CERTIFICATE OF ANALYSIS

BODY MILK UNSCENTED

Batch No.: 4338602
Best Before End: October 2020

Analysis Description	Minimum Value	Maximum Value	Result	Compliance
Appearance			Mobile lotion	Pass
Colour			White	Pass
Odour			Virtually none	Pass
pH @ 20 Degrees C	6.0	7.0	6.42	Pass
Viscosity RVT 20C SpindleB 4RPM	12000	25000	16000	Pass
Total Viable Count cfu/g		100	<100	Pass
Gram Negative Bacteria			Absent	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.

DECLARATION OF ALLERGENS

BODY MILK - UNSCENTED

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 CARBOXALDEHYDE	31906-04-4	-
ISO EUGENOL	97-54-1	-
LIMONENE	5989-27-5	-
LINALOOL	78-70-6	-
METHYL 2-OCTYNOATE	111-12-6	-
		No Allergens

Revision Date: 21/04/2015
Revision: 0

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

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

BOM: 2 Revision: 0

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

CONTENTS

Volume 1

Volume 2

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 characterisitics 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.

Appendix 1 – GMP Certificate

Certificate GB13/87972

The management system of

[redacted]

Has been assessed and certified as meeting the requirements of

ISO 22716
Cosmetics – Guidelines on Good Manufacturing Practices (GMP)
(First edition 2007-11-15)

For the following activities

Manufacture of cosmetics and personal care liquids, emulsions, creams, lotions, oils, gels and balms, this includes both ambient and hot fill.

The responsibility for the quality of the individual batches of the cosmetic products labelled, packed and stored lies with the organization

This certificate is valid from 19/02/2016 until 19/02/2019
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 19/02/2013

Authorised by

Pieter Weterings
Certification Manager
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Page 1 of 1

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-gylcerides 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
.

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 ≅ 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 x 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 x .78) = 65% 0.67 x 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 = 372x10 = 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*0.001 = 0.00016%

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

0.0000128 g PA = 0.00128mg PA = 0.128 μg PA

SED = 0.002 μg /kg b.w./day
Adjusted SED (10% dermal uptake)
SED = 0.0002 μg /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 μg /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 fromThe 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 Na_3EDTA (Scientific Committee On Toxicity, Ecotoxicity and the Environment (CSTEE) opinion on the results of the risk assessment of:tetrasodium ethylenediamine tetraacetate (Na_4EDTA) 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%

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

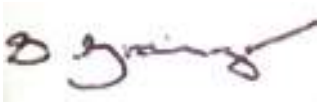
Dermal irritants / sensitizers – No significant exposure. Compatibility testing is generally advised if the product formulation uses ingredients at concentrations significantly greater than in previously well tolerated formulations. This formulation is very similar to other formulations that have been 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

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 207890

SAFETY DATA SHEET
BODY MILK UNSCENTED

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

1.1. Product identifier

Product name BODY MILK UNSCENTED

Product code TBBODYMILK

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

Identified uses Cosmetics

1.3. Details of the supplier of the safety data sheet

Supplier MADAR Corporation Limited
19-20 Sandleheath Industrial Estate
Fordingbridge
Hampshire
SP6 1PA

Telephone No 01425 655555

Approved sellers Mystic Moments, New Directions, World of Moulds

1.4. Emergency telephone number

Emergency telephone +44 (0) 1425 655555 Office Hours are 09:00 - 16:30 weekdays only

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification

Physical hazards Not Classified

Health hazards Eye Irrit. 2 - H319

Environmental hazards Not Classified

Classification (67/548/EEC or 1999/45/EC) Xi; R36

2.2. Label elements

Pictogram

Signal word Warning

Hazard statements H319 Causes serious eye irritation.

BODY MILK UNSCENTED

Precautionary statements P264 Wash contaminated skin thoroughly after handling.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
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.

