9202000G – MONOI OIL

Version: 23 - 03/APR/2018

1. PRODUCT IDENTIFICATION

Trade Name:	MONOI OIL
Manufacturer:	PROVITAL
Responsible for the Safety Assessment:	Lourdes Mayordomo
Tf./Fax:	3493-7192350/7190294
e-mail:	l.mayordomo@provitalgroup.com
Kind of Raw Material:	Active Ingredient
Function of the Ingredient (PCPC Inventory):	Fragrance Ingredients; Hair Conditioning Agents; Skin-Conditioning Agents - Miscellaneous; Skin-Conditioning Agents - Occlusive
Function of the Ingredient (UE Inventory):	Emollient, Hair conditioning, Masking, Skin conditioning, Solvent, Perfuming

2. PRODUCT COMPOSITION

Components Breakdown (INCI). Including actives, solvents, preservatives, antioxidants and other additives:

[EU]		CAS	EINECS
Cocos Nucifera Oil	95,1 - 99,2 %	8001-31-8	232-282-8
Gardenia Taitensis Flower Extract	1 - 5 %	---	---
Antioxidants			
Tocopherol	0,06 - 0,2 %	59-02-9	200-412-2
		54-28-4	200-201-5
		119-13-1	204-299-0
		1406-66-2	---

PCPC [CTFA]		CAS	EINECS
Cocos Nucifera (Coconut) Oil	95,1 - 99,2 %	8001-31-8	232-282-8
Gardenia Taitensis Flower Extract	1 - 5 %	---	---
Antioxidants			
Tocopherol	0,06 - 0,2 %	10191-41-0	233-466-0
		59-02-9	200-412-2
		119-13-1	204-299-0
		1406-66-2	---

3. TOXICOLOGICAL INFORMATION

Data obtained in our own toxicological tests and/or bibliographical research

Animal testing:

This product has not been the subject of animal testing or retesting for cosmetic purposes by or on behalf of this company.

General information:

It exists a CIR Final Report on Safety Assessment of Coconut Oil, Coconut Acid, Hydrogenated Coconut Acid and Hydrogenated Coconut Oil including all the toxicological data: JACT, 5 (3) 1986

The Tocopherol has the GRAS status ('Generally Recognized As Safe'): (21CFR 182.3890), (21 CFR 182.8890),

(21CFR 184.1890).

The CIR panel concluded that the Tocopherol is safe in the present practices of use and concentration in cosmetics when formulated to be nonirritating (CIR Final Amended Report March, 2014)

alfa-Tocopherol: Clinical experience indicates that the safety margin is substantial even with the prolonged daily administration (Fed. Reg. 1979; Briggs 1978).

Classification according to Council of Europe (*):

Non-classified.

*(1)- Non-recommended ingredients (2)-Ingredients which could not be assessed (3) –Recommended ingredients

Cytotoxicity:

No data available.

Skin Irritation:

A randomized double-blind clinical trial with Cocos nucifera Oil showed negative patch-test results in 34 volunteers (Dermatitis; 2004 Sep; 15(3):109-16).

Undiluted coconut oil was applied to the skin of 9 rabbits by means of a 24-hour occlusive patch-test; no irritation was observed (Journal of the American College of Toxicology; 1986; vol.5, nr.3).

A skin irritation test was made with a 1% aqueous solution of a bar soap containing 13% Coconut Oil. Very minimal skin reactions were recorded in 106 volunteers. The product was considered safe. (Journal of the American College of Toxicology; 1986; vol.5, nr.3).

Monoi oil: Cutaneous irritation test in a reconstituted epidermis. The oil didn't cause any signs of skin irritation. (Supplier data)

Clinical study of skin tolerance. In the experimental conditions Monoi oil doesn't cause any histological alteration. According to the protocol realized in 10 volunteers Monoi oil is not irritating. (Supplier data)

Skin Sensitization:

An assay evaluates the allergenic potential of coconut oil at concentrations of 50 and 100% in guinea pigs; the oil showed to be non-irritating and failed to produce an allergic response (Journal of the American College of Toxicology; 1986; vol.5, nr.3).

A skin sensitization assay with coconut oil at 2.5% (nine 24h-induction-patches applied over a 3-week period) did not show erythematous reactions (Journal of the American College of Toxicology; 1986; vol.5, nr.3).

