



CERTIFICATE OF ANALYSIS

BODY MILK UNSCENTED

Batch No.: 4439010

Best Before End: July 2023

Analysis Description	Specification	Result	Compliance
Appearance	Opaque Lotion	Matches Standard	Pass
Colour	White – Off White	Matches Standard	Pass
Odour	Virtually None	Matches Standard	Pass
PH	6.50 ± 0.50	6.57	Pass
Viscosity	18500 ± 6500cps RV spindle TB speed 4	23460	Pass
Total Viable Count	<100	<10	Pass
Specific Gravity at 20°C	0.935- 1.035	1.023	Pass

Shelf life of this product depends very much on storage conditions, particularly temperature and exposure to light and air.

Expiry date must be considered as subjective; the expiry date given here is based on the best of our knowledge and experience of the material when stored under recommended conditions in original unopened containers.

Due to the natural ingredients contained in many of our products, there may be a slight batch to batch variation in the colour, odour or consistency. However, we ensure that this does not affect the quality and efficacy of the products in any way.

We hereby certify that the above material meets the required specification and is released for free sale.



ALLERGEN STATEMENT

MATERIAL	Body Milk

Material	CAS Number	Total Allergen Inclusion Level (%)
ALPHA-ISOMETHYL IONONE	127-51-5	-
AMYL CINNAMAL	122-40-7	-
AMYL CINNAMYL ALCOHOL	101-85-9	-
ANISE ALCOHOL	105-13-5	-
BENZYL ALCOHOL	100-51-6	-
BENZYL BENZOATE	120-51-4	-
BENZYL CINNAMATE	103-41-3	-
BENZYL SALICYLATE	118-58-1	-
BUTYLPHENYL METHYLPROPIONAL	80-54-6	-
CINNAMAL	104-55-2	-
CINNAMYL ALCOHOL	104-54-1	-
CITRAL	5392-40-5	-
CITRONELLOL	106-22-9	-
COUMARIN	91-64-5	-
EUGENOL	97-53-0	-
EVERNIA FURFURACEA EXTRACT	90028-67-4	-
EVERNIA PRUNASTRI EXTRACT	90028-68-5	-
FARNESOL	4602-84-0	-
GERANIOL	106-24-1	-
HEXYL CINNAMAL	101-86-0	-
HYDROXYCITRONELLAL	107-75-5	-
HYDROXYISOHEXYL 3-CYCLOHEXENE CARBOXYALDEHYDE	31906-04-4	-
ISO EUGENOL	97-54-1	-
LIMONENE	5989-27-5	-
LINALOOL	78-70-6	-
METHYL 2-OCTYNOATE	111-12-6	-
		No Allergens

Date: 14/07/2021



STATEMENT ON CMR SUBSTANCES

MATERIAL	Body Milk

This serves to confirm that the above product is not classified as carcinogenic, mutagenic or toxic to reproduction, as defined by Regulation (EC) No. 1272/2008 (CLP Regulation), the Dangerous Substances Directive (67/548/EEC), or the Dangerous Preparations Directive (1999/45/EC) including all its amendments.

We hereby confirm that no substances classified as carcinogenic, mutagenic or toxic to reproduction, category 1A, 1B or 2 under Annex VI to Regulation (EC) No. 1272/2008 are added to this product.

14/07/2021



CPNP INCI BANDING

BODY MILK - UNSCENTED

	Banding	INCI Name
INCI Listing	>75.0 to ≤100.0	Aqua
	>5.0 to ≤10.0	Prunus amygdalus dulcis Oil
	>1.0 to ≤5.0	Stearic Acid
	>1.0 to ≤5.0	Glycerin
	>1.0 to ≤5.0	Cetearyl Alcohol
	>0.1 to ≤1	Ceteareth-20
	>0.1 to ≤1	Dimethicone
	≤0.1	Lavandula angustifolia Flower Extract
	≤0.1	Symphytum officinale Leaf Extract
	≤0.1	Panax ginseng Root Extract
	≤0.1	Chamomilla recutita Flower Extract
	>0.1 to ≤1	Triethanolamine
	>0.1 to ≤1	Caprylyl Glycol
	>0.1 to ≤1	Sodium PCA
	≤0.1	Disodium EDTA
	≤0.1	Tocopheryl Acetate
	≤0.1	Carbomer
	≤0.1	Decylene Glycol
	≤0.1	Alcohol Denat.
	≤0.1	Lactic Acid
>0.1 to ≤1	Phenoxyethanol	

Allergens	Nil
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Ingredients in grey area are below 1% and can be listed in any order

INCI names listed have been sourced from the CosIng European Commission database

The INCI listing is to the best of our knowledge, based on the information supplied, correct at the time of sending

Issue Date: 11/02/2015

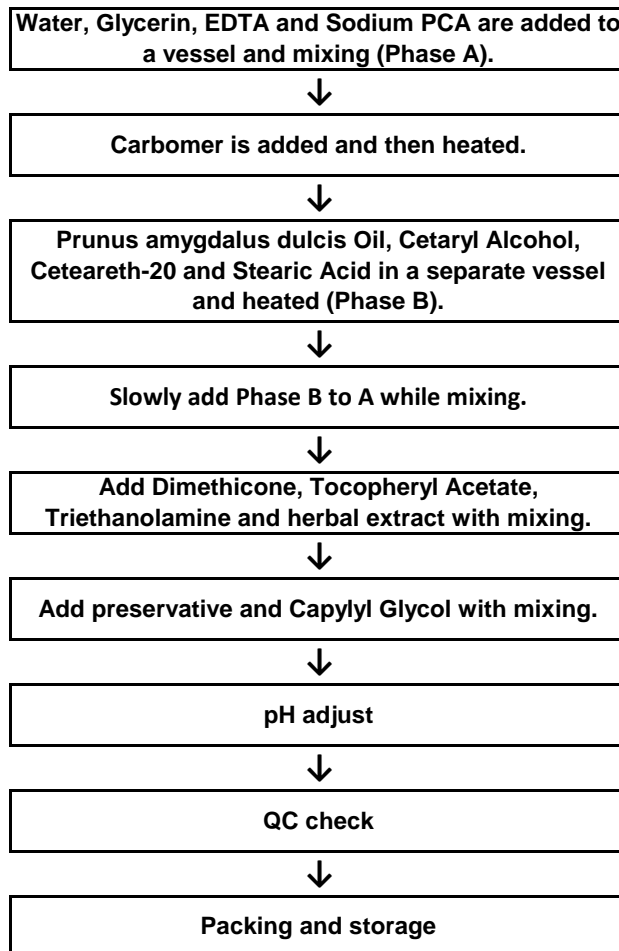
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PRODUCTION FLOW CHART

Body Milk Unscented

Part Number: 20116A





STATEMENT ON GENETICALLY MODIFIED ORGANISMS

Body Milk Unscented

Part Number: 20116A

We confirm to the best of our knowledge that the above product does not contain, nor has been produced with the aid of any genetically modified organism. In consequence, this product will not contain any detectable residues of protein or DNA resultant from genetic modification.

PRODUCT INFORMATION FILE

Prepared according to EC 1223/2009

**Product Name:
Body Milk**

**Product Code:
TBBODYMILK**

**Supplier:
MADAR Corporation Ltd, 19-20 Sandleheath Industrial
Estate, Fordingbridge, Hampshire, SP6 1PA**

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A statement confirming the name and place of manufacture

A statement confirming compliance with good manufacturing practice (GMP) and referring to a description of the method of manufacturing

A statement confirming that no animal testing is performed by the manufacturer, his agents or suppliers, relating to the safety of this product

Composition of the Product

Physical / Chemical Characteristics

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VOLUME 1

Name and Place of Manufacture

The product is manufactured at:
Our supplier in Cambridgeshire

Good Manufacturing Practice Statement

The management system of the Manufacturer has been assessed by SGS United Kingdom Ltd and certified as meeting the requirements of ISO 22716:2007, Cosmetics – Guidelines on Good Manufacturing Practices (GMP). A copy of the certificate can be seen in Appendix 1.

It is confirmed that the product is manufactured to Cosmetic Good Manufacturing Practice (GMP).

A description of the method of manufacturing is held on file at the Manufacturer's site.

Animal Non-testing Declaration

It is confirmed that the product, and the individual ingredients in the product, have not been the subject of animal testing or retesting.

It is also confirmed that no animal testing is carried out via third parties on behalf of the company.

Composition of the Product

The detailed quantitative formulation (exact % of each ingredient) is held on file at the Manufacturer's site.

Physical/Chemical Characteristics

The raw material specifications and the finished product specification are held on file at the Manufacturer's site.

Raw Material Quality/Purity

Raw Material Manufacturers' material safety data sheets, specifications and certificates of analysis are held on file at the Manufacturer's site.

Stability

The stability of the product is acceptable. Stability data is held on file at the Manufacturer's site.

At the time of submission of the data to the safety assessor, 12 weeks stability testing under accelerated conditions had been completed. From the Cosmetic Product Safety Report, Part A, Section 2, it can be seen that the safety assessor concluded that the product may be described as nominally stable with a shelf life of minimum 24 months un-opened. The stability testing under accelerated conditions was continued to 18 weeks validating a 30 plus month shelf life and a period after opening (PAO) of 6 months.

Where there is slight change in odour characteristics this change is to aesthetic properties only and safety will not be affected.

Where there is a slight change in appearance this change is to aesthetic properties only and safety will not be affected.

Microbial Quality - Ingredients

It is a requirement that all raw materials / ingredients meet a microbial quality of < 1000 cfu/gram for adult products (from the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation, 8th Revision, 2012). All the raw materials / ingredients comply with this requirement.

Microbial Quality – Finished Product

It is a requirement that the finished product meets a microbial quality of < 1000 cfu / gram for adult products and zero harmfuls (from the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation, 8th Revision, 2012). The finished product complies with this requirement.

Finished Product Safety

The microbial content (Total Viable Count) at time of manufacture must be within recognised limits: nmt 1000 cfu and zero harmfuls / gram (from the SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation, 8th Revision, 2012). The microbial content at time of manufacture complies with these recognised limits.

Challenge Test Data

The product will pass a Microbial Challenge Test. Challenge Test data is held on file at the Manufacturer's site.

Allergens Declarations

Allergens Declarations are held on file at MADAR Corporation.

IFRA Statement

IFRA Statements are held on file at MADAR Corporation.

Wording or Artwork for the Pack Labelling

The product is supplied commercially as a cosmetic base product to which a number of additional ingredients may be added by the end user and, therefore, there is no retail pack labelling or artwork.

Undesirable Effects and Serious Undesirable Effects

MADAR Corporation is not aware of any available data on undesirable effects and serious undesirable effects relating to the product, or other similar cosmetic products.

VOLUME 2

Cosmetic Product Safety Report

Conforming to

REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of
30 November 2009 on Cosmetic Products

By

Cosmetic Safety Consultants Ltd on behalf of the named manufacturer below

CSC Reference – II010614 WLB LAB2204

Product: Body Lotion

Manufacturer's Reference LAB2204

Product Category - Cosmetic Emulsion

Manufacturer Cambridgeshire

Safety Report Part A

1. Quantitative and qualitative composition of the product

INCI Name	Banding %	CAS Number
Aqua	>75.0 to ≤100.0	7732-18-5
Prunus amygdalus dulcis Oil	>5.0 to ≤10.0	8007-69-0 / 90320-37-9
Glycerin	>1.0 to ≤5.0	56-81-5
Stearic Acid	>1.0 to ≤5.0	57-11-4
Cetearyl Alcohol	>1.0 to ≤5.0	67762-27-0 / 8005-44-5
Ceteareth-20	>0.1 to ≤1	68439-49-6
Dimethicone	>0.1 to ≤1	63148-62-9 / 9006-65-9 / 9016-00-6
Triethanolamine	>0.1 to ≤1	102-71-6
Lavandula angustifolia Flower Extract	≤0.1	90063-37-9
Symphytum officinale Leaf Extract	≤0.1	84696-05-9
Panax ginseng Root Extract	≤0.1	84650-12-4
Chamomilla recutita Flower Extract	≤0.1	84082-60-0
Caprylyl Glycol	>0.1 to ≤1	1117-86-8
Sodium PCA	>0.1 to ≤1	28874-51-3
Tocopheryl Acetate	≤0.1	7695-91-2 / 58-95-7
Decylene Glycol	≤0.1	1119-86-4
Lactic Acid	≤0.1	50-21-5
Alcohol Denat.	≤0.1	-
Carbomer	≤0.1	9007-20-9 / 9003-01-4 / 76050-42-5 / 9062-04-8 / 9007-16-3 / 9007-17-4
Disodium EDTA	≤0.1	139-33-3 / 6381-92-6
Phenoxyethanol	>0.1 to ≤1	122-99-6

2. Physical/chemical characteristics and stability of the cosmetic product

Appearance: Mobile lotion

Colour: White

Odour: Virtually odourless

pH: 6.5 – 7.5

Viscosity cps at 20°C: 15000 - 30000
(Brookfield LVT, Spindle 4, 6rpm)

Raw Materials

Physical/chemical characteristics - detailed as appropriate to individual ingredients in the supplier Material Safety Data Sheets (reviewed and approved by assessor) – see Annex 1

Stability Testing

The product has successfully completed stability testing under accelerated conditions. All stability data have been considered and the product may be described as nominally stable with a shelf life of minimum 24 months un-opened (assuming the temperature dependence of the stability kinetics does not deviate substantially from the Arrhenius model)

Slight variation in product pH is not significant and is typical of the precision associated with pH measurement of this type of sample matrix

See stability test report - Annex 1

3. Microbiological quality

The product has successfully completed preservative efficacy testing according to British Pharmacopoeia criteria for topical products.

Donnington Laboratories Ltd. Report reference M-4A352-2 – see Annex 1

4. Impurities, traces, information about the packaging material

Ingredient Purity

None of the ingredients used have specific prescribed purity criteria according to Regulation (EC) No 1223/2009 . General purity criteria apply and a review of supplier specifications and certificates of analysis indicate that general ingredient purity is acceptable.

The nature of the raw materials used in this formulation, together with associated manufacturing techniques indicate that the introduction of contaminants during production is unlikely – EU standard GMP procedures are in place. The presence of trace contaminants with toxicological significance (heavy metals, polycyclic aromatic hydrocarbons etc.) in raw materials is also unlikely – none of the components used are associated with the presence of these types of contamination.

– see Annex 1

Packaging

Absence of nitrosating agents **Regulation (EC) No 1223/2009 due to presence of TEA.**

The product is supplied in a number of different containers composed of a number of generally inert polymeric materials. The materials used conform to EU regulations relating to suitability for food contact and hence, are acceptable for use with the cosmetic product matrices associated with this product formulation. Packaging material purity with regard to presence of trace monomeric materials and other toxicologically significant substances (e.g. heavy metals) is acceptable. The potential for migration of substance from packaging to product is negligible

5. Normal and reasonably foreseeable use

The product is intended for use as moisturising lotion for topical application in a number of potential exposure scenarios. Full body, face, neck, hand and foot, eye contour area. The product is supplied commercially as a cosmetic base product to which a number of additional active ingredients may be included by the end user, however this assessment relates to the use of this formulation as a finished cosmetic product.

Variations on this formulation, based on the inclusion of additional ingredients by subsequent users of this product would require a separate, specific safety report.

Target Population

Marketed as a product for general population – not specifically marketed for infant use or for application to mucous membranes.

6. Exposure to the cosmetic product

7. Exposure to the substances

Several product exposure characteristics have been calculated based on the end use of the formulation. Values used for amount of product, site of exposure and frequency of application are derived from the Scientific Committee on Consumer Safety NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION – 7th revision and Regulatory Toxicology and Pharmacology VOLUME 52, NUMBER 1, OCTOBER 2008

Route of exposure to the product is primarily dermal. Inhalation is not likely because there are no volatile components present and the product is applied by hand, rather than spray or aerosol. Ingestion is unlikely, however a 100% retention value has been used for all components, and a 100% value for dermal uptake / systemic availability – in the unlikely event of ingestion, the calculated total systemic availability value(100% retention and dermal uptake) would remain unchanged.

Summary of exposure product and substance characteristics are as follows.

	Product Category	Amount per application / g	Frequency of application	g / day applied	Retention factor	g/day exposure	Surface Area Exp cm3	Potential Systemic Exposure Dose (mg/kg) (based on 60kg)	Specific Exposure mg/cm2
Maximum component (%)	Full Body Products	7.82	1	7.82	100%	7.820	15670	130.33	0.4990
100	Aqua	7.820	1	7.820	100%	7.820	15670	130.333	0.4990
10	Prunus amygdalus dulcis Oil	0.782	1	0.782	100%	0.782	15670	13.033	0.0499
5	Glycerin	0.391	1	0.391	100%	0.391	15670	6.517	0.0250
5	Stearic Acid	0.391	1	0.391	100%	0.391	15670	6.517	0.0250
5	Cetearyl Alcohol	0.391	1	0.391	100%	0.391	15670	6.517	0.0250
1	Ceteareth-20	0.078	1	0.078	100%	0.078	15670	1.303	0.0050
1	Dimethicone	0.078	1	0.078	100%	0.078	15670	1.303*	0.0050
1	Triethanolamine	0.078	1	0.078	100%	0.078	15670	1.303	0.0050
0.1	Lavandula angustifolia Flower Extract	0.008	1	0.008	100%	0.008	15670	0.130	0.0005
0.1	Symphytum officinale Leaf Extract	0.008	1	0.008	100%	0.008	15670	0.130	0.0005
0.1	Panax ginseng Root Extract	0.008	1	0.008	100%	0.008	15670	0.130	0.0005
0.1	Chamomilla recutita Flower Extract	0.008	1	0.008	100%	0.008	15670	0.130	0.0005
1	Caprylyl Glycol	0.078	1	0.078	100%	0.078	15670	1.303	0.0050
1	Sodium PCA	0.078	1	0.078	100%	0.078	15670	1.303	0.0050
0.1	Tocopheryl Acetate	0.008	1	0.008	100%	0.008	15670	0.130	0.0005
0.1	Decylene Glycol	0.008	1	0.008	100%	0.008	15670	0.130	0.0005
0.1	Lactic Acid	0.008	1	0.008	100%	0.008	15670	0.130	0.0005
0.1	Alcohol Denat.	0.008	1	0.008	100%	0.008	15670	0.130	0.0005
0.1	Carbomer	0.008	1	0.008	100%	0.008	15670	0.130	0.0005
0.1	Disodium EDTA	0.008	1	0.008	100%	0.008	15670	0.130	0.0005
1	Phenoxyethanol	0.078	1	0.078	100%	0.078	15670	1.303	0.0050

	Product Category	Amount per application / g	Frequency of application	g / day applied	Retention factor	g/day exposure	Surface Area Exp cm3	Potential Systemic Exposure Dose (mg/kg) (based on 60kg)	Specific Exposure mg/cm2
Maximum component (%)	Face Products	1.54	1	1.54	100%	1.540	565	25.67	2.7257
100	Aqua	1.540	1	1.540	100%	1.540	565	25.667	2.7257
10	Prunus amygdalus dulcis Oil	0.154	1	0.154	100%	0.154	565	2.567	0.2726
5	Glycerin	0.077	1	0.077	100%	0.077	565	1.283	0.1363
5	Stearic Acid	0.077	1	0.077	100%	0.077	565	1.283	0.1363
5	Cetearyl Alcohol	0.077	1	0.077	100%	0.077	565	1.283	0.1363
1	Ceteareth-20	0.015	1	0.015	100%	0.015	565	0.257	0.0273
1	Dimethicone	0.015	1	0.015	100%	0.015	565	0.257*	0.0273
1	Triethanolamine	0.015	1	0.015	100%	0.015	565	0.257	0.0273
0.1	Lavandula angustifolia Flower Extract	0.002	1	0.002	100%	0.002	565	0.026	0.0027
0.1	Symphytum officinale Leaf Extract	0.002	1	0.002	100%	0.002	565	0.026	0.0027
0.1	Panax ginseng Root Extract	0.002	1	0.002	100%	0.002	565	0.026	0.0027
0.1	Chamomilla recutita Flower Extract	0.002	1	0.002	100%	0.002	565	0.026	0.0027
1	Caprylyl Glycol	0.015	1	0.015	100%	0.015	565	0.257	0.0273
1	Sodium PCA	0.015	1	0.015	100%	0.015	565	0.257	0.0273
0.1	Tocopheryl Acetate	0.002	1	0.002	100%	0.002	565	0.026	0.0027
0.1	Decylene Glycol	0.002	1	0.002	100%	0.002	565	0.026	0.0027
0.1	Lactic Acid	0.002	1	0.002	100%	0.002	565	0.026	0.0027
0.1	Alcohol Denat.	0.002	1	0.002	100%	0.002	565	0.026	0.0027
0.1	Carbomer	0.002	1	0.002	100%	0.002	565	0.026	0.0027
0.1	Disodium EDTA	0.002	1	0.002	100%	0.002	565	0.026	0.0027
1	Phenoxyethanol	0.015	1	0.015	100%	0.015	565	0.257	0.0273

