

Summary of product characteristics for a biocidal product

Product name: Verotex Anti Myggespray børn

Product type(s): PT19 - Repellents and attractants (Pest control)

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Authorisation number: 897-3

R4BP 3 asset reference number: DK-0024357-0000

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Administrative information

1.1. Trade names of the product

REPULSIF ANTI-MOUSTIQUES ENFANTS (RAME) Verotex Anti Myggespray børn

1.2. Authorisation holder

Name and address of the authorisation holder	Name	LIMARU NV
	Address	Business Center Mezzo Paalsesteenweg 170 bus 7 3583 Beringen Belgium
Authorisation number	897-3	
R4BP 3 asset reference number	DK-0024357-0000	
Date of the authorisation	29/01/2015	
Expiry date of the authorisation	21/11/2024	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	SARL SPRING
Address of the manufacturer	4, rue Blaise Pascal Z.I. du Bois de Leuze 13310 Saint-Martin-de-Crau France
Location of manufacturing sites	4, rue Blaise Pascal Z.I. du Bois de Leuze 13310 Saint-Martin-de-Crau France

1.4. Manufacturer(s) of the active substance(s)

Active substance	23 - N,N-diethyl-meta-toluamide
Name of the manufacturer	Vertellus Performance Materials Inc.
Address of the manufacturer	2110 High Point Road NC 27403 Greensboro United States
Location of manufacturing sites	2110 High Point Road NC 27403 Greensboro United States

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal 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	10

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	Flammable liquid and vapour. Causes serious eye irritation.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Read carefully and follow all instructions. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep container tightly closed. Wash hands thoroughly after handling.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If eye irritation persists: Get medical advice.

4. Authorised use(s)

4.1 Use description

Use 1 - Spraying on skin

Product type

PT19 - Repellents and attractants (Pest control)

Where relevant, an exact description of the authorised use

RAME is a ready-to-use lotion to spray and spread on the surface of exposed human skin.

Target organism(s) (including development stage)

Scientific name: Culex spp.
Common name: Mosquitoes
Development stage: Adults

Scientific name: Aedes spp.
Common name: Mosquitoes
Development stage: Adults

Scientific name: Anopheles spp.
Common name: Mosquitoes
Development stage: Adults

Field(s) of use

Indoor
Outdoor

Application method(s)

Method: Spraying
Detailed description:
The product is sprayed on the palms of the hands and spread on exposed skin surfaces (face, neck, 1/2 arms, hands and 1/2 legs)

Application rate(s) and frequencies

Application Rate: 0,95 mg product/cm² of skin, up to 2 times a day for adults and children 12 years and older and up to one time a day for children between two and 12 years.
Dilution (%): 0
Number and timing of application:
0,95 mg product/cm² skin, up to 2 times a day for adults and children 12 years and older, and up to one time for children between two and 12 years. (5 sprays per adult forearm, 1 spray per child forearm).

Complete protection time in a temperate environment: 4 hours

Complete protection time in a tropical environment: 3.5 hours

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

Spray bottles:
PET with PP/ polyoxymethylene spray : 80mL, 100mL, 150mL.

4.1.1 Use-specific instructions for use

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4.1.2 Use-specific risk mitigation measures

Do not exceed two applications per day for adults and children 12 years and older.
Do not exceed one application per day for children between two and 12 years.
Only apply on uncovered skin.
Wash hands before handling food.
Do not treat hands of children.

