COSMETIC PRODUCT SAFETY REPORT

According to the requirements of Regulation No 1223/2009 of the European Parliament and of the Council on the cosmetic products.

No. 276/1/2016 from 23.09.2016

Contract partner of responsible person: **Pro4Care s.r.o.**
Head office: **Viničná 82, 615 00 Brno**

Assessed product:

SORRY MOM Tattoo Soap

PART A – cosmetic product safety information

1. Quantitative and qualitative composition of cosmetic product

Ingredient INCI	CAS number	EINECS number	Intended function	Content	Restriction
Aqua	7732-18-5	231-791-2	solvent	ad 100	---
Sodium Coco-Sulfate	97375-27-4	306-683-4	surfactant, emulsifying, cleansing	6,50	---
Cocamidopropyl Betaine	61789-40-0	263-058-8	viscosity controlling, surfactant, hair conditioning, foam boosting, cleansing, antistatic	3,20	---
Coco-Glucoside	---	---	surfactant, foaming, cleansing	2,08	---
Macadamia Seed Oil Glycereth-8 Esters	---	---	surfactant	2,00	---
Glycerin	56-81-5	200-289-5	perfuming, solvent, humectant, denaturant	1,98	---
Sodium Chloride	7647-14-5	231-598-3	bulking, masking, oral care, viscosity controlling	1,00	---
Sodium Benzoate	532-32-1	208-534-8	preservative, masking, anticorrosive	0,50	Max. 2,5 %
Aloe Barbadensis Leaf Juice Powder	85507-69-3	287-390-8	skin conditioning	0,05	---
Citric Acid	77-92-9	201-069-1	buffering, chelating, masking	q.s.	---

2. Physical and chemical characteristics and stability of the cosmetic product

2.1 Cosmetic product

Physical-chemical properties of cosmetic product were tested by the testing laboratory EUROFINS BEL/NOVAMANN s.r.o., analytical report No. 84151/2016 with satisfactory results.

2.2 Cosmetic ingredients

Physical-chemical properties of each substance were tested by supplier according their specification and each substance satisfies requirements.

Ingredient	Synonym	Characters
Aqua	Water; Oxidane	Molecular formula: H_2O Molar mass: 18,01 g mol^{-1} Appearance: Colorless liquid Boiling point: 99,98 °C

Ingredient	Synonym	Characters
Sodium Coco-Sulfate		Sodium Coco-Sulfate is a sodium salt of the sulfate ester of coconut alcohol
Cocamidopropyl Betaine	1-Propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-, N-coco acyl derivs., hydroxides, inner salts; {[3-(Dodecanoyl amino) propyl](dimethyl) ammonio}acetate	Molecular formula: C19H38N2O3 Molar mass: 342,52 g mol−1
Coco-Glucoside		Alcohols, coco, reaction products with glucose
Macadamia Seed Oil Glycereth-8 Esters		
Glycerin	Propane-1,2,3-triol; Glycerol	Molecular formula: C3H8O3 Molar mass: 182,17 g mol−1 Appearance: Colorless liquid Density: 1,261 g/cm3 Boiling point: 290 °C Melting point: 17,8 °C Refractive index: 1,4746
Sodium Chloride	Halite	Molecular formula: NaCl Molar mass: 58,44 g mol−1 Appearance: Colorless crystals Melting point: 801 °C
Sodium Benzoate		Molecular formula: NaC6H5CO2 Molar mass: 144,11 g mol−1 Appearance: White or colorless crystalline powder Density: 1,497 g/cm3 Melting point: 300 °C
Aloe Barbadensis Leaf Juice Powder		Aloe Barbadensis Leaf Juice Powder is the powder obtained from the dried juice leaves of the aloe, Aloe barbadensis, Liliaceae
Citric Acid	2-Hydroxy-1,2,3-propanetricarboxylic acid	Molecular formula: C6H8O7 Molar mass: 192,12 g mol−1 Appearance: crystalline white solid Melting point: 153 °C

2.3 Stability of cosmetic product

Stability of cosmetic product was tested under storage conditions at laboratory temperature and 37°C, 3 months. According these tests it can be confirmed that the final product is stable at usual storage conditions and foreseeable usage during declared expiry period, which was set to be 2 years.

