SAFETY ASSESSMENT OF COSMETIC PRODUCT

Cosmetic product listed below do not pose a risk to human health and meets the requirements of the Regulation of the European Parliament and Council Regulation (EC) No. 1223/2009 of 30 November 2009 relating to cosmetic products (Journal of Law UE L 342/59 with all amendments).

IDENTIFICATION OF THE PRODUCT AND COMPANY

DATE	2023-04-05
VERSION	1
NOTIFICATION No.	
PRODUCT NAME	**PROTECTIVE HAND CREAM WITH HEMP OIL RCP DEL/0033822**
PRODUCER	INDIA Cosmetics Europe Sp. z o. o. ul. Dworcowa 8A 62-023 Gadki, k. Poznania
RESPONSIBLE PERSON	INDIA Cosmetics Europe Sp. z o. o. ul. Dworcowa 8A 62-023 Gadki, k. Poznania

REMARK

1. Any qualitative and quantitative change in the composition, any changes in the scope or manner of use needs to be re-examined by a safety assessor.
2. This opinion does not apply to cases of people who have an allergy to any component of the product being evaluated.
3. With the current state of knowledge the safety assessor can only estimate that the cosmetic product does not have any foreseeable risk to human health under normal, foreseeable conditions of use.

DATE

5.04.2023

SIGNED BY

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Karol Brąszewski

Safety Assessor

PART A – COSMETIC PRODUCT SAFETY INFORMATION

1. QUANTITATIVE AND QUALITATIVE COMPOSITION OF THE COSMETIC PRODUCT

Trade name	Chemical name	CAS	EINECS/ ELINCS	INCI	Intended function	[%]
Water	Aqua	7732-18-5	231-791-2	Aqua	Solvent	AD 100%
DUB IPP/Radia 7732/Isopropyl Palmitate	Isopropyl Palmitate	142-91-6	142-91-6	Isopropyl Palmitate	Emollient	1%-5%
Paraffinum Liquidum	Paraffin oils. Liquid hydrocarbons from petroleum	8012-95-1 / 8042-47-5	232-384-2 / 232-455-8	Paraffinum Liquidum	Emollient	1%-5%
Belsil DM 350/ Mirasil DM 350/Xiameter PMX-200 Silicone Fluid 350CS/BRB Silicone Oil 350 cSt	Dimethicone, $CH_3[Si(CH_3)2O]nSi(CH3)3$, PDMS	9006-65-9	618-433-4	Dimethicone	Emollient, Skin Protecting	1%-5%
Glycerin	Glicerol, $C_3H_8O_3$	56-81-5	200-289-5	Glycerin	Humektant	1% – 5%
Alkinol B/Cosmowax D/Ercawax BM2	Mixture of cetyl alcohol $C_{16}H_{34}O$ and stearyl alcohol $C_{18}H_{38}O$	67762-27-0	267-008-6	Cetearyl Alcohol	Emulsifying	1% – 5%
	C16-18 alcohols, ethoxylated (20 mol EO average molar ratio)	68439-49-6	-	Ceteareth-20		0,1% – 1%
Bergabest MCT-Oil 60/40/Radia 7104/Myritol 318/ Palmester 3595/Rofetam GTCC/Ester 610	Decanoic acid, ester with 1,2,3-propanetriol octanoate; Glycerides, mixed decanoyl and octanoyl	73398-61-5/ 65381-09-1	277-452-2/ 265-724-3	Caprylic/Capric Triglyceride	Emollient	1% - 5%
Alkohol cetostearylowy C 1618/ Ercanol CS/ Lanette D	Mixture of cetyl alcohol $C_{16}H_{34}O$ and stearyl alcohol $C_{18}H_{38}O$	67762-27-0	267-008-6	Cetearyl Alcohol	Emulsifying	0,1% – 1%
Kahlwax 1540	Microcrystalline wax	63231-60-7	264-038-1	Cera Microcrystallina	Binder, emulsion stabilizer, rheology modifier, emollient	0,1% – 1%
	Hydrogenated vegetable fat	68334-28-1	269-820-6	Hydrogenated Vegetable Oil		0,1% – 1%
	Bee wax	8012-89-3	232-383-7	Cera Alba		0,1% – 1%
	Hydrogenated palm acid	84238-17-5	282-486-6	Hydrogenated Palm Acid		≤0,1%
	Stearyl stearate (stearyl alcohol ester)	2778-96-3	220-476-5	Stearyl Stearate		≤0,1%
Cannabis Oil	Cannabis Sativa Seed Oil is the fixed oil expressed from the seeds of Cannabis sativa L., Cannabaceae	89958-21-4	289-644-3	Cannabis Sativa Seed Oil	Emollient	0,1% – 1%

	Propane-1,2-diol	57-55-6	200-338-0	Propylene Glycol	Active ingredient	0,1% – 1%
Salvia Officinalis Extract	Salvia Officinalis Extract is an extract of the whole plant the Sage, Salvia officinalis L., Lamiaceae	8022-56-8 / 84082-79-1	282-025-9 / 282-025-9	Salvia Officinalis Extract		≤0,1%
	Propane-1,2-diol	57-55-6	200-338-0	Propylene Glycol		0,1% – 1%
Quercus Petraea Bark Extract	Quercus Petraea Bark Extract is an extract of the bark of the Oak, Quercus petraea, Fagaceae	90082-12-5	290-100-2	Quercus Petraea Bark Extract	Active ingredient	≤0,1%
D-Pantenol	H_2O	7732-18-5	231-791-2	Aqua	Solvent	0,1% - 1%
	(2R)-2,4-dihydroxy-N-(3-hydroxypropyl)-3,3-dimethyl-butanamide	81-13-0 / 16485-10-2	201-327-3 / 240-540-6	Panthenol	Skin Conditioning	0,1% - 1%
	2-Hydroxy-1,2,3-propanetricarboxylic acid	77-92-9 / 5949-29-1	201-069-1	Citric Acid	Buffering, Chelating	≤0,1%
Luvigel EM	H_2O	7732-18-5	231-791-2	Aqua	Solvent	0,1% - 1%
	Decanoic acid, ester with 1,2,3-propanetriol octanoate; Glycerides, mixed decanoyl and octanoyl	73398-61-5/ 65381-09-1	277-452-2/ 265-724-3	Caprylic/Capric Triglyceride	Emollient	0,1% - 1%
	Sodium Acrylates Copolymer is the sodium salt of a polymer consisting of acrylic acid, methacrylic acid or one of their simple esters	-	-	Sodium Acrylates Copolymer	Binding, Opacifying, Film Forming	0,1% - 1%
Rheocare C Plus	2-Propenoic acid, polymer with 2,2-bis(hydroxymethyl)propane-1,3-diol 2-propenyl ether	9007-20-9 / 9003-01-4 / 76050-42-5 / 9062-04-8 / 9007-16-3 / 9007-17-4	-	Carbomer	Gel forming, emulsion stabilising, viscosity controlling	0,1% - 1%
Metylparaben/Paridol M	Methyl 4-hydroxybenzoate	99-76-3	202-785-7	Methylparaben	Preservative	0,2%
Allantoina	(2,5-diokso-4-imidazolidyno)moczanik	97-59-6	202-592-8	Allantoin	Active ingredient	0,1% - 1%
Zielona Herbata D878/L	-	-	-	Parfum	Parfum	0,2%
Witamin E/Octan witaminy E	Tokoferol	7695-91-2 / 58-95-7	231-710-0 / 200-405-4	Tocopheryl Acetate	Active ingredient	≤ 0,1%

Propylparaben	Propyl 4-hydroxybenzoate	94-13-3	202-307-7	Propylparaben	Preservative	0,14%
Disodium EDTA	Disodium dihydrogen ethylenediaminetetra acetate	139-33-3 --- 6381-92-6	205-358-3	Disodium EDTA	Chelating	≤ 0,1%
Sodium Hydroxide	NaOH	1310-73-2	215-185-5	Sodium Hydroxide	pH regulator	≤ 0,1%
Bronopol	2-Bromo-2-Nitropropane-1,3-Diol	52-51-7	200-143-0	2-Bromo-2-Nitropropane-1,3-Diol	Preservative	0,03%

NAME AND CODE OF THE AROMATIC COMPOSITION: Zielona Herbata D878/L
IDENTITY OF THE SUPPLIER: Pollena Aroma

The list of potential allergens included in the aromatic composition (from the list of 26 potential allergens):

