

## COSMETIC PRODUCT SAFETY REPORT

**PRODUCT:** Coccole Body Soap Lemon & Lemon Verbena

**DATE:** 13 August 2021

Responsible Person: Giovanna Mantini



## 2. Physical & chemical properties and stability

### 2.1.1 Physical/chemical properties of ingredients (substances or mixtures)

See section 1. Quantitative and qualitative composition – additional specification of ingredients.

#### Ref. 1. 1 **Sodium cocoate**

Sodium cocoate is the product of the saponification of Coconut oil by Sodium hydroxide. It is the sodium salt of fatty acids derived from Coconut oil, *Cocos nucifera*.

#### Ref. 1. 2 **Aqua**

Aqua (water) is a liquid at standard temperature and pressure with the chemical formula  $H_2O$ : one molecule of water has two hydrogen atoms covalently bonded to a single oxygen atom.

#### Ref. 1. 3 **Glycerin**

Glycerin, or glycerol, is a simple polyol compound, with three hydroxyl groups, which is a colourless, odourless, viscous liquid. Glycerin is naturally occurring in all animals and plant matter in combined form as glycerides in fats and oils, or, in intracellular spaces, as lipids. The glycerol backbone is central to all triglycerides, and its molecular formula is  $C_3H_8O_3$ . In December 2014 the Cosmetic Ingredient Review (CIR) Expert Panel also noted the high frequency of use that is reported for glycerin and the low instances of reports of toxicity, irritation, and sensitisation and that glycerin is GRAS for food packaging and as a multiple-purpose food substance. When considering the safety of glycerin, the Panel noted that it is naturally occurring in animal and human tissues, including the skin and blood. The data demonstrated low oral and dermal toxicity for multiple animal species and humans, in both acute and long-term studies. The CIR Expert Panel concluded that glycerin is safe in the present practices of use and concentration described in this safety assessment.

#### Ref. 1. 4 **Sodium citrate**

Sodium citrate is the sodium salt of citric acid with the molecular formula  $Na_3C_6H_5O_7$

#### Ref. 1. 5 **Chamomilla recutita flower**

Chamomilla recutita flower is the flower of *Chamomilla recutita* (L.), Asteraceae.

#### Ref. 1. 6 **Citrus limon peel oil**

Citrus limon peel oil is the volatile oil obtained from the fresh peel of the Lemon, *Citrus limon* (L.), Rutaceae.

#### Ref. 1. 7 **Lippia citriodora leaf oil**

Lippia citriodora leaf oil is the volatile oil obtained from the leaves of *Lippia citriodora*, Verbenaceae.

## 2. Physical & chemical properties and stability

### 2.1.1 Physical/chemical properties of ingredients (substances or mixtures)

See section 1. Quantitative and qualitative composition – additional specification of ingredients.

#### Ref. 1.8 **Sodium lactate**

Sodium lactate is the sodium salt of lactic acid with the molecular formula:  $C_3H_5NaO_3$ . The safety of sodium lactate was assessed by the Cosmetic Ingredient Review (CIR) Expert Panel in 1998. The CIR Expert Panel evaluated the scientific data and concluded that Sodium lactate, was safe for use in cosmetics and personal care products at concentrations of 10% or less, at final formulation pH of 3.5 or greater, when formulated to avoid increasing sun sensitivity or when directions for use include the daily use of sun protection. These ingredients were found safe for use in salon products at concentrations of 30% or less, at final formulation pH of 3.0 or greater, in products designed for brief, discontinuous use followed by thorough rinsing from the skin, when applied by trained professionals, and when application is accompanied by directions for the daily use of sun protection. In September 2013 the CIR Expert Panel looked at the new data and decided the data were not sufficient to re-open the report. The conclusion in the 1998 report was confirmed. Additionally, the US Food and Drug Administration (FDA) includes Sodium lactate on its list of substances considered Generally Recognised As Safe (GRAS) as direct food additives.

#### Ref. 1.9 **Zea mays starch**

Zea mays starch is a high-polymeric carbohydrate material usually derived from the peeled seeds of the Corn, *Zea mays* L., Gramineae.

#### Ref. 1.10 **Calendula officinalis flower**

Calendula officinalis flower is plant material derived from the flowers of the Calendula, *Calendula officinalis* L., Compositae.

The Food and Drug Administration (FDA) includes *Calendula officinalis* on its list of substances considered Generally Recognized As Safe (GRAS) as a spice and natural seasoning/ flavoring. The safety of *Calendula officinalis* flower has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated scientific data and concluded that *Calendula*-derived ingredients are safe as used in cosmetics and personal care products.

## **PART A – Cosmetic Product Safety Information** *continued*

### 2. Physical & chemical properties and stability *continued*

#### 2.1.2 Physical/chemical properties of the cosmetic product

<b>Appearance</b>	Solid/Pressed Powder
<b>Colour</b>	Yellow
<b>Aroma</b>	Citrus
<b>pH</b>	7.5

\*RP: Responsible Person: Dani & Jo Ltd

#### 2.2 Stability of the cosmetic product

The ingredients used in the production of the cosmetic product comply with the relevant legal regulations.

Both the product and constituent ingredients are stable under normal use and warehousing conditions during the entire time of the BBE period.

2.2.1 Dani & Jo Ltd confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 Dani & Jo Ltd uses a BBE based on the results of Dani & Jo Ltd's stability testing, including shelf life stability testing.

2.2.3 A Preservative Efficacy Test was not necessary since this is not a water-based product.

### 3. Microbiological quality

#### 3.1.1 Microbiological specification of ingredients (substances and mixtures).

Based on available information from the ingredient specification (see section 1. Quantitative and qualitative composition – specification of ingredients), the ingredients used can be assessed as microbiologically safe.

#### 3.1.2 Microbiological specification of the finished product

The given cosmetic product can be regarded as microbiologically safe for consumers' health

under the ISO 29621:2010 standard “Cosmetics -- Microbiology -- Guidelines for the risk assessment and identification of microbiologically low-risk products”.

The microbiological harmlessness of the ingredients and the cosmetic product is assessed according to COLIPA: Guideline for Microbiological Quality Management (MQM).

A Preservative Efficacy Test was not necessary since this is not a water-based product.