2.3. Other hazards

SECTION 3: Composition/information on ingredients

3.2. Mixtures

GLYCERIN **1-5%**

CAS number: 56-81-5 EC number: 200-289-5

Classification
Not Classified

CETEARETH-20 **1-5%**

CAS number: 68439-49-6

Classification
Acute Tox. 4 - H302
Eye Dam. 1 - H318
Aquatic Chronic 2 - H411

Classification (67/548/EEC or 1999/45/EC)
Xn; R22. Xi; R41. N; R51/53

ALCOHOL **<1%**

CAS number: 64-17-5 EC number: 200-578-6 REACH registration number: 01-2119457610-43-XXXX

Classification
Flam. Liq. 2 - H225

Classification (67/548/EEC or 1999/45/EC)
F; R11

CYCLOHEXANE **<1%**

CAS number: 110-82-7 EC number: 203-806-2

M factor (Acute) = 1 M factor (Chronic) = 1

Classification
Flam. Liq. 2 - H225
Skin Irrit. 2 - H315
STOT SE 3 - H336
Asp. Tox. 1 - H304
STOT SE 3 - H336
Aquatic Acute 1 - H400
Aquatic Chronic 1 - H410

Classification (67/548/EEC or 1999/45/EC)
F; R11. Xn; R65. Xi; R38. N; R50/53. R67

BODY MILK UNSCENTED

T-BUTYL ALCOHOL		<1%
CAS number: 75-65-0	EC number: 200-889-7	REACH registration number: 01-2119444321-51-XXXX

Classification	Classification (67/548/EEC or 1999/45/EC)
Flam. Liq. 2 - H225 Acute Tox. 4 - H332 Eye Irrit. 2 - H319 STOT SE 3 - H335 STOT SE 3 - H335	F; R11. Xn; R20. Xi; R36/37

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation Move affected person to fresh air at once. Get medical attention if any discomfort continues.

Ingestion Rinse mouth thoroughly with water. Give plenty of water to drink. Get medical attention immediately.

Skin contact Remove contaminated clothing immediately and wash skin with soap and water. Get medical attention if symptoms are severe or persist after washing.

Eye contact Remove any contact lenses and open eyelids wide apart. Rinse immediately with plenty of water. Continue to rinse for at least 15 minutes. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed

General information Persons suffering from asthma, eczema or skin problems should avoid contact, including dermal contact, with this product. See Section 11 for additional information on health hazards.

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

Notes for the doctor No specific recommendations.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media Extinguish with the following media: Foam, carbon dioxide or dry powder.

Unsuitable extinguishing media Water.

5.2. Special hazards arising from the substance or mixture

Specific hazards Toxic gases or vapours.

5.3. Advice for firefighters

Protective actions during firefighting Containers close to fire should be removed or cooled with water.

Special protective equipment for firefighters Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing.

BODY MILK UNSCENTED

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Wear suitable protective equipment, including gloves, goggles/face shield, respirator, boots, clothing or apron, as appropriate. No smoking, sparks, flames or other sources of ignition near spillage.

6.2. Environmental precautions

Environmental precautions Do not discharge into drains or watercourses or onto the ground.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Keep combustible materials away from spillage. Eliminate all sources of ignition. Provide adequate ventilation. Contain and absorb spillage with sand, earth or other non-combustible material. The contaminated absorbent may pose the same hazard as the spilled material. Collect and place in suitable waste disposal containers and seal securely. Label the containers containing waste and contaminated materials and remove from the area as soon as possible. Wash thoroughly after dealing with a spillage.

6.4. Reference to other sections

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions Wear protective clothing as described in Section 8 of this safety data sheet. Avoid contact with skin, eyes and clothing.

Advice on general occupational hygiene Do not eat, drink or smoke when using this product. Wash at the end of each work shift and before eating, smoking and using the toilet.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Store in tightly-closed, original container in a dry, cool and well-ventilated place. Keep away from heat, sparks and open flame. Protect from freezing and direct sunlight.

