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Cosmetic Product Safety Report

Product name	Minimalist Nonapeptide + AHA 06% Underarm Roll-On
Product type	Skin care
Category / Usage	Underarm deodorant
Leave-on / Rinse-off	Leave-on
Report prepared for	Uprising Science Pvt Ltd 21, Aarna 2 Tower Kartarpura Industrial Area, 22 Godown Jaipur (Rajasthan), 302006, India
Report date	17 May 2024
Report number	Minimalist.024
Version history	V001: initial report (7 November 2023) V002: formula correction, change of Mandelic Acid and Glycolic Acid concentration, change of the Sodium PCA raw material

This document has been prepared in accordance with Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products and its amendments. It was also prepared in accordance with Schedule 34 of the Product Safety and Metrology Statutory Instrument: Amendment of Regulation (EC) No 1223/2009 and related amendments. This safety report refers to a cosmetic product for human use with no medicinal properties.

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Part A – Cosmetic Product Safety Information

1. Quantitative and qualitative composition

The qualitative and quantitative composition was prepared based on the documentation provided by the manufacturer.

Raw material trade name	INCI name	Maximum level of individual ingredient in raw material (%)	CAS #	Function	Maximum level of raw material in product (%)	Maximum level of individual ingredient in product (%)
Water	Aqua	100.00	7732-18-5	Solvent	71.60	71.60
Novaguard HG	1,2-Hexanediol	100.00	6920-22-5	Emollient	4.00	4.00
(R)-(-)-Mandelic acid, ChiPros 99%	Mandelic Acid	100.00	611-71-2	Exfoliating	3.50	3.50
Glypure 70	Glycolic Acid	72.00	79-14-1	Exfoliating	3.55	2.56
	Aqua	30.00	7732-18-5			1.07
Dermofeel Tec Eco	Triethyl Citrate	100.00	77-93-0	Solvent	3.00	3.00
Gransolve DMI	Dimethyl Isosorbide	100.00	5306-85-4	Emollient	3.00	3.00
Zemea Propanediol	Propanediol	100.00	504-63-2	Emollient	3.00	3.00
Transcutol CG	Ethoxydiglycol	100.00	111-90-0	Solvent	2.00	2.00
Gluadin WLM Benz	Aqua	77.90	7732-18-5	Skin conditioning	1.00	0.779
	Hydrolyzed Wheat Protein	24.00	70084-87-6			0.24
	Sodium Benzoate	1.10	532-32-1			0.011
Euxyl PE 9010	Phenoxyethanol	91.50	122-99-6	Preservative	0.90	0.81
	Ethylhexylglycerin	11.50	70445-33-9			0.09
Sodium Hydroxide	Sodium Hydroxide	100.00	1310-73-2	pH adjuster	0.88	0.88
AJIDEW® NL-50	Sodium PCA	52.00	28874-51-3	Humectant	0.80	0.416
	Aqua	52.00	7732-18-5			0.416
Ronacare Salicylic Acid	Salicylic Acid	100.00	69-72-7	Keratolytic	0.50	0.50

Raw material trade name	INCI name	Maximum level of individual ingredient in raw material (%)	CAS #	Function	Maximum level of raw material in product (%)	Maximum level of individual ingredient in product (%)
SymClariol	Decylene Glycol	100.00	1119-86-4	Emollient	0.20	0.20
SymDeo B125	2-Methyl 5-Cyclohexylpentanol	100.00	1141487-548	Deodorant	0.20	0.20
Hydrolite 5 Green	Pentylene Glycol	100.00	5343-92-0	Emollient	0.80	0.80
Natrosol 250HHR	Hydroxyethylcellulose	100.00	9004-62-0	Thickening	0.80	0.80
Kopcinol	4-Butylresorcinol	100.00	18979-61-8	Antioxidant	0.10	0.10
Natrlquest E30	Trisodium Ethylenediamine Disuccinate	60.00	178949-82-1	Chelating	0.10	0.06
	Aqua	60.00	7732-18-5			0.06
Nonapeptide-1	Nonapeptide-1	100.00	15858-45-2	Skin conditioning	0.01	0.01
Glycrrhiza Glabra Extract	Glycerin	80.00	56-81-5	Antioxidant	0.50	0.40
	Glycyrrhiza Glabra Root Extract	20.00	84775-66-6			0.10

2. Further information on ingredients

The product contains no nanomaterials and no fragrance. The product contains salicylic acid which has been classified as a CMR substance (carcinogenic, mutagenic, or toxic to reproduction) of category 2 (Repr. 2). According to the Cosmetic Regulation 1223/2009, a substance classified in this category may be used in cosmetic products when the substance has been evaluated by the Scientific Committee on Consumer Safety (SCCS) and found safe for use in cosmetic products. Based on the latest SCCS opinion (SCCS/1601/18), salicylic acid is considered safe when used as preservative at a concentration of 0.5% in cosmetic products and for purposes other than preservative at a concentration up to 3.0% for the cosmetic rinse-off hair products and up to 2.0% for other products. In body lotion, eye shadow, mascara, eyeliner, lipstick and roll-on deodorant applications, salicylic acid is considered safe up to 0.5 %. Hence, the use of salicylic acid in the formula at 0.5% is compliant with current requirements (function in the product: keratolytic). Based on the available information the product contains no other substances defined as carcinogenic, mutagenic, or toxic to reproduction (CMR) except possibly technologically unavoidable trace amounts as manufacturing impurities, which are not considered to present a significant health risk. No allergens are present in the product at concentration greater than 0.001% and should be declared on the label.

Ingredient list suitable for product labelling:
Aqua, 1,2-Hexanediol, Mandelic Acid, Triethyl Citrate, Dimethyl Isosorbide, Propanediol, Glycolic Acid, Ethoxydiglycol, Sodium Hydroxide, Phenoxyethanol, Pentylene Glycol, Hydroxyethylcellulose, Salicylic Acid, Sodium PCA, Glycerin, Hydrolyzed Wheat Protein, Decylene Glycol, 2-Methyl 5-Cyclohexylpentanol, 4-Butylresorcinol, Glycyrrhiza Glabra Root Extract, Ethylhexylglycerin, Trisodium Ethylenediamine Disuccinate, Sodium Benzoate, Nonapeptide-1

3. Physical/chemical characteristics

3.1 Physical/chemical characteristics of substances or mixtures

All physical and chemical characteristics of the raw materials/ingredients are included in the specifications, TDSs or MSDSs. This information is considered in the toxicological profile of each ingredient and is taken into account during the toxicological evaluation and final product safety assessment. The physicochemical properties of the raw materials used in the product do not raise any safety concerns.

3.2 Physical/chemical characteristics of the finished cosmetic product

Appearance	Transparent, viscous liquid
Colour	Brownish
Odour	Characteristic
pH	3.5 – 4.5

4. Product stability

The product underwent a 3-month stability and compatibility test at room temperature, and +40°C with relative humidity of 75% (accelerated ageing conditions). The formulation was tested for appearance, colour, odour, pH, and viscosity. No significant changes in the physical and chemical properties occurred and the product was concluded to be stable and compatible with the packaging.

Product durability	The product is expected to remain stable for no less than 18 months before opening. The exact expiry date is compulsory to be present on the packaging for products with durability ≤ 30 months.
Period-After-Opening (PAO)	For products with a durability ≤ 30 months the PAO symbol is not compulsory.

5. Microbiological quality

The microbiological purity test was performed, and the product has been tested in an antimicrobial preservation effectiveness test (Report No. RR230820). It was concluded that the product purity met the requirements set out in the ISO 17516 Standard and that the product met the USP <51> requirements for antimicrobial preservative effectiveness. The sample does not create danger to humans in terms of microbiological purity and the preservative system is effective in maintaining the sterility of the product. The product does not sustain and/or support microbial growth.

6. Impurities, traces, information about the packaging material

6.1 Ingredients and final product purity details

The purity of the ingredients and their possible impurities are stated in the documentation provided by the ingredient suppliers. Based on that information, it is concluded that the listed impurities are in line with the relevant regulations and generally accepted industry limits. This assessment has identified no concerns in relation to any health effects based on EU regulatory compliance or on the normal or reasonably foreseeable use of this product. Additionally, the heavy metals (HM) assay was performed on the final product, estimating the HM (Arsenic and Lead) content to be less than 22 ppm in the finished product.

6.2 Packaging material and formulation compatibility with packaging

The packaging for the product is stated to be a glass bottle with a plastic (PP) roll and a plastic (PP) cap. Compatibility of the packaging with the product has been confirmed during the stability testing. Interaction between the product and its packaging is not expected. It is concluded that this product packaging does not raise any safety concerns.

7. Normal and reasonably foreseeable use

The product is an underarm deodorant and therefore the site of application is intended to be the axillae area. Adults are the target consumer group. The product should be used according to the instructions of use present on the packaging: ‘Use AM. Apply on clean and dry armpits using the roller. Allow to dry before getting dressed.’.

