

Summary of product characteristics for a biocidal product

Product name: Gurkha Protec Active Head Lice Repellent

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

Authorisation number: 2019-03-21-B02

R4BP 3 asset reference number: MT-0020464-0000

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Administrative information

1.1. Trade names of the product

Gurkha Protec Active Head Lice Repellent
Gurkha Protec "Ed Lice" Active Head Lice Repellent

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-B02	
R4BP 3 asset reference number	MT-0020464-0000	
Date of the authorisation	21/03/2019	
Expiry date of the authorisation	06/04/2027	

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	Fairfield, Bradshaw Lane, Greenhalgh PR4 3JA Kirkham 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 Spain

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			64-17-5	200-578-6	35
denatonium benzoate	N-benzyl-2-[(2,6-dimethylphenyl)amino]-N,N-diethyl-2-oxoethanaminium benzoate hydrate		3734-33-6	223-095-2	0,0088
water	water		7732-18-5	231-791-2	31,5
polyglycol	Not applicable, ingredient is a UVCB substance		25322-68-3	500-038-2	4
polyglycol	Not applicable, ingredient is a UVCB substance		25322-68-3	500-038-2	5
polysorbate	2-[2-[3,4-bis(2-hydroxyethoxy)oxolan-2-yl]-2-(2-hydroxyethoxy)ethoxy]eth		9005-64-5	500-018-3	1,5
Polyoxypropylene monostearyl ether	1-octadecoxypropan-2-ol		25231-21-4		3

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

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.
If eye irritation persists: Get medical advice.
Keep out of reach of children.
Read carefully and follow all instructions.
Avoid breathing spray.
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

Use 1 - Head Lice repellent

Product type

PT19 - Repellents and attractants (Pest control)

Where relevant, an exact description of the authorised use

If the hair is free of head lice and/or eggs, spray on to dry hair outwards from the scalp to the tip ensuring that the hair is covered with "Ed Lice" repellent. Take particular care to spray behind the ears and on the neck. Protec Ed Lice can safely be applied directly on to skin. If there are signs of a head lice infestation or head lice eggs, use a head lice treatment to clear the infestation and then apply repellent as above.

Target organism(s) (including development stage)

Scientific name: Pediculidae:
Common name: Human head louse
Development stage: Adults

Field(s) of use

Indoor
Well ventilated areas

Application method(s)	Spraying - The ready to use product is a pump spray which is sprayed directly onto the hair.
Application rate(s) and frequencies	0.5 mL - 100 - The head lice repellent spray is intended to be used to prevent infestation with lice and also to prevent a re-infestation with lice after a pediculicide treatment. It is usually applied once a day. The application must be repeated after washing of the hair.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Bottle - Plastic: HDPE - > 25.0 - < 250.0 mL

4.1.1 Use-specific instructions for use

Spray the product evenly onto the hair from the root to the hair tip, taking care to also treat the nape of the neck and hair behind the ears. Reapply the product after having washed the hair. An adult should apply the product to children below 10 years of age. 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
 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

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 un-cleaned containers like the product itself.

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: 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 use

5.1. Instructions for use

If the hair is free of head lice and/or eggs, spray on to dry hair outwards from the scalp to the tip ensuring that the hair is covered with "Ed Lice" repellent. Take particular care to spray behind the ears and on the neck. The head Lice product can safely be applied directly on to skin. If there are signs of a head lice infestation or head lice eggs, use a head lice treatment to clear the infestation and then apply the product as above.

FOR CONTINUED PROTECTION REPEAT TREATMENT EVERY TWO DAYS, AFTER WASHING HAIR OR SWIMMING.

Do not spray onto broken or damaged skin.

Protect eyes when spraying on to hair. Avoid inhaling the spray.

The product is suitable for adults, children and infants of all ages.

Protect from frost.

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

6. Other information

This application when approved will replace existing product notified as "Gurkha Protec Head Lice Repellent/Gurkha Protec 'Ed Lice" Head Lice Repellent".

From the risk assessments in the present dossier, it is concluded that the product can be used without concern once per day for adults, children as well as infants. For children and infants, the product should only be applied by adults. Use only in well-ventilated areas and avoid breathing spray.