OXFORD BIOSCIENCES
Safety Assessment, Analysis, Research & Testing

Oxford Biosciences Ltd.
Magdalen Centre, The Oxford Science Park,
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COSMETIC PRODUCT SAFETY REPORT

PRODUCT: DIVINE Gua Sha Oil

DATE: 16 December 2019

Responsible Person: Heidi Gordon-Smith
11 11 Ltd
24 Sleford Close
Balsham
Cambridge CB21 4DP

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PART A – Cosmetic Product Safety Information

1. Quantitative and qualitative composition

	Ingredient INCI name	CAS	Function	Limits	Amount
1	Pinus sibirica seed oil		Hair conditioning, skin		72.1129
2	Adansonia digitata seed oil	91745-12-9	Emollient, hair conditioning,		15.4528
3	Helianthus annuus hybrid oil	164250-88-8	Emollient		4.71977
4	Rubus idaeus seed oil	84929-76-0	Emollient		3.0906
5	Tocopherol	1406-66-2 /	Antioxidant, masking, skin		2.0604
6	Citrus aurantium flower oil	8016-38-4 /	Perfuming		0.7726
7	Borago officinalis seed oil	225234-12-8	Emollient, skin conditioning		0.5151
8	Ribes nigrum seed extract	68606-81-5	Emollient, humectant		0.51407
9	Calendula officinalis flower extract	84776-23-8	Masking, perfuming, skin		0.425979
10	Bursera graveolens wood oil		Flavouring, masking,		0.1854
11	Simmondsia chinensis seed oil	90045-98-0	Emollient, hair conditioning,		0.0927
12	Helianthus annuus seed oil	8001-21-6	Emollient, masking, skin		0.027417
13	Rosmarinus officinalis leaf extract	84604-14-8	Antimicrobial, masking,		0.019964
14	Chamomilla recutita flower extract	84082-60-0	Masking, skin conditioning		0.0103

Allergens present in this product and estimated amounts*:
Limonene: 0.27375062%; Geraniol: 0.02364156%; Linalol: 0.27064178%; Farnesol: 0.01305694%; Citral: 0.0007416%

* 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 **Pinus sibirica seed oil**

Pinus sibirica seed oil is the oil expressed from the seeds of the Siberian Pine, Pinus sibirica, Pinaceae.

Ref. 1. 2 **Adansonia digitata seed oil**

Adansonia digitata seed oil is the oil expressed from the seeds of the Monkey Bread Tree or the Baobab, Adansonia digitata L., Bombacaceae.

Baobab oil (Mbuyu in Swahili) is derived from the seeds of the baobab native to Eastern and Southern Africa. Baobab oil has a high content of vitamins A, D, E and essential fatty acids. Baobab oil is extremely stable against rancidity. No adverse effects are reported or expected from the topical application to the skin.

Fatty acid profile of baobab seed oil:

Saturated	%
C14:0	0.2
C16:0	24.2
C18:0	4.6
C20:0	1.3
C22:0	0.7
C24:0	0.2

Monounsaturated	
C17:1	0.3
C18:1	35.8
2C0:1	0.9

Polyunsaturated	
C18:2	30.7
C18:3	1.0

Ref. 1. 3 **Helianthus annuus hybrid oil**

Helianthus annuus hybrid oil is the oil derived from the seeds of a hybrid strain of sunflower that contains predominantly oleic fatty acid as distinct from sunflower seed oil. The Hi-oleic sunflower seed is cold-pressed, refined and deodorised to organic standards.
From the seeds of the organic sunflower, Helianthus annuus, Compositae

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2. Physical & chemical properties and stability

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Ref. 1. 4 **Rubus idaeus seed oil**

Rubus idaeus seed oil is the fixed oil obtained from the seeds of the raspberry, Rubus idaeus L., Rosaceae. An edible oil, the most abundant fatty acids of raspberry seed oil are linoleic, α-linolenic, and oleic acids, which comprise 96% of the total fatty acid. The seed oil is rich in tocopherols with mg/100 g): α-tocopherol 71 mg/100 g; γ-tocopherol 272 mg/100 g; δ-tocopherol 17.4 mg/100 g; and total vitamin E equivalent of 97 mg/100 g. The ratio of the tocopherol isomers α:γ:δ in raspberry seed oil is 20:75:5. Actual carotenoid content of raspberry seed oil is 23 mg/100 g of oil.

Raspberry seed oil shows absorbance in the UV-B and UV-C ranges with potential for use as a broad spectrum UV protectant. In the UV- B range, the wavelengths of ultraviolet light responsible for most cellular damage, raspberry seed oil can shield against UV-A induced damage by scattering (high transmission), as well as by absorption. The shielding power in the UV-A (320 ±400 nm) range depends mostly on the scattering effect. Thus, raspberry seed oil may act as a broad spectrum UV protectant and provide protection against both UV-A, an exogenous origin of oxidative stress to the skin, and UV-B. The optical transmission of raspberry seed oil, especially in the UV range (290±400 nm) is comparable to that of titanium dioxide preparations with sun protection factor for UV- B (SPF) and protection factor for UV-A (PFA) values between 28 ±50 and 6.75±7.5, respectively. If raspberry seed oil is used in products to confer ultraviolet protection, the SPF values of the whole product would need to be independently verified.

Ref. 1. 5 **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. 6 **Citrus aurantium flower oil**

Citrus aurantium flower oil is an essential oil obtained from the flowers of the Sour orange, Citrus aurantium, Rutaceae. It contains limonene, L-linalool, geraniol, linalyl acetate, some methyl anthranilate, nerol and neroli camphor.