Chemical name	EINECS /ELINCS	CAS	INCI	Content in the composition [%]	Content in the finished product [%]
Benzyl Alcohol	202-859-9	100-51-6	Benzyl Alcohol	0,0025	0,0000050
2,6-Octadienal	**226-394-6**	**5392-40-5**	**Citral**	**0,5034**	**0,0010068**
Phenol, 2-methoxy-4-(1-propenyl)-	**202-590-7**	**97-54-1**	**Isoeugenol**	**0,8000**	**0,0016000**
Benzyl Salicylate	204-262-9	118-58-1	Benzyl Salicylate	0,1175	0,0002350
2,6-Octadien-1-ol	**203-377-1**	**106 - 24 - 1**	**Geraniol**	**3,0331**	**0,0060662**
2,6,10-Dodecatrien-1-ol, 3,7,11-trimethyl-	225-004-1	4602-84-0	Farnesol	0,0002	0,0000004
3,7-Dimethyl octa-1,6-diene-3-ol	**201-134-4**	**78 - 70 - 6**	**Linalool**	**1,5161**	**0,0030322**
3,7-Dimethyl-6-octen-1-ol	**203-375-0**	**106-22-9**	**Citronellol**	**10,075**	**0,0201500**
Aldehyd heksylocynamonowy	**202-983-3**	**101-86-0**	**Hexyl Cinnamal**	**7,0500**	**0,0141000**
d-Limonen	**227-813-5**	**5989-27-5**	**Limonene**	**8,6629**	**0,0173258**

The presence of the ingredients included in aromatic composition must be indicated in the list of ingredients referred to in Article 19(1)(g) of Regulation 1223/2009 when its concentration exceeds:
— 0,001 % in leave-on products
— 0,01 % in rinse-off products

2. PHYSICAL/CHEMICAL CHARACTERISTIC AND STABILITY OF THE COSMETIC PRODUCT

2.1. THE PHYSICAL AND CHEMICAL CHARACTERISTIC OF RAW MATERIALS AND MIXTURES

The Material Safety Data Sheets (MSDS) and Certifications of Analysis (CoA) allows for full identification of all substances used in production of this cosmetic product. These documents contain the detailed characteristic and description of physicochemical properties as well as information about additional (intentional added) substances or impurities. Documents provided by suppliers constitute the integral part of this report.

2.2. THE PHYSICAL AND CHEMICAL CHARACTERISTIC OF FINISHED COSMETIC PRODUCT

Property	Test method	Requirement	Result
Appearance	organoleptic	A homogeneous white cream without impurities	Consistent
Odour	organoleptic	Characteristic of the fragrance composition used	Consistent
pH (20° C)	According to internal instruction I.R5.01	5,4 – 6,1	Consistent
Density (20° C)	According to internal instruction I.R5.04	0,92 -1,02 g/cm^3	Consistent
Stability (5 °C)	According to internal instruction I.R9.01	No changes in appearance, colour, odour	Consistent
Stability (room temperature)	According to internal instruction I.R9.01	No changes in appearance, colour, odour	Consistent
Stability (40° C)	According to internal instruction I.R9.01	No changes in appearance, colour, odour	Consistent

2.3. THE STABILITY OF THE COSMETIC PRODUCT UNDER REASONABLY FORESEEABLE STORAGE CONDITIONS

The stability and compatibility of the mass of **PROTECTIVE HAND CREAM WITH HEMP OIL RCP DEL/0033822** in the final packaging were tested according to the internal instruction F.I.R9.01 „Estimation of the stability of the cosmetic product". Results were placed into the form no. F.I.R9.01.01. The final evaluation was determined after three months of storage in different temperatures: + 5° C, room temperature and + 40° C. No change in investigated parameters was observed after the end of the test. The product was stable and compatible with the package.
On the basis of these results the expiry date and storage conditions were determined:

Expiry date: 36 months

Period after opening (PAO) was estimated according to internal instruction I.R9.03 „Method for PAO determination". The results were placed in the form F.I.R9.03.01 „Test confirmation of the

stability of the cosmetic product – PAO determination"

PAO: 6M
Storage conditions: od +5 °C do +25 °C

3. MICROBIOLOGICAL QUALITY

3.1. Microbiological investigation

Each batch of the cosmetic product **PROTECTIVE HAND CREAM WITH HEMP OIL RCP DEL/0033822** being produced, is under microbiological control. The microbiological quality of the product complies with the requirements posed on category[1] II of the cosmetic products, according to the Regulation of the Parliament and of the Council (WE) no 1223/2009 (with all amendments). The product under control fulfils the requirements of the norm ISO 17516:2014. Raw materials used in the formulation are subject to the microbiological purity control as well.

[1] – category I: products dedicated for children < 3 years old, applied around eyes and/or mucous membranes. The total count of the mesophilic aerobic microorganisms shall not exceed 100 cfu/g or ml of the product. Absence of the pathogenic bacteria in 0,1 g or 0,1 ml of the product.
- category II: all other products. The total count of the mesophilic aerobic microorganisms shall not exceed 1000 cfu/g or ml of the product. Absence of the pathogenic bacteria in 0,1 g or 0,1 ml of the product.

3.2. Results of the preservation challenge test.

The challenge test was carried out according to norm PN-EN ISO 11930:2012 by JARS
Challenge test report number: **1488/01/2014/M/4**

Conclusion:
The product fulfils the requirements of category A of the antimicrobial activity against all strains of the bacteria and fungi under investigation.

4. IMPURITIES, TRACES, INFORMATION ABOUT THE PACKAGING MATERIAL

Avoiding impurities / traces of prohibited substances present in raw materials is impossible for technical reasons. Only raw materials of the highest quality were chosen for the production process. Impurities / traces of prohibited substances, other than described, that may affect the safety of the product should not be expected.

All impurities of raw materials are in accordance with actual law requirements, and do not pose a threat to human health.

From the point of view of compatibility of the cosmetic product with the packaging, essential elements of packaging having direct contact with the ground they are:

Producer	Witoplast		
Packaging	**Type of packaging**	**Type of the material**	**Impurities / traces of prohibited substances**
	Tube 100ml	PE	1. Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. 2. Commission Regulation (EU) No 10/2011 of 14 January 2011 on materials and articles intended to came into contact with food. 3. Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food. 4. Resolution of the council of Europe AP89 (1). 5. Directive 94/62/WE of the European Parlament andof the Council of 20 December 1994 on packaging and packaging waste.
	Head	Polyethylene copolymer	
	Cap	PP	
Interactions between cosmetics mass and packaging	Evaluation was performed after three months of storage of the product at temperatures of + 5 ° C, room temperature and + 40 ° C. After the end of the storage period, investigated parameters were identical to the initial values. The cosmetic mass was found to be compatible with the packaging.		

The packaging material is appropriate for use as a primary packaging of the cosmetic product. Impurities or instabilities that could affect the safety of the finished product are not expected. The compatibility of the cosmetic mass and packaging material has been confirmed in the physicochemical studies of the stability performer for the final packaging or for container of the same material. There was no effect of packaging on the stability or efficacy of the product preservation. There was no direct packaging impact on product safety and quality.
On the basis of the documentation collected it shows that one should not expect the migration of substances from / to the material, which may affect the safety of the product.

5. NORMAL AND REASONABLY FORESEEABLE USE

The product **PROTECTIVE HAND CREAM WITH HEMP OIL RCP DEL/0033822** is intended for skin care of the hands. Destination of the cosmetic product directly results from name and appearance of the product. In addition, an accurate description of how to use the product was printed on the packaging. Other application is not expected.

6. EXPOSURE TO THE COSMETIC PRODUCT

Exposure to the cosmetic product was evaluated in accord with the guideline SCCS/1564/15 (The SCCS's note of guidance for the testing of cosmetic substances and their safety evaluation 9th revision).

The sites of application	Hands
The target and exposed population	Adults
Type of the product	Leave on product
Area of exposure	860 cm^2
The normal an reasonably foreseeable exposure routs	Through skin
Retention factor (R)	1
The amount of product applied	2.16 g per day
The duration and frequency of use	2 times per day
Calculated relative daily exposure	32,70 mg/kg bw/day

Calculation of the Margin of Safety:

$$\text{SED [mg/kg bw/day]} = \text{A [mg/kg bw/day]} \times \text{C [\%/100]} \times \text{DAp [\%/100]}$$

$$MoS = \frac{NOAEL}{SED}$$

where:

A – daily exposition

C – concentration of the ingredient in the finished product

DAp – epidermis absorption (in case of the lack of data on penetration of individual components, the total absorption (100%) should be taken into account)

SED - Systemic Exposure Dosage

NOAEL - No Observable Adverse Effect Level

7. EXPOSURE TO THE SUBSTANCES

Data on the exposure to the substances contained in the cosmetic product for the relevant toxicological endpoints taking into account the information under Section 6.

