

**EN**

***ANNEX***

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

Mosquito Milk Spray 9.5% DEET

**Product type(s)**

PT19: Repellents and attractants

**Authorisation number:** 1160-2

**R4BP asset number:** DK-0012103-0000

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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 Dublin 2 Dublin Ireland
Authorisation number	1160-2	
<i>R4BP asset number</i>	DK-0012103-0000	
Date of the authorisation	08/11/2013	
Expiry date of the authorisation	12/01/2025	

### 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

### 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)

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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	9,5
Ethanol		Non-active substance	64-17-5	200-578-6	36,87

### 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. 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 spray. 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. The product is intended for non-professional use only. This product provides on average 1.5 hours of protection against the most common mosquito species in Denmark. For malaria mosquitos the protection time is 4 hours. Factors such as temperature, humidity and transpiration can influence the efficacy.
Target organism(s) (including development stage)	Scientific name: Culicidae: Culicidae: Common name: Aedes mosquitoes Development stage: adults  Scientific name: Culicidae: Culicidae: Common name: Anopheles mosquitoes Development stage: adults  Scientific name: Culicidae: Culicidae: Common name: house mosquito Development stage: adults
Field(s) of use	indoor use outdoor use
Application method(s)	Method: spraying  Detailed description: Spray evenly and softly over the skin that needs to be protected.
Application rate(s) and frequency	Application Rate: 1 ml / 600 cm <sup>2</sup>  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 - 75 mL Bottle - Plastic: composite: - 75 mL

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

Spray evenly and softly over the skin that needs to be protected. For use on the face: spray on hands first and apply to the face. Repeat application if necessary after swimming, bathing or when efficacy decreases.

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

Spray evenly and softly over the skin that needs to be protected. For use on the face: spray on hands first and apply to the face. Avoid contact with eyes, mucous membranes and damaged skin. Avoid contact with food, plastics and painted surfaces. Use only outdoors or in a well ventilated place and do not inhale mist. Do not use more than twice a day. Do not use in children under 2 years, and limit the use on children of ages between 2 and 12 years old.

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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**

Avoid contact with eyes, mucous membranes and damaged skin. Avoid contact with food, plastics and painted surfaces. Use only outdoors or in a well ventilated place and do not inhale mist. Do not use more than twice a day. Do not use in children under 2 years, and limit the use on children of ages between 2 and 12 years old. Repeat application if necessary after swimming, bathing or when efficacy decreases.

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

Keep out of reach of children, store in a dry place, out of direct sunlight. Keep container tightly closed. Prevent release to the environment and do not reuse packaging.

**4.1.5. Where specific to the use, the 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, out of direct sunlight. Keep container tightly closed. Shelf-life 5 years.

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## **5. GENERAL DIRECTIONS FOR USE<sup>1</sup>**

### **5.1. Instructions for use**

This product gives an average of 1.5 hours of protection against the most common mosquito species in Denmark. For malaria mosquitoes it is 4 hours. Factors like temperature, humidity and sweating may affect the efficacy of the product. Spray evenly and softly over bare the skin that needs to be protected. For use on the face: spray on hands first and apply to the face. Avoid contact with eyes, mucous membranes and damaged skin. Avoid contact with food, plastics and painted surfaces. Use only outdoors or in a well ventilated place and do not inhale mist. Do not use more than twice a day. Do not use in children under 2 years, and limit the use on children of ages between 2 and 12 years old. Repeat application if necessary after swimming, bathing or when efficacy decreases.

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

Spray evenly and softly over the skin that needs to be protected. For use on the face: spray on hands first and apply to the face. Avoid contact with eyes, mucous membranes and damaged skin. Avoid contact with food, plastics and painted surfaces. Use only outdoors or in a well ventilated place and do not inhale mist. Do not use more than twice a day. Do not use in children under 2 years, and limit the use on children of ages between 2 and 12 years old.

