service public fédéral
SANTE PUBLIQUE,
SECURITE DE LA CHAINE ALIMENTAIRE
ET ENVIRONNEMENT

federale overheidsdienst
VOLKSGEZONDHEID,
VEILIGHEID VAN DE VOEDSELKETEN
EN LEEFMILIEU

Product Assessment Report
Mouskito Travel Roller

February 2021

R4BP Case no:	(NA-MIC): BC-RM061274-27
Authorisation/Registration no:	BE2014-0028
Granting date/entry into force of authorisation/ registration:	31/07/2014
Expiry date of authorisation/ registration:	31/07/2024
Active ingredient:	*N,N*- diethyl-meta-toluamide (DEET)
Product type:	19

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

Contents

1 General information about the product application 1

1.1 Applicant 1
1.1.1 Person authorised for communication on behalf of the applicant 1
1.2 Current authorisation holder 1
1.3 Proposed authorisation holder 2
1.4 Information about the product application 2
1.5 Information about the biocidal product 2
1.5.1 General information 2
1.5.2 Information on the intended use(s) 3
1.5.3 Information on active substance(s) 3
1.5.4 Information on the substance(s) of concern 4
1.6 Documentation 4
1.6.1 Data submitted in relation to product application 4
1.6.2 Access to documentation 5

2 Summary of the product assessment 6

2.1 Identity related issues 6
2.2 Classification, labelling and packaging 6
2.2.1 Harmonised classification and labelling of the biocidal product 6
2.2.2 Labelling of the biocidal product 7
2.2.3 Packaging of the biocidal product 8
2.3 Physico/chemical properties and analytical methods 8
2.3.1 Physico-chemical properties 8
2.3.2 Analytical methods 15
2.4 Risk assessment for Physico-chemical properties 17
2.5 Effectiveness against target organisms 17
2.5.1 Function 17
2.5.2 Field of Use Envisaged 17
2.5.3 Target organisms to be controlled 18
2.5.4 Effects on Target Organisms - Mode of action 18
2.5.5 Efficacy data 18
2.5.6 Occurrence of resistance 19
2.5.7 Final conclusion 19
2.6 Exposure assessment 19
2.6.1 Description of the intended use(s) 19
2.6.2 Assessment of exposure to humans and the environment 20
2.7 Risk assessment for human health 21
2.7.1 Hazard potential 21
2.7.2 Exposure 27
2.7.3 Risk Characterisation 28
2.8 Risk assessment for the environment 30
2.8.1 Fate and distribution of the active substance in the environment 30
2.8.2 Effects assessment 30
2.8.3 Exposure assessment 31
2.8.4 Risk Characterisation 36
2.9 Measures to protect man, animals and the environment 37

3 Proposal for decision 38

ADDENDUM : AMENDMENT (ART. 48) 54

RE-EVALUATION OF HUMAN EXPOSURE- EFFICACIOUS DOSE.. 54

Conclusion 54

Summary of the product assessment 54

1.1.1 Administrative information 54

1.1.2 Hazard and precautionary statements 56

1.1.3 Authorised use(s) 56

1.1.4 General directions for use 58

1.1.5 Other information 58

Assessment of the product 59

Confidential annex 64

Overview of applications

Overview regarding all relevant applications

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	**BE**	**No case number (submitted under 98/8/EC)**	**31/07/14**	**First authorisation**
NA-MIC	**BE**	**BC-KM027243-41**	**03/08/17**	**Minor Change** **Remark: BC-YH028526-26, ADC change formulating location of the biocidal product was not approved, but taken into account during the process for the MIC case.**
NA-AAT	**BE**	**BC-RP044861-17**	**13/11/18**	**Amendment by CA (dissemination)**
NA-AAT	**BE**	**BC-YN049628-03**	**15/10/2019**	**Amendment by CA (Art.48)**
NA-ADC	**BE**	**BC-DL055343-44**	**19/12/2019**	**ADC addition of an AS supplier**
NA-MIC	**BE**	**BC-RM061274-27**	**10/02/2021**	**Minor Change**

1 General information about the product application

1.1 Applicant

Company Name:	Laboratoria QUALIPHAR N.V./S.A.
Address:	Rijksweg 9
City:	Bornem
Postal Code:	2880
Country:	Belgium
Telephone:	+32 3 889 17 21
Fax:	+32 3 889 37 00
E-mail address:	[redacted]

1.1.1 Person authorised for communication on behalf of the applicant

Name:	[redacted]
Function:	[redacted]
Address:	Rijksweg 9
City:	Bornem
Postal Code:	2880
Country:	Belgium
Telephone:	+32 3 889 17 21
Fax:	+32 3 889 37 00
E-mail address:	[redacted]

1.2 Current authorisation holder[1]

Company Name:	Laboratoria QUALIPHAR N.V./S.A.
Address:	Rijksweg 9
City:	Bornem
Postal Code:	2880
Country:	Belgium
Telephone:	+32 3 889 17 21
Fax:	+32 3 889 37 00
E-mail address:	[redacted]
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	No

[1] Applies only to existing authorisations

1.3 Proposed authorisation holder

Company Name:	Laboratoria QUALIPHAR N.V./S.A.
Address:	Rijksweg 9
City:	Bornem
Postal Code:	2880
Country:	Belgium
Telephone:	+32 3 889 17 21
Fax:	+32 3 889 37 00
E-mail address:	[redacted]
Letter of appointment for the applicant to represent the authorisation holder provided (yes/no):	No

1.4 Information about the product application

Application received:	01/08/2012
Application reported complete:	
Type of application:	Application for first authorisation
Further information:	Mouskito Travel Roller is currently authorised in Belgium under national legislation for the use as a repellent. (PT19). The current application is for PT 19 use. This application will be assessed and authorised under 98/8/EC.

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	Mouskito Travel Roller
Manufacturer's development code number(s), if appropriate:	[redacted]
Product type:	19 Insect repellent against mosquitoes and flies.
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential annex):	30% DEET [redacted]
Formulation type:	Liquid, provided in a bottle with a roller on top to apply the product
Ready to use product (yes/no):	yes
Is the product the very same (identity and content) to another product already	No

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

1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	Mouskito Travel Roller is an insect repellent against flying insects such as mosquitoes, wasps and flies that is applied on the uncovered skin of non-professional users.
Target organisms:	The target species are mosquitoes (*Culex* and *Aedes)*, biting flies *(Stomoxys Calcitrans)* and wasps *(Vespula sp.)*.
Category of users:	non-professional users
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	Mouskito Travel Roller protects against mouskitos and wasps during 8 h and against flies during 5 h. Maximum 2 applications a day. The product has to be applied sufficiently on the exposed skin. Avoid every contact with eyes, mouth an mucous membranes. Use limited to children > 2 years and to adults.
Potential for release into the environment (yes/no):	yes
Potential for contamination of food/feedingstuff (yes/no)	no
Proposed Label:	Xi, R36 – 52/53 – 10; S2-46-61 H226-319-412; P102-273-301+310
Use Restrictions:	For adults and children from the age of 2. The use of the product needs to be limited in children between 2 and 12 years old.

1.5.3 Information on active substance(s)[2]

Active substance chemical name:	N,N-diethyl-m-toluamide'(DEET)
CAS No:	134-62-3
EC No:	205-149-7
Purity (minimum, g/kg or g/l):	98% (w/w)

[2] Please insert additional columns as necessary

Inclusion directive:	2010/51/EU
Date of inclusion:	01/08/12
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	yes
Manufacturer of active substance(s) used in the biocidal product:	
Company Name:	Vertellus Specialities Inc.
Address:	[redacted]
City:	[redacted]
Postal Code:	[redacted]
Country:	[redacted]
Telephone:	[redacted]
Fax:	[redacted]
E-mail address:	[redacted]

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

None of the non-active ingredients has an influence on the classification and labelling of the final product in the concentration that they are present in the formula. Therefore, none of the non-active ingredients was considered to be a substance of concern and no further additional data were considered to be required.

1.6 Documentation

1.6.1 Data submitted in relation to product application

Specific data were provided for the identification of the product, the physico-chemical properties and analytical methods.

Efficacy studies with the product performed on common house mosquito (*Culex Pipiens*) and yellow fever mosquito (*Aedes aegypti*), stable fly (*Stomoxys Calcitrans*) and wasps (*Vespula sp.*) were provided.

With regard to acute oral and dermal toxicity, skin irritation and skin sensitization toxicological studies performed on a former formula of Mouskito Travel Spray were provided. This formula is very similar to the formula of Mouskito Travel Roller described in the dossier.

A full-length toxicological study with Mouskito Travel Roller was provided for Dermal absorption.

No new studies with the product were performed with regard to the ecotoxicology.

[3] Please insert additional columns as necessary

1.6.2 Access to documentation

The applicant has submitted a letter of access of the owner of the data on the active substance DEET submitted for the inclusion of DEET into Annex I of Directive 98/8/EC.

2 Summary of the product assessment

2.1 Identity related issues

The source and manufacturing route of the active substance is unchanged to this of the N,N-diethyl-m-toluamide'(DEET) listed in Annex I of 98/8/EC (Vertellus, member of DEET EU Joint Venture).

Mouskito Travel Roller contains 30% DEET, with a minimum purity of 98%.

None of the non-active ingredients has an influence on the classification and labelling of the final product in the concentration that they are present in the formula. Therefore, none of the non-active ingredients was considered to be a substance of concern;

Mouskito Travel Roller is not identical to the representative biocidal product evaluated with the Annex I inclusion of DEET

2.2 Classification, labelling and packaging

Under this heading the assessment of the classification, labelling and packaging should be summarised. Further, any result of the assessments made under the following headings that require recommendations or restrictions appearing on the label should be summarised here.

It should be noted that labelling of biocidal products goes way beyond the requirements of directive 19999/45/EC or regulation 1272/2008 (in the future) but is regulated in Art. 20 of directive 98/8/EC. Especially, the points a) - m) of Art. 20 (3) need to be addressed here in detail.

2.2.1 Harmonised classification and labelling of the biocidal product

2.2.1.1 Proposed classification based on Directive 1999/45/EC:

Category of danger:	Xi (irritating)
Risk Phrases:	R36 (Irritating to eyes) R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Safety Phrases:	S2 : Keep out of the reach of children S13 : Keep away from food, drink and animal foodstuffs S25 : Avoid contact with eyes S46 : If swallowed, seek medical advice immediately and show this container or label S61: Avoid release into the environment. Refer to special instructions/Safety data sheets.

2.2.1.2 Proposed classification based on Regulation EC 1272/2008 :

Signal Word	Warning		
Pictogram	GHS07		
	Hazard class & category	**Code**	**Hazard Statement**
Hazard statements:	Eye Irrit. 2	H319	Causes serious eye irritation
	Aquatic chronic 3	H412	Harmful to aquatic life with long lasting effects
Precautionary statements		P102 P305+P351+P338 +P310 P273 P501	Keep out of reach of children IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing Immediately call a POISON CENTER or doctor/physician Avoid release to the environment Dispose of contents/container ... (in accordance with local/regional/national/international regulation (to be specified)).

The classification of the product was derived based on the results of the acute toxicological studies for the product combined with the classification and labelling of DEET as established in the CAR fot this active substance.

2.2.2 Labelling of the biocidal product

Since the product is sold in a polypropylene bottle of 75 ml some R&S-phrases and H&P phrases should not be on the label.

Following R&S-phrases and H&P statements should not be on the label based on the fact that the packaging the content do not exceed 125 ml:

- R36 / H319 and S25 / P305+P351+P338+P310
- S61 / P273, P501

So the labelling according to Directive 1999/45/EC and Regulation (EC) 1272/2008 can be displayed here as appropriate.

Category of danger:	Xi (irritating)
Risk Phrases:	R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment
Safety Phrases:	S2 : Keep out of the reach of children S13 : Keep away from food, drink and animal foodstuffs S46 : If swallowed, seek medical advice immediately and show this container or label

Signal Word	Warning		
Pictogram			
	Hazard class & category	**Code**	**Hazard Statement**
Hazard statements:	Aquatic chronic 3	H412	Harmful to aquatic life with long lasting effects
Precautionary statements		P102	Keep out of reach of children

The content of the label should be updated to comply with the labelling requierements established in Article 20(3) of Directive 98/8/EC.
The safety data sheet should comply with the requierements in Regulation (EC) 1907/2006.

2.2.3 Packaging of the biocidal product

Mouskito Travel Roller is packed in polypropylene bottles of 75 ml with a polypropylene cap.

2.3 Physico/chemical properties and analytical methods

2.3.1 Physico-chemical properties

Table 2.3.1-1, containing the physico-chemical properties of the active substance is not needed since the necessary letter of access has been supplied for the active substance DEET.