8. Exposure to the cosmetic product

The SCCS Notes of Guidance (SCCS/1647/22, 12th revision, 2023) were used as part of this product exposure evaluation. Data for a non-spray deodorant were used for calculations.

Site of application:	Axillae area (both)
Frequency of application:	2/day
Expected amount applied:	1.50 g/day
Retention factor:	1.0
Leave-on/ rinse-off:	Leave-on
Target consumer group:	Adults
Calculated relative daily exposure:	22.08 mg/kg bw/day

9. Exposure to the substances – margins of safety

Method of calculation was taken from the SCCS Notes of Guidance (SCCS/1647/22). The calculations included the highest possible concentration of each substance in the finished product. The conventional conservative approach of assuming a dermal absorption of 100% was taken for all substances. Margin of Safety (MoS) values have been calculated for individual product ingredients for which a toxicological No Observed Adverse Effect Level (NOAEL) is available. Where data are available, the MoS values calculated for each ingredient are in line

with the SCCS recommendations. It is concluded that these substances are safe for human health. Substances for which the MoS value could not be calculated do not raise any safety concerns.

INCI name	Ingredient content (%)	Dermal absorption (%)	SED: Systemic Exposure Dosage (mg/kg bw/d)	NOAEL: Toxicological No Observed Adverse Effect Level (mg/kg bw/d)	MoS: Margin of Safety
Aqua	73.920	100	16.322	-	-
1,2-Hexanediol	4.000	100	0.883	500	566
Mandelic Acid	3.500	100	0.773	-	-
Triethyl Citrate	3.000	100	0.662	250	377
Dimethyl Isosorbide	3.000	100	0.662	375	566
Propanediol	3.000	100	0.662	1000	1510
Glycolic Acid	2.556	100	0.564	150	266
Ethoxydiglycol	2.000	100	0.442	1000	2264
Sodium Hydroxide	0.880	100	0.194	1000	5147
Phenoxyethanol	0.810	100	0.179	369	2063
Pentylene Glycol	0.800	100	0.177	300	1698
Hydroxyethylcellulose	0.800	100	0.177	903	5112
Salicylic Acid	0.500	100	0.110	50	453
Sodium PCA	0.416	100	0.092	1000	10887
Glycerin	0.400	100	0.088	1180	13361
Hydrolyzed Wheat Protein	0.240	100	0.053	-	-
Decylene Glycol	0.200	100	0.044	100	2264
2-Methyl 5-Cyclohexylpentanol	0.200	100	0.044	100	2264
4-Butylresorcinol	0.100	100	0.022	-	-
Glycyrrhiza Glabra Root Extract	0.100	100	0.022	-	-
Ethylhexylglycerin	0.090	100	0.020	50	2516
Trisodium Ethylenediamine Disuccinate	0.060	100	0.013	300	22645
Sodium Benzoate	0.011	100	0.002	500	205863
Nonapeptide-1	0.010	100	0.002	-	-

10. Toxicological profile of the ingredients

Aqua; Water		
INCI: Aqua or Water	**CAS #:** 7732-18-5	**EC #:** 231-791-2
COSING listed: Yes	**MW:** 18.015 g/mol	**Log Pow:** N/A
Cosmetic function: Solvent	**Dermal absorption:** N/A	
Regulatory restrictions in the EU: No restrictions	**NOAEL:** N/A	
Toxicological summary: Water appears as a clear, nontoxic liquid composed of hydrogen and oxygen, essential for life and the most widely used solvent. It is not expected to cause irritation, allergy or harm at any level when used in consumer products.		
EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.	

1,2-Hexanediol		
INCI: 1,2-Hexanediol	**CAS #:** 6920-22-5	**EC #:** 230-029-6
COSING listed: Yes	**MW:** 118.1 g/mol	**Log Pow:** 0.58 (REACH)
LD50 oral > 6 166 mg/kg bw (rat)	**LD50 dermal >** 2 000 mg/kg bw (rat)	**LC50 inhalation >** 7015 mg/m³ air (rat)
Cosmetic function: Skin conditioning, Solvent		
Dermal absorption: 80% (REACH); may act as penetration enhancer for other ingredients (CIR)		
Regulatory restrictions in the EU: No restrictions		
NOAEL: 700 mg/kg/day based on a dermal 91-day study in rats (REACH) 500 mg/kg/day based on a short-term developmental toxicity oral study in rats (REACH)		
Toxicological summary: 1,2-Hexanediol is an organic solvent conforming to the formula C6H14O2. According to the REACH dossier, 1,2-Hexanediol is considered to be non-irritating to the skin but it is irritating to the eyes. It is considered to be non-sensitizing. It is not acutely toxic, not carcinogenic and not toxic to reproduction. It was not mutagenic in Ames test. 1,2-hexandiol can be absorbed well mainly via oral and dermal exposure (80% absorption assumed). No accumulation in the body is expected due to efficient metabolic pathways and formation of soluble degradation products with established elimination routes. The safety of 1,2-Hexanediol was reviewed by the CIR Expert Panel who concluded that it is safe as a cosmetic ingredient up to 10% in both leave-on and rinse-off products. Additional studies suggested that this compound is metabolized in the skin before it reaches the systemic circulation.		
EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.	
References: 1. REACH dossier, DL-hexane-1,2-diol, 2020 2. CIR, IJT 31(Suppl. 2):147-168, 2012		

Mandelic acid		
INCI: Mandelic acid	**CAS #:** 90-64-2	**EC #:** 202-007-6
COSING listed: Yes	**MW:** 152.15 g/mol	**Log Pow:** 0.5 (REACH)
LD50 oral > 2 000 mg/kg bw (rat)	**LD50 dermal:** No data available	**LC50 inhalation:** No data available
Cosmetic function: Antimicrobial		
Dermal absorption: 100% absorption is taken into account as default		
Regulatory restrictions in the EU: No restrictions		
NOAEL: No data available		
Toxicological summary: Mandelic acid is an aromatic alpha hydroxy acid. In cosmetics industry, it is used as a mild peeling agent due to its antibacterial and anti-inflammatory properties. In clinical studies, mandelic acid showed better safety and tolerability profile than salicylic acid. According to the REACH dossier, mandelic acid is considered not irritating to the skin, but it can induce serious eye damage. Based on the results of Local Lymph Node Assay (LLNA), the substance does not have any sensitising potential. It was also non-mutagenic in in-vitro gene mutation study in bacteria. Although there is no specific information with regards to long-term toxicity, carcinogenicity, and toxicity to reproduction for mandelic acid, based on the nature of this ingredient and its known history of use in personal care products, there are no safety concerns. No significant toxicity is expected when used as a cosmetic ingredient.		

EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.
References: 1. REACH dossier, Mandelic acid, 2021 2. Dayal S, Kalra KD, Sahu P, "Comparative study of efficacy and safety of 45% mandelic acid versus 30% salicylic acid peels in mild-to-moderate acne vulgaris", J Cosmet Dermatol, 19(2): 393-399, 2020	

Dimethyl isosorbide		
INCI: Dimethyl isosorbide	**CAS #:** 5306-85-4	**EC #:** 226-159-8
COSING listed: Yes	**MW:** 174.19 g/mol	**Log Pow:** -1.62 (REACH)
LD50 oral > 5000 mg/kg bw (rat)	**LD50 dermal:** No data available	**LD50 inhalation:** No data available
Cosmetic function: Solvent, Viscosity controlling		
Dermal absorption: Unlikely to be significant		
Regulatory restrictions in the EU: No restrictions		
NOAEL: 375 mg/kg bw/day based on a 13-week oral study in rats (REACH)		
Toxicological summary: Dimethyl isosorbide is a dimethyl ester of isosorbide. According to the REACH dossier, dimethyl isosorbide is not irritating to the eyes. The substance does not possess a skin irritating potential and it is also considered to be non-sensitizing to the skin. It is of low acute toxicity and it was not genotoxic when tested in bacteria. Dimethyl isosorbide is not teratogenic or developmentally toxic. Available research suggests that dimethyl isosorbide can act as a penetration enhancer, influenced by the efficiency of the formulation.		
EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.	
References: 1. REACH dossier, 1,4:3,6-dianhydro-2,5-di-O-methyl-D-glucitol, 2019 2. Oliveira, Hadgraft & Lan. The influence of volatile solvents on transport across model membranes and human skin. Int J Pharm. 2012 Oct 1;435(1):38-49 3. Otto et al. Effect of penetration modifiers on the dermal and transdermal delivery of drugs and cosmetic active ingredients. Skin Pharmacol Physiol. 2008;21(6):326-34.		

