

EN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Insect Repellent Pump Spray IR3535 20%

Product type(s)

PT19: Repellents and attractants

Authorisation number: RO/2022/0342/MRP/ BE2017-0016

R4BP asset number: RO-0029431-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Insect Repellent Pump Spray IR3535 20%
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Merck KGaA
	Address	Frankfurter Strasse 250 64293 Darmstadt Germany
Authorisation number	RO/2022/0342/MRP/ BE2017-0016	
<i>R4BP asset number</i>	RO-0029431-0000	
Date of the authorisation	07/06/2022	
Expiry date of the authorisation	16/05/2027	

1.3. Manufacturer(s) of the product

Name of manufacturer	Merck KGaA
Address of manufacturer	Frankfurter Strasse 250 64293 Darmstadt Germany
Location of manufacturing sites	Frankfurter Strasse 250 64293 Darmstadt Germany

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

Active substance	IR3535
Name of manufacturer	Merck S.L.U.
Address of manufacturer	Calle Maria de Molina, 40 28006 Madrid Spain
Location of manufacturing sites	Polígono Merck 08100 Mollet de Vallés, Barcelona Spain

Active substance	IR3535
Name of manufacturer	Merck KGaA
Address of manufacturer	Frankfurter Straße 250 64293 Darmstadt Germany
Location of manufacturing sites	Polígono Merck 08100 Mollet del Vallés, Barcelona 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 (%)
IR3535		active substance	52304-36-6	257-835-0	20
denatonium benzoate	N-benzyl-2-[(2,6-dimethylphenyl)amino]-N,N-diethyl-2-oxoethanaminium benzoate hydrate	Non-active substance	3734-33-6	223-095-2	0,0088
Polyoxypropylene monostearyl ether	1-octadecoxypropan-2-ol	Non-active substance	25231-21-4		1
polyglycol	Not applicable, ingredient is a UVCB substance	Non-active substance	25322-68-3	500-038-2	4
PVP/VA copolymer E-735	ethenyl acetate;1-ethenylpyrrolidin-2-one	Non-active substance	25086-89-9		1
water	water	Non-active substance	7732-18-5		31,5
polyglycol	Not applicable, ingredient is a UVCB substance	Non-active substance	25322-68-3	500-038-2	5
polysorbate	2-[2-[3,4-bis(2-hydroxyethoxy)oxyethyl]-2-(2-hydroxyethoxy)ethoxy]ethyl dodecanoate	Non-active substance	9005-64-5	500-018-3	1,5
ethanol	ethanol	Non-active substance	64-17-5	200-578-6	36

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.
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. 1-Application to skin

Product type	PT19: Repellents and attractants
Where relevant, an exact description of the authorised use	Insect repellent pump spray IR3535® 20 % is a ready to use product. The repellent is sprayed onto the skin. 3 g Product is sufficient for the application to approximately 50% of the body surface (face, hands, arms and legs as assessed in the CAR for IR3535). For treatment of the face, spray the repellent solution onto the palm of the hand and distribute the solution over the skin of the face thereby taking care to protect the eyes. Relevant codes: VI.1.1 and VI.9 (manual distribution over skin).
Target organism(s) (including development stage)	Scientific name: Culicidae: Culicidae: Common name: mosquitoes Development stage: adults Scientific name: Ixodidae: Ixodidae: Common name: ticks Development stage: nymphs Scientific name: Ixodidae: Ixodidae: Common name: ticks Development stage: adults
Field(s) of use	Other use in well ventilated areas
Application method(s)	Method: spraying Detailed description: The ready to use product is a pump spray which is sprayed directly onto the exposed skin.
Application rate(s) and frequency	Application rate: 3.0 gram Dilution (%): 100 Number and timing of application: Insect Repellent Pump Spray IR3535 20% is intended to be used in summer when insects are frequent. It is usually applied once a day depending on outdoor activities, weather and presence of insects. The application can be repeated when necessary (noticeable reduction in repellence). The pump spray can be applied up to 3 times per day for adults, up to 2 times by children between the age of 3 and 10 years and maximally 1 time per day for children below 3 years.
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Plastic: HDPE, Bottle, > 25.0 - < 750.0 mL The bottle is closed with a pump head covered by a cap. None required

4.1.1. Use-specific instructions

Spray the product evenly onto exposed skin. For treatment of the face, spray the repellent solution onto the palm of the hand and distribute the solution over the skin of the face thereby taking care to protect the eyes. An adult should apply the product to children below 10 years of age. Do not apply the product to the hands of children. In case of strong perspiration and after having taken a swim, the repellent will need to be reapplied early. The product should not be used under clothing. Synthetic materials should be protected during spraying and the compatibility with textiles should be tested on a non visible part of clothes before use.

