

# **COSMETIC PRODUCT SAFETY REPORT**

According to EC Regulation 1223/2009 and SCHEDULE 34

## **ANTI-WRINKLE ROCK SALT GOLD EYE CREAM**

**ISSUE DATE: July 5, 2023**

**SAFETY ASSESSMENT REFERENCE NO.: L7150**

**VERSION: I**

**SAFETY ASSESSOR**

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## PART A - COSMETIC PRODUCT SAFETY INFORMATION

Product name	ANTI-WRINKLE ROCK SALT GOLD EYE CREAM
Shade names	/
Product type	Eye care cream
Formula number	/
Category of the product	Eye care cream
Physical form of the product	Cream
Target population	Adults
Primary site of application	Eye contour
Packaging type and size	40ml HDPE tube
Manufacturer name and address	Biosal, Korea
Producer name and address	Biosal, Korea

### 1. QUANTITATIVE AND QUALITATIVE COMPOSITION OF THE COSMETIC PRODUCT

INCI name	CAS	EINECS/ELIN CS	% active in the raw material	Concentration in the final product	Function
AQUA	7732-18-5	231-791-2	100	47,519	Solvent
PROPYLENE GLYCOL	57-55-6	200-338-0	100	10,000	Humectant, Skin Conditioning, Solvent, Viscosity Controlling
BUTYROSPERMUM PARKII BUTTER	194043-92-0 / 91080-23-8	293-515-7	100	10,000	SKIN CONDITIONING, VISCOSITY CONTROLLING
GLYCERIN	56-81-5	200-289-5	100	10,000	Denaturant, Hair Conditioning, Humectant, Masking, Oral Care, Perfuming, Skin Protecting, Viscosity Controlling
DIMETHICONE	63148-62-9 / 9006-65-9 / 9016-00-6	Not available	100	10,000	ANTIFOAMING, EMOLLIENT, SKIN CONDITIONING, SKIN PROTECTING
CETEARYL ALCOHOL	67762-27-0 / 8005-44-5	267-008-6 / -	100	5,000	EMOLLIENT, EMULSIFYING, EMULSION STABILISING, FOAM BOOSTING, OPACIFYING, SURFACTANT, VISCOSITY CONTROLLING
GLYCERYL STEARATE	31566-31-1	250-705-4/286-490-9	100	4,000	EMOLLIENT, EMULSIFYING
SODIUM HYALURONATE	9067-32-7	Not available	1	1,000	HUMECTANT, SKIN CONDITIONING



AQUA	7732-18-5	231-791-2	99		Solvent
BEESWAX	8006-40-3 4,8012-89-3	232-383-7 (I)	100	0,500	EMOLLIENT, EMULSIFYING, FILM FORMING, PERFUMING
BETAINE	107-43-7	203-490-6	100	0,300	ANTISTATIC, HAIR CONDITIONING, HUMECTANT, SKIN CONDITIONING, VISCOSITY CONTROLLING
PHENOXYETHANOL	122-99-6	204-589-7	100	0,150	PRESERVATIVE
METHYLPARABEN	99-76-3	202-785-7	100	0,150	PRESERVATIVE
PROPYLPARABEN	94-13-3	202-307-7	100	0,100	PERFUMING, PRESERVATIVE
ALLANTOIN	97-59-6	202-592-8	100	0,100	Skin Conditioning, Skin Protecting, Soothing
ADENOSINE	58-61-7	200-389-9	100	0,040	SKIN CONDITIONING
COLLAGEN	9007-34-5	232-697-4	100	0,030	HAIR CONDITIONING, MOISTURISING, SKIN CONDITIONING
AQUA	7732-18-5	231-791-2	100	0,957	Solvent
PROPYLENE GLYCOL	57-55-6	200-338-0	100	0,110	Humectant, Skin Conditioning, Solvent, Viscosity Controlling
CAMELLIA SINENSIS LEAF EXTRACT	84650-60-2	283-519-7	1	0,011	ANTIMICROBIAL, ANTIOXIDANT, ASTRINGENT, EMOLLIENT, HUMECTANT, MASKING ORAL CARE, SKIN CONDITIONING, SKIN PROTECTING, TONIC, UV ABSORBER
PROPANEDIOL	504-63-2 / 26264-14-2	207-997-3	99		SOLVENT, VISCOSITY CONTROLLING
GLYCYRRHIZA GLABRA ROOT EXTRACT	84775-66-6	283-895-2	10	0,011	BLEACHING, EMOLLIENT, PERFUMING, SKIN CONDITIONING, SMOOTHING, SOOTHING
AQUA	7732-18-5	231-791-2	90		Solvent
PANAX GINSENG ROOT EXTRACT	84650-12-4	283-493-7	1	0,011	EMOLLIENT, HAIR CONDITIONING, SKIN PROTECTING, TONIC
ALCOHOL	64-17-5	200-578-6	45	0,011	ANTIFOAMING, ANTIMICROBIAL, ASTRINGENT, MASKING, SOLVENT, VISCOSITY CONTROLLING



AQUA	7732-18-5	231-791-2	54		Solvent
GOLD	7440-57-5	231-165-9	100	0,001	COSMETIC COLORANT
MINERAL SALTS	Not available	Not available	100	0,010	SKIN CONDITIONING

## 2. PHYSICAL/CHEMICAL CHARACTERISTICS AND STABILITY OF THE COSMETIC PRODUCT

### a. PHYSICAL/CHEMICAL CHARACTERISTICS AND STABILITY OF SUBSTANCES OR MIXTURES

Substance (INCI) / Mixture	Chemical NAME	Physical form	Molecular weight (g/mol)	Water Solubility /Solubility	Partition coefficient	Absorption spectra (UV absorbers)
AQUA	Water	Liquid	18.02 g/mol	Soluble in alcohol	Not available	Not applicable
PROPYLENE GLYCOL	Propane-1,2-diol	Liquid	76.09	Fully miscible (100%) with water in all proportions at 20 °C and pH = 7.1-7.8; miscible with alcohol and many organic solvents.	log POW = -1.07 at 20 °C	Not applicable
BUTYROSPERMUM PARKII BUTTER	Not available	Solid	Not available	Insoluble in water	Not available	Not applicable
GLYCERIN	Glycerol	Liquid	92.09	Completely miscible with water at 25 °C. The compound is also completely miscible with methanol, ethanol, and the isomers of propanol, butanol, and pentanol.	log POW = -1.75 at 25 °C	Not applicable
DIMETHICONE	Dimethicone	Liquid	Not available	Not available	Not available	Not applicable
CETEARYL ALCOHOL	Not available	Solid (waxy)	512.93	Soluble in alcohols, oils	Not available	Not applicable
GLYCERYL STEARATE	Stearic acid, monoester with glycerol	Wax-like solid	358.56	Insoluble in water; soluble in alcohol, acetone	log POW = 7.09	Not applicable
BEESWAX	Not applicable	Solid (wax)	Not available	Insoluble in water; slightly soluble in alcohol; soluble in chloroform, ether, oils	Not available	Not applicable
BETAINE	Not available	Solid (crystalline)	117.15	160 g/l (very soluble in water)	log POW = -3.1 at 20 °C	Not applicable
PHENOXYETHANOL	2-Phenoxyethanol	Liquid	138.17	26.7 g/l at 20 °C	log Pow = 1.16	Not applicable
METHYLPARABEN	Methyl 4-hydroxybenzoate	Colourless crystals or white crystalline powder	152.15	2.5 g/l	log POW = 1.96	Not applicable
PROPYLPARABEN	Propyl 4-hydroxybenzoate	Crystals	180.20	500 mg/l (in water)	log POW = 3.04	Not applicable
ALLANTOIN	Urea, (2,5-dioxo-4-imidazolidinyl)-	Solid (powder)	158.12	4.9 g/L at 20 °C (water solubility)	log POW = -2.26 at 20 °C	Not applicable. (absorption of allantoin in aqueous solution is most stable at 225 nm at pH 10.5-11.5)
ADENOSINE	6-Amino-9-beta-D-ribofuranosyl-9H-purine	White liquid	267.245 g/mol	Dispersible	Not available	Not available