Propanediol		
INCI: Propanediol	**CAS #:** 504-63-2 / 26264-14-2	**EC #:** 207-997-3
COSING listed: Yes	**MW:** 76.09 g/mol	**Log Pow:** -0.71 (REACH)
LD50 oral > 2000 mg/kg bw	**LD50 dermal >** 4200 mg/kg/day	**LC50 inhalation >** 1800 mg/m3
Cosmetic function: Solvent, Viscosity controlling		
Dermal absorption: 0.12% (CIR)		
Regulatory restrictions in the EU: No restrictions		
NOAEL: 1000 mg/kg bw/d based on a 90-day oral study in rats (REACH)		
Toxicological summary: Propanediol is the organic compound that conforms to the formula CH2(CH2OH)2. According to the REACH dossier, propanediol is slightly or mildly irritating to the skin but is not irritating to the eyes. It has a low potential for skin sensitization. The substance is not acutely toxic. Propanediol was not genotoxic in in vitro and in vivo genotoxicity tests and was not toxic to reproduction. No test results for carcinogenicity were available, however, data from reproductive toxicity and other studies suggest that this endpoint is of low concern. The safety of propanediol was also reviewed by the CIR Expert Panel who concluded that it is safe as a cosmetic ingredient up to 39.9% in leave-on and 12% in rinse-off products.		
EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.	
References: 1. REACH dossier, Propane-1,3-diol, 2020 2. "Safety Assessment of Alkane Diols as Used in Cosmetics", CIR, 2018		

Triethyl citrate		
INCI: Triethyl citrate	**CAS #:** 77-93-0	**EC #:** 201-070-7
COSING listed: Yes	**MW:** 276.28 g/mol	**Log Pow:** 1.17 (REACH)
LD50 oral > 2000 mg/kg bw (rat)	**LD50 dermal >** 5000 mg/kg bw (rabbit)	**LC50 inhalation >** 14927 mg/m3 (rat)

Cosmetic function: Fragrance, Perfuming, Plasticizer, Solvent, Viscosity controlling	
Dermal absorption: 100% absorption is taken into account as default	
Regulatory restrictions in the EU: No restrictions	
NOAEL: 1000 mg/kg bw/day based on various repeated-dose oral toxicity study in different animals (REACH) 250 mg/kg bw/day based on a 9-month developmental toxicity study in rats (REACH)	
Toxicological summary: Triethyl citrate is the triester of ethyl alcohol and citric acid. It is a colorless liquid used as a food additive, emulsifier, and solvent to stabilize foams. Triethyl citrate is classified by the Food and Drug Administration (FDA) as Generally Recognized as Safe (GRAS) as a direct food additive. In the EU it is approved as a food improvement agent (E 1505). Therefore, it does not raise any concerns with regards to systemic toxicity when used in cosmetic products. According to the REACH dossier, triethyl citrate is not acutely toxic via oral, dermal or inhalation route. Based on various human and animal studies, it is not irritating to the skin, however it is slightly irritating to the eyes. Triethyl citrate (20% in petrolatum) was not irritating in repeated closed patch testing in human volunteers. It is not sensitizing to the skin. It is not genotoxic or mutagenic, and not toxic to reproduction or carcinogenic. The safety of triethyl citrate was reviewed by the CIR Expert Panel who concluded that it is safe as a cosmetic ingredient up to 6% in leave-on and 0.2% in rinse-off products.	
EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.
References: 1. REACH dossier, Triethyl citrate, 2022 2. CIR, IJT 33(Suppl.2):16-46, 2014 3. FDA, 21CFR184.1911	

Glycolic acid		
INCI: Glycolic acid	**CAS #:** 79-14-1	**EC #:** 201-180-5
COSING listed: Yes	**MW:** 76.05 g/mol	**Log Pow:** -1.07 (REACH)
LD50 oral > 2 000 mg/kg bw (rat)	**LD50 dermal:** No data available	**LC50 inhalation >** 3.6 mg/L air (rat)
Cosmetic function: Buffering		
Dermal absorption: 2.6% (REACH)		
Regulatory restrictions in the EU: No restrictions		
NOAEL: 150 mg/kg bw/day based on a subchronic toxicity oral study in rats (REACH)		
Toxicological summary: Glycolic acid is an organic acid, and it belongs to the group of chemicals commonly known as AHAs (alpha hydroxy acids). Glycolic acid is approved by the Food and Drug Administration (FDA) as an indirect food additive in adhesives. Safety concerns for glycolic acid are limited to the site of contact and are due to the low pH of the substance in aqueous conditions. According to the REACH dossier, glycolic acid is a dermal irritant, but such effects are concentration and pH dependent. Under extreme conditions glycolic acid may be corrosive to the skin. Glycolic acid presents a serious risk of damage to the eyes and may cause ocular corrosion as well. It is not a skin sensitizer, and it shown no evidence of genotoxic or mutagenic potential. In a single generation rat study, there were no effects on fertility or parental reproductive performance. The safety of glycolic acid was reviewed by the CIR Expert Panel who concluded that it is safe for use in cosmetic products at concentrations ≤10%, at final formulation pH ≥3.5, when formulated to avoid increasing sun sensitivity or when directions for use include the daily use of sun protection. It was also concluded that glycolic acid is safe for use in salon products at concentrations ≤30%, at final formulation pH ≥3.0, in products designed for brief, discontinuous use followed by thorough rinsing from the skin, when applied by trained professionals, and when application is accompanied by directions for the daily use of sun protection. The SCCNFP has also assessed the safety of alpha-hydroxy acids and indicated that pH is the most important factor affecting the irritancy of AHA products and is more important than concentration. The SCCNFP recommended a maximum level of 4% of glycolic acid in cosmetic products and a pH >3.8.		
EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.	
References: 1. REACH dossier, Glycollic acid, 2021 2. CIR, IJT 36(Suppl 2):14-58, 2017 3. CIR, IJT 17(S1):1-241, 1998 4. SCCNFP, “Position paper on the Safety of alpha-Hydroxy Acids”, SCCNFP/0370/00 5. SCCNFP, “Updated position paper concerning consumer Safety of alpha-hydroxy acids”, SCCNFP/0799/04 6. FDA: 21CFR175.105		

Ethoxydiglycol		
INCI: Ethoxydiglycol	**CAS #:** 111-90-0	**EC #:** 203-919-7
COSING listed: Yes	**MW:** 134.17 g/mol	**Log Pow:** 0.54 (SCCS)
LD50 oral > 6 031 mg/kg bw (mouse)	**LD50 dermal >** 9 143 mg/kg bw (rabbit)	**LC0 inhalation >** 0.025 mg/L air (rat)

Cosmetic function: Humectant, Perfuming, Solvent
Dermal absorption: 100% absorption is taken into account as default
Regulatory restrictions in the EU: Annex III/297: Approved at maximum concentration of: (a) 7% in oxidative hair dye products (b) 5% in non-oxidative hair dye products (c) 10% in rinse-off products other than hair dye products (d) 2.6% in other non-spray cosmetic products (e) 2.6% in the following spray products: fine fragrances, hair sprays, antiperspirants, and deodorants in ready for use preparation. The level of ethylene glycol impurity in Ethoxydiglycol must be ≤ 0.1%. Not to be used in eye products and oral products.
NOAEL: 1000 mg/kg bw/day based on a 90-day repeated dose oral toxicity study in non-rodents (REACH)
Toxicological summary: Ethoxydiglycol is the ether alcohol. According to the REACH dossier, ethoxydiglycol is not irritating to the skin and eyes. The substance is considered non-mutagenic. No adverse effects were observed in a multi-generation fertility study in mice, as well as in a developmental toxicity study in rats. The safety of ethoxydiglycol was reviewed by the CIR Expert Panel who concluded that it is safe as a cosmetic ingredient up to 80% depending on the product type (up to 15% in leave-on products). The safety of ethoxydiglycol was also reviewed by the SCCS on several occasions. In the latest opinion the SCCS concluded that the use of diethylene glycol monoethyl ether (DEGEE) at a maximum concentration of 2.6% in cosmetic products taking into account the other uses previously assessed (10% in rinse-off products, 7.0% in oxidative and 5% in non-oxidative hair dye formulation) does not pose a risk to the health of the consumer. Additionally, the use of DEGEE in the following spray products: fine fragrances, hair sprays, antiperspirants, and deodorants in a concentration up to 2.6% does not pose a risk to the health of the consumer. Since the systemic daily dose with the current levels and uses of DEGEE considered to be safe for the consumers, is higher than that permitted in previous opinions, the SCCS was of the opinion that the level of ethylene glycol impurity in DEGEE should be decreased from <0.2% to ≤0.1% in order to avoid consumer exposure to higher dose of this toxic impurity.

EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.

