

Summary of product characteristics for a biocidal product

Product name: Free Lotion Plus

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

Authorisation number: (10-14 17.5 Mr)BPR-22(A-19BAP1204201-23-15)

R4BP 3 asset reference number: LT-0030351-0000

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Administrative information

1.1. Trade names of the product

Free Lotion Plus

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	(10-14 17.5 Mr)BPR-22(A-19BAP1204201-23-15)	
R4BP 3 asset reference number	LT-0030351-0000	
Date of the authorisation	27/01/2023	
Expiry date of the authorisation	27/01/2033	

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 28006 Madrid Spain
Location of manufacturing sites	Polígono Merck 08100 Mollet de 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 de 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	ethyl 3-[N-acetyl-N-butyl] aminopropionate	Active Substance	52304-36-6	257-835-0	10
xanthan gum		Non-active substance	11138-66-2	234-394-2	0,2
butane-1,3-diol	butane-1,3-diol	Non-active substance	107-88-0	203-529-7	4
Carbomer		Non-active substance	9007-20-9		0,3
SP Arlancel 165-FP MBAL-PA-(RB)	Not applicable, the ingredient is a mixture containing Octadecanoic acid, monoester with 1,2,3-propanetriol (CAS No. 31566-31-1) and Poly(oxy-1,2-ethanediyl), .alpha.-(1-oxooctadecyl)-.omega.-hydroxy- (100 mol EO average molar ratio) (CAS No. 9004-99-3).	Non-active substance			3,5
water	water	Non-active substance	7732-18-5	231-791-2	70

Citric acid monohydrate	2-Hydroxypropane-1,2,3-tricarboxylic acid;hydrate	Non-active substance	5949-29-1	611-842-9	0,11
isopropyl palmitate	isopropyl palmitate	Non-active substance	142-91-6	205-571-1	4
stearic acid	stearic acid	Non-active substance	57-11-4	200-313-4	2
PPG-3 benzyl ether myristate	Poly[oxy(methyl-1,2-ethanediyl)],alpha-(1-oxotetradecyl)-thetaphenoxy	Non-active substance	642443-86-5		2
hexadecan-1-ol	hexadecan-1-ol	Non-active substance	36653-82-4	253-149-0	1
Sepigel 305	Not applicable, the ingredient is a mixture containing 1) hydrocarbons, C11-C13, isoalkanes, <2% aromatics, 2) Hydrocarbons, C12-C16, isoalkanes, cyclics, <2% aromatics and 3) 3,6,9,12,15,18,21-heptaotriacontan-1-ol (CAS No. 3055-97-8).	Non-active substance			1
2,2',2''-nitrilotriethanol	2,2',2''-nitrilotriethanol	Non-active substance	102-71-6	203-049-8	0,4
Disodium hydrogen phosphate dihydrate	disodium;hydrogen phosphate;dihydrate	Non-active substance	10028-24-7	600-053-5	0,89
disodium dihydrogen ethylenediaminetetraacetate	disodium dihydrogen 2,2',2'',2'''-(ethane-1,2-diyl)dinitrilo)tetraacetate	Non-active substance	139-33-3	205-358-3	0,1
poly(dimethylsiloxane)	dimethyl(oxo)silane	Non-active substance	63148-62-9		0,5

2.2. Type of formulation

EW - Emulsion, oil in water

3. Hazard and precautionary statements

Hazard statements

Causes serious eye irritation.

Precautionary statements

Keep out of reach of children.

Read carefully and follow all instructions.

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

If eye irritation persists:Get medical advice.

4. Authorised use(s)

4.1 Use description

Use 1 - Insect repellent for human use

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)
Target organism(s) (including development stage)	Scientific name: Ixodidae: Ixodes ricinus and Ixodes scapularis Common name: Ticks Development stage: Nymphs Scientific name: Ixodidae: Ixodes ricinus and Ixodes scapularis Common name: Ticks Development stage: Adults Scientific name: Culicidae: Aedes, Anopheles, Culex and Mansonia species Common name: Mosquitoes Development stage: Adults
Field(s) of use	Outdoor Other Use in well ventilated area
Application method(s)	Method: Manual application Detailed description: Apply directly on to exposed skin
Application rate(s) and frequencies	Application Rate: 3.00 g Dilution (%): 100 Number and timing of application: Adults - Apply 3.0g of product onto skin up to 7 times per day. Children - Apply 3.0 g product onto skin up to 4 times per day. Infants - Apply 3.00 g products onto skin no more than twice a day for infants. The frequency should be reduced if applied to the body trunk. Use clothing to protect babies under 1 Re-apply after swimming or bathing.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	Bottle - Plastic: HDPE - 100ml Bottle - Plastic: HDPE - 200 ml

4.1.1 Use-specific instructions for use

Adults, apply directly on to the skin every 4-6 hours. Apply to children under 10 no more than four times 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.
Protect from frost.

4.1.2 Use-specific risk mitigation measures

None required

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

For handling large quantities e.g. during production:
After inhalation: fresh air.
For Consumers:
After eye contact rinse out with plenty of water. After swallowing: make victim drink water (two glasses at most). Consult doctor if feeling unwell.
Most important symptoms and effects both acute and delayed: We have no description of toxic symptoms.
Indication of any immediate medical attention and special treatment needed: No information available.
Do not let the product enter drains.
Methods and materials for containment and cleaning up: Cover drains. Collect, bind, pump spills. Observe possible material restrictions. Take up with liquid-absorbent material (e.g. Chemizorb). 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

Consumers: Dispose via municipal waste unless national regulations state differently.
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: Tightly closed. Recommended storage temperature; ambient temperature. Protect from frost

5. General directions for use

5.1. Instructions for use

Adults, apply directly on to the skin every 4-6 hours. Apply to children under 10 no more than four times 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.
Protect from frost.

5.2. Risk mitigation measures

Do not apply the product to the hands of children. Take care to protect the eyes.

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

No observations of undesirable side effects when using IR3535®-based products are known to the applicant.
For handling large quantities e.g. during production:
After inhalation: fresh air. In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.
Also for consumers:
After eye contact: rinse out with plenty of water. After swallowing: make victim drink water (two glasses at most). Consult doctor if feeling unwell.
Most important symptoms and effects, both acute and delayed: We have no description of any toxic symptoms.
Indication of any immediate medical attention and special treatment needed: No information available.
Environmental precautions: Do not let product enter drains. Methods and materials for containment and cleaning up: Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions. Take up with liquid-absorbent material (e.g. Chemizorb®). Dispose of properly. Clean up affected area.

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

Consumers: Dispose via municipal waste unless national regulations state differently. 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: Tightly closed. Recommended storage temperature: ambient temperature. Protect from frost.

6. Other information

This application when approved will replace existing product registration: Free Losjonas, BSV-2680
The product can be used up to seven times per day in adults and four times per day for children under 10 years of age when face, arms, legs and hands are treated. Reduce the frequency in case more body parts are treated. In small children and infants, the use of Insect Repellent Lotion IR3535® 10 % must be limited to two applications per day (treatment of face, arms and legs). The use for children 1 year is not recommended. 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. 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 not to use creams or perfumes on top of the applied repellents.