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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Mosquito Milk Stick 20% DEET

Product type(s)

PT19: Repellents and attractants

Authorisation number: 1160-3

R4BP asset number: DK-0025566-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Mygga Stick 20% DEET

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		1160-3
R4BP asset number		DK-0025566-0000
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

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	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)

Active substance	N,N-diethyl-meta-toluamide
Name of manufacturer	Vertellus Specialties Belgium NV
Address of manufacturer	Havenlaan 86C - box 204 1000 Brussels Belgium
Location of manufacturing sites	2110 West Gate City Boulevard NC 27403 Greensboro 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	20

2.2. Type(s) of formulation

Stick

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	EUH208: Contains <name of sensitising substance>. May produce an allergic reaction.
Precautionary statements	P102: Keep out of reach of children. P103: Read carefully and follow all instructions.

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	Insect Repellent for human use
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 mosquitoe Development stage: adults
Field(s) of use	indoor use outdoor use Use only outdoors or in a well-ventilated area
Application method(s)	Method: spreading Detailed description: Spread gently and evenly over the skin that needs to be protected. Avoid contact with eyes, mucous membranes and damaged skin.
Application rate(s) and frequency	Application Rate: Spread gently and evenly over the skin that needs to be protected Dilution (%): 0 Number and timing of application: 2 / day
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Cartridge, Plastic: composite: , 50 ml PP cartridge. Oval opening: 49x29 mm. PP cap

4.1.1. Use-specific instructions for use

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4.1.2. Use-specific risk mitigation measures

See General Directions 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

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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 USE[1]

5.1. Instructions for use

Only authorise for use as a means of repelling mosquitoes in humans.
This product is authorized for non-professional use
This product gives an average of 7 hours of protection against the most common mosquito species in the Netherlands. The duration can be shorter for some tropical species, with an average of 3 hours of protection for the yellow fever mosquito and 5 hours against malaria mosquitoes.
Factors like temperature, humidity and sweating may affect the efficacy of the product..
Spread gently and evenly over the skin that needs to be protected.
Avoid contact with eyes, mucous membranes and damaged skin.
Avoid contact with food, plastics and painted surfaces.
Use only outdoors or in awell-ventilated area.
Do not use more than twice a day.
Do not use in children under 13 years.Repeat application if necessary after swimming, bathing or when efficacy decreases.

5.2. Risk mitigation measures

The following risk mitigation measures are added as an adjustment to terms and conditions in Denmark, pursuant to BPR article 37 (1), b and c.
This derogation from mutual recognition has been agreed upon by the applicant on March 22nd 2021, pursuant to BPR article 37 (2).
The product may only be applied to the following areas:
Face, neck, lower arms, the back of the hands and the upper
surface of the feet.
(The rest of the body should be protected by clothing.)

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

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

6. OTHER INFORMATION

Bilag 1
Oplysninger til etiket og brugsanvisning for
Mosquito Milk Stick 20% DEET,
BPR-reg. nr.
567-5
I. Etiketten skal udformes i overensstemmelse med det godkendte resumé af det biocidholdige produkts egenskaber, jf. artikel 69, stk. 1, i biocidforordningen (Forordning (EU) nr. 528/2012), og CLP-Forordningen.

II. Det er udelukkende ansøgers/godkendelsesindehaverens ansvar, at etiket, mærkning og pakning lever op til lovens krav, jf. biocidforordningen artikel 69. Etiket og mærkning skal være på dansk.
Nedenstående 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 nedenstående oplysninger. Oplysninger i citationstegn skal angives ordret:
1) I hovedfeltet:
”Afskrækningsmiddel
Må kun anvendes som afskrækningsmiddel mod myg.”
2) I advarselsfeltet:
”FORSIGTIG
Læs etiketten før brug.
Undgå at produktet kommer i kontakt med øjnene, slimhinder og beskadiget hud.
Vask huden med vand og sæbe når beskyttelse ikke længere er nødvendig, eller hvis der opstår bivirkninger.
Vask hænder før du spiser eller håndterer fødevarer.
Må kun anvendes udendørs eller i et rum med god udluftning.
Undgå udledning til miljøet.
Opbevares et tørt sted. Beskyttes mod sollys.

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 kun anvendes to gange dagligt.
Må kun anvendes til voksne og børn over 13 år.
Må kun anvendes ved påføring i ansigtet og på halsen samt på underarme, håndryg og på det øverste af fødderne, mens resten af kroppen beskyttes med beklædning.
Opbevares utilgængeligt for børn.
Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer.

Evt. oplysninger om førstehjælp.
3) I deklarationsfeltet:
a) Teksten ”Afskrækningsmiddel BPR-reg. nr. 567-5. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)”.
b) Oplysning om præparattype: ”stift” for dette præparat.
c) Indholdet af aktivstofi vægtprocent (% w/w) og g/kg.
d)Sætningen: ”Indeholder linalool og benzyl benzoate. Kan udløse allergisk reaktion.”
e) Udløbsdatoen skal anføres. Denne dato må højst være fem år efter produktionsdatoen. Etikettens dato kan udformes som en henvisning til en produktionsdato andetsteds på emballagen.
f) Batchnummer eller – betegnelse skal anføres.
g) Pakningsstørrelse i kg.
h) Godkendelsesindehavers navn og adresse.
4) Brugsanvisningen:
Oplysninger om skadevoldere, anvendelsesområdeog doseringer.
Følgende retningslinjer gælder i forhold til bortskaffelse.
Der skal mærkes med sikkerhedssætning P501: ”Indholdet/beholderen bortskaffes i overensstemmelse med kommunale regler for affaldshåndtering.”
Derudover skal mærkningen ske efter retningslinjerne:
”Tom emballage og rester kan bortskaffes med dagrenovationen."