjustified. None of ingredient of the product are classified as RESP SENS. 1 (H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled). Please refer to the confidential annex for information on the substances and their concentration.
Justification	There are valid data available on each of the components in the mixture sufficient to allow classification of the mixture according to the rules laid down in Regulation (EC) No 1272/2008 (CLP).

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	The product is not expected to cause respiratory sensitisation.
Justification for the value/conclusion	According to the harmonized classification and labelling of the active substance DEET, it is not a respiratory sensitizer. None of the other ingredients have respiratory sensitization properties.
Classification of the	No classification needed

product according to CLP and DSD	

Acute toxicity

Acute toxicity by oral route

Summary table of animal studies on acute oral toxicity						
Method Guideline GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance Dose levelsType of administration**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 423 GLP 1	Rat, Crl:(WI)BR females 3/group	Biocidal product Gavage 2000 mg/kg bw	Decreased activity, abnormal gait, incoordination, decreased body tone, piloerection, increased respiration rate and hydrometra No mortality; no clinical signs or abnormalities noted at necropsy.	> 2000 mg/kg bw	No remarks	Toxi-Coop Zrt., PiroskaMácsaiKuthy, Acute oral toxicity study (acute toxic class method) of test item Szuku Mosquito- and Tick Repellent Gel in rats

No human data are available.

Value used in the Risk Assessment – Acute oral toxicity	
Value	LD_{50} > 2000 mg/kg bw
Justification for the selected value	Based on the provided study
Classification of the product according to CLP and DSD	No classification needed

Acute toxicity by inhalation

Data waiving	
Information requirement	Study scientifically unjustified.
Justification	The active substance, DEET is not volatile and was not found to be toxic via inhalation route (LD_{50}>2.02 mg/L). The product Szuku Mosquito- and Tick Repellent Gel is composed of a (solid) white emulsion gel that has to be applied directly onto skin. Furthermore, it is stated on the label that indoor use is not recommended. Application of insect repellents takes place mainly outdoors or during the summer in situations where there is a high ventilation rate. Thus inhalation is not expected to occur.

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	The product is not expected to cause inhalation toxicity.
Justification for the selected value	According to the harmonized classification and labelling of the active substance DEET, it is not an inhalatory toxicant. None of the other ingredients are toxic via inhalation.
Classification of the product according to CLP and DSD	No classification needed

Acute toxicity by dermal route

Summary table of animal studies on acute dermal toxicity						
Method, Guideline, GLP status, Reliability	**Species, strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Surface area**	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 402 GLP 1	Rat, Hsd.Brl.Han: WIST Preliminary study: females Main study: females and males 3/group	Biocidal product Preliminary study: 5, 50, 300 and 2000 mg/kg bw Main study: 2000 mg/kg bw	Main study: No mortality, no behavioural changes, the observed slight body weight loss in 2 females during the first week could not be evaluated as a toxic effect of test item either. No other clinical signs no	> 2000 mg/kg bw	No remarks	Toxi-Coop Zrt., PiroskaMácsai Kuthy, Acute dermal toxicity study of test item Szuku mosquito- and tick repellent gel in rats;

			abnormalities noted at necropsy.			2012

No human data are available.

Value used in the Risk Assessment – Acute dermal toxicity	
Value	> 2000 mg/kg bw
Justification for the selected value	Based on the provided study
Classification of the product according to CLP and DSD	No classification needed

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	DEET
Value(s)	20%
Justification for the selected value(s)	No specific data regarding Szuku mosquito- and tick repellent gel formulation is available. Value determined in the CAR of DEET is deemed acceptable, as in the test the concentration of the active substance was similar and the vehicle contained ethanol, which enhances absorption.

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

The active substance DEET is the only toxicologically relevant component in the product. The non-active substances present in Szuku Mosquito- and Tick Repellent Gel are either present in a very low concentration or do not give rise to any toxicological concern.

Denatonium benzoate (Bitrex) is an aversive agent intended to deter humans from consuming the product and is classified into health hazard classes, but this component is only present at aextremely low concentration, denatonium benzoate is not to be considered as a substance of concern.

Potassium sorbate is an approved biocidal active substance in PT8 and classified as eye irritant, however due to the low concentration of the substance in the product the component does not pose any further concern. The applicant classified the product already as Eye Irrit 2.

Sodium hydroxide is classified as skin corrosive substance; however the concentration of sodium hydroxide does not indicate any toxicological concerns.

According to the submitted documents Carbopol Ultrez 20 are irritating to skin and eyes and classified as Skin Irrit. 2 and Eye irrt. 2.

Other components are non-hazardous to human health. Thus, the product contains irritating substances, nonetheless due to their low concentration in the product they are of no concern.

2.2.6.2 Exposure assessment

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

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

Inhalation exposure

The proposed uses of Szuku Mosquito- and Tick Repellent Gel is very similar to the representative product evaluated during Annex I inclusion of the active substance and the assessment of inhalation exposure is in accordance with that for the representative product.