A summary of the physical and chemical properties of the biocidal product is given in table 2.3.1-2.

Table 2.3.1-2: Physico-chemical properties of MOUSKITO TRAVEL ROLLER:

Subsection (Annex Point/TNsG)		Methods	Results	Remarks / Justification	GLP (Y/N)	Reference
B3.1	**Appearance (IIB3.1/Pt. I-B3.1)**					
B3.1.1	Physical state and nature	Organoleptic	Homogeneous lotion	/	NA	Qualiphar - Mouskito Travel Roller: Appearance Test Report (17/01/2014)
B3.1.2	Colour	Organoleptic	White	/	NA	
B3.1.3	Odour	Organoleptic	Characteristic	/	NA	
B3.2	**Explosive properties (IIB3.2/Pt. I-B3.2)**	Statement	Waived	None of the ingredients of the product is classified as explosive.	Waived	Justification Laboratoria Qualiphar (07/01/2014)
B3.3	**Oxidising properties (IIB3.3/Pt. I-B3.3)**	Statement	Waived	None of the ingredients of the product is classified as oxidising.	Waived	Justification Laboratoria Qualiphar (07/01/2014)
B3.4	**Flash-point and other indications of flammability or spontaneous ignition (IIB3.4/Pt. I-B3.4)**					
B3.4.1	Flash point	EC A9	> 93 °C	The test irem is not flammable	Y	CRA-W (Gembloux) Project QUALIFAR / FO23504 / Ch.5822 / 2014 / A (2014)
B3.4.2	Auto-flammability	Statement	Waived	None of the ingredients of the product is classified as auto-flammable.	Waived	Justification Laboratoria Qualiphar (07/01/2014)
B3.4.3	Other indications of flammability	-	-	-	-	-

Subsection (Annex Point/TNsG)		Methods	Results	Remarks / Justification	GLP (Y/N)	Reference
B3.5	**Acidity / Alkalinity (IIB3.5/Pt. I-B3.5)**	CIPAC MT 75.3	pH = 5.63	/	Y	CRA-W (Gembloux) Project QUALIFAR / FO23504 / Ch.5822 / 2014 / A (2014)
B3.6	**Relative density / Bulk density (IIB3.6/Pt. I-B3.6)**	EC A3	0,9940 g/ml 0.9848 g/ml	At 20 ± 0.5 °C At 40 ± 0.5 °C	Y	CRA-W (Gembloux) Project QUALIFAR / FO23504 / Ch.5822 / 2014 / A (2014)
B3.7	**Storage stability / Stability and shelf life (IIB3.7/Pt. I-B3.7)**					
B3.7.1	Effects of temperature	CIPAC MT 46 Accelerated study for 8 weeks at 40 °C (dry conditions)	Variation of 1 % after storage: 30.59 % w/w versus 30.29 % w/w	MOUSKITO TRAVEL ROLLER is considered to be physically and chemically stable.	NA	Qualiphar - Mouskito Travel Roller: Storage Stability Report (17/01/2014)
		CIPAC MT 46 Accelerated study for 8 weeks at 40 °C (75 % relative humidity)	Variation of 0.46 % after storage: 30.43 % w/w versus 30.29 % w/w	MOUSKITO TRAVEL ROLLER is considered to be physically and chemically stable.	NA	Qualiphar - Mouskito Travel Roller: Storage Stability Report (17/01/2014)

Subsection (Annex Point/TNsG)	Methods	Results	Remarks / Justification	GLP (Y/N)	Reference
	NA-MIC 2020: Shelf life at ambient temperature (25 °C/60 % relative humidity) over 6- 12-24-36-48-60 months	T0: 30.29 % w/w T6m: 31.27 % w/w - Variation: 3.24% T12m: 32.42 % w/w – Variation: 7.03 % T24m: 31.74 % w/ w – Variation: 4.79 % T36m: 31.87 % w/ w – Variation: 5.22 % T48m: 30.59 % w/ w – Variation: 0.99 % Appearance not affected by storage, both in the accelerated test at dry and 75% RH conditions, and the ambient temperature test (48 months): homogenous white solution with a characteristic odour pH and relative density only very slightly affected by storage, both in the accelerated test at dry and 75% RH conditions, and the ambient temperature test (48 months).	MOUSKITO TRAVEL ROLLER is considered to be physically and chemically stable *for up to 48 months*.	NA	Qualiphar - Mouskito Travel Roller: Stability Commitment (17/01/2014) Qualiphar - Mouskito Travel Roller: Storage Stability Report (23/09/2016) Qualiphar - Mouskito Travel Roller: Storage Stability Report (05/08/2020)

Subsection (Annex Point/TNsG)	Methods	Results	Remarks / Justification	GLP (Y/N)	Reference
B3.7.2 Effects of light	IHC Q1B	Variation of 1.37 % after photostabillity study: 28.8 % w/w versus 29.2 % w/w	/	NA	Qualiphar - Mouskito Travel Roller: Storage Stability Report (03/02/2014) Qualiphar - Photostability Testing (15/04/2014)
B3.7.3 Reactivity towards container material	CIPAC MT 46 Accelerated study for 8 weeks at 40 °C (dry conditions)	None	Interaction with primary packaging is monitored during the temperature-effects studies under B3.7.1.	NA	Qualiphar - Mouskito Travel Roller: Storage Stability Report (03/04/2014)
	CIPAC MT 46 Accelerated study for 8 weeks at 40 °C (75 % relative humidity)	None			
	Shelf life at ambient temperature (25 °C/60 % relative humidity) over 6 months	None			
	Shelf life at ambient temperature (25 °C/60 % relative humidity) over 48 months	None			Qualiphar - Mouskito Travel Roller: Storage Stability Report (05/08/2020)
B3.7.4 Other	-	-	-	-	-
B3.8 Technical characteristics (IIB3.8/Pt. I-B3.8)					

Subsection (Annex Point/TNsG)	Methods	Results	Remarks / Justification	GLP (Y/N)	Reference
B3.8.1 Wettability/Suspensibility	-	-	Not applicable since biocidal product is not wettable/water dispersable.	-	-
B3.8.2 Wet sieve analysis	-	-	Not applicable since biocidal product is not used with spray equipment.	-	-
B3.8.3 Emulsifiability	-	-	Not applicable since biocidal product does not need to be emulsified.	-	-
B3.8.4 Disintegration time	-	-	Not applicable since biocidal product is not a tablet and is not used in a water soluble bag.	-	-
B3.8.5 Attrition / Friability of granules Integrity of tablets	-	-	Not applicable since biocidal product is not a granule or tablet.	-	-
B3.8.6 Persistence of foaming	-	-	Not applicable since biocidal product is a ready for use product.	-	-
B3.8.7 Flowability / Pourability	-	-	Not applicable since biocidal product is not granular/a suspension.	-	-
B3.8.8 Dustability	-	-	Not applicable since biocidal product is not granular.	-	-
Additional technical properties					
B3.8.9 Burning rate smoke generators	-	-	Not applicable since the biocidal product is no smoke generator.	-	-
B3.8.10 Burning completeness smoke generators	-	-	Not applicable since the biocidal product is no smoke generator.	-	-
B3.8.11 Composition smoke of smoke generators	-	-	Not applicable since the biocidal product is no smoke generator.	-	-
B3.8.12 Spraying pattern aerosols	-	-	Not applicable since the biocidal product is no aerosol.	-	-

Subsection (Annex Point/TNsG)	Methods	Results	Remarks / Justification	GLP (Y/N)	Reference
B3.9 Compatibility with other products (IIB3.9/Pt. I-B3.9)	-	-	The biocidal product is not intended to be added or mixed with any other products.	-	-
B3.10 Surface tension and viscosity (IIB3.10/Pt. I-B3.10)					
B3.10.1 Surface Tension	PA-U10-METTENS (equivalent to method EC A5)	36.8 mN/m	Product is surface active. Tested at 25 ± 0.5 °C	Y	CRA-W (Gembloux) Project QUALIFAR / FO23504 / Ch.5822 / 2014 / A (2014)
B3.10.2 Viscosity	CIPAC MT 192 OECD 114	10474 mPa.s to 609 mPa.s 618.4 $x10^{-6}$ m^2/s	Dynamic viscosity at 40 ± 0.5 °C, dependent on the shear rate applied to the sample (1.594 - 100.3 s^{-1}) Calculation of kinematic viscosity at 40 ± 0.5 °C	Y	CRA-W (Gembloux) Project QUALIFAR / FO23504 / Ch.5822 / 2014 / A (2014)
B3.11 Particle size distribution (IIB3.11/Pt. I-B3.11)	-	-	Not applicable since biocidal product is not a granule or powder.	-	-

2.3.2 Analytical methods

2.3.2.1 Formulation analysis

A general analytical method for the determination of DEET and the impurities in the technical material was developed and evaluated in the DEET CAR, Document III-A, section 4.1. For the determination of DEET in the reference product, a HPLC-UV method was provided. However, supporting validation data was only provided for the 15% DEET aerosol.

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

For other products except the 15 % DEET aerosols, analytical methods with supporting validation data are needed at the product authorisation stage. The applicant introduced a validation for a HPLC-DAD method according to B.E.A.Gx method MR-116-01-01. The results are given in Table 2.3.1-4. The BE CA considers this method suitable for the determination of the DEET content in MOUSKITO TRAVEL ROLLER.

Table 2.3.1-4: Analytical method for formulation analysis:

Sample	Test Substance	Analytical Method	Number of Measurements / Fortification Range	Linearity	Specificity	Recovery Rate (%)			Limit of Quantitation (LOQ)	Reference
						Range	Mean	RSD		
Roller with 30% DEET	DEET	HPLC-DAD	9 levels triplicate injection	Calibration curve between 0 and 6.75 µg/ml $r^2 = 0.9999$ Calibration curve between 0 and 9 µg/ml $r^2 = 0.9997$	No interference	Range: 98.6 - 103.0 % Mean: 100.3 % Range: 99.0 - 101.0 % Mean: 100.0 % RSD: < 4 % for all levels < 15% at LOQ level			20 mg/g	Université de Liège - Gembloux Agro-Bio Tech (Gembloux) 4-QUADEET 12/03 (19/07/2012)

2.3.2.2 Residue analysis

Analytical methods for the determination of DEET in relevant environmental media (soil, air, water), residues in animal/human body fluids/tissues and in/on food or feedstuffs have not been submitted for the biocidal product. These points have been covered by the data set for the active substance, which can be found in the DEET CAR, Document II-A, section 1.3.3, and the DEET Assessment Report, section 2.1.1. Because MOUSKITO TRAVEL ROLLER is a roller and not a spray, with expected negligible contamination of the air compartment, the BE CA could agree with non submission of a method for air.

2.3.2.2.1 Justification of non-submission of data on the active ingredient

Not applicable.

2.3.2.2.2 Justification of non-submission of data on the substances of concern

Not applicable.

2.4 Risk assessment for Physico-chemical properties

As described in the DEET CAR, the active ingredient does not exhibit hazardous physic-chemical properties.

NA-MIC 2020:

Based on the provided study report, regarding stability study at ambient temperature for up to 48 months, MOUSKITO TRAVEL ROLLER is considered stable for up to 48 months.

2.5 Effectiveness against target organisms

Mouskito Travel Roller is a ready-for-use water-based roller containing 30% DEET. This product is used by the non-professional user/consumer to repel flying insects. This product is intended to be used on the skin.

2.5.1 Function

MG03: Pest control
PT19: Repellents and attractants

2.5.2 Field of Use Envisaged

Mouskito Travel Roller is intended to be used on the uncovered skin by adults and children from the age of 2. Between the age of 2 and 12 years the use of the product should be limited.

2.5.3 Target organisms to be controlled

The target species are mosquitoes (*Culex* and *Aedes),* biting flies *(Stomoxys Calcitrans)* and wasps *(Vespula sp.).*

2.5.4 Effects on Target Organisms - Mode of action

The Mouskito Travel Roller is an insect repellent without time delay. The mechanism of action of the active ingredient *N*,*N*-diethyl-meta-tolueenamide (DEET) is not revealed yet. However its effectiveness is determined experimentally.
In the CAR, one laboratory test and different field tests revealed already a limited activity of the active substance against: mosquitoes (*Aedes aegypti, Culex annulirostris,…*), flies (*Stomoxys calcitrans*), black flies, deer flies and chiggers (*Trombicula sp.*) (DOC III–A5).
Due to the low concentration of perfume and the fact that the most important perfume-elements in the product are also present in the product in the CAR, we may assume that the perfume himself will be of no importance regarding the repelling activity of the product.

