

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Lotion IR Lice

Product type(s)

PT19: Repellents and attractants

Authorisation number: 2023-06-20-B01

R4BP asset number: MT-0030975-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

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

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-B01	
<i>R4BP asset number</i>	MT-0030975-0000	
Date of the authorisation	20/06/2023	
Expiry date of the authorisation	06/04/2027	

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 del 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 butylacetylaminopropionate		active substance	52304-36-6	257-835-0	20 % (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 spray 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 contents to local/regional/national/international regulations.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Spray to repel human head lice (general public)

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	Repellent
Target organism(s) (including development stage)	Scientific name: Pediculidae: Pediculidae: Common name: human head louse Development stage: adults
Field(s) of use	indoor use Indoors in well ventilated areas Insect repellent Pump Spray Lice IR3535® 20% is a ready to use repellent product to prevent reinfestation with human head lice (<i>Pediculus humanus capitis</i>) only after a pediculicidal treatment. It is to be applied on hair, the nape of the neck and behind the ears.
Application method(s)	Method: spraying Detailed description: The ready to use product is a pump spray which is sprayed directly onto the hair.
Application rate(s) and frequency	Application rate: Adults: up to 1.05 g product or approx. 9 spray hubs per application; Children from 0 to 11 years old: 0.5g or approx. 4 spray hubs per application Dilution (%): Ready-to-use (no dilution needed) Number and timing of application: RTU leave-on product Timing: Insect Repellent Pump Spray Lice IR3535® 20 % is intended to be used to prevent reinfestation with human head lice (<i>Pediculus humanus capitis</i>) only after a pediculicidal treatment. Reapply after washing the hair and at the latest after 2 days. Dose per application: • Adults: up to 1.05 g product or approx. 9 spray hubs per application. • Children from 0 to 11 years old: 0.5g or approx. 4 spray hubs per application Product is usually applied only once per day. When reapplying, respect the allowed maximum number of applications per day: • Adults and children older than 1 year: 3 times a day

	<ul style="list-style-type: none"> • Children between 0 and 1 year old: 2 times a day <p>When the biocidal product is applied to children under 11 years old, the product should be applied by an adult.</p>
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	<p>Bottle, Plastic: HDPE , ≥ 25.0 - ≤ 250.0 mL</p> <p>The bottle is closed with a pump head covered by a cap.</p>

4.1.1. Use-specific instructions

Ensure that no lice are present. First use a pediculicide.

Evenly apply the product on clean and dry or towel dried hair close to the scalp and take care to first treat the nape of the neck and behind the ears. Then spray on the totality of hair like a lacquer. Make sure that the scalp and hair are sufficiently moistened.

The application must be repeated after washing the hair. When the biocidal product is applied to children under 11 years old, the product should be applied by an adult.

The product is usually applied only once per day. When reapplying, respect the allowed maximum number of applications per day:

- Adults and children older than 1 year: 3 times a day.
- Children between 0 and 1 year old: 2 times a day.

For continued protection: Reapply at the latest after 2 days on cleaned and dry or towel dried hair. Reapply earlier, if the hair was in contact with water (like after rain or swimming) until there is no longer a risk of infestation.

4.1.2. Use-specific risk mitigation measures

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

Do not spray into the face or apply to eye area.

Protect children's eyes and protect the child against inhalation during spraying.

Do not apply over cuts, wounds or irritated skin.

Only for external use.

Use in well-ventilated areas.

Avoid breathing vapours/spray.

Synthetic materials should be protected during spraying.

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