References: 1. REACH dossier, 2-(2-ethoxyethoxy)ethanol, 2021
2. SCCS opinions on Diethylene Glycol Monoethyl Ether (Degee): SCCS/1507/13 (2013), SCCS/1316/10 (2010), SCCP/1200/08 (2008), SCCP/1044/06 (2006)
3. CIR, IJT 25(Suppl. 2) :1-89, 2006
4. CIR, JACT 4(5):223-248, 1985

Sodium hydroxide		
INCI: Sodium hydroxide	**CAS #:** 1310-73-2	**EC #:** 215-185-5
COSING listed: Yes	**MW:** 39.997 g/mol	**Log Pow:** N/A
LD50 oral: No data available	**LD50 dermal:** No data available	**LD50 inhalation:** No data available

Cosmetic function: Buffering, Denaturant
Dermal absorption: Unlikely to be significant
Regulatory restrictions in the EU: Annex III/15a - approved for the following uses: • Nail cuticle solvent: max. 5% in ready for use preparation. The following wording must be included: “Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children”. • Hair straightener: max. 2% in ready for use preparation for general use. The following wording must be included: “Contains alkali. Avoid contact with eyes. Can cause blindness. Keep out of reach of children”. • Hair straightener: max. 4.5% in ready for use preparation for professional use. The following wording must be included: “For professional use only. Avoid contact with eyes. Can cause blindness”. • pH adjuster for depilatories at pH < 12.7. The following wording must be included: “Keep out of reach of children. Avoid contact with eyes”. • Other uses as pH adjuster at pH < 11.
NOAEL: 1000 mg/kg bw/day based on a read-across from parental and offspring effects following oral exposure to magnesium hydroxide (CIR)
Toxicological summary: Sodium hydroxide is the inorganic base that conforms to the formula NaOH. Sodium hydroxide is classified by the Food and Drug Administration (FDA) as Generally Recognized as Safe (GRAS) for direct addition to food and it is also approved as food additive in the EU (E524). Additionally, it was assessed by the Joint FAO/WHO (Food and Agriculture Organization/World Health Organization) Committee on Food Additives and by the Scientific Committee for Food, and both set an acceptable daily intake (ADI) of “not specified”. Therefore, sodium hydroxide does not raise any concerns with regards to systemic toxicity when used in cosmetic products. According to the safety assessment performed by the CIR Expert Panel, the effects of sodium hydroxide are predominantly local and are a consequence of its high pH in aqueous solutions. Sodium hydroxide was irritating and/or corrosive in a concentration dependent manner in rat, rabbit, and pig studies. Acute oral studies of sodium hydroxide led to extensive gastric damages in the animal tested at concentrations of up to 8.3%. In acute dermal toxicity studies,

mice treated with 50% sodium hydroxide had better survival rates when the test compound was washed off within an hour of application. The Panel concluded that sodium hydroxide is safe in hair straighteners and depilatories under conditions of recommended use and it is safe for all other present practices of use up to 10% in leave-on and 12.9% in rinse-off products when formulated to be non-irritating. According to the REACH dossier, sodium hydroxide is irritating to the skin and eyes but it is not a skin sensitizer. There is no evidence of mutagenicity in vitro or in vivo and no indication of developmental toxicity, reproductive toxicity and carcinogenicity.	
EU hazard classification: Classification in Annex VI of the CLP Regulation: Skin Corr. 1A.	**Conclusion**: This ingredient is safe for use at the levels present in this product.
References: 1. FDA, 21CFR184.1763 2. REACH dossier, Sodium hydroxide, 2020 3. "Safety Assessment of Inorganic Hydroxides as Used in Cosmetics", CIR, 2015 4. Joint FAO/WHO Expert Committee on Food Additives, NMRS 40/TRS 339-JECFA 9/16, 1965 5. "Scientific Opinion on the safety and efficacy of sodium hydroxide for dogs, cats and ornamental fish", EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), EFSA Journal 2012; 10(10):2882	

Phenoxyethanol		
INCI: Phenoxyethanol	**CAS #:** 122-99-6	**EC #:** 204-589-7
COSING listed: Yes	**MW:** 138.16 g/mol	**Log Pow:** 1.2 (REACH)
LD50 oral > 1840 mg/kg bw	**LD50 dermal >** 2214 mg/kg bw	**LC50 inhalation >** 1000 mg/m³
Cosmetic function: Preservative		
Dermal absorption: Experimental data indicate a high level of dermal absorption, with levels around 65% in unoccluded conditions and close to 100% in occluded conditions.		
Regulatory restrictions in the EU: Annex V/29: Approved as a preservative at maximum concentration of 1.0% in ready for use preparation.		
NOAEL: Oral NOAEL = 369 mg/kg bw/d based on a 90-day oral study in rats (REACH) Dermal NOAEL = 500 mg/kg bw/d based on a 90-day dermal study in rabbits (REACH)		
Toxicological summary: Phenoxyethanol is an aromatic ether alcohol. According to the REACH dossier, phenoxyethanol is not irritating to the skin but it is irritating to the eyes. It is not a skin sensitizer and it is of low acute toxicity. Both in vitro and in vivo studies show a lack of genetic toxicity. Available data suggest the ingredient is not toxic to reproduction, has no effects on development and is not a carcinogen. The safety of phenoxyethanol was reviewed by the CIR Expert Panel who concluded that it is safe as a cosmetic ingredient up to 1%. The safety of phenoxyethanol was also reviewed by the Scientific Committee on Consumer Safety (SCCS) who concluded that the ingredient is safe for use as a preservative with a maximum concentration of 1%. The SCCS also took into account specific considerations to assess safety of phenoxyethanol in children, and concluded the ingredient is also safe for use in products for this age group.		
EU hazard classification: Classification in Annex VI of the CLP Regulation: Acute Tox. 4 and Eye Irrit. 2	**Conclusion**: This ingredient is safe for use at the levels present in this product.	
References: 1. REACH dossier, 2-phenoxyethanol, 2020 2. CIR, JACT 9(2):259-277, 1990 3. CIR, IJT 30(Suppl. 2):73-127, 2011 4. "Opinion on Phenoxyethanol", Scientific Committee on Consumer Safety, SCCS/1575/16		

Hydroxyethylcellulose		
INCI: Hydroxyethylcellulose	**CAS #:** 9004-62-0	**EC #:** -
COSING listed: Yes	**MW:** 806.9 g/mol	**Log Pow:** -3 (PubChem)
LD50 oral > 8 700 mg/kg bw (rat)	**LD50 dermal:** No data available	**LC50 inhalation >** 0.19 mg/L air (rat)
Cosmetic function: Binding, Emulsion stabilising, Film forming, Light stabilizer, Viscosity controlling		
Dermal absorption: Unlikely to be significant		
Regulatory restrictions in the EU: No restrictions		
NOAEL: 903 mg/kg bw/day based on a subchronic toxicity oral study in rats (read across from ethylcellulose, CIR)		
Toxicological summary: Hydroxyethylcellulose is a modified cellulose polymer which contains hydroxyethyl side chains. Hydroxyethylcellulose is approved by the Food and Drug Administration (FDA) as an indirect food additive that can be safely used in adhesives in contact with food. The FDA has also approved the use of hydroxyethylcellulose as ophthalmic demulcents in over-the-counter (OTC) drug products for the eyes. The safety of hydroxyethylcellulose was reviewed by the CIR Expert Panel who concluded that it is safe as a cosmetic ingredient up to 25% in leave-on and 39% in rinse-off products. Hydroxyethylcellulose was, at most, slightly irritating to rabbit eyes and not irritating to the rabbit skin. The test substance was also not phototoxic. In a clinical RIPT study, undiluted hydroxyethylcellulose was non-irritating and non-sensitizing. The cellulose derivatives pass		

essentially unchanged through the gastrointestinal tract following oral administration. They are practically nontoxic when administered by inhalation, oral, intraperitoneal, subcutaneous, or dermal routes. Subchronic and chronic oral studies indicated that the cellulose derivatives were non-toxic. No significant mutagenic, developmental, or reproductive effects were demonstrated.	
EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.
References: 1. FDA: 21CFR175.105 and 21CFR349.12 2. CIR, JACT 5(3):1-59, 1986 3. CIR, Amended Safety Assessment of Cellulose and Related Polymers as used in Cosmetics, Final Report, 2009	

Pentylene glycol		
INCI: Pentylene glycol	**CAS #:** 5343-92-0	**EC #:** 226-285-3
COSING listed: Yes	**MW:** 104.15 g/mol	**Log Pow:** 0,06 (REACH) / -0.278 ± 0,215 (CIR)
LD50 oral > 5 000 mg/kg bw (rat)	**LD50 dermal >** 2 000 mg/kg bw (rat)	**LC50 inhalation >** 7015 mg/m³ air (rat)
Cosmetic function: Skin conditioning, Solvent		
Dermal absorption: May act as penetration enhancer for other ingredients (CIR). 100% absorp. is taken into account as default		
Regulatory restrictions in the EU: No restrictions		
NOAEL: 700 and 1000 mg/kg/day (for local and systemic effects, respectively) based on dermal 91-day study in rats (REACH) 300 mg/kg/day based on short-term developmental toxicity oral study in rats on 1,2 butanediol (read-across, REACH)		
Toxicological summary: Pentylene glycol is an organic solvent conforming to the formula C5H12O2. According to the REACH dossier, pentylene glycol is considered to be non-irritating to the skin but it is irritating to the eyes. It is considered to be non-sensitizing. It is not acutely toxic, not carcinogenic and not toxic to reproduction. It was not mutagenic in Ames test. The safety of pentylene glycol was reviewed by the CIR Expert Panel who concluded that it is safe as a cosmetic ingredient up to 5% in both leave-on and rinse-off products. Additional studies suggested that this compound is metabolized in the skin before it reaches the systemic circulation.		
EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.	
References: 1. REACH dossier, Pentane-1,2-diol, 2020 2. CIR, IJT 31(Suppl. 2):147-168, 2012 3. Steiner et al. (2017). Margin of safety of pentylene glycol derived using measurements of cutaneous absorption and volatility. Regul Toxicol Pharmacol. Jul;87:106-111.		