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

Spray evenly and softly over the skin that needs to be protected. For use on the face: spray on hands first and apply to the face. Avoid contact with eyes, mucous membranes and damaged skin. Avoid contact with food, plastics and painted surfaces. Use only outdoors or in a well ventilated place and do not inhale mist. Do not use more than twice a day. Do not use in children under 2 years, and limit the use on children of ages between 2 and 12 years old.

### **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, out of direct sunlight. Keep container tightly closed. Shelf-life 5 years.

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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

### Bilag 1

#### Oplysninger

til etiket og brugsanvisning for Mosquito Milk Spray 9.5% DEET, BPR-reg. nr. 567-4

I. Etiketten skal udformes i overensstemmelse med artikel 69 i biocidforordningen (Forordning (EU) nr. 528/2012), og CLP-Forordningen[1].

#### II. Det er udelukkende

ansøgers/godkendelsesindehaverens ansvar, at etiket, mærkning og pakning lever op til lovens krav, jf. biocidforordningen artikel 69.

Nedstående tekst i afsnit III er bidrag til overholdelsen af reglerne og således kun en del af de krav, som stilles til blandt andet etiketten.

#### III. Etiketten skal indeholde

nedestående oplysninger. Oplysninger i citationstegn skal angives ordret:

##### 1) I hovedfeltet:

”Afskrækningsmiddel (PT19)

Må kun anvendes som afskrækningsmiddel mod myg.”

##### 2) I advarselsfeltet:

”**ADVARSEL**

Brandfarlig væske og damp (H226)

Forårsager alvorlig øjenirritation (H319)

Holdes væk fra varme, varme overflader, gnister, åben ild og andre antændelseskilder. Rygning forbudt.

Undgå indånding af spray.

Ved brand: (udfyldes af ansøger)til brandslukning.

Vask huden efter arbejdet.

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

**Må kun anvendes som afskrækningsmiddel mod myg.**

**Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte.**

**Produktet må højst bruges to gange dagligt. Må ikke bruges på børn under to år.**

**Begræns brugen på børn mellem to og 12 år.**

**Holdes væk fra varme/gnister/åben ild/varme overflader. Rygning forbudt.**

**Spray ikke mod åben ild eller andre antændelseskilder.**

#### **Brug**

**kun udendørs eller i et rum med god udluftning.**

**Opbevares utilgængeligt for børn.**

**Må ikke opbevares**

**sammen med fødevarer, drikkevarer og foderstoffer.”**

Farepiktogrammerne GHS02 for

fysiske fare og GHS07 for sundhedsfare.

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre oplysninger om førstehjælp, herunder:

Hvis der er brug for lægehjælp, medbring da beholderen eller etiketten.

VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let. Fortsæt skylning.

##### 3) I deklarationsfeltet:

a) Teksten ”Afskrækningsmiddel BPR-reg. nr.567-4.

Aktivstof DEETog biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)”.

b) Oplysning om præparattype: ”spray” for dette præparat.

c) Indholdet af DEET i vægtprocent (% w/w) og g/L

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ved 20 °C.

d) Sætningen: ”Indeholder citronella, lavendelolie og geraniumolie. Kan udløse allergisk reaktion”.

e) Udløbsdatoen skal anføres.

Denne dato må højst være 5år efter produktionsdatoen. Etikettens dato kan udformes som en henvisning til en produktionsdato andetsteds på emballagen.

f) Batchnummer eller –

betegnelse skal anføres.

g) Pakningsstørrelse i L.

h) Godkendelsesindehavers navn

og adresse.

4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Brugsanvisningen skal rettes til efter den vedlagte

effektivitetsvurdering fra Institut

for Agroøkologi, Aarhus Universitet, DCA.

Følgende

retningslinjer gælder i forhold til bortskaffelse.

Der skal mærkes med

sikkerhedssætning P501: ”Indholdet/holderen bortskaffes i overensstemmelse med kommunale regler for affaldshåndtering.”

Derudover skal

mærkningen ske efter følgende retningslinjer:

Tom emballage og rester skal afleveres til den kommunale affaldsordning for

farligt affald.