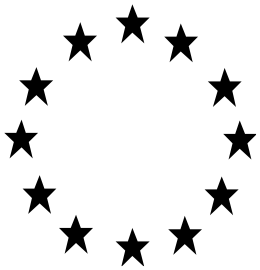
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT (FAMILY) FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



SZUKU szúnyog- és kullancsriasztó folyadék mechanikus pumpával

SZUKU mosquito- and tick repellent spray

Product type 19

DEET (N,N-dietil-m-toluamid) 23% w/w

Current case Number in R4BP: BC CL068574-31
Previous authorization Number in R4BP: HU-2014-PA-19-00087-0000

Evaluating Competent Authority: HUNGARY

Date: 30 June 2022

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1 CONCLUSION

Szuku Mosquito- and Tick Repellent Spray is a ready-for-use product applied by trigger sray containing 23% 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, authorisation number HU-2014-PA-19-00087-0000.
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 product 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 Spray 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 (0.6% pine scent) has been completely removed from it, concentration of ethyl alcohol was increased accordingly.
The concentration of the active ingredient and all other components remain unchanged.

Physical hazard and physico-chemical properties
Physical hazard is identified: Flam. Liq. 2;

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 fragrance has positive impact on shelf life. Accelerated and long-term storage stability data at ambient temperature for the product have been provided, GLP data support the shelf life of 24 months, The shelf life of the product is two years, however post-authorization data requirements are set as more data will need to be provided to demonstrate satisfactory operation of trigger spray and MMAD value of droplets should be given.

Post-authorization data requirements:
According to the ECHA guidance, the MMAD of droplets should be determined before and after storage.
Data on satisfactory operation of the trigger spray prior to and after storage should be submitted. These should include the spray pattern, the amount of spray delivered with each operation and nozzle observations for clogging, the periodic use of the spray during the storage interval should also be addressed.
As these data are not required for the risk assessment they can be addressed as post-authorization data requirements
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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, the risk is very close to the maximum safe level. In order to reduce the risk, additional RMMs should be used, 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 Spray 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 Spray 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 spray. 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 / product family

Identifier[1]	**Country (if relevant)**
SZUKU szúnyog- és kullancsriasztó folyadék mechanikus pumpával	Hungary
SZUKU mosquito- and tick repellent spray	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-19-00400-0000	
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)
Address of manufacturer	Avenue du Port 86 C BP 204 1000, Bruxelles Belgium
Location of manufacturing sites	2110 High Point Road, Greensboro NC 27403, USA

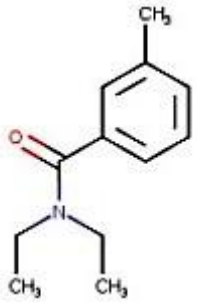
1 Please fill in here the identifying product name from R4BP.

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

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	23.00
Ethanol	ethyl alcohol	Solvent	64-17-5	200-578-6	44.6
Isopropanol	Isopropyl alcohol	Solvent	67-63-0	200-661-7	12.00
BHT	2,6-di-tert-butyl-p-cresol	Antioxidant	128-37-0	204-881-4	0.40

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 form Vertellus Chemicals SA (acting for Vertellus LLC (United States)), who is among the sponsors of DEET in review program.

2.1.2.5 Information on the substance(s) of concern

The product contains ethyl alcohol and isopropyl alcohol.
These substances have harmonized classification at EU level:
Classification of ethyl alcohol by the supplier: Flam. Liq. 2, Eye Irrit. 2;
Harmonised classification of isopropyl alcohol: Flam. Liq. 2, Eye Irrit. 2 and STOT SE 3.

Classification of isopropyl alcohol: Flam. Liq. 2, Eye Irrit. 2 and STOT SE 3.
No harmonized classification is available for BHT, according to the SDS of the supplier classification of BHT is: Aquatic Chronic 1
Ethyl alcohol and isopropyl alcohol are considered as substance of concern (SoC) in relation to physical-chemical and also to human-health endpoints of the product. Due to the BHT concentration and its classification as Aquatic Chronic 1 the product should be classified into Aquatic Chronic 3 hazard class and category, and therefore BHT is considered as substance of concern in relation to environmental endpoints of the product.

2.1.2.6 No other substances of concern have been identified in the formulation.Type of formulation

AL – any other liquid; ready to use

2.1.3 Hazard and precautionary statements[2]

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

Classification	
Hazard class/category	Flammable Liquids, Category 2 - **Flam. Liq. 2.** Serious Eye Damage/eye irritation Category 2 - **Eye Irrit 2** Long term (chronic) Aquatic Hazard – Category 3 – **Aquatic Chronic 3**
Hazard statements	H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation. H412 Harmful to aquatic life with long lasting effect.
Labelling	
Signal word-	DANGER
Pictograms	 GHS02 GHS07
Hazard statements	H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation. H412 Harmful to aquatic life with long lasting effect
Precautionary statements	P102 Keep out of reach of children. P210 Keep away from heat, sparks,open flames,hot surfaces. No smoking. P260 Do not breathe spray. 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 according 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. P233 statement (Keep container tightly closed) is triggered by Flam. Liq. 2 hazard class and category. . Due to the type of closure (pump spray cap) typically used for repellents this statement is not relevant since the bottle is not supposed to open by the user.