DEET has a vapour pressure of 0.23 Pa (25°C) and a Henry's law constant of 3.93-3 Pa*m^3/mol, therefore inhalation exposure from vapours is very low. Formation of inhalable particles is not expected. It can be concluded that the risk of inhalation exposure to DEET for general public during use of the product Szuku Mosquito- and Tick Repellent Gel is negligible.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Application (adult)	The user applies the product on the his/her body. Primary exposure.	general population
2.	Application (adult, limited)	The product applied only on the hands, face and neck. Primary exposure.	general population
3.	Application (child)	The adult user applies the product on the skin of a child. Primary exposure.	general population
4.	Hand-to-mouth exposure	Eating food (e. g. sandwiches) with contaminated hands. Secondary exposure.	general population

Industrial exposure

The product is not intended for industrial use.

Professional exposure

The product is not intended for professional use.

Non-professional exposure

Scenario 1

Description of Scenario 1
Szuku Mosquito- and Tick Repellent gel is used on the bare skin and spread on it by hand. Therefore, the intended route of exposure is predominantly dermal; oral and inhalation routes are negligible in the actual scenario. The method of assessment is based on the method #3 in the recommendation no. 11 of the Ad hoc Working Group on Human Exposure. The default value for the amount of the insect repellent applied to the skin is based on an analogy with suntan creams and body lotions (RIVM Report 320005002/2006 Pest Control Products Fact Sheet). According to a study (Bremmer et. al., 2002) 8-10 g of these products are used per application, which after a modification with the covered body areas (36% is covered, thus 64% is affected), results in a 6 g default value for repellents per application. These data are rather conservative, as sunscreen needs to be applied in large amounts to be sufficiently protective, and its viscosity tends to be much higher than that of a repellent product, which allows much thicker layers to be applied onto skin.

	Parameters	Value
Tier 1	Body weight	60 kg
	Concentration of the active substance	24.8%
	Applied amount	6 g
	Number of applications per day	1
	Dermal absorption	20%

Calculations for Scenario 1

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 1	Tier 1	NA	4.96 mg/kg bw	NA	4.96 mg/kg bw

Scenario 2

Description of Scenario 2		
In case the user wears a long-sleeved shirt, long trousers and shoes (e.g. hiking in a forest) the product is applied only on the face, neck, hands and part of the lower arms. According to the recommendation no. 14 of the Ad hoc Working Group on Human Exposure the combined surface of these body parts is 2734 cm^2, which is 16% of the total body surface (16 600 cm^2). The applied amount of the product is therefore 1.6 g.		
	Parameters	Value
Tier 1	Body weight	60 kg
	Concentration of the active substance	24.8%
	Applied amount	1.6 g
	Number of applications per day	1
	Dermal absorption	20%

Calculations for Scenario 2

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 2	Tier 1	NA	1.32 mg/kg bw	NA	1.32 mg/kg bw

Scenario 3

Description of Scenario 3		
The product can be applied on children (older than two years, as – according to its CAR - DEET is not intended for infants or toddlers; also, they should not use it themselves, only by adults). The default body surface of 2-6 years old children is 6800 cm^2 which is 2.44 times smaller than an adult's and assuming a linear relationship between the body surface and the amount of repellent used, their exposure is 2.46 g. For 6-12 years old children the corresponding numbers are 9200 cm^2, and 3.33 g.		
	Parameters	Value
Tier 1	Body weight (2-6 years)	15.6 kg
	Body weight (6-12 years)	23.9 kg
	Concentration of the active substance	24.8%
	Applied amount (2-6 years)	2.46 g
	Applied amount (6-12 years)	3.33 g
	Number of applications per day	1
	Dermal absorption	20%

Calculations for Scenario 3

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 3a (children 2-6)	Tier 1	NA	7.82 mg/kg bw	NA	7.82 mg/kg bw
Scenario 3b (children 6-12)	Tier 1	NA	6.92 mg/kg bw	NA	6.92 mg/kg bw

Scenario 4

Description of Scenario 4
Some repellent on the hands can end up on handled food and eventually ingested. It is assumed that 50% of product on the palms and fingers is rubbed off and available for ingestion. For adults the surface of palms and fingers is 410 cm^2, which is 2,47% of their total body area (see recommendation No. 14 of HEAadhoc). The amount of repellent on this surface is 247 mg (taking into consideration 10 g of exposure of total body area) and 123.5 mg is ingested. For children 2-6 years old the corresponding data are 165.5 cm^2 and 100 mg (50 mg is ingested). For children 6-12 years old the hand surface is 213.9 cm^2 and the product amount on them is 129 (64.5) mg.