	Product Category	Amount per application / g	Frequency of application	g / day applied	Retention factor	g/day exposure	Surface Area Exp cm ³	Potential Systemic Exposure Dose (mg/kg) (based on 60kg average)	Specific Exposure mg/cm ²
Maximum component (%)	Hand / Foot products	2.16	1	2.16	100%	2.160	860	36.00	2.5116
100	Aqua	2.160	1	2.160	100%	2.160	880	36.000	2.4545
10	Prunus amygdalus dulcis Oil	0.216	1	0.216	100%	0.216	880	3.600	0.2455
5	Glycerin	0.108	1	0.108	100%	0.108	880	1.800	0.1227
5	Stearic Acid	0.108	1	0.108	100%	0.108	880	1.800	0.1227
5	Cetearyl Alcohol	0.108	1	0.108	100%	0.108	880	1.800	0.1227
1	Ceteareth-20	0.022	1	0.022	100%	0.022	880	0.360	0.0245
1	Dimethicone	0.022	1	0.022	100%	0.022	880	0.360*	0.0245
1	Triethanolamine	0.022	1	0.022	100%	0.022	880	0.360	0.0245
0.1	Lavandula angustifolia Flower Extract	0.002	1	0.002	100%	0.002	880	0.036	0.0025
0.1	Symphytum officinale Leaf Extract	0.002	1	0.002	100%	0.002	880	0.036	0.0025
0.1	Panax ginseng Root Extract	0.002	1	0.002	100%	0.002	880	0.036	0.0025
0.1	Chamomilla recutita Flower Extract	0.002	1	0.002	100%	0.002	880	0.036	0.0025
1	Caprylyl Glycol	0.022	1	0.022	100%	0.022	880	0.360	0.0245
1	Sodium PCA	0.022	1	0.022	100%	0.022	880	0.360	0.0245
0.1	Tocopheryl Acetate	0.002	1	0.002	100%	0.002	880	0.036	0.0025
0.1	Decylene Glycol	0.002	1	0.002	100%	0.002	880	0.036	0.0025
0.1	Lactic Acid	0.002	1	0.002	100%	0.002	880	0.036	0.0025
0.1	Alcohol Denat.	0.002	1	0.002	100%	0.002	880	0.036	0.0025
0.1	Carbomer	0.002	1	0.002	100%	0.002	880	0.036	0.0025
0.1	Disodium EDTA	0.002	1	0.002	100%	0.002	880	0.036	0.0025
1	Phenoxyethanol	0.022	1	0.022	100%	0.022	880	0.360	0.0245

	Product Category	Amount per application / g	Frequency of application	g / day applied	Retention factor	g/day exposure	Surface Area Exp cm ³	Potential Systemic Exposure Dose (mg/kg) (based on 60kg average)	Specific Exposure mg/cm ²
Maximum component (%)	Eye Contour Area	0.5	1	0.5	100%	0.500	24	8.33	20.83
100	Aqua	0.500	1	0.500	100%	0.500	24	8.333	20.8333
10	Prunus amygdalus dulcis Oil	0.050	1	0.050	100%	0.050	24	0.833	2.0833
5	Glycerin	0.025	1	0.025	100%	0.025	24	0.417	1.0417
5	Stearic Acid	0.025	1	0.025	100%	0.025	24	0.417	1.0417
5	Cetearyl Alcohol	0.025	1	0.025	100%	0.025	24	0.417	1.0417
1	Ceteareth-20	0.005	1	0.005	100%	0.005	24	0.083	0.2083
1	Dimethicone	0.005	1	0.005	100%	0.005	24	0.083*	0.2083
1	Triethanolamine	0.005	1	0.005	100%	0.005	24	0.083	0.2083
0.1	Lavandula angustifolia Flower Extract	0.001	1	0.001	100%	0.001	24	0.008	0.0208
0.1	Symphytum officinale Leaf Extract	0.001	1	0.001	100%	0.001	24	0.008	0.0208
0.1	Panax ginseng Root Extract	0.001	1	0.001	100%	0.001	24	0.008	0.0208
0.1	Chamomilla recutita Flower Extract	0.001	1	0.001	100%	0.001	24	0.008	0.0208
1	Caprylyl Glycol	0.005	1	0.005	100%	0.005	24	0.083	0.2083
1	Sodium PCA	0.005	1	0.005	100%	0.005	24	0.083	0.2083
0.1	Tocopheryl Acetate	0.001	1	0.001	100%	0.001	24	0.008	0.0208
0.1	Decylene Glycol	0.001	1	0.001	100%	0.001	24	0.008	0.0208
0.1	Lactic Acid	0.001	1	0.001	100%	0.001	24	0.008	0.0208
0.1	Alcohol Denat.	0.001	1	0.001	100%	0.001	24	0.008	0.0208
0.1	Carbomer	0.001	1	0.001	100%	0.001	24	0.008	0.0208
0.1	Disodium EDTA	0.001	1	0.001	100%	0.001	24	0.008	0.0208
1	Phenoxyethanol	0.005	1	0.005	100%	0.005	24	0.083	0.2083

	Product Category	Amount per application / g	Frequency of application	g / day applied	Retention factor	g/day exposure	Surface Area Exp cm ³	Potential Systemic Exposure Dose (mg/kg) (based on 60kg average)	Specific Exposure mg/cm ²
Maximum component (%)	General Purpose cream / Lotion	1.2	1	1.2	100%	1.200	6725	20.00	0.1784
100	Aqua	1.200	1	1.200	100%	1.200	6725	20.000	0.1784
10	Prunus amygdalus dulcis Oil	0.120	1	0.120	100%	0.120	6725	2.000	0.0178
5	Glycerin	0.060	1	0.060	100%	0.060	6725	1.000	0.0089
5	Stearic Acid	0.060	1	0.060	100%	0.060	6725	1.000	0.0089
5	Cetearyl Alcohol	0.060	1	0.060	100%	0.060	6725	1.000	0.0089
1	Ceteareth-20	0.012	1	0.012	100%	0.012	6725	0.200	0.0018
1	Dimethicone	0.012	1	0.012	100%	0.012	6725	0.200*	0.0018
1	Triethanolamine	0.012	1	0.012	100%	0.012	6725	0.200	0.0018
0.1	Lavandula angustifolia Flower Extract	0.001	1	0.001	100%	0.001	6725	0.020	0.0002
0.1	Symphytum officinale Leaf Extract	0.001	1	0.001	100%	0.001	6725	0.020	0.0002
0.1	Panax ginseng Root Extract	0.001	1	0.001	100%	0.001	6725	0.020	0.0002
0.1	Chamomilla recutita Flower Extract	0.001	1	0.001	100%	0.001	6725	0.020	0.0002
1	Caprylyl Glycol	0.012	1	0.012	100%	0.012	6725	0.200	0.0018
1	Sodium PCA	0.012	1	0.012	100%	0.012	6725	0.200	0.0018
0.1	Tocopheryl Acetate	0.001	1	0.001	100%	0.001	6725	0.020	0.0002
0.1	Decylene Glycol	0.001	1	0.001	100%	0.001	6725	0.020	0.0002
0.1	Lactic Acid	0.001	1	0.001	100%	0.001	6725	0.020	0.0002
0.1	Alcohol Denat.	0.001	1	0.001	100%	0.001	6725	0.020	0.0002
0.1	Carbomer	0.001	1	0.001	100%	0.001	6725	0.020	0.0002
0.1	Disodium EDTA	0.001	1	0.001	100%	0.001	6725	0.020	0.0002
1	Phenoxyethanol	0.012	1	0.012	100%	0.012	6725	0.200	0.0018

*Systemic exposure is significantly reduced from the potential values quoted due to limited dermal uptake – please see individual entry

8. Toxicological profile of the substances

Margins of safety are based on maximum Systemic Exposure Doses derived from the exposure characteristics detailed above (Full body product)

INCI Name PRUNUS AMYGDALUS DULCIS OIL

Description Prunus Amygdalus Dulcis Oil is the fixed oil obtained from the ripe seed kernel of the Sweet Almond Tree, Prunus amygdalus var. dulcis, Rosaceae

CAS # 8007-69-0 / 90320-37-9

EINECS/ELINCS # - / 291-063-5

Functions SKIN CONDITIONING

SED 13.0 mg/kg bw/ day

MOS information / References

Plant-Derived Fatty Acid Oils as Used in Cosmetics (CIR December 2010)

Draft Report of the Plant-derived edible oil group (CIR November 2010)

No toxicological significance.

INCI Name GLYCERIN

INN Name glycerol

Ph. Eur. Name glycerolum

CAS # 56-81-5

EINECS/ELINCS # 200-289-5

Chemical/IUPAC Name Glycerol

Functions DENATURANT, HUMECTANT, PERFUMING, SOLVENT

SED 6.52 mg/kg bw/ day

MOS information / References

Glycerol is a polyhydric alcohol found abundantly in nature in the form of tri-glycerides in edible fats – glycerol is released as part of the natural metabolism of fats

OECD SIDS Initial Assessment report – Glycerol – Lowest published NOAEL data (based on teratogenic endpoint)1180 mg/kg/day

MOS = 1180/6.25 = >180

INCI Name STEARIC ACID
INN Name stearic acid
CAS # 57-11-4
EINECS/ELINCS # 200-313-4
Chemical/IUPAC Name Stearic acid

Functions CLEANSING, EMULSIFYING

SED 6.52 mg/kg bw/ day

MOS information / References

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Read across from the following data

Oleic Acid (C18:1)

NOAEL >7,500 mg/kg body weight per day (24 week oral study in Wister Rats)

IUCLID, 2000e

Lauric Acid NOEL >6000mg/kg was reported for lauric acid (18 week oral study, male rats)

Palmitic acid NOEL >5000mg/kg 150 days oral study in wister Rats)

Burdock GA, Carabin IG. Food Chem Toxicol. 2007 Apr;45(4):517-29.Safety assessment of myristic acid as a food ingredient.

Caprenin, (mixture of caprylic (C8), capric (C10), and behenic (C22) acids)

NOAEL 15% w/w i.e. 150000 mg/kg body weight per day

Webb, D.R., Wood, F.E., Bertram, T.A., and Fortier, N.E. (1993) A 91-day feeding study in rats with caprenin. Food and Chemical Toxicology, 31(12): 935-946.

Calculated MOS > 1000

INCI Name CETEARYL ALCOHOL

Description Alcohols, C16-18

Ph. Eur. Name alcohol cetylicus et stearylicus

CAS # 67762-27-0 / 8005-44-5

EINECS/ELINCS # 267-008-6 / -

Functions EMOLLIENT, EMULSIFYING, EMULSION STABILISING, OPACIFYING
VISCOSITY CONTROLLING

SED 6.52 mg/kg bw/ day

MOS information / References

There are no significant toxicological issues with this ingredient and NOAEL data do not exist for this reason.

Read across from the following data

Oleic Acid (C18:1)

NOAEL >7,500 mg/kg body weight per day (24 week oral study in Wister Rats)

IUCLID, 2000e

Lauric Acid NOEL >6000mg/kg was reported for lauric acid (18 week oral study, male rats)

Palmitic acid NOEL >5000mg/kg 150 days oral study in wister Rats)

Burdock GA, Carabin IG. Food Chem Toxicol. 2007 Apr;45(4):517-29.Safety assessment of myristic acid as a food ingredient.

Caprenin, (mixture of caprylic (C8), capric (C10), and behenic (C22) acids)

NOAEL 15% w/w i.e. 150000 mg/kg body weight per day

Webb, D.R., Wood, F.E., Bertram, T.A., and Fortier, N.E. (1993) A 91-day feeding study in rats with caprenin. Food and Chemical Toxicology, 31(12): 935-946.

Calculated MOS > 1000

INCI Name CETEARETH-20

Description C16-18 alcohols, ethoxylated (20 mol EO average molar ratio)

CAS # 68439-49-6

Functions CLEANSING, EMULSIFYING, SURFACTANT

SED = 1.30 mg/kg bw/ day

MOS information / References

Read across from PEG and Cetearyl alcohol (CETEARETH-20 is one of a number of polyethylene glycol ethers of Cetearyl Alcohol used commonly in cosmetics)

Polyethylene glycols (483. WHO Food Additives Series 14) - PEG ADI 10 mg/kg bw / day \approx NOAEL 1000 mg/kg bw / day

Cetearyl alcohol - Read across from Oleic Acid (C18:1)

NOAEL >7,500 mg/kg body weight per day (24 week oral study in Wister Rats)

IUCLID, 2000e

Lauric Acid NOEL >6000mg/kg was reported for lauric acid (18 week oral study, male rats)

Palmitic acid NOEL >5000mg/kg 150 days oral study in wister Rats)

Burdock GA, Carabin IG. Food Chem Toxicol. 2007 Apr;45(4):517-29.Safety assessment of myristic acid as a food ingredient.

Calculated MOS > 1000

INCI Name DIMETHICONE

Description

INN Name dimeticone

Ph. Eur. Name dimeticonum

CAS # 63148-62-9 / 9006-65-9 / 9016-00-6

EINECS/ELINCS # - / - / - /

Chemical/IUPAC Name Dimethicone

Functions ANTIFOAMING, EMOLLIENT, SKIN CONDITIONING, SKIN PROTECTING

SED = 1.30 mg/kg bw/ day (potential)

MOS information / References

Adjusted SED (based on 0.5% dermal absorption) = 0.007

Dermal absorption rate of 0.5% has been used for calculation of systemic exposure doses for dimethylpolysiloxane based on information provided in SCCS/1241/10 Opinion on Cyclomethicone (D4 / D5)

Eighteenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 557.

FAO Nutrition Meetings Report Series, 1974, No. 54.

DIMETHYLPOLYSILOXANE – ADI 0-1.5 mg/kg bw/day

NOAEL = ADI × 100

NOAEL = 150 mg/kg bw/day

SED calculated using skin absorption at 0.5%)

MOS = 150/0.007 =>15000

Local Toxicity - Skin/eye irritation and sensitisation - Polydimethylsiloxanes are generally non- irritating to skin or mucous membranes

INCI Name TRIETHANOLAMINE

Description

INN Name trolamine

Ph. Eur. Name

CAS # 102-71-6

EINECS/ELINCS # 203-049-8

Chemical/IUPAC Name 2,2',2''-Nitrilotriethanol

Cosmetic Restriction III/62

Functions BUFFERING, EMULSIFYING, MASKING, SURFACTANT

Annex/Part, Ref # III/1,62

Field of application and/or use

(a) Non-rinse-off products

(b) Other products

Maximum authorized concentration in the finished cosmetic product (a) 2.5%

Other limitations and requirements (a) (b)

- Do not use with nitrosating systems
- Minimum purity: 99%
- Maximum secondary amine content: 0.5% (applies to raw materials)
- Maximum nitrosamine content: 50 microgram/kg
- Keep in nitrite-free containers

SED = 1.30 mg/kg bw/ day

MOS information

Quality and concentration comply with Annex III / 1,62 as verified by certificates of analysis / supplier specification – see Annex 1

INCI Name LAVANDULA ANGUSTIFOLIA FLOWER EXTRACT

Description Lavandula Angustifolia Extract is the extract of the flowers of the Lavender, Lavandula angustifolia, Labiatae

INN Name

Ph. Eur. Name

CAS # 90063-37-9

EINECS/ELINCS # 289-995-2

Chemical/IUPAC Name

Cosmetic Restriction

Other Restriction(s)

Functions SKIN CONDITIONING

SED = 0.13 mg/kg bw/ day

MOS information / References

Based on linalool / linalyl acetate model – OECD SIDS Lowest NOAEL (several endpoints considered including reproductive, maternal , mutagenicity and immunotoxicity) is 160mg/kg (based on liver and kidney weight increase) Linalyl acetate is metabolised to linalool, producing a total linalool equivalent content of $45 + (25 \times .78) = 65\%$ $0.67 \times 0.65 =$ SED of 0.43 linalool $MOS = 160/0.43 = 372$

Read Across from Lavender essential oil - MOS for 1% oil (SED 0.67) =372

Oil present in lavender at <10% - MOS = $372 \times 10 = 3720 * (0.67/0.13)$

Calculated MOS for extract >19000

INCI Name SYMPHYTUM OFFICINALE LEAF EXTRACT

Description Symphytum Officinale leaf Extract is an extract of the leaves of the Comfrey, Symphytum officinale L., Boraginaceae

CAS # 84696-05-9

EINECS/ELINCS # 283-625-3

Functions SKIN CONDITIONING

SED = 0.13 mg/kg bw/ day (to extract)

MOS information / References – based on Pyrrolizidine alkaloid content

PA (Pyrrolizidine alkaloid) content in leaf 8g /kg = 0.8% PA (Maximum potential value)

20% extraction efficiency of PAs into extract = 0.16% PA in extract

Used at 0.1% (extract) in final formulation, the concentration of PA in the final product is

$0.16 \times 0.001 = 0.00016\%$

8g per day usage of the final product equates to exposure to PAs of

$0.0000128 \text{ g PA} = 0.00128 \text{ mg PA} = 0.128 \text{ } \mu\text{g PA}$

SED = 0.002 $\mu\text{g /kg b.w./day}$

Adjusted SED (10% dermal uptake)

SED = 0.0002 $\mu\text{g /kg b.w./day}$

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS
AND THE ENVIRONMENT

COT Statement on Pyrrolizidine Alkaloids in Food

COT Statement 2008/06

October 2008

In line with COC65 and EFSA66 opinions, the Committee considered that MOEs of 10,000 and above, corresponding to doses of up to 0.007 $\mu\text{g /kg b.w./day}$, would be unlikely to be of concern.

INCI Name PANAX GINSENG ROOT EXTRACT

Description

Panax Ginseng Root Extract is an extract of the roots of the Ginseng, *Panax ginseng*,
Araliaceae

INN Name

Ph. Eur. Name

CAS # 84650-12-4

EC # 283-493-7

Chemical/IUPAC Name

Cosmetic Restriction

Other Restriction(s)

Functions EMOLLIENT, SKIN PROTECTING, TONIC

SED = 0.13 mg/kg bw/ day (to extract)

MOS information / References

NOAEL >100 mg/kg bw / day

MOS =100/0.13 = >700

Read across from The American Journal of Chinese Medicine, January 2011, Vol. 39, No. 04 :
pp. 779-788 Two-Year Toxicity and Carcinogenicity Studies of *Panax ginseng* in Fischer 344
Rats and B6C3F1 Mice Po-Chuen Chan, John C. Peckham, David E. Malarkey, Grace E.
Kissling, Gregory S. Travlos, and Peter P. Fu

J Acupunct Meridian Stud 2008;1(2):121–127 - Toxicological Study on MUNOPHIL, Water
Extract of *Panax ginseng* and *Hericium erinaceum* in Rats
Il-Dong Park, Hwa-Seung Yoo, Yeon-Weol Lee, Chang-Gue Son, Min Kwon, Ha-Jung Sung,
Chong-Kwan Cho

INCI Name CHAMOMILLA RECUTITA FLOWER EXTRACT

Description

Chamomilla Recutita Flower Extract is an extract of the flowerheads of the matricaria, Chamomilla recutita (L.), Compositae

CAS # 84082-60-0

EC # 282-006-5

Functions MASKING, SKIN CONDITIONING

SED = 0.13 mg/kg bw/ day (to extract)

MOS information

Taken widely as an infusion (chamomile tea) - Intake from diet is likely to be greater than from cosmetic use in this context - no safety concerns.

Extraction of essential oil component is likely to a small degree (based on max 5% EO component in starting material) leading to SED for essential oil component of <0.01 mg/kg bw/ day which is below the level of toxicological concern for this category of substance

INCI Name CAPRYLYL GLYCOL

CAS # 1117-86-8

EC # 214-254-7

Chemical/IUPAC Name Octane-1,2-diol

Functions EMOLLIENT, HUMECTANT, SKIN CONDITIONING

SED = 1.30 mg/kg bw/ day

MOS information / References

In this formulation, this ingredient is present to support the function of the preservative phenoxyethanol. Aliphatic diols are generally well tolerated with regard to chronic exposure, with increasing chain length indicating decreasing toxicological potential.

Read across from Hexylene Glycol - The systemic NOAEL for this guideline study is considered to be 450 mg/kg/day, SIDS. Screening Information Data Set for High Production Volume Chemicals. (2003) 136 p

Assuming a minimum NOAEL value of 450 mg/kg/day

Calculated MOS = $450/1.30 = 346$

INCI Name SODIUM PCA

CAS # 28874-51-3

EINECS/ELINCS # 249-277-1

Chemical/IUPAC Name Sodium 5-oxo-2-pyrrolidinecarboxylate

Functions HUMECTANT, SKIN CONDITIONING

SED = 1.30 mg/kg bw/ day

MOS information / References

Cosmetic Ingredient Review Expert Panel. Final Report on the Safety Assessment for PCA and Sodium PCA. International Journal of Toxicology. 1999;18(Supplement 2).

These ingredients are recommended to be used in a concentration range of 0.2-4%.

Specific note - Should not be used in formulations that contain N-nitrosating agents – this formulation does not contain nitrosating agents.

INCI Name TOCOPHERYL ACETATE

CAS # 7695-91-2 / 58-95-7

EC # 231-710-0 / 200-405-4

Chemical/IUPAC Name 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate

Functions ANTIOXIDANT, SKIN CONDITIONING

SCCS opinions •0494/01 - Opinion concerning The Use of alpha-Tocopherol Acetate in Cosmetic Products

SED = 0.13 mg/kg bw/ day

MOS information / References

NOAEL: 800-1600 IU/day (540 – 970 mg d- α -tocopherol equivalents/day)

Key studies: Gillilan et al. (1977); Meydani et al. (1996); Stephens et al. (1996)

MOS = 540/0.13 = >4000

INCI Name DECYLENE GLYCOL

CAS # 1119-86-4

EC # 214-288-2

Chemical/IUPAC Name 1,2-Decanediol

Cosmetic Restriction

Other Restriction(s)

Functions SKIN CONDITIONING

SED = 0.13 mg/kg bw/ day

MOS information / References

Aliphatic diols are generally well tolerated with regard to chronic exposure, with increasing chain length indicating decreasing toxicological potential.

Read across from Hexylene Glycol - The systemic NOAEL for this guideline study is considered to be 450 mg/kg/day, SIDS. Screening Information Data Set for High Production Volume Chemicals. (2003) 136 p

Assuming a minimum NOAEL value of 450 mg/kg/day

Calculated MOS = $450/0.13 = 3460$

INCI Name LACTIC ACID

INN Name lactic acid

Ph. Eur. Name acidum lacticum

CAS # 50-21-5

EINECS/ELINCS # 200-018-0

Chemical/IUPAC Name Propanoic acid, 2-hydroxy-

Functions BUFFERING, HUMECTANT, SKIN CONDITIONING

SED = 0.13 mg/kg bw/ day

MOS information

Lactic acid is produced during metabolism – it is present in dairy products and is consumed at levels which exceed exposure from cosmetic sources - in this context there is no toxicological significance.

