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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Mosquito Milk Spray 9.5% DEET

Product type(s)

PT19: Repellents and attractants

Authorisation number: UST202005-046

R4BP asset number: IS-0024139-0000

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1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Mygga Spray 9.5% 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	UST202005-046	
<i>R4BP asset number</i>	IS-0024139-0000	
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	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 NC27403 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 NC28120 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	9,5
Ethanol		Non-active substance	64-17-5	200-578-6	36,87

2.2. Type(s) of formulation

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H226: Flammable liquid and vapour. H319: Causes serious eye irritation. EUH208: Contains <name of sensitising substance>. May produce an allergic reaction.
Precautionary statements	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 mist. P270: Do not eat, drink or smoke when using this product. 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.

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	This product can only be used to repel mosquitoes to protect people.
Target organism(s) (including development stage)	Scientific name: Culicidae: Culicidae: Common name: Aedes mosquitoes Development stage: Adults (Insects, mammals (e.g. rodents)) Scientific name: Culicidae: Culicidae: Common name: Anopheles mosquitoes Development stage: Adults (Insects, mammals (e.g. rodents)) Scientific name: Culicidae: Culicidae: Common name: house mosquito Development stage: Adults (Insects, mammals (e.g. rodents))
Field(s) of use	indoor use outdoor use Use only indoors in a well-ventilated area or outdoors.
Application method(s)	Method: spraying Detailed description: Spray evenly and softly over the skin that needs protection. Avoid contact with eyes, mucous membranes and damaged skin.
Application rate(s) and frequency	Application Rate: Spray evenly and softly over the skin that needs protection. Dilution (%): 0 Number and timing of application: 2 times/day
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Bottle - Plastic: HDPE 15 - 250 ml Bottle - Plastic: PP: 15 - 250 ml Opening: 13 mm

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.

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.

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 6 hours of protection against the most common European mosquito species.

For some tropical mosquito species the protection time can be much shorter: on average 2 hours against the yellow fever mosquito and 5 hours against the malaria mosquito.

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

Spray evenly and softly over the bare skin that needs protection.

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 on in a well-ventilated area and do not inhale the product.

Do not use more than twice a day.

Do not use on children under 2 years old and minimize the use for children between 2 and 12 years old.

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

Prevent release to the environment and do not reuse packaging.

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

Keep out of reach of children.

Store in a dry place.

Protect from direct sunlight.

Keep container tightly closed.

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

The signal word, hazard and precautionary statements shall be in Icelandic on the label.

Signal word:

Varúð

Hazard statements:

H226: Eldfímur vökvi og gufa.

H319: Veldur alvarlegri augnertingu.

EUH 208: Inniheldur ísóevgenól, línalól, línalýl asetat og sítrónellal. Getur framkallað ofnæmisviðbrögð.

Precautionary statements:

P102: Geymist þar sem börn ná ekki til.

P260: Andið ekki að ykkur úða.

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

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

P271: Notið eingöngu utandyra eða í vel loftræstu rými.

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