	Parameters	Value
	Body weight (adult)	60 kg
Tier 1	Body weight (2-6 years)	15.6 kg
	Body weight (6-12 years)	23.9 kg
	Concentration of the active substance	24.8%
	Ingested amount (adult)	123.5
	Ingested amount (2-6 years)	50
	Applied amount (6-12 years)	64.5
	Number of applications per day	1
	Oral absorption	100%

Calculations for Scenario 4

Summary table: systemic exposure from non-professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario 4a (adult)	Tier 1	NA	NA	0.51 mg/kg bw	0.51 mg/kg bw
Scenario 4b (children 2-6)	Tier 1	NA	NA	0.79 mg/kg bw	0.79 mg/kg bw
Scenario 3c (children 6-12)	Tier1	NA	NA	0.67 mg/kg bw	0.67 mg/kg bw

Combined scenarios

Summary table: combined systemic exposure from non-professional uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios 1+4a	NA	4.96 mg/kg bw	0.51 mg/kg bw	5.47 mg/kg bw
Scenarios 2+4a	NA	1.32 mg/kg bw	0.51 mg/kg bw	1.83 mg/kg bw
Scenarios 3a+4b	NA	7.82 mg/kg bw	0.79 mg/kg bw	8.61 mg/kg bw
Scenarios 3b+4c	NA	6.92 mg/kg bw	0.67 mg/kg bw	7.59 mg/kg bw

Exposure of the general public

See exposure assessment of non-professionals.

Dietary exposure

Food can be contaminated with the biocidal product (for exposure assessment see Scenario 4 of non-professionals). Other dietary exposure (animal husbandry, food industry etc.) is not foreseen.

Information of non-biocidal use of the active substance

DEET is only used for biocidal purposes.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Livestock exposure is not foreseen.

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

Production and formulation of the biocidal product are not within the scope of BPR, and therefore, have not been addressed within this dossier as other legislation applies.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1.	non-professionals	Tier 1	4.96 mg/kg bw
2.	non-professionals	Tier 1	1.32 mg/kg bw
3a	non-professionals	Tier 1	7.82 mg/kg bw
3b	non-professionals	Tier 1	6.92 mg/kg bw
4a	non-professionals	Tier 1	0.51 mg/kg bw
4b	non-professionals	Tier 1	0.79 mg/kg bw
4c	non-professionals	Tier 1	0.67 mg/kg bw

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral absorption	Value
AELshort-term (oral)	8-week oral capsule study in dogs	75 mg/kg bw/d	100	-	0.75
AELlong-term	90 day dermal rat study	1000 mg/kg bw/d	100	-	8.2*

* Corrected for a dermal absorption of approximately 82% in the rat

Maximum residue limits or equivalent

In 2018, it was agreed that MRLs would not be established, instead the following 'reference values for intra EU trade' were established (SCoPAFF (section Novel Food and Toxicological Safety of the Food Chain) 17 September 2018):

- Pine nut kernels 0.5 mg/kg
- Berries and small fruits except grapes 0.1 mg/kg
- Wild fungi 1.0 mg/kg
- Herbal infusions from flowers and leaves 0.3 mg/kg
- Spices 0.5 mg/kg

Risk for industrial users

Szuku Mosquito- and Tick Repellent Gel is only for non-professional use.

Risk for professional users

Szuku Mosquito- and Tick Repellent Gel is only for non-professional use.

Risk for non-professional users

Systemic effects

Task/ Scenario	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1	Tier 1	8.2	4.96	60.49	Yes
Scenario 2	Tier 1	8.2	1.32	16.10	Yes
Scenario 3a	Tier 1	8.2	7.82	95.36	Yes
Scenario 3b	Tier 1	8.2	6.92	84.39	Yes
Scenario 4a	Tier 1	8.2	0.51	6.22	Yes
Scenario 4b	Tier 1	8.2	0.79	9.63	Yes
Scenario 4c	Tier 1	8.2	0.67	8.17	Yes

Combined scenarios

Scenarios combined	Tier	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenarios 1+4a	Tier 1	8.2	5.47	66.7	Yes
Scenarios 2+4a	Tier 1	8.2	1.83	22.3	Yes
Scenarios 3a+4b	Tier 1	8.2	8.61	105	No
Scenarios 3b+4c	Tier 1	8.2	7.59	92.6	Yes

Local effects

The product is classified as an eye irritant. Consideration of local effects is presented below.

Hazard category		Exposure				Risk	
Hazard category	Effects in terms of C&L	Who is exposed	Tasks, uses, processes	Potential exposures route	Frequency and duration of potential exposure	Relevant RMM & PPE	Conclusion on risk
low	Eye irrit. Cat 2, H319	Non-professionals	Application of product	Skin, Eye (hand to eye transfer)	One application /d	labelling as eye irritant instructions for use (applied by adults only) No potential for splashes Washing of hands after use	Acceptable: + reversible effect + low potential for eye exposure

Conclusion

The risk to non-professionals is acceptable with some risk management measures. In line with HEAdhoc recommendation 11, specific labelling instructions for adults, adolescents (≥ 12 years) and children (< 12 years) are required.

- For adults: one application per day is considered safe with standard use pattern: the product is applied to the face, neck, shoulders, upper and lower arms, hands, upper and lower legs, feet.

- On limited body surface (face, neck, lower arms, hands) Szuku Mosquito- and Tick Repellent Gel safe to use up to four times a day. It should be noted, that according to the conclusions of the CG-16 meeting, wearing long-sleeved shirts and trousers is not considered to be an acceptable RMM to reduce the exposure to repellents to

acceptable levels; in this case it is considered only an alternative way to the main RMM of one application/day.