2.5.5 Efficacy data

2.5.5.1 Efficacy data on the active substance used in the Assessment Report for inclusion to Annex I

The assessment of the biocidal activity of DEET demonstrates that it has a brief but sufficient activity against the target organisms in a concentration of 0,23 mg/cm^2 (15% DEET).
In Mouskito Travel Roller, DEET is present in an increased concentration of 0,5 mg/cm^2 (30% DEET).

2.5.5.2 Efficacy data on the representative products used in the Assessment Report for inclusion to Annex I

The Mouskito Travel Roller formulation is different from that of OFF!TM Aerosol. The concentration of the active substance is doubled and there is a change in the non-active substances. As a result of the changes, you can see a prolonged repellent effect of the product in the test.

2.5.5.3 Efficacy test with Mouskito Travel Roller

The efficacy studies are performed in conditions with a temperature of 20 +/-1°C and a relative humidity of 60+/- 5%. As a result they are only valid for an environment with a moderate climate. The product is applied during the test with a concentration of 1g / 600cm^2. The recommended use level should be the same. A lower concentration of 0,5 g / 600cm^2 is used during the test with wasps.

Summary of efficacy test on Mouskito Travel Roller				
Test organism	Test conditions	Results	Comments	Reference
Common house mosquito (*Culex Pipiens*) and Yellow fever mosquito (*Aedes aegypti*)	Arm in cage method	100% protection against bites during 8 hours	Studies are performed according to the WHO and EPA guidelines. Also according the Draft Guideline to replace part of Appendices to chapter 7 (page 187 to 200) from TNsG on	Report number: 1477b3-PIR/1211

			Product evaluation.	
Stable Fly (*Stomoxys Calcitrans*)	Arm in cage method	100% protection against bites during 5 hours	Studies are performed according to the WHO guidelines. Also according the Draft Guideline to replace part of Appendices to chapter 7 (page 187 to 200) from TNsG on Product evaluation.	Report number: 1693cPIR/0713
Wasps (*Vespula sp*.)	Use of trapping devices placed in an orchard.	100% protection against stings during 8 hours	The test system was based on a TEC methodology following the General principles of the Manual for the Authorization of Pesticides-EU part-Biocides- chapter 7 Efficacy – version 1.1	Report number: 1639e-PIR/0713

Mouskito Travel roller has a proven efficacy against mosquitoes and wasps with a general protection time of 8 hours and against flies a general protection time of 5 hours.

2.5.6 Occurrence of resistance

There is no known resistance.

2.5.7 Final conclusion

According to the product claim, all the submitted data are acceptable, they meet the data requirements as set out in the TNsG on Product Evaluation, Appendices to Chapter 7 (page 187 to 200), Product Type 18.
Following the RVIM Report 320005002/2006: Pest control Products Fact Sheet, H.J. Bremmer et al. an adult will apply an amount of about 3g on his body surface instead of 6g. This results in a reduction of the protection time. The recommended use level is 2 times a day. The applicant needs to mention the factors who will reduce the protection time namely: swimming, strong transpiration and an insufficient quantity applied to the body surface.
The BE MRS considers that the results demonstrate that Mouskito Travel Roller has a good efficacy against flying insects. The estimated protection time is approximately 8hours against mosquitoes and wasps and approximately 5hours against flies. This results in a general protection time of approximately 5hours.
Authorization of Mouskito Travel Roller can be granted.

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

Mouskito Travel Roller is sold in 75 ml roller and can only be applied twice a day. It cannot be used for children younger than two years old. For children between 2 and 12 years old use should be restricted to one application a day.

MG/PT	Field of uses envisaged	Likely concentrations at which a.s. will be used
19	Insect repellent against mosquitoes and flies	**DEET: 30%**

2.6.2 Assessment of exposure to humans and the environment

2.6.2.1 Environmental exposure assessment

Mouskito Travel Roller is used as an insect repellent (PT19) that is applied on uncovered human skin. The product can be expected to be used both indoors and outdoors at a maximum application rate of 2 applications per day.

Mouskito Travel Roller contains 30 % (300 g/kg) N,N-Diethyl-*m*-toluamide, a.k.a. DEET, as active substance. None of its other components are considered relevant for the environmental exposure assessment or have an influence on the environmental classification and labelling.

The main route into the environment of insect repellents used on human skin is assumed to be indirect. It results from the showering and bathing of the end-user after application of the product, washing away residual product down the drain, via the STP, to the surface water.
An additional route of exposure identified for repellents is the direct release to surface waters as a result of swimming. However, as no generally approved scenario was available at the time this PAR was made, this was not assessed.
For the full exposure assessment, please refer to section 2.8.3 below.

2.6.2.2 Human exposure assessment

Exposure path	Industrial use	Professional use	General public	*via* the environment
Inhalation	Negligible	Not applicable	Negligible	Negligible
Dermal	Negligible	Not applicable	Main route of exposure	Negligible
Oral	Negligible	Not applicable	Negligible	Negligible

Mouskito Travel Roller is intended for consumer application, where the route of exposure is mainly dermal and is applied directly on human skin. The inhalation exposure is considered to be negligible (TNsG 2002 part 2 p. 272), due to fact due to the use outdoors, and because use indoors only takes place in the summer where there is a high ventilation rate.

Oral exposure by hand-to-mouth transfer is not considered to be a significant route of exposure because the smell and taste of DEET acts as a self-deterrent against this type of activity. More importantly, Mouskito Travel Roller contains an ingredient that acts as a strong deterrent for ingestion (Bitrex).

2.7 Risk assessment for human health

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

Absorption, distribution, metabolism and excretion studies showed that more than 80% of *N*,*N*-diethyl-meta-toluamide (DEET) given orally to rats is absorbed and excreted in the urine. DEET showed no evidence for accumulation. When applied dermally to rats, 74-78% is absorbed and excreted in the urine. The dermal absorption of DEET occurred at a slower rate than oral absorption. As much as 74-91% of the administered radioactivity was excreted *via* urine and about 3-7% was excreted *via* the faeces. DEET was metabolised completely in all oral and dermal treatment groups with little or no parent compound excreted in the urine. DEET is extensively metabolised to 2 major metabolites, namely m-[(*N*,*N*-diethylamino)carbonyl]-benzoic acid and m-[(ethylamino)carbonyl]-benzoic acid. DEET is absorbed slowly, metabolised completely and excreted rapidly when applied to human skin. Less than 20% of a dermally applied dose of DEET, either as a 15% solution in ethanol or as the undiluted technical grade material, is absorbed through the skin during an 8h exposure period.

Acute toxicity studies show that the oral LD_{50} for DEET warrants a classification as Xn and R22 (harmful if swallowed). The rabbit acute dermal LD_{50} of DEET is greater than 2000 mg/kg body weight and the rodent acute dermal LD_{50} is above 5000 mg/kg body weight. The acute inhalation LD_{50} of DEET is greater than 2.02 mg/L, the highest concentration tested which is lower than the upper European classification limit, acute toxicity category 4 according to GHS and recommended highest dose according to the OECD guideline. Even if no mortality was observed at the limit dose tested (2.02 mg/L/4h), it cannot be fully ensured that the LC_{50} would be above 5 mg/L/4h.

DEET is slightly irritating to the skin. Dermal repeated dose studies in pigs and rats showed that repeated dermal dosing resulted in dermal irritation at all doses tested and remained at the end of the study. A classification as R36 (irritating to eyes) is not warranted based on the results of the eye irritation test. However, the mean score for corneal opacity is 1 for 3 animals at 24h, 48h and 72h, and warrants a classification as eye irritation class 2/H319 according to the GHS.

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

Several repeated dose toxicity studies for the oral and dermal route were submitted for DEET. Male rats were the most sensitive gender to DEET for repeated dose effects. Male rats developed α_{2u}-globulin nephropathy that is considered gender-specific and species-specific. Other studies were submitted to support the conclusion that the kidney effects observed in rats were species-specific. This effect was not considered relevant for risk assessment. Clinical signs of neurotoxicity also occurred in dogs shortly after oral dosing. In both rats and dogs, decreased body weights were observed after oral dosing with DEET. Dermal application of DEET to rats and minipigs resulted mainly in skin irritations, but no systemic toxicity or pathological findings.

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

The teratogenicity of DEET was investigated in 2 species, namely rat and rabbit. The studies were performed according to the OECD guideline No. 414 and both studies were preceded by dose finding studies. However, these studies were performed *prior* to the revision of the OECD guideline in 2001 and has therefore some discrepancies compared to the current guideline. The mothers were treated only during organogenesis and not to scheduled sacrifice. The studies therefore have some

limitations in assessing potential effects during later stages of embryonal development. However, given that the 2-generation study in rats gave no further indications of embryotoxic or teratogenic effects at comparable doses, these studies are considered acceptable for risk assessment purposes. There were no teratogenic effects observed in the studies up to maternally toxic doses. Embryotoxicity was only expressed as decreased foetal body weights in rat. There were no effects on reproduction in a 2-generation study in rats. Parental males were the most sensitive gender based on kidney effects that were considered species-specific and irrelevant for risk assessment to man. There were no effects on reproduction. The effects observed in mothers and offspring were reduced body weights and in offspring during later parts of the lactation period. The study was performed in 1989 and shows some discrepancies compared to the current OECD guideline No. 416. The 2-generation study was considered suitable for risk assessment despite deviations from the current OECD guideline No. 416.

No studies were submitted that specifically investigated neurotoxicity after dermal application. However, neurotoxicity of DEET was investigated in an acute oral delayed neurotoxicity study and in a delayed neurotoxicity study following multigenerational exposure in rats. In the acute neurotoxicity study, an increased response time to heat stimulus and decreased rearing activity at 1h postdose was observed in the high dose group. The multigenerational exposure resulted in a transient increase in locomotor activity in the high dose group. The multigenerational neurotoxicity study has some limitations in assessing the risk for exposure to the developing brain in children, since there was no information on exposure to pups during lactation and no functional tests were performed on young animals.

2.7.1.2 Toxicology of the substance(s) of concern

The biocidal product contains the following substances of concern:

- DEET.
- [redacted]

Given the relatively low hazard potential and/or concentration in Mouskito Tropical Roller, the latter 3 substances will not be taken further into consideration.

2.7.1.3 Toxicology of the biocidal product

2.7.1.3.1 Introduction

A full-length toxicological study with Mouskito Travel Roller was provided for Dermal absorption.

No toxicological studies with Mouskito Travel Roller were provided for :

- Acute oral toxicity.
- Acute dermal toxicity.
- Skin irritation.
- Skin sensitisation.

For these studies the applicant refers to the corresponding tests performed on a former formula of Mouskito Travel Spray.
This formula is very similar to the formula of Mouskito Travel Roller described in the dossier.

[redacted]

The concentration of the active ingredient is the same for both formulas.

All of these studies will be discussed hereafter.

2.7.1.3.2 Acute oral toxicity

The test was performed on a former formula of Mouskito Travel Spray.

Outline
Mouskito Travel Spray (old formula) was administered to 2 groups of each 3 female Sprague-Dawley rats . A limit test at one dose level of 2000 mg/kg body weight was carried out with six animals in two steps (3 animals per step). The experimental protocol was established according to the official method as defined in the OECD guideline No. 423.

In conclusion, the LD50 of Mouskito Travel Spray (old formula) is higher than 2000 mg/kg body weight by oral route in the rat.
In accordance with the OECD guideline No. 423, the LD50 cut-off of the test item may be considered as 5000 mg/kg body weight by oral route in the rat.

According to the criteria for classification, packaging and labelling of dangerous substances and preparations in accordance with the EEC Directives 67/548, 2001/59 and 99/45, the test item must not be classified. No symbol or risk phrase is required.
In accordance with the Regulation EC No. 1272/2008 on classification, labelling and packaging of substances and mixtures, the test item must not be classified. No signal word or hazard statement is required.

Reference
F. Richeux (2011) Mouskito Travel Spray: evaluation of acute oral toxicity in rats - acute toxic class method. TAO423-PH-11/0192.

2.7.1.3.3 Acute dermal toxicity

The test was performed on a former formula of Mouskito Travel Spray.

Outline
Mouskito Travel Spray (old formula) was applied onto the intact skin of 10 Sprague-Dawley rats (5 males and 5 females) at a single dose of 2000 mg/kg body weight. The experimental protocol was established on the basis of the official method as defined in the OECD guideline No. 402.

[redacted]

In conclusion, the LD_{50} of the test item Mouskito Travel Spray is higher than 2000 mg/kg body weight by dermal route in the rat.

