

Cosmetic Product Safety Report

Cosmetic Safety Consultants Ltd on behalf of the named manufacturer below

CSC Reference - NB – Jessica011014BODYCCPSR

Product: Body Cream

Product Category - Premanufactured cosmetic cream base plus additions in the following variants; Mango & Passion Fruit, Rose & Sandalwood, Lemon & Coconut, Lavender & Neroli, Orange & Geranium, Honey & Mango

Responsible person- Naturally Balmy
30 Southbourne Road, Southbourne, Bournemouth BH6 5AD

Report content

Report Part A

Quantitative Formulation

MSDS sheets - held by the named Responsible Person

Final Product characteristics (including stability, microbiology etc.)

Packaging

Warnings

Normal and reasonably foreseeable use

Target Population

Undesirable effects and serious undesirable effects

Product and substance exposure characteristics & Margin of Safety Summary

Substance toxicity profiles – see annex 1

Calculated MOS values – see annex 1

Report Part B

Data review

Assessment summary

Warnings and instructions of use

Reasoning

Assessment conclusion

Safety Report Part A

Report Validity Conditions

This Safety Assessment Report is valid only for the named responsible person and is not transferable to any other party without prior written agreement from Cosmetic Safety Consultants Ltd.

Cosmetic Safety Consultants ltd. and its directors will accept no liability for the misuse of this document or for any cosmetic product formulated outside the remit of this document.

All manufacture must comply with appropriate standards of Good Manufacturing Practice as detailed in REGULATION (EC) No 1223/2009

All raw material specifications and finished product specifications must comply with any restrictions (purity etc.) detailed in REGULATION (EC) No 1223/2009

Any deviation from the prescribed formulation and list of permitted ingredients is NOT covered by this safety report.

MSDS sheets for all materials used must be included by the manufacturer as part of Safety Report Part A – additional information on raw materials (Identification and function) - <http://ec.europa.eu/consumers/cosmetics/cosing/>

Product and Substance exposure characteristics & Margin of Safety Summary

Exposure is by dermal absorption only under foreseeable conditions of use – a retention factor of 100% has been used and calculations are based on typical exposure values (Regulatory Toxicology and Pharmacology VOLUME 52, NUMBER 1, OCTOBER 2008)

Mango & Passion Fruit

Maximum % component	Body lotion / cream/butter	8	1	8	100%	8	12895	133.33	0.6	>100
100.0	Aqua	8	1	8	100%	8	12895	133.33	0.62	>100
12.0	Aloe barbadensis (Organic Aloe leaf) extract	0.96	1	0.96	100%	0.96	12895	16.00	0.07	>100
12.0	Helianthus annuus (Organic Sunflower) Oil	0.96	1	0.96	100%	0.96	12895	16.00	0.07	>100
7.0	Butyrospermum Parkii (Organic Shea) Butter	0.56	1	0.56	100%	0.56	12895	9.33	0.04	>100
7.0	Cetearyl alcohol	0.56	1	0.56	100%	0.56	12895	9.33	0.04	>100
5.0	Stearic acid	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Cetyl alcohol	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Glycerin	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Coco caprylate	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Theobroma cacao (Organic Cocoa) Seed Butter	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
3.0	Glyceryl stearate	0.24	1	0.24	100%	0.24	12895	4.00	0.02	>100
1.0	Phenoxyethanol & Ethylhexylglycerin	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Coco glucosides	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Tocoherol	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Sodium hydroxide	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Phytic acid	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
0.7	Parfum - Mango - Naturally Balmy	0.056	1	0.056	100%	0.056	12895	0.93	0.00	>100
0.8	Parfum - Passion Fruit - Naturally Balmy	0.064	1	0.064	100%	0.064	12895	1.07	0.00	>100
0.5	Mandarin Essential Oil	0.040	1	0.04	100%	0.04	12895	0.67	0.00	>100

Rose & Sandalwood

Maximum % component	Body lotion / cream/butter	8	1	8	100%	8	12895	133.33	0.6	>100
100.0	Aqua	8	1	8	100%	8	12895	133.33	0.62	>100
12.0	Aloe barbadensis (Organic Aloe leaf) extract	0.96	1	0.96	100%	0.96	12895	16.00	0.07	>100
12.0	Helianthus annus (Organic Sunflower) Oil	0.96	1	0.96	100%	0.96	12895	16.00	0.07	>100
7.0	Butyrospermum Parkii (Organic Shea) Butter	0.56	1	0.56	100%	0.56	12895	9.33	0.04	>100
7.0	Cetearyl alcohol	0.56	1	0.56	100%	0.56	12895	9.33	0.04	>100
5.0	Stearic acid	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Cetyl alcohol	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Glycerin	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Coco caprylate	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Theobroma cacao (Organic Cocoa) Seed Butter	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
3.0	Glyceryl stearate	0.24	1	0.24	100%	0.24	12895	4.00	0.02	>100
1.0	Phenoxyethanol & Ethylhexylglycerin	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Coco glucosides	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Tocoherol	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Sodium hydroxide	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Phytic acid	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.5	Parfum - Rose - Naturally Balmy	0.12	1	0.12	100%	0.12	12895	2.00	0.01	>100
0.03	Sandalwood Essential Oil	0.002	1	0.0024	100%	0.0024	12895	0.04	0.00	>100
0.47	Amyris Essential Oil	0.038	1	0.0376	100%	0.0376	12895	0.63	0.00	>100

