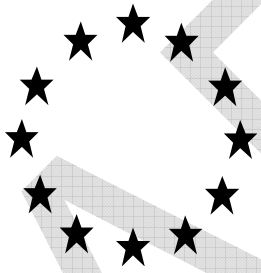
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

DRAFT PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



PANKO

Product type 19

DEET

Case Number in R4BP: BC-XC010801-53

Evaluating Competent Authority: PL
Date: [July 2018]

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1 CONCLUSION

PANKO is a pump spray (liquid) for direct application containing 15% (w/w) of DEET. Its physicochemical properties are considered to be acceptable. Acceptable analytical methods have been also submitted.

Based on efficacy reports, which were submitted, the product is effective as a repellent. Product can be used indoor (against mosquitoes) and outdoor (against mosquitoes and ticks).

The biocidal product contains ethanol which is classified as a substance of concern. However, according to DOCIII of CAR for DEET, during application or release of the product, the ethanol evaporates rapidly and dissipates in the air. Therefore, PANKO would not pose unacceptable risk to human health for adults and children over 12 years old when the product is applied twice a day. The product can be used on children under 12 years old once a day with restrictions that the product should not be applied to the hands, around eyes and mouth. Due to the unacceptable risk, children under 2 years must not be treated with PANKO.

The environmental risk assessment was prepared with using FOCUS PEARL MODEL 4.4.4. An unacceptable risk have occurred in case of ticks control (2 applications per day) in fresh water, sediment, soil and groundwater. For other applications (use against ticks – 1 application per day and against mosquito – 2 and 1 applications per day), the unacceptable risk have occurred in groundwater.

PANKO is effective product against ticks and mosquitoes for 4 hours after 2 applications.
Risk for environment is however unacceptable based on standard application scenarios and conditions of article 19.1 iii) are not met for this biocidal product.
Given the need to repel ticks from human to prevent Lyme disease and other diseases carried by ticks or mosquitoes, Poland agrees to grant authorisation for PANKO for use on human against the ticks and mosquitoes according to article 19.5 with appropriated risk mitigation measures.

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)**
PANKO	Poland

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Tadeusz Karolak "MABI"
	Address	Mieszka I 13/88, 26-617 Radom, Poland
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the biocidal product

Name of manufacturer	Tadeusz Karolak "MABI"
Address of manufacturer	Mieszka I 13/88, 26-617 Radom, Poland
Location of manufacturing sites	Mieszka I 13/88, 26-617 Radom, Poland

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

Active substance	N,N-diethyl-meta-toluamide
Name of manufacturer	Clariant Corporation Industrial and Consumer Care
Address of manufacturer	625E. Catawba Avenue Mt. Holly, NC 28120 USA
Location of manufacturing sites	625E. Catawba Avenue Mt. Holly, NC 28120 USA

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

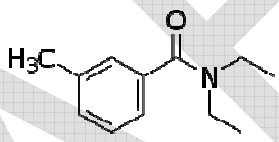
2.1.2 Product (family) composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

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

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	N,N-diethyl-meta-toluamide
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	97%
Structural formula	

2.1.2.2 Candidate(s) for substitution

The active substance DEET contained in the biocidal product PANKO is not a candidate for substitution in accordance with Article 10 of BPR.

*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 (%)
DEET	N,N-diethyl-meta-toluamide	Active substance	134-62-3	205-149-7	15.00
Ethanol	ethanol	solvent	64-17-5	200-578-6	82.09

* The product contains a taste deterrent – 0.04%

2.1.2.4 Information on technical equivalence

The source of active substance used in the biocidal product PANKO is identical to the source of active substance a Union list of approved active substances. Therefore no technical equivalence evaluation is necessary.

2.1.2.5 Information on the substance(s) of concern

The biocidal product contains ethanol which is classified as a substance of concern. However, according to DOCIII of CAR for DEET, during application or release of the product, the ethanol evaporates rapidly and dissipates in the air. Therefore, only the active substance needs to be considered.

2.1.2.6 Type of formulation

Pump spray (liquid) for direct application

2.1.3 Authorised use(s)

2.1.3.1 Use description

Table 1. Use # 1 – direct application on human skin or clothes

Product Type	19 (Repellents and attractants)
Where relevant, an exact description of the authorised use	Ready to use product intended to use directly on skin and clothes.
Target organism (including development stage)	adult mosquitoes adult ticks
Field of use	indoor (against mosquitoes) outdoor (against mosquitoes and ticks)
Application method(s)	Spray application - product applied directly to the exposed skin or clothes
Application rate(s) and frequency	Repellent against mosquitoes: dose 0.58 mg/cm^2 applied on skin (efficacy for 3-4 h after the application). Repellent against ticks: dose 2.48 mg/cm^2 applied on skin (efficacy for 2 h after the application). Product can be used on children between 2 and 12 years old once a day.

	Product can be used on children over 12 years old and adults twice a day. Do not use on children under 2 years old.
Category(ies) of users	Non-professional
Pack sizes and packaging material	Please see the relevant section.

2.1.3.2 Use-specific instructions for use

Spray evenly to the exposed skin or clothes outdoor or well ventilated areas. For facial application, spray your hands and rub the product over the face.

Product can be used on children between 2 and 12 years old once a day.

Product can be used on children over 12 years old and adults twice a day.

Do not use on children under 2 years old.

Do not smoke during application.

2.1.3.3 Use-specific risk mitigation measures

Read label before use.

Do not use on children under 2 years old.

Do not use on children between 2 and 12 years old more than once a day.

Do not use more than twice a day (for adults and children over 12 years old).

Do not spray on an open flame or other ignition source.

Do not eat, drink or smoke when using this product.

Use only outdoors or in a well-ventilated area.

Do not inhale the spray.

Avoid contact with eyes and areas around eyes, mouth, mucous membranes and damaged skin.

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

Wash hands after application.

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

First aid instructions:

General advice: Move the victim to fresh air. If any symptoms occur, seek medical advice immediately or take the victim to hospital in recovery position and show the container or label. Do not give anything by mouth to an unconscious person.

Ingestion: Rinse mouth. Call a physician or poison control center immediately and show the container or label.

Inhalation: Avoid inhaling sprayed liquid. Move the victim to fresh air and keep at rest, protect against heat loss. Call a physician immediately.

Skin contact: Take off contaminated clothing. Wash before reuse. Immediately wash

with plenty of soap and water. In case of skin irritation, indicated dermatological consultation.

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Ophthalmological consultation is necessary.

Emergency measures to protect the environment:

Avoid release to environment.
Dispose of contents/containers in accordance with the national regulations.
Prevent product from entering the environment (surface and ground water), sewerage, drainage, etc.
Communicate to the relevant authorities on tipping leaks into waterways, drains, sewers.

Methods and materials for containment and cleaning: Absorb spill on inert material (i.e. sand), collect and place in containers for later properly identified as a hazardous waste management. Rinse the contaminated surface with water, collect the slops and treat as waste.

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

Dispose of contents/containers in accordance with the national regulations.

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

Product should be stored in original, labelled and closed container, at room temperature, in dry place inaccessible to children and pets.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

Protect from frost.

Keep this product away from children.

Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F.

Shelf life of up to 5 years supported.

2.1.4 Hazard and precautionary statements

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

Based on the information provided, it has been proposed that the biocidal product meets the criteria for classification and labelling under Regulation (EC) 1272/2008 as:

Classification	
Hazard category	Flammable Liquid 1 Eye Irritation 2 Aquatic Chronic 3
Hazard statement	H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation H412: Harmful to aquatic life with long lasting effects.

Labelling	
Signal words	 Danger
Hazard statements	H225 Highly flammable liquid and vapour. H319 Causes serious eye irritation. H412 Harmful to aquatic life with long lasting effects.
Precautionary statements	P102 Keep out of reach of children. P103 Read label before use. P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P211 Do not spray on an open flame or other ignition source. P233 Keep container tightly closed. P261 Avoid breathing spray. P264 Wash hands thoroughly after handling. P270 Do not eat, drink or smoke when using this product. P271 Use only outdoors or in a well-ventilated area. P273 Avoid release to the environment. P301+P312 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. P330 Rinse mouth. 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.
Note	EUH 208 Contains Lemon, ext., Citronellol, 2-benzylideneheptanal, Benzyl salicylate, 2-(4-tert-butylbenzyl)propionaldehyde . May produce an allergic reaction.

2.1.5 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)**
Pump-spray bottle	50 ml; 75 ml; 90 ml; 100 ml; 150 ml; 200 ml;	HDPE	PP, HDPE	Non-professional	Yes

	250 ml				

2.1.6 Directions for use

2.1.6.1 Instructions for use

Use # 1 - direct appliacation on human skin or clothes

Direct application to the skin and clothes, outdoor or well ventilated areas.

2.1.6.2 Risk mitigation measures

- Read label before use.
- Do not use on children under 2 years old..
- Do not use on children between 2 and 12 years old more than once a day.
- Do not use more than twice a day (for adults and children over12 years old).
- Do not spray on an open flame or other ignition source.
- Do not eat, drink or smoke when using this product.
- Use only outdoors or in a well-ventilated area.
- Do not inhale the spray.
- Avoid contact with eyes and areas around eyes, mucous membranes and damaged skin.
- The product is not to be used with other products (biocidal and suntan products).
- For facial application, spray your hands and rub the product over the face.
- Wash hands after application.

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

First aid instructions:

General advice: Move the victim to fresh air. If any symptoms occur, seek medical advice immediately or take the victim to hospital in recovery position and show the container or label. Do not give anything by mouth to an unconscious person.

Ingestion: Rinse mouth. Call a physician or poison control center immediately and show the container or label.

Inhalation: Avoid inhaling sprayed liquid. Move the victim to fresh air and keep at rest, protect against heat loss. Call a physician immediately.

Skin contact: Take off contaminated clothing. Wash before reuse. Immediately wash with plenty of soap and water. In case of skin irritation, indicated dermatological consultation.

Eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Ophthalmological consultation is necessary.

Emergency measures to protect the environment:

Avoid release to environment.
Dispose of contents/containers in accordance with the national regulations.
Prevent product from entering the environment (surface and ground water), sewerage, drainage, etc.

Communicate to the relevant authorities on tipping leaks into waterways, drains, sewers.
Methods and materials for containment and cleaning: Absorb spill on inert material (i.e. sand), collect and place in containers for later properly identified as a hazardous waste management. Rinse the contaminated surface with water, collect the slops and treat as waste.

2.1.6.4 Instructions for safe disposal of the product and its packaging

Dispose of contents/containers in accordance with the national regulations.

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

Product should be stored in original, labelled and closed container, at room temperature, in dry place inaccessible to children and pets.

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Protect from frost.

Keep this product away from children.

Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F.
Shelf life of up to 5 years supported

2.1.7 Documentation

2.1.7.1 Data submitted in relation to product application

Please refer to Annex 3.1 – List of studies for biocidal product.

2.1.7.2 Access to documentation

The letter of access from McKenna Long & Aldridge LLP (representative of UE DEET Joint Venture) granted to PANKO Tadeusz Karolak, has been submitted for the active substance, therefore no additional information for this point is needed.

2.1.8 Other information

In the Competent Assessment Report for DEET it was stated that some elements should be taken into account by Member States when authorising product:

1. Member states may require monitoring methods for analysing residues of DEET in the air compartment might be required for authorisation of DEET containing biocidal products, whose use pattern result in significant exposure to the air compartment.

   The calculated half life of DEET equals 15.2 hr what is below the trigger of < 2 days used as cut-off value to identify chemicals that could be of potential concern for with the potential for long-range transport through the atmosphere. The substance unlikely shows significant long-range transport, and it is considered of no concern for ozone depletion.

For above reasons monitoring methods for analysing residues of DEET in the air compartment were assumed to be not needed.

2. Member states may need to consider inclusion of DEET in national programs for monitoring groundwater.

   PEARL model calculation allowed to conclude that predicted groundwater concentration will not exceed the trigger value of 0.1 µg/l. For above reasons monitoring of DEET in the groundwater was assumed to be not needed.

