

COSMETIC PRODUCT SAFETY REPORT

PRODUCT: Balance Roller

DATE: 24 March 2022

Responsible Person: The LDN Dispensary Ltd
The LDN Dispensary Ltd
86-90 Paul Street
London EC2A 4NE



PART A – Cosmetic Product Safety Information

1. Quantitative and qualitative composition

	Ingredient INCI name	CAS	Function	Limits	Amount
1	Oenothera biennis oil	90028-66-3	Emollient		
2	Rosa canina seed oil	84696-47-9 /	Emollient, skin conditioning		
3	Persea gratissima oil	8024-32-6	Skin conditioning		
4	Prunus persica kernel oil	8002-78-6 / 8023	Emollient, skin conditioning		
5	Cannabis sativa extract		Anti-sebum, antimicrobial,	II/306	
6	Menthol	1490-04-6 / 2216	Denaturant, fragrance,		
7	Caprylic/ capric triglyceride	73398-61-5 /	Emollient, fragrance,		
8	Helianthus annuus seed oil	8001-21-6	Emollient, fragrance, skin		
9	Citrus aurantium dulcis peel oil	8008-57-9	Perfuming		
10	Eucalyptus globulus leaf oil	8000-48-4 /	Fragrance, skin		
11	Melaleuca alternifolia leaf oil	85085-48-9 /	Antioxidant, perfuming		
12	Cocos nucifera oil	8001-31-8	Emollient, hair		
13	Arnica montana flower extract	68990-11-4	Fragrance, perfuming, skin		
14	Anthemis nobilis flower oil	84649-86-5 /	Fragrance, perfuming, skin		

Allergens present in this product and estimated amounts*:

C tra : 0.0525%; L na o : 0.061%; L monene: 1.0675%; Geran o : 0.0025%; C trone o : 0.0025%

* 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 **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. 2 **Rosa canina seed oil**

Rosa canina seed oil is the oil from the seeds of the Hip Rose, Rosa canina L., Rosaceae.

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 **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. 1.4 **Prunus persica kernel oil**

Prunus persica kernel oil is the oil expressed from the kernels of the Peach, *Prunus persica*, Rosaceae.

Ref. 1.5 **Cannabis sativa extract**

Cannabis sativa extract is the extract of the whole plant, *Cannabis sativa*. There are no drug effects from the extract. The topical application of the extract has no reported adverse effects and none are to be expected.

Ref. 1.6 **Menthol**

Menthol is an organic compound obtained from corn mint, peppermint or other mint oils. A waxy, crystalline substance, clear or white in color, it is solid at room temperature. The main form of menthol occurring in nature is (–)-menthol. Menthol has local anesthetic and counter-irritant qualities. Molecular formula: $C_{10}H_{20}O$

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 **Caprylic/ capric triglyceride**

Caprylic/capric triglyceride is a medium-chain triglyceride (MCT) containing 8–10 carbon fatty acid esters of glycerol. The fatty acids found in MCTs are medium-chain fatty acids. MCTs are composed of a glycerol backbone and three fatty acids, therefore named triglyceride; in the case of MCTs, 2 or 3 of the fatty acid chains attached to glycerol are medium chain in length. Fractionated coconut oil is often used to make caprylic/capric triglyceride, which is commonly used in nutritional supplements. The FDA recognises Caprylic/capric triglycerides as a Generally Recognised As Safe (GRAS) food additive.

The Cosmetic Ingredient Review (CIR) Expert Panel evaluated the scientific data in 1980 and concluded that Caprylic/ capric triglyceride was safe as a cosmetic ingredient in the present practices of use and concentration as described in this safety assessment. In 2017 the CIR Expert panel reconfirmed this conclusion.

Ref. 1.8 **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. 1.9 **Citrus aurantium dulcis peel oil**

Citrus aurantium dulcis peel oil is the volatile oil obtained by expression from the fresh peel of the ripe fruit of the sweet orange, *Citrus aurantium* var. *dulcis*, Rutaceae.

Ref. 1.10 **Eucalyptus globulus leaf oil**

Eucalyptus globulus leaf oil is the volatile oil obtained from the fresh leaves of the Eucalyptus, *Eucalyptus globulus* and other species of Eucalyptus, Myrtaceae. Syn. Yuukari Yu (Japanese).

