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. 402/1/2013 from 04.11.2013

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

Assessed product:

Sorry Mum TATTOO BALM

eurofins | ELI NOVAMANN
Komjatická 73, 940 02 Nové Zámky
IČO: 31329209 DIČ: 2020297697
IČ DPH: SK2020297697 15

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	---
Lanolin	8006-54-0	232-348-6	antistatic, emollient, emulsifying, hair conditioning, skin conditioning, surfactant	10,0-25,0	---
Parrafinum Liquidum	8012-95-1	232-384-2	antistatic, emollient, skin protecting, solvent	10,0-25,0	---
Panthenol	81-13-0	201-327-3	antistatic, hair conditioning, skin conditioning	5,0-10,0	---
Petrolatum	8009-03-8	232-373-2	antistatic, emollient	1,0-5,0	---
Ozokerite	64742-33-2	265-134-6	binding, emulsion stabilising, opacifying, viscosity controllingc	1,0-5,0	---
Prunus Amygdalus Dulcis Oil	8007-69-0	---	skin conditioning	1,0-5,0	---
Glycerin	56-81-5	200-289-5	denaturant, humectant, solvent, perfuming	1,0-5,0	---
Glyceryl Oleate	25496-72-4	247-038-6	emollient, emulsifying, perfuming	1,0-5,0	---
Lanolin Alcohol	8027-33-6	232-430-1	antistatic, binding, emollient, emulsifying, hair conditioning, viscosity controlling	1,0-5,0	---
Cera Alba	8012-89-3	232-383-7	mollient, emulsifying, film forming, perfuming	1,0-5,0	---

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Ingredient INCI	CAS number	EINECS number	Intended function	Content	Restriction
Hydrogenated Castor Oil	8001-78-3	232-292-2	emollient, emulsifying, skin conditioning, surfactant, viscosity controlling	1,0-5,0	---
Magnesium Sulfate	7487-88-9	231-298-2	bulking, hair conditioning, viscosity controlling	0,1-1,0	---
Hippophae Rhamnoides Fruit Extract	90106-68-6	290-292-8	skin conditioning	0,1-1,0	---
Phenoxyethanol	122-99-6	204-589-7	preservative	0,75	Max. 1,0%
Calendula Officinalis Flower Extract	84776-23-8	283-949-5	masking, skin conditioning, perfuming	≤0,1	---
Rosmarinus Officinalis Leaf Extract	84604-14-8	283-291-9	antimicrobial, masking, skin conditioning	≤0,1	---

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.

Product is stable at usual storage conditions and foreseeable usage during declared expiry period.

2.2 Cosmetic ingredients

For manufacturing of cosmetic product were used ingredients, which fulfill requirements for cosmetic ingredients.

Ingredient	Synonym	Characters
Aqua	Water; Oxidane	Molecular formula: H2O 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: C9H19NO4 Molar mass: 205,25 g mol−1 Melting point: 66-69 °C
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

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Ingredient	Synonym	Characters
Parrafinum 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: 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
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
Lanolin Alcohol	Alcohols, lanolin. A complex combination of organic alcohols obtained by the hydrolysis of lanolin	Lanolin Alcoholis a non-drying organic compound produced from lanolin, the fat of wool shearings, which has been reacted with acetic acid and a small amount of lye.
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 *castor seed* as the castor plant, *Ricinus communis* (Euphorbiaceae), is not a member of the bean family.
Magnesium Sulfate		Molecular formula: MgSO4 (anhydrous) Molar mass: 120,37 g mol−1 Appearance: White crystalline solid Melting point: 1124 °C (anhydrous)

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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: 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
Calendula Officinalis Flower Extract		Calendula Officinalis Flower Extract is an extract obrained 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

3. Microbial quality

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

Traces of heavy metals were tested by the testing laboratory EUROFINS BEL/NOVAMANN s.r.o., analytical report No. 85796/2013 with satisfactory results.

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

a. *The site of application:* Product is applied on the skin of 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:* skin of the 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:

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Ingredient	SED (mg/kg bw/day)
Aqua	61,60
Lanolin	30,80
Parrafinum Liquidum	30,80
Panthenol	12,32
Petrolatum	6,16
Ozokerite	6,16
Prunus Amygdalus Dulcis Oil	6,16
Glycerin	6,16
Glyceryl Oleate	6,16
Lanolin Alcohol	6,16
Cera Alba	6,16
Hydrogenated Castor Oil	6,16
Magnesium Sulfate	1,23
Hippophae Rhamnoides Fruit Extract	1,23
Phenoxyethanol	2,018
Calendula Officinalis Flower Extract	0,12
Rosmarinus Officinalis Leaf Extract	0,12

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
Petrolatum		Can cause irritation of eyes and skin.
	NOAEL = 5 000 mg/kg bw/day	MoS = NOAEL / SED = 811
Phenoxyethanol	Harmless if swallowed. Causes serious eye irritation.	LD50 oral- rat: 1 260 mg/kg LD50 dermal- rat: 14 422 mg/kg Can cause eye and skin irritation.
	NOAEL = 500 mg/kg bw/day	MoS = NOAEL / SED = 248

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

Not expected during normal and reasonably foreseeable use of cosmetic product.

Undesirable inhalation can cause headache and dizziness.

10. Information on the cosmetic product

Toxicological effect of product were 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, 7th revision
- http://www.specialchem4cosmetics.com
- http: //en.wikipedia.org
- http: //www.sigmaaldrich.com
- http://www.lookchem.com
- http://www.chemsynthesis.com

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 toxiceffects 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

Bratislava, 04.11.2013 .....