Sapo Soap

COSMETIC PRODUCT SAFETY ASSESSMENT

MINT 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 : **MINT 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
RICINUS COMMUNIS SEED OIL	232-293-8	8001-79-4	5,0	FRAGRANCE PERFUMING

				SKIN CONDITIONING
MENTHA PIPERITA OIL	8006-90-4 / 84082-70-2	282-015-4	3,0	FRAGRANCE PERFUMING REFRESHING TONIC
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
OrganolepticCharacteristics	**Appearance**	SOLID SOAP	APPROVED
	Color	CHARACTERISTIC	APPROVED
	Odor	CHARACTERISTIC	CHARACTERISTIC
Physicochemical	**pH**	10 – 10,5	APPROVED

Characteristic			

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

MINT 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	**MENTHA PIPERITA OIL**
Konsantrasyon C	**%3**
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 3 (%) / 100 X 100 (%) / 100

SED = 0,0837 (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)

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
MENTHA PIPERITA OIL	3,0	0,01	100	0,0837
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	1,674	N/A	N/A	according to CIR Expert Panel

FRUIT OIL				(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 mineral oil when used as a moisturizer.	N/A	https://www.cir-safety.org/sites/default/files/115_buff3e_suppl.pdf
MENTHA PIPERITA OIL	0,1395	40 mg/kg	286	https://www.cir-safety.org/sites/default/files/peppermint.pdf
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
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

MENTHA PIPERITA OIL

CAS NO: 8006-90-4 / 84082-70-2

EC NO: 282-015-4

Toxicological Studies

Acute Toxicity Studies

Oral

Mentha Piperita (Peppermint) Oil

Mentha Piperita (Peppermint) Oil had a 24-h oral LD50 of 4441 mg/kg in fasted Wistar rats; the 48-h LD50 was 2426 mg/kg. In a study involving fasted mice, an LD50 of 2410 mg/kg was reported for Mentha Piperita (Peppermint) Oil diluted in olive oil.

Short-Term Toxicity Studies

Oral

Mentha Piperita (Peppermint) Oil and Components

In 3 of 4 short-term oral toxicity studies (28-day or 5-week studies) involving 20 to 28 rats per group, brain lesions (specifically, cyst-like spaces in the cerebellum) were observed at Mentha Piperita (Peppermint) Oil doses up to 100 mg/kg/day. In the remaining study (12 rats per group), these lesions were not observed in rats dosed with Mentha Piperita (Peppermint) Oil at doses of 20, 150, or 500 mg/kg/day for 5 weeks. In short-term oral toxicity studies (28-day studies; 20 rats per group) on components of Mentha Piperita (Peppermint) Oil, brain lesions (specifically, cyst-like spaces in the cerebellum) were also observed in rats given pulegone doses up to 160 mg/kg/day and menthone doses up to 800 mg/kg/day. These lesions were not observed in groups of 20 rats given oral doses of menthol up to 800 mg/kg/day for 28 days.

Subchronic Toxicity Studies

Oral

Mentha Piperita (Peppermint) Oil

Groups of 28 Wistar rats were given oral doses of 10, 40, and 100 mg/kg Mentha Piperita (Peppermint) Oil (diluted with soybean oil) daily for 90 days. All hematological and biochemical parameters were within normal range, and there were no significant differences in absolute and relative organ weights. Brain lesions (specifically, cyst-like spaces in the cerebellum) were observed in all dose groups, but these results were classified as significant only for animals of the 100 mg/kg/day dose group. No other lesions of encephalopathy were observed. Nephropathy (hyaline droplet formation) was observed only in male rats of the 100 mg/kg/day dose group, and there was no evidence of epithelial degeneration. The noobserved-adverse-effect level (NOAEL) for Mentha Piperita (Peppermint) Oil was 40 mg/kg/day in this study.

Chronic Toxicity Studies

Dermal

Exposure Assessment

Mentha Piperita (Peppermint) Oil

The FDA calculated an estimated human exposure from cosmetic use based on the concentration of use information supplied by industry. Using a body splash product containing 0.2% Mentha Piperita (Peppermint Oil) and assuming 100% absorption over a body surface of 17,000 cm2 and a daily application of 1 mg/cm2 (~17 ml of the product), the FDA estimated an exposure of 34 mg/day. For a 60-kg person, this amounted to an estimated daily dose of 0.6 mg/kg/day.

