

# 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

<b>CSC Reference</b>	NB-NB010120 SLBO
<b>Product line</b>	Lip Balms
<b>Product variants</b>	<ol style="list-style-type: none"><li>1. Rose</li><li>2. Strawberry</li><li>3. Coconut</li><li>4. Vanilla</li><li>5. Honey</li><li>6. Peppermint</li><li>7. Mandarin</li><li>8. Cherry</li><li>9. Berry</li><li>10. Prosecco</li></ol>
<b>Product category</b>	Leave on product for application to oral labia
<b>Responsible person</b>	Jessica Smith Naturally Balmy Ltd, 8 Benson Road, Nuffield Industrial Estate, Poole BH17 0GB

## **Report content**

Report Validity Conditions

### **Report Part A**

1. Quantitative formulations, concentration ranges (CPNP) and toxicity classes
2. Final Product characteristics (including stability, microbiology etc.)
3. Packaging
4. Warnings
5. Normal and reasonably foreseeable use
6. Target Population
7. Undesirable effects and serious undesirable effects
8. Information on the cosmetic product / Proof of effects
9. Product and substance exposure characteristics
10. Ingredient toxicity profiles and MOS calculations

### **Report Part B**

1. Assessment Conclusion
2. Labelled Warnings and Instructions for Use
3. Reasoning
4. Assessor's credentials and approval of part B

## **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; this includes, but is not limited to 'cupcake' type soaps or any product which may be mistaken for food and is subsequently in violation the European food imitation regulations.**

**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/>**

**The supplier for all ingredients is Naturally Balmy, 30 Southbourne Road, Southbourne, Bournemouth, BH6 5AD, United Kingdom. No substitution of suppliers is permitted.**

# Safety Report Part A

## 1. Quantitative formulations, concentration ranges (CPNP) and toxicity classes

Concentration ranges (CPNP):

A	>75% - ≤100%
B	>50% - ≤75%
C	>25% - ≤50%
D	>10% - ≤25%
E	>5% - ≤10%
F	>1% - ≤5%
G	>0.1% - ≤1%
H	≤0.1%

**Base ingredients\*:**

INCI	Banding, %	Concentration Range (CPNP)	Toxicity Class †
Ricinus Communis (Castor) Seed Oil	25 - 50	C	A
Simmondsia Chinensis (Jojoba) Seed Oil	25 - 50	C	A
Cera Alba (Beeswax)	10 - 25	D	A
Theobroma Cacao (Cocoa) Seed Butter	10 - 25	D	A

\*Organic Luxury Lip Balm Base - Naturally Balmy.

† See Section 10 for detailed toxicity class information.

**Product variants:**

Product variant	Ingredient	Weight, %	Concentration Range (CPNP)	Toxicity Class†
1. Rose	<b>Additional Ingredients</b>			
	Aroma - Natural 'Fresh Rose' Lip Balm Flavour Oil	Up to 1.00%	G	C

Product variant	Ingredient	Weight, %	Concentration Range (CPNP)	Toxicity Class†
2. Strawberry	<b>Additional Ingredients</b>			
	Aroma - Organic Strawberry Lip Balm Flavour Oil	Up to 2.00%	F	C

Product variant	Ingredient	Weight, %	Concentration Range (CPNP)	Toxicity Class <sup>†</sup>
3. Coconut	<b>Additional Ingredients</b>			
	Aroma - Organic Coconut Lip Balm Flavour Oil	Up to 2.00%	F	C

Product variant	Ingredient	Weight, %	Concentration Range (CPNP)	Toxicity Class <sup>†</sup>
4. Vanilla	<b>Additional Ingredients</b>			
	Aroma - Organic Vanilla Lip Balm Flavour Oil	Up to 2.00%	F	C

Product variant	Ingredient	Weight, %	Concentration Range (CPNP)	Toxicity Class <sup>†</sup>
5. Honey	<b>Additional Ingredients</b>			
	Aroma - Organic Honey Lip Balm Flavour Oil	Up to 2.00%	F	C

Product variant	Ingredient	Weight, %	Concentration Range (CPNP)	Toxicity Class <sup>†</sup>
6. Peppermint	<b>Additional Ingredients</b>			
	Mentha Piperita (Peppermint) Oil	Up to 1.00%	G	C

