OXFORD BIOSCIENCES
Safety Assessment, Analysis, Research & Testing

Oxford Biosciences Ltd.
Magdalen Centre,
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COSMETIC PRODUCT SAFETY REPORT

PRODUCT: Vegan Lip Balm

DATE: 24 March 2022

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

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PART A – Cosmetic Product Safety Information

1. Quantitative and qualitative composition

	Ingredient INCI name	CAS	Function	Limits	Amount
1	Cannabis sativa seed oil	89958-21-4	Emollient, skin conditioning		[redacted]
2	Theobroma cacao seed butter	84649-99-0 /	Emollient, fragrance, skin		
3	Cocos nucifera oil	8001-31-8	Emollient, hair		
4	Hydrogenated soy polyglycerides	912810-05-0	Skin conditioning, viscosity		
5	Butyrospermum parkii butter	194043-92-0	Skin conditioning, viscosity		
6	Persea gratissima oil	8024-32-6	Skin conditioning		
7	Mentha piperita oil	8006-90-4 /	Fragrance, perfuming,		
8	Cannabis sativa extract		Anti-sebum, antimicrobial,	II/306	

Allergens present in this product and estimated amounts*:
L monene: 0.1%

* 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

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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 **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. 2 **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%),
    - α-Linolenic acid (0–1%)

Ref. 1. 3 **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.

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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 **Hydrogenated soy polyglycerides**

Hydrogenated soy polyglycerides is the product obtained by the catalytic metathesis of Glycine soja (Soybean) Oil with subsequent hydrogenation.

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.

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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 **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-, ɣ-, 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. 7 **Mentha piperita oil**

Mentha piperita oil is the volatile oil obtained from the whole plant of the Peppermint, Mentha piperita (L.), Labiatae.

The Food and Drug Administration (FDA) includes peppermint on its list of spices and other natural seasonings and flavoring considered Generally Recognized As Safe (GRAS). Peppermint is also on the list of GRAS essential oils, oleoresins and natural extractives. The safety of Mentha piperita oil has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Mentha piperita oil was safe as used in cosmetics and personal care products.

Ref. 1. 8 **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.

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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	Amber
Aroma	Peppermint
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

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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	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.

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.

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5. Normal and reasonably foreseeable use

The current label advice:

Apply with finger to lips and enjoy the smooth and silky buttery goodness. Use as required throughout the day, especially in colder weather.

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	Lips
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

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7. Exposure to the ingredients

	Ingredient INCI name	Concentration	SED
1	Cannabis sativa seed oil		
2	Theobroma cacao seed butter		
3	Butyrospermum parkii butter		
4	Cocos nucifera oil		
5	Hydrogenated soy polyglycerides		
6	Persea gratissima oil		
7	Cannabis sativa extract		
8	Mentha piperita oil		

***SED**: Systemic Exposure Dose*

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8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name		MOS
1	Cannabis sativa seed oil		[redacted]
2	Theobroma cacao seed butter		
3	Butyrospermum parkii butter		
4	Cocos nucifera oil		
5	Hydrogenated soy polyglycerides		
6	Persea gratissima oil		
7	Cannabis sativa extract		
8	Mentha piperita oil		

***MOS**: Margin of Safety*

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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.

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11. References

- THE SCCS'S NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC SUBSTANCES AND THEIR SAFETY EVALUATION 8TH REVISION
  http://eur- ex.europa.eu/LexUr Serv/LexUr Serv.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/hea th/sc ent f c_ comm ttees/consumer_ safety/op n ons/ ndex_ en.htm
- CosIng: the European Commission database on cosmetic substances
  http://ec.europa.eu/consumers/cosmet cs/cos ng/ ndex.cfm?fuseact on=search.s mp e
- REGULATION 1223/2009 ANNEXES
  http://ec.europa.eu/consumers/cosmet cs/cos ng/ ndex.cfm?fuseact on=ref_ data.annexes_ v2

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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*:

Limonene: 0.1%

* 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.

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4. Assessor's credentials and approval of Part B

Safety Assessor: Allison Wild
Oxford Biosciences Ltd.
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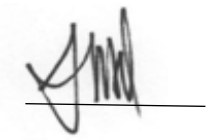
Experience and qualifications:

- 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