COSMETIC PRODUCT

SAFETY REPORT

Absolute Shampoo

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

Cosmetic product safety report of the product: Absolute Shampoo hereinafter called Absolute Shampoo 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.

Icid	Wt (%)	CAS No.	Ingredient function
Ammonium Laureth Sulfate	40,0000	32612-48-9	Cleansing Agent
Aqua	37,9342	7732-18-5	rozpuszczalnik
Ammonium Lauryl Sulfate	10,0000	2235-54-3	Cleansing Agent
Cocamidopropyl Betaine	5,0000	61789-40-0	Cleansing Agent
Cocamide Mea	1,2000	68140-00-1	Viscosity increasingAgent
Menthol	0,9500	99-78-1	Fragrance
Parfum	0,4591	-	Fragrance
Linalool	0,0296	78-70-6	Fragrance
Limonene	0,0272	5989-27-5	Fragrance
Hexyl Cinnamal	0,0270	101-86-0	Fragrance
Citronellol	0,0176	106-22-9	Fragrance
Hydroxycitronellal	0,0154	107-75-5	Fragrance
Alpha-isomethyl ionone	0,0135	127-51-5	Fragrance
Benzyl Salicylate	0,0107	118-58-1	Fragrance
Polyquaternium-10	0,3000	53568-66-4	Antistatic Agent
Undaria Pinnatifida Extract	0,4000	7732-18-5	Skin Conditioning
Laminaria Cloustoni Extract	0,4000	-	Skin Conditioning
Glycine Max Seedcoat Extract	0,3000	-	Skin Conditioning
Polygonum Multiflorum Root Extract	0,3000	-	Skin Conditioning
Poria Cocos Extract	0,3000	-	Skin Conditioning
Morus Alba Bark Extract	0,3000	-	Skin Conditioning
Pinus Densiflora Leaf Extract	0,2000	94167-05-2	Skin Conditioning
Artemisia Vulgaris Extract	0,2000	-	Skin Conditioning
Rehmannia Chinensis Root Extract	0,2000	84775-45-1	Skin Conditioning
Thuja Orientalis Leaf Extract	0,2000	-	Skin Conditioning
Sesamum Indicum Seed Extract	0,2000	-	Skin Conditioning
Sodium Benzoate	0,0250	532-32-1	Preservaitive
Hamamelis Virginiana Extract	0,0300	84696-19-5	Skin Conditioning
Phenyl Trimethicone	0,2000	2116-84-9	Skin Conditioning
Hydroxyethyl Urea	0,2000	1320-51-0	Skin Conditioning
Caramel	0,1000	8028-89-5	Colorant
Climbazole	0,1000	38083-17-9	Cosmetic Biocide
Cetearyl Alcohol	0,1000	8005-44-5	Emulsion Stabilizer
Sodium Chloride	0,1000	7647-14-5	Viscosity increasingAgent
Salicylic Acid	0,0500	69-72-7	Antiacne Agent
Pyridoxine Hcl	0,0500	58-56-0	Hair Conditioning

Disodium Edta	0,0300	139-33-3	Chelating Agent
Panthenol	0,0300	16485-10-2	Skin Conditioning
Methylchloroisothiazolinone	0,0006	26172-55-4	Preservative
Methylisothiazolinone	0,0002	2682-20-4	Preservative
	100,000		

[redacted]

Allergens above 0,01% to be declared on the label: Linalool, Limonene, Hexyl Cinnamal, Citronellol, Hydroxycitronellal, Alpha-isomethyl ionone, Benzyl Salicylate

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 Absolute Shampoo 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 Absolute Shampoo meet requirements of internal standard:

Parameter	Requirements
Appearance	Green brown, viscous liquid. To Match Standard
Color	To Match Standard
Odor	To Match Standard. Characteristic for the fragrance composition used and for the raw materials used, menthol
Density	0.95~ 1.05 / [20 °C]
pH [20 °C]	5-6,5
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.

