

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Mosquito Milk Spray 50% DEET

Product type(s)

PT19: Repellents and attractants

Authorisation number: UST202005-047

R4BP asset number: IS-0024140-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Mygga Spray 50 % DEET
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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	UST202005-047	
<i>R4BP asset number</i>	IS-0024140-0000	
Date of the authorisation	08/07/2020	
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 Material 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 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-meta-toluamide	N,N-diethyl-m-toluamide	active substance	134-62-3	205-149-7	50
Alcohol Denaturans	Ethyl Alcohol	Non-active substance	64-17-5	200-578-6	37,77

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. EUH208: Contains linalool, linalyl acetate, 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 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. Non-professional

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	This product can only be used to repel mosquitoes
Target organism(s) (including development stage)	Scientific name: Culicidae: Culicidae: Common name: mosquitoes Development stage: adults
Field(s) of use	indoor use outdoor use IV.1 Indoor use (in well ventilated areas) IV.2 Outdoor use
Application method(s)	Method: spraying Detailed description: Spraying: topically applied to human skin
Application rate(s) and frequency	Application rate: 4057.mg to 2669.5cm ² of skin per day Dilution (%): 100 Number and timing of application: Effective as a repellent against mosquitoes and tropical mosquitoes: Culex spp - up to 9 hours Aedes spp - up to 4 hours Anopheles soo - up to 8 hours To be applied once per day
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Plastic HDPE spray bottle: 15-250mL

4.1.1. Use-specific instructions

The following information is required on the biocidal product label: Instructions which clearly inform the user how, when and at what frequency (including maximum number of daily applications) the product is to be applied directly to the skin.

For adults with simultaneous use with other products the following may be treated: face, neck, backs of hands and both lower arms, or equivalent.

This product can only be used to repel mosquitoes to protect people

This product is intended for non-professional use only.

Factors such as temperature, humidity and transpiration can influence the efficacy.

Effectively repels mosquitoes, including aggressive species, for a maximum protection period of 4 hours per application.

It is recommended that clothing is used to cover any untreated areas of skin and so restrict access by biting insects.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

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.

Do not inhale the product

Do not use more than once a day.

Not for use on children under 18 years.

Effectively repels mosquitoes, including aggressive species, for a maximum protection period of 4 hours per application.

It is recommended that clothing is used to cover any untreated areas of skin and so restrict access by biting insects.

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

Inhalation: When inhaled remove to fresh air and seek medical aid

Contact with eyes: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

Ingestion: If swallowed, seek medical advice immediately and show this container or label.

4.1.5. 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.

4.1.6. 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 this product away from children.

Store only in original container.

Shelf-life 2 years.

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

See authorised uses

5.2. Risk mitigation measures

See authorised uses

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

See authorised uses

5.4. Instructions for safe disposal of the product and its packaging

See authorised uses

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

See authorised uses

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

6. OTHER INFORMATION

Hazard and precautionary statements in Icelandic

Hætta

Hazard statements

H225: Mjög eldfimur vövkí og gufa.

H319: Veldur alvarlegri augnertingu.

EUH 208: Inniheldur línalól, línalýl asetat, bensýl bensóat. Getur framkallað ofnæmisviðbrögð.

Precautionary statements

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

P102: Geymist þar sem börn ná ekki til.

P210: Haldið frá hitagjöfum, heitum flötum, neistagjöfum, þnum eldi og öðrum íkveikivöldum. Reykingar bannaðar.

P260: Andið ekki að ykkur úða.

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

P271: Notið eingöngu utandyra eða í vel loftræstu rými.