COSMETIC PRODUCT SAFETY REPORT

According to EC Regulation 1223/2009

ORGANIC ARGAN OIL

ISSUE DATE: July 2017

SAFETY ASSESSMENT REFERENCE NO.: 37_07_17

VERSION: I

SAFETY ASSESSOR

Kristina Vrtačnik

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PART A - COSMETIC PRODUCT SAFETY INFORMATION

Product name	Organic Argan Oil
Shade names	/
Product type	Leave on
Formula number	/
Category of the product	Body Care Products
Physical form of the product	Liquid
Target population	Adults
Primary site of application	Skin, hair, nails
Packaging type and size	30 ml , 50 ml , 100 ml , 250 ml glass bottle with cap
Manufacturer name and address	Oriental Group SARL AU. N°200 Lot Elmassar, Sidi Ghanem Industrial Estate, Rtede Safi 40 100 Marrakesh(MA)MOROCCO
Producer name and address	Oriental Group SARL AU. N°200 Lot Elmassar, Sidi Ghanem Industrial Estate, Rtede Safi 40 100 Marrakech Morocco. Fax: + (212) 524457961 Tel: 1 + (212) 675438658 Tel 2: + (212) 675437458

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1. QUANTITATIVE AND QULITATIVE COMPOSITION OF THE COSMETIC PRODUCT

INCI name	Trade name	CAS	EINECS/ELINCS	% active in the raw material	Concentration in the final product	Function
Argania Spinosa Kernel Oil	Twichya /BioPro Green	223747-87-3 ; 299184-75-1	-	100	100	EMOLLIENT, SKIN CONDITIONING

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2. PHYSICAL/CHEMICAL CHARACTERISTICS AND STABILITY OF THE COSMETIC PRODUCT

a. PHYSICAL/CHEMICAL CHARACTERISTICS AND STABILITY OF SUBSTANCES OR MIXTURES

Substance (INCI) / Mixture	Chemical NAME	Physical form	Molecular weight (g/mol)	Water Solubility /Solubility	Partition coefficient	Absorption spectra (UV absorbers)
Argania Spinosa Kernel Oil	**Not available (Glycerol triesters and fatty acids)**	**Yellow, clear oily liquid**	**Not applicable**	**Not soluble in water, slightly soluble in ethanol (96%), miscible with light petroleum**	**Not detremined**	**Not applicable**

b. PHYSICAL/CHEMICAL CHARACTERISTICS OF THE FINISHED COSMETIC PRODUCT

Parameter	Specification	Result
Physical state	Clear oily liquid	Conforms
Colour	Very light yellow	Conforms
pH	Neutral	Conforms
Odour	Characteristic	Conforms
Peroxide value: (meq/O2 active per kg)	0,90-3,10	1,30
Water content and volatile matter: (% m/m)	0,01-1,01	0,04

c. STABILITY OF THE COSMETIC PRODUCT

The physical stability of the finished product is justified on the basis of the STABILITY AND COMPATIBILITY TEST REPORT document, which is ensuring that no changes in physical state of the finished product occur during transport, storage or handling of the product.

The stability testing was performed according to the generally accepted method (attached stability test results/ final report is in the PIF).

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EVALUATION OF PHYSICHAL PROPERTIES OF THE PRODUCT IN GLASS CONTAINER

Parameter	Initial	Accelerated study 40°C				Accelerated study 5°C			
		2 weeks	6 weeks	10 weeks	12 weeks	2 weeks	6 weeks	10 weeks	12 weeks
Date	13.4.2017	27.4.2017	25.5.2017	22.6.2017	6.7.2017	27.4.2017	25.5.2017	22.6.2017	6.7.2017
Appearance	Oily liquid	Oily liquid	Oily liquid	Oily liquid	Oily liquid	Oily liquid	Oily liquid	Oily liquid	Oily liquid
Colour	Yellow transparent	Yellow transparent	Yellow transparent	Yellow transparent	Yellow transparent	Yellow transparent	Yellow transparent	Yellow transparent	Yellow transparent
Odour	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic
pH	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Density (g/ml)	0,907	0,907	0,906	0,907	0,907	0,912	0,911	0,910	0,911
Phase separation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

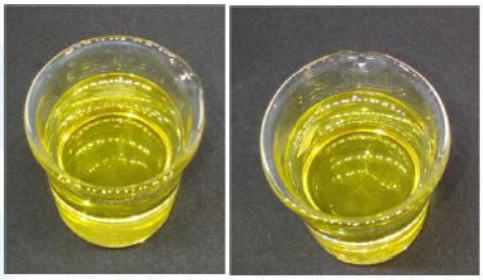


Figure 1: Product in glass container before (left) and at the end (right) of the 40°C stability test.

