OXFORD BIOSCIENCES
Safety Assessment, Analysis, Research & Testing

Oxford Biosciences Ltd.
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COSMETIC PRODUCT SAFETY REPORT

PRODUCT: Roses Face & Body Cream with Patchouli

DATE: 19 October 2020

Responsible Person: Giovanna Mantini
Dani & Jo Ltd
[redacted]

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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 **Rosa damascena flower water**

Rosa damascena flower water is the distillate obtained from the flowers of the Damask rose, Rosa damascena, Rosaceae.

Ref. 1. 2 **Prunus armeniaca kernel oil**

Prunus armeniaca kernel oil, Apricot kernel oil, is the fixed oil expressed from the kernels of the Apricot, Prunus armeniaca L., Rosaceae. The oil comprises predominantly unsaturated fatty acids (oleic and linoleic) as well as traces of vitamin E and carotenoids.

Typical fatty acid profile:

Oleic acid	58 - 72 %
Linoleic acid	22 - 32.5 %
Palmitic acid	3 -8%
Palmitoleic acid	Max. 1.5 %
Stearic acid	Max. 3.5 %
Linolenic acid	Max. 0.8 %

Ref. 1. 3 **Butyrospermum parkii butter**

Butyrospermum parkii butter is the fat obtained from the fruit of the Shea tree, Butyrospermum parkii, Sapotaceae. The tree has been recently reclassified as Vitellaria paradoxa although the INCI name still remains Butyrospermum parkii butter.

About 85 to 90% of the fatty acid composition is stearic and oleic acids.

Typical fatty acid profile:

oleic acid (40-60%)
stearic acid (20-50%)
linoleic acid (3-11%)
palmitic acid (2-9%)
linolenic acid (<1%)
arachidic acid (<1%)

In March 2011, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Butyrospermum parkii butter is safe in the present practices of use and concentration described in this safety assessment.

Ref. 1. 4 **Cetearyl olivate**

Cetearyl olivate is the ester of Cetearyl alcohol and the fatty acids derived from olive oil.

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

Ref. 1. 5 **Sorbitan olivate**

Sorbitan olivate is a sorbitan fatty acid ester formed by the esterification of sorbitan with the wax obtained by partial hydrogenation of olive oil. It is an ivory-coloured, waxy solid at 20°C with a slight, characteristic odour. The melting point is 52°C to 55°C. Sorbitan olivate has acid, iodine, and saponification values of 10 to 12,3.0 (maximum), and 155 to 165, respectively. It is soluble in ethanol, almost soluble in vegetable oils, and dispersible in warm water.

The CIR (Cosmetic Ingredient Review) Expert Panel reviewed the safety of Sorbitan olivate in 2002 and concluded that it is safe for use in cosmetic formulations under the present practices of use.

Ref. 1. 6 **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. 7 **Pogostemon cablin oil**

Pogostemon cablin oil is the volatile oil obtained from the Patchouli, Pogostemon cablin, Labiatae.

Ref. 1. 8 **Tocopherol**

Tocopherol is a series organic compounds with vitamin E activity consisting of various methylated phenols which feature a chromanol ring, with a free hydroxyl group on the aromatic ring that can donate a hydrogen atom to reduce free radicals, and a hydrophobic side chain which allows for penetration into biological membranes.

The Food and Drug Administration (FDA) includes Tocopherol on its list of nutrients considered Generally Recognized As Safe (GRAS).

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

Ref. 1. 9 **Benzyl alcohol**

Benzyl alcohol is an aromatic alcohol with the formula C_7H_8O. Benzyl Alcohol is used as a food additive, in OTC drug preparations, and in clinical settings. It is a membrane fluidiser and a local anesthetic. Benzyl alcohol is metabolised to Benzoic acid, which is then conjugated with glycine and excreted as hippuric acid. EPA reviews of mouse and rat oral-dosing studies conducted by the NTP determined subchronic and chronic oral reference doses for humans of 1 and 0.3 mg/kg/day, respectively. The WHO established an ADI of up to 5 mg/kg. Investigators considered Benzyl alcohol to be a moderate respiratory hazard and toxic when administered by the parenteral route. It produced severe irritation when applied to the skin of nude mice. In clinical settings, Benzyl alcohol can produce nonimmunologic contact urticaria or nonimmunologic immediate contact reactions. It was not a sensitiser when tested in a maximisation test at 10% in petrolatum, and demonstrated a low incidence of sensitisation in provocation studies. Based on the available data, the Cosmetic Ingredient Review (CIR) Expert Panel concluded in 2001, and reconfirmed their conclusion in 2011, that Benzyl alcohol is safe for use in cosmetic formulations at concentrations up to 5% although Cosmetics Europe limits its maximum usage to 1%.