INCI Name ALCOHOL DENAT.

Description Ethanol denatured in accordance with Customs and Excise regulations

Functions ANTIFOAMING, ANTIMICROBIAL, ASTRINGENT, MASKING, SOLVENT, VISCOSITY CONTROLLING

SED = 0.13 mg/kg bw/ day

MOS information

At 0.13 mg/kg bw ethanol exposure is significantly lower than widespread EU published values for safe levels of consumption. No toxicological significance in this context

INCI Name CARBOMER

Description

2-Propenoic acid, polymer with 2,2-bis(hydroxymethyl)propane-1,3-diol 2-propenyl ether

CAS # 9007-20-9 / 9003-01-4 / 76050-42-5 / 9062-04-8 / 9007-16-3 / 9007-17-4

Functions EMULSION STABILISING, GEL FORMING, VISCOSITY CONTROLLING

SED = 0.13 mg/kg bw/ day

MOS information / References

NOAEL = 3000 mg/kg bw

Effects of oral administration of a high-molecular-weight crosslinked polyacrylate in rats. Lindenschmidt RC, Stone LC, Seymour JL, Anderson RL, Forshey PA, Winrow MJ. Fundam Appl Toxicol. 1991 Jul;17(1):128-35.

MOS = 3000/0.13 = >23000

INCI Name DISODIUM EDTA

INN Name edetate disodium

Ph. Eur. Name natrii edetas

CAS # 139-33-3 --- 6381-92-6

EC # 205-358-3

Chemical/IUPAC Name Disodium dihydrogen ethylenediaminetetraacetate

Cosmetic Restriction

Other Restriction(s)

Functions CHELATING, VISCOSITY CONTROLLING

SED = 0.13 mg/kg bw/ day

MOS information / References

NOAEL of 500 mg/kg/day is derived for Na₃EDTA (Scientific Committee On Toxicity, Ecotoxicity and the Environment (CSTEE) opinion on the results of the risk assessment of: tetrasodium ethylenediamine tetraacetate (Na₄EDTA) CAS n°: 64-02-8 and edetic acid (EDTA) cas no. 60-00-4

Calculated MOS = 500/0.13 = 3846

Preservatives

The use of preservatives in cosmetic products is governed by Annex V of Regulation (EC) No 1223/2009

This formulation contains phenoxyethanol which is authorised by Annex V at a maximum concentration of 1%. The concentration at which this component is present in this formulation meets these specifications and the preservation system used in this product is compliant with Regulation (EC) No 1223/2009

Phenoxyethanol	Substance 2- Phenoxyethanol CAS # 122-99-6 EC # 204-589-7 Name of Common Ingredients Glossary PHENOXYETHANOL INN/ISO/AN	Regulation (EC) No 1223/2009 Regulated By 2007/17/EC Other Directives/Regulations Annex/Ref # V/29 Product Type, body parts Maximum concentration in ready for use preparation 1.0%
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9. Undesirable effects and serious undesirable effects

None declared at the time of preparation of this document – a separate file must be made to record any declared incidences of undesirable effects – any serious undesirable effects must be notified to the competent authority and or local poison control agency

10. Information on the cosmetic product

The product is an established category of cosmetic products in current widespread use – no specific therapeutic claims are made. All constituents have been used widely in cosmetic preparations – no newly introduced or novel ingredients are used.

Cosmetic product safety Report Part B

CSC Reference – II010614 WLB LAB2204

Product: White Lotion Base
Manufacturer's Reference LAB2204

Product Category - Cosmetic Emulsion

Manufacturer Cambridgeshire

1. Assessment Conclusion

This product meets the criteria for safety specified by the requirements of Article 3 of REGULATION (EC) No 1223/2009

2. Labelled Warnings and Instruction for Use

No specific warnings required other than standard product usage instructions. If the product is used around the eye area, warning must be given to avoid direct eye contact. No other specific instructions for use are prescribed.

Allergen declaration

In a leave on product, any of the 26 allergens detailed in the European Commission Directive **2003/15/EC**, that are present in the final product at a concentration greater than or equal to 0.001% must be declared on the product labelling.

None present

3. Reasoning

Appropriate data were available for all components and a full review of this information has been made. The following information was reviewed as a minimum requirement

Relating to the final product -

Physical and Chemical Properties
Stability and Reactivity
Microbiological Purity
Packaging

Normal and reasonably foreseeable use
Target Population

And specifically

The general toxicological profile of each ingredient used:

The chemical structure of each ingredient:

The level of exposure of each ingredient;

The specific exposure characteristics of the areas on which the cosmetic product will be applied;

The specific exposure characteristics of the class of individuals for whom the cosmetic product is intended.

Margins of safety have been calculated for all components, with additional safety factors applied where appropriate due to the use of data from structurally related compounds.

CALCULATION OF THE MARGIN OF SAFETY

Maximum amount of ingredient applied (mg) **I**

Typical body weight of human (kg) **60**

Maximum absorption through the skin (%) **A**

Systemic Exposure Dose (mg/Kg/Bw) SED = **I x A / 60**

Margin of Safety **NOAEL / SED**

Where NOAEL equals no observed adverse effect level in mg/kg/bw from appropriate repeated dose studies.

MOS values for all toxicologically significant components (other than those whose presence is governed / prescribed specifically by the Annexes of Regulation (EC) No 1223/2009) have been calculated and are satisfactory (MOS >100)

Local toxicity – Phototoxic materials are not included in this formulation at levels of concern

CMRs – not included in this formulation

Nano materials – not included in this formulation

Dermal irritants / sensitizers – No significant exposure. Compatibility testing is generally advised if the product formulation uses ingredients at concentrations significantly greater than in previously well tolerated formulations. This formulation is very similar to other formulations that have been marketed previously, over a number of years without report of adverse reaction.

Interaction of substances

No significant interactions expected, based on a review of the chemical properties of the species included in this formulation. There are no components present that are likely to undergo spontaneous reaction – no species are present that have structural alerts with regard to carcinogenic activity.

4. Assessor's credentials and approval of part B

Approved - This product meets the criteria for safety specified by the requirements of Article 3 of REGULATION (EC) No 1223/2009



Scott Grainger BSc (Hons) MSc CSci CChem MRSC

01/06/14

Chartered Chemist, Chartered Scientist

On behalf of Cosmetic Safety Consultants Ltd Reg. 07175899 DL14 6SX

England

Scott Grainger MSc BSc (Hons) CSci CChem MRSC

22, Rosemount Road, Bishop Auckland, County Durham DL14 6SX United Kingdom
7, Route de Rosnay Vendoeuvres 36500 France

Email info@cosmeticsafetyassessment.com

Qualifications

MSc Applied Chemistry

BSc (Hons) Combined Sciences 1st Class (Chemistry with Microbiology and Mathematics)

Chartered Chemist (CChem)

Chartered Scientist (CSci)

Full member of the Royal Society of Chemistry (MRSC)

Experience

20+ years in chemical and product safety of which cosmetic toxicology forms a minimum of 3 years

5+ years in small scale manufacturing of cosmetics

Member of the advisory panel of the [GuildofCraftSoapandToiletryMakers](#)

THIS IS TO CERTIFY THAT

SCOTT GRAINGER

HAS BEEN AWARDED THE DESIGNATION

CHARTERED CHEMIST

BY THE ROYAL SOCIETY OF CHEMISTRY

AND IS ENTITLED TO USE THE LETTERS CChem



Royal Society of Chemistry
Founded 1847
Incorporated by Royal Charter 1965
Pursue the Mastery of Science

President

Registrar

Date of Award

14 November 2008

RSC Membership Number

378846

The certificate is issued subject to the provisions of the Charter and By-Laws
Registered Charity Number 207806



DATA SHEET

Body Milk - Unscented

Part Number: 20116A

General Description:

Traditional oil in water lotion base, made with a blend of oils to include Sweet Almond Oil, moisturising agents to include Sodium PCA, which is a naturally occurring humectant found in human skin, and anti-oxidant, Vitamin E Acetate to leave skin feeling soft, smooth and nourished.

Instructions For Use & Suggested Use Levels:

Gently stir in perfume, essential oils, dye or additive to the iBase Lotion at ambient temperature, until uniform. Discharge through a fine mesh filter into suitable packaging.

	Suggested %	Recommended max %
Floral water/ aqueous extracts	1.0	2.0
Veg/seed oils	0.1	1.0
Essential oils /fragrances	0.5*	1.0*^

* Dependent on the actual IFRA

^ Higher levels may be used but testing would definitely be required

NB: All bases have been stability tested as sold. Inovia recommends that you stability/ compatibility test the finished product in the actual finished product packaging before placing on the market.

Origin:

Inovia International certifies that to the best of their knowledge the above product was manufactured in the UK.

Allergens and IFRA

Contains none of the 26 allergens designated by the EU in European Union Cosmetics Regulation (EC) No 1223/2009 Annex III.

Does not contain material restricted/prohibited by IFRA and therefore does not require an IFRA statement.

Animal Non-Testing Declaration

Inovia International has never been involved in animal testing or retesting for any of its products, nor has it sanctioned any third party to conduct such testing.

Transmissible/ Bovine Spongiform Encephalopathy (T.S.E/B.S.E)

This product does not contain, and is not derived from, specified risk material as defined in Commission Decision 97/534/EC or mechanically recovered meat obtained from the vertebral column of bovine, ovine or caprine animals. During production, storage and transport there is no contact with any extracts of animal (cattle, sheep, goat etc) origin and a cross contamination is excluded.

Product is therefore free from Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE).

Statement on Genetically Modified Organisms

We confirm to the best of our knowledge that this product does not contain nor has been produced with the aid of any genetically modified organism. In consequence, this product will not contain any detectable residues of protein or DNA resultant from genetic modification.

Packaging

This product is available in 5kg, 25kg and 200kg containers, other sizes are available upon request.

It is the user's responsibility to determine safe conditions for the use of this product, and to assume liability for loss, injury, damage or expense arising from improper use of this product. The information provided does not constitute a

contract to supply to any specification, or for any given application, and buyers should seek to verify their requirements and product use.

Revision Date: 06/12/2017
Revision: 0

Body Milk

Version No: 1.2.13.8

Safety data sheet according to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758

Issue Date: 15/07/2021

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L.REACH.GB.EN

SECTION 1 Identification of the substance / mixture and of the company / undertaking

1.1. Product Identifier

Product name	IBASE LOTION
Chemical Name	Not Applicable
Synonyms	INO20116A
Other means of identification	Not Available

1.2. Relevant identified uses of the substance or mixture and uses advised against

Chemical Product Category	PC39	Cosmetics, personal care products
Sectors of Use	SU3	Industrial uses: Uses of substances as such or in preparations* at industrial sites
Relevant identified uses	Use according to manufacturer's directions.	
Uses advised against	Not Applicable	

1.3. Details of the supplier of the safety data sheet

Registered company name	Madar Corporation Limited	
Address	19 - 20 Sandheath Industrial Estate, Fordingbridge, SP6 1PA	
Telephone	01425 655 555	
Fax	Not Available	
Email	technical@madarcorporation.co.uk	

1.4. Emergency telephone number


Association / Organisation	Not Available
Emergency telephone numbers	Not Available
Other emergency telephone numbers	Not Available

SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

Classified according to GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567 [1]	H319 - Eye Irritation Category 2
Legend:	1. Classified by Chemwatch; 2. Classification drawn from GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567

2.2. Label elements

Hazard pictogram(s)	
Signal word	Warning

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IBASE LOTION

Hazard statement(s)

H319	Causes serious eye irritation.
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Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

P280	Wear protective gloves, protective clothing, eye protection and face protection.
P264	Wash all exposed external body areas thoroughly after handling.

Precautionary statement(s) Response

P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

2.3. Other hazards

May produce discomfort of the eyes*.

ETHANOL TSDA1 DEB 100	Listed in the Europe Regulation (EC) No 1907/2006 - Annex XVII (Restrictions may apply)
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SECTION 3 Composition / information on ingredients

3.1.Substances

See 'Composition on ingredients' in Section 3.2

3.2.Mixtures

1.CAS No 2.EC No 3.Index No 4.REACH No	%[weight]	Name	Classified according to GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567	Nanoform Particle Characteristics
1.56-81-5 2.200-289-5 3.Not Available 4.Not Available	1-5	<u>glycerol</u>	Not Classified [3]	Not Available
1.57-11-4* 2.200-313-4 3.Not Available 4.01-2119543894-28-XXXX 01-2120763582-50-XXXX	1-5	<u>stearic acid</u>	Not Applicable	Not Available
1.7732-18-5* 2.231-791-2 3.Not Available 4.Not Available	75-100	<u>water</u>	Not Applicable	Not Available
1.90320-37-9* 2.291-063-5 3.Not Available 4.01-2120737768-38-XXXX	5-10	<u>almond, sweet, extract</u>	Not Applicable	Not Available
1.68439-49-6 2.500-212-8 3.Not Available 4.Not Available	0.1-1	<u>alcohols C16-18 ethoxylated</u>	Acute Tox. 4, Serious Eye Damage/Eye Irritation Category 1, Acute Aquatic Hazard Category 1; H302, H318, H400 [3]	Not Available
1.9006-65-9 2.Not Available 3.Not Available 4.Not Available	0.1-1	<u>dimethicone</u>	Not Classified [3]	Not Available
1.122-99-6 2.204-589-7 3.603-098-00-9 4.Not Available	0.1-1	<u>ethylene glycol phenyl ether</u>	Acute Toxicity (Oral) Category 4, Eye Irritation Category 2; H302, H319 [2]	Not Available
1.102-71-6* 2.203-049-8 3.Not Available 4.01-2119486482-31-XXXX	0.1-1	<u>triethanolamine</u>	Not Applicable	Not Available
1.1117-86-8 2.214-254-7 3.Not Available 4.Not Available	0.1-1	<u>1,2-octanediol</u>	Eye Irritation Category 2; H319 [3]	Not Available
1.54571-67-4 2.259-234-9 3.Not Available	0.1-1	<u>sodium pyroglutamate</u>	Not Classified [3]	Not Available

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1.CAS No 2.EC No 3.Index No 4.REACH No	[%weight]	Name	Classified according to GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567	Nanoform Particle Characteristics
4.Not Available				
1.139-33-3 2.205-358-3 3.Not Available 4.Not Available	<0.1	<u>EDTA disodium salt</u>	Acute Tox. 4, Skin Corrosion/Irritation Category 2, Eye Irritation Category 2, Resp. STOT SE 3; H302, H315, H319, H335 [3]	Not Available
1.7695-91-2* 2.231-710-0 3.Not Available 4.01-2119457641-38-XXXX	<0.1	<u>DL-alpha-tocopherol acetate</u>	Not Applicable	Not Available
1.9003-01-4* 2.Not Available 3.Not Available 4.01-2120754771-50-XXXX	<0.1	<u>Carbomer</u>	Not Applicable	Not Available
1.1119-86-4 2.214-288-2 3.Not Available 4.Not Available	<0.1	<u>1,2-decanediol</u>	Serious Eye Damage/Eye Irritation Category 1; H318 [3]	Not Available
1.64-17-5* 2.200-578-6 3.603-002-00-5 4.01-2119457610-43-xxxx	<0.1	<u>ETHANOL TSDA1 DEB 100</u>	Flammable Liquid Category 2, Eye Irritation Category 2; H225, H319 [1]	Not Available
1.8022-15-9 2.Not Available 3.Not Available 4.Not Available	<0.1	<u>lavandin oil</u>	Skin Corrosion/Irritation Category 2, Skin Sensitizer Category 1, Chronic Aquatic Hazard Category 3; H315, H317, H412, EUH001, EUH019 [3]	Not Available
1.84696-05-9 2.283-625-3 3.Not Available 4.Not Available	<0.1	<u>Symphytum officinale (comfrey) extract</u>	Not Classified [3]	Not Available
1.84650-12-4 2.283-493-7 3.Not Available 4.Not Available	<0.1	<u>Ginseng extract</u>	Flammable Liquid Category 3; H226 [3]	Not Available
1.84082-60-0* 2.282-006-5 3.Not Available 4.01-2120763571-53-XXXX	<0.1	<u>Chamomile recutica oil</u>	Not Applicable	Not Available
1.50-21-5* 2.200-018-0 3.Not Available 4.01-2119548400-48-XXXX	<0.1	<u>lactic acid</u>	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 1; H315, H318 [1]	Not Available
Legend:	1. Classified by Chemwatch; 2. Classification drawn from GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties			

SECTION 4 First aid measures

4.1. Description of first aid measures

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ Wash out immediately with fresh running water. ▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▶ Seek medical attention without delay; if pain persists or recurs seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> ▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area. ▶ Other measures are usually unnecessary.
Ingestion	<ul style="list-style-type: none"> ▶ Immediately give a glass of water. ▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Firefighting measures

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Continued...

IBASE LOTION

5.1. Extinguishing media

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

5.2. Special hazards arising from the substrate or mixture

Fire Incompatibility	▸ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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5.3. Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▸ Alert Fire Brigade and tell them location and nature of hazard. ▸ Wear breathing apparatus plus protective gloves in the event of a fire. ▸ Prevent, by any means available, spillage from entering drains or water courses. ▸ Use fire fighting procedures suitable for surrounding area. ▸ DO NOT approach containers suspected to be hot. ▸ Cool fire exposed containers with water spray from a protected location. ▸ If safe to do so, remove containers from path of fire.
Fire/Explosion Hazard	carbon dioxide (CO ₂) other pyrolysis products typical of burning organic material. May emit corrosive fumes.

SECTION 6 Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

See section 8

6.2. Environmental precautions

See section 12

6.3. Methods and material for containment and cleaning up

Minor Spills	<ul style="list-style-type: none"> ▸ Clean up all spills immediately. ▸ Avoid breathing vapours and contact with skin and eyes. ▸ Control personal contact with the substance, by using protective equipment. ▸ Contain and absorb spill with sand, earth, inert material or vermiculite. ▸ Wipe up. ▸ Place in a suitable, labelled container for waste disposal.
Major Spills	<p>Moderate hazard.</p> <ul style="list-style-type: none"> ▸ Clear area of personnel and move upwind. ▸ Alert Fire Brigade and tell them location and nature of hazard. ▸ Wear breathing apparatus plus protective gloves. ▸ Prevent, by any means available, spillage from entering drains or water course. ▸ Stop leak if safe to do so. ▸ Contain spill with sand, earth or vermiculite.

