COSMETIC PRODUCT

SAFETY REPORT

Ultimate Serum

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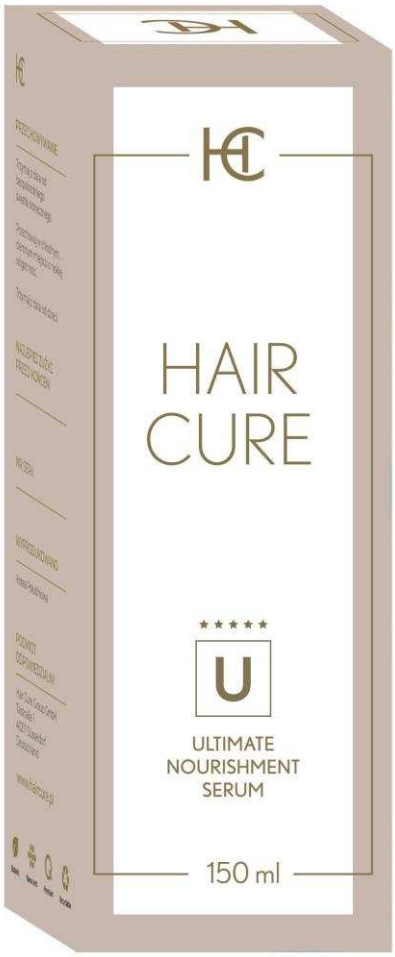
Product:	Ultimate Serum
	
Responsible person:	Hair Cure Polska Sp. z o.o. [redacted] KRS 0000877478 NIP 5213917297

Cosmetic product safety report of the product: Ultimate Serum hereinafter called Ultimate Serum has been compiled according to Regulation (EC) No 1223/2009 of the European Parliament and of the Council

*This assessment is based solely on the list of ingredients and cosmetic product safety information submitted for toxicological risk assessment, and assumes that this list is accurate and there are no additional ingredients present or intentionally added or data which are not listed. If this information is incorrect, please contact the toxicological safety assessor with the correct data.

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Wykaz stosowanych skrótów / ABBREVIATIONS

ADI Acceptable Daily Intake
AF Assessment Factor
ASTM American Society for Testing and Materials
ATP Adaptation to Technical Progress
B Bioaccumulation
BBA Biologische Bundesanstalt für Land- und Forstwirtschaft
BCF Bioconcentration Factor
BMC Benchmark Concentration
BMD Benchmark Dose
BMF Biomagnification Factor
BOD Biochemical Oxygen Demand bw body weight / Bw, bw
CA Chromosome Aberration
CA Competent Authority
CAS Chemical Abstract Services
CEC Commission of the European Communities
CEN European Standards Organisation / European Committee for Normalisation
CEPE European Committee for Paints and Inks
CMR Carcinogenic, Mutagenic and toxic to Reproduction
ELINCS European List of New Chemical Substances
EN European Norm
EPA Environmental Protection Agency (USA)
ErC50 Effect Concentration measured as 50% reduction in growth rate in algae tests
ESD Emission Scenario Document
EU European Union
EUSES European Union System for the Evaluation of Substances [software tool in support of the Technical Guidance Document on risk assessment]
FAO Food and Agriculture Organisation of the United Nations
GLP Good Laboratory Practice
HEDSET EC/OECD Harmonised Electronic Data Set (for data collection of existing substances) HELCOM Helsinki Commission -Baltic Marine Environment Protection Commission
HPLC High Pressure Liquid Chromatography
HPVC High Production Volume Chemical (> 1000 t/a)
IARC International Agency for Research on Cancer
IC50 median Immobilisation Concentration or median Inhibitory Concentration
LOEL Lowest Observed Effect Level MAC Maximum Allowable Concentration
MATC Maximum Acceptable Toxic Concentration
MC Main Category
MOE Margin of Exposure
MOS Margin of Safety
MW Molecular Weight
NAEL No Adverse Effect Level
NOAEL No Observed Adverse Effect Level
NOEL No Observed Effect Level
NOEC No Observed Effect Concentration
NTP National Toxicology Program (USA)
OC Organic Carbon content
OECD Organisation for Economic Cooperation and Development
OEL Occupational Exposure Limit
P Persistent
PBT Persistent, Bioaccumulative and Toxic
PBPK Physiologically Based PharmacoKinetic modelling
PBTK Physiologically Based ToxicoKinetic modelling
pKa logarithm (to the base 10) of the acid dissociation constant
pKb logarithm (to the base 10) of the base dissociation constant
PNEC Predicted No Effect Concentration
POP Persistent Organic Pollutant
PPE Personal Protective Equipment
CSTEE Scientific Committee for Toxicity, Ecotoxicity and the Environment (DG SANCO)
DIN Deutsche Industrie Norm (German norm)
DNA DeoxyriboNucleic Acid
DOC Dissolved Organic Carbon
DT50 Degradation half-life or period required for 50 percent dissipation / degradation
DT90 Period required for 90 percent dissipation / degradation
EASE Estimation and Assessment of Substance Exposure Physico-chemical properties [Model]
EC European Communities
EC10 Effect Concentration measured as 10% effect
EC50 median Effect Concentration
ECETOCEuropean Centre for Ecotoxicology and Toxicology of Chemicals
ECVAMEuropean Centre for the Validation of Alternative Methods
EDCEndocrine Disrupting Chemical
EEC European Economic Communities
EINECS European Inventory of Existing Commercial Chemical Substances

IPCS International Programme on Chemical Safety
ISO International Organisation for Standardisation
IUCLID International Uniform Chemical Information Database (existing substances)
IUPAC International Union for Pure and Applied Chemistry
JEFCA Joint FAO/WHO Expert Committee on Food Additives
JMPR Joint FAO/WHO Meeting on Pesticide Residues
Koc organic carbon normalised distribution coefficient
Kow octanol/water partition coefficient
Kp solids-water partition coefficient
L(E)C50 median Lethal (Effect) Concentration
LAEL Lowest Adverse Effect Level
LC50 median Lethal Concentration
LD50 median Lethal Dose
LEV Local Exhaust Ventilation
LLNA Local Lymph Node Assay
LOAEL Lowest Observed Adverse Effect Level
LOEC Lowest Observed Effect Concentration
LOED Lowest Observed Effect Dose
QSAR (Quantitative) Structure-Activity Relationship
RAR Risk Assessment Report
RC Risk Characterisation
RfC Reference Concentration
RfD Reference Dose
RNA RiboNucleic Acid
RWC Reasonable Worst Case
SDS Safety Data Sheet
SSD Species Sensitivity Distribution
TDI Tolerable Daily Intake
TG Test Guideline
TGD Technical Guidance Document
US EPA Environmental Protection Agency,
UVCB Unknown or Variable composition, Complex reaction products of Biological material
vB very Bioaccumulative
VOC Volatile Organic Compound
vP very Persistent
vPvB very Persistent and very Bioaccumulative
v/v volume per volume ratio
w/w weight per weight ratio
WHO World Health Organization