#### 4. Impurities, trace amounts of forbidden substances, & information about packaging material

##### 4.1 Impurities and trace amounts of forbidden substances

According to specifications (see section 2.1.1 Physical/chemical properties of ingredients (substances or mixtures) submitted by ingredient suppliers, the ingredients do not contain impurities or trace amounts of forbidden substances.

Any impurities or traces identified in any ingredient above standard tolerances are noted against each respective ingredient in section 2.1.1.

##### 4.2 Information about packaging material

The packaging material applied is suitable for the given type of cosmetic product and meets the predictable use requirements.

<b>Container</b>	Box
<b>Container Material</b>	Cardboard
<b>Airless Container</b>	No

Cardboard is a heavy-duty paper which ranges from a simple arrangement of a single thick sheet of paper to complex configurations featuring multiple corrugated and uncorrugated layers commonly used as a food container.

This material is safe for use in cosmetic packaging.

Dani & Jo Ltd confirms that the results of reference sample monitoring show no reaction between the packaging material and the product during the product's stated minimum useable life. During that life no changes to physical and chemical properties of the product were noticed that would affect its usability and safety.

5. Normal and reasonably foreseeable use

The current label advice:

*Not for human or animal consumption.*

The label of this cosmetic product should include this special note regarding its use, in compliance with Article 19(1)(d) of *Cosmetic Regulation* (EC) No. 1223/2009:

*For external use only. Keep out of reach of children.*

6. Exposure to the cosmetic product

Area of application	Body
Product type: Leave-on or Rinse-off	Rinse Off
Duration and frequency	1.43
Possible additional routes of exposure	Face
Estimated skin surface area (cm <sup>2</sup> )	17500
Estimated amount of the product applied according to the SCCS (g/day)	18.67 g
Estimated retention factor according to the SCCS	.01
Target group	Adult
Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	2.79

#### 8. Toxicological profile of the ingredients in the formulation - continued

Based on the calculation of MoS (Margin of Safety) for ingredients that can be classified as hazardous to human health, the product does not contain ingredients with toxicologically significant profiles in terms of consumer health.

An ingredient with an MoS above 1000 is considered safe. An ingredient with an MoS above 100 but lower than 1000 must be further considered by the assessor.

Since all of the ingredients have a margin of safety above 1,000 this product is considered safe for consumers to use.

#### 9. Undesirable effects and serious undesirable effects

The cosmetic product with a similar composition has been supplied to the market in the long term and until nowadays, no undesired effects to human health have been noticed in relation to the use of this product. Therefore, no undesired effects are anticipated at the common and reasonably predictable application of the given cosmetic product.

After its launch, the cosmetic product will be further monitored by Dani & Jo Ltd in accordance to procedures detailed in *Cosmetic Regulation* (EC) No 1223/2009. The safety of the product should be reviewed on a regular basis. To that end, undesirable and serious undesirable effects on human health during in market use of the product should be filed (complaints during normal and improper use, and the follow-up done) and details forwarded to the safety assessor.

The safety assessor will then update the Cosmetic Product Safety Report (CPSR) based on the new findings and the adopted corrective measures.

#### 10. Additional information on the product

No additional information is available and no additional studies were carried out.

## 11. References

- **THE SCCS'S NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC SUBSTANCES AND THEIR SAFETY EVALUATION 8TH REVISION**  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF>
- **MSDS of ingredients**
- **Commission Implementing Decision of 25<sup>th</sup> November 2013 Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products**
- **SCCS - Opinions**  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/opinions/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm)
- **CosIng: the European Commission database on cosmetic substances**  
<http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple>
- **REGULATION 1223/2009 ANNEXES**  
[http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=ref\\_data.annexes\\_v2](http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=ref_data.annexes_v2)



## **PART B – Cosmetic Product Safety Assessment**

### 1. Assessment conclusion

**Based on the information supplied, the cosmetic product detailed in this report is safe for human health when used in common or reasonably predictable conditions in compliance with the instructions provided for the consumer.**

This conclusion is only applicable to this cosmetic product with the composition, properties, purpose, and method of use of which are detailed in this documentation, and laboratory tests attached to this assessment, including the detailed production and labelling which has been assessed as meeting the requirements of *Cosmetic Regulation* (EC) No. 1223/2009 effective on the date this report was issued.

### 2. Labelled warnings and instructions of use

The label of this cosmetic product should include this special note regarding its use, in compliance with Article 19(1)(d) of *Cosmetic Regulation* (EC) No. 1223/2009:

*For external use only. Keep out of reach of children.*

Allergens present in this product and estimated amounts\*:

*Limonene: 0.9633858576%; Linalol: 0.0069881892%; Citral: 0.1996063056%; Citronellol: 0.001968504%; Geraniol: 0.006889764%; Eugenol: 0.0003937008%*

\* The presence of these allergens must be indicated in the list of ingredients when their concentration exceeds: 0.001% in leave-on products or 0.01% in rinse-off products. Only the allergen, not the estimated amount, is required on the label.

### 3. Reasoning

Based on the formulation of this cosmetic product, its qualitative and quantitative composition according to its INCI ingredients, basic physical and chemical characteristics and microbiology, Preservation Challenge Test performed, classification of the cosmetic product type, including its purpose and method of application, and available toxicological information and safety sheets of the ingredients used, the cosmetic product safety has been assessed for the consumer by assessing the toxicological profile of all ingredients, their chemical structure, exposure level and Margin of Safety (MoS) depending on the purpose of use in this cosmetic product.

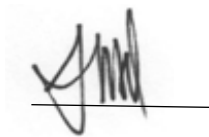
This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The evaluation of the entire composition and applied ingredient concentrations indicate that as a whole the composition of this cosmetic product complies with the requirements of *Cosmetic Regulation* (EC) No. 1223/2009 of the European Parliament and of the Council.

#### 4. Assessor's credentials and approval of Part B

Safety Assessor: Allison Wild  
Oxford Biosciences Ltd.  
The Oxford Science Park  
Magdalen Centre  
Oxfordshire  
OX4 4GA

#### Experience and qualifications:

- MSc in Clinical Pharmacology, University of Oxford
- 15+ years experience formulating cosmetic products
- Full member of the Society of Cosmetic Scientists (SCS)
- Member of the British Pharmacological Society



*Signature*

13 August 2021

*Date*

## COSMETIC PRODUCT SAFETY REPORT

**PRODUCT:** Coccole Body Soap Orange & Mandarin

**DATE:** 13 August 2021

Responsible Person: Giovanna Mantini



## 2. Physical & chemical properties and stability

### 2.1.1 Physical/chemical properties of ingredients (substances or mixtures)

See section 1. Quantitative and qualitative composition – additional specification of ingredients.