3. Member states should address any potential for direct exposure to surface water as a consequence of swimming etc, which has not been assessed at the European level

In the presented Assesment Report exposure and risk for surface water due to swimming was already assessed by using revised ESD for PT 19 (2015).

2.2 ASSESSMENT OF THE BIOCIDAL PRODUCT (FAMILY)

2.2.1 Physical, chemical and technical properties

Property	**Guideline and Method**	**Purity of the test substance (% (w/w)**	**Results**	**Reference**
Physical state at 20 °C and 101.3 kPa	Visual	Not reported	liquid	Information provided by the applicant in the product SDS
Colour at 20 °C and 101.3 kPa	Visual	Not reported	clear, transparent	Information provided by the applicant in the product SDS
Odour at 20 °C and 101.3 kPa	Olfactory	Not reported	characteristic	Information provided by the applicant in the product SDS
Acidity / alkalinity	CIPAC MT 75.2	Panko, liquid contain 15 % DEET	pH of 1 % water solution 5.49	Idris Al Amin, 2014
Relative density / bulk density	EEC A.3	Panko przeciwko komarom i kleszczom	0.825 g/cm^3	B. Krzysiak-Warzała, 2012
Storage stability test – **accelerated storage**	CIPAC MT 46	Panko, liquid in an atomizer contain 15 % DEET	Before storage: DEET 15.81 %, pH (1 % water solution) 5.49; After 4 week storage at 50 °C: DEET 15.66 %, pH (1 % water solution) 5.14	Idris Al Amin, 2012
Storage stability test – **long term storage at ambient temperature**	CIPAC MT 46	Panko, liquid in an atomizer contain 15 % DEET	Before storage: DEET 15.81 %, pH (1 % water solution) 5.49, package: white packages of HDPE with atomizer; After 1 year storage: DEET 15.58 %, pH (1 % water	Idris Al Amin, 2014; Idris Al Amin, 2015; Idris Al Amin, 2017

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			solution) 5.39, package: white packages of HDPE with atomizer; After 2 year storage: DEET 15.75 %, pH (1 % water solution) 5.59, package: white packages of HDPE with atomizer; After 3 year storage: DEET 15.17 %, pH (1 % water solution) 5.54, package: white packages of HDPE with atomizer; After 5 year storage: DEET 15.84 %. pH (1 % water solution) 5.88, package: stable with no visible changes.	
Storage stability test – **low temperature stability test for liquids**			Cold temperature storage data were not evaluated.”Protect from frost” should appear on the label.	
Effects on content of the active substance and technical characteristics of the biocidal product - **light**			The product was packaged in to not-transparent containers.	
Effects on content of the active substance and technical			The product was packaged in to closed	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
characteristics of the biocidal product – **temperature and humidity**			containers. "Protect to high temperature" should appear on the label.	
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	SPR/BF/07/b according to Technical Monograph GIFAP No. 17	Panko, liquid in an atomizer contain 15 % DEET	During the third years storage at 20 °C thr shape and colour of the HDPE packages were stable. The minor mass change of the packages had no effect on the physicochemical properties of the tested preparation.	Idris Al Amin, 2015
Chemical compatibility			The product will not be used with other products.	
Surface tension	ECC A.5	Panko przeciwko komarom i kleszczom	50.5 mN/m	B. Krzysiak-Warzała, 2012
Viscosity	OECD 114	Panko	20 °C: 1.872 (±0.016) mm^2/s 40 °C: 1.301 (±0.017) mm^2/s	I. Bonk-Barbara, 2012

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

The product PANKO is ready-to-use spray repellent containing DEET as the active substance. The product PANKO is a clear, transparent liquid with characteristic odour. For this product the relative density (D^{20}_4) was equal to 0.825 and it pH = 5.49. It is characterized by kinematic viscosity equal to 1.872 mm^2/sec in 20°C.

The active substance content decreased from 15.81 %, to 15.66 % after accelerated storage stability test (4 weeks in temperature 50°C). In the real-time stability test the active substance content decreased from 15.81 %, to 15.17 % after 36 month. The loss of 0.69% is acceptable taking into consideration formulation type. Taking into consideration results from above storage stability tests, the shelf life of the product is considered acceptable up to five years in ambient conditions. Cold temperature storage data were not evaluated. The cold temperature storage was not relevant to the proposed use around the home. The proposed uses being supported for the authorization of the product are not specifically in the home and hence statement "Protect from Frost" should appear on the

label.

2.2.2 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	EEC A.14	Panko, liquid contain 15 % DEET	Not explosive	Sałaciński, 2012
Flammable liquids	EEC A.9,	Panko przeciwko komarom i kleszczom	Flash point at 16 (±1) °C	B. Krzysiak-Warzała, 2012
Auto-ignition temperatures of products (liquids and gases)	EEC A.15	Panko przeciwko komarom i kleszczom	Self-ignition temperature 420 °C	B. Krzysiak-Warzała, 2012

Conclusion on the physical hazards and respective characteristics of the product
The product PANKO has non-explosive properties. The flash-point of the product was determined and is equal to 16°C. Taking into consideration this fact and also information that one of the components of the product is classified as flammable liquid category 2 (ethanol 82.09 %), the product PANKO should be classified as flammable liquid category 2.

2.2.3 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
DEET	Reverce phase HPLC with DAD detection	0.499 mg/mL; 0.745 mg/mL; 0.846 mg/mL; n=3	0.36-1.11 mg/mL 6 standards, r^2=0.9915	Retention time of sample with standard and no peak in blank formulation.	69-211	101.11	1.12		Rafał Mróz, 2012

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
DEET	Termal desorption GC-MS	0.5 ng; 5 ng; n=5	0.01 – 20 ng; r^2 > 0.990					LOD=0.02 ng; LOQ=0.1 ng	Noelia Ramirez, Rosa Maria Marce, Francesc Borrull, 2010

Conclusion on the methods for detection and identificationof the product

HPLC-DAD is an analytical method for determination of the active substance in the biocidal product PANKO. The analytical method is based on dilution with acetonitrile, using an amount of 35 mg product, diluted in 10 ml acetonitrile (placed to ultrasonic bath for 5 min) and injected into the HPLC system.

Specificity:
No interference based on representative chromatograms.

Linearity:
r^2 = 0.9915; y = 46954547.5447x + 10777842.4587, n = 6, range 69 – 211 % of the theoretical concentration (100 % = 0.525 mg/mL)

Accuracy:
Mean recovery 101.11 %

Precision:
0.249 %SD, 1.58 %RSD

Residue analytical method in air

In the reference document, the analytical method for determination of residue of DEET and 8 different substance in air samples was provided. Thermal desorption – gas chromatography – mass spectrometry is suitable method for determination of DEET's residue in air samples in range 0.01 – 20 ng.

The analytical methods for determination of residues of active substance in different matrices (drinking and surface water, body fluids and tissues) are presented in the CAR of the active substance. No contamination of food is expected. So, no method is required.

2.2.4 Efficacy against target organisms

2.2.4.1 Function and field of use

PANKO product is an insect repellent (PT19) based on 15% (w/w) DEET. Product can be used indoor (against mosquitoes) and outdoor (against mosquitoes and ticks).

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

Product PANKO is used to repel mosquitoes (*Culicidae*) and ticks (*Ixodidae*). PANKO is an insect repellent that should be applied to the skin on exposed body parts or clothes with the purpose to protect humans from bites.

2.2.4.3 Effects on target organisms, including unacceptable suffering

Product PANKO is applied directly onto human skin or clothes. The active substance DEET evaporates from the skin surface or clothes into air surrounding the skin. The target organisms sense the repellent and refrain from landing on the skin and next from biting.

2.2.4.4 Mode of action, including time delay

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

2.2.4.5 Efficacy data

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
repellent	indoor	PANKO (DEET 15%) Batch No: 2015 04	adult mosquitoes (*Aedes aegypti)* 50 female adults/cage	laboratory test	simulated-use test "arm-in-cage"/ 0.24 ml product per upper and lower surface of hand and wrist/ 10 minutes exposure time at 1 hour intervals	Repellency during 2 hour of application was 100%. Repellency during 4 hour of application was over the 95%. *According to the Poland CA: on the basis of this study it is acceptable efficacy only against*	Ocena skuteczności repelentnego działania preparatu PANKO w odniesieniu do komarów. Gdański Uniwersytet Medyczny Wydział Nauk o Zdrowiu z Oddziałem Pielęgniarstwa i Instytutem Medycyny Morskiej i Tropikalnej, Katedra Medycyny Tropikalnej i Parazytologii, Zakład Parazytologii Tripokalnej.

						Aedes aegypti for 4 h after the application (indoor use). The study is not enough to provide efficacy against mosquitoes	Gdynia 1.06.2012 r.
repellent	outdoor	PANKO (DEET 15%) Batch No: 2018 04	adult mosquitoes (*Aedes* spp. *Culex* spp.) 189 female adults/3 tests	field trials	field trials/ 0.65 g product per surface of forearm/ 10 minutes exposure time at 1 hour intervals	Repellency during 2 hour of application was 100%. Repellency during 3 hour of application was over the 93%. Repellency after 4 hours of application was under 80%. According to the Poland CA: on the basis of this study it is acceptable efficacy against adult mosquitoes (*Aedes* spp. *Culex* spp.) for 2-3 h after the application (outdoor use).	Sprawozdanie z badań terenowych w zakresie stwierdzenia odstraszającego działania na komary preparatu Panko stosowanego na skórę. Narodowy Instytut Zdrowia Publicznego Państwowy Zakład Higieny, Samodzielna Pracownia Entomologii Medycznej i Zwalczania Szkodników. Warszawa 21.07.2015 r.
repellent	indoor	PANKO (DEET 15%) Batch No: 2016 04	adult ticks (*Dermacentor reticulatus*) 30 female and male adults/test	laboratory test	simulated-use test on rabbits skin/ 0.12 ml per 40 cm^2 surface of rabbits skin/ 10 minutes exposure time at 30 minutes or 1	Repellency during 2 hour of application was at least 95%.	Wyniki badań nad działaniem odstraszającym produktu PANKO, firmy Mabi na postacie dorosłe kleszcza

					hour intervals (also after 23 h and 47 h)	According to the CA Poland: on the basis of this study it is acceptable efficacy against ticks for 2 h after the application	*Dermacentor reticulatus*. Prof. dr hab. n. biol. A. Buczek - Fundacja na Rzecz Zwalczania Kleszczy i Chorób Odkleszczowych. Lublin 2014 r.

Conclusion on the efficacy of the product

The TNsG on PT18 and PT19, defines that to show efficacy of products intended for use as repellent on skin or clothes against mosquitoes, both simulated-use test (arm-in-cage) and field study showing repellence in the field should be provided. Therefore on the basis of laboratory study there was no proved efficacy against mosquitoes outdoor. However during evaluation there was also field study supplied. According to this additional field test, it is acceptable efficacy against adult mosquitoes (*Aedes* spp., *Culex* spp.) for 3-4 h after the application (outdoor use). Efficient dose is 0.65 g of product which is applied to the exposed skin or clothes.

According to the TNsG on PT18 and PT19, efficacy of products intended for use as repellent against ticks only laboratory test (study on animal skin is acceptable) to be provided. Consequently, based on studies carried out on ticks *Dermacentor* spp. can be accepted efficacy of the product against ticks for 2 h after application outdoor. According to this data it is acceptable efficacy against adult ticks for 2 h after the application (outdoor use). Efficient dose is 0.12 ml of product applied to the of exposed skin (40 cm^2 surface) or clothes.

References:

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

2.2.4.6 Occurrence of resistance and resistance management

Development of resistance to DEET is not known and not expected. Mosquitoes or ticks exposed to DEET are repelled only. There is low selection pressure because the insects do not die and there are many other food sources available for these insects.

2.2.4.7 Known limitations

According to lack of information about development of resistance to DEET, it is considered unnecessary to take actions to prevent development of resistance by target organisms.

