Cosmetic Product Safety Report
Cosmetic Safety Consultants Ltd on behalf of the named manufacturer below

CSC Reference - SK - ML031213 CPSR1

Product Category - Soap

Solid product comprising primarily of saponified edible grade oils (Sodium salts after saponification) with the addition of fillers, exfoliants, herbal and fragrance ingredients.

Products – Pure Basic Soap

Responsible person – Monica Lewis T/A Bulrush and Bramble – United Kingdom

Report content

Report Part A

Quantitative Formulation
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; 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
### Final Product Formulation, exposure values and margin of safety summary

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Amount per application / g</th>
<th>Frequency of application</th>
<th>g / day applied</th>
<th>Retention factor</th>
<th>g/day exposure</th>
<th>Surface Area Exp cm³</th>
<th>Systemic Exposure Dose (mg/kg) (based on 60kg average)</th>
<th>Specific Exposure mg/cm²</th>
<th>MOS Summary – See external link below</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum weight / volume component (%)</td>
<td>Soap</td>
<td>5</td>
<td>1</td>
<td>5</td>
<td>1%</td>
<td>0.0500</td>
<td>12895</td>
<td>0.83</td>
<td>0.0039</td>
</tr>
<tr>
<td>68.1</td>
<td>Sodium Olivate</td>
<td>3.406</td>
<td>1</td>
<td>3.406287</td>
<td>1%</td>
<td>0.0341</td>
<td>12895</td>
<td>0.568</td>
<td>0.0026</td>
</tr>
<tr>
<td>17.3</td>
<td>Sodium Cocoate</td>
<td>0.867</td>
<td>1</td>
<td>0.867217</td>
<td>1%</td>
<td>0.0087</td>
<td>12895</td>
<td>0.145</td>
<td>0.0007</td>
</tr>
<tr>
<td>8.5</td>
<td>Water</td>
<td>0.427</td>
<td>1</td>
<td>0.42735</td>
<td>1%</td>
<td>0.0043</td>
<td>12895</td>
<td>0.071</td>
<td>0.0003</td>
</tr>
<tr>
<td>6.0</td>
<td>Glycerine</td>
<td>0.299</td>
<td>1</td>
<td>0.299145</td>
<td>1%</td>
<td>0.0030</td>
<td>12895</td>
<td>0.050</td>
<td>0.0002</td>
</tr>
</tbody>
</table>

### 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

Soap – Solid bar soaps with colour and fragrance according to additives used.

Physical And Chemical Properties

pH – expected range 9.5-10.5

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)

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 be not be present. GMP controlled processes are unlikely to introduce contaminants with toxicological significance during manufacture.

Microbiological Purity

Product does not support microbial growth under normal storage conditions due to elevated pH and limited water availability (Osmotic potential).

Packaging

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

Warnings

No specific warnings required other than standard usage instructions.

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.
Normal and reasonably foreseeable use
Used as per typical bar soap or solid cleansing product

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 (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.

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 x A / 60

Margin of Safety  NOAEL / SED

where NOAEL equals no observed adverse effect level in mg/kg bw from appropriate repeated dose toxicity 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)
CSC Reference - SK - ML031213 CPSR1

Product Category - Soap

Solid product comprising primarily of saponified edible grade oils (Sodium salts after saponification) with the addition of fillers, exfoliants, herbal and fragrance ingredients.

Products – Pure Basic Soap

Responsible person – Monica Lewis T/A Bulrush and Bramble – United Kingdom

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 03/12/13

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

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 – 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

The certificate is issued subject to the provisions of the Charter and By-Laws.
Registered Charity Number 207890

Royal Society of Chemistry
Founded 1841
Incorporated by Royal Charter 1907
Patron Her Majesty the Queen

President

Registrar

Date of Award

14 November 2008

RSC Membership Number

378846
Cosmetic Product Safety Report
Cosmetic Safety Consultants Ltd on behalf of the named manufacturer below

CSC Reference - SK - ML031213 CPSR2

Product Category - Soap

Solid product comprising primarily of saponified edible grade oils (Sodium salts after saponification) with the addition of fillers, exfoliants, herbal and fragrance ingredients.

