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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

CINQ SUR CINQ ZONES TEMPEREES

Product type(s)

PT19: Repellents and attractants

Authorisation number: FR-2019-0092 1-2

R4BP asset number: FR-0013302-0002

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	CINQ SUR CINQ ZONES TEMPEREES
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Laboratoire Chauvin
	Address	416 rue Samuel Morse CS 99535 34961 Montpellier Cedex 2 France
Authorisation number	FR-2019-0092 1-2	
<i>R4BP asset number</i>	FR-0013302-0002	
Date of the authorisation	23/07/2019	
Expiry date of the authorisation	22/07/2029	

1.3. Manufacturer(s) of the product

Name of manufacturer	Laboratoire CHAUVIN
Address of manufacturer	416 rue Samuel Morse - CS 99535 34961 Montpellier cedex 2 France
Location of manufacturing sites	Laboratoire CHAUVIN site 1 FABRICATION CHIMIQUE ARDECHOISE LES ILES FERAYS 07300 Tournon cedex France

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

Active substance	Ethyl butylacetylaminopropionate
Name of manufacturer	Merck KGaA
Address of manufacturer	Frankfurter Strasse 250 64293 Darmstadt Germany
Location of manufacturing sites	Merck KGaA site 1 Merck S.L.U. Poligono Merck 08100 Mollet del Valles Spain

2. PRODUCT COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Ethyl butylacetyl aminopropionate		active substance	52304-36-6	257-835-0	25 % (w/w)

2.2. Type(s) of formulation

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H226: Flammable liquid and vapour. H319: Causes serious eye irritation. EUH208: Contains benzyl 2-hydroxybenzoate and linallyl acetate. May produce an allergic reaction.
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P264: Wash hands thoroughly after handling. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P337+P313: If eye irritation persists: Get medical advice.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Skin repellent against mosquitoes

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	Insect repellents
Target organism(s) (including development stage)	Scientific name: Aedes spp. Common name: Aedes mosquitoes Development stage: adults Scientific name: Culex spp. Common name: Culex mosquitoes Development stage: adults
Field(s) of use	Other Skin application
Application method(s)	Method: spraying Detailed description: Spraying on skin at 10 cm on head, hands (adults only), ¾ arms and 1/2 legs
Application rate(s) and frequency	Application rate: 0,68 mg/cm ² Number and timing of application: The application rate is 0.68 mg product / cm ² of skin Protection time: 7 hours in temperate condition <u>For European conclusion:</u> Number and timing of application: - Child to Adult (> 11 years): 1 application per day <u>For French conclusion:</u> Number and timing of application: - Child from 2 years up to 11 years: 1 application per day - Child to Adult (> 11 years): 2 applications per day
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	- Bottle spray: 75 mL HDPE for the bottle and PE-LD/PP for the dip tube inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap. - Bottle spray: 100 mL HDPE for the bottle and PE-LD/PP for the dip tube inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap.

4.1.1. Use-specific instructions

The product must not be used for tropical species.

4.1.2. Use-specific risk mitigation measures

For European conclusion: Do not apply the product more than one time per day.

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

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

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

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4.2. Use description

Table 2. Skin repellent against ticks

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	Insect repellents
Target organism(s) (including development stage)	Scientific name: Ixodes ricinus Common name: - Development stage: adults Scientific name: Ixodes ricinus Common name: - Development stage: nymphs
Field(s) of use	Other Skin application
Application method(s)	Method: spraying Detailed description: Spraying on skin at 10 cm on head, hands (adults only), ¾ arms and 1/2 legs
Application rate(s) and frequency	Application rate: 0,93 mg/cm ² Number and timing of application: The application rate is 0.93 mg product / cm ² of skin Protection time: 5 hours in temperate condition

	<p><u>For European conclusion:</u> Number and timing of application: - Child to Adult (> 11 years): 1 application per day</p> <p><u>For French conclusion:</u> Number and timing of application: - Child from 2 years up to 11 years: 1 application per day - Child to Adult (> 11 years): 1 application per day</p>
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	<ul style="list-style-type: none"> - Bottle spray: 75 mL HDPE for the bottle and PE-LD/PP for the dip tube inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap. - Bottle spray: 100 mL HDPE for the bottle and PE-LD/PP for the dip tube inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap.

4.2.1. Use-specific instructions

The product must not be used for tropical species.

4.2.2. Use-specific risk mitigation measures

For European conclusion: Do not apply the product on children under 11 years.

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

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

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

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5. GENERAL DIRECTIONS FOR USE¹

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 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, exposure to water, etc.) can lower it.
- Retreat after water exposure without exceeding the maximal recommended application number.

5.2. Risk mitigation measures

- Do not spray directly on the face, spray the product in the hand and then spread it onto the face.
- For children, the product must be applied by an adult.
- Do not apply on hands of children.
- Apply the product on skin and spread it uniformly with hands on following areas:
 - o Adults and children (> 11 years old): apply on head, neck, hands (palms and backs), lower arms, lower legs, feet and 70% of upper arms and thighs
 - o Children from 2 years to 11 years old: apply on head, neck, lower arms, lower legs, feet and 70% of upper arms and thighs.
- Wash hands before handling food.
- Keep out of reach of children.
- Avoid breathing vapours/spray.
- Use only outdoors or in a well-ventilated area.

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.

Keep the container or label available.

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.
- The packaging must not be reused.

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

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

Do not store the product more than 3 years.

6. OTHER INFORMATION

- Number of pump sprays indicated on the label should be in accordance with the application rate.