

Summary of product characteristics for a biocidal product

Product name: Paranix Impotriva Tantarilor MAX

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

Authorisation number: RO/2016/0176/MRA/14286N

R4BP 3 asset reference number: RO-0017145-0000

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Administrative information

1.1. Trade names of the product

Paranix Impotriva Tantarilor MAX

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	RO/2016/0176/MRA/14286N	
R4BP 3 asset reference number	RO-0017145-0000	
Date of the authorisation	01/08/2014	
Expiry date of the authorisation	01/08/2024	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Omega Pharma International n.v.
Address of the manufacturer	Benzstrasse 25 71083 Herrenberg Germany
Location of manufacturing sites	Benzstrasse 25 71083 Herrenberg Germany
Name of the manufacturer	Medgenix Benelux n.v.
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	23 - N,N-diethyl-meta-toluamide
Name of the manufacturer	Vertellus
Address of the manufacturer	2110 High Point Road NC 27403 Greensboro United States
Location of manufacturing sites	2110 High Point Road NC 27403 Greensboro United States
Active substance	23 - N,N-diethyl-meta-toluamide
Name of the manufacturer	Clariant Corporation
Address of the manufacturer	625 E. Catawba Avenue NC 28120 Mt. Holly United States
Location of manufacturing sites	625 E. Catawba Avenue NC 28120 Mt. Holly United States

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 (%)
N,N-diethyl-meta-toluamide	N,N-diethyl-m-toluamide	Active Substance	134-62-3	205-149-7	48,5
Alcohol Denaturans	Ethyl Alcohol	Non-active substance	64-17-5	200-578-6	37,77

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements

Highly flammable liquid and vapour.
Causes serious eye irritation.
Contains geraniol. May produce an allergic reaction.
Harmful to aquatic life with long lasting effects.

Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Keep out of reach of children.
Do not breathe spray.
Do not eat, drink or smoke when using this product.
Use only outdoors or in a well-ventilated area.

4. Authorised use(s)

4.1 Use description

Use 1 - Insect Repellent

Product type

PT19 - Repellents and attractants (Pest control)

Where relevant, an exact description of the authorised use

Insect repellent for human use

Target organism(s) (including development stage)

Scientific name: Culicidae:
Common name: House mosquito
Development stage: Adults

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

	<p>Scientific name: Culicidae: Common name: Anopheles mosquitoes Development stage: Adults</p>
Field(s) of use	Other
Application method(s)	<p>Method: Spraying Detailed description: Apply sparingly on the uncovered parts of the body. Spread equally. Do not apply near eyes, lips and damaged skin. Use ca. 1 ml per 600cm² of skin (corresponds with 1 ml per adult male arm)</p>
Application rate(s) and frequencies	<p>Application Rate: 1 ml per 600 cm² of skin Dilution (%): 50 Number and timing of application: 1 time a day</p>
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	<p>Bottle, Plastic: HDPE , 15-250 mL Bottle, Plastic: composite: , 15-250 mL</p> <p>composite is polypropylene standard pump and USD pump PP Cap carton box</p>

4.1.1 Use-specific instructions for use

This product can only be used to repel mosquitoes to protect people. This product is intended for non-professional use only. This product provides on average 9 hours of protection against the most common mosquito species in the Netherlands. For some tropical mosquito species the protection time can be much shorter: on average 4 hours against the yellow fever mosquito and 8 hours against the malaria mosquito. Factors such as temperature, humidity and transpiration can influence the efficacy. Apply softly and evenly over the bare skin that needs protection. Avoid contact with eyes, mucous membranes and damaged skin. Avoid contact with food, plastics and lacquered surfaces. Use only outdoors or in a well-ventilated area and do not inhale the product. Do not use more than once a day. Do not use on children 18 years old. Keep this product away from children. Close the bottle well.

4.1.2 Use-specific risk mitigation measures

This product can only be used to repel mosquitoes to protect people. This product is intended for non-professional use only. This product provides on average 9 hours of protection against the most common mosquito species in the Netherlands. For some tropical mosquito species the protection time can be much shorter: on average 4 hours against the yellow fever mosquito and 8 hours against the malaria mosquito. Factors such as temperature, humidity and transpiration can influence the efficacy. Apply softly and evenly over the bare skin that needs protection. Avoid contact with eyes, mucous membranes and damaged skin. Avoid contact with food, plastics and lacquered surfaces. Use only outdoors or in a well-ventilated area and do not inhale the product. Do not use more than once a day. Do not use on children 18 years old. Keep this product away from children. Close the bottle well.

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

Do not reuse the packaging and do not dump the product into the environment.

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

Do not reuse the packaging and do not dump the product into the environment.

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

Keep the product dry and do not place it in direct sunlight. Keep out of reach of children. Close the bottle well. Shelf-life 5 years.

5. General directions for use

5.1. Instructions for use

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6. Other information