#### Ref. 1. 1 **Sodium cocoate**

Sodium cocoate is the product of the saponification of Coconut oil by Sodium hydroxide. It is the sodium salt of fatty acids derived from Coconut oil, *Cocos nucifera*.

#### Ref. 1. 2 **Aqua**

Aqua (water) is a liquid at standard temperature and pressure with the chemical formula  $H_2O$ : one molecule of water has two hydrogen atoms covalently bonded to a single oxygen atom.

#### Ref. 1. 3 **Glycerin**

Glycerin, or glycerol, is a simple polyol compound, with three hydroxyl groups, which is a colourless, odourless, viscous liquid. Glycerin is naturally occurring in all animals and plant matter in combined form as glycerides in fats and oils, or, in intracellular spaces, as lipids. The glycerol backbone is central to all triglycerides, and its molecular formula is  $C_3H_8O_3$ . In December 2014 the Cosmetic Ingredient Review (CIR) Expert Panel also noted the high frequency of use that is reported for glycerin and the low instances of reports of toxicity, irritation, and sensitisation and that glycerin is GRAS for food packaging and as a multiple-purpose food substance. When considering the safety of glycerin, the Panel noted that it is naturally occurring in animal and human tissues, including the skin and blood. The data demonstrated low oral and dermal toxicity for multiple animal species and humans, in both acute and long-term studies. The CIR Expert Panel concluded that glycerin is safe in the present practices of use and concentration described in this safety assessment.

#### Ref. 1. 4 **Sodium citrate**

Sodium citrate is the sodium salt of citric acid with the molecular formula  $Na_3C_6H_5O_7$

#### Ref. 1. 5 **Citrus aurantium dulcis peel oil**

Citrus aurantium dulcis peel oil is the volatile oil obtained by expression from the fresh peel of the ripe fruit of the sweet orange, *Citrus aurantium* var. *dulcis*, Rutaceae.

#### Ref. 1. 6 **Citrus nobilis peel oil**

Citrus nobilis peel oil is the oil expressed from the peel of the Mandarin, *Citrus nobilis*, Rutaceae.

#### Ref. 1. 7 **Solanum lycopersicum fruit extract**

Solanum lycopersicum fruit extract is an extract obtained from the fruit of the Tomato, *Solanum lycopersicum* L., Solanaceae.

## 2. Physical & chemical properties and stability

### 2.1.1 Physical/chemical properties of ingredients (substances or mixtures)

See section 1. Quantitative and qualitative composition – additional specification of ingredients.

#### Ref. 1.8 **Sodium lactate**

Sodium lactate is the sodium salt of lactic acid with the molecular formula:  $C_3H_5NaO_3$ . The safety of sodium lactate was assessed by the Cosmetic Ingredient Review (CIR) Expert Panel in 1998. The CIR Expert Panel evaluated the scientific data and concluded that Sodium lactate, was safe for use in cosmetics and personal care products at concentrations of 10% or less, at final formulation pH of 3.5 or greater, when formulated to avoid increasing sun sensitivity or when directions for use include the daily use of sun protection. These ingredients were found safe for use in salon products at concentrations of 30% or less, at final formulation pH of 3.0 or greater, in products designed for brief, discontinuous use followed by thorough rinsing from the skin, when applied by trained professionals, and when application is accompanied by directions for the daily use of sun protection. In September 2013 the CIR Expert Panel looked at the new data and decided the data were not sufficient to re-open the report. The conclusion in the 1998 report was confirmed. Additionally, the US Food and Drug Administration (FDA) includes Sodium lactate on its list of substances considered Generally Recognised As Safe (GRAS) as direct food additives.

#### Ref. 1.9 **Zea mays starch**

Zea mays starch is a high-polymeric carbohydrate material usually derived from the peeled seeds of the Corn, *Zea mays* L., Gramineae.

#### Ref. 1.10 **Citric acid**

Citric acid is a hygroscopic  $\alpha$  and  $\beta$  hydroxytricarboxylic acid, naturally found in citrus fruits, with the molecular formula  $C_6H_8O_7$ . Structurally Citric acid is an  $\alpha$ -hydroxy acid (AHA) and is a slightly stronger acid than typical carboxylic acids because the anion can be stabilised by intramolecular hydrogen-bonding from other protic groups on citric acid. Industrial Citric acid is produced by mycological fermentation of crude sugar stocks by strains of *Aspergillus niger*. The FDA has listed Citrus acid as Generally Recognized As Safe (GRAS) and it is commonly used in the food industry as an acidifier and flavouring agent and has the food additive number E330. In 2014 the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Citric acid is safe in the present practices of use and concentration, as described in this safety assessment.

## PART A – Cosmetic Product Safety Information *continued*

### 2. Physical & chemical properties and stability *continued*

#### 2.1.2 Physical/chemical properties of the cosmetic product

<b>Appearance</b>	Solid/Pressed Powder
<b>Colour</b>	Orange
<b>Aroma</b>	Citrus
<b>pH</b>	7.5

\*RP: Responsible Person: Dani & Jo Ltd

#### 2.2 Stability of the cosmetic product

The ingredients used in the production of the cosmetic product comply with the relevant legal regulations.

Both the product and constituent ingredients are stable under normal use and warehousing conditions during the entire time of the BBE period.

2.2.1 Dani & Jo Ltd confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 Dani & Jo Ltd uses a BBE based on the results of Dani & Jo Ltd's stability testing, including shelf life stability testing.

2.2.3 A Preservative Efficacy Test was not necessary since this is not a water-based product.

### 3. Microbiological quality

#### 3.1.1 Microbiological specification of ingredients (substances and mixtures).

Based on available information from the ingredient specification (see section 1. Quantitative and qualitative composition – specification of ingredients), the ingredients used can be assessed as microbiologically safe.

#### 3.1.2 Microbiological specification of the finished product

The given cosmetic product can be regarded as microbiologically safe for consumers' health

under the ISO 29621:2010 standard “Cosmetics -- Microbiology -- Guidelines for the risk assessment and identification of microbiologically low-risk products”.