According to Directive 67/548/EEC and Directive 1999/45/EC, Mouskito Travel Spray must not be classified. No symbol or risk phrase is required.
In accordance with Regulation 1272/2008/EC, Mouskito Travel Spray must not be classified. No signal word or hazard statement is required.

Reference
F. Richeux (2011), Mouskito Travel Spray: evaluation of acute dermal toxicity in rats. TAD-PH-11/0192.

2.7.1.3.4 Acute inhalation toxicity

No test for inhalation toxicity was performed.
According to the TNsG, biocidal products other than gases shall be administered via at least two routes, one of which should be the oral route. The choice of the second route depends upon the nature of the product and the likely route of human exposure. Because Mouskito Travel Roller is a liquid that is applied on the human skin, the dermal route was chosen. Because inhalation is considered to be negligible taking into account the use pattern and the characteristics of the product, no test for the inhalation route was performed.

2.7.1.3.5 Skin irritation

The test was performed on a former formula of Mouskito Travel Spray.

Outline
Mouskito Travel Spray (old formula) was applied onto the intact skin of 3 female Albino New Zealand rabbits at a dose of 0.5 mL under a semi-occlusive patch during 4 hours. The experimental protocol was established on the basis of the official method as defined in the OECD guideline No. 404.

[redacted]

In conclusion, the test item Mouskito Travel Spray is not irritating for the skin and must not be classified according to Directive 67/548/EEC and Directive 1999/45/EC No symbol or risk phrase is required.
In accordance with the Regulation (EC) No. 1272/2008, the test item must not be classified. No signal word or hazard statement is required.

Reference
F. Richeux (2011), Mouskito Travel Spray: assessment of acute dermal irritation. IC-OCDE- PH-11/0192.

2.7.1.3.6 Eye irritation

The active ingredient DEET is labelled R36 – Irritating for the eyes. Because DEET is present in the formula at a concentration of 30%, according to European Directive 1999/45/EC it can be expected that the biocidal product itself is also irritating for the eyes. According to the TNsG, it is not necessary to perform a test on eye irritation test if it can be expected that the formula is irritating. Therefore, to avoid the additional use of test animals no test for eye irritation was performed and the product was labelled R36 – Irritating for the eyes. A warning is added to avoid contact with the eyes. According to Regulation (EC) 1272/2008 the hazard statement H319 - Causes serious eye irritation was added to the label of the product, together with the necessary precautionary statements.

2.7.1.3.7 Skin sensitisation

The test was performed on a former formula of Mouskito Travel Spray.

Outline
After induction (intradermal injection at 1% and topical application at 100%) of 11 guinea pigs (female) of treated group with Mouskito Travel Spray (old formula) and a 10-day rest phase, the challenge phase, under occlusive dressing for 24h, consisted of a single topical application of Mouskito Travel Spray at 100 % and diluted at 50% in distilled water. The experimental protocol was established according the OECD guideline No. 406.

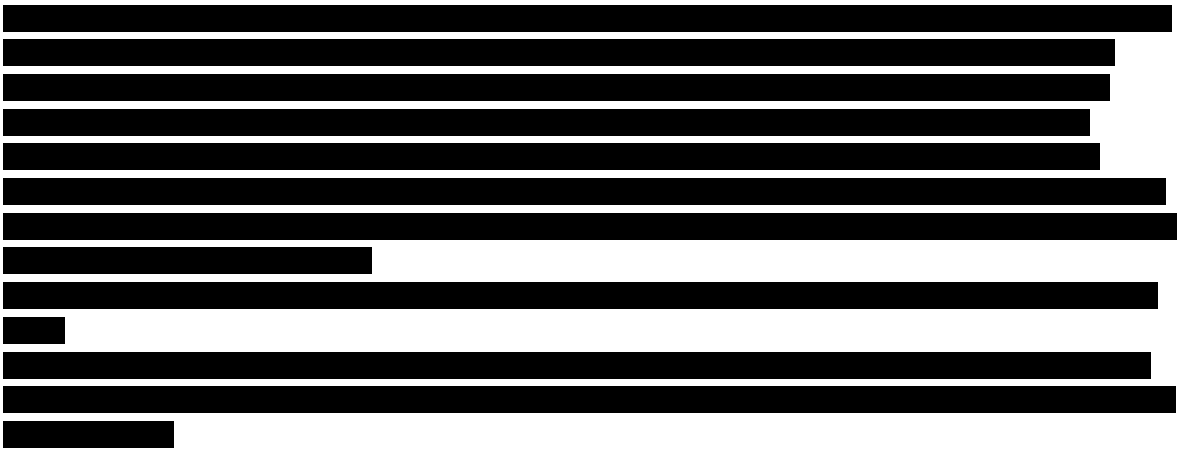
[redacted]

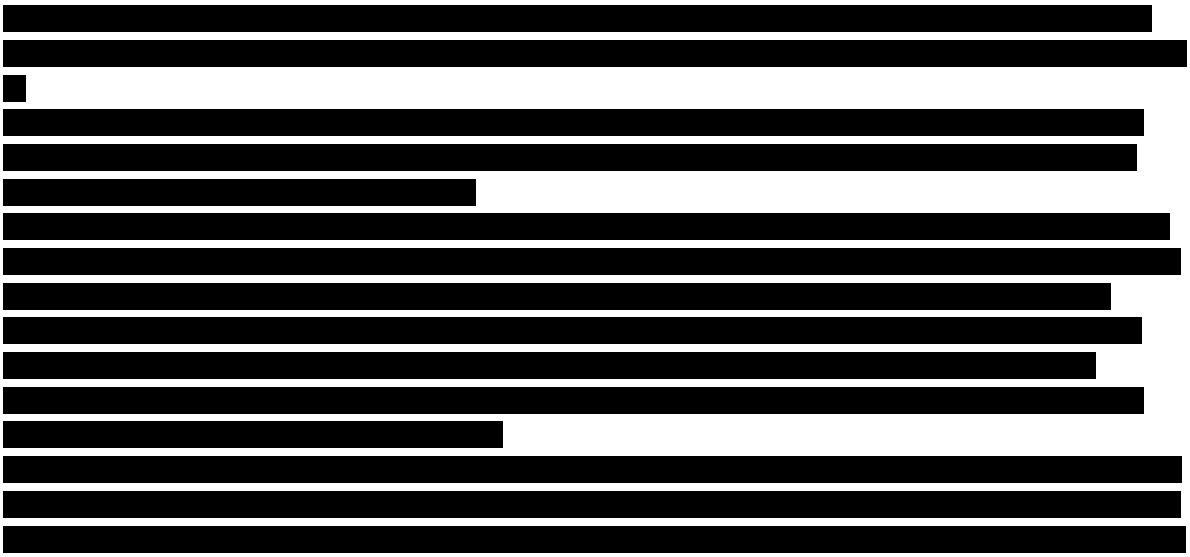
According to Directive 67/548/EEC and Directive 1999/45/EC, Mouskito Travel Spray must not be classified. No symbol or risk phrase is required. In accordance with Regulation 1272/2008/EC, Mouskito Tropical Spray must not be classified. No signal word or hazard statement is required.

Reference
F. Richeux (2011), Mouskito Travel Spray: assessment of sensitising properties on albino guinea pigs - maximisation test according to Magnusson and Kligman. SMK-PH-11/0192

2.7.1.3.8 Dermal absorption

Outline
The dermal absorption was tested on Mouskito Travel Roller as defined in the OECD guideline No. 428.





The recoveries obtained with the Mouskito Travel Roller formulation were all within the aimed 100 ± 10%, with an average of 96 ± 9%.
The in vitro dermal absorption of DEET in Mouskito Travel Roller was 9.5 ± 0.3%.

Reference
I.A.T.M. Meerts (2012) Determination of the dermal absorption of N,N-diethyl-m-toluamide (DEET) in different formulations through human skin in vitro. NOTOX 500039.

2.7.2 Exposure

Mouskito Travel Roller contains 30 % (300 g/kg) N,N-Diethyl-*m*-toluamide, a.k.a. DEET, as active substance. None of its other components are considered relevant for the exposure assessment

2.7.2.1 Exposure of professional users

The product is intended for non-professional use only; The exposure of professional users is not relevant.

2.7.2.2 Exposure of non-professional users and the general public

The representative DEET product is intended for consumer application, where the route of exposure is mainly dermal.

2.7.2.2.1 Direct exposure

The exposure is calculated, like suggested in the CAR of DEET, based on 75th percentile of the data of a mail survey and usage study from Boomsma, JC and Parthasarathy, M (1990) Human Use and Exposure to Insect Repellants Containing DEET.

The 75th percentile of human dermal exposure per application is estimated to be 1.5 g a.s.for males (70 kg), 1.0 g a.s. for females (60 kg), 1.66 g a.s. for children > 12 years (62.5 kg) and 1.42 g a.s. for children < 12years (25.5 kg) (CAR DEET Doc II P62).This is an underestimation of dermal exposure for the representative product since in the usage study mentioned above the average percentage of DEET in product was 26.1% and the concentration of product Mouskito Travel Roller is 30 % DEET.

The systemic exposure to DEET following dermal application of Mouskito Travel Roller is calculated using the following formula:

Systemic exposure = Cf / Cr x Q x F x R x DA / BW
With parameters: Cf = concentration of DEET in the final product (30 %)
Cr = concentration of DEET in the usage study (26.1%)
Q = quantity of the final product for each application
F = frequency of applications = 2 applications per day
R = retention factor
DA = dermal absorption (9.5%)
BW = body weight (p. 63 doc II CAR DEET)

Subject	Systemic exposure
Child < 12 years (25.5 kg)	12.2 mg/kg bw/day
Child > 12 years (62.8 kg)	5.8 mg/ kg bw/day
Adult woman (60 kg)	3.6 mg/ kg bw/day
Adult man (70 kg)	4.7 mg/ kg bw/day

2.7.2.2.2 Indirect exposure

The degree of indirect exposure is considered negligible as the primary route of exposure

is direct application to the skin.

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

2.7.2.3 Exposure to residues in food

Not relevant, the product is not intended for use in contact with food or feed.

2.7.3 Risk Characterisation

2.7.3.1 Risk for Professional Users

Because automated equipment is used to add the formulation ingredients and to fill the product in the respective vessels and because the workers are trained professionals wearing personal protective equipment like gloves, the exposure during the formulation task can be seen as negligible. Consequently, the risk for professional users is also considered negligible.

2.7.3.2 Risk for non-professional users and the general public

Dermal exposure is the main pathway of contact for non-professional users and the general public.

The exposure is calculated, like suggested in the CAR of DEET, based on 75th percentile of the data of a mail survey and usage study from Boomsma, JC and Parthasarathy, M (1990) Human Use and Exposure to Insect Repellants Containing DEET.

The 75th percentile of human dermal exposure per application is estimated to be 1.5 g a.s.for males (70 kg), 1.0 g a.s. for females (60 kg), 1.66 g a.s. for children > 12 years (62.5 kg) and 1.42 g a.s. for children < 12years (25.5 kg) (CAR DEET Doc II P62).This is an underestimation of dermal exposure for the representative product since in the usage study mentioned above the average percentage of DEET in product was 26.1% and the concentration of product Mouskito Travel Roller is 30 % DEET.

The systemic exposure to DEET following dermal application of Mouskito Travel Roller is calculated using the following formula:

Systemic exposure = Cf / Cr x Q x F x R x DA / BW
With parameters: Cf = concentration of DEET in the final product (30 %)
Cr = concentration of DEET in the usage study (26.1%)
Q = quantity of the final product for each application
F = frequency of applications = 2 applications per day
R = retention factor
DA = dermal absorption (9.5%)
BW = body weight (p. 63 doc II CAR DEET)

Subject	Systemic exposure
Child < 12 years (25.5 kg)	12.2 mg/kg bw/day
Child > 12 years (62.8 kg)	5.8 mg/ kg bw/day
Adult woman (60 kg)	3.6 mg/ kg bw/day
Adult man (70 kg)	4.7 mg/ kg bw/day

A first strategy for risk characterisation is through calculation of the margin of exposure (MoE). For this purpose, the NOAEL value of 1000 mg/kg body weight/day derived from the 90-day dermal study in rat is used as a reference. The MoE is calculated as the ratio of this NOAEL value over the systemic exposure. Calculations of the MoE for Mouskito Travel Roller for the different subject types are presented in Table 2.7.3.2.-1.

Table 2.7.3.2.-1: Risk characterisation of Mouskito Travel Roller for non-professional users based upon the calculation of the MoE.