2.1.4 Authorised use(s)

2.1.4.1 Use description

Table 1. Use # 1 – Ready-to-use mosquito- and tick repellent spray 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 development stage)	**Culicidae (mosquitoes)** Stage: adults **Ixodidae (hard ticks)** Stages: Adults, nymphs
Field of use	Outdoor use
Application method(s)	Spraying, 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	PE/PP/HDPE bottle with integral trigger sprayer. ready-to-use formulation with 30 ml, 40 ml, 50 ml or 90 ml filling; with closure cap

2.1.4.2 Use-specific instructions for use

See general instructions of use

2.1.4.3 Use-specific risk mitigation measures

See general instructions of use

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 general instructions of use

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

See general instructions of use

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 general instructions of use

2.1.5 General directions for use

2.1.5.1 Instructions for use

Shake well before use. Spread the spray from 20-25 cm 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 of the product.
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 out immediately with plenty of water. If there are contact lens 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 liquid placed in a PE or PP crucible with 30 ml filling weight.	30 ml	PE or PP plastic jar	Mechanical pump screwable on a crucible, fitted with a closer-cap.	non-professional (amateur use)	Yes
Ready-to-use mosquito- and tick repellent liquid placed in a PE or PP crucible with 40 ml filling weight.	40 ml	PE or PP plastic jar	Mechanical pump screwable on a crucible, fitted with a closer-cap.	non-professional (amateur use)	Yes
Ready-to-use mosquito- and tick repellent liquid placed in a PE or PP crucible with 50 ml filling weight.	50 ml	PE or PP plastic jar	Mechanical pump screwable on a crucible, fitted with a closer-cap.	non-professional (amateur use)	Yes
Ready-to-	90 ml	PE or PP	Mechanical	non-	Yes

use mosquito- and tick repellent liquid placed in a PE or PP crucible with 90 ml filling weight.		plastic jar	pump screwable on a crucible, fitted with a closer-cap.	professional (amateur use)	

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 spray 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)	Spraying, 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/HDPE bottle with integral trigger sprayer. ready-to-use formulation with 30 ml, 40 ml, 50 ml or 90 ml filling; with closure cap

2.2.2 Physical, chemical and technical properties

The biocidal product is a ready to use formulation.

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: 20220405/1	Transparent clear liquid	Metatox in house results e.g. Study Report on physical state, colour and odour by sensorial, organoleptic
Colour at 20°C and 101.3 kPa	visual inspection	Batch No: 20220405/1	Colourless	
Odour at 20°C and 101.3 kPa	olfactory characterisa	Batch No: 20220405/1	Alcoholic	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	tion			methods; 20 April 2022.
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: 20130624/1	No need because pH is between 4 – 10 pH: 9.1 (20°C)	Study no.: 671.191.4442 (GLP)
Relative density / bulk density	Method A.3. OECD No.109	Batch No: 20130624/1	D_4^{20}:0.913	Study no.: 671.191.4440 (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: 22.8±0.1% End: 22.9±0.2%	Accelerated Storage Stability Test: Study no.: 671.105.4448 (GLP) Date of Study Report: Sept. 25. 2013.
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	Batch No: 20130624/1 in sales pack 19-21.1°C Appearance: Colourless liquid, alcoholic,	No significant change after 6, 12 and 24 months storage at ambient temp. **DEET conc.:** Start: 22.8±0.1% 6 months: 22.6±0.1% 12 months: 23.5±0.2% 24 months: 22.3±0.1% **pH at 20°C** Start: 8.9 6 months:9.1 12 months: 8.7 24 months: 9.1 **Appearance:** does not change during the study **Container:** intact package and label dispenser works properly.	Determination of Storage Stability of Szuku folyadék: GLP Study no: 671.105.4448 (GLP).Date of Study Report: Sept. 09, 2015
Storage stability test – **low temperature stability test for**	Low temperature storage was		On the label must appear: Protect from frost.	-

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
liquids	not addressed.		Storage 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. Stability data and long years of commercial experience with the product shows there are no indications that the container materials reacts with the product.	
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 applicable. The products are not powders or granules.	
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	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
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	
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.		Not relevant as it is a RTU product. 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.	
Viscosity	OECD 114	Batch No: 20130624/1	at 20°C dynamic: 4.23 mPas kinematic: 4.63 mm^2/s at 40°C dynamic: 2.50 mPa.s kinematic: 2.76 mm^2/s	Study no: 671.191.4446 (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 the product. Storage stability study (GLP) at ambient temperature was performed with the composition containing 0.6% pine scent (old formulation), read-across of these results are acceptable as the concentration of DEET and all other component except ethyl alcohol remain the same and absence of fragrance is beneficial for shelf life. The ethyl alcohol concentration is increased by 0.6%.
As the product is applied via trigger sprayer according to the ECHA guidance, the MMAD (mass medium aerodynamic diameter) of droplets should be also determined before and after storage, moreover data on satisfactory operation of the trigger spray prior to and after storage should be submitted as follows: spray pattern, the amount of spray delivered with each operation, nozzle observations for clogging and the intermittent use of the spray during the storage interval should also be addressed.
These data should be handled as post-authorization data requirements.
As the product has been on the market for decades, years of experience and observations show no visible signs of build-up on the pump mechanism and no dripping, clogging or blockage during spray operation.
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.