2.2.4.8 Evaluation of the label claims

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

- „Ocena skuteczności repelentnego działania preparatu PANKO w odniesieniu do komarów". Gdański Uniwersytet Medyczny Wydział Nauk o Zdrowiu z Oddziałem Pielęgniarstwa i Instytutem Medycyny Morskiej i Tropikalnej, Katedra Medycyny Tropikalnej i Parazytologii, Zakład Parazytologii Tropikalnej. Gdynia 1.06.2012 r. Aneks z 27.04.2015 r.
- „Sprawozdanie z badań terenowych w zakresie stwierdzenia odstraszającego działania na komary preparatu Panko stosowanego na skórę". Narodowy Instytut Zdrowia Publicznego Państwowy Zakład Higieny, Samodzielna Pracownia Entomologii Medycznej i Zwalczania Szkodników. Warszawa 21.07.2015.
- „Wyniki badań nad działaniem odstraszającym produktu PANKO, firmy Mabi na postacie dorosłe kleszcza *Dermacentor reticulatus*". Prof. dr hab. n. biol. Alicja Buczek - Fundacja na Rzecz Zwalczania Kleszczy i Chorób Odkleszczowych. Lublin 2014 r. Aneks z 28.05.2015 r.

On the basis of these studies is accepted efficacy of this product against:
- mosquitoes for 3-4 h after use on the skin (indoor and outdoor),
- ticks for 2 h after use on the skin (outdoor).

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

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

2.2.5 Risk assessment for human health

2.2.5.1 Assessment of effects on Human Health

The applicant has submitted an effect and exposure assessment for the product PANKO. The human health exposure and risk assessment of the product PANKO were examined by the PL CA appropriately according to standard requirements. Only one study with product have been provided. No new studies have been provided concerning the active substance and human health exposure. The product was not reference product in the EU-review program for inclusion of the active substance in Annex I of Directive 98/8/EC. The PL CA has revised this risk assessment for the human health aspect.
Study with the product have been submitted by the applicant to address skin corrosion/irritation and skin sensitization. The results of these studies are presented below.

Skin corrosion and irritation

Summary table of human data on skin corrosion irritation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
Contact test Reliability : 2	PANKO	Study was conducted on skin of 31 volunteers. Test substance was applied on paper disks which was fixed onto upper part of an arm of each volunteer. Results were examined after 48, 78 and 96 hours.	No reaction was observed on the skin of volunteers	"Świadectwo właściwości drażniących i uczulających", Kosmetyczno-Lekarska Spółdzielnia Pracy „IZIS", Świadectwo badania nr 13370/13, 2013

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Product is not irritating to skin
Justification for the value/conclusion	No reaction was observed on the skin of volunteers
Classification of the product according to CLP and DSD	Product is not irritating to skin

Eye irritation

Data waiving	
Information requirement	Testing on the product does not need to be conducted
Justification	There are valid data available on each of the components in the product. Based on the classification of active substance and co-formulants, product does meet criteria for classification as an eye irritant. Classification: Eye Irrit 2, H319: Causes serious eye irritation

Respiratory tract irritation

Data waiving	
Information requirement	Testing on the product does not need to be conducted – additional data
Justification	None of the components are classified as respiratory tract irritant so it can be concluded, that the product PANKO is not a respiratory tract irritant.

Skin sensitization

Summary table of human data on skin sensitisation				
Type of data/ report, Reliability	**Test substance**	**Relevant information about the study**	**Observations**	**Reference**
Contact test Reliability: 2	PANKO	Study was conducted on skin of 31 volunteers. Test substance was applied on paper disks which was fixed onto upper part of an arm of each volunteer. Results were examined after 48, 78 and 96 hours.	No reaction was observed on the skin of volunteers	"Świadectwo właściwości drażniących i uczulających", Kosmetyczno-Lekarska Spółdzielnia Pracy „IZIS", Świadectwo badania nr 13370/13, 2013

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Product is not sensitizing to skin
Justification for the value/conclusion	No reaction was observed on the skin of volunteers
Classification of the product according to	No classification is warranted.

CLP and DSD	

Respiratory sensitization (ADS)

Data waiving	
Information requirement	Testing on the product does not need to be conducted – additional data
Justification	None of the components are classified as respiratory sensitizer so it can be concluded, that the product PANKO is not a respiratory sensitizer as well.

Acute toxicity

Acute toxicity by oral route

Data waiving	
Information requirement	Testing on the product does not need to be conducted
Justification	The acute oral toxicity PANKO can be derived from the product component data. Besides of DEET, there are no other components in the product which are classified with respect to acute oral toxicity. Therefore, a study on the acute oral toxicity of the biocidal product is considered scientifically unjustified and has been waived for animal welfare reasons. PANKO does not have to be classified according to CLP Regulation.

Acute toxicity by inhalation

Data waiving	
Information requirement	Testing on the product does not need to be conducted
Justification	For the acute inhalative toxicity neither DEET nor any of the other ingredients of the product are classified. Therefore a low order of acute inhalative toxicity is assumed for PANKO and no classification is warranted.

Acute toxicity by dermal route

Data waiving	
Information requirement	Testing on the product does not need to be conducted
Justification	For the acute dermal toxicity neither DEET nor any of the other ingredients of the product are classified. Therefore a low order of acute dermal toxicity is assumed for PANKO and no classification is warranted.

Information on dermal absorption

Data waiving	
Information requirement	Testing on the product does not need to be conducted
Justification	No dermal absorption study is available for PANKO. However, in the CAR on DEET, a dermal absorption of 20% was derived from the results obtained in a dermal penetration study using a 15% w/w

	ethanol solution of DEET and undiluted technical grade DEET. The results demonstrated that the dermal absorption of DEET is independent from the applied concentration (valid for concentrations between 15% and 100%). Since the concentration of DEET in PANKO is covered by the active substance concentrations tested and as both PANKO and the product used in the skin absorption study are ethanol-based, the dermal absorption of 20% as derived in the CAR can be used in the exposure assessment of PANKO.

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

PANKO contains ethanol which is classified as a substance of concern. However, according to DOCIII of CAR for DEET, during application or release of the product, the ethanol evaporates rapidly and dissipates in the air. Therefore, only the active substance needs to be considered.

LIST OF ENDPOINTS[2]

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

No fertility or developmental effects were seen at inhalation exposures up to 16000 ppm (30,400 mg/m^3). The lowest reported NOAEL for fertility by the oral route was 2000 mg/kg

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

bw in rats, equivalent to a blood alcohol concentration of 1320 mg/l, although this was based on a significant increase in the number of small pups rather than a direct effect on fertility; such direct effects are not seen until much higher doses. Many studies exist examining the developmental end point for ethanol. However, most use very high doses and few are individually robust enough to allow a NOAEL to be established. However, the collective weight of evidence is that the NOAEL for developmental effects in animals is high, typically >=6400 mg/kg bw, compared to maternally toxic effects at 3600 mg/kg bw. The potential for reproductive and developmental toxicity exists in humans from deliberate over-consumption of ethanol. Blood ethanol concentrations resulting from ethanol exposure by any other route are unlikely to produce reproductive or developmental effects.

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

Although there are no exact values available for dermal absorption of ethanol in adults, values of 2.3% dermal absorption is used based on studies of Kirschner et al.[3]

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

The biocidal product contains ethanol which is classified as a substance of concern. However, according to DOCIII of CAR for DEET, during application or release of the product, the ethanol evaporates rapidly and dissipates in the air. Therefore, only the active substance needs to be considered.

Available toxicological data relating to a mixture

Not relevant.

2.2.5.2 Exposure assessment

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

[3] Lachenmeier D.W., Safety evaluation of topical applications of ethanol on the skin and inside the oral cavity, J Occup Med Toxicol. 2008; 3: 26.

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

The product PANKO is pump spray for direct application containing DEET at a concentration of 15%. It contains one substance of toxicological concern – ethanol at concentration 82.09%. However, according to DOCIII of CAR for DEET, during application or release of the product, the ethanol evaporates rapidly and dissipates in the air. Therefore, only the active substance needs to be considered. The detailed composition of the product is provided in Confidential Annex to this PAR.

From the risk assessment for human health described in chapter 2.7, it is concluded that for adults and children over 12 years an application twice a day is possible without restrictions. Children between 2 and 12 years, must not be treated with product more than once a day. Moreover, the product should not be applied to the hands, around eyes and mouth of children under 12 years old. Children under 2 years must not be treated with PANKO. To avoid accidental oral uptake, recommendation "Wash hands after application" is necessary.

The direct exposure of humans to the active ingredient DEET from biocidal uses of PANKO has been estimated using valid exposure models and approaches as described in Document IIB, Chapter 8.2 of the CAR on DEET. The indirect exposure is not relevant.

The evaluation of professional exposure is not relevant since the product PANKO is intended for non-professional use only.

PANKO is intended for non-professional application, where the route of exposure is mainly dermal. Product is applied directly on human skin or clothing. The exposure assessment is based on an application frequency of 1-2 times per day. The product is a 15% DEET pump spray for direct application.

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

According to 'Technical Notes for Guidance - Human Exposure to Biocidal Products – Guidance on Exposure Estimation' (European Commission, 2002, part 2) it is stated in section 5.2 Exposure: "*The inhalation route is excluded due to the use outdoors, and because use indoors only takes place in the summer in situations where there is a high ventilation rate. On these grounds, the inhalation exposure to aerosol sprays is also considered to be negligible.*"

According to HEAdhoc Recommendation no. 11[5] "*exposure via inhalation (including oral uptake of non-respirable particles), if applied outdoors or in well/ventilated areas, is normally considered lower or negligible. This also applies for aerosol sprays. (…) Exposure via inhalation cannot be fully ruled out, therefore a recommendation on ventilation is*

[5] Recommendation no. 11 of the BPC Ad hoc Working Group on Human Exposure, Proposal for harmonising the assessment of human exposure to repellents (PT19) (Agreed at the Human Health Working Group III on 25 May 2016), ECHA

considered necessary for spray formulations (e.g. safety phrases comparable to S23, S51). Appropriate label statements should also be indicated as risk mitigation measures to minimise inhalation exposure".

In the CAR on DEET, this argument was adopted and consequently, exposure of PANKO by inhalation was not assessed. Exposure via inhalation (including oral uptake of non-respirable particles) was considered low if applied outdoors or in well-ventilated areas. However, inhalational exposure cannot be fully ruled out on these grounds, and therefore a recommendation on ventilation is considered necessary on spray formulations. This requirement will be complied with in the case of PANKO: the product label must include a respective statement e.g. precautionary statements comparable to P260, P271.

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							
Exposurepath	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a	n.a	no	n.a	n.a	no	n.a
Dermal	n.a	n.a	yes	n.a	n.a	no	n.a
Oral	n.a	n.a	Negligible	n.a	n.a	no	n.a

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.	Dermally applied insect repellent	Primary exposure. Product is applied directly on human skin or clothing so the route of exposure is mainly dermal. The exposure assessment is based on an application frequency of 1-2 times per day. The product is a pump spray for direct application. The two tired approach was assumed for 2 and 12-years children and for adults.	non-professionals
2.	Reverse reference scenario	A reverse reference scenario for oral ingestion was considered by RMS for exposure assessment.	non-professionals

Industrial exposure

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

Professional exposure

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

Non-professional exposure

Active substance

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

Tier 1

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

surface of these body parts is 64% of the total body surface (Bremmer and van Veen, 2000). If the use of repellents is comparable to that of suntan creams and body lotions, 5 to 6 g is used per application. Based on the above, the default value and the amount of repellent per application is set at 6 g for adults. The total body surface of an adult is 1.75 m2 (Bremmer and van Veen, 2000). If it is assumed that there is a linear relationship between the body surface and the amount of repellent used, the amount of repellent used for a child of 2 years would be 1.81 grams per application and for a child of 12.5 years would be 4.49 grams per application. Default values of body weight and body surface of 2 years (based on average values for children 1.5 years and 2.5 years old) and 12.5 years children are assumed based on General Fact Sheet Limiting conditions and reliability, ventilation, room size, body surface area (RIVM report 320104002/2006). Exposure due to hand to mouth transfer has also been included in the calculations as a worst-case approach. According to TNsG on Human Exposure, 2002 for infants 10.5 mounths of age, the surface of the hands is approximately 10% of the total treated body surface (head, hands, arms, legs and feet), and this value is applicable for children in all age groups; for adults it is proposes that 4% (the amount on fingers only) of 6 g is taken in by hand to mounth contact. Two applications are assumed per day for a 19.5% product and dermal absorption value of 20% was used to calculate internal exposure in humans according to CAR for active substance DEET. Body weights of 60 kg are assumed for adults, both males and females and a body weight of 11.2 kg was assumed for 2 years child and 39.3 kg for 12.5 years children.

