Sapo Soap

COSMETIC PRODUCT SAFETY ASSESSMENT

PATCHOULI SOAP

This report prepared based on the
Regulation (EC)No.1223/2009 and the
SCCS's Notes Of Guidance For The
Testing of Cosmetic Ingredients And Their
Safety Evaluation 9th Revision 2015

COSMETIC PRODUCT SAFETY ASSESSMENT
Accordingto (EC) No 1223/2009 Cosmetic Regulation

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A. COSMETIC PRODUCT SAFETY INFORMATION

Information on Product Identity:

Product Name : **PATCHOULI SOAP**

IntendedUse : Skin Care Product/ Soap / Rinse-off Product

Manufacturer : Fratello Kuyumculuk Hediyelik Eşya Ve Temizlik Ürünleri Sanayi Dış Ticaret Limited Şirketi

Adress : Maltepe Mah. Maltepe Cad. No:15 Zeytınburnu/Istanbul

Telephone : +905367126565

1. Qualitative and Quantitative Composition of the Cosmetic Product

INCI NAME	EINECS/ ELINCS NO	CAS NO	CONCENTRATION (%)	FUNCTION
OLEA EUROPAEA FRUIT OIL	232-277-0	8001-25-0	60,0	FRAGRANCE PERFUMING SKIN CONDITIONING
AQUA	231-791-2	7732-18-5	30,0	SOLVENT
COCOS NUCIFERA OIL	232-282-8	8001-31-8	20,0	FRAGRANCE HAIR CONDITIONING PERFUMING SKIN CONDITIONING
SODIUM HYDROXIDE	215-185-5	1310-73-2	10,0	BUFFERING DENATURANT

POGOSTEMON CABLIN LEAF OIL	8014-09-3 / 84238-39-1	- / 282-493-4	1,0	FRAGRANCE
PAPAVER SOMNIFERUM SEED	84650-40-8	283-510-8	1,0	ABRASIVE
PARFUM			1,0	FRAGRANCE SKIN CONDITIONING

***SODIUM HYDROXIDE** is allowed in cosmetic products under the following conditions set in Annex III (15a) of Regulation (EC) No 1223/2009:

Annex III: List of substances which cosmetic products must not contain except subject to the restrictions laid down

1.2. Control of Substances Compliance with Regulation

List of Substances which cosmetic products must not contain except subject to the restriction slaid down Cosmetic Regulation (EC) No 1223/2009

2. Physical/Chemical Characteristics and Stability of theCosmetic Product

2.1. Physical / Chemical Characteristics

The following table was formed by examining the specification of the final product.

The cosmetic product ''argania" soap has the following physical/chemical characteristics:

Parameter		**Specifications**	**Result**
Organoleptic characteristics	**Appearance**	SOLID SOAP	APPROVED

	Color	CHARACTERISTIC	APPROVED
	Odor	CHARACTERISTIC	CHARACTERISTIC
Physicochemical Characteristic	**pH**	10 – 10,5	APPROVED

The stability of the product has been tested at, 25°C 12 months and in the original package of the product.
During this period, appearance, color, odor, pH and other parameters were tested.
It was stated that during the stability tests, no deviation/separation from the original condition of the product was observed.
The results obtained from the stability test are considered to be acceptable.
The durability period of the product after opening is stated on the label as 12 months.
The protocol with results of stability testing is attached in **Annex.**

3. Microbiological Quality

Staphylococcus aureus, *Pseudomonas aeruginosa*, and *Candida albicans* and *Escherichia coli* are the microorganisms that should not be present in cosmetic products. Since different skin areas may have different sensitivity, two different categories have been defined for cosmetic products;
Category 1 Products for children under 3 years of age, products applied to the eye area, products applied to mucosmembranes, products not rinsed

Category 2 Other products, rinsed productsCategory 1: Total number of live aerobic mesophilic microorganisms (bacteria, yeast and mold) should not exceed 10^2cfu/g or 10^2cfu / ml. Staphylococcus aureus, Pseudomonas aeruginosa, Candida albicans or Escherichia coli should not be present.

Category 2: The total number of live Aerobic mesophilic microorganisms must not exceed 10^3cfu / g or 10^3cfu / ml. *Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Candida albicans* and *Escherichia coli*should not be present.

pH: 10-10.5 ; therefore there is no risk of microbial contamination.

