

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Mosquito Milk Spray 50% DEET

Product type(s)

PT19: Repellents and attractants

Authorisation number: CH-2017-0004

R4BP asset number: CH-0017335-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Jungle formula maximum original
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Omega Pharma International n.v.
	Address	Venecoweg, 26 9810 nazareth Belgium
Authorisation number		CH-2017-0004
<i>R4BP asset number</i>		CH-0017335-0000
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	Jaico RDP NV
Address of manufacturer	Nijverheidslaan 1545 3660 Opglabbeek Belgium
Location of manufacturing sites	Nijverheidslaan 1545 3660 Opglabbeek Belgium

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 Belgium

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)

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	48,5 % (w/w)
Alcohol Denatur ans	Ethyl Alcohol	Non-Active substance	64-17-5	200-578-6	37,77 % (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. H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects. EUH208: Contains geraniol. 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

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	Insect repellent for human use
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
Field(s) of use	Other
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. Use ca. 1 ml per 600cm ² of skin (corresponds with 1 ml per adult male arm)
Application rate(s) and frequency	Application rate: 1 ml per 600 cm ² of skin Dilution (%): 50 Number and timing of application: 1 time a day
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Bottle, Plastic: HDPE , 15-250 mL Bottle, Plastic: composite: , 15-250 mL composite is polypropylene standard pump and USD pump PP Cap carton box

4.1.1. Use-specific instructions

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 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. Factors such as temperature, humidity and transpiration can influence the efficacy. Apply softly and evenly over the

bare skin that needs protection. 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. Do not use on children < 18 years old. Keep this product away from children. Close the bottle well.

4.1.2. Use-specific risk mitigation measures

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 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. Factors such as temperature, humidity and transpiration can influence the efficacy. Apply softly and evenly over the bare skin that needs protection. 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. Do not use on children < 18 years old. Keep this product away from children. Close the bottle well.

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

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

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

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

4.1.5. Where specific to the use, the 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. Close the bottle well. Shelf-life 5 years.

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 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. Factors such as temperature, humidity and transpiration can influence the efficacy. Apply softly and evenly over the bare skin that needs protection. 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. Do not use on children < 18 years old. Keep this product away from children. Close the bottle well.

5.2. Risk mitigation measures

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 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. Factors such as temperature, humidity and transpiration can influence the efficacy. Apply softly and evenly over the bare skin that needs protection. 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. Do not use on children < 18 years old. Keep this product away from children. Close the bottle well.

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 out of reach of 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