Subject	Systemic exposure	MoE
Child < 12 years (25.5 kg)	12.2 mg/body weight/day	82
Child > 12 years (50 kg)	5.8 mg/body weight/day	172
Adult woman (60 kg)	3.6 mg/body weight/day	278
Adult man (70 kg)	4.7 mg/body weight/day	213

A second strategy for risk characterisation relies on directly comparing the calculated systemic exposure with the acceptable exposure level (AEL). An AELchronic value for DEET of 8.2 mg/kg body weight/day has been proposed (see annex 4), based upon the NOAEL value of 1000 mg/kg body weight/day in the 90-day dermal study in rat as well as upon the observed 82% absorption in a rat dermal absorption study. Calculations of the systemic exposure/AELchronic ratio for Mouskito Travel Roller for the different subject types are presented in Table 2.7.3.2.-2.

Table 2.7.3.2.-2: Risk characterisation of Mouskito Travel Roller for non-professional users based upon the calculation of the systemic exposure/$AEL_{chronic}$ ratio.

Subject	Systemic exposure	Systemic exposure/$AEL_{chronic}$
Child < 12 years (25.5 kg)	12.2 mg/body weight/day	1.49
Child > 12 years (50 kg)	5.8 mg/body weight/day	0.71
Adult woman (60 kg)	3.6 mg/body weight/day	0.44
Adult man (70 kg)	4.7 mg/body weight/day	0.57

MoE values above 100 and systemic exposure/AELchronic ratios below 1 (100%) are considered to reflect safe use. For adults and children > 12 years this is the case. Therefore, no harmful effects to human health are to be expected for these groups of population when applying Mouskito Travel Roller under reasonable conditions of use (i.e. 2 applications per day). For children < 12 years the MoE value is lower than 100 and systemic exposure/AELchronic ratio is above 1, so safe use is not guaranteed. Therefore we propose that the use of the repellent for children < 12 years should be restricted to one application per day.

2.7.3.3 Risk for consumers via residues

Human exposure *via* food is not considered to be relevant, because DEET is not used for and/or during food production or in rooms where food is produced, processed or stored. Taking into account the use pattern of the product, exposure *via* drinking water can be seen as negligible. The degree of indirect exposure *via* the environment as a result of use of the active substance in the final product is considered negligible, as the primary route of exposure is direct application to the skin. The environmental risk assessment has shown that little direct transfer occurs of the active substance to the environment during use of the final product.

2.8 Risk assessment for the environment

2.8.1 Fate and distribution of the active substance in the environment

No new data on the fate and behaviour of the active substance in the environment was submitted, nor was data submitted for the product itself. The data available in the CAR of DEET is acceptable and deemed sufficient for the evaluation of this product. Mouskito Travel Roller is not the reference product in the DEET CAR, but its use-pattern is fairly similar to that of the reference product assessed.

In the CAR, fate and effect data are only provided for the parent structure. DEET is considered to be ready biodegradable and no major transformation products (> 10 %) were formed in the studies for hydrolysis and aquatic phototransformation. DEET is extensively metabolised and excreted through the urine in all assessed mammals, and because the parent structure is ready biodegradable, and the metabolite structures found in urine do not differ significantly from the parent structure it is likely that they are also ready biodegradable.

DEET is moderately volatile and absorbs UV in the region 200-250 nm. The substance is predicted to have an atmospheric half-life of 0.63 days (15.2 hours). Thus an extensive accumulation of DEET in air and long range transport is unlikely.

DEET is a liquid at room temperature, and it has a water solubility of 11.2 g/L and its log P_{ow} is 2.4. It is hydrolytically stable under acidic, basic and neutral conditions, and photolytically stable in sterile distilled water.

According to the submitted study reports in the CAR, DEET is ready biodegradable and causes only minor inhibitory effects on (STP) microbial activity.

Because the substance will primarily end up in sewage treatment plants before any major release to the environment, final environmental exposure will to a large extent depend on whether households are connected to STPs equipped with at least secondary (biological) treatment.

Based on the calculated BCFs for aquatic and terrestrial organisms in the CAR, DEET is considered to have very little or no potential to bioaccumulate.
DEET has a K_{oc} of 43.3, suggesting that it is very mobile in soil and therefore could leach to the groundwater. However, DEET will not be directly emitted to soil and exposure is expected to be negligible.

2.8.2 Effects assessment

No new ecotoxicity data for DEET was submitted for the product authorisation dossier of Mouskito Travel Roller. The PNECs calculated in the CAR, based on the submitted data for Annex I inclusion, are still valid to be used in the assessment of Mouskito Travel Roller.

Table 8.2-1: Summary of PNEC values for DEET as agreed upon in the CAR

Compartment	Critical endpoint	AF	PNEC
Freshwater	$EC_{50\ algae}$ = 43 mg/L	1000	0.043 mg/L
Saltwater	$EC_{50\ algae}$ = 43 mg/L	10 000	0.0043 mg/L
STP micro-organisms	EC_{50} > 1000 mg/L	100	> 10 mg/L
Sediment, freshwater	EPM	/	0.0741 mg/kg_{ww}
Soil	EPM	/	0.0379 mg/kg_{ww}

2.8.3 Exposure assessment

For all PT19 DEET-repellents, including Mouskito Travel Roller, the main route of exposure to the environment results from showering and bathing of the users, washing away residual product from the skin down the drain, via the STP, to the surface water. There, emissions primarily remain in the water compartment due to the physiochemical properties of DEET, supported by level III fugacity modelling. Therefore, the most relevant environmental compartment of concern for DEET is the aquatic compartment.

In the following paragraphs, PECs are estimated by two different approaches:

- Exposure modelling through EUSES, based on tonnage data.
- Exposure assessment based on the Emission Scenario Document (ESD) for PT1 and the TGD

2.8.3.1 EUSES model based on tonnage information

2.8.3.1.1 EUSES model based on tonnage of DEET placed on the EU market (cfr. DEET CAR – RMS SE)

In the CAR for DEET, written by the Swedish CA, environmental exposure calculations were done, based on submitted information on tonnage of DEET placed on the EU market. In the calculations, made through EUSES, it was assumed that the entire EU tonnage would be consumed over a peak period of 3 months (91 days).
As this is a general assessment for all DEET-containing repellents and not based on any specific use-product, these calculated PECs can be considered to remain valid for the assessment of Mouskito Travel Roller.
However, it has to be borne in mind that these calculations are highly subjective to the specific tonnage consumed and should be revised when it comes to the attention that the tonnage of DEET placed on the EU market has been significantly augmented throughout the years.

Table 8.2-2: Summary of the PEC values calculated in the DEET CAR, based on European tonnage information

Compartment	**PEC**
STP micro-organisms	0.0322 mg/L
Freshwater	$3.3x10^{-3}$ mg/L
Sediment, freshwater	$5,7x10^{-3}$ mg/kg_{ww}
Saltwater	$2.56x10^{-3}$ mg/L
Sediment, saltwater	$4.42x10^{-3}$ mg/kg_{ww}
Air, annual average	$2.02x10^{-6}$ mg/m^3
Agricultural soil, 30-d average	$2.74x10^{-3}$ mg/kg_{ww}
Pore/ground water of agric soil	$9.88x10^{-4}$ mg/L

2.8.3.1.2 EUSES model based on yearly tonnage of Mouskito Travel Roller placed on the Belgian market

The applicant for Mouskito Travel Roller also submitted real sales volumes for the years 2011 and 2012 for Mouskito Travel Roller, specifically sold on the Belgian market. Using this information, a EUSES simulation can be run again, assuming this tonnage information to be the regional volume.

Mouskito Travel Roller, yearly volume on the Belgian market: see annex 7 with confidential information for the used volumes

All other EUSES parameters were the same as for the EUSES simulation in the CAR.

Table 8.2-3: Summary of the PEC values calculated based on specific tonnage information for the Belgian market

Compartment	PEC
STP micro-organisms	$4.7x10^{-4}$ mg/L
Freshwater	$4.7x10^{-5}$ mg/L
Sediment, freshwater	$8.1x10^{-5}$ mg/kg_{ww}
Saltwater	$3.8x10^{-5}$ mg/L
Sediment, saltwater	$6.55x10^{-5}$ mg/kg_{ww}
Air, annual average	$4.03x10^{-9}$ mg/m^3
Agricultural soil, 30-d average	$3.78x10^{-5}$ mg/kg_{ww}
Pore/ground water of agric soil	$1.2x10^{-5}$ mg/L

2.8.3.2 Specific product calculations using ESD for PT1

2.8.3.2.1 Local emissions to wastewater

Specific emissions for the product at hand can be calculated using the Emission Scenario Document (ESD) for PT1 (human hygiene products) and input data consisting of data on the average consumption.
In the CAR for DEET, a survey by Boomsma & Parathasarathy is presented as a source for some DEET-specific input data (Doc.IIIB6.6(2)):

- **Finh**: The survey describes that a fraction of 37 % of the inhabitants use an insect repellent
- **$Qform_{appl}$:** The 75th percentile of dermal exposure presented in the DEET CAR is as follows:

Table 8.2-4: 75th percentile of dermal exposure

	75th percentile DEET (a.i.) applied [g]	Average concentration in DEET-products [%]	75th percentile of product applied [g]
adult male	1.5	26.11	5.74
adult female	1	26.11	3.83
Child > 12y	1.66	26.11	6.36
Child < 12y	1.42	26.11	5.44

The worst case exposure is the one for children older than 12 years, with an application rate of 6.36 g product per application. This will be used as $Qform_{appl}$ for the worst case calculations of the local emissions.

- **Fpenetr:** According to the survey, the market share is 0.28 as opposed to the default of 0.5

For the other values, defaults or product label-data are used.
A deviation from the CAR was made for the fraction released to wastewater. In the CAR, it is considered that a fraction of the applied product is lost through evaporation and through dermal absorption. However for the calculations in this PAR a worst case release of 100 % is assumed, because it was shown that the dermally absorbed fraction will eventually still be released to wastewater through excretion via the urine.

Table 8.2-5: Calculation of the local emission to wastewater for Mouskito Travel Roller

$$Elocal_{water} = Nlocal \times Nappl \times Finh \times Fwater \times Qform_{appl} \times Cform_{weight} \times Fpenetr \times 10^{-6}$$

Variable/Parameter	Symbol	Unit	Value	Source
INPUT:				
Number of inhabitants feeding one STP	Nlocal	inh	10 000	Default TGD
Number of applications per day	Nappl	appl/day	2	Label applicant, worst case
Fraction of inhabitants using product	Finh	[-]	0.37	CAR DEET, III-B-6.6(2); DEET specific survey
Fraction released to wastewater	Fwater	[-]	1	Worst case assumption
Consumption per application	$Qform_{appl}$	g/appl	6.36	CAR DEET, III-B-6.6(2); worst case application rate
Amount of active substance in product	$Cform_{weight}$	g/kg	300	Applicant data
Market share of products applied for this purpose	Fpenetr	[-]	0.28	CAR DEET, III-B-6.6(2); DEET specific survey
OUTPUT:				
Local emission to wastewater due to showering/bathing	**$Elocal_{water}$**	**kg/d**	**3.95**	**Formula ESD PT1**

This local emission is considered to be emitted directly to a sewage treatment plant (STP). Predicted Environment Concentrations (PECs) can then be calculated based on the equations and values presented in the appropriate paragraphs of the EU TGD (Chapter 3: Environmental Risk Assessment).

2.8.3.2.2 PEC for the STP micro-organisms

The concentration in the influent of the STP, i.e. the untreated wastewater, can be calculated from the local emission to wastewater and the influent flow to the STP. This influent flow is equal to the effluent discharge, which is based on an average wastewater flow of 200 L per day per capita for a population of 10 000, resulting in an effluent discharge of 2 000 000 L per day.

In the STP, a part of the active ingredients will be removed, in the case for DEET mainly through degradation. The fraction removed from the influent concentration is estimated through the Simple Treat model, presented in the TGD Appendix II (pages 278 to 283). Assuming ready biodegradability passing the 10-day window, a log H of -2 (-2.40) and a log P_{ow} of 2 (2.4) a degradation of 87 % is reached, leaving 13 % of the active ingredient in the water.

