

Summary of product characteristics for a biocidal product

Product name: Isdin insect repellent IR3535 20%

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

Authorisation number: ES/APP(NA)-2023-19-00895

R4BP 3 asset reference number: ES-0031604-0000

Table Of Contents

Administrative information	1
1.1. Trade names of the product	1
1.2. Authorisation holder	1
1.3. Manufacturer(s) of the biocidal products	1
1.4. Manufacturer(s) of the active substance(s)	1
2. Product composition and formulation	2
2.1. Qualitative and quantitative information on the composition of the biocidal product	2
2.2. Type of formulation	2
3. Hazard and precautionary statements	2
4. Authorised use(s)	3
5. General directions for use	5
5.1. Instructions for use	5
5.2. Risk mitigation measures	5
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	6
5.4. Instructions for safe disposal of the product and its packaging	6
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	6
6. Other information	6

Administrative information

1.1. Trade names of the product

ISDIN ANTIMOSQUITOS REPELENTE USO HUMANO
--

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)-2023-19-00895	
R4BP 3 asset reference number	ES-0031604-0000	
Date of the authorisation	20/10/2023	
Expiry date of the authorisation	20/10/2033	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Laboratorios Montplet S.L.U.
Address of the manufacturer	Vía Trajana 53-55 08020 Barcelona Spain
Location of manufacturing sites	Vía Trajana 53-55 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 08100 Mollet de Valles 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	20

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.

If eye irritation persists: Get medical attention.

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

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	Repellent.
Target organism(s) (including development stage)	<p>Scientific name: Culex spp Common name: Mosquitoes Development stage: Adults</p> <p>Scientific name: Aedes spp Common name: Mosquitoes Development stage: Adults</p> <p>Scientific name: Anopheles spp Common name: Mosquitoes Development stage: Adults</p>
Field(s) of use	<p>Indoor</p> <p>Outdoor</p> <p>Outdoor and indoor use in well ventilated areas</p> <p>Only for use in temperate zones. This repellent is not authorized for tropical areas</p>
Application method(s)	<p>Method: Spraying Detailed description:</p> <p>Apply on the skin zones to be protected. Do not spray the product directly on the face Apply sparingly and spread evenly a thin layer on the uncovered skin (face, hands, arms, legs and feet) to be protected.</p>
Application rate(s) and frequencies	<p>Application Rate: Application rate: Up to 1 application per day. Dose per application: 0,67mg/ cm²*. *The pump releases a dose of 0.1949 ml (0.1866 g) per spray burst (Applicant data). Dilution (%): 0</p>

	<p>Number and timing of application:</p> <p>Do not use in children younger than 1 year.</p> <p>Application rate:</p> <ul style="list-style-type: none"> • Adults: 31 spray pumps • Children 6-12y: 17 spray pumps • Children 2-6y: 13 spray pumps • Toddlers: 9 spray pumps. <p>Protection time:</p> <ul style="list-style-type: none"> • against mosquitoes: up to 7 hours <p>This product is not intended to be reapplied.</p>
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Packaging material: HDPE and recycled HDPE spray bottle (trigger spray) Pack sizes: 50 ml, 75 ml, 100 ml y 125 ml

4.1.1 Use-specific instructions for use

See general directions for use

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

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 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 general directions for use

5. General directions for use

5.1. Instructions for use

- Comply with the instructions for use
 - Apply and spread evenly on the skin areas to be protected. Do not spray directly on the face, but apply it with your hands, avoiding contact with eyes and mouth. Wash hands thoroughly after applying the product.
 - Inform the registration holder if the treatment is ineffective.
 - The use of the product with other repellent products is not recommended.
 - In case of a concomitant use of the product with sunscreen, first apply the sunscreen and wait 20 minutes before the application of the product.
 - The protection time is only indicative. Environmental factors (e.g. high temperature, wind velocity, exposure to water) can modify it.
 - Adults: 31 spray pumps a day (8 on arm, 14 on leg, 4 on the face, 1 on hands and 4 on feet).
 - Children 6-12y: 17 spray pumps a day (4 on arm, 9 on leg, 2 on the face, 2 on feet).
 - Children 2-6y: 13 spray pumps a day (3 on arm, 6 on leg, 2 on the face, 2 on feet).
 - Toddlers: 9 spray pumps a day (2 on arm, 4 on leg, 1 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 use in children younger than 1 years old. If necessary, consult your pediatrician.
 - Only for use in temperate zones. This repellent is not authorized for tropical areas. Please, consult your pharmacist or physician if you are planning to travel to areas with risk of vector-borne diseases in order to receive specific instructions for your protection.
 - The instructions above should be followed. Nevertheless, in areas where there is a high risk of disease transmission through mosquito bites and under those circumstances where it is advised, the preventive measures dictated by the health authorities should be embraced.
 - Do not throw the product on the ground, into a water course, into the sink or down the drain
 - Avoid contact of the treated skin or clothes with food.
- Do not use the product near food and surfaces that may come into contact with food and feed or drinks for human consumption.

5.2. Risk mitigation measures

- Do not storage at temperatures above 30°C
 - Before use the product, read carefully the label. The instructions above should be followed.
 - Do not inhale.
 - Do not swallow. Avoid any direct or indirect contact with food and feed.
 - Avoid contact with eyes.
 - Frequent application is unnecessary.
 - Keep out of reach of children
 - Use in well ventilated areas.
 - Keep the container upright.
 - Applying sun care products or cosmetic formulations after repellent use will decrease the efficacy of the repellent.
- Do not use in people sensitive to its components

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

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

Empty containers, unused product and other waste generated during the treatment are considered hazardous waste. Dispose of in accordance with current regulations.

Do not release to soil, ground, surface water or any kind of sewer.

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

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

Protect from frost.

Shelf-life: 36 months.

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.