- For children between 2 and 6 years: Use of product once per day is safe. However, when we take into account the possibility of hand-to-mouth behaviour, an unacceptable risk is identified. Additional RMMs are requested, as adding a bittering agent (Bitrex) to the product to reduce ingestion and the repellent must be labelled according to the following: it must be applied only by adults; do not apply to children's palms; keep out of reach of children. In addition, the label should direct adults to wash their hands following application.

- For children more than 6 years of age: Use of the Szuku Mosquito- and Tick Repellent Gel once per day is considered safe.

Risk for the general public

See section of non-professional users.

Risk for consumers via residues in food

Dietary exposure to the product is not foreseen.

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

The product contains only one active substance.

2.2.7 Risk assessment for animal health

Animals are not expected to be exposed from the proposed use.

2.2.8 Risk assessment for the environment

No new environmental related studies have been submitted for the product. The ecotoxicologically relevant constituents in the Szuku mosquito- and tick repellent gel are the active substance N,N-diethyl-meta-toluamide (DEET) and the Etoxylated stearyl alcohol (Brij S2) as a substance of concern.

2.2.8.1 Effects assessment on the environment

The ecotoxicological properties of the active substance was taken from the Competent Authority Report of DEET. No other ecotoxicological studies have been submitted for the product. Etoxylated stearyl alcohol (Octadecan-1-ol, etoxylated; CAS: 9005-00-9).is identified as a substance of concern and its environmental fate and ecotoxicological data

were taken from the associated Reach Registration dossier and the HERA (2009)[3] document.

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

The freshwater PNEC is based on the ErC_{50} of 43 mg/L obtained in an acute toxicity test with algae (*Selenastrum capricornutum)*.
The active substance had only a minor inhibitory effect on the respiration rate of aquatic microorganisms in activated sludge.
There are no ecotoxicity results available for freshwater sediment organisms exposed through the sediment. In addition, the low Koc value indicates that sorption to sediment is low. Therefore, the PNEC for sediment was calculated using the equilibrium partitioning method based on $PNEC_{water}$.
The PNEC derivation for soil is based on the equilibrium partitioning method and according to the Assessment Report of DEET, it has an 0.0379 mg/kg wet weight.
The Assessment Report summarises that the low BCF values suggest that DEET has a low bioaccumulation potential. Therefore, no risk of secondary poisoning via ingestion of potentially contaminated food by birds or mammals was identified.

The PNEC values used for the risk assessment are summarised in the following table.

Compartment	**Test results**	**PNEC**
Surface water	ErC50= 43 mg/L acute algae test (*Selenastrum capricornutum)*	0.043 mg/L (AF: 1000)
STP microorganisms	EC50 > 1000 mg/L respiration inhibition test	10 mg/L (AF: 100)
Sediment	equilibrium partitioning	0.0741 mg/kg ww
Soil	equilibrium partitioning	0.0379 mg/kg ww

Etoxylated stearyl alcohol (Octadecan-1-ol, etoxylated; CAS: 9005-00-9)

According to the REACH Registration Dossier, currently no studies are available for alcohol ethoxylate (C18, < 2.5 EO, CAS 9005-00-9), only a read-across is prepared to a chronic invertebrate study conducted with a similar alcohol ethoxylate (C12-13, 6.5 EO). The reported NOEC for reproduction is 0.77 mg/L. Nevertheless the data allow not to derive a precise long-term effect value for the described mixture (C18, < 2.5 EO). For all three aquatic trophic levels, alcohol ethoxylate specific QSARs were developed to describe the toxicity of varying mixtures. The effects are described as EC20 values, since the QSARs are more robust for the EC20 values than for NOEC or EC10 values. Although this method is only used for the classification as a key value, since no other data is available, this value was used for this risk assessment. The evaluation of the *Octadecan-1-ol, etoxylated* is still ongoing, information is requested on long-term aquatic tests.

The PNEC values used for the risk assessment are summarised in the following table:

Compartment	PNEC
surface water	0.005 mg/L
STP microorganisms	1.4 mg/L

[3] Human & Environmental Risk Assessment on ingredients of European household cleaning products; Alcohol Ethoxylates v2.0, September 2009

Sediment	230.37 mg/kg dw
Soil	1 mg/kg dw

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

The Szuku mosquito- and tick repellent gel contains 3.8% Etoxylated stearyl alcohol (Brij S2) which has been identified as substance of concern. It is classified as Aquatic chroic 2 and its concentration leads the product to be regarded as hazardous. Consequently, the product Szuku mosquito- and tick repellent gel is environmentally classified as Aquatic chronic 3.

Further Ecotoxicological studies

No data is available

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

No data is available

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

No data is available

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

No data is available. The product is not in the form of bait or granules

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

Not relevant

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

The Szuku mosquito- and tick repellent gel is a RTU product which is used outdoor directly on human skin by non-professionals. The main emission pathway to the environment is considered to be indirect via the STP after showering and bathing the treated skin. Direct emission to surface water is also considered when people go swimming with treaded skin. Direct emission to soil during the application phase is of minor importance since it takes place non-repeatedly on a very limited area and it is therefore not assessed.

