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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

GOIBI XTREME FORTE REPELENTE DE INSECTOS SPRAY

Product type(s)

PT19: Repellents and attractants

Authorisation number: ES/APP(NA)-2016-19-00365

R4BP asset number: ES-0008618-0000

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1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	GOIBI XTREME FORTE REPELENTE DE INSECTOS SPRAY
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Laboratorios Cinfa, S.A.
	Address	Olaz-Chipi, 10. P.I Areta 31620 Huarte-Pamplona Spain
Authorisation number	ES/APP(NA)-2016-19-00365	
<i>R4BP asset number</i>	ES-0008618-0000	
Date of the authorisation	19/05/2016	
Expiry date of the authorisation	31/01/2025	

1.3. Manufacturer(s) of the product

Name of manufacturer	Laboratorios Cosméticos Feltor, S.A. (bulk product manufacture)
Address of manufacturer	Pol. Ind. "Molí de les Planes" C/ Roques Blanques, 3-5 08470 San Celoni (Barcelona) Spain 08470 San Celoni (Barcelona) Spain
Location of manufacturing sites	Laboratorios Cosméticos Feltor, S.A. (bulk product manufacture) site 1 Pol. Ind. "Molí de les Planes" C/ Roques Blanques, 3-5 08470 San Celoni (Barcelona) Spain 08470 San Celoni (Barcelona) Spain

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

Active substance	N,N-diethyl-meta-toluamide
Name of manufacturer	Vertellus Performance Materials Inc. (formerly Morflex, Inc.)
Address of manufacturer	Vertellus Performance Materials Inc. 2110 High Point Road Greensboro (NC) NC 27403 (USA) 2110 High Point Road Greensboro United States (the)
Location of manufacturing sites	Vertellus Performance Materials Inc. (formerly Morflex, Inc.) site 1 Vertellus Performance Materials Inc. 2110 High Point Road Greensboro (NC) NC 27403 (USA) 2110 High Point Road Greensboro United States (the)

Active substance	N,N-diethyl-meta-toluamide
Name of manufacturer	Clariant Corporation
Address of manufacturer	500 East Morehead St. 28202 Charlotte United States (the)

Location of manufacturing sites	625 East Catawba Avenue, Mt. Holly, NC 28120, USA
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Active substance	N,N-diethyl-meta-toluamide
Name of manufacturer	Cangzhou Panoxi Chemical Co. Ltd
Address of manufacturer	Chemical 1 Road, Lingang Economic Development Zone, Bohai New Zone, Cangzhou City, Hebei Province, China -
Location of manufacturing sites	Chemical 1 Road, Lingang Economic Development Zone, Bohai New, Zone, Cangzhou City, Hebei Province, China

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	45
ETANOL		Non-active substance	64-17-5	200-578-6	49,9996

2.2. Type(s) of formulation

Spray

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H225: Highly flammable liquid and vapour. H319: Causes serious eye irritation. H412: Harmful to aquatic life with long lasting effects. 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. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233: Keep container tightly closed. P264: Wash thoroughly after handling. P273: Avoid release to the environment. P370+P378: In case of fire: Use to extinguish. P501: Dispose of container to and / or its container as hazardous waste according to the regulations in force..

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Use 1 – Repellent – Mosquitoes and ticks– Non-professional user (general public) – Adults and children > 2 years of age -Spray – Indoor and Outdoor use

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	Repellent against mosquitoes and ticks for human hygiene
Target organism(s) (including development stage)	Scientific name: Culicidae: Culicidae: Common name: Aedes albopictus Development stage: adults Scientific name: Culicidae: Culicidae: Common name: Anopheles gambiae Development stage: adults Scientific name: Ixodidae: Ixodidae: Common name: Ixodes ricinus Development stage: adults
Field(s) of use	indoor use outdoor use Outdoor and indoor and use in a well-ventilated area
Application method(s)	Method: Topical application in human skin by spray Detailed description: Topical application in human skin by spray
Application rate(s) and frequency	Application Rate: The product is to be applied only once a day for adults and children over 2 years of age. Dilution (%): 0 Number and timing of application: The product is to be applied only once a day for adults and children over 2 years of age. The maximum time protection is 12 hours for mosquitoes and until 8 hours for ticks. Application doses: 1ml/600 cm ²
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	The biocidal product is packaged in a PP container of 75 ml and 200 ml with cap dispensers of 0.14 ml.

