

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Lotion IR10

Product type(s)

PT19: Repellents and attractants

Authorisation number: 2023-06-20-B02

R4BP asset number: MT-0030974-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Lotion IR10 Antipuncture Lotion IR DERM IR Lotion
---------------	---

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-B02	
<i>R4BP asset number</i>	MT-0030974-0000	
Date of the authorisation	20/06/2023	
Expiry date of the authorisation	04/11/2029	

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 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 de 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 butylacetylaminopropionate		active substance	52304-36-6	257-835-0	10 % (w/w)

2.2. Type(s) of formulation

EW Emulsion, oil in water

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	
Precautionary statements	P102: Keep out of reach of children. P103: Read carefully and follow all instructions.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Application to human skin to repel mosquitoes - RTU - 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: Culex spp. Common name: mosquitoes Development stage: adults</p> <p>Scientific name: Culicidae: Aedes spp. Common name: mosquitoes Development stage: adults</p> <p>Scientific name: Culicidae: Anopheles spp. Common name: mosquitoes Development stage: adults</p>
Field(s) of use	<p>indoor use outdoor use</p> <p>Indoors (only in well ventilated area) and outdoors Insect repellent lotion IR3535® 10% is a ready-to-use insect repellent used to protect humans against mosquitoes in temperate areas only.</p>
Application method(s)	<p>Method: manual application</p> <p>Detailed description: -</p>
Application rate(s) and frequency	<p>Application rate: 1.16 ml/cm²</p> <p>Dilution (%): -</p> <p>Number and timing of application: Application rate for mosquitoes (1.16 ml/cm²) – protection time 8 hours</p> <ul style="list-style-type: none"> o Adult : 10.58 ml / application on uncovered body parts*. <p>Apply sparingly to uniformly cover uncovered parts of the face, hands, arms, legs and feet. The product can be reapplied 2 times maximum per day.</p> <ul style="list-style-type: none"> o Child (6-12y) : 5.87 ml / application on uncovered body parts*. Maximum one application per day. o Child (2-6y) : 4.33 ml / application on uncovered body parts*. Maximum one application per day. o Toddler (1-2y) : 3.06 ml / application on uncovered body parts*. Maximum one application per day. o Infant (0-1y) : 2.61 ml / application on uncovered body parts*. Maximum one application per day. <p>* The product can be applied on uncovered parts of the body, limited to the face, arms, legs and feet. Do not apply on the whole body.</p>

Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	<ul style="list-style-type: none"> • Squeeze tube - with snap cap, screw cap, top cap or flip top cap (PP) - (PE; HDPE; LDPE; PP; HDPE/LDPE ; HDPE/EVOH; HDPE/F; HDPE/PA ; LDPE/EVOH ; LDPE/F ; LDPE/PA) • Squeeze tube - with snap cap, screw cap, top cap or flip top cap (PP) - (in aluminium with inner layer of: PE; HDPE; LDPE; PP; HDPE/LDPE ; HDPE/EVOH; HDPE/F; HDPE/PA ; LDPE/EVOH ; LDPE/F ; LDPE/PA) • Bottle - with screw cap, top cap or pump dispenser- (PE; HDPE; LDPE; PP; HDPE/LDPE ; HDPE/EVOH; HDPE/F; HDPE/PA ; LDPE/EVOH ; LDPE/F ; LDPE/PA) <p>For all packaging types, size: 25-250 mL in steps of 5 ml</p>