EVALUATION OF ORGANOLEPTIC PROPERTIES OF AFTER FREEZE-THAW TESTING (-30°C → 25°C)

Parameter	Cycle 1	Cycle 2	Cycle 3
Date	Oily liquid	Oily liquid	Oily liquid
Appearance	Yellow transparent	Yellow transparent	Yellow transparent
Colour	Characteristic	Characteristic	Characteristic
Odour	Oily liquid	Oily liquid	Oily liquid
Phase separation	N/A	N/A	N/A

Based on the test results, the date of minimum durability is equal to 24 months from the date of manufacturing.

The product should be stored in dark and dry place.

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3. MICROBIOLOGICAL QUALITY

a. MICROBIOLOGICAL QUALITY OF SUBSTANCES AND MIXTURES

Substances and mixtures susceptible to microbial growth (water based mixtures, protein - rich materials, plant or animal raw materials)	Not present
Raw materials which do not support microbial growth (organic solvents)	Present

b. MICROBIOLOGICAL QUALITY OF THE FINISHED COSMETIC PRODUCT

According to the 'Guidelines on Microbiological Quality of the finished product' (SCCS Notes of Guidance), the following limits apply:

Category 1: Products specifically intended for children under 3 years, eye area and mucous membranes.

Category 2: Other cosmetic products.

Types of microorganism	Products specifically intended for children under three years of age, the eye area or the mucous membranes	Other products
Total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mould)	**≤ 1 x 10^2 CFU per g or ml [a]**	**≤ 1 x 10^3 CFU per g or ml [b]**
Escherichia coli	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Pseudomonas aeruginosa	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Staphyloccocus aureus	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Candida albicans	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Due to inherent variability of the plate count method, according to USP Chapter 61 or EP Chapter 2.6.12, Interpretation of results, results considered out of limit if **a > 200 CFU/g or ml,** **b > 2 000 CFU/g or ml.** NOTE When colonies of bacteria are detected on Sabouraud Dextrose agar, Sabouraud Dextrose agar containing antibiotics may be used.		

(Source: The SCCS Notes of Guidance for testing of cosmetic ingredients and their safety evaluation)

This product was evaluated according to the category 2, and the following results were obtained:

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EVALUATION OF MICROBIOLOGICAL STABILITY OF THE PRODUCT – INITIAL

Test	Method	Result
Total aerobic mesophilic bacteria	According to ISO 21149:2009	‹ 10 CFU/g
Enumeration of yeast and mould	According to ISO 16212:2008	‹ 10 CFU/g
Presence of Candida albicans	According to ISO 18416:2009	Absent in 1g
Presence of Pseudomonas aeruginosa	According to ISO 22717:2016	Absent in 1g
Presence of Staphylococcus aureus	According to ISO 22718:2016	Absent in 1g
Presence of Eschericchia coli	According to ISO 21150:2010	Absent in 1g

EVALUATION OF MICROBIOLOGICAL STABILITY OF THE PRODUCT – FINAL

Test	Method	Result
Total aerobic mesophilic bacteria	According to ISO 21149:2009	‹ 10 CFU/g
Enumeration of yeast and mould	According to ISO 16212:2008	‹ 10 CFU/g
Presence of Candida albicans	According to ISO 18416:2009	Absent in 1g
Presence of Pseudomonas aeruginosa	According to ISO 22717:2016	Absent in 1g
Presence of Staphylococcus aureus	According to ISO 22718:2016	Absent in 1g
Presence of Eschericchia coli	According to ISO 21150:2010	Absent in 1g

The results show, that the microbiological purity of the product is acceptable and meets the criteria listed above.

The efficacy of the preservation of a finished cosmetic product was not assessed experimentally.

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4. IMPURITIES, TRACES, INFORMATION ABOUT THE PACKAGING MATERIAL

a. IMPURITIES AND TRACES

The test stability and compatibility test was performed according to the generally accepted method, the results below were obtained:

EVALUATION OF PHYSICHAL PROPERTIES OF THE PRODUCT IN ORIGINAL PACKAGING

Parameter	Initial	Accelerated study 40°C				Accelerated study 5°C			
		2 weeks	6 weeks	10 weeks	12 weeks	2 weeks	6 weeks	10 weeks	12 weeks
Date	13.4.2017	27.4.2017	25.5.2017	22.6.2017	6.7.2017	27.4.2017	25.5.2017	22.6.2017	6.7.2017
Appearance	Oily liquid	Oily liquid	Oily liquid	Oily liquid	Oily liquid	Oily liquid	Oily liquid	Oily liquid	Oily liquid
Colour	Yellow transparent	Yellow transparent	Yellow transparent	Yellow transparent	Yellow transparent	Yellow transparent	Yellow transparent	Yellow transparent	Yellow transparent
Odour	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic
pH	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Density (g/ml)	0,908	0,906	0,906	0,907	0,907	0,912	0,912	0,914	0,911
Phase separation	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A



Figure 2: Product in its original packaging before (left) and at the end (right) of the 40°C stability test.