INCI	MoS	Source
Aqua	Water is used as solvent. Topical toxicity is irrelevant. Water quality is regulated under Regulation of the Ministry of Health on 29th Match 2007 (Dz.U.10.72.466). **This ingredient used in the declared concentration does not pose the risk to the human health.**	www.mz.gov.pl
Isopropyl Palmitate	A = 32,70 mg/kg bw/day DAp = 100% SED = 1,635 mg/kg bw/day NOAEL = 1000 mg/kg bw/day **MoS = 611,62** **This ingredient used in the declared concentration does not pose the risk to the human health.**	ECHA
Paraffinum Liquidum	A = 32,70 mg/kg bw/day DAp = 100% NOAEL = 1600 mg/kg bw/day SED = 1,635 mg/kg bw/day **MoS = 978,59** **This ingredient used in the declared concentration does not pose the risk to the human health.**	ECHA
Dimethicone	Dimethylpolysiloxane. The concentration up to 24% in the cosmetic products has been approved by Cosmetic Ingredient Review (CIR) to be safe for human health. The substance is not subject to any restrictions of the Regulation no. 1223/2009. A= 32,70 mg/kg bw/day SED = 1,635 mg/kg bw/day **This ingredient used in the declared concentration does not pose the risk to the human health.**	CIR
Glycerin	Glycerine is one of the basic substance present in all living organisms. It is one of the major building blocks of fats and one of the metabolites. Glycerol is also one of the products of metabolism of glucose. Glycerine was assessed by many international organizations including WHO, JECFA and European SCF- National Centre for Ecotoxicology & Hazardous Substances. It has a GRAS status - 21CFR182.1320. A = 32,70 mg/kg bw/day DAp = 100% NOAEL = 2000 mg/kg bw/day SED =1,635 mg/kg bw/day **MoS = 1223,24**	ECHA, CIR, HSDB Database

	This ingredient used in the declared concentration does not pose the risk to the human health.	
Cetearyl Alcohol	The margin of safety is calculated based on the read-across approach. The toxicological data for alcohols C16-18 were applied. A= 32,70 mg/kg bw/day NOAEL = 1000 mg/kg bw/day SED = 1,962mg/kg bw/day **MoS = 509,68** **This ingredient used in the declared concentration does not pose the risk to the human health.**	ECHA
Ceteareth-20	A= 32,70 mg/kg bw/day NOAEL = 100 mg/kg bw/day SED = 0,327 mg/kg bw/day **MoS = 305,81** **This ingredient used in the declared concentration does not pose the risk to the human health.**	HERA
Caprylic/Capric Triglyceride	A = 32,70 mg/kg bw/day DAp = 100% NOAEL = 1000 mg/kg bw/day SED = 1,962 mg/kg bw/day **MoS = 509,68** **This ingredient used in the declared concentration does not pose the risk to the human health.**	ECHA
Hydrogenated Vegetable Oil	The CIR Expert Panel recognized the hydrogenated vegetable oil raw material as safe for use in cosmetic products in an amount from 0.0004% to 60%. A quantitative risk assessment is not necessary. A= 32,70 mg/kg bw/day DAp = 100% SED = 0,327 mg/kg bw/day **This ingredient used in the declared concentration does not pose the risk to the human health.**	CIR
Cera Microcristallina	A = 32,70 mg/kg bw/day DAp = 100% NOAEL = 2000 mg/kg bw/day SED = 0,327 mg/kg bw/day **Mos = 6116,21** **This ingredient used in the declared concentration does not pose the risk to the human health.**	EFSA, FDA
Cera Alba	When calculating the safety margin, the read-across approach was used (for Beeswax). The CIR Expert Panel recognized this raw material as safe for use in cosmetic products in a concentration not exceeding 18%. A = 32,70 mg/kg bw/day DAp = 100% NOAEL = 1000 mg/kg bw/day SED = 0,327 mg/kg bw/day **MoS = 2666,67**	CIR

	This ingredient used in the declared concentration does not pose the risk to the human health.	
Hydrogenated Palm Acid	Read across analysis was carried out as for Hydrogenated Palm Oil. A panel of CIR experts stated that in the current use and concentration described in report 03/11, 244 oils of vegetable origin and fatty acids derived from them are considered safe. This raw material can be used in cosmetic products in a concentration of 0.2 to 30%. A= 32,70 mg/kg bw/day DAp = 100% SED = 0,0327 mg/kg bw/day **This ingredient used in the declared concentration does not pose the risk to the human health.**	IJT 19(S2):7-28, 2000; CIR, Final amended report 03/11
Stearyl Stearate	The CIR Expert Panel recognized Stearyl Stearate as safe for use in cosmetic products in an amount of 0.02% to 4%. A= 32,70 mg/kg bw/day DAp = 100% SED = 0,0327 mg/kg bw/day **This ingredient used in the declared concentration does not pose the risk to the human health.**	CIR, Final report 08/10
Cannabis Sativa Seed Oil	A= 32,70 mg/kg bw/day DAp = 100% **SED = 0,327 mg/kg bw/day** Mixture of triglycerides of octanoic and decanoic acid.The substance is not classified as harmful to human health or the environment **This ingredient used in the declared concentration does not pose the risk to the human health.**	De Wit Speciality Oils b.v., MSDS Hemp Seed Oil, Safety and Side Effects of Cannabidiol, a Cannabis sativa Constituent
Parfum	Composition Zielona Herbata D878/L applied according to International Fragrance Association recommendations. The amount used does not raise any objections. Quantitative risk assessment is not necessary. **This ingredient used in the declared concentration does not pose the risk to the human health.**	IFRA
Propylene Glycol	A = 32,70 mg/kg bw/day DAp = 100% NOAEL = 1700 mg/kg bw/day SED =0,654 mg/kg bw/day **MoS = 2599,39** **This ingredient used in the declared concentration does not pose the risk to the human health.**	INCHEM
Salvia Officinalis Extract	A = 32,70 mg/kg bw/day SED = 0,0327 mg/kg bw/day **This ingredient used in the declared concentration does not pose the risk to the human health.**	EMEA

Quercus Petraea Bark Extract	A = 32,70 mg/kg bw/day SED = 0,0327 mg/kg bw/day **This ingredient used in the declared concentration does not pose the risk to the human health.**	MSDS
Panthenol	CIR Expert Panel stated that panthenol is safe in concentrations up to 25%. FDA listed panthenol as a food additive. Panthenol is classified as a substance that has no adverse influence on human health, by Environment Canada. A = 32,70 mg/kg bw/day DAp = 100% NOAEL = 200 mg/kg bw/day SED = 0,327mg/kg bw/day **MoS = 611,62** **This ingredient used in the declared concentration does not pose the risk to the human health.**	ECHA, CIR
Citric Acid	A = 32,70 mg/kg bw/day DAp = 100% NOAEL = 1200 mg/kg bw/day SED = 0,0327 mg/kg bw/day **MoS =36697,25** **This ingredient used in the declared concentration does not pose the risk to the human health.**	ECHA
Sodium Acrylates Copolymer	Sodium salt copolymer of acrylic acid and methacrylic acid. Positively approved by the American Cosmetics Ingredients Review, which oversees the safety of using cosmetic raw materials. In the application conditions, the amount used does not raise any objections, and a quantitative risk assessment is not required due to lack of systemic bioavailability. It is not a subject of restrictions imposed by Regulation 1223/2009. A = 32,70 mg/kg bw/day DAp = 100% NOAEL = no data SED = 0,327 mg/kg bw/day **MoS = undetermined** **This ingredient used in the declared concentration does not pose the risk to the human health.**	CIR
Carbomer	A = 32,7 mg/kg bw/day SED = 0,327 mg/kg bw/day NOAEL = 2000 mg/kg bw/day **MoS = 6116,21** **This ingredient used in the declared concentration does not pose the risk to the human health.**	CIR
Methylparaben	Methylparaben is a preservative listed in Annex V of the Regulation of the European Parliament and of the Council (WE) No 1223/2009, position 12. Its maximum safe concentration cannot exceed 0,4% for individual paraben and 0,8% as a sum of parabens.	Regulation 1223/2009/EC

	A = 32,7 g/kg bw/day DAp = 100% SED = 0,0654 mg/kg bw/day **This ingredient used in the declared concentration does not pose the risk to the human health**	
Allantoin	Allantion is an active substance widely used in cosmetic products. It supports the regeneration and reconstruction of the epidermis and has a strong moisturizing effect. The amount of 2% has been approved by the US Cosmetics Ingredients Review supervising the safety of cosmetic ingredients. Allantoin is an endogenous substance in the human body. Quantitative risk assessment is not required. A = 32,70 mg/kg bw/day DAp = 100% SED = 0,327 mg/kg bw/day **This ingredient used in the declared concentration does not pose the risk to the human health.**	CIR, ECHA
Tocopheryl Acetate	The FDA has placed vitamin E on the list of GRAS (Generally recognized as safe) ingredients. Also, the CIR Expert Panel recognized vitamin E and its derivatives as safe for use in cosmetics and the food industry. A = 32,70 mg/kg bw/day DAp = 100% NOAEL = 500 mg/kg bw/day SED =0,327 mg/kg bw/day **MoS = 1543,21** **This ingredient used in the declared concentration does not pose the risk to the human health.**	ECHA
Propylparaben	Conservant listed in Annex V (item 12) to Regulation (EC) No 1223/2009 as amended. Approved to use up to 0.14% (as acid). The manufacturer has complied with the applicable restrictions. The amount applied under the application conditions does not raise any objections. Quantitative risk assessment is not necessary. A = 32,70 mg/kg bw/day DAp = 100% SED = 0,04578 mg/kg bw/day **This ingredient used in the declared concentration does not pose the risk to the human health.**	Regulation 1223/2009/EC (Annex V/12)
Disodium EDTA	A = 32,70 mg/kg bw/day DAp = 100% NOAEL = 500 mg/kg bw/day SED = 0,0327 mg/kg bw/day **MoS = 15290,52** Disodium salt of ethylenediaminetetraacetic acid. It is a typical compound chelating metal ions of con-nections and iron. Widely used in cosmetics and pharmacy as a substance that removes the use of	CIR, ECHA