PART A
COSMETIC PRODUCT SAFETY INFORMATION

1. Quantitative and qualitative composition of the cosmetic product.

Ingredients(ICID)	RM or Ingredient % in fla	Ingredients % in RM	Actual Wt(%)	Function	CAS No.
Water	78.1000	70.00	54.00	Solvent	7732-18-5
Laminaria Cloustoni Extract		5.12	4.00	Skin Conditioning Agent	92128-82-0
Undaria Pinnatifida Extract		5.12	4.00	Skin Conditioning Agent	
Camellia Sinensis Leaf Extract		4.48	3.50	Skin Conditioning Agent	84650-60-2
Pinus Densiflora Leaf Extract		2.56	2.00	Skin Conditioning Agent	
Thuja Orientalis Leaf Extract		2.56	2.00	Skin Conditioning Agent	
Morus Alba Bark Extract		2.56	2.00	Skin Conditioning Agent	94167-05-2
Artemisia Vulgaris Extract		2.56	2.00	Skin Conditioning Agent	84775-45-1
Acanthopanax Senticosus (Eleuthero) Root Ext		1.28	1.00	Skin Conditioning Agent	
Glycine Soja (Soybean) Seed Extract		1.28	1.00	Skin Conditioning Agent	
Rehmannia Chinensis Root Extract		1.28	1.00	Skin Conditioning Agent	
Sophora Angustifolia Root Extract		0.77	0.60	Skin Conditioning Agent	
Poria Cocos Extract		0.64	0.50	Skin Conditioning Agent	
Cnidium Officinale Root Extract		0.64	0.50	Skin Conditioning Agent	
Alcohol	21.0000	100.00	21.00	Solvent	64-17-5
Sodium Benzoate	0.2500	100.00	0.25	Antiseptic	532-32-1
Flavor	0.2500	100.00	0.25	Fragrance	
sh-Oligopeptide-2	0.2000	0.00	0.000002	Skin Conditioning Agent	
Polysorbate 20		0.05	0.000100	Skin Conditioning Agent	9005-64-5
Lecithin		0.03	0.000060	Skin Conditioning Agent	8002-43-5
Butylene Glycol		0.02	0.000040	Skin Conditioning Agent	107-88-0
Phenoxyethanol		0.50	0.001000	Antiseptic	122-99-6
water		99.40	0.198798	Solvent	7732-18-5
sh-Polypeptide-13	0.1000	0.001	0.000001	Skin Conditioning Agent	
Phenoxyethanol		0.500	0.000500	Antiseptic	77-92-9
Polysorbate 20		0.005	0.000005	Skin Conditioning Agent	53568-66-4
Lecithin		0.003	0.000003	Skin Conditioning Agent	84604-16-0
Butylene Glycol		0.002	0.000002	Skin Conditioning Agent	107-88-0
water		99.489	0.099489	Solvent	6920-22-5
Copper Tripeptide-1	0.1000	0.100	0.000100	Skin Conditioning Agent	
Phenoxyethanol		0.500	0.000500	Antiseptic	7732-18-5
Water		99.400	0.099400	Solvent	122-99-6

Water (INCI: Aqua); Flavor (INCI: Parfum):

[redacted]

Contains Limonene 9,65% in perfum oil which means 0,024% in final product and traces of Linalool <<0,001% in final product. Allergens above 0,001% to be declared on the label: Limonene

Ingredients	%	CAS
Limonene	0,024	5989-27-5

2. Physical/Chemical characteristics and stability of the cosmetic product

2.1. Physical/ Chemical characteristics of the substances or mixture and cosmetic product.

2.1.1. Physical/Chemical characteristics of the substances or mixtures.

Physical and chemical properties of the raw materials, has been used to make the Ultimate Serum in accordance with Material Safety Data Sheet or Specification of particular raw material made available by the producer of the final product.

2.1.2. Physical/Chemical characteristics and stability of the cosmetic product

The final product Ultimate Serum meet requirements of internal standard:

Parameter	Requirements
Appearance	hazy liquid. To Match Standard
Color	Green-brown, To Match Standard
Odor	To Match Standard. Characteristic for the fragrance composition used and for the raw materials used, menthol
Density	0,950-1,05/ [20 ºC]
pH [20 ºC]	4,00-5,50
Microbiological quality	$\leq 10^2$ cfu/g Absence of: Pseudomonas aeruginosa – in 1g Staphylococcus aureus – in 1g Candida albicans - in 1g Escherichia coli – in 1g

2.2. Stability of cosmetic product in foreseeable conditions of storage.

Ultimate Serum has been tested for stability. Based on the tests conducted at different temperature conditions for a period of 30days the sample tested is in accordance with the control sample for the parameters tested. The product has been found to be stable / no significant odor change over time. No significant color changes, product specifications are in accordance with specifications.

Conclusions: Based on composition analysis, stability test results, type of package applied, and recommended usage, a shelf life of more than 30 months from the date of production.

3. Microbiological quality

The product Ultimate Serum has been subject to microbiology tests. The product has been qualified as product of category II.

Equally verified results to accordance with requirements of SCCS Notes of Guidance for Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation in microbiological quality the following conclusions has been obtained:

Marked parameter	Requirements (according SCCS)	Result
General value of aerobic mezophilic microbes (bacteria and yeast) in lg or 1 ml sample	$< 2*10^3$ cfu	$< 10^2$ cfu
Escherichia coli in 1 g or 1 ml sample	Absent	Absent
Staphylococcus aureus in 1 g or 1 ml sample	Absent	Absent
Pseudomonas aeruginosas in lg or 1 ml sample	Absent	Absent
Candida albicans in lg or 1 ml sample	Absent	Absent

The results are based on microbiological requirements prescribed both in Annexe 1 and guidelines in SCCS Notes of Guidance the tested cosmetic product meets requirement of the microbiology standards.

Challenge test

The Hair Medic Intense Serum cosmetic product is not subject to challenge tests, it is classified as a low microbiological risk product due to the high alcohol content in the finished product (> 20%) - in accordance with PN-EN ISO 29621: 2017, there is no need to present these tests results.

4. Impurities, traces, information about the packaging material

4.1. The purity of substances and compound.

There are no concerns on safety of finished product. The conclusion is based on available data regarding the particular raw materials, used in cosmetic product, present traces of impurities. Moreover, the producer confirm that the final product does not contain any pollution or banned traces descended from or developed during the manufacturing process of the product.

4.2. Information about the packaging material.

Ultimate Serum is packaged in: 150ml Plastic Bottle (PET) with Pump, head made of PP, Cap made of PP, PE suction tube.

According to supplier Additives and Components used to produce this cap meet with the EC Directive 10/2011 relating to use in contact of plastics materials with food substances.
Raw materials used in cosmetic packaging are not hazardous substances and do not require additional warnings. The package is stable and compatible in temp range +5°C/+ 40°C

The type of materials used for the cosmetic product guarantee high tenacity and chemical resistance, including cosmetic substances. These materials are not classified as hazardous and there is no need to give any special precautionary information in labeling. Moreover, the producer states, that there is no interaction between packaging and ingredients of finished cosmetic product. The statement is based on results of compatibility tests of bulk and packaging.

5. Normal and reasonably foreseeable use

The product Ultimate Serum is classified as a cosmetic of category Hair and scalp care and cleansing products: Shampoo

Both, the offered kind of packaging and the way of presentation show the reasonably foreseeable use. Directions for use on the packaging.

6. Exposure to the cosmetic product

Exposure to the Ultimate Serum has been assessed on the basis of the amount of cosmetic product applied on specific parts of human body. In order to develop the evaluation the following guidelines has been used: SCCS's Notes for Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation

The following factors has been included:
- Type of product – leave-on product
- Potentially exposed population – people above 16 years old
- The normal way of exposure: dermal
- Application surface: area hands+1/2area head: 1440cm^2
- The amount of applied product in recommended and reasonably foreseeable use:4-6,6ml/day
- Calculated daily exposure: 0,67g/day
- Retention factor: 0,1
- Frequency of use: average 2-5x/day
- Estimated daily exposure to the product: 11,12mg/kg bw/day.

Exposure to the particular substance has been described in point 7 and based on toxicological profile of substances appeared in formulation the cosmetic product (details in point 8).

7. Exposure to the substances

To estimete the exposure to the particular substances of cosmetic product it is used the Margin of Safety (MoS). MoS value is calculated by dividing the lowest value of NOAEL by SED (Systemic Exposure Dosage).

When MoS is at least 100 the substance is considered as safe. Some components of the formulation do not have a specific NOAEL value, hence to evaluate them it is common to use other scientific information about safety.

SED has been calculated for all substances used as compounds of the Ultimate Serum. MoS value for substances with available NOAEL was also calculated.

INCI	SED	NOAEL	MOS
Alcohol	2,3352	1730	741
Laminaria Cloustoni Extract	0,4448	----	---
Undaria Pinnatifida Extract	0,4448	----	---
Camellia Sinensis Leaf Extract	0,3892	----	---
Pinus Densiflora Leaf Extract	0,2224	----	---
Thuja Orientalis Leaf Extract	0,2224	----	---
Morus Alba Bark Extract	0,2224	----	---
Artemisia Vulgaris Extract	0,2224	----	---
Acanthopanax Senticosus Root Extract	0,1112	----	---
Glycine Soja Seed Extract	0,1112	----	---
Rehmannia Chinensis Root Extract	0,1112	----	---
Sophora Angustifolia Root Extract	0,0667	----	---
Poria Cocos Extract	0,0556	----	---
Cnidium Officinale Root Extract	0,0556	----	---
Sodium Benzoate	0,0278	400	14 388
Parfum	0,0278	----	---
Limonene	0,0027	30	11 183
sh-Oligopeptide-2	0,0000	----	---
Polysorbate 20	0,0000	----	---
Butylene Glycol	0,0000	2500	535 286 057
Phenoxyethanol	0,0003	357	1 070 144

sh-Polypeptide-13	0,0000	----	---
Lecithin	0,0000	1000	142 742
Copper Tripeptide-1	0,0000	----	---

8. Toxicological profile of the substances

Based on:

- The Directive of The European Parliament and Council (WE) Nr 1223/2009 dated 30 November 2009 r. about cosmetic products with recent amendments,

the composition of Ultimate Serum has been verified and it is concluded that the product:

- does not consist substances that are not allowed in cosmetics products,

Toxicological profile of particular substances used to produce Ultimate Serum has been compiled based on data from (i.a. TOXNET, PubMed, CIR, European Chemical Agency, ECHA and others) and information made available by producer of final cosmetic product, including information described in point 11 and Material Safety Data Sheet of particular substances.

Ingredient Name: Alcohol
Acute toxicity, by oral route: LD5010470mg/kg Rat OECD 401 (Acute Oral Toxicity)
Acute toxicity, by dermal route: LD50>2000mg/kg Rabbit OECD 402 (Acute Dermal Toxicity)
Acute toxicity, by inhalation: LC5095,6-125mg/l/4h Rat OECD 403 (Acute Inhalation Toxicity)
Skin corrosion/irritation: Rabbit OECD 404 (Acute Dermal Irritation/Corrosion)Not irritant
Serious eye damage/irritation: Rabbit OECD 405 (Acute Eye Irritation/Corrosion) Mild irritant
Respiratory or skin sensitisation: Mouse OECD 429 (Skin Sensitisation - Local Lymph Node Assay)Not sensitizising
Germ cell mutagenicity:Mouse OECD 476 (In Vitro Mammalian Cell Gene Mutation Test) Negative
Germ cell mutagenicity:Salmonella typhimurium OECD 471 (Bacterial Reverse Mutation Test) Negative
Carcinogenicity: NOAEL>3000mg/kg Rat OECD 451 (Carcinogenicity Studies)2 4 mon
Reproductive toxicity: NOAEL5200mg/kg bw/d Rat
Specific target organ toxicity - repeated exposure (STOT-RE):N OAEL1730mg/kg/d Rat OECD 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents)Female
Specific target organ toxicity - repeated exposure (STOT-RE):NOAL>20mg/l Rat OECD 403 (Acute Inhalation Toxicity)
Experiences in humans: Excessive alcohol consumption during pregnancy induces the foetus alcohol syndrome (reduced weight at birth, physical and mental disorders)., There is no sign that this syndrome is also caused by dermal or inhalative absorption.

Ingredient Name: Camellia Sinensis Leaf Extract
Tea tree leaf extract. It is used as an antioxidant in cosmetic products to protect the skin against UV radiation. Fresh leaves contain flavanols, polysaccharides, proteins, carotenoids,

chlorophylls, enzymes, flavonoids and quercetins. Edible serums (infusions). The oral exposure to components of this plant exceeds the systemic exposure resulting from the use of cosmetic products many times over. Acute toxicity of rat-catechin dermal (OECD 402; semi-occlusion) LD50 EGCG (epigallocatechin-3-gallate) (2000 mg / kg extract; 1860 mg EGCG / kg; 93% in distilled water; 4 mL / kg)> 1860. Reproductive effects: NOAEL = 100 mg / kg bw / day EGCG. Historical data indicate safe use in cosmetic products as well as when ingested. The substance is considered safe for cosmetic use. Tea is the second most consumed drink in the world, after water. It appeared in China in 2737 BC. A raw material known for its antioxidant properties.

Ingredient Name: Sophora Angustifolia Root Extract
Extract from the roots of the narrow-leaved pearl. The flowers, leaves and fruits contain a large amount of rutin, vitamin C and bactericidal substances. The extract has bactericidal, antioxidant, healing, regenerating and vitaminizing properties. It is used in creams for dry, sensitive and flabby skin, after-shave creams, tonics against hair loss and for strengthening them.
Acute toxicity No data available
Irritating effect No data available
Corrosive effect No data available
Sensitizing effect No data available
Repeated dose toxicity No data available
Carcinogenicity No data available
Mutagenicity No data available
Phototoxicity No data available
Harmful effect on reproduction No data available

Ingredient Name: Cnidium Officinale Root Extract
Cnidium Officinale Root Extract is an extract of the roots of Cnidium officinale, Apiaceae
Acute toxicity No data available
Irritating effect No data available
Corrosive effect No data available
Sensitizing effect No data available
Repeated dose toxicity No data available
Carcinogenicity No data available
Mutagenicity No data available
Phototoxicity No data available
Harmful effect on reproduction No data available