Product variant	Ingredient	Weight, %	Concentration Range (CPNP)	Toxicity Class <sup>†</sup>
7. Mandarin	<b>Additional Ingredients</b>			
	Citrus Nobilis (Mandarin) Peel Oil	Up to 2.00%	F	C

Product variant	Ingredient	Weight, %	Concentration Range (CPNP)	Toxicity Class <sup>†</sup>
8. Cherry	<b>Additional Ingredients</b>			
	Aroma - Organic Cherry Lip Balm Flavour Oil	Up to 2.00%	F	C

Product variant	Ingredient	Weight, %	Concentration Range (CPNP)	Toxicity Class <sup>†</sup>
9. Berry	<b>Additional Ingredients</b>			
	Aroma - Organic Berry Lip Balm Flavour Oil	Up to 2.00%	F	C

Product variant	Ingredient	Weight, %	Concentration Range (CPNP)	Toxicity Class <sup>†</sup>
10. Prosecco	<b>Additional Ingredients</b>			
	Aroma - Prosecco Lip Balm Flavour Oil	Up to 2.00%	F	C

### **+/- Colourants added to the above recipes (optional)**

A list of colourants may be included which, in line with EU Regulation 1223/2009 may be included / labelled on a “may or not contain” basis - thus allowing a number of aesthetically different, but toxicologically equivalent products.

<b>INCI</b>	<b>Max. % TOTAL in addition to the above recipes</b>	<b>Concentration Range (CPNP)</b>	<b>Toxicity Class <sup>†</sup></b>
Pearlescent Candy Pink Mica (CI 77019, 77891, 77491, 77742, 77861); Coral Sparkler Orange Mica (CI 77019, 77891, 77492); Jazzberry Crush Mica (CI 77019, 77891, 77491, 77007, 77861); Sangria Red Mica (CI 77019, 77491);	10.00	E	B

<sup>†</sup> See Section 10 for detailed toxicity class information

## **2. Final product characteristics**

### **Physical and Chemical Properties:**

Appearance - semi-solid balm. Colour characteristic of cosmetic pigments used.

Odour - characteristic of fragrance / flavour ingredients used.

### **Raw Materials:**

Please refer to supplier MSDS and CoA information which should be used in conjunction with this report.

### **Stability and Reactivity / Interaction of Substances:**

The product is expected to be nominally stable at ambient storage conditions – to be confirmed by manufacturer based on observation of previous products made.

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.

### **Ingredient Purity:**

Approved cosmetic, pharmaceutical or food grade ingredients are used. 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 be not be present. GMP controlled processes are unlikely to introduce contaminants with toxicological significance during manufacture.

**Microbiological Purity:**

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

The product is not specifically marketed as a product for use by children under 3 years, in the eye area and on mucous membranes, therefore it is classified as a Category 2 product: “Other products”.

For cosmetics classified as Category 2, the total viable count for aerobic mesophilic microorganisms (bacteria plus yeast and mould) should not exceed 10<sup>3</sup> CFU per g or ml of product (CFU - colony forming unit).

*Escherichia coli*, *Pseudomonas aeruginosa*, *Staphylococcus aureus* and *Candida albicans* are considered the main potential pathogens in cosmetic products. These specific potential pathogens must not be detectable in 1 g or ml of a cosmetic product.

**3. Packaging**

No specific requirements (e.g. absence of nitrosating agents). Cosmetic grade packaging materials must be used.

**4. 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.

**5. Normal and reasonably foreseeable use**

To be applied frequently to oral labia. Leave on product.

The product is intended for external use only and is not marketed for infant use, or for application to mucous membranes, broken skin or the eye area.

## **6. 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.

## **7. 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.

## **8. Information on the cosmetic product / Proof of effects**

No specific medicinal claims are made. All constituents have been used widely in cosmetic preparations – no newly introduced or novel ingredients are used.