ChallengeTest ; ISO 11930

The test involves preparing appropriate microorganisms at certain inoculum levels and counting the microorganisms in the sample by sowing from the sample containing the microorganism at specific time intervals

. It is judged whether the protective property of the product is sufficient by observing whether a significant decrease or increase of the microorganisms in the test conditions on days 7, 14 and 28 is observed appropriately

pH: 10-10.5 ; therefore considered as no risk

4. Impurities, Traces, Informations about the Packaging Material

PATCHOULI SOAP is presented to the consumer in 135 g packaging.

The product was analyzed according to the packaging standards. Raw material specifications are available upon request.

It consists of suitable cosmetic quality components, which are the packaging materials of the product. There is no negative result with regard to any interaction or deterioration of the packaging material with the product.

5. Normal and Reasonably Foreseeable Use

Warnings on the product label:

Avoid contact with eyes and mouth. In case of contact,
rinse thoroughly with plenty of water.

Application of the Product:

Before use, read
the instructions of your product at sopna.co, you can
access the site with QR code. Keep in a dry place

6. Exposure to the Cosmetic Product

Product type: Leave-on product

The sites of aplication:Area body

The surface areas of application (cm^2): 17500

Estimated amount of product applied (g): 18,67g

The duration and frequency of use: 1,43/day

Retention factor: 0,01

The normal and reasonably foreseeable exposure route:Dermal

Exposed popultion:Adulds

A = 2,79 mg/kg bw /day

('The SCCS's Notes Of Guidance For The Testing Of Cosmetic Ingredients And Their Safety Evaluation 9th Revision 2015)

7. Exposure to the Substances

Dermal absorption reported as a percentage of the amount of substances applied:

SED = A (mg/kg bw/day) × C(%)/100 × DAp (%)/100

SED A (mg/kg bw/day) :Systemic exposure dosage

A (mg/kg bw/day): Estimated daily exposure to a cosmetic product per kg body weight,based upon the amount applied and the frequency of application

C (%):The concentration of the ingredient under study in the finished cosmetic product on the application site.

DAp (%): Dermal Absorption expresed as a percentage of the test dose assumed to be applied in real-life conditions

A = 2,79mg/kg bw/day. An adult's body weigth was accepted 60 kg(Base on The SCCS's Notes Of Guidance For The Testing Of Cosmetic Ingredients And Their Safety Evaluation 9th Revision, 2015.)

Hamaddenin INCI Adı	**OLEA EUROPAEA FRUIT OIL**
Konsantrasyon C	**% 60**

A (mg/kg vücut ağırlığı/gün)	2.79
Dermal Absorbsiyon DAp (%)	**% 100**

SED = A (mg/kg vücut ağırlığı/gün) X C (%) / 100 X DAp (%) / 100

SED =2.79 (mg/kg vücut ağırlığı/gün) X 50 (%) / 100 X 100 (%) / 100

SED = 1.674 (mg/kg vücut ağırlığı/gün)

Hamaddenin INCI Adı	**COCOS NUCIFERA OIL**
Konsantrasyon C	**%20**
A (mg/kg vücut ağırlığı/gün)	2.79
Dermal Absorbsiyon DAp (%)	**% 100**

SED = A (mg/kg vücut ağırlığı/gün) X C (%) / 100 X DAp (%) / 100

SED =2,79 (mg/kg vücut ağırlığı/gün) X 15 (%) / 100 X 100 (%) / 100

SED = 0,558 (mg/kg vücut ağırlığı/gün)

Hamaddenin INCI Adı	**RICINUS COMMUNIS SEED OIL**
Konsantrasyon C	**%5**
A (mg/kg vücut ağırlığı/gün)	2.79
Dermal Absorbsiyon DAp (%)	**% 100**

SED = A (mg/kg vücut ağırlığı/gün) X C (%) / 100 X DAp (%) / 100

SED =2,79 (mg/kg vücut ağırlığı/gün) X 5 (%) / 100 X 100 (%) / 100

SED = 0,1395 (mg/kg vücut ağırlığı/gün)

Hamaddenin INCI Adı	**PARFUM**
Konsantrasyon C	**%1**
A (mg/kg vücut ağırlığı/gün)	2.79
Dermal Absorbsiyon DAp (%)	**% 100**