6.4. Reference to other sections

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage**7.1. Precautions for safe handling**

Safe handling	<ul style="list-style-type: none"> ▸ Avoid all personal contact, including inhalation. ▸ Wear protective clothing when risk of exposure occurs. ▸ Use in a well-ventilated area. ▸ Avoid contact with moisture. ▸ Avoid contact with incompatible materials. ▸ When handling, DO NOT eat, drink or smoke. ▸ Keep containers securely sealed when not in use.
Fire and explosion protection	See section 5
Other information	

7.2. Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▸ Polyethylene or polypropylene container. ▸ Packing as recommended by manufacturer. ▸ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	▸ Avoid reaction with oxidising agents

7.3. Specific end use(s)

See section 1.2

SECTION 8 Exposure controls / personal protection

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Tel: 01425 655555 Email: technical@madarcorporation.co.uk

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8.1. Control parameters

Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
glycerol	Inhalation 56 mg/m ³ (Local, Chronic) Oral 229 mg/kg bw/day (Systemic, Chronic) * Inhalation 33 mg/m ³ (Local, Chronic) *	0.885 mg/L (Water (Fresh)) 0.088 mg/L (Water - Intermittent release) 8.85 mg/L (Water (Marine)) 3.3 mg/kg sediment dw (Sediment (Fresh Water)) 0.33 mg/kg sediment dw (Sediment (Marine)) 0.141 mg/kg soil dw (Soil) 1000 mg/L (STP)
stearic acid	Dermal 10 mg/kg bw/day (Systemic, Chronic) Inhalation 17.632 mg/m ³ (Systemic, Chronic) Dermal 5 mg/kg bw/day (Systemic, Chronic) * Inhalation 4.348 mg/m ³ (Systemic, Chronic) * Oral 2.5 mg/kg bw/day (Systemic, Chronic) *	Not Available
alcohols C16-18 ethoxylated	Dermal 2 080 mg/kg bw/day (Systemic, Chronic) Inhalation 294 mg/m ³ (Systemic, Chronic) Dermal 1 250 mg/kg bw/day (Systemic, Chronic) * Inhalation 87 mg/m ³ (Systemic, Chronic) * Oral 25 mg/kg bw/day (Systemic, Chronic) *	0.003 mg/L (Water (Fresh)) 0.003 mg/L (Water - Intermittent release) 0.1 mg/L (Water (Marine)) 68.3 mg/kg sediment dw (Sediment (Fresh Water)) 68.3 mg/kg sediment dw (Sediment (Marine)) 1 mg/kg soil dw (Soil) 1.4 mg/L (STP)
ethylene glycol phenyl ether	Dermal 20.83 mg/kg bw/day (Systemic, Chronic) Inhalation 5.7 mg/m ³ (Systemic, Chronic) Inhalation 5.7 mg/m ³ (Local, Chronic) Dermal 10.42 mg/kg bw/day (Systemic, Chronic) * Inhalation 2.41 mg/m ³ (Systemic, Chronic) * Oral 9.23 mg/kg bw/day (Systemic, Chronic) * Inhalation 2.41 mg/m ³ (Local, Chronic) * Oral 9.23 mg/kg bw/day (Systemic, Acute) *	0.943 mg/L (Water (Fresh)) 0.094 mg/L (Water - Intermittent release) 3.44 mg/L (Water (Marine)) 7.237 mg/kg sediment dw (Sediment (Fresh Water)) 0.724 mg/kg sediment dw (Sediment (Marine)) 1.31 mg/kg soil dw (Soil) 36 mg/L (STP)
triethanolamine	Dermal 7.5 mg/kg bw/day (Systemic, Chronic) Dermal 140 µg/cm ² (Local, Chronic) Inhalation 1 mg/m ³ (Local, Chronic) Dermal 2.66 mg/kg bw/day (Systemic, Chronic) * Oral 3.3 mg/kg bw/day (Systemic, Chronic) * Dermal 70 µg/cm ² (Local, Chronic) * Inhalation 0.4 mg/m ³ (Local, Chronic) *	0.32 mg/L (Water (Fresh)) 0.032 mg/L (Water - Intermittent release) 5.12 mg/L (Water (Marine)) 1.7 mg/kg sediment dw (Sediment (Fresh Water)) 0.17 mg/kg sediment dw (Sediment (Marine)) 0.151 mg/kg soil dw (Soil) 10 mg/L (STP)
1,2-octanediol	Dermal 1.5 mg/kg bw/day (Systemic, Chronic) Inhalation 10.6 mg/m ³ (Systemic, Chronic) Dermal 0.75 mg/kg bw/day (Systemic, Chronic) * Inhalation 2.6 mg/m ³ (Systemic, Chronic) * Oral 0.75 mg/kg bw/day (Systemic, Chronic) *	0.002 mg/L (Water (Fresh)) 0 mg/L (Water - Intermittent release) 0.022 mg/L (Water (Marine)) 0.031 mg/kg sediment dw (Sediment (Fresh Water)) 0.003 mg/kg sediment dw (Sediment (Marine)) 0.003 mg/kg soil dw (Soil) 10 mg/L (STP)
sodium pyroglutamate	Dermal 2 000 mg/kg bw/day (Systemic, Chronic) Inhalation 141 mg/m ³ (Systemic, Chronic) Dermal 1 000 mg/kg bw/day (Systemic, Chronic) * Inhalation 35 mg/m ³ (Systemic, Chronic) * Oral 10 mg/kg bw/day (Systemic, Chronic) *	0.1 mg/L (Water (Fresh)) 0.01 mg/L (Water - Intermittent release) 1 mg/L (Water (Marine)) 0.37 mg/kg sediment dw (Sediment (Fresh Water)) 0.037 mg/kg sediment dw (Sediment (Marine)) 0.015 mg/kg soil dw (Soil) 10 mg/L (STP)
EDTA disodium salt	Inhalation 1.5 mg/m ³ (Local, Chronic) Inhalation 3 mg/m ³ (Local, Acute) Oral 25 mg/kg bw/day (Systemic, Chronic) * Inhalation 0.6 mg/m ³ (Local, Chronic) * Inhalation 1.2 mg/m ³ (Local, Acute) *	2.2 mg/L (Water (Fresh)) 0.22 mg/L (Water - Intermittent release) 1.2 mg/L (Water (Marine)) 0.72 (Soil) 43 mg/L (STP)
DL-alpha-tocopherol acetate	Dermal 416.6 mg/kg bw/day (Systemic, Chronic) Inhalation 73.5 mg/m ³ (Systemic, Chronic) Dermal 250 mg/kg bw/day (Systemic, Chronic) * Inhalation 21.7 mg/m ³ (Systemic, Chronic) * Oral 12.5 mg/kg bw/day (Systemic, Chronic) *	0.27 mg/L (Water (Fresh)) 0.027 mg/L (Water - Intermittent release) 0.27 mg/L (Water (Marine)) 212000 mg/kg sediment dw (Sediment (Fresh Water)) 21200 mg/kg sediment dw (Sediment (Marine)) 74800 mg/kg soil dw (Soil) 100 mg/L (STP)
Carbomer	Dermal 0.56 mg/kg bw/day (Systemic, Chronic) Inhalation 1.97 mg/m ³ (Systemic, Chronic) Dermal 0.2 mg/kg bw/day (Systemic, Chronic) * Inhalation 0.348 mg/m ³ (Systemic, Chronic) * Oral 0.2 mg/kg bw/day (Systemic, Chronic) *	0.003 mg/L (Water (Fresh)) 0 mg/L (Water - Intermittent release) 0.001 mg/L (Water (Marine)) 0.021 mg/kg sediment dw (Sediment (Fresh Water)) 0.002 mg/kg sediment dw (Sediment (Marine)) 0.003 mg/kg soil dw (Soil) 0.9 mg/L (STP)
1,2-decanediol	Dermal 0.33 mg/kg bw/day (Systemic, Chronic) Inhalation 1.18 mg/m ³ (Systemic, Chronic) Dermal 0.17 mg/kg bw/day (Systemic, Chronic) * Inhalation 0.29 mg/m ³ (Systemic, Chronic) * Oral 0.17 mg/kg bw/day (Systemic, Chronic) *	0.014 mg/L (Water (Fresh)) 0.001 mg/L (Water - Intermittent release) 0.141 mg/L (Water (Marine)) 0.073 mg/kg sediment dw (Sediment (Fresh Water)) 7.32 µg/kg sediment dw (Sediment (Marine)) 0.006 mg/kg soil dw (Soil) 2 mg/L (STP)
ETHANOL TSDA1 DEB 100	Dermal 343 mg/kg bw/day (Systemic, Chronic) Inhalation 950 mg/m ³ (Systemic, Chronic) Inhalation 1 900 mg/m ³ (Local, Acute) Dermal 220 mg/kg bw/day (Systemic, Chronic) *	0.96 mg/L (Water (Fresh)) 0.79 mg/L (Water - Intermittent release) 2.75 mg/L (Water (Marine)) 212000 mg/kg sediment dw (Sediment (Fresh Water))

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Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
	Inhalation 114 mg/m ³ (Systemic, Chronic) * Oral 87 mg/kg bw/day (Systemic, Chronic) * Inhalation 950 mg/m ³ (Local, Acute) *	2.9 mg/kg sediment dw (Sediment (Marine)) 0.63 mg/kg soil dw (Soil) 580 mg/L (STP) 0.38 g/kg food (Oral)
lavandin oil	Dermal 0.249 mg/kg bw/day (Systemic, Chronic) Inhalation 0.877 mg/m ³ (Systemic, Chronic) Dermal 88.9 µg/kg bw/day (Systemic, Chronic) * Inhalation 0.132 mg/m ³ (Systemic, Chronic) * Oral 88.9 µg/kg bw/day (Systemic, Chronic) *	2.9 µg/L (Water (Fresh)) 0.29 µg/L (Water - Intermittent release) 29 µg/L (Water (Marine)) 1.13 mg/kg sediment dw (Sediment (Fresh Water)) 0.113 mg/kg sediment dw (Sediment (Marine)) 47.7 µg/kg soil dw (Soil) 1 mg/L (STP) 7.8 mg/kg food (Oral)
lactic acid	Inhalation 592 mg/m ³ (Local, Chronic) Inhalation 592 mg/m ³ (Local, Acute) Inhalation 296 mg/m ³ (Local, Acute) *	Not Available

* Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
UK Workplace Exposure Limits (WELs)	glycerol	Glycerol, mist	10 mg/m ³	Not Available	Not Available	Not Available
UK Workplace Exposure Limits (WELs)	ETHANOL TSDA1 DEB 100	Ethanol	1000 ppm / 1920 mg/m ³	Not Available	Not Available	Not Available

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
glycerol	45 mg/m ³	180 mg/m ³	1,100 mg/m ³
stearic acid	14 mg/m ³	150 mg/m ³	910 mg/m ³
alcohols C16-18 ethoxylated	3.8 mg/m ³	42 mg/m ³	250 mg/m ³
ethylene glycol phenyl ether	1.5 ppm	16 ppm	97 ppm
triethanolamine	15 mg/m ³	240 mg/m ³	1,500 mg/m ³
EDTA disodium salt	11 mg/m ³	120 mg/m ³	730 mg/m ³
EDTA disodium salt	30 mg/m ³	330 mg/m ³	2,000 mg/m ³
ETHANOL TSDA1 DEB 100	Not Available	Not Available	15000* ppm

Ingredient	Original IDLH	Revised IDLH
glycerol	Not Available	Not Available
stearic acid	Not Available	Not Available
water	Not Available	Not Available
almond, sweet, extract	Not Available	Not Available
alcohols C16-18 ethoxylated	Not Available	Not Available
dimethicone	Not Available	Not Available
ethylene glycol phenyl ether	Not Available	Not Available
triethanolamine	Not Available	Not Available
1,2-octanediol	Not Available	Not Available
sodium pyroglutamate	Not Available	Not Available
EDTA disodium salt	Not Available	Not Available
DL-alpha-tocopherol acetate	Not Available	Not Available
Carbomer	Not Available	Not Available
1,2-decanediol	Not Available	Not Available
ETHANOL TSDA1 DEB 100	3,300 ppm	Not Available
lavandin oil	Not Available	Not Available
Symphytum officinale (comfrey) extract	Not Available	Not Available
Ginseng, extract	Not Available	Not Available
Chamomile recutica oil	Not Available	Not Available
lactic acid	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
alcohols C16-18 ethoxylated	E	≤ 0.1 ppm

Notes:

Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of 0-20 Sandehealth Industrial Estate, Fordingbridge, Hampshire, SP6 1PA, UK

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Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
ethylene glycol phenyl ether	E	≤ 0.1 ppm
EDTA disodium salt	E	≤ 0.01 mg/m ³
lavandin oil	E	≤ 0.1 ppm
lactic acid	E	≤ 0.1 ppm
Notes:	<i>Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.</i>	

MATERIAL DATA

Fragrance substance with is an established contact allergen in humans.

Scientific Committee on Consumer Safety SCCS OPINION on Fragrance allergens in cosmetic products 2012

for camphor

Odour Threshold Value: 0.079 ppm (detection)

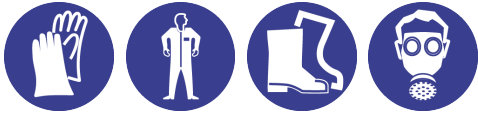
The TLV-TWA is thought to be protective against physical irritation of the eyes and nose and anosmia (loss of smell) which occurred in workers at concentrations above 2 ppm.

Anosmia may occur in concentrations ranging from 35-194 mg/m³. In addition the limit is thought to be sufficiently low to prevent irritation of the central nervous system (which produces nausea, vomiting, excitement and confusion).

Odour Safety Factor(OSF)

OSF=7.4 (CAMPHOR)

8.2. Exposure controls

8.2.1. Appropriate engineering controls	<p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.</p> <p>Employers may need to use multiple types of controls to prevent employee overexposure.</p>
8.2.2. Personal protection	
Eye and face protection	<ul style="list-style-type: none"> ▶ Safety glasses with side shields. ▶ Chemical goggles. ▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable.
Skin protection	See Hand protection below
Hands/feet protection	<p>The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.</p> <p>The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.</p> <p>Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.</p> <ul style="list-style-type: none"> ▶ Wear chemical protective gloves, e.g. PVC. ▶ Wear safety footwear or safety gumboots, e.g. Rubber
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> ▶ Overalls. ▶ P.V.C apron. ▶ Barrier cream. ▶ Skin cleansing cream. ▶ Eye wash unit.

Respiratory protection

Type A Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

- ▶ Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content.
- ▶ The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.
- ▶ Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used

8.2.3. Environmental exposure controls

See section 12

SECTION 9 Physical and chemical properties**9.1. Information on basic physical and chemical properties**

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Tel: 01425 655555 Email: technical@madarcorporation.co.uk

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Ingestion	The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.
Skin Contact	The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.
Eye	Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals and/or may produce significant ocular lesions which are present twenty-four hours or more after instillation into the eye(s) of experimental animals. Repeated or prolonged eye contact may cause inflammation characterised by temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); temporary impairment of vision and/or other transient eye damage/ulceration may occur.
Chronic	Long-term exposure to the product is not thought to produce chronic effects adverse to health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course.

IBASE LOTION	TOXICITY	IRRITATION
	Not Available	Not Available
glycerol	TOXICITY	IRRITATION
	dermal (guinea pig) LD50: 58500 mg/kg ^[1] Oral(Rat) LD50; >20<39800 mg/kg ^[1]	Not Available
stearic acid	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >5000 mg/kg ^[2]	Eye: no adverse effect observed (not irritating) ^[1]
	Intravenous (Mouse) LD50: 23 mg/kg ^[2]	Skin (human): 75 mg/3d-I-mild
	Intravenous (rat) LD50: 21.5 mg/kg ^[2]	Skin (rabbit):500 mg/24h-moderate Skin: no adverse effect observed (not irritating) ^[1]
water	TOXICITY	IRRITATION
	Oral(Rat) LD50; >90000 mg/kg ^[2]	Not Available
almond, sweet, extract	TOXICITY	IRRITATION
	Not Available	Not Available
alcohols C16-18 ethoxylated	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >3000 mg/kg ^[1]	Eye : Severe (analogy) *
	Inhalation(Rat) LC50; >1.6 mg/4h ^[1] Oral(Rat) LD50; 1260 mg/kg ^[2]	Skin: not irritating * (analogy) *
dimethicone	TOXICITY	IRRITATION
	Oral(Mouse) LD50; >20000 mg/kg ^[2]	Not Available
ethylene glycol phenyl ether	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >2214 mg/kg ^[1]	Eye (rabbit): 250 ug/24h - SEVERE
	Oral(Rat) LD50; 2937 mg/kg ^[2]	Eye (rabbit): 6 mg - moderate Skin (rabbit): 500 mg/24h - mild
triethanolamine	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >20000 mg/kg ^[2]	Eye (rabbit): 0.1 ml -
	Dermal (rabbit) LD50: 16 ml/kg * ^[2]	Eye (rabbit): 10 mg - mild
	dermal (rat) LD50: >16000 mg/kg ^[2]	Eye (rabbit): 5.62 mg - SEVERE
	Intraperitoneal (mouse) LD50: 1450 mg/kg ^[2]	minor conjunctival irritation
	Intraperitoneal (rat) LD50: 1510 mg/kg ^[2]	no irritation *
	Oral (g.pig) LD50: 2200 mg/kg ^[2]	Skin (human): 15 mg/3d (int)-mild
	Oral (rabbit) LD50: 2200 mg/kg ^[2]	Skin (rabbit): 4 h occluded
	Oral(Guinea) LD50; 2200 mg/kg ^[2]	Skin (rabbit): 560 mg/24 hr- mild
	Oral(Mouse) LD50; 5846 mg/kg ^[2]	
	Oral(Rat) LD50; 4.92 ml/kg (female) * ^[2]	
	Oral(Rat) LD50; 4920 ul/kg ^[2]	
	Oral(Rat) LD50; 5560 mg/kg (calc.) ^[2]	
Oral(Rat) LD50; 8.37 ml/kg (male)		

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	Oral(Rat) LD50; 8000 mg/kg ^[2]	
1,2-octanediol	TOXICITY	IRRITATION
	Inhalation(Rat) LC50; >7.015 mg/l4h ^[1]	Eye: adverse effect observed (irritating) ^[1]
	Oral(Rat) LD50; >2000 mg/kg ^[1]	Skin: no adverse effect observed (not irritating) ^[1]
sodium pyroglutamate	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg ^[1]	Eye: no adverse effect observed (not irritating) ^[1]
	Oral(Rat) LD50; >2000 mg/kg ^[1]	Skin: no adverse effect observed (not irritating) ^[1]
EDTA disodium salt	TOXICITY	IRRITATION
	Oral(Mouse) LD50; 400 mg/kg ^[2]	Not Available
DL-alpha-tocopherol acetate	TOXICITY	IRRITATION
	Oral(Mouse) LD50; >49700 mg/kg ^[2]	Eye (rabbit): non-irritating *
		Skin (rabbit): non-irritating *
Carbomer	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >2000 mg/kg ^[1]	Eye: adverse effect observed (irreversible damage) ^[1]
	Inhalation(Rat) LC50; >5.1 mg/l4h ^[1]	Skin: no adverse effect observed (not irritating) ^[1]
	Oral(Rat) LD50; 146-468 mg/kg ^[1]	
1,2-decanediol	TOXICITY	IRRITATION
	dermal (rat) LD50: >2000 mg/kg ^[1]	Not Available
	Oral(Rat) LD50; >2500 mg/kg ^[1]	
ETHANOL TSDA1 DEB 100	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: 17100 mg/kg ^[1]	Eye: adverse effect observed (irritating) ^[1]
	Inhalation(Mouse) LC50; 39 mg/L4h ^[2]	Skin: no adverse effect observed (not irritating) ^[1]
	Oral(Rat) LD50; >7692 mg/kg ^[1]	
lavandin oil	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >5000 mg/kg ^[2]	Eye: adverse effect observed (irritating) ^[1]
	Oral(Rat) LD50; >5000 mg/kg ^[2]	Skin (rabbit): 500 mg/24h mild
		Skin: no adverse effect observed (not irritating) ^[1]
Symphytum officinale (comfrey) extract	TOXICITY	IRRITATION
	Not Available	Not Available
Ginseng, extract	TOXICITY	IRRITATION
	Oral(Mouse) LD50; 54 mg/kg ^[2]	Not Available
Chamomile recutita oil	TOXICITY	IRRITATION
	Intraperitoneal (Rat) LD50: >4000 mg/kg ^[2]	Eye: adverse effect observed (irritating) ^[1]
		Skin: adverse effect observed (irritating) ^[1]
lactic acid	TOXICITY	IRRITATION
	Oral(Rat) LD50; 3730 mg/kg ^[2]	Eye (rabbit): 0.750 mg SEVERE
		Skin (rabbit): 5 mg/24h SEVERE
Legend:	1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. * Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances	

IBASE LOTION	<p>Fragrance allergens act as haptens, i.e. low molecular weight chemicals that are immunogenic only when attached to a carrier protein. However, not all sensitising fragrance chemicals are directly reactive, but require previous activation. A prohaptens is a chemical that itself is non- or low-sensitising, but that is transformed into a hapten outside the skin by simple chemical transformation (air oxidation, photoactivation) and without the requirement of specific enzymatic systems. A prohaptens is a chemical that itself is non- or low-sensitising but that is transformed into a hapten in the skin (bioactivation) usually via enzyme catalysis. It is not always possible to know whether a particular allergen that is not directly reactive acts as a prohaptens or as a prohaptens, or both, because air oxidation and bioactivation can often give the same product (geraniol is an example). Some chemicals might act by all three pathways.</p> <p>Prohaptens Compounds that are bioactivated in the skin and thereby form haptens are referred to as prohaptens. In the case of prohaptens, the possibility to become activated is inherent to the molecule and activation cannot be avoided by extrinsic measures. Activation processes increase the risk for cross-reactivity between fragrance substances.</p>
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IBASE LOTION