The microbiological harmlessness of the ingredients and the cosmetic product is assessed according to COLIPA: Guideline for Microbiological Quality Management (MQM).

A Preservative Efficacy Test was not necessary since this is not a water-based product.

#### 4. Impurities, trace amounts of forbidden substances, & information about packaging material

##### 4.1 Impurities and trace amounts of forbidden substances

According to specifications (see section 2.1.1 Physical/chemical properties of ingredients (substances or mixtures) submitted by ingredient suppliers, the ingredients do not contain impurities or trace amounts of forbidden substances.

Any impurities or traces identified in any ingredient above standard tolerances are noted against each respective ingredient in section 2.1.1.

##### 4.2 Information about packaging material

The packaging material applied is suitable for the given type of cosmetic product and meets the predictable use requirements.

<b>Container</b>	Box
<b>Container Material</b>	Cardboard
<b>Airless Container</b>	No

Cardboard is a heavy-duty paper which ranges from a simple arrangement of a single thick sheet of paper to complex configurations featuring multiple corrugated and uncorrugated layers commonly used as a food container.

This material is safe for use in cosmetic packaging.

Dani & Jo Ltd confirms that the results of reference sample monitoring show no reaction between the packaging material and the product during the product's stated minimum useable life. During that life no changes to physical and chemical properties of the product were noticed that would affect its usability and safety.

5. Normal and reasonably foreseeable use

The current label advice:

*Not for human or animal consumption.*

The label of this cosmetic product should include this special note regarding its use, in compliance with Article 19(1)(d) of *Cosmetic Regulation* (EC) No. 1223/2009:

*For external use only. Keep out of reach of children.*

6. Exposure to the cosmetic product

Area of application	Body
Product type: Leave-on or Rinse-off	Rinse Off
Duration and frequency	1.43
Possible additional routes of exposure	Face
Estimated skin surface area (cm <sup>2</sup> )	17500
Estimated amount of the product applied according to the SCCS (g/day)	18.67 g
Estimated retention factor according to the SCCS	.01
Target group	Adult
Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	2.79



#### 8. Toxicological profile of the ingredients in the formulation - continued

Based on the calculation of MoS (Margin of Safety) for ingredients that can be classified as hazardous to human health, the product does not contain ingredients with toxicologically significant profiles in terms of consumer health.

An ingredient with an MoS above 1000 is considered safe. An ingredient with an MoS above 100 but lower than 1000 must be further considered by the assessor.

Since all of the ingredients have a margin of safety above 1,000 this product is considered safe for consumers to use.

#### 9. Undesirable effects and serious undesirable effects

The cosmetic product with a similar composition has been supplied to the market in the long term and until nowadays, no undesired effects to human health have been noticed in relation to the use of this product. Therefore, no undesired effects are anticipated at the common and reasonably predictable application of the given cosmetic product.

After its launch, the cosmetic product will be further monitored by Dani & Jo Ltd in accordance to procedures detailed in *Cosmetic Regulation* (EC) No 1223/2009. The safety of the product should be reviewed on a regular basis. To that end, undesirable and serious undesirable effects on human health during in market use of the product should be filed (complaints during normal and improper use, and the follow-up done) and details forwarded to the safety assessor.

The safety assessor will then update the Cosmetic Product Safety Report (CPSR) based on the new findings and the adopted corrective measures.

#### 10. Additional information on the product

No additional information is available and no additional studies were carried out.

## 11. References

- **THE SCCS'S NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC SUBSTANCES AND THEIR SAFETY EVALUATION 8TH REVISION**  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF>
- **MSDS of ingredients**
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- **SCCS - Opinions**  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/opinions/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm)
- **CosIng: the European Commission database on cosmetic substances**  
<http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple>
- **REGULATION 1223/2009 ANNEXES**  
[http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=ref\\_data.annexes\\_v2](http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=ref_data.annexes_v2)

## **PART B – Cosmetic Product Safety Assessment**

### 1. Assessment conclusion

**Based on the information supplied, the cosmetic product detailed in this report is safe for human health when used in common or reasonably predictable conditions in compliance with the instructions provided for the consumer.**

This conclusion is only applicable to this cosmetic product with the composition, properties, purpose, and method of use of which are detailed in this documentation, and laboratory tests attached to this assessment, including the detailed production and labelling which has been assessed as meeting the requirements of *Cosmetic Regulation* (EC) No. 1223/2009 effective on the date this report was issued.

### 2. Labelled warnings and instructions of use

The label of this cosmetic product should include this special note regarding its use, in compliance with Article 19(1)(d) of *Cosmetic Regulation* (EC) No. 1223/2009:

*For external use only. Keep out of reach of children.*

Allergens present in this product and estimated amounts\*:

*Limonene: 1.59461181%; Linalol: 0.008869905%*

\* The presence of these allergens must be indicated in the list of ingredients when their concentration exceeds: 0.001% in leave-on products or 0.01% in rinse-off products. Only the allergen, not the estimated amount, is required on the label.

### 3. Reasoning

Based on the formulation of this cosmetic product, its qualitative and quantitative composition according to its INCI ingredients, basic physical and chemical characteristics and microbiology, Preservation Challenge Test performed, classification of the cosmetic product type, including its purpose and method of application, and available toxicological information and safety sheets of the ingredients used, the cosmetic product safety has been assessed for the consumer by assessing the toxicological profile of all ingredients, their chemical structure, exposure level and Margin of Safety (MoS) depending on the purpose of use in this cosmetic product.

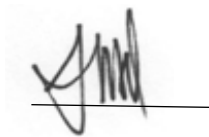
This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The evaluation of the entire composition and applied ingredient concentrations indicate that as a whole the composition of this cosmetic product complies with the requirements of *Cosmetic Regulation* (EC) No. 1223/2009 of the European Parliament and of the Council.

#### 4. Assessor's credentials and approval of Part B

Safety Assessor: Allison Wild  
Oxford Biosciences Ltd.  
The Oxford Science Park  
Magdalen Centre  
Oxfordshire  
OX4 4GA

#### Experience and qualifications:

- MSc in Clinical Pharmacology, University of Oxford
- 15+ years experience formulating cosmetic products
- Full member of the Society of Cosmetic Scientists (SCS)
- Member of the British Pharmacological Society



*Signature*

13 August 2021

*Date*

## COSMETIC PRODUCT SAFETY REPORT

**PRODUCT:** Coccole Body Soap Ylang Ylang & Tea Tree

**DATE:** 13 August 2021

Responsible Person: Giovanna Mantini



## 2. Physical & chemical properties and stability

### 2.1.1 Physical/chemical properties of ingredients (substances or mixtures)

See section 1. Quantitative and qualitative composition – additional specification of ingredients.