Absolute Shampoo has been tested for stability. Based on the tests conducted at different temperature conditions for a period of 5 weeks 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 internal 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 Absolute Shampoo 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

In accordance with the conducted challenge test preservatives contained in the product are efficient with respect to microorganisms of three bacteria and fungi strains (Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 90207, Candida albicans ATCC 10231). The results of the test confirm that the preservatives were correctly composed.

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.

Absolute Shampoo is packaged in: Plastic Bottle (PET) 200ml PET with flip-top cap.
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 Absolute Shampoo 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 Absolute Shampoo 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 – rinse-off 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:10,46g/day
- Calculated daily exposure: 0,11g/day
- Retention factor: 0,01
- Frequency of use: average 1,0x/day
- Relative amount applied: 150,49mg/kg bw/day
- Estimated daily exposure to the product: 1,51 mg/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 Absolute Shampoo. MoS value for substances with available NOAEL was also calculated.

INCI	SED	NOAEL	MOS
Ammonium Laureth Sulfate	0,6040	250	414
Ammonium Lauryl Sulfate	0,1510	250	1 656
Cocamidopropyl Betaine	0,0755	75	993
Cocamide Mea	0,0181	---	---
Menthol	0,0143	---	---
Parfum	0,0069	---	---
Linalool	0,0004	50	111 965
Limonene	0,0004	30	73 000
Hexyl Cinnamal	0,0004	30	73 584
Citronellol	0,0003	50	188 354
Hydroxycitronellal	0,0002	250	1 077 884

Alpha-isomethyl ionone	0,0002	3,55	17 399
Benzyl Salicylate	0,0002	180	1 116 154
Polyquaternium-10	0,0045	---	---
Undaria Pinnatifida Extract	0,0060	---	---
Laminaria Cloustoni Extract	0,0060	---	---
Glycine Max Seedcoat Extract	0,0045	---	---
Polygonum Multiflorum Root Extract	0,0045	---	---
Poria Cocos Extract	0,0045	---	---
Morus Alba Bark Extract	0,0045	---	---
Pinus Densiflora Leaf Extract	0,0030	---	---
Artemisia Vulgaris Extract	0,0030	---	---
Rehmannia Chinensis Root Extract	0,0030	---	---
Thuja Orientalis Leaf Extract	0,0030	---	---
Sesamum Indicum Seed Extract	0,0030	---	---
Sodium Benzoate	0,0004	400	1 059 603
Hamamelis Virginiana Extract	0,0005	---	---
Phenyl Trimethicone	0,0030	---	---
Hydroxyethyl Urea	0,0030	1000	331 126
Caramel	0,0015	---	---
Climbazole	0,0015	5	3 333
Cetearyl Alcohol	0,0015	1000	662 252
Sodium Chloride	0,0015	1000	662 252
Salicylic Acid	0,0008	80	105 960
Pyridoxine Hcl	0,0008	---	---
Disodium Edta	0,0005	237	523 179
Panthenol	0,0005	200	400 000
Methylchloroisothiazolinone	0,0000	2,8	294 334
Methylisothiazolinone	0,0000	2,8	883 002