Products – Gentle Soap

Responsible person – Monica Lewis T/A Bulrush and Bramble – United Kingdom

Report content

Report Part A

Quantitative Formulation
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

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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
## Final Product Formulation, exposure values and margin of safety summary

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Maximum weight / volume component (%)</th>
<th>Amount per application / g</th>
<th>Frequency of application</th>
<th>g / day applied</th>
<th>Retention factor</th>
<th>g/day exposure</th>
<th>Surface Area Exp cm$^3$</th>
<th>Systemic Exposure Dose (mg/kg) (based on 60kg average)</th>
<th>Specific Exposure mg/cm$^2$</th>
<th>MOS Summary</th>
<th>MOS Summary - See external reference below</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soap</td>
<td>78.7</td>
<td>5</td>
<td>1</td>
<td>5</td>
<td>1%</td>
<td>0.0500</td>
<td>12895</td>
<td>0.83</td>
<td>0.0039</td>
<td>&gt;100</td>
<td><a href="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</a></td>
</tr>
<tr>
<td>Sodium Olivate</td>
<td>6.8</td>
<td>3.933</td>
<td>1</td>
<td>3.93289</td>
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<td>12895</td>
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<td>0.0030</td>
<td>&gt;100</td>
<td><a href="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</a></td>
</tr>
<tr>
<td>Sodium Castorate</td>
<td>8.5</td>
<td>0.341</td>
<td>1</td>
<td>0.340615</td>
<td>1%</td>
<td>0.0034</td>
<td>12895</td>
<td>0.057</td>
<td>0.0003</td>
<td>&gt;100</td>
<td><a href="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</a></td>
</tr>
<tr>
<td>Water</td>
<td>6.0</td>
<td>0.427</td>
<td>1</td>
<td>0.42735</td>
<td>1%</td>
<td>0.0043</td>
<td>12895</td>
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<tr>
<td>Glycerine</td>
<td>6.0</td>
<td>0.299</td>
<td>1</td>
<td>0.299145</td>
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<td>0.0030</td>
<td>12895</td>
<td>0.050</td>
<td>0.0002</td>
<td>&gt;100</td>
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</tr>
<tr>
<td>Chamomile Flowers</td>
<td>0.3</td>
<td>0.015</td>
<td>1</td>
<td>0.015</td>
<td>1%</td>
<td>0.0002</td>
<td>12895</td>
<td>0.003</td>
<td>0.0000</td>
<td>&gt;100</td>
<td><a href="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</a></td>
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</tbody>
</table>
Final Product characteristics

Soap – Solid bar soaps with colour and fragrance according to additives used.

Physical And Chemical Properties

pH – expected range 9.5-10.5

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)

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 be not be present. GMP controlled processes are unlikely to introduce contaminants with toxicological significance during manufacture.

Microbiological Purity

Product does not support microbial growth under normal storage conditions due to elevated pH and limited water availability (Osmotic potential).

Packaging

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

Warnings

No specific warnings required other than standard usage instructions.

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.
Normal and reasonably foreseeable use
Used as per typical bar soap or solid cleansing product

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 (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.

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 x A / 60

Margin of Safety  NOAEL / SED

where NOAEL equals no observed adverse effect level in mg/kg bw from appropriate repeated dose toxicity 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)
CSC Reference - SK - ML031213 CPSR2

Product Category - Soap

Solid product comprising primarily of saponified edible grade oils (Sodium salts after saponification) with the addition of fillers, exfoliants, herbal and fragrance ingredients.

Products – Gentle Soap

Responsible person – Monica Lewis T/A Bulrush and Bramble – United Kingdom

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  03/12/13

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

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 – 5 years.

5+ years in small scale manufacturing of cosmetics

Member of the advisory panel of the GuildofCraftSoapandToiletryMakers
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CHARTERED CHEMIST

BY THE ROYAL SOCIETY OF CHEMISTRY

AND IS ENTITLED TO USE THE LETTERS CChem

Date of Award
14 November 2008

RSC Membership Number
378846
Cosmetic Product Safety Report
Cosmetic Safety Consultants Ltd on behalf of the named manufacturer below

CSC Reference - SK - ML031213 CPSR3

Product Category - Soap

Solid product comprising primarily of saponified edible grade oils (Sodium salts after saponification) with the addition of fillers, exfoliants, herbal and fragrance ingredients.