Tier 2

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

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

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

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

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

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

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

Scenario 1

Description of Scenario 1		
Parameters of exposure calculation for 2 years child		
	Parameters	Value
Tier 1	Body weight	11.2 kg
	Weight fraction compound	15%
	Exposed area	0.349 m^2
	Applied amount	1.81 g
	Dermal uptake fraction	20%
	Ingestion rate	1.01 mg/min
	Exposure time	180 min
	Oral uptake fraction	100%
Tier 2	For detailed information please see the Confidential Annex of PAR	

Description of Scenario 1		
Parameters of exposure calculation for 12,5 years child		
	Parameters	Value
Tier 1	Body weight	39.3 kg
	Weight fraction compound	15%
	Exposed area	0.875 m^2
	Applied amount	4.49 g
	Dermal uptake fraction	20%
	Ingestion rate	2,49 mg/min
	Exposure time	180 min
	Oral uptake fraction	100%
Tier 2[2]	For detailed information please see the Confidential Annex of PAR	

Description of Scenario 1		
Parameters of exposure calculation for adult		
	Parameters	Value
Tier 1	Body weight	60 kg
	Weight fraction compound	15%
	Exposed area	1.09E4 cm^2
	Applied amount	6 g
	Dermal uptake fraction	20%
	Ingestion rate	1.33 mg/min
	Exposure time	180 min
	Oral uptake fraction	100%
Tier 2[2]	For detailed information please see the Confidential Annex of PAR	

Calculations for Scenario 1

Summary table: systemic exposure from non-professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated oral uptake [mg/kg bw/day]**
Dermally applied insect repellent	Tier 1*	Not applicable	2 years child, 1 application/day: 4.8 12.5 years child, 1 application/day: 3.4 12.5 years child, 2 applications/day: 6.9 Adult male and female, 1 application/day: 3 Adult male and female, 2 applications/day: 6	2 years child, 1 application/day: 2.4 12.5 years child, 1 application/day: 1.7 12.5 years child, 2 applications/day: 3.4 Adult male and female, 1 application/day: 0.6 Adult male and female, 2 applications/day: 1.2

Dermally applied insect repellent	Tier 2**	Not applicable	2 years child, 1 application/day: 6.4 12.5 years child, 1 application/day: 3.03 12.5 years child, 2 applications/day: 6.08 Adult male, 1 application/day: 2.46 Adult male, 2 applications/day: 4.93 Adult female, 1 application/day: 1.92 Adult female, 2 applications/day: 3.83	2 years child, 1 application/day: 2.56 12.5 years child, 1 application/day: 1.22 12.5 years child, 2 applications/day: 2.43 Adult male, 1 application/day: 0,5 Adult male, 2 applications/day: 0.99 Adult female, 1 application/day: 0.38 Adult female, 2 applications/day: 0.77

*Based on the TNsG proposal

** Based on exposure data on amount applied to skin from the usage study for the 75th percentile of Boomsma and Parthasarathy study.

Substance of concern – ethanol

The biocidal product contains ethanol which is classified as a substance of concern. However, according to DOCIII of CAR for DEET, during application or release of the product, the ethanol evaporates rapidly and dissipates in the air. Therefore, only the active substance needs to be considered

Summary table: systemic exposure from non-professional uses				
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated oral uptake [mg/kg bw/day]**
Dermally applied insect repellent	Tier 1*	Not applicable	2 years child, 1 application/day: 34 12.5 years child, 1 application/day: 24 12.5 years child, 2 applications/day: 47 Adult male and female, 1 application/day: 1.9 Adult male and female, 2 applications/day: 3.8	2 years child, 1 application/day: 13 12.5 years child, 1 application/day: 9,5 12.5 years child, 2 applications/day: 19 Adult male and female, 1 application/day: 3.2 Adult male and female, 2 applications/day: 6.4
Dermally applied insect repellent	Tier 2**	Not applicable	2 years child, 1 application/day: 43.79 12.5 years child, 1 application/day: 20.78 12.5 years child, 2 applications/day: 41.57 Adult male, 1 application/day: 1.55 Adult male, 2 applications/day: 3.1 Adult female, 1 application/day: 1.21 Adult female, 2 applications/day: 2.41	2 years child, 1 application/day: 14.01 12.5 years child, 1 application/day: 6.65 12.5 years child, 2 applications/day: 13.3 Adult male, 1 application/day: 2.72 Adult male, 2 applications/day: 5.39 Adult female, 1 application/day: 2.1 Adult female, 2 applications/day: 4.19

* Based on the TNsG proposal

** Based on exposure data on amount applied to skin from the usage study for the 75th percentile of Boomsma and Parthasarathy study.

Further information and considerations on scenario [n]
No combined scenarios or risk characterisation for local effects was performed.

Exposure of the general public

No applicable. Only non-professional consumers are likely to be exposed to the product PANKO during use. No residents or bystanders may be exposed directly, via environment nor any other route to product PANKO.

Monitoring data

No monitoring data were submitted on product PANKO. Therefore exposure assessment is based on default values (**Tier 1**) and and refinement by using exposure data on amount applied to skin from a usage study for the 75th percentile (Boomsma and Parthasarathy, 1990) (**Tier 2**) from CAR on DEET.

Dietary exposure

The application of PANKO does not result in residues in food, water or environment to which consumers might become exposed dietary.

Information of non-biocidal use of the active substance

Active substance DEET is not foreseen to be use as non-biocidal substance, therefore no exposure is assumed.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

The product PANKO is not intended to be used on livestock, therefore no exposure via this route is assumed.

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

The biocidal PANKO is not intended to be use near foods. Moreover the recommendation to wash hands after application, before eating or smoking should be included in the label. Therefore it is assumed that no transfer of biocidal active substances into foods as a result of professional and/or industrial application(s) is possible.

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

The biocidal PANKO is not intended to be use near foods. Moreover the recommendation to wash hands after application, before eating or smoking should be included in the label. Therefore it is assumed that no transfer of biocidal active substances into foods as a result of non-professional application(s) is possible.

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

DEET European Union Joint Venture members do not manufacture the a.s within the EU. The active substance (produced by Clariant) is manufactured in a closed system which is described in the confidential annex of the dossier supporting the Annex I inclusion. Full PPE is required (gloves, coverall, face-shield and respirator) during filling and maintenance. No cleaning of the apparatus occurs since only DEET is produced in the system. The only operator contact with the active ingredient is during sampling for quality.

According to a brief description of the production process provided by applicant:

During production of product PANKO ingredients packed and labelled by suppliers are used.
Production process is carried out in well ventilated area and the workers are equipped with personal protective equipment (in accordance with factory standards). Manufacturing process involves measurement of the ingredients to 200 L container and mixing it with compressed air. Ready mixture is poured to single package with a dispenser. All of these operations are carried out In well ventilated areas and the protective equipment is used – protective gloves (e.g. latex, nitrile) and face protection (plastic visor). Therefore all exposure paths can be eliminated.

Taking into account above description provided by applicant, In opinion of PL CA risk of dermal and inhalation exposure can not be fully excluded during mixing and loading process. However, due to the fact that the manufacturing process is carried out by qualified professional workers using full personal protection equipment, it can be assumed that exposure during formulation is negligible. Moreover safety of industrial workers is regulated by specific regulations and is not covered by BPR.

It should be also mentioned that the Biocides Competent Authorities meeting (CA meeting, 7–8th September 2006) agreed that a risk assessment for the manufacture of the active substance or the biocicdal product is not required unless the active substance was totally new to the EEA and manufactured in the EEA.

2.2.5.3 Risk characterisation for human health

Reference values for DEET to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF	Correction for dermal/oral absorption	Value
$AEL_{acute\ oral}$	8-week oral capsule study in dogs	75 mg/kg bw/day	100	Unnecessary (oral absorption of DEET = 100%)	0.75 mg/kg bw/day
$AEL_{repeated\ dermal}$	90 day dermal study in rats	1000 mg/kg bw/day	100	Dermal absorption approx. 82% in rats	8.2 mg/kg bw/day
ARfD	The ARfD of a chemical can be defined as "an estimate of a substance in food and/or drinking water, normally expressed on a body weight basis, that can be ingested in a period of 24 hours or less, without appreciable health risk to the consumer on the basis of all the known facts at the time of evaluation" (EU guidance, 7199/VI/99/rev 6). By this definition, the				

	setting of ARfD for DEET which is used as an insect repellent directly applied to the skin (PT19) is considered not to be relevant by RMS, since there will be no exposure of DEET via food or drinking water.
ADI	The application of PANKO does not result in residues in food, water or environment to which consumers might become exposed dietary. Setting of ADI is considered not relevant.

The biocidal product contains ethanol which is classified as a substance of concern. However, according to DOCIII of CAR for DEET, during application or release of the product, the ethanol evaporates rapidly and dissipates in the air. Therefore, only the active substance needs to be considered.

Maximum residue limits or equivalent

The application of PANKO does not result in residues in food, water or environment to which consumers might become expose. Setting of MRL is considered not relevant.

Risk for industrial users

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

Risk for professional users

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

Risk for non-professional users

Active substance - DEET

Two approaches have been taken to risk characterisation based on traditional method comparing the estimated exposure with an AEL: based on default values (Tier 1) and based on the 75th percentile of human dermal exposure based on the USA survey study (Tier 2). The main exposure route is dermal; however there is a possibility of minimal oral exposure via hand-to-mouth behaviour if the product is applied to hands. As a worst-case approach, the RMS has also performed the assessment of the oral exposure. The resulting oral exposure estimates were compared with $AEL_{acute\ oral}$ of 0.75 mg/kg bw/day and dermal exposure estimates were compared with $AEL_{repeated\ dermal}$ of 8.2 mg/kg bw/day.

Both systemic dermal and systemic oral exposure to DEET of non-professional users applying PANKO on the skin was estimated.

Systemic effects

Tier 1

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)	
			dermal	oral	dermal	oral	dermal	oral	dermal	oral	dermal	oral
<12 years child*	1 application per day	1	1000	75	8.2	0.75	4.8	2.4	59	320	YES	**NO**
>12 years child	1 application per day						3.4	1.7	41	227	YES	**NO**
	2 applications per day						6.9	3.4	84	453	YES	**NO**
Adult (male and female	1 application per day						3	0.6	37	80	YES	YES
	2 applications per day						6	1.2	73	160	YES	**NO**

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

Systemic risk

Tier 2

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)	
			dermal	oral	dermal	oral	dermal	oral	dermal	oral	dermal	oral
<12 years child	1 application per day	2	1000	75	8.2	0.75	6.4	2.56	78	341	YES	**NO**
>12 years child	1 application per day						3.03	1.22	37	163	YES	**NO**
	2 applications per day						6.08	2.43	74	324	YES	**NO**
Adult male	1 application per day						2.46	0.5	30	66	YES	YES
	2 applications per day						4.93	0.99	60	132	YES	**NO**
Adult female	1 application per day						1.92	0.38	23	51	YES	YES
	2 applications per day						3.83	0.77	47	102	YES	**NO**

Reverse reference scenario for 75th percentile of use for DEET (Scenario 2)

Reverse reference scenario is included to show how much DEET anyone can be exposed to, after dermal or oral exposure without exceeding reference doses.