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 and commercial use over many years has not shown any evidence of these activities.	
Flammable gases	waived		Not relevant. The product is liquid.	
Flammable aerosols	waived		Not relevant. the product is not an aerosol	
Oxidising gases	waived		Not relevant. The product is	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			liquid.	
Gases under pressure	waived		Not relevant. The product is liquid.	
Flammable liquids	Method A.9	Batch No.: OTH 2799/2006-	Flash point: 20°C. The product is considered flammable liquid, category: 2	Study no.: 14/023-352/AN (GLP)
Flammable solids	waived		Not relevant. The product is liquid.	
Self-reactive substances and mixtures	waived		There are no chemical groups present in the molecules of ingredients associated with explosive or self-reactive properties; examples of such groups are given in Tables in Appendix 6 of the UN RTDG.	
Pyrophoric liquids	waived		During production, handling and, storage no experience has shown evidence that the liquid ignites spontaneously on coming into contact with air at normal. Not relevantthe formulation does not contain any components that are reactive towards air, or any other	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			components/ substances therefore are not pyrophoric.	
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/ reported 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 oxidising potential. Widespread experiments and commercial use over many years has not shown any evidence of these activities.	
Oxidising solids	waived		Not relevant. The product is not solid.	
Organic peroxides	waived		Not relevant. No organic peroxide is	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			among the components.	
Corrosive to metals	waived	Neither the product is corrosive to metals nor to human skin according to the OECD 404 study results. Based on the scores obtained for erythema and oedema, the reversibility of symptoms and taking into account the provisions CLP criteria, classification of the product for skin irritation and for skin corrosivity is not required.	There are no strongly acidic/basic substances in concentrations that would cause considerable acidity/ alkalinity and consequently initiate the corrosion process.	
Auto-ignition temperatures of products (liquids and gases)	Justification of no submission data		The product is not autoflammable, itc ontains no autoflammable components. Auto-ignition temperature: 363°C (ethyl alcohol) 456°C (isopropyl alcohol)	Data from ICSC card (ICSC 00445, ICSC 0554)
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 and corrosive properties are not expected according to available data and information. The product is classified into physical hazard class, Flam. Liq. 2 based on its flash point due to its ethyl-alcohol and isopropyl alcohol content.

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 spray (nominal content: 23%)

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/five replicates two series	0.8 - 2 mg DEET/mL 6 conc. levels /3 parallel each – four series r^2: 0.993 – 1.000	no interfering peak	24.6 – 25.4 n=5	100	0.3	0.8 mg DEET /mL	GLP*:

* Validation of the Analytical Method for Determination of the Active Ingredient Content of SZUKU folyadék (GLP) Toxi-Coop Zrt., Study no.: 671.199.4450, 14 August 2013

Validation data for DEET demonstrate that this method is suitable for the determination of the active substance content in the product.

According to TAB analytical methods are not required for SoCs that are not formed during the storage and their concentration remains unchanged, so analytical methods for ethyl alcohol and isopropyl alcohol and BHT are not provided as their concentrations are unlikely to change during the storage period.

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								-	*

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 Performance Materials Inc. 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 theactive 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 theactive 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 pattern 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

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. 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 Spray will be used to repel mosquitoes and ticks. The amateur user will use the repellent 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 Spray 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.

Evaluation of possible insecticide effect by HUCA:

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 borwser 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

[Please include here any experimental data on the efficacy of the active substance against target organism(s).]

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 liquid*	*(Aedes eagypti L.)* *Laboratory-bred wild strain (5-9*	*Laboratory test. Repellence test.* *Application of*	*Duration: exposure for a 7-hour period; subjects exposed for 5 minutes every*	*The first confirmed events occurred at 6 hours for 6 of the*	*MATE Hungarian University of Agriculture and Life Sciences,*

			days old adult females)	*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.*	*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)*	*volunteers.*	*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 liquid (aerosol)**	*field-collected ticks, unfed adult females and nymphs mixed.*	*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.* *Ticks were*	*Duration: 8-hour period; subjects exposed for 5 minutes every hour.* *Concentration applied: 1 g product / 600 cm2 of exposed area.* *Temperature: 22.1 °C – 24.8 °C* *relative humidity: 60-72 %*	*The SZUKU mosquito- and tick-repellent liquid (23% DEET) was effective in an average of 94.7% and 86% of tick tests within 3 and 5 hours, respectively*	*MATE Hungarian University of Agriculture and Life Sciences, Department of Ecotoxicology, Agro-environmental Research Centre, Institute of Environmental Science* *Data owner: METATOX Kft.*

				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.			

**** The name of the product in the efficacy study was SZUKU mosquito- and tick repellent liquid. At some point the study refers to the product as SZUKU mosquito- and tick repellent aerosol. For clarity, the study was performed with the current SZUKU mosquito- and tick repellent spray, only different names were used in the study record.***

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 94.7% and 86% 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 feces. 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 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 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 23% 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 spray 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 criteria of CLP, classification of the test item Szuku mosquito- and tick repellent spray for skin irritation and corrosivity is not required.