Genotoxicity Studies

In Vitro

Mentha Piperita (Peppermint) Oil and Components

The mutagenic potential of Mentha Piperita (Peppermint) Oil and its components was investigated using the Salmonella/mammalian microsome test. The following Salmonella strains were used: TA1535, TA100, TA1537, and TA98. The sample tested contained 38.1% menthol, 33.7% menthone, and 1.7% pulegone; the remaining components were not identified. Mentha Piperita (Peppermint) Oil, menthol, and pulegone, all tested at doses of 6.4, 32, and 160 μg/plate, produced the same number of revertants as the negative control. Toxicity was noted at the next (and maximum) dose of 800 μg/plate. Metabolic activation appeared to have made the compounds less toxic to the bacteria. In contrast, menthone, induced a statistically significant number of revertants in strain TA1537 at doses of 6.4 and 32 μg/plate without metabolic activation. Menthone was further tested using the more sensitive TA97 strain. Statistically significant increases in the number of revertants were noted at all doses tested without metabolic activation; the results were dose-related (though toxicity was observed at a dose of 800 μg/plate). The researchers remarked on the unexpected results – methone was mutagenic, but Mentha Piperita (Peppermint) Oil, which contained 33.7% menthone, was not.

In an in vitro chromosomal aberration test using a Chinese hamster fibroblast cell line, Mentha Piperita (Peppermint) Oil, at a maximum concentration of 0.25 mg/ml (in ethanol), produced polyploidism in 3% of the cells and structural aberrations in 7% of the cells at 48 h after treatment. The results were considered equivocal, as scores of either ≥ 10% or ≤ 4.9% were necessary for classification as either positive or negative, respectively. The results for Mentha Piperita (Peppermint) Oil (150 μg/ml) were negative in a mouse lymphoma L5178Y TK +/- cell mutagenesis assay. Results were also negative for this ingredient (at 155 μg) in an unscheduled DNA synthesis assay using rat hepatocytes.

The genotoxicity of Mentha Piperita (Peppermint) Oil was evaluated in a chromosome aberration test using human peripheral blood lymphocytes.32 Lymphocyte cultures were incubated for 24 h with test substance concentrations up to 0.30 μl/ml. When chromosome aberrations (chromatid breaks, chromatid exchanges, chromosome breaks, and chromosome exchanges) were scored, not less than 100 metaphases per culture were analyzed. Mentha Piperita (Peppermint) Oil was the most clastogenic at a concentration of 0.20 μl/ml (8-fold increase over acetone solvent control); the number of aberrant cells decreased at higher concentrations. The

authors noted that the dose-response curve for Mentha Piperita (Peppermint) Oil was complicated, with a clear peak response at a concentration of 0.20 µl/ml.

Mentha Piperita (Peppermint) Oil was tested at concentrations up to 0.30 µl/ml in the sister chromatid exchange (SCE) test involving human lymphocytes. 32 The test conditions were essentially the same as those in the preceding chromosome aberration test, with the exception that 5-bromo-2'-deoxyuridine was added (10 µg/ml) to cultures initially. To determine the replicative index, 200 cells were scored. Mentha Piperita (Peppermint) Oil induced sister chromatid exchanges in a dose-independent manner. The authors noted that, seemingly, the saturation of SCE-inducing capacity occurred at high concentrations of Mentha Piperita (Peppermint) Oil. Results also indicated that Mentha Piperita (Peppermint) Oil inhibited cell replicative kinetics, some signs of which were observed at a concentration of 0.15 µl/ml. At concentrations ≥ 0.20 µl/ml, statistically significant inhibition of cell replicative kinetics was evident.

Carcinogenicity Studies

Oral

Mentha Piperita (Peppermint) Oil

In a carcinogenicity study of toothpaste and its components, groups of 52 male pathogen-free CFLP (ICI-redefined) mice were dosed by gavage with 4 or 16 mg Mentha Piperita (Peppermint) Oil/kg/day, 6 days per week for 80 weeks. Treatment was followed by a 16- to 24-week observation period. An untreated group of 52 male mice and a vehicle control group of 260 male mice that received the toothpaste base (which did not contain chloroform, eucalyptol, or Mentha Piperita (Peppermint) Oil) were maintained as controls. At least one neoplasm at any site was observed in 73%, 69%, 65%, and 71% of mice of the low-dose, high-dose, untreated control, and vehicle control groups, respectively. The incidence of neoplasms of the lungs and kidneys was comparable among mice of the treated and nontreated groups. Hepatic cell tumor incidence for Mentha Piperita (Peppermint) Oil-dosed mice (25%) was comparable to the incidence for mice of the vehicle control group (27%); the incidence for the untreated group was 19%. Malignant lymphoma was found in 25%, 21%, 10%, and 14% of mice of the low-dose, high-dose, untreated, and vehicle control groups, respectively. The researchers did not discuss whether the differences in tumor incidence were significant.