GLYCEROL	<p>For glycerol:</p> <p>Acute toxicity: Glycerol is of a low order of acute oral and dermal toxicity with LD50 values in excess of 4000 mg/kg bw. At very high dose levels, the signs of toxicity include tremor and hyperaemia of the gastro-intestinal tract. Skin and eye irritation studies indicate that glycerol has low potential to irritate the skin and the eye. The available human and animal data, together with the very widespread potential for exposure and the absence of case reports of sensitisation, indicate that glycerol is not a skin sensitizer.</p> <p>Repeat dose toxicity: Repeated oral exposure to glycerol does not induce adverse effects other than local irritation of the gastro-intestinal tract. The overall NOEL after prolonged treatment with glycerol is 10,000 mg/kg bw/day (20% in diet). At this dose level no systemic or local effects were observed. For inhalation exposure to aerosols, the NOAEC for local irritant effects to the upper respiratory tract is 165 mg/m3 and 662 mg/m3 for systemic effects.</p> <p>Genotoxicity: Glycerol is free from structural alerts, which raise concern for mutagenicity.</p>
stearic acid	Equivocal tumorigen by RTEC criteria
almond, sweet, extract	<p>Polyunsaturated fats (PUFAs) protect against cardiovascular disease by providing more membrane fluidity than monounsaturated fats (MUFAs), but they are more vulnerable to lipid peroxidation (rancidity). On the other hand, some monounsaturated fatty acids (in the same way as saturated fats) may promote insulin resistance, whereas polyunsaturated fatty acids may be protective against insulin resistance. Furthermore, one the large scale study found that increasing monounsaturated fat and decreasing saturated fat intake could improve insulin sensitivity, but only when the overall fat intake of the diet was low. Studies have shown that substituting dietary monounsaturated fat for saturated fat is associated with increased daily physical activity and resting energy expenditure. More physical activity was associated with a higher-oleic acid diet (a MUFA) than one of a palmitic acid diet (saturated fat). From the study, it is shown that more monounsaturated fats lead to less anger and irritability. Foods containing monounsaturated fats reduce low-density lipoprotein (LDL) cholesterol, while possibly increasing high-density lipoprotein (HDL) cholesterol. However, their true ability to raise HDL is still in debate.</p> <p>Levels of oleic along with other monounsaturated fatty acids in red blood cell membranes were positively associated with breast cancer risk. A high consumption of oxidised polyunsaturated fatty acids (PUFAs), which are found in most types of vegetable oil, may increase the likelihood that postmenopausal women will develop breast cancer. Similar effect was observed on prostate cancer, but the study was performed on mice. Another "analysis suggested an inverse association between total polyunsaturated fatty acids and breast cancer risk, but individual polyunsaturated fatty acids behaved differently [from each other]. [...] a 20:2 derivative of linoleic acid [...] was inversely associated with the risk of breast cancer"</p> <p>PUFAs are prone to spontaneous oxidation/ peroxidation. The feeding of lipid oxidation products and oxidised fats has been reported to cause adverse biological effects on laboratory animals, including growth retardation, teratogenicity, tissue damage and increased liver and kidney weights, as well as cellular damage to the testes and epididymes, increased peroxidation of membrane and tissue lipids and induction of cytochrome P450 activities in the colon and liver.</p> <p>The propensity for PUFAs to oxidise leads to the generation of free radicals and eventually to rancidity.</p> <p>Culinary oils, when heated, undergo important chemical reaction involving self-sustaining, free radical-mediated oxidative deterioration of PUFAs. Such by-products may be cytotoxic, mutagenic, reproductive toxins and may produce chronic disease. Samples of repeatedly used oils collected from fast-food retail outlets and restaurants have confirmed the production of aldehydic lipid oxidation products (LOPs) at levels exceeding 10 exp-2 moles per kilogram (mol/kg) during "on-site" frying episodes. Volatile emissions from heated culinary oils used in Chinese-style cooking are mutagenic; exposure to such indoor air pollution may render humans more susceptible to contracting lung or further cancers, together with rhinitis and diminished lung function. Group A aliphatic monoesters (fatty acid esters) According to a classification scheme described by the American Chemistry Council' Aliphatic Esters Panel. Group A substances are simple monoesters derived from a monofunctional alcohol, such as 2-ethylhexyl alcohol (C8-alcohol) or tridecyl alcohol (C13 alcohol) and fatty acids such as palmitic, stearic, oleic or linoleic acid. Metabolism of the parent esters is expected to yield the corresponding fatty acids and alcohols. The fatty acids are naturally occurring and have a low order of toxicity. Group A substances are rather lipophilic (log Kow 10-15) in character due to the large number of carbon numbers in the ester molecule (e.g., 24,26, 31 carbons) and have relatively high boiling points. Owing to the non-volatile nature of these esters, their vapour pressures are very low and difficult to determine experimentally. Water solubility is also very low. Mammalian Toxicity: Acute Toxicity.</p> <p>For polyunsaturated fatty acids and oils (triglycerides)</p> <p>Studies on animals have shown a link between polyunsaturated fat and the incidence of tumours. In some of these studies the incidence of tumours increased with increasing intake of polyunsaturated fat, up to about 5% of total energy, near to the middle of the current dietary intake in humans.</p> <p>The propensity for polyunsaturated fats to oxidise is another possible risk factor. This leads to the generation of free radicals and eventually to rancidity</p> <p>Research evidence suggests that consuming high amounts of polyunsaturated fat may increase the risk of cancer spreading.</p> <p>Researchers found that linoleic acid in polyunsaturated fats produced increasing membrane phase separation, and thereby increased adherence of circulating tumour cells to blood vessel walls and remote organs.</p> <p>At least one study in mice has shown that consuming high amounts of polyunsaturated fat (but not monounsaturated fat) may increase the risk of metastasis in cancer.</p> <p>Lipid peroxides with complex components can damage macromolecules, such as DNA, proteins, and membrane lipids. Some components of lipid peroxides, for example, 4,5(E)-epoxy-2(E)-heptenal (EH) can react with L-lysine and damage proteins. 4,5-epoxy-2-alkenals can react with phenylalanine and cause strecker-type degradation of amino acids. Autoxidized methyl linoleate can decrease DNA synthesis in thymocytes</p> <p>Animals consuming oxidized lipids suffered a wide array of biological consequences, such as decreased feed utilization and performance, oxidative stress and tissue lipid oxidation and, most strikingly, adverse effects on redox indices and shelf life of meat.</p> <p>For omega 6 fatty acids and derivatives:</p> <p>Some medical research suggests that excessive levels of certain omega-6 fatty acids relative to certain omega-3 fatty acids may increase the probability of a number of diseases.</p> <p>Modern Western diets typically have ratios of omega-6 to omega-3 in excess of 10 to 1, some as high as 30 to 1; the average ratio of omega-6 to omega-3 in the Western diet is 15:1–16.7:1. Humans are thought to have evolved with a diet of a 1-to-1 ratio of omega-6 to omega-3 and the optimal ratio is thought to be 4 to 1 or lower although some sources suggest ratios as low as 1:1). A ratio of 2–3:1 omega 6 to omega 3 helped reduce inflammation in patients with rheumatoid arthritis. A ratio of 5:1 had a beneficial effect on patients with asthma but a 10:1 ratio had a negative effect. A ratio of 2.5:1 reduced rectal cell proliferation in patients with colorectal cancer, whereas a ratio of 4:1 had no effect.</p> <p>Excess omega-6 fatty acids from vegetable oils interfere with the health benefits of omega-3 fats, in part because they compete for the same rate-limiting enzymes. A high proportion of omega-6 to omega-3 fat in the diet shifts the physiological state in the tissues toward the pathogenesis of many diseases: prothrombotic, proinflammatory and proconstrictive.</p> <p>Chronic excessive production of omega-6 eicosanoids is correlated with arthritis, inflammation, and cancer. Many of the medications used to treat and manage these conditions work by blocking the effects of the COX-2 enzyme.</p>
ALCOHOLS C16-18 ETHOXYLATED	<p>Polyethers, for example, ethoxylated surfactants and polyethylene glycols, are highly susceptible towards air oxidation as the ether oxygens will stabilize intermediary radicals involved. Investigations of a chemically well-defined alcohol (pentaethylene glycol mono-n-dodecyl ether) ethoxylate, showed that polyethers form complex mixtures of oxidation products when exposed to air.</p> <p>Sensitization studies in guinea pigs revealed that the pure nonoxidized surfactant itself is nonsensitizing but that many of the investigated oxidation products are sensitizers. Two hydroperoxides were identified in the oxidation mixture, but only one (16-hydroperoxy-3,6,9,12,15-pentaoxaheptacosan-1-ol) was stable enough to be isolated. It was found to be a strong sensitizer in LLNA (local lymph node assay for detection of sensitization capacity). The formation of other hydroperoxides was indicated by the detection of their corresponding aldehydes in the oxidation mixture .</p> <p>On the basis of the lower irritancy, nonionic surfactants are often preferred to ionic surfactants in topical products. However, their susceptibility towards autoxidation also increases the irritation. Because of their irritating effect, it is difficult to diagnose ACD to these compounds by patch testing.</p> <p>Allergic Contact Dermatitis—Formation, Structural Requirements, and Reactivity of Skin Sensitizers. Ann-Therese Karlberg et al; Chem.</p> <p>Human beings have regular contact with alcohol ethoxylates through a variety of industrial and consumer products such as soaps, detergents,</p>

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and other cleaning products . Exposure to these chemicals can occur through ingestion, inhalation, or contact with the skin or eyes. Studies of acute toxicity show that volumes well above a reasonable intake level would have to occur to produce any toxic response. Moreover, no fatal case of poisoning with alcohol ethoxylates has ever been reported. Multiple studies investigating the acute toxicity of alcohol ethoxylates have shown that the use of these compounds is of low concern in terms of oral and dermal toxicity .

Clinical animal studies indicate these chemicals may produce gastrointestinal irritation such as ulcerations of the stomach, pilo-erection, diarrhea, and lethargy. Similarly, slight to severe irritation of the skin or eye was generated when undiluted alcohol ethoxylates were applied to the skin and eyes of rabbits and rats. The chemical shows no indication of being a genotoxin, carcinogen, or mutagen (HERA 2007).

Alcohol ethoxylates are according to CESIO (2000) classified as Irritant or Harmful depending on the number of EO-units:
 EO < 5 gives Irritant (Xi) with R38 (Irritating to skin) and R41 (Risk of serious damage to eyes)
 EO > 5-15 gives Harmful (Xn) with R22 (Harmful if swallowed) - R38/41
 EO > 15-20 gives Harmful (Xn) with R22-41
 >20 EO is not classified (CESIO 2000)
 Oxo-AE, C13 EO10 and C13 EO15, are Irritating (Xi) with R36/38 (Irritating to eyes and skin) .
 AE are not included in Annex 1 of the list of dangerous substances of the Council Directive 67/548/EEC

In general, alcohol ethoxylates (AE) are readily absorbed through the skin of guinea pigs and rats and through the gastrointestinal mucosa of rats. AE are quickly eliminated from the body through the urine, faeces, and expired air (CO₂). Orally dosed AE was absorbed rapidly and extensively in rats, and more than 75% of the dose was absorbed. When applied to the skin of humans, the doses were absorbed slowly and incompletely (50% absorbed in 72 hours). Half of the absorbed surfactant was excreted promptly in the urine and smaller amounts of AE appeared in the faeces and expired air (CO₂) . The metabolism of C12 AE yields PEG, carboxylic acids, and CO₂ as metabolites. The LD50 values after oral administration to rats range from about 1-15 g/kg body weight indicating a low to moderate acute toxicity.

The ability of nonionic surfactants to cause a swelling of the stratum corneum of guinea pig skin has been studied. The swelling mechanism of the skin involves a combination of ionic binding of the hydrophilic group as well as hydrophobic interactions of the alkyl chain with the substrate. For high boiling ethylene glycol ethers (typically triethylene- and tetraethylene glycol ethers):

Skin absorption: Available skin absorption data for triethylene glycol ether (TGBE), triethylene glycol methyl ether (TGME), and triethylene glycol ethylene ether (TGEE) suggest that the rate of absorption in skin of these three glycol ethers is 22 to 34 micrograms/cm²/hr, with the methyl ether having the highest permeation constant and the butyl ether having the lowest. The rates of absorption of TGBE, TGEE and TGME are at least 100-fold less than EGME, EGEE, and EGBE, their ethylene glycol monoalkyl ether counterparts, which have absorption rates that range from 214 to 2890 micrograms/ cm²/hr . Therefore, an increase in either the chain length of the alkyl substituent or the number of ethylene glycol moieties appears to lead to a decreased rate of percutaneous absorption. However, since the ratio of the change in values of the ethylene glycol to the diethylene glycol series is larger than that

of the diethylene glycol to triethylene glycol series , the effect of the length of the chain and number of ethylene glycol moieties on absorption diminishes with an increased number of ethylene glycol moieties. Therefore, although tetraethylene glycol methyl ether (TetraME) and tetraethylene glycol butyl ether (TetraBE) are expected to be less permeable to skin than TGME and TGBE, the differences in permeation between these molecules may only be slight.

Metabolism: The main metabolic pathway for metabolism of ethylene glycol monoalkyl ethers (EGME, EGEE, and EGBE) is oxidation via alcohol and aldehyde dehydrogenases (ALD/ADH) that leads to the formation of an alkoxy acids. Alkoxy acids are the only toxicologically significant metabolites of glycol ethers that have been detected *in vivo*. The principal metabolite of TGME is believed to be 2-[2-(2-methoxyethoxy)ethoxy] acetic acid . Although ethylene glycol, a known kidney toxicant, has been identified as an impurity or a minor metabolite of glycol ethers in animal studies it does not appear to contribute to the toxicity of glycol ethers.

The metabolites of category members are not likely to be metabolized to any large extent to toxic molecules such as ethylene glycol or the mono alkoxy acids because metabolic breakdown of the ether linkages also has to occur

Acute toxicity: Category members generally display low acute toxicity by the oral, inhalation and dermal routes of exposure. Remarks: Patch test on human volunteers did not demonstrate sensitization properties. * Cognis MSDS for Ceteraeth -20 The skin sensitizing potential was assessed with C16-18AE (CAS 68439-49-6) in a Buehler Test according to OECD Guideline 406. In this study 20 female guinea pigs were induced by an epicutaneous occlusive dressing with 100% test substance (in maize oil) for 6 h on Day 0, 7 and 14. Two weeks after the last induction animals were challenged by epicutaneous occlusive exposure for 6 h to 100% test substance (in maize oil). 24 and 48 h after patch removal the application site was assessed for signs of local irritation. No dermal reactions were observed in any test animal at any time point. Available oral toxicity studies provide a coherent picture on the subchronic and chronic oral toxicity of AE. Based on the described effects and argumentations, the dietary NOAEL of 500 mg/kg bw/day (Shell, 1982) representing an average of all NOAELs, was chosen for the risk assessment. The clastogenic potential was assessed in a chromosomal aberration test with C16-18AE (CAS 68439-49-6) in mammalian cells according to OECD Guideline 473. Chinese hamster ovary cells (CHO) were exposed to 313, 625, 1250, 2500 and 5000 µg/mL in the presence and 1.25, 2.5, 5, 10, 20, 39 and 78 µg/mL in the absence of metabolic activation. Positive and vehicle (1% ethanol) control cultures were included in each assay. No increases in the number of chromosome aberrations in the presence or absence of metabolic activation were seen at any concentration tested. Appropriate reference mutagens used as positive controls showed a significant increase in chromosome aberrations, thus indicating the sensitivity of the assay, and the efficacy of the S9-mix. Hence, the test substance can not be regarded as clastogenic. The mutagenic potential in mammalian cells was assessed with C16-18AE (CAS 68439-49-6) by a HPRT-assay according to OECD Guideline 476. Following pre-tests with the concentration ranging from 1-100 µg/mL, the latter being the solubility limit of the test substance, Chinese hamster ovary cells were exposed for 4 h to concentrations of 1.8, 6, 18, 60 and 100 µg/mL in the absence and presence of metabolic activation by rat liver S9-mix. No dose-related increases in mutant colony numbers were obtained in two independent experiments with the test substance in either the presence or absence of S9-mix. Appropriate reference mutagens used as positive controls produced highly significant increases in mutation frequency, thus indicating the sensitivity of the assay. Therefore, the test substance is regarded as not mutagenic in mammalian cells. In conclusion, C16AE (CAS 52609-19-5) is regarded as non-genotoxic a reproductive toxicity study on a structurally similar material, C14-15AE7 (CAS 68951-67-7) was conducted at dietary levels of 25, 50 and 250 mg/kg bw/day. The 2-generation study (Procter and Gamble Ltd., 1977: Long term reproduction and teratology study in rats with Neodol 45-7; unpublished report) did not show any potential for reproductive toxicity at the tested dose levels. The NOAEL for reproductive effects was greater than the highest tested dose of 250 mg/kg bw/day. Although the study was pre-GLP and not in full compliance with current OECD guidelines, the study provided sufficient information and was assessed to be scientifically reliable. The comparable toxicokinetic and metabolic profiles, as well as their toxicological similarities for this and other toxicological endpoints, support the conclusion that insights from the reproductive toxicity study on higher ethoxylated AE are applicable to AE with an ethoxylation degree of 1 - 2.5. * REACh Dossier

DIMETHICONE

Substance has been investigated as a tumorigen and reproductive effector in rats.

ETHYLENE GLYCOL PHENYL ETHER

Bacterial cell mutagen

The aryl alkyl alcohol (AAA) fragrance ingredients are a diverse group of chemical structures with similar metabolic and toxicity profiles.

The AAA fragrances demonstrate low acute and subchronic dermal and oral toxicity.

At concentrations likely to be encountered by consumers, AAA fragrance ingredients are non-irritating to the skin.

The potential for eye irritation is minimal.

With the exception of benzyl alcohol and to a lesser extent phenethyl and 2-phenoxyethyl AAA alcohols, human sensitization studies, diagnostic patch tests and human induction studies, indicate that AAA fragrance ingredients generally have no or low sensitization potential. Available data indicate that the potential for photosensitization is low.

NOAELs for maternal and developmental toxicity are far in excess of current human exposure levels.

No carcinogenicity in rats or mice was observed in 2-year chronic testing of benzyl alcohol or a-methylbenzyl alcohol; the latter did induce species and gender-specific renal adenomas in male rats at the high dose. There was no to little genotoxicity, mutagenicity, or clastogenicity in the mutagenicity *in vitro* bacterial assays, and *in vitro* mammalian cell assays. All *in vivo* micronucleus assays were negative.

It is concluded that these materials would not present a safety concern at current levels of use as fragrance ingredients

The Research Institute for Fragrance Materials (RIFM) Expert Panel

19-20 Sandehealth Industrial Estate, Fordingbridge, Hampshire, SP6 1PA, UK

Tel: 01425 655555 Email: technical@madarcorporation.co.uk

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	<p>While it is difficult to generalise about the full range of potential health effects posed by exposure to the many different amine compounds, characterised by those used in the manufacture of polyurethane and polyisocyanurate foams, it is agreed that overexposure to the majority of these materials may cause adverse health effects.</p> <ul style="list-style-type: none"> ▶ Many amine-based compounds can induce histamine liberation, which, in turn, can trigger allergic and other physiological effects, including bronchoconstriction or bronchial asthma and rhinitis. ▶ Systemic symptoms include headache, nausea, faintness, anxiety, a decrease in blood pressure, tachycardia (rapid heartbeat), itching, erythema (reddening of the skin), urticaria (hives), and facial edema (swelling). Systemic effects (those affecting the body) that are related to the pharmacological action of amines are usually transient. <p>Typically, there are four routes of possible or potential exposure: inhalation, skin contact, eye contact, and ingestion.</p> <p>Inhalation: Inhalation of vapors may, depending upon the physical and chemical properties of the specific product and the degree and length of exposure, result in moderate to severe irritation of the tissues of the nose and throat and can irritate the lungs. Products with higher vapour pressures have a greater potential for higher airborne concentrations. This increases the probability of worker exposure. Higher concentrations of certain amines can produce severe respiratory irritation, characterised by nasal discharge, coughing, difficulty in breathing, and chest pains. Chronic exposure via inhalation may cause headache, nausea, vomiting, drowsiness, sore throat, bronchopneumonia, and possible lung damage. Also, repeated and/or prolonged exposure to some amines may result in liver disorders, jaundice, and liver enlargement. Some amines have been shown to cause kidney, blood, and central nervous system disorders in laboratory animal studies. While most polyurethane amine catalysts are not sensitizers, some certain individuals may also become sensitized to amines and may experience respiratory distress, including asthma-like attacks, whenever they are subsequently exposed to even very small amounts of vapor. Once sensitized, these individuals must avoid any further exposure to amines. Although chronic or repeated inhalation of vapor concentrations below hazardous or recommended exposure limits should not ordinarily affect healthy individuals, chronic overexposure may lead to permanent pulmonary injury, including a reduction in lung function, breathlessness, chronic bronchitis, and immunologic lung disease. Inhalation hazards are increased when exposure to amine catalysts occurs in situations that produce aerosols, mists, or heated vapors. For triethanolamine (and its salts): Acute toxicity: Triethanolamine is of low toxicity by the oral, dermal and inhalation routes of exposure. Oral LD50 values have been shown to range from approximately 5-10 g/kg. The dermal LD50 is greater than 2 g/kg. The inhalation LC50 is greater than a saturated atmosphere Repeat Dose Toxicity: The studies to determine toxicity of triethanolamine from repeated exposure were conducted for a duration of 91 days or 2 years. In both studies the NOAEL was at least 1000 mg/kg. There was no evidence of gross or histopathological change that could be attributed to treatment. Also, triethanolamine was shown to be non-carcinogenic. Genetic Toxicity: Mutation (bacterial); This endpoint has been satisfied by two studies using 4 strains (TA 98, TA 100, TA 1535 and TA 1537) of <i>Salmonella typhimurium</i>. Triethanolamine was not mutagenic in any of the tester strains. Chromosomal aberration (mammalian, <i>in vitro</i>) – This endpoint was satisfied by a cytogenetic assay using Chinese hamster lung cells. A Cosmetic Ingredient Review (CIR) expert panel conducted a review of triethanolamine-containing personal care products The panel was concerned with the levels of free diethanolamine that could be present as an impurity in TEA or TEA-containing ingredients. The panel stated that the amount of free diethanolamine available must be limited to the present practices of use and concentration of diethanolamine. The Panel concluded that TEA and 31 related TEA-containing ingredients, are safe when formulated to be nonirritating and when the levels of free diethanolamine do not exceed the prescribed levels. These ingredients should not be used in cosmetic products in which N-nitroso compounds can be formed. Dermal carcinogenicity studies performed by the NTP on TEA reported equivocal evidence of carcinogenic activity in male mice based on the occurrence of liver hemangiosarcoma, some evidence of carcinogenic activity in female mice based on increased incidences of hepatocellular adenoma, and equivocal evidence of carcinogenic activity in male rats based on a marginal increase in the incidence of renal tubule cell adenoma. It has been hypothesized that TEA may cause liver tumours in mice via a choline-depletion mode of action. Humans are much less sensitive to this deficiency, and these hepatic findings are considered to have little relevance to humans regarding the safety of the use of TEA in personal care products. The panel was concerned that the potential exists for dermal irritation with the use of products formulated using TEA or TEA-related ingredients. The panel specified that products containing these ingredients must be formulated to be nonirritating. Tertiary alkyl amines such as TEA do not react with N-nitrosating agents to directly form nitrosamines. However, tertiary amines can act as precursors in nitrosamine formation by undergoing nitrosative cleavage. The resultant secondary amine (ie, diethanolamine) can then be N-nitrosated to products that may be carcinogenic. The substance is classified by IARC as Group 3: NOT classifiable as to its carcinogenicity to humans. Evidence of carcinogenicity may be inadequate or limited in animal testing. Lachrymation, diarrhoea, convulsions, urinary tract changes, changes in bladder weight, changes in testicular weight, changes in thymus weight, changes in liver weight, dermatitis after systemic exposure, kidney, ureter, bladder tumours recorded. Equivocal tumourigen by RTECS criteria. Dermal rabbit value quoted above is for occluded patch in male or female animals * Union Carbide</p>
SODIUM PYROGLUTAMATE	<p>For L-pidolic acid (syn: pyroglutamic acid, 5-oxoproline, 2-pyrrolidone-5-carboxylic acid) its salts and compounds: From the available data it can be concluded that calcium, iron, magnesium, potassium and zinc are absorbed from L-pidolates. Their bioavailability is comparable to that from other water-soluble and dissociable calcium, iron, magnesium, potassium and zinc salts permitted to be used in food supplements and foods intended for particular nutritional uses. L-pidolic acid occurs in numerous plants and is a natural constituent of a number of foods. It is formed in human metabolism from glutamic acid and can be metabolised after oral intake to glutamic acid. Bioavailability: A number of studies with animals, healthy persons and patients show that calcium, iron, magnesium, potassium and zinc are absorbed after ingestion of their L-pidolates. The bioavailability of these cations is expected to be similar to that from other water-soluble and dissociable salts of these metals. Toxicological data: Metabolism and kinetics L-pidolic acid is a cyclisation product and metabolite of glutamic acid and plays an important role in the endogenous gamma-glutamyl cycle. It is formed from glutamic acid or gamma-glutamyl amino acids by gamma-glutamylcyclotransferase and retransformed to glutamic acid by 5-oxo-prolinase. It has been reported to be present in human plasma. It can be expected from data in mice, that orally ingested L-pidolates are absorbed and at certain doses will result in increased plasma levels of L-pidolic acid.</p>
EDTA DISODIUM SALT	<p>For ethylenediaminetetraacetic acid (EDTA) and its salts: EDTA is a strong organic acid (approximately 1000 times stronger than acetic acid). It has a high affinity for alkaline-earth ions (for example, calcium and magnesium) and heavy-metal ions (for example, lead and mercury). This affinity generally results in the formation of highly stable and soluble hexadentate chelate complexes. EDTAs ability to complex is used commercially to either promote or inhibit chemical reactions, depending on application. EDTA and its salts are expected to be absorbed by the lungs and gastrointestinal tract; absorption through the skin is unlikely. In general, EDTA and its salts are mild skin irritants but considered severe eye irritants. The greatest risk in the human body will occur when the EDTA attempts to scavenge the trace metals used and required by the body. The binding of divalent and trivalent cations by EDTA can cause mineral deficiencies, which seem to be responsible for all of the known pharmacological effects. Sensitivity to the toxic effects of EDTA is, at least in part, related to the deficiency of zinc. Several short term studies, reported no adverse effects from administering doses up to 5% of EDTA and its salts to lab rodents daily and for several weeks. Only diarrhoea and lowered food consumption were reported in animals given 5% disodium EDTA.</p>
DL-alpha-tocopherol acetate	<p>May cause skin and eye irritation * Reproductive and mutagenic effects have been observed in tests with laboratory animals * * Alfa Aeser MSDS</p>

LAVANDIN OIL

For monoterpenes:

The chemical category designated terpenoid hydrocarbons includes three simple C10 isomeric monocyclic terpene hydrocarbons (*d*-limonene, *d*-limonene, and terpinolene) two simple C10 acyclic terpene hydrocarbons (*beta*-myrcene and dihydromyrcene) and mixtures composed primarily of *d*-limonene, *d*-limonene (dipentene), terpinolene, myrcene, and *alpha* and *beta*-pinene. Monoterpene hydrocarbons are mainly released by coniferous woodland such as pine trees, cedars, redwood and firs. To a lesser extent, they are also produced and released by deciduous plants. They are common components of traditional foods occurring in essentially all fruits and vegetables.