SED = A (mg/kg vücut ağırlığı/gün) X C (%) / 100 X DAp (%) / 100

SED =2,79 (mg/kg vücut ağırlığı/gün) X 2 (%) / 100 X 100 (%) / 100

SED = 0,0279(mg/kg vücut ağırlığı/gün)

Hamaddenin INCI Adı	**POGOSTEMON CABLIN LEAF OIL**
Konsantrasyon C	**%1**
A (mg/kg vücut ağırlığı/gün)	2.79
Dermal Absorbsiyon DAp (%)	**% 100**

SED = A (mg/kg vücut ağırlığı/gün) X C (%) / 100 X DAp (%) / 100

SED =2,79 (mg/kg vücut ağırlığı/gün) X 2 (%) / 100 X 100 (%) / 100

SED = 0,0279(mg/kg vücut ağırlığı/gün)

Hamaddenin INCI Adı	**LAURUS NOBILIS LEAF**
Konsantrasyon C	**%1**
A (mg/kg vücut ağırlığı/gün)	2.79
Dermal Absorbsiyon DAp (%)	**% 100**

SED = A (mg/kg vücut ağırlığı/gün) X C (%) / 100 X DAp (%) / 100

SED =2,79 (mg/kg vücut ağırlığı/gün) X 2 (%) / 100 X 100 (%) / 100

SED = 0,0279(mg/kg vücut ağırlığı/gün)

INCI NAME	**CONCENTRATION (%)**	**RETANTION FACTOR (R)**	**DERMAL ABSORPTION DAp (%)**	**SED (mg/kg bw/day)**
OLEA EUROPAEA FRUIT OIL	60,0	0,01	100	1,674
COCOS NUCIFERA OIL	20,0	0,01	100	0,558
RICINUS COMMUNIS SEED OIL	5,0	0,01	100	0,1395
POGOSTEMON CABLIN LEAF OIL	1,0	0,01	100	0,0279
PAPAVER SOMNIFERUM SEED	1,0	0,01	100	0,0279
PARFUM	1,0	0,01	100	0,0279

8. Toxicological Profile of the Substances Involved in the Formula

8.1. Calculation of Margin of Safety (Mos)

The product itself has not been subjected to animal experiments.Information about raw materials has been benefited from previous studies.

$$MoS = \frac{NO(A)EL}{SED} \geq 100$$

MoS: Margin of safety of an ingredient

NO(A)EL: The highest exposure of a chemical, determined in toxicity tests etc., having no adverse effect(e.g, onset of sickness) even when the chemical is taken (exposed) daily for the rest of one's life. In practice, mise, rats or other animals are forced to take a chemical for a certain period of time. Usually NOAEL is expressed in the amount of a chemical taken daily per kg body weight (e.g.,mg/kg/day)Safety limit of raw materials with NOAEL value is calculated and stated in the table below

INCI Name	**SED (mg/kg/ bw/day)**	**NO(A)EL (mg/kg vücutağırlığı/gün)**	**MoS (NOAEL/SED)**	**Reference**
OLEA EUROPAEA FRUIT OIL	1,674	N/A	N/A	according to CIR Expert Panel (2011), for more information see the toxicological profile of OLEA EUROPAEA FRUIT OIL; https://www.cir-safety.org/sites/default/files/118_final_oils_web.pdf
AQUA	0,6975	-	-	-
COCOS NUCIFERA OIL	0,558	No adverse effects were noted in either test group during the test period. The authors concluded that Coconut Oil was as effective and safe as	N/A	https://www.cir-safety.org/sites/default/files/115_buff3e_suppl.pdf

		mineral oil when used as a moisturizer.		
RICINUS COMMUNIS SEED OIL	0,1395	N/A	N/A	The very limited data on acute toxicity in target animals comprise mainly information on castor bean products rather than on purified ricin. Amongst ruminants, cattle appear to tolerate higher intakes than sheep. In horses severe colic and death have been observed after a single dose of approximately 7-8 mg ricin/kg b.w. Toxic effects in pigs and birds have been reported as well as accidental poisonings in dogs with vomiting, depression and diarrhoea as the main clinical signs. No- or lowest observed adverse effect levels (NOAELs or LOAELs) for acute effects of ricin could not be identified for any of the animal species. https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2008.726
POGOSTEMON CABLIN LEAF OIL	0,0279	50	1792	**REFERENCE:** Teris A. van Beek, Daniel Joulain,The essential oil of patchouli, Pogostemon cablin: A review, Flavour Fragr J. 2017;1–46.