	heavy metals. FDA approved as a food additive (preservative (OECD 422)). Concentration covered by the guarantee according to CIR report <36% **This ingredient used in the declared concentration does not pose the risk to the human health.**	
Sodium Hydroxide	Sodium hydroxide is on the list of Annex III of Regulation 1223/2009, point 15a. Its maximum concentration for the buffering function is determined by the pH of the finished product. The pH must not exceed 12,7. A = 32,70 mg/kg bw/day DAp = 100% NOAEL = 373 mg/kg bw/day SED = 0,0327mg/kg bw/day **MoS = 11406,73** **This ingredient used in the declared concentration does not pose the risk to the human health.**	ECHA, Regulation of the European Parliament and of the Council (WE) No 1223/2009
2-Bromo-2-Nitropropane-1,3-diol	2-Bromo-2-Nitropropane-1,3-diol is a preservative listed in Annex V under item 21 of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council. Its maximum permissible concentration in the finished cosmetic product may be 0.1%. A = 32,70 mg/kg bw/day DAp = 100% SED = 0,00981 mg/kg bw/day **This ingredient used in the declared concentration does not pose the risk to the human health.**	Regulation 1223/2009/EC (Annex V/21)

None of the ingredients used by the producer is either in the list of the prohibited substances (Annex II of the Regulation of the Parliament and the Council (WE) No 1223/2009), or on the list of substances classified as CMR (Carcinogenic – Mutagenic – Reprotoxic, Regulation of the European Parliament and of the Council (WE) No 1272/2008).

8. TOXICOLOGICAL PROFILE OF THE SUBSTANCES

Only the toxicological profile of the substances not listed in Regulation 1223/2009 are described.

INCI	Toxicological data	Information source
Aqua	Water serves as a solvent. In the field of topical application its toxicity is irrelevant from the toxicological point of view. The quality of water is determined by the Ordinance of the Minister of Health of 29 March 2007 (Dz.U.10.72.466).	**www.mz.gov.pl**
Isopropyl Palmitate	**Acute toxicity** **orally:** LD_{50} (rat) > 64 ml/kg LD_{50} (mouse)> 5000 mg/kg **inhalation:** LC_{50} (rat) > 5000 mg/l **Irritating and corrosive** Skin: non-irritating (rabbit, OECD 404) eyes: not irritating (rabbit, OECD 405) **Skin sensitization** - non-sensitizing Absorption through the skin - creates an occlusive layer on the skin, does not penetrate the skin. **Repeated dose toxicity -** NOAEL = 1000 mg/kg bw/day **Mutagenic / genotoxic effects -** in-vitro: negative Ames-Test The product has not been tested. The statement is based on substances / products of similar structure or composition. **Carcinogenicity** Of the total information recorded, no indication of a carcinogenic effect is evident **Reproductive toxicity** - On the basis of the information presented, the product is not toxic to reproduction **Toxicokinetics** Metabolized by beta-oxidation **Phototoxicity** - does not cause photoallergy	CIR, ECHA, TOXNET
Paraffinum Liquidum	**Acute toxicity** oral: LD_{50} rat > 5000 mg/kg (OECD 401) dermal: LD_{50} rabbit > 2000 mg/kg (OECD 402) inhalation: LC_{50} rat > 5 ml/l air/4h (OECD 403) **Irritation and corrosivity** skin: not irritating (rabbit, OECD 404) eyes: irritation transient completely after 72h, classified as non-irritant (rabbit, OECD 405) **Skin sensitisation** Not sensitising (guinea pig, Buehler test, OECD 406) **Dermal/percutaneous absorption** No dermal absorption **Repeat dose toxicity** NOAEL rat 1600 mg/kg bw/day (oral route, 13 weeks, OECD 408) NOAEL rat 2000 mg/kg bw/day (dermal rout, 13	ECHA, HSDB

	weeks, OECD 411) **Mutagenicity/genotoxicity** *in vitro:* negative (*S.typhimurium*, Ames test, OECD 471) *in vivo:* negative (rat, Chromosome aberration asay) **Carcinogenicity** Highly refined base oils are not carcinogenic via oral, dermal, or inhalation exposures (OECD 453). NOAEL rat 1200 mg/kg bw/day **Reprotoxicity** Toxicity to reproduction: NOAEL rat 2000 mg/kg bw/day (dermal rout, generation F1, OECD 415) Developmental toxicity/ Teratogenicity No adverse effects were noted on reproductive parameters or on the in utero suvival or development of the offspring. The developmental NOAELs are greater than or equal to the highest dose tested **Toxicokinetics** Metabolized and excreted **Photo-induced toxicity** No data	
Dimethicone	**Acute toxicity** oral: LD_{50} > 17 g/kg bw, rat Dermal: LD_{50} > 2000 mg/kg bw, rabbit **Irritation and corrosion** dermal: Dimethicone may cause slight irritation (rabbit) or no irritation (human, patch tests) eye: Dimethicone is irritating to eyes. Irritation is reversible after 24h (rabbit) **Skin sensitization:** Dimethicone does not induce sensitization (maximization test of the Magnusson-Kligmann type on genuine pigs) **Dermal/percutaneous absorption:** No data. **Repeat dose toxicity:** Oral: No toxic effects detected after addition of 10% of dimethicone into the diet of rats and mice for 90 days. The dose of 3 g/kg bw/day for six months administrated to dogs caused a toxic influence on liver cells. **Mutagenicity/genotoxicity:** *In vitro:* negative (Ames test on *S. typhimurium*) *In vivo:* negative (mouse, micronucleus test) **Carcinogenicity:** Dimethicone is not carcinogenic. It is not classified as CMR (Carcinogenic/Mutagenic/Reprotoxic). **Reproduction toxicity:** Tests on rabbits and rats do not indicate any of such properties.	ECHA, HSDB

	Toxicokinetics (ADME analysis): No data. It is not absorbed and metabolized. **Photo-induced toxicity:** No photo-induced toxicity.	
Glycerin	Glycerine is a natural alcohol, widely used in the cosmetics industry. It has excellent moisturizing properties. It has the ability to penetrate the stratum corneum, thus acts as a promoter of penetration – it facilitates transport of other substances into the skin. Also acts as a humectant - it prevents crystallization and drying of the mass of cosmetics, eg. at the mouth of the bottle. **Acute toxicity:** oral: LD_{50} = 12.6 g/kg bw, rat LD_{50} = 4.1 g/kg bw, mouse LD_{50} = 7.75 g/kg bw, Guinea pig LD_{50} = 27 g/kg bw, rabbit Inhalation: LC_{50} = 570 mg/m3, duration: 1h, rat Dermal: LD_{50} = 56.75 g/kg bw, rabbit Intravenous: LD_{50} = 4.25 g/kg bw, mouse LD_{50} = 0.05 g/kg bw, rat Intraperitoneal: LD_{50} = 4.42 g/kg bw, rat **Irritation and corrosivity:** dermal: Glycerine is not irritating to the skin. Applied to the shaved skin of albino rabbits did not cause any symptoms eye: Glycerine applied directly to the membrane does not irritate the eyes. **Skin sensitisation:** There is no data in the literature about any sensitizing properties of glycerol. It is not suspected of such properties. **Dermal/percutaneous absorption:** Glycerine is very well absorbed by the skin. **Repeat dose toxicity:** Oral: NOAEL = 8 g/kg bw/day, rat Long-Evans, duration of the test: 2 years Inhalation: NOAEL = 167 mg/m3 of air, rat Sprague-Dawley Dermal: NOAEL = 5040 mg/kg bw/day, rabbit, duration – 90 days **Mutagenicity/genotoxicity:** *In vitro:* Ames test on Salmonella typhimurium - negative *In vivo:* Test on rats – negative. Glycerine is neither genotoxic nor mutagenic. **Carcinogenicity:**	Baza ECHA, raport CIR, baza HSDB