Members of this chemical category are of very low acute toxicity

Studies of terpene hydrocarbons indicate that they are rapidly absorbed, distributed, metabolised and excreted. The principal metabolic pathway involves side chain oxidation to yield monocyclic terpene alcohols and carboxylic acids. These metabolites are mainly conjugated with glucuronic acid and excreted in the urine, or to a lesser extent in the feces. A secondary pathway involves epoxidation of either the exocyclic or endocyclic double bond yielding an epoxide that is subsequently detoxicated *via* formation of the corresponding diol or conjugation with glutathione.

Although some species- and sex-specific differences exist, studies for *d*-limonene and *beta*-myrcene indicate that the monoterpene hydrocarbons in this chemical category will participate in common pathways of absorption, distribution, metabolism and excretion.

Genotoxicity: Based on the results of this *in vivo* genotoxicity assay and the numerous *in vitro* genotoxicity assays, it is unlikely that any of these materials would exhibit a significant genotoxic potential *in vivo*.

Carcinogenicity: Under the conditions of 2-year gavage studies, conducted by NTP, there was clear evidence of carcinogenic activity of *d*-limonene for male F344/N rats as shown by increased incidences in tubular cell hyperplasia, adenomas, and adenocarcinomas of the kidney. Current opinion holds that there are no safety concerns regarding the unsaturated branched chain non-cyclic alcohols, as fragrance ingredients, under the present declared levels of use and exposure; use of these materials at higher maximum dermal levels or higher systemic exposure levels requires re-evaluation. This opinion was based on the following reasons:

- ▶ No evidence or only minimal evidence of skin irritation in humans was associated with current levels of use at 2–30% for individual compounds considered.
- ▶ Sensitizing hydroperoxides may be formed by contact with air. It should be ensured that oxidation reactions are prevented in the end product. The use of these materials under the declared levels of use and exposure will not induce sensitization.
- ▶ The compounds have a low order of acute toxicity.
- ▶ The branched chain, unsaturated alcohols tested were of low systemic toxicity after repeated application.

A member or analogue of a group of aliphatic and alicyclic terpenoid tertiary alcohols and structurally related substances generally regarded as safe (GRAS based, in part, on their self-limiting properties as flavouring substances in food; their rapid absorption, metabolic conversion, and excretion in humans and experimental animals; their low level of flavour use; the wide margins of safety between the conservative estimates of intake and the no-observed-adverse effect levels (NOAEL) determined from subchronic and chronic studies and the lack of genotoxic and mutagenic potential. This evidence of safety is supported by the fact that the intake of aliphatic acyclic and alicyclic terpenoid tertiary alcohols and structurally related substances as natural components of traditional foods is greater than their intake as intentionally added flavoring substances.

Oral median lethal dose (LD50) values have been reported for 24 of the 43 substances in this group. LD50 values range from 1300 to greater than 36300 mg/kg bw, demonstrating that the oral acute toxicity of tertiary alcohols and related esters is extremely low.

Genotoxicity: the testing of representative materials *in vitro* in bacterial test systems (Ames assay) and *in vivo* in mammalian test systems (micronucleus assay) showed no evidence of mutagenic or genotoxic potential.

Based on the results of studies under a wide variety of conditions, including aqueous buffered media, simulated gastric juice, simulated human intestinal fluid, blood plasma, whole hepatocytes and liver microsome preparations, terpene esters formed from tertiary alcohols (for example, linalool), and simple aliphatic carboxylic acids are expected to undergo hydrolysis. Bicyclic tertiary alcohols are relatively stable *in vivo*, but are eventually conjugated with glucuronic acid and excreted. Although differences in the rates of hydrolysis occur under *in vitro* conditions in gastric juice and intestinal fluids, ready hydrolysis is observed in tissue preparations that have an abundant concentration of carboxylesterases (CES), especially the liver. The most important class of these enzymes is the B-esterases, which are members of the serine esterase superfamily. Generally, CES enzymes are ubiquitous throughout mammalian tissues and are found at the highest levels in hepatocytes.

In general, the esters are hydrolysed to their corresponding alcohol and carboxylic acid. It is expected that the tertiary aromatic alcohols will undergo direct conjugation of the hydroxyl group with glucuronic acid while the tertiary terpenoid alcohols formed as a result of hydrolysis are rapidly absorbed and converted to the glucuronic acid conjugates which are excreted in the urine, or are further oxidised to CO₂ that is subsequently expired.

Aliphatic acyclic and alicyclic terpenoid tertiary alcohols and structurally related substances often have a sweet floral rose to a fruity citrus green organoleptic profile. Twenty-two of the 44 flavor ingredients in this group have been reported to occur naturally, and can be found in chamomile, cocoa, coffee, a variety of fruits and especially citrus fruit varieties and vegetables, lemon juice, black and green teas, calamus, soybean, pepper, strawberry guava, beer and wine.

Flavor and Extract Manufacturers' Association (FEMA)

Cross-reactivity is also expected between ester derivatives and their parent alcohols, as the esters will be hydrolysed by esterases in the skin. Esters of important contact allergens that can be activated by hydrolysis in the skin are isoeugenol acetate, eugenyl acetate and geranyl acetate all of which are known to be used as fragrance ingredients.

Opinion holds that there are no safety concerns for linalool and the linalyl esters, as fragrance ingredients, under the present declared levels of use and exposure for the following reasons:

- Linalool and the linalyl esters have a low order of acute toxicity.
- No significant toxicity was observed in subchronic tests; it is concluded that these materials have dermal and oral NOAELS of 50 mg/kg/day or greater.
- Based on a critical review of all available mutagenicity and genotoxicity studies, it has been determined that these materials are negative in short-term tests and therefore would have no significant potential to produce genotoxic effects.
- The metabolic fate of linalool and the linalyl esters is either known or assumed from analogies with structurally related substances that indicate no production of toxic or persistent metabolites and the structural analogies indicate no concern.
- Human dermatological studies show that these materials are not irritating, phototoxic or sensitizing.
- These materials are used at low levels of exposure relative to doses that elicit adverse effects. The estimate for maximum systemic exposure by humans using cosmetic products is 0.3 mg/kg/day for linalool and linalyl acetate and 0.1 mg/kg/day or lower for the other linalyl esters. Using the NOAELs (50 mg/kg/day or greater) and the maximum exposure estimates and assuming 100% absorption, a margin of safety for the exposure of humans to linalool and the linalyl esters may conservatively be calculated as 167 times the maximum daily exposure for linalool and linalyl acetate (50 mg/kg/day / 0.3 mg/kg/day for linalool or linalyl acetate=167) and 500 times the maximum daily exposure for the other individual linalyl esters (50 mg/kg/day / 0.1 mg/kg/day for the other individual linalyl esters=500).

In general, linalool esters are hydrolyzed to their corresponding alcohol (linalool) and carboxylic acid. Hydrolysis is catalyzed by carboxylesterases or esterases. Tertiary alcohols such as linalool are metabolized primarily through conjugation with glucuronic acid and are excreted in the urine and to a lesser extent faeces. Alkyl or alkenyl substituents may undergo oxidation to form polar metabolites that may also be excreted free or in the conjugated form. Oxidation is mediated by cytochrome P-450 dependant mono-oxygenases.

With few exceptions * (see below) there are no safety concerns regarding certain cyclic and non-cyclic terpene alcohols **, as fragrance ingredients, under the present declared levels of use and exposure for the following reasons

- The non-cyclic and cyclic terpene alcohols have a low order of acute toxicity
- No significant toxicity was observed in repeated dose toxicity tests; it is concluded that these materials have dermal and oral NOAELs of 50 mg/kg body weight/day or greater.
- These materials were inactive in mutagenicity and genotoxicity tests.
- Based on data on metabolism it is concluded that members of this category exhibit similar chemical and biochemical fate.
- Although there is some indication for the production of reactive metabolites by some materials, these metabolites appear to be short-lived and are not expected to result in adverse effects. There is no indication for the production of persistent

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metabolites.

- The results from materials studied to date are indicative of the group and there are no grounds for environmental concern with respect to cyclic and non-cyclic terpene alcohol compounds as currently used in fragrance compounds.
- Human dermatological studies show that, at current use levels, these materials are practically non-irritating.
- The sensitization potential is generally low.
- The margin of safety is generally greater than 100 times the maximum daily exposure.

Sufficient data are available from farnesol, linalool, menthol and a-terpineol, i.e., compounds that contain all key structural elements and potential sites of metabolism of all other members in the group, to demonstrate that the non-cyclic and cyclic terpenes share common metabolic pathways. In most cases, metabolism yields innocuous metabolites. Some materials, however, may generate alpha, b-unsaturated compounds or be oxidized to hydroperoxides. Such compounds have the capacity to participate in a range of nucleophilic and electrophilic addition reactions with biological material.

* Safety concerns exist for the following substances for the following reasons.

- 6,7-Dihydrogeraniol, hydroabietyl alcohol and 6-isopropyl-2-decahydro-naphthalenol are potent skin sensitizers. These materials are prohibited for use in fragrance materials by IFRA Standards.
- Farnesol is a weak sensitizer. Its use in fragrance materials is therefore restricted by IFRA Standards.
- Sclareol and linalool may contain impurities and/or oxidation products that are strong sensitizers.

For linalool:

Linalool gradually breaks down when in contact with oxygen, forming an oxidized by-product that may cause allergic reactions such as eczema in susceptible individuals. Between 5 and 7% of patients undergoing patch testing in Sweden were found to be allergic to the oxidized form of linalool. [

Linalool has an acute oral mammalian LD50 close to 3,000 mg/kg bw; the acute dermal toxicity is ~ 2,000 mg/kg bw. After inhalation exposure of mice and man, slight sedative effects were observed; however a dose response characteristic could not be determined. Linalool is irritating to the skin, based on animal studies, and is a mild irritant from human experience. It may be moderately irritant to the eyes at the same concentration where it produces nasal pungency. Linalool is considered not to be a sensitizer. The incidence of dermal reaction to linalool is below 1% in naive probands (not knowingly pre-sensitized) while in subjects pre-sensitized to fragrances it is up to 10%. In a 28-day oral rat study (72.9% linalool) findings were increased liver and kidney weight, thickened liver lobes and pale areas on the kidneys and in females only hepatocellular cytoplasmic vacuolisation.

For terpenoid tertiary alcohols and their related esters:

Substances assigned to this category, as part of the HPV Challenge Program, possess close structural relationships, similar physicochemical properties and participate in the same pathways of metabolic detoxification and have similar toxicologic potential.

Acute Toxicity: Oral and dermal LD50 values for members of this chemical category indicate a low order of both oral and dermal toxicity. All rabbit dermal, and mouse and rat oral LD50 values exceed 2000 mg/kg with the majority of values greater than 5000 mg/kg

Repeat dose toxicity: In a safety evaluation study, a 50/50 mixture of linalool and citronellol was fed to male and female rats (number and strain not specified) in the diet. The daily intake was calculated to be 50 mg/kg bw of each. Measurements of haematology, clinical chemistry, and urinalysis at weeks 6 and 12 showed no statistically significant differences between test and control groups. Histopathology revealed no dose-related lesions. A slight retardation of growth was observed in males only, but was concluded by the authors to be biologically insignificant

Reproductive toxicity: Four groups of 10 virgin Crl CD rats were administered 0,250,500, or 1000 mg/kg bw of an essential oil (coriander oil) known to contain 73% linalool by mass. The test material was given by gavage once daily, 7 days prior to cohabitation, through cohabitation (maximum of 7 days), gestation, delivery, and a 4-day post-parturition period.

Camphor appears to have moderate acute oral toxicity, with an LD50 of 1310 mg/kg in mice. It demonstrated moderate to high toxicity in acute inhalation studies (450 mg/m³ (72 ppm) in mice and 500 mg/m³ (80 ppm) in rats). In subchronic studies, inhaled camphor resulted in emphysema in mice at 210 mg/m³ (33 ppm) and rabbits at 33 mg/m³ (5 ppm). In 13-week subchronic dermal studies, camphor had NOAELs of 1000 mg/kg bw/day in mice and 250 mg/kg bw/day in rats. IPCS reported negative results in carcinogenicity tests for camphor. In addition, camphor was negative for genotoxicity in a microsome mutagenesis test, and a peripheral blood micronucleus assay. Reproductive toxicity studies were not available for camphor, however, in developmental toxicity studies, camphor demonstrated no foetal toxicity (with NOAELs 800 mg/kg bw/day in rats) at dose levels that resulted in maternal toxicity

For alkyl alcohols C6-13:

This group of products are very similar in terms of physicochemical and toxicological properties. Interpolation of data can be used to assess the alkyl alcohols for which data is not available.

Acute toxicity: All of these alcohols have a low order of toxicity in rats via the oral route. The LD50 for C6-branched and linear alcohols were >3700 mg/kg; LD50s for the C6-8, C7-9, C8-10, C9-11 and C11-14 branched alkyl alcohols were all >2000 mg/kg.

These alcohols have a low order of toxicity via the dermal route. Dermal LD50s were greater than 2600 mg/kg.

Subchronic toxicity: Repeat dose studies indicate these alcohols have a low order of subchronic toxicity by both the oral and dermal route.

Further they demonstrate that these alcohols display a consistent degree of subchronic toxicity by these routes

Developmental toxicity: Studies demonstrate that the alcohols are not selective developmental toxicants by either the oral or inhalation route of exposure. Inhalation of alkyl alcohols C6-13 is a primary concern during industrial use, particularly for lower molecular weight alcohols.

Collectively the weight of evidence demonstrates that these alcohols have a low order of maternal toxicity and do not induce signs of developmental toxicity until maternal toxicity is observed. The NOAELs for inhalation reflect the maximum achievable vapour concentration.

Reproductive toxicity: Developmental toxicity studies for several of these alcohols, conducted by the oral route, produce consistent results and demonstrate that these substances do not affect reproductive parameters. Although a slight increase in resorptions was observed in several studies, this occurred only in the highest dose group and in the presence of overt maternal toxicity.

Genotoxicity: The weight of evidence from existing data supports the conclusion that these materials are not genotoxic.

Further data to support this assessment comes from a series of alkyl acetates C6-13. Alkyl acetates are produced from alkyl alcohols and undergo metabolism by esterases to produce acetic acid and the corresponding alkyl alcohol.

d-Limonene is readily absorbed by inhalation and ingestion. Dermal absorption is reported to be lower than by the inhalation route.

d-Limonene is rapidly distributed to different tissues in the body, readily metabolised and eliminated primarily through the urine.

Limonene exhibits low acute toxicity by all three routes in animals. Limonene is a skin irritant in both experimental animals and humans.

Limited data are available on the potential to cause eye and respiratory irritation. Autooxidised products of d-limonene have the potential to be skin sensitizers. Limited data are available in humans on the potential to cause respiratory sensitisation.