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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. 7 **Borago officinalis seed oil**

Borago officinalis seed oil is the fixed oil obtained from the seeds of Borago officinalis L., Boraginaceae.

Borage seed oil has one of the highest amounts of γ-linolenic acid (GLA) of seed oils. GLA comprises around 24% of the oil typically.

Typical fatty acid composition:

Linoleic acid	35 - 42 %
Linolenic acid	20 - 25 %
Oleic acid	15 - 20 %
Palmitic acid	9 - 12 %

In March 2011, the Cosmetic Ingredient Review (CIR) Expert Panel concluded that Borago officinalis seed oil is safe in the present practices of use and concentration described in this safety assessment.

Ref. 1. 8 **Ribes nigrum seed extract**

Ribes nigrum seed extract is an extract of the seeds of Black Currant, Ribes nigrum L., Saxifragaceae.

Ref. 1. 9 **Calendula officinalis flower extract**

Calendula officinalis flower extract is an extract obrained 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. 10 **Bursera graveolens wood oil**

Bursera graveolens wood oil is the volatile oil obtained from the wood of Bursera graveolens, Burseraceae.

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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. 11 **Simmondsia chinensis seed oil**

Simmondsia chinensis seed oil is the fixed oil expressed or extracted from seeds of the desert shrub, Jojoba, Simmondsia chinensis, Buxaceae.

Simmondsia chinensis (Jojoba) seed oil is obtained by pressing the seed kernels of an evergreen shrub native to the Sonoran and Mojave deserts of Arizona, California and Mexico. This oil is different from other common plant oils in that it is composed almost completely (97%) of wax esters of monounsaturated, straight-chain acids and alcohols with high molecular weights (carbon chain lengths from 36 to 46). This makes Jojoba Oil and its derivative Jojoba Esters more similar to sebum and whale oil than to traditional vegetable oils.

Ref. 1. 12 **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. 13 **Rosmarinus officinalis leaf extract**

Rosmarinus officinalis leaf extract is an extract of the leaves of the Rosemary, Rosmarinus officinalis L., Lamiaceae.

Ref. 1. 14 **Chamomilla recutita flower extract**

Chamomilla recutita flower extract is an extract of the flowerheads of the matricaria, Chamomilla recutita (L.), Compositae.

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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	Liquid
Colour	Golden yellow
Aroma	Woody
pH	n/a

*RP: Responsible Person: 11 11 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 BBE period.

2.2.1 11 11 Ltd confirms that all product stability tests reflect the stability of the product which is to be placed on the market.

2.2.2 11 11 Ltd uses a BBE based on the results of 11 11 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.

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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 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	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.

11 11 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 2-3 drops prior to doing facial gua sha. Rub between palms and gently pat onto face and neck. Avoid contact with eyes: if contact occurs, rinse thoroughly with water.

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	Face
Product type: Leave-on or Rinse-off	Leave On
Duration and frequency	2.14
Possible additional routes of exposure	none
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

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7. Exposure to the ingredients

	Ingredient INCI name	Concentration	SED
1	Pinus sibirica seed oil	0.72113	17.40805
2	Adansonia digitata seed oil	0.15453	3.73031
3	Helianthus annuus hybrid oil	0.04720	1.13935
4	Calendula officinalis flower extract	0.00426	0.10283
5	Rubus idaeus seed oil	0.03091	0.74607
6	Tocopherol	0.02060	0.49738
7	Citrus aurantium flower oil	0.00773	0.18651
8	Borago officinalis seed oil	0.00515	0.12435
9	Ribes nigrum seed extract	0.00514	0.12410
10	Rosmarinus officinalis leaf extract	0.00020	0.00482
11	Helianthus annuus seed oil	0.00027	0.00662
12	Bursera graveolens wood oil	0.00185	0.04476
13	Simmondsia chinensis seed oil	0.00093	0.02238
14	Chamomilla recutita flower extract	0.00010	0.00249

***SED**: Systemic Exposure Dose*

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8. Toxicological profile of the ingredients in the formulation

	Ingredient INCI name	MOS
1	Pinus sibirica seed oil	395.21940
2	Adansonia digitata seed oil	1340.37260
3	Helianthus annuus hybrid oil	4388457.56390
4	Calendula officinalis flower extract	19449.32530
5	Rubus idaeus seed oil	6701.77650
6	Tocopherol	10052.66470
7	Citrus aurantium flower oil	30562.07840
8	Borago officinalis seed oil	40210.65880
9	Ribes nigrum seed extract	16116.49020
10	Rosmarinus officinalis leaf extract	2240984.89130
11	Helianthus annuus seed oil	755462317.40360
12	Bursera graveolens wood oil	36866.92780
13	Simmondsia chinensis seed oil	446871.85230
14	Chamomilla recutita flower extract	2010923.33560

***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.

In line with WHO guidelines, recommending a minimum value of 100, it is generally accepted that the MoS should at least be 100 to conclude that a substance is safe for use. Since the ingredients used in this formulation have a long worldwide history of use and have an MOS value above 100 then the conclusion is that they are safe for use in this formulation.

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 11 11 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-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

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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: 0.27375062%; Geraniol: 0.02364156%; Linalol: 0.27064178%; Farnesol: 0.01305694%; Citral: 0.0007416%

* 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.
The Oxford Science Park
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Oxfordshire
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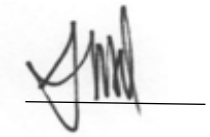
Experience and qualifications:

- 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

16 December 2019

Date