Summary table of animal studies on skin corrosion /irritation

Method, Guideline, GLP status, Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, Duration of exposure**	**Results** *Average score (24, 48, 72h)/ observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological findings*	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 404 GLP 1	Rabbit NZW 3 males	Szuku mosquito- and tick repellent spray, in pure state single dose of 0.5 ml 4 hours	Erythema: 1.33-0.00-0.66 Oedema: 0.00-0.00-0.00 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 in Rabbits; 2012 Study nr.: 671.550.3361

No human data is 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 and DSD	Not recessary

Eye irritation

An Isolated Chicken Eye Test (ICET) according to OECD method 438 was performed with Szuku Mosquito- and Tick Repellent spray. 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 by the pictogram GHS07.

Summary table of in vitro studies on serious eye damage and eye irritation					
Method, Guideline, GLP status, Reliability	**Test substance, Doses**	**Relevant information about the study**	**Results**	**Remarks** *(e.g. major deviations)*	**Reference**
Isolated Chicken Eye Test OECD 438 GLP 1	0.1 g of the test item Szuku Mosquito- and Tick Repellent spray	Positive (Trichloroacetic acid 30 (w/v) %) and negative (NaCl (9g/L saline)) controls showed the expected results. The experiment was considered to be valid.	The mean values of the treated eyes for maximum corneal thickness were 7 and 8% at 75 min and 240 min, respectively. Corneal opacity of 0.00 and fluorescein retention of 2.17. The results suggest that the test item was moderately irritating.	No deviation	Toxi-Coop Zrt., István Buda, Szuku Mosquito- and Tick Repellent spray - In vitro test for eye corrosives and severe irritants in isolated chicken eyes; 2012 Study nr.: 671.549.3529

No human data is 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 and DSD	Eye Irrit. 2 - 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 to 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 and DSD	No classification needed

Skin sensitization

In order to evaluate the sensitising potential of the product, a local lymph node assay was performed by applying the test item on the ears of the test animals. This test allows the quantitative assessment of the lymphoproliferative response to the test substance. No significant, treatment-related effects on the body weights of test animals; no clinical signs and mortality were observed. No erythema was visible in the test animals. Larger than normal lymph nodes were observed in the 10 % test item treated group. The product caused significant lymphoproliferative responses (SI ≥ 3) in 50% and 10 % test item treated groups, whereas in the 100 % and 25 % treatment groups the SI values remained below 3. The higher SI values in the 50% and 10 % treatment groups might be the result of an increased absorption rate of the test item mediated by the vehicle. Although no visible sign of irritation was observed during the main test it is considered that the higher proliferation values (around the borderline) observed in case of the formulations might have been caused by a slight irritation as a consequence of an enhancer effect of the vehicle rather than a real sensitisation effect. It is also supported by the fact that the observed effect was not in accordance with a biological dose-related response. Since no SI value above 3 was observed at test concentration of 100% when the test item was used in its marketed form and the proliferation values observed for the formulations in the selected vehicle (AOO) were on the borderline and were not compatible with a biologically relevant dose-response, Szuku Mosquito- and Tick Repellent spray was considered to be a non-sensitiser in the LLNA in accordance with the evaluation criteria of the relevant

guidelines and also considering that the test item is marketed and used in its undiluted form. Classification according to Directive 1272/2008/EC and CLP.

Summary table of animal studies on skin sensitisation					
Method, Guideline, GLP status, . Reliability	**Species, Strain, Sex, No/group**	**Test substance, Vehicle, Dose levels, duration of exposure Route of exposure** *(topical/intradermal, if relevant)*	**Results** *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)*	**Remarks** *(e.g. major deviations)*	**Reference**
Local Lymph Node Assay, OECD 429 GLP 1	Mouse, CBA/Ca, Female 4 animals / groups (28 animals)	Szuku Mosquito- and Tick Repellent spray at four different concentrations of 100 % and 50, 25 & 10% in Acetone: Olive oil 4:1 (v/v) mixture. The test substance was applied on the external surface of each ear (25 µL/ear) for three consecutive days.	Non-sensitiser Stimulation indices; 100% = 1.2 50% = 2.9 25% = 2.2 10% = 1.7 No mortality, no signs of systemic toxicity or irritation.	No deviation	Toxi-Coop Zrt., Mária Pénzes, Skin sensitization study: Local lymph node assay of test item Szuku mosquito- and tick repellent spray in mice, 2012 Study nr.: 671.553.3531

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	not sensitising
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 spray 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 product according to CLP and DSD	No classification needed.