Salicylic acid		
INCI: Salicylic acid	**CAS #:** 69-72-7	**EC #:** 200-712-3
COSING listed: Yes	**MW:** 138.12 g/mol	**Log Pow:** 2.64 (REACH)
LD50 oral > 891 mg/kg bw	**LD50 dermal >** 2000 mg/kg bw	**LD50 inhalation:** No data available
Cosmetic function: Anti-seborrheic, Fragrance, Hair conditioning, Keratolytic, Preservative, Skin conditioning		
Dermal absorption: Up to 50% depending on the study (strongly dependent on vehicle composition, pH, structure of the skin and conditions of application to the skin). It may enhance penetration of other ingredients, e.g. vitamin A (CIR).		

Regulatory restrictions in the EU:
Annex III/98 (salicylic acid):

- approved at max. 3% in rinse-off hair products in ready for use preparation
- approved at max. 2% in other products except body lotion, eye shadow, mascara, eyeliner, lipstick and roll-on deodorant in ready for use preparation
- approved at max. 0.5% in body lotion, eye shadow, mascara, eyeliner, lipstick and roll-on deodorant in ready for use preparation
- Not to be used in preparations for children under 3 years of age. Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Not to be used in oral products. For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product
- The following wording must be included in the product label solely for products which might be used for children under 3 years of age: "Not to be used for children under 3 years of age"

Annex V/3 (salicylic acid and its salts):

- approved as a preservative at max. 0.5% (acid) in ready for use preparation
- Not to be used in products for children under 3 years of age. Not to be used in oral products. Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Not to be used in products for children under 3 years of age, except for shampoos.

• The following wording must be included in the product label solely for products which might be (1) used for children under 3 years of age and (2) used for children under 3 years of age which remain in prolonged contact with the skin: "Not to be used for children under 3 years of age".
NOAEL: 75 mg/kg bw/d based on reproductive and developmental studies (SCCS) 50 mg/kg bw/d identified in subchronic and chronic toxicity studies (RIFM)
Toxicological summary: Salicylic acid is an aromatic acid that conforms to the formula $C_7H_6O_3$. Salicylic acid has been classified as a CMR substance of category 2. According to the Cosmetic Regulation 1223/2009, a substance classified in this category may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products. Based on the latest SCCS opinion, salicylic acid is considered safe when used as preservative at a concentration of 0.5 % in cosmetic products and for purposes other than preservative at a concentration up to 3.0 % for the cosmetic rinse-off hair products and up to 2.0 % for other products, considering its current restrictions in place. However, in body lotion, eye shadow, mascara, eyeliner, lipstick and roll on deodorant applications, salicylic acid is considered safe up to 0.5 %. The SCCS position is that these levels are inclusive of any use of salicylic acid, i.e. should not exceed the stated levels with additional use as a preservative. This Opinion is not applicable to any oral product (such as toothpaste and mouthwash) with the exception of lipsticks. Sprayable products that could lead to exposure of the consumer's lung by inhalation are also excluded. Additionally, the SCCS agrees that, based on the submitted studies (in human and in mice), salicylic acid does not have photo-irritant, photosensitising or photocarcinogenic properties. Finally, the SCCS concluded that salicylic acid is an eye irritant with the potential to cause serious damage to the eyes and pointed out that specific tests are currently on-going to assess whether salicylic acid has endocrine disrupting properties and that depending the outcome of these tests, the potential endocrine disrupting properties of salicylic acid in cosmetics may need to be considered. The safety of salicylic acid was also reviewed by the CIR Expert Panel who concluded that it is safe as a cosmetic ingredient up to 2% in leave-on and 30% in rinse-off products when formulated to be non-irritating and non-sensitizing. According to the REACH dossier, salicylic acid is not a primary skin irritant but it is a severe eye irritant. It is not a skin sensitizer and it is not acutely toxic via dermal route. It shows low acute toxicity via oral route. The substance is not carcinogenic or genotoxic. It is not expected to pose a risk for reproductive or developmental effects in humans when used in cosmetic products. The Food and Drug Administration (FDA) has issued a final rule for OTC drug products that permits the use of salicylic acid, at concentrations of 0.5 to 2%, as an active ingredient in topical acne drug products..
EU/UK hazard classification: Classification in Annex VI of the CLP Regulation: Acute Tox. 4, Eye Dam. 1 and Repr. 2 (CMR Cat. 2). | **Conclusion**: This ingredient is safe for use at the levels present in this product.
References: 1. "Opinion on salicylic acid", Scientific Committee on Consumer Safety (SCCS), SCCS/1601/18, 2019 2. CIR, IJT 22(Suppl 3):1-108, 2003 3. „Amended Safety Assessment of Salicylic Acid and Salicylates as Used in Cosmetics", CIR, 2019 4. REACH dossier, Salicylic acid, 2020 5. „A toxicologic and dermatologic assessment of salicylates when used as fragrance ingredients", Research Institute for Fragrance Materials (RIFM), Food and Chemical Toxicology 45 (2007) S318–S361 6. FDA: 21CFR333.310

Sodium PCA		
INCI: Sodium PCA	**CAS #:** 28874-51-3	**EC #:** 249-277-1
COSING listed: Yes	**MW:** 151.1 g/mol	**Log Pow <** 1.0 (REACH)
LD50 oral > 2000 mg/kg bw	**LD50 dermal >** 2000 mg/kg bw	**LD50 inhalation:** No data available
Cosmetic function: Antistatic, Hair conditioning, Humectant, Skin conditioning		
Dermal absorption: Dermal absorption is assumed at 1% as a worst-case estimate (REACH)		
Regulatory restrictions in the EU: No restrictions		
NOAEL: 7200 mg/kg bw/day based on a 26-week subchronic oral study in rats (REACH) 1000 mg/kg bw/day based on a subacute study in rats (REACH)		
Toxicological summary: Sodium PCA is the sodium salt of PCA, which is a natural amino acid derivative. According to the REACH dossier, sodium PCA is not irritating to the skin and eyes. It is not a skin sensitizer and it is not acutely toxic. The substance is not genotoxic. The safety of sodium PCA was reviewed by the CIR Expert Panel who concluded that it is safe as a cosmetic ingredient up to 2.5% in leave-on and 3% in rinse-off products. In range of clinical tests sodium PCA was found to be non-irritating and non-sensitizing (with and without UV exposure). No evidence of phototoxicity, sensitization, or comedogenicity was found. The Panel noted that sodium PCA should not be used in cosmetic products containing nitrosating agents.		
EU hazard classification: No official classification in Annex VI of the CLP Regulation. | **Conclusion**: This ingredient is safe for use at the levels present in this product.		
References: 1. REACH dossier, Sodium 5-oxo-L-prolinate, 2020 2. CIR, IJT 18(S2):25-34, 1999 3. CIR, IJT 38(Suppl. 2):5-11, 2019 4. "Safety Assessment of PCA (2-Pyrrolidone-5-Carboxylic Acid) and Its Salts as Used in Cosmetics", CIR, 2014		

Glycerin		
INCI: Glycerin	**CAS #:** 56-81-5	**EC #:** 200-289-5
COSING listed: Yes	**MW:** 92.09 g/mol	**Log Pow:** -1.75 (REACH)
LD50 oral > 11 500 mg/kg bw	**LD50 dermal >** 56 750 mg/kg	**LD50 inhalation >** 275 mg/L
Cosmetic function: Denaturant, Hair conditioning, Humectant, Oral care, Perfuming, Skin conditioning, Skin protecting, Solvent, Viscosity controlling		
Dermal absorption: Unlikely to be significant		
Regulatory restrictions in the EU: No restrictions		
NOAEL: 1180 mg/kg bw/day based on developmental toxicity studies in rabbits (REACH) 4580 mg/kg bw/day based on a subchronic study in rats (REACH)		
Toxicological summary: Glycerin is a polyhydric alcohol that conforms generally to the formula C3H8O3. Glycerin is naturally occurring in all animals and plant matter in combined form as glycerides in fats and oils, or, in intracellular spaces as lipids. While the compounds are identical, there is naturally occurring glycerin, derived from plants and animals, and synthetic glycerin, obtained from non-triglyceride sources. Glycerin is classified by the Food and Drug Administration (FDA) as Generally Recognized as Safe (GRAS) for its use in food packaging and it is a multiple-purpose GRAS food substance when used in accordance with good manufacturing practices. Glycerin is on FDA's list of approved direct and indirect food additives. Also, glycerin is FDA-approved for use in over-the-counter (OTC) drugs. Therefore, it does not raise any concerns with regards to systemic toxicity when used in cosmetic products. According to the REACH dossier, glycerin is not irritating to the skin and eyes. It is not a skin sensitizer and it is not acutely toxic. Glycerin was not mutagenic in bacteria. It is not carcinogenic and not toxic to reproduction. The safety of glycerin was reviewed by the CIR Expert Panel who concluded that it is safe as a cosmetic ingredient up to 79.2% in leave-on and 99.4% in rinse-off products. The safety of glycerin was also reviewed by the OECD who concluded that it is a low hazard potential substance.		
EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.	
References: 1. REACH dossier, Glycerol, 2020 2. "Safety Assessment of Glycerin as Used in Cosmetics", CIR, 2014 3. FDA: 21CFR182.90, 21CFR182.1320, 21CFR172.866, 21CFR178.3500, 21CFR346.14, 21CFR347.10, 21CFR349.12 4. OECD SIDS, Glycerin, 2002		