7.3. Specific end use(s)

SECTION 8: Exposure Controls/personal protection

8.1. Control parameters

Occupational exposure limits

GLYCERIN

Long-term exposure limit (8-hour TWA): WEL 10 mg/m³

ALCOHOL

Long-term exposure limit (8-hour TWA): WEL 1000 ppm 1920 mg/m³

CYCLOHEXANE

Long-term exposure limit (8-hour TWA): WEL 100 ppm 350 mg/m³
Short-term exposure limit (15-minute): WEL 300 ppm 1050 mg/m³

T-BUTYL ALCOHOL

Long-term exposure limit (8-hour TWA): WEL 100 ppm 308 mg/m³
Short-term exposure limit (15-minute): WEL 150 ppm 462 mg/m³

WEL = Workplace Exposure Limit

BODY MILK UNSCENTED

8.2. Exposure controls

Protective equipment

Appropriate engineering controls	Provide adequate ventilation.
Eye/face protection	Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible. The following protection should be worn: Chemical splash goggles or face shield.
Hand protection	Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible.
Other skin and body protection	Wear appropriate clothing to prevent any possibility of skin contact. Wear apron or protective clothing in case of contact.
Hygiene measures	No specific hygiene procedures recommended but good personal hygiene practices should always be observed when working with chemical products.
Respiratory protection	No specific recommendations. Respiratory protection may be required if excessive airborne contamination occurs.
Environmental exposure controls	Residues and empty containers should be taken care of as hazardous waste according to local and national provisions.

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance	Viscous liquid.
Colour	White.
Odour	Almost odourless.
pH	pH (concentrated solution): ~6.5

9.2. Other information

SECTION 10: Stability and reactivity

10.1. Reactivity

10.2. Chemical stability

Stability	Stable at normal ambient temperatures.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	Will not polymerise.

10.4. Conditions to avoid

Conditions to avoid	Avoid heat, flames and other sources of ignition.

10.5. Incompatible materials

Materials to avoid	Strong oxidising agents. Strong acids. Strong alkalis.

BODY MILK UNSCENTED

10.6. Hazardous decomposition products

Hazardous decomposition products Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - oral

ATE oral (mg/kg) 126,000.0

Eye contact Causes serious eye irritation.

SECTION 12: Ecological Information

Ecotoxicity The product is not expected to be hazardous to the environment.

12.1. Toxicity

12.2. Persistence and degradability

Persistence and degradability The product contains substances which are not expected to be biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential The product does not contain any substances expected to be bioaccumulating.

12.4. Mobility in soil

Mobility The product is soluble in water.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment This product does not contain any substances classified as PBT or vPvB.

12.6. Other adverse effects

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal methods Dispose of waste product or used containers in accordance with local regulations

SECTION 14: Transport information

General The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

No transport warning sign required.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

BODY MILK UNSCENTED

Environmentally hazardous substance/marine pollutant

No.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable.

SECTION 15: Regulatory information

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

EU legislation	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (as amended).
Guidance	Workplace Exposure Limits EH40.

15.2. Chemical safety assessment

SECTION 16: Other information

Key literature references and sources for data	European Chemicals Agency, http://echa.europa.eu/
Issued by	Regulatory Manager
Revision date	26/05/2015
Revision	0
Risk phrases in full	R11 Highly flammable. R20 Harmful by inhalation. R22 Harmful if swallowed. R36/37 Irritating to eyes and respiratory system. R38 Irritating to skin. R41 Risk of serious damage to eyes. R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R65 Harmful: may cause lung damage if swallowed. R67 Vapours may cause drowsiness and dizziness.
Hazard statements in full	H302 Harmful if swallowed. H318 Causes serious eye damage. H319 Causes serious eye irritation. H411 Toxic to aquatic life with long lasting effects.

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty, guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.

MATERIAL SPECIFICATION

BODY MILK - UNSCENTED

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

Issue Date: 17/11/15

Revision: 3 Revision Date: 17/11/15

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 the products in any way.