This product is manufactured according to Good Manufacturing Practice (ISO 22716). Ingredients used throughout must be of a high quality and (where specified) they have to meet purity criteria listed in the Cosmetics legislation. Information provided on ingredient purity and representative certificates of analysis are held in the PIF and are acceptable.

b. THE RELEVANT CHARACTERISTICS OF PACKAGING MATERIAL

The product is packaged in a glass bottle of different sizes (30 mL, 50 mL, 100 mL, 250 mL) with plastic cap (PS) and plastic pump (PP). These packaging components are widely used for consumer products. They are non-porous to inks and adhesives and are unlikely to react chemically with this product. They are considered to be safe since there is no evidence of a possible migration of packaging components into the product. Documentation about the packaging material is kept in the PIF.

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5. NORMAL AND RESONABLY FORSEEABLE USE

This product is a leave – on body oil, targeted population adults.

Instructions for use written on the label	Apply a few drops on your skin, hair, nails.
Precautions for use written on the label	Keep out from direct sunlight. Discontinue use if an allergic reaction occurs.

A clear explanation of the normal intended use and the reasonably foreseeable use is provided on the product label and therefore a mistaken use (not a misuse) is not recognisable.

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6. EXPOSURE TO THE COSMETIC PRODUCT

Product Type:	Body Oil
Targeted Population:	Adults
Estimated daily amount applied (g):	7,82*
Skin Surface Area of Application/cm^2:	15670*
Calculated daily exposure (g/day)	7,82
Calculated relative daily exposure (mg/kg bw/day):	123,2*
Amount Per Unit Area of Skin per day mg/cm^2/day:	0,5
Exposure time:	12 h**
Frequency of application:	2,28**
Part of the body exposed:	Whole body

*SCCS Body lotion; ** RIVM, body lotion

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7. EXPOSURE TO THE SUBSTANCES

INCI	Retention factor	NOAEL	SED	MoS
Argania Spinosa Kernel Oil	1	Not available	130,33	Not available

Calculations of Margin of Safety (MoS) have been determined for all ingredients where this is possible from published toxicity information. The method used to do this is:

SED (whole product)*% ingredient = SED (ingredient)

MoS = NOAEL (ingredient)/SED (ingredient).

In every case, the MoS is >100 which is considered to be acceptable. In addition, calculations are also presented to show by how much each ingredient is below the recommendations of industry (CTFA) and those required by European cosmetic legislation. All ingredients fall below any recommended maxima.

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8. TOXICOLOGICAL PROFILE OF THE SUBSTANCES

INCI name	Argania Spinosa Kernel Oil
Restriction	None
General description	Argania Spinosa Kernel Oil, also called argan oil, is the oil expressed from the kernels of the argan tree. The argan tree is found primarily in Morocco, where its nutritional oil is eaten. The oil from argan tree kernels contains about 45-55% oleic acid, 28-36% linoleic acid, 10-15% palmitic acid and 5-7% stearic acid. When used in cosmetics and personal care products, Argania Spinosa Kernel Oil functions as skin-conditioning agents - emollient, skin-conditioning agents - miscellaneous and skin-conditioning agents – occlusive. Argan oil is generally classified as not toxic or harmful. The safety of Plant-Derived Fatty Acid Oils including Argania Spinosa Kernel Oil have been assessed by the CIR Expert Panel. CIR Expert Panel concluded that Argania Spinosa Kernel Oil is safe in the present practices of use and concentrations. There are no reported adverse effects or expected adverse effects from the topical application of this oil.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 5000 mg/kg
Skin irritation and skin corrosivity	5% Argania Spinosa Kernel Oil in a face serum was not an irritant (HRIPT)
Mucous membrane irritation (eye irritation)	May cause irritation, burning, lachrymation, blurred vision after liquid splash
Skin Sensitization	5% Argania Spinosa Kernel Oil in a face serum and 10% Argania Spinosa Kernel Oil in a skin salve were not sensitizers (HRIPT)
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	No data available
Mutagenicity/ genotoxicity	No data available
Carcinogenicity	No data avialble
Reproduction toxicity	No data available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	/
Reference	(1) CIR Expert Panel. Plant-Derived Fatty Acid Oils as Used in Cosmetics, Final Report. March 4, 2011.