	External exposure per application mg/kg bw/day	**Internal dose (dermal only*) mg/kg bw/day**	**AEL_{acute}** / external exposure**	**$AEL_{repeated}$*** / internal exposure (dermal only)**
Children <12 years	32	6.4	0.023	1.3
Children >12 years	15.2	3	0.049	2.7
Adult males	12.3	2.5	0.061	3.3
Adult females	9.6	1.9	0.078	4.3

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

To exceed an $AEL_{repeated}$ of 8.2 mg/kg bw/day for dermal exposure, a 15% DEET solution can be applied 3.3, 4.3, 2.7 and 1.3 times per day for adult male, adult female, child >12 years and <12 years respectively.

Conclusion

It was decided at TM I and II 2009 that risk characterisation for DEET products should be performed for two daily applications and by using the 75th percentile of human dermal exposure based on the USA survey study. Taking into account only dermal exposure in Tier 2, the use of the product with 15% DEET, 1 time per day is considered acceptable for adults and children >2 years old. Oral exposure by hand-to-mouth transfer is considered by RMS to be a less significant route of exposure because according to CAR of DEET the smell and taste of DEET act as a self deterrent against this type of activity. Additionally product contains denatonium benzoate which acts as strong deterrents for ingestion. Moreover according to CAR of DEET it was concluded that the oral dose is likely to be largely overestimated given the short half life after oral exposure in dogs and rats and the rapid achievement of Cmax. The risk by oral route have been included to present worst case calculation. Taking into account exposure by oral route the risk for adult and children is exceeded.

Substance of concern - ethanol

The biocidal product contains ethanol which is classified as a substance of concern. However, according to DOCIII of CAR for DEET, during application or release of the product, the ethanol evaporates rapidly and dissipates in the air. Therefore, only the active substance needs to be considered.

Conclusion from risk assessment of active substance DEET and ubstance of concern ethanol

In summary risk characterisation of non-professionals users to the biocidal products containing 15% DEET as active substance is considered acceptable, if the biocidal product is used by adults and children over12 years twice a day and in children under 12 years once a day. The product should not be used on children under 2 years old.
The biocidal product contains ethanol which is classified as a substance of concern. According to DOCIII of CAR for DEET, during application or release of the product, the ethanol evaporates rapidly and dissipates in the air. Therefore, only the active substance needs to be considered.
The hand-to-mouth behaviour is more frequent in small children. Recommendation "wash hands after application" should be included on product label in order to limit the potential oral exposure. For adult and children over 12 years it might be a suitable risk mitigation measure to prevent oral ingestion due to hand-to-mouth contact.

Taking into account formulation and since the inhalation fraction is excluded from the risk characterization calculations of product, following recommendations should be applied:

- Use outdoor or in well ventilated areas
- Do not breathe spray. Use only outdoors or in a well-ventilated area.
- For facial application, spray your hands and rub the product over the face.
- Avoid contact with eyes and areas around eyes, mucous membranes and damaged skin.
- Keep this product away from children.
- Wash hands after application.

Risk for the general public

No applicable. Only non-professional consumers are likely to be exposed to the product PANKO during use. No residents or bystanders may be exposed directly, via environment nor any other route to product PANKO.

Risk for consumers via residues in food

The application of PANKO does not result in residues in food, water or environment to which consumers might become exposed dietary.

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

The risk from combined exposure to an active substance DEET and substance of concern ethanol cannot be assessed, since the toxicological pathways are different for these

substances and therefore cannot simply be added. Furthermore the guidance for assessing mixture toxicity has still not been finalized.

2.2.6 Risk assessment for animal health

The product is not intended to be used on animals therefore risks posed to animals from the biocidal product in terms of immediate or delayed unacceptable effects itself, or as a result of its residues, directly or through drinking water, feed, air, or through other indirect effects is not for seen.

2.2.7 Risk assessment for the environment

PANKO contains DEET as the only active substance. The other substance present in PANKO are out of environmental concern.
No fate and behaviour or ecotoxicological studies were submitted with the product authorisation application for the active substance or for the products that were not already described in the CAR for DEET by Rapporteur Member State Sweden. Applicant submitted the literature data on DEET only, however they just can be considered as the additional information.

Assuming all above all fate and behaviour and ecotoxicological data for biocidal product PANKO are based on data presented in CAR for DEET.

2.2.7.1 Effects assessment on the environment

According to CAR the following PNECs values were derived for DEET.

Compartment	PNEC values
STP	10 mg/l
surface water	0.043 mg/l
sediment	0.0741 mg/l
soil	0.0379 mg/kg_{wwt}
ground water	0.1 µg/l (Directive 98/83/EC)

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 product *PANKO* contains two potential substances of concern (lemon fragrance and denatonium benzoate) classified and labelled under CLP regulation 1272/2008. However concentrations of these substances in biocidal product are very low (0.6%, 0.001% respectively) and do not affect overall classification of the product. Therefore only active substance DEET was considered as of concern for environment and the risk characterisation was performed for this substance only.

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

There is no data available which suggests that the ecotoxicity of the product cannot be extrapolated from the information on the active substance DEET. The active substance is the only ingredient of environmental concern.

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

The product is not in the form of bait or granules, therefore these studies are not required. Moreover as already stated above there is no data available which suggests that the ecotoxicity of the product cannot be extrapolated from the information on the active substance DEET.

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

Please refer to section *Fate and distribution in exposed environmental compartments*.

Further studies on fate and behaviour in the environment, testing for distribution and dissipation in soil, testing for distribution and dissipation in water and sediment and testing for distribution and dissipation in air (ADS)

No additional data is required. There is no data available which suggests that the fate and behaviour of the product cannot be extrapolated from the information on the active substance DEET.

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)

So far there is no harmonized approach available for the risk assessment of biocides. Some presumption for DEET may be given on the basis of data from the open literature. However it needs to be aware that presented measured values may be uncertain and thus should be regarded as the examples only.

According to review publication provided by Applicant (Weeks et al., 2011) measured concentration of DEET in surface waters was found to range up to 1.1 µg/L in US waters and 0.013 µg/L in Norwegian waters. It was also stated that distribution of DEET concentration from multiple monitoring studies was fund to have a median of 0.046 µg/L.

In the screening study provided by SWECO (2010) the occurrence of DEET in environment was measured. The project was initiated because transnational and national studies had shown a high prevalence of DEET in both surface waters and ground waters in Europe, USA and Australia. The active substance DEET was detected in water in STPs, surface waters downstream of STPs and in a groundwater. In addition, DEET was found in water and sediments at recreational bathing sites. The obtained results demonstrated that DEET did not occur in sewage sludge or in surface waters and sediments that were not influenced by STPs. In risk assessment only DEET concentrations of 200 ng/L in downstream of STPs were used. The main reason was that water samples taken in the close vicinity of bathers that has applied DEET to their skin could not be viewed as representative of concentrations in the water of these lakes.

In compare to the presented monitoring data all estimated values for DEET in this report are more conservative (please refer to point *PEC values*). Despite this, no risk for environment was for DEET detected (please refer to point Risk characterization).

Acute aquatic toxicity

Data waiving	
Information requirement	Studies on PANKO are not needed to be conducted. Ecotoxicological data for biocidal product PANKO can be extrapolated from data presented in CAR for DEET.
Justification	There is no evidence of synergistic activity between active substance and coformulants. The active substance DEET is the only constituent of the product which may influence on the environment.

Estimated bioconcentration

Data waiving	
Information requirement	Estimation for PANKO is not needed to be conducted. BCF values for biocidal product PANKO can be extrapolated from data presented in CAR for DEET.
Justification	There is no evidence of synergistic activity between active substance and coformulants. The active substance DEET is the only constituent of the product which may influence on the environment.

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)

Despite outdoor use of PANKO its direct outdoor emissions will be probably very limited as it is used directly on human skin.

From this point of view it was assumed that risk to bees and non-target arthropods will be negligible.

Acute toxicity to birds

Data waiving	
Information requirement	Studies on PANKO are not needed to be conducted. Ecotoxicological data for biocidal product PANKO can be extrapolated from data presented in CAR for DEET.
Justification	There is no evidence of synergistic activity between active substance and coformulants. The active substance DEET is the only constituent of the product which may influence on the environment.

2.2.7.2 Exposure assessment

General information

Assessed PT	PT19
Assessed scenarios	Scenario 1a,b: Indirect emission to water – removal through showering and bathing of humans (a) as well as washing of garments (b) Scenario 2: direct emission to water – release to surface water bodies through swimming
ESD(s) used	Emission Scenario Document for Product Type 19: Repellents and attractants, May 2015
Approach	Scenario 1a,b: Consumption-based approach Scenario 2: Consumption-based approach
Distribution in the environment	Calculated based on TGD 2003 (alternative: based on measured data)
Groundwater simulation	FOCUS PEARL MODEL for Scenario 1
Confidential Annexes	NO
Life cycle steps assessed	Scenario 1 (a, b) and 2: Production: No Formulation No Application: No Service life: No Removal of the repellent: Yes
Remarks	-

Emission estimation

PANKO is a ready-to-use spray applied on human skin or clothes. It contains 150 g/kg of DEET and is intended to be used by non-professional users. According to applicant declaration biocidal product will be applied maximum twice per day.

The formulation of the repellent product, and waste disposal are life cycle steps which were not considered. Recovery and disposal is not a matter of concern since recovery is not intended for this type of products. The packaging material with possible residual

amounts of the product will be disposed of as municipal waste. In this case, the general risk management measures based on EU waste legislation apply.

According to ESD for PT 19 (2015) emissions of this product to environment can take place during the application. Then fraction can be released to the floor when repellent is applied indoors or to paved or unpaved ground during outdoor applications. However, according to TM IV/2013, emissions resulting from the stage of application on human skin or garment are of minor importance since they take place non-repeatedly on a very limited area and are therefore not considered.

According to ESD for PT 19 (2015) relevant environmental emissions of repellents used on human skin and garments result only from removal stage. Removal of the biocidal product from human skin or clothes can either take place:

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

2.2.7.2.1 Scenario 1a,b – Indirect emission to water – removal through showering and bathing of humans as well as washing of garments

According to ESD for PT 19 emission to STP takes place via showering/bathing of humans or via washing of treated clothes.

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

Calculations for Scenario 1a,b – Indirect emission to water – removal through showering and bathing of humans

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

$$Elocal_{water} = Nlocal \times N_{appl} \times Qform_{appl} \times AREA_{skin/garment} \times Cform_{weight} \times F_{inh} \times F_{water} \times F_{penetr} \times 10^{-9}$$

As for certain values the applicant has not confirmed the access, the input parameters for calculation are presented in Confidential Annex.

For the risk assessment purpose the worst-case scenario (after application on skin - Scenario 1a) was chosen.

2.2.7.2.2 Scenario 2 – direct emission to water – release to surface water bodies through swimming

The input parameters for calculation of environmental emission due to release to water bodies via swimming are presented in table below. The release of repellents from the skin of treated humans into pounds, lakes or reservoirs during swimming represents a realistic

worst-case scenario. The term "surface water body" means only ponds, lakes or reservoirs and not following waters such as coastal waters and rivers.

Parameters for calculating the release of repellents used on human skin due to swimming activities in surface water bodies				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Scenario: Indirect emission to water				
Daily number of swimmers	$N_{swimmer}$	1 500	-	ESD for PT19
Fraction of swimmers using the repellent product	F_{swim}	0.1[1]	-	ESD for PT19
Number of applications per day	N_{appl}	1[1]	/d	ESD for PT19
Fraction released to surface water body	$F_{waterbody}$	1	-	ESD for PT19
Active substance in product	$Cform_{weight}$	150	g/kg	Information provided by Applicant
Consumption per application	$Qform_{appl}$	0.56	mg/cm^2	According to Appendix 3.1 to ESD for PT19
Treated area of human skin	$AREA_{skin}$	10 660	cm^2	ESD for PT19 Appendix 3.1 to ESD for PT19
Output				
Local emission rate to surface water	$Elocal_{water}$	0.13	kg/d	ESD for PT19

[1] For product authorisation , value of 0.1) can be appropriate to cover areas with higher insect infestation.
[2] The interlink between the number of applications and the efficacy of the product does not apply in this respekt. According to ESD for PT 19 (20015) visit of swimmers at water sites is quite short thus during this time period treatment with repellent will take place only once,

Calculated concentration of DEET in surface water after swimming of people whose skin was treated with *PANKO are* presented in table below.