#### Ref. 1. 1 **Sodium cocoate**

Sodium cocoate is the product of the saponification of Coconut oil by Sodium hydroxide. It is the sodium salt of fatty acids derived from Coconut oil, *Cocos nucifera*.

#### Ref. 1. 2 **Aqua**

Aqua (water) is a liquid at standard temperature and pressure with the chemical formula  $H_2O$ : one molecule of water has two hydrogen atoms covalently bonded to a single oxygen atom.

#### Ref. 1. 3 **Glycerin**

Glycerin, or glycerol, is a simple polyol compound, with three hydroxyl groups, which is a colourless, odourless, viscous liquid. Glycerin is naturally occurring in all animals and plant matter in combined form as glycerides in fats and oils, or, in intracellular spaces, as lipids. The glycerol backbone is central to all triglycerides, and its molecular formula is  $C_3H_8O_3$ . In December 2014 the Cosmetic Ingredient Review (CIR) Expert Panel also noted the high frequency of use that is reported for glycerin and the low instances of reports of toxicity, irritation, and sensitisation and that glycerin is GRAS for food packaging and as a multiple-purpose food substance. When considering the safety of glycerin, the Panel noted that it is naturally occurring in animal and human tissues, including the skin and blood. The data demonstrated low oral and dermal toxicity for multiple animal species and humans, in both acute and long-term studies. The CIR Expert Panel concluded that glycerin is safe in the present practices of use and concentration described in this safety assessment.

#### Ref. 1. 4 **Sodium citrate**

Sodium citrate is the sodium salt of citric acid with the molecular formula  $Na_3C_6H_5O_7$

#### Ref. 1. 5 **Cananga odorata flower oil**

Cananga odorata flower oil is the oil obtained from the flower, *Cananga odorata*, Anonaceae. The majority of constituents are sesquiterpenes, esters and monoterpenols.

#### Ref. 1. 6 **Melaleuca alternifolia leaf oil**

Melaleuca alternifolia leaf oil is the oil distilled from the leaves of the Tea tree, *Melaleuca alternifolia*, Myrtaceae.

#### Ref. 1. 7 **Papaver somniferum seed**

Papaver somniferum seed is the seed of the Opium poppy, *Papaver somniferum* L., Papaveraceae.

## 2. Physical & chemical properties and stability

### 2.1.1 Physical/chemical properties of ingredients (substances or mixtures)

See section 1. Quantitative and qualitative composition – additional specification of ingredients.

#### Ref. 1. 8 **Sodium lactate**

Sodium lactate is the sodium salt of lactic acid with the molecular formula:  $C_3H_5NaO_3$ . The safety of sodium lactate was assessed by the Cosmetic Ingredient Review (CIR) Expert Panel in 1998. The CIR Expert Panel evaluated the scientific data and concluded that Sodium lactate, was safe for use in cosmetics and personal care products at concentrations of 10% or less, at final formulation pH of 3.5 or greater, when formulated to avoid increasing sun sensitivity or when directions for use include the daily use of sun protection. These ingredients were found safe for use in salon products at concentrations of 30% or less, at final formulation pH of 3.0 or greater, in products designed for brief, discontinuous use followed by thorough rinsing from the skin, when applied by trained professionals, and when application is accompanied by directions for the daily use of sun protection. In September 2013 the CIR Expert Panel looked at the new data and decided the data were not sufficient to re-open the report. The conclusion in the 1998 report was confirmed. Additionally, the US Food and Drug Administration (FDA) includes Sodium lactate on its list of substances considered Generally Recognised As Safe (GRAS) as direct food additives.

#### Ref. 1. 9 **Zea mays starch**

Zea mays starch is a high-polymeric carbohydrate material usually derived from the peeled seeds of the Corn, *Zea mays* L., Gramineae.

#### Ref. 1. 10 **Montmorillonite**

Montmorillonite is a very soft phyllosilicate group of minerals that typically form in microscopic crystals, forming a clay.

The safety of Montmorillonite has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient was safe as used in cosmetics and personal care products.

#### Ref. 1. 11 **Illite**

Illite is a clay mineral having an intermediate composition between montmorillonite and muscovite.

#### Ref. 1. 12 **Kaolin**

Kaolin (kaolinite) is a naturally occurring clay mineral with the chemical composition  $Al_2Si_2O_5(OH)_4$ . It is a layered silicate mineral, with one tetrahedral sheet linked through oxygen atoms to one octahedral sheet of alumina octahedra.

## PART A – Cosmetic Product Safety Information *continued*

### 2. Physical & chemical properties and stability *continued*

#### 2.1.2 Physical/chemical properties of the cosmetic product

<b>Appearance</b>	Solid/Pressed Powder
<b>Colour</b>	Pink
<b>Aroma</b>	Sweet
<b>pH</b>	7.5

\*RP: Responsible Person: Dani & Jo Ltd

#### 2.2 Stability of the cosmetic product

The ingredients used in the production of the cosmetic product comply with the relevant legal regulations.

Both the product and constituent ingredients are stable under normal use and warehousing conditions during the entire time of the BBE period.

2.2.1 Dani & Jo Ltd confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 Dani & Jo Ltd uses a BBE based on the results of Dani & Jo Ltd's stability testing, including shelf life stability testing.

2.2.3 A Preservative Efficacy Test was not necessary since this is not a water-based product.

### 3. Microbiological quality

#### 3.1.1 Microbiological specification of ingredients (substances and mixtures).

Based on available information from the ingredient specification (see section 1. Quantitative and qualitative composition – specification of ingredients), the ingredients used can be assessed as microbiologically safe.

#### 3.1.2 Microbiological specification of the finished product

The given cosmetic product can be regarded as microbiologically safe for consumers' health



under the ISO 29621:2010 standard “Cosmetics -- Microbiology -- Guidelines for the risk assessment and identification of microbiologically low-risk products”.

The microbiological harmlessness of the ingredients and the cosmetic product is assessed according to COLIPA: Guideline for Microbiological Quality Management (MQM).