	Glycerine given to rats at concentrations up to 20% for 1 year or 10 g / kg for 2 years did not cause an increase in cancer cases. Glycerine does not have carcinogenic properties and is not classified as CMR (Carcinogenic/Mutagenic/Reprotoxic). **Reproduction toxicity:** Numerous studies on reproduction in rats and mice (multi generations) did not show any harmful properties for reproduction and fertilization. **Toxicokinetics (ADME analysis):** Glycerine is one of the basic substance present in all living organisms. It is one of the major building blocks of fats and one of the metabolites. Glycerol is also one of the products of metabolism of glucose. It does not bioaccumulate. It is a part of natural and basic thermodynamic cycles occurring in living organisms. **Photo-induced toxicity:** No literature data. Glycerine is not suspected of having such properties.	
Cetearyl Alcohol	**Acute toxicity:** oral: LD_{50} = 6000 - 10000 mg/kg bw, rat, data for alcohols C16-18, read-across approach Dermal: LD_{50} = 2000 - 5200 mg/kg bw, rabbit, data for alcohols C16-18, read-across approach LD_{50} = 800 - 5000 mg/kg bw, rat, data for alcohols C16-18, read-across approach **Irritation and corrosivity:** dermal: Cetearyl alcohol does not irritate the skin (rabbit, OECD 404). Cetearyl Alcohol is classified as non-irritating. eye: Cetearyl alcohol slightly irritate the eye mucous membrane (rabbit, OED 405). Cetearyl Alcohol is classified as non-irritating. **Skin sensitisation:** Cetearyl Alcohol does not exhibit any sensitisation properties – negative results of the maximization test on genuine pigs. Draize test on human – negative result (clinical tests on 25 volunteers). **Dermal/percutaneous absorption:** No data. Cetearyl Alcohol is not suspected of being absorbed through the skin. It forms the thin film layer on the surface so the skin. **Repeat dose toxicity:** Oral: NOAEL = 1000 mg/kg bw/day (rat, duration of the test: 90 days, OECD 408, the value is determined for alcohols C16-18). **Mutagenicity/genotoxicity:** *In vitro:* Ames test on *Salmonella typhimurium* – negative (OECD 471) *In vivo:*	IUCLID, CIR, HERA, ECHA, MSDS BASF

	Test on mouse – negative (OECD 474, data derived for alcohols C16-18) **Carcinogenicity:** Cetearyl alcohol does not have carcinogenic properties. It is not classified as CMR (Carcinogenic/Mutagenic/Reprotoxic). **Reproduction toxicity:** NOAEL = 2000 mg/kg bw/day, rat, (OECD 422 – reproduction toxicity, maternal toxicity, teratogenicity, data obtained for alcohols C16-18). **Toxicokinetics (ADME analysis):** Cetearyl alcohol is included in one of the basic metabolic pathways. **Photo-induced toxicity:** No literature data. The structure of this compounds does not suggest any possible photo-induced toxicity properties.	
Ceteareth-20	**Acute toxicity** oral: LD_{50} > 2000 mg/kg bw, rat Dermal: LD_{50} = 800 - 5000 mg / kg bw, rat LD_{50} = 2000 - 5000 mg / kg bw, rabbit **Irritation and corrosion** dermal: Ceteareth-20 slightly irritate the skin (rabbit). eye: Ceteareth-20 irritates the eyes (rabbit, pure substance). Ceteareth-20 is practically non-irritating in the usual concentrations in cosmetics. **Skin sensitization:** Ceteareth-20 is not sensitizing to the skin (maximization test on genuine pigs). **Dermal/percutaneous absorption:** DAp = 10% **Repeat dose toxicity:** Oral: NOAEL = 100 mg/kg bw/day (rat, duration of the test: 90 days, OECD 408) **Mutagenicity/genotoxicity:** *In vitro:* Ames test on *Salmonella typhimurium* – negative (OECD 471) *In vivo:* negative **Carcinogenicity:** Ceteareth-20 does not induce any carcinogenic changes. It is not classified as CMR (Carcinogenic/Mutagenic/Reprotoxic). **Reproduction toxicity:** NOAEL = 250 mg/kg bw/day, rat, (reproduction toxicity). **Toxicokinetics (ADME analysis):** Ceteareth-20 is excreted with urine and faces. **Photo-induced toxicity:** No literature data.	IUCLID, HERA, CIR
Caprylic/Capric	**Acute toxicity**	CIR

Triglyceride	orally: LD_{50}> 5000 mg / kg mouse LD_{50}> 5000 mg / kg rat Wistar inhalation: LC_{50}> 1.86 mg / l of air, time inhalation - 6h dermal: LD_{50}> 2000 mg / kg rat Wistar **Irritation and corrosivity:** dermal: The component does not have irritating properties when tested in rabbits. eyes: The component does not have irritating properties when tested in rabbits. **Skin sensitisation:** The component does not exhibit sensitizing based on tests performed on guinea pigs (Buehler test, OECD 406). **Dermal absorption** No literature data. This ingredient forms a thin layer on the skin. **Repeated dose toxicity** orally: NOAEL = 5000 mg / kg bw / day; Wistar rat (OECD 408). NOAEL = 5000 mg / kg bw / day; male Fischer 344 rat. **Mutagenic / genotoxic** In vitro tests for the strains *Sallmonella typhimurium* were negative. Raw material does not induce chromosomal aberrations in mammalian cells - does not indicate mutagenic potential. **Carcinogenicity:** No scientific data. Not classified as CMR Cat. 1 or 2. **Reproduction toxicity:** NOAEL = 5000 mg / kg bw / day for rats NOAEL = 15000 mg / kg bw / day for mice - test duration - 13 weeks NOAEL = 1000 mg / kg bw / day for rats - developmental toxicity **Toxicokinetics (ADME studies):** Raw material involved in the metabolic pathway of fats. Is hydrolysed to glycerol and fatty acids. **Photo-induced toxicity:** No scientific data.	
Ethylhexylglycerin	**Acute toxicity:** oral: LD_{50} > 2000 mg/kg bw (female rats Wistar) inhalation: LC_{50} > 3,07 mg/l of air (rat Sprague-Dawley) dermal: LD_{50} > 2000 mg/kg bw (rat Wistar) **Irritation and corrosivity:** dermal: Not irritant. In vivo tests on the skin of rabbits of New Zealand White compound showed no irritating the skin.	MSDS BRENNTAG, CIR

	eye: Not irritant. Irritation of the substance on a scale of 0 to 4 for the eyes of rabbits New Zealand White amounted to 0. **Skin sensitisation:** No allergic reaction were detected on pigs breed Pil Bright White. The substance was applied to the skin and intradermally. Readings were made after 24 and 48 hours. Numerous tests HRIPT cosmetic products containing in its composition Ethylhexylglycerin were negative. Ethylhexylglycerin does not exhibit photoallergenic after application to the skin of guinea pigs in the presence of UVA and UVB rays. **Dermal/percutaneous absorption:** Ethylhexylglycerin very poorly absorbed through the skin. Only 0.025% of the substance is absorbed by 6 hours after application to the skin of rabbits. After 24 hours the concentration of the substance is below the detection limit. The average rate of penetration through human skin are (depending on concentration), 2.38, 8.19 and 20.38 mg / cm2 / h. **Repeat dose toxicity:** oral: NOAEL = 100 mg/kg bw/day (rat, 28 days) LOAEL = 50 mg/kg bw/day (rat Sprague-Dawley, 13 weeks) **Mutagenicity/genotoxicity:** Ames tests with and without metabolic activation were negative. Ethylheksylglycerin is also not clastogenic (research on Chinese hamster lung cells). **Carcinogenicity:** No data. This substance is not classified as CMR (Carcenogenic/Mutagenic/Reprotoxic). **Reprotoxicity:** NOAEL = 50 mg/kg bw/day (rat, developmental toxicity) **Toxicokinetics:** No data. **Photo-induced toxicity:** The substance does not exhibit phototoxic properties on skin of guinea pigs in the presence of UVA. Checked concentration were up to 100%.	
Hydrogenated Castor Oil	**Acute toxicity** no toxic effect **Irritating effect** skin: not irritating eyes: not irritating **Skin sensitization** It is not skin sensitizing **Absorption through the skin** No data **Repeated dose skin toxicity** No data **Mutagenic / genotoxic effects** It has no genotoxic effect **Carcinogenic effects**	CIR

	Not classified as CMR **Harmful effect on reproduction** It is not harmful to reproduction **Toxicokinetics** No data **phototoxicity** No data	
Cera Microcristallina	**Acute toxicity** LD50 rat (oral)> 2000 mg / kg **Irritant / corrosive effects** skin: may slightly irritate, the effect disappears completely after 72 hours, classified as non-irritating (rabbit), non-irritating (human) eyes: slightly irritant, classified as non-irritant (rabbit) **Skin sensitization** no data **Absorption through the skin** no data **Repeated dose toxicity** NOAEL rat 1850 mg / kg bw / day (90 days, oral route) **Carcinogenic effects** It is not carcinogenic **Genotoxic / mutagenic effects** It is not genotoxic **Harmful effect on reproduction** Based on read across analysis, low viscosity mineral oil is not harmful to reproduction and fetal development **Toxicokinetics** The panel of experts, due to the large number of carbon atoms, estimates slight absorption **phototoxicity** No data	MSDS Biesterfeld, EFSA
Cera Alba	A read-across approach for Besswax **Acute toxicity** no acute toxicity **Irritant / corrosive effects** eyes / mucous membranes: causes slight irritation skin: does not cause irritation **Skin sensitization** Has no sensitizing effect **Absorption through the skin** no data **Repeated dose toxicity** NOAEL of 1000 mg / kg bw / day JECFA based on a NOEL of 1200 mg / kg bw / day **Mutagenic / genotoxic effects** It is not mutagenic - Ames Salmonella test typhimurium - negative	CIR, ECHA , RTECS, EFSA

