

**EN**

***ANNEX***

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

Jungle Formula Medium Spray

**Product type(s)**

PT19: Repellents and attractants

**Authorisation number:** IE/BPA 70315

**R4BP asset number:** IE-0009800-0000

## 1. ADMINISTRATIVE INFORMATION

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

Trade name(s)	Jungle Formula Medium Spray
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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 70315	
<i>R4BP asset number</i>	IE-0009800-0000	
Date of the authorisation	08/11/2013	
Expiry date of the authorisation	12/01/2025	

### 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 United States (the)
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	19,4
ethyl alcohol		Non-active substance	64-17-5	200-578-6	30,2

### 2.2. Type(s) of formulation

AL Any other liquid

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### 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H319: Causes serious eye irritation. H226: Flammable liquid and vapour.
Precautionary statements	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 spray. P270: Do not eat, drink or smoke when using this product. P271: Use only outdoors or in a well-ventilated area. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

## 4. AUTHORISED USE(S)

### 4.1. Use description

**Table 1. Repelling mosquitoes**

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	repellent
Target organism(s) (including development stage)	Scientific name: Culicidae: Culicidae: Common name: culex Development stage: adults  Scientific name: Culicidae: Culicidae: Common name: Anopheles mosquitoes Development stage: adults  Scientific name: Culicidae: Culicidae: Common name: Aedes mosquitoes Development stage: adult
Field(s) of use	indoor use outdoor use  Indoors in well ventilated areas and outdoors.
Application method(s)	Method: spraying  Detailed description: Apply sparingly on the uncovered parts of the body. Spread equally. Do not apply near eyes, lips and damaged skin.
Application rate(s) and frequency	Application rate: Use ca. 1 ml per 600 cm <sup>2</sup> of skin (corresponds with 1 ml per adult male arm)  Dilution (%): 0  Number and timing of application: Do not use more than twice a day
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Airspray, Plastic: HDPE , 15-250ml 15-250 mL HDPE or PP flask. USD and standard Pump Closure PP cap and PP/PE/steel/alu spray pump. Carton box

#### 4.1.1. Use-specific instructions

see general directions for use

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

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

see general directions for use

#### 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

see general directions for use

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

see general directions for use

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

see general directions for use

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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 provides on average 6 hours of protection against the most common mosquito species in North-Western Europe (Culex species). For some (tropical) mosquito species the protection time can be shorter: on average 3 hours against Aedes species (tested against yellow fever mosquitoes) and 4 hours against Anopheles species (tested against malaria mosquitoes).

Apply softly and evenly over the bare skin that needs protection.

For use on the face apply the product first on the hand and then use the hand to apply it to the face.

Do not use more than twice a day.

Not for use on children under 13 years.

Factors such as temperature, humidity and transpiration can influence the efficacy. Repeat use after swimming, showering or when the efficacy decreases.

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

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 and do not inhale the product.

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

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

### **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 2 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