

## COSMETIC PRODUCT SAFETY REPORT

**PRODUCT:** ReviHydrate Cream

**DATE:** 6 October 2023

Responsible Person: Eunice Opong  
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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	Aqua	7732-18-5	Solvent		50.249
2	Chamomilla recutita flower water	84082-60-0	Fragrance		10.00
3	Glycerin	56-81-5	Denaturant, hair		5.80
4	Carthamus tinctorius seed oil	8001-23-8	Fragrance, skin		3.999905
5	Vitis vinifera seed oil	84929-27-1 /	Emollient, skin conditioning		3.999905
6	Theobroma cacao seed butter	84649-99-0 /	Emollient, fragrance, skin		3.00
7	Cannabis sativa seed oil	89958-21-4	Emollient, skin conditioning		3.00
8	Triticum vulgare germ oil	68917-73-7 /	Emollient, skin conditioning		2.9955
9	Cetearyl olivate		Hair conditioning		2.70
10	Sorbitan olivate	223706-40-9	Emulsifying		2.675
11	Mangifera indica seed butter	90063-86-8	Skin conditioning		2.50
12	Butyrospermum parkii butter	194043-92-0	Skin conditioning, viscosity		2.00
13	Persea gratissima oil	8024-32-6	Skin conditioning		2.00
14	Cetyl palmitate	540-10-3	Emollient, fragrance, skin		1.125
15	Sorbitan palmitate	26266-57-9	Emulsifying		0.875
16	Benzyl alcohol	100-51-6	Perfuming, preservative,	III/45, V/34	0.86
17	Euphorbia cerifera cera	8006-44-8	Astringent, emulsion,		0.50
18	Hippophae rhamnoides fruit oil	225234-03-7	Skin protecting		0.40
19	Rosa canina fruit oil	84696-47-9 /	Emollient, skin conditioning		0.40
20	Pelargonium graveolens flower oil	90082-51-2 /	Fragrance		0.40
21	Cananga odorata flower extract	83863-30-3	Perfuming, skin		0.30
22	Citrus aurantium amara leaf/ twig oil	68916-04-1 /	Flavouring, fragrance		0.30
23	Sodium hyaluronate	9067-32-7	Humectant, skin		0.20
24	Salicylic acid	69-72-7	Antidandruff, hair	III/98, V/3	0.15
25	Quillaja saponaria wood extract	68990-67-0	Skin conditioning		0.049
26	Sorbic acid	110-44-1	Preservative	V/4	0.04
27	Saponaria officinalis leaf/root extract	84775-97-3	Skin conditioning		0.009
28	Tocopherol	1406-66-2 /	Antioxidant, fragrance, skin		0.0045
29	Calendula officinalis flower extract	84776-23-8	Fragrance, perfuming, skin		0.000095
30	Urtica dioica leaf extract	84012-40-8	Skin conditioning		0.000032
31	Plantago major leaf extract	84929-43-1	Skin conditioning		0.000032
32	Foeniculum vulgare seed extract	92623-75-1	Skin conditioning		0.000031

Allergens present in this product and estimated amounts\*:

Benzyl Alcohol: 0.86%; Linalol: 0.12561%; Citral: 0.0016%; Geraniol: 0.05249%; Limonene: 0.054%

\* 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 **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. 2 **Chamomilla recutita flower water**

Chamomilla recutita flower water is an aqueous solution of the steam distillate obtained from the flowers of Chamomilla recutita (L.), Compositae.

#### 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 **Carthamus tinctorius seed oil**

Carthamus tinctorius seed oil is the oily liquid obtained from the seeds of Safflower, Carthamus tinctorius L., Compositae. It consists principally of the triglycerides of linoleic acid.

Fatty acids	Range
Palmitic	C16:0 4.0 - 9.0 %
Palmitoleic	C16:1 trace
Stearic	C18:0 trace - 2.5 %
Oleic	C18:1 72.0 - 80.0 %
Linoleic	C18:2 12.0 - 16.0 %
Linolenic	C18:3 trace - 0.5 %

In March 2011, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Carthamus tinctorius seed oil 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. 1.5 **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. 1.6 **Theobroma cacao seed butter**

Theobroma cacao seed butter is a yellowish white solid material obtained from the roasted seeds of the Cocoa, *Theobroma cacao* L., Sterculiaceae. Cocoa butter contains a high proportion of saturated fats, derived from stearic and palmitic acids.