## 9. Product and Substance exposure characteristics

Exposure is by dermal absorption and ingestion under foreseeable conditions of use – a retention factor of 100 % has been used for all ingredients and calculations are based on typical exposure values (RIVM report 320104001/2006 Cosmetics Fact Sheet. H.J. Bremmer, L.C.H. Prud'homme de Lodder, J.G.M. van Engelen).

	Product category	Amount per application / g	Potential frequency of application	g / day applied	Retention factor	g / day exposure	Surface area cm <sup>2</sup>	Systemic Exposure Dose (SED) mg/kgbw/day (based on 60 kg avg.)	Specific Exposure mg/cm <sup>2</sup>	MOS Summary - see external reference below
Maximum component, %	Lip products (lipstick, lip salve, lip balm)	0.1	4	0.4	100 %	0.4	4.8	6.667	83.333	
<b>Common Base - Organic Luxury Lip Balm Base - Naturally Balmy</b>										
50	Ricinus Communis (Castor) Seed Oil	0.0500	4	0.2000	100 %	0.2000	4.8	3.333	41.667	>100
50	Simmondsia Chinensis (Jojoba) Seed Oil	0.0500	4	0.2000	100 %	0.2000	4.8	3.333	41.667	>100
25	Cera Alba (Beeswax)	0.0250	4	0.1000	100 %	0.1000	4.8	1.667	20.833	>100
25	Theobroma Cacao (Cocoa) Seed Butter	0.0250	4	0.1000	100 %	0.1000	4.8	1.667	20.833	>100
<b>Fragrance variants</b>										
<b>1. Rose</b>										
1.00	Aroma - Natural 'Fresh Rose' Lip Balm Flavour Oil	0.0010	4	0.0040	100 %	0.0040	4.8	0.067	0.8333	>100
<b>2. Strawberry</b>										
2.00	Aroma - Organic Strawberry Lip Balm Flavour Oil	0.0020	4	0.0080	100 %	0.0080	4.8	0.133	1.6667	>100
<b>3. Coconut</b>										
2.00	Aroma - Organic Coconut Lip Balm Flavour Oil	0.0020	4	0.0080	100 %	0.0080	4.8	0.133	1.6667	>100
<b>4. Vanilla</b>										
2.00	Aroma - Organic Vanilla Lip Balm Flavour Oil	0.0020	4	0.0080	100 %	0.0080	4.8	0.133	1.6667	>100
<b>5. Honey</b>										
2.00	Aroma - Organic Honey Lip Balm Flavour Oil	0.0020	4	0.0080	100 %	0.0080	4.8	0.133	1.6667	>100
<b>6. Peppermint</b>										
1.00	Mentha Piperita (Peppermint) Oil	0.0010	4	0.0040	100 %	0.0040	4.8	0.067	0.8333	>100
<b>7. Mandarin</b>										
2.00	Citrus Nobilis (Mandarin) Peel Oil	0.0020	4	0.0080	100 %	0.0080	4.8	0.133	1.6667	>100
<b>8. Cherry</b>										
2.00	Aroma - Organic Cherry Lip Balm Flavour Oil	0.0020	4	0.0080	100 %	0.0080	4.8	0.133	1.6667	>100

<b>9. Berry</b>										
2.00	Aroma - Organic Berry Lip Balm Flavour Oil	0.0020	4	0.0080	100 %	0.0080	4.8	0.133	1.6667	>100
<b>10. Prosecco</b>										
2.00	Aroma - Prosecco Lip Balm Flavour Oil	0.0020	4	0.0080	100 %	0.0080	4.8	0.133	1.6667	>100
<b>+/- Colourants added to the above recipes (optional)</b>										
10.00	Pearlescent Candy Pink Mica (CI 77019, 77891, 77491, 77742, 77861); Coral Sparkler Orange Mica (CI 77019, 77891, 77492); Jazzberry Crush Mica (CI 77019, 77891, 77491, 77007, 77861); Sangria Red Mica (CI 77019, 77491);	0.0100	4	0.0400	100 %	0.0400	4.8	0.667	8.3333	>100

## 10. Ingredient toxicity profiles and MOS calculations based on maximum percentages

### External CSC reference for MOS summary and toxicological data:

[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)

