

Summary of product characteristics for a biocidal product

Product name: Gurkha Protec Active Aerosol

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

Authorisation number: 2019-03-21-B01

R4BP 3 asset reference number: MT-0020470-0000

Table Of Contents

Administrative information	1
1.1. Trade names of the product	1
1.2. Authorisation holder	1
1.3. Manufacturer(s) of the biocidal products	1
1.4. Manufacturer(s) of the active substance(s)	1
2. Product composition and formulation	2
2.1. Qualitative and quantitative information on the composition of the biocidal product	2
2.2. Type of formulation	2
3. Hazard and precautionary statements	3
4. Authorised use(s)	3
5. General directions for use	5
5.1. Instructions for use	5
5.2. Risk mitigation measures	5
5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment	5
5.4. Instructions for safe disposal of the product and its packaging	6
5.5. Conditions of storage and shelf-life of the product under normal conditions of storage	6
6. Other information	6

Administrative information

1.1. Trade names of the product

Gurkha Protec Active Aerosol

1.2. Authorisation holder

Name and address of the authorisation holder	Name	ACP Insect Repellents Limited
	Address	Ground Floor 8-9 Marino Mart, Fairview D03 P590 Clontarf, Dublin 3 Ireland
Authorisation number	2019-03-21-B01	
R4BP 3 asset reference number	MT-0020470-0000	
Date of the authorisation	21/03/2019	
Expiry date of the authorisation	16/05/2027	

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	ACP Solutions Ltd
Address of the manufacturer	Unit 41b, Nailsworth Mills Estate GL6 0BS Nailsworth United Kingdom
Location of manufacturing sites	Hickmans Road CN41 iJH Birkenhead United Kingdom

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 butylacetylaminopropionate		Active Substance	52304-36-6	257-835-0	20
ethanol	ethanol		64-17-5	200-578-6	22,53
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		0,87
water	water		7732-18-5	231-791-2	17,26

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.
 If eye irritation persists: Get medical advice.
 Read carefully and follow all instructions.
 Keep out of reach of children.
 Do not spray on an open flame or other ignition source.
 Do not pierce or burn, even after use.
 Avoid breathing spray.

4. Authorised use(s)

4.1 Use description

Use 1 - Insect repellent for human use - general public (non-professional)

Product type

PT19 - Repellents and attractants (Pest control)

Where relevant, an exact description of the authorised use

Insect repellent for human use - general public (non-professional).
 To be applied to exposed 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	Outdoor Other well-ventilated areas
Application method(s)	Spraying - Spray directly on to exposed skin. For application to face first of all spray on to hand and then apply to face.
Application rate(s) and frequencies	3.0 gram - 100 - Reapply when effectiveness diminishes. Repeat application after swimming or if perspiring heavily. Adults - apply no more than 6.0 g of product on to skin every 24 hours. Children below 10, apply no more than 3.0 g of product on to skin every 24 hours. Product can be used on children older and 1. For small babies use protective clothing.
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

Adults, apply directly on to the skin every 6-8 hours. Adults should apply to children under 10 no more than once per day. To maintain protection re-apply if perspiring or after bathing. Adults should apply to young children under 10. For babies, use protective clothing. Do not apply to children's hands.

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
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.
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 use

5.1. Instructions for use

Spray product evenly onto exposed skin. For application to the face, first spray product on to hand and then apply to face, avoiding the eyes.
Adults should apply to children below 10 years of age.
Do not apply to the hands of children.
Re-apply as required after swimming or heavily perspiring.
Only apply to exposed skin.
Avoid spraying onto synthetic material. Test on non visible part of clothing, if to be sprayed on to clothing.

5.2. Risk mitigation measures

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

Pressurised gas bottle: dispose of only in empty condition. Do not pierce container. Do not throw on to fire.

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. Protect from frost.
Shelf-life: at least 2 years

6. Other information

This application when approved will replace the existing product notified to MCCA Gurkha Protec Aerosol.

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.