

COSMETIC PRODUCT SAFETY REPORT

PRODUCT: CBD Hydro Rescue Night Moisturiser - Lavender

DATE: 30 March 2020



PART A – Cosmetic Product Safety Information

1. Quantitative and qualitative composition

	Ingredient INCI name	CAS	Function	Limits	Amount
1	Aqua	7732-18-5	Solvent		85.00
2	Persea gratissima oil	8024-32-6	Skin conditioning		10.00
3	Cetearyl alcohol	8005-44-5,	Emollient, emulsifying,		7.50
4	Prunus armeniaca kernel oil	68650-44-2 /	Masking, skin conditioning		5.00
5	Butyrospermum parkii butter	194043-92-0	Skin conditioning, viscosity		5.00
6	Helianthus annuus seed oil	8001-21-6	Emollient, masking, skin		3.50
7	Glycerin	56-81-5	Denaturant, humectant,		3.00
8	Olea europaea fruit oil	8001-25-0	Emollient, perfuming,		3.00
9	Cocos nucifera oil	8001-31-8	Emollient, hair		3.00
10	Polysorbate 60	9005-67-8	Emulsifying, surfactant		2.5
11	Cannabidiol	13956-29-1	Antioxidant,	not in list	2.00
12	Stearic acid	57-11-4	Cleansing, emulsifying,		1.00
13	Allantoin	97-59-6	Skin conditioning, skin		1.00
14	Avena sativa meal extract	84012-26-0	Soothing		1.00
15	Sodium hyaluronate	9067-32-7	Humectant, skin		1.00
16	Xanthan gum	11138-66-2	Binding, emulsifying,		1.00
17	Oenothera biennis oil	90028-66-3	Emollient		1.00
18	Rosa canina fruit oil	84696-47-9 /	Emollient, skin conditioning		1.00
19	Lavandula angustifolia oil	8000-28-0 /	Masking, tonic		0.90
20	Phenoxyethanol	122-99-6	Preservative	V/29	0.90
21	Tocopherol	1406-66-2 /	Antioxidant, masking, skin		0.75
22	Ethylhexylglycerin	70445-33-9	Deodorant, skin		0.10

Allergens present in this product and estimated amounts*:

Limonene: 0.0036%; Geraniol: 0.00558%; Linalol: 0.24453%

* 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 **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 α -tocopherol, which is present at levels of 70-190 mg/kg oil. β -, γ -, and δ -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.

Ref. 1. 3 **Cetearyl alcohol**

Cetearyl alcohol, (C16-18) Alkyl alcohol, Cetostearyl alcohol or cetylstearyl alcohol is a mixture of fatty alcohols, consisting predominantly of cetyl and stearyl alcohols. Its molecular formula is $C_{16}H_{34}O$. Cetearyl alcohol is produced from natural fats and oils by reduction of the fatty acid carboxyl group (-COOH) to the hydroxyl (-OH) function.

The Food and Drug Administration (FDA) includes synthetic fatty alcohols including Cetearyl alcohol on its list of food additives permitted for direct addition to food as multipurpose food additives. The safety of Cetearyl alcohol has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Cetearyl alcohol was safe for use as cosmetic ingredients. In 2005, the CIR Expert Panel considered available new data on Cetearyl alcohol 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. 1.4 **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. 1.5 **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.

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. 1.6 **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.

Ref. 1.7 **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. 1.8 **Olea europaea fruit oil**

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

Palmitic acid (saturated): 7.5–20%

Stearic acid (saturated): 0.5–5%

Oleic acid (monounsaturated omega-9): 55–83%

Linoleic acid (polyunsaturated omega-6): 3.5–21%

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. 9 **Cocos nucifera oil**

Cocos nucifera oil is the fixed oil obtained by expression of the kernels of the seeds of the Coconut, *Cocos nucifera* L., Palmaceae. The oil is high in saturated fats therefore it is slow to oxidise and, thus, resistant to rancidification. About 60% of the fatty acids in coconut oil are medium chain triglycerides (MCT) 12 carbon atoms or shorter.

Ref. 1. 10 **Polysorbate 60**

Polysorbate 60 is a mixture of stearate esters of sorbitol and sorbitol anhydrides, consisting predominantly of the monoester, condensed with approximately 20 moles of ethylene oxide.

The Food and Drug Administration (FDA) permits Polysorbate 60 to be directly added to food as adjuvants of flavoring agents or as multipurpose additives. The FDA also includes Polysorbate 60 on its list of indirect food additives as emulsifiers and/ or surface active agents. The safety of Polysorbate 60 has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Polysorbate 60 was safe as a cosmetic ingredient.