Ref. 1. 10 **Helianthus annuus seed oil**

Helianthus annuus seed oil is the edible oil expressed from the seeds of the Sunflower, Helianthus annuus L., Compositae.

Sunflower oil is a monounsaturated (MUFA)/polyunsaturated (PUFA) mixture of mostly oleic acid (omega-9)-linoleic acid (omega-6) group of oils. Sunflower oil is mainly a triglyceride edible oil which the FDA has classed as GRAS. The British Pharmacopoeia lists the fatty acid profile as:

Palmitic acid (saturated): 4–9%
Stearic acid (saturated): 1–7%
Oleic acid (monounsaturated omega-9): 14–40%
Linoleic acid (polyunsaturated omega-6): 48–74%

In March 2011, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Helianthus annuus seed oil is safe in the present practices of use and concentration described in this safety assessment.

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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. 11 **Salicylic acid**

Salicylic acid is an aromatic monohydroxybenzoic acid (2-hydroxybenzoic acid), a crystalline organic acid that can be derived from salicin (a β-glucoside in willow bark) with the formula $C_6H_4(OH)COOH$, where the OH group is ortho to the carboxyl group. Salicylic acid is prohibited in products for children under three years old, unless used in a shampoo.

In 2003 the safety of Salicylic acid was assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated scientific data and concluded that Salicylic acid was safe as used when formulated to avoid skin irritation and when formulated to avoid increasing the skin's sun sensitivity, or, when increased sun sensitivity would be expected, directions for use include the daily use of sun protection.

A Scientific Committee on Consumer Safety (SCCS) 2018 Final Opinion on Salicylic acid supports the Cosmetic Europe's concentration limits in ready-for-use cosmetic preparations of 3% in rinse-off hair products and 2% in other products.

In June 2019 the CIR Expert Panel re-reviewed Salicylic acid and concluded it is safe in cosmetics in the present practices of use and concentration described in the safety assessment, when formulated to be non-irritating and non-sensitising, which may be based on a quantitative risk assessment (QRA).

Ref. 1. 12 **Sorbic acid**

Sorbic acid is straight-chain monocarboxylic acid with the molecular formula $C_6H_8O_2$. Specifically, Sorbic acid is a hexadienoic acid with double bonds at C-2 and C-4; it has four geometrical isomers, of which the trans,trans-form is naturally occurring. It is a polyunsaturated fatty acid, a medium-chain fatty acid and an alpha,beta-unsaturated monocarboxylic acid, a conjugate acid of a sorbate. Sorbic acid occurs naturally as the lactone, parasorbic acid, in berries of the mountain ash, Sorbus aucuparia L., Rosaceae. It can be synthesised by various processes, which include condensation of crotonaldehyde and acetic or malonic acid in pyridine solution, condensation of crotonaldehyde and ketene in the presence of boron trifluoride, preparation from 1,1,3,5-tetraalkoxyhexane, and dealkanolation and hydrolysis of a 3,5-dialkoxyhexanal dialkyl acetal under oxidative conditions. The trans,transisomer is usually obtained and is the commercial product. Sorbic acid is also used as a food preservative and has the e number E200. The FDA has conferred Generally Recognised as Safe (GRAS) status to Sorbic acid. In 1988, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Sorbic acid is safe in the present practices of use and concentration described in this safety assessment. In 2008 The CIR Expert Panel reconfirmed the 1988 decision.