### Ingredient Toxicity profile

Substance classification of toxicological significance

- A Low or limited toxicological significance – edible and inert ingredients with NOAEL values of  $>1000 \text{ mg kg bw}^{-1}\text{d}^{-1}$  or non-determined due to no toxicological concerns. Cramer class I – no structural alerts – no determined CMR activity.  
Examples – edible and/or plant-derived fixed oils and fats, water, bulking minerals, saponified oils and fats, BP grade mineral oils.  
MOS  $>100$
- B Limited toxicological significance – functional components with determined NOAEL values  $100\text{-}500 \text{ mg kg bw}^{-1}\text{d}^{-1}$ . Cramer Class I / Cramer class II – no structural alerts - no determined CMR activity.  
Examples – surfactants, emulsifiers, conditioning agents.  
SED  $<1 - 5 \text{ mg kg bw}^{-1}\text{d}^{-1} = \text{MOS } >100$
- C Moderate toxicological significance – active components with determined NOAEL values  $50\text{-}100 \text{ mg kg bw}^{-1}\text{d}^{-1}$ . Cramer Class I / Cramer class II – potential structural alerts – no determined CMR activity at concentrations used in formulation.  
Examples – essential oils\* and fragrance ingredients, plant extracts<sup>†</sup>.  
SED  $<0.5 - 1.0 \text{ mg kg bw}^{-1}\text{d}^{-1} = \text{MOS } >100$

\* - Absence of Cramer class III components (e.g. Methyleugenol, safrole, estragole).

† - Absence of Cramer class III components (e.g. Pyrrolizidine alkaloids).

- D High toxicological significance – active components with determined NOAEL Values  $<50 \text{ mg kg bw}^{-1}\text{d}^{-1}$ . Cramer class II / Cramer class III – structural alerts – potential CMR activity.  
Examples – active ingredients with presence of restricted components (Rose essential oil, Basil essential oil, Comfrey extract, Peptides, skin lightening, some anti-wrinkle actives).  
MOS to be detailed specifically on report.

TTC values:

Human exposure thresholds of 1800, 540, and 90  $\mu\text{g/person/d}$  (corresponding to 30, 9, and 1.5  $\mu\text{g/kg bw/d}$ ) were proposed for Cramer Class I, II and III, respectively, using the 5th percentile value of distribution of NOELs for each class of chemicals, a body weight of 60 kg, and a safety factor of 100 (Munro *et al.*, 1996). When organophosphates were excluded from Class III, the human exposure threshold increased to 180  $\mu\text{g/person/d}$  (3.0  $\mu\text{g/kg bw/d}$ ; Munro *et al.*, 2008). Due to high potential toxicity, a specific TTC of 18  $\mu\text{g/person/d}$  may be applicable for organophosphates.

SCCP/1171/08

Scientific Committee on Consumer Safety (SCCS)

Scientific Committee on Health and Environmental Risks (SCHER)

Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

OPINION ON Use of the Threshold of Toxicological Concern (TTC) Approach for Human Safety Assessment of Chemical Substances with focus on Cosmetics and Consumer Products

# Safety Report Part B

<b>CSC Reference</b>	NB-NB010120 SLBO
<b>Product line</b>	Lip Balms
<b>Product variants</b>	1. Rose 2. Strawberry 3. Coconut 4. Vanilla 5. Honey 6. Peppermint 7. Mandarin 8. Cherry 9. Berry 10. Prosecco
<b>Product category</b>	Leave on product for application to oral labia
<b>Responsible person</b>	Jessica Smith Naturally Balmy Ltd, 8 Benson Road, Nuffield Industrial Estate, Poole BH17 0GB

**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.**

## *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.

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.

### **Fragrance Oils**

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

### **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 (bw) of human (kg) **60**  
Maximum absorption through the skin (%) **A**  
Systemic Exposure Dose (mg/kgbw)  $SED = I \times A / 60$   
Margin of Safety **NOAEL / SED**

Where NOAEL equals no observed adverse effect level in mg/kgbw 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**

**01/01/20**

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 – 5 years.

5+ years in small scale manufacturing of cosmetics.

Member of the advisory panel of the Guild of Craft Soap and Toiletry Makers.



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

President

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  
Registered Charity Number 207890