Hydrolyzed wheat protein		
INCI: Hydrolyzed wheat protein	**CAS #:** 94350-06-8 / 222400-28-4 / 70084-87-6 / 100209- 50-5	**EC #:** 305-225-0 / - / 309-358-5
COSING listed: Yes	**MW:** 0.1 – 90 kDa	**Log Pow:** No data available
LD50 oral: No data available	**LD50 dermal:** No data available	**LC50 inhalation:** No data available
Cosmetic function: Antistatic, Hair conditioning, Skin conditioning		
Dermal absorption: Unlikely to be significant		
Regulatory restrictions in the EU: Annex III/307: Maximum molecular weight average of the peptides in hydrolysates: 3.5 kDa.		
NOAEL: No data available		
Toxicological summary: Hydrolyzed wheat protein (HWP) is the hydrolysate of wheat protein (Triticum aestivum and other Triticum species) derived by acid, enzyme, or other method of hydrolysis. Wheat is widely consumed as a part of human diet. Therefore, wheat protein does not raise any concerns with regards to systemic toxicity when used in cosmetic products for non-sensitized population. The safety of wheat hydrolysate was reviewed by the SCCS who concluded that there is evidence that sensitization to HWP is possible via exposure to cosmetics. There are indications that the risk of sensitization is higher when hydrolyzed wheat proteins of higher molecular weight are used on the skin, in particular as an ingredient of products that have strong surfactant properties such as soaps and liquid soaps. The SCCS considered the use of hydrolyzed wheat proteins safe for consumers in cosmetic products, provided that the maximum molecular weight average of the peptides in hydrolysates is 3.5 kDa. The safety of hydrolyzed wheat protein was also reviewed by the CIR Expert Panel who concluded that it is safe as a cosmetic ingredient up to 1% in leave-on and 1.7% in rinse-off products, when formulated to restrict peptides to an average molecular weight of 3.5 kDa or less. The Panel noted generally non-irritating character of wheat proteins.		
EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.	
References: 1. CIR, IJT 37(Suppl. 1):55-66, 2018 2. SCCS/1534/14, Scientific Committee on Consumer Safety SCCS Opinion on Hydrolysed wheat proteins, 2014 3. REACH dossier, Wheat, ext., hydrolyzed, 2011		

2-methyl 5-cyclohexylpentanol		
INCI: 2-methyl 5-cyclohexylpentanol	**CAS #:** 1141487-54-8	**EC #:** 700-146-1
COSING listed: Yes	**MW:** 184.32 g/mol	**Log Pow:** 5.3 (REACH)
LD50 oral > 2 000 mg/kg bw (rat)	**LD50 dermal >** 2 000 mg/kg bw (rat)	**LC50 inhalation:** No data available
Cosmetic function: Deodorant, Skin conditioning, Skin protecting		
Dermal absorption: 100% absorption is taken into account as default		
Regulatory restrictions in the EU: No restrictions		
NOAEL: 100 mg/kg bw/day based on a 28-day oral toxicity study in rats (REACH)		
Toxicological summary: 2-methyl 5-cyclohexylpentanol is an aromatic alcohol. It is an effective microbiome-friendly cosmetic deodorant with highly specific anti-bacterial properties. According to the REACH dossier, 2-methyl 5-cyclohexylpentanol is of a low acute toxicity via oral or dermal route. It was not irritating to the skin and eyes, when tested in vivo in laboratory animals. It was also not a skin sensitizer. Based on patch test results from 50 human volunteers, there were no signs of dermal irritation. 2-methyl 5-cyclohexylpentanol is not genotoxic and not toxic to reproduction. No significant toxicity is expected when used in cosmetic products.		
EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.	
References: 1. REACH dossier, Cyclohexanepentanol, .beta.-methyl-, 2023		

Decylene glycol		
INCI: Decylene glycol	**CAS #:** 1119-86-4	**EC #:** 214-288-2
COSING listed: Yes	**MW:** 174.28 g/mol	**Log Pow:** 1.99 (REACH)
LD50 oral > 5 000 mg/kg bw (rat)	**LD50 dermal >** 5 000 mg/kg bw (rat)	**LC50 inhalation:** No data available
Cosmetic function: Skin conditioning		
Dermal absorption: 100% absorption is taken into account as default		
Regulatory restrictions in the EU: No restrictions		
NOAEL: 100 mg/kg bw/day based on a 28-day oral study in rats (REACH)		
Toxicological summary: Decylene glycol, or decane-1,2-diol, is an aliphatic diol. According to the REACH dossier, decylene glycol is not acutely toxic via oral or dermal route. It is a moderate skin irritant, based on two in vivo studies. An in vivo eye irritation study in rabbits also indicated irreversible damage, which was supported by positive results in a non-regulatory HET-CAM test. Therefore, decylene glycol is considered irritating to the eyes. It is not a skin sensitizer, and it is not mutagenic, carcinogenic, or toxic to reproduction. A repeat insult patch test was conducted in a panel of 55 volunteers, decylene glycol did not indicate a potential for dermal irritation or allergic contact sensitization. The safety of decylene glycol was reviewed by the CIR Expert Panel who concluded that it is safe as a cosmetic ingredient (concentration of use not reported).		
EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.	
References: 1. REACH dossier, Decane-1,2-diol, 2018 2. CIR, IJT 31(Suppl. 2):147-168, 2012		

4-Butylresorcinol		
INCI: 4-Butylresorcinol	**CAS #:** 18979-61-8	**EC #:** 606-191-2
COSING listed: Yes	**MW:** 166.22 g/mol	**Log Pow:** 2.8 (REACH)
LD50 oral > 500 mg/kg bw (rat)	**LD50 dermal:** No data available	**LC50 inhalation:** No data available
Cosmetic function: Antioxidant		
Dermal absorption: 100% absorption is taken into account as default		
Regulatory restrictions in the EU: No restrictions		
NOAEL: No data available		
Toxicological summary: 4-Butylresorcinol, also known as rucinol, is a highly effective resorcinol derivative that inhibits both tyrosinase and tyrosinase-related protein-1 (TRP-1). It posseses skin hypopigmentation properties. Serval studies reported its use as an anti-aging ingredient in cosmetics and it also found application in treatment of skin conditions like melasma. Studies explored the efficacy and safety of 4-n-Butylresorcinol (0.3%) cream applied topically and it was well tolerated, with no adverse reactions reported. According to the REACH dossier, 4-Butylresorcinol was irritating to the skin in in-vitro skin model test, and it		

was a severe eye irritant in BCOP assay. However, the ingredient is non-sensitizing to the skin. 4-Butylresorcinol was non-mutagenic in Ames test. No significant toxicity is expected when used as a cosmetic ingredient.	
EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.
References: 1. Diana I. S. P. Resend, Marta S. Ferreira, José M. S. Lobo, Emília Sousa, Isabel F. Almeida, "skin Depigmenting Agents in Anti-Aging Cosmetics: A Medicinal Perspective on Emerging Ingredients" applied sciences, 12, 2022 2. REACH dossier, 4-butylbenzene-1,3-diol, 2010 3. Madan Mohan, N. T., Gowda, A., Jaiswal, A. K., Sharath Kumar, B. C., Shilpashree, P., Gangaboraiah, B., & Shamanna, M. (2016). Assessment of efficacy, safety, and tolerability of 4-n-butylresorcinol 0.3% cream: an Indian multicentric study on melasma. Clinical, cosmetic and investigational dermatology, 9, 21–27. 4. Garcia-Jimenez, A., Teruel-Puche, J. A., Ortiz-Ruiz, C. V., Berna, J., Tudela, J., & Garcia-Canovas, F. (2016). 4-n-butylresorcinol, a depigmenting agent used in cosmetics, reacts with tyrosinase. IUBMB Life, 68(8), 663–672.	