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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4.2 Use description

Use 2 - Spraying on clothes

Product type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	The product RAME is a ready-to-use lotion to be sprayed on clothes.
Target organism(s) (including development stage)	Scientific name: Culex spp Common name: Mosquitoes Development stage: Adults Scientific name: Aedes spp Common name: Mosquitoes Development stage: Adults Scientific name: Anopheles spp Common name: Mosquitoes Development stage: Adults
Field(s) of use	Indoor Outdoor -
Application method(s)	Method: Spraying on clothes Detailed description: -
Application rate(s) and frequencies	Application Rate: 1,54 mg product/cm ² clothes, up to 2 times a day for adults and children three years and older, and up to one time per day for children between two and three years old Dilution (%): 0 Number and timing of application: 1,54 mg product/cm ² clothes, up to 2 times a day for adults and children three years and older, and up to one time per day for children between two and three years old 8 sprays on adult forearm fabric (cotton) and 2 sprays on child forearm fabric (cotton). Complete protection time: 3,5 hours.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Spray bottles : PET with PP/ polyoxymethylene spray : 80mL, 100mL, 150mL.

4.2.1 Use-specific instructions for use

4.2.1 Use-specific instructions for use

Only apply on cotton clothes.

4.2.2 Use-specific risk mitigation measures

Do not exceed two applications per day for adults and children of three years and older.
Do not exceed one application per day for children between the age of two and three years.

4.2.3 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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4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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4.3 Use description

Use 3 - Combined spray on skin and clothes

Product type

PT19 - Repellents and attractants (Pest control)

Where relevant, an exact description of the authorised use

The product RAME is a ready-to-use lotion to be sprayed and spread on the exposed area of human skin, and to be sprayed on clothes.

Target organism(s) (including development stage)

Scientific name: Culex spp
Common name: Mosquitoes
Development stage: Adults

Scientific name: Aedes spp
Common name: Mosquitoes
Development stage: Adults

Scientific name: Anopheles spp
Common name: Mosquitoes
Development stage: Adults

Field(s) of use	Indoor Outdoor -
Application method(s)	Method: Spraying Detailed description: The product is sprayed on the palms of the hands and spread over exposed skin surfaces (face, neck, 1/2 arms, hands and 1/2 legs). The product is sprayed on clothes.
Application rate(s) and frequencies	Application Rate: 0.95 mg product / cm ² of skin, up to 1 time per day for adults and children 12 years and older. 1.54 mg product / cm ² of clothing, up to 1 time per day for adults and children 12 years and older Dilution (%): 0 Number and timing of application: 0.95 mg product / cm ² of skin, up to 1 time per day for adults and children 12 years and older. (5 sprays per adult forearm, 1 spray per child forearm). 1.54 mg product / cm ² of clothing, up to 1 time per day for adults and children 12 years and older. (8 sprays on adult forearm fabric (cotton) and 2 sprays on child forearm fabric (cotton)). Full protection time: 3.5 hours.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Spray bottles : PET with PP/ polyoxymethylene spray : 80mL, 100mL, 150mL.

4.3.1 Use-specific instructions for use

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4.3.2 Use-specific risk mitigation measures

Do not exceed one application on skin combined to one application on clothes per day for adults and children of 12 years old and older.
Do not combine the use on skin and clothes for children younger than 12 years.
Wash hands before handling food.
Do not treat hands of children.

4.3.3 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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4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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4.3.5 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

5.1. Instructions for use

Respect the recommended application doses.

The users should report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.

Protection time can be lowered by sweating, water wash off, rubbing, high temperature (>30°C), wind velocity, etc.

Shaken before use.

Use in well ventilated areas.

When applying a sunscreen, wait at least 20 minutes after application of the sunscreen to apply the product.

5.2. Risk mitigation measures

Keep out of the reach of children.

Do not use the product before bathing or showering.

Do not spray directly on face but spray on hands and apply to face.

Do not apply to damaged skin (wounds, sunburn, skin disease...).

To prevent contamination of food, avoid contact of treated skin with food.

Do not use the spray near food and surfaces that may come into contact with food or drink intended for human consumption.

For children until 12 years: the repellent must be applied by adults.

Do not apply on eyelids and eyes.

Do not use product for children younger than two years old.

