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.371/1/2016 from 12.12.2016

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

Assessed product:

SORRY MOM Stencil Solution CH-98-7

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	do 100	---
Propylene Glycol	57-55-6	200-338-0	viscosity controlling, solvent, skin conditioning, humectant	10,00	---
Sodium Stearate	822-16-2	212-490-5	viscosity controlling, surfactant, emulsifying, cleansing	2,50	---
Phenoxyethanol	122-99-6	204-589-7	preservative	0,72	Max. 1,0 %
Carbomer	9007-20-9	---	viscosity controlling, gel forming, emulsion stabilising	0,55	---
Steareth-20	9005-00-9	---	surfactant, emulsifying, cleansing	0,50	---
Polysorbate-20	9005-64-5	---	surfactant, emulsifying	0,50	---
Parfum MANGO BOOM ANTIALERGIC ISM 103511 (Aroma)	---	---	perfuming	0,30	---
Ethylhexylglycerin	70445-33-9	408-080-2	skin conditioning	0,08	---
Aloe Barbadensis Leaf Juice Powder	85507-69-3	287-390-8	skin conditioning	0,1	---
Sodium Hydroxide	1310-73-2	215-185-5	denaturant, buffering	q.s.	pH<11

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. 128902/2016 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: H2O Molar mass: 18,01 g mol−1 Appearance: Colorless liquid Boiling point: 99,98 °C

Ingredient	Synonym	Characters
Propylene Glycol	Propane-1,2-diol; methyl ethyl glycol; 1,2-Dihydroxypropane	Molecular formula: C3H8O2 Molar mass: 76,09 g mol−1 Appearance: Colorless viscous liquid Boiling point: 188,2 °C Melting point: -59 °C
Sodium Stearate	Octadecanoic acid sodium salt, Stearic acid sodium salt	Molecular formula: CH3(CH2)16COONa Molar mass: 306,46 g mol−1
Phenoxyethanol	2-Phenoxy-1-ethanol; Ethylene glycol monophenyl ether; 1-Hydroxy-2-phenoxyethane	Molecular formula: C2H6O Molar mass: 138,16 g mol−1 Appearance: Colorless oily liquid Density: 1,102 g/cm3 Boiling point: 247 °C Melting point: 11-13°C
Carbomer	2-Propenoic acid, polymer with 2,2-bis (hydroxymethyl) propane-1,3-diol 2-propenyl ether	Polymers primarily made from acrylic acid. Appearance: White powder
Steareth-20	Poly(oxy-1,2-ethanediyl), .alpha.-octadecyl-.omega.-hydroxy	synthetic surfactant composed of polyethylene glycol polymer and stearyl alcohol.
Polysorbate-20	Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.	Molecular formula: C58 H114 O26 Molar mass: 1227,54 g mol−1
Ethylhexylglycerin	3-[(2-Ethylhexyl)oxy]- 1,2-propandiol	Molecular formula: C11H24O3 Molar mass: 204,31 g mol−1
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
Sodium Hydroxide	Caustic soda	Molecular formula: NaOH Molar mass: 39,99 g mol−1 Appearance: white, waxy opaque crystals Melting point: 318 °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 12 months after opening.

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. 128898/2016 with satisfactory results.

Preservation challenge tests were tested by the testing laboratory EUROFINS BEL/NOVAMANN s.r.o., analytical report No. 128894/2016 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.

Subsance	Inpurity	Result
Polysorbate-20	Ethylene Oxide	Max. 2 ppm
	Dioxan	Max. 1 ppm
Steareth-20	Ethylene Oxide	Max. 1 ppm
	Dioxan	Max. 5 ppm
Phenoxyethanol/ Ethylhexylglycerin	Phenol	Max. 50 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. 128902/2016 with satisfactory results.

4.3 Packaging of cosmetic product

The primary packaging material is plastic bottle with dosier. Material meets the requirements on the content of dangerous substances according to the directives 1935/2004/EC, 90/128/EEC 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. Physical/chemical properties of the final product exhibited no granges. Supplier of packaging material is M&G Polimeri Italia S.p.A, Bergmann TG-GmbH and VEXEL.

Cosmetic product is packaged in packages intended for this use.

5. Normal and reasonably foreseeable use

Product is intended for around 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 cm^2.
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	104,47
Propylene Glycol	12,23
Sodium Stearate	3,08
Phenoxyethanol	1,937
Carbomer	0,68
Steareth-20	0,62
Polysorbate-20	0,62
Parfum	0,37
Ethylhexylglycerin	0,099
Aloe Barbadensis Leaf Juice Powder	0,12
Sodium Hydroxide	0,012

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
Propylene Glycol	Causes mild eye and skin irritation.	LD50 oral -rabbit: 18 500 mg/kg LD50 dermal -rabbit: 20 800 mg/kg Can cause mild irritation of eyes and skin.
	NOAEL = 2 000 mg/kg bw/day	MoS = NOAEL / SED = 164
Sodium Stearate	Causes serious eye irritation. Causes skin irritation.	Can cause irritation of eyes and skin.
	NOAEL = 1 000 mg/kg bw/day	MoS = NOAEL / SED = 325
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 = 258
Carbomer	Causes mild eye and skin irritation.	Can cause irritation of eyes and skin. Can be harmful if swallowed. Can cause respirátory irritation.
	NOAEL = 100 mg/kg bw/day	MoS = NOAEL / SED = 147
Steareth-20	Causes mild eye and skin irritation.	LD50 oral –rat: >2 000 mg/kg Causes mild eye and skin irritation.
	NOAEL = 2 000 mg/kg bw/day	MoS = NOAEL / SED = 3 226
Polysorbate-20	Causes mild eye irritation.	Can cause irritation of eyes and skin.
	NOAEL = 5 000 mg/kg bw/day	MoS = NOAEL / SED = 8 065
Ethylhexylglycerin	Causes mild eye and skin irritation	Can cause irritation of eyes and skin.
	NOAEL = unavailable	MoS = NOAEL / SED = ---

Component	Classification	Toxicological profile
Aloe Barbadensis Leaf Juice Powder	Causes eye irritation.	Can cause eye irritation.
	NOAEL = 1 000 mg/kg bw/day	MoS = NOAEL / SED = 8 333
Sodium hydroxide	Causes severe skin burns and eye damage.	Material is extremely destructive to the tissue of the mucous membranes and upper respiratory tract. May be harmful if absorbed through skin. Causes eye and skin burns.
	NOAEL = 10 mg/kg bw/day	MoS = NOAEL / SED = 833

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. 178-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 in a form of occlusive plaster 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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