Glycyrrhiza glabra root extract		
INCI: Glycyrrhiza glabra root extract	**CAS #:** 84775-66-6	**EC #:** 283-895-2
COSING listed: Yes	**MW:** N/A	**Log Pow:** No data available
LD50 oral: No data available	**LD50 dermal:** No data available	**LC50 inhalation:** No data available
Cosmetic function: Bleaching, Perfuming, Skin conditioning, Emollient, Smoothing, Soothing		
Dermal absorption: 100% absorption is taken into account as default		
Regulatory restrictions in the EU: No restrictions		
NOAEL: No data available		
Toxicological summary: Glycyrrhiza glabra root extract is an extract of the roots of the Licorice, Glycyrrhiza glabra L., Leguminosae. Licorice plants are native to the Mediterranean region and parts of Asia and are cultivated worldwide. The Food and Drug Administration (FDA) lists Licorice (the dried and ground rhizome and root portions of Glycyrrhiza glabra as well as other species of Glycyrrhiza) as a direct food substance Generally Recognized as Safe (GRAS). Therefore, Glycyrrhiza glabra root extract does not raise any concerns with regards to systemic toxicity when used in cosmetic products. The safety of Glycyrrhiza glabra root extract was reviewed by the CIR Expert Panel who concluded that it is safe as a cosmetic ingredient up to 0.4% depending on the product type (including leave-on products). Licorice root extract was not a reproductive toxicant at oral doses up to 2 g/kg/d in rats. A repeat insult patch on human subjects of an "essence" containing oil soluble Glycyrrhiza glabra root extract (0.105%) resulted in no evidence of sensitization or significant irritation. In a dermal patch test of a product containing Glycyrrhiza glabra root extract (0.0001%) there was no evidence of sensitization or irritation. In an irritation test of the substance (2%) on guinea pigs, there were no signs of irritation at any observation period.		
EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.	
References: 1. "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", CIR, 2008 2. FDA: 21CFR184.1408		

Ethylhexylglycerin		
INCI: Ethylhexylglycerin	**CAS #:** 70445-33-9	**EC #:** 408-080-2
COSING listed: Yes	**MW:** 204.31 g/mol	**Log Pow:** 2.53 (REACH)
LD50 oral > 2 000 mg/kg bw	**LD50 dermal** > 2 000 mg/kg bw	**LD50 inhalation:** No data available
Cosmetic function: Deodorant, Skin conditioning		
Dermal absorption: Minimal dermal absorption is expected (0.02% was reported in an acute toxicokinetic study in rabbits) but it may show skin penetration enhancement effect (CIR).		
Regulatory restrictions in the EU: No restrictions		
NOAEL: 50 mg/kg bw/d based on a 90-day reproductive toxicity study in rats (REACH)		
Toxicological summary: Ethylhexylglycerin is an alkyl glyceryl ether. According to the safety assessment performed by the CIR Expert Panel, ethylhexylglycerin is neither a skin irritant nor sensitizer nor photosensitizer. When undiluted it is strongly irritating to the eyes, but 5% ethylhexylglycerin was mildly irritating when tested in rabbits. It was non-genotoxic when tested in bacteria and it shown no reproductive and developmental toxicity in oral studies. The Panel concluded that ethylhexylglycerin is safe as a cosmetic ingredient up to 2% in leave-on and 8% in rinse-off products. According to the REACH dossier, ethylhexylglycerin is of low acute oral and dermal toxicity.		

EU hazard classification: Classification in Annex VI of the CLP Regulation: Eye Dam. 1 and Aquatic Chronic 3.	**Conclusion**: This ingredient is safe for use at the levels present in this product.
References: 1. REACH dossier, 3-(2-ethylhexyloxy)propane-1,2-diol, 2020 2. CIR, IJT 32(Suppl. 3):5-21, 2013	

Trisodium ethylenediamine disuccinate		
INCI: Trisodium ethylenediamine disuccinate	**CAS #:** 20846-91-7 / 178949-82-1	**EC #:** 439-840-1 **/** 605-842-8
COSING listed: Yes	**MW:** 292.24 g/mol	**Log Pow:** -1.4 (REACH)
LD50 oral > 2000 mg/kg bw (rat)	**LD50 dermal >** 2000 mg/kg bw (rat)	**LD50 inhalation >** 1.49 mg/L (rat)
Cosmetic function: Chelating		
Dermal absorption: 11% (REACH)		
Regulatory restrictions in the EU: No restrictions		
NOAEL: 300 mg/kg bw/d based on a 90-day oral study in rats (REACH)		
Toxicological summary: Trisodium ethylenediamine disuccinate is a sodium salt of ethylenediamine-N,N'-disuccinic acid (called EDDS), which is a biodegradable aminopolycarboxylic acid. According to the REACH dossier, trisodium ethylenediamine disuccinate is not a skin and eye irritant and is not sensitising to the skin. The substance it not genotoxic and it is not classified as reprotoxic or carcinogenic. Trisodium ethylenediamine disuccinate is of a low acute toxicity via oral and dermal routes.		
EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.	
References: 1. REACH dossier, L-Aspartic acid, N,N'-1,2-ethanediylbis-, 2013		

Sodium benzoate		
INCI: Sodium benzoate	**CAS #:** 532-32-1	**EC #:** 208-534-8
COSING listed: Yes	**MW:** 144.1 g/mol	**Log Pow:** 1.88 (REACH)
LD50 oral > 2000 mg/kg bw	**LD50 dermal:** No data available	**LD50 inhalation:** No data available
Cosmetic function: Anticorrosive, Masking, Preservative		
Dermal absorption: Might be significant taking into account the substance's physical/chemical properties.		
Regulatory restrictions in the EU: Annex V/1: Approved as a preservative at max. concentration of: • 2.5% (acid) in rinse-off products, except oral products • 1.7% (acid) in oral products • 0.5% (acid) in leave-on products in ready for use preparation.		
NOAEL: 1000 mg/kg bw based on a dietary study in rats (REACH) 500 mg/kg bw/d based on a four-generation reproductive toxicity study in rats performed with benzoic acid (SCCP)		
Toxicological summary: Sodium benzoate is the sodium salt of benzoic acid. Sodium benzoate is classified by the Food and Drug Administration (FDA) as Generally Recognized as Safe (GRAS) as a direct food substance. In the EU it is also approved as a food preservative (E211). Therefore, it does not raise any concerns with regards to systemic toxicity when used in cosmetic products. According to the REACH dossier, sodium benzoate is not a skin irritant but it is slightly irritating to the eyes. No skin sensitisation potential is predicted based on a studies run on a structural analogue substance (benzoic acid). Sodium benzoate is not acutely toxic via oral route. It is not expected to be acutely toxic via dermal and inhalation routes based a read-across from benzoic acid. Both in vitro and in vivo studies show a lack of genotoxicity, carcinogenicity, toxicity to reproduction and developmental toxicity. The safety of sodium benzoate was reviewed by the CIR Expert Panel who concluded that it is safe as a cosmetic ingredient up to 1% in both leave-on and rinse-off products. The safety of sodium benzoate was also evaluated by the Scientific Committee on Consumer Products who reaffirmed that it is safe for preservative and non-preservative purposes in cosmetic rinse-off products at a max. concentration of 2.5%, in oral-care products at a max. concentration of 1.7% and in leave-on products up to 0.5%.		
EU hazard classification: No official classification in Annex VI of the CLP Regulation.	**Conclusion**: This ingredient is safe for use at the levels present in this product.	
References: 1. REACH dossier, Sodium benzoate, 2020 2. FDA: 21CFR184.1733 3. CIR, IJT 20(suppl 3):23-50, 2001 4. CIR, IJT 36(Suppl. 3):5-30, 2017 5. "Opinion on Benzoic Acid and Sodium Benzoate", Scientific Committee on Consumer Products, SCCP/0891/05, 2005		