Ref. 1. 11 **Cannabidiol**

Cannabidiol (CBD) is a naturally occurring cannabinoid constituent of cannabis. CBD is a 21 carbon terpenophenolic compound which is formed following decarboxylation from a cannabidiolic acid precursor. Unlike Tetrahydrocannabinol (THC), CBD does not have any psychoactive effects due to its very low affinity for the cannabinoid CB₁ and CB₂ receptors. In November 2017 The World Health Organisation (WHO) published their report entitled "Cannabidiol" in which the WHO concluded that "CBD is generally well tolerated with a good safety profile. To date, there is no evidence of recreational use of CBD or any public health related problems associated with the use of pure CBD."

Ref. 1. 12 **Stearic acid**

Stearic acid, or octadecanoic acid, is an 18-carbon length saturated fatty acid with a terminal carboxyl group with the molecular formula C₁₈H₃₆O₂. The US Food and Drug Administration (FDA) includes Stearic acid on its list of direct food additives considered Generally recognised As Safe (GRAS). Stearic Acid is also permitted as a direct food additive in chewing gum base. In 1987 the Cosmetic Ingredient Review (CIR) Expert Panel evaluated the scientific data and concluded that Stearic acid is safe for use in cosmetic products.

Ref. 1. 13 **Allantoin**

Allantoin, also called 5-ureidohydantoin or glyoxyldiureide is a diureide of glyoxylic acid with the molecular formula C₄H₆N₄O₃

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 **Avena sativa meal extract**

Avena sativa meal extract is an extract of the meal of the Oat, *Avena sativa* L., Poaceae.

Ref. 1. 15 **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.

Ref. 1. 16 **Xanthan gum**

Xanthan gum is a high molecular weight heteropolysaccharide gum secreted by the bacterium *Xanthomonas campestris*, commonly used as a food additive, rheology modifier, and a stabiliser with the molecular formula $C_{35}H_{49}O_{29}$. It is composed of pentasaccharide repeat units, comprising glucose, 6-acetyl mannose, 4,6-pyruvylated mannose and glucuronic acid in the molar ratio 2.0:2.0:1.0. Xanthan gum is produced by a pure culture fermentation of a carbohydrate (glucose, sucrose, or lactose) with *Xanthomonas campestris* and is composed of glucose, glucuronic acid, 6-acetyl mannose and 4,6-pyruvylated mannose residues. After a fermentation period, the polysaccharide is precipitated from a growth medium with isopropyl alcohol, dried, and ground into a fine powder. Xanthan gum has a long history of safe use worldwide. It was approved for use in foods in 1968 and is accepted as a safe food additive in the USA, Canada, and European countries, with the E number E415. In 2016 the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Xanthan gum is safe in the present practices of use and concentration, as 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. 17 **Oenothera biennis oil**

Oenothera biennis oil is the fixed oil derived from the seeds of the Evening primrose, *Oenothera biennis*, Onagraceae.

Evening primrose oil contains a high percentage of gamma linolenic acid (GLA) and other omega-6 fatty acids usually totalling approximately 85% of the oil.

Typical fatty acid profile:

Palmitic	C16:0	5.5 - 7.0 %
Stearic	C18:0	1.5 - 2.5 %
Oleic	C18:1	5.0 - 11.0 %
Linoleic	C18:2	70.0 - 77.0 %
γ-linolenic	C18:3	9.0 - 10.9 %
α-linolenic	C18:3	1.0 % max
Icosanoic	C20:0	1.0 % max
Icosenoic	C20:1	1.0 % max

Oenothera biennis oil is edible and is classified as a dietary supplement under the Dietary Supplement Health and Education Act of 1994 consequently there is no concern when the oil is applied topically.

The CIR Expert Panel concluded in March 2011 that *Oenothera biennis* oil is safe in the present practices of use and concentration described in this safety assessment.

Ref. 1. 18 **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 α-linolenic acid (35%), omega-3.

Ref. 1. 19 **Lavandula angustifolia oil**

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.

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. 20 **Phenoxyethanol**

Phenoxyethanol is an aromatic glycol ether with an alcohol moiety, used in cosmetics as a preservative at concentrations below 1%, with the molecular formula $C_8H_{10}O_2$. Phenoxyethanol is made by reacting phenol with ethylene oxide in the presence of a basic catalyst under pressure and with heating; the resulting product is neutralised, and purified to the point where 4-8% of the Phenoxyethanol is converted to the diethoxylate, thereby reducing the free phenol content. In 1990 the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Phenoxyethanol is safe for use as a cosmetic ingredient in the present practice of use and concentration detailed in this safety assessment. In 2011 The CIR Expert Panel reconfirmed that conclusion.