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 Absolute Shampoo 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 Absolute Shampoo 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: AMMONIUM LAURETH SULFATE
(LD50> 4.7g / kg) For other toxicological data see:
Ingredient Name: AMMONIUM LAURYL SULFATE
Acute toxicity: Sulfuric acid, mono-C12-14 (even numbered) -alkyl esters, ammonium salts
LD50 Dermal Rabbit 2000 mg / kg; LD50 Oral Rat -Male, Female 1800 mg / kg
Skin corrosion / irritation:
OECD 405 Acute Eye Irritation / Corrosion Rabbit Eyes Severely irritating
OECD 404 Acute Dermal Irritation / Corrosion Rabbit Skin Irritant
Irritating to the skin. Severely irritating to the eyes.
Sensitization: OECD 406 Skin Sensitization skin Guinea pig Not sensitizing
Mutagenicity:
OECD 471 Bacterial Reverse Mutation Test Negative
OECD 476 In vitro Mammalian Cell Gene Mutation Test Negative
OECD 474 Mammalian Erythrocyte Micronucleus Test Negative
OECD 475 Mammalian Bone Marrow Chromosomal Aberration Test Negative
Carcinogenicity: OECD 453 Combined Chronic Toxicity / Carcinogenicity Studies Rat - Negative oral
Reproductive toxicity: OECD 414 Prenatal Developmental Toxicity Study Rat Oral: 250 mg / kg NOAEL
Teratogenicity: OECD 414 Prenatal Developmental Toxicity Study Rat 250 mg / kg NOAEL
Specific target organ toxicity - single exposure - Not available.
Specific target organ toxicity - repeated exposure - Not available.
Potential chronic health effects: OECD 408 Repeated Dose
90-Day Oral Toxicity Study in Rodents NOAEL - 488 mg / kg / d

Ingredient: Cocamidopropyl Betaine
1-propanaminium, 3-amino-N-(carboxymethyl)-N,Ndimethyl-,N-(C12-18(even numbered) acyl) derivs.,hydroxides, inner salts. LD50 Dermal. Rat - Male, Female >620 mg/kg
LD50 Oral. Rat - Male, Female 2430 mg/kg
Irritation/Corrosion: Rabbit Skin Non-irritant.
OECD 405 Acute Eye Irritation/ Corrosion Rabbit Eyes Corrosive
Conclusion/Summary: Skin: Non-irritating to the skin./ Eyes: Corrosive to eyes.
Sensitiser. OECD 406 Skin Sensitization. Guinea pig. Not sensitizing
Mutagenicity: OECD 471 Bacterial Reverse Mutation Test: Negative
EU EC B.13/14 Mutagenicity - Reverse Mutation Testing using Bacteria. Negative
OECD 476 In vitro Mammalian Cell. Gene Mutation Test. Negative
OECD 474 Mammalian Erythrocyte. Micronucleus Test. Negative
Conclusion/Summary. No mutagenic effect.
Carcinogenicity. Conclusion/Summary: In accordance with section 1 of Regulation (EC) No 1907/2006, Annex XI, this test does not appear scientifically necessary.

Reproductive toxicity. Conclusion/Summary: In accordance with column 2 of Annex VII - X of Regulation (EC) No 1907/2006, the test for this property of the substance does not need to be conducted.
Teratogenicity: OECD 414 Prenatal Developmental Toxicity Study. Rat 300 mg/kg NOAEL
Potential acute health effects
Inhalation: Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
Ingestion: No known significant effects or critical hazards.
Skin contact: No known significant effects or critical hazards.
Eye contact: Severely irritating to eyes. Risk of serious damage to eyes.
Symptoms related to the physical, chemical and toxicological characteristics
Skin contact. Ingestion. Inhalation No specific data.
Eye contact: Adverse symptoms may include the following:pain or irritation, waterin, redness
Delayed and immediate effects and also chronic effects from short and long term exposure
Short term exposure. Long term exposure. Potential immediate effects: Not available.
Other information :Not available.
Potential chronic health effects: OECD 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents: NOEL - 300 mg/kg
Carcinogenicity: No known significant effects or critical hazards.
Mutagenicity: No known significant effects or critical hazards.
Teratogenicity: No known significant effects or critical hazards.
Developmental effects: No known significant effects or critical hazards.
Fertility effects: No known significant effects or critical hazards.

