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***ANNEX***

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

Jungle Formula Maximum Spray

**Product type(s)**

PT19: Repellents and attractants

**Authorisation number:** IE/BPA 70318

**R4BP asset number:** IE-0009719-0000

## 1. ADMINISTRATIVE INFORMATION

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

Trade name(s)	Jungle Formula Maximum 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 70318	
<i>R4BP asset number</i>	IE-0009719-0000	
Date of the authorisation	01/08/2014	
Expiry date of the authorisation	31/01/2025	

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

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

Name of manufacturer	Omega Pharma Manufacturing GmbH
Address of manufacturer	Benzstrasse 25 71083 Herrenberg Germany
Location of manufacturing sites	Benzstrasse 25 71083 Herrenberg Germany

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

Active substance	N,N-diethyl-meta-toluamide
Name of manufacturer	Vertellus
Address of manufacturer	2110 High Point Road NC 27403 Greensboro United States (the)
Location of manufacturing sites	2110 High Point Road 3660 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	48,5
Ethanol	Ethyl Alcohol	Non-active substance	64-17-5	200-578-6	37,77

### 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. H319: Causes serious eye irritation. EUH208: Contains linalool, linalyl acetate. May produce an allergic reaction.
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P102: Keep out of reach of children. 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.

## 4. AUTHORISED USE(S)

### 4.1. Use description

**Table 1. Insect Repellent for human use**

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: house mosquito Development stage: adults  Scientific name: Culicidae: Culicidae: Common name: Aedes mosquitoes Development stage: adults  Scientific name: Culicidae: Culicidae: Common name: Anopheles mosquitoes Development stage: adults  Scientific name: Ixodidae: Ixodidae: Common name: ticks Development stage: adults  Scientific name: Ixodidae: Ixodidae: Common name: ticks Development stage: nymphs
Field(s) of use	indoor use outdoor use  Indoors in well ventilated areas and outdoors
Application method(s)	Method: spraying  Detailed description: Use ca. 1 ml per 600 cm <sup>2</sup> of skin (corresponds with 1 ml per adult male arm). Apply sparingly to the uncovered parts of the body.
Application rate(s) and frequency	Application rate: 1 ml per 600 cm <sup>2</sup> of skin  Dilution (%): 50  Number and timing of application: Apply 1 time per day
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	15-250 mL PP or HDPE flask.  Opening 13 mm  Closure PP cap and PP/PE/steel/alu spray pump.

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**4.1.1. Use-specific instructions**

See directions for use

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

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

See 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 directions for use

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

See 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 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 and ticks to protect people from bites.

This product is intended for non-professional use only.

This product provides on average 9 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 4 hours against the yellow fever mosquito and 8 hours against the malaria mosquito.

The product provides 8.5 hours protection against ticks.

Factors like temperature, humidity and transpiration may affect the efficacy of the product.

Apply sparingly and evenly on the skin that needs to be protected.

For use on the face apply the product first on the hand and then use the hand to apply it to 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 and do not inhale the product.

Do not use more than once a day.

Not for use on children < 18 years old.

Wash hands after use.

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

Do not breathe spray

Use only outdoors or in a well-ventilated area

Do not use more than once a day

Do not use on children < 18 years old

Wash hands after use

Apply sparingly, do not apply to the whole body but only to exposed skin areas.

### **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 re-use 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 out of reach of children.

Keep container tightly closed.

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 the instructions of the National Coordination Centre Travellers Information (LCR) when travelling abroad.