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** *(gavage, in diet, other)*	**Signs of toxicity** *(nature, onset, duration, severity, reversibility)*	**Value LD50**	**Remarks** *(e.g. major deviations)*	**Reference**
OECD 423 GLP 1	Rat, Crl:(WI)BR female 3/group	Biocidal product 2000 mg/kg bw Gavage	Decreased activity, abnormal gait, incoordination, decreased righting reflex, decreased grip- and limb tone, decreased body tone, decreased plantary reflex and dyspnoea, on the treatment day. No mortality; no clinical signs or abnormalities noted at necropsy.	> 2000 mg/kg bw	-	Toxi-Coop Zrt., PiroskaMácsai Kuthy, Acute oral toxicity study (acute toxic class method) of test item Szuku Mosquito- and Tick Repellent Spray in rats, 2012 Study nr.: 671.321.3359

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	An acute inhalation study was not deemed necessary due to the physical properties and use pattern of the product. The product is a liquid. The active substance, DEET is not volatile and was not found to be toxic via inhalation route (LD50>2.02 mg/L). As it was accepted in the DEET Annex I inclusion dossier, the mass median aerodynamic diameter (MMAD) of aerosol particles is too large and the sedimentation velocity of the particles is too rapid to pose a significant inhalation hazard for humans. Furthermore, the product is used mainly outdoors or the use indoors only takes place in the summer in situations where there is a high ventilation rate.

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 2/dose,	Szuku mosquito- and tick repellent aerosol Preliminary study: 5, 50, 300 and 2000	Main study: No mortality, no behavioural changes, dermal irritation symptoms or systemic toxic	> 2000 mg/kg bw	-	Toxi-Coop Zrt., PiroskaMácsaiKuthy, Acute dermal toxicity study of

	Main study: females and males 5/dose/sex	mg/kg bw Main study: 2000 mg/kg bw	signs. 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 or abnormalities noted at necropsy.			test item Szuku mosquito- and tick repellent aerosol in rats; 2012 Study nr.: 671.321.3360

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 spray 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 product contains isopropyl alcohol (IPA) as a solvent, which is an approved biocidal active substance in PT 1, PT 2 and PT 3, and has a harmonised classification as Flam. Liq. 2 – H225, Eye Irrit. 2 – H319 and STOT SE 3 – H336. Thus IPA is considered as substance of concern (SoC) in relation to physical chemical and human-health endpoints. Due to the presence of IPA only in its given concentration, the product would be classified as Eye Irrit 2, but the product is already classified as Eye Irritant Category 2 – H319 because of the active substance. According to the banding evaluation scheme in the SoC Guidance for human heath toxicology eye irritant 2 SoCs belong to Band A for which a quantitative risk assessment is not needed. Appropriate risk mitigation measures in the form of the precautionary (P)-statements associated with the concerned hazard (H)-statements are applied.

The other solvent in the product is ethyl alcohol (ethanol) which is currently evaluated as an active substance in several product types, and it has a harmonised classification as Flam. Liq. 2 – H225. In addition, the manufacturer of ethanol also classified it as Eye Irritant, Category 2 – H319. Thus ethanol is also considered as substance of concern (SoC) in relation to physical chemical and human-health endpoints. Appropriate risk mitigation measures are applied, and a quantitative risk assessment is not needed.

No other substances of concern have been identified in the formulation.

Available toxicological data relating to a mixture

There are no other toxicologically relevant data available on the product apart from the ones already presented above.

Other

There are no other data available.

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.	yes	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

The product is an arthropod repellent which is applied on the skin by users from the general public, typically during outdoor activities. Target organisms are mosquitoes and ticks.

Inhalation exposure

The proposed uses of Szuku Mosquito- and Tick Repellent Spray 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 3.93E-3 Pa*m3/mol, therefore inhalation exposure from vapours is very low. As the product is marketed in a trigger spray bottle, its potential for formation of respirable particles is low.

Oral exposure

Oral exposure by hand-to-mouth transfer is not considered to be a significant route of exposure because the smell and taste of DEET acts as a self deterrent against this type of activity. Oral exposure due to hand to mouth behaviour is included in the exposure scenarios in DEET's Annex I inclusion dossier, but only to represent worst case calculations in case no deterrent is added to products. The product contains an ingredient that acts as a strong deterrent for ingestion (denatonium benzoate). However, as the product is applied by hand accidental mouth contact can not be ruled out.

Dermal exposure

Szuku Mosquito- and Tick Repellent spray is used on the skin and spread on the skin by hand. Therefore the intended route of exposure is predominantly dermal.

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.	Spray application of the product (adult)	Primary exposure. The user applies the product on his/her body.	Non-professional
2.	Spray application of the product (adult, limited)	Primary exposure. The product applied only on the hands, face and neck.	Non-professional
3.	Spray application of the product (child)	Primary exposure. The adult user applies the product on the skin of a child.	Non-professional
4.	Hand-to-mouth exposure	Secondary exposure. Eating food (e. g. sandwiches) with contaminated hands.	Non-professional

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 Spray is applied directly on the bare skin. Therefore, the intended route of exposure is predominantly dermal; oral and inhalation routes are secondary.

