

Summary of product characteristics for a biocidal product family

Family name: FAMILLE JUVA REPULSIF INSECTES

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

Authorisation number: FR-2018-0041

R4BP 3 asset reference number: FR-0013218-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

FAMILLE JUVA REPULSIF INSECTES

1.2. Product type(s)

PT19 - Repellents and attractants (Pest control)

1.3. 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

R4BP 3 asset reference number

FR-0013218-0000

Date of the authorisation

15/10/2018

Expiry date of the authorisation

10/06/2028

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

LABORATOIRES JUVA SANTE

Address of the manufacturer

8 rue Christophe Colomb 75008 Paris France

Location of manufacturing sites

Laboratoires Juva Production Rue Avogadro Technopole Forbach Sud 57600 Forbach France

TUNAP Cosmetics Bahnhofstraße 47 6175 Kematen in Tirol Austria

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

1.5. 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 family composition and formulation

2.1. Qualitative and quantitative information on the composition of the family

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Ethyl butylacetylaminopropionate		Active Substance	52304-36-6	257-835-0	9,625 - 19,8
Denatured alcohol (EtOH 50-100% with propan-2-ol 5% and 2-methylpropan-2-ol 0.1%)	Mixture	Non-active substance			20 - 55,53

2.2. Type(s) of formulation

AL- Autre liquide sous forme de spray
AE - Aerosol
AL - Any other liquid
AE - Aerosol dispenser

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

META SPC-1 Aerosol

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

PT19 - Repellents and attractants (Pest control)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Ethyl butylacetylaminopropionate		Active Substance	52304-36-6	257-835-0	9,625 - 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 - 55,53

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AE - Aerosol dispenser

3. Hazard and precautionary statements of the meta SPC

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) of the meta SPC

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 Development stage: Adults Scientific name: Phlebotomus spp. Common name: Sandflies Development stage: Adults
Field(s) of use	Outdoor Autre Skin application
Application method(s)	Method: Spraying Detailed description: Spraying application on skin
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: 7 hours. 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
Aerosol can in aluminium, inner coating with standard epoxy phenolic varnish

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 of the meta SPC

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.

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	MARIE ROSE AEROSOL PROTECTION ANTI-MOUSTIQUES	Market area: FR
	MARIE ROSE ANTI-MOUSTIQUES PROTECTION FAMILLE LONGUE DUREE	Market area: FR
Authorisation number (R4BP 3 asset reference number - National Authorisation)	FR-0013218-0001 1-1	

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

1. Meta SPC administrative information

1.1. Meta SPC identifier

META SPC-2 Sprays

1.2. Suffix to the authorisation number

1-2

1.3 Product type(s)

PT19 - Repellents and attractants (Pest control)

2. Meta SPC composition

2.1. Qualitative and quantitative information on the composition of the meta SPC

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Ethyl butylacetylaminopropionate		Active Substance	52304-36-6	257-835-0	19,8 - 19,8
Denatured alcohol (EtOH 50-100% with propan-2-ol 5% and 2-methylpropan-2-ol 0.1%)	Mixture	Non-active substance			20 - 20

2.2. Type(s) of formulation of the meta SPC

Formulation(s)

AL - Any other liquid

3. Hazard and precautionary statements of the meta SPC

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) of the meta SPC

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)	<p>Scientific name: Culicidae: Common name: Aedes mosquitoes Development stage: Adults</p> <p>Scientific name: Culicidae: Common name: Anopheles mosquitoes Development stage: Adults</p> <p>Scientific name: Culex spp. Common name: Culex mosquitoes 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>

Application method(s)

Method: Spraying
Detailed description:
Spraying application

Application rate(s) and frequencies

Application Rate: 5.83 g/m²
Dilution (%):
Number and timing of application:

The application rate is 5.83 g/m².
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	-
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/m ² Dilution (%): Number and timing of application:

	<p>The application rate is 7.5 g/m².</p> <p>Protection time: 6 hours</p> <p>Number and timing of application:</p> <p>Adult and Child (from 3 years old): 1 application per day</p>
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 of the meta SPC

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

7. Third information level: individual products in the meta SPC

7.1 Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)	MARIE ROSE REPULSIF ANTI-MOUSTIQUES	Market area: FR
	MARIE ROSE REPULSIF ANTI-TIQUES	Market area: FR

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

MARIE ROSE SPRAY CORPOREL REPULSIF ANTI-MOUSTIQUES	Market area: FR
MARIE ROSE ANTI MOUSTIQUES HAUTE PROTECTION MOUSTIQUES TIGRES	Market area: FR
FR-0013218-0002 1-2	

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

Trade name(s)**Authorisation number**

(R4BP 3 asset reference number - National Authorisation)

MARIE ROSE SPRAY REPULSIF ET APAISANT ANTI-MOUSTIQUES	Market area: FR
MARIE ROSE SPRAY CORPOREL 2 EN 1 ANTI-MOUSTIQUES	Market area: FR
MARIE ROSE ANTI-MOUSTIQUES PROTECTION FAMILLE REPULSIF & APAISANT	Market area: FR
FR-0013218-0003 1-2	

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