

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Lotion IR20

Product type(s)

PT19: Repellents and attractants

Authorisation number: 2023-06-20-B03

R4BP asset number: MT-0030976-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Antipuncture Lotion IR20 DERM IR20 Lotion Lotion IR20
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	INCOS Cosmeceutica Industriale
	Address	Via P. Gobetti 4 40050 Funo di Argelato Italy
Authorisation number		2023-06-20-B03
<i>R4BP asset number</i>		MT-0030976-0000
Date of the authorisation		20/06/2023
Expiry date of the authorisation		16/05/2027

1.3. Manufacturer(s) of the product

Name of manufacturer	LCS SpA
Address of manufacturer	Strada del Marano, 95 47896 Faetano San Marino
Location of manufacturing sites	LCS SpA site 1 Strada del Marano, 95 47896 Faetano San Marino

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

Active substance	Ethyl butylacetylaminopropionate
Name of manufacturer	Merck S.L.U.
Address of manufacturer	Calle Maria de Molina, 40 28006 Madrid Spain
Location of manufacturing sites	Merck S.L.U. site 1 Polígono Merck 08100 Mollet de Vallés, Barcelona Spain

Active substance	Ethyl butylacetylaminopropionate
Name of manufacturer	Merck KGaA
Address of manufacturer	Frankfurter Straße 250 64293 Darmstadt Germany
Location of manufacturing sites	Merck KGaA site 1 Polígono Merck 08100 Mollet del Vallés, Barcelona Spain

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 (%)
Ethyl butylacetyl aminopropionate		active substance	52304-36-6	257-835-0	20 % (w/w)
Ethanol 96%	Ethanol	Non-Active substance	64-17-5	200-578-6	35 % (w/w)

2.2. Type(s) of formulation

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H226: Flammable liquid and vapour. H319: Causes serious eye irritation.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand. P102: Keep out of reach of children. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P264: Wash hands thoroughly after handling. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P501: Dispose of container to in accordance with local /regional/national/international regulations.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Spray to repel mosquitoes and ticks from human skin (general public)

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	Repellent
Target organism(s) (including development stage)	<p>Scientific name: Culicidae: Culicidae: Common name: mosquitoes Development stage: adults</p> <p>Scientific name: Ixodidae: Ixodidae: Common name: ticks Development stage: all</p>
Field(s) of use	<p>indoor use outdoor use</p> <p>Use indoors only in well ventilated areas and outdoors Insect repellent pump spray IR3535® 20% is a ready-to-use insect repellent used to protect humans against mosquitoes and ticks in temperate areas only. The product is not intended to be used in tropical areas. The repellent is sprayed onto the skin, only on uncovered parts of the body (face, hands, arms, legs and feet only)</p>
Application method(s)	<p>Method: spraying</p> <p>Detailed description: Spray directly onto the exposed skin and distribute the liquid on the skin by hand.</p>
Application rate(s) and frequency	<p>Application rate: adults: 3g or approx. 26 sprays; Child: 1.6 g or approx. 14 sprays; toddler: 0.83 g or approx. 7 sprays</p> <p>Dilution (%): Ready-to-use (no dilution needed)</p> <p>Number and timing of application:</p> <p>Apply sparingly to uniformly cover uncovered parts of the body (face, hands, arms, legs and feet only). Dose per application:</p> <ul style="list-style-type: none"> • adult: 3 g or approx. 26 sprays • Child: 1.6 g or approx. 14 sprays • toddler: 0.83 g or approx. 7sprays <p>Insect Repellent Pump Spray IR3535® 20% is intended to be used in summer when insects are frequent. It is usually</p>

	applied once a day depending on outdoor activities, weather and presence of insects. The application can be repeated if necessary (noticeable reduction in repellence) and when allowed (see label instructions). The pump spray can be applied up to 3 times per day for adults, up to 2 times per day for children above the age of 2 years and once a day for children between 1 and 2 years. The product is suitable only for children older than 1 year.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Bottle, Plastic: HDPE , ≥ 25.0 - ≤ 750.0 mL The bottle is closed with a pump head covered by a cap.

4.1.1. Use-specific instructions

Apply the product evenly onto exposed skin and distribute the applied spray liquid on the skin by hand. ONLY apply to uncovered parts of the body, limited to arms, hands, legs, feet and face. Do not spray directly on the face. For treatment of the face, spray the repellent solution onto the palm of the hand and distribute the solution over the skin of the face thereby taking care to protect the eyes. Do not spray into the eyes or apply to eye area.

An adult should apply the product to children below 11 years of age. Do not use on children's hands. Do not apply over cuts, wounds, freshly shaven or irritated skin. Do not use under clothing. Only for external use.

In case of strong perspiration and after having taken a swim, the repellent will need to be reapplied. Reapply only when noticeable reduction in repellence is observed and no later than eight hours after first application.

When reapplying, respect the allowed maximum number of applications per day: three times for adults, twice for children above the age of 2 years and once for children between 1 and 2 years.

Product can be used for children older than 1 year. Caution must be taken when using these products on children. Use products very responsibly. Mechanical protection (clothing, mosquito nets) is to be preferred at all times.

Avoid contact with synthetic materials. Synthetic materials should be protected during spraying. Applying sun care products or cosmetic formulations after repellent use will decrease the efficacy of the repellent considerably.

The product is not intended for use on animals/pets.

4.1.2. Use-specific risk mitigation measures

Use repellent safely. Always read the label and product information before use.

Suitable only for children older than 1 year.

Keep out of reach of children.

Avoid breathing spray. Do not spray directly on the face.

Use only outdoors or in a well-ventilated area.

ONLY apply to arms, hands, legs, feet and face. Do not use under clothing.

Mechanical protection (clothing, mosquito nets) is to be preferred at all times. Only for external use. Use only as directed.

The users should inform if the treatment is ineffective and report straightforward to the registration holder.

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

Causes serious eye irritation.

After inhalation: fresh air.

After eye contact: rinse out with plenty of water. Call in ophthalmologist.

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

Most important symptoms and effects, both acute and delayed: irritant effects

Indication of any immediate medical attention and special treatment needed: No information available

Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

Environmental precautions: Do not discharge superfluous fluids to the drain.

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

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

Do not discharge superfluous fluids to the drain.

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

Storage conditions:

Keep container tightly closed in a dry and well-ventilated place. Keep away from heat and sources of ignition.

The product should not be stored for prolonged times at temperatures >40°C.

Shelf-life: 18 months

Advice on safe handling: Observe label precautions. Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge.

Environmental exposure controls: Do not let product enter drains.

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

See use-specific instructions for use.

5.2. Risk mitigation measures

See use-specific risk mitigation measures.

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

See use-specific particulars.

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

See use-specific instructions

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

See use-specific conditions

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

6. OTHER INFORMATION