The method of assessment is based on the method #3 in the recommendation no. 11 of the Ad hoc Working Group on Human Exposure. Inhalation exposure is calculated via ConsExpo Web, using the RIVM Report 320005002/2006 Pest Control Fact Sheet (non-respirable particles are added to the oral 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 (Pest Control Products Fact Sheet). According to a study (Bremmer et. al., 2002) 8-10g 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 6g 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[1]	Value
Tier 1	Body weight	60 kg
	Concentration of the active substance	23%
	Applied amount	6 g
	Number of applications per day	1
	Dermal absorption	20%
	Spray/exposure duration	6 min
	Room volume	20 m^3
	Room height	2.5 m
	Ventilation rate	0.6/h
	Inhalation rate	1.25 m^3/h
	Mass generation rate	0.38 g/s
	Airborne fraction	0.2
	Density non volatile	1.8
	Mean event concentration	0.093 mg/m^3

Calculations for Scenario [1]

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	0.0034 mg/kg bw	4.6 mg/kg bw	0.039	4.6424 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	23%
	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	0.0034 mg/kg bw	1.23 mg/kg bw	0.039	1.2724 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 apply 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	23%
	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%
	Inhalation rate (2-6 years)	1.26 m^3/hr
	Inhalation rate (6-12 years)	1.32 m^3/hr

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	0.013 mg/kg bw	7.25 mg/kg bw	0.15	7.413 mg/kg bw
Scenario 3b (children 6-12)	Tier 1	0.0091 mg/kg bw	6.41 mg/kg bw	0.1	6.5191 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	23%
	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	0.47 mg/kg bw	0.47 mg/kg bw
Scenario 4b (children 2-6)	Tier 1	NA	NA	0.74 mg/kg bw	0.74 mg/kg bw
Scenario 4c (children 6-12)	Tier1	NA	NA	0.62 mg/kg bw	0.62 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	0.0034 mg/kg bw	4.6 mg/kg bw	0.509 mg/kg bw	5.1124 mg/kg bw
Scenarios 2+4a	0.0034 mg/kg bw	1.23 mg/kg bw	0.509 mg/kg bw	1.7424 mg/kg bw
Scenarios 3a+4b	0.013 mg/kg bw	7.25 mg/kg bw	0.89 mg/kg bw	8.153 mg/kg bw
Scenarios 3b+4c	0.0091 mg/kg bw	6.41 mg/kg bw	0.72 mg/kg bw	7.1391 mg/kg bw

Exposure of the general public

See exposure assessment of non-professionals.

Monitoring data

[Please add any information on surveys or studies with the actual product or with a surrogate.]

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

There are no non-biocidal uses of the active substance DEET.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Livestock exposure is not foreseen.

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

The product has no professional/industrial uses; there is no potential for transfer of the biocidal active substance into food as a result of professional/industrial use.

Estimating transfer of biocidal active substances into foods as a result of non-professional use

The use of the product does not pose a dietary risk to the consumer.

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	4.6424 mg/kg bw
2.	non-professionals	Tier 1	1.2724 mg/kg bw
3a	non-professionals	Tier 1	7.413 mg/kg bw
3b	non-professionals	Tier 1	6.5191 mg/kg bw
4a	non-professionals	Tier 1	0.47 mg/kg bw
4b	non-professionals	Tier 1	0.74 mg/kg bw
4c	non-professionals	Tier 1	0.62 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*

[1] Standard assessment factor

* 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 Spray is intended for non-professional use only.

Risk for professional users

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

Risk for non-professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1	Tier 1	1000	8.2	4.6424	56.6	Yes
Scenario 2	Tier 1	1000	8.2	1.2724	15.52	Yes
Scenario 3a	Tier 1	1000	8.2	7.413	90.4	Yes
Scenario 3b	Tier 1	1000	8.2	6.5191	79.5	Yes
Scenario 4a	Tier 1	1000	8.2	0.47	5.73	Yes
Scenario 4b	Tier 1	1000	8.2	0.74	9.02	Yes
Scenario 4c	Tier 1	1000	8.2	0.62	7.56	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1+4a	Tier 1		8.2	5.1124	62.35	Yes
Scenarios 2+4a	Tier 1		8.2	1.7424	21.25%	Yes
Scenario 3a+4b	Tier 1		8.2	8.153	99.43	Yes
Scenario 3b+4c	Tier 1		8.2	7.1391	87.06	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 /day	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 Spray is 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, the risk is very close to the maximum safe level. In order to reduce the risk, additional RMMs should be used, 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 Spray 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 spray are the active substance N,N-diethyl-meta-toluamide (DEET) and the 2,6-di-tert-butyl-p-cresol (butylated hydroxy toluene; BHT; CAS: 128-37-0) 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. BHT.is identified as a substance of concern and its environmental fate and ecotoxicological data were taken from the associated Reach Registration dossier.

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	0.043 mg/L

	(*Selenastrum capricornutum)*	(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