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

No data is available

Leaching behaviour (ADS)

Not relevant

Testing for distribution and dissipation in soil (ADS)

No data is available

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

No data is available

Testing for distribution and dissipation in air (ADS)

No data is available

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

Not relevant

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not relevant

2.2.8.2 Exposure assessment

General information

Assessed PT	PT 19
Assessed scenarios	Scenario 1: Removal through showering and bathing of humans Scenario 2: Release to surface water bodies through swimming
ESD(s) used	Emission Scenario Document for Product Type 19: Repellents and attractants, ECHA May 2015
Approach	Scenario 1: Average consumption Scenario 2: Average consumption
Distribution in the environment	Calculated based on Guidance on the BPR Vol IV Environment (Parts B+C) v2.0 October 2017
Groundwater simulation	Scenario 1: FOCUS PEARL 4.4.4
Confidential Annexes	NO

Life cycle steps assessed	Scenario 1-2: Production: No Formulation No Use: No Service life: No Removal: Yes
Remarks	

Emission estimation

Scenario1 – Removal through showering and bathing of humans

The affected main compartment is the water compartment. Users of the general public may apply the product once per day (this restriction is also indicated on the label) directly onto skin, which is later washed off during bathing or showering. Consequently, exposure arises indirectly from STP effluents. Based on the efficacy data, the application rate of 1.67 mg/cm^2 is used. The number of applications (N_{appl}) is restricted to one application per day. 55% of the body surface is considered as uncovered and is treated with the product. No dermal absorption is taken into account.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Removal through showering and bathing of humans			
Number of inhabitants feeding one STP (Nlocal)	10000	[cap]	D
Active substance in the product ($Cform_{weight}$)	248	g/kg	S
SoC in the product	38	g/kg	S
Consumption per application ($Qform_{appl}$)	1.67	mg/cm^2	S; efficacy data
Number of applications per day (N_{appl})	1	1/d	S; label
Treated area of human skin ($AREA_{skin}$)	9130	cm^2	D/S; TAB ENV172
Treated area of garments ($AREA_{garments}$)	0	cm^2	S
Fraction released to air (F_{air})	0	-	D
Fraction dermally absorbed (F_{skin})	0	-	D
Fraction released to wastewater (F_{water})	1	-	S
Fraction of inhabitants using a repellent product (F_{inh})	0.2		P

Market share of repellent (F_{penetr})	0.5	-	D

Calculations for Scenario 1

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission ($Elocal_{compartment}$) [kg/d]**	**Remarks**
Local emission rate to wastewater ($Elocal_{water}$) - DEET	3.78	O; ESD Eq. 3.8
Local emission rate to wastewater ($Elocal_{water}$) - SoC	0.58	O; ESD Eq. 3.8

Scenario 2 – Release to surface water bodies through swimming

The release from the treated skin into surface water can occur during swimming in natural waters. As a worst-case to cover areas with higher insect infestation, it is considered that 10 % of the swimmers use the product before entering the water body.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: Release to surface water bodies through swimming			
Daily number of swimmers ($N_{swimmer}$)	1500	-	D
Fraction of swimmers using the repellent product (F_{swim})	0.1	-	D
Number of applications per day (N_{appl})	1	1/d	D
Fraction released to surface water body ($F_{waterbody}$)	1	-	D
Active substance in the product ($Cform_{weight}$)	248	g/kg	S
SoC in the product	38	g/kg	S
Consumption per application ($Qform_{appl}$)	1.67	mg/cm^2	S; efficacy data
Treated area of human skin ($AREA_{skin}$)	9130	cm^2	D; TAB ENV172
Volume of water body ($V_{waterbody}$)	435000	m^3	D
First order rate constant for biodegradation in surface water ($kdeg_{water}$); active substance	0.047	1/d	S; readily biodegradable

First order rate constant for biodegradation in surface water ($kdeg_{water}$); SoC	0.047	1/d	S; readily biodegradable
Number of emission days ($T_{emission,1d}$)	1	d	D
Number of emission days ($T_{emission,91d}$)	91	d	D
Number of emission events ($N_{emission,91d}$)	91	-	D

Calculations for Scenario 2

Resulting local emission to relevant environmental compartments		
Compartment	**Local emission/concentration ($Elocal_{water}$/$Clocal_{water}$) [kg/d]/[mg/L]**	**Remarks**
Local emission rate to surface water body ($Elocal_{water}$) - DEET	0.567	O; ESD Eq. 3.12
Local concentration in water body after one day ($Clocal_{water,1d}$) – DEET	1.3E-03	O; ESD Eq. 3.13
Local concentration in water body over 91 days ($Clocal_{water,91d}$) – DEET	1.19E-01	O; ESD Eq. 3.14
Refined local concentration in water body over 91 days ($Clocal_{water,91d\text{-}ref}$) - DEET	2.8E-02	O; including degradation; ESD Eq. 3.15
Local emission rate to surface water body ($Elocal_{water}$); SoC	0.087	O; ESD Eq. 3.12
Local concentration in water body after one day ($Clocal_{water,1d}$); SoC	2E-04	O; ESD Eq. 3.13
Local concentration in water body over 91 days ($Clocal_{water,91d}$); SoC	1.82E-02	O; ESD Eq. 3.14
Refined local concentration in water body over 91 days ($Clocal_{water,91d\text{-}ref}$); SoC	4.29E-03	O; including degradation; ESD Eq. 3.15