Lemon & Coconut

Maximum % component	Body lotion / cream/butter	8	1	8	100%	8	12895	133.33	0.6	>100
100.0	Aqua	8	1	8	100%	8	12895	133.33	0.62	>100
12.0	Aloe barbadensis (Organic Aloe leaf) extract	0.96	1	0.96	100%	0.96	12895	16.00	0.07	>100
12.0	Helianthus annus (Organic Sunflower) Oil	0.96	1	0.96	100%	0.96	12895	16.00	0.07	>100
7.0	Butyrospermum Parkii (Organic Shea) Butter	0.56	1	0.56	100%	0.56	12895	9.33	0.04	>100
7.0	Cetearyl alcohol	0.56	1	0.56	100%	0.56	12895	9.33	0.04	>100
5.0	Stearic acid	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Cetyl alcohol	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Glycerin	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Coco caprylate	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Theobroma cacao (Organic Cocoa) Seed Butter	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
3.0	Glyceryl stearate	0.24	1	0.24	100%	0.24	12895	4.00	0.02	>100
1.0	Phenoxyethanol & Ethylhexyglycerin	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Coco glucosides	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Tocoherol	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Sodium hydroxide	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Phytic acid	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.25	Parfum - Coconut - Naturally Balmy	0.1	1	0.1	100%	0.1	12895	1.67	0.01	>100
0.75	Lemon Essential Oil	0.060	1	0.06	100%	0.06	12895	1.00	0.00	>100

Lavender & Neroli

Maximum % component	Body lotion / cream/butter	8	1	8	100%	8	12895	133.33	0.6	>100
100.0	Aqua	8	1	8	100%	8	12895	133.33	0.62	>100
12.0	Aloe barbadensis (Organic Aloe leaf) extract	0.96	1	0.96	100%	0.96	12895	16.00	0.07	>100
12.0	Helianthus annus (Organic Sunflower) Oil	0.96	1	0.96	100%	0.96	12895	16.00	0.07	>100
7.0	Butyrospermum Parkii (Organic Shea) Butter	0.56	1	0.56	100%	0.56	12895	9.33	0.04	>100
7.0	Cetearyl alcohol	0.56	1	0.56	100%	0.56	12895	9.33	0.04	>100
5.0	Stearic acid	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Cetyl alcohol	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Glycerin	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Coco caprylate	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Theobroma cacao (Organic Cocoa) Seed Butter	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
3.0	Glyceryl stearate	0.24	1	0.24	100%	0.24	12895	4.00	0.02	>100
1.0	Phenoxyethanol & Ethylhexylglycerin	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Coco glucosides	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Tocoherol	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Sodium hydroxide	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Phytic acid	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Lavender Essential Oil	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Neroli Essential Oil	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100

Orange & Geranium

Maximum % component	Body lotion / cream/butter	8	1	8	100%	8	12895	133.33	0.6	>100
100.0	Aqua	8	1	8	100%	8	12895	133.33	0.62	>100
12.0	Aloe barbadensis (Organic Aloe leaf) extract	0.96	1	0.96	100%	0.96	12895	16.00	0.07	>100
12.0	Helianthus annus (Organic Sunflower) Oil	0.96	1	0.96	100%	0.96	12895	16.00	0.07	>100
7.0	Butyrospermum Parkii (Organic Shea) Butter	0.56	1	0.56	100%	0.56	12895	9.33	0.04	>100
7.0	Cetearyl alcohol	0.56	1	0.56	100%	0.56	12895	9.33	0.04	>100
5.0	Stearic acid	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Cetyl alcohol	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Glycerin	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Coco caprylate	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Theobroma cacao (Organic Cocoa) Seed Butter	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
3.0	Glyceryl stearate	0.24	1	0.24	100%	0.24	12895	4.00	0.02	>100
1.0	Phenoxyethanol & Ethylhexylglycerin	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Coco glucosides	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Tocoherol	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Sodium hydroxide	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Phytic acid	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.25	Orange Essential Oil	0.1	1	0.1	100%	0.1	12895	1.67	0.01	>100
0.75	Geranium Essential Oil	0.060	1	0.06	100%	0.06	12895	1.00	0.00	>100