<table>
<tr><th colspan="3">Nonapeptide-1</th></tr>
<tr><td>INCI: Nonapeptide-1</td><td>CAS #: -</td><td>EC #: -</td></tr>
<tr><td>COSING listed: Yes</td><td>MW: 1206.5 g/mol</td><td>Log Pow: No data available</td></tr>
<tr><td>LD50 oral: No data available</td><td>LD50 dermal: No data available</td><td>LC50 inhalation: No data available</td></tr>
<tr><td colspan="3">Cosmetic function: Skin conditioning, Hair conditioning</td></tr>
<tr><td colspan="3">Dermal absorption: Unlikely to be significant</td></tr>
<tr><td colspan="3">Regulatory restrictions in the EU: No restrictions</td></tr>
<tr><td colspan="3">NOAEL: No data available</td></tr>
<tr><td colspan="3">Toxicological summary: Nonapeptide-1 is a synthetic nonapeptide derived from arginine, lysine, methionine, phenylalanine, proline, tryptophan, and valine. Nonapeptide-1 is reported to inhibit melanin synthesis by interfering with the action of tyrosinase in melanocytes. Tyrosinase inhibition reduces the formation of unwanted pigmentation allowing for control over skin tone and brown spots. Nonapeptide-1 can reduce hyperpigmentation. At a concentration of 200 ug/mL, the ingredient is capable of fully inhibiting the synthesis of melanin in fungi. At 100 micromolar concentration, nonapeptide-1 can inhibit 25-35% of tyrosinase activity in animal models and can reduce the melanin content of melanocytes by 27-43%. Although there is no specific information with regards to dermal and eye irritation, dermal sensitisation, long-term toxicity, mutagenicity, carcinogenicity, and toxicity to reproduction for nonapeptide-1, based on the nature of this ingredient, there are no safety concerns. No significant toxicity is expected when used as a cosmetic ingredient.</td></tr>
<tr><td colspan="2">EU hazard classification: No official classification in Annex VI of the CLP Regulation.</td><td>Conclusion: This ingredient is safe for use at the levels present in this product.</td></tr>
<tr><td colspan="3">References: 1. Jayawickreme, C. K., Quillan, J. M., Graminski, G. F., & Lerner, M. R. (1994). Discovery and structure-function analysis of alpha-melanocyte-stimulating hormone antagonists. The Journal of biological chemistry, 269(47), 29846–29854.
2. M.C.Biotec Inc., Nonapeptide-1, http://www.mcbiotec.com/?t=view&id=96, accession date: 12 Oct 2023
3. Mohammed, Y. H., et al. (2017). Efficacy, Safety and Targets in Topical and Transdermal Active and Excipient Delivery. Percutaneous Penetration Enhancers Drug Penetration Into/Through the Skin: Methodology and General Considerations, 369–391.</td></tr>
</table>

11. Undesirable effects and serious undesirable effects

No undesirable or serious undesirable effects were reported for this product. According to the Regulation (EC) 1223/2009 and the Schedule 34 of the Product Safety and Metrology SI, it is required to document, determine the root-cause, and report any known undesirable or serious undesirable effects caused by this product.

12. Further information on the product

12.1 GMP Compliance

The product is manufactured in compliance with the Good Manufacturing Practices to ensure the quality and the safety of the product.

12.2 Animal testing

According to the declaration provided by the manufacturer, the product has not been tested on animals. The manufacturer ensured the raw materials used in the product were also not tested on animals.

12.3 Dermatological testing

In order to assess the irritation potential of the finished product, a 24 hrs occlusive patch test was carried out (study no. D01-6Q01-FL-NR20). In the group of 24 people who underwent the study, no adverse reactions of any kind were reported. The product indicated no potential to elicit dermal irritation.

12.4 Proof of claims

No safety related claims are present on the product label. All claims and statements present on the label have to be substantiated by the Responsible Person in accordance with the Regulation 655/2013 on cosmetic product claims.

Part B – Cosmetic product safety assessment

1. Assessment conclusion

Based on all data provided for the cosmetic product and in light of the present law and state of knowledge, it can be concluded that the product is safe for human health when used under normal and reasonably foreseeable conditions and it complies with the EU Cosmetic Regulation (EC) No 1223/2009 and the Schedule 34 of the Product Safety and Metrology SI. The safety assessment is not reliable for people who are allergic to any of the ingredients of the product.

2. Labelled warnings and instructions of use

Warnings and instructions of use present on the labels do not raise any concern and comply with the EU Cosmetic Regulation (EC) No 1223/2009 and the Schedule 34 of the Product Safety and Metrology SI. An obligatory warning indicating to avoid eye area has to be added due to the presence of Ethoxydiglycol (e.g., “Avoid eye area” or “Avoid contact with eyes”). No other obligatory warnings have to be added. Nevertheless, considering the product type it is recommended to add a warning “Do not apply immediately after shaving or waxing.”. The product does not belong to the group of products for professional use.

3. Reasoning

Normal and reasonably foreseeable consumer use

The product is an underarm deodorant. Product presentation and labelling clearly indicate the method of use and therefore using the product for different purpose is not expected. Based on the nature of the product, it is not expected to cause any safety concerns when used under normal and reasonably foreseeable scenarios.

Product labelling and claims

The artwork of the product has been provided and reviewed. Misuse as a foodstuff is not to be expected due to the packaging design. No safety related claims are present on the product label. All claims and statements present on the label have to be substantiated by the Responsible Person in accordance with the Regulation 655/2013 on cosmetic product claims.

Product packaging

No interaction is expected between the product and its packaging. No safety concerns are predicted for the product packaging. Compatibility of the packaging with the product has been confirmed during the stability testing.

Quantitative and qualitative composition

All ingredients used in the product are allowed for use in cosmetic products. They are used at permitted concentrations and are in line with the requirements of the EU Cosmetic Regulation (EC) No 1223/2009 and the Schedule 34 of the Product Safety and Metrology SI. The product contains no nanomaterials and no fragrance. The product contains no nanomaterials and no fragrance. The product contains salicylic acid which has been classified as a CMR substance (carcinogenic, mutagenic, or toxic to reproduction) of category 2 (Repr. 2). According to the Cosmetic Regulation 1223/2009, a substance classified in this category may be used in cosmetic products when the substance has been evaluated by the Scientific Committee on Consumer Safety (SCCS) and found safe for use in cosmetic products. Based on the latest SCCS opinion (SCCS/1601/18), salicylic acid is considered safe when used as preservative at a concentration of 0.5% in cosmetic products and for purposes other than preservative at a concentration up to 3.0% for the cosmetic rinse-off hair products and up to 2.0% for other products. In body lotion, eye shadow, mascara, eyeliner, lipstick and roll-on deodorant applications, salicylic acid is considered safe up to 0.5 %. Hence, the use of salicylic acid in the formula at 0.5% is compliant with current requirements (function in the product: keratolytic). Based on the available information the product contains no other substances defined as carcinogenic, mutagenic, or toxic to reproduction (CMR) except possibly technologically unavoidable trace amounts as manufacturing impurities, which are not

considered to present a significant health risk. No allergens are present in the product at concentration greater than 0.001% and should be declared on the label.

Impurities
The product contains technologically unavoidable trace amounts of impurities. Their concentrations do not exceed the maximum permitted and accepted limits. They do not affect the overall safety of the finished product and are not considered to present a significant health risk during normal and reasonably foreseeable use of the product. The heavy metals (HM) assay was performed on the final product, estimating the HM (Arsenic and Lead) content to be less than 22 ppm in the finished product.

Microbiological specifications
Performed microbiological testing confirmed the microbiological purity of the product and the effectiveness of the preservative system.

Product stability
The stability testing confirmed that the final product is stable.

Toxicological analysis
Toxicological profiles of ingredients used in the product were prepared based on the information included in the Material Safety Data Sheets, toxicological databases such as TOXNET, ECHA, HERA, PubMed and PubChem, and scientific opinions and publications of organizations like CIR (Cosmetic Ingredient Review), SCCS (Scientific Committee on Consumer Safety) or WHO (World Health Organization), as well as other available scientific literature. The toxicological profiles of individual components of the product do not raise any objections.

Exposure to the product was calculated according to the SCCS Notes of Guidance (SCCS/1647/22). The potential exposure (SED) was calculated for all the individual ingredients of the formulation. Margin of Safety (MoS) has been calculated for individual product ingredients for which a toxicological NOAEL is available. Where data are available, the MoS values calculated for each ingredient are in line with the SCCS recommendations. It is concluded that these substances are safe for human health. Substances for which the MoS value could not be calculated do not raise any safety concerns.

Reported UEs / SUEs
No undesirable or serious undesirable effects have been reported on this cosmetic product to date. In the case of this product causing a significant number of undesirable events or a serious undesirable event, the safety assessor should be informed, and a new assessment considered.

4. Assessor's credentials and approval of part B

	Written by	Approved by
Name and surname	**Małgorzata Wojciechowska**	**Sonia Antkowiak**
Qualifications*	• MSc Cosmetics Sciences, Maria Sklodowska-Curie Medical School in Warsaw, Poland, 2022 • European Professional Safety Assessor, Vrije Universiteit Brussel, Belgium, 2021 • Member of the Cosmetic, Toiletry and Perfumery Association (CTPA) on behalf of Freyr Solutions	• MSc Chemistry, University of Strathclyde, United Kingdom, 2013 • European Professional Safety Assessor, Vrije Universiteit Brussel, Belgium, 2016 • Member of the Cosmetic, Toiletry and Perfumery Association (CTPA) on behalf of Freyr Solutions
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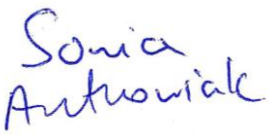
Date	17 May 2024	17 May 2024
Signature		

* CV and proof of qualification are available on request

Note: The safety assessment is valid only for a cosmetic product corresponding to the formula presented in Part A of this report. Any changes made to the formula will require this assessment to be updated. The product was not specifically assessed for use by children below 3 years old.