

COSMETIC PRODUCT SAFETY REPORT

PRODUCT: ReviHelax Soap

DATE: 6 October 2023

Responsible Person: Eunice Opong
Lifestyle and Medical Practice Ltd
34 Dukeshill Road
Bracknell
Berkshire RG42 2DT



PART A – Cosmetic Product Safety Information

1. Quantitative and qualitative composition

	Ingredient INCI name	CAS	Function	Limits	Amount
1	Sodium olivate	61789-88-6	Cleansing, emulsifying,		20.77
2	Sodium palmate	61790-79-2	Cleansing, emulsifying,		20.77
3	Sodium cocoa butterate		Cleansing, surfactant		10.38
4	Sodium cocoate	61789-31-9	Cleansing, emulsifying,		10.38
5	Aqua	7732-18-5	Solvent		8.6525
6	Glycerin	56-81-5	Denaturant, hair		7.2534
7	Sodium shea butterate		Cleansing, emulsifying,		3.46
8	Sodium castorate	8013-06-7	Emulsifying, surfactant		3.46
9	Honey	8028-66-8	Flavouring, humectant, skin		0.92
10	Cymbopogon flexuosus oil	91844-92-7	Fragrance		0.66
11	Lavandula angustifolia oil - Bay House	8000-28-0 /	Fragrance, tonic		0.66
12	Cymbopogon citratus leaf powder	89998-14-1	Humectant, skin		0.33

Allergens present in this product and estimated amounts*:

Linalol: 0.245256%; Geraniol: 0.20526%; Citronellol: 0.15906%; Citral: 0.15774%; Coumarin: 0.00066%; Limonene: 0.0033%

* 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 **Sodium olivate**

Sodium olivate is the product of the saponification of Olive oil by Sodium hydroxide. Sodium olivate is the sodium salt of olive oil, *Olea europaea*, Lamiales.

Ref. 1. 2 **Sodium palmate**

Sodium palmate is the product of the saponification of palm oil by sodium hydroxide. It the sodium salt of fatty acids derived from the oil palm, *Elaeis guineensis*.

Ref. 1. 3 **Sodium cocoa butterate**

Sodium cocoa butterate is the product of the saponification of Cocoa butter by Sodium hydroxide. It is the sodium salt of the fatty acids derived from Cocoa butter, *Theobroma cacao*.

Ref. 1. 4 **Sodium cocoate**

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

Ref. 1. 5 **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. 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.

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 **Sodium shea butterate**

Sodium shea butterate is the product of the saponification of Shea butter by Sodium hydroxide. It is the sodium salt of the fatty acids derived from Shea butter, *Butyrospermum parkii*.

Ref. 1. 8 **Sodium castorate**

Sodium castorate is the product of the saponification of castor oil by Sodium hydroxide. Sodium castorate is the sodium salt of the fatty acids derived from Castor oil, *Ricinus communis*.

Ref. 1. 9 **Honey**

Honey, a naturally occurring substance, is the edible saccharic secretion gathered and stored by honey bees, *Apis mellifera*.

Honey has long been consumed in foods and as an ingredient of food and beverages. The primary sugars of honey are also found as components of food and are considered to be Generally Recognized As Safe (GRAS) by the Food and Drug Administration (FDA).

Ref. 1. 10 **Cymbopogon flexuosus oil**

Cymbopogon flexuosus oil is the volatile oil obtained from the dried Lemongrass, *Cymbopogon flexuosus*, Poaceae.

Ref. 1. 11 **Lavandula angustifolia oil - Bay House Aromatics 06.07.21**

Lavandula angustifolia oil is the volatile oil obtained by the steam distillation of the flowers of the Lavender, *Lavandula angustifolia*, Labiatae. The majority of constituents are monoterpenols and esters.

Ref. 1. 12 **Cymbopogon citratus leaf powder**

Cymbopogon citratus leaf powder is the powder obtained from the dried, ground leaves of the Lemon Grass, *Cymbopogon citratus*, Poaceae.

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	Solid/Pressed Powder
Colour	Off white/brown/green
Aroma	Oriental
pH	7.0 - 8.0

*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.

Container	Box
Container Material	Cardboard
Airless Container	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.

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:

Use with warm water to create a lather. Avoid contact with eyes. If product enters the eyes, rinse well.

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 ²)	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

7. Exposure to the ingredients

	Ingredient INCI name	Concentration	SED
1	Aqua	0.08653	0.00241
2	Sodium shea butterate	0.03460	0.00097
3	Sodium cocoa butterate	0.10380	0.00290
4	Sodium castorate	0.03460	0.00097
5	Sodium olivate	0.20770	0.00579
6	Sodium palmate	0.20770	0.00579
7	Sodium cocoate	0.10380	0.00290
8	Honey	0.00920	0.00026
9	Cymbopogon flexuosus oil	0.00660	0.00018
10	Lavandula angustifolia oil - Bay House Aromatics	0.00660	0.00018
11	Cymbopogon citratus leaf powder	0.00330	0.00009
12	Glycerin	0.07253	0.00202

SED: Systemic Exposure Dose

8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name	MOS
1	Aqua	41424205.61320
2	Sodium shea butterate	2071808.89630
3	Sodium cocoa butterate	690602.96540
4	Sodium castorate	2071808.89630
5	Sodium olivate	345135.23260
6	Sodium palmate	345135.23260
7	Sodium cocoate	690602.96540
8	Honey	115708274.89480
9	Cymbopogon flexuosus oil	27153252.95970
10	Lavandula angustifolia oil - Bay House Aromatics 06.07.21	23080265.01570
11	Cymbopogon citratus leaf powder	54306505.91940
12	Glycerin	6226223.60860

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.

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 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 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

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*:

Linalol: 0.245256%; Geraniol: 0.20526%; Citronellol: 0.15906%; Citral: 0.15774%; Coumarin: 0.00066%; Limonene: 0.0033%

* 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.

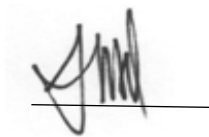
This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The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

6 October 2023

Date