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***ANNEX***

**SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT**

Jungle Formula Maximum Roll-on

**Product type(s)**

PT19: Repellents and attractants

**Authorisation number:** IE/BPA 70320

**R4BP asset number:** IE-0010148-0000

## 1. ADMINISTRATIVE INFORMATION

### 1.1. Trade name(s) of the product

Trade name(s)	Mosquito Milk Roll On 50% DEET
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### 1.2. Authorisation holder

Name and address of the authorisation holder	Name	Perrigo Supply Chain International DAC
	Address	The Sharp Building - Hogan Place D02 TY74 Dublin Ireland
Authorisation number	IE/BPA 70320	
<i>R4BP asset number</i>	IE-0010148-0000	
Date of the authorisation	12/07/2016	
Expiry date of the authorisation	30/04/2024	

### 1.3. Manufacturer(s) of the product

Name of manufacturer	Omega Pharma Manufacturing GmbH & Co. KG
Address of manufacturer	Benzstraße 25 71083 Herrenberg Germany
Location of manufacturing sites	Benzstraße 25 71083 Herrenberg Germany

Name of manufacturer	Medgenix Benelux n.v.
Address of manufacturer	Vliegveld 21 8560 Wevelgem Belgium
Location of manufacturing sites	Vliegveld 21 8560 Wevelgem Belgium

### 1.4. Manufacturer(s) of the active substance(s)

Active substance	N,N-diethyl-meta-toluamide
Name of manufacturer	Vertellus Performance Materials Inc.
Address of manufacturer	2110 High Point Road NC 27403 Greensboro United States (the)
Location of manufacturing sites	2110 High Point Road NC 27403 Greensboro United States (the)

Active substance	N,N-diethyl-meta-toluamide
Name of manufacturer	Clariant Corporation
Address of manufacturer	625 E. Catawba Avenue NC 28120 Mt. Holly Belgium
Location of manufacturing sites	625 E. Catawba Avenue NC 28120 Mt. Holly United States (the)

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## 2. PRODUCT COMPOSITION AND FORMULATION

### 2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
N,N-diethyl-meta-toluamide	N,N-diethyl-m-toluamide	active substance	134-62-3	205-149-7	50
Ethanol	Ethyl alcohol	Non-active substance	64-17-5	200-578-6	38,31

### 2.2. Type(s) of formulation

AL Any other liquid

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### 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H225: Highly flammable liquid and vapour. H318: Causes serious eye damage. EUH208: Contains linalool, benzyl benzoate. May produce an allergic reaction.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P260: Do not breathe vapours. P271: Use only outdoors or in a well-ventilated area. P305: IF IN EYES: P351: Rinse cautiously with water for several minutes. P338: Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER.

## 4. AUTHORISED USE(S)

### 4.1. Use description

**Table 1. Mosquito repellent**

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	This product can only be used to repel mosquitoes to protect people.
Target organism(s) (including development stage)	Scientific name: Culicidae: Culicidae: Common name: house mosquito Development stage: no data  Scientific name: Culicidae: Culicidae: Common name: Anopheles mosquitoes Development stage: no data  Scientific name: Culicidae: Culicidae: Common name: Aedes mosquitoes Development stage: no data
Field(s) of use	indoor use outdoor use Other  Indoors in well ventilated areas and outdoors. Use on Skin.
Application method(s)	Method: Roll on  Detailed description: Apply sparingly on the uncovered parts of the body. Spread equally. Do not apply on the face. Do not apply on damaged skin. Use ca. 1 ml per 600 cm <sup>2</sup> of skin (corresponds with 1 ml per adult male arm)
Application rate(s) and frequency	Application rate: 1 ml/ 600 cm <sup>2</sup>  Dilution (%): 0  Number and timing of application: 1 / day
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Bottle, Glass , 50 mL Bottle, Plastic: HDPE , 50 mL 50 mL glass or HDPE flask Opening 30 mm Closure PP cap and PE fitment with PP ball

#### 4.1.1. Use-specific instructions

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#### 4.1.2. Use-specific risk mitigation measures

#### 4.1.3. Use-specific risk mitigation measures

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

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**4.1.5. Where specific to the use, the instructions for safe disposal of the product and its packaging**

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

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## **5. GENERAL DIRECTIONS FOR USE<sup>1</sup>**

### **5.1. Instructions for use**

This product can only be used to repel mosquitoes to protect people.

This product is intended for non-professional use only.

This product provides on average 12 hours of protection against the most common mosquito species in the Netherlands. For some tropical mosquito species the protection time can be much shorter: on average 7 hours against the yellow fever mosquito and 10 hours against the malaria mosquito.

Factors such as temperature, humidity and transpiration can influence the efficacy.

Apply softly and evenly over the bare skin that needs protection. Do not apply on the face.

Avoid contact with eyes, mucous membranes and damaged skin.

Avoid contact with food, plastics and lacquered surfaces.

Use only outdoors or in a well-ventilated area.

Do not use more than once a day.

Not for use on children under 18 years.

### **5.2. Risk mitigation measures**

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### **5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

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### **5.4. Instructions for safe disposal of the product and its packaging**

Do not reuse the packaging and do not dump the product into the environment.

### **5.5. Conditions of storage and shelf-life of the product under normal conditions of storage**

Keep the product dry and do not place it in direct sunlight.

Keep this product away from children.

Close the bottle well

Shelf-life 5 years.

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<sup>1</sup>Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

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## **6. OTHER INFORMATION**

It is recommended that users of products based on DEET consult relevant healthcare professionals when travelling abroad.