Parameters for calculating of surface water concentrations following swimming of humans having used an insect repellent on their skin				
Input	**Nomenclature**	**Value**	**Unit**	**Remarks**
Scenario: Indirect emission to water				
Local emission rate to surface water	$Elocal_{water}$	0.13	kg/d	Please refer to table above
Volume of water body	$V_{waterbody}$	435 000	m^3	ESD for PT19
First order rate constant for biodegradation in surface water	$kdeg_{water}$	0.047	/d	Data for DEET

Number of emission day	$T_{emission,1d}$	1	d	ESD for PT19
	$T_{emission,91d}$	91	d	ESD for PT19
Number of emission events	$N_{emission,91d}$	91	-	ESD for PT19
Output				
Local concentration in water body after one day	$Clocal_{water,1d}$	2.99E-04	mg/L	ESD for PT19
Local concentration in water body over 91 day	$Clocal_{water,91d}$	2.72E-02	mg/L	ESD for PT19

Calculations for Scenario 2 - direct emission to water – release to surface water bodies through swimming

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

$$Elocal_{water} = N_{\ swimmer} \times N_{appl} \times Qform_{appl} \times AREA_{skin} \times Cform_{weight} \times F_{swim} \times F_{waterbody} \times 10^{-9}$$

Local concentration in water body was calculated using formulas presented below:

$$Clocal_{water,1d} = Elocal_{water} \times \frac{T_{emission,1d}}{V_{waterbody}}$$

$$Clocal_{water,91d} = Elocal_{water} \times \frac{T_{emission,91d}}{V_{waterbody}}$$

$$PEClocal_{water} = Clocal_{water,91d}$$

Resulting local emission to relevant environmental compartments		
	Local emission ($Elocal_{water}$) [kg/d]	**Remarks**
Scenario 1a: Indirect emision to water – removal through showering and bathing of humans as weel as washing of garments		
STP	1.65*	-
Scenario 1b: Indirect emision to water – removal through washing of garments		
STP	1.47	-
Scneario 2: Indirect emision to water – removal through showering and bathing of humans as weel as washing of garments		
Freshwater	0.13	-

* The worst-case value used for risk assessment in Scenario 1.

Fate and distribution in exposed environmental compartments

Exposure of the environmental compartments (soil, water, air) is highly dependent on the formulation type, physical-chemical properties of the substance involved and the mode of application and use.

The biocidal product *PANKO* contains 150 g/kg DEET and is intended to be used by non-professional users as repellent. According to applicant declaration biocidal product will be applied on human skin or clothes, maximum twice per day.

The biocidal product *PANKO* contains two potential substances of concern (lemon fragrance and denatonium benzoate) classified and labeled under CLP regulation 1272/2008. However concentrations of these substances in biocidal product are very low (0.6%, 0.004% respectively) and do not affect overall classification of the product. Therefore only active substance DEET was considered as of concern for environment and the risk characterisation was performed for this substance.

No studies were submitted on environmental fate and behavior of the biocidal product *PANKO.* Applicant provided only some literature data on DEET, however they are considered just as additional information.

As only active substance (DEET) was considered to be substance of concern to environment, fate and distribution of PANKO was based on data for DEET. All endpoints necessary to estimate fate and behavior of PANKO in the environment were derived from the CAR for DEET.

The environmental exposure assessment was performed using the ESD for PT19 (2015). According to this document PANKO (DEET) from human skin or from clothes can be released:

1) to STP (and then to surface water, sediment, air, soil and groundwater) or,
2) directly to surface water and sediment (for details please refer to chapter *Emission estimation*)

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 1a,b	yes	yes	no	no	yes*	yes	yes	yes	no
Scenario 2	yes*	yes	no	no	no	no	yes	yes	no

* direct release

Input parameters (only set values) for calculating the fate and distribution in the environment			
Input	Value	Unit	Remarks
Molecular weight	191.27	g/mol	Final CAR for DEET
Melting point	<-20	°C	Final CAR for DEET
Boiling point	284.2	°C	Final CAR for DEET
Vapour pressure (at 20°C)	0.11	Pa	Final CAR for DEET
Water solubility (at 25°C)	11.2	mg/l	Final CAR for DEET
Log Octanol/water partition coefficient	2.4	Log 10	Final CAR for DEET
Organic carbon/water partition coefficient (Koc)	43.3	L/kg	Final CAR for DEET
Henry's Law Constant	3.93×10^{-3}	Pa/m3/mol	Calculated from vapour pressure at 25ºC and water solibility
Biodegradability	Ready biodegradable		Final CAR for DEET
DT_{50} for degradation in air	15.2	hr	Final CAR for DEET

Calculated fate and distribution in the STP		
Compartment	Percentage [%]	Remarks
	Scenario 1	
Air	8.16E-04	-
Water	12.6	
Sludge	0.41	
Degraded in STP	87	

In scenario 2 no release to STP is considered.

Calculated PEC values according to Efficient dose: 2.48 mg b.p./cm² of skin (ticks 2 application per day)

Summary table on calculated PEC values						
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**[1]	**PEC_{soil}**	**PEC_{GW}**[2]	**PEC_{air}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
Scenario 1	4.60E-01	4.60E-02	7.92E-02	3.89E-02	13.8	1.65E-08

Scenario 2	n.a	2.94E-02	Not relevant	n.a	n.a	n.a

[1] As the PNEC sediment is derived by Equilibrium partitioning method (EPM) from the PNEC water, the risk ratios for surface water and sediment will be identical. Therefore no PEC values for sediment are derived.

[2] Calculated also in PEARL model. For detail please see table below.

Calculated PEC values according to Efficient dose: 2.48 mg b.p./cm² of skin (ticks 1 application per day)

Summary table on calculated PEC values						
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}[1]**	**PEC_{soil}**	**PEC_{GW}[2]**	**PEC_{air}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
Scenario 1	2.30E-01	2.30E-02	3.96E-02	1.94E-02	6.89	8.25E-09
Scenario 2	n.a	2.94E-02	Not relevant	n.a	n.a	n.a

[1] As the PNEC sediment is derived by Equilibrium partitioning method (EPM) from the PNEC water, the risk ratios for surface water and sediment will be identical. Therefore no PEC values for sediment are derived.

[2] Calculated also in PEARL model. For detail please see table below.

Calculated PEC values according to Efficient dose: 1.08 mg b.p./cm² of skin (mosquitoes 2 application per day)

Summary table on calculated PEC values						
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}[1]**	**PEC_{soil}**	**PEC_{GW}[2]**	**PEC_{air}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
Scenario 1	2.00E-01	2.00E-02	3.45E-02	1.69E-02	6.00	7.19E-09
Scenario 2	n.a	1.28E-02	Not relevant	n.a	n.a	n.a

[1] As the PNEC sediment is derived by Equilibrium partitioning method (EPM) from the PNEC water, the risk ratios for surface water and sediment will be identical. Therefore no PEC values for sediment are derived.

[2] Calculated also in PEARL model. For detail please see table below.

Calculated PEC values according to Efficient dose: 1.08 mg b.p./cm² of skin (mosquitoes 1 application per day)

Summary table on calculated PEC values						
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}[1]**	**PEC_{soil}**	**PEC_{GW}[2]**	**PEC_{air}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/kg_{wwt}]	[µg/l]	[mg/m^3]
Scenario 1	1.00E-01	1.00E-02	1.73E-02	8.48E-03	3.01	3.61E-09
Scenario 2	n.a	1.28E-02	Not	n.a	n.a	n.a

			relevant			

[1] As the PNEC sediment is derived by Equilibrium partitioning method (EPM) from the PNEC water, the risk ratios for surface water and sediment will be identical. Therefore no PEC values for sediment are derived.

[2] Calculated also in PEARL model. For detail please see table below.

Since predicted groundwater concentration of DEET calculated in EUSES model in scenario 1 (for every efficient dose) exceeds 0.1 µg/L, FOCUS PEARL model was also used.

Summary of data used and assumptions made to calculate $PEC_{groundwater}$ for active substance DEET in FOCUS scenarios (Scenario 1)	
Parameter	**Value**
Model used	FOCUS PEARL ver. 4.4.4.
Years of simulation	26 (including 6 yrs "warming-up" period)
Application rate	0.0425 kg/ha[1]
Application method	To the soil surface
Date of application	1 October annually for 20 years[2]
Molar mass	191.27 g/mol
Vapour pressure	0.23 Pa (25°C)
Solubility in water	11 200 mg/l (25°C)
K_{om}	25.1 L/kg[3]
Freundlich sorption exponent 1/n	0.9 (FOCUS default)
DT_{50} soil	30 days (12°C)[4]
Coefficient for uptake in plants	0

[1] Calculated form EUSES output concentration of DEET in dry sewage sludge of 98.49 mg/kg_{dw} and application of 5 000 kg dry sludge/ha and year to agricultural land (at a single event as suggested in the TGD, section 2.3.8.5)
[2] Autumn application assumed to represent a worst-case situation
[3] Calculated from K_{oc} as 43.3/1.724
[4] In accordance with TGD section 2.3.6.5, for ready biodegradable substances

The data generates a value for the 80th percentile of levels of substance present in groundwater at a depth of 1 m as an annual average in µg/L. Values beyond 0.1 µg/l are unacceptable according to the EU Drinking Water Directive.

Efficient dose: 2.48 mg b.p./cm² of skin (ticks 2 application per day)

PECs $_{GW}$ (PEARL model) [µg · L^{-1}]									
Scenario	**Chat**	**Ham**	**Jok**	**Krem**	**Okeh**	**Piac**	**Por**	**Sev**	**Thiv**
maize	0.08	**0.8**	x	**0.48**	**0.88**	**0.15**	**0.13**	0.01	0.01
grass	0.01	0.07	0.06	0.04	0.06	0.04	0.02	0.00	0.00

Conclusions:

The results show that the predicted groundwater concentrations of DEET following the intended use of PANKO are >0.1 µg/L for 5 from 9 FOCUS scenarios (maize).

Efficient dose: 2.48 mg b.p./cm² of skin (ticks 1 application per day)

PECs GW (PEARL model) [µg · L⁻¹]									
Scenario	**Chat**	**Ham**	**Jok**	**Krem**	**Okeh**	**Piac**	**Por**	**Sev**	**Thiv**
maize	0.04	**0.42**	X	**0.25**	**0.46**	**0.08**	**0.07**	0.00	0.00
grass	0.00	0.03	0.03	0.02	0.03	0.02	0.01	0.00	0.00

Conclusions:

The results show that the predicted groundwater concentrations of DEET following the intended use of PANKO are >0.1 µg/L for 5 from 9 FOCUS scenarios (maize).

Efficient dose: 1.08 mg b.p./cm² of skin (mosquitoes 2 application per day)

PECs GW (PEARL model) [µg · L⁻¹]									
Scenario	**Chat**	**Ham**	**Jok**	**Krem**	**Okeh**	**Piac**	**Por**	**Sev**	**Thiv**
maize	0.03	**0.34**	X	**0.21**	**0.38**	0.07	0.06	0.00	0.00
grass	0.00	0.03	0.03	0.02	0.03	0.02	0.01	0.00	0.00

Conclusions:

The results show that the predicted groundwater concentrations of DEET following the intended use of PANKO are >0.1 µg/L for 3 from 9 FOCUS scenarios (maize).