Table 8.2-6: Caclulations for STP influent and effluent

$$Clocal_{inf} = \frac{Elocal_{water} \times 10^6}{EFFLUENT_{STP}}$$ *(TGD Eq.32)*

$$Clocal_{eff} = Clocal_{inf} \times Fstp_{water}$$ *(TGD Eq.33)*

Variable/parameter	Symbol	Unit	Value	S/D/O/P*
Input:				
Local emission to wastewater	$Elocal_{water}$	kg/d	3.95	O
Influent flow = Effluent discharge rate	$EFFLUENT_{STP}$	L/d	2000000	D
Fraction of emission directed to water by STP	$Fstp_{water}$	[-]	0.13	P
Output:				
Local concentration of STP influent	$Clocal_{inf}$	mg/L	**1.98**	O
Concentration of substance in the STP effluent	$Clocal_{eff}$	mg/L	**$2.57x10^{-1}$**	O

* S/D/O/P: Set, Default, Output, Pick-list value

In the CAR, a discussion is included to evaluate which of the above calculated concentrations should be considered as the $PEC_{micro\text{-}organisms}$.
When a product is used during a specific period of the year, emissions to the environment for this product will be intermittent. Due to intermittent release, the bacteria in the STP could become deadapted, which would result in a $PEC_{micro\text{-}organisms}$ close to the influent concentration. If continuous release is envisioned, the $PEC_{micro\text{-}organisms}$ will correspond more to the effluent concentration.
Insect repellent are mostly used during peak periods, where the insect population peaks. This means that the actual PEC values can vary substantially depending on the time of the year. Worst case $PEC_{micro\text{-}organisms}$ can therefore be assumed to be equal to the above calculated $Clocal_{inf}$. However, in the CAR is was decided to consider the $Clocal_{eff}$ as the actual $PEC_{micro\text{-}organisms}$, because if intermittent release is assumed, the calculated emissions would be smaller than considered in the ESD PT1 calculations.

$PEC_{micro\text{-}organisms}$ = 0.257 mg/L

2.8.3.2.3 PEC for the surface water

Table 8.2-7: Calculation of $PEC_{surface\ water}$

$$Kp_{susp} = Foc_{susp} \times Koc$$ *(TGD Eq.23)*

$$Clocal_{water} = \frac{Clocal_{eff}}{\left(1 + Kp_{susp} \times SUSP_{water} \times 10^{-6}\right) \times DILUTION}$$ *(TGD Eq45)*

Variable/parameter (units)	Symbol	Unit	Value	S/D/O/P*
Input:				
Concentration of substance in the STP effluent	$Clocal_{eff}$	mg/L	0.257	O
Partition coefficient organic carbon-water	Koc	L/kg	43.3	S
Weight fraction of organic carbon in the	Foc_{susp}	[-]	0.1	D

suspended solids				
Solids-water partitioning coefficient of suspended matter	Kp_{susp}	L/kg	4.33	O
Concentration of suspended matter in river	$SUSP_{water}$	mg/L	15	D
Dilution factor	DILUTION	[-]	10	D
Output:				
Local concentration in surface water	$Clocal_{water}$	mg/L	**$2.57x10^{-2}$**	O

* S/D/O/P: Set, Default, Output, Pick-list value

$Clocal_{water}$ can be regarded as the $PEC_{surface\ water}$.

$$\mathbf{PEC_{surface\ water} = 0.0257\ mg/L}$$

2.8.3.3 Exposure monitoring and additional thoughts

2.8.3.3.1 DEET in the aquatic compartment

According to the applicant, the release of DEET to groundwater and surface water is insignificant due to the use-pattern of the repellent product.

At the contrary, DEET is systematically detected in waters[4].
In a pan-European study on groundwater contaminants in 23 European countries (Loos et al. (2010)), DEET was classified among the most relevant compounds in terms of both frequency of detection and maximum concentrations detected (up to 0.454 µg/L).
Quednow & Püttmann (2009) identified DEET levels in freshwater up to 1.3 µg/L in summer in Germany.
Similar findings have been observed in other transnational and national studies with a high prevalence of DEET in both surface waters and ground waters in USA and Australia.
A recent study for Swedish EPA (2010) confirmed also that DEET is common in both incoming and outgoing waste water in STPs and is very prevalent in watercourses downstream of STPs.
Weigel et al (2002) demonstrated the ubiquity if DEET in the North Sea, with pollution gradients related to the dominant water currents and concentrations up to 1.1 ng/L.
Such data strengthen the suggestion made at the 2009 meeting, as cited in DEET CAR, that a monitoring method is needed for DEET, and specific provisions are recommended.

Additionally, when reviewing the available aquatic ecotoxicity data for DEET, only acute data is available.

---

[4] Mark W. Sandstrom, Dana W. Kolpin, E. Michael Thurman, And Steven D. Zaugg (2005). Widespread Detection Of N,N-Diethyl-M-Toluamide In U.S. Streams: Comparison With Concentrations Of Pesticides, Personal Care Products, And Other Organic Wastewater Compounds . Environmental Toxicology And Chemistry; Vol. 24, No. 5, p. 1029–1034. Setac (Printed USA)

Kristin Quednow and Wilhelm Püttmann (2009) Temporal concentration changes of DEET, TCEP, terbutryn, and nonylphenols in freshwater streams of Hesse, Germany: possible influence of mandatory regulations and voluntary environmental agreements. Environ Sci Pollut Res.; Vol. 16, p 630–640; DOI 10.1007/s11356-009-0169-6

Stefan Weigel, Jan Kuhlmann, Heinrich Hu¨hnerfuss (2002). Drugs and personal care products as ubiquitous pollutants: occurrence and distribution of clofibric acid, caffeine and DEET in the North Sea. Sci Total Env.. Vol 295; p 131–141

Sweco Environment (2011). Screening of N,N-dietyl-m-toluamid (DEET) Report to Swedish Environmental Protection Agency. SWECO Environment Screening, 29 p

Robert Loos, Giovanni Locoro, Sara Comero, Serafino Contini, David Schwesig, Friedrich Werres, Peter Balsaa, Oliver Gans, Stefan Weiss, Ludek Blaha,Monica Bolchi, Bernd Manfred Gawlik (2010). Pan-European survey on the occurrence of selected polar organic persistent pollutants in ground water. Water Research, Vol 44; p 4115-4126.

Acute toxicity of DEET to fish, daphnia and algae is low, but studying effects of long term, chronic, exposure appears relevant, given the widespread distribution of DEET in fresh and marine waters and possible uptake. For example, DEET might facilitate the passage of organophosphorus pesticides through the blood–brain barrier and raise effects of these compounds which are present in many parts of the North Sea, in marine organisms.

Nevertheless, as was the case for the monitoring data evaluated in the CAR, the noted peak maximum measured concentrations in waters (fresh, salt, and ground) were all in the range of, or below the estimated values, indicating that the calculated PECs do represent a realistic worst case exposure.

2.8.3.3.2 DEET in the atmosphere

According to the assessment report, emission to air due to spraying product does not need consideration, given the use pattern, vapour pressure and Henry's law constant.
However, DEET concentration has been measured in the PM2.5 faction in traffic-tunnel exit, in urban parks and rural sites in Canada, indicating widespread of DEET with relation both to summer consumer use and spraying livestock [5].

2.8.4 Risk Characterisation

In order to evaluate if the intended use of the product Mouskito Travel Roller, containing 50 % DEET as active substance, poses unacceptable risks for the environment, the ecotoxicity of DEET is compared with the exposure estimates by dividing the latter by the former. This ratio is also known as the RCR of risk characterisation ratio.

2.8.4.1 Aquatic compartment (incl. sediment)

In the tables below, the exposure estimates for the aquatic compartment for each of the calculated scenarios are compared to their respective PNEC value.

Table 8.2-8: Aquatic risk characterisation for the EUtonnage based scenario (cfr. DEET CAR)

Compartment		**PEC**	**PNEC**	**RCR**
STP micro-organisms	[mg/L]	0.0322	> 10	< 0.0032
Freshwater	[mg/L]	$3.3x10^{-3}$	0.043	0.077
Sediment, freshwater	[mg/kg_{ww}]	$5,7x10^{-3}$	0.0741	0.077
Saltwater	[mg/L]	$2.56x10^{-3}$	0.0043	0.60

All calculated RCRs, based on the exposure estimates from the estimated EU tonnage for DEET, are below 1.
As mentioned before, care has to be taken when reusing these calculations in the future that the tonnage of DEET placed on the EU market has not been significantly augmented throughout the years.

Table 8.2-9: Aquatic risk characterisation for the BE tonnage based scenario

Compartment	**PEC**	**PNEC**	**RCR**

[5] Cheng Y, Li S-M, Leithead A (2006) Chemical characteristics and origins on nitrogen containing organic compounds in the Lower Fraser Valley Environ Sci Technol vol 40, p:5846–5852

STP micro-organisms	[mg/L]	$4.7x10^{-4}$	> 10	$< 4.7x10^{-5}$
Freshwater	[mg/L]	$4.7x10^{-5}$	0.043	$1.09x10^{-3}$
Sediment, freshwater	[mg/kg_{ww}]	$8.1x10^{-5}$	0.0741	$1.09x10^{-3}$
Saltwater	[mg/L]	$3.8x10^{-5}$	0.0043	$8.84x10^{-3}$

All calculated RCRs, based on the exposure estimates from the annual sales volume of Mouskito Travel Roller in Belgium for the years 2011 and 2012, are below 1.

Table 8.2-10: Aquatic risk characterisation for the exposure estimates based on the PT1 scenario

Compartment		**PEC**	**PNEC**	**RCR**
STP micro-organisms	[mg/L]	0.257	> 10	0.03
Freshwater	[mg/L]	0.0257	0.043	0.598

All RCRs calculated based on the PT1 scenario are below 1.

Overall conclusion for the aquatic compartment
Non of the calculated emission rates exceeded their respective PNECs. Therefore it can be concluded that no risks for the aquatic compartment are expected when using Mouskito Travel Roller as intended.

2.8.4.2 Terrestrial compartment

None of the calculated PEC/PNEC ratios exceed 1.

Table 8.2-11: Terrestrial risk characterisatio

Scenario		**PEC**	**PNEC**	**RCR**
EUSES EU tonnage	[mg/kg_{ww}]	$2.74x10^{-3}$	0.0379	0.073
EUSES BE tonnage	[mg/kg_{ww}]	$3.78x10^{-5}$	0.0379	$9.98x10^{-4}$

Overall conclusion for the aquatic compartment
No risks for the terrestrial compartment are expected when using Mouskito Travel Roller as intended.

2.9 Measures to protect man, animals and the environment

The instructions for use must contain the following indications:

The recommended use level is 2 times a day.
The applicant needs to mention the factors who will reduce the protection time, namely: swimming, strong transpiration and an insufficient quantity applied to the body surface.

Mouskito Travel Roller should only be applied to children older than 2 years.
The use of the repellent for children between 2 and 12 years should be restricted to one application per day.

To prevent children from ingestion of the product via hand to mouth the label should indicate that the product should not be applied to the hands of children younger than 12 years old.

There are no specific instructions with regard to transport of the product.

The instructions for use contain the following indications with regard to first aid measures:

- In case of ingestion : rinse the mouth. Call the Antipoison Centre to ask if it is recommended to drink an active coal suspension. Immediately consult a physician. Show the label, the packaging or the notice.
- In case of contact with the eyes : rinse abundantly with water during 10 minutes. Rinse in the direction away from the non affected eye. In case of contact lenses : if they are easy to remove, remove the lenses before rinsing. Consult a physician. Show him the label, the packaging or the notice.

These instructions and safety measures are compliant with relevant legislation and appropriately cover potential hazards and risks related to the product.

3 Proposal for decision

The assessment presented in this report has shown that the ready-to-use product, Mouskito Travel Roller formulated by Laboratoria QUALIPHAR N.V./S.A. with the active substance DEET, at a level of 30 % w/w, may be authorised for use as a repellent (product-type 19) against mosquitoes, biting flies and wasps.

This authorisation of the product Mouskito Travel Roller has duly taken in to consideration the conclusions and recommendations of both the Swedish Assessment Report for the active substance, DEET and Commission Directive 2010/51/EU including DEET in Annex I of Directive 98/8/EC.

Regarding the physico-chemical properties the storage stability is a point of concern. The only acceptable result in a study at ambient temperature that is available for MOUSKITO TRAVEL ROLLER is after 6 months. This is not an acceptable shelf life for this type of product. However, two accelerated stability tests were introduced and give acceptable results. Furthermore, the applicant has committed to continue an on-going study at ambient temperature up to 60 months, and introduce the results when they are available. We therefore propose to consider the formulation MOUSKITO TRAVEL ROLLER as stable for two years, but set the condition that the applicant has to submit the results of the stability study at ambient temperature over one year before September 15th 2014, and two years before September 15th 2015. If the applicant fails to comply with this condition, or the submitted results are not acceptable, the authorisation for MOUSKITO TRAVEL ROLLER has to be revoked immediately.

The product was shown to be efficacious against the intended target organisms. However following the RVIM Report 320005002/2006: Pest control Products Fact Sheet, H.J. Bremmer et al. an adult will apply an amount of about 3g on his body surface instead of 6g. This results in a reduction of the protection time. The recommended use level is 2 times a day. The applicant needs to mention the factors who will reduce the protection time namely: swimming, strong transpiration and an insufficient quantity applied to the body surface.
The BE MRS considers that the results demonstrate that Mouskito Travel Roller has a good efficacy against flying insects. The estimated protection time is approximately 8hours against mosquitoes and wasps and approximately 5hours against flies. This results in a general protection time of approximately 5hours.

Regarding the toxicology the product Mouskito Travel Roller has to be classified as irritating to the eyes. Safety phrases and precautionary statements are proposed. Except for the active substance DEET, the biocidal product contains no other substances in quantities that would be of toxicological concern.

The exposure assessment shows when applying Mouskito Travel Roller under reasonable conditions of use (i.e. 2 applications per day), no harmful effects to human health are to be expected for adults and children > 12 years. However for children < 12 years the use of the product should be restricted to one application per day. Otherwise the acceptable exposure could be exceeded and no safe use is guaranteed.

The environmental assessment shows that no risks for the aquatic or terrestrial compartment are expected when using Mouskito Travel Roller as intended
A classification as “Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment” is required.

Annex:

1. **Summary of product characteristics : see separate document**
2. **List of studies reviewed**
3. **Toxicology and metabolism –active substance**
4. **Toxicology – biocidal product**
5. **Safety for professional operators**
6. **Safety for non-professional operators and the general public**
7. **Confidential information**

Annex 2: List of studies reviewed

List of <u>new data</u>[6] submitted in support of the evaluation of the active substance

No new data submitted.

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

Concerning the toxicology of the product :

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
IIIb annex 5a	TAO423-PH-11/0192	F. Richeux	2011	Mouskito Travel Spray: evaluation of acute oral toxicity in rats - acute toxic class method	Laboratoria Qualiphar N.V./S.A.		X	X	
IIIb annex 5b	TAD-PH-11/0192	F. Richeux	2011	Mouskito Travel Spray: evaluation of acute dermal toxicity in rats	Laboratoria Qualiphar N.V./S.A.		X	X	
IIIb annex 5c	IC-OCDE-PH-11/0192	F. Richeux	2011	Mouskito Travel Spray: assessment of acute dermal irritation	Laboratoria Qualiphar N.V./S.A.		X	X	
IIIb annex 5d	SMK-PH-11/0192	F. Richeux	2011	Mouskito Travel Spray: assessment of sensitising properties on albino guinea pigs - maximisation test according to Magnusson and Kligman.	Laboratoria Qualiphar N.V./S.A.		X	X	

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

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
IIIb annex 5e	NOTOX 500039	I.A.T.M. Meerts	2012	Determination of the dermal absorption of N,N-diethyl-m-toluamide (DEET) in different formulations through human skin in vitro	Laboratoria Qualiphar N.V./S.A.	Not specified		X	
Add rows as necessary									

Concerning the efficacy of the product :

Section No	Reference No	Author	Year	Title	Owner of data	Letter of Access		Data protection claimed	
						Yes	No	Yes	No
DOC III-B5	1477-PIR/1211	Bruno Serrano	2011	Laboratory assessment of five personal skin repellents against mosquitoes	Qualiphar N.V.		X	X	
DOC III-B5	1639c-PIR/0713	Bruno Serrano	2013	Laboratory assessment of a personal skin repellent against stomoxys biting flies	Qualiphar N.V.		X	X	
DOC III-B5	1477b3-PIR/1211	Bruno Serrano	2011	Laboratory assessment of a personal skin repellent against mosquitoes	Qualiphar N.V.		X	X	
DOC III-B5	1639e-PIR/0713	Bruno Serrano	2013	Laboratory assessment of a personal skin repellent against Wasps	Qualiphar N.V.		X	X	
Add rows as necessary									

N,N- diethylmetatoluamide (DEET)

Threshold Limits and other Values for Human Health Risk Assessment

Summary

	Value	Study	Safety factor
AEL_{acute}	0.75 mg/kg body weight/day	8-week oral study in dog (NOAEL: 75 mg/kg body weight/day)	100
$AEL_{chronic}$	8.2 mg/kg body weight/day	90-day dermal study in rat (NOAEL: 1000 mg/kg body weight/day; 82% absorption)	100

Inhalative absorption	No data submitted
Oral absorption	> 80% (rat)
Dermal absorption	82% (rat) and < 20% (human)

Classification

with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	-  (Xn; Harmful) - R22 (Harmful if swallowed) -  (Xi; Irritating) - R36/38 (Irritating to eyes and skin) - R52-53 (Harmful to aquatic organisms; May cause long-term adverse effects in the aquatic environment)
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	* Hazard class and category codes - Acute Toxicity category 4 - Eye Irritation category 2 - Skin Irritation category 2 - Aquatic Chronic category 3 * Hazard statement codes - H302 (Harmful if swallowed) - H315 (Causes skin irritation) - H319 (Causes serious eye irritation) - H412 (Harmful to aquatic life with long lasting effects)

Mouskito Travel Roller

General information

Formulation Type	Roller
Active substance(s) (incl. content)	N,N- diethyl-meta-toluamide 50 w/w %
Category	Product-Type 19

Acute toxicity, irritancy and skin sensitisation of the preparation (Annex IIIB, point 6.1, 6.2, 6.3)	
Rat LD50 oral (OECD 420)	> 2000 mg/kg body weight
Rat LD50 dermal (OECD 402)	> 2000 mg/kg body weight
Rat LC50 inhalation (OECD 403)	No data submitted
Skin irritation (OECD 404)	Not irritating to skin
Eye irritation (OECD 405)	Considered irritating to eyes
Skin sensitisation (OECD 429; LLNA)	No skin sensitising properties

Additional toxicological information (e.g. Annex IIIB, point 6.5, 6.7)	
Short-term toxicity studies	No additional data submitted
Toxicological data on active substance(s) (not tested with the preparation)	- LD50 dermal: > 2000 mg/kg body weight (rabbit) and > 5000 mg/kg body weight (rat) - LD50 inhalation: > 2.02 mg/L - Slightly irritating to skin - Not skin sensitising - Not genotoxic - Not carcinogenic - Not embryotoxic or teratogenic - Not toxic to reproductive system - Rat-specific nephrotoxic - Ambivalent data on neurotoxicity - NOAEL (90-day dermal toxicity study in rat): 1000 mg/kg body weight/day - NOAEL (8-week study in dog): 75 mg/kg body weight/day
Toxicological data on non-active substance(s)	No data submitted
Further toxicological information	No data submitted

Classification proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Directive 1999/45/EC	- Xi (irritating) R36 (Irritating to eyes)
Regulation 1272/2008/EC	Pictogram GHS07

	- Wng (Warning) - Eye Irrit. 2, H319 (Causes serious eye irritation)

Labelling of the polypropylene bottles of 75 ml with a polypropylene cap proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Directive 1999/45/EC	- Xi (irritating) S2 : Keep out of the reach of children S13 : Keep away from food, drink and animal foodstuffs S46 : If swallowed, seek medical advice immediately and show this container or label
Regulation 1272/2008/EC	Pictogram GHS07 - Wng (Warning) P102 : Keep out of reach of children P270 : Do not eat, drink or smoke when using this product P301+P312 : IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

Product is not intended for professional use.

Annex 6: Safety for non-professional operators and the general public

Mouskito Travel Roller

General information	
Formulation Type	Any other liquid
Active substance(s) (incl. content)	DEET (300 g/kg)
Category	PT19
Authorisation number	

DEET

Data base for exposure estimation	
based on Users study - Boomsma, JC and Parthasarathy, M (1990) Human Use and Exposure to Insect Repellants Containing DEET	Appendix: Toxicology and metabolism – active substance/CAR

Exposure scenarios for intended uses (Annex IIIB, point 6.6)	
Primary exposure	Non-professional users (consumers, adults and children)
Secondary exposure, acute	Not relevant
Secondary exposure, chronic	Not relevant

Conclusion:
Exposure of non-professionals and the general public to the biocidal product containing DEET as active substance is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

Details for the exposure estimates:

Mouskito Travel Roller **adult man**

	Value	Unit	
Remark :			
Concentration a.s. in used product	300	g / kg	DEET
User :	general public		

Dermal exposure

Amount of DEET from a 26.1% DEET repellent	1500	mg	Users study[7]
Total deposit of product	5747	mg	
Total deposit of active substance	1724	mg	
Exposure to active substance via the skin	1724	mg / event	
Number of events per day	2	/ d	
Bodyweight	70	kg	
External Dermal exposure on contact day	**49**	**mg / kg bw**	
Dermal Absorption	**9.5**	**%**	
Internal Dermal exposure on contact day	**4.68**	**mg / kg bw**	
Number of contact days per year	27	/ year	
Year averaged internal dermal exposure	**0.35**	**mg / kg bw / d**	

[7] Boomsma, JC and Parthasarathy, M (1990) Human Use and Exposure to Insect Repellants Containing DEET

Mouskito Travel Roller — adult woman

	Value	Unit	
Remark :			
Concentration a.s. in used product	300	g / kg	DEET
User :	general public		

Dermal exposure

Amount of DEET from a 26.1% DEET repellent	1000	mg	Users study
Total deposit of product	3831	mg	
Total deposit of active substance	1149	mg	
Exposure to active substance via the skin	1149	mg / event	
Number of events per day	2	/ d	
Bodyweight	60	kg	
External Dermal exposure on contact day	**38**	**mg / kg bw**	
Dermal Absorption	**9.5**	**%**	
Internal Dermal exposure on contact day	**3.6**	**mg / kg bw**	
Number of contact days per year	27	/ year	
Year averaged internal dermal exposure	**0.27**	**mg / kg bw / d**	

Mouskito Travel Roller — Child > 12 years

	Value	Unit	
Remark :			
Concentration a.s. in used product	300	g / kg	DEET
User :	general public		

Dermal exposure

Amount of DEET from a 26.1% DEET repellent	1660	mg	Users study
Total deposit of product	6360	mg	
Total deposit of active substance	1908	mg	
Exposure to active substance via the skin	1908	mg / event	
Number of events per day	2	/ d	
Bodyweight	62.8	kg	
External Dermal exposure on contact day	**61**	**mg / kg bw**	
Dermal Absorption	**9.5**	**%**	
Internal Dermal exposure on contact day	**5.77**	**mg / kg bw**	
Number of contact days per year	27	/ year	
Year averaged internal dermal exposure	**0.34**	**mg / kg bw / d**	

Mouskito Travel Roller **Child** **< 12 years**

	Value	Unit	
Remark :			
Concentration a.s. in used product	300.00	g / kg	DEET
User :	general public		

Dermal exposure

Amount of DEET from a 26.1% DEET repellent	1420	mg	Users study
Total deposit of product	5441	mg	
Total deposit of active substance	1632	mg	
Exposure to active substance via the skin	1632	mg / event	
Number of events per day	2	/ d	
Bodyweight	25.5	kg	
External Dermal exposure on contact day	**128**	**mg / kg bw**	
Dermal Absorption	**9.5**	**%**	
Internal Dermal exposure on contact day	**12.16**	**mg / kg bw**	
Number of contact days per year	27	/ year	
Year averaged internal dermal exposure	**0.90**	**mg / kg bw / d**	

[redacted]

- [redacted]
- [redacted]

[redacted]

ADDENDUM : AMENDMENT (ART. 48)

RE-EVALUATION OF HUMAN EXPOSURE-EFFICACIOUS DOSE

Following the Art.36 decision of the Commission on the terms and conditions of the authorisations of biocidal products containing IR3535 (discrepancy Efficacy-HH), the exposure assessment of PT19 products containing DEET must be performed according to the validated efficacious dose.
BE was rMS for the product “Mouskito Travel Roller” containing DEET. In the original PAR, the exposure assessment has not been performed using the validated efficacious dose.
As a consequence of the Commission implementing decision (EU) 2018/1477 we have amended the authorization of the dossier taking into account the efficacious dose according to the provisions of art.48.

Conclusion

The general conclusions regarding the authorization of “Mouskito Travel Roller” are not affected by the present amendment. This amendment affects only the application dose and number of authorized uses per age class.
Proper use, i.e. use in compliance with correct and complete conditions on the label, of Mouskito travel Roller is considered safe for adults when applied once a day.