Other Relevant Studies

Cytotoxicity

Mentha Piperita (Peppermint) Oil

The cytotoxicity of Mentha Piperita (Peppermint) Oil was evaluated in the (3-(4,5-dimethylthiazol-2-yl)-2,5- diphenyltetrazolium bromide (MTT) assay using 2 human cancer cell lines, MCF-7 and LNCaP.39 Mentha

Piperita (Peppermint) Oil from plants that were harvested during the summer and winter was tested. The following IC50 values were reported: MCF-7 cell line (75.2 ± 2.9 [summer]; 80.8 ± 3.2 [winter]) and LNCaP cell line (90.4 ± 3.7 [summer]; 95.7 ± 4.5 [winter]). IC50 values in the 10 to 100 µg/ml range represented a potentially toxic chemical, and IC50 values < 10µg/ml represented a potentially very toxic chemical.

In another study, essential oil was extracted from the leaves of Mentha piperita. 40 This extract was found to be cytotoxic in the following following 4 human cancer cell lines: human lung carcinoma SPC-A1 cells (IC50 = 10.89 µg/ml), human leukemia K562 cells (IC50 = 16.16 µg/ml) and human gastric cancer SGC-7901 cells (IC50 = 38.76 µg/ml). The extract was inactive against human hepatocellular carcinoma BEL-7402 cells.

Immune System Effects

Mentha Piperita (Peppermint) Oil

The results of a host-resistance assay involving groups of 20 mice that had been dosed orally with Mentha Piperita (Peppermint) Oil (up to 1250 mg/kg/day for 5 days) suggested immunosuppression and/or increased susceptibility to bacterial-induced mortality. The results of a plaque-forming assay involving groups of 10 mice that received the same oral doses were negative.

DERMAL IRRITATION AND SENSITIZATION STUDIES

Irritation

Animal

Mentha Piperita (Peppermint) Oil

Hairless sites on 5 white rabbits were injected intradermally with 0.05 ml Mentha Piperita (Peppermint) Oil. Gross examinations were performed at 24 h and 48 h, at 1 and 2 weeks, and, in some cases, at 1 month after dosing. Dosing was repeated between 5 and 10 times. At microscopic examination of skin samples, moderate reactions characterized by polymorphonuclear leucocytes, lymphocytes, and plasma cells (without necrosis) were observed in 3 rabbits. Severe reactions, which were marked by the above as well as necrosis, were observed in the other 2 rabbits.

Sensitization

Human

Mentha Piperita (Peppermint) Oil

In the maximization test, 25 healthy male panelists received five 48-h occlusive induction patch (containing 8% Mentha Piperita (Peppermint) Oil) applications. Pre-treatment was for 24 h with an occlusive patch containing 5% sodium lauryl sulfate (SLS) prior to each exposure. After a 10-day non-treatment period,

the subjects were challenged on the back with a 48-h patch (also preceded by SLS treatment). No evidence of sensitization was found.

Photosensitization/Phototoxicity

Animal

Mentha Piperita (Peppermint) Oil

Undiluted Mentha Piperita (Peppermint) Oil was applied to the backs of 6 Skh:hairless mice. Thirty minutes later, the mice were irradiated for either 1 h with light from a fluorescent blacklight at an integrated UVA of 3 W/m2 , or for 40 minutes with light from a Xenon lamp at a weighted erythema energy of 0.1667 W/m2 . The mice were examined at 4 h, 24 h, 48 h, 72 h, and 96 h after radiation treatment. No effects were noted. In a second experiment, using 2 miniature swine and following the same protocol, no effect was produced by 100% Mentha Piperita (Peppermint) Oil.

REFERENCE:

https://www.cir-safety.org/sites/default/files/peppermint.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

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 **MINT 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

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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: