

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. 246/1/2017 from 07.09.2017

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

Assessed product:

Sorry Mom Process Butter



PART A – cosmetic product safety information

1. Quantitative and qualitative composition of cosmetic product

Ingredient INCI	CAS number	EINECS number	Intended function	Restriction
Cocos Nucifera Oil	8001-31-8	232-282-8	solvent, skin conditioning, masking, hair conditioning, emollient	---
Butyrospermum Parkii Butter	194043-92-0	---	viscosity controlling, skin conditioning	---
Cera Alba	8012-89-3	232-383-7	mollient, emulsifying, film forming, perfuming	---
Mangifera Indica Seed Butter	90063-86-8	290-045-4	skin conditioning	---
Oryza Sativa Bran Oil	68553-81-1	271-397-8	emollient	---
Cetearyl Alcohol	67762-27-0	267-008-6	viscosity controlling, surfactant, opacifying, foam boosting, emulsion stabilising, emulsifying, emollient	---
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	---
Helianthus Annuus Seed Oil	8001-21-6	232-273-9	skin conditioning, masking, emollient	---
Parfum MANGO BOOM ANTIALERGIC ISM Z 3554 (Aroma)	---	---	perfuming	---
Tocopherol	1406-66-2	---	skin conditioning, masking, antioxidant	---

Ingredient INCI	CAS number	EINECS number	Intended function	Restriction
Aloe Ferox Leaf Extract	84649-82-1	283-462-8	skin conditioning	---
Rosmarinus Officinalis Oil	84604-14-8	283-291-9	skin conditioning, masking	---

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. 87807/2017 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
Cocos Nucifera Oil		Cocos Nucifera Oil is the fixed oil obtained by expression of the kernels of the seeds of the Coconut, <i>Cocos nucifera</i> L., Palmaceae
Butyrospermum Parkii Butter		Butyrospermum Parkii Butter is the fat obtained from the fruit of the Shea Tree, <i>Butyrospermum parkii</i> , Sapotaceae
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
Mangifera Indica Seed Butter		Mangifera Indica Seed Butter is the fat obtained from the seeds of the Mango, <i>Mangifera indica</i> L., Anacardiaceae
Oryza Sativa Bran Oil		Oryza Sativa Bran Oil is the fixed oil expressed from the bran of the Rice, <i>Oryza sativa</i> L., Poaceae. It consists primarily of the glycerides of the fatty acids linoleic, oleic, palmetic and stearic
Cetearyl Alcohol	Alcohols, C16-18	mixture of cetyl and stearyl alcohols Melting point: 48 °C
Stearyl Stearate	Octadecyl stearate	Molecular formula: C36H72O2 Molar mass: 536,97 g mol ⁻¹
Cetyl Palmitate	Hexadecyl hexadecanoate	Molecular formula: C32H64O2 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 C20 / 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 C20 through C50

Ingredient	Synonym	Characters
Helianthus Annuus Seed Oil		Helianthus Annuus Seed Oil is the oil expressed from the seeds of the Sunflower, <i>Helianthus annuus</i> L., Compositae
Tocopherol	3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-ol; .alpha-tocopherol; Vitamin E	Molecular formula: C ₂₉ H ₅₀ O ₂ Molar mass: 430,71 g mol ⁻¹ Melting point: 2,5-3,5 °C
Aloe Ferox Leaf Extract		Aloe Ferox Leaf Extract is an extract of the leaf of the aloe, <i>Aloe ferox</i> , Liliaceae
Rosmarinus Officinalis Oil		Rosmarinus Officinalis Oil is the essential oil obtained from the flowering tops and leaves of the Rosemary, <i>Rosmarinus officinalis</i> 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, which 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. 87802/2017 with satisfactory results.

Preservation challenge tests were not tested according to ČTN EN ISO 29621 as the product is of low microbiological risk.

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.

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. 87807/2017 with satisfactory results.

4.3 Packaging of cosmetic product

The primary packaging is plastic bottle 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 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:* 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)
Cocos Nucifera Oil	39,36
Butyrospermum Parkii Butter	36,96
Cera Alba	17,35
Mangifera Indica Seed Butter	14,78
Oryza Sativa Bran Oil	6,16
Cetearyl Alcohol	3,70
Stearyl Stearate	1,47
Cetyl Palmitate	1,23
Paraffin	0,39
Helianthus Annuus Seed Oil	1,13
Parfum	0,62
Tocopherol	0,62
Aloe Ferox Leaf Extract	0,15
Rosmarinus Officinalis Oil	0,0086

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
Cocos Nucifera Oil		Substance not classified as toxic.
	NOAEL = unavailable	MoS = NOAEL / SED = ---
Butyrospermum Parkii Butter		Substance not classified as toxic.
	NOAEL = unavailable	MoS = NOAEL / SED = ---
Cera Alba		Substance not classified as toxic.
	NOAEL = unavailable	MoS = NOAEL / SED = ---
Mangifera Indica Seed Butter		Substance not classified as toxic.
	NOAEL = unavailable	MoS = NOAEL / SED = ---
Oryza Sativa Bran Oil		Substance not classified as toxic.
	NOAEL = unavailable	MoS = NOAEL / SED = ---
Cetearyl Alcohol	Causes eye and skin irritation.	LD50 oral -mouse: 3 200 mg/kg LD50 dermal -rabbit: >2 600 mg/kg Can causes eye and skin irritation.
	NOAEL = 1 000 mg/kg bw/day	MoS = NOAEL / SED = 270
Stearyl 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 = 680
Cetyl Palmitate	Causes mild eye and skin irritation.	Can causes mild eye and skin irritation.
	NOAEL = 70 mg/kg bw/day	MoS = NOAEL / SED = 100
Paraffin	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 = 12 821
Helianthus Annuus Seed Oil		Substance not classified as toxic.
	NOAEL = unavailable	MoS = NOAEL / SED = ---
Tocopherol	Causes mild eye and skin irritation.	LD50 oral- mouse: 5 000 mg/kg Can cause mild irritation of eyes and skin.
	NOAEL = 2 000 mg/kg bw/day	MoS = NOAEL / SED = 3 226
Aloe Ferox Leaf Extract	Causes eye irritation.	Can cause eye irritation.
	NOAEL = 1 000 mg/kg bw/day	MoS = NOAEL / SED = 6 667
Rosmarinus Officinalis Extract		Substance not classified as toxic.
	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 MUDr. Jarmmila Rulcová, CSc., report No. 131-E-2017, 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 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:

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