PAPAVER SOMNIFERUM SEED	0,0279	50	1792	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7009406/
PARFUM	0,0279	N/A	N/A	

8.**2. Toxicological Assessment of the Subtances Involved in the Formula**

Raw materials and mixtures involved in the formula has been evaluated by classifying according to their trade names:

Olea Europaea (Olive) Fruit Oil

1.6% Olea Europaea (Olive) Fruit Oil in a body lotion	HRIPT with 0.02 ml test material , occluded	1 subject had slight erythema following the 7th patch that did not reoccur, no other reactions observed. Not a dermal irritant or sensitizer
22% Olea Europaea (Olive) Fruit Oil in a body moisturizer	HRIPT, semi-occluded	Not a dermal irritant or sensitizer
58.7% Olea Europaea (Olive) Fruit Oil in a conditioning not a dermal irritant or sensitizer	HRIPT with 0.2 ml, semi-occluded	Not a dermal irritant or sensitizer
69.6% Olea Europaea (Olive) Fruit Oil in a foundation	HRIPT with 200 µl test material, occluded	Not a dermal irritant or sensitizer

https://www.cir-safety.org/sites/default/files/118_final_oils_web.pdf

Cocos Nucifera (Coconut) Oil

The oil is obtained from the pulp of coconut palm nuts. Contains triglycerides of fatty acidssuch as: lauric, myristine, oleic, capric and capron. According to the CIR opinioncoconut oil and its derivatives, coconut acid, hydrogenated coconut oil and hydrogenated acidCoconut has been recognized as safe for use in products in current practicesuse and concentrations (Final Report Cosmetic Ingredient Review Expert Panel Amended SafetyAssessment of Cocos Nucifera (Coconut) Oil, Coconut Acid, Hydrogenated Coconut Acid, HydrogenatedCoconut Oil, Ammonium Cocomonoglyceride Sulfate, Butylene Glycol Cocoate, Caprylic / Capric / CocoGlycerides, Cocoglycerides, Coconut Alcohol, Coconut Oil Decyl Esters, Decyl Cocoate, EthylhexylCocoate, Hydrogenated Coco-Glycerides, Isodecyl Cocoate, Lauryl Cocoate, Magnesium Cocoate,Methyl Cocoate, Octyldodecyl Cocoate, Pentaerythrityl Cocoate, Potassium Cocoate, PotassiumHydrogenated Cocoate, Sodium Cocoate, Sodium Cocomonoglyceride Sulfate, Sodium HydrogenatedCocoate, and Tridecyl Cocoate September 23, 2008 Safety Assessment). Maximum safethe concentration in the cosmetic is up to 80%.
https://www.cir-safety.org/sites/default/files/119_draft_decylg_suppl1.pdf

RICINUS COMMUNIS SEED OIL

SUMMARY Ricin is a toxic glycoprotein (with several minor variants) belonging to the type II group of ribosome inactivating proteins (type II RIP) found in the seeds (beans) of the castor oil plant (Ricinus communis L. (Euphorbiaceae)). It is composed of two polypeptide chains of approximately 30 kDa joined by a disulfide bond. A limited number of other plants in the same family contain type II RIPs, i.a. subtropical leguminous climber Abrus precatorius L. and, Croton 1 For citation purposes: Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on ricin (from Ricinus communis) as undesirable substances in animal feed. The EFSA Journal (2008) 726, 1-38. Opinion on ricin as undesirable substance in animal feed The EFSA Journal (2008) 726, 2-38 tiglium L. which contain abrin and crotin I, respectively. The seeds of Croton tiglium contain a number of other toxins which make it unsuitable as a feed for livestock. In the Terms of Reference, the plant Jatropha curcas was also requested to be considered, however, it does not contain a RIP II protein. The toxicity of its seeds can be ascribed to the oil, which contain phorbol esters and this plant is therefore not relevant for this opinion on ricin.

Following extraction of castor oil, ricin is left in the press-cake/castor bean meal2 . Castor oil production mainly takes place outside the EU. Because of its low value of the press-cake as feed no import to the EU is expected.