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PART A – Cosmetic Product Safety Information *continued*

2. Physical & chemical properties and stability *continued*

2.1.2 Physical/chemical properties of the cosmetic product

Appearance	Cream/Paste/Gel
Colour	White
Aroma	Floral
pH	n/a

*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 This product was subjected to Preservative Efficacy Testing and proved that it did not support microbial growth. PET reference: OB PET 2145

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.

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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).

This product was subjected to Preservative Efficacy Testing and proved that it did not support microbial growth. PET reference: OB PET 2145

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 1. Quantitative and qualitative composition – specification of ingredients) submitted by ingredient suppliers, the ingredients do not contain impurities or trace amounts of forbidden substances.

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.

Container	Tin
Container Material	Epoxy phenolic lined aluminium
Airless Container	No

EPA is an epoxy phenolic resin. Phenolic resins are prepared by the reaction of phenol or substituted phenol with an aldehyde, especially formaldehyde, in the presence of an acidic or basic catalyst. With a large global production representing 1-5 million tonnes/year, these resins are ubiquitous and therefore have a long history of safe use. EPA polymers are high modulus, relatively heat resistant, and have good properties against chemical leaching.

The supplier provided test results which confirmed the epoxy did not leach into products in the containers.

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.

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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. Not to be used on children under 3yrs.

6. Exposure to the cosmetic product

Area of application	Body
Product type: Leave-on or Rinse-off	Leave On
Duration and frequency	2.28
Possible additional routes of exposure	Face
Estimated skin surface area (cm^2)	15670
Estimated amount of the product applied according to the SCCS (g/day)	7.82 g
Estimated retention factor according to the SCCS	1
Target group	Adult
Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	123.2

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8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name	MOS
1	Rosa damascena flower water	255.17450
2	Prunus armeniaca kernel oil	1633.11690
3	Butyrospermum parkii butter	3266.23370
4	Glycerin	5068.29290
5	Pogostemon cablin oil	4082.79130
6	Cetearyl olivate	1134.10890
7	Sorbitan olivate	1701.16330
8	Tocopherol	5832.56070
9	Helianthus annuus seed oil	13609295.29240
10	Benzyl alcohol	1946.44920
11	Salicylic acid	23589.52430
12	Sorbic acid	250409.77380

***MOS**: Margin of Safety*

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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.

In line with WHO guidelines, recommending a minimum value of 100, it is generally accepted that the MoS should at least be 100 to conclude that a substance is safe for use. Since the ingredients used in this formulation have a long worldwide history of use and have an MOS value above 200 then the conclusion is that they are safe for use in this formulation.

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.

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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 25th 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
- 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

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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. Not to be used on children under 3yrs.

Allergens present in this product and estimated amounts*:

Benzyl Alcohol: 0.512922%

* 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.

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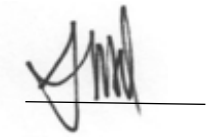
4. Assessor's credentials and approval of Part B

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
- 10+ years experience formulating cosmetic products
- Full member of the Society of Cosmetic Scientists (SCS)
- Member of the British Pharmacological Society



Signature

19 October 2020

Date

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COSMETIC PRODUCT SAFETY REPORT

PRODUCT: Roses Face & Body Cream with Geranium and Grapefruit

DATE: 19 October 2020

Responsible Person: Giovanna Mantini
Dani & Jo Ltd
[redacted]

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Ref. 1. 2 **Prunus armeniaca kernel oil**

Prunus armeniaca kernel oil, Apricot kernel oil, is the fixed oil expressed from the kernels of the Apricot, Prunus armeniaca L., Rosaceae. The oil comprises predominantly unsaturated fatty acids (oleic and linoleic) as well as traces of vitamin E and carotenoids.

Typical fatty acid profile:

Oleic acid	58 - 72 %
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Palmitic acid	3 -8%
Palmitoleic acid	Max. 1.5 %
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Linolenic acid	Max. 0.8 %

Ref. 1. 3 **Butyrospermum parkii butter**

Butyrospermum parkii butter is the fat obtained from the fruit of the Shea tree, Butyrospermum parkii, Sapotaceae. The tree has been recently reclassified as Vitellaria paradoxa although the INCI name still remains Butyrospermum parkii butter.

About 85 to 90% of the fatty acid composition is stearic and oleic acids.