Ingredient: Cocamide MEA
Amides, coco, N-(hydroxyethyl)
EMULSION STABILISING, SURFACTANT – CLEANSING, SURFACTANT – MULSIFYING, SURFACTANT - FOAM BOOSTING, VISCOSITY CONTROLLING
evaluated by CIR in 1999; The team found it safe, used in rinse-off cosmetic products, and safe at concentrations up to 10% in left-on products. LD50 = 2 g / kg (skin, rabbit). Acute toxicity, oral (rat) 3.3 g / kg. No skin reactions were observed when a 25% solution in dilution with olive oil was applied to mice for 1 week 2x / day.
LD50> 5.000 mg / kg oral rat
Respiratory or skin sensitization: not sensitizing / guinea pig test
Germ cell mutagenicity: negative / bacterial reverse mutation assay (e.g Ames test)
Repeated dose toxicity: 750 - 1500 mg / kg orally: gavage 28 days 1x / day, 5 days / week rat
Reproductive toxicity NOAEL> 750 mg / hg / day (rat, oral, OECD 407)
Teratogenicity NOAEL: 1000 mg / kg, rat OECD 414

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: 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: Polygonum Multiflorum Root Extract
Large-leaved knotweed extract (Chinese knotweed). Product obtained from the root of a twisting perennial grass climber, large-flowered knotweed (Polygonum multiflorum), plants from the knotweed family widespread in East Asia (China and Korea). One of the most popular herbs in oriental folk medicine, used as a "health tonic". It has a rejuvenating, anti-inflammatory, antioxidant and toning effect. Shou-Wu (Chinese for "anti-graying") has a unique ability to rebuild the natural hair pigment, is a recognized remedy against graying and brittleness. It promotes skin regeneration, normalizes pigmentation exchange (reduces pigmentation spots), slows down the aging process. on a decoction of knotweed herb they give shine to the hair, strengthen the bulbs, support hair regeneration.
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 Max (Soybean) Seedcoat Extract
Glycine Max Seedcoat Extract
Glycine Max (soybean) Seedcoat Extract is an extract of the seedcoat of the Soybean, Glycine max (L.), Leguminosae
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: Sesamum Indicum Seed Extract / Sesamum Indicum (Sesame) Seed Extract
The product is obtained from sesame or Indian sesame (Sesamum indicum), plants of the type sesame (Sesamum). Sesame seeds contain phytoestrogens, amino acids (histidine, tryptophan), and tocopherol (vitamin E). The extract rebuilds the structure of the skin's lipids, removes dryness and flaking, rebuilds the barrier functions, promotes rejuvenation.
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: Menthol
LD50 orally cat 800 mg / kg; LD50 (oral rats): 3180-3300 mg / kg,
LD50 (rabbit skin):> 5000 mg / kg
skin corrosion / irritation; Irritating to the skin
serious eye damage / irritation; Irritating to eyes.
Sensitization: No sensitization known
Summary / Conclusions: Possible sensitization by skin irritation.
Carcinogenicity, mutagenicity and toxicity to reproduction (CMR): No data available
Specific target organ toxicity single exposure: No data available.
Specific target organ toxicity repeated exposure: No data available.
Danger of exposure by inhalation: No data available
Route Species Test Value
ORAL RAT LD50 2615 mg / kg; DUST / MIST RAT 4H LC50 5289 mg / l; DERMAL RBT LD50> 5000 mg / kg

Ingredient name: POLYQUATERNIUM-10
Cellulose, 2-(2-hydroxy-3-(trimethylammonium)propoxy)ethyl ether, chloride; Cellulose, 2-hydroxyethyl 2-[2-hydroxy-3-(trimethylammonio)propoxy]ethyl 2-hydroxy-3-(trimethylammonio)propyl ether, chloride Cellulose, ether with alpha-[2-hydroxy-3-(trimethylammonio)propyl]-omega-hydroxypoly(oxy-1,2-ethanediyl), chloride
Direct contact: may cause slight skin irritation
LD50, rat> 10,000 mg / kg (Estimated)
There was no significant skin irritation after single contact / short-term exposure. The LD50 for skin is estimated to be> 4.0 g / kg
Inhalation: High concentrations of dust are irritating to the lungs
Ingestion: Low risk of ingestion under normal conditions of use. LD50 is estimated to be> 16.0; 1 ml = 0.20 g in corn oil.
Repeated or prolonged exposure may cause irritation.
Repeated consumption of large amounts can cause internal damage.
No significant adverse effects were found after single exposure during normal use
Serious eye damage / eye irritation: May cause slight eye irritation. Corneal damage is unlikely.
Irritation: When tested on marine humans, it did not cause allergic skin reactions.
Respiratory sensitization: No relevant data found.
Toxic effect on target organs - single exposure
Evaluation of the available data suggests that this material does not induce specific target organ toxicity after a single exposure.
In animals, effects have been reported on the following organs: Liver. The kidneys.
Effects on the kidneys were observed in adult rats. These effects are believed to be species-specific and unlikely to occur in humans
Animal observations include: Lethargy.
Carcinogenicity: No relevant data found.
Mutagenicity: Most of the results of in vitro mutagenicity studies were negative.
Mutagenicity studies in animals yielded negative results.

Ingredient: Sodium chloride
natrii chloridum
Acute oral toxicity LD50 (rat) 3000 mg/kg
Acute dermal toxicity (LD50): >10000 mg/kg [Rabbit].
Acute toxicity of the dust (LC50): >42000 mg/m3 /1 hour [Rat].

Table salt /Sodium chloride NaCl/ Lethal Dose LD50 3 g/kg (rat, oral); 12357 mg/kg (human, oral)/ White cubic crystal Eye irritant, elevated blood pressure
Lowest Published Lethal Dose (LDL) [Man] - Route: Oral; Dose: 1000 mg/kg
Inhalation: May cause mild skin irritation, or irritation to damaged skin, resulting in redness and itching. Absorption can occur with effects similar to those via ingestion.
Skin: Eye May cause mild to moderate eye irritation, with redness, itching and pain.
Carcinogenicity Not listed in the IARC Monographs.
Reproductive Toxicity: Causes adverse reproductive effects in humans (fetotoxicity, abortion) by intraplacental route.
May cause adverse reproductive effects and birth defects in animals, particularly rats and mice
Mutagenicity: DNA inhibition system-human: fibroblast 125mmol/l.
Log Pow : -3.0
NOAEL (mg/kg bw/day) = 100 / human data / Results from a recently published study show that a sodium chloride intake above 12.5 g/day (208 mg/kg bw for a 60 kg person) increases blood pressure to dangerous levels. 6 grams per day (100 mg/kg bw/day for a 60 kg person) recommended by the Swedish National Food Agency.

Ingredient: Panthenol
Acute oral toxicity : LD50 (rat): ca. 21,000 mg/kg: LD50 (mouse): 15,000 mg/kg
Acute dermal toxicity : LD50 (rat): > 3,500 mg/kg
Skin irritation : No skin irritation (rabbit, OECD Test Guideline 404)
: no phototoxic skin reaction (guinea pig, CTFA Test Guideline)
Eye irritation : No eye irritation (rabbit, OECD Test Guideline 405)
Sensitisation : Did not cause sensitization. (guinea pig): no photoallergenic skin reaction (guinea pig, CTFA Test Guideline)
Carcinogenicity : No indication for carcinogenicity known.
Genotoxicity in vitro : not mutagenic (In vitro gene mutation study in mammalian cells, OECD Test Guideline 476): not genotoxic (Chromosome aberration test in vitro, OECD Test Guideline 473)
Reproductive toxicity: This information is not available.
Teratogenicity : No human information is available.
Experience with human exposure: Hypervitaminosis from provitamin B5 and vitamin B5 is unknown. Experience with human exposure: Skin contact: Allergic contact dermatitis (Cases have been reported rarely.). Aspiration toxicity : No aspiration toxicity classification
STOT - single exposure (Acute exposure): The substance or mixture is not classified as specific target organ toxicant, single exposure.
STOT - repeated exposure Chronic exposure:NOAEL(Oral,rat):200mg/kg bw/d/ Sub-chronic toxicity study (90-day)

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 21 day dermal study with male/female New Zealand white rabbits dosed with 100, 500, or 2500
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 2500 mg/kg level. NOAEL = 2500 mg/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)