Following cell uptake by endocytosis, ricin causes acute cell death by inactivation of ribosomal RNA. Acute symptoms in humans after intake of castor beans are hematemesis (vomiting containing blood), diarrhoea, haemorrhagic necroses in several organs, renal failure, circulatory collapse and death after 6 to 14 days with a fatal oral dose of about 1 mg/kg b.w. (5-10 castor beans). Because of its destruction in the intestinal tract, ricin is approximately 1000-fold more toxic following parenteral administration or inhalation, than by the oral route. Oral LD50 values in rats and mice were 20 to 30 mg/kg b.w., and the corresponding intra peritoneal LD50 value

for mice is 22 µg/kg b.w. There are no data on chronic or reproductive toxicity, or genotoxicity of ricin. Crotin I showed LD50 i.p. values in mice of 20 mg/kg b.w.

The very limited data on acute toxicity in target animals comprise mainly information on castor bean products rather than on purified ricin. Amongst ruminants, cattle appear to tolerate higher intakes than sheep. In horses severe colic and death have been observed after a single dose of approximately 7-8 mg ricin/kg b.w. Toxic effects in pigs and birds have been reported as well as accidental poisonings in dogs with vomiting, depression and diarrhoea as the main clinical signs. No- or lowest observed adverse effect levels (NOAELs or LOAELs) for acute effects of ricin could not be identified for any of the animal species.

https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2008.726

PAPAVER SOMNIFERUM SEED OIL

CAS NO: 84650-40-8

EC NO: 283-510-8

Opium alkaloids detected in samples of poppy seeds and poppy seed-containing foods include the phenanthrenes: principally morphine, codeine, thebaine and oripavine, and the benzylisoquinolines: principally papaverine and noscapine. In this Scientific Opinion, the term 'opium alkaloids' refers to these compounds.

Hazard identification and characterisation

Toxicokinetics

Morphine

Morphine is extensively absorbed from the GI tract and is distributed throughout the body. The oral bioavailability of morphine is reduced by both Phase I and II presystemic metabolism in the GI tract and liver.

Morphine diffuses across the placenta, and transfers into milk.

Morphine is metabolised via N-demethylation and O-glucuronidation in the gut and the liver. Metabolites are normorphine, M3G and M6G.

The rate and pathways of opioid metabolism and distribution of morphine may be influenced by genetic factors (active transport proteins, including the *P*-glycoprotein) and medical conditions (liver and kidney disease), which can account for part of the observed inter-individual variation in morphine effects.

Codeine

Codeine is readily and extensively absorbed from the GI tract following oral administration and is distributed throughout the body.

Codeine penetrates the placental barrier and enters fetal circulation. It is also excreted in breast milk.

Codeine is metabolised via O-demethylation, N-demethylation and O-glucuronidation in the liver and gut. Main metabolites are morphine, norcodeine and C6G. The formed morphine is further metabolised into normorphine, M3G and M6G.

Codeine metabolism to morphine is dependent of the CYP2D6 activity. Individuals can be classified into poor metaboliser, intermediate metaboliser, extensive metaboliser or ultra-rapid metaboliser. The extensive metaboliser represents the majority of the Caucasian population. The phenotypes generated by different CYP2D6 alleles affects the sensitivity of humans to adverse effects of codeine.

There is a sharp increase in both morphine AUC and Cmax following codeine exposure in extensive/ultra-rapid metabolisers.

No new data were identified that provide a basis to change the previous conclusion from 2011 that the maximal metabolic conversion of codeine into morphine does not exceed 20%.

Thebaine, oripavine, noscapine and papaverine

Based on limited information, oral bioavailability of thebaine, oripavine, noscapine and papaverine appears to be reduced due to pre-systemic metabolism in the GI tract and liver primarily involving demethylation reactions but also glucuronidation.

There are indications that thebaine is metabolised into several metabolites, including oripavine and morphine.

Toxicity in experimental animals

Morphine

In experimental animals, morphine acts on the nervous system and its development. Most of the available data were generated by using routes of administration and doses that are not relevant for the purpose of the present opinion.

Chronic toxicity, including carcinogenicity, of morphine has not been systematically evaluated. Based on the lack of carcinogenicity of codeine which is metabolised to morphine, it is unlikely that morphine is carcinogenic.

Morphine is genotoxic only *in vivo* but most likely by a non-DNA reactive mode of action.