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

The active substance contained in the product (DEET) is liable to induce nervehyperexcitability especially in susceptible persons (epileptic) or in the case of co-exposure with a convulsant product.
Ingestion : Risk of dizziness and loss of consciousness. Ingestion may lead to acute intoxication. Immediately contact poison control center. Do not induce vomiting without medical advice.
Eyes contact : Remove the contact lenses. Wash eyes under a stream of lukewarm water for about 10 minutes, eyes open, not forgetting to wash under the eyelids. If the eyes remain red two hours after washing , consult a doctor.
Skin contact : if redness or persistent pain after application, consult a physician.

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

Dispose of contents / container to an appropriate collection point.
Do not transfer the product. Do not mix with other waste.
Containers containing product residues should be treated in accordance with national regulations.
Do not discharge the product into the environment or the pipelines.
In case of accidental release of the product, collect the product with a liquid-absorbing material (eg sand, diatomaceous earth) and dispose of as a hazardous waste.

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

Do not store more than 2 weeks at 54 ° C.
The product can be stored for 2 years at 25 ° C from the date of manufacture.

6. Other information

Set up a program to monitor the resistance of mosquito populations to the active substance DEET and provide the results of this monitoring every 5 years

Bilag 1

Oplysninger til etiket og brugsanvisning for Verotex Anti Myggespray børn, BPR-reg. nr. 897-3.

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.
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 nedenstående oplysninger. Oplysninger i citationstegn skal angives ordret:

1) I hovedfeltet:

"Afskrækningsmiddel.

Må kun anvendes som afskrækningsmiddel mod myg."

2) I advarselsfeltet:

"Advarsel

Brandfarlig væske og damp. (H226)

Forårsager alvorlig øjenirritation. (H319)

Læs etiketten før brug.

Hold beholderen tæt lukket.

Vask hænder grundigt efter brug.

Vask huden når beskyttelse ikke længere er nødvendig eller hvis der opstår bivirkninger.

For påføring i ansigtet, spray produktet i hænderne og påfør det i ansigtet.
Undgå at produktet kommer i kontakt med øjne og øjenlåg.
Undgå at produktet kommer i kontakt med beskadiget hud (fx sår, solbrændt hud, hudlidelser).

Hvis der anvendes solcreme, vent da 30 minutter med at påføre Verotex Anti Myggespray børn. Undgå badning efter påførsel af produktet.
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.

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

Må ikke anvendes til børn under to år.

Ved behandling af hud må produktet kun påføres to gange om dagen af voksne og børn over 12 år, og kun en gang af børn mellem to og 12 år.

Ved behandling af tøj må produktet kun påføres to gange om dagen af voksne og børn over tre år, og kun en gang af børn mellem to og tre år.

Ved behandling af både hud og tøj må produktet kun påføres en gang om dagen af voksne og børn over 12 år. Produktet må ikke påføres på både hud og tøj samme dag hos børn under 12 år.

Børn under 12 år må ikke selv påføre produktet, produktet skal påføres af voksne.

Må ikke påføres på hænderne af børn, der er under 12 år gamle.

Må ikke tømmes i kloak afløb.

Opbevares utilgængeligt for børn.

Må ikke anvendes i nærheden af fødevarer og overflader, der kan komme i kontakt med fødevarer.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer"

Farepiktogrammerne GHS02 og GHS07

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.

Ved vedvarende øjenirritation: Søg lægehjælp."

3) I deklaraionsfeltet:

a) Teksten "Afskrækningsmiddel BPR-reg. nr. 897-3. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".

b) Oplysning om præparattype: "væske" for dette præparat.

c) Indholdet af aktivstof i vægtprocent (% w/w) og g/L ved 20 °C.

d) Udløbsdatoen skal anføres. Denne dato må højst være 2 år efter produktionsdatoen. Etikettens dato kan udformes som en henvisning til en produktionsdato andetsteds på emballagen.

e) Batchnummer eller – betegnelse skal anføres.

f) Pakningsstørrelse i L.

g) Godkendelsesindehavers navn og adresse.

4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og 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:

Rester skal afleveres til den kommunale affaldshåndtering for farligt affald. Tomme beholdere kan bortskaffes som dagrenovation.