COLLAGEN	Not available		Not available	Practically insoluble in water, but lowering the pH of solution can increase solubility	Not available	Not applicable
PROPANEDIOL	1,3-dihydroxypropane	Liquid	76.09	Freely soluble in water	Not available	Not applicable
SODIUM HYALURONATE	Hyaluronic acid, sodium, salt	Powder	403.31 g/mol	Soluble	Not available	Not available
MINERAL SALTS	Not available	Liquid	Not available	Not available	Not available	Not available
ALCOHOL	Ethanol	Liquid	46.07	Soluble	log POW = -0.31	Not applicable
GLYCYRRHIZA GLABRA ROOT EXTRACT	Not applicable	Liquid	Not available	Fully miscible in water	Not available	Not applicable
GOLD	Not available	Liquid	196.97	Not available	Not available	Not applicable
CAMELLIA SINENSIS LEAF EXTRACT	Not applicable	Liquid	Not available	Not available	Not available	Not applicable
PANAX GINSENG ROOT EXTRACT	Not applicable	Liquid	Not available	Not available	Not available	Not applicable

**b. PHYSICAL/CHEMICAL CHARACTERISTICS OF THE FINISHED COSMETIC PRODUCT**

ANALYSIS	SPECIFICATIONS	MAT./METH
ASPECT	GOLD IN CREAM	VISUAL
COLOR	PALE YELLOW	VISUAL
ODOR	FRESH FLOWERLY	OLFACTIVE
VISCOSITY(CPS)25°C	21,000CPS	BROOFIELD LVDVE spindle No.4
STABILITY	STABLE	3 DAY IN 40°C
DENSITY	0.997	PAAR
CAPACITY	50ML	
pH	6.13	pH METER



### c. STABILITY OF THE COSMETIC PRODUCT

The physical stability of the finished product is justified on the basis of the stability report document, which is ensuring that no changes in physical state of the finished product occur during transport, storage or handling of the product.

The stability testing was performed according to the accelerated method (12 weeks at 40 °C and 5 °C; product stored in its original packaging and glass container), results below were obtained:

PARAMETER	INITIAL	ACCELERATED STUDY 40 °C				ACCELERATED STUDY 5 °C			
		2 weeks	6 weeks	10 weeks	12 weeks	2 weeks	6 weeks	10 weeks	12 weeks
DATE	4.8.2022	18.8.2022	15.9.2022	13.10.2022	27.10.2022	18.8.2022	15.9.2022	13.10.2022	27.10.2022
APPEARANCE	Cream	Cream	Cream	Cream	Cream	Cream	Cream	Cream	Cream
COLOUR	Off white with golden particles	Off white with golden particles	Off white with golden particles	Off white with golden particles	Off white with golden particles	Off white with golden particles	Off white with golden particles	Off white with golden particles	Off white with golden particles
ODOUR	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic
PH (at 22 °C)	6,15	6,41	6,36	6,22	6,17	6,29	6,34	6,11	6,05
PHASE SEPARATION	0,99	0,99	0,99	1,00	1,01	1,01	1,00	1,00	1,01

Based on the test results, the shelf life is equal to 36 months.

## 3. MICROBIOLOGICAL QUALITY

### a. MICROBIOLOGICAL QUALITY OF SUBSTANCES AND MIXTURES

Substances and mixtures susceptible to microbial growth (water based mixtures, protein - rich materials, plant or animal raw materials)	Present
Raw materials which do not support microbial growth (organic solvents)	Not present

### b. MICROBIOLOGICAL QUALITY OF THE FINISHED COSMETIC PRODUCT

According to the 'Guidelines on Microbiological Quality of the finished product' (SCCS Notes of Guidance), the following limits apply:

Category 1: Products specifically intended for children under 3 years, eye area and mucous membranes.

Category 2: Other cosmetic products.



Types of microorganism	Products specifically intended for children under three years of age, the eye area or the mucous membranes	Other products
Total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mould)	$\leq 1 \times 10^2$ CFU per g or ml <sup>a</sup>	$\leq 1 \times 10^3$ CFU per g or ml <sup>b</sup>
<i>Escherichia coli</i>	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
<i>Pseudomonas aeruginosa</i>	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
<i>Staphylococcus aureus</i>	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
<i>Candida albicans</i>	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Due to inherent variability of the plate count method, according to USP Chapter 61 or EP Chapter 2.6.12, Interpretation of results, results considered out of limit if <b>a &gt; 200 CFU/g or ml,</b> <b>b &gt; 2 000 CFU/g or ml.</b> NOTE When colonies of bacteria are detected on Sabouraud Dextrose agar, Sabouraud Dextrose agar containing antibiotics may be used.		

(Source: The SCCS Notes of Guidance for testing of cosmetic ingredients and their safety evaluation, SCCS/1628/21, March 2021)

This product was evaluated according to the category 1, and the following results were obtained:

TEST	METHOD	RESULT
TOTAL AEROBIC MESOPHILIC BACTERIA	According to ISO 21149:2017	< 100 CFU/g
ENUMERATION OF YEAST AND MOULD	According to ISO 16212:2017	< 100 CFU/g
PRESENCE OF CANDIDA ALBICANS	According to ISO 18416:2015	Absent in 1g
PRESENCE OF PSEUDOMONAS AERUGINOSA	According to ISO 22717:2016	Absent in 1g
PRESENCE OF STAPHYLOCOCCUS AUREUS	According to ISO 22718:2016	Absent in 1g
PRESENCE OF ESCHERICCHIA COLI	According to ISO 21150:2015	Absent in 1g

The results show, that the microbiological purity of the product is acceptable and meets the criteria listed above.

The efficacy of the preservation of a finished cosmetic product was assessed experimentally in order to ensure microbial stability and preservation during storage and use. The challenge test was performed according to the ISO 11930 method and meets the industry requirements specified in the





Notes of guidance for testing of cosmetic ingredients for their safety evaluation, 11th revision (SCCS/1628/21, March 2021)

#### **4. IMPURITIES, TRACES, INFORMATION ABOUT THE PACKAGING MATERIAL**

##### **a. IMPURITIES AND TRACES**

The test stability and compatibility test was performed according to the generally acceptable method.

This product is manufactured according to Good Manufacturing Practice (ISO 22716). Ingredients used throughout must be of a high quality and (where specified) they have to meet purity criteria listed in the Cosmetics legislation. Information provided on ingredient purity and representative certificates of analysis are held in the PIF and are acceptable.

##### **b. THE RELEVANT CHARACTERISTICS OF PACKAGING MATERIAL**

The product is packaged in a 40ml HDPE tube. These packaging components are widely used for consumer products. They are non-porous to inks and adhesives and are unlikely to react chemically with this product. They are considered to be safe since there is no evidence of a possible migration of packaging components into the product.

#### **5. NORMAL AND REASONABLY FORSEEABLE USE**

This product is a leave on facial cream intended to be used by adults on daily basis.

Instructions for use written on the label	Take an appropriate amount of this product and spread it around your eyes and pat it until it absorbs into your skin.
Precautions for use written on the label	When using or after using cosmetics, the area of use has abnormal symptoms or side effects such as red spots, swelling due to direct sunlight- stop using.

A clear explanation of the normal intended use and the reasonably foreseeable use is provided on the product label and therefore a mistaken use (not a misuse) is not recognisable.



## 6. EXPOSURE TO THE COSMETIC PRODUCT

Product Type:	Leave on
Targeted Population:	Adults
Estimated daily amount applied (g):	0,1363*
Skin Surface Area of Application/cm <sup>2</sup> :	50*
Calculated daily exposure (g/day)	0,2626*
Calculated relative daily exposure (mg/kg bw/day):	4,5*
Amount Per Unit Area of Skin per day mg/cm <sup>2</sup> /day:	5,45*
Exposure time:	12h
Frequency of application:	2*
Part of the body exposed:	Eye Contour

\* AEMPS



## 7. EXPOSURE TO THE SUBSTANCES

INCI	Retention factor	POD	SED	MoS
AQUA	1	Not available	2,1698	/
PROPYLENE GLYCOL	1	1700	0,4383	3878,326996
BUTYROSPERMUM PARKII BUTTER	1	Not available	0,4383	/
GLYCERIN	1	2000	0,4383	4562,737643
DIMETHICONE	1	Not available	0,4383	/
CETEARYL ALCOHOL	1	300	0,2192	1368,821293
GLYCERYL STEARATE	1	2500	0,1753	14258,55513
BEESWAX	1	500	0,0219	22813,68821
BETAINE	1	5771	0,0132	438859,3156
PHENOXYETHANOL	1	80	0,0066	12167,30038
METHYLPARABEN	1	1000	0,0066	152091,2548
PROPYLPARABEN	1	2	0,0044	456,2737643
ALLANTOIN	1	Not available	0,0044	/
ADENOSINE	1	Not available	0,0018	/
COLLAGEN	1	Not available	0,0013	/
PROPANEDIOL	1	1000	0,0005	2094920,864
SODIUM HYALURONATE	1	Not available	0,0004	/
MINERAL SALTS	1	Not available	0,0004	/
ALCOHOL	1	2400	0,0002	11061182,16
GLYCYRRHIZA GLABRA ROOT EXTRACT	1	Not available	0,00001	/
GOLD	1	Not available	0,00001	/
CAMELLIA SINENSIS LEAF EXTRACT	1	Not available	0,00001	/
PANAX GINSENG ROOT EXTRACT	1	Not available	0,00001	/

Calculations of Margin of Safety (MoS) have been determined for all ingredients where this is possible from published toxicity information. The method used to do this is:

$SED (\text{whole product}) \times \% \text{ ingredient} = SED (\text{ingredient})$

$MoS = POD (\text{ingredient}) / SED (\text{ingredient})$ .

