

EN

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 |
|---------------|--------------------------------|

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 | 01/08/2014 | |
| Expiry date of the authorisation | 31/01/2025 | |

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 S tates (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) |

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-met a-toluamide | N,N-diethyl-m-to luamide | active substance | 134-62-3 | 205-149-7 | 50 % (w/w) |
| Ethanol | Ethyl alcohol | Non-Active substance | 64-17-5 | 200-578-6 | 38,31 % (w/w) |

2.2. Type(s) of formulation

AL Any other liquid

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 ² of skin (corresponds with 1 ml per adult male arm) |
| Application rate(s) and frequency | Application rate: 1 ml/ 600 cm ² 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

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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

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

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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

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5. GENERAL DIRECTIONS FOR USE¹

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.

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

6. OTHER INFORMATION

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