Efficient dose: 1.08 mg b.p./cm² of skin (mosquitoes 1 application per day)

PECs GW (PEARL model) [µg · L⁻¹]									
Scenario	**Chat**	**Ham**	**Jok**	**Krem**	**Okeh**	**Piac**	**Por**	**Sev**	**Thiv**
maize	0.02	**0.19**	X	**0.11**	**0.21**	0.04	0.03	0.00	0.00
grass	0.00	0.02	0.01	0.01	0.01	0.01	0.01	0.00	0.00

Conclusions:

The results show that the predicted groundwater concentrations of DEET following the intended use of PANKO are >0.1 µg/L for 3 from 9 FOCUS scenarios (maize).

Primary and secondary poisoning

Primary poisoning of birds and mammals due to intake of the product is not expected to be relevant. Considering the low acute toxicity of DEET to birds (LD_{50} 1375 mg/kg bw) and the type of use intake by birds and mammals of the active substance via water is considered as negligible.

PEC/PNEC ratios could not be calculated, however it can be concluded that no risk for secondary poisoning has been identified based on the low BCF value for DEET. In addition as the log Kow for DEET is <3 (2.4), a risk for bioconcentration and biomagnification is not expected.

2.2.7.3 Risk characterisation

Atmosphere

The PEC/PNEC value was not calculated. Physic-chemical properties of DEET indicate that the active substance located in PANKO is not relevant for the atmosphere.

Calculated half-life of 15.2 hr suggest that it has low potential for long-range transport through the atmosphere. It is also considered of no concern for ozone depletion.

Sewage treatment plant (STP)

Efficient dose: 2.48 mg b.p./cm^2 of skin (ticks 2 application per day)

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{STP}$
Scenario 1	4.60E-02
Scenario 2	n.a.

Conclusion:

The calculated value of the PEC / PNEC indicates that DEET in biocidal product PANKO does not pose a risk to sewage treatment plant.

Efficient dose: 2.48 mg b.p./cm^2 of skin (ticks 1 application per day)

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{STP}$
Scenario 1	2.30E-01
Scenario 2	n.a.

Conclusion:

The calculated value of the PEC / PNEC indicates that DEET in biocidal product PANKO does not pose a risk to sewage treatment plant.

Efficient dose: 1.08 mg b.p./cm^2 of skin (mosquitoes 2 application per day)

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{STP}$
Scenario 1	2.00E-02
Scenario 2	n.a.

Conclusion:

The calculated value of the PEC / PNEC indicates that DEET in biocidal product PANKO does not pose a risk to sewage treatment plant.

Efficient dose: 1.08 mg b.p./cm^2 of skin (mosquitoes 1 application per day)

Summary table on calculated PEC/PNEC values	
	PEC/PNEC$_{STP}$
Scenario 1	1.00E-02
Scenario 2	n.a.

Conclusion:

The calculated value of the PEC / PNEC indicates that DEET in biocidal product PANKO does not pose a risk to sewage treatment plant.

Aquatic compartment

Efficient dose: 2.48 mg b.p./cm^2 of skin (ticks 2 application per day)

Summary table on calculated PEC/PNEC values		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
Scenario 1	**1.07**	Not relevant
Scenario 2	6.84E-01	Not relevant

Conclusion:

Calculated PEC/PNEC values in the worst case for ticks indicate that there is risk for aquatic environment as a result of using PANKO. The PEC/PNEC value for water was greater than 1. As the PNEC sediment is derived by Equilibrium partitioning method (EPM) from the PNEC water, the risk ratios for surface water and sediment will be identical.

Efficient dose: 2.48 mg b.p./cm^2 of skin (ticks 1 application per day)

Summary table on calculated PEC/PNEC values		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
Scenario 1	5.35E-01	Not relevant
Scenario 2	6.84E-01	Not relevant

Conclusion:

The calculated value of the PEC / PNEC indicates that DEET in biocidal product PANKO does not pose a risk to water and sediment. As the PNEC sediment is derived by Equilibrium partitioning method (EPM) from the PNEC water, the risk ratios for surface water and sediment will be identical.

Efficient dose: 1.08 mg b.p./cm^2 of skin (mosquitoes 2 application per day)

Summary table on calculated PEC/PNEC values		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
Scenario 1	4.65E-01	Not relevant
Scenario 2	2.98E-01	Not relevant

Conclusion:

The calculated value of the PEC / PNEC indicates that DEET in biocidal product PANKO does not pose a risk to water and sediment. As the PNEC sediment is derived by Equilibrium partitioning method (EPM) from the PNEC water, the risk ratios for surface water and sediment will be identical.

Efficient dose: 1.08 mg b.p./cm^2 of skin (mosquitoes 1 application per day)

Summary table on calculated PEC/PNEC values		
	PEC/PNEC$_{water}$	**PEC/PNEC$_{sed}$**
Scenario 1	1.00E-01	Not relevant
Scenario 2	1.28E-02	Not relevant

Conclusion:

The calculated value of the PEC / PNEC indicates that DEET in biocidal product PANKO does not pose a risk to water and sediment. As the PNEC sediment is derived by Equilibrium partitioning method (EPM) from the PNEC water, the risk ratios for surface water and sediment will be identical.

Terrestrial compartment

Efficient dose: 2.48 mg b.p./cm^2 of skin (ticks 2 application per day)

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
Scenario 1	**1.03**
Scenario 2	n.a.

Conclusion:

Calculated PEC/PNEC in the worst case for ticks indicate that there is a risk for soil compartment when using PANKO. The PEC/PNEC value for soil was greater than 1.

Efficient dose: 2.48 mg b.p./cm^2 of skin (ticks 1 application per day)

Calculated PEC/PNEC values

	PEC/PNEC$_{soil}$
Scenario 1	5.12E-01
Scenario 2	n.a.

Conclusion:

The calculated value of the PEC / PNEC indicates that DEET in biocidal product PANKO does not pose a risk to the soil.

Efficient dose: 1.08 mg b.p./cm^2 of skin (mosquitoes 2 application per day)

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
Scenario 1	4.46E-01
Scenario 2	n.a.

Conclusion:

The calculated value of the PEC / PNEC indicates that DEET in biocidal product PANKO does not pose a risk to the soil.

Efficient dose: 1.08 mg b.p./cm^2 of skin (mosquitoes 1 application per day)

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
Scenario 1	2.24E-01
Scenario 2	n.a.

Conclusion:

The calculated value of the PEC / PNEC indicates that DEET in biocidal product PANKO does not pose a risk to sewage treatment plant.

Groundwater

Efficient dose: 2.48 mg b.p./cm^2 of skin (ticks 2 application per day)

Calculated PEC/PNEC values in EUSES model	
	PEC/PNEC$_{GW}$
Scenario 1	**138**
Scenario 2	n.a.

Since PEC/PNEC value for groundwater was greater than 1 FOCUS PEARL model was also used.

PEC/PNEC $_{GW}$ (PEARL model) [µg · L^{-1}]									
Scenario	**Chat**	**Ham**	**Joko**	**Krem**	**Okeh**	**Piac**	**Por**	**Sev**	**Thiv**
maize	0.8	**8**	X	**4,8**	**8,8**	**1,5**	**1,3**	0,1	0,1
grass	0.1	0.7	0.6	0.4	0.6	0.4	0.2	0.00	0.00

Conclusion:
Considering calculation of PECgw in PEARL model PEC/PNEC value for DEET in groundwater was greater than 1. The same result, calculations in FOCUS PEARL model allowed to conclude that DEET in biocidal PANKO will pose risk for groundwater. PEC/PNEC values for Hamburg, Kremsmunster, Okehampton, Piacenza and Porto (for maize scenario) from FOCUS scenarios are greater than one.

Efficient dose: 2.48 mg b.p./cm^2 of skin (ticks 1 application per day)

Calculated PEC/PNEC values in EUSES model	
	PEC/PNEC$_{GW}$
Scenario 1	6.89E-02
Scenario 2	n.a.

Since PEC/PNEC value for groundwater was greater than 1 FOCUS PEARL model was also used.

PEC/PNEC $_{GW}$ (PEARL model) [µg · L^{-1}]									
Scenario	**Chat**	**Ham**	**Joko**	**Krem**	**Okeh**	**Piac**	**Por**	**Sev**	**Thiv**
maize	0.4	**4.2**	X	**2.5**	**4.6**	0.8	0.7	0.00	0.00
grass	0.00	0.3	0.3	0.2	0.3	0.2	0.1	0.00	0.00

Conclusion:
Considering calculation of PECgw in PEARL model PEC/PNEC value for DEET in groundwater was greater than 1. The same result, calculations in FOCUS PEARL model allowed to conclude that DEET in biocidal PANKO will pose risk for groundwater. PEC/PNEC values for Hamburg, Kremsmunster, Okehampton (for maize scenario) from FOCUS scenarios are greater than one.

Efficient dose: 1.08 mg b.p./cm^2 of skin (mosquitoes 2 application per day)

Calculated PEC/PNEC values in EUSES model	
	PEC/PNEC$_{GW}$
Scenario 1	3.01-E-02
Scenario 2	n.a.

Since PEC/PNEC value for groundwater was greater than 1 FOCUS PEARL model was also used.

PEC/PNEC $_{GW}$ (PEARL model) [µg · L^{-1}]									
Scenario	**Chat**	**Ham**	**Joko**	**Krem**	**Okeh**	**Piac**	**Por**	**Sev**	**Thiv**
maize	0.3	**3.4**	X	**2.1**	**3.8**	0.7	0.6	0.00	0.00
grass	0.00	0.3	0.3	0.2	0.3	0.2	0.1	0.00	0.00

Conclusion:
Considering calculation of PECgw in PEARL model PEC/PNEC value for DEET in groundwater was greater than 1. The same result, calculations in FOCUS PEARL model allowed to conclude that DEET in biocidal PANKO will pose risk for groundwater. PEC/PNEC values for Hamburg, Kremsmunster, Okehampton (for maize scenario) from FOCUS scenarios are greater than one.

Efficient dose: 1.08 mg b.p./cm^2 of skin (mosquitoes 1 application per day)

Calculated PEC/PNEC values in EUSES model	
	PEC/PNEC$_{GW}$
Scenario 1	
Scenario 2	n.a.

Since PEC/PNEC value for groundwater was greater than 1 FOCUS PEARL model was also used.

PEC/PNEC $_{GW}$ (PEARL model) [µg · L^{-1}]									
Scenario	**Chat**	**Ham**	**Joko**	**Krem**	**Okeh**	**Piac**	**Por**	**Sev**	**Thiv**
maize	0.2	**1.9**	X	**1.1**	**2.1**	0.4	0.3	0.00	0.00
grass	0.00	0.2	0.1	0.1	0.1	0.1	0.1	0.00	0.00

Conclusion:
Considering calculation of PECgw in PEARL model PEC/PNEC value for DEET in groundwater was greater than 1. The same result, calculations in FOCUS PEARL model allowed to conclude that DEET in biocidal PANKO will pose risk for groundwater. PEC/PNEC values for Hamburg, Kremsmunster, Okehampton (for maize scenario) from FOCUS scenarios are greater than one.

Primary and secondary poisoning

Primary poisoning of birds and mammals due to intake of the product is not expected to be relevant. Considering the low acute toxicity of DEET to birds (LD_{50} 1375 mg/kg bw) and the type of use intake by birds and mammals of the active substance via water is considered as negligible.

PEC/PNEC ratios could not be calculated, however it can be concluded that no risk for secondary poisoning has been identified based on the low BCF value for DEET. In addition as the log Kow for DEET is < 3 (2.4), a risk for bioconcentration and biomagnification is not expected.

Mixture toxicity
Not relevant.

2.2.8 Measures to protect man, animals and the environment

For PANKO biocidal product containing 15%w/w DEET no unacceptable risk was identified for environment and no risk mitigation measures are required.

- Avoid release to environment
- Dispose of contents/containers in accordance with the national regulations.