Typical fatty acid profile:

oleic acid (40-60%)
stearic acid (20-50%)
linoleic acid (3-11%)
palmitic acid (2-9%)
linolenic acid (<1%)
arachidic acid (<1%)

In March 2011, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Butyrospermum parkii butter is safe in the present practices of use and concentration described in this safety assessment.

Ref. 1. 4 **Cetearyl olivate**

Cetearyl olivate is the ester of Cetearyl alcohol and the fatty acids derived from olive oil.

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2. Physical & chemical properties and stability

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The CIR (Cosmetic Ingredient Review) Expert Panel reviewed the safety of Sorbitan olivate in 2002 and concluded that it is safe for use in cosmetic formulations under the present practices of use.

Ref. 1. 6 **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. 7 **Tocopherol**

Tocopherol is a series organic compounds with vitamin E activity consisting of various methylated phenols which feature a chromanol ring, with a free hydroxyl group on the aromatic ring that can donate a hydrogen atom to reduce free radicals, and a hydrophobic side chain which allows for penetration into biological membranes.

The Food and Drug Administration (FDA) includes Tocopherol on its list of nutrients considered Generally Recognized As Safe (GRAS).

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Ref. 1. 9 **Pelargonium graveolens oil**

Pelargonium graveloens oil is is the volatile oil obtained from the whole plant of the Bourbon geranium, Pelargonium graveolens (L.), Geraniaceae.

Ref. 1. 10 **Citrus paradisi peel oil**

Citrus paradisi peel oil is the volatile oil from the peel of the grapefruit, Citrus paradisi, Rutaceae. The majority of constituents are monoterpenes.

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

Ref. 1. 11 **Helianthus annuus seed oil**

Helianthus annuus seed oil is the edible oil expressed from the seeds of the Sunflower, Helianthus annuus L., Compositae.

Sunflower oil is a monounsaturated (MUFA)/polyunsaturated (PUFA) mixture of mostly oleic acid (omega-9)-linoleic acid (omega-6) group of oils. Sunflower oil is mainly a triglyceride edible oil which the FDA has classed as GRAS. The British Pharmacopoeia lists the fatty acid profile as:

Palmitic acid (saturated): 4–9%
Stearic acid (saturated): 1–7%
Oleic acid (monounsaturated omega-9): 14–40%
Linoleic acid (polyunsaturated omega-6): 48–74%

In March 2011, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Helianthus annuus seed oil is safe in the present practices of use and concentration described in this safety assessment.

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Salicylic acid is an aromatic monohydroxybenzoic acid (2-hydroxybenzoic acid), a crystalline organic acid that can be derived from salicin (a β-glucoside in willow bark) with the formula $C_6H_4(OH)COOH$, where the OH group is ortho to the carboxyl group. Salicylic acid is prohibited in products for children under three years old, unless used in a shampoo.

In 2003 the safety of Salicylic acid was assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated scientific data and concluded that Salicylic acid was safe as used when formulated to avoid skin irritation and when formulated to avoid increasing the skin's sun sensitivity, or, when increased sun sensitivity would be expected, directions for use include the daily use of sun protection.

A Scientific Committee on Consumer Safety (SCCS) 2018 Final Opinion on Salicylic acid supports the Cosmetic Europe's concentration limits in ready-for-use cosmetic preparations of 3% in rinse-off hair products and 2% in other products.

In June 2019 the CIR Expert Panel re-reviewed Salicylic acid and concluded it is safe in cosmetics in the present practices of use and concentration described in the safety assessment, when formulated to be non-irritating and non-sensitising, which may be based on a quantitative risk assessment (QRA).

