

# 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-NB241117 HBW  |
| <b>Product line</b>      | Hand & Body Washes   |
| <b>Names of products</b> | 1. Lavender & Geranium Hand & Body Wash<br>2. Orange & Bergamot Hand & Body Wash           |
| <b>Product category</b>  | Surfactant based cleanser prepared from<br>commercially available base - rinse off product |
| <b>Manufacturer</b>      | Naturally Balmy  |
| <b>Contact person</b>    | Naturally Balmy<br>30 Southbourne Road<br>Bournemouth<br>BH6 5AD                           |

## **Report content**

Report Validity Conditions

### **Report Part A**

1. Quantitative formulation and MSDS sheets
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/>**

# Safety Report Part A

## 1. Quantitative formulations

### Base ingredients (98 %)\*:

| Ingredient   | Max. weight, % |
|--|----------------|
| Aqua & Avena Sativa Kernel Extract                               | 98,00          |
| Decyl Glucoside  | 9,80           |
| Sodium Cocoamphoacetate  | 6,86           |
| Coco Glucoside   | 6,86           |
| Aloe Barbadensis Leaf Extract                                    | 6,86           |
| Glycerin   | 6,86           |
| Glyceryl Stearate  | 3,92           |
| Xanthan Gum  | 3,92           |
| Benzyl Alcohol & Dehydroacetic Acid & Sorbic Acid & Benzoic Acid | 0,98           |
| Argania Spinosa Nut Oil  | 0,98           |
| Quillaja Saponaria   | 0,98           |
| Sodium Bicarbonate   | 0,98           |

\* Cosmetic Base Oat & Argan Shampoo/Wash (Naturally Balmy).

### Essential oil variants (2 %):

| Product Name                            | Ingredient             | Weight, % |
|---|------------------------|-----------|
| 1. Lavender & Geranium Hand & Body Wash | Lavender Essential Oil | 1,00      |
|   | Geranium Essential Oil | 1,00      |

| Product Name                          | Ingredient                 | Weight, % |
|---------------------------------------|----------------------------|-----------|
| 2. Orange & Bergamot Hand & Body Wash | Sweet Orange Essential Oil | 1,00      |
|                                       | Bergamot FCF Essential Oil | 1,00      |

## 2. Final product characteristics

### Physical and Chemical Properties:

Viscous cleanser with fragrance characteristic of essential oils used.

### Stability and Reactivity:

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

**Ingredient Purity:**

Approved cosmetic, pharmaceutical or food grade ingredients are used. Where specific purity criteria (e.g. secondary amine content, heavy metals content) apply (as detailed in Ingredient toxicity profiles and MOS calculations section) these remain the responsibility of the responsible person.

**Microbiological Purity:**

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

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  $10^3$  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**

150 ml bottle with pump dispenser. No specific requirements (e.g. absence of nitrosating agents). Cosmetic grade packaging materials must be used.

**4. Warnings**

No specific warnings required other than standard usage instructions.

**5. Normal and reasonably foreseeable use**

The product is intended for use as full body & hand cleanser for topical application. Rinse off product.

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

## **6. Target Population**

Marketed as products for general population – not specifically marketed for infant use.

## **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 only under foreseeable conditions of use – a retention factor of 1 % has been used for all ingredients (rinse off products) 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).

### 1. Lavender & Geranium Hand & Body Wash

|                             | 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> | Toxicity Class |
|-----------------------------|--|----------------------------|------------------------------------|-----------------|------------------|------------------|------------------------------|--|--------------------------------------|----------------|
| <b>Maximum component, %</b> | <b>Liquid soap / shower gel</b>                                  | 8.7                        | 1                                  | 8.7             | 1 %              | 0.087            | 17500                        | 1.450  | 0.0050                               |                |
| 98.00                       | Aqua & Avena Sativa Kernel Extract                               | 8.526                      | 1                                  | 8.526           | 1 %              | 0.0853           | 17500                        | 1.421  | 0.0049                               | A              |
| 9.80                        | Decyl Glucoside  | 0.853                      | 1                                  | 0.853           | 1 %              | 0.0085           | 17500                        | 0.142  | 0.0005                               | A              |
| 6.86                        | Sodium Cocoamphoacetate  | 0.597                      | 1                                  | 0.597           | 1 %              | 0.0060           | 17500                        | 0.099  | 0.0003                               | B              |
| 6.86                        | Coco Glucoside   | 0.597                      | 1                                  | 0.597           | 1 %              | 0.0060           | 17500                        | 0.099  | 0.0003                               | A              |
| 6.86                        | Aloe Barbadensis Leaf Extract                                    | 0.597                      | 1                                  | 0.597           | 1 %              | 0.0060           | 17500                        | 0.099  | 0.0003                               | C              |
| 6.86                        | Glycerin   | 0.597                      | 1                                  | 0.597           | 1 %              | 0.0060           | 17500                        | 0.099  | 0.0003                               | A              |
| 3.92                        | Glyceryl Stearate  | 0.341                      | 1                                  | 0.341           | 1 %              | 0.0034           | 17500                        | 0.057  | 0.0002                               | A              |
| 3.92                        | Xanthan Gum  | 0.341                      | 1                                  | 0.341           | 1 %              | 0.0034           | 17500                        | 0.057  | 0.0002                               | A              |
| 0.98                        | Benzyl Alcohol & Dehydroacetic Acid & Sorbic Acid & Benzoic Acid | 0.085                      | 1                                  | 0.085           | 1 %              | 0.0009           | 17500                        | 0.014  | 0.0000                               | B              |
| 0.98                        | Argania Spinosa Nut Oil  | 0.085                      | 1                                  | 0.085           | 1 %              | 0.0009           | 17500                        | 0.014  | 0.0000                               | A              |
| 0.98                        | Quillaja Saponaria   | 0.085                      | 1                                  | 0.085           | 1 %              | 0.0009           | 17500                        | 0.014  | 0.0000                               | A              |
| 0.98                        | Sodium Bicarbonate   | 0.085                      | 1                                  | 0.085           | 1 %              | 0.0009           | 17500                        | 0.014  | 0.0000                               | A              |
| 1.00                        | Lavender Essential Oil   | 0.087                      | 1                                  | 0.087           | 1 %              | 0.0009           | 17500                        | 0.015  | 0.0000                               | C              |
| 1.00                        | Geranium Essential Oil   | 0.087                      | 1                                  | 0.087           | 1 %              | 0.0009           | 17500                        | 0.015  | 0.0000                               | C              |

