

Summary of product characteristics for a biocidal product

Product name: Meta04.SE

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

Authorisation number:

R4BP 3 asset reference number: NL-0016700-0005

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)	2
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	3
4. Authorised use(s)	3
5. General directions for use	5
5.1. Instructions for use	5
5.2. Risk mitigation measures	6
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	7
6. Other information	7

Administrative information

1.1. Trade names of the product

Paranix Head Lice Repellent
Paranix Head Lice Protection
Paranix Protection, Repel, Prevent

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Omega Pharma International n.v.
	Address	Venecoweg, 26 9810 nazareth Belgium
Authorisation number	1-4	
R4BP 3 asset reference number	NL-0016700-0005	
Date of the authorisation	02/12/2022	
Expiry date of the authorisation	02/12/2032	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Omega Pharma manufacturing GmbH&co.KG
Address of the manufacturer	Benzstrasse 25 71083 Herrenberg Germany
Location of manufacturing sites	Benzstrasse 25 71083 Herrenberg Germany

Name of the manufacturer	Medgenix Benelux
Address of the manufacturer	Vliegveld 21 8560 Wevelgem Belgium
Location of manufacturing sites	Vliegveld 21 8560 Wevelgem Belgium

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	Poligono Merck 08100 Barcelone 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	20,9
Ethanol als Ethylalcohol Absoluut gedenatureerd met 0.1% TBA en 10 ppm Bitrex	Ethanol	Non-active substance	64-17-5	200-578-6	29,1
Phenoxyethanol	2-phenoxethanol	Non-active substance	122-99-6	204-589-7	0
Propyleenglycol lauraat		Non-active substance	27194-74-7	248-315-4	0

2.2. Type of formulation

3. Hazard and precautionary statements

Hazard statements

Causes serious eye irritation.
Flammable liquid and vapour.
Contains alfa- en beta-pinenen en limonene. May produce an allergic reaction.

Precautionary statements

If medical advice is needed, have product container or label at hand.
Keep out of reach of children.
Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.
Keep cool.
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 - Repellent – Human head lice – general public (2 years and older) – use on human hair - in- and outdoor

Product type

PT19 - Repellents and attractants (Pest control)

Where relevant, an exact description of the authorised use

Repellent

Target organism(s) (including development stage)

Scientific name: Pediculidae:
Common name: human head lice
Development stage: Adults

Field(s) of use

Indoor
Outdoor

	Indoor, outdoor
Application method(s)	Method: Open system Detailed description: Pump spray - application on hair.
Application rate(s) and frequencies	Application Rate: Children of 2 years and older: apply up to 11 sprays on the scalp hair of children. Adults: apply up to 22 spray on the scalp hair to fully wet in-depth all the hairs on the scalp area. Spray the rest of the hair in order to get it completely wet. Dilution (%): 0 Number and timing of application: Once a day
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	From 15ml to 125ml Bottle: PP/HDPE Pump: PE-LD/PP Cap: PP Secondary packaging: Carton box

4.1.1 Use-specific instructions for use

See general directions for use section

4.1.2 Use-specific risk mitigation measures

See general directions for use section

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 section

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

See general directions for use section

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 section

5. General directions for use

5.1. Instructions for use

Comply with the instructions for use.
Ensure that no lice are present.
First use a pediculicide if needed. The product repels only new infestation
After application, this product repels head lice up to 24 hours.
Apply every morning on clean and towel dried hair after styling it in the usual way.
Spray the product on the hair close to the scalp (between 2-5 cm) on the totality of the hair like a lacquer.
Be sure to cover all the hair, paying particular attention to the areas close to the neck and behind the ears. Make sure that the scalp and hair are sufficiently moistened.
Allow the hair to dry naturally without applying heat. Do not use a hairdryer.
The application must be repeated after washing the hair.
Suitable for use by adults and children as of 2 years and older.
Inform the registration holder if the treatment is ineffective.

5.2. Risk mitigation measures

For external use only.
When spraying indoor, make sure the room is well ventilated and avoid breathing in spray.
Do not spray in eyes.
Avoid contact with eyes, mucous membranes, nose, lips and damaged skin.
For application on children's hair, the product is to be applied by an adult.
The product is not intended for use on animals/pets. Do not apply when animals/pets are present.
Avoid breathing vapours/spray. Use only outdoors or in a well-ventilated area.

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

If medical advice is needed, have product container and label at hand. First aid instructions:
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 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 ON SKIN: If irritation occurs wash with water and seek medical advice. In cases of unintentional skin exposure: wash with water.
IF INHALED: If symptoms occur call a POISON CENTRE or a doctor.
Methods for cleaning up/taking up: Adsorb onto sand, earth or a similar adsorbent material. Transfer to a container for disposal.
Dispose of absorbed material in accordance with the regulations.

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

Do not reuse the packaging and do not dump the product/packaging into the environment.
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

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: 24 months (in PP/HDPE)

6. Other information