Taking into account outputs from the human health assessment of product PANKO, the instructions for use of PANKO must contain the following indications:

- Do not use on children under2 years old.
- On children between 2 and 12 years old use only once a day. On adults and children over12 years old use only twice a day
- Do not use more than twice a day.
- Use only outdoors or in a well-ventilated area.
- Do not inhale the spray.
- For facial application, spray your hands and rub the product over the face.
- Avoid contact with eyes and areas around eyes, mouth, mucous membranes and damaged skin.
- Keep this product away from children.
- Wash hands after application.

In the Competent Assessment Report for DEET it was stated that some elements should be taken into account by Member States when authorising product:

1. Member states may require monitoring methods for analysing residues of DEET in the air compartment might be required for authorisation of DEET containing biocidal products, whose use pattern result in significant exposure to the air compartment.

   The calculated half life of DEET equals 15.2 hr what is below the trigger of < 2 days used as cut-off value to identify chemicals that could be of potential concern for with the potential for long-range transport through the atmosphere. The substance unlikely shows significant long-range transport, and it is considered of no concern for ozone depletion.

   For above reasons monitoring methods for analysing residues of DEET in the air compartment were assumed to be not needed.

2. Member states may need to consider inclusion of DEET in national programs for monitoring groundwater.

   PEARL model calculation allowed to conclude that predicted groundwater concentration will not exceed the trigger value of 0.1 µg/l. For above reasons monitoring of DEET in the groundwater was assumed to be not needed.

3. Member states should address any potential for direct exposure to surface water as a consequence of swimming etc, which has not been assessed at the European level

   In the presented Assesment Report exposure and risk for surface water due to swimming was already assessed by using revised ESD for PT 19 (2015).

2.2.9 Assessment of a combination of biocidal products

Biocidal product PANKO is not intended to be authorised for the use with other biocidal products.

3 ANNEXES[6]

3.1 LIST OF STUDIES FOR THE BIOCIDAL PRODUCT (FAMILY)

Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
				Yes	No	Yes	No
Kamila Padlewska	2013	Świadectwo własności drażniących i uczulających	„MABI" Tadeusz Karolak	☐	☒	☒	☐
Izabela Semeniuk, B. Krzysiak-Warzała	2012	Badanie właściwości fizykochemicznych próbki „Panko przeciwko komarom i kleszczom (metodyka zgodna z Rozporządzeniem Komisji (WE) nr 440/2008) Report no 34/2012/BA-AD	„MABI" Tadeusz Karolak	☐	☒	☒	☐
Izabela Semeniuk, B. Krzysiak-Warzała	2012	Badanie palności wyrobu aerozolowego "Panko przeciwko komarom i kleszczom" Report no 38/2012/BA-AD	„MABI" Tadeusz Karolak	☐	☒	☒	☐
Beata Biernat	2012	Sprawozdanie z wykonania badań w zakresie skuteczności repelencyjnego działania preparatu „Panko środek przeciw komarom i kleszczom" w odniesieniu do komarów	„MABI" Tadeusz Karolak	☐	☒	☒	☐
Urszula Wyrzykowska, Rafał Mróz	2012	Panko. Opracowanie i walidacja metody oraz oznaczenie substancji aktywnej DEET. Study code: BA-13/12	„MABI" Tadeusz Karolak	☐	☒	☒	☐
Urszula Wyrzykowska, Tomasz Sałaciński	2012	Panko – Oznaczanie właściwości wybuchowych Study code: BW-04/12	„MABI" Tadeusz Karolak	☐	☒	☒	☐
Urszula Wyrzykowska, Idris Al Amin	2012	Panko. Etap I: Oznaczanie właściwości fizykochemicznych preparatu Study code: BF-19/12	„MABI" Tadeusz Karolak	☐	☒	☒	☐
Urszula Wyrzykowska, Idris Al Amin	2014	Panko. Etap III: Oznaczanie właściwości fizykochemicznych preparatu po drugim roku składowania Study code: BF-19/12	„MABI" Tadeusz Karolak	☐	☒	☒	☐

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

Idris Al Amin	2017	Panko Oznaczanie właściwości fizykochemicznych Study code: BF-97/17	„MABI” Tadeusz Karolak	☐	☒	☒	☐
Alicja Buczek, Katarzyna Bartosik		Badanie skuteczności repelentów na skórze żywiciela w odniesieniu do kleszczy oparta o wytyczne Prezesa Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych z dnia 7 listopada 2006 roku	„MABI” Tadeusz Karolak	☐	☒	☒	☐

3.2 PEARL MODEL –EMISSION *VIA* STP – INDIRECT EMISSION TO WATER – REMOVAL THROUGH SHOWERING AND BATHING OF HUMANS (A) AS WELL AS WASHING OF GARMENTS (B), *ACCORDING TO EFFICIENT DOSE: 2.48 MG B.P./CM^2 OF SKIN (TICKS AS WORST-CASE).*

PEARL model needs several input data to calculate concentration in a groundwater. The first ones are application rates. Calculation of application rates was based on the C_{sludge} values as follows:

$C_{sludge} = E_{local} \cdot F_{STP\ sludge} \cdot 10^6$ / SLUDGERATE

$Appl_{rate} = App_{sludge} \cdot C_{sludge} \cdot 10^{-6}$,

$Dosage_{arrableland} = 5000 \cdot Appl_{rate} \cdot 10^{-6}$,

$Dosage_{grassland} = 1000 \cdot Appl_{rate} \cdot 10^{-6}$

where sewage sludge application rate (App_{sludge}) expressed as the maximum sewage sludge application of 5000 kg/ha (on arable land) and 1000 kg/ha (on grassland).

According to calculations presented earlier the highest local emission to STP (7.29 kg $\cdot$ d^{-1}) was calculated according to efficient dose: 2.48 mg b.p./cm^2 of skin (ticks as worst case). For the purpose of this PAR PEARL modelling was run for every efficient dose:

Efficient dose: 2.48 mg b.p./cm^2 of skin (ticks 2 application per day)

$C_{sludge} = 7.29 \cdot 0.0041 \cdot 10^6 / 710 = 42.1$ [mg/kg]

$Dosage_{arrableland} = 5000 \cdot 42.1 \cdot 10^{-6} = 0.210$ [kg $\cdot$ ha^{-1}]

$Dosage_{grassland} = 1000 \cdot 42.1 \cdot 10^{-6} = 0.042$ [kg $\cdot$ ha^{-1}]

Efficient dose: 2.48 mg b.p./cm^2 of skin (ticks 1 application per day)

$C_{sludge} = 3.64 \cdot 0.0041 \cdot 10^6 / 710 = 21.02$ [mg/kg]

$Dosage_{arrableland} = 5000 \cdot 21.02 \cdot 10^{-6} = 0.11$ [kg $\cdot$ ha^{-1}]

$Dosage_{grassland} = 1000 \cdot 21.02 \cdot 10^{-6} = 0.02$ [kg $\cdot$ ha^{-1}]

Efficient dose: 1.08 mg b.p./cm^2 of skin (mosquitoes 2 application per day)

$C_{sludge} = 3.17 \cdot 0.0041 \cdot 10^6 / 710 = 18.31$ [mg/kg]

$Dosage_{arrableland} = 5000 \cdot 18.31 \cdot 10^{-6} = 0.09$ [kg $\cdot$ ha^{-1}]

$Dosage_{grassland} = 1000 \cdot 18.31 \cdot 10^{-6} = 0.02$ [kg $\cdot$ ha^{-1}]

Efficient dose: 1.08 mg b.p./cm^2 of skin (mosquitoes 1 application per day)

$C_{sludge} = 1.59 \cdot 0.0041 \cdot 10^6 / 710 = 9.18$ [mg/kg]

$Dosage_{arrableland} = 5000 \cdot 9.18 \cdot 10^{-6} = 0.05$ [kg $\cdot$ ha^{-1}]

$Dosage_{grassland} = 1000 \cdot 9.18 \cdot 10^{-6} = 0.01$ [kg $\cdot$ ha^{-1}]

The sludge application on arable land can be calculated for maize or winter cereals. For purpose of report calculations for maize were chosen with: application mode on arable land by incorporation into a depth of 20 cm.

The sludge application on grassland is calculated for grass/alfa-alfa by incorporation into a depth of 10 cm.

According to TAB (and WG II-2014 agreement) for running sewage sludge application scenarios in FOCUS groundwater in case of:

- grassland application the scenario considers one sewage sludge application per year on 1st of March (absolute application),
- agricultural land application the scenario considers one sewage sludge application per year 20 days before crop event "emergence" (relative application).

All input parameters are presented in table below.

PEARL inputs - sludge application scenario	
Parameter	**Value**
Tab Scenario	
Location	all 9 EU scenarios
Crop Calendar	maize and grass alfa-alfa
Irrigation	no irrigation
Tillage	no tillage
Repeat interval for application events (years)-	1
Parent substance	
Substance	DEET
Application	STP sludge
Deposition	no deposition
Tab Simulation control	
Start date	01/01/1901
Stop date	31/12/1926
Stop criterion (kg/ha)	0
Repeat hydrology	unchecked
Tab Output control	
Format of time column	Number of days since start of simulation
Print method	other
Print step (d)	1
Depth of Focus target layer (m)	1
Format for reals in output file	G12.4
Summary output	checked
Detailed output	checked
Output cumulative	checked
Summary report	FOCUS report
Tab SWAP hydrological module	
Minimum timestep (d)	1E-07
Maximum timestep (d)	0.2
Tolerance in SWAP (-)	0.001
Tolerance for groundwater level (m)	1

PEARL inputs - sludge application scenario	
Parameter	**Value**
Maximum number of iterations (-)	30
Option hydrology	Run SWAP and the PEARL
Option hysteresis	Not considered
Minimum pressure head to switch drying/wetting	0.2
Tab Diffusion	
Reference temperature for diffusion (°C)	20 (default)
Reference diffusion coefficient in water (m^2/d)	4.3E-5 (default)
Reference diffusion coefficient in air (m^2/d)	0.43 (default)
Tab Crop	
Wash-off factor (/m)	0.0001
Canopy process option	lumped
Half-life at crop surface (d)	1 000000
Coefficient for uptake by plant (-)	0 (no uptake by plants)
Application	
Code	STP sludge
Application type	incorporation
Date: for arable land for grassland	Once per year: 20 days before crop event "emergence" (relative application) 1st of March (absolute application)
Depth (m): for arable land for grassland	 0.2 0.1
Substances	
DEET	
Tab General	
Code	DEET
Parent	checked
Name	DEET
Molar mass (g· mol^{-1})	191.27
Saturated vapour pressure (Pa)	0.23
Measured at (°C)	25
Molar enthalpy of vaporisation (kJ/mol)	95 (default)
Solubility in water (mg/L)	11200
Measured at (°C)	25
Molar enthalpy of dissolution (kJ/mol)	27 (default)
Tab Freundlich sorption	
Option	pH-independent
Kom = Koc/1.724	25.1
Molar enthalpy of sorption (kJ/mol)	0
Reference concentration in liquid phase (mg/L)	1 (default)
Freundlich sorption exponent (-)	1 (worst-case)
Desorption rate coefficient(/d)	0 (default)

PEARL inputs - sludge application scenario	
Parameter	**Value**
Factor relating CofFreNeq and COFFreEql (-)	0 (default)
Tab Transformation	
Half-life (d)	30
Measured at (°C)	12
Optimum moisture conditions (pF2 or wetter)	checked
Liquid content in incubation experiment (mg/kg)	1 (default)
Exponent for the effect liquid (-)	0.7 (default)
Molar activation energy (kJ/mol)	54 (default)

3.3 OUTPUT TABLES FROM EXPOSURE ASSESSMENT TOOLS

3.4 NEW INFORMATION ON THE ACTIVE SUBSTANCE

No new information on the active substance were submitted.

3.5 RESIDUE BEHAVIOUR

3.6 SUMMARIES OF THE EFFICACY STUDIES (B.5.10.1-XX)[7]

3.7 CONFIDENTIAL ANNEX

Please refer to the separate file „Annex Confidential PANKO".

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