

Summary of product characteristics for a biocidal product

Product name: MARIE ROSE AEROSOL PROTECTION ANTI-MOUSTIQUES

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

Authorisation number: FR-2018-0041

R4BP 3 asset reference number: FR-0013218-0001

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	3
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	5
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	6
6. Other information	6

Administrative information

1.1. Trade names of the product

MARIE ROSE AEROSOL PROTECTION ANTI-MOUSTIQUES
MARIE ROSE ANTI-MOUSTIQUES PROTECTION FAMILLE LONGUE DUREE

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Laboratoires Juva santé
	Address	8 rue Christophe Colomb 75008 Paris France
Authorisation number	FR-2018-0041 1-1	
R4BP 3 asset reference number	FR-0013218-0001	
Date of the authorisation	15/10/2018	
Expiry date of the authorisation	10/06/2028	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Laboratoire Juva Santé
Address of the manufacturer	8 rue Christophe Colomb 750008 Paris France
Location of manufacturing sites	Rue Avogadro, Technopole Forbach Sud 57600 Forbach France
	TUNAP Cosmetics, Bahnhofstrasse 47 6175 Kematen in Tirol Austria

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

Active substance	1320 - Ethyl butylacetylaminopropionate
Name of the manufacturer	Merck KGaA
Address of the manufacturer	FranckfurterStrasse 250 64293 Darmstadt Germany
Location of manufacturing sites	Merck S.L.U. Poligono Merck 08100 Mollet de Valles (Barcelona) Spain

Active substance	1320 - Ethyl butylacetylaminopropionate
Name of the manufacturer	Merck S.L.U.
Address of the manufacturer	Calle Maria de Molina 28006 Madrid Spain
Location of manufacturing sites	Merck S.L.U. Poligono Merck 08100 Mollet de Valles (Barcelona) Spain

Active substance	1320 - Ethyl butylacetylaminopropionate
Name of the manufacturer	Merck KGaA
Address of the manufacturer	FranckfurterStrasse 250 64293 Damstadt Germany
Location of manufacturing sites	Poligono Merck 08100 Moller de Valles (Barcelona) 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	9,625
Denatured alcohol (EtOH 50-100% with propan-2-ol 5% and 2-methylpropan-2-ol 0.1%)	Mixture	Non-active substance			55,53

2.2. Type of formulation

AE - Aerosol dispenser

3. Hazard and precautionary statements

Hazard statements

Extremely flammable aerosol.
Pressurised container: May burst if heated
Causes serious eye irritation.

Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. -
No smoking.
Do not spray on an open flame or other ignition source.
Do not pierce or burn, even after use.
Wash protection/face protection 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 .
If medical advice is needed, have product container or label at hand.
Keep out of reach of children.

4. Authorised use(s)

4.1 Use description

Use 1 - Use # 1 – Mosquitoes+Phlebotomes / Aerosol / Skin

Product type

PT19 - Repellents and attractants (Pest control)

Where relevant, an exact description of the authorised use

-

Target organism(s) (including development stage)

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

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

Scientific name: Culicidae:
Common name: Culex mosquitoes

	<p>Development stage: Adults</p> <p>Scientific name: Phlebotomus spp. Common name: Sandflies Development stage: Adults</p>
Field(s) of use	<p>Outdoor</p> <p>Autre</p> <p>Skin application</p>
Application method(s)	<p>Method: Spraying Detailed description: Spraying application on skin</p>
Application rate(s) and frequencies	<p>Application Rate: 5.83 g/m² Dilution (%): Number and timing of application:</p> <p>The application rate is 5.83 g/m² Protection time: 7 hours.</p> <p>Adult and child (from 3 years old) : 1 application per day</p>
Category(ies) of users	<p>General public (non-professional)</p>
Pack sizes and packaging material	<p>100 and 150 mL Aerosol can in aluminium, inner coating with standard epoxy phenolic varnish</p>

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

5. General directions for use

5.1. Instructions for use

- Always read the label or leaflet before use and follow all the instructions provided.
 - Respect the recommended application doses.
 - The users should report straightforward to the registration holder any alarming signals which could be assumed to be resistance development.
 - 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 modify it.

5.2. Risk mitigation measures

- Use only outdoors or in a well-ventilated area.
- Do not use on child below 36 months.
- For adults and children from 3 years old : 1 application per day
- For children between 3 and 11 years old, the product has to be applied by an adult
- Do not apply directly on the face, spray the product in the hand and then spread it onto the face.
- Apply only on area of body without clothes.
- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not pierce or burn, even after use
- Avoid any direct or indirect contact with food and feed.

- Application instructions:

- o Adult: 1.2 second/head and neck, 1.4 second/arm and hand, 2.3 second/leg and foot
- o children (6-11 years old): 0.7 second/head and neck, 0.7 second/arm and hand, 1.3 second/leg and foot
- o children (3-5 years old) : 0.7 second/head and neck, 0.6 second/arm and hand, 0.8 second/leg and foot

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 warm 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 (Left sideways position with the knees bent) and seek medical advice immediately.
- Keep the container or label available.
- Do not allow product to spread into the environment.
- Methods and material for containment and cleaning up: Mechanically ventilate the spillage area. Take up liquid spill into absorbent material, e.g.: sand, saw dust, forward for disposal, clean up affected area.

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

- Shelf life : 2 years
- Do not expose to temperatures exceeding 40°C and lower than 0°C.

6. Other information

- Long term tests are ongoing, shelf-life study should be provided within two years.
- Considering the importance of this active substance in vector control, the authorisation holder has to implement a monitoring of scientific literature toward the active substance IR3535. Results of this assessment must be submitted to the Competent Authorities (CA) or other appointed bodies involved in resistance management every 5 years.
- Do not use for pregnant or breast-feeding women.