Ingredient Name: Acanthopanax Senticosus Root Extract
Acanthopanax Senticosus Root Extract is an extract of the roots of the Siberian Ginseng, Acanthopanax senticosus, Araliaceae
Acute toxicity No data available
Irritating effect No data available
Corrosive effect No data available
Sensitizing effect No data available
Repeated dose toxicity No data available
Carcinogenicity No data available
Mutagenicity No data available

Phototoxicity No data available
Harmful effect on reproduction No data available

Ingredient Name: Undaria Pinnatifida Extract
Seaweed extract - has anti-irritating, soothing and anti-radical properties. Potentially does not pose a significant risk to human health in cosmetic use. The seaweed is edible. Historical data indicate safe use in cosmetic products. Substance considered to be non-toxic, non-irritating and non-sensitizing.
Acute toxicity No data available
Irritating effect No data available
Corrosive effect No data available
Sensitizing effect No data available
Repeated dose toxicity No data available
Carcinogenicity No data available
Mutagenicity No data available
Phototoxicity No data available
Harmful effect on reproduction No data available

Ingredient Name: Poria Cocos Extract
(Wolfiporia extensa (Peck) Ginns fungus of the Polyporaceae family) Considered non-toxic. In tests on volunteers (patch test, HRIPT) of the cream extract, no irritating properties (including contact with the mucosa) and no sensitizing properties were observed. A substance with a known history of use as an ingredient in cosmetics and in dietary supplements. Often used in after-sun cosmetics on sun-irritated skin, in cosmetics for the care of atopic and particularly sensitive skin. The substance does not meet the criteria for classification as carcinogenic, mutagenic or toxic to reproduction. It contains polysaccharides, amino acids and triterpene compounds.
Acute toxicity No data available
Irritating effect No data available
Corrosive effect No data available
Sensitizing effect No data available
Repeated dose toxicity No data available
Carcinogenicity No data available
Mutagenicity No data available
Phototoxicity No data available
Harmful effect on reproduction No data available

Ingredient Name: Rehmannia Chinensis Root Extract
Traditional Asian plant known to be anti-irritant. A substance with a known history of use as an ingredient in cosmetics. Often used in after-sun cosmetics on sun-irritated skin, in cosmetics for the care of atopic and particularly sensitive skin.
Acute toxicity No data available
Irritating effect No data available
Corrosive effect No data available
Sensitizing effect No data available
Repeated dose toxicity No data available
Carcinogenicity No data available
Mutagenicity No data available

Phototoxicity No data available
Harmful effect on reproduction No data available

Ingredient Name: Glycine Soja Seed Extract / Glycine Soja (Soybean) Seed Extract
Edible soybean extract. Considered non-toxic. In tests on volunteers (patch test, HRIPT) of the cream extract, no irritating properties (including contact with the mucosa) and no sensitizing properties were observed. A substance with a known history of use as an ingredient in cosmetics and in dietary supplements. The substance does not meet the criteria for classification as carcinogenic, mutagenic or toxic to reproduction.
Acute toxicity No data available
Irritating effect No data available
Corrosive effect No data available
Sensitizing effect No data available
Repeated dose toxicity No data available
Phototoxicity No data available

Ingredient Name: Artemisia Vulgaris Extract
Artemisia vulgaris L. Asteraceae (Compositae) / Mugwort, Indian wormwood
Source: Aerial parts of flowering plant
Maximum adult daily oral dose: 56 mg; Maximum dermal use level: 2%
Our oral and dermal restrictions are based on 20.8% camphor and 11.4% a-thujone content with limits of 2.0 mg/kg and 4.5% for camphor and 0.1 mg/kg and 0.25% for thujone
Thujone is banned as a food additive in
the USA and its presence in foods and beverages is regulated in several countries; the limits for a- and/or b-thujone in Europe vary from 5–35 mg/kg depending on beverage type.
Thujone is listed in the EPA's Toxic Substances Control Act inventory. In 1999 the Council of Europe allocated a TDI of 10 mg/kg of thujone, based on the NOAEL of 5 mg/kg in female rats and an uncertainty factor of 500 (Council of Europe 1999, cited in SCF 2003b). However, in a subsequent
SCF report on thujone it was concluded that the available data were inadequate to establish a TDI/ADI (SCF 2003b).European Medicines Agency proposed an oral limit for thujone of 3 mg/adult, in 2009 (EMA 2009) and later revised this to 5 mg/kg (EMA 2010).
Our safety advice: Lachenmeier & Uebelacker (2010) have proposed an oral limit for thujone isomers of 0.11 mg/kg/day, based on benchmark dose modeling of the rodent data, including the NTP 2011 report. This is derived from a BMDL10 value of 11 mg/kg/day for clonic sezures in male rats, and uncertainty factors of 10 for interspecies and 10 for interindividual differences. We recommend a rounded down value of 0.1 mg/kg/day. This is equivalent to 7 mg per adult, and a dermal exposure of 0.25%.
Organ-specific effects: The thujone NOAEL for convulsions was reported to be 10 mg/kg in male rats and 5 mg/kg in females (Margaria 1963).
Both a- and b-thujone are moderately toxic, with reported oral LD50 values ranging from 190–500 mg/kg for different species.
Carcinogenic: Artemisia vulgaris var. indica oil was antimutagenic in an assay with S. typhimurium /TA98

Ingredient Name: Pinus Densiflora Leaf Extract
Pinus densiflora is one of the traditional medicinal plants found in East Asia. The extract has antimicrobial and antioxidant properties. Water extracts from needles Pinus Sp. inhibit seed germination and seedling growth in many plant species and nitrifying bacteria (Lodhi and

Killingbeck 1982, Fernandez et al. 2006). They have long been used in folk medicine. The terpene compounds present in the extract may be irritating and allergenic. The substance does not meet the criteria for classification as carcinogenic (IARC). Acute toxicity - inhalation effects: Studies show that volunteers experience eye, nose and throat irritation after exposure to turpentine concentrations in the range of 125 - 175 ppm. Most people can tolerate a daily exposure of 100 ppm. The American Conference on Industrial Hygiene (ACGIH) recommends a limit value (TLV - TWA) of up to 100 ppm to minimize the potential for irritation of the upper respiratory tract. No maximum exposure limit (TLV) is specified due to limited data. No effects of chronic exposure other than contact dermatitis.
Acute toxicity No data available
Irritating effect No data available
Corrosive effect No data available
Sensitizing effect No data available
Repeated dose toxicity No data available
Carcinogenicity No data available
Mutagenicity No data available
Phototoxicity No data available
Harmful effect on reproduction No data available

Ingredient Name: Thuja Orientalis Leaf extract
Eastern biota, Eastern Platykladus, formerly Eastern Thuja, a species of coniferous plant belonging to the cypress family. Originally, this species was included in the genus Thuja orientalis (Polish thuja orientalis), but now it has been isolated in its own single-species genus Platycladus (Polish biota) due to morphological differences. Externally, it may be irritating to the skin. Contains Thujon, which cannot be added specifically to food. It can, however, be present in food products as an integral component of the raw materials from which the food was produced, e.g. in the form of mugwort herb, which naturally contain thujone, in the form of a flavor component made from natural plant materials or essential oils. Beverages and foodstuffs made of such raw materials may contain a maximum of 0.5 mg of thujon-alpha and -beta per kg. Thujon is an inseparable component of some vodkas, liqueurs and herbal tinctures, e.g. absinthe (wormwood, absinthe)
Acute toxicity No data available
Irritating effect No data available
Corrosive effect No data available
Sensitizing effect No data available
Repeated dose toxicity No data available
Carcinogenicity No data available
Mutagenicity No data available
Phototoxicity No data available
Harmful effect on reproduction No data available

