

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. 225/1/2017 from 21.07.2017

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

Assessed product:

SORRY MOM Tattoo Balm

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	---
Lanolin	8006-54-0	232-348-6	antistatic, emollient, emulsifying, hair conditioning, skin conditioning, surfactant	---
Paraffinum Liquidum	8012-95-1	232-384-2	antistatic, emollient, skin protecting, solvent	---
Panthenol	81-13-0	201-327-3	antistatic, hair conditioning, skin conditioning	---
Petrolatum	8009-03-8	232-373-2	antistatic, emollient	---
Ozokerite	64742-33-2	265-134-6	binding, emulsion stabilising, opacifying, viscosity controlling	---
Prunus Amygdalus Dulcis Oil	8007-69-0	---	skin conditioning	---
Glycerin	56-81-5	200-289-5	denaturant, humectant, solvent, perfuming	---
Glyceryl Oleate	25496-72-4	247-038-6	emollient, emulsifying, perfuming	---
Cholesterol	57-88-5	200-353-2	viscosity controlling, stabilising, skin conditioning, emulsifying, emollient	---
Cera Alba	8012-89-3	232-383-7	mollient, emulsifying, film forming, perfuming	---

Ingredient INCI	CAS number	EINECS number	Intended function	Restriction
Hydrogenated Castor Oil	8001-78-3	232-292-2	emollient, emulsifying, skin conditioning, surfactant, viscosity controlling	---
Magnesium Sulfate	7487-88-9	231-298-2	bulking, hair conditioning, viscosity controlling	---
Hippophae Rhamnoides Fruit Extract	90106-68-6	290-292-8	skin conditioning	---
Phenoxyethanol	122-99-6	204-589-7	preservative	Max. 1,0%
Stearyl Stearate	2778-96-3	220-476-5	viscosity controlling, skin conditioning, emollient	---
Cetyl Palmitate	540-10-3	208-736-6	skin conditioning, masking, emollient	---
Paraffin	8002-74-2	232-315-6	viscosity controlling, emollient	---
Calendula Officinalis Flower Extract	84776-23-8	283-949-5	masking, skin conditioning, perfuming	---
Rosmarinus Officinalis Leaf Extract	84604-14-8	283-291-9	antimicrobial, masking, 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. 85796/2013 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
Lanolin		Lanolin is a refined derivative of the unctuous fat-like sebaceous secretion of sheep. It consists of a highly complex mixture of esters of high molecular weight aliphatic, steroid or triterpenoid alcohols and fatty acids
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

Ingredient	Synonym	Characters
Petrolatum		Petrolatum. A complex combination of hydrocarbons obtained as a semi-solid from dewaxing paraffinic residual oil. It consists predominantly of saturated crystalline and liquid hydrocarbons having carbon numbers predominantly greater than C25
Paraffinum Liquidum	mineral oil	White mineral oil (petroleum) a highly refined petroleum mineral oil consisting of a complex combination of hydrocarbons obtained from the intensive treatment of a petroleum fraction with sulfuric acid and oleum, or by hydrogenation, or by a combination of hydrogenation and acid treatment. Additional washing and treating steps may be included in the processing operation. It consists of saturated hydrocarbons having carbon numbers predominantly in the range of C15 through C50.
Ozokerite		Hydrocarbon waxes (petroleum), chemically neutralized. A complex combination of hydrocarbons produced by a treating process to remove acidic materials. It consists predominantly of saturated straight chain hydrocarbons having carbon numbers predominantly in the range of C20 through C50
Prunus Amygdalus Dulcis Oil		Prunus Amygdalus Dulcis Oil is the fixed oil obtained from the ripe seed kernel of the Sweet Almond Tree, Prunus amygdalus var. dulcis, Rosaceae
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
Glyceryl Oleate	Oleic acid, monoester with glycerol	Molecular formula: C ₂₁ H ₄₀ O ₄ Molar mass: 356,54 g mol ⁻¹ Boiling point: 485,4 °C
Cholesterol	Cholest-5-en-3-ol (beta)-	Molecular formula: C ₂₇ H ₄₅ OH
Cera Alba		Beeswax. The wax obtained from the honeycomb of the bee. It consists primarily of myricyl palmitate, cerotic acid and esters and some high-carbon paraffins
Hydrogenated Castor Oil	Castor oil, hydrogenated	Castor oil is a vegetable oil obtained from the castor bean (technically <i>castor seed</i> as the castor plant, <i>Ricinus communis</i> (Euphorbiaceae), is not a member of the bean family.
Magnesium Sulfate		Molecular formula: MgSO ₄ (anhydrous) Molar mass: 120,37 g mol ⁻¹ Appearance: White crystalline solid Melting point: 1124 °C (anhydrous)

