

Summary of product characteristics for a biocidal product

Product name: APAISYL REPULSIF MOUSTIQUES LOTION

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

Authorisation number: FR-2019-0042

R4BP 3 asset reference number: FR-0013142-0000

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)	1
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	2
4. Authorised use(s)	3
5. General directions for use	4
5.1. Instructions for use	5
5.2. Risk mitigation measures	5
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	5
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	6
6. Other information	6

Administrative information

1.1. Trade names of the product

APAISYL REPULSIF MOUSTIQUES LOTION

1.2. Authorisation holder

Name and address of the authorisation holder	Name	P&G Health France
	Address	18C bd Winston Churchill BP 77035 21070 Dijon France
Authorisation number	FR-2019-0042	
R4BP 3 asset reference number	FR-0013142-0000	
Date of the authorisation	11/04/2019	
Expiry date of the authorisation	16/05/2027	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	FCA Fabrication Chimique Ardéchoise
Address of the manufacturer	Les îles Ferays 07300 Tournon-sur-Rhône France
Location of manufacturing sites	Les îles Ferays 07300 Tournon-sur-Rhône France

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

Active substance	1320 - Ethyl butylacetylaminopropionate
Name of the manufacturer	Merck S.L.U.
Address of the manufacturer	Calle Maria de Molina, 40 28006 Madrid Spain
Location of manufacturing sites	Polígono Merck 08100 Mollet de Vallés, Barcelone Spain

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	Polígono Merck 08100 Mollet del Vallés, 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 96%	Ethanol		64-17-5	200-578-6	35

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	Flammable liquid and vapour. Causes serious eye irritation.
--------------------------	--

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.

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.

Dispose of to .

4. Authorised use(s)

4.1 Use description

Use 1 - Skin application

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: Culex spp.
Common name: House mosquito
Development stage: Adults

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

Scientific name: Anopheles spp
Common name: Anopheles mosquitoes
Development stage: Adults

Scientific name: Ixodes ricinus
Common name: Hard ticks
Development stage: Adults and nymphs

Scientific name: Ixodes scapularis
Common name: Hard ticks
Development stage: Adults and nymphs

Field(s) of use

Indoor

Outdoor

Indoor and outdoor

Application method(s)

Spraying -
Apply by spraying on exposed skin, and spread on the skin with the hand

Mosquitoes : 0,00067 g/cm² of skin - Ticks: 0,00067 g/cm² of skin - 0 -

Application rate(s) and frequencies

Mosquitoes : 0,00067 g/cm² of skin
Protection time : 8 hours

Ticks: 0,00067 g/cm² of skin
Protection time : 12 hours

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

HDPE bottle, from 25 to 750 mL

4.1.1 Use-specific instructions for use

-

4.1.2 Use-specific risk mitigation measures

-

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

-

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

-

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

See directions of use.

5. General directions for use

5.1. Instructions for use

- Efficacy in tropical conditions has not been verified.
- Respect the recommended application doses.
- Always read the label or leaflet before use and follow all the instructions provided.
- The user should inform the registration holder if the treatment is ineffective.
- The use of the product with other repellent products is not recommended.
- In case of a concomitant use of the product with sunscreen, first apply the sunscreen and wait 20 minutes before the application of the product.
- The protection time is only indicative. Environmental factors (e.g. high temperature, wind velocity) can lower it.

5.2. Risk mitigation measures

- Keep out of reach of children
- Avoid breathing vapors/aerosols
- Only use outdoor or in a well ventilated area
- Apply only on exposed skin, not protected by clothes
- Do not apply directly on the face, spray the product in the hand and then spread it onto the face.
- For adults and children from 6 years old: maximum 2 applications per day
- For children between 1 and 5 years old : maximum 1 application per day
- Do not apply the product on the hands of children
- For children, the product must be applied by an adult
- Wash hands before handling food.
- Do not use the product near food and surfaces that may come into contact with food and feed or drinks for human consumption

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

- Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
- Skin contact: In case of skin lesions, redness or persistent pain after application, consult a doctor.
- Inhalation of large quantities: keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur.
- Mouth contact: Wash out mouth with water. Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities.
- Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.

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

- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

- Keep container tightly closed
- Store in a dry and well-ventilated place
- Store at a temperature below 40°C
- Shelf-life : 24 months

6. Other information

- In case of inefficacy, the authorisation holder should inform the competent authority