

Summary of product characteristics for a biocidal product

Product name: ANTIMOSQUITOS ISDIN XTREME REPELENTE INSECTOS

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

Authorisation number: ES/APP(NA)-2023-19-00897

R4BP 3 asset reference number: ES-0030652-0000

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Administrative information

1.1. Trade names of the product

ANTIMOSQUITOS ISDIN XTREME REPELENTE INSECTOS

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Laboratorios Montplet, S.L.U.
	Address	Vía Trajana 53-59 08020 Barcelona Spain
Authorisation number	ES/APP(NA)-2023-19-00897	
R4BP 3 asset reference number	ES-0030652-0000	
Date of the authorisation	26/10/2023	
Expiry date of the authorisation	26/10/2033	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Laboratorios Montplet, S.L.U.
Address of the manufacturer	Vía Trajana 53-59 E-08020 Barcelona Spain
Location of manufacturing sites	Vía Trajana 53-59 E-08020 Barcelona Spain

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

Active substance	1320 - Ethyl butylacetylaminopropionate
Name of the manufacturer	Merck KGaA
Address of the manufacturer	Frankfurter Straße 250 64293 Darmstadt Germany
Location of manufacturing sites	Merck S.L.U., Poligono Merck, Mollet de Valles 08100 Barcelona Spain

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 (%)
Ethyl butylacetylaminopropionate		Active Substance	52304-36-6	257-835-0	30

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. 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 - Use # 1 – Mosquitoes repellent – spray to apply on human skin – General public

Product type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	Ready-to-use insect repellent spray.
Target organism(s) (including development stage)	Scientific name: Culicidae: Common name: Aedes mosquitoes Development stage: Adults Scientific name: Culicidae: Common name: Anopheles mosquitoes Development stage: Adults Scientific name: Culicidae: Common name: Culex spp Development stage: Adults
Field(s) of use	Indoor Outdoor Outdoor and indoor use in well ventilated areas This repellent is authorized for tropical areas.
Application method(s)	Method: Spraying Detailed description: Spraying with trigger spray. Apply on the skin zones to be protected. Do not spray the product directly on the face. Apply the product over the body with the hand. Do not apply on children's hands. Frequent and repeated application of this product is unnecessary.
Application rate(s) and frequencies	Application Rate: 0.56 mg/cm ² . See * Number and timing of application Dilution (%): . Number and timing of application: Dose per application: 0.56 mg/cm ² . - Adults: 5.11 g or aprox. 27 pump strokes - Children (6-12 years): 2.83 g or aprox. 15 pump strokes

Do not use in children younger than 6 years old.

Frequency of application: Only one application/day

Protection time against mosquitoes:

- up to 6 hours against Aedes and Anopheles mosquitoes
- up to 7 hours against Culex mosquitoes

The protection time is only indicative. Environmental factors (e.g. high temperature, wind velocity, exposure to water) can modify it.

This product is **not intended to be reapplied**.

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

HDPE, recycled HDPE, PET spray bottle (trigger spray) of the following volumes: 50ml ; 75ml; 100 ml and 125ml.

4.1.1 Use-specific instructions for use

- Apply and spread evenly on the skin zones to protect (arms, hands, legs, feet and face).

Adults: 27 spray pump a day (5 on arms, 12 on legs, 5 on the face, 1 on hands and 4 on feet)

Children (6-12 years): 15 spray pump a day (3 on arm, 8 on leg, 2 on the face, 2 on feet)

- Spray directly on the exposed skin and distribute the liquid with the hand. Do not spray the product directly on the face. Spray the product on your hands first if you want to protect your face. Wash your hands thoroughly after applying the product.
- Once the time of protection is over properly wash the body area where the product has been applied
- CHILDREN MUST NOT APPLY THIS PRODUCT. An adult should apply the product on children. Do not apply on children's hands.
- Do not use in children younger than 6 years. If necessary, consult your pediatrician.
- Frequent and repeated application of this product is unnecessary
- The use of the product with other repellent products is not recommended.

- If the product is to be used in combination with sunscreen, first apply the sunscreen and wait 30 minutes before applying the product.
- The protection time is only indicative. Environmental factors (e.g. high temperature, wind velocity, exposure to water) can modify it.

4.1.2 Use-specific risk mitigation measures

- Always read the label and product information before use. Avoid breathing the spray.
- Use only outdoors or in well ventilated areas.
- Do not swallow.
- Avoid breathing vapours/spray.
- Do not use on children's hands.
- For children of 6 to 12 years: the repellent must be applied by adults.
- Do not use near food and surfaces that may come into contact with food and feed or drinks for human consumption and animal feedingstuffs.
- Avoid contact of the treated skin with food and feed.
- Do not use near domestic animals.
- Do not use in people sensitive to its components.
- Keep the container upright.
- In natural water bodies, such as lakes or rivers, do not go swimming after application of the 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

See general directions for use.

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

See general instructions 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

Shelf-life of the product: 3 years

5. General directions for use

5.1. Instructions for use

- Read attached instructions before use.
- Apply the product sparingly and carefully to parts of the body that are not covered.
- Do not throw the product on the ground, into a water course, into the sink or down the drain
- Do not apply on clothes; divide the product evenly over the skin.

5.2. Risk mitigation measures

See this section in Use-specific risk mitigation measures

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

IF INHALED: If symptoms occur call a POISON CENTRE or a doctor

IF SWALLOWED: Rinse mouth. Give something to drink, if exposed person is able to swallow. DO NOT induce vomiting. Call a POISON CENTRE or a doctor.

IF ON SKIN: Wash skin with water. Only the part of the skin that were not supposed to be exposed should be washed. If irritation occurs the skin should be washed and medical advice should be sought.

IF IN EYES: Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing for 5 minutes. Call a POISON CENTRE or a doctor

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

- Use for repellent purpose only. Once this purpose has been fulfilled, discard properly to avoid its release to the environment.

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

- Empty containers should be deposited in separate collection containers according to the material of the containers.

-Unused product and other waste generated during the treatment must be deposited in the residual fraction or in the collecting facilities.

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

Protect from frost.

Store the product at temperatures lower than 30°C.

Protect from direct sunlight

Shelf-life: 36 months.

Keep out of reach of children and non-target animals/pets.

6. Other information

Definition of non professional (general public): Users who are not professionals and who apply the product in the context of their private life.