

## COSMETIC PRODUCT SAFETY REPORT

**PRODUCT:** ReviHelo

**DATE:** 16 July 2024

Responsible Person: Eunice Opong  
Lifestyle and Medical Practice Ltd  
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Bracknell  
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## PART A – Cosmetic Product Safety Information

### 1. Quantitative and qualitative composition

	<b>Ingredient INCI name</b>	<b>CAS</b>	<b>Function</b>	<b>Limits</b>	<b>Amount</b>
1	Vitis vinifera seed oil	84929-27-1 /	Emollient, skin conditioning		40.000000
2	Corylus avellana seed oil	84012-21-5 /	Fragrance		35.000000
3	Simmondsia chinensis seed oil	90045-98-0	Emollient, hair conditioning,		13.000000
4	Triticum vulgare germ oil	68917-73-7 /	Emollient, skin conditioning		10.000000
5	Citrus bergamia peel oil expressed	89957-91-5	Perfuming		1.000000
6	Pelargonium graveolens oil	90082-51-2	Fragrance, perfuming		0.500000
7	Piper nigrum fruit oil	84929-41-9	Fragrance , perfuming		0.500000

#### Allergens present in this product and estimated amounts\*:

Citral: 0.007%; Geraniol: 0.101%; Limonene: 0.56005%; Linalol: 0.2562%; Citronellol: 0.19%

\* 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

## 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 **Vitis vinifera seed oil**

Vitis vinifera seed oil is the fixed oil, consisting primarily of the glycerides of the fatty acids, obtained by pressing the seeds of the red grape, Vitis vinifera L., Vitaceae.

Typical fatty acid profile of grape seed oil:

Linoleic acid ( $\omega$ -6, unsaturated)	69.6%
Oleic acid ( $\omega$ -9, unsaturated)	15.8%
Palmitic acid (saturated)	7.0%
Stearic acid (saturated)	4.0%
Palmitoleic acid ( $\omega$ -7, unsaturated)	<1.0%
$\alpha$ -linolenic acid ( $\omega$ -3, unsaturated)	0.1%

The total phytosterol concentrations range between 5179 and 5480 mg/kg, where beta-sytosterol represents more than the 66% in grape seed oils.

The alpha and gamma isomers of the tocotrienols account for more than the 80% of the tocochromanols present in the oil, while the tocopherols represented only 10%. The deep green colour observed in the oil is due to the presence of chlorophylls and other vegetable pigments.

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

#### Ref. 1. 2 **Corylus avellana seed oil**

Corylus avellana seed oil is the edible oil expressed from the nuts of the hazelnut, Corylus avellana L., Betulaceae.

Typical fatty acid profile:

Palmitic	C16:0	4.0- 8.0 %
Palmitoleic	C16:1	0.1 - 0.6 %
Stearic	C18:0	1.5 - 3.5 %
Oleic	C18:1	68.0 - 85.0 %
Linoleic	C18:2	7.0 - 15.0 %
Linolenic	C18:3	0.1 - 0.5 %
Arachidic	C20:0	0.1 - 0.5 %
Gadoleic	C20:1	0.1 - 0.3 %
Behenic	C22:0	3.0 % MAX

The safety of Corylus avellana seed (hazelnut) oil has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded in December 2010 that Corylus avellana seed (hazelnut) oil was safe for use as used in cosmetics and personal care products.

## 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 **Simmondsia chinensis seed oil**

Simmondsia chinensis seed oil is the fixed oil expressed or extracted from seeds of the desert shrub, Jojoba, Simmondsia chinensis, Buxaceae.

Simmondsia chinensis (Jojoba) seed oil is obtained by pressing the seed kernels of an evergreen shrub native to the Sonoran and Mojave deserts of Arizona, California and Mexico. This oil is different from other common plant oils in that it is composed almost completely (97%) of wax esters of monounsaturated, straight-chain acids and alcohols with high molecular weights (carbon chain lengths from 36 to 46). This makes Jojoba Oil and its derivative Jojoba Esters more similar to sebum and whale oil than to traditional vegetable oils.