In every case, the MoS is >100 which is considered to be acceptable. In addition, calculations are also presented to show by how much each ingredient is below the recommendations of industry (CTFA) and those required by European cosmetic legislation. All ingredients fall below any recommended maxima.



## 8. TOXICOLOGICAL PROFILE OF THE SUBSTANCES

INCI name	AQUA
Restriction	None
General description	Simply water unlikely to cause irritation, allergy or harm. Used in many cosmetic products as a solvent and necessary to sustain biological life. The source of water should be known, monitored to GMP and either a deionised or high purity grade free from toxins, pollutants and bacteriological contamination should be used in cosmetic products.
Acute toxicity via relevant routes of exposure	Not toxic. The actual or estimated LD50 value: 100000 mg/kg. Oral Rat LD50: >90 mL/kg.
Skin irritation and skin corrosivity	Not irritating
Mucous membrane irritation (eye irritation)	Not irritating
Skin Sensitization	Not sensitizing
Dermal/ percutaneous absorption	Non-permeator by skin
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) Dweck A. C. Handbook of Cosmetics Ingredients - their use, safety and toxicology. Third edition, 2012.

INCI name	PROPYLENE GLYCOL
Restriction	None
General description	Propylene Glycol is an organic alcohol. It is one of the most widely used ingredients in cosmetics and personal care products. Propylene Glycol is used in many types of cosmetic formulations including fragrances. It can act as a penetration enhancer for some chemicals and under some conditions. Often, it works synergistically with other enhancers; mechanism has not been definitively identified. The safety of Propylene Glycol has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Propylene Glycol is safe for use in cosmetic products at



	concentrations up to 50%. Not considered to be acute or chronic toxicant in oral or dermal studies, not genotoxic or carcinogenic, not reproductive or developmental toxicant.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat): 20000 mg/kg; Oral LD50 (mouse): 22000 mg/kg; Oral LD50 (rabbit): 18500 mg/kg; Dermal LD50 (rabbit) > 2000 mg/kg.
Skin irritation and skin corrosivity	Not irritating to rabbit skin. Undiluted Propylene Glycol minimally irritating to mice.
Mucous membrane irritation (eye irritation)	Undiluted Propylene Glycol less than marginally irritating to the eyes of rabbits.
Skin Sensitization	Not sensitizing. In a provocative study in which the sensitization potential of Propylene Glycol (PG) was evaluated in patients with contact dermatitis, 5% PG in petrolatum did not cause any positive reactions in a patch test.
Dermal/ percutaneous absorption	Dermal penetration of propylene glycol from a ternary cosolvent solution through hairless mouse skin was 57% over a 24-hour period. Propylene glycol molecules did not reach the dermis in human skin.
Repeated dose toxicity (normally 28- or 90-day studies)	In long-term (2-year) oral toxicity study of propylene glycol in rats there were no adverse effects noted at the highest dose tested: NOAEL (male, rat) = 1700 mg/kg bw/day (actual dose received); NOAEL (female, rat) = 2100 mg/kg bw/day (actual dose received). In this study next to histopathological examinations and gross necropsy haematological examination and urinalysis were performed.
Mutagenicity/ genotoxicity	Not genotoxic
Carcinogenicity	There was no evidence of carcinogenicity in rats treated by repeated oral administration, and more limited skin-painting studies in mice and rabbits also failed to detect carcinogenic potential.
Reproduction toxicity	Not reproductive or developmental toxicant
Toxicokinetics (ADME studies)	Available data indicate rapid and extensive absorption in humans as well as animals. The distribution in total body water is rapid. The excretion of propylene glycol is species-dependent. Humans clear about 45% of propylene glycol via kidney.
Phototoxicity / Photosensitization	No data
Nanomaterials	Not applicable



Reference	<p>(1) ECHA. Retrieved from <a href="http://echa.europa.eu/information-on-chemicals/registered-substances">http://echa.europa.eu/information-on-chemicals/registered-substances</a></p> <p>(2) Gaunt et al. Long-term toxicity of propylene glycol in rats. <i>Fd Cosmet Toxicol</i>, 10, 151-162, 1972. (NOAEL)</p> <p>(3) CIR Expert Panel, Fiume et al. Safety assessment of propylene glycol, tripropylene glycol, and PPGs as used in cosmetics. <i>International Journal of Toxicology</i>. 31(5):245-260, 2012.</p> <p>(4) Dweck A. C. <i>Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology</i>. Third edition, 2012.</p>
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INCI name	BUTYROSPERMUM PARKII BUTTER
Restriction	None
General description	Butyrospermum Parkii Butter is the fat obtained from the fruit of the Shea Tree, <i>Butyrospermum parkii</i> , Sapotaceae. The US FDA includes sheanut oil on its list of direct food substances affirmed as GRAS. The safety of Butyrospermum Parkii (Shea) Butter has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics and personal care products in concentrations up to 60%.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 20000 mg/kg
Skin irritation and skin corrosivity	Not irritating (human data)
Mucous membrane irritation (eye irritation)	Not irritating
Skin Sensitization	Not sensitizing (patch test, human)
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not phototoxic
Nanomaterials	Not applicable
Reference	(1) Dweck A. C. <i>Handbook of Cosmetics Ingredients - their use, safety and toxicology</i> . Third edition, 2012.



	(2) CIR Expert Panel. Plant-Derived Fatty Acid Oils as Used in Cosmetics - Final Report. March 4,2011.
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INCI name	GLYCERIN
Restriction	None
General description	Glycerol is widely distributed in food as a natural constituent, and it has undergone review and approval for use as both a direct and indirect food additive and is GRAS by US FDA. Animal studies involving single or repeated exposure by various routes indicated a low order of toxicity, the possible target sites (particularly following repeated oral administration) being the kidney and gastrointestinal tract. Glycerol appears to be of generally low oral toxicity in humans.
Acute toxicity via relevant routes of exposure	The reported oral LD50 of glycerin ranged from 2530-58400 mg/kg in rats, 4090-38000 mg/kg in mice, 27000 mg/kg in rabbits, and 77500 mg/kg in guinea pigs. The dermal LD50 of glycerin in rats was reported to be > 21900 mg/kg and >18700 mg/kg in rabbits. The approximate Lt50 for rats was determined to be 423 min for exposure to glycerin vapors at 11.0 mg/L. The intraperitoneal LD50 of glycerin in rats ranged from 4420-10100 mg/kg and 8600-9500 mg/kg in mice. The subcutaneous LD50 of glycerin was 100 mg/kg in rats and ranged from 91-10000 mg/kg in mice. The intravenous LD50 of glycerin ranged from 5200-6600 mg/kg in rats, 4250-6700 mg/kg in mice, and 53000 mg/kg in rabbits.
Skin irritation and skin corrosivity	Not dermally irritating to rabbits when applied at concentrations up to 100% to up to 30% of the body surface. Mild dermal irritant at 100% in guinea pigs.
Mucous membrane irritation (eye irritation)	Undiluted glycerin was not irritating when administered to the eyes of human subjects. There was a strong burning and stinging sensation, with tear production but no injury was observed.
Skin Sensitization	A moisturizer containing 65.9% glycerin was not sensitizing to human subjects. Natural and synthetic glycerin were not sensitising to white male guinea pigs at 0.1%.
Dermal/ percutaneous absorption	No data



Repeated dose toxicity (normally 28- or 90-day studies)	There were no signs of toxicity or effects on blood or on urine production when human subjects were orally administered approximately 1300-2200 g/kg/d glycerin for 50 days. The NOAEL was $\geq 2200$ mg/kg/d. There were no treatment effects when 100% glycerin was topically applied daily to 30% of the body surfaces of rabbits for 45 weeks. The inhalation LOAEL was 1000 mg/m <sup>3</sup> for glycerin administered 6 h/d, 5 d/week for 2 weeks in rats. The inhalation NOAEL was 0.167 mg/L for glycerin administered for 5 h/d, 5 d/week for 13 weeks in rats.
Mutagenicity/ genotoxicity	Glycerin was not genotoxic in multiple Ames tests using multiple strains of <i>S. typhimurium</i> at concentrations up to 50 mg/plate. It was not genotoxic in a cytogenetic assay, X-linked HGPRT, sister chromatid exchange assay, unscheduled DNA synthesis assay, and chromosome aberration test at concentrations up to 1.0 mg/mL.
Carcinogenicity	Glycerin administered in the feed of rats at doses up to 20% in feed for 1 year or up to 10 g/kg for 2 years did not increase the incidence of tumors. Orally administered glycerin, in concentrations up to 5%, had a potentiating effect on the carcinogenicity of 4NQO in mice.
Reproduction toxicity	No convincing evidence of reproductive effects have been seen in rats treated orally or dermally, or in mice fed glycerol during pregnancy. Glycerin is transferred across the placenta in small amounts. May cause some adverse reproductive effects based on animal data, but there was no evidence of teratogenicity. No effects on fertility and reproductive performance were observed in a two generation study with glycerol administered by gavage (NOAEL 2000 mg/kg bw/day).
Toxicokinetics (ADME studies)	Glycerin is rapidly absorbed in the intestine and the stomach, distributed throughout the extracellular fluids through much of the body. It is mostly metabolized by the liver and kidneys with the remainder excreted in urine. Free glycerin is naturally present in humans, primarily in plasma.
Phototoxicity / Photosensitization	No data
Nanomaterials	Not applicable





Reference	(1) CIR Expert Panel. Safety assessment of glycerin as used in cosmetics - final report (January 14, 2015). (2) ECHA. Retrieved from <a href="http://echa.europa.eu/information-on-chemicals/registered-substances">http://echa.europa.eu/information-on-chemicals/registered-substances</a>
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INCI name	DIMETHICONE
Restriction	None
General description	Dimethicone is a fluid mixture of fully methylated linear siloxane polymers end-blocked with trimethylsiloxy units. It has both food and OTC drug use. Its use in food is limited by molecular weight. The safety of dimethicone has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics at concentrations up to 80% in hair preparations; up to 24% in makeup.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat): 20000 mg/kg; Dermal LD50 (rat, rabbit) > 2000 mg/kg
Skin irritation and skin corrosivity	Minimal irritant (rabbit)
Mucous membrane irritation (eye irritation)	Mild to minimal irritant (rabbit). The most common finding was a conjunctival reaction. However, a few studies reported severe reactions.
Skin Sensitization	Not sensitizing (undiluted, guinea pig); not sensitizing (at 5%, HRIPT).
Dermal/ percutaneous absorption	Not significantly absorbed into the skin due to its large molecular weight.
Repeated dose toxicity (normally 28- or 90-day studies)	Mice and rats were dosed for 90 days with up to 10% dimethicone without adverse effects. Changes in body weight or spleen weight were observed in some rat studies. No adverse reactions were found in rabbits following short-term dermal dosing with 6% to 79% dimethicone.
Mutagenicity/ genotoxicity	Negative in all mutagenicity assays.
Carcinogenicity	Negative in both an oral and dermal carcinogenicity assay using mice.
Reproduction toxicity	Tested in numerous oral-dose (using rats) and dermal-dose (using rats, rabbits, monkeys) reproductive and developmental toxicity studies. In a few studies, treated males had significantly decreased body weight and/or decreased testes or seminal vesicles weights.



Toxicokinetics (ADME studies)	Clinical and animal administration studies generally reported that dimethicone was not absorbed following oral or dermal exposure, although some absorption was seen in humans following ingestion of a dimethicone sample containing low-molecular-weight polymers.
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012. (2) CIR Expert Panel. Final report on the safety assessment of stearoxy dimethicone, dimethicone, methicone, amino bispropyl dimethicone, aminopropyl dimethicone ... IJT 22(2), 11-35, 2003.

INCI name	CETEARYL ALCOHOL
Restriction	None
General description	It is a mixture of mostly cetyl and stearyl alcohols. The safety of Cetearyl Alcohol has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this fatty alcohol is safe for use as cosmetic ingredient in the present practices of use and concentrations up to 25%.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat): 5000 mg/kg; Oral LD50 (mouse): 3200 mg/kg; Dermal LD50 (rabbit): 2600 mg/kg
Skin irritation and skin corrosivity	Mild irritation (3.0% in cream, rabbit)
Mucous membrane irritation (eye irritation)	Not irritating (3.0% in cream, rabbit)
Skin Sensitization	No sensitization (3.0% in cream, clinical study)
Dermal/percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	No data available for the ingredient Cetearyl Alcohol. Read across is made from Alcohols, C10-16 (CAS 67762-41-8) on the basis of similarities in structural, physicochemical, environmental and health parameters (long chain alcohols category according to US EPA). A 28-day oral repeated-dose toxicity study in rats with CAS 67762-41-8 shows decreased body weight gain (10%) in males and liver effects (increased alanine transaminase, alkaline phosphatase and cholesterol) in females at 1000 mg/kg/day. The NOAEL for systemic toxicity is 300 mg/kg/day.



Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	<p>(1) US EPA. Hazard Characterization Document, SCREENING-LEVEL HAZARD CHARACTERIZATION, Long Chain Alcohols Category. December, 2009. Retrieved from <a href="http://www.epa.gov/hpvis/hazchar/Category_Long%20Chain%20Alcohols_December2009.pdf">http://www.epa.gov/hpvis/hazchar/Category_Long%20Chain%20Alcohols_December2009.pdf</a> (NOAEL)</p> <p>(2) CIR Expert Panel. Final Report on the Safety Assessment of Cetearyl Alcohol, Cetyl Alcohol, Isostearyl Alcohol, Myristyl Alcohol, and Behenyl Alcohol. IJT 7(Suppl. 3):359-, 1988.</p> <p>(3) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.</p>

INCI name	GLYCERYL STEARATE
Restriction	None
General description	GRAS food substance regulated by US FDA. Approved as an indirect food additive by US FDA. The safety of glyceryl stearate SE has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics at concentrations up to 50%.
Acute toxicity via relevant routes of exposure	Oral LD50 (mouse) > 5000 mg/kg
Skin irritation and skin corrosivity	Single and repeated insult patch tests showed this ingredient to be nonirritating. Non to mildly irritating (rabbit)
Mucous membrane irritation (eye irritation)	Non to mildly irritating (up to 100%, rabbit)
Skin Sensitization	Not sensitizing (human)
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Glyceryl stearate had no adverse effects in the diet of rats for three consecutive generations. In subchronic and chronic dermal toxicity tests, glyceryl stearate was nontoxic to rabbits but did cause moderate irritation. No NOAEL available for glyceryl stearate. Repeated dose 90-day oral toxicity study in rats was conducted for monoglyceride with CAS 61790-12-3 (supporting substance for read-across)



	approach). There were no adverse effects of treatment reported. The NOAEL was >2500 mg/kg bw, indicating the monoglyceride members are not toxic.
Mutagenicity/ genotoxicity	Negative in in vitro bacterial reverse mutation assay.
Carcinogenicity	5% glyceryl stearate did not promote the carcinogenicity of DMBA in mouse skin.
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Nonphototoxic and nonphotoallergenic
Nanomaterials	Not applicable
Reference	(1) OECD. SIDS INITIAL ASSESSMENT PROFILE, Glycerides Category. October, 2014. (2) CIR Expert Panel. Final Report on the Safety Assessment of Glyceryl Stearate and Glyceryl Stearate/SE. JACT 1(4):169-192, 1982.