4.1.1. Use-specific instructions for use

See this point in Directions for use

4.1.2. Use-specific risk mitigation measures

See this point in 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

See this point in Directions for use

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

See this point in Directions 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 this point in Directions for use

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Read attached instructions before use.

The biocidal product acts against vector-borne topical diseases as for example malaria, yellow fever, zika virus, dengue fever or chikungunya.

Apply only on the uncovered skin. Do not apply on clothing.

Apply the product sparingly and carefully; divide the product evenly over the skin.

Keep the spray bottle at least 15 cm from the skin; do not spray directly on the face. To protect the face from insect bites, first spray or spread a small quantity of the product onto the palm of the hand and then spread on the face.

The application for adults and children over 2 years of age must be restricted to one application a day.

Children under 2 years must not be treated with this product.

The biocidal product is not for use on children under 2 years of age.

5.2. Risk mitigation measures

Apply in areas where there is significant risk of infection by vector-borne diseases.

Avoid contact with eyes, mucous membranes, nose, lips and damaged skin. Apply carefully to areas where skin folds normally occur.

Do not apply on young children's hands. For other users, wash your hands thoroughly with soap and water before eating or drinking.

The product contains an aversive or bittering agent.

Do not mix with other chemical substances/mixtures.

When used in combination with sun block lotion, apply sun block first then wait 30 minutes before applying the biocidal product.

Wash the areas of skin that have been treated when protection is no longer needed or if side effects occur.

The biocidal product must not be applied where food, feeding stuffs or drinking water can become contaminated.

Apply hygiene measures: do not eat, drink or smoke during the applying of the product and wash hands after use.

Use only outdoors or in a well-ventilated area.

Do not inhale the product.

Keep this product away from children.

Avoid contact with plastics, synthetic-/leather clothing and painted surfaces.

The packaging of the product placed on the market has to be limited to a maximum size of 200ml.

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

Poisoning may cause:

- Irritation of the eyes, skin, mucous membranes, respiratory and gastrointestinal tract.
- Allergic skin reaction (including anaphylaxis).
- Overuse and/or multiples dermal applications may cause neuronal disorders (behavioural disorders, ataxia, hypertonia, seizures, encephalopathy and coma).

Basic first aid procedures

- Move the person away from the contaminated area and remove contaminated or spattered clothing
- If contact in eyes, rinse with plenty of water for 15 minutes. Do NOT forget to remove the contact lenses.
- If contact on skin, wash with soap and plenty of water, without rubbing. Remove the product from skin folds and from under fingernails.

- If swallowed, do NOT induce vomiting unless told to do so by poison control or a health care professional.

Call immediately to a poison control center and if necessary take the person to a hospital and show the label or packaging whenever possible.

- Keep the patient at rest and maintain the body temperature.

- If the person is unconscious, turn the patient sideways with the head at lower than the rest of the body and the knees bended.

- If necessary take the person to a hospital and show the label or packaging whenever possible.

DO NOT LEAVE THE POISONED PERSON ALONE UNDER ANY CIRCUMSTANCE

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

Medical advice for doctors and sanitary staff

- Gastrointestinal decontamination is not recommended.
- Contraindication: Syrup of Ipecac
- Symptomatic and supportive treatment.

IF MEDICAL ADVICE IS NEEDED, HAVE THE PRODUCT CONTAINER OR LABEL AT HAND AND CONTACT THE POISON CONTROL CENTER.

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

Dispose of content and / or its container as hazardous waste according to the regulations in force.

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

The product is stable for 24 months.

6. OTHER INFORMATION

The packaging of the biocidal product shall be fitted with a tactile warning of danger.

Definition of non-professional users (general public): users who are not professionals and that apply the biocidal product in his private life.