2,6-di-tert-butyl-p-cresol (CAS: 128-37-0) as substance of concern

Summary table for aquatic toxicity					
Guideline/Test method/GLP status/reliability	Species	End point	Duration	Result	Reference
Fish					
OECD 203 GLP	*Oryzias latipes*	*LC50*	*96h - acute*	*1.1 mg/L*	*Registration Dossier*
OECD 210 GLP	*Oryzias latipes*	*NOEC*	*30d - chronic*	*0.053 mg/L*	*Registration Dossier*
Invertebrates					
OECD 202	*Daphnia magna*	*EC50*	*48h – acute*	*0.48 mg/L*	*Registration Dossier*
OECD 202 GLP	*Daphnia magna*	*LC50*	*48h – acute*	*0.84 mg/L*	*Registration Dossier*
OECD 211 GLP	*Daphnia magna*	*NOEC*	*21d – chronic*	*0.069 mg/L*	*Registration Dossier*
Algae (growth inhibition)					
OECD 201 GLP	*Pseudokirchneriella subcapitata*	*EC50*	*72h – acute*	*>0.24 mg/L*	*Registration Dossier*
OECD 201 GLP	*Pseudokirchneriella subcapitata*	*NOEC*	*72h - chronic*	*0.24 mg/L*	*Registration Dossier*
microorganisms					
	Tetrahymena pyriformis	*EC50*	*24h - acute*	*1.7 mg/L*	*Registration Dossier*
	Photobacterium phosphoreum	*EC50*	*30min - acute*	*8.98 mg/L*	*Registration Dossier*
	Pseudomona fluorescens	*NOEC*	*36h*	*50 mg/L*	*Registration Dossier*
Soil organisms					
OECD 222 GLP	*Eisenia fetida*	*EC50/NOEC*	*56d*	*87.9 mg/kg dw/25 mg/kg dw*	*Registration Dossier*
	Allium cepa	*EC50/NOEC*		*20.9/4.74 mg/kg dw*	*Registration Dossier*
[1] calculated from the area under the growth curve *[2] calculated from growth rate*					

Compartment	**Test results**	**PNEC**
Surface water	NOEC: 0.053 mg/L chronic fish test	5.3 µg/L

		(AF: 10)
STP microorganisms	EC50: 1.7 mg/L growth inhibition	0.17 mg/L (AF: 10)
Sediment	equilibrium partitioning	12.2 mg/kg dw
Soil	equilibrium partitioning	2.44 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 spray contains 0.4% 2,6-di-tert-butyl-p-cresol which has been identified as substance of concern. It is classified as Aquatic chroic 1 and its concentration leads the product to be regarded as hazardous. Consequently, the product Szuku mosquito- and tick repellent spray 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 spray 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 ($Cform_{weight}$)	230	g/kg	S
SoC in the product	4	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	3.51	O; ESD Eq. 3.8
Local emission rate to wastewater ($Elocal_{water}$) - SoC	0.061	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 ($Cform_{weight}$)	230	g/kg	S
SoC in the product	4	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	1/d	S; not 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	0.526	O; ESD Eq. 3.12
Local concentration in water body after one day ($Clocal_{water,1d}$) – DEET	1.21E-03	O; ESD Eq. 3.13
Local concentration in water body over 91 days ($Clocal_{water,91d}$) – DEET	1.1E-01	O; ESD Eq. 3.14
Refined local concentration in water body over 91 days ($Clocal_{water,91d\text{-}ref}$) - DEET	2.6E-02	O; including degradation; ESD Eq. 3.15
Local emission rate to surface water body ($Elocal_{water}$); SoC	0.00915	O; ESD Eq. 3.12
Local concentration in water body after one day ($Clocal_{water,1d}$); SoC	2.1E-05	O; ESD Eq. 3.13
Local concentration in water body over 91 days ($Clocal_{water,91d}$); SoC	1.91E-03	O; ESD Eq. 3.14
Refined local concentration in water body over 91 days ($Clocal_{water,91d\text{-}ref}$); SoC	1.91E-03	O; no degradation

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.

2,6-di-tert-butyl-p-cresol (butylated hydroxy toluene; BHT) is presumed to be non volatile based on the data from the registration dossier. The Henry's Law constants (9.05-0.34 Pa/m3/mol) in the dossier indicate moderate volatility from water, although adsorption to suspended solids is expected to attenuate it, since the estimated Koc value is 23030. BHT is considered as not readily biodegradable. BHT is not stable in water, it can degrade to several transformation products and an unidentified one exceeds 10%. BHT is estimated to be rapidly photodegradable in air by hydroxyl radicals with a half-life of 7 hours.

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; 2,6-di-tert-butyl-p-cresol			
Input	Value	Unit	Remarks
Molecular weight	220.35		
Vapour pressure (at 25°C)	0.39	Pa	Reach Registration dossier
Water solubility (at 25°C)	0.6	mg/l	Registration dossier
Log Octanol/water partition coefficient	5.03	Log 10	Registration dossier
Organic carbon/water partition coefficient (Koc)	23030	l/kg	Registration dossier
Biodegradability	not readily biodegr.		Registration dossier
First order rate constant for removal from top soil (k)	0	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	20.46	SimpleTreat 4.0
Water	7.992	16.45	
Sludge	0.403	63.09	
Degraded in STP	91.6	0	

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/L]	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg/kg]	[µg/l]	[mg/m^3]
Scenario 1 – DEET	0.14	0.014	(0.024)	-	-	0.0186	6.6	-
Scenario 2 - DEET	-	0.026	-	-	-	-	-	-
Scenario 1 – SoC	0.005	0.00048	(0.24)			0.716	1.76	
Scenario 2 - SoC		0.0019						

[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

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 2,6-di-tert-butyl-p-cresol are > 100 L/kgww, which may be an indication of bioaccumulation potential. In addition, the logKow value of >4.5 may idicate that other uptake routes besides uptake from the water phase may be important, so the uptake through the food chains leading to secondary poisdoning should be considered. The next step is to consider whether the substance has the potential to cause toxic effects. This assessment is based on classifications on the basis of mammalian toxicity data. 2,6-di-tert-butyl-p-cresol is not classified for any health hazards, although it is under assessment for its potential ED properties, the results are not yet available. Therefore, there is currently no need to assess risks due to secondary poisoning of 2,6-di-tert-butyl-p-cresol, but depending on the results of the ED evaluation, this may be necessary afterwards.