Depressed sexual activity, reduced testicular function and spermatogenesis, disruption of ovarian cyclicity and decreased pregnancy rate have been observed in rats exposed to morphine.

Oral morphine exposure of pregnant rats or mice affects the normal development of the placenta and the brain.

Morphine causes immunosuppressive actions.

Codeine

Long-term feeding studies in rats and mice showed no evidence of carcinogenic activity.

Codeine is not genotoxic.

Based on limited data it is concluded that oral administration of codeine did not result in teratogenicity.

There are no data to make conclusions on the neurotoxic effects of codeine.

Thebaine and oripavine

Based on LD_{50} values, thebaine and oripavine are more toxic than morphine.

Noscapine

Noscapine has a lower acute toxicity compared to the other opium alkaloids considered in this Scientific Opinion.

Repeated exposure of rats and dogs to noscapine did not result in adverse effects.

Noscapine is an aneugen *in vitro* most likely by a non-DNA reactive mechanism. Taking into account also its low systemic availability, a risk of genotoxic damage *in vivo* is very unlikely**.**

Papaverine

The LD_{50} values, by oral and parenteral administration are similar to those for morphine. However, evidence of toxicity was not seen following oral administration of papaverine to rats at 50 and 100 mg/kg bw per day and to dogs at 10 mg/kg bw per day.

REFERENCE:

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7009406/

EFSA (European Food Safety Authority) Update of the Scientific Opinion on opium alkaloids in poppy seeds, EFSA Journal 2018;16(5):5243

POGOSTEMON CABLIN LEAF OIL

CAS NO: 8014-09-3 / 84238-39-1

EC NO: - / 282-493-4

Toxicology And Skin Sensitization

The skin contact allergy of essential oils or their constituents is a concern in fragrance compounding, and PEO is not an exception. Neat or as the main constituent of PEO, patchoulol is a fragrance ingredient used in decorative cosmetics, fine fragrances, shampoos, toilet soaps and other toiletries as well as in non-cosmetic products such as household cleaners and detergents. In neat form, its use annual worldwide use is 0.5-1 metric tonne, whereas the consumption of the essential oil is much bigger at ~1300 tonnes. Belsito et al. have made an assessment of the general toxicological and dermatological risk of many terpene alcohols including patchoulol-containing products.374 Their conclusion was that patchoulol has a low order of acute toxicity with dermal and oral **NOAELs (no observed adverse effect levels) of 50 mg/kg body** weight/day or greater and is negative in mutagenicity and genotoxicity tests. At current use levels, patchoulol is non-irritating and sensitisation potential is generally low. In a separate note the results specific to patchoulol were summarised by Bhatia et al.375 In a rat study, PEO orally administered for 90 days at a level in excess of at least 100 times the maximum estimated daily dietary intake in man evoked no adverse effect on growth, food consumption, haematology, blood chemistry, liver and kidney weights or on gross and microscopic appearance of major organs at autopsy.

Over time, various groups have investigated PEO in more detail with respect to the risk of triggering allergic reactions on the skin. Nakayama et al. found 3 “strongly positive” and 8 “weakly positive” reactions to “Patchouli oil” (unknown test concentration) in patch tests with 183 patients.377 The number of patients, mostly Japanese women, with pigmented cosmetic dermatitis thought to be caused in part by PEO, decreased significantly after 1978 when major cosmetic manufacturers began to eliminate strong contacts sensitizers (e.g., cinnamaldehyde) from their products.378 Clinical data published in 2002 reported that 0.8% positive reactions to PEO (10% in petrolatum) in 1606 consecutive patients were observed.379 A more recent study on patch results with PEO identified 0.6% positive reactions in 2446 consecutively tested patients and 1.4% positive reactions in 828 patients tested in the context of a special series.380 For assessing skin contact allergy of cosmetics, two "fragrances mixes" (14 components in total), the 26 allergens,381 which need to declared in cosmetics, and several essential oils were tested. When PEO was patch-tested in this study (10% concentration in petrolatum), 53 patients out of 5539 (1%) gave a positive reaction.382 It is regrettable that, no information was given in this report about the intensities of the reactions, and none of these reports gave any information about the quality of the tested essential oils (origin, genuineness, age, peroxide

value, etc.). Some of the above studies have been summarised by the Scientific Committee on Consumer Safety of the EU.383

The European Chemicals Agency (ECHA) is the driving force among regulatory authorities in implementing the European Union's groundbreaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness. Just as for any other chemical entering the EU or used in the EU, ECHA provides information on PEO and addresses toxicological concerns.