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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. 13 **Sorbic acid**

Sorbic acid is straight-chain monocarboxylic acid with the molecular formula $C_6H_8O_2$. Specifically, Sorbic acid is a hexadienoic acid with double bonds at C-2 and C-4; it has four geometrical isomers, of which the trans,trans-form is naturally occurring. It is a polyunsaturated fatty acid, a medium-chain fatty acid and an alpha,beta-unsaturated monocarboxylic acid, a conjugate acid of a sorbate. Sorbic acid occurs naturally as the lactone, parasorbic acid, in berries of the mountain ash, Sorbus aucuparia L., Rosaceae. It can be synthesised by various processes, which include condensation of crotonaldehyde and acetic or malonic acid in pyridine solution, condensation of crotonaldehyde and ketene in the presence of boron trifluoride, preparation from 1,1,3,5-tetraalkoxyhexane, and dealkanolation and hydrolysis of a 3,5-dialkoxyhexanal dialkyl acetal under oxidative conditions. The trans,transisomer is usually obtained and is the commercial product. Sorbic acid is also used as a food preservative and has the e number E200. The FDA has conferred Generally Recognised as Safe (GRAS) status to Sorbic acid. In 1988, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Sorbic acid is safe in the present practices of use and concentration described in this safety assessment. In 2008 The CIR Expert Panel reconfirmed the 1988 decision.

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PART A – Cosmetic Product Safety Information *continued*

2. Physical & chemical properties and stability *continued*

2.1.2 Physical/chemical properties of the cosmetic product

Appearance	Cream/Paste/Gel
Colour	White
Aroma	Floral
pH	4.5-5.5

*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 This product was subjected to Preservative Efficacy Testing and proved that it did not support microbial growth. PET reference: OB PET 2145

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.

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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).

This product was subjected to Preservative Efficacy Testing and proved that it did not support microbial growth. PET reference: OB PET 2145

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 1. Quantitative and qualitative composition – specification of ingredients) submitted by ingredient suppliers, the ingredients do not contain impurities or trace amounts of forbidden substances.

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.

Container	Tin
Container Material	Epoxy phenolic lined aluminium
Airless Container	No

EPA is an epoxy phenolic resin. Phenolic resins are prepared by the reaction of phenol or substituted phenol with an aldehyde, especially formaldehyde, in the presence of an acidic or basic catalyst. With a large global production representing 1-5 million tonnes/year, these resins are ubiquitous and therefore have a long history of safe use. EPA polymers are high modulus, relatively heat resistant, and have good properties against chemical leaching.

The supplier provided test results which confirmed the epoxy did not leach into products in the containers.

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.

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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. Not to be used on children under 3yrs.

6. Exposure to the cosmetic product

Area of application	Body
Product type: Leave-on or Rinse-off	Leave On
Duration and frequency	2.28
Possible additional routes of exposure	Face
Estimated skin surface area (cm^2)	15670
Estimated amount of the product applied according to the SCCS (g/day)	7.82 g
Estimated retention factor according to the SCCS	1
Target group	Adult
Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	123.2

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8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name	MOS
1	Rosa damascena flower water	255.17450
2	Prunus armeniaca kernel oil	1633.11690
3	Butyrospermum parkii butter	3266.23370
4	Glycerin	5068.29290
5	Pelargonium graveolens oil	8165.58270
6	Cetearyl olivate	1134.10890
7	Sorbitan olivate	1701.16330
8	Tocopherol	5832.56070
9	Helianthus annuus seed oil	13609295.29240
10	Benzyl alcohol	1946.44920
11	Salicylic acid	23589.52430
12	Sorbic acid	250409.77380
13	Citrus paradisi peel oil	8165.58270

***MOS**: Margin of Safety*

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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.

In line with WHO guidelines, recommending a minimum value of 100, it is generally accepted that the MoS should at least be 100 to conclude that a substance is safe for use. Since the ingredients used in this formulation have a long worldwide history of use and have an MOS value above 200 then the conclusion is that they are safe for use in this formulation.

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.

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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 25th 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
- 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

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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. Not to be used on children under 3yrs.

Allergens present in this product and estimated amounts*:

Citral: 0.008200797%; Citronellol: 0.17892648%; Geraniol: 0.08946324%; Limonene: 0.5121273472%; Benzyl Alcohol: 0.512922%

* 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.

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4. Assessor's credentials and approval of Part B

Safety Assessor: Allison Wild
Oxford Biosciences Ltd.
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Oxfordshire
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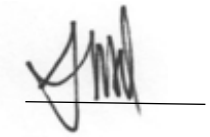
Experience and qualifications:

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



Signature

19 October 2020

Date