## 2. Orange & Bergamot Hand & Body Wash

|                             | 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> | Toxicity Class |
|-----------------------------|--|----------------------------|------------------------------------|-----------------|------------------|------------------|------------------------------|--|--------------------------------------|----------------|
| <b>Maximum component, %</b> | <b>Liquid soap / shower gel</b>                                  | 8.7                        | 1                                  | 8.7             | 1 %              | 0.087            | 17500                        | 1.450  | 0.0050                               |                |
| 98.00                       | Aqua & Avena Sativa Kernel Extract                               | 8.526                      | 1                                  | 8.526           | 1 %              | 0.0853           | 17500                        | 1.421  | 0.0049                               | A              |
| 9.80                        | Decyl Glucoside  | 0.853                      | 1                                  | 0.853           | 1 %              | 0.0085           | 17500                        | 0.142  | 0.0005                               | A              |
| 6.86                        | Sodium Cocoamphoacetate  | 0.597                      | 1                                  | 0.597           | 1 %              | 0.0060           | 17500                        | 0.099  | 0.0003                               | B              |
| 6.86                        | Coco Glucoside   | 0.597                      | 1                                  | 0.597           | 1 %              | 0.0060           | 17500                        | 0.099  | 0.0003                               | A              |
| 6.86                        | Aloe Barbadensis Leaf Extract                                    | 0.597                      | 1                                  | 0.597           | 1 %              | 0.0060           | 17500                        | 0.099  | 0.0003                               | C              |
| 6.86                        | Glycerin   | 0.597                      | 1                                  | 0.597           | 1 %              | 0.0060           | 17500                        | 0.099  | 0.0003                               | A              |
| 3.92                        | Glyceryl Stearate  | 0.341                      | 1                                  | 0.341           | 1 %              | 0.0034           | 17500                        | 0.057  | 0.0002                               | A              |
| 3.92                        | Xanthan Gum  | 0.341                      | 1                                  | 0.341           | 1 %              | 0.0034           | 17500                        | 0.057  | 0.0002                               | A              |
| 0.98                        | Benzyl Alcohol & Dehydroacetic Acid & Sorbic Acid & Benzoic Acid | 0.085                      | 1                                  | 0.085           | 1 %              | 0.0009           | 17500                        | 0.014  | 0.0000                               | B              |
| 0.98                        | Argania Spinosa Nut Oil  | 0.085                      | 1                                  | 0.085           | 1 %              | 0.0009           | 17500                        | 0.014  | 0.0000                               | A              |
| 0.98                        | Quillaja Saponaria   | 0.085                      | 1                                  | 0.085           | 1 %              | 0.0009           | 17500                        | 0.014  | 0.0000                               | A              |
| 0.98                        | Sodium Bicarbonate   | 0.085                      | 1                                  | 0.085           | 1 %              | 0.0009           | 17500                        | 0.014  | 0.0000                               | A              |
| 1.00                        | Sweet Orange Essential Oil                                       | 0.087                      | 1                                  | 0.087           | 1 %              | 0.0009           | 17500                        | 0.015  | 0.0000                               | C              |
| 1.00                        | Bergamot FCF Essential Oil                                       | 0.087                      | 1                                  | 0.087           | 1 %              | 0.0009           | 17500                        | 0.015  | 0.0000                               | C              |



## 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 origin or with determined NOAEL values  $>1000 \text{ mg kg bw}^{-1}\text{d}^{-1}$  Cramer class I – no structural alerts – no determined CMR activity  
Examples – Edible oils and fats, water, bulking minerals, saponified oils and fats  
 $\text{SED} < 10.0 \text{ mg kg bw}^{-1}\text{d}^{-1} = \text{MOS} >100$
- 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  
 $\text{SED} < 1 \text{ mg kg bw}^{-1}\text{d}^{-1} = \text{MOS} >100$
- C Moderate toxicological significance – active components with determined NOAEL Values  $50 - 100 \text{ mg kg bw}^{-1}\text{d}^{-1}$  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>  
 $\text{SED} < 0.5 - 1.0 \text{ mg kg bw}^{-1}\text{d}^{-1} = \text{MOS} >100$

\* - 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-NB241117 HBW   |
| <b>Product line</b>      | Hand & Body Washes  |
| <b>Names of products</b> | 1. Lavender & Geranium Hand & Body Wash<br>2. Orange & Bergamot Hand & Body Wash        |
| <b>Product category</b>  | Surfactant based cleanser prepared from commercially available base - rinse off product |
| <b>Manufacturer</b>      | Naturally Balmy   |
| <b>Contact person</b>    | Naturally Balmy<br>30 Southbourne Road<br>Bournemouth<br>BH6 5AD                        |

## ***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 rinse off 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 0.01% 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**

**24/11/17**

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

22, Rosemount Road, Bishop Auckland, County Durham DL14 6SX United Kingdom  
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 in Great Britain 1867  
Part of the Materials Centre

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 207800