Monoi oil: Cutaneous sensitization test according to the Marzulli and Maibach method in 25 healthy volunteers. There were no symptoms of cutaneous Sensitization in the 25 volunteers. The study concluded that in normal conditions of use the oil is well tolerated. (Supplier data)

Evaluation of skin tolerance and allergic potential: According to the results in 107 volunteers who said they have sensitive skin, in the certain experimental conditions, Monoi oil didn't show any skin irritant or allergic potential. (Supplier data)

Eye Irritation:

Undiluted coconut oil was assayed for eye irritation in rabbits; the results were indicative of minimal eye irritation (Journal of the American College of Toxicology; 1986; vol.5, nr.3).

Monoi oil: Ocular irritation In vitro Test in fibroblasts. The oil was classified as a very mild irritant. (Supplier data)

Mutagenicity:

Vanillin: Negative in Micronucleus Test and negative in Salmonella (NTP Testing Status, M20110)

Vanillin (RTECS nº YW5775000): Cytogenetic analysis on human lymphocytes = 4mmol/L; Sister chromatid exchange = 750 umol/L; DNA damage on human cells = 2,5 mmol/L/4H.

Coconut oil, saponified: Salmonella typhimurium, Dose: 62,5 ng/plate/2D. (RTECS nº GG6465000)

Acute toxicity:

Coconut Oil: LD50> 5 g/kg rat p.o. (Journal of the American College of Toxicology; 1986; vol.5, nr.3).

Subchronic and chronic toxicity:

Coconut Oil (RTECS GG6040000): TDLo p.o. rat = 1688 g/kg/90D-C

Coconut oil at 25% in the diet showed no toxic effects in a study in rats for 90 days. (Journal of the American College of Toxicology; 1986; vol.5, nr.3).

Reproductive effects:

No data available.

Other data:

A phototoxicity test was made with a 3% aqueous solution of a bar soap containing 13% Coconut Oil. The

occlusive patches and UVA exposure were applied to 10 volunteers over a 6-week period; no evidence of phototoxicity was observed (Journal of the American College of Toxicology; 1986; vol.5, nr.3).

A photosensitization test was made with a 3% aqueous solution of a bar soap containing 13% Coconut Oil. The product was tested in 52 volunteers; it was applied during 3 weeks before exposition to sunlight. No evidence of photosensitization was noted (Journal of the American College of Toxicology; 1986; vol.5, nr.3).

4. ECOLOGICAL DATA

Biodegradability:

Vanillin: The study of biodegradability under anaerobic conditions shows that vanillin degrades rapidly (OECD Screening Information Data Sets, SIDS, Vanilin)

Aquatic Toxicity:

Vanillin: Acute toxicity (fish): CL50/pimephales promelas: 57-123 mg/l/96h Acute toxicity (daphnia) : CL50 (24h) : 180 mg/l (OECD Screening Information Data Sets, SIDS, Vanilin)

Other data:

Vanillin: There is no trend to bioaccumulation. (OECD Screening Information Data Sets, SIDS, Vanilin)

5. CONCLUSION

The European cosmetics legislation (Regulation (EC) No 1223/2009) establishes the need to assess the safety of cosmetic products, taking into account the toxicological profile of the ingredients. To do this, in the case of possible systemic effects, it is necessary to obtain the NOAEL (no observed adverse effects level) for the calculation of MoS (margin of safety). The absence of these considerations shall be duly justified.

The NOAEL value, or else other data used for the same purpose (LOAEL, LD50, etc.), can only be calculated experimentally from toxicological studies that require the use of animals. Since Provital does not perform any animal testing, it has established a system to ensure the safety of its products without the need of NOAEL and the subsequent calculation of MoS. This systematic, in the case of natural complex substances (NCS) has been endorsed by international organisms and renowned toxicologists.

The safety of this ingredient is then established based on the following information: known uses of the active in different fields (medicine, food, cosmetics, etc.), profile of the chemical compounds of the ingredient and bibliographic toxicological information available for the active and its components. The integration and study of all these data allows for a conclusion on the safety of the ingredient.

The components of this product have registered adverse effects neither in its described uses nor in the historical marketing of this company. These data and the available toxicological information lead to the conclusion that the use of this product, under the normal conditions of cosmetic use, involves no risk for consumers.