

# Summary of product characteristics for a biocidal product

**Product name:** Meta03.CM

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

**Authorisation number:**

**R4BP 3 asset reference number:** NL-0016700-0004

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## Administrative information

### 1.1. Trade names of the product

Moustikologne Haute tolérance crème bébé
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### 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	1-3

**R4BP 3 asset reference number**

NL-0016700-0004
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**Date of the authorisation**

02/12/2022
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**Expiry date of the authorisation**

02/12/2032
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### 1.3. Manufacturer(s) of the biocidal products

**Name of the manufacturer**

Omega Pharma manufacturing GmbH&co.KG
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**Address of the manufacturer**

Benzstrasse 25 71083 Herrenberg Germany
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**Location of manufacturing sites**

Benzstrasse 25 71083 Herrenberg Germany
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<b>Name of the manufacturer</b>	Medgenix Benelux
<b>Address of the manufacturer</b>	Vliegveld 21 8560 Wevelgem Belgium
<b>Location of manufacturing sites</b>	Vliegveld 21 8560 Wevelgem Belgium

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

<b>Active substance</b>	1320 - Ethyl butylacetylaminopropionate
<b>Name of the manufacturer</b>	Merck KGaA
<b>Address of the manufacturer</b>	Frankfurter Strasse 250 64293 Darmstadt Germany
<b>Location of manufacturing sites</b>	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	0,82
Propyleenglycol lauraat		Non-active substance	27194-74-7	248-315-4	6

### 2.2. Type of formulation

### 3. Hazard and precautionary statements

#### Hazard statements

Causes serious eye irritation.  
Very toxic to aquatic life with long lasting effects.

#### 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.  
Avoid release to the environment.  
Collect spillage.  
Dispose of contents to .  
Dispose of container to .

### 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

	<p>Indoor</p> <p>Outdoor</p> <p>Indoor; outdoor</p>
<b>Application method(s)</b>	<p>Method: Open system Detailed description:</p> <p>Spreading of product onto skin by smearing</p>
<b>Application rate(s) and frequencies</b>	<p>Application Rate: 1.0 g per 600 cm<sup>2</sup> (equivalent to the size of a cherry on arms and legs in total for a child and the size of a walnut on arms and legs in total for adults) 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</p> <p>Application rate: 1.0 g per 600 cm<sup>2</sup> (equivalent to the size of a cherry on arms and legs in total for a child and the size of a walnut on arms and legs in total for adults)</p> <p>Do not use on children younger than 6 months.</p>
<b>Category(ies) of users</b>	<p>General public (non-professional)</p>
<b>Pack sizes and packaging material</b>	<p>From 15ml to 100ml</p> <p>Tube and neck: PP/HDPE Cap: PP Secondary packaging: Carton box</p>

#### 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.

After application, this product offers 5 hours of protection against mosquitoes.

Use is only demonstrated under temperate conditions.

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.

Do not apply to children's hands.

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

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 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: 30 months (in PP/HDPE)

#### 6. Other information