INCI name	SODIUM HYALURONATE
Restriction	None
General description	The safety of Hyaluronic Acid, Sodium Hyaluronate and Potassium Hyaluronate has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Hyaluronic Acid, Sodium Hyaluronate and Potassium Hyaluronate were safe as cosmetic ingredients.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 800 mg/kg body weight.
Skin irritation and skin corrosivity	Not irritating
Mucous membrane irritation (eye irritation)	Not available
Skin Sensitization	Not sensitizing (rabbits)
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not genotoxic
Carcinogenicity	No evidence of cytotoxicity form sodium hyaluronate to mouse bone marrow cells
Reproduction toxicity	Not toxic for the reproduction
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	
Reference	(1) CIR Expert Panel. Final Report of the Safety Assessment of Hyaluronic Acid, Potassium Hyaluronate, and Sodium Hyaluronate. IJT 28(Suppl. 1):5-67, 2009.



	(2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.
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INCI name	BEESWAX
Restriction	None
General description	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. The US FDA includes beeswax on its list of substances considered GRAS for direct addition to food. The safety of Beeswax has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics and personal care products at concentrations up to 56%.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat) > 5000 mg/kg
Skin irritation and skin corrosivity	Not irritating (rabbits); not irritating to mildly irritating (clinical studies, HRPIT)
Mucous membrane irritation (eye irritation)	Not irritating to mildly irritating (rabbits)
Skin Sensitization	Not sensitizing (clinical studies)
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Two formulations containing 13% Beeswax were tested for subchronic dermal toxicity in rabbits and rats with no topical or systemic toxic effects. A NOEL of 500 mg/kg bw/d was identified.
Mutagenicity/ genotoxicity	Not mutagenic to multiple strains of <i>S. typhimurium</i> or to <i>S. cerevisiae</i> , in plate and suspension tests, with or without metabolic activation.
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not phototoxic (mice, swine)
Nanomaterials	Not available
Reference	(1) CIR Expert Panel. Final Report on the Safety Assessment of Candelilla Wax, Carnauba Wax, Japan Wax, and Beeswax. JACT 3(3):1-41, 1984. (2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.



INCI name	BETAINE
Restriction	None
General description	Betaine is a common food component. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics when formulated to be non-irritating.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat): 11.1 g/kg
Skin irritation and skin corrosivity	Not irritating; anti-irritating effect on the skin in several efficacy studies in humans
Mucous membrane irritation (eye irritation)	Not irritating (rabbit)
Skin Sensitization	Not sensitizing (non-human, human)
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	In a repeated dose 28-day oral toxicity study in rats according to OECD 407, NOAEL of > 5771 mg/kg was determined.
Mutagenicity/ genotoxicity	Not genotoxic in in vitro and in vivo studies
Carcinogenicity	Not carcinogenic when tested up to 5% in a 104-week dietary rat study
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Absorption and elimination of betaine in humans were dose dependent, with urinary excretion of betaine increasing with betaine dose.
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) CIR Expert Panel. Safety Assessment of Alkyl Betaines as Used in Cosmetics. April 4, 2014.

INCI name	PHENOXYETHANOL
Restriction	V/29
General description	European Cosmetics Regulation Annex V (Line 29) lists phenoxyethanol as an approved preservative in the EU at concentrations up to 1%. In terms of Regulation (EC) No 1272/2008 (CLP) the following hazard classes are assigned to this ingredient (EU harmonized classification): Acute Tox. 4, Eye Irrit. 2.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat): 1386 - 4013 mg/kg; Dermal LD50 (rat): 14300 mg/kg
Skin irritation and skin corrosivity	Not skin irritating (humans); slightly irritating (animals)
Mucous membrane irritation (eye irritation)	Irritating (rabbit)
Skin Sensitization	Not sensitizing (human, animal)



Dermal/ percutaneous absorption	Rapidly absorbed through the rat skin.
Repeated dose toxicity (normally 28- or 90-day studies)	The critical impact of phenoxyethanol is assessed to be kidney toxicity if swallowed. A 90 days repeated test with oral exposure of rats with the doses 80, 400 and 2000 mg/kg/day showed no impacts at 80 mg/kg/day (NOAEL value). At 400 mg/kg/day kidney toxicity and changes in grooming behavior were seen. At a dose of 2000 mg/kg/day toxicity towards red blood corpuscles was seen.
Mutagenicity/ genotoxicity	Nonmutagenic in the Ames test and in the mouse micronucleus test.
Carcinogenicity	Not expected to be carcinogenic.
Reproduction toxicity	Phenoxyethanol has shown damaging impacts on reproduction and developmental toxicity in animal tests with mice. In several reproduction studies with mice the impacts were decreasing body weight on the mice and their progeny as well as increased liver weight at high doses of between 1875 and 4000 mg/kg/day.
Toxicokinetics (ADME studies)	Tests with rats show that more than 75% and up to 99% of the phenoxyethanol after either oral or dermal exposure can be found unchanged in the urine together with small quantities of two substances to which the phenoxyethanol has metabolized. One of the metabolism products is phenoxyacetic acid.
Phototoxicity / Photosensitization	In clinical studies phenoxyethanol was nonphototoxic.
Nanomaterials	Not applicable
Reference	(1) Danish Ministry of Environment, EPA. A survey and health assessment of cosmetic products for children. Survey of Chemical Substances in Consumer Products, No. 88 2007. (2) CIR Expert Panel. Final Report on the Safety Assessment of Phenoxyethanol. JACT 9(2):259-277, 1990.

INCI name	METHYLPARABEN
Restriction	V/12





General description	Methylparaben is currently authorized in EU as preservative at a maximum concentration of 0.4% when used individually or 0.8% when used as a mixture of esters. The safety of methylparaben has been assessed also by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics at concentrations up to 0.4% if used alone; parabens mixture up to 0.8%. Acute, subchronic, and chronic studies in rodents generally indicate that parabens have a low toxicological potential. In individuals with normal skin, parabens are for the most part non-irritating and non-sensitizing. However, application of products containing parabens to damaged or broken skin has resulted in sensitization.
Acute toxicity via relevant routes of exposure	Acute toxicity studies in animals indicate that methyl paraben is practically non-toxic by both oral and parenteral routes. The actual or estimated LD50 value: 3000 mg/kg.
Skin irritation and skin corrosivity	In a population with normal skin, methyl paraben is practically non-irritating.
Mucous membrane irritation (eye irritation)	Skin irritant in man.
Skin Sensitization	In a population with normal skin, methyl paraben is practically non-sensitizing. Paraben esters are rare sensitizers when applied to the intact skin of man. Application to the damaged skin is a more common cause of sensitization.
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Subchronic and chronic oral studies indicate that parabens are practically non-toxic. In chronic administration studies, NOEL as high as 1050 mg/kg have been reported and a NOAEL in the rat of 5700 mg/kg is posited for methylparaben.
Mutagenicity/ genotoxicity	Not mutagenic
Carcinogenicity	Not carcinogenic
Reproduction toxicity	The maternal NOAEL of 100 mg/kg/day and developmental NOAEL of 1000 mg/kg/day were established for butylparaben in developmental study in rats according to OECD Guideline. Methylparaben was not shown to adversely affect the secretion of sex hormones or male reproduction function up to about 1000 mg/kg bw/day. Generally, methylparaben is considered to have a much lower potential for





	causing endocrine disrupting effects compared to propyl- and butylparaben.
Toxicokinetics (ADME studies)	Methylparaben is readily and completely absorbed through the skin and from the gastrointestinal tract. It is hydrolyzed to p-hydroxybenzoic acid, conjugated, and the conjugates are rapidly excreted in the urine. There is no evidence of accumulation.
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	<p>(1) CIR Expert Panel. Final amended report of the safety assessment of methylparaben, ethylparaben,...IJT 27 (Suppl. 4):1-82, 2008.(1) SCCS. Opinion on Parabens. Updated request for a scientific opinion on propyl- and butylparaben. SCCS/1514/13, 2013. (NOAEL reprod.)</p> <p>(2) Danish Ministry of Environment. Survey of parabens. Part of the LOUS-review. Environmental Project No. 1474, 2013.</p> <p>(3) Danish Ministry of Environment. Survey and health assessment of preservatives in toys. Survey of chemical substances in consumer products no. 124, 2014.</p> <p>(4) SCCS. Opinion on Parabens. SCCS/1348/10, 2011.</p> <p>(5) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.</p>

