

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. 131/1/2015 from 06.07.2015

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

Assessed product:

SORRY MOM Tattoo Cleanser

PART A – cosmetic product safety information

1. Quantitative and qualitative composition of cosmetic product

Ingredient INCI	CAS number	EINECS number	Intended function	Restriction
Aqua	7732-18-5	231-791-2	solvent	---
Poloxamer 184	9003-11-6	---	surfactant, emulsifying	---
Glycerin	56-81-5	200-289-5	perfuming, solvent, humectant, denaturant	---
Phenoxyethanol	122-99-6	204-589-7	preservative	Max. 1,0 %
Hamamelis Virginiana Water	84696-19-5	283-637-9	soothing, skin conditioning, hair conditioning, astringent	---
Parfum MANGO BOOM ANTIALERGIC ISM/E2 Z 3570 (Aroma)	---	---	perfuming	---
Panthenol	81-13-0	201-327-3	skin conditioning, hair conditioning, antistatic	---
Cetrimonium Bromide	57-09-0	200-311-3	surfactant, preservative, emulsifying, antistatic, antimicrobial	Max. 0,1 %
Aloe Barbadensis Leaf Juice Powder	85507-69-3	287-390-8	skin conditioning	---

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. 28009/2015 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 ₂ O Molar mass: 18,01 g mol ⁻¹ Appearance: Colorless liquid Boiling point: 99,98 °C

Ingredient	Synonym	Characters
Poloxamer 184	Oxirane, methyl-, polymer with oxirane (13;30)	Hydrophilic non-ionic surfactant. Triblock copolymer consisting of a central hydrophobic block of polypropylene glycol flanked by two hydrophilic blocks of polyethylene glycol.
Glycerin	Propane-1,2,3-triol; Glycerol	Molecular formula: C ₃ H ₈ O ₃ Molar mass: 182,17 g mol ⁻¹ Appearance: Colorless liquid Density: 1,261 g/cm ³ Boiling point: 290 °C Melting point: 17,8 °C Refractive index: 1,4746
Phenoxyethanol	2-Phenoxy-1-ethanol; Ethylene glycol monophenyl ether; 1-Hydroxy-2-phenoxyethane	Molecular formula: C ₂ H ₆ O Molar mass: 138,16 g mol ⁻¹ Appearance: Colorless oily liquid Density: 1,102 g/cm ³ Boiling point: 247 °C Melting point: 11-13°C
Hamamelis Virginiana Water		Hamamelis Virginiana Water is an aqueous solution containing natural volatile oils obtained by the distillation of twigs, bark and leaves of of the Witch Hazel, Hamamelis virginiana L., Hamamelidaceae
Panthenol	Butanamide, 2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethyl-, (2R)-; dl-Panthenol	Molecular formula: C ₉ H ₁₉ NO ₄ Molar mass: 205,25 g mol ⁻¹ Melting point: 66-69 °C
Cetrimonium Bromide	1-Hexadecanaminium, N,N,N-trimethyl-, bromide	Molecular formula: C ₁₉ H ₄₂ BrN Molar mass: 364,45 g mol ⁻¹ Appearance: white powder Melting point: 237-243 °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

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, the period-after opening was set to be 24 months.

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 CZ s.r.o., analytical report No. 28007/2015 with satisfactory results.

Preservation challenge tests were tested by the testing laboratory EUROFINS BEL/NOVAMANN s.r.o., analytical report No. 57906/2015 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
Panthenol	3-Aminopropanol	Max. 1,0 %
Phenoxyethanol	Phenol	Max. 25 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. 28009/2015 with satisfactory results.

4.3 Packaging of cosmetic product

The primary packaging material 200 mL bottle with foamier. Material meets the requirements on the content of dangerous substances. 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. Supplier of packaging material is Shangyu Kaifeng Packaging Products, China.

Cosmetic product is packaged in packages intended for this use.

5. Normal and reasonably foreseeable use

Product is intended for body care.

6. Exposure to the cosmetic product

- The site of application:* Product is applied on body.
- The surface area of application:* 17 500 cm².
- The amount of product applied:* up to 18.67 g/day.
- Duration and frequency of use:* twice a day; washes off.
- The normal and reasonably foreseeable exposure route:* body.
- 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.

- 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	2,59
Poloxamer 184	0,11
Glycerin	0,056
Phenoxyethanol	2,576

Ingredient	SED (mg/kg bw/day)
Hamamelis Virginiana Water	0,014
Parfum	0,084
Panthenol	0,0042
Cetrimonium Bromide	0,269
Aloe Barbadensis Leaf Juice Powder	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
Poloxamer 184	Causes mild eye and skin irritation.	LD50 oral- rat: 5 000 mg/kg Can cause mild irritation of eyes and skin.
	NOAEL = 750 mg/kg bw/day	MoS = NOAEL / SED = 6 818
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 = 35 714
Phenoxyethanol	Harmful if swallowed. Causes serious eye irritation.	LD50 oral -rat: 1 260 mg/kg LD50 dermal -rat: 14 422 mg/kg Can cause irritation of eyes and skin.
	NOAEL = 500 mg/kg bw/day	MoS = NOAEL / SED = 194
Hamamelis Virginiana Water		Substance is not classified as toxic.
	NOAEL = unavailable	MoS = NOAEL / SED = ---
Panthenol	Causes mild eye and skin irritation.	Causes mild eye and skin irritation
	NOAEL = 600 mg/kg bw/day	MoS = NOAEL / SED = 142 857
Cetrimonium Bromide	Harmful if swallowed. Causes irritation of respiratory tract and skin. Causes serious eye damage.	LD50 dermal- rabbit: 4 300 mg/kg Can cause serious irritation of eyes. Can cause irritation of skin.
	NOAEL = 1 000 mg/kg bw/day	MoS = NOAEL / SED = 3 717
Aloe Barbadensis Leaf Juice Powder	Causes eye irritation.	Can cause eye irritation.
	NOAEL = 1 000 mg/kg bw/day	MoS = NOAEL / SED = 714 586

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. 38-E-2015, 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 arm 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, 8th 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://cosmetics.specialchem.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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