3. Microbial quality

3.1 Microbial quality of raw materials

Microbial quality of each substance was tested by supplier according its specification and each substance satisfies requirements.

3.2 Microbial quality of cosmetic product

Microbiological properties of cosmetic product were tested by the testing laboratory EUROFINS BEL/NOVAMANN s.r.o., analytical report No. 84151/2016 with satisfactory results.

Preservation challenge tests were tested by the testing laboratory EUROFINS BEL/NOVAMANN s.r.o., analytical report No. 84150/2016 with satisfactory results.

4. Impurities and traces

4.1 Impurities and traces of raw materials

Each raw material was tested to the content of impurities. Traces were evaluated with regard to the safety of the finished product. In case of material containing traces of prohibited substances, the evidence of their technical unavoidability was tested by supplier.

Substance	Impurity	Result
Cocamidopropyl Betaine	Sodium Monochloacetate	Max. 20 ppm

4.2 Impurities and traces of cosmetic product

Traces of heavy metals were tested by the testing laboratory EUROFINS BEL/NOVAMANN s.r.o., analytical report No. 84151/2016 with satisfactory results.

4.3 Packaging of cosmetic product

The primary packaging material is plastic bottle with cover. Material meets the requirements on the content of dangerous substances according to the directives 10/2011/EC, 1935/2004/EC and 2023/2006/EC. Based on long-term monitoring, back analysis of reference samples showed no signs of reactions between the product and packaging materials at least until the end of the minimum durability of the product. Physical/chemical properties of the final product exhibited no granges. Suppliers of packaging material are EASTMAN and BOREALIS.

Cosmetic product is packaged in packages intended for this use.

5. Normal and reasonably foreseeable use

Product is intended for body care.

5.1 Product package information:

Product package information was not assessed as a part of safety report. Customer himself is responsible for product package information.

6. Exposure to the cosmetic product

a. *The site of application:* Product is applied on the body.
b. *The surface area of application:* 17 500 cm^2.
c. *The amount of product applied:* up to 18.67 g/day.
d. *Duration and frequency of use:* once a day; washes off.
e. *The normal and reasonably foreseeable exposure route:* body.
f. *The targeted populations:* women, men.

Predictable wrong use: Possible contact with mucous membrane of eye and eye irritation. In case of contact eyes should be washed-off with lukewarm water.

g. *Estimated daily exposure:* 2.79 mg/kg bw/day.

7. Exposure to the substances

Calculated systematic exposure dosage (SED) for individual ingredients:

Ingredient	SED (mg/kg bw/day)
Aqua	0,82
Sodium Coco-Sulfate	0,18
Cocamidopropyl Betaine	0,089
Coco-Glucoside	0,058
Macadamia Seed Oil Glycereth-8 Esters	0,056
Glycerin	0,055
Sodium Chloride	0,028
Sodium Benzoate	1,345
Aloe Barbadensis Leaf Juice Powder	0,0014
Citric Acid	0,0014

According to calculated SED, product does not contain components, which may have an influence on user's health.

8. Toxicological profile of the substances

Component	Classification	Toxicological profile
Sodium Coco-Sulfate		Substance not classified as toxic.
	NOAEL = unavailable	MoS = NOAEL / SED = ---
Cocamidopropyl Betaine	Causes skin and eye irritation.	LD50 oral- rat: 2 000 mg/kg LD50 dermal- rat: 2 000 mg/kg Can cause irritation of eyes and skin.
	NOAEL = 1 000 mg/kg bw/day	MoS = NOAEL / SED = 11 236
Coco-Glucoside	Causes skin and eye irritation. Causes eye damage.	Can cause irritation of eyes and skin.
	NOAEL = 1 000 mg/kg bw/day	MoS = NOAEL / SED = 17 241
Macadamia Seed Oil Glycereth-8 Esters		Substance not classified as toxic.
	NOAEL = unavailable	MoS = NOAEL / SED = ---
Glycerin	Causes eye and skin irritation.	LD50 oral -mouse: 4 090 mg/kg LD50 oral -rat: 12 600 mg/kg Can cause irritation of eyes and skin.
	NOAEL = 2 000 mg/kg bw/day	MoS = NOAEL / SED = 36 364
Sodium Chloride	Causes eye and skin irritation.	LD50 oral- rat: 3 000 mg/kg LD50 dermal- rabbit: 10 000 mg/kg Can cause mild irritation of eyes and skin.
	NOAEL = 5 820 mg/kg bw/day	MoS = NOAEL / SED = 207 857
Sodium Benzoate	Causes serious eye irritation.	LD50 oral -rat: 2 100 mg/kg Can cause irritation of eyes and skin. Can cause respiratory problems. May be harmful if absorbed through skin.
	NOAEL = 1 310 mg/kg bw/day	MoS = NOAEL / SED = 974
Aloe Barbadensis Leaf Juice Powder	Causes eye irritation.	Can cause irritation of eyes.
	NOAEL = 1 000 mg/kg bw/day	MoS = NOAEL / SED = 714 286