REFERENCE:

Teris A. van Beek, Daniel Joulain,The essential oil of patchouli, Pogostemon cablin: A review, Flavour Fragr J. 2017;1–46.

9. Undesirable Effects and Serious Undesirable Effects

Not known or reported. Any adverse reactions and serious adverse effects will be reported. Any serious adverse effect will be notified to the Ministry of Health. If the supplier is a ware of costumer complaints the supplier must bring this to the attention of the safety assessor and submit this formulation for reassessment and notify the competent authorities of corrective actions taken.

10. Information on the Cosmetic Product

The information contained in the reportare as follows:

- Certificate of Analysis orSpecifications of Finished Product
- Certification of Analysis and Specifications of Ingredients
-Formulation of the Product
- Packaging Quality Certificate
-Stability Test report
- Physical and chemical test report

B. COSMETIC PRODUCT SAFETY ASSESSMENT

1. Assessment Conclusion

The safety assessment report of this product is prepared for adults use. MoS>100 is found for raw materials. The calculation was performed assuming that dermal absorption is 100 %. With this worst case study, it is evaluated that the use of this raw material in this product is safe.

In addition to MoS calculations, the IFRA certificate of conformity provided by the manufacturer was also used in the safety assessment of this product. The perfume concentration (1%) in the product is below the maximum concentration that can be used according to the acceptance criteria set by IFRA for this category. (Class 9A, maximum utilization rate 5.00%). MoS>100 is found for perfume components.

The ingredients of the product are permitted ingredients for cosmetics. All raw materials are not toxic under normal or reasonably unforeseeable conditions of use at this concentration. The product does not contain prohibited substances listed in annexes of Regulation (EC) No. 1223/2009. Composition of the product complies with the requirements of the EU Cosmetic Regulations.

Based on all data available it can be assumed that the cosmetic product **PATCHOULI SOAP** is safe for human health when used under normal or reasonably foreseeable conditions of use in accordance with Regulation (EC) No 1223/2009.

There are restrictions for SODIUM HYDROXIDE which is allowed in cosmetic products as pH adjuster when pH <11. Based on the fact, that Sodium hydroxide is consumed during the soap-making process and it is not contained in the final product, the restriction does not apply.

The list of ingredients is based on the ingredients that are used to make the soap.

Following review of the information provided for the above product and its ingredients, the product is considered safe for the intended application and complies with EC Regulation 1223/2009.

This safety assessment for human health is based upon information available at this date. Reviews of this assessment will be made as and when new information becomes available.

2. Labelled Warnings and Instructions of Use

Warnings on the product label:

Avoid contact with eyes and mouth. In case of contact,

rinse thoroughly with plenty of water.

Application of the Product:

Before use, read

the instructions of your product at sopna.co, you can

access the site with QR code. Keep in a dry place

3. Reasoning

This report is prepared based on the Regulation (EC) No. 1223/2009 on cosmetic products and The SCCS's Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation 9th Revision 2015.

The Product is a body soap.Application area is the body area. Rinse-off Product.100% use in cosmetic products is safe.Attached information and documents (MSDS's, TDS's, , etc) and the references at the product Microbiology, Stability and Free claim test results Safety information report is also used.

Physical-chemical specifications, microbiological data are acceptable.

All the ingredients Mos value is above >100. The product is safe to use as cosmetic product according to cosmetic regulations. The margin of safety for ingredients which have no NO(A)EL value could not calculate. The toxicological profile have been assessed for substances that missing NO(A)EL values. components in the product has no risk to the consumers.This type of formulation has been in common usein cosmetics over many years without any particular concerns. In the table the margin of safety of each of the ingredients used are given. All the results contained in the report in section A reasoning that product is safe.

4. Assessor's Credentials and Approval of Part B

Name : Fatih KEÇELİ, RPh.,

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Proof of qualification of safety assessor:

Pharmacist,

Graduated School : Gazi University Faculty of Pharmacy

Master's Degree : Ankara University faculty of Pharmacy

Diploma attached.

Date and signature of safety assessor: