

**EN**

***ANNEX***

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

Mosquito Milk Roll On 20% DEET

**Product type(s)**

PT19: Repellents and attractants

**Authorisation number:** UST202005-048

**R4BP asset number:** IS-0024141-0000

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## 1. ADMINISTRATIVE INFORMATION

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

|               |                         |
|---------------|-------------------------|
| Trade name(s) | Mygga Roll-on 20 % DEET |
|---------------|-------------------------|

### 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<br>Dublin Ireland |
| Authorisation number                         | UST202005-048   |   |
| <i>R4BP asset number</i>                     | IS-0024141-0000 |   |
| Date of the authorisation                    | 08/11/2013      |   |
| Expiry date of the authorisation             | 28/03/2024      |   |

### 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 & Co. KG |
| 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 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 Greensboro Belgium            |

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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 | 21,29       |

### 2.2. Type(s) of formulation

AL Any other liquid

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### 3. HAZARD AND PRECAUTIONARY STATEMENTS

|                          |   |
|--------------------------|---|
| Hazard statements        | H226: Flammable liquid and vapour.<br>H318: Causes serious eye damage.<br>EUH208: Contains <name of sensitising substance>. May produce an allergic reaction.   |
| Precautionary statements | P101: If medical advice is needed, have product container or label at hand.<br>P102: Keep out of reach of children.<br>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.<br>P270: Do not eat, drink or smoke when using this product.<br>P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.<br>P310: Immediately call a POISON CENTER. |

## 4. AUTHORISED USE(S)

### 4.1. Use description

**Table 1. Insect Repellent**

|  |  |
|--|--|
| Product type   | PT19: Repellents and attractants   |
| Where relevant, an exact description of the authorised use | Mosquito repellent to protect people   |
| Target organism(s) (including development stage)           | Scientific name: Culicidae: Culicidae:<br>Common name: Aedes mosquitoes<br>Development stage: adults<br><br>Scientific name: Culicidae: Culicidae:<br>Common name: Anopheles mosquitoes<br>Development stage: adults<br><br>Scientific name: Culicidae: Culicidae:<br>Common name: house mosquito<br>Development stage: adults |
| Field(s) of use  | indoor use<br>outdoor use<br><br>Indoors in well ventilated areas and outdoors..   |
| Application method(s)                                      | Method: Rolling<br><br>Detailed description: Apply sparingly on the uncovered parts of the body. Spread equally. Do not apply on the face. Do not apply near damaged skin.   |
| Application rate(s) and frequency                          | Application Rate: apply sparingly<br><br>Dilution (%): 0<br><br>Number and timing of application:<br>Use two times a day maximally   |
| Category(ies) of users                                     | general public (non-professional)  |
| Pack sizes and packaging material                          | Bottle, Glass , 50 mL<br>Bottle, Plastic: HDPE , 50 mL<br>30 mm opening<br>PP dop of PE kop met PP roller  |

#### 4.1.1. Use-specific instructions for use

See general instructions for use

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

See general instructions for use

#### 4.1.3. 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 instructions for use

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

See general instructions for use

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

See general instructions 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 is intended for non-professional use only.

This product provides on average 7 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 6 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 twice a day.

Not for use on children under 13 years.

Re-use after swimming or showering when efficacy decreases.

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

see above

### **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 this product away from children.

Close the bottle well.

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

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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.

Icelandic H and P statements

Hætta

H226: Eldfimir vökvi og gufa.

H318: Veldur alvarlegum augnskaða.

EUH208: Inniheldur línalól, bensýl bensóat. Getur framkallað ofnæmisviðbrögð.

P101: Ef leita þarf læknis skal hafa ílát eða merkimiða tilæk.

P102: Geymist þar sem börn ná ekki til.

P210: Haldið frá hitagjöfum, heitum flötum, neistagjöfum, opnum eldi og öðrum íkveikjuvöldum. reykingar bannaðar.

P270: Neytið ekki matar, drykkjar eða tóbaks við notkun þessarar vöru.

P305+P351+P338: BERIST EFNID Í AUGU: Skolið varlega með vatni í nokkrar mínútur. Fjarlægið snertilinsur ef það er auðvelt. Skolið áfram.

P310: Hringið umsvifalaust í EITRUNARMÍÐSTÖÐ s. 543 2222.