INCI name	PROPYLPARABEN
Restriction	V/12
General description	<p>Propylparaben is currently authorized in EU as preservative at a maximum concentration of 0.4% when used individually or 0.8% when used as a mixture of esters. The safety of propylparaben has been assessed also by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics at concentrations up to 0.4% if used alone; parabens mixture up to 0.8%. Acute, subchronic, and chronic studies in rodents generally indicate that parabens have a low toxicological potential. In individuals with</p>



	normal skin, parabens are for the most part non-irritating and non-sensitizing. However, application of products containing parabens to damaged or broken skin has resulted in sensitization.
Acute toxicity via relevant routes of exposure	Propylparaben was shown to possess very low acute toxicity.
Skin irritation and skin corrosivity	At most mildly irritating to rabbit skin (at 10%).
Mucous membrane irritation (eye irritation)	Not available
Skin Sensitization	No evidence of sensitizing potential in a human study. Paraben esters are rare sensitizers when applied to the intact skin of man. Application to the damaged skin is a more common cause of sensitization.
Dermal/ percutaneous absorption	Dermal absorption value was set to 3.7% by SCCS.
Repeated dose toxicity (normally 28- or 90-day studies)	Subchronic and chronic oral studies indicate that parabens are practically non-toxic. The study chosen by the SCCS for the risk assessment was that of Fisher et al. (1999) with a NOEL value of 2 mg/kg bw/day derived from a study where juvenile rats were exposed after subcutaneous administration of 2 mg butylparaben/kg/day 35 for 17 days (postnatal days 2-18). In other studies in female and male rodents, often (much) higher dose levels (several hundred up to 1200 mg/kg bw) were administered.
Mutagenicity/ genotoxicity	Genotoxicity testing of parabens in a variety of in vitro and in vivo studies primarily gave negative results.
Carcinogenicity	The paraben structure is not indicative of carcinogenic potential, and experimental studies support these observations.
Reproduction toxicity	The maternal NOAEL of 100 mg/kg/day and developmental NOAEL of 1000 mg/kg/day were established for butylparaben in developmental study in rats according to OECD Guideline.
Toxicokinetics (ADME studies)	Parabens are well absorbed after oral and subcutaneous administration. Parabens are excreted in urine as the metabolite p-hydroxybenzoic acid (PHBA) or as conjugates of the parent compound with either glycine, glucuronide or sulphate. Total levels of metabolites and parent compounds excreted in urine of orally and dermally exposed rats and rabbits are high, indicating that parabens and/or their metabolites are taken up in



	considerable amounts but rapidly metabolized and excreted.
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) SCCS. Opinion on Parabens. Updated request for a scientific opinion on propyl- and butylparaben. SCCS/1514/13, 2013. (NOAEL repeat.) (2) SCCS. Opinion on Parabens. SCCS/1348/10, 2011. (3) Danish Ministry of Environment. Survey of parabens. Part of the LOUS-review. Environmental Project No. 1474, 2013. (4) CIR Expert Panel. Final amended report of the safety assessment of methylparaben, ethylparaben,...IJT 27 (Suppl. 4):1-82, 2008.

INCI name	ALLANTOIN
Restriction	None
General description	The safety of allantoin has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that allantoin is safe as cosmetic ingredient at concentration up to 2 %.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat) > 5000 mg/kg; Dermal LD50 (rabbit) > 5000 mg/kg (with intact and abraded skin)
Skin irritation and skin corrosivity	Not irritating
Mucous membrane irritation (eye irritation)	Not irritating
Skin Sensitization	Not sensitizing
Dermal/ percutaneous absorption	Allantoin (1%) penetration of human skin after 3- and 6-hour exposures was in average 5 % and 6.9% in a hydrophilic gel, 13% and 15.4% for an oil/water cream, and 12.5% and 20% for a water/oil ointment, respectively.
Repeated dose toxicity (normally 28- or 90-day studies)	No data
Mutagenicity/ genotoxicity	Not mutagenic in an Ames test.
Carcinogenicity	Not carcinogenic
Reproduction toxicity	No data
Toxicokinetics (ADME studies)	There was 98% recovery of allantoin in urine in dogs 5 hours after intravenous administration. When allantoin was administered orally, elimination was complete at 4 hours. Recovery averaged 66% when allantoin was administered in feed. In sheep, most of the intravenously



	administered allantoin was excreted in the urine; degradation in the gut occurred post ruminally.
Phototoxicity / Photosensitization	No data
Nanomaterials	Not applicable
Reference	(1) CIR Expert Panel, Becker et al. Final report of the safety assessment of allantoin and its related complexes. International Journal of Toxicology. 29(2):84-97, 2010. (2) ECHA. Retrieved from <a href="http://echa.europa.eu/information-on-chemicals/registered-substances">http://echa.europa.eu/information-on-chemicals/registered-substances</a>

INCI name	ADENOSINE
Restriction	None
General description	Adenosine is a purine nucleoside comprising a molecule of adenine attached to a ribose sugar molecule (ribofuranose) moiety via a $\beta$ -N9-glycosidic bond. Adenosine plays an important role in biochemical processes, such as energy transfer—as adenosine triphosphate (ATP) and adenosine diphosphate (ADP)—as well as in signal transduction as cyclic adenosine monophosphate, cAMP. It is also an inhibitory neurotransmitter, believed to play a role in promoting sleep and suppressing arousal, with levels increasing with each hour an organism is awake. Extracellular adenosine concentrations from normal cells are approximately 300 nM; however, in response to cellular damage (e.g. in inflammatory or ischemic tissue), these concentrations are quickly elevated (600–1,200 nM). Thus, in regard to stress or injury, the function of adenosine is primarily that of cytoprotection preventing tissue damage during instances of hypoxia, ischemia, and seizure activity. Activation of A2A receptors produces a constellation of responses that in general can be classified as anti-inflammatory.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat): 2,000 mg/kg; Oral LD50 (mouse): 2,000 mg/kg.
Skin irritation and skin corrosivity	Rabbit: mild irritation
Mucous membrane irritation (eye irritation)	Rabbit: mild irritation
Skin Sensitization	Not available
Dermal/ percutaneous absorption	Not available



Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	
Reference	(1) Dweck A. C. Handbook of Cosmetics Ingredients - their use, safety and toxicology. Third edition, 2012. (2) NLT AdenoSphere 2.0 MSDS, BioSpectrum, Inc.

INCI name	COLLAGEN
Restriction	None
General description	A fibrous protein comprising one third of the total protein in mammalian organisms. Approved by US FDA to be added directly to food - approved either as a food additive or listed or affirmed as GRAS (EAFUS list of ingredients). Hydrolyzed Collagen was practically nontoxic in acute oral and dermal animal toxicity studies, and minimally irritating to rabbit eyes and skin when tested full-strength. Subchronic dermal studies on 2 cosmetic formulations containing 2 percent of compound were negative for systemic toxicity. It was nonsensitizing in guinea pigs. It produced no skin irritation, sensitization, or indication of phototoxicity in clinical studies.
Acute toxicity via relevant routes of exposure	LD50 Rat >3750 mg/kg
Skin irritation and skin corrosivity	nonsensitizing in guinea pigs. It produced no skin irritation, sensitization, or indication of phototoxicity in clinical studies.
Mucous membrane irritation (eye irritation)	Not available
Skin Sensitization	nonsensitizing in guinea pigs. It produced no skin irritation, sensitization, or indication of phototoxicity in clinical studies.
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available



Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) CIR Expert Panel. Final report on the safety assessment of hydrolyzed collagen. JICT 4(5), 1985.

INCI name	CAMELLIA SINENSIS LEAF EXTRACT
Restriction	None
General description	Camellia sinensis leaf extract is an extract of the leaves of the Tea, Camellia sinensis, Theaceae. A beverage and the topical application of this extract are not expected to cause adverse effect. The US FDA considers Camellia sinensis to be GRAS for use as a food additive. The safety of camellia sinensis leaf extract has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetic products when formulated to be non-sensitizing. The use of the leaf ingredients in beverages results in larger oral exposures than those from cosmetic uses. Therefore, this safety assessment did not focus on systemic toxicity potential.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat) > 2000 mg/kg
Skin irritation and skin corrosivity	Camellia sinensis leaf extracts, that contained 10% dry green or black tea, were not dermally irritating to rabbits. Camellia sinensis leaf extract was not irritating in HIRPT conducted on cosmetic products. Camellia sinensis catechins were not irritating to rabbits with intact skin with a content of 93.4% EGCG.
Mucous membrane irritation (eye irritation)	Slightly irritating (rabbit), not irritating (HRIPT).
Skin Sensitization	Camellia sinensis catechins were sensitizing to guinea pigs at 0.1% and 5%.
Dermal/ percutaneous absorption	Catechins from camellia sinensis leaf extract penetrated pig ear skin as did caffeine in in vitro studies.
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not genotoxic in Ames tests.
Carcinogenicity	Camellia sinensis extract was not cytotoxic to rat pheochromocytoma cells up to 100 µg/mL but induced apoptosis to neonatal human dermal fibroblasts at 400 and 800 µmol/l. Camellia sinensis extract at 500 mg/kg/d was not carcinogenic to p53 mice after 26 weeks.