Ingredient Name: Laminaria Cloustoni Extract
Brown algae extract. No figures available, plant with known use as a cosmetic ingredient and dietary supplement. There are no significant literature data on the toxicity of this ingredient. Potentially does not pose a significant risk to human health in cosmetic use. Historical data indicate safe use in cosmetic products. Substance considered to be non-toxic, non-irritating and non-sensitizing.
Acute toxicity No data available
Irritating effect No data available

Corrosive effect No data available
Sensitizing effect No data available
Repeated dose toxicity No data available
Carcinogenicity No data available
Mutagenicity No data available
Phototoxicity No data available
Harmful effect on reproduction No data available

Ingredient Name: Morus Alba Bark Extract
White mulberry bark extract. There are no significant literature data on the toxicity of this ingredient. The terpene compounds present in the extract may be irritating and allergenic. Historical data indicate safe use in cosmetic products as well as in dietary supplements.
Acute toxicity No data available
Irritating effect No data available
Corrosive effect No data available
Sensitizing effect No data available
Repeated dose toxicity No data available
Carcinogenicity No data available
Mutagenicity No data available
Phototoxicity No data available
Harmful effect on reproduction No data available

Ingredient name: Sh-Oligopeptide-2
It is a single chain recombinant human peptide,produced by fermentation in E. coli. The starting gene is a synthesized copy of the human gene which codes for Insulin-Like Growth Factor used as such or adapted to the production host. In vitro, human keratinocyte cell : SAFE (No Cellular Toxicity) up to tested 10,000ppm (µg/ml)
Acute toxicity No data available
Irritating effect No data available
Corrosive effect No data available
Sensitizing effect No data available
Repeated dose toxicity No data available
Carcinogenicity No data available
Mutagenicity No data available
Phototoxicity No data available
Harmful effect on reproduction No data available

Ingredient name: Copper Tripeptide-1
Copper Tripeptide-1 is a copper complex of Tripeptide-1
Tripeptide-1 is a synthetic peptide containing glycine, histidine, and lysine
Toxicity Data : Acute toxicity: LD50 mouse (I.P.): =160mg/kg, (I.V.)=110-120mg/kg
Rat (I.V.)≥75mg/kg, Rat (oral) ≥150mg/kg
May be harmful by inhalation, ingestion, or skin absorption. May cause irritation. To the best of our knowledge the chemical, physical, and toxicological properties have not been completely investigated. Moderate irritant to skin on direct contact. In vitro, human keratinocyte cell : SAFE (No Cellular Toxicity) up to tested 10,000ppm (µg/ml)

Ingredient name: Polysorbate 20
Polysorbate-20

Sorbitan, monododecanoate, poly (oxy-1,2-ethanediyl) derivs.
LD50 (rat, oral) = 36700 µL / kg; LD 50 (mouse, oral): 33,000 mg / kg. May be irritating to skin and eyes. World literature reports that in the case of a 24-hour application of 0.5 ml of polysorbate 20 to the skin of rabbits using patch tests, little or no irritation was observed. The substance is not listed as carcinogenic in the ACGIH, IARC, NTP, CA Prop 65 databases.

Ingredient name: Sh-Polypeptide-13
Chemical/IUPAC Name: NOG
sh-Polypeptide-13 is a single chain synthetic human peptide, produced by fermentation in E. coli. The starting gene is a synthesized copy of the human gene which codes for Noggin Protein used as such or adapted to the production host. It contains a maximum of 232 amino acids which may contain disulfide bonds and/or glycosylation. The protein consists of the proper sequence of the 20 standard amino acids.

Ingredient Name: Lecithin
There are no data on LD50 in the literature. According to some sources, based on many human observations, it is not necessary to determine the maximum dose of human consumption. However, there is information that high doses (25-40 g) administered over several months lower serum cholesterol levels. Acute oral, short-term oral, and sub-dermal toxicity studies in animals have shown lecithin to be practically non-toxic. Lecithin is not harmful to reproductive processes and does not show any mutagenic effect in tests on animals. In carcinogenicity studies (oral administration), brain tumors were found in mice exposed to lecithin. No tumors were found in mice and rats treated with lecithin when administered subcutaneously. Studies on lecithin and hydrogenated lecithin showed no irritating and sensitizing properties for animal and human skin. Based on the available data, lecithin and hydrogenated lecithin are safe when used in rinse-off cosmetics; in cosmetics remaining on the skin, they can be safely used up to 15%, the highest concentration tested in clinical irritation and allergy studies. (CIR)

Ingredient: Butylene Glycol
Substance considered low toxic. The following were determined in the acute toxicity tests:
LD_{50}(a rat, oral exposure): 22,800mg/kg; LD_{50} (mouse, subcutaneous exposure);12,980mg/kg
LD_{50}(a guinea pig, oral exposure): 11,460mg/kg; LD_{50}(rabbit, dermal exposure):>20,000mg/kg
It may cause eye irritation. When tested on a rabbit eye it did not cause permanent irritation. Application of larger quantity of the tested substance (through bursting) caused pain and temporary changes in the cornea epithelium. No irritating effect on human and animal skin or mucosal tissue were observed. In the patch tests repeated for 5 weeks on 200 humans no sensitizing effect of a 50% water solution of the substance was observed. Temporary skin irritation was observed in two persons after 24 hours' exposure repeated after 2 weeks in the same place of exposure. NOAEL in the sub-chronic toxicity tests on rats, after oral exposure, was determined as: 1,429 mg/kg of a body weight per day and in other test: 5,000 mg/kg of a body weight per day; for dogs: 6,000 or 9,000 mg/kg of a body weight per day (sub-chronic tests), 286 mg/kg of a body weight per day (in dogs). After dermal exposure in guinea pigs NOAEL was determined as 20,100 mg/kg of a body weight per day. No genotoxic or carcinogenic effects observed.

Acute toxic effect	LD_{50} (oral exposure, rat): 22,800 mg/kg LD_{50} (dermal exposure, rat): no data LD_{50} (inhalation exposure, rat): 290 mg/l (4 hours' exposure) Chronic toxicity: NOAEL: 5,000 mg/kg/day (a rat)
Irritating /Corrosive effect	No irritating effect on skin (a rabbit)

on skin	
Serious damage to eyes/irritating effect for eyes	Light irritation of eyes (a rabbit)
Sensitisation effect or respiratory track or skin	No data about sensitizing effect on respiratory track No sensitizing effect on skin (test on humans, patch test)
Mutagenic effect on reproductive cells	In vivo tests - negative
Carcinogenicity	NOAEL: 5,000 mg/kg/day (a rat)
Harmful effect on fertility	NOAEL: 5,000 mg/kg/day (a rat, oral exposure) LOAEL: 12,000 mg/kg/day (a rat, oral exposure) Development toxicity: Maternity toxicity: NOAEL 2,500 mg/kg/day (a rat, oral exposure); Teratogenicity: NOAEL 12,000 mg/kg/day (a rat, oral exposure) Fetus toxicity: NOAEL: 2,500 mg/kg/day (a rat, oral exposure) LOAEL: 5,000 mg/kg/day (a rat, oral exposure) Concentration with no toxic effects in mothers: 300 mg/kg (a rabbit)
Toxic effects on the target organs - single exposure	No data
Toxic effects on the target organs- repeated exposure	No data
Threat caused by aspiration	No data