Fate and distribution in exposed environmental compartments

The environmental fate and behaviour of DEET has been evaluated during the assessment for Annex I inclusion. DEET is readily biodegradable and no major transformation products were formed in studies of hydrolysis and aquatic phototransformation.
The predicted atmospheric half-life, the vapour pressure and the low Henry's law constant indicate that DEET is not volatile and does not persist in air in significant quantities. No hydrolytisis was found and it was found to be photolytically stable in water.
The Koc value is 43.3 L/kg, suggesting that it is very mobile in soil and therefore could leach to the groundwater.

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other
Scenario 1	yes	yes	no	no	yes	no	yes	yes	no
Scenario 2	yes	n.r.	n.r.	n.r.	no	no	no	no	no

Input parameters (only set values) for calculating the fate and distribution in the environment; active substance			
Input	Value	Unit	Remarks
Molecular weight	191.27		LoEP
Melting point	<-20	°C	LoEP
Boiling point	284.2	°C	LoEP
Vapour pressure (at 25°C)	0.23	Pa	LoEP
Water solubility (at 25°C)	11200	mg/l	LoEP
Log Octanol/water partition coefficient	2.4	Log 10	LoEP
Organic carbon/water partition coefficient (Koc)	43.3	l/kg	LoEP
Henry's Law Constant (at X C)*[if measured data available]*	3.93E-03	$Pa/m^3/mol$	LoEP
Biodegradability	Ready biodegradable		LoEP
Rate constant for STP *[if measured data available]*	ready biodegr.	h^{-1}	
DT_{50} for biodegradation in surface water	ready biodegr.	d or hr (at 12ºC)	
DT_{50} for hydrolysis in surface water	≥1 year	pH 4, 7, 9	LoEP
DT_{50} for photolysis in surface water	stable	d or hr	LoEP
DT_{50} for degradation in soil	ready biodegr.	d or hr (at 12ºC)	
DT_{50} for degradation in air	15.2	hr	LoEP
First order rate constant for removal from top soil (k)	0.0247	d^{-1}	S; Guidance on BPR vol. IV: Eq. 32 and Eq. 55-56

Input parameters (only set values) for calculating the fate and distribution in the environment; Etoxylated stearyl alcohol (Brij S2)			
Input	Value	Unit	Remarks
Molecular weight	270-402		
Vapour pressure (at 20°C)	0.00012	Pa	Reach Registration dossier
Water solubility (at 25°C)	0.0153	mg/l	Registration dossier

Log Octanol/water partition coefficient	7.07	Log 10	Registration dossier
Organic carbon/water partition coefficient (Koc)	426579	l/kg	Registration dossier
Biodegradability	Ready biodegradable		Registration dossier
First order rate constant for removal from top soil (k)	0.023	d^{-1}	S

Calculated fate and distribution in the STP *[if STP is a relevant compartment]*			
Compartment	Percentage [%]		Remarks
	Scenario 1	Scenario n	
Air	9E-04	0.044	SimpleTreat 4.0
Water	7.992	5.982	
Sludge	0.403	83.37	
Degraded in STP	91.6	10.6	

Calculated PEC values

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}[1]**	**PEC_{air}**
	[mg/m^3]	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg/m^3]	[µg/l]	[mg/m^3]
Scenario 1 – DEET	0.15	0.015	(0.026)	-	-	0.02	7.15	-
Scenario 2 - DEET	-	0.028	-	-	-	-	-	-
Scenario 1 – SoC	0.017	0.001	9.8			0.649	0.028	
Scenario 2 - SoC		0.0043						

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

Primary and secondary poisoning

Primary poisoning

Not relevant

Secondary poisoning

Not relevant. Based on the calculated BCFs for aquatic and terrestrial organisms, DEET is considered to have very little or no potential to bioaccumulate.

According to the Reach registration dossier, the reported BCF values for the Etoxylated stearyl alcohol range from <5 to 387.5 and the elimination rates vary from 3.3 to 59 per day, suggesting that the tested fathead minnow efficiently biotransform alcohol ethoxylate, thereby preventing them from attaining high concentrations in fish.

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: Emission to the air is negligible. The product Szuku Mosquito- and Tick Repellent Gel is not expected to pose a risk to the atmospheric environment. The conclusion was the same for the active substance DEET as well.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{STP}$
Scenario 1- DEET	0.015
Scenario 2- DEET	-
Scenario 1 – SoC	0.012
Scenario 2 - SoC	-

[Please insert/delete rows as needed.]