Typical fatty acid profile:

Saturated fats

Total saturated	57–64%:
stearic acid	(24–37%)
palmitic acid	(24–30%)
myristic acid,	(0–4%)
arachidic acid	(1%)
lauric acid	(0–1%)

Unsaturated fats

Total unsaturated	36–43%
Monounsaturated	29–43%:
oleic acid	(29–38%)
palmitoleic acid	(0–2%)
Polyunsaturated	0–5%:
linoleic acid	(0–4%),
$\alpha$ -Linolenic acid	(0–1%)

## 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 **Cannabis sativa seed oil**

Cannabis sativa seed oil is the fixed oil expressed from the seeds of Cannabis sativa L., Cannabaceae.

The oil has a 3:1 ratio of omega-6 to omega-3 essential fatty acids. Cannabis sativa seed oil is comprised of mostly unsaturated fatty acids and is listed as a substance Generally Recognised as Safe (GRAS) by the US FDA. The Cosmetic Ingredient Review (CIR) Expert Panel evaluated the scientific data and concluded that Cannabis sativa seed oil is safe for use as a cosmetic ingredient. There are no drug effects from the seed. The topical application of the seed oil has no reported adverse effects and none are to be expected.

#### Ref. 1.8 **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. 1.9 **Cetearyl olivate**

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

## 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. 10 **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. 11 **Mangifera indica seed butter**

Mangifera indica seed butter is obtained from the fruit kernels of the Mango tree, Mangifera indica by physical extraction of the deshelled mango kernels. Mangifera indica seed butter has a low Tocopherol content (13 mg / 100 g) and low unsaponifiable content (0.5-1%).

Iodine value: 40-54

Saponification value: 180-200

Melting range: 31-39 ° C

Typical composition:

C18:0 Stearic acid: 33-44%

C18:1 Oleic acid: 44-53%

C16:0 Palmitic acid: 6.7-9.7%

C18:2 Linoleic acid: 3.6-6.9%

C20:0 Arachic acid: 2.5-4%

Mango seed butter is edible and is safe as a cosmetic ingredient in the practices of use and concentration given 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. 12 **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. 13 **Persea gratissima oil**

*Persea gratissima* oil is the edible oil obtained by pressing the flesh of the avocado pear, *Persea gratissima*, Lauraceae.

The process for recovering oil from ripe avocados is a mechanical extraction, after removing the skin and stone (seed). After this, the flesh is ground to a paste and then malaxed for 40-60 minutes at 45-50°C. This is a higher malaxing temperature than used for olive oil extraction, but it is still considered to be cold-pressed extraction for avocado oil. The slightly higher temperature aids the extraction of the oil from the oil-containing cells and does not affect the quality of the oil. The oil and water phases are separated from the pulp using a high-speed decanting centrifuge, and then the oil is separated from the water in final polishing centrifuges. A typical fatty acid profile for avocado oil is 76% monounsaturates (oleic and palmitoleic acids), 12% polyunsaturates (linoleic and linolenic acids), and 12% saturates (palmitic and stearic acids); these values are given as percentage of fatty acid/total fatty acids. The main antioxidant in the oil is  $\alpha$ -tocopherol, which is present at levels of 70-190 mg/kg oil.  $\beta$ -,  $\gamma$ -, and  $\delta$ -tocopherols are only present in minor amounts (<10 mg/kg oil). Other nonlipid components present in the oil include chlorophylls (11-19 mg/kg oil) and carotenoids (1.0-3.5 mg/kg oil).

The safety of *Persea gratissima* (Avocado) oil has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that *Persea gratissima* (Avocado) 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. 14 **Cetyl palmitate**

Cetyl palmitate is the ester derived from cetyl alcohol and palmitic acid. In 2001, the CIR Expert Panel considered available new data on Cetyl palmitate and reaffirmed that Cetyl palmitate is safe as a cosmetic ingredient. Molecular formula:  $C_{32}H_{64}O_2$

#### Ref. 1. 15 **Sorbitan palmitate**

Sorbitan palmitate is a monoester of palmitic acid and hexitol anhydrides, derived from sorbitol. Molecular formula:  $C_{22}H_{42}O_6$

The safety of Sorbitan palmitate has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated scientific data and concluded that this ingredient was safe as a cosmetic ingredient under present conditions of concentration and use.

#### Ref. 1. 16 **Benzyl alcohol**

Benzyl alcohol is an aromatic alcohol with the formula  $C_7H_8O$ . Benzyl alcohol is an aromatic alcohol that is used in cosmetics as a fragrance component, preservative, solvent, and/or viscosity decreasing agent. 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. The available data are insufficient to support the safety of Benzyl alcohol in cosmetic products in which a primary route of exposure is inhalation. 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. 17 **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.



## 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. 18 **Hippophae rhamnoides fruit oil**

Hippophae rhamnoides fruit oil is the oil expressed from the fruit of the Sea buckthorn, *Hippophae rhamnoides* L., Elaeagnaceae.