Ingredient: Phenoxyethanol
V/29. Max 1.0%
Acute toxicity: LD50 Oral - rat 1.260 mg/kg/ Remarks: Behavioral:General anesthetic. Gastrointestinal:Other changes. Kidney, Ureter, Bladder:Other changes.
LD50 Dermal - rat - 14.422 mg/kg. Remarks: Lungs, Thorax, or Respiration:Acute pulmonary edema. Skin corrosion/irritation: Skin - rabbit - Mild skin irritation - 24 h
Serious eye damage/eye irritation: Eyes - rabbit - Moderate eye irritation
Respiratory or skin sensitization: no data available
Germ cell mutagenicity: no data available
Carcinogenicity: IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
Reproductive toxicity: no data available. May cause reproductive disorders.
Specific target organ toxicity - single exposure: no data available
Specific target organ toxicity - repeated exposure: no data available
Aspiration hazard: no data available. RTECS: KM0350000
CLP Proposal: Acute Tox. 4, H302, Eye Dam. 1, H318, STOT SE 3, H335.
Oral: ATE = 1394 mg/kg bw

Ingredient: Sodium Benzoate
V/1
Product Type, body parts: a) Rinse-off products, except oral care products; b) Oral care products; c) Leave-on products. Maximum concentration in ready for use preparation
a) 2.5% (acid); b) 1.7% (acid); c) 0.5% (acid)

Salt of benzoic acid. Preserving substance - protects against bacterial contamination during storage and use of the cosmetic. The substance is considered a safe ingredient of cosmetics in a concentration of up to 0.5%. In oral acute toxicity tests in rats, LD50> 2000 mg / kg bw / day was determined. Low dermal toxicity has also been demonstrated. In chronic toxicity studies, the NOAEL was determined at the level of 1000 mg / kg bw / day. (rat orally). At higher doses, increased mortality, weight loss, changes in kidney and liver were observed. No skin irritation was observed in rabbits and slight eye irritation occurred. No sensitizing properties. It has no negative effects on reproductive function (NOAEL: 750 mg / kg bw / d) and embryo development (NOAEL for female rats: 1400 mg / kg bw / d), both in oral and dermal administration. No in vivo genotoxic and carcinogenic effects (up to 2% in rats).
Acute oral toxicity: LD50 Oral: 4070 mg/kg, rat. ADI 0-5 mg/kg
Acute inhalation toxicity
Skin irritation: rabbit, Classification: No skin irritation
Additional data: please see benzoic acid.

Ingredient: Benzoic Acid
Annex/Ref # V/1. Product Type, body parts: a) Rinse-off products, except oral care products, b) Oral care products, c) Leave-on products . Maximum concentration in ready for use preparation: a) 2.5% (acid), b) 1.7% (acid), c) 0.5% (acid)
For benzoic acid repeated dose oral toxicity studies give a NOAEL of 800 mg/kg/day. For the salts values > 1000 mg/kg/day are obtained. At higher doses increased mortality, reduced weight gain,liver and kidney effects were observed. It can be concluded that benzoic acid and its salts exhibit very low repeated dose toxicity.
In a 4-generation study with benzoic acid no effects on reproduction were seen (NOAEL ≥ 750mg/kg). No compound related effects on reproductive organs (gross and histopatology examination) could be found in the (sub) chronic studies in rats and mice with benzyl acetate, benzyl alcohol, benzaldehyde, sodium benzoate and supports a non-reprotoxic potential of these compounds. In addition, data from reprotoxicity studies on benzyl acetate (NOAEL >2000 mg/kg bw/d; rats and mice) and benzaldehyde (tested only up to 5 mg/kg bw; rats) support the non-reprotoxicity of benzyl alcohol and benzoic acid and its salts.
The Joint FAO/WHO Expert Committee on Food Additives (JEFCA) has established a group Acceptable Daily Intake (ADI) for benzoic acid of 5 mg benzoic acid equivalent/kg bodyweight. LD50/ rat =2565 mg/kg/ Directive 84/449/EEC
LD50/ mouse =2250 mg/kg/ OPPTS 870.1100
Acute Dermal Toxicity: rabbit EPA OTS .798.1100.LD50= > 2000 mg/kg
Acute Inhalation Toxicity: Benzoic acid/ rat EPA OTS.798.1150.LC50 = >12.2 mg/l/4h.
No mortality at 12.2mg/l as dust.
The compounds exhibit low acute toxicity,
Skin Irritation: Rabbit . EPA OTS 798.4470. not irritating; Directive 84/449/EEC: slightly irritating
Eye Irritation. Rabbit. Directive 84/449/EEC: highly irritating; EPA OTS. 798.4500- severely irritating
Sensitization: The available studies for benzoic acid gave no indication for a sensitizing effect in animals, however some weak positive reactions were recorded with the human patch test.
Guinea pig: Draize. not sensitizing; Guinea pig maximization test- not sensitizing; human Patch test: occasional positive result
Repeat Dose Toxicity
In a 4-generation study 20 rats/sex/group were dosed continuously by diet with 375 or 750

mg/kg/day benzoic acid. In all 4 generations no influence on growth (weight, weight gain and food efficiency (measured by protein efficiency)) and organ weights was found. The animals of the 3rd generation were killed and examined histopathologically after 16 weeks (after lactation of the pups). No histo-pathological findings were found. In the paper, no information is given on the
organs investigated, however the robustness of the total study, the reputation of the investigators, as well as the reputation of the Professor who did the histopathologic investigation, a high scientific quality has to be assumed even though the studies were performed many years ago. From other parameters it can be assumed that as a minimum the brains, heart, liver, kidney, testis and spleen were examined.
Feeding of 375 mg/kg/day led to prolongation of survival compared to controls
NOAEL > 750 mg/kg/day (Kieckebusch & Lang, 1960)
Due to missing hematological and clinical chemistry investigations in all studies only a preliminary NO(A)EL of about 800 mg/kg can be derived for rats which is based on the studies from Kieckbusch & Lang (1960), Kreis et al. (1967) and Bio-Fax (1973) (Details to be found in the IUCLID).
A 21day dermal study with male/female New Zealand white rabbits dosed with 100,500, or 25k mg/kg bw benzoic acid 5 days/week showed no compound related effects in behavior, body weight organ weights, clinical laboratory tests or survival. Very slight dermal irritation was noted for 1/8 rabbits at the 2500mg/kg level. NOAEL=2500mg/kg/day. (IRDC#163-675, 1981)
Genetic Toxicity: Benzoic acid was not mutagenic in Ames tests with and without metabolic activation (EGG# 580-192-1-78, 1978). The Sister Chromatid Exchange assay with human lymphocytes was negative – no metabolic activation was used (Jansson, 1988; Tohda, 1980). A Chromosome Aberration study with CHL cells was ambiguous - no metabolic activation was used (Ishidate, et al., 1984). A recombination assay with Bacillus subtilus H17 and M45 was positive (reported with minimal documentation in an abstract, Nonaka, 1989).
Studies of these chemicals in the Ames point mutation assay do not show evidence of mutagenicity.
The compounds exhibit no carcinogenicity. Toxicity to Reproduction: In a 4-generation study 20 rats/sex/group were dosed continuously by diet with 375 or 750mg/kg/day benzoic acid. In all 4 generations, no effects on fertility (“Fortpflanzung”) and lactation (“Aufzugt der Jungen”) were found. In addition a so-called “Alters Paarung” after 48 weeks gave no influence on start of menopauze. NOAEL (Parental) > 750 mg/kg/day; NOAEL (F1 Offspring) > 750 mg/kg/day NOAEL (F2 Offspring) > 750 mg/kg/day;(Kieckebusch & Lang, 1960)
Developmental Toxicity. Pregnant Wistar rats were treated on day 9 of gestation with one dose of 510 mg/kg benzoic acid in carboxymethylcellulose. Animals were sacrificed on Day 20 of gestation and the uterus observed in situ for implantation and resorption sites. Live fetuses were removed, examined for gross malformations, weighed, and prepared for histopathological examination. Treatment with benzoic acid resulted in no dead or resorbed implants and 3 % abnormal survivors, rates comparable to the control animals.NOAEL Maternal toxicity: 510 mg/kg bw. NOAEL Teratogenicity: 510 mg/kg bw; (Kimmel et al., 1971)