Conclusion: The PEC/PNEC values are below 1. The risk is acceptable for the STP microorganisms following indirect release via STP after skin application

Aquatic compartment

Summary table on calculated PEC/PNEC values				
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**	**PEC/PNEC$_{seawater}$**	**PEC/PNEC$_{seased}$**
Scenario 1 – DEET	0.35	0.35	-	-
Scenario 2 - DEET	0.65	-	-	-
Scenario 1 – SoC	0.2	0.043	-	-
Scenario 2 - SoC	0.86	-	-	-

Conclusion: The PEC/PNEC ratios calculated for the aquatic compartment do not exceed the trigger value of 1. The releases of DEET represented by the scenarios above do not pose a risk to surface water and sediment.

Terrestrial compartment

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
Scenario 1 – DEET	0.53
Scenario 2 - DEET	-
Scenario 1 – SoC	0.65
Scenario 2 - SoC	-

Conclusion: The PEC/PNEC ratios calculated for the terrestrial compartment are below 1. The releases of DEET do not pose a risk to soil.

Groundwater

The calculated value of PECgw for scenario 1 is higher than the trigger value of 0.1 µg/L for pesticides (maximum permissible concentration laid down by Directive 98/83/EC). Formation of major metabolites are not relevant, but DEET does not meet one of the cut-off criteria (Koc <500 L/kg) so the simulation model of FOCUS PEARL 4.4.4 was used to refine the estimated PECgw values.

Input parameters used to calculate PECgw (FOCUS PEARL 4.4.4)			
Input	Value	Unit	Remarks
Years of simulation	26	years	incl. 6 years warming-up period
Application rate	agr: 0.096 grass: 0.019	kg/ha	S
Application method	agr: incorporation; 0.2m grass: incorporation; 0.1m	-	D
Date of application	agr: 20d before emergence grass: 01/03/1901	-	D
Molar mass	191.27	g/mol	S
Vapour pressure	0.23	Pa	S; 25°C
Water solubility	11200	mg/L	S; 25°C
Kom	25.1	L/kg	S

Freundlich exponent	1	-	D; TAB ENV22
Half-life	30	d	D; 12°C
Coefficient for uptake in plants	0	-	D

FOCUS PEARL 4.4.4 modelled values (80th percentile annual average groundwater concentrations of DEET at 1m depth)

Scenario	PECgw [µg/L] arable land	PECgw [µg/L] grassland
Chateaudun	0.0645	0.0123
Hamburg	**0.233**	0.0322
Jokioinen	-	0.03
Kremsmuenster	**0.186**	0.0175
Okehampton	**0.268**	0.0287
Piacenza	0.0623	0.0205
Porto	0.019	0.0075
Sevilla	0.0012	0.00088
Thiva	0.011	0.00071

The modelled concentrations still exceed the limit value of 0.1 µg/L for three agricultural soil scenarios, so further refinements were needed for the treated skin area and dermal absorption. The treated area was reduced in accordance with the RMM of "*When outdoors, preferably wear long-legged trousers and a long-sleeved shirt to reduce the amount of product needed for protection.*" in line with the Recommendation 11 of the Adhoc WG on Human Exposure. In addition, dermal absorption of 9% was also taken into account as proposed in the CAR. Based on the above, the table below shows which values have changed:

Parameter	Tier1	Tier2
Treated area [cm^2]	9130	3290
Fraction dermally absorbed [-]	0	0.09
emission rate to wastewater [kg/d]	3.78	1.24
concentration in sludge [mg/kg]	19.29	6.33
Application rate [kg/ha]	0.096	0.032

Scenario	PECgw [µg/L] arable land Tier 2
Chateaudun	0.0215
Hamburg	0.078
Jokioinen	-
Kremsmuenster	0.0621
Okehampton	0.0892
Piacenza	0.021
Porto	0.0064
Sevilla	0.0004
Thiva	0.0037

The refined groundwater concentrations are not exceed the threshold value of 0.1 µg/L for all the Focus PEARL scenarios.

Primary and secondary poisoning

Primary poisoning

Not relevant

Secondary poisoning

Conclusion: Based on the calculated BCFs for aquatic and terrestrial organisms, DEET is considered to have very little or no potential to bioaccumulate.
According to the Reach registration dossier, the reported BCF values for the Etoxylated stearyl alcohol range from <5 to 387.5 and the elimination rates vary from 3.3 to 59 per day, suggesting that the tested fathead minnow efficiently biotransform alcohol ethoxylate, thereby preventing them from attaining high concentrations in fish.

Mixture toxicity

Screening step

Screening Step 1: Identification of the concerned environmental compartments

The envioronmental compartments that are likely to be at risk are the STP, water and soil.

Screening Step 2: Identification of relevant substances

The relevant substances are the active substance DEET and Etoxylated stearyl alcohol (Octadecan-1-ol, etoxylated; CAS: 9005-00-9) as substance of concern.