Ref. 1.11 **Melaleuca alternifolia leaf oil**

Melaleuca alternifolia leaf oil is the oil distilled from the leaves of the Tea tree, *Melaleuca alternifolia*, Myrtaceae.

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 **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.

Coconut oil is also listed as a substance Generally Recognized as Safe (GRAS) by the US FDA. The safety of Coconut oil has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel in 1986 and 2011. The CIR Expert Panel evaluated the scientific data and in 2017 reaffirmed their earlier conclusions that Coconut oil is safe for use as a cosmetic ingredient.

Ref. 1. 13 **Arnica montana flower extract**

Arnica montana flower extract is an extract of the dried flower heads of the arnica, *Arnica montana* L., Asteraceae.

Ref. 1. 14 **Anthemis nobilis flower oil**

Anthemis nobilis flower oil is the volatile oil distilled from the dried flower heads of the Roman chamomile, *Anthemis nobilis* L., Asteraceae.

The Food and Drug Administration (FDA) includes flowers from *Anthemis nobilis* on its list of essential oils and natural extractives considered Generally Recognized As Safe (GRAS) for human consumption. Botanical and botanically derived ingredients used in the formulation of cosmetics are generally mild and safe.

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	Liquid
Colour	Amber
Aroma	Fresh
pH	n/a

*RP: Responsible Person: The LDN Dispensary 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 6M period.

2.2.1 The LDN Dispensary Ltd confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 The LDN Dispensary Ltd uses a PAO 6M based on the results of The LDN Dispensary 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	Bottle
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.

The LDN Dispensary 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:

Remove lid and apply onto a pulse point such as the temples, wrists, or soles of your feet in a circular motion. Take a moment to enjoy the balancing botanical blend. Can also be used on muscles to locally apply CBD.

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	Pulse points
Product type: Leave-on or Rinse-off	Leave On
Duration and frequency	2
Possible additional routes of exposure	none
Estimated skin surface area (cm ²)	4.8
Estimated amount of the product applied according to the SCCS (g/day)	0.057 g
Estimated retention factor according to the SCCS	1
Target group	Adult
Calculated relative daily exposure according to the SCCS (mg/kg bw/day)	.9

7. Exposure to the ingredients

	Ingredient INCI name	Concentration			SED
1	Oenothera biennis oil				
2	Rosa canina seed oil				
3	Persea gratissima oil				
4	Prunus persica kernel oil				
5	Cannabis sativa extract				
6	Menthol				
7	Caprylic/ capric triglyceride				
8	Helianthus annuus seed oil				
9	Melaleuca alternifolia leaf oil				
10	Eucalyptus globulus leaf oil				
11	Arnica montana flower extract				
12	Cocos nucifera oil				
13	Citrus aurantium dulcis peel oil				
14	Anthemis nobilis flower oil				

SED: Systemic Exposure Dose

8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name	MOS
1	Oenothera biennis oil	
2	Rosa canina seed oil	
3	Persea gratissima oil	
4	Prunus persica kernel oil	
5	Cannabis sativa extract	
6	Menthol	
7	Caprylic/ capric triglyceride	
8	Helianthus annuus seed oil	
9	Melaleuca alternifolia leaf oil	
10	Eucalyptus globulus leaf oil	
11	Arnica montana flower extract	
12	Cocos nucifera oil	
13	Citrus aurantium dulcis peel oil	
14	Anthemis nobilis flower oil	

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 The LDN Dispensary 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/LexUrServ/LexUrServ.do?ur=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.smp_e
- 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*:

Citral: 0.0525%; Linalol: 0.061%; Limonene: 1.0675%; Geraniol: 0.0025%; Citronellol: 0.0025%

* 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.

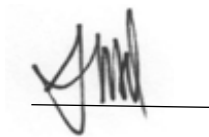
This cosmetic product contains only the allowed ingredients in allowed concentrations. For ingredients with safety limits as specified in Annexes to *Cosmetic Regulation* (EC) No. 1223/2009, no ingredient exceeds the allowable safety limit therefore is a safe concentration in this cosmetic product. The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

24 March 2022

Date