Products – Wildflower Meadow Soap

Responsible person – Monica Lewis T/A Bulrush and Bramble – United Kingdom

Report content

Report Part A

Quantitative Formulation
Final Product characteristics (including stability, microbiology etc.)
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Safety Report Part A

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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
## Final Product Formulation, exposure values and margin of safety summary

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Amount per application / g</th>
<th>Frequency of application</th>
<th>g / day applied</th>
<th>Retention factor</th>
<th>g/day exposure</th>
<th>Surface Area Exp cm$^3$</th>
<th>Systemic Exposure Dose (mg/kg) (based on 60kg average)</th>
<th>Specific Exposure mg/cm$^2$</th>
<th>MOS Summary</th>
<th>External reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum weight / volume component (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Soap</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium Olivate</td>
<td>2.778</td>
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<td>2.777778</td>
<td>1%</td>
<td>0.0278</td>
<td>12895</td>
<td>0.463</td>
<td>0.0022</td>
<td>&gt;100</td>
<td></td>
</tr>
<tr>
<td>Sodium Cocoate</td>
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<td>1</td>
<td>1.282051</td>
<td>1%</td>
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<td>12985</td>
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<td>0.0010</td>
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<tr>
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<td>0.213675</td>
<td>1%</td>
<td>0.0021</td>
<td>12895</td>
<td>0.036</td>
<td>0.0002</td>
<td>&gt;100</td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td>0.427</td>
<td>1</td>
<td>0.42735</td>
<td>1%</td>
<td>0.0043</td>
<td>12895</td>
<td>0.071</td>
<td>0.0003</td>
<td>&gt;100</td>
<td></td>
</tr>
<tr>
<td>Glycerine</td>
<td>0.299</td>
<td>1</td>
<td>0.299145</td>
<td>1%</td>
<td>0.0030</td>
<td>12895</td>
<td>0.050</td>
<td>0.0002</td>
<td>&gt;100</td>
<td></td>
</tr>
<tr>
<td>Goats Milk Powder</td>
<td>0.095</td>
<td>1</td>
<td>0.095</td>
<td>1%</td>
<td>0.0010</td>
<td>12895</td>
<td>0.016</td>
<td>0.0001</td>
<td>&gt;100</td>
<td></td>
</tr>
<tr>
<td>Calendula Petals</td>
<td>0.010</td>
<td>1</td>
<td>0.01</td>
<td>1%</td>
<td>0.0001</td>
<td>12895</td>
<td>0.002</td>
<td>0.00001</td>
<td>&gt;100</td>
<td></td>
</tr>
<tr>
<td>Rose Petals</td>
<td>0.010</td>
<td>1</td>
<td>0.01</td>
<td>1%</td>
<td>0.0001</td>
<td>12895</td>
<td>0.002</td>
<td>0.00001</td>
<td>&gt;100</td>
<td></td>
</tr>
</tbody>
</table>

Annex 1 – External reference (Competent authority access)

http://cosmetic-compliance.co.uk/web_documents/grainger_100713_toxicology_and_mos_data.xlsx
Final Product characteristics

Soap – Solid bar soaps with colour and fragrance according to additives used.

Physical And Chemical Properties

pH – expected range 9.5-10.5

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)

Generally stable at ambient storage conditions – nominally stable for 30 months+ 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 be not be present. GMP controlled processes are unlikely to introduce contaminants with toxicological significance during manufacture.

Microbiological Purity

Product does not support microbial growth under normal storage conditions due to elevated pH and limited water availability (Osmotic potential).

Packaging

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

Warnings

No specific warnings required other than standard usage instructions.

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.
Normal and reasonably foreseeable use
Used as per typical bar soap or solid cleansing product

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 / sensitzers – 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.

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) $\text{SED} = \frac{I \times A}{60}$

Margin of Safety $\text{NOAEL} / \text{SED}$

where NOAEL equals no observed adverse effect level in mg/kg bw from appropriate repeated dose toxicity 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).
CSC Reference - SK - ML031213 CPSR3

Product Category - Soap

Solid product comprising primarily of saponified edible grade oils (Sodium salts after saponification) with the addition of fillers, exfoliants, herbal and fragrance ingredients.

Products – Wildflower Meadow Soap

Responsible person – Monica Lewis T/A Bulrush and Bramble – United Kingdom

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 03/12/13

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

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 – 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

Date of Award

14 November 2008

RSC Membership Number

378846
Cosmetic Product Safety Report
Cosmetic Safety Consultants Ltd on behalf of the named manufacturer below

CSC Reference - SK - ML031213 CPSR4

Product Category - Soap

Solid product comprising primarily of saponified edible grade oils (Sodium salts after saponification) with the addition of fillers, exfoliants, herbal and fragrance ingredients.

