Summary of product characteristics for a biocidal product

Product name: Insect Repellent Aerosol IR3535 30%

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

Authorisation number: KY-0105

R4BP 3 asset reference number: CY-0018087-0000

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Administrative information

1.1. Trade names of the product

Insect Repellent Aerosol IR3535 30%	

1.2. Authorisation holder

1.2. Addionsation noider			
Name and address of the	Name	Merck KGaA	
authorisation holder	Address	Frankfurter Strasse 64293 Darmstadt Germany	
Authorisation number	KY-0105		
R4BP 3 asset reference number	CY-0018087-0000		
Date of the authorisation	20/10/2017		
Expiry date of the authorisation	16/05/2027		

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Merck KGaA
Address of the 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	1320 - Ethyl butylacetylaminopropionate		
Name of the manufacturer	Merck S.L.U.		
Address of the manufacturer	Calle Maria de Molina, 40 28006 Madrid Spain		
Location of manufacturing sites	Polígono Merck 08100 Mollet del Vallés, Barcelona Spain		
Active substance	1320 - Ethyl butylacetylaminopropionate		
Name of the manufacturer	Merck KGaA		
Address of the manufacturer	Frankfurter Straße 250 64293 Darmstadt Germany		
Location of manufacturing sites	Polígono Merck 08100 Mollet del Vallés, Barcelona Germany		

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 butylacetylaminopropiona te		Active Substance	52304-36-6	257-835-0	20
ethanol	ethanol		64-17-5	200-578-6	22,535
Isobutane	isobutane		75-28-5	200-857-2	35
denatonium benzoate	N-benzyl-2-[(2,6- dimethylphenyl)amino]- N,N-diethyl-2- oxoethanaminium benzoate hydrate		3734-33-6	223-095-2	0,012
1,2-propanediol	propylene glycol		57-55-6	200-338-0	4,34
PVP/VA copolymer E-735	ethenyl acetate;1- ethenylpyrrolidin-2-one		25086-89-9		0,865
water	water		7732-18-5	231-791-2	17,248

2.2. Type of formulation

3. Hazard and precautionary statements

Hazard statements

Extremely flammable gas.

Contains gas under pressure; may explode if heated

Causes serious eye irritation.

Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking.

IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing.

Protect from sunlight.

Store in a well-ventilated place.

4. Authorised use(s)

4.1 Use description

Use 1 - 1-Application to skin

Product type

PT19 - Repellents and attractants (Pest control)

Where relevant, an exact description of the authorised use

Insect Repellent Aerosol IR3535® 30 % is a ready to use product. The repellent is sprayed onto the skin. 3 g solution 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: Common name: Mosquitoes Development stage: Adults

Scientific name: Ixodidae: Common name: Ticks Development stage: Nymphs

Scientific name: Ixodidae: Common name: Ticks Development stage: Adults

Field(s) of use

Other

well-ventilated areas

Application method(s)

Spraying -

The ready-to-use product is an aerosol spray for direct application on the skin.

Application rate(s) and frequencies

3.0 gram - 100

Insect Repellent Aerosol IR3535® 30 % 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. Reapplyonly when effectiveness diminishes. The aerosol spray can be applied up to 2 times per day for adults and maximally 1 time per day for children below 10 years of age. Product can be used for children older than 1 year.

Category(ies) of users

General public (non-professional)

Pack sizes and packaging material

Aerosol can - Metal: - >= 25.0 - <= 250.0 mL

4.1.1 Use-specific instructions for use

ONLY apply to arms, hands, legs and face. 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. 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

Use in well ventilated areas.

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

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

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.

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

Pressurised gas bottle: dispose of only in empty condition. Waste material must be disposed of in accordance with the Directive on waste 2008/98/EC as well as other national and local regulations.

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

Storage conditions: Tightly closed. Keep away from combustible materials 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. Eve/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 entrepeneur 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 use

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 the 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 effectsIndication of any immediate medical attention and special treatment needed: No information available Personal precautions, protective equipment and emergency proceduresAdvice for non-emergency personnel: Do not breathe vapours, aerosols. Avoid substancecontact. Ensure adequate ventilation. Evacuate the danger area, observe emergencyprocedures, consult an expert.Environmental precautionsDo not let product enter drains. Risk of explosion.Methods and material for containment and cleaning upCover 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

Pressurised gas bottle: dispose of only in empty condition.

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

Storage conditions: Tightly closed. Keep away from combustible materials and sources of ignition.

Recommended storage temperature see product label.

Shelf-life: at least 2 years

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 two times per day in adults and one time per day for children below 10 years of age. The product is not suitable for small infants (3 months). For children 1 year the product should only be used in regions where vector diseases 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.