#### Ref. 1.4 **Triticum vulgare germ oil**

Triticum vulgare (wheat) germ oil is the oil obtained from the expression or extraction of the Wheat germ, Triticum vulgare, Poaceae. Wheat germ oil is extracted from the germ of the wheat kernel, which makes up only 2.5% by weight of the kernel and is relatively high in vitamin E ( $\alpha$ -tocopherol) at 255 mg/100g.

Typical fatty acid composition:

Linoleic acid (omega-6)	55%
Palmitic acid	16%
Oleic acid	14%
Linolenic acid (omega-3)	7%

The safety of Triticum vulgare (wheat) germ oil has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Triticum vulgare (wheat) germ oil was safe as a cosmetic ingredient in the present practices of use and concentration. In 2001, as part of the scheduled re-evaluation of ingredients, the CIR Expert Panel considered available new data on this ingredient and reaffirmed the above conclusion.

#### Ref. 1.5 **Citrus bergamia peel oil expressed**

Citrus bergamia peel oil expressed is an essential oil expressed from the epicarps of the Bergamot, Citrus bergamia risso, Rutaceae. The majority of constituents are monoterpenes and esters such as 35-45% l-linalyl acetate, about 6% linalol, d-limonene, dl-limonene and bergaptene.

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

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

## 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 **Piper nigrum fruit oil**

Piper nigrum fruit oil is the volatile oil distilled from the dried ripe fruit of Black Pepper, *Piper nigrum* L., Piperaceae.

## **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>	Liquid
<b>Colour</b>	Transparent
<b>Aroma</b>	Oriental
<b>pH</b>	n/a

\*RP: Responsible Person: Lifestyle and Medical Practice 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 PAO 12M period.

2.2.1 Lifestyle and Medical Practice Ltd confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 Lifestyle and Medical Practice Ltd uses a PAO 12M based on the results of Lifestyle and Medical Practice 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>	Bottle
<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.

Lifestyle and Medical Practice 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:

*At the beginning of love-making, each partner should massage the oil onto the other, beginning from the shoulder and whole back. (Note: It takes longer for ladies to be turned on therefore LADIES FIRST PLEASE)*

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	Leave On
Duration and frequency	2.28
Possible additional routes of exposure	Face
Estimated skin surface area (cm <sup>2</sup> )	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



## 7. Exposure to the ingredients

	Ingredient INCI name	Concentration	SED
1	Vitis vinifera seed oil	0.40000	49.28000
2	Corylus avellana seed oil	0.35000	43.12000
3	Simmondsia chinensis seed oil	0.13000	16.01600
4	Triticum vulgare germ oil	0.10000	12.32000
5	Citrus bergamia peel oil expressed	0.01000	1.23200
6	Pelargonium graveolens oil	0.00500	0.61600
7	Piper nigrum fruit oil	0.00500	0.61600

*SED: Systemic Exposure Dose*

8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name	MOS
1	Vitis vinifera seed oil	202.92210
2	Corylus avellana seed oil	115.95550
3	Simmondsia chinensis seed oil	624.37560
4	Triticum vulgare germ oil	405.84420
5	Citrus bergamia peel oil expressed	9350.64940
6	Pelargonium graveolens oil	8116.88310
7	Piper nigrum fruit oil	8116.88310

*MOS: Margin of Safety*

#### 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 100 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 Lifestyle and Medical Practice 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](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\*:

*Citral: 0.007%; Geraniol: 0.101%; Limonene: 0.56005%; Linalol: 0.2562%; Citronellol: 0.19%*

\* 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.

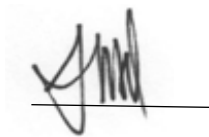
This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The 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*

16 July 2024

*Date*