4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

Use in well-ventilated areas.

4.1.4. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

After inhalation: fresh air. In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/shower.

After eye contact: rinse out with plenty of water. Call in ophthalmologist.

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

Most important symptoms and effects, both acute and delayed: irritant effects

Indication of any immediate medical attention and special treatment needed: No information available

Personal precautions, protective equipment and emergency procedures

Advice for non-emergency personnel: Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

Environmental precautions Do not let product enter drains. Risk of explosion. Methods and material for containment and cleaning up Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions. Take up with liquid-absorbent and neutralising material (e.g. Chemizorb® H⁺, Merck Art. No. 101595). Dispose of properly. Clean up affected area.

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

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

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

Storage conditions: Keep container tightly closed in a dry and well-ventilated place. Keep away from heat and sources of ignition.

Recommended storage temperature see product label.

Advice on safe handling: Observe label precautions. Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge.

Hygiene measures: Change contaminated clothing. Wash hands after working with substance. Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

Individual protection measures Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

Eye/face protection Safety glasses

Hand protection required

Other protective equipment: Flame retardant antistatic protective clothing.

Respiratory protection required when vapours/aerosols are generated. Recommended Filter type: filter ABEK

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Environmental exposure controls Do not let product enter drains. Risk of explosion.

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Spray the product evenly onto exposed skin. For treatment of the face, spray the repellent solution onto the palm of the hand and distribute the solution over the skin of the face thereby taking care to protect the eyes. An adult should apply the product to children below 10 years of age. Do not apply the product to the hands of children. In case of strong perspiration and after having taken a swim, the repellent will need to be reapplied early. The product should not be used under clothing. Synthetic materials should be protected during spraying and the compatibility with textiles should be tested on a non visible part of clothes before use.

5.2. Risk mitigation measures

Do not apply the product to the hands of children. Use in well-ventilated areas. Do not spray into the face.

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

Causes serious eye irritation. After inhalation: fresh air. In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/shower. After eye contact: rinse out with plenty of water. Call in ophthalmologist. After swallowing: immediately make victim drink water (two glasses at most). Consult a physician. Most important symptoms and effects, both acute and delayed: irritant effects. Indication of any immediate medical attention and special treatment needed: No information available. Personal precautions, protective equipment and emergency procedures. Advice for non-emergency personnel: Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert. Environmental precautions. Do not let product enter drains. Risk of explosion. Methods and material for containment and cleaning up. Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions. Take up with liquid-absorbent and neutralising material (e.g. Chemizorb® H⁺, Merck Art. No. 101595). Dispose of properly. Clean up affected area.

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

Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

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

Storage conditions: Keep container tightly closed in a dry and well-ventilated place. Keep away from heat and sources of ignition.

Recommended storage temperature see product label.

Shelf-life: at least 2 years

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

6. OTHER INFORMATION

Merck KGaA is not a formulator of biocidal products. Merck KGaA holds data for reference formulations and authorises these formulations. Merck KGaA clients that actually produce these formulations can make reference to this authorisation and apply for same products authorisation.

The product can be used three times per day by adults and two times per day for children between 3 and 10 years of age. In small children and infants, the use of Insect Repellent Pump Spray IR3535® 20 % must be limited to one application per day. The use for children < 1 year is not recommended unless disease vectors are present. Physical protection (clothing and mosquito nets) is to be preferred.

The product should be applied sparingly and only to skin areas which are not covered by clothes and therefore accessible for insects. The label shall therefore state 'ONLY apply to arms, hands, legs, and face'. Only intact skin should be treated.

To children and infants, the product should only be applied by adults. To avoid oral uptake, care must be taken not to apply the product to the hands of the children or the infants and to the regions around the mouth.

It is further recommended to use the product only in well-ventilated areas and to avoid breathing in spray. It is further recommended not to use creams or perfumes on top of the applied repellents.