Ingredient: Parfum

[redacted]

[redacted]

Limonene from list of potential allergens to be on the label

Applied fragrance composition has IFRA Certificate to a maximum concentration of 5% for category 9a, 2% for category 8a. When used appropriately, it does not pose a threat to health

and life. Due to the presence of small amounts of sensitizing substances, individual hypersensitivity to this component is not excluded.
Any cosmetic product containing any of 26 raw materials identified by the SCCS intended for Consumers as likely to cause a contact allergy when present above certain trigger levels to be declared on the package label.
According to the manufacturer's declaration applied composition contains potentially allergenic substances in quantities requiring them to declare on the packaging of the finished product, ie. At a concentration exceeding 0,001%:

Ingredient: Limonene
III/88.
The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1)g when its concentration exceeds: 0.001% in leave-on products; 0.01% in rinse-off products
Peroxide value less than 20 mmoles/L /This limit applies to the substance and not to the finished cosmetic product.
TOXICITY: Oral (rat) LD50: 4400 mg/kg/ Oral (Rat) LD50: 5300 mg/kg
Inhalation (rat) LC50: 90860 mg/m3; Dermal (Rabbit) LD50: >5000 mg/kg
IRRITATION: Skin (rabbit): 500mg/24h Moderate
Skin sensitization: May cause an allergic skin reaction. – mouse. Result: May cause sensitisation by skin contact. (OECD Test Guideline 429)
Germ cell mutagenicity: mouse –lymphocyte. Result: negative / rat – male.Result: negative
d-Limonene is readily absorbed by inhalation and ingestion. Dermal absorption is reported to be lower than by the inhalation route. d-Limonene is rapidly distributed to different tissues in the body, readily metabolised and eliminated primarily through the urine. Limonene exhibits low acute toxicity by all three routes in animals. Limonene is a skin irritant in both experimental animals and humans. Limited data are available on the potential to cause eye and respiratory irritation. Autooxidised products of d-limonene have the potential to be skin sensitisers. Limonene is neither genotoxic or teratogenic nor toxic to the reproductive system. The substance is classified by IARC as Group 3: NOT classifiable as to its carcinogenicity to humans. This product is not expected to cause reproductive or developmental effects.
Repeated dose toxicity - mouse - male and female - No observed adverse effect level - 1,650 mg/kg - Lowest observed adverse effect level - 3,300 mg/kg

9. Undesirable effects and serious undesirable effects

There is no data regarding to side effects or serious side effects after use of this cosmetic product. Thereby it implicates a high safety profile of the product.

10. Information on the cosmetic product

The finished product and raw materials from which it was made have not been tested on animals.

The conformity of marketing claims and their legality were not assessed here. Technological diagram in the attachment.

CZĘŚĆ B
OCENA BEZPIECZEŃSTWA PRODUKTU KOSMETYCZNEGO

PART B
COSMETIC PRODUCT SAFETY ASSESSMENT

1. Wniosek z oceny/ Assessment conclusion

Zgodnie z Rozporządzeniem Parlamentu Europejskiego i Rady (WE) Nr 1223/2009 z dnia 30 listopada 2009 r. dotyczącym produktów kosmetycznych na podstawie przeprowadzonej w punkcie A oceny bezpieczeństwa produktu kosmetycznego Absolute Shampoo, przeznaczonego do mycia i pielęgnacji włosów oświadczam, że omawiany produkt można uznać za bezpieczny dla zdrowia ludzi w normalnych lub dających się przewidzieć warunkach stosowania.

Oceny dokonano w oparciu o deklarowany przez producenta skład oraz udostępnione dane dotyczące składników i produktu gotowego.

According to The Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products and on the basis of safety assessment, conducted in part A, for the cosmetic product named Ultimate Serum, intended for Hair and scalp care. I declare that this product is safe for human health when used under normal or reasonably foreseeable conditions of use.

The safety assessment was based on product's composition and data on ingredients and finished product provided by the manufacturer.

2. Ostrzeżenia i instrukcje stosowania umieszczane na etykiecie/Labelled warnings and instructions for use

Opakowanie produktu kosmetycznego Ultimate Serum zapewnia odpowiednią prezentację omawianego produktu, a tym samym gwarantuje przewidywane warunki stosowania oraz jego przeznaczenie. Według deklaracji producenta tekst etykiety na opakowaniu zawiera informację o składnikach, jak również dane dotyczące numeru serii oraz datę minimalnej trwałości.

Treści etykiety nie weryfikowano.

Z uwagi na skład produktu kosmetycznego Ultimate Serum, na jego przeznaczenie oraz na fakt, że nie należy on do grupy produktów do stosowania profesjonalnego niniejszym oświadczam, że nie ma konieczności umieszczenia na opakowaniu określonych środków ostrożności oraz instrukcji stosowania przewidzianych dla specjalnej grupy kosmetyków (zgodnie z Art.19(1)(d) Rozporządzenia KE Nr 1223/2009).

The type of packaging used for the cosmetic product Ultimate Serum ensures appropriate product's presentation what guaranties established and foreseeable conditions of use. The labeling contains information about ingredients, the date of the minimum durability as well as responsible person data.

Regarding to the composition of the cosmetic product Ultimate Serum, its intended use and the fact that this product is not included for the professional there is no need to give any special

precautionary information and instruction for use in labeling (as stated in Art. 19(1)(d) of Regulation CE No 1223/2009)

The label content was not verified.

3. Rozumowanie/Reasoning

Wniosek opisany w punkcie 1 jest wynikiem analizy danych, przeprowadzonej w części A, tj.