Honey & Mango

Maximum % component	Body lotion / cream/butter	8	1	8	100%	8	12895	133.33	0.6	>100
100.0	Aqua	8	1	8	100%	8	12895	133.33	0.62	>100
12.0	Aloe barbadensis (Organic Aloe leaf) extract	0.96	1	0.96	100%	0.96	12895	16.00	0.07	>100
12.0	Helianthus annus (Organic Sunflower) Oil	0.96	1	0.96	100%	0.96	12895	16.00	0.07	>100
7.0	Butyrospermum Parkii (Organic Shea) Butter	0.56	1	0.56	100%	0.56	12895	9.33	0.04	>100
7.0	Cetearyl alcohol	0.56	1	0.56	100%	0.56	12895	9.33	0.04	>100
5.0	Stearic acid	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Cetyl alcohol	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Glycerin	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Coco caprylate	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
5.0	Theobroma cacao (Organic Cocoa) Seed Butter	0.4	1	0.4	100%	0.4	12895	6.67	0.03	>100
3.0	Glyceryl stearate	0.24	1	0.24	100%	0.24	12895	4.00	0.02	>100
1.0	Phenoxyethanol & Ethylhexylglycerin	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Coco glucosides	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Tocoherol	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Sodium hydroxide	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Phytic acid	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Parfum - Mango - Naturally Balmy	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100
1.0	Parfum - Honey - Naturally Balmy	0.08	1	0.08	100%	0.08	12895	1.33	0.01	>100

Annex 1 – External reference (Competent authority access) - http://cosmetic-compliance.co.uk/web_documents/grainger_100713_toxicology_and_mos_data.xlsx

Final Product characteristics

Physical and Chemical Properties

Odour: Characteristic odour of fragrance ingredients

Appearance: Opaque Viscous Emulsion

pH – expected range 6-6.5

Stability and Reactivity

The product is expected to be nominally stable at ambient storage conditions.

Ingredient Purity

A review of the ingredients indicates satisfactory general purity criteria. The manufacturer is responsible for ensuring that all ingredients used fulfil EU criteria for purity where applicable, and do not contain any substances prohibited by the regulations for inclusion in cosmetic formulations.

Microbiological Purity

Product has undergone microbiological quality and preservative challenge testing by the primary manufacturer – product conforms to manufacturer's specifications

Packaging

Absence of nitrosating agents– Suitable packaging includes glass, food grade PE or PTE jars or dispensers . The product is packaged in a clear plastic PET or glass jar.

Warnings

No specific warnings required other than standard usage instructions.

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.

Normal and reasonably foreseeable use

The product is intended for use as a general purpose cream to be applied to the skin up to twice daily. For external use – not for application to mucous membranes or eye area

Target Population

General Population – not marketed for infant use.

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

Information on the cosmetic product / Proof of effects

The product is an established category of skin care 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

The report validity conditions detailed in Part A must be adhered to by the manufacturer; otherwise this report is null and void and may not be used in relation to the criteria set out in REGULATION (EC) No 1223/2009 relating to the safety of cosmetic products placed on the market in the EU.

A review of the information contained within this report, taking into account the requirements of Article 3 of REGULATION (EC) No 1223/2009 and including, at least the following considerations

Relating to the final product -

Physical and Chemical Properties

Stability and Reactivity

Microbiological Purity

Packaging

Normal and reasonably foreseeable use

Target Population

And in general

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.

Assessment conclusion

The data review indicates no significant risk under normal and foreseeable conditions of use, and the product fulfils the required criteria to be marketed in the EU.

Reasoning

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) $SED = I \times A / 60$

Margin of Safety **NOAEL / SED**

where NOAEL equals no observed adverse effect level in mg/kg bw from appropriate oral repeated dose study.

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)

Additional Reasoning

The fragrances used are compliant with current IFRA standards at the level of inclusion in this product category

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 (leave on), however compatibility testing is advised if the product formulation uses ingredients at concentrations significantly greater than in previously well tolerated formulations, or if new ingredients (without supplier confirmation of dermal compatibility) are used by the manufacturer.

Warnings and instructions of use

No specific safety warnings are required, other than general information on how the product is to be used.

Standard usage instructions associated with this type of product – for external use only - not to be used around the eyes, mucous membranes or on broken skin. If irritation occurs discontinue use

Interaction of substances

No significant interactions expected, based on a review of the chemical properties of the species included in this formulation

CSC Reference - NB – Jessica011014BODYCCPSR

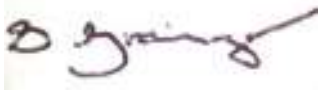
Product: Body Cream

Product Category - Premanufactured cosmetic cream base plus additions in the following variants; Mango & Passion Fruit, Rose & Sandalwood, Lemon & Coconut, Lavender & Neroli, Orange & Geranium, Honey & Mango

Responsible person- Naturally Balmy
30 Southbourne Road, Southbourne, Bournemouth BH6 5AD

Assessment Conclusion

This product meets specified criteria for safety .



Scott Grainger BSc (Hons) MSc CSci CChem MRSC

01/10/14

Chartered Chemist, Chartered Scientist

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

Cosmetic Safety Consultants Ltd.

Safety Assessor Information

Scott Grainger MSc BSc (Hons) CSci CChem MRSC

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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 4 years

Radiation protection supervisor and University Chemical Safety Committee member /
Departmental chemical safety advisor with responsibility for chemical and radiation risk assessment
including dosimetric and quantitative assessment of risk – 5years.

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 1840
Incorporated by Royal Charter 1965
Pursue the Vision of the Queen

President

A handwritten signature in cursive script, appearing to read "C. David Jones".

Registrar

A handwritten signature in cursive script, appearing to read "Richard A. Pike".

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 207800