#### Ref. 1. 19 **Rosa canina fruit oil**

*Rosa canina* fruit oil is the oil from the hip of the dog rose, *Rosa canina* L., Rosaceae. It contains levels up to .357 ml/L of tretinoin or all-trans retinoic acid, a precursor of retinol. The oil is high in the essential fatty acids linoleic acid (44%), omega-6, and  $\alpha$ -linolenic acid (35%), omega-3.

#### Ref. 1. 20 **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. 21 **Cananga odorata flower extract**

*Cananga odorata* flower extract is an extract of the flowers of the ylang-ylang, *Cananga odorata*, Anonaceae

#### Ref. 1. 22 **Citrus aurantium amara leaf/ twig oil**

*Citrus aurantium amara* leaf/twig oil is the volatile oil obtained from the leaves and twigs of the Bitter orange, *Citrus aurantium* L. var. *amara* L., Rutaceae.

#### Ref. 1. 23 **Sodium hyaluronate**

Sodium hyaluronate is the sodium salt of hyaluronic acid, a glycosaminoglycan found in various connective, epithelial, and neural tissues. Sodium hyaluronate is a long-chain polymer containing repeating disaccharide units of Na-glucuronate-N-acetylglucosamine.

The safety of Sodium hyaluronate has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Sodium hyaluronate was safe as a cosmetic ingredient.

## 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. 24 **Salicylic acid**

Salicylic acid is an aromatic monohydroxybenzoic acid (2-hydroxybenzoic acid), a crystalline organic acid that can be derived from salicin (a  $\beta$ -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).

Cosmetics Europe considers Salicylic acid a CMR substance and requires additional notification on electronic portals. CMR substances are substances that are carcinogenic, mutagenic or toxic to reproduction (CMR). They are of specific concern due to the long term and serious effects that they may exert on human health. Under GHS, CMR substances can be classified into 3 categories depending on the severity of hazards. Salicylic acid is classed as CMR 2. CMR Category 2 defines a substance which is a suspected carcinogen (H341), mutagen (H351) or reproductive toxicant (H361) based on limited evidence from animal and/or human studies.

Based on the data provided and available literature, the SCCS considers Salicylic acid safe when used for purposes other than preservative at a concentration up to 3.0 % for the cosmetic rinse-off hair products and up to 2.0 % for other products, considering its current restrictions in place. However, in body lotion, eye shadow, mascara, eyeliner, lipstick and roll on deodorant applications, salicylic acid is considered safe up to 0.5 %. The SCCS position is that these levels are inclusive of any use of salicylic acid, i.e. should not exceed the stated levels with additional use as a preservative.

The EU Scientific Committee on Consumer Safety (SCCS) concluded in June 2019 (pdf attached) that on the balance of evidence and giving the OECD guideline test study the most weight, salicylic acid is not genotoxic in bacterial assays. In an OECD guideline 476 study, salicylic acid did not induce mutations. Salicylic acid also did not lead to chromosome aberrations in an OECD guideline 473 equivalent study. The study by Giri et al 1996, is the key in vivo study for mutagenicity cited in the REACH dossier for salicylic acid. Salicylic acid neither induced sister chromatid exchanges (SCE) nor chromosomal aberrations (CA) in i.p. or oral studies in vivo in mice. This indicates that salicylic acid is not genotoxic in the bone marrow cells of mice. Applicants' conclusion: The overall conclusion from the weight of evidence in vitro and in vivo is that salicylic acid is not mutagenic/genotoxic. that under the experimental conditions reported the test item did not induce mutations in the mouse lymphoma thymidine kinase locus assay using the cell line L5178Y in the absence and presence of metabolic activation. Based on the results provided salicylic acid can be considered to pose no genotoxic hazard.

#### Ref. 1. 25 **Quillaja saponaria wood extract**

Quillaja saponaria wood extract is the extract of the wood obtained from Panama bark, Quillaja saponaria, Rosaceae.

#### Ref. 1. 26 **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,trans-isomer 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.

#### Ref. 1. 27 **Saponaria officinalis leaf/root extract**

Saponaria officinalis leaf/root extract is an extract of the leaves and roots of the Soap wort, Saponaria officinalis L., Caryophyllaceae.

## 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. 28 **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. 29 **Calendula officinalis flower extract**

Calendula officinalis flower extract is an extract obtained 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 extract 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.

#### Ref. 1. 30 **Urtica dioica leaf extract**

*Urtica dioica* leaf extract is an extract of the leaves of the Nettle, *Urtica dioica* L., Urticaceae.

#### Ref. 1. 31 **Plantago major leaf extract**

*Plantago major* leaf extract is an extract of the leaves of the Large plantain, *Plantago major* L., Plantaginaceae.

