

Safety Report Part B

CSC Reference	SD130317LBCPSR
Product line	Lip Balms
Names of products	1. Mint Cake Lip Balm 2. Vanilla Latte Lip Balm 3. Gingerbread Lip Balm
Product category	Cosmetic balms - leave on products
Manufacturer	Siobhan Dawson - The Little Lakeland Soap Company
Contact person	Siobhan Dawson 1 Wintergreen Lane Kendal Cumbria LA9 7FP

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 Instructions for Use

No specific warnings required other than standard product usage instructions – for external use only - not to be used around the eyes, mucous membranes or on broken skin. If irritation occurs discontinue use.

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.

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) $SED = I \times A / 60$

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

13/03/17

Chartered Chemist, Chartered Scientist

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

Cosmetic Safety Consultants Ltd.

Safety Assessor Information

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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 1841
Incorporated by Royal Charter 1848
Patron Her Majesty the Queen

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A handwritten signature in cursive script, likely belonging to the President of the Royal Society of Chemistry.

Registrar

A handwritten signature in cursive script, likely belonging to the Registrar of the Royal Society of Chemistry.

Date of Award

14 November 2008

RSC Membership Number

378846

The certificate is issued subject to the provisions of the Charter and By-Laws
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