	Carcinogenic effects It is not carcinogenic - NOAEL 500 mg / kg bw / day **Harmful effect on reproduction** Does not affect reproduction - NOAEL 500 mg / kg bw / day (highest dose tested) **Toxicokinetics** no data **phototoxicity** It is not phototoxic	
Hydrogenated Palm Acid	**Acute toxicity** no toxic effect **Irritant / corrosive effects** skin: not irritating eyes: not irritating **Skin sensitization** It is not skin sensitizing **Absorption through the skin** No data **Repeated dose skin toxicity** No data **Mutagenic / genotoxic effects** It has no genotoxic effect **Carcinogenic effects** Not classified as CMR **Harmful effect on reproduction** It is not harmful to reproduction **Toxicokinetics** No data **phototoxicity** No data	CIR
Stearyl Stearate	**Acute toxicity** no data **Irritant / corrosive effects** skin: not irritating eyes: not irritating **Skin sensitization** It is not skin sensitizing **Absorption through the skin** No data **Repeated dose skin toxicity** No data **Mutagenic / genotoxic effects** Does not show mutagenic / genotoxic activity (bacteria and micronucleus test) **Carcinogenic effects** Not classified as CMR **Harmful effect on reproduction** It is not harmful to reproduction **Toxicokinetics** No data	CIR

	phototoxicity does not show	
Cannabis Sativa Seed Oil	Cannabidiol (CBD) is a component of Cannabis sativa and makes up to 40% of plant extracts. Numerous studies indicate that CBD (Cannabidiol) is well tolerated and safe in humans at high doses and during chronic use. However, in vitro and in vivo studies have shown the potential for drug interaction with metabolism, cytotoxicity. Human CBD should be carefully monitored, especially when used in clinical practice, for example in the treatment of psychiatric disorders or as an alternative to drug treatment. **Acute toxicity** oral In vivo: - human, 1mg / kg dose - has no significant effect on heart and body rate - human, dose of 3mg / kg body weight; 200 and 300mg / day - has no significant neurological effect on physical examination, blood and urine analysis, ECG and electroencephalogram - human, dose 600 mg / kg - has no significant effect on heart rate, blood pressure, skin conductance, bodily symptoms and psychological measurements - human, dose 150-400 mg / day - no significant side effect In vivo: - monkey, 30-300mg / kg heart rate, changes in kidneys and liver weight, testicular fragmentation and inhibition of spermatogenesis intraperitoneal In vivo: - mouse, dose of 10 mg / kg - it has no significant effect on weight gain and motor activity - mouse, dose 0-100 mg / kg; has no significant effect on weight gain dermal: no data inhalation: no data **Irritating effect:** Skin: does not irritate Eyes: does not irritate **Sensitizing effects:** not sensitizing **Absorption through the skin** No data **Repeated dose toxicity**	De Wit Speciality Oils b.v., MSDS Hemp Seed Oil, Safety and Side Effects of Cannabidiol, a *Cannabis sativa* Constituent

	No data **Mutagenic / genotoxic effects** No data. Not classified as CMR category 1 and 2 **Carcinogenic effects** No data. Not classified as CMR category 1 and 2 **Harmful effect on reproduction** No toxic effects expected **Toxicokinetics** No data **phototoxicity** No data	
Propylene Glycol	**Acute toxicity** orally: LD50 rat 22000 mg / kg bw / day LD50 guinea pig 19700 mg / kg bw / day LD50 mouse 24900 mg / kg bw / day inhalation: LC50 rabbit> 317042 mg / m3 air / 2h dermal: LD50 rabbit> 2000 mg / kg / day **Irritating and corrosive** Skin: non-irritating (rabbit, OECD 404) eyes: not irritating (rabbit, OECD 405) **Skin sensitization** Non-sensitizing (guinea pig, Maximization test, OECD 406) **Absorption through the skin** Absorption 0.1% (OECD 428). It enhances the absorption of other ingredients **Repeated dose toxicity** NOAEL rat os. male 1700 mg / kg bw / day chronic toxicity (24 months), route of exposure: oral NOAEL rat os. female 2100 mg / kg bw / day chronic toxicity (24 months), route of exposure: oral NOAEC rat os. male 1000 mg / m3 air 90-day toxicity, route of exposure: inhalation NOAEC rat os. female 2200 mg / m3 air 90-day toxicity, route of exposure: inhalation **Mutagenic / genotoxic effects** in vitro: negative result (S. typhimurium, Ames test) in vivo: negative result (mouse, micronucleus assay) **Carcinogenicity** NOAEL rat os. male 1700 mg / kg / day NOAEL rat os. female 2100 mg / kg / day Harmful effect on reproduction NOAEL rat 1600 mg / kg bw / day - toxicity maternity NOAEL rat 1600 mg / kg bw / day - teratogenicity NOAEL mouse 1600 mg / kg bw / day - toxicity maternity NOAEL mouse 1600 mg / kg bw / day - teratogenicity NOAEL rabbit 1230 mg / kg bw / day - toxicity maternity NOAEL rabbit 1230 mg / kg bw / day - teratogenicity **Toxicokinetics** Metabolized and excreted.	ECHA, CIR, INCHEM

	phototoxicity No toxic effect.	
Salvia Officinalis Extract	Sage essential oil is characterised by high levels of thujone. Consumption of sage essential oil in single ingredient products involves a high risk of exceeding the maximum recommended daily intake of thujone(Public statement on the use of herbal medicinal products containing thujone (EMA/HMPC/732886/2010 Rev.1)). Thujone is toxic and may cause seizures at high doses as shown in animal studies and indicated from case reports. The available clinical and toxicological data on sage essential oil cannot be considered adequate to fulfil the criteria required for developing a European Unionherbal monograph. For this reason, no monograph will be made on sage essential oil before supplementary information on clinical and toxicological data for sage essential oil are considered adequate to fulfil those criteria	EMA (Assessment report on *Salvia officinalis* L., folium and *Salvia officinalis* L., aetheroleum-20.09.2016)
Quercus Petraea Bark Extract	Quercus Petraea Bark Extract is an extract of the bark of the Oak, Quercus petraea, Fagaceae. Due to the lack of data on acute and chronic toxicity, repeated dose toxicity, mutagenicity, carcinogenicity, reproductive and developmental toxicity, a list entry for Quercus cortex cannot be recommended.	EMA (Assessment report on Quercus robur L., Quercus petraea (Matt.) Liebl., Quercus pubescens Willd., cortex – 25.11.2010)
Panthenol	**Acute toxicity:** oral: One-time oral administration is generally recognized as non-toxic. LD_{50} > 10000 mg/kg bw, rat OECD 401 LD_{50} > 15000 mg/kg bw, mouse LD_{50} > 4000 mg/kg bw, rabbit Dermal: LD_{50} > 2000 mg/kg bw (OECD 402) Intravenous: LD_{50} = 7000 mg/kg bw Intraperitoneal: LD_{50} = 9000 mg/kg bw **Irritation and corrosion:** skin: non-irritating (rabbit, OECD 404) Eye: Non-irritation (rabbit, OECD 405) **Sensitization:** Panthenol does not influence the skin when exposed to light (guinea pig, Buehler test, OECD 406); the occurrence of allergic changes in humans (skin) is very rare. **Dermal absorption** panthenol is absorbed by the skin. **Repeated dose toxicity:** orally: Low toxicity to human. There are known cases of hypervitaminosis of pantothenic acid (vitamin B5). Increases the amount of available Coenzyme A for the synthesis of acetylcholine. D-panthenol is easily	ECHA, TOXNET

	absorbed and converted to D-pantothenic acid. NOAEL = 200 mg/kg bw/day, rat, OECD 408 NOAEL = 1000 mg/kg bw/day, rat, OECD 407 **Mutagenicity/genotoxicity:** In vitro: negative (Ames test on S. typhimurium, OECD 471) In vivo: negative **Carcinogenicity:** Panthenol is not classified as carcinogenic. **Reproduction toxicity:** NOAEL > 1000 mg/kg bw/day for maternal and developmental toxicity, rat, OECD 421. **Toxicokinetics (ADME analysis):** Panthenol is a precursor of vitamin B5. In the living organism panthenol is converted to vitamin B5 and metabolized. **Photo-induced toxicity:** Panthenol does not induce phototoxicity or photoallergy.	
Citric Acid	Citric acid is a compound naturally occurring in animals. Is an important intermediate in the Krebs cycle. In the case of a man of about 2kg of citric acid is formed and metabolized every day. Normal concentration of citric acid in human blood is 25 mg/l. **Acute toxicity:** orally: LD_{50} = 5400 mg/kg bw (mouse Füllinsdorf Albino (SPF), OECD 401) LD_{50} = 11700 mg/kg bw (rat (ICR-JCL), OECD 401) dermal: LD_{50} > 2000 mg/kg bw (Sprague-Dawley rat, OECD 402) IV: LD_{50} = 42 mg/kg bw mouse LD_{50} = 330 mg/kg bw rabbit ip: LD_{50} = 903 mg/kg bw mouse LD_{50} = 883 mg/kg bw rat sc: LD_{50} = 2700 mg/kg mouse LD_{50} = 5500 mg/kg rat **Irritation and corrosion:** skin: The potential irritating properties of citric acid has been tested on rabbits New Zealand White and Wistar rats. The concentration range was from 15% up to 100%. The acid in these studies has been classified as not irritating or slightly irritating. 0.2 ml quantity of citric acid, administrated on scratch human skin cause irritation far milder compared to other organic acids. Eyes: Citric acid may cause eye irritation from mild to severe, depending on the concentration and amount of the applied. **Sensitization:**	ECHA, CIR, TOXNET, EWG