Ref. 1. 21 **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. 22 **Ethylhexylglycerin**

Ethylhexylglycerin is an alkyl glyceryl ether in which the ethylhexyl group is bound to glycerin at one end by an ether linkage as the condensation product of 2-ethylhexanol and glycerin. Its molecular formula is $C_{11}H_{24}O_3$

Ethylhexylglycerin's efficacy as a preservative enhancer is derived by reducing interfacial tension on the cellular walls of micro-organisms, promoting rapid destruction across a wider spectrum. In 2013 the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Ethylhexylglycerin is safe for use as cosmetic ingredient in the present practice of use and concentration detailed in this safety assessment.

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	Green
Aroma	Floral
pH	4.9

*RP: Responsible Person: Taylor Mammon CBD

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 period.

2.2.1 Taylor Mammon CBD confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 Taylor Mammon CBD uses a PAO based on the results of Taylor Mammon CBD'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: Melbec Microbiology 5029

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: Melbec Microbiology 5029

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	Jar
Container Material	Glass
Airless Container	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.

Taylor Mammon CBD 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:

For external use only, avoid direct contact with the eyes. Keep out of reach of children. Store in a cool dry place out of direct sunlight.

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:

No additional wording recommended.

6. Exposure to the cosmetic product

Area of application	Face
Product type: Leave-on or Rinse-off	Leave On
Duration and frequency	2.14
Possible additional routes of exposure	Body
Estimated skin surface area (cm ²)	565
Estimated amount of the product applied according to the SCCS (g/day)	1.54 g
Estimated retention factor according to the SCCS	1
Target group	Adult
Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	24.14

7. Exposure to the ingredients

	Ingredient INCI name	Concentration	SED
1	Aqua	0.85000	20.51900
2	Persea gratissima oil	0.10000	2.41400
3	Prunus armeniaca kernel oil	0.05000	1.20700
4	Butyrospermum parkii butter	0.05000	1.20700
5	Glycerin	0.03000	0.72420
6	Helianthus annuus seed oil	0.03500	0.84490
7	Olea europaea fruit oil	0.03000	0.72420
8	Cocos nucifera oil	0.03000	0.72420
9	Stearic acid	0.01000	0.24140
10	Allantoin	0.01000	0.24140
11	Avena sativa meal extract	0.01000	0.24140
12	Tocopherol	0.00750	0.18105
13	Sodium hyaluronate	0.01000	0.24140
14	Xanthan gum	0.01000	0.24140
15	Oenothera biennis oil	0.01000	0.24140
16	Rosa canina fruit oil	0.01000	0.24140
17	Cannabidiol	0.02000	0.48280
18	Lavandula angustifolia oil	0.00900	0.21726
19	Phenoxyethanol	0.00900	0.21726
20	Ethylhexylglycerin	0.00100	0.02414
21	Cetearyl alcohol	0.07500	1.81050
22	Polysorbate 60	0.02500	0.60350

8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name	MOS
1	Aqua	4873.53180
2	Persea gratissima oil	4971.00250
3	Prunus armeniaca kernel oil	8285.00410
4	Butyrospermum parkii butter	16570.00830
5	Glycerin	17398.50870
6	Helianthus annuus seed oil	5917860.10180
7	Olea europaea fruit oil	55233.36100
8	Cocos nucifera oil	27616.68050
9	Stearic acid	41425.02070
10	Allantoin	8285.00410
11	Avena sativa meal extract	70422.53520
12	Tocopherol	27616.68050
13	Sodium hyaluronate	3314.00170
14	Xanthan gum	186412.59320
15	Oenothera biennis oil	20712.51040
16	Rosa canina fruit oil	8285.00410
17	Cannabidiol	16570.00830
18	Lavandula angustifolia oil	19561.81530
19	Phenoxyethanol	5799.50290
20	Ethylhexylglycerin	82850.04140
21	Cetearyl alcohol	2761.66800
22	Polysorbate 60	3314.00170

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 Taylor Mammon CBD 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:

No additional wording recommended.

Allergens present in this product and estimated amounts*:

Limonene: 0.0036%; Geraniol: 0.00558%; Linalol: 0.24453%

* 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

30 March 2020

Date