- ilościowego i jakościowego składu produktu wraz z ograniczeniami dotyczącymi określonych substancji, wymaganymi przez przepisy Rozporządzenia WE Nr 1223/2009,
- właściwości fizycznych i chemicznych substancji oraz związanej z nimi stabilności wyrobu gotowego, w tym danych mikrobiologicznych,
- danych toksykologicznych poszczególnych składników, z uwzględnieniem danych dotyczących toksyczności miejscowej i systemowej oraz narażenia na działanie tych substancji,
- wyników badań produktu gotowego w tym testów dermatologicznych,
- informacji o zaobserwowanych lub potencjalnych działaniach niepożądanych.

Składniki, które podlegają ograniczeniom, zgodnie z Rozporządzeniem WE 1223/2009, zostały użyte w dozwolonych stężeniach i warunkach stosowania.

Profil toksykologiczny poszczególnych substancji zastosowanych w produkcie nie budzi zastrzeżeń.

Dla składników, dla których dostępne były wartości NOAEL wyznaczono marginesy bezpieczeństwa (MoS). We wszystkich przypadkach wyniosły one powyżej 100. Dla pozostałych składników, dla których nie są dostępne dane dotyczące toksyczności przewlekłej lub inne dane toksyczności ostrej, lokalnej lub udokumentowana historia bezpiecznego użycia pozwalają na zastosowanie substancji w produkcie w zalecanym stężeniu i warunkach użycia.

Ponadto w niniejszej ocenie zostały uwzględnione następujące dane:

- Czystość substancji i ewentualne zanieczyszczenia – nie budzą zastrzeżeń,
- Czystość i stabilność materiału opakowaniowego – nie budzą zastrzeżeń,
- Interakcje składników produktu, interakcje składników z materiałem opakowaniowym – nie są spodziewane,
- Sposób oznakowania produktu – nie budzi zastrzeżeń.

The conclusion given in point 1 is the result of analysis conducted in part A ie.

- quantitative and qualitative composition of the cosmetic product including appropriate restrictions required by the Regulation CE No 1223/2009

- physical and chemical properties of substances/mixtures and related to them the stability of the finished cosmetic product including microbiological quality
- toxicological data of substances/mixtures including local and systemic toxicity and exposure
- analysis of finished product including dermatological and application tests
- information on undesirable effects or serious undesirable effects

Substances with restrictions of use (according to the Regulation CE No 1223/2009) have been used in the permitted concentrations and conditions of use.
There are no concerns on toxicology profile of applied substances.
Margins of Safety (MoS) have been calculated for substances with NOAEL value. All of MoS have been >> 100. For the other ingredients for which there were no chronic, acute or local toxicity data the safe use in history allows to use them in recommended concentration and conditions of use.

Moreover, in this assessment the following data were considered:

- purity of ingredients – without objections
- packaging choice and its stability – without objections
- ingredients interactions and their interaction with packaging – not expected
- labelling – without objections.

Uwagi:

Niniejsza ocena wymaga aktualizacji w przypadku:

- modyfikacji receptury przez producenta,
- zmiany specyfikacji składnika,
- zmiany aktualnego stanu wiedzy, np. pojawienia się nowych danych wskazujących na ryzyko określonego składnika lub produktu gotowego,
- zmiany wymogów prawnych,
- wzrostu przypadków działań niepożądanych, zarówno w wyniku stosowania produktu zgodnie z przeznaczeniem, lub wynikających z niewłaściwego użycia.

Comments:

The safety assessment has to be updated in the case of:

- changes in the formulation
- changes of specifications of raw materials
- new scientific findings and toxicological data on the substances which could modify the result of the existing safety assessment
- changes in the legal requirements
- the rising of incidence of undesirable effects, both under reasonably conditions of use and in the case of misuse.

4. Kwalifikacje eksperta i zatwierdzenie części B/Assessor's credentials and approval of part B

Krzysztof Piotrowski, mgr inż.

Wydział Chemii Spożywczej i Biotechnologii Politechniki Łódzkiej;

kierunek: Technologia Chemiczna

Dowód kwalifikacji osoby przeprowadzającej ocenę bezpieczeństwa – CV w załączeniu

kopie dyplomów dostępne na żądanie

European Cosmetic Product Safety Assessor

Krzysztof Piotrowski, M.Sc. Eng.

Department of Food Chemistry and Biotechnology Technical University of Lodz; Major: Chemical Technology

Proof of safety assessor's qualification – CV attached, M.Sc. Eng. proof on request

2023-07-27 Krzysztof Piotrowski

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Date Podpis/Signature

Piśmiennictwo/ Literature:

Rozporządzeniem Parlamentu Europejskiego i Rady (WE) Nr 1223/2009 z dnia 30 listopada 2009 r. dotyczącym produktów kosmetycznych wraz z późniejszymi zmianami

AEM. https://aem.asm.org/content/
Agency for Toxic Substances and Disease Registry https://www.atsdr.cdc.gov/toxprofiles/
Annex XVII REACH
https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02006R1907-20200227&from=EN
Australian National Health and Medical Research Council (NHMRC)
https://www.nhmrc.gov.au/sites/default/files/images/Nutrient-reference-aus-nz-executive-summary.pdf
Canada DSL. https://pollution-waste.canada.ca/substances-search/Substance
Canada Gazette Publication. https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics/cosmetic-ingredient-hotlist-prohibited-restrictedingredients/hotlist.html#tbl1
Canada Hotlist. https://www.canada.ca/en/health-canada/services/consumer-product-safety/cosmetics/cosmetic-ingredient-hotlist-prohibited-restrictedingredients/hotlist.html#tbl1
Candidate List of SVHC. https://echa.europa.eu/candidate-list-table
Chemblink. http://www.chemblink.com/products/
ChemSpider. http://www.chemspider.com/
CIR. https://www.cir-safety.org/sites/default/files/
CIR review. https://www.cir-safety.org/sites/default/files/
CLP Regulation. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1272-20200101&from=EN
Eur-lex.europa.eu. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?
European Food Safety Authority (EFSA). https://efsa.onlinelibrary.wiley.com/doi/epdf/
FDA. https://www.fda.gov/cosmetics/cosmetic-ingredient-names/color-additives-permitted-use-cosmetics
Food intolerance and allergy. https://www.nhs.uk/conditions/food-intolerance/
IFRA InternationalFragranceAssocication https://ifrafragrance.org/
International Journal of Toxicology. https://onlinelibrary.wiley.com/doi/full/
MSDS. https://www.chemblink.com/MSDS/MSDSFiles/
National Library of Medicine. https://webwiser.nlm.nih.gov
NCBI. https://www.ncbi.nlm.nih.gov/pubmed
New Zealand gov. https://www.epa.govt.nz/industry-areas/hazardous-substances/guidance-for-importers-and-manufacturers/cosmetics/
NHS. https://www.nhs.uk/conditions/food-allergy/
NICNAS. https://www.industrialchemicals.gov.au/chemicals/lanolin
NICNAS Assessment Report. https://www.nicnas.gov.au/chemical-information/
Oehha. https://oehha.ca.gov/media/downloads/proposition-65/
Proposal for Harmonised Classification and Labelling, 2018. https://echa.europa.eu/documents/
PubMed – NCBI. https://pubchem.ncbi.nlm.nih.gov/compound/

Toxicity testing and derivation of the ADI
RAC Opinion
https://echa.europa.eu/documents/
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