

Summary of product characteristics for a biocidal product

Product name: MARIE ROSE REPULSIF ANTI-MOUSTIQUES

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

PT19 - Repellents and attractants (Pest control)

Authorisation number: FR-2018-0041

R4BP 3 asset reference number: FR-0013218-0002

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Administrative information

1.1. Trade names of the product

MARIE ROSE REPULSIF ANTI-MOUSTIQUES
MARIE ROSE REPULSIF ANTI-TIQUES
MARIE ROSE SPRAY CORPOREL REPULSIF ANTI-MOUSTIQUES
MARIE ROSE ANTI MOUSTIQUES HAUTE PROTECTION MOUSTIQUES TIGRES

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 1-2

R4BP 3 asset reference number

FR-0013218-0002

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 75008 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	19,8
Denatured alcohol (EtOH 50-100% with propan-2-ol 5% and 2-methylpropan-2-ol 0,1%)	Mixture	Non-active substance			20

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

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.
Keep container tightly closed.
Keep cool.
Wash ??? 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 .
Store in a well-ventilated place.
Dispose of contents to in accordance with local/regional/national/international regulation.
Keep out of reach of children.
If medical advice is needed, have product container or label at hand.
Store in a well-ventilated place. Keep cool.

4. Authorised use(s)

4.1 Use description

Use 1 - Use # 1- Mosquitoes+Phlebotomes / Spray / 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: Culex spp. Common name: Culex mosquitoes Development stage: Adults Scientific name: Phlebotomus spp. Common name: Sandflies Development stage: Adults
Field(s) of use	Outdoor Autre
Application method(s)	Method: Spraying Detailed description: Spraying application
Application rate(s) and frequencies	Application Rate: 5.83 g/m ² Dilution (%): Number and timing of application: The application rate is 5.83 g/m ² . Protection time: 6.5 hours. Number and timing of application: Adult and children from 12 years old: 2 applications per day Child (3-11years old): 1 application per day
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100 and 150 mL Airspray in plastic PEHD or PP.

4.1.1 Use-specific instructions for use

-

4.1.2 Use-specific risk mitigation measures

- Do not apply directly on the face, spray the product on the hand first and spread it on the face.
- Application instructions:
 - o adult: 4-5 stroke/head and neck, 5 stroke/arm and hand, 8 stroke/leg and foot
 - o children (6 -11 years old)-: 3 stroke/head and neck, 3-4 stroke/arm and hand, 4-5 stroke/leg and foot
 - o For children (3-5 years old) : 2-3 stroke/head and neck 2 stroke/arm and hand, 3 stroke/leg and foot

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

- Not specific.

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

Not specific.

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

Not specific.

4.2 Use description

Use 2 - Use # 2 - Ticks / Spray / Skin

Product type

PT19 - Repellents and attractants (Pest control)

Where relevant, an exact description of the authorised use

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Target organism(s) (including development stage)

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

Scientific name: Ixodes ricinus
Common name: Hard ticks
Development stage: Nymphs

Field(s) of use

Outdoor

Autre

Application method(s)

Method: Spraying
Detailed description:
Spraying application

Application rate(s) and frequencies

Application Rate: 7.5 g/m²
Dilution (%):
Number and timing of application:

The application rate is 7.5 g/m².

Protection time: 6 hours

Number and timing of application:

Adult and Child (from 3 years old): 1 application per day

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

100 and 150 mL
Airspray in plastic PEHD or PP

4.2.1 Use-specific instructions for use

- Not to use for tropical species, demonstrated efficacy for temperate species only.

4.2.2 Use-specific risk mitigation measures

- Do not apply on the face.
- Application instructions:
 - o adult: 4-5 stroke/head and neck, 5 stroke/arm and hand, 8 stroke/leg and foot
 - o children (6 -11 years old):- 3 stroke/head and neck, 3-4 stroke/arm and hand, 4-5 stroke/leg and foot
 - o For children (3-5 years old) : 2-3 stroke/head and neck 2 stroke/arm and hand, 3 stroke/leg and foot

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

Not specific.

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

Not specific.

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

Not specific.

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

- Do not inhale.
- Do not use on child below 36 months.
- For children below 11 years old, the product has to be applied by an adult.
- Do not apply on child's hand.
- Apply only on area of body without clothes
- Avoid any direct or indirect contact with food and feed.
- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- Avoid any direct or indirect contact with food and feed.

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: Remove victim to fresh air and keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
- 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.
- Keep the container or label available.
- Symptomatic treatment, no antidote 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

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