Screening Step 3: Screen on synergistic interactions

Screening step	
	Significant exposure of environmental compartments? Y
	Number of relevant ssubstances >1? Y (2)
	Indication for synergistic effects for the product or its constituents in the literature? N

Tiered approach

Tier 1. PEC/PNEC summation

Tier 1		
RQ product	Acceptable risk for the environment? N	Remarks
0.027	STP	acceptable
0.55	water (indirect emission)	acceptable
1.51	water (direct emission)	unacceptable
1.18	soil	unacceptable

Conclusion: Above Tier1 was not investigated because the risk assessment of *Etoxylated stearyl alcohol (Brij S2)* (EC Name: Octadecan-1-ol, etoxylated; CAS: 9005-00-9) as substance of concern in the product is subject to uncertainties. The evaluation of Octadecan-1-ol, etoxylated <2.5 EO is still ongoing within REACH, information is requested on long-term aquatic toxicity tests.
However, taking into account the proposed RMM (see overall conclusion) the risk seems to be acceptable, no further evaluation of mixture toxicity is required.

Aggregated exposure (combined for relevant emmission sources)

Conclusion: No aggregated exposure estimation required

Overall conclusion on the risk assessment for the environment of the product
In conclusion for the environment, the risk is expected to be unacceptable from indirect emission to groundwater from the use of Szuku mosquito- and tick repellent gel. The following risk mitigation measure is proposed to reduce the risk: *„Preferably wear long-legged trousers and a long-sleeved shirt to reduce the amount of product needed for protection*." Furthermore, the risk assessment of *Etoxylated stearyl alcohol (Brij S2)* (EC Name: Octadecan-1-ol, etoxylated; CAS: 9005-00-9) as substance of concern in the product is subject to uncertainties. The evaluation of Octadecan-1-ol, etoxylated <2.5 EO is still ongoing within REACH, information is requested on long-term aquatic toxicity tests. If necessary on the basis of subsequent information, the assessment of the SoC should be revised accordingly.

2.2.9 Measures to protect man, animals and the environment

Please refer to the SDS and label of the product.

The product must not penetrate sewers, surface water, groundwater and neighbouring areas. Avoid contact with soil.
The empty container of the product may be disposed of as household waste.
The product is intended to be used by the general public as an arthropod repellent against blood sucking arthropods, such as mosquitoes and ticks to protect humans from their bite and potentially, transmission of vector-borne pathogens by blood feeding.

Szuku Mosquito- and Tick Repellent Gel repels blood sucking arthropods (e.g. mosquitoes and ticks) upon direct contact with the product. When applied to the skin, it vaporizes to discourage the approach of insects and ticks and consequently protects the skin from bites.

The product repels arthropods upon direct contact; the exact mode of action is still not completely clarified. A theory suggests that DEET interferes with and masks the olfactory system of target organisms. Some results show that repellency is a matter of direct detection leading to mosquitoes smelling and avoiding DEET (Syed and Leal 2008). The mode of action of DEET is still under discussion. Direct toxic effects on target organisms could not be observed. There is no time delay for effectiveness after application, the product provides protection instantly.

Efficacy reports are presented for laboratory evaluation of this formulation against *Aedes aegypti* and *Ixodes ricinus*.
It can be concluded from the test results that Szuku Mosquito- and Tick Repellent gel is effective in the repellency of mosquitoes and ticks.

Physical-chemical hazard: No proposal is given for the classification and labelling according to physical chemical hazard in accordance with CLP Regulation 1272/2008/EC.

From the human health risk assessment of SZUKU mosquito- and tick repellent gel for the purpose of product authorization, the following conclusion can be drawn:
Health risks for the adult non-professional users of the biocidal product are at an acceptable level if it is not applied more than once daily. Children under age of 13 should not apply the product. Users must be warned about these limitations on the label.

It should not be used to sunburnt or injured skin, known allergies shall be considered. Contact with mucosa and the immediate surroundings of eyes, mouth and ears should be avoided.

First aid instructions

In case of poisoning or suspected poisoning always consult a doctor and show a label to the doctor.

Inhalation: Move to fresh air. Consult a specialist if you have a complaint.

Eye contact: Keep your eyes open and wash out immediately with plenty of water for several minutes. If there is a contact lens in the eye, remove it and continue washing out the eye. Consult a specialist if you have a complaint.

Ingestion: Get immediate medical advice and show the label

Skin: The product may cause irritation. In case of allergic symptoms wash affected area with plenty of water.

Instructions for safe disposal

Do not re-use the product packaging for any purpose.

Unused product and packaging may be thrown into the household garbage in Hungary.
Do not flush into surface water or sanitary sewer system.

Do not contaminate ponds, waterways or ditches with the product or used container.

3 ANNEXES[4]

3.1 List of studies for the biocidal product (family): please check list generated by IUCLID

3.2 Output tables from exposure assessment tools: see relevant sections.

New information on the active substance: The active substance DEET is included in the Union list of approved active substances, the approval of DEET for use in biocidal products of product-type 19 expires on 31 July
2022. The expiry date of approval of DEET for use in biocidal products of product type 19 was postponed to 31 January 2025 by Decision (EU) 2021/2146.

3.3 Residue behaviour: not relevant for this product.

3.4 Summaries of the efficacy studies (B.5.10.1-xx)[5]: please see IUCLID

3.5 Confidential annex: See file: Confidental Annex to PAR file

3.6 Other: not available

4 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

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