	Tests HRIPT on large groups of people have shown that the incidence of allergy to citric acid occurs sporadically and are not a threat. **Dermal absorption** No data. **Repeated dose toxicity:** orally: NOAEL = 4000 mg/kg bw/day (rat, test duration 10 days) **Mutagenic / genotoxic:** Ames tests - in vitro - negative. In vivo tests on rats - negative. **Carcinogenic:** From the chemical structure does not suggest for such action. **Reproductive toxicity:** 5% citric acid content in the diet does not affect the fertility of mice and rats. NOAEL, teratogenicity > 295 mg/kg bw/day (Wistar rat) NOAEL > 425 mg/kg bw/day (rabbit race Doutch belted, teratogenicity) **Toxicokinetics:** Swallowed citric acid absorbs well. It is a key intermediate in the Krebs cycle. **Phototoxicity:** Because of the structure of the citric acid, there is no suspicion of possession of phototoxic potential.	
Sodium Acrylates Copolymer	Most of the available data have been published for Acrylates Copolymer - a similar polymer property. Toxicology is based on the read across approach. **Adverse toxicity:** oral: LD_{50} > 9000 mg/kg bw, rat LD_{50} > 16000 mg/kg bw, rabbit **Irritation and corrosivity:** dermal: Non to mild irritating (rabbit) eye: Irritating (rabbit) **Skin sensitisation:** Non-sensitizing (genuine pig) **Dermal/percutaneous absorption:** No data. Due to high molar mass, the absorption may be excluded. **Repeat dose toxicity:** oral: No data. **Mutagenicity/genotoxicity:** in vitro: negative (Ames test on S. typhimurium) **Carcinogenicity:** Acrylates copolymer is not classified as CMR (Carcinogenic/Mutagenic/Reprotoxic). **Reprotoxicity:** Acrylates copolymer is not classified as CMR	CIR, TOXNET, EWG

	(Carcinogenic/Mutagenic/Reprotoxic). **Toxicokinetics:** Copolymer is not bio-available. **Photo-induced toxicity:** No data.	
Carbomer	A copolymer consisting of repeating units of acrylic acid and polyether blocks. There are various types of carbomers, differing only in length. Physical and chemical properties of all carbomers are similar. **Acute toxicity:** oral: LD_{50} = 10.25 g/kg bw (rat) LD_{50} = 4600 mg/kg bw (mouse) LD_{50} = 2500 mg/kg bw (genuine pig) ip: LD_{50} > 150 mg/kg bw (dog Beaglet) LD_{50} = 40 mg/kg bw (mouse) Dermal: LD_{50} > 3 g/kg bw (rat albino) LD_{50} = 10 g/kg bw (rabbit) inhalation: LC_{50} = 30 mg/l of air/4h, rat Iv: LD_{50} = 70 mg/kg bw, mouse **Irritation and corrosivity:** dermal: None of the carbomer is not classified as a skin irritant. In the Draize test on albino rabbits after application of the carbomers' solution, experience mild erythema, which completely within 24 hours. eyes: Carbomers can seriously irritate the eyes at very high concentrations (100%). At lower concentrations <1% carbomer minimally irritates eyes or is no irritating. **Sensitization:** Numerous tests on human proves that carbomers do not have a sensitization properties. **Dermal absorption** Due to the structure, carbomers do not absorb. **Repeated dose toxicity:** oral: Groups of eight individuals of rats received different doses of the carbomer. At doses up to 0.95 g / kg bw / day (for a period of 49 days) no changes were observed among the tested individuals. For a dose of 5 g / kg bw / day a significant decrease in body weight was observed. Chronic toxicity tests were carried out on rat and beagle dogs as well. The presence of carbomer in an amount of 0.5% in the diet of the rats did not show any pathological changes. Similar conclusions wysnuto for dogs at a dose of 0.1 g / kg bw / day. Read-across Acrylate Copolymer NOAEL ≥ 2000 mg/kg mc/bw, rat 26 weeks **Mutagenicity/genotoxicity:** No evidence of any mutagenic or genotoxic properties of carbomer. This substance is not classified as CMR	CIR, HSDB

	(Carcenogenic/Mutagenic/Reprotoxic). **Carcinogenicity:** This substance is not classified as CMR (Carcenogenic/Mutagenic/Reprotoxic). **Reprotoxicity:** There are no data in the literature indicating that raw material toxic effects on reproductive function. **Toxicokinetics:** No data. **Photo-induced toxicity:** In two studies, the phototoxicity dose of 0.25% of carbomer was tested on people - negative results - carbomer has no phototoxic, or photosensitizing potential.	
Allantoin	**Acute toxicity** oral: LD_{50} > 5000 mg/kg bw, rat LD_{50} > 10000 mg/kg bw, rabbit dermal: LD_{50} > 5000 mg/kg bw, rat **Irritation and corrosion** dermal: non-irritating (rabbit, OECD 404) eye: non-irritating (rabbit, OECD 405) **Skin sensitization:** Non-sensitizing (mouse LLNA, OECD 429) **Dermal/percutaneous absorption:** It is absorbed by the skin, in vivo: 5% - 20%. **Repeat dose toxicity:** Oral: No data. **Mutagenicity/genotoxicity:** *In vitro:* negative (Ames test on S. typhimurium, OECD 471) *In vivo:* no data. **Carcinogenicity:** Allantoin is not expected of having such properties. No carcinogenic properties were detected in 2-year studies on rat **Reproduction toxicity:** No data. It is not classified as CMR cat. 1 or 2. **Toxicokinetics (ADME analysis):** 95% of the administrated amount is excreted with urine. **Photo-induced toxicity:** No data.	ECHA, CIR, HSDB
	Adverse toxicity: oral: LD_{50} > 4 g/kg bw, rat LD_{50} > 25 ml/kg bw, mouse dermal: LD_{50} > 3 g/kg bw, rat **Irritation and corrosivity:** dermal: Non-irritating (patch tests, clinical studies)	CIR, SCCS, ECHA

	eye: Non-irritating. Single cases of irritation were documented.	
Tocopheryl Acetate	**Skin sensitisation:** Non-sensitizing (patch tests, clinical studies) **Dermal/percutaneous absorption:** in vivo and in vitro studies resulted in absorption coefficient of 10%. **Repeat dose toxicity:** oral: NOAEL = 500 mg/kg bw/day, rat **Mutagenicity/genotoxicity:** in vitro: negative in vivo: negative It is classified as CMR (Carcinogenic/Mutagenic/Reprotoxic). **Carcinogenicity:** Tocopheryl acetate is not carcinogenic. **Reprotoxicity:** Tocopheryl acetate does not influence the reproduction an developmental of foetuses. **Toxicokinetics:** After oral administration, tocopheryl acetate is present in tissues (rat). **Photo-induced toxicity:** Tocopheryl acetate is not inducing phototoxicity.	
Disodium EDTA	**Acute toxicity** LD50 rat (oral)> 2000 - 3700 mg / kg LD50 mouse (oral) 2050 mg / kg LD50 rabbit (oral) 2300 mg / kg LD50 rabbit (intravenously) 47 mg / kg LD50 mouse (intravenously) 56 mg / kg **Irritating and corrosive effect** Skin: non-irritant (rabbit, OECD 404; non-irritant -26 volunteers, 72h patch test) Eyes: not irritating (rabbit, OECD 405) **Sensitizing effects** Non-sensitizing, OECD 406) **Absorption through the skin** The substance is not absorbed through the skin **Toxicity increases repeated** NOAEL rat (oral) 500 mg / kg bw / day - subchronic toxicity LOAEL rat (by inhalation) 30 mg / m3 (OECD 412) **Mutagenic / genotoxic effects** in vitro: negative (mouse L5178Y cell lymphoma Mammalian gene mutation test, OECD 476) in vivo: negative (OECD 474) **Carcinogenic effects** It is not carcinogenic **Harmful to reproduction** NOAEL rat 1243 mg / kg / day developmental toxicity NOAEL rat 1243 mg / kg / day developmental toxicity	ECHA , TOXNET