A Preservative Efficacy Test was not necessary since this is not a water-based product.

#### 4. Impurities, trace amounts of forbidden substances, & information about packaging material

##### 4.1 Impurities and trace amounts of forbidden substances

According to specifications (see section 2.1.1 Physical/chemical properties of ingredients (substances or mixtures) submitted by ingredient suppliers, the ingredients do not contain impurities or trace amounts of forbidden substances.

Any impurities or traces identified in any ingredient above standard tolerances are noted against each respective ingredient in section 2.1.1.

##### 4.2 Information about packaging material

The packaging material applied is suitable for the given type of cosmetic product and meets the predictable use requirements.

<b>Container</b>	Box
<b>Container Material</b>	Cardboard
<b>Airless Container</b>	No

Cardboard is a heavy-duty paper which ranges from a simple arrangement of a single thick sheet of paper to complex configurations featuring multiple corrugated and uncorrugated layers commonly used as a food container.

This material is safe for use in cosmetic packaging.

Dani & Jo Ltd confirms that the results of reference sample monitoring show no reaction between the packaging material and the product during the product's stated minimum useable life. During that life no changes to physical and chemical properties of the product were noticed that would affect its usability and safety.

5. Normal and reasonably foreseeable use

The current label advice:

*Not for human or animal consumption.*

The label of this cosmetic product should include this special note regarding its use, in compliance with Article 19(1)(d) of *Cosmetic Regulation* (EC) No. 1223/2009:

*For external use only. Keep out of reach of children.*

6. Exposure to the cosmetic product

Area of application	Body
Product type: Leave-on or Rinse-off	Rinse Off
Duration and frequency	1.43
Possible additional routes of exposure	Face
Estimated skin surface area (cm <sup>2</sup> )	17500
Estimated amount of the product applied according to the SCCS (g/day)	18.67 g
Estimated retention factor according to the SCCS	.01
Target group	Adult
Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	2.79

#### 8. Toxicological profile of the ingredients in the formulation - continued

Based on the calculation of MoS (Margin of Safety) for ingredients that can be classified as hazardous to human health, the product does not contain ingredients with toxicologically significant profiles in terms of consumer health.

An ingredient with an MoS above 1000 is considered safe. An ingredient with an MoS above 100 but lower than 1000 must be further considered by the assessor.

Since all of the ingredients have a margin of safety above 1,000 this product is considered safe for consumers to use.

#### 9. Undesirable effects and serious undesirable effects

The cosmetic product with a similar composition has been supplied to the market in the long term and until nowadays, no undesired effects to human health have been noticed in relation to the use of this product. Therefore, no undesired effects are anticipated at the common and reasonably predictable application of the given cosmetic product.

After its launch, the cosmetic product will be further monitored by Dani & Jo Ltd in accordance to procedures detailed in *Cosmetic Regulation* (EC) No 1223/2009. The safety of the product should be reviewed on a regular basis. To that end, undesirable and serious undesirable effects on human health during in market use of the product should be filed (complaints during normal and improper use, and the follow-up done) and details forwarded to the safety assessor.

The safety assessor will then update the Cosmetic Product Safety Report (CPSR) based on the new findings and the adopted corrective measures.

#### 10. Additional information on the product

No additional information is available and no additional studies were carried out.

## 11. References

- **THE SCCS'S NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC SUBSTANCES AND THEIR SAFETY EVALUATION 8TH REVISION**  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF>
- **MSDS of ingredients**
- **Commission Implementing Decision of 25<sup>th</sup> November 2013 Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products**
- **SCCS - Opinions**  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/opinions/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm)
- **CosIng: the European Commission database on cosmetic substances**  
<http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple>
- **REGULATION 1223/2009 ANNEXES**  
[http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=ref\\_data.annexes\\_v2](http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=ref_data.annexes_v2)

## **PART B – Cosmetic Product Safety Assessment**

### 1. Assessment conclusion

**Based on the information supplied, the cosmetic product detailed in this report is safe for human health when used in common or reasonably predictable conditions in compliance with the instructions provided for the consumer.**

This conclusion is only applicable to this cosmetic product with the composition, properties, purpose, and method of use of which are detailed in this documentation, and laboratory tests attached to this assessment, including the detailed production and labelling which has been assessed as meeting the requirements of *Cosmetic Regulation* (EC) No. 1223/2009 effective on the date this report was issued.

### 2. Labelled warnings and instructions of use

The label of this cosmetic product should include this special note regarding its use, in compliance with Article 19(1)(d) of *Cosmetic Regulation* (EC) No. 1223/2009:

*For external use only. Keep out of reach of children.*

Allergens present in this product and estimated amounts\*:

*Geraniol: 0.0116524056%; Linalol: 0.0550033044%; Farnesol: 0.0210335796%; Benzyl Benzoate: 0.0710006748%; Benzyl Salicylate: 0.0191573448%; Eugenol: 0.005431206%; Limonene: 0.010862412%*

\* The presence of these allergens must be indicated in the list of ingredients when their concentration exceeds: 0.001% in leave-on products or 0.01% in rinse-off products. Only the allergen, not the estimated amount, is required on the label.

### 3. Reasoning

Based on the formulation of this cosmetic product, its qualitative and quantitative composition according to its INCI ingredients, basic physical and chemical characteristics and microbiology, Preservation Challenge Test performed, classification of the cosmetic product type, including its purpose and method of application, and available toxicological information and safety sheets of the ingredients used, the cosmetic product safety has been assessed for the consumer by assessing the toxicological profile of all ingredients, their chemical structure, exposure level and Margin of Safety (MoS) depending on the purpose of use in this cosmetic product.

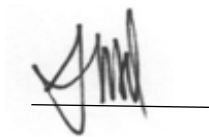
This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The evaluation of the entire composition and applied ingredient concentrations indicate that as a whole the composition of this cosmetic product complies with the requirements of *Cosmetic Regulation* (EC) No. 1223/2009 of the European Parliament and of the Council.

