

Summary of product characteristics for a biocidal product

Product name: VEROTEX-REPELENTE ANTIZANZARA

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

Authorisation number: IT/2018/000484/MRS

R4BP 3 asset reference number: IT-0018312-0000

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Administrative information

1.1. Trade names of the product

VEROTEX - REPELLENTE ANTIZANZARA pronto all'uso

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	IT/2018/000484/MRS	
R4BP 3 asset reference number	IT-0018312-0000	
Date of the authorisation	29/01/2015	
Expiry date of the authorisation	31/01/2025	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	SPRING
Address of the manufacturer	4 RUE BLAISE PASCAL ZI DU BOIS DE LEUZE 13310 ST MARTIN DE CRAU France
Location of manufacturing sites	4 RUE BLAISE PASCAL ZI DU BOIS DE LEUZE 13310 ST 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
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	30

2.2. Type of formulation

Liquid, ready for use

3. Hazard and precautionary statements

Hazard statements	<p>Causes serious eye damage.</p> <p>Flammable liquid and vapour.</p>
Precautionary statements	<p>If medical advice is needed, have product container or label at hand.</p> <p>Keep out of reach of children.</p> <p>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.</p> <p>Keep container tightly closed.</p> <p>Use non-sparking tools.</p> <p>Take action to prevent static discharges.</p>

Wear eye protection.

IF IN EYES:

Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a POISON CENTER or a doctor.

If eye irritation persists:

Get medical advice.

In case of fire:

Use water to extinguish.

Store in a well-ventilated place.

Keep cool.

Dispose of contents to national legislation.

4. Authorised use(s)

4.1 Use description

Use 1 - BODY REPELLENT

Product type

PT19 - Repellents and attractants (Pest control)

Where relevant, an exact description of the authorised use

Spray pump application. The product is sprayed in the hand and then spread on the exposed area of the skin (i.e. face, neck, three quarter arms, hands and half-legs) to protect people.

Target organism(s) (including development stage)

Scientific name: Other: Aedes aegypti, Anopheles gambiae, Aedes albopictus, Culex quinquefasciatus
 Common name: Mosquitoes
 Development stage: Adults

Field(s) of use

Outdoor

see decision

Application method(s)

Method: Spraying
 Detailed description:
 Use on skin
 Spray pump application. The product is sprayed in the hand and then spread on the exposed area of the skin (i.e. face, neck, three quarter arms, hands and half-legs) to protect people.

Application rate(s) and frequencies

Application Rate: 1,1 mg/cm² of skin
Dilution (%): 0
Number and timing of application:
A maximum of 1 application per day. Duration of the protection: up to 4 hours.

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

VEROTEX repellente antizanzara is packaged in bottles in polypropylene from 80 to 150 mL, with a pump in polypropylene/polyoxymethylene.

4.1.1 Use-specific instructions for use

The product must be shaken before use. Use only in well-ventilated areas. Do not use on children less than 2 years old. Do not use on children between 2 and 12 years old and for pregnant women, except where motivated by the risk for human health through e.g. outbreaks of insect-borne diseases. For children between 2 and 12 years old, the repellent must be applied by adults. Warning: For children between 2 and 12 years: Wear long-sleeved shirt and long trousers.

Respect the recommended application doses.

Use only by adults.

Do not exceed one application of the product per day.

Only apply on uncovered skin (face, neck, three quarter arms, hands and half-legs).

Spray the product on the hands and spread it only on the exposed parts of the body to be protected.

Do not spray directly in the face, e.g. spray your hands and rub them over the face. Do not apply on damaged skin (skin lesions, sunburn, skin disease...). Concomitant use with biocides and sunscreen is not recommended. In case the use of sunscreen is necessary, it shall be applied 20 minutes before the repellent.

Do not put hands in mouth after application. Wash the palm of hands after application of the product.

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. Keep away from food, drink and animal feeding stuff. Do not use the product before bathing or showering. Protection time can be lowered by sweating, water wash off, rubbing, high temperature (>30°C), wind velocity, etc. The authorisation holder should be informed in case of inefficiency of the treatment.

4.1.2 Use-specific risk mitigation measures

Only apply on uncovered skin. Only use by adults.

If swallowed: Risk of dizziness and loss of consciousness. Ingestion may lead to acute poisoning. Immediately contact the 15 (or 112) or poison control center. Do not induce vomiting without medical advice.

In case of contact with eyes: If necessary, remove contact lenses. Wash under tepid water for about ten minutes, eyes open, do not forget to wash under eyelids. If the eye remains red two hours washing, consult and visit a doctor.

In case of skin lesions, red patches or persistent pain after applying the product, consult a doctor.

The active substance in the product (DEET) is likely to induce a nervous hyperexcitability especially with sensitive person (epileptic) or when co-exposure with a convulsant product.

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

Dispose of contents/container to a suitable collection point. Leave biocidal products in original containers. Do not mix with other wastes. Containers containing residues of the product have to be handled according to national regulations. Do not allow product to directly reach sewage system, surface waters or ground water. In case of accidental spillage of this product collect escaping product by means of liquid binding material (e.g. grit, universal binder material, diatomaceous earth) and dispose off as hazardous waste.

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

Where specific to the use, the instructions for safe disposal of the product and its 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 the reach of children.
The product could be conserved 2 years at 25°C since the manufacturing date.
The product must not be stored more than 2 weeks at 54°C

5. General directions for use

5.1. Instructions for use

The product must be shaken before use. Use only in well-ventilated areas. Do not use on children less than 2 years old. Do not use on children between 2 and 12 years old and for pregnant women, except where motivated by the risk for human health through e.g. outbreaks of insect-borne diseases. For children between 2 and 12 years old, the repellent must be applied by adults. Warning: For children between 2 and 12 years: Wear long-sleeved shirt and long trousers.

Respect the recommended application doses.

Do not exceed one application of the product per day.

Only apply on uncovered skin (face, neck, three quarter arms, hands and half-legs). Do not spray directly in the face, e.g. spray your hands and rub them over the face.

Spray the product on the hands and spread it on the exposed parts of the body to be protected.

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5.2. Risk mitigation measures

Wash the palm of hands after application of the product.
Only use by adults.

- Do not exceed one application per day.
- Only apply on uncovered skin.
- Do not put hands in mouth after application.
- Keep out of the reach of children
- Do not spray directly in the face
- Wash the palm of hands after application
- Do not use the spray near food and surfaces that may come into contact with food or drink intended for human consumption
- Do not use the product before bathing or showering
- Do not exceed one application of the product per day.

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

If swallowed: Risk of dizziness and loss of consciousness. Ingestion may lead to acute poisoning. Immediately contact poison control center or 112. Do not induce vomiting without medical advice.
In case of contact with eyes: If necessary, remove contact lenses. Wash under tepid water for about ten minutes, eyes open, do not forget to wash under eyelids. If the eye remains red two hours washing, consult a doctor.
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5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

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6. Other information

Data requirement after the authorisation:

- Provide the CAs at the submission of the renewal application with a long term storage stability study in commercial packaging at ambient temperature including data on volume delivered by pump after 2 years.
- A monitoring of the resistance phenomenon must be put in place. The collected information must be sent every 5 years to the CAs.