4.1.1. Use-specific instructions

See section 5.1

4.1.2. Use-specific risk mitigation measures

See section 5.2

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 section 5.3

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

See section 5.4

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

See section 5.5

4.2. Use description

Table 2. Application to human skin to repel ticks - RTU - 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: Ixodes ricinus Common name: ticks Development stage: Nymphs and Adults</p> <p>Scientific name: Ixodes scapularis Common name: ticks Development stage: Nymphs and Adults</p>
Field(s) of use	<p>indoor use outdoor use</p> <p>Indoors (only in well ventilated area) and outdoors Insect repellent lotion IR3535® 10% is a ready-to-use insect repellent used to protect humans against ticks in temperate areas only.</p>
Application method(s)	<p>Method: manual application</p> <p>Detailed description: -</p>
Application rate(s) and frequency	<p>Application rate: 1.01 ml/cm²</p> <p>Dilution (%): -</p> <p>Number and timing of application: Application rate for ticks (1.01 ml/cm²) – protection time 7 hours</p> <ul style="list-style-type: none"> o Adult : 9.20 ml / application on uncovered body parts*. The product can be reapplied 2 times maximum per day. o Child (6-12y) : 5.10 ml / application on uncovered body parts*. Maximum one application per day. o Child (2-6y) : 3.77 ml / application on uncovered body parts*. Maximum one application per day. o Toddler (1-2y) : 2.66 ml / application on uncovered body parts*. Maximum one application per day. o Infant (0-1y) : 2.27 ml / application on uncovered body parts*. Maximum one application per day. <p>* The product can be applied on uncovered parts of the body, limited to the face, arms, legs and feet. Do not apply on the whole body.</p>
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	<ul style="list-style-type: none"> • Squeeze tube - with snap cap, screw cap, top cap or flip top cap (PP) - (PE; HDPE; LDPE; PP; HDPE/LDPE ; HDPE/EVOH; HDPE/F; HDPE/PA ; LDPE/EVOH ; LDPE/F ; LDPE/PA) • Squeeze tube - with snap cap, screw cap, top cap or flip top cap (PP) - (in aluminium with inner layer of: PE; HDPE; LDPE;

	<p>PP; HDPE/LDPE ; HDPE/EVOH; HDPE/F; HDPE/PA ; LDPE/EVOH ; LDPE/F ; LDPE/PA)</p> <ul style="list-style-type: none">• Bottle - with screw cap, top cap or pump dispenser- (PE; HDPE; LDPE; PP; HDPE/LDPE ; HDPE/EVOH; HDPE/F; HDPE/PA ; LDPE/EVOH ; LDPE/F ; LDPE/PA) <p>For all packaging types, size: 25-250 mL in steps of 5 ml</p>
--	--

4.2.1. Use-specific instructions

See section 5.1

4.2.2. Use-specific risk mitigation measures

See section 5.2

4.2.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See section 5.3

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

See section 5.4

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

See section 5.5

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Use repellent safely. Always read the label or leaflet before use and follow all the instructions provided.

Keep out of reach of children.

Place a right amount of lotion on the palm of the hand and distribute the lotion over the exposed skin. ONLY apply to uncovered parts of the body, limited to the face, arms, legs and feet. Do not apply on the whole body.

Make sure to protect the eyes. Do not apply to eye area.

Do not apply over cuts, wounds, freshly shaven or irritated skin. Do not use under clothing. Only for external use.

Applying sun care products or cosmetic formulations after repellent use will alter the efficacy of the repellent considerably. 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.

In case of strong perspiration and after having taken a swim, the effectiveness will diminish. The product can be applied once a day for children under 12 years old and twice a day for adult and children above 12 years old.

Caution must be taken when using these products on infants and mechanical protection (clothing, mosquito nets) is to be preferred.

Avoid contact with synthetic materials. Synthetic materials should be protected during application.

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

The use of the product with other repellent products is not recommended.

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

5.2. Risk mitigation measures

ONLY apply to uncovered parts of the body, limited to the face, arms, legs and feet.

Do not use on children's hands. An adult should apply the product to children below 12 years of age. and wash his hands after application. Do not use on children's hands.

Wash hands before handling food. Do not apply directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks. To prevent contamination of food, avoid contact of treated skin with food.

Only apply outdoor or in well ventilated area.

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

In case of inhalation: bring to fresh air.

In case of eye contact: check for and remove any contact lenses if easy to do. Rinse out with plenty of water.

Call in ophthalmologist.

In case of skin contact: in case of skin lesions, redness or persistent pain after application, consult a doctor.

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

Most important symptoms and effects, acute or delayed: no description of any toxic symptoms

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

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

5.4. 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.

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

5.5. 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.

Recommended storage temperature: Room temperature (18-25°C). The product should not be stored for a prolonged period at temperatures >40°C.

Shelf-life: 18 months

Environmental exposure controls: Do not let product enter drains.

6. OTHER INFORMATION

The authorisation holder must provide the eCA with the results of the long term stability test at ambient temperature, which supports the 18 or 24 months stability, within a respectively 2 or 2.5 year period post-approval.