

# Cosmetic Product Safety Report

Cosmetic Safety Consultants Ltd on behalf of the named manufacturer below

Product Category - Leave on product for general purpose use AND application to oral labia

An anhydrous product made primarily using food grade vegetable oils, butters and waxes

CSC Reference - NB010915 CC

Products – Balm – Calming Calendula

Responsible person: Naturally Balmy

30 Southbourne Road, Southbourne, Bournemouth BH6 5AD

Report content

## **Report Part A**

**Quantitative Formulation**

**Final Product characteristics (including stability, microbiology etc.)**

**Packaging**

**Warnings**

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# 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**

### Quantitative Final Product Formulation, Exposure Characteristics and Margin of Safety Summary

	Product Category	Amount per application / g	Frequency of application	g / day applied	Retention factor	g/day exposure	Surface Area Exp cm <sup>3</sup>	Systemic Exposure Dose (mg/kg) (based on 60kg average)	Specific Exposure mg/cm <sup>3</sup> /day	MOS Summary - see external reference detailed below
Maximum weight / volume component (%)	Balm - all purpose, limited area	5	1	5	100%	5.000	555	83.33	9.0090	
29.71	Organic Castor Oil	1.486	1	1.486	100%	1.486	555	24.760	2.6768	>100
29.71	Organic Jojoba Oil	1.486	1	1.486	100%	1.486	555	24.760	2.6768	>100
15.31	Organic Cocoa Butter	0.765	1	0.765	100%	0.765	555	12.755	1.3790	>100
15.31	Organic Beeswax	0.765	1	0.765	100%	0.765	555	12.755	1.3790	>100
7.20	Organic Shea Butter	0.360	1	0.360	100%	0.360	555	6.003	0.6489	>100
2.16	Organic Calendula extract	0.108	1	0.108	100%	0.108	555	1.801	0.1947	>100
0.40	Lavender Essential oil	0.020	1	0.020	100%	0.020	555	0.330	0.0357	>100
0.20	Mandarin Essential oil	0.010	1	0.010	100%	0.010	555	0.165	0.0178	>100

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Maximum weight / volume component (%)	Lip Balm	0.1	4	0.4	100%	0.400	4	6.67	100.0000	
29.71	Organic Castor Oil	0.030	4	0.119	100%	0.119	4	1.981	29.7126	>100
29.71	Organic Jojoba Oil	0.030	4	0.119	100%	0.119	4	1.981	29.7126	>100
15.31	Organic Cocoa Butter	0.015	4	0.061	100%	0.061	4	1.020	15.3065	>100
15.31	Organic Beeswax	0.015	4	0.061	100%	0.061	4	1.020	15.3065	>100
7.20	Organic Shea Butter	0.007	4	0.029	100%	0.029	4	0.480	7.2031	>100
2.16	Organic Calendula extract	0.002	4	0.009	100%	0.009	4	0.144	2.1609	>100
0.40	Lavender Essential oil	0.000	4	0.002	100%	0.002	4	0.026	0.3962	>100
0.20	Mandarin Essential oil	0.000	4	0.001	100%	0.001	4	0.013	0.1981	>100

### Annex 1 – External reference (Competent authority access)

– [http://cosmetic-compliance.co.uk/web\\_documents/grainger\\_100713\\_toxicology\\_and\\_mos\\_data.xlsx](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: Solid with odour and colours according to those used.

pH – expected range 6.5-7.5

### **Stability and Reactivity**

#### **Interaction of substances –**

No major interactions are expected – possible interaction between labile components of fragrance materials (esters, alcohols) – no resulting components that are likely to alter the toxicity profile of the initial ingredients (e.g. transesterification does not lead to the methylation of eugenol)

#### **Single phase product – nominally stable**

Generally stable at ambient storage conditions – nominally stable for 30months+ in sealed container

### **Ingredient Purity**

Specific purity criteria (e.g. secondary amine content) are not applicable in this formulation. General ingredient purity remains the responsibility of the manufacturer – specifically prohibited ingredients as defined by Annex II (REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL) must not be present. GMP controlled processes are unlikely to introduce contaminants with toxicological significance during manufacture.

### **Microbiological Purity**

Product is anhydrous and does not support microbial growth under normal storage conditions.

### **Packaging**

No specific requirements (e.g. absence of nitrosating agents)

### **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**

For external use – not marketed as a product for infant use, or for application to mucous membranes or eye area. To be applied frequently to oral labia and to other limited areas of the skin.

**Target Population**

Marketed as a product for general population – not specifically marketed for infant use. The scale of manufacture appropriate to this type of safety report (small / artisanal with a typical customer base of 100-10000 sales per annum) indicates limited population exposure.

**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

## 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.

**Warnings and instructions of use**

**Warnings**

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.

## **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 (rinse-off), 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.

## **Interaction of substances**

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

## **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)**



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#### **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.**



**Scott Grainger BSc (Hons) MSc CSci CChem MRSC**

**01/09/15**

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](mailto:info@cosmeticsafetyassessment.com)

## Qualifications

MSc Applied Chemistry

BSc (Hons) Combined Sciences 1<sup>st</sup> 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  
Incorporated 1800  
Incorporated by Royal Charter 1880  
Pursue the Matter the Quare

President

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

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 207885