Reproduction toxicity	In a two-generation study, camellia sinensis catechins up to 3600 ppm in feed caused no clinical signs and no effects to embryo/fetal survival, fetal weights, or sex ratios. The offspring of the 12000 ppm group had decreased growth rates, and there was an increase in pup loss. While there were some decreased organ weights, histological examination revealed no abnormalities. The NOAEL was 200 mg/kg/d EGCG (epigallocatechin gallate, that is the most abundant type of catechin in green tea).
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) CIR Expert Panel. Safety Assessment of Camellia sinensis-Derived Ingredients as Used in Cosmetics. Final Report. October 15, 2014. (2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

INCI name	PROPANEDIOL
Restriction	None
General description	This ingredient appears to be of very low toxicity following acute or sub-chronic oral administration, with a NOAEL of 1000 mg/kg bw/day from the 13-week study and a LOAEL for marginal fetal effects (retarded ossification) of 250 mg/kg bw/day.
Acute toxicity via relevant routes of exposure	Of low toxicity following oral administration. Oral LD50 (mouse): 4773 mg/kg; Oral LD50 (rat): 10 g/kg
Skin irritation and skin corrosivity	Not available
Mucous membrane irritation (eye irritation)	Not available
Skin Sensitization	Not available
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	There was no evidence of any systemic toxicity from administration of 1,3-propanediol up to 1000 mg/kg bw/day for 13 weeks. The NOAEL of 1000 mg/kg bw/day (highest dose tested) was derived from this study.
Mutagenicity/ genotoxicity	Negative in a test for gene mutations in bacteria and negative in a test for gene mutation in cultured mammalian Chinese hamster V79 cells in vitro. It did however show a clastogenic effect in a test for chromosome aberrations in Chinese hamster V79 cells in vitro, at the highest dose tested, in the





	absence but not in the presence of metabolic activation. When tested in vivo in a mouse micronucleus test, 1,3-propanediol was negative.
Carcinogenicity	Not available
Reproduction toxicity	A conventional developmental toxicity study was conducted in the rat using dose of 0, 250 and 1000 mg/kg bw/day. The LOAEL determined was 250 mg/kg bw/day for marginal fetal effects (retarded ossification).
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) EC SCF. Updated opinion of the Scientific Committee on Food on the potential risk to human health arising from the transport in ships' tanks of oils and fats from substances proposed as acceptable previous cargoes. SCF/CS/CNTM/CARGO/16 Final. 4 April 2003. Accessed August 2015 at <a href="http://ec.europa.eu/food/fs/sc/scf/out189_en.pdf">http://ec.europa.eu/food/fs/sc/scf/out189_en.pdf</a> (2) ECHA Information on Chemicals. REACH Registered Substance CAS 504-63-2. Joint Submission. First published 03 Mar 2011, Last modified 09 Feb 2015. Accessed August 2015 at <a href="http://echa.europa.eu/information-on-chemicals/registered-substances">http://echa.europa.eu/information-on-chemicals/registered-substances</a> (NOAEL: Exp Key Repeated dose toxicity: oral.001 = Gingell et al. Subchronic toxicity study of 1,3-propanediol administered orally to rats. Int. J. Toxicology, 19:27-32, 2000.)

INCI name	GLCYRRHIZA GLABRA ROOT EXTRACT
Restriction	None
General description	The US FDA lists licorice (the dried and ground rhizome and root portions of Glycyrrhiza glabra) as a GRAS direct food substance. It is widely used in flavouring foods. The safety of licorice-derived ingredients including Glycyrrhiza Glabra Root Extract has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics at concentrations up to 0.4%.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 20000 mg/kg
Skin irritation and skin corrosivity	Not irritating (animal, human)
Mucous membrane irritation (eye irritation)	Not irritating (animal)





Skin Sensitization	Not sensitizing (animal, human)
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not a reproductive toxicant at oral doses up to 2 g/kg/day in rats.
Toxicokinetics (ADME studies)	Chemical constituents of this ingredient vary in their dermal penetration and intestinal absorption, but once absorbed are metabolized and widely distributed.
Phototoxicity / Photosensitization	Not photosensitizing (animal, human)
Nanomaterials	Not applicable
Reference	(1) CIR Expert Panel. Final Report on the Safety Assessment of Glycyrrhiza Glabra (Licorice) Rhizome/root, Glycyrrhiza Glabra (Licorice) Leaf Extract, Glycyrrhiza Glabra (Licorice) Root, Glycyrrhiza Glabra (Licorice) Root Extract, Glycyrrhiza Glabra (Licorice) Root Juice, Glycyrrhiza Glabra (Licorice) Root Powder, Glycyrrhiza Glabra (Licorice) Root Water, Glycyrrhiza Inflata Root Extract, and Glycyrrhiza Uralensis (Licorice) Root Extract. September 23, 2008. (2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

INCI name	PANAX GINSENG ROOT EXTRACT
Restriction	None
General description	Panax Ginseng Root Extract is an extract of the roots of the Ginseng, Panax ginseng, Araliaceae. The safety of Panax Ginseng Root Extract has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics at concentrations up to 0.5%.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 2000 mg/kg. Ginseng root extract had an i.p. LD50 637 mg/kg.
Skin irritation and skin corrosivity	Not irritating to mice up to 0.1% or humans up to 100 mg/ml
Mucous membrane irritation (eye irritation)	Not available
Skin Sensitization	Not sensitizing (up to 1% in formulation, HRIPT)
Dermal/ percutaneous absorption	Not available



Repeated dose toxicity (normally 28- or 90-day studies)	Oral administration of panax ginseng root extract was nontoxic to rats up to 5000 mg/kg/d for up to 105 weeks, up to 5000 mg/kg for life for mice, and 15 mg/kg/d for 90 days for dogs.
Mutagenicity/ genotoxicity	Not mutagenic in Ames tests.
Carcinogenicity	Not carcinogenic to rats or mice up to 5000 mg/kg for 105 weeks. Panax ginseng root extract suppressed TPA-induced skin tumor promotion in mice. Antitumor effects have not been established in humans.
Reproduction toxicity	There were no adverse effects reported in an oral reproductive study at 15 mg/kg/day or a developmental study up to 20 mg/kg/day panax ginseng root extract using rats.
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Panax ginseng root extract was not phototoxic in <i>C. albicans</i> assays up to 100%. Panax ginseng root extract was not phototoxic to mice when administered dermally up to 0.2 mg/cm <sup>2</sup> , intraperitoneally at 25 mg/kg, or orally up to 2.25%.
Nanomaterials	Not applicable
Reference	(1) CIR Expert Panel. Final Report for public distribution, Safety Assessment of Panax spp. Root-Derived Ingredients as Used in Cosmetics. October 5, 2012. (2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

INCI name	ALCOHOL
Restriction	None
General description	CIR Expert Panel evaluated the safety of Alcohol in cosmetic products and concluded that it is safe in the present practices of use and concentration.
Acute toxicity via relevant routes of exposure	Low order of acute toxicity by all routes of exposure. Oral LD <sub>50</sub> (rat): 7060 and 10600 mg/kg; (mouse): 3450 mg/kg; (rabbit): 6300 mg/kg.
Skin irritation and skin corrosivity	Not irritating
Mucous membrane irritation (eye irritation)	Moderate eye irritant
Skin Sensitization	Not sensitizing
Dermal/ percutaneous absorption	No data



Repeated dose toxicity (normally 28- or 90-day studies)	For repeat dose effects, the lowest reported NOAEL is approximately 2400 mg/kg bw/day from a dietary study with rats.
Mutagenicity/ genotoxicity	Not genotoxic
Carcinogenicity	Epidemiological studies assessing the impact of alcoholic beverage consumption show no hazard.
Reproduction toxicity	No data
Toxicokinetics (ADME studies)	Readily absorbed by the oral and inhalation routes and subsequently, metabolized and excreted in humans. Not accumulated in the body. Dermal uptake of ethanol is very low.
Phototoxicity / Photosensitization	No data
Nanomaterials	Not applicable
Reference	(1) OECD. SIDS Initial Assessment Report, Ethanol. 2004. Retrieved from <a href="http://www.inchem.org/">http://www.inchem.org/</a> (2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