Ingredient	Synonym	Characters
Hippophae Rhamnoides Fruit Extract		Hippophae Rhamnoides Fruit Extract is an extract of the fruit of the Sea Buckthorn, Hippophae rhamnoides L., Elaeagnaceae
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
Stearyl Stearate	Octadecyl stearate	Molecular formula: C ₃₆ H ₇₂ O ₂ Molar mass: 536,97 g mol ⁻¹
Cetyl Palmitate	Hexadecyl hexadecanoate	Molecular formula: C ₃₂ H ₆₄ O ₂ Appearance: Colorless wax
Paraffin		Paraffin waxes and Hydrocarbon waxes. A complex combination of hydrocarbons obtained from petroleum fractions by solvent crystallization (solvent deoiling) or by the sweating process. It consists predominantly of straight chain hydrocarbons having carbon numbers predominantly greater than C ₂₀ / Paraffin waxes (petroleum), hydrotreated. A complex combination of hydrocarbons obtained by treating a petroleum wax with hydrogen in the presence of a catalyst. It consists predominantly of straight chain paraffinic hydrocarbons having carbon numbers predominantly in the range of about C ₂₀ through C ₅₀
Calendula Officinalis Flower Extract		Calendula Officinalis Flower Extract is an extract obtained from the flowers of the Calendula, Calendula officinalis L., Compositae
Rosmarinus Officinalis Leaf Extract		Rosmarinus Officinalis Leaf Extract is an extract of the leaves of the Rosemary, Rosmarinus officinalis L., Lamiaceae

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 3 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 BEL/NOVAMANN s.r.o., analytical report No. 85796/2013 with satisfactory results.

Preservation challenge tests were tested by the testing laboratory EUROFINS BEL/NOVAMANN s.r.o., analytical report No. 72256/2013 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 %
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. 85796/2015 with satisfactory results.

4.3 Packaging of cosmetic product

The primary packaging is aluminium tube with cover, polyethylene tube with cover or laminate tube with cover. Materials meet the requirements the requirements on the content of dangerous substances according to the directives 1935/2004/EC, 2023/2006/EC and 10/2011/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. Packaging material was observed by TUBEX SLOVAKIA s.r.o. and ADA Zlín s.r.o. Polyethylene tubes with cover were tested by Institut pro testování a certifikaci, report No. 3133000404/2012. Laminate tubes with cover were tested by Institut pro testování a certifikaci, report No. 3133000405/2012.

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:* 15 670 cm².
- c. The amount of product applied:* up to 7.82 g/day.
- d. Duration and frequency of use:* twice a day; doesn't wash 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:* 123.20 mg/kg bw/day.

7. Exposure to the substances

Calculated systematic exposure dosage (SED) for individual ingredients:

Ingredient	SED (mg/kg bw/day)
Aqua	37,91
Lanolin	30,43
Paraffinum Liquidum	19,42
Panthenol	6,16
Petrolatum	6,16
Ozokerite	4,93
Prunus Amygdalus Dulcis Oil	4,93
Glycerin	3,05
Glyceryl Oleate	2,46
Cholesterol	1,23
Cera Alba	1,43
Hydrogenated Castor Oil	1,85
Magnesium Sulfate	1,23
Hippophae Rhamnoides Fruit Extract	0,62
Phenoxyethanol	2,018
Stearyl Stearate	0,23
Cetyl Palmitate	0,14
Paraffin	0,062
Calendula Officinalis Flower Extract	0,12
Rosmarinus Officinalis Leaf Extract	0,00012