2.2.8.3 Risk characterisation

Atmosphere

Conclusion: The product Szuku Mosquito- and Tick Repellent Spray is not expected to pose a risk to the atmospheric environment. 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. 2,6-di-tert-butyl-p-cresol as substane of concern is estimated to be rapidly photodegradable in air by hydroxyl radicals with a half-life of 7 hours.

Sewage treatment plant (STP)

Summary table on calculated PEC/PNEC values	
	$PEC/PNEC_{STP}$
Scenario 1 – DEET	0.014
Scenario 2 - DEET	-
Scenario 1 – SoC	0.029
Scenario 2 - SoC	-

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	
	$PEC/PNEC_{water}$
Scenario 1 – DEET	0.33
Scenario 2 – DEET	0.6
Scenario 1 – SoC	0.09
Scenario 2 - SoC	0.36

Conclusion: The PEC/PNEC ratios calculated for the aquatic compartment do not exceed the trigger value of 1. The PEC/PNEC ratios for sediment are the same, since both PECs and PNECs are calculated using EPM method. The releases of the product 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	0.49
Scenario 2 – DEET	-
Scenario 1 – SoC	0.29
Scenario 2 - SoC	-

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

Groundwater

The calculated values of PECgw for scenario 1 are higher than the trigger value of 0.1 µg/L for pesticides (maximum permissible concentration laid down by Directive 98/83/EC). For the active substance, formation of major metabolites is 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: 0.089 grass: 0.018	kg/ha	S
Application method	agr: incorporation; 0.2m	-	D

	grass: incorporation; 0.1m		
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	0.06	0.011
Hamburg	**0.217**	0.03
Jokioinen	-	0.0277
Kremsmuenster	**0.173**	0.0162
Okehampton	**0.249**	0.0266
Piacenza	0.058	0.019
Porto	0.0178	0.0069
Sevilla	0.001	0.0008
Thiva	0.01	0.00066

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]	3.51	1.15
concentration in sludge [mg/kg]	17.89	5.866
Application rate [kg/ha]	0.0894	0.0293

Scenario	PECgw [µg/L]

	arable land Tier 2
Chateaudun	0.0197
Hamburg	0.071
Jokioinen	-
Kremsmuenster	0.0569
Okehampton	0.0818
Piacenza	0.019
Porto	0.00585
Sevilla	0.00035
Thiva	0.0034

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

The calculated PECgw for BHT also exceeds the value of 0.1 µg/L so the simulation model of FOCUS PEARL 4.4.4 was used to refine the estimated PECgw values. BHT is quite unstable in soil and it was found to degrade rapidly to several transformation products but these products did not build up over the study period but declined over time. As these products are very numerous and some of them have not been identified, they are not taken into account in the groundwater simulation and a half-life of 1000 days as a worst-case has been set for the parent.

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: 0.244 grass: 0.0487	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	220.35	g/mol	S
Vapour pressure	0.39	Pa	S; 25°C
Water solubility	0.6	mg/L	S; 25°C
Kom	13358.47	L/kg	S
Freundlich exponent	1	-	D; TAB ENV22
Half-life	1000	d	S
Coefficient for uptake in plants	0	-	D

Scenario	PECgw [µg/L] arable land	PECgw [µg/L] grassland
Chateaudun	<0.0001	<0.0001
Hamburg	0.0003	<0.0001
Jokioinen	-	<0.0001
Kremsmuenster	<0.0001	<0.0001
Okehampton	0.0005	<0.0001
Piacenza	0.0009	<0.0001
Porto	<0.0001	<0.0001
Sevilla	0.0046	<0.0001
Thiva	0.0006	<0.0001

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 2,6-di-tert-butyl-p-cresol are > 100 L/kgww, which may be an indication of bioaccumulation potential. In addition, the logKow value of >4.5 may idicate that other uptake routes besides uptake from the water phase may be important, so the uptake through the food chains leading to secondary poisdoning should be considered. The next step is to consider whether the substance has the potential to cause toxic effects. This assessment is based on classifications on the basis of mammalian toxicity data. 2,6-di-tert-butyl-p-cresol is not classified for any health hazards, although it is under assessment for its potential ED properties, the results are not yet available. Therefore, there is currently no need to assess risks due to secondary poisoning of 2,6-di-tert-butyl-p-cresol, but depending on the results of the ED evaluation, this may be necessary afterwards.

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 2,6-di-tert-butyl-p-cresol (BHT; CAS: 128-37-0) 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? Y	Remarks
0.04	STP	
0.42	water (indirect emission)	
0.96	water (direct emission)	
0.78	soil	

Conclusion: The summation of PEC/PNEC values are below 1 for all environmental compartments. 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 spray. 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*."

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 Spray 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 spray 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 spray 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. The product should not be used on children under 2 years. Children under age of 12 should not apply the product themselves, only by adults. 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[3]

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)[4]: please see IUCLID

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

3.6 Other: not available

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

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