INCI name	GOLD
Restriction	IV/133
General description	Gold is a metallic element. This ingredient is not listed as an approved colorant by the US FDA. To identify the colorant allowed for use in the European Union (EU), the INCI Name CI 77480 will be used except when used in hair dye products.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 5,000 mg/kg body weight.
Skin irritation and skin corrosivity	Not available
Mucous membrane irritation (eye irritation)	Not available
Skin Sensitization	Several studies have reported debut of gold allergy as determined by positive patch test after colloidal gold treatment.
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	In vitro studies indicate that gold nanoparticles induce DNA damage in mammalian cells. In vivo, gold nanoparticles induce genotoxic effects in <i>Drosophila melanogaster</i> ; however, genotoxicity studies in mammals are lacking.
Carcinogenicity	Not available
Reproduction toxicity	Not available



Toxicokinetics (ADME studies)	Elemental gold, or the released ions, is, to some extent, absorbed in the gastrointestinal tract. Gold is distributed to organs such as the liver, heart, kidneys and lungs. The main excretion route of absorbed gold is through urine.
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not available
Reference	(1) Hadrup et al. Toxicological risk assessment of elemental gold following oral exposure to sheets and nanoparticles - A review. Regul Toxicol Pharmacol. 2015 Apr 27;72(2):216-221. (2) PubChem; Stejskal J, Stejskal V; Neuroendocrinology Letters 20: 351-364 (1999) (3) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

INCI name	MINERAL SALTS
Restriction	None
General description	Mixture of inorganic salts derived from mineral water. Human skin is the largest organ of the integumentary system and is made up of multiple layers of ectodermal tissue. It is a dynamic organ containing complex biological processes. Our skin interfaces with the environment, where it serves as a barrier that protects the body against pathogens, foreign bodies, water loss, solar radiation and has a key role in temperature regulation, sensation and vitamin D production. The skin is dependent on the systemic circulatory system to supply it with nutrients and thus reflects systemic nutritional deficiencies. For individuals with adequate nutritional status, the question remains: what value does topical supplementation provide to overall skin health? The cosmetic industry has demonstrated the benefits for topical supplementation of the skin with vitamins such as vitamin A, vitamin C, vitamin E and nicotinamide as well as numerous other natural antioxidants. However, evidences supporting the benefits of minerals have been limited to several such as ZnO, TiO <sub>2</sub> and Se (anti-fungal



	agent). Although there is much work published on Mg-rich Dead Sea salts, Cu and Se, additional rigorous, hypothesis-driven clinical studies are necessary.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: above 2,000 mg/kg body weight.
Skin irritation and skin corrosivity	Not expected to cause irritation
Mucous membrane irritation (eye irritation)	Not expected to cause irritation
Skin Sensitization	Not expected to cause irritation
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	
Reference	(1) Polefka, T.G., Bianchini, R.J. and Shapiro, S. (2012), Interaction of mineral salts with the skin: a literature survey. Int J Cosmet Sci, 34: 416-423. <a href="https://doi.org/10.1111/j.1468-2494.2012.00731.x">https://doi.org/10.1111/j.1468-2494.2012.00731.x</a>

#### Perfume compliance to IFRA regulations:

This product contains fragrances from natural oils/extracts (IFRA not provided).



## 9. UNDESIRABLE EFFECTS AND SERIOUS UNDESIRABLE EFFECTS

The product is available on the market, no undesirable effects have been reported till now. Rarely, reports of skin and eye irritation may be received on this type of product.

## 10. INFORMATION ON THE COSMETIC PRODUCT

- The product has not been tested on animals
- The products does not contain CMR, nanoparticles...
- Additional testing: /



## PART B - COSMETIC PRODUCT SAFETY ASSESSMENT

### 1. ASSESSMENT CONCLUSION

The cosmetic product ANTI-WRINKLE ROCK SALT GOLD EYE CREAM can be assessed as **SAFE** for normal and reasonably foreseeable use in accordance with the European Cosmetics Regulation (EC) No 1223/2009 and SCHEDULE 34 (as amended) respectively.

### 2. LABELLED WARNINGS AND INSTRUCTIONS FOR USE

The following instructions for use and warnings are written on both, primary and secondary packaging:

Instructions for use written on the label	Take an appropriate amount of this product and spread it around your eyes and pat it until it absorbs into your skin.
Precautions for use written on the label	When using or after using cosmetics, the area of use has abnormal symptoms or side effects such as red spots, swelling due to direct sunlight- stop using.

The labelled instructions for use and the general description of the product indicate the explicit use of the finished product as a leave on eye cream intended for daily use. A reasonably foreseeable mistaken use additional to this use (not a misuse) is not recognisable

### 3. REASONING

#### a. SAFETY EVALUATION OF SUBSTANCES AND/OR MIXTURES

The margin of safety, which takes into account all systemic toxicity endpoints, has been calculated for each of the ingredient used in this cosmetic product. All ingredients (where the NOAEL value was available) have a sufficiently large MoS (>100), which is supporting the safety of the finished product. Specific exposure consideration for the targeted consumer group (adults) has been taken into account as documented in the exposure and MoS calculation.

#### b. SAFETY EVALUATION OF COSMETIC PRODUCT

##### Stability data

The stability data (microbiological and physical-chemical stability) of the formula after storage meet the previously specified characteristics. They confirm a sufficient stability of the formula. The shelf life for the final product is 36 months. Based on the above mentioned the product is rated as safe.



## Packaging

The package consists of a 40ml HDPE tube. The packaging of the product is made to protect the product during shelf life and use and to enable the safe use of the product. No interaction with packaging material is expected as the packaging compatibility with the formulation was confirmed during its stability test. Based on that the packaging is rated to be suitable and safe for this specific product type. This package does not contain hazardous materials that require special markings or labelling on the shippers.

## Normal and reasonably foreseeable use

A reasonably foreseeable mistaken use (not a misuse), is not recognizable.

## Undesirable effects and serious undesirable effects

From the market launch until today the complaint statistics as documented in the Consumer Response System (CRS) of the manufacturer of this product show no remarkable consumer complaints regarding undesirable effects or serious undesirable effects in general.

## Information on the cosmetic product

The product is a leave on eye contour cream intended to be used by adults on daily basis.

The packaging of cosmetic product should include the following information in indelible, easily legible and visible lettering:

- Brand name
- Name of the product
- Function of the cosmetic product (unless it is clear from its presentation)
- Ingredients list (ingredients present **in more than 1%** in the end product should follow in the same order as here): **AQUA, PROPYLENE GLYCOL, BUTYROSPERMUM PARKII BUTTER, GLYCERIN, DIMETHICONE, CETEARYL ALCOHOL, GLYCERYL STEARATE, BEESWAX, BETAINE, PHENOXYETHANOL, METHYLPARABEN, PROPYLPARABEN, ALLANTOIN, ADENOSINE, COLLAGEN, PROPANEDIOL, SODIUM HYALURONATE, MINERAL SALTS, ALCOHOL, GLYCYRRHIZA GLABRA ROOT EXTRACT, GOLD, CAMELLIA SINENSIS LEAF EXTRACT, PANAX GINSENG ROOT EXTRACT**
- Particular precautions for use: When using or after using cosmetics, the area of use has abnormal symptoms or side effects such as red spots, swelling due to direct sunlight- stop using.
- Instructions for use: Take an appropriate amount of this product and spread it around your eyes and pat it until it absorbs into your skin.
- Date of minimum durability (for products with a minimum durability  $\leq 30$  months) or PAO (for products with a minimum durability  $> 30$  months)





- Nominal quantity (except for packaging containing less than 5 grams or 5 millilitres, free samples and single-application packs)
- Batch number or the reference for identifying the cosmetic product
- Responsible person name and address
- Manufacturer name and address
- Products' country of origin



## SUMMARY

The safety assessment is based on the chemical specification and toxicological profile of the ingredients as supplied at the time of assessment and an assessment of the final cosmetic product.

All statements in this safety assessment were elaborated on the recent level of knowledge. Every change in the formulation or changes and/or additional information of relevant data respectively will require an immediate re-evaluation of this safety assessment.

Concerning the skin tolerance, the final product is expected to be well tolerated and to have a good cosmetic acceptability.

Safety assessor: Tanja Židan, MPharm

Signature:



We confirm that the product is safe in the stated application when used under normal and reasonably foreseeable use. Its composition complies with EC Regulation 1223/2009, SCHEDULE 34 and all its annexes.