According to calculated MoS (Margin of Safety) for ingredients that are classified as dangerous for human health, product does not contain components with significant toxicological profile from user's health aspect.

Ingredient with calculated MoS greater than 100 is considered to be safety.

9. Undesirable effects

As this is new product, undesirable effects are not expected during normal and reasonably foreseeable use of cosmetic product.

10. Information on the cosmetic product

Epicutaneous test of product was performed according to COLIPA Guidelines for testing the assessment of human skin compatibility under expert supervision of Doc. MUDr. Jarmila Rulcová,CSc., report No. 132-E-2016, with result not irritating.

Tests were performed on group of volunteers. All of the participants fulfilled all the criteria for assign to the study, were clearly informed regarding the study and gave their written informed consent before participation in the study.

Product was applied as 10 % solution on the forearm of volunteers repeatedly.

All of the volunteers were visually controlled in periodical intervals since application.

Visually were assessed viewable skin changes on application area, for example redness.

Volunteers subjective commented product properties like unpleasant feelings, itching and burning on application area.

Information sources:

- SCCS´S Notes of Guidance for testing of cosmetic ingredients and their safety evaluation, 9th revision
- Commission implementing decision of Guidelines on Annex I to regulation (EC) No. 1223/2009 of the European Parliament and of the Council on cosmetic products (2013/674/EU)
- supplier`s specifications on raw materials
- http://www.specialchem4cosmetics.com
- http: //en.wikipedia.org
- http: //www.sigmaaldrich.com
- http://www.echa.europa.eu/web/guest/information-on-chemicals
- http://www.epa.gov
- http://oehha.ca.gov

PART B – cosmetic product safety assessment

1. Assessment conclusion

In the common use of the cosmetic products according to the information enclosed for consumers and other available materials, no risk of irritation, sensitivity, local or systematic reactions to healthy people will occur.

From the point of view of the safety of human health and on the basis of the, aforesaid, the cosmetic product assessed can be assumed as safe for human health if their use stated in the instructions for consumers and the essential marking on the container of the cosmetic products are maintained according to European legislation valid on the date of issuance of this assessment

2. Labelled warnings and instruction of use

In accordance with article 19, there must be warnings stated on the label: ---

3. Reasoning

This assessment includes the conclusions of the total toxicological profile of the cosmetic product. The basic safety assessment feature observed is the identification of the dangerousness of the particular components of the cosmetic product, including their reciprocal interaction. The assessment is aimed at the risk (probability) of the creation of an undesirable effect (the method of application, the amount applied, the frequency of application, etc.). The risk is assessed on the basis of a synthesis of all the accessible data according to the current scientific knowledge referring to the determination of the type and degree of danger of the cosmetic substance or product. In relation to the particular components of the cosmetic product, the following undesirable effects are assessed: irritating, allergenic, mutagenic, teratogenic, carcinogenic and systematic (neurotoxic, hepatotoxic, nephrotoxic, hematotoxic, cardiotoxic and toxic effects for gastrointestinal and respiratory systems). Particularly in the case of leave-on products (permanent application – they are not washed-off), the possibility of health impairment after a long lasting effect of low concentrations of potentially toxic components is assessed.

4. Assessor´s credentials

This assessment relates only to the cosmetic products assessed; their composition, properties, information for customers and other materials essential for assessment (stated in point IV.) shall agree with the documents submitted for this assessment.

The evaluation of the functional properties of the product declared by the manufacturer is not part of this assessment.

Name and the address of the safety assessor:
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