

## COSMETIC PRODUCT SAFETY REPORT

**PRODUCT:** Dulcis Hand Cream

**DATE:** 15 August 2019

Responsible Person: Giovanna Mantini

**Dani & Jo Ltd**

BN11 2HH



## 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 **Prunus amygdalus dulcis oil**

Prunus amygdalus dulcis oil, Sweet almond oil, is the fixed oil obtained from the ripe seed kernel of the sweet almond tree, Prunus amygdalus var. dulcis, Rosaceae. The oil comprises approximately 62% monounsaturated oleic acid (an omega-9 fatty acid), 29% linoleic acid (a polyunsaturated omega-6 essential fatty acid), and 9% saturated fatty acid.

The safety of Prunus amygdalus dulcis (Sweet almond) oil has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated scientific data and concluded that Prunus amygdalus dulcis (Sweet almond) oil was safe for topical application to humans in the present practices of use and concentration. In 2002, as part of the scheduled re-evaluation of ingredients, the CIR Expert Panel considered available new data on Prunus amygdalus dulcis (Sweet almond) oil and reaffirmed the above conclusion.

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

## 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. 1.3 **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 **Rosa damascena flower water**

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

#### Ref. 1.5 **Euphorbia cerifera cera**

Euphorbia cerifera cera is a wax obtained from the Candelilla, Euphorbia cerifera, Euphorbiaceae.

The Food and Drug Administration (FDA) includes Candelilla wax, on its list of substances considered Generally Recognized As Safe (GRAS) for direct addition to food. The safety of plant waxes has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Euphorbia cerifera (Candelilla) wax was safe for use in cosmetics and personal care products. In 2003, the CIR Expert Panel considered available new data on this ingredient and reaffirmed the above conclusion.

#### Ref. 1.6 **Pelargonium graveolens flower oil**

Pelargonium graveolens flower oil is the volatile oil obtained from the flowers of the Bourbon geranium, Pelargonium graveolens (L.), Geraniaceae.

#### Ref. 1.7 **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.

## 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 **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).

#### Ref. 1. 9 **Polysorbate 20**

Polysorbate 20 is a polysorbate surfactant. It is a polyoxyethylene derivative of sorbitan monolaurate, distinguished from the other members in the polysorbate range by the length of the polyoxyethylene chain and the fatty acid ester moiety. Molecular formula:  $C_{58}H_{114}O_{26}$ .

#### Ref. 1. 10 **Citric acid**

Citric acid is a hygroscopic carboxylic acid, found in citrus fruits, with the formula  $C_6H_8O_7$ . Citric acid 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. Citrus acid is commonly used in the food industry as an acidifier and flavouring agent and has the food additive number E330.

#### Ref. 1. 11 **Potassium benzoate**

Potassium benzoate, or E212) is the potassium salt of benzoic acid, It works best in low-pH products, below 4.5, where it exists as benzoic acid. Potassium benzoate naturally occur in some foods such as berries, cranberries, apples and cinnamon.

#### Ref. 1. 12 **Rosa damascena flower oil**

Rosa damascena flower oil is the volatile oil obtained from the flowers of the Damask rose, *Rosa damascena*, Rosaceae.

## PART A – Cosmetic Product Safety Inform*i continued*

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

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

<b>Appearance</b>	Cream/Paste/Gel
<b>Colour</b>	Cream
<b>Aroma</b>	Fresh
<b>pH</b>	4.5 - 5.0

\*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 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.

<b>Container</b>	Jar
<b>Container Material</b>	Glass
<b>Airless Container</b>	No

Glass is resilient and resistant to most solvents and represents a low hazard in terms of chemical leaching. Glass can be attacked by weak acids or bases and thus can leach sodium and calcium ions into the cosmetic product.

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	Hand
Product type: Leave-on or Rinse-off	Leave On
Duration and frequency	2
Possible additional routes of exposure	Body
Estimated skin surface area (cm <sup>2</sup> )	860
Estimated amount of the product applied according to the SCCS (g/day)	2.16 g
Estimated retention factor according to the SCCS	1
Target group	Adult
Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	32.700000000000003

#### 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 ingredient used in this formulation is edible and has an MOS value above 100 then the conclusion is that it is 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.



## 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 Asses:**

### 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: 0.00258923192%; Limonene: 0.000120461592%; Linalol: 0.000077538496%; Farnesol: 0.000095538504%*

\* 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.

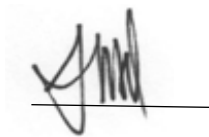
This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The 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
- 10+ years experience formulating cosmetic products
- Full member of the Society of Cosmetic Scientists (SCS)
- Member of the British Pharmacological Society



*Signature*

15 August 2019

*Date*