#### 4. Assessor's credentials and approval of Part B

Safety Assessor: Allison Wild  
Oxford Biosciences Ltd.  
The Oxford Science Park  
Magdalen Centre  
Oxfordshire  
OX4 4GA

#### Experience and qualifications:

- MSc in Clinical Pharmacology, University of Oxford
- 15+ years experience formulating cosmetic products
- Full member of the Society of Cosmetic Scientists (SCS)
- Member of the British Pharmacological Society



*Signature*

13 August 2021

*Date*

## COSMETIC PRODUCT SAFETY REPORT

**PRODUCT:** Coccole Body Soap Rosemary & Peppermint

**DATE:** 13 August 2021

Responsible Person: Giovanna Mantini



## 2. Physical & chemical properties and stability

### 2.1.1 Physical/chemical properties of ingredients (substances or mixtures)

See section 1. Quantitative and qualitative composition – additional specification of ingredients.

#### Ref. 1. 1 **Sodium cocoate**

Sodium cocoate is the product of the saponification of Coconut oil by Sodium hydroxide. It is the sodium salt of fatty acids derived from Coconut oil, *Cocos nucifera*.

#### Ref. 1. 2 **Aqua**

Aqua (water) is a liquid at standard temperature and pressure with the chemical formula  $H_2O$ : one molecule of water has two hydrogen atoms covalently bonded to a single oxygen atom.

#### Ref. 1. 3 **Glycerin**

Glycerin, or glycerol, is a simple polyol compound, with three hydroxyl groups, which is a colourless, odourless, viscous liquid. Glycerin is naturally occurring in all animals and plant matter in combined form as glycerides in fats and oils, or, in intracellular spaces, as lipids. The glycerol backbone is central to all triglycerides, and its molecular formula is  $C_3H_8O_3$ . In December 2014 the Cosmetic Ingredient Review (CIR) Expert Panel also noted the high frequency of use that is reported for glycerin and the low instances of reports of toxicity, irritation, and sensitisation and that glycerin is GRAS for food packaging and as a multiple-purpose food substance. When considering the safety of glycerin, the Panel noted that it is naturally occurring in animal and human tissues, including the skin and blood. The data demonstrated low oral and dermal toxicity for multiple animal species and humans, in both acute and long-term studies. The CIR Expert Panel concluded that glycerin is safe in the present practices of use and concentration described in this safety assessment.

#### Ref. 1. 4 **Sodium citrate**

Sodium citrate is the sodium salt of citric acid with the molecular formula  $Na_3C_6H_5O_7$

#### Ref. 1. 5 **Spinacia oleracea leaf**

Spinacia oleracea leaf is the leaves of Spinach, *Spinacia oleracea* L., Chenopodiaceae.

#### Ref. 1. 6 **Rosmarinus officinalis leaf oil**

Rosmarinus officinalis leaf oil is the essential oil obtained from the flowering tops and leaves of the Rosemary, *Rosmarinus officinalis* L., Lamiaceae. The majority of constituents are monoterpenes and oxides.



## 2. Physical & chemical properties and stability

### 2.1.1 Physical/chemical properties of ingredients (substances or mixtures)

See section 1. Quantitative and qualitative composition – additional specification of ingredients.

#### Ref. 1.7 **Mentha piperita oil**

Mentha piperita oil is the volatile oil obtained from the whole plant of the Peppermint, *Mentha piperita* (L.), Labiatae.

The Food and Drug Administration (FDA) includes peppermint on its list of spices and other natural seasonings and flavoring considered Generally Recognized As Safe (GRAS). Peppermint is also on the list of GRAS essential oils, oleoresins and natural extractives. The safety of *Mentha piperita* oil has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that *Mentha piperita* oil was safe as used in cosmetics and personal care products.

#### Ref. 1.8 **Sodium lactate**

Sodium lactate is the sodium salt of lactic acid with the molecular formula:  $C_3H_5NaO_3$ . The safety of sodium lactate was assessed by the Cosmetic Ingredient Review (CIR) Expert Panel in 1998. The CIR Expert Panel evaluated the scientific data and concluded that Sodium lactate, was safe for use in cosmetics and personal care products at concentrations of 10% or less, at final formulation pH of 3.5 or greater, when formulated to avoid increasing sun sensitivity or when directions for use include the daily use of sun protection. These ingredients were found safe for use in salon products at concentrations of 30% or less, at final formulation pH of 3.0 or greater, in products designed for brief, discontinuous use followed by thorough rinsing from the skin, when applied by trained professionals, and when application is accompanied by directions for the daily use of sun protection. In September 2013 the CIR Expert Panel looked at the new data and decided the data were not sufficient to re-open the report. The conclusion in the 1998 report was confirmed. Additionally, the US Food and Drug Administration (FDA) includes Sodium lactate on its list of substances considered Generally Recognised As Safe (GRAS) as direct food additives.

#### Ref. 1.9 **Zea mays starch**

Zea mays starch is a high-polymeric carbohydrate material usually derived from the peeled seeds of the Corn, *Zea mays* L., Gramineae.

## **PART A – Cosmetic Product Safety Information** *continued*

### 2. Physical & chemical properties and stability *continued*

#### 2.1.2 Physical/chemical properties of the cosmetic product

<b>Appearance</b>	Solid/Pressed Powder
<b>Colour</b>	Green
<b>Aroma</b>	Fresh
<b>pH</b>	7.5

\*RP: Responsible Person: Dani & Jo Ltd

#### 2.2 Stability of the cosmetic product

The ingredients used in the production of the cosmetic product comply with the relevant legal regulations.

Both the product and constituent ingredients are stable under normal use and warehousing conditions during the entire time of the BBE period.

2.2.1 Dani & Jo Ltd confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 Dani & Jo Ltd uses a BBE based on the results of Dani & Jo Ltd's stability testing, including shelf life stability testing.

2.2.3 A Preservative Efficacy Test was not necessary since this is not a water-based product.

### 3. Microbiological quality

3.1.1 Microbiological specification of ingredients (substances and mixtures).

Based on available information from the ingredient specification (see section 1. Quantitative and qualitative composition – specification of ingredients), the ingredients used can be assessed as microbiologically safe.

3.1.2 Microbiological specification of the finished product

The given cosmetic product can be regarded as microbiologically safe for consumers' health

under the ISO 29621:2010 standard “Cosmetics -- Microbiology -- Guidelines for the risk assessment and identification of microbiologically low-risk products”.

The microbiological harmlessness of the ingredients and the cosmetic product is assessed according to COLIPA: Guideline for Microbiological Quality Management (MQM).

A Preservative Efficacy Test was not necessary since this is not a water-based product.