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	(2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

Perfume compliance to IFRA regulations:

This product is fragrance free.

9. UNDESIRABLE EFFECTS AND SERIOUS UNDESIRABLE EFFECTS

The product is available on the market since December 2017. No undesirable effects have been reported till now.

10. INFORMATION ON THE COSMETIC PRODUCT

- The product has not been tested on animals
- The products does (not) contain CMR, nanoparticles...

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PART B - COSMETIC PRODUCT SAFETY ASSESSMENT

1. ASSESSMENT CONCLUSION

The cosmetic product Organic Argan Oil can be assessed as **SAFE** for normal and reasonably foreseeable use in accordance with the European Cosmetics Regulation (EC) No 1223/2009 (as amended) respectively.

2. LABELLED WARNINGS AND INSTRUCTIONS FOR USE

The following instructions for use and warnings are written on both, primary and secondary packaging:

Instructions for use written on the label	Apply a few drops on your skin, hair, nails.
Precautions for use written on the label	Keep out from direct sunlight. Discontinue use if an allergic reaction occurs.

The labelled instructions for use and the general description of the product indicate the explicit use of the finished product as a leave on body oil intended for daily use. A reasonably foreseeable mistaken use additional to this use (not a misuse) is not recognisable

3. REASONING

a. SAFETY EVALUATION OF SUBSTANCES AND/OR MIXTURES

The margin of safety, which takes into account all systemic toxicity endpoints, has been calculated for each of the ingredient used in this cosmetic product. All ingredients (where the NOAEL value was available) have a sufficiently large MoS (>100), which is supporting the safety of the finished product. Specific exposure consideration for the targeted consumer group (adults) has been taken into account as documented in the exposure and MoS calculation.

b. SAFETY EVALUATION OF COSMETIC PRODUCT

Stability data

The stability data (microbiological and physical-chemical stability) of the formula after storage meet the previously specified characteristics. They confirm a sufficient stability of the formula. The shelf life for the final product is 36 months from the date of manufacturing. Based on the above mentioned the product is rated as safe.

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Packaging

The package consists of a glass bottle (different sizes), plastic pump and plastic cap. The packaging of the product is made to protect the product during shelf life and use and to enable the safe use of the product. No interaction with packaging material is expected as the packaging compatibility with the formulation was confirmed during its stability test. Based on that the packaging is rated to be suitable and safe for this specific product type. This package does not contain hazardous materials that require special markings or labelling on the shippers.

Normal and reasonably foreseeable use

A reasonably foreseeable mistaken use (not a misuse), is not recognizable.

Undesirable effects and serious undesirable effects

From the market launch until today the complaint statistics as documented in the Consumer Response System (CRS) of the manufacturer of this product show no remarkable consumer complaints regarding undesirable effects or serious undesirable effects in general.

Information on the cosmetic product

The product is a leave-on body (care) oil intended for daily use, targeted population adults.

The packaging of cosmetic product should include the following information in indelible, easily legible and visible lettering:

- Brand name
- Name of the product
- Function of the cosmetic product (unless it is clear from its presentation)
- Ingredients list (ingredients present **in more than 1%** in the end product should follow in the same order as here): **ARGANIA SPINOSA KERNEL OIL**
- Particular precautions for use:
  Keep out from direct sunlight.
  Discontinue use if an allergic reaction occurs.
- Instructions for use:

  Apply a few drops on your skin, hair, nails.
- Date of minimum durability (for products with a minimum durability ≤ 30 months) or PAO (for products with a minimum durability > 30 months)

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- Nominal quantity (except for packaging containing less than 5 grams or 5 millilitres, free samples and single-application packs)
- Batch number or the reference for identifying the cosmetic product
- Responsible person name and address
- Manufacturer name and address
- Products' country of origin

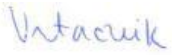
SUMMARY

The safety assessment is based on the chemical specification and toxicological profile of the ingredients as supplied at the time of assessment and an assessment of the final cosmetic product.

All statements in this safety assessment were elaborated on the recent level of knowledge. Every change in the formulation or changes and/or additional information of relevant data respectively will require an immediate re-evaluation of this safety assessment.

Concerning the skin tolerance, the final product is expected to be well tolerated and to have a good cosmetic acceptability.

Safety assessor: Kristina Vrtačnik, MPharm

Signature: 

We confirm that the product is safe in the stated application when used under normal and reasonably foreseeable use. Its composition complies with EC Regulation 1223/2009 and all its annexes.

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