

Summary of product characteristics for a biocidal product

Product name: Meta02.MB

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

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Authorisation number:

R4BP 3 asset reference number: NL-0016700-0003

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Administrative information

1.1. Trade names of the product

Jungle Formula Kids spray
Moustikologne Lotion bébé

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	1-2	
R4BP 3 asset reference number	NL-0016700-0003	
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
Ethanol als Ethylalcohol Absoluut gedenatureerd met 0.1% TBA en 10 ppm Bitrex	Ethanol	Non-active substance	64-17-5	200-578-6	0
Phenoxyethanol	2-phenoxethanol	Non-active substance	122-99-6	204-589-7	0,92
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.

Precautionary statements

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

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 – Mosquitoes – general public (above 6 months) – use on human skin - in- and outdoor - Use proposed to be authorised under Article 19(5) of the BPR in the refMS and only relevant for those MSs where the conditions in that Article are met

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: Culicidae:
Common name: Aedes mosquitoes
Development stage: Adults

Scientific name: Culicidae:
Common name: Culex mosquitoes
Development stage: Adults

Field(s) of use

Indoor

Outdoor

Indoor; outdoor

Application method(s)

Method: Open system
Detailed description:
Pump spray application on skin.

Application rate(s) and frequencies

Application Rate: 1.0 g per 600 cm². Amount of pump sprays (0.190 mL per spray) on arms and legs in total: Adult: 80 pump sprays (0.190 mL per spray) Children ≥ 6 years: 45 pump sprays Age 6 years and older: maximum 2 applic
Dilution (%): 0
Number and timing of application:

Age 6 years and older: maximum 2 applications / day
Age 6 months to 6 years: maximum 1 application / day

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

From 15ml to 250ml

Bottle: PP/HDPE

Pump: PE-PP
Cap: PP
Secondary packaging: Carton box

4.1.1 Use-specific instructions for use

Adults and children older than 6 months.

After application, this product offers 4 hours of protection against mosquitoes.

Use is only demonstrated under temperate conditions.

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

4.2 Use description

Use 2 - Repellent – Ticks – general public (above 6 months) – use on human skin - in- and outdoor - Use proposed to be authorised under Article 19(5) of the BPR in the refMS and only relevant for those MSs where the conditions in that Article are met

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: Ixodes ricinus
Common name: Ticks
Development stage: Adults

Field(s) of use	Indoor Outdoor Indoor; outdoor
Application method(s)	Method: Open system Detailed description: Pump spray application on skin.
Application rate(s) and frequencies	Application Rate: 1.0 g per 600 cm ² . Amount of pump sprays (0.190 mL per spray) on arms and legs in total: Adult: 80 pump sprays (0.190 mL per spray) Children ≥ 6 years: 45 pump sprays Age 6 years and older: maxi Dilution (%): 0 Number and timing of application: Age 6 years and older: maximum 2 applications / day Age 6 months to 6 years: maximum 1 application / day
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	From 15ml to 250ml Bottle: PP/HDPE Pump: PE-PP Cap: PP Secondary packaging: Carton box

4.2.1 Use-specific instructions for use

Adults and children older than 6 months.

After application, this product offers 8 hours of protection against ticks.

4.2.2 Use-specific risk mitigation measures

See general directions for use section

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 general directions for use section

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

See general directions for use section

4.2.5 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

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4.3 Use description

Use 3 - Repellent – Biting insects – general public (above 6 months) – use on human skin - in- and outdoor - Use proposed to be authorised under Article 19(5) of the BPR in the refMS and only relevant for those MSs where the conditions in that Article are met

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: Culicoides spp. Common name: midges Development stage: Adults Scientific name: Phlebotomus spp. Common name: Sandflies Development stage: Adults Scientific name: Vespula spp. Common name: Wasps Development stage: Adults
Field(s) of use	Indoor Outdoor Indoor; outdoor
Application method(s)	Method: Open system Detailed description: Pump spray - application on human skin.
Application rate(s) and frequencies	Application Rate: 1.0 g per 600 cm ² . Amount of pump sprays (0.190 mL per spray) on arms and legs in total: Adult: 80 pump sprays (0.190 mL per spray) Children ≥ 6 years: 45 pump sprays Age 6 years an Dilution (%): 0 Number and timing of application: Age 6 years and older: max 2 applications / day Age 6 months to 6 years: max 1 application / day

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

From 15ml to 250ml
Bottle: PP/HDPE
Pump: PE-PP
Cap: PP
Secondary packaging: Carton box

4.3.1 Use-specific instructions for use

Adults and children older than 6 months.
After application, this product offers 1 hour of protection against midges,
After application, this product offers 6 hours of protection against Sand flies.
Repels wasps from skin for up to 2.5 hours

4.3.2 Use-specific risk mitigation measures

See general directions for use section

4.3.3 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

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

See general directions for use section

4.3.5 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.

Apply carefully to all exposed clean and dry skin except eyes and lips.

Factors such as high temperature, humidity and transpiration can influence the duration of protection. Repeat application after swimming or showering.

In case of concomitant use of the product with sunscreen, first apply the sunscreen and wait 20 minutes before application of the product.

Inform the registration holder if the treatment is ineffective.

5.2. Risk mitigation measures

For external use only

The product should be applied only on uncovered skin areas such as arms, hands, legs and face.

For application on the face: spray onto adult's hand and apply sparingly onto adult's or child's face, avoiding eyes and mouth.

Do not apply to children's hands.

For use on infants or young children, mechanical protection (clothing, mosquito nets) is recommended as primary protection.

When spraying indoor, make sure the room is well ventilated and avoid breathing in spray;

Avoid contact of the treated skin or clothes with food.

Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed or drinks.

Wash hands before handling food.

Avoid contact with eyes, mucous membranes, nose, lips and damaged skin.

For children up to 12 years of age: The product must be applied by adults.

The product is not intended for use on animals/pets. Do not apply when animals/pets are present.

Reapply only if necessary, especially in cases of strong perspiration or after swimming.

If it is no longer necessary for protection, it is recommended to wash the product down.

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 or 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