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
Lanolin	Causes mild eye and skin irritation.	Causes mild skin irritation.
	NOAEL = unavailable	MoS = NOAEL / SED = ---
Paraffinum Liquidum	Harmful if swallowed. Causes irritation of skin and eyes.	Can cause irritation of eyes and skin.
	NOAEL = 5 000 mg/kg bw/day	MoS = NOAEL / SED = 162
Panthenol	Causes mild eye and skin irritation.	Causes mild eye and skin irritation.
	NOAEL = 600 mg/kg bw/day	MoS = NOAEL / SED = 100
Petrolatum		Can cause irritation of eyes and skin.
	NOAEL = 5 000 mg/kg bw/day	MoS = NOAEL / SED = 812
Ozokerite		Substance not classified as toxic.
	NOAEL = unavailable	MoS = NOAEL / SED = ---
Prunus Amygdalus Dulcis Oil		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 = 656
Glyceryl Oleate		Substance not classified as toxic.
	NOAEL = 1 000 mg/kg bw/day	MoS = NOAEL / SED = 407

Component	Classification	Toxicological profile
Cholesterol	Causes mild eye and skin irritation. NOAEL = 1 000 mg/kg bw/day	Causes mild eye and skin irritation MoS = NOAEL / SED = 813
	NOAEL = unavailable	Substance not classified as toxic. MoS = NOAEL / SED = ---
Cera Alba		Substance not classified as toxic. MoS = NOAEL / SED = ---
	NOAEL = 15 000 mg/kg bw/day	MoS = NOAEL / SED = 8 108
Hydrogenated Castor Oil		Substance not classified as toxic. MoS = NOAEL / SED = 8 108
	NOAEL = 15 000 mg/kg bw/day	MoS = NOAEL / SED = 8 108
Magnesium Sulfate	Harmful if swallowed. Causes mild eye and skin irritation. NOAEL = 450 mg/kg bw/day	Causes mild eye and skin irritation. Can be harmful if swallowed. MoS = NOAEL / SED = 366
		Substance not classified as toxic. MoS = NOAEL / SED = ---
Hippophae Rhamnoides Fruit Extract		Substance not classified as toxic. MoS = NOAEL / SED = ---
	NOAEL = unavailable	MoS = NOAEL / SED = ---
Phenoxyethanol	Harmful if swallowed. Causes serious eye irritation. NOAEL = 500 mg/kg bw/day	LD50 oral -rat: 1 260 mg/kg LD50 dermal -rat: 14 422 mg/kg Can cause irritation of eyes and skin. MoS = NOAEL / SED = 248
		MoS = NOAEL / SED = 248
Stearyl Stearate	Causes serious eye irritation. Causes skin irritation. NOAEL = 1 000 mg/kg bw/day	Can cause irritation of eyes and skin MoS = NOAEL / SED = 4 348
		MoS = NOAEL / SED = 4 348
Cetyl Palmitate	Causes mild eye and skin irritation. NOAEL = 70 mg/kg bw/day	Causes mild eye and skin irritation MoS = NOAEL / SED = 500
		MoS = NOAEL / SED = 500
Paraffin	Harmful if swallowed. Causes irritation of skin and eyes. NOAEL = 5 000 mg/kg bw/day	Can cause irritation of eyes and skin. MoS = NOAEL / SED = 80 645
		MoS = NOAEL / SED = 80 645
Calendula Officinalis Flower Extract		Substance not classified as toxic. MoS = NOAEL / SED = ---
	NOAEL = unavailable	MoS = NOAEL / SED = ---
Rosmarinus Officinalis Leaf Extract		Substance not classified as toxic. MoS = NOAEL / SED = ---
	NOAEL = unavailable	MoS = NOAEL / SED = ---

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. 88-E-2013, 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 undiluted on the back 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:

PharmDr. Lucia Kalinovská, PhD.
EUROFINS BEL/NOVAMANN s.r.o.
Kollárovo nám. 9, Bratislava, Slovakia



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