#### 4. Impurities, trace amounts of forbidden substances, & information about packaging material

##### 4.1 Impurities and trace amounts of forbidden substances

According to specifications (see section 2.1.1 Physical/chemical properties of ingredients (substances or mixtures) submitted by ingredient suppliers, the ingredients do not contain impurities or trace amounts of forbidden substances.

Any impurities or traces identified in any ingredient above standard tolerances are noted against each respective ingredient in section 2.1.1.

##### 4.2 Information about packaging material

The packaging material applied is suitable for the given type of cosmetic product and meets the predictable use requirements.

<b>Container</b>	Box
<b>Container Material</b>	Cardboard
<b>Airless Container</b>	No

Cardboard is a heavy-duty paper which ranges from a simple arrangement of a single thick sheet of paper to complex configurations featuring multiple corrugated and uncorrugated layers commonly used as a food container.

This material is safe for use in cosmetic packaging.

Dani & Jo Ltd confirms that the results of reference sample monitoring show no reaction between the packaging material and the product during the product's stated minimum useable life. During that life no changes to physical and chemical properties of the product were noticed that would affect its usability and safety.

5. Normal and reasonably foreseeable use

The current label advice:

*Not for human or animal consumption.*

The label of this cosmetic product should include this special note regarding its use, in compliance with Article 19(1)(d) of *Cosmetic Regulation* (EC) No. 1223/2009:

*For external use only. Keep out of reach of children.*

6. Exposure to the cosmetic product

Area of application	Body
Product type: Leave-on or Rinse-off	Rinse Off
Duration and frequency	1.43
Possible additional routes of exposure	Face
Estimated skin surface area (cm <sup>2</sup> )	17500
Estimated amount of the product applied according to the SCCS (g/day)	18.67 g
Estimated retention factor according to the SCCS	.01
Target group	Adult
Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	2.79

#### 8. Toxicological profile of the ingredients in the formulation - continued

Based on the calculation of MoS (Margin of Safety) for ingredients that can be classified as hazardous to human health, the product does not contain ingredients with toxicologically significant profiles in terms of consumer health.

An ingredient with an MoS above 1000 is considered safe. An ingredient with an MoS above 100 but lower than 1000 must be further considered by the assessor.

Since all of the ingredients have a margin of safety above 1,000 this product is considered safe for consumers to use.

#### 9. Undesirable effects and serious undesirable effects

The cosmetic product with a similar composition has been supplied to the market in the long term and until nowadays, no undesired effects to human health have been noticed in relation to the use of this product. Therefore, no undesired effects are anticipated at the common and reasonably predictable application of the given cosmetic product.

After its launch, the cosmetic product will be further monitored by Dani & Jo Ltd in accordance to procedures detailed in *Cosmetic Regulation* (EC) No 1223/2009. The safety of the product should be reviewed on a regular basis. To that end, undesirable and serious undesirable effects on human health during in market use of the product should be filed (complaints during normal and improper use, and the follow-up done) and details forwarded to the safety assessor.

The safety assessor will then update the Cosmetic Product Safety Report (CPSR) based on the new findings and the adopted corrective measures.

#### 10. Additional information on the product

No additional information is available and no additional studies were carried out.

## 11. References

- **THE SCCS'S NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC SUBSTANCES AND THEIR SAFETY EVALUATION 8TH REVISION**  
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF>
- **MSDS of ingredients**
- **Commission Implementing Decision of 25<sup>th</sup> November 2013 Guidelines on Annex I to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products**
- **SCCS - Opinions**  
[http://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/opinions/index\\_en.htm](http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm)
- **CosIng: the European Commission database on cosmetic substances**  
<http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple>
- **REGULATION 1223/2009 ANNEXES**  
[http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=ref\\_data.annexes\\_v2](http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=ref_data.annexes_v2)

## **PART B – Cosmetic Product Safety Assessment**

### 1. Assessment conclusion

**Based on the information supplied, the cosmetic product detailed in this report is safe for human health when used in common or reasonably predictable conditions in compliance with the instructions provided for the consumer.**

This conclusion is only applicable to this cosmetic product with the composition, properties, purpose, and method of use of which are detailed in this documentation, and laboratory tests attached to this assessment, including the detailed production and labelling which has been assessed as meeting the requirements of *Cosmetic Regulation* (EC) No. 1223/2009 effective on the date this report was issued.

### 2. Labelled warnings and instructions of use

The label of this cosmetic product should include this special note regarding its use, in compliance with Article 19(1)(d) of *Cosmetic Regulation* (EC) No. 1223/2009:

*For external use only. Keep out of reach of children.*

Allergens present in this product and estimated amounts\*:

*Limonene: 0.062286444%; Linalol: 0.0105453315%; Citronellol: 0.0004927725%; Eugenol: 0.0000985545%*

\* The presence of these allergens must be indicated in the list of ingredients when their concentration exceeds: 0.001% in leave-on products or 0.01% in rinse-off products. Only the allergen, not the estimated amount, is required on the label.

### 3. Reasoning

Based on the formulation of this cosmetic product, its qualitative and quantitative composition according to its INCI ingredients, basic physical and chemical characteristics and microbiology, Preservation Challenge Test performed, classification of the cosmetic product type, including its purpose and method of application, and available toxicological information and safety sheets of the ingredients used, the cosmetic product safety has been assessed for the consumer by assessing the toxicological profile of all ingredients, their chemical structure, exposure level and Margin of Safety (MoS) depending on the purpose of use in this cosmetic product.

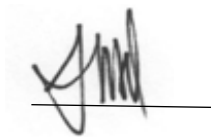
This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The evaluation of the entire composition and applied ingredient concentrations indicate that as a whole the composition of this cosmetic product complies with the requirements of *Cosmetic Regulation* (EC) No. 1223/2009 of the European Parliament and of the Council.

#### 4. Assessor's credentials and approval of Part B

Safety Assessor: Allison Wild  
Oxford Biosciences Ltd.  
The Oxford Science Park  
Magdalen Centre  
Oxfordshire  
OX4 4GA

#### Experience and qualifications:

- MSc in Clinical Pharmacology, University of Oxford
- 15+ years experience formulating cosmetic products
- Full member of the Society of Cosmetic Scientists (SCS)
- Member of the British Pharmacological Society



*Signature*

13 August 2021

*Date*