	<p>metabolites.</p> <ul style="list-style-type: none"> • The results from materials studied to date are indicative of the group and there are no grounds for environmental concern with respect to cyclic and non-cyclic terpene alcohol compounds as currently used in fragrance compounds. • Human dermatological studies show that, at current use levels, these materials are practically non-irritating. • The sensitization potential is generally low. • The margin of safety is generally greater than 100 times the maximum daily exposure. <p>Sufficient data are available from farnesol, linalool, menthol and a-terpineol, i.e., compounds that contain all key structural elements and potential sites of metabolism of all other members in the group, to demonstrate that the non-cyclic and cyclic terpenes share common metabolic pathways. In most cases, metabolism yields innocuous metabolites. Some materials, however, may generate alpha, b-unsaturated compounds or be oxidized to hydroperoxides. Such compounds have the capacity to participate in a range of nucleophilic and electrophilic addition reactions with biological material.</p> <p>* Safety concerns exist for the following substances for the following reasons.</p> <ul style="list-style-type: none"> • 6,7-Dihydrogeraniol, hydroabietyl alcohol and 6-isopropyl-2-decahydro-naphthalenol are potent skin sensitizers. These materials are prohibited for use in fragrance materials by IFRA Standards. • Farnesol is a weak sensitizer. Its use in fragrance materials is therefore restricted by IFRA Standards. • Sclareol and linalool may contain impurities and/or oxidation products that are strong sensitizers. <p>For linalool:</p> <p>Linalool gradually breaks down when in contact with oxygen, forming an oxidized by-product that may cause allergic reactions such as eczema in susceptible individuals. Between 5 and 7% of patients undergoing patch testing in Sweden were found to be allergic to the oxidized form of linalool. [</p> <p>Linalool has an acute oral mammalian LD50 close to 3,000 mg/kg bw; the acute dermal toxicity is ~ 2,000 mg/kg bw. After inhalation exposure of mice and man, slight sedative effects were observed; however a dose response characteristic could not be determined. Linalool is irritating to the skin, based on animal studies, and is a mild irritant from human experience. It may be moderately irritant to the eyes at the same concentration where it produces nasal pungency. Linalool is considered not to be a sensitizer. The incidence of dermal reaction to linalool is below 1% in naive probands (not knowingly pre-sensitized) while in subjects pre-sensitized to fragrances it is up to 10%. In a 28-day oral rat study (72.9% linalool) findings were increased liver and kidney weight, thickened liver lobes and pale areas on the kidneys and in females only hepatocellular cytoplasmic vacuolisation.</p> <p>For terpenoid tertiary alcohols and their related esters:</p> <p>Substances assigned to this category, as part of the HPV Challenge Program, possess close structural relationships, similar physicochemical properties and participate in the same pathways of metabolic detoxification and have similar toxicologic potential.</p> <p>Acute Toxicity: Oral and dermal LD50 values for members of this chemical category indicate a low order of both oral and dermal toxicity. All rabbit dermal, and mouse and rat oral LD50 values exceed 2000 mg/kg with the majority of values greater than 5000 mg/kg</p> <p>Repeat dose toxicity: In a safety evaluation study, a 50/50 mixture of linalool and citronellol was fed to male and female rats (number and strain not specified) in the diet. The daily intake was calculated to be 50 mg/kg bw of each. Measurements of haematology, clinical chemistry, and urinalysis at weeks 6 and 12 showed no statistically significant differences between test and control groups. Histopathology revealed no dose-related lesions. A slight retardation of growth was observed in males only, but was concluded by the authors to be biologically insignificant</p> <p>Reproductive toxicity: Four groups of 10 virgin Crl CD rats were administered 0,250,500, or 1000 mg/kg bw of an essential oil (coriander oil) known to contain 73% linalool by mass. The test material was given by gavage once daily, 7 days prior to cohabitation, through cohabitation (maximum of 7 days), gestation, delivery, and a 4-day post-parturition period.</p> <p>Camphor appears to have moderate acute oral toxicity, with an LD50 of 1310 mg/kg in mice. It demonstrated moderate to high toxicity in acute inhalation studies (450 mg/m³ (72 ppm) in mice and 500 mg/m³ (80 ppm) in rats). In subchronic studies, inhaled camphor resulted in emphysema in mice at 210 mg/m³ (33 ppm) and rabbits at 33 mg/m³ (5 ppm). In 13-week subchronic dermal studies, camphor had NOAELs of 1000 mg/kg bw/day in mice and 250 mg/kg bw/day in rats. IPCS reported negative results in carcinogenicity tests for camphor. In addition, camphor was negative for genotoxicity in a microsome mutagenesis test, and a peripheral blood micronucleus assay. Reproductive toxicity studies were not available for camphor, however, in developmental toxicity studies, camphor demonstrated no foetal toxicity (with NOAELs 800 mg/kg bw/day in rats) at dose levels that resulted in maternal toxicity</p> <p>For alkyl alcohols C6-13:</p> <p>This group of products are very similar in terms of physicochemical and toxicological properties. Interpolation of data can be used to assess the alkyl alcohols for which data is not available.</p> <p>Acute toxicity: All of these alcohols have a low order of toxicity in rats via the oral route. The LD50 for C6-branched and linear alcohols were >3700 mg/kg; LD50s for the C6-8, C7-9, C8-10, C9-11 and C11-14 branched alkyl alcohols were all >2000 mg/kg.</p> <p>These alcohols have a low order of toxicity via the dermal route. Dermal LD50s were greater than 2600 mg/kg.</p> <p>Subchronic toxicity: Repeat dose studies indicate these alcohols have a low order of subchronic toxicity by both the oral and dermal route.</p> <p>Further they demonstrate that these alcohols display a consistent degree of subchronic toxicity by these routes</p> <p>Developmental toxicity: Studies demonstrate that the alcohols are not selective developmental toxicants by either the oral or inhalation route of exposure. Inhalation of alkyl alcohols C6-13 is a primary concern during industrial use, particularly for lower molecular weight alcohols.</p> <p>Collectively the weight of evidence demonstrates that these alcohols have a low order of maternal toxicity and do not induce signs of developmental toxicity until maternal toxicity is observed. The NOAELs for inhalation reflect the maximum achievable vapour concentration.</p> <p>Reproductive toxicity: Developmental toxicity studies for several of these alcohols, conducted by the oral route, produce consistent results and demonstrate that these substances do not affect reproductive parameters. Although a slight increase in resorptions was observed in several studies, this occurred only in the highest dose group and in the presence of overt maternal toxicity.</p> <p>Genotoxicity: The weight of evidence from existing data supports the conclusion that these materials are not genotoxic.</p> <p>Further data to support this assessment comes from a series of alkyl acetates C6-13. Alkyl acetates are produced from alkyl alcohols and undergo metabolism by esterases to produce acetic acid and the corresponding alkyl alcohol.</p> <p>d-Limonene is readily absorbed by inhalation and ingestion. Dermal absorption is reported to be lower than by the inhalation route.</p> <p>d-Limonene is rapidly distributed to different tissues in the body, readily metabolised and eliminated primarily through the urine.</p> <p>Limonene exhibits low acute toxicity by all three routes in animals. Limonene is a skin irritant in both experimental animals and humans.</p> <p>Limited data are available on the potential to cause eye and respiratory irritation. Autooxidised products of d-limonene have the potential to be skin sensitizers. Limited data are available in humans on the potential to cause respiratory sensitisation.</p>
<p>SYMPHYTUM OFFICINALE (COMFREY) EXTRACT</p>	<p>The use of Comfrey should be restricted to topical use, and should never be ingested, as it contains dangerous amounts of hepatotoxic pyrrolizidine alkaloids (PAs). Excessive doses of symphytine, one of the PAs in comfrey, may cause cancer in rats. This was shown by injection of the pure alkaloid. The whole plant has also been shown to induce precancerous changes in rats. Studies associating comfrey with veno-occlusive disease (VOD), do not differentiate between Russian and common comfrey, plants with very different levels of PAs. VOD can in turn lead to liver failure, and comfrey has been implicated in at least one death though type of comfrey being consumed, other dietary, physiological and pharmacodynamic factors were not accounted for. In 2001, the United States Food and Drug Administration issued a warning against internal usage of herbal products containing comfrey, and eventually banned Comfrey products intended for internal use. In addition to restrictions on oral use, scientists and medical professionals recommend applying Comfrey extracts no longer than 10 days in a row, and no more than 4-6 weeks a year</p>
<p>GINSENG, EXTRACT</p>	<p>Ginseng Leaves-Crude Saponin (mainly ginsenoside F) [RETECS No.: LY 9533000] Ginseng Leaves-Saponins [RETECS No.: LY 9533500] Ginseng Root-Neutral Saponins mixture of ginsenosides Rb and RC [RETECS No.: LY 9534000] Rat mutagen in vivo Ginseng, saponin extract [RETECS No.: LY 9534500]</p>
<p>Chamomile recutica oil</p>	<p>* Botanical Specialities MSDS</p>

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lactic acid	<p>for acid mists, aerosols, vapours</p> <p>Data from assays for genotoxic activity in vitro suggest that eukaryotic cells are susceptible to genetic damage when the pH falls to about 6.5. Cells from the respiratory tract have not been examined in this respect. Mucous secretion may protect the cells of the airways from direct exposure to inhaled acidic mists, just as mucous plays an important role in protecting the gastric epithelium from its auto-secreted hydrochloric acid. In considering whether pH itself induces genotoxic events in vivo in the respiratory system, comparison should be made with the human stomach, in which gastric juice may be at pH 1-2 under fasting or nocturnal conditions, and with the human urinary bladder, in which the pH of urine can range from <5 to >7 and normally averages 6.2. Furthermore, exposures to low pH in vivo differ from exposures <i>in vitro</i> in that, <i>in vivo</i>, only a portion of the cell surface is subjected to the adverse conditions, so that perturbation of intracellular homeostasis may be maintained more readily than in vitro.</p> <p>for simple alpha-hydroxy carboxylic acids and their salts:</p> <p>The US Food and Drug Administration (FDA) received a total of 114 adverse dermatologic experience reports for alpha-hydroxy acids (AHA)-containing skin care products between 1992 and February 2004, with the maximum number in 1994. The reported adverse experiences included burning (45), dermatitis or rash (35), swelling (29), pigmentary changes (15), blisters or welts (14), skin peeling (13), itching (12), irritation or tenderness (8), chemical burns (6), and increased sunburn (3). The frequency of such reports for skin exfoliating products that contain AHAs has been considerably lower in subsequent years. The more serious adverse reactions appear to occur most often with products that cause the greatest degree of exfoliation, such as "skin peelers."</p> <p>Various studies confirmed previous industry studies indicating that applying AHAs to the skin results in increased UV sensitivity. After four weeks of AHA application, volunteers' sensitivity to skin reddening produced by UV increased by 18 percent. Similarly, the volunteers' sensitivity to UV-induced cellular damage doubled, on average, with considerable differences among individuals. Topical glycolic acid enhances photodamage by ultraviolet light.</p> <p>However, the studies also indicated that this increase in sensitivity is reversible and does not last long after discontinuing use of the AHA cream.</p>
IBASE LOTION & LAVANDIN OIL & Chamomile recutica oil	<p>Adverse reactions to fragrances in perfumes and in fragranced cosmetic products include allergic contact dermatitis, irritant contact dermatitis, photosensitivity, immediate contact reactions (contact urticaria), and pigmented contact dermatitis. Airborne and connubial contact dermatitis occur.</p> <p>Intolerance to perfumes, by inhalation, may occur if the perfume contains a sensitising principal. Symptoms may vary from general illness, coughing, phlegm, wheezing, chest-tightness, headache, exertional dyspnoea, acute respiratory illness, hayfever, and other respiratory diseases (including asthma). Perfumes can induce hyper-reactivity of the respiratory tract without producing an IgE-mediated allergy or demonstrable respiratory obstruction. This was shown by placebo-controlled challenges of nine patients to "perfume mix". The same patients were also subject to perfume provocation, with or without a carbon filter mask, to ascertain whether breathing through a filter with active carbon would prevent symptoms. The patients breathed through the mouth, during the provocations, as a nose clamp was used to prevent nasal inhalation.</p>
GLYCEROL & stearic acid & almond, sweet, extract & triethanolamine & EDTA DISODIUM SALT & Carbomer & LAVANDIN OIL & lactic acid	<p>Asthma-like symptoms may continue for months or even years after exposure to the material ceases. This may be due to a non-allergenic condition known as reactive airways dysfunction syndrome (RADS) which can occur following exposure to high levels of highly irritating compound. Key criteria for the diagnosis of RADS include the absence of preceding respiratory disease, in a non-atopic individual, with abrupt onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. A reversible airflow pattern, on spirometry, with the presence of moderate to severe bronchial hyperreactivity on methacholine challenge testing and the lack of minimal lymphocytic inflammation, without eosinophilia, have also been included in the criteria for diagnosis of RADS. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. Industrial bronchitis, on the other hand, is a disorder that occurs as result of exposure due to high concentrations of irritating substance (often particulate in nature) and is completely reversible after exposure ceases. The disorder is characterised by dyspnea, cough and mucus production.</p>
stearic acid & Carbomer	<p>The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling the epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.</p>
water & almond, sweet, extract & DIMETHICONE & 1,2-OCTANEDIOL & Carbomer & 1,2-DECANEDIOL & LAVANDIN OIL & SYMPHYTUM OFFICINALE (COMFREY) EXTRACT & Chamomile recutica oil	<p>No significant acute toxicological data identified in literature search.</p>
almond, sweet, extract & LAVANDIN OIL	<p>Epoxidation of double bonds is a common bioactivation pathway for alkenes. The allylic epoxides, so formed, were found to possess sensitising capacity in vivo and in vitro and to chemically reactive towards a common hexapeptide containing the most common nucleophilic amino acids. Further-more, a SAR study of potentially prohaptenic alkenes demonstrated that conjugated dienes in or in conjunction with a six-membered ring are prohaptenes, whereas related alkenes containing isolated double bonds or an acyclic conjugated diene were weak or nonsensitizing compounds. This difference in sensitizing capacity of conjugated dienes as compared to alkenes with isolated double bonds was found to be due to the high reactivity and sensitizing capacity of the allylic epoxides metabolically formed from conjugated dienes.</p> <p>Allergic Contact Dermatitis—Formation, Structural Requirements, and Reactivity of Skin Sensitizers.</p> <p>Ann-Therese Karlberg et al: Chem. Res. Toxicol. 2008, 21, pp 53–69</p> <p>http://ftp.cdc.gov/pub/Documents/OEL/06.%20Dotson/References/Karlberg_2008.pdf</p>
ALCOHOLS C16-18 ETHOXYLATED & ETHYLENE GLYCOL PHENYL ETHER & triethanolamine & Carbomer & lactic acid	<p>The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.</p>
ALCOHOLS C16-18 ETHOXYLATED & ETHYLENE GLYCOL PHENYL ETHER & triethanolamine	<p>The material may cause skin irritation after prolonged or repeated exposure and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) and swelling epidermis. Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis.</p>
triethanolamine & EDTA DISODIUM SALT & LAVANDIN OIL & Chamomile recutica oil	<p>The following information refers to contact allergens as a group and may not be specific to this product.</p> <p>Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. A weakly sensitising substance which is widely distributed can be a more important allergen than one with stronger sensitising potential with which few individuals come into contact. From a clinical point of view, substances are noteworthy if they produce an allergic test reaction in more than 1% of the persons tested.</p>
triethanolamine & DL-alpha-tocopherol acetate	<p>NOTE: Substance has been shown to be mutagenic in at least one assay, or belongs to a family of chemicals producing damage or change to cellular DNA.</p>
LAVANDIN OIL & Chamomile recutica oil	<p>Allergic reactions which develop in the respiratory passages as bronchial asthma or rhinoconjunctivitis, are mostly the result of reactions of the allergen with specific antibodies of the IgE class and belong in their reaction rates to the manifestation of the immediate type. In addition to the allergen-specific potential for causing respiratory sensitisation, the amount of the allergen, the exposure period and the genetically determined disposition of the exposed person are likely to be decisive in determining the severity of the disease. The sensitivity of the mucosa may play a role in predisposing a</p>

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	<p>person to allergy. They may be genetically determined or acquired, for example, during infections or exposure to irritant substances. Immunologically the low molecular weight substances become complete allergens in the organism either by binding to peptides or proteins (haptens) or after metabolism (prohaptens).</p> <p>Particular attention is drawn to so-called atopic diathesis which is characterised by an increased susceptibility to allergic rhinitis, allergic bronchial asthma and atopic eczema (neurodermatitis) which is associated with increased IgE synthesis.</p> <p>Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following exposure.</p> <p>Fragrance allergens act as haptens, i.e. low molecular weight chemicals that are immunogenic only when attached to a carrier protein. However, not all sensitising fragrance chemicals are directly reactive, but require previous activation. A prehapten is a chemical that itself is non- or low-sensitising, but that is transformed into a hapten outside the skin by simple chemical transformation (air oxidation, photoactivation) and without the requirement of specific enzymatic systems.</p> <p>In the case of prehaptens, it is possible to prevent activation outside the body to a certain extent by different measures, e.g. prevention of air exposure during handling and storage of the ingredients and the final product, and by the addition of suitable antioxidants. When antioxidants are used, care should be taken that they will not be activated themselves and thereby form new sensitisers.</p> <p>Prehaptens</p> <p>Most terpenes with oxidisable allylic positions can be expected to autoxidise on air exposure due to their inherent properties. Depending on the stability of the oxidation products that are formed, a difference in the sensitisation potency of the oxidised terpenes can be seen. Autoxidation is a free radical chain reaction in which hydrogen atom abstraction in combination with addition of oxygen forms peroxy radicals. The reaction shows selectivity for positions where stable radicals can be formed. So far, all fragrance substances that have been investigated with regard to the influence of autoxidation on the allergenic potential, including identification of formed oxidation products, have oxidisable allylic positions that are able to form hydroperoxides and/or hydrogen peroxide as primary oxidation products upon air exposure.</p>
LAVANDIN OIL & lactic acid	<p>The material may produce severe skin irritation after prolonged or repeated exposure, and may produce a contact dermatitis (nonallergic). This form of dermatitis is often characterised by skin redness (erythema) thickening of the epidermis.</p> <p>Histologically there may be intercellular oedema of the spongy layer (spongiosis) and intracellular oedema of the epidermis. Prolonged contact is unlikely, given the severity of response, but repeated exposures may produce severe ulceration.</p>

Acute Toxicity	✗	Carcinogenicity	✗
Skin Irritation/Corrosion	✗	Reproductivity	✗
Serious Eye Damage/Irritation	✓	STOT - Single Exposure	✗
Respiratory or Skin sensitisation	✗	STOT - Repeated Exposure	✗
Mutagenicity	✗	Aspiration Hazard	✗

Legend: ✗ – Data either not available or does not fill the criteria for classification
 ✓ – Data available to make classification

11.2.1. Endocrine Disruption Properties

Not Available

SECTION 12 Ecological information

12.1. Toxicity

IBASE LOTION	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
glycerol	Endpoint	Test Duration (hr)	Species	Value	Source
	EC0(ECx)	24h	Crustacea	>500mg/l	1
	LC50	96h	Fish	885mg/l	2
stearic acid	Endpoint	Test Duration (hr)	Species	Value	Source
	NOEC(ECx)	504h	Crustacea	>0.22mg/l	2
	EC50	72h	Algae or other aquatic plants	>0.9mg/l	2
EC50	48h	Crustacea	>4.8mg/l	2	
water	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
almond, sweet, extract	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50(ECx)	24h	Crustacea	>100mg/l	2
	EC50	72h	Algae or other aquatic plants	>1050mg/l	2
EC50	48h	Crustacea	>100mg/l	2	
alcohols C16-18 ethoxylated	Endpoint	Test Duration (hr)	Species	Value	Source
	EC20(ECx)	72h	Algae or other aquatic plants	0.06mg/l	2
	EC50	72h	Algae or other aquatic plants	>100mg/l	2
LC50	96h	Fish	108mg/l	2	
dimethicone	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available

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ethylene glycol phenyl ether	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	>100mg/l	2
	LC50	96h	Fish	154mg/l	2
	EC50	48h	Crustacea	460mg/l	2
	NOEC(ECx)	24h	Fish	5mg/l	2
triethanolamine	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	>107<260mg/l	2
	EC50	48h	Crustacea	565.2-658.3mg/l	4
	LC50	96h	Fish	11800mg/l	2
	EC10(ECx)	96h	Algae or other aquatic plants	7.1mg/l	1
	BCF	1008h	Fish	<0.4	7
	EC50	96h	Algae or other aquatic plants	169mg/l	1
1,2-octanediol	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96h	Fish	>2.2<22mg/l	2
	EC50	72h	Algae or other aquatic plants	35mg/l	2
	EC50	48h	Crustacea	176mg/l	2
	NOEC(ECx)	72h	Algae or other aquatic plants	15mg/l	2
sodium pyroglutamate	Endpoint	Test Duration (hr)	Species	Value	Source
	NOEC(ECx)	72h	Algae or other aquatic plants	12.5mg/l	2
	EC50	72h	Algae or other aquatic plants	68.87mg/l	2
	LC50	96h	Fish	>100mg/l	2
	EC50	48h	Crustacea	>100mg/l	2
EDTA disodium salt	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	2.77mg/l	2
	LC50	96h	Fish	41mg/l	2
	EC50	48h	Crustacea	140mg/l	2
	NOEC(ECx)	72h	Algae or other aquatic plants	0.39mg/l	2
DL-alpha-tocopherol acetate	Endpoint	Test Duration (hr)	Species	Value	Source
	NOEC(ECx)	96h	Fish	11mg/l	2
	EC50	72h	Algae or other aquatic plants	>27.8mg/l	2
	LC50	96h	Fish	>11mg/l	2
	EC50	48h	Crustacea	>20.6mg/l	2
Carbomer	Endpoint	Test Duration (hr)	Species	Value	Source
	EC10(ECx)	72h	Algae or other aquatic plants	0.03-0.031mg/l	2
	EC50	72h	Algae or other aquatic plants	0.13-0.205mg/l	2
	LC50	96h	Fish	27mg/l	2
	EC50	48h	Crustacea	47mg/l	2
1,2-decanediol	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96h	Fish	14.1mg/l	2
	EC50	72h	Algae or other aquatic plants	23.3mg/l	2
	EC50	48h	Crustacea	25.5mg/l	2
	NOEC(ECx)	72h	Algae or other aquatic plants	12.5mg/l	2
ETHANOL TSDA1 DEB 100	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50(ECx)	96h	Algae or other aquatic plants	<0.001mg/L	4
	EC50	72h	Algae or other aquatic plants	275mg/l	2
	LC50	96h	Fish	>100mg/l	2
	EC50	48h	Crustacea	>79mg/L	4
	EC50	96h	Algae or other aquatic plants	<0.001mg/L	4
lavandin oil	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50(ECx)	48h	Crustacea	0.41mg/l	2
	EC50	72h	Algae or other aquatic plants	0.5mg/l	2
	LC50	96h	Fish	0.29mg/l	2

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	EC50	48h	Crustacea	0.41mg/l	2
Symphytum officinale (comfrey) extract	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
Ginseng, extract	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
Chamomile recutica oil	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
lactic acid	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50(ECx)	48h	Crustacea	130mg/l	2
	EC50	72h	Algae or other aquatic plants	>2800mg/L	2
	LC50	96h	Fish	130mg/l	2
	EC50	48h	Crustacea	130mg/l	2
Legend:	Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data				

Harmful to aquatic organisms.

12.2. Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
glycerol	LOW	LOW
stearic acid	LOW	LOW
water	LOW	LOW
ethylene glycol phenyl ether	LOW	LOW
triethanolamine	LOW	LOW
1,2-octanediol	LOW	LOW
EDTA disodium salt	LOW	LOW
DL-alpha-tocopherol acetate	HIGH	HIGH
Carbomer	LOW	LOW
1,2-decanediol	LOW	LOW
ETHANOL TSDA1 DEB 100	LOW (Half-life = 2.17 days)	LOW (Half-life = 5.08 days)
lactic acid	LOW	LOW

12.3. Bioaccumulative potential

Ingredient	Bioaccumulation
glycerol	LOW (LogKOW = -1.76)
stearic acid	LOW (LogKOW = 8.23)
ethylene glycol phenyl ether	LOW (LogKOW = 1.16)
triethanolamine	LOW (BCF = 3.9)
1,2-octanediol	LOW (LogKOW = 1.6735)
EDTA disodium salt	LOW (LogKOW = -3.8573)
DL-alpha-tocopherol acetate	LOW (LogKOW = 11.9136)
Carbomer	LOW (LogKOW = 0.4415)
1,2-decanediol	LOW (LogKOW = 2.6557)
ETHANOL TSDA1 DEB 100	LOW (LogKOW = -0.31)
lactic acid	LOW (LogKOW = -0.649)

12.4. Mobility in soil

Ingredient	Mobility
glycerol	HIGH (KOC = 1)
stearic acid	LOW (KOC = 11670)
ethylene glycol phenyl ether	LOW (KOC = 12.12)
triethanolamine	LOW (KOC = 10)
1,2-octanediol	LOW (KOC = 10)
EDTA disodium salt	LOW (KOC = 1046)
DL-alpha-tocopherol acetate	LOW (KOC = 1046)

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Ingredient	Mobility
Carbomer	HIGH (KOC = 1.201)
1,2-decanediol	LOW (KOC = 10)
ETHANOL TSDA1 DEB 100	HIGH (KOC = 1)
lactic acid	HIGH (KOC = 1)

12.5. Results of PBT and vPvB assessment

	P	B	T
Relevant available data	Not Available	Not Available	Not Available
PBT	✗	✗	✗
vPvB	✗	✗	✗
PBT Criteria fulfilled?	No		
vPvB	No		

12.6. Endocrine Disruption Properties

Not Available

12.7. Other adverse effects

One or more ingredients within this SDS has the potential of causing ozone depletion and/or photochemical ozone creation.