Products – Dorset Coast Soap

Responsible person – Monica Lewis T/A Bulrush and Bramble – United Kingdom

Report content

Report Part A

Quantitative Formulation
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; 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
Final Product Formulation, exposure values and margin of safety summary

<table>
<thead>
<tr>
<th>Product Category</th>
<th>Amount per application / g</th>
<th>Frequency of application</th>
<th>g / day applied</th>
<th>Retention factor</th>
<th>g/day exposure</th>
<th>Surface Area Exp cm²</th>
<th>Systemic Exposure Dose (mg/kg) (based on 60kg average)</th>
<th>Specific Exposure mg/cm²</th>
<th>MOS Summary - See external reference below</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum weight / volume component (%)</td>
<td>5</td>
<td>1</td>
<td>5</td>
<td>1%</td>
<td>0.050</td>
<td>12895</td>
<td>0.83</td>
<td>0.0039</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Soap</td>
<td>1.709</td>
<td>1</td>
<td>1.71</td>
<td>1%</td>
<td>0.017</td>
<td>12895</td>
<td>0.28</td>
<td>0.0013</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Sodium Olivate</td>
<td>1.709</td>
<td>1</td>
<td>1.71</td>
<td>1%</td>
<td>0.017</td>
<td>12895</td>
<td>0.28</td>
<td>0.0013</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Sodium Cocoate</td>
<td>0.855</td>
<td>1</td>
<td>0.86</td>
<td>1%</td>
<td>0.009</td>
<td>12895</td>
<td>0.14</td>
<td>0.0007</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Sodium Hempseedate</td>
<td>0.427</td>
<td>1</td>
<td>0.43</td>
<td>1%</td>
<td>0.004</td>
<td>12895</td>
<td>0.07</td>
<td>0.0003</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Water</td>
<td>0.299</td>
<td>1</td>
<td>0.30</td>
<td>1%</td>
<td>0.003</td>
<td>12895</td>
<td>0.05</td>
<td>0.0002</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Aloe Vera Gel</td>
<td>0.405</td>
<td>1</td>
<td>0.41</td>
<td>1%</td>
<td>0.004</td>
<td>12895</td>
<td>0.07</td>
<td>0.0003</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Kelp Powder</td>
<td>0.085</td>
<td>1</td>
<td>0.09</td>
<td>1%</td>
<td>0.001</td>
<td>12895</td>
<td>0.01</td>
<td>0.00007</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Calendula Petals</td>
<td>0.010</td>
<td>1</td>
<td>0.01</td>
<td>1%</td>
<td>0.0001</td>
<td>12895</td>
<td>0.002</td>
<td>0.00001</td>
<td>&gt;100</td>
</tr>
<tr>
<td>Rose Petals</td>
<td>0.010</td>
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<td>0.01</td>
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<td>12895</td>
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<td>0.00001</td>
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Annex 1 – External reference (Competent authority access)

http://cosmetic-compliance.co.uk/web_documents/grainger_100713_toxicology_and_mos_data.xlsx
Final Product characteristics

Soap – Solid bar soaps with colour and fragrance according to additives used.

Physical And Chemical Properties

pH – expected range 9.5-10.5

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)

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 be not be present. GMP controlled processes are unlikely to introduce contaminants with toxicological significance during manufacture.

Microbiological Purity
Product does not support microbial growth under normal storage conditions due to elevated pH and limited water availability (Osmotic potential).

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

Warnings
No specific warnings required other than standard usage instructions.

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.
Normal and reasonably foreseeable use
Used as per typical bar soap or solid cleansing product

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 (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.

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 x A / 60

Margin of Safety NOAEL / SED

where NOAEL equals no observed adverse effect level in mg/kg bw from appropriate repeated dose toxicity 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).
CSC Reference - SK - ML031213 CPSR4

Product Category - Soap

Solid product comprising primarily of saponified edible grade oils (Sodium salts after saponification) with the addition of fillers, exfoliants, herbal and fragrance ingredients.

Products – Dorset Coast Soap

Responsible person – Monica Lewis T/A Bulrush and Bramble – United Kingdom

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  03/12/13

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

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 – 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

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BY THE ROYAL SOCIETY OF CHEMISTRY

AND IS ENTITLED TO USE THE LETTERS CChem

President

Registrar

Date of Award

14 November 2008

RSC Membership Number

378846