#### Ref. 1. 32 **Foeniculum vulgare seed extract**

*Foeniculum vulgare* seed extract is an extract of the seeds of the Fennel, *Foeniculum vulgare*, Umbelliferae.

## **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>	Cream/Paste/Gel
<b>Colour</b>	Yellow
<b>Aroma</b>	Floral
<b>pH</b>	5.0 - 6.0

\*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 This product was subjected to Preservative Efficacy Testing and proved that it did not support microbial growth. PET reference: OB PET 4986

### 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).

This product was subjected to Preservative Efficacy Testing and proved that it did not support microbial growth. PET reference: OB PET 4986

#### 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>	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.

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:

*Rub in between hands and apply all over body, hands and feet regularly to keep skin moisturised paying attention to problematic areas.*

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	Butyrospermum parkii butter	0.02000	2.46400
2	Theobroma cacao seed butter	0.03000	3.69600
3	Mangifera indica seed butter	0.02500	3.08000
4	Cetearyl olivate	0.02700	3.32640
5	Sorbitan olivate	0.02675	3.29560
6	Cetyl palmitate	0.01125	1.38600
7	Sorbitan palmitate	0.00875	1.07800
8	Euphorbia cerifera cera	0.00500	0.61600
9	Sodium hyaluronate	0.00200	0.24640
10	Triticum vulgare germ oil	0.02996	3.69046
11	Tocopherol	0.00005	0.00554
12	Benzyl alcohol	0.00860	1.05952
13	Salicylic acid	0.00150	0.18480
14	Sorbic acid	0.00040	0.04928
15	Glycerin	0.05800	7.14560
16	Hippophae rhamnoides fruit oil	0.00400	0.49280
17	Rosa canina fruit oil	0.00400	0.49280
18	Aqua	0.50249	61.90677
19	Quillaja saponaria wood extract	0.00049	0.06037
20	Saponaria officinalis leaf/root extract	0.00009	0.01109
21	Persea gratissima oil	0.02000	2.46400
22	Foeniculum vulgare seed extract	0.00000	0.00004
23	Urtica dioica leaf extract	0.00000	0.00004
24	Plantago major leaf extract	0.00000	0.00004
25	Calendula officinalis flower extract	0.00000	0.00012
26	Carthamus tinctorius seed oil	0.04000	4.92788
27	Cannabis sativa seed oil	0.03000	3.69600
28	Vitis vinifera seed oil	0.04000	4.92788
29	Chamomilla recutita flower water	0.10000	12.32000
30	Cananga odorata flower extract	0.00300	0.36960
31	Citrus aurantium amara leaf/ twig oil	0.00300	0.36960
32	Pelargonium graveolens flower oil	0.00400	0.49280

*SED: Systemic Exposure Dose*

8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name	MOS
1	Butyrospermum parkii butter	8116.88310
2	Theobroma cacao seed butter	1352.81390
3	Mangifera indica seed butter	1623.37660
4	Cetearyl olivate	1503.12650
5	Sorbitan olivate	1517.17440
6	Cetyl palmitate	10101.01010
7	Sorbitan palmitate	28756.95730
8	Euphorbia cerifera cera	8116.88310
9	Sodium hyaluronate	3246.75320
10	Triticum vulgare germ oil	1354.84610
11	Tocopherol	901875.90190
12	Benzyl alcohol	1160.90310
13	Salicylic acid	14069.26410
14	Sorbic acid	149350.64940
15	Glycerin	1763.32290
16	Hippophae rhamnoides fruit oil	20292.20780
17	Rosa canina fruit oil	4058.44160
18	Aqua	1615.33230
19	Quillaja saponaria wood extract	37271.40210
20	Saponaria officinalis leaf/root extract	180375.18040
21	Persea gratissima oil	4870.12990
22	Foeniculum vulgare seed extract	78550481.77630
23	Urtica dioica leaf extract	405844155.84420
24	Plantago major leaf extract	101461038.96100
25	Calendula officinalis flower extract	17088174.98290
26	Carthamus tinctorius seed oil	10146.34490
27	Cannabis sativa seed oil	2705.62770
28	Vitis vinifera seed oil	2029.26900
29	Chamomilla recutita flower water	2029.22080
30	Cananga odorata flower extract	13528.13850
31	Citrus aurantium amara leaf/ twig oil	13528.13850
32	Pelargonium graveolens flower oil	10146.10390

*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 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\*:

*Benzyl Alcohol: 0.86%; Linalol: 0.12561%; Citral: 0.0016%; Geraniol: 0.05249%;  
Limonene: 0.054%*

\* 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.

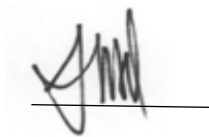
This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The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