SECTION 13 Disposal considerations

13.1. Waste treatment methods

Product / Packaging disposal	<p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> ▶ Reduction ▶ Reuse ▶ Recycling ▶ Disposal (if all else fails) <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.</p> <ul style="list-style-type: none"> ▶ DO NOT allow wash water from cleaning or process equipment to enter drains. ▶ It may be necessary to collect all wash water for treatment before disposal. ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▶ Where in doubt contact the responsible authority. ▶ Recycle wherever possible. ▶ Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified. ▶ Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or incineration in a licensed apparatus (after admixture with suitable combustible material). ▶ Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.
Waste treatment options	Not Available
Sewage disposal options	Not Available

SECTION 14 Transport information

Labels Required

Marine Pollutant	NO
HAZCHEM	Not Applicable

Land transport (ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable								
14.2. UN proper shipping name	Not Applicable								
14.3. Transport hazard class(es)	<table border="1"> <tbody> <tr> <td>Class</td> <td>Not Applicable</td> </tr> <tr> <td>Subrisk</td> <td>Not Applicable</td> </tr> </tbody> </table>	Class	Not Applicable	Subrisk	Not Applicable				
Class	Not Applicable								
Subrisk	Not Applicable								
14.4. Packing group	Not Applicable								
14.5. Environmental hazard	Not Applicable								
14.6. Special precautions for user	<table border="1"> <tbody> <tr> <td>Hazard identification (Kemler)</td> <td>Not Applicable</td> </tr> <tr> <td>Classification code</td> <td>Not Applicable</td> </tr> <tr> <td>Hazard Label</td> <td>Not Applicable</td> </tr> <tr> <td>Special provisions</td> <td>Not Applicable</td> </tr> </tbody> </table>	Hazard identification (Kemler)	Not Applicable	Classification code	Not Applicable	Hazard Label	Not Applicable	Special provisions	Not Applicable
Hazard identification (Kemler)	Not Applicable								
Classification code	Not Applicable								
Hazard Label	Not Applicable								
Special provisions	Not Applicable								

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	Limited quantity	Not Applicable
	Tunnel Restriction Code	Not Applicable

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable	
14.2. UN proper shipping name	Not Applicable	
14.3. Transport hazard class(es)	ICAO/IATA Class	Not Applicable
	ICAO / IATA Subrisk	Not Applicable
	ERG Code	Not Applicable
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	Special provisions	Not Applicable
	Cargo Only Packing Instructions	Not Applicable
	Cargo Only Maximum Qty / Pack	Not Applicable
	Passenger and Cargo Packing Instructions	Not Applicable
	Passenger and Cargo Maximum Qty / Pack	Not Applicable
	Passenger and Cargo Limited Quantity Packing Instructions	Not Applicable
	Passenger and Cargo Limited Maximum Qty / Pack	Not Applicable

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable	
14.2. UN proper shipping name	Not Applicable	
14.3. Transport hazard class(es)	IMDG Class	Not Applicable
	IMDG Subrisk	Not Applicable
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	EMS Number	Not Applicable
	Special provisions	Not Applicable
	Limited Quantities	Not Applicable

Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

14.1. UN number	Not Applicable	
14.2. UN proper shipping name	Not Applicable	
14.3. Transport hazard class(es)	Not Applicable	Not Applicable
14.4. Packing group	Not Applicable	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	Classification code	Not Applicable
	Special provisions	Not Applicable
	Limited quantity	Not Applicable
	Equipment required	Not Applicable
	Fire cones number	Not Applicable

14.7. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

14.8. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
glycerol	Not Available
stearic acid	Not Available
water	Not Available
almond, sweet, extract	Not Available
alcohols C16-18 ethoxylated	Not Available
dimethicone	Not Available
ethylene glycol phenyl ether	Not Available

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Product name	Group
triethanolamine	Not Available
1,2-octanediol	Not Available
sodium pyroglutamate	Not Available
EDTA disodium salt	Not Available
DL-alpha-tocopherol acetate	Not Available
Carbomer	Not Available
1,2-decanediol	Not Available
ETHANOL TSDA1 DEB 100	Not Available
lavandin oil	Not Available
Symphytum officinale (comfrey) extract	Not Available
Ginseng, extract	Not Available
Chamomile recutica oil	Not Available
lactic acid	Not Available

14.9. Transport in bulk in accordance with the ICG Code

Product name	Ship Type
glycerol	Not Available
stearic acid	Not Available
water	Not Available
almond, sweet, extract	Not Available
alcohols C16-18 ethoxylated	Not Available
dimethicone	Not Available
ethylene glycol phenyl ether	Not Available
triethanolamine	Not Available
1,2-octanediol	Not Available
sodium pyroglutamate	Not Available
EDTA disodium salt	Not Available
DL-alpha-tocopherol acetate	Not Available
Carbomer	Not Available
1,2-decanediol	Not Available
ETHANOL TSDA1 DEB 100	Not Available
lavandin oil	Not Available
Symphytum officinale (comfrey) extract	Not Available
Ginseng, extract	Not Available
Chamomile recutica oil	Not Available
lactic acid	Not Available

SECTION 15 Regulatory information

15.1. Safety, health and environmental regulations / legislation specific for the substance or mixture

glycerol is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

stearic acid is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

water is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

almond, sweet, extract is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

alcohols C16-18 ethoxylated is found on the following regulatory lists

Europe EC Inventory

dimethicone is found on the following regulatory lists

Not Applicable

ethylene glycol phenyl ether is found on the following regulatory lists

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Tel: 01425 655555 Email: technical@madarcorporation.co.uk

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Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI
International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

triethanolamine is found on the following regulatory lists

EU European Chemicals Agency (ECHA) Community Rolling Action Plan (CoRAP) List of Substances

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)
International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

1,2-octanediol is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

sodium pyroglutamate is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

EDTA disodium salt is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

DL-alpha-tocopherol acetate is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

Carbomer is found on the following regulatory lists

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs

1,2-decanediol is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

ETHANOL TSDA1 DEB 100 is found on the following regulatory lists

EU REACH Regulation (EC) No 1907/2006 - Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)
European Union (EU) Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures - Annex VI

lavandin oil is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

Symphytum officinale (comfrey) extract is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

Ginseng, extract is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

Chamomile recutica oil is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

lactic acid is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

ECHA SUMMARY

Ingredient	CAS number	Index No	ECHA Dossier
glycerol	56-81-5	Not Available	01-2119471987-18-XXXX

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified	Not Available	Not Available
2	Eye Irrit. 2; Skin Irrit. 2; STOT RE 1; Resp. STOT SE 3; STOT RE 2	GHS07; Wng; GHS08; Dgr	H319; H315; H372; H335

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
stearic acid	57-11-4*	Not Available	01-2119543894-28-XXXX 01-2120763582-50-XXXX

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Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified	Not Available	Not Available
2	Eye Irrit. 2; Resp. STOT SE 3; Aquatic Chronic 3; Skin Corr. 1B; Acute Tox. 4; Flam. Sol. 1; Eye Irrit. 2A; Acute Tox. 3; Aquatic Acute 1	GHS07; Wng; GHS05; Dgr; GHS02; GHS08; GHS09; GHS06	H319; H335; H412; H314; H302; H332; H228; H400

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
water	7732-18-5*	Not Available	Not Available

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified	Not Available	Not Available
2	Flam. Liq. 3; Acute Tox. 3; Skin Corr. 1A; Acute Tox. 2	GHS05; GHS07; Dgr; GHS02; Wng; GHS06	H318; H226; H314; H301; H411

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
almond, sweet, extract	90320-37-9*	Not Available	01-2120737768-38-XXXX

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified	Not Available	Not Available
2	Flam. Liq. 3; Eye Irrit. 2	GHS02; GHS07; Wng	H226; H319

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
alcohols C16-18 ethoxylated	68439-49-6	Not Available	01-2119977094-30-XXXX

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 4; Eye Dam. 1; Aquatic Acute 1	GHS09; GHS05; GHS07; Dgr	H302; H318; H400
2	Acute Tox. 4; Eye Dam. 1; Aquatic Acute 1; Skin Irrit. 2; Aquatic Chronic 1	GHS09; GHS05; GHS07; Dgr; Wng	H302; H318; H400; H315; H410; H317

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
dimethicone	9006-65-9	Not Available	Not Available

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified	Not Available	Not Available
2	Eye Irrit. 2	GHS07; Wng	H319

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
ethylene glycol phenyl ether	122-99-6	603-098-00-9	01-2119488943-21-XXXX

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 4; Eye Irrit. 2	GHS07; Wng	H302; H319
2	Acute Tox. 4; Eye Irrit. 2; Resp. STOT SE 3; Repr. 2; Skin Irrit. 2; Flam. Liq. 3; Muta. 2; Carc. 2; Eye Irrit. 2A	GHS07; Wng; Dgr; GHS09; GHS06; None Specified	H302; H319; H335; H351; H315
1	Skin Irrit. 2; Acute Tox. 4; Eye Dam. 1	GHS07; Wng; GHS05; Dgr	H315; H302; H318
2	Acute Tox. 4; Eye Dam. 1; Skin Irrit. 2; Resp. STOT SE 3	GHS05; GHS07; Dgr; Wng	H302; H318; H315; H332; H341; H350; H373; H412; H335

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
triethanolamine	102-71-6*	Not Available	01-2119486482-31-XXXX

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified	Not Available	Not Available
2	Eye Dam. 1; Repr. 2; Acute Tox. 4; STOT RE 2; Resp. STOT SE 3; Skin Sens. 1; Met. Corr. 1; Acute Tox. 4; Acute Tox. 4; Skin Corr. 1C; Resp. Sens. 1	GHS08; GHS05; Dgr; GHS07; Wng	H318; H361; H302; H373; H335; H317; H290; H312; H332; H314; H334

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
1,2-octanediol	1117-91-2	Not Available	01-2119699522-XX-XXXX

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Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Eye Irrit. 2	GHS07; Wng	H319
2	Acute Tox. 4; Eye Dam. 1	GHS07; Wng; GHS05; Dgr	H302; H318

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
sodium pyroglutamate	54571-67-4	Not Available	01-2119986878-07-XXXX 01-2120763560-56-XXXX

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified	Not Available	Not Available
2	Not Classified	Not Available	Not Available
1	Not Classified	Not Available	Not Available
2	Not Classified	Not Available	Not Available

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
EDTA disodium salt	139-33-3	Not Available	01-2119486775-20-XXXX

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 4; Skin Irrit. 2; Eye Irrit. 2; Resp. STOT SE 3	GHS07; Wng	H302; H315; H319; H335
2	Acute Tox. 4; STOT RE 2; Acute Tox. 4; Skin Irrit. 2; Eye Irrit. 2; Resp. STOT SE 3; Carc. 2	GHS08; GHS07; Wng	H332; H373; H302; H315; H319; H335; H351

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
DL-alpha-tocopherol acetate	7695-91-2*	Not Available	01-2119457641-38-XXXX

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified	Not Available	Not Available
2	Aquatic Chronic 4		H413

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
Carbomer	9003-01-4*	Not Available	01-2120754771-50-XXXX

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified	Not Available	Not Available
2	Acute Tox. 4; Eye Dam. 1; Resp. STOT SE 3; Aquatic Acute 1; Aquatic Chronic 2; Muta. 1B; Carc. 1A; Acute Tox. 4; Flam. Liq. 3; Acute Tox. 4; Met. Corr. 1; Skin Corr. 1	GHS09; GHS05; GHS07; Dgr; Wng; GHS08; GHS02	H302; H318; H335; H400; H411; H340; H350; H332; H226; H312; H317; H290; H314

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
1,2-decanediol	1119-86-4	Not Available	01-2120119760-62-XXXX

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Eye Dam. 1	GHS05; Dgr	H318
2	Eye Dam. 1	GHS05; Dgr	H318

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
ETHANOL TSDA1 DEB 100	64-17-5*	603-002-00-5	01-2119457610-43-xxxx

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Flam. Liq. 2	GHS02; Dgr	H225
2	Flam. Liq. 2; Resp. STOT SE 3; STOT RE 1; Narc. STOT SE 3; Muta. 1B; Repr. 1A; Carc. 1A; Met. Corr. 1; Skin Corr. 1B; Aquatic Acute 1; Aerosol 1; Acute Tox. 3; Acute Tox. 3; Acute Tox. 3; STOT SE 1; Eye Dam. 1; Skin Sens. 1	GHS02; Dgr; GHS07; GHS08; GHS01; Wng; GHS09; GHS05; GHS03; GHS06	H225; H411; H335; H304; H336; H372; H315; H340; H360; H350; H318; H220; H301; H311; H331; H370; H317

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
lavandin oil	8022-19-20	Not Available	01-2119457610-43-xxxx

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Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Skin Irrit. 2; Skin Sens. 1; Aquatic Chronic 3	GHS07; Wng	H315; H317; H412
2	Skin Irrit. 2; Skin Sens. 1; Asp. Tox. 1; Eye Irrit. 2; Resp. STOT SE 3; Aquatic Chronic 2; Acute Tox. 4; Acute Tox. 4; Acute Tox. 4	GHS07; Wng; GHS08; Dgr; GHS09	H315; H317; H304; H319; H335; H411; H302; H312; H332
1	Skin Sens. 1; Aquatic Chronic 3	GHS07; Wng	H317; H412
2	Skin Sens. 1; Skin Irrit. 2; Aquatic Chronic 2; Eye Irrit. 2; Asp. Tox. 1	GHS07; Wng; GHS09; GHS08; Dgr	H317; H315; H411; H319; H304

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
Symphytum officinale (comfrey) extract	84696-05-9	Not Available	Not Available

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not Classified	Not Available	Not Available
2	Not Classified	Not Available	Not Available

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
Ginseng, extract	84650-12-4	Not Available	Not Available

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Flam. Liq. 3	GHS02; Wng	H226
2	Flam. Liq. 3; Skin Sens. 1	GHS02; Wng; GHS07	H226; H317; H302
1	Flam. Liq. 3	GHS02; Wng	H226
2	Flam. Liq. 3	GHS02; Wng	H226

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
Chamomile recutica oil	84082-60-0*	Not Available	01-2120763571-53-XXXX

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Asp. Tox. 1; Skin Irrit. 2; Skin Sens. 1; Aquatic Chronic 3	GHS08; GHS07; Dgr	H304; H315; H317; H412
2	Asp. Tox. 1; Skin Irrit. 2; Eye Irrit. 2; Aquatic Chronic 2; Skin Sens. 1; Flam. Liq. 3; Resp. STOT SE 3	GHS09; GHS08; GHS07; Dgr; GHS02; Wng	H304; H315; H319; H411; H317; H226; H402; H335; H302

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

Ingredient	CAS number	Index No	ECHA Dossier
lactic acid	50-21-5*	Not Available	01-2119548400-48-XXXX

Harmonisation (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Skin Irrit. 2; Eye Dam. 1	GHS05; Dgr	H315; H318
2	Eye Dam. 1; Resp. STOT SE 3; Met. Corr. 1; Aquatic Acute 1; Acute Tox. 3; Skin Corr. 1	GHS05; Dgr; GHS07; Wng; GHS09; GHS06	H318; H335; H290; H400; H331; H281; H314

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

National Inventory Status

National Inventory	Status
Australia - AIIIC / Australia Non-Industrial Use	No (Chamomile recutica oil)
Canada - DSL	No (1,2-decanediol; Chamomile recutica oil)
Canada - NDSL	No (glycerol; stearic acid; water; almond, sweet, extract; alcohols C16-18 ethoxylated; dimethicone; ethylene glycol phenyl ether; triethanolamine; 1,2-octanediol; sodium pyroglutamate; EDTA disodium salt; DL-alpha-tocopherol acetate; Carbomer; 1,2-decanediol; ETHANOL TSDA1 DEB 100; lavandin oil; Symphytum officinale (comfrey) extract; Ginseng, extract; Chamomile recutica oil; lactic acid)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	No (dimethicone; Carbomer)
Japan - ENCS	No (almond, sweet, extract; dimethicone; 1,2-decanediol; lavandin oil; Symphytum officinale (comfrey) extract; Ginseng, extract; Chamomile recutica oil)
Korea - KECI	No (almond, sweet, extract; dimethicone; Symphytum officinale (comfrey) extract; Ginseng, extract; Chamomile recutica oil)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (almond, sweet, extract; 1,2-decanediol; Symphytum officinale (comfrey) extract; Chamomile recutica oil)
USA - TSCA	No (almond, sweet, extract; dimethicone; 1,2-decanediol; Symphytum officinale (comfrey) extract; Ginseng, extract; Chamomile recutica oil)
Taiwan - TCSI	Yes 19-20 Sandleheath Industrial Estate, Fordingbridge, Hampshire, SP6 1PA, UK

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National Inventory	Status
Mexico - INSQ	No (almond, sweet, extract; alcohols C16-18 ethoxylated; DL-alpha-tocopherol acetate; 1,2-decanediol; lavandin oil; Symphytum officinale (comfrey) extract; Ginseng, extract; Chamomile recutica oil)
Vietnam - NCI	Yes
Russia - FBEPH	No (almond, sweet, extract; alcohols C16-18 ethoxylated; dimethicone; 1,2-octanediol; sodium pyroglutamate; 1,2-decanediol; Symphytum officinale (comfrey) extract; Ginseng, extract; Chamomile recutica oil)
Legend:	Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

SECTION 16 Other information

Revision Date	15/07/2021
Initial Date	15/07/2021

Full text Risk and Hazard codes

H220	Extremely flammable gas.
H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H228	Flammable solid.
H281	Contains refrigerated gas; may cause cryogenic burns or injury.
H290	May be corrosive to metals.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H304	May be fatal if swallowed and enters airways.
H311	Toxic in contact with skin.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H331	Toxic if inhaled.
H332	Harmful if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H340	May cause genetic defects.
H341	Suspected of causing genetic defects.
H350	May cause cancer.
H351	Suspected of causing cancer.
H360	May damage fertility or the unborn child.
H361	Suspected of damaging fertility or the unborn child.
H370	Causes damage to organs.
H372	Causes damage to organs through prolonged or repeated exposure.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H402	Harmful to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.

SDS Version Summary

Version	Date of Update	Sections Updated
0.2.13.8	15/07/2021	Appearance, Fire Fighter (fire/explosion hazard), Ingredients, Physical Properties, Supplier Information

Other information

Ingredients with multiple cas numbers

Name	CAS No
glycerol	56-81-5, 29796-42-7, 30049-52-6, 37228-54-9, 75398-78-6, 78630-16-7, 8013-25-0, 8043-29-6, 1400594-62-8
ethylene glycol phenyl ether	122-99-6, 37220-49-8, 134367-25-2, 18249-17-7, 200260-63-5, 79586-53-1, 9004-78-8, 56257-90-0, 1219804-65-5
sodium pyroglutamate	54571-87-4, 28874-51-3, 333832-15-6

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Tel: 01425 655555 Email: technical@madarcorporation.co.uk

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Name	CAS No
EDTA disodium salt	139-33-3, 69772-70-9, 6381-92-6
lavandin oil	8022-15-9, 91722-69-9, 93455-97-1
Ginseng, extract	84650-12-4, 90045-38-8

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection

EN 340 Protective clothing

EN 374 Protective gloves against chemicals and micro-organisms

EN 13832 Footwear protecting against chemicals

EN 133 Respiratory protective devices

Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average

PC—STEL: Permissible Concentration-Short Term Exposure Limit

IARC: International Agency for Research on Cancer

ACGIH: American Conference of Governmental Industrial Hygienists

STEL: Short Term Exposure Limit

TEEL: Temporary Emergency Exposure Limit.

IDLH: Immediately Dangerous to Life or Health Concentrations

ES: Exposure Standard

OSF: Odour Safety Factor

NOAEL :No Observed Adverse Effect Level

LOAEL: Lowest Observed Adverse Effect Level

TLV: Threshold Limit Value

LOD: Limit Of Detection

OTV: Odour Threshold Value

BCF: BioConcentration Factors

BEI: Biological Exposure Index

AIIIC: Australian Inventory of Industrial Chemicals

DSL: Domestic Substances List

NDSL: Non-Domestic Substances List

IECSC: Inventory of Existing Chemical Substance in China

EINECS: European INventory of Existing Commercial chemical Substances

ELINCS: European List of Notified Chemical Substances

NLP: No-Longer Polymers

ENCS: Existing and New Chemical Substances Inventory

KECI: Korea Existing Chemicals Inventory

NZIoC: New Zealand Inventory of Chemicals

PICCS: Philippine Inventory of Chemicals and Chemical Substances

TSCA: Toxic Substances Control Act

TCSI: Taiwan Chemical Substance Inventory

INSQ: Inventario Nacional de Sustancias Químicas

NCI: National Chemical Inventory

FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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MATERIAL SPECIFICATION

MATERIAL	Body Milk

Analysis Description	Minimum Value	Maximum Value	Description
Appearance			Mobile lotion
Colour			White
Odour			Virtually none
pH @ 20 Degrees C	6.0	7.0	
Viscosity RTV 20C SpindleB 4RPM	12000	25000	
Total Viable Count		100	<100
Gram Negative Bacteria			Absent

Shelf life of this product depends very much on storage conditions, particularly temperature and exposure to light and air.

Shelf Life must be considered as subjective; the shelf life given here is based on the best of our knowledge and experience of the material when stored under recommended conditions, see SDS, in original unopened containers.

Due to the natural ingredients contained in many of our products, there may be a slight batch to batch variation in the colour, odour or consistency. However, we ensure that this does not affect the quality and efficacy of the product in any way.

Issue Date: 14/07/2021

Shelf Life: 36 Months

Revision: 5

Issue Date: 02/02/2021

Shelf Life: 12 Months

Revision: 3

Revision Date: 14/07/2021

Revision Date: 10/03/2021