

COSMETIC PRODUCT SAFETY REPORT

According to EC Regulation 1223/2009 and SCHEDULE 34

ROCK SALT MINERAL GOLD MASK PACK

ISSUE DATE: July 4, 2023

SAFETY ASSESSMENT REFERENCE NO.: L7130

VERSION: I

SAFETY ASSESSOR

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PART A - COSMETIC PRODUCT SAFETY INFORMATION

Product name	ROCK SALT MINERAL GOLD MASK PACK
Shade names	/
Product type	Face care product
Formula number	/
Category of the product	Facial sheet mask
Physical form of the product	Liquid
Target population	Adults
Primary site of application	Face area
Packaging type and size	110g PE plastic sachet
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/ELINCS	% active in the raw material	Concentration in the final product	Function
AQUA	7732-18-5	231-791-2	100	78,6589	Solvent
GLYCERIN	56-81-5	200-289-5	100	15,0000	Denaturant, Hair Conditioning, Humectant, Masking, Oral Care, Perfuming, Skin Protecting, Viscosity Controlling
NIACINAMIDE	98-92-0	202-713-4	100	2,0000	SMOOTHING
SODIUM HYALURONATE	9067-32-7	Not available	1	1,0000	HUMECTANT, SKIN CONDITIONING
AQUA	7732-18-5	231-791-2	99		Solvent
CAMELLIA SINENSIS LEAF EXTRACT	84650-60-2	283-519-7	10	0,5000	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	90		SOLVENT, VISCOSITY CONTROLLING
GLYCYRRHIZA GLABRA ROOT EXTRACT	84775-66-6	283-895-2	10	0,5000	BLEACHING, EMOLLIENT, PERFUMING, SKIN CONDITIONING, SMOOTHING, SOOTHING
AQUA	7732-18-5	231-791-2	90		Solvent
ARONIA MELANOCARPA FRUIT EXTRACT	Not available	Not available	2	0,5000	SKIN CONDITIONING



GLYCERIN	56-81-5	200-289-5	98		Denaturant, Hair Conditioning, Humectant, Masking, Oral Care, Perfuming, Skin Protecting, Viscosity Controlling
SODIUM BENZOATE	532-32-1	208-534-8	0,4		ANTICORROSIVE, MASKING, PRESERVATIVE
POTASSIUM SORBATE	24634-61-5 / 590-00-1	246-376-1 / -	0,4		PRESERVATIVE
BENZYL ALCOHOL	100-51-6	202-859-9	0,5		Perfuming, Preservative Solvent, Viscosity Controlling
DEHYDROACETIC ACID	520-45-6 / 771-03-9 / 16807-48-0	208-293-9 / 212-227-4 / -	0,04		PRESERVATIVE
ALCOHOL	64-17-5	200-578-6	100	0,5000	ANTIFOAMING, ANTIMICROBIAL, ASTRINGENT, MASKING, SOLVENT, VISCOSITY CONTROLLING
PANTHENOL	81-13-0 / 16485-10-2	201-327-3 / 240-540-6	100	0,3000	ANTISTATIC, HAIR CONDITIONING, SKIN CONDITIONING
POLYSORBATE 80	9005-65-6	500-019-9	100	0,3000	DENATURANT, EMULSIFYING, SURFACTANT
PHENOXYETHANOL	122-99-6	204-589-7	100	0,2000	PRESERVATIVE
METHYLPARABEN	99-76-3	202-785-7	100	0,1500	PRESERVATIVE
ALLANTOIN	97-59-6	202-592-8	100	0,1000	Skin Conditioning, Skin Protecting, Soothing
TRIETHANOLAMINE	102-71-6	203-049-8	100	0,1000	BUFFERING, EMULSIFYING, MASKING, SURFACTANT
CARBOMER	9007-20-9 / 9003-01-4 / 76050-42-5 / 9062-04-8 / 9007-16-3 / 9007-17-4	Not available	100	0,1000	EMULSION STABILISING, GEL FORMING, VISCOSITY CONTROLLING
ADENOSINE	58-61-7	200-389-9	100	0,0400	SKIN CONDITIONING
PARFUM	NA	NA	100	0,0200	DEODORANT, MASKING, PERFUMING
TOCOPHERYL ACETATE	7695-91-2 / 58-95-7	231-710-0 / 200-405-4	100	0,0100	ANTIOXIDANT, SKIN CONDITIONING
DISODIUM EDTA	139-33-3 / 6381-92-6	205-358-3	100	0,0100	CHELATING, VISCOSITY CONTROLLING



COLLAGEN	9007-34-5	232-697-4	100	0,0100	HAIR CONDITIONING, MOISTURISING, SKIN CONDITIONING
GOLD	7440-57-5	231-165-9	100	0,0001	COSMETIC COLORANT
MINERAL SALTS	Not available	Not available	100	0,0010	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
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
NIACINAMIDE	3-Pyridinecarboxamide	Crystalline powder	122.14	Soluble in water and organic solvents	log POW = 0.37	UV radiation absorption tail in the UVB region, with the peak absorption at 262 nm.
ALCOHOL	Ethanol	Liquid	46.07	Soluble	log POW = -0.31	Not applicable
PROPANEDIOL	1,3-dihydroxypropane	Liquid	76.09	Freely soluble in water	Not available	Not applicable
PANTHENOL	Butanamide, 2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethyl-, (2R)-; dl-Panthenol	Liquid	205.25	Freely soluble in water and alcohol	log POW = -1.06 at 22 °C	Not applicable
POLYSORBATE 80	Sorbitan, mono-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivs., (Z)-	Liquid	1309.7	Soluble in water	Not available	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
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)
TRIETHANOLAMINE	2,2',2''-Nitrilotriethanol	Liquid	149.19	Miscible in water	log POW = -1.59 at 20 °C	Not applicable
CARBOMER	Not available	Liquid	Not available	Not available	Not available	Not applicable
CAMELLIA SINENSIS LEAF EXTRACT	Not applicable	Liquid	Not available	Not available	Not available	Not applicable
GLYCYRRHIZA GLABRA ROOT EXTRACT	Not applicable	Liquid	Not available	Fully miscible in water	Not available	Not applicable
ADENOSINE	6-Amino-9-beta-D-ribofuranosyl-9H-purine	White liquid	267.245 g/mol	Dispersible	Not available	Not available
PARFUM	Not applicable	Liquid	Not applicable	Not available	Not available	Not applicable



SODIUM HYALURONATE	Hyaluronic acid, sodium, salt	Powder	403.31 g/mol	Soluble	Not available	Not available
ARONIA MELANOCARPA FRUIT EXTRACT	Not available	Powder	Not available	Soluble	Not available	Not available
TOCOPHERYL ACETATE	3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-benzopyran-6-yl acetate	Powder	472.7	Insoluble in water	log POW = 12 (estimated)	Tocopheryl acetate absorbs in the UVB range. Absorption maxima are 284 nm (in ethanol) and 285.5 nm (in cyclohexane).
DISODIUM EDTA	Disodium dihydrogen ethylenediaminetetracetate	Solid (crystalline)	336.21	108 g/l at 20 °C (soluble in water); insoluble in organic solvents	log POW = -4.3 at 25 °C	Not applicable
COLLAGEN	Not available	Liquid	Not available	Practically insoluble in water, but lowering the pH of solution can increase solubility	Not available	Not applicable
BENZYL ALCOHOL	Benzyl alcohol	Liquid	108.14	Very soluble in water as 1 g is dissolved in 25 mL water at 25 °C.	log POW = 1.1 at 20 °C	Not applicable
SODIUM BENZOATE	Sodium benzoate	Solid	144.11	556 g/l at 20 °C (soluble in water), hygroscopic	log POW = -2.269	Not applicable
POTASSIUM SORBATE	Potassium (E,E)-hexa-2,4-dienoate	Crystalline powder	150.22	543 g/l at 20 °C (water solubility)	log POW = 1.32 at 20 °C and pH 2.5	Not applicable
MINERAL SALTS	Not available	Solid	Not available	Not available	Not available	Not available
DEHYDROACETIC ACID	3-Acetyl-6-methyl-2H-pyran-2,4(3H)-dione	Powder	168.16	< 1 g/l at 25 °C	Not available	Not applicable
GOLD	Not available	Liquid	196.97	Not available	Not available	Not applicable



b. PHYSICAL/CHEMICAL CHARACTERISTICS OF THE FINISHED COSMETIC PRODUCT

ANALYSIS	SPECIFICATIONS	MAT./METH
ASPECT	GOLD IN LIQUID	VISUAL
COLOR	PALE WHITE	VISUAL
ODOR	FRESH FLOWERLY	OLFACTIVE
VISCOSITY(CPS)25°C	1,000-3,000	BROOFIELD LVDVE spindle No.4
STABILITY	STABLE	3 DAY IN 40°C
DENSITY	0.99+/- 0.05	PAAR
CAPACITY	22ML	
pH	6.0+/- 0.50	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	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid	Liquid
COLOUR	Yellowish translucent	Yellowish translucent	Yellowish translucent	Yellowish translucent	Yellowish translucent	Yellowish translucent	Yellowish translucent	Yellowish translucent	Yellowish translucent
ODOUR	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic	Characteristic
PH (at 22 °C)	5,11	5,41	5,62	5,48	5,12	5,29	5,38	5,40	5,19
PHASE SEPARATION	0,98	0,98	0,97	0,96	0,96	0,97	0,97	0,98	0,98

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 ^a	$\leq 1 \times 10^3$ CFU per g or ml ^b
<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 a > 200 CFU/g or ml, b > 2 000 CFU/g or ml. 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 2, 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 110g PE plastic sachet. 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 mask intended to be used by adults on daily basis.

Instructions for use written on the label	Clean your face and apply the mask pack evenly to entire face, starting with the eyes and nose of your face. After taking a break for about 15 to 20 minutes, remove the mask and gently tap the remaining contents to the skin to absorb it.
Precautions for use written on the label	Consult a specialist when using cosmetics or if there are abnormal symptoms or side effects such as red spots, swelling or itching due to direct sunlight. Refrain from using it in areas with wound, eczema, dermatitis, etc. Avoid using around eyes.

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:	Face Cream
Targeted Population:	Adults
Estimated daily amount applied (g):	1,54*
Skin Surface Area of Application/cm ² :	565*
Calculated daily exposure (g/day)	1,54*
Calculated relative daily exposure (mg/kg bw/day):	24,14*
Amount Per Unit Area of Skin per day mg/cm ² /day:	2,73
Exposure time:	12h
Frequency of application:	2,14*
Part of the body exposed:	1/2 area head*

* SCCS, face cream



7. EXPOSURE TO THE SUBSTANCES

INCI	Retention factor	POD	SED	MoS
AQUA	1	Not available	20,5333	/
GLYCERIN	1	2000	3,9758	503,0476302
NIACINAMIDE	1	215	0,5133	418,8311688
ALCOHOL	1	2400	0,1283	18701,2987
PROPANEDIOL	1	1000	0,1155	8658,008658
PANTHENOL	1	200	0,0770	2597,402597
POLYSORBATE 80	1	1000	0,0770	12987,01299
PHENOXYETHANOL	1	80	0,0513	1558,441558
METHYLPARABEN	1	1000	0,0385	25974,02597
ALLANTOIN	1	Not available	0,0257	/
TRIETHANOLAMINE	1	80	0,0257	3116,883117
CARBOMER	1	Not available	0,0257	/
CAMELLIA SINENSIS LEAF EXTRACT	1	Not available	0,0128	/
GLYCYRRHIZA GLABRA ROOT EXTRACT	1	Not available	0,0128	/
ADENOSINE	1	Not available	0,0103	/
PARFUM	1	Not available	0,0051	/
SODIUM HYALURONATE	1	Not available	0,0026	/
ARONIA MELANOCARPA FRUIT EXTRACT	1	Not available	0,0026	/
TOCOPHERYL ACETATE	1	360	0,0026	140259,7403
DISODIUM EDTA	1	692	0,0026	269610,3896
COLLAGEN	1	Not available	0,0026	/
BENZYL ALCOHOL	1	200	0,0006	311688,3117
SODIUM BENZOATE	1	500	0,0005	974025,974
POTASSIUM SORBATE	1	1000	0,0005	1948051,948
MINERAL SALTS	1	Not available	0,0003	/
DEHYDROACETIC ACID	1	100	0,0001	1948051,948
GOLD	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:

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



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

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	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 ≥ 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 ³ 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 http://echa.europa.eu/information-on-chemicals/registered-substances

INCI name	NIACINAMIDE
Restriction	None
General description	The safety of niacinamide 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 3%.
Acute toxicity via relevant routes of exposure	Non-toxic in acute studies.
Skin irritation and skin corrosivity	Not irritating (up to 5%, human)
Mucous membrane irritation (eye irritation)	Niacinamide, evaluated in an in vitro test to predict ocular irritation, was not an acute ocular hazard. Animal testing of niacinamide in rabbits in actual formulations produced mostly non-irritant reactions, with only some marginally irritating responses.



Skin Sensitization	Not sensitizing (up to 10%, human)
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Short-term oral, parenteral, or dermal toxicity studies did not identify significant irreversible effects. The NOAEL value of 215 mg/kg bw was reported based on a 28-day oral toxicity study in rats. Study was conducted according to EU Method B.7 and OECD Guideline 407.
Mutagenicity/ genotoxicity	Not mutagenic in Ames tests; negative in chromosome aberration test in CHO cells at 2 mg/ml, but did produce large structural chromosome aberrations at 3mg/ml. It induced sister chromatid exchanges in Chinese hamster ovary cells.
Carcinogenicity	It was not carcinogenic when administered (1%) in the drinking water of mice. Niacinamide can moderate the induction of tumors by established carcinogens.
Reproduction toxicity	Niacinamide evaluated in in vitro test systems did affect development, but it reduced the reproductive/developmental toxicity of 2-aminonicotinamide-amino-1,3,4-thiadiazole hydrochloride and urethane.
Toxicokinetics (ADME studies)	Readily absorbed from the skin, blood, and the intestines and widely distributed throughout the body. Excretion is primarily through the urinary tract.
Phototoxicity / Photosensitization	Not photosensitizing
Nanomaterials	Not applicable
Reference	(1) ECHA Information on Chemicals. REACH Registered Substance CAS 98-92-0. Joint Submission. First published 17 May 2013, Last modified 12 Sep 2014. Accessed August 2015 at http://echa.europa.eu/information-on-chemicals/registered-substances (NOAEL: Exp Key Repeated dose toxicity: oral.001) (2) CIR Expert Panel. Final Report on the Safety assessment of niacinamide and niacin. IJT 24(Suppl 5):1-31, 2005.

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.

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 http://ec.europa.eu/food/fs/sc/scf/out189_en.pdf (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 http://echa.europa.eu/information-on-chemicals/registered-substances (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	GLYCYRRHIZA GLABRA ROOT EXTRACT
Restriction	None
General description	The US FDA lists licorice (the dried and ground rhizome and root portions of <i>Glycyrrhiza glabra</i>) as a GRAS direct food substance. It is widely used in flavouring foods. The safety of licorice-derived ingredients including <i>Glycyrrhiza Glabra</i> 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 <i>Glycyrrhiza Glabra</i> (Licorice) Rhizome/root, <i>Glycyrrhiza Glabra</i> (Licorice) Leaf Extract, <i>Glycyrrhiza Glabra</i> (Licorice) Root, <i>Glycyrrhiza Glabra</i> (Licorice) Root Extract, <i>Glycyrrhiza Glabra</i> (Licorice) Root Juice, <i>Glycyrrhiza Glabra</i> (Licorice) Root Powder, <i>Glycyrrhiza Glabra</i> (Licorice) Root Water, <i>Glycyrrhiza Inflata</i> Root Extract, and <i>Glycyrrhiza Uralensis</i> (Licorice) Root Extract. September 23, 2008. (2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.



INCI name	ARONIA MELANOCARPA FRUIT EXTRACT
Restriction	None
General description	<p>Aronia Melanocarpa Fruit Extract is the extract of the fruit of Aronia melanocarpa, Rosaceae. Aronia berry is "extremely rich" in antioxidants and has higher concentrations of this phytochemical than any other red or blue berry. It has one of the highest free radicalscavenging scores. Also known as black chokeberry, aronia berries have an ORAC value of more than 7,300 micromoles per gram. The United States Department ofAgricultures says the ORAC values for one granny smith apple is 5,381 and a one cupserving of blueberry would have a value of 13,427. The aronia plant, which is native to eastern North America and commonly knownas black chokeberry, produces violet-black berries. Aronia also contains high amounts of proanthocyanidins, which have been documented in the past as helping to inhibit the growth of human lung, colon and leukaemia cells in culture, without affecting healthy cells. Antioxidants have the ability to neutralise free radicals that can damage the body's cells. Free radicals and can cause oxidative stress by building up in the body. Oxidative stress is thought to contribute to the ageing process and several diseases.</p>
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 5,000 mg/kg body weight
Skin irritation and skin corrosivity	Nor irritating
Mucous membrane irritation (eye irritation)	Not irritating (Draize test)
Skin Sensitization	Not sensitizing
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Notmutagenic
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.



INCI name	SODIUM BENZOATE
Restriction	V/1
General description	Assessed by SCCP The safety of sodium benzoate 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 1%. Considered GRAS by US FDA.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat) > 2000 mg/kg; Dermal LD50 (rat) > 2000 mg/kg
Skin irritation and skin corrosivity	Not irritating (rabbit)
Mucous membrane irritation (eye irritation)	Mildly irritating (rabbit)
Skin Sensitization	Non-sensitizing in animal test but showed a very low incidence in humans (patients) tested by the patch test. It has been suggested that these positive reactions are a non-immunologic contact urticaria, but the risk of this is very low if the EU annex restrictions are adhered to.
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Low toxic potential in rodents in repeat dose studies.
Mutagenicity/ genotoxicity	Non-genotoxic based on several in vitro and in vivo genotoxicity assays.
Carcinogenicity	Not available
Reproduction toxicity	NOAEL for benzoic acid from a 4-generation reproduction study of 500 mg/kg/day was used by SCCP for the calculation of MoS.
Toxicokinetics (ADME studies)	Rapidly metabolized and excreted within 24hrs.
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) SCCP/0891/05. Opinion on Benzoic Acid and Sodium Benzoate. 21 June 2005.

INCI name	POTASSIUM SORBATE
Restriction	V/4
General description	US FDA reviewed the safety of Potassium Sorbate and determined that it is GRAS as preservative for direct addition to food. The safety of Potassium Sorbate 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 1%.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat): 4920 mg/kg; Oral LD50 (mouse): 3800 mg/kg. Potassium sorbate is not acutely toxic or harmful when applied by the oral, dermal, or inhalative route.



Skin irritation and skin corrosivity	Not irritating (rabbit). However, reversible skin reactions have frequently been reported for humans.
Mucous membrane irritation (eye irritation)	Irritating to eyes (rabbit)
Skin Sensitization	Not sensitizing
Dermal/percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	ANNEX VI DOSSIER – HARMONISATION OF C&L: The limit dose level of 1000 mg/kg bw/d which proved safe in the 90-d study in dogs as well as in the multi-generation studies in rats and which was also exceeded by the NOAEL in the 18-month mouse study, should be used as the starting point for deriving any toxicological limit values for long-term exposure in humans.
Mutagenicity/genotoxicity	Potassium sorbate did not display a genotoxic potential either in vitro or in vivo.
Carcinogenicity	Not considered carcinogenic.
Reproduction toxicity	Not considered toxic to reproduction.
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) PROPOSAL FOR HARMONISED CLASSIFICATION AND LABELLING - potassium sorbate. Submitted by Germany, November 2011. Accessed August 2015 at http://echa.europa.eu/documents/10162/13626/clh_potassium_sorbate_en.pdf (2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

INCI name	BENZYL ALCOHOL
Restriction	III/45 V/34
General description	An US FDA-approved diluent in color additive mixtures for external drug use and US FDA-approved anesthetic ingredient in OTC drugs. Evidence is provided for the safe use of benzyl alcohol and the read across substances, since they have been used for decades in pharmaceuticals, cosmetics and/or food as preservatives and flavoring/fragrance agents. In terms of Regulation (EC) No 1272/2008 (CLP)



	benzyl alcohol is classified as Acute Tox. 4. IFRA restricted. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics at concentrations up to 10%.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat): 1610 mg/kg; Oral LD50 (mouse): 1580 mg/kg; Dermal LD50 (rabbit): 2000 mg/kg
Skin irritation and skin corrosivity	Slightly irritating (undiluted)
Mucous membrane irritation (eye irritation)	Irritating (4% aq., rabbit).
Skin Sensitization	Both positive and negative results in animal studies. A maximum skin sensitization incidence of 1% was reported for benzyl alcohol in human patch tests. Occupational exposure to benzyl alcohol has not resulted in skin sensitization over a period of decades.
Dermal/ percutaneous absorption	It is lipophilic and therefore has the potential to be readily absorbed through skin. The percutaneous absorption through human skin (in vitro test) was <80% in 24 hours, and through occluded skin of rhesus monkeys (in vivo test) was 56-80% in 24 hours. No correlation was seen between skin penetration and the octanol-water partition coefficient.
Repeated dose toxicity (normally 28- or 90-day studies)	For benzyl alcohol the long-term studies indicate a NOAEL > 400 mg/kg bw/d for rats and > 200 mg/kg bw/d for mice. At higher doses effects on bodyweights, lesions in the brains, thymus, skeletal muscle and kidney were observed.
Mutagenicity/ genotoxicity	No mutagenic activity in in vitro Ames tests. No genotoxicity in vivo. While some mixed and/or equivocal in vitro chromosomal/chromatid responses have been observed, no genotoxicity was observed in the in vivo cytogenetic, micronucleus, or other assays. The weight of evidence of the in vitro and in vivo genotoxicity data indicates that this chemical is not mutagenic or clastogenic.
Carcinogenicity	Not carcinogenic in long-term carcinogenicity studies.
Reproduction toxicity	Not classified as reproductive/developmental toxicant in oral and dermal animal studies.
Toxicokinetics (ADME studies)	Rapidly metabolized to benzoic acid via simple oxidation. Benzoic acid is rapidly absorbed from the gastrointestinal tract of mammals,



	conjugated with glycine in the liver, and then excreted as hippuric acid.
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) OECD. SIDS Initial Assessment Report - Benzoates. November 2001. (NOAEL; also available from ECHA website) (2) CIR Expert Panel. Amended Final Safety Assessment - Benzyl Alcohol, and Benzoic Acid and its Salts and Benzyl Ester. October 17, 2011. (3) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

INCI name	DEHYDROACETIC ACID
Restriction	V/13
General description	The US FDA permits Dehydroacetic Acid to be used as a preservative in food. The safety of Dehydroacetic Acid 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 0.7%.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat): 500 mg/kg; Oral LD50 (mouse): 1330 mg/kg; LDLO (rabbits): 5000 mg/kg; considered to have low acute dermal toxicity.
Skin irritation and skin corrosivity	Not considered to cause skin irritation.
Mucous membrane irritation (eye irritation)	Considered to cause minimal eye irritation.
Skin Sensitization	May have some potential to cause skin sensitisation in humans when absorbed through the broken skin.
Dermal/ percutaneous absorption	Readily absorbed dermally in rabbits. Dermal absorption was high (50 % more) from a washable base medium (composition not stated) compared with from an aqueous solution.
Repeated dose toxicity (normally 28- or 90-day studies)	The short-term repeated dose toxicity studies in rats indicate anticoagulant activity and haemorrhage from doses around 100 mg/kg bw/d. Based on a 34-day oral gavage study in rats, a NOAEL value of 100 mg/kg/day was established.
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Studies indicate no carcinogenic potential.
Reproduction toxicity	Not expected to have developmental toxicity.



Toxicokinetics (ADME studies)	Rapidly absorbed following oral administration in humans, monkeys, rats and dogs. Readily absorbed dermally in rabbits. Three main metabolites: triacetic acid lactone, hydroxy-dehydroacetic acid and 'metabolite X' (presumed to be the salt of triacetic acid lactone 3-carboxylic acid). Rabbits excreted 70–80 % of the 14C label in urine, 7–10 % as exhaled carbon dioxide and 2–3 % in faeces (after 3–7 days) leaving 8–11 % in tissues. Excretion in rats was 20–40 % in urine, 10–25 % by respiration, 10–20 % in faeces (after 4–5 days) and 5–26 % in tissues.
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) NICNAS (2015). Inventory Multi-tiered Assessment and Prioritisation (IMAP): Human health Tier II assessment for dehydroacetic acid and its sodium salt. Accessed June 2015 at http://www.nicnas.gov.au/chemical-information/imap-assessments/imap-group-assessment-report?assessment_id=1141

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 LD50 (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 http://www.inchem.org/ (2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

INCI name	PANTHENOL
Restriction	None
General description	US FDA includes Panthenol on its list of nutrients and/or dietary supplements generally recognized as safe. The safety of Pantheol 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 25%.
Acute toxicity via relevant routes of exposure	Oral LD50 (animal) > 10000 mg/kg
Skin irritation and skin corrosivity	Not irritating (undiluted, rabbit)
Mucous membrane irritation (eye irritation)	Not irritating (undiluted, rabbit)
Skin Sensitization	Not sensitizing (0.5%, human and 5%, guinea pig). A survey of the published dermatological literature indicates clinical reports of allergic contact dermatitis are extremely rare.
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	No toxicological effects were associated with the subchronic and/or chronic oral administration of panthenol to rats. A NOAEL of 200 mg/kg bw/day (highest dose tested) was determined for panthenol based on a 90-day repeated dose oral toxicity study in rats.
Mutagenicity/ genotoxicity	Negative in in vitro genotoxicity studies. It is noted that the level of panthenol ingredient required by humans exceeds the amount that could be absorbed from the low concentrations used in cosmetic products. The human metabolic requirement would preclude the likelihood of genotoxicity.
Carcinogenicity	Not available
Reproduction toxicity	Neither teratogenic nor foetotoxic effects were seen in the offspring when rats were fed calcium pantothenate prior to mating and throughout gestation.
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	No phototoxic or photoallergic potential (guinea pig)



Nanomaterials	Not applicable
Reference	<p>(1) ECHA Information on Chemicals. REACH Registered Substance CAS 81-13-0. Joint Submission. First published 27 Feb 2013, Last modified 18 May 2015. Accessed August 2015 at http://apps.echa.europa.eu/registered/data/dossiers/DISS-d6b1c29b-71b9-6467-e044-00144f67d031/DISS-d6b1c29b-71b9-6467-e044-00144f67d031_DISS-d6b1c29b-71b9-6467-e044-00144f67d031.html (NOAEL: Exp Supporting Repeated dose toxicity: oral.001)</p> <p>(2) CIR Expert Panel. Final report on the safety assessment of panthenol and pantothenic acid. JACT 6(1):139-62, 1987 confirmed 12/04 IJT 25(S2), 2006</p> <p>(3) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.</p>

INCI name	POLYSORBATE 80
Restriction	None
General description	The US FDA permits Polysorbate 80 to be directly added to food as adjuvants of flavoring agents or as multipurpose additives. US FDA also includes Polysorbate 80 on its list of indirect food additives as emulsifiers and/or surface active agents. The safety of Polysorbate 80 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 25%, when formulated to be non-irritating.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat): 38999 mg/kg
Skin irritation and skin corrosivity	Not irritating (undiluted, human)
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)	For polysorbate 80, the highest oral NOAEL for 90 days in dogs was 5 mL/kg/d, and for 4 weeks in rats was 5 mL/kg/d. There were no adverse effects or mortalities related to polysorbate 80 (up to 0.15 g/kg) when administered by gavage to rats for 5 days or in rats orally administered polysorbate 80 (up to 3700 mg/kg/d) for 28 days. The minimum NOAEL of polysorbates is set at 2% (1000 mg/kg bw/day) based on diarrhea observed in the 13-week dietary administration study of polysorbate 60 in rats.



Mutagenicity/ genotoxicity	Not genotoxic to <i>S. typhimurium</i> and <i>E. coli</i> .
Carcinogenicity	Not available
Reproduction toxicity	In a reproductive and developmental study where polysorbate 80 was administered by gavage to rats on gestation days 6-15, the maternal and the developmental NOAELs were reported to be >5000 mg/kg/d.
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) Food Safety Commission. Evaluation Report of Food Additives, Polysorbates (Polysorbates 20, 60, 65 and 80). June 2007. Accessed August 2015 at https://www.fsc.go.jp/english/evaluationreports/foodadditive/polysorbate_report.pdf (2) CIR Expert Panel. Safety Assessment of Polysorbates as Used in Cosmetics. Final Amended Report. July 10, 2015. (3) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

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>
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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 http://echa.europa.eu/information-on-chemicals/registered-substances

INCI name	TRIETHANOLAMINE
Restriction	III/62
General description	The safety of triethanolamine 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 when formulated to be non-irritating; should not be used in cosmetic products in which N-nitroso compounds can be formed.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat): 4190 - 11260 mg/kg; Dermal LD50 (rabbit) > 2000 mg/kg
Skin irritation and skin corrosivity	Irritating (neat triethanolamine). Clinical testing in humans with 1-5% triethanolamine has induced mild skin irritation.
Mucous membrane irritation (eye irritation)	Irritating (neat triethanolamine)



Skin Sensitization	Not sensitizing (neat triethanolamine, guinea pig). Clinical testing in humans with 1-5% triethanolamine has induced in rare cases sensitization.
Dermal/percutaneous absorption	In in vitro study using human skin samples, the absorption of triethanolamine through human skin was low under conditions simulating perceived cosmetic use, that is, 1% to 5% at pH 7.0; approximately 5.5% to 9.5% of the dose was recovered in the skin after 24 to 72 hours; however only 0.5% was recovered in the receptor fluid. In mice, triethanolamine in acetone was rapidly absorbed, and absorption increased with increasing dose. Absorption was greater in mice than in rats.
Repeated dose toxicity (normally 28- or 90-day studies)	Dermally, there were no signs of systemic toxicity in studies amongst rats up to 90 days duration with exposure levels up to 2000 mg/kg/day. There were signs of local irritation (mild hyperplasia) at approximately 125 mg/kg/day and above. Hence, the NOAEL for systemic effects based on this study was 2000 mg/kg/day. From a repeated oral study in rats (administration by drinking water) NOEL of 80 mg/kg/day was obtained.
Mutagenicity/genotoxicity	Not genotoxic in a full range of genetic toxicity studies; Ames tests, gene conversion assay, rec assay, sister chromatid exchange assay, chromosomal aberration assay, and cell transformation assay.
Carcinogenicity	Triethanolamine has given some indication of carcinogenic activity in a feeding study in mice, but the evidence was inconclusive in rats receiving it in the drinking water. Triethanolamine had no carcinogenic activity when dermally applied to mice.
Reproduction toxicity	There was no evidence of developmental toxicity in the offspring of pregnant rats and mice (exposed during the major period of organogenesis to up to 30 mg/kg/day, and to 1125 mg/kg/day respectively using the oral route).
Toxicokinetics (ADME studies)	Experimental studies have shown that triethanolamine is rapidly absorbed when orally administered and that it is absorbed by the skin in rats and mice; however, the rate of absorption is greater in mice than in rats. It does not extensively biotransform and is mainly eliminated in the urine.
Phototoxicity / Photosensitization	Not phototoxic (guinea pig)
Nanomaterials	Not applicable
Reference	<p>(1) Nordic Council of Ministers. Health effects of selected chemicals. Volume 2. 1993. https://books.google.si/books?id=JpBNjBAMogYC&pg=PA239&lpg=PA239&dq=triethanolamine+noael+80+mg/kg&source=bl&ots=q_nucre7gQ&sig=m99ZVktYmXLffPrhol-VzPPyOUM&hl=sl&sa=X&ved=0CDgQ6AEwBGoVChMlounCtZyUxgIVxUvbCh2jHQAf#v=onepage&q=triethanolamine%20noael%2080%20mg%2Fkg&f=false</p> <p>(2) OECD SIDS Initial Assessment Report For SIAM 3. Triethanolamine. February 1995.</p> <p>(3) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.</p> <p>(4) CIR Expert Panel. Safety assessment of triethanolamine and triethanolamine-containing ingredients as used in cosmetics. IJT 32(Suppl. 1):59-83, 2013.</p>



INCI name	CARBOMER
Restriction	None
General description	The safety of Carbomer has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that Carbomer polymers were safe as ingredients in cosmetics and personal care products at concentrations up to 2%.
Acute toxicity via relevant routes of exposure	Acute oral animal studies showed that carbomers have low toxicities when ingested. LD50 values fell in the range of 2500 to 10250 mg/kg depending on the molecular weight of the polymer.
Skin irritation and skin corrosivity	Minimal skin irritation (rabbit). Low potential for skin irritation at concentrations up to 100% (clinical studies).
Mucous membrane irritation (eye irritation)	Zero to moderate eye irritation (rabbit). Carbomer dust (powder) may cause irritation to the eyes.
Skin Sensitization	Low potential for sensitization at concentrations up to 100% (clinical studies).
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Subchronic feeding of rats and dogs with Carbomer-934 in the diet resulted in lower than normal body weights, but no pathological changes were observed. Dogs chronically fed Carbomer-934P manifested gastrointestinal irritation and marked pigment deposition within Kupffer cells of the liver.
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Carbomer-934 demonstrated low potential for phototoxicity and photocontact allergenicity.
Nanomaterials	Not applicable
Reference	(1) CIR Expert Panel. Final Report on the Safety Assessment of Carbomers-934, -910, -934P, -940, -941, and -962. JACT 1(2)109-41, 1982.

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 β -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	PARFUM
Restriction	Cosing makes the following cosmetic restrictions regarding allergens (Annex III):



	<p>The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1) g when its concentration exceeds: 0.001% in leave-on products; 0.01% in rinse-off products.</p> <ul style="list-style-type: none"> • Limonene (Annex III/88): Peroxide value less than 20 mmoles/L. This limit applies to the substance and not to the finished cosmetic product. • Benzyl Alcohol (Annex III/45): For purposes other than inhibiting the development of microorganisms in the product. This purpose has to be apparent from the presentation of the product.
General description	Not available
Acute toxicity via relevant routes of exposure	Not available
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)	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	

INCI name	TOCOPHERYL ACETATE
Restriction	None
General description	<p>Tocopheryl acetate is in terms of Regulation (EC) No 1907/2006 (REACH) exempt from the obligation to register, as sufficient information is known about this substance that it is considered to cause minimum risk because of its intrinsic properties. SCCNFP is of the opinion that alpha-tocopherol acetate does not pose a threat to the health of the consumer and therefore does not propose any restrictions or conditions on the use of alpha-tocopherol acetate in cosmetic products. The safety of Tocopheryl Acetate has also 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</p>



	at concentrations up to 36% (100% in Vitamin E oil).
Acute toxicity via relevant routes of exposure	Oral LD50 (rat) > 16 g/kg; Oral LD50 (mouse) > 4 g/kg
Skin irritation and skin corrosivity	Not irritating (rabbit)
Mucous membrane irritation (eye irritation)	Not irritating to moderately irritating (undiluted, rabbit)
Skin Sensitization	Not sensitizing (undiluted, human). It produced skin sensitization in one animal test, was not sensitizing in the "guinea pig maximization test", but can cause sensitization in the "open epicutaneous test" (>30% tocopheryl acetate).
Dermal/ percutaneous absorption	Dermally applied tocopheryl acetate is hydrolyzed to tocopherol upon exposure to UV.
Repeated dose toxicity (normally 28- or 90-day studies)	Tocopheryl acetate was not toxic in an 8-wk feeding study. A short-term repeated dose toxicity study (28 days) resulted in the following NOAEL values (racemic tocopheryl acetate): Rat: 1111 mg/kg; Dog: 360 mg/kg.
Mutagenicity/ genotoxicity	Not genotoxic in Ames tests or a chromosomal aberration assay
Carcinogenicity	Tocopheryl acetate (≤ 2 g/kg/day) was not carcinogenic in a dietary study. Dermally applied tocopheryl acetate was reported to enhance photocarcinogenesis. Orally administered tocopheryl acetate reduced the incidence of skin cancer, but toxicity was observed.
Reproduction toxicity	Oral administration of tocopheryl acetate (≤ 1.6 g/kg/day) generally did not have any reproductive or developmental effects in rabbits, hamsters, rats, or mice. Tocopheryl acetate had some effect on reducing the number of malformations observed in neonates from diabetic dams. In some studies, tocopheryl acetate potentiated the embryo-lethal effects of cortisone acetate.
Toxicokinetics (ADME studies)	In a dermal absorption study using human subjects, tocopheryl acetate was substantially absorbed in the skin, but systemic availability was not observed. Also, conversion to tocopherol was not seen. In a study using rats, approximately 6% of the applied dose penetrated into the epidermis after 5 days. Most studies found that some tocopheryl acetate was converted to tocopherol. Irradiation of the animals dosed with tocopheryl acetate resulted in a significant increase in the amount of tocopheryl acetate found in the skin as compared to non-irradiated animals, and



	irradiation significantly increased the amount of tocopherol found in the skin of test animals.
Phototoxicity / Photosensitization	Not photoallergenic (guinea pig); photoprotective effects observed in mice and humans
Nanomaterials	Not applicable
Reference	(1) Norwegian Food Safety Authority. Risk profile Vitamin E. 10.12.2012. (NOAEL) (2) CIR Expert Panel. Safety Assessment of Tocopherols and Tocotrienols as Used in Cosmetics. April 4, 2014. (3) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