Summary of the product assessment

1.1.1 Administrative information

1.1.1.1 Identifier of the product

Identifier[8]	**Country (if relevant)**
Mouskito Travel Roller	Belgium

1.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Laboratoria QUALIPHAR N.V./S.A.
	Address	Rijksweg 9 – 2880 Bornem - Belgium

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

Authorisation number	BE2014-0028
Date of the authorisation	2014-07-29
Expiry date of the authorisation	2024-07-31

1.1.1.3 Manufacturers of the products

Name of manufacturer	Cosmade BVBA
Address of manufacturer	Impulsstraat 3A – 2220 Heist-op-den-Berg - Belgium
Location of manufacturing sites	Belcofill BVBA - Impulsstraat 7 – 2220 Heist-op-den-Berg - Belgium

1.1.1.4 Manufacturer of the active substance

Active substance	N,N-Diethyl-meta-toluamide
Name of manufacturer	Vertellus Performance Materials Inc.
Address of manufacturer	High Point Road 2110 27403-2642 Greensboro , North Carolina USA
Location of manufacturing sites	High Point Road 2110 27403-2642 Greensboro , North Carolina USA

1.1.1.5 Qualitative and quantitative information on the composition of the biocidal product[9]

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
N,N-Diethyl-metatoluamide	N,N-diethyl-m-toluamide	Active substance	134-62-3	205-149-7	30

1.1.1.6 Type of formulation

AL Any other liquid

[9] Please delete as appropriate.

1.1.2 Hazard and precautionary statements

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

Classification	
Hazard category	Eye irritation, category 2 Aquatic chronic category 3
Hazard statement	H319: Causes serious eye irritation H412: Harmful to aquatic life with long lasting effects
Labelling (75 ml bottle)	
Signal words	Warning
Hazard statements	H412: Harmful to aquatic life with long lasting effects
Precautionary statements	P102 Keep out of reach of children.
Note	GHS07

For reduced labelling (volumes <125ml) art. 29(2) and Annex I pt 1.5.2.1 of Regulation (EC) No 1272/2008 was followed.

1.1.3 Authorised use(s)

1.1.3.1 Use description[10]

Table 1. Use # 1 – Spray to repel mosquitoes, flies and wasps from human skin (general public)	
Product Type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	Repellent
Target organism (including development stage)	Culicidae:-all stadia-House mosquitoe Culicidae:-all stadia-Aedes mosquitoes Muscidae:-all stadia-Stable flies Hymenoptera: Vespinae:-all stadia-Common wasp Mouskito Travel Roller is a repellent used to protect humans against flying insects such as mosquitoes, flies and wasps. It is applied on unprotected skin.
Field of use	indoors in well ventilated areas and outdoors
Application method(s)	Spreading Bottle with roller, applied directly on unprotected skin.
Application rate(s) and frequency	Maximum number of applications per day: Adults: 1 application per day Not suitable for children <12 years Mouskito Travel Roller applied on the skin in areas with moderate climate at a dose of 1 g for 600 cm^2 provides a protection time of 8 hours against mosquitoes and wasps and of 5 hours against flies. Dose per application: Adults: 15.2 g

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

Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Please see the relevant section. **Type** **Material** **Size** Bottle Plastic: PP 75 mL

1.1.3.2 Use-specific instructions for use[11]

Adults: max 1 application per day. Not suitable for children under 12 years of age.

Apply to the uncovered skin. Moisturize the skin sufficiently with the product. The product should be applied to dry skin. Ensure that there is a minimum interval of 30 minutes between application of the product and the application of other skin care products (e.g. sunscreen).

Mouskito Travel Roller protects in temperate areas during 8 hours against mosquitoes and wasps, and during 5 hours against flies.
The protection time will be reduced by: swimming, excessive transpiration and an insufficient quantity applied to the skin.

1.1.3.3 Use-specific risk mitigation measures

Use repellents safely. Always read the label and product information before use.
Not suitable for children below 12 years of age.
Keep out of reach of children.
Avoid breathing vapours.
Use only outdoors or in a well-ventilated area.
ONLY apply to uncovered parts of the arms, hands, legs, feet and face. Do not apply to the eye area. Do not use on children's hands. Do not use under clothing.

Avoid every contact with eyes, mouth and mucous membranes.

Wash hands before handling food. Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed and drinks. To prevent contamination of food, avoid contact of treated skin with food.

Adults and children > 12 years: max. 1 application per day. Not suitable for children <12 years.

The protection time will be reduced by: swimming, excessive transpiration and an insufficient quantity applied to the skin.

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

In case of ingestion: Rinse mouth thoroughly with water. Call a poison center to ask if it is recommended to drink a suspension of activated carbon. Get medical advice/attention. Show the product label, packaging or instructions.
Eye contact: Rinse thoroughly with water for 10 minutes. Rinse away from the unaffected

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

eye. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice. Show the product label, packaging or instructions.

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

Dispose of contents/container in accordance with local/regional/national/international regulations.

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

Shelf life: 4 years

1.1.4 General directions for use

1.1.4.1 Instructions for use

/

1.1.4.2 Risk mitigation measures

/

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

/

1.1.4.4 Instructions for safe disposal of the product and its packaging

/

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

/

1.1.5 Other information

The product is commercialized in a 75 ml bottle. For this volume, only H412 labeling is mandatory. Labeling with H319 is not required on packaging of this size.

Assessment of the product

According to Commission implementing decision (EU) 2018/1477 the amendment of the authorization only concerns the Efficacy and the Human exposure and risk characterization.

I. Efficacy:

Tests submitted by the applicant validate an application rate of 1 g product to be applied on 600 cm² of skin to ensure a CPT of approximately 8 hours against mosquitoes (*Culex pipiens* and *Aedes aegypti*) and wasps (*Vespula sp.*) and approximately 5 hours against flies (*Stomoxys calcitrans*). In the test carried out against wasps, an application rate of 0.5 g / 600 cm² was used. However, this test was not carried out according to the intended use, meaning an application on skin, the validated application rate remains 1 g of product for 600 cm², which corresponds to for 1.6 mg product/cm² (0.5 mg DEET/cm²). The efficacy conclusions remain valid.

II. Human exposure and risk characterisation:

1. Exposure assessment

PAR 1.5.2: Information on the intented uses: Use limited to children > 2 years and to adults.

(I) General information

General default values for exposure assessment

Age groups	Body weight [kg]	Total body surface area [cm²]
ADULT irrespective of gender (based on female 30 to <40 years old)	60	16600
CHILD 6 to < 12 years old irrespective of gender (based on female 6 to <11 years old)	23.9	9200
CHILD 2 to < 6 years old irrespective of gender (based on data from female 2 to <6 years old)	15.6	6800

[1] Recommendation no. 14 of the BPC Ad hoc Working Group on Human Exposure Default human factor values for use in exposure assessments for biocidal products (revision of HEEG opinion 17 agreed at the Human Health Working Group III on 12 June 2017)

Treated surface and applied amount of biocidal product:

Treated surface:

The treated surface is assumed to be the uncovered parts of the body. According to Recommendation no. 11 of the BPC Ad hoc Working Group on Human Exposure : Proposal for harmonising the assessment of human exposure to repellents (PT19) (Version 2.1 agreed at Human Health Working Group V on 22 November 2017), the uncovered body surface area corresponds to 55% of the total body surface.

Amount of biocidal product:

Following the efficacy assessment for this product, the efficacious application rate is 1g product/600 cm^2 skin, or 1.67 mg/cm^2 skin.

Summary : Amount of product used per application for the relevant age groups, treated surface and number of applications per day			
Age groups	**Amount of product used per application [g]**	**Treated surface [cm^2]**	**number of applications per day**
ADULT irrespective of gender (based on female 30 to <40 years old)	15.2	9130	2 applications/day
CHILD 6 to < 12 years old irrespective of gender (based on female 6 to <11 years old)	8.5	5060	1 application/day
CHILD 2 to < 6 years old irrespective of gender (based on data from female 2 to <6 years old)	6.2	3740	1 application/day

Dermal absorption:

Dermal absorption : 9.5 % ±0.3%; value used for RA = 9.8%[12]

[12] Data derived from in vitro tests done on Mouskito Travel Roller (30% DEET); calculated by addition of the standard deviation to the mean value (EFSA Guidance on Dermal Absorption, EFSA Journal 2012; 10(4):2665 section 5.4)

(II) Non-professional exposure

Scenario 1: Primary exposure: Dermal exposure assessment for adults, children

Description of Scenario 1
In the previous risk assessment, the exposure was calculated, as suggested in the CAR for DEET, based on the 75th percentile of the data of a mail survey and usage study from Boomsma, JC and Parthasarathy, M (1990) Human Use and Exposure to Insect Repellents Containing DEET (see also HEAdHoc Recommendation 11[13]). However, pursuant to Article 48(1)(a) of the BPR and following CA-Nov-Doc.4.7-Final[14], eCA BE amends the authorisation for Mouskito Travel Roller as we consider that the conditions referred to in Article 19 are not satisfied. More specifically, the exposure assessment should be performed according to the validated efficacious dose.
Dermal exposure: Number of applications/day x amount b.p./application x percent of a.s. in b.p. **Systemic exposure:** Dermal exposure x percent of dermal absorption **Dermal systemic exposure:** Systemic exposure / body weight

	Parameters	Value
For All categories	Dermal absorption	9.8%
	% of active substance in biocidal product[1]	30%
Tier 1- Adult	Number of applications / day	2
	Body weight[1]	60 kg
	Amount of biocidal product/ application[1]	15.2 g
Tier 1- Child 6 to < 12 years old	Number of applications / day	1
	Body weight[1]	23.9 kg
	Amount of biocidal product/ application[1]	8.5 g
Tier 1- Child 2 to < 6 years old	Number of applications / day	1
	Body weight[1]	15.6 kg
	Amount of biocidal product/ application[1]	6.2 g
Tier 2- Adult	Number of applications / day	1

[13] HEAdHoc Recommendation 11, Proposal for harmonising the assessment of human exposure to repellents (PT19), Jan 18th 2018.

[14] CA-Nov-Doc.4.7-Final - Note agreed by Member States' Competent Authorities for Biocidal Products - Insect repellents: adaptation of products already authorised with a discrepancy between the dose used in the efficacy studies and in the exposure assessment

Calculations for scenario 1

Summary table: estimated exposure for Dermal Primary exposure		
Exposure scenario	**Tier/PPE**	**Estimated dermal uptake**
Scenario 1 – ADULT 2 applications/day	Tier 1 / no PPE	14.9 mg/kg bw/day
Scenario 1 – CHILD (6-12) 1 application/day	Tier 1 / no PPE	10.4 mg/kg bw/day
Scenario 1 – CHILD (2-6) 1 application/day	Tier 1 / no PPE	11.8 mg/kg bw/day
Scenario 1 – ADULT 1 application/day	Tier 2 / no PPE	7.5 mg/kg bw/day

(III) Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1.	Non-professionals, adult	Tier 1, no PPE, dermal, 2 applications/day	14.9 mg/kg bw/day
	Non-professionals, child (6-12)	Tier 1, no PPE, dermal, 1 application/day	10.4 mg/kg bw/day
	Non-professionals, child (2-6)	Tier 1, no PPE, dermal, 1 application/day	11.8 mg/kg bw/day
	Non-professionals, adult	Tier 2, no PPE, dermal, 1 application/day	7.5 mg/kg bw/day

2. Risk characterisation for human health

2.1 Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL)	AF[1]	Correction for oral/dermal absorption	Value
AEL_{acute}	Dog, oral, 8-week toxicity study	75 mg/kg bw/d	100	100%	0.75 mg/kg bw/d
$AEL_{long\text{-}term}$	Rat, dermal, 90-days toxicity study	1000 mg/kg bw/d	100	82%	8.2 mg/kg bw/d

2.2 Risk for non-professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL [mg/kg bw/d]	AEL [mg/kg bw/d]	Estimated Uptake [mg/kg bw/d]	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Scenario 1, dermal, adult	1	1000	8.2	14.9	182	No
Scenario 1, dermal, child (6-12)	1	1000	8.2	10.4	127	No
Scenario 1, dermal, child (2-6)	1	1000	8.2	11.8	144	No
Scenario 1, dermal, adult	2	1000	8.2	7.5	91	Yes

Conclusion

Safe uses are identified for this product, Mouskito Travel Roller, for **adults**, when the product is applied **once per day**.
For children, no safe use was identified.

Proper use, i.e. use in compliance with correct and complete conditions on the label, of Mouskito Travel Roller is considered safe for adults when applied once a day.

The following RMM are required:

- Use repellents safely. Always read the label and product information before use.
- Not suitable for children below 12 years of age. Keep out of reach of children. Avoid breathing vapours. Use only outdoors or in a well-ventilated area.
- ONLY apply to uncovered parts of the arms, hands, legs, feet and face. Do not apply to the eye area. Do not use on children's hands. Do not use under clothing.
- Wash hands before handling food.
- Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed and drinks.
- To prevent contamination of food, avoid contact of treated skin with food.

Maximum number of applications per day: adults: once a day.