	Toxicokinetics Excreted in urine and faeces within 24 hours **phototoxicity** No data.	
Sodium Hydroxide	**Acute toxicity** orally: LD_{50} = 325 mg / kg, rabbit LD_{50} = 140 - 340 mg / kg, rat ip: LD_{50} = 40 mg / kg, mouse dermal: LD_{50} = 1350 mg / kg, rabbit **Irritating and corrosivity** skin: the ingredient has irritating and corrosive properties. A 2% solution causes only slight irritation in human studies. eyes: the ingredient has irritating and corrosive properties. The 1% solution is classified as non-irritating (test on rabbits). **Skin sensitization** Does not cause an allergic reaction - application of patch tests (HRIPT) on humans containing a preparation containing 0.125% to 1.0% sodium hydroxide. **Dermal/percutaneous absorption:** No data. **Repeated dose toxicity** NOAEL = 373 mg / kg / day, Wistar rat, duration - 10 months **Mutagenicity/genotoxicity:** in vitro: negative result in numerous studies with and without metabolic activation and Ames tests in vivo: negative result on Swiss and CD mice. **Carcinogenicity:** No proper carcinogenicity studies. NaOH is not suspected of having carcinogenic properties. It does not induce mutagenic changes and the availability of NaOH under normal and foreseeable conditions is very low. Not classified as CMR. **Reproduction toxicity:** No literature data available. NaOH is not suspected of having such properties. It is not classified as CMR. **Toxicokinetics (ADME analysis):** NaOH is not bioaccumulable. Jon Na + is a natural component of physiological fluids. **Photo-induced toxicity:** No data. NaOH is not suspected of having phototoxic and photoallergic properties	ECHA, CIR European Union Risk Assessment Report vol. 73,

9. UNDESIRABLE EFFECTS AND SERIOUS UNDESIRABLE EFFECTS

The monitoring of serious undesirable effects is carried out according to the guidelines of the European Commission.

Confirmed reports of undesirable effects: none
Confirmed reports of serious undesirable effects: none

10. INFORMATION ON COSMETIC PRODUCT

- **Dermatological examination of the finished cosmetic product (patch test)** – the product has been tested by SkinLab, test reference: 27/07/21/D/17. There was no positive response among the respondents. The cosmetic product does not exhibit any irritating or sensitizing properties.

- **Application test of the finished cosmetic product** – the product has been tested by Biogena Dystrybucja, test reference A/02/03/2014.
  The product under investigation has fulfilled all declared application properties.

- **Stability test** – the product is stable – the test has been carried out in three temperatures: +5 °C; room temperature and +40 °C for 3 months.

- **Compatibility test** – the product is compatible with the final packaging- the test has been carried out in three temperatures: +5 °C; room temperature and +40 °C for 3 months.

- **Challenge test** – the product has been investigated by JARS Sp. z o. o., test reference: **1488/01/2014**. The method of preservation of the product met requirements.

- **Animal testing** – the finished product has not been not tested on animals.

- This cosmetic product is manufactured according to good manufacturing practice (ISO 22716:2007) and ISO 9001:2008.

The product fulfils all the requirements laid down to cosmetic products according to the Regulation of European Parliament and of the Council (EC) No 1223/2009 form 30th November 2009.

PART B – COSMETIC PRODUCT SAFETY ASSESSMENT

1. ASSESSMENT CONCLUSION

The product **PROTECTIVE HAND CREAM WITH HEMP OIL RCP DEL/0033822** is safe and does not pose a reasonably foreseeable risk to the human health when it is used in declared manner, according to the instruction and in reasonably foreseeable conditions, taking into account the current state of knowledge.

2. LABELLED WARNINGS AND INSTRUCTIONS OF USE.

Responsible person is liable for the content of the label and compliance of label elements and the label itself with the law.

3. REASONING

The conclusion derived in point 1 is based on:

- Safety assessment of each raw material used in manufacturing the cosmetic product, including:
  - Risk assessment based on toxicological profile of each ingredient, taking into account, in justified cases, read-across approach.
  - Analysis of systemic exposition to the ingredients.
  - Margin of safety calculations.
- Reports and results of each tests of the finished cosmetic product.

The raw materials and ingredients are typical cosmetic substrates and are usually applied in the cosmetic industry. Moreover, all ingredients included in assessed product are used in compliance with the annexes III – VI of the Regulation of the European Parliament and of the Council (WE) No 1223/2009 with all amendments.
The available data in sufficient to conduct safety assessment. The toxicological profile of the used ingredients is satisfactory and has been selected according to the type and intended purpose of the cosmetic. For ingredients for which the systemic toxicity - NOAEL parameter was available, margins of safety were determined, which in all cases satisfy a relationship MoS >> 100. For ingredients for which there are no available chronic toxicity values or other systemic toxicological data allowing to assess the substance as safe, other sources like opinions of CIR, FDA, SCCS, as well as a documented history of safe use can be cited. Furthermore, the following data was taken into account in the safety assessment:

- The purity of the raw materials – does not raise objections
- Interactions between the product and material of the packaging – not expected
- Interactions between ingredients – not expected
- The physicochemical and microbiological stability – proven by tests
- Patch test report – non irritating properties of the product have been proven. Potential allergic reactions cannot be excluded in patients who have an allergy to any ingredient of the product.

4. ASSESSOR'S CREDENTIALS

4.1. Name and address of the Safety Assessor

mgr inż. Karol Brąszewski

ul. Zamenhofa 36/24

90-547 Łódź

Phone: +48 608 390 944

4.2. Proof of qualification of Safety Assessor

EDUCATION

2004 – 2005	Postgraduate studies at the Faculty of Biotechnology and Food Sciences, Technical University of Lodz, specializing in cosmetology.
1998 – 2000	Graduate studies at the Faculty of Organization and Management, Technical University of Lodz, Institute of Management, specializing in Marketing and Management.
1996 –1998	Studies of the Faculty of Chemistry, Technical University of Lodz, Institute of General and Ecological Chemistry, specialty chemical technology.
1994 – 1996	College studies at the Technical University of Lodz, diploma engineering chemist at the Institute of General and Ecological Chemistry.

EXPERIENCE

Since 01.11.2019	Director R&D, Delia Cosmetics Sp. z o.o
Since 2015	Head of Dr Szmich – Centre of Research and Development of cosmetics, pharmaceuticals and medical devices.
2012 – 2016	Member of the Business Council of the Faculty of Biology and Environmental Protection, University of Lodz
since 01.06.2007	Director R&D and Production, Delia Cosmetics Sp. z o.o.
2006 - 2016	Lecturer at the Technical University of Lodz Faculty of Biotechnology and Food Sciences, Postgraduate specialization cosmetology.
01.10.2004 – 31.05.2007	Chief Technologist - Head of Production and Quality Control, Quality Management Representative Delia Cosmetics Sp. z o.o.
01.09.2003 – 30.09.2004	Technologist, Delia Cosmetics Sp. z o.o.

15.10.2001 – 31.08.2003	Technologist, BARBRA Sp. z o.o.
15.09.1999 – 30.09.2000	Production specialist, Cosmetic Factory Pollena Ewa S.A.

TRAINING

12.2009	Training in new technologies and applications of active ingredients in cosmetics IMCD COM TECH, Bergamo, Italy
05.2006	Training in technology nail polish and active ingredients Durlin France, Bergerac, France
03.2005	Training in the new trends and technology in the colour cosmetics Engelhard Netherlands
04.2004	Training in the new trends and technology in the colour cosmetics Engelhard Netherlands
02.2004	Training on the new developments in the technology of hair dyes jos. H. Lowenstein Sons, USA

4.3. APPROVAL of part B / conclusion of safety of the product

Based on all accessible data on the cosmetic product **PROTECTIVE HAND CREAM WITH HEMP OIL RCP DEL/0033822, I state that this product is approved for use as intended**.
The influence of this cosmetic product on human safety and health was estimated according to the present state of knowledge. Revision of this safety assessment will be made as soon as new information becomes available. This report fulfils the formal requirements for influence assessment on the safety of cosmetics on human health, included in the Regulation of the European Parliament and Council Regulation (EC) No 1223/2009 with all subsequent amendments.
The cosmetic product **PROTECTIVE HAND CREAM WITH HEMP OIL RCP DEL/0033822,** if the production complies with the guidelines included in Regulation of the European Parliament and of the Council (WE) No 1223/2009 with all amendments.

Safety Assessor does not bear responsibility for the authenticity of the data provided by the responsible person.

DATE

05.04.2023

SIGNATURE

Karol Braszewski
Safety Assessor