INCI name	DISODIUM EDTA
Restriction	None
General description	The US FDA reviewed the safety of disodium EDTA and approved its use as food preservative for direct addition to food. The safety of disodium EDTA 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 1%.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat) > 2000 mg/kg. Inhalation exposure to 1000 mg/m ³ disodium EDTA for 6 hours caused lethality in 6 out of 20 male rats. Inhalation exposure of rats to disodium EDTA for 6 hours per day, 5 consecutive days cause concentration dependant lesions in the larynx and lungs that were fully reversible within 14 days.
Skin irritation and skin corrosivity	Not irritating (rabbit)
Mucous membrane irritation (eye irritation)	Not irritating (rabbit)
Skin Sensitization	Not sensitizing (guinea pig)
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	In a 13-week repeated-dose toxicity study, rats fed Na ₂ EDTA (0, 1, 5, 10%) showed mortality at the highest dose. In addition, there was decreased food consumption at 10% and diarrhea at doses of 5% and above. The NOAEL was 1% (approximately 692 mg/kg bw/day).
Mutagenicity/ genotoxicity	It does not present a genotoxic hazard.
Carcinogenicity	Not available
Reproduction toxicity	Not expected to exhibit reproductive and developmental effects in the absence of a metal deficiency which is not expected under normal nutrition. The weight of evidence from a two-generation reproductive toxicity study in rats showed that dietary ingestion of 1% Na ₂ EDTA had no



	effect on reproduction; however, no litters were produced at 5%; the NOAEL for reproductive toxicity was 920 mg/kg bw/day.
Toxicokinetics (ADME studies)	Poorly absorbed in mammals after oral administration. EDTA and its salts are eliminated from the body, 95% via the kidneys and 5% by the bile, along with the metals and free ionic calcium which was bound in transit through the circulatory system. In whatever salt EDTA is administered, it is likely to chelate metal ions in vivo.
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) OECD. SIDS INITIAL ASSESSMENT PROFILE, Amino Carboxylic Acid-Based Chelants Category. COCAM 3, 16-18 October 2012. Retrieved from http://webnet.oecd.org/Hpv/UI/handler.axd?id=823fc6fd-affd-4610-8e57-87e17b72f9f3 (2) ECHA Information on Chemicals. REACH Registered Substance CAS 139-33-3. Joint Submission. First published 20 Dec 2010, Last modified 08 Jun 2015. Retrieved from http://echa.europa.eu/information-on-chemicals/registered-substances

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	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	<p>(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.</p> <p>(2) PubChem; Stejskal J, Stejskal V; Neuroendocrinology Letters 20: 351-364 (1999)</p> <p>(3) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.</p>

INCI name	MINERAL SALTS
Restriction	None
General description	<p>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, TiO₂ 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.</p>
Acute toxicity via relevant routes of exposure	The actual or estimated LD ₅₀ 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. https://doi.org/10.1111/j.1468-2494.2012.00731.x

Perfume compliance to IFRA regulations:

Fragrance ROSE POMPON HP-BC22490 conforms to 50th Amendment, which is currently applicable Standard of the International Fragrance Association (IFRA).

% Perfume in the product	IFRA category	Maximum allowed concentration (IFRA)	IFRA product type
0,02	5B	2,625%	Face cream



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 ROCK SALT MINERAL GOLD MASK PACK 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	Clean your face and apply the mask pack evenly to entire face, starting with the eyes and nose of your face. After taking a break for about 15 to 20 minutes, remove the mask and gently tap the remaining contents to the skin to absorb it.
Precautions for use written on the label	Consult a specialist when using cosmetics or if there are abnormal symptoms or side effects such as red spots, swelling or itching due to direct sunlight. Refrain from using it in areas with wound, eczema, dermatitis, etc. Avoid using around eyes.

The labelled instructions for use and the general description of the product indicate the explicit use of the finished product as a leave on face mask 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 110g PE pouch. 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 n face care sheet mask, 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, GLYCERIN, NIACINAMIDE**, ALCOHOL, PROPANEDIOL, PANTHENOL, POLYSORBATE 80, PHENOXYETHANOL, METHYLPARABEN, ALLANTOIN, TRIETHANOLAMINE, CARBOMER, CAMELLIA SINENSIS LEAF EXTRACT, GLYCYRRHIZA GLABRA ROOT EXTRACT, ADENOSINE, PARFUM, SODIUM HYALURONATE, ARONIA MELANOCARPA FRUIT EXTRACT, TOCOPHERYL ACETATE, DISODIUM EDTA, COLLAGEN, BENZYL ALCOHOL, SODIUM BENZOATE, POTASSIUM SORBATE, MINERAL SALTS, DEHYDROACETIC ACID, GOLD
- Particular precautions for use: Consult a specialist when using cosmetics or if there are abnormal symptoms or side effects such as red sports, swelling or itching due to direct



sunlight. Refrain from using it in areas with wound, eczema, dermatitis, etc. Avoid using around eyes.

- Instructions for use: Clean your face and apply the mask pack evenly to entire face, starting with the eyes and nose of your face. After taking a break for about 15 to 20 minutes, remove the mask and gently tap the remaining contents to the skin to absorb it.
- Date of minimum durability (for products with a minimum durability ≤ 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.