<u>Ingredient: Hamamelis Virginiana Extract</u>
Hamamelis Virginiana (Witch Hazel) Extract
Hamamelis Virginiana Extract is the extract of the whole plant, Hamamelis virginiana, Hamamelidaceae.
CAS # 84696-19-5 Function: ANTI-SEBUM, ASTRINGENT, SKIN CONDITIONING
Inhalation exposure: low toxicity, LC50> vapor concentration close to saturation.
Skin exposure: low toxicity, LD50> 2000 mg / kg (rabbit)
Eye exposure: no data available

low toxicity, LD50> 2000 mg / kg
Irritation: no irritation is to be expected
Sensitization: does not sensitize the skin
Mutagenic effect: not mutagenic
Carcinogenicity: no carcinogenic effects were found in animal studies.
Reproductive toxicity: does not affect fertility
Other information: no data available

Ingredient: Phenyl Trimethicone
1,1,5,5,5-Hexamethyl-3-phenyl-3-[(trimethylsilyl)oxy]trisiloxane
Acute inhalation toxicity: LC50 (Rat): 0.467 mg/l; Exposure time: 4 h. Test atmosphere: dust/mist
Remarks: Based on test data
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg. Assessment: The substance or mixture has no acute dermal toxicity. Remarks: Based on test data
Skin corrosion/irritation: Species: Rabbit . Result: No skin irritation
Serious eye damage/eye irritation : Species: Rabbit. Result: No eye irritation
Skin sensitization: Assessment: Does not cause skin sensitization. Test Type: Maximization
Species: Guinea pig. Result: negative
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES). Result: negative
Reproductive toxicity: Test Type: Prenatal development toxicity study (teratogenicity)
Species: Rat, female. Application Route: Ingestion. Symptoms: No effects on fetal development.
STOT-repeated exposure: Routes of exposure: Ingestion. Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

Ingredient Name: HYDROXYETHYL UREA
Urea derivative. Hydrophilic (water-soluble) moisturizing substance capable of penetrating the stratum corneum. It has a keratoplastic effect (softens the stratum corneum), and in higher concentrations, it has keratolytic properties (it exfoliates the callous epidermis) Although the product has not been tested for chronic effects, based on the available information, the ingredient is assessed as having a low level of toxicity. No evidence of a carcinogenic effect.
LD50> 2000 mg / kg. the substance has low toxicity when administered orally.
The test substance is slightly irritating to the skin and eyes.
There is no evidence of skin sensitization reactions for the test substance.
(NO (A) EL = 1000mg / kg
Mutagenicity: Not mutagenic on bacteria. Genotoxicity: Not genotoxic

Ingredient Name: Caramel
IV/146. Brown
Caramel is the concentrated solution obtained from heating sucrose or glucose solutions.
Caramel (color). The substance obtained by controlled heat treatment of food-grade carbohydrates. Food-grade acids, alkalies, and salts may be used to assist carmelization. Food-grade antifoaming agents may be used in an amount not greater than that required to produce the intended effect. Consists essentially of colloidal aggregates that are dispersible in water but only partly dispersible in alcohol-water solutions. Depending upon the particular carmelizing agent used, may have a positive or negative colloidal charge in solution.
Purity criteria as set out in Commission Directive 95/45/EC (E150a-d)

Ingredient Name: PYRIDOXINE HCL
Pyridoxine is a derivative of pyridine, one of the forms of vitamin B6.
LD50 rat, oral: 4gm / kg; LD50 mouse, oral: 5,500 mg / kg
Primary irritant effect: Effect Species Method:
On the skin: No irritating effect. On the eye: No irritating effect.
Sensitization: No sensitization known.
Additional toxicological information: According to our experience and the information we have, it does not cause any harmful effects when used correctly and in accordance with the intended use.

Ingredient Name: CLIMBAZOLE
1-(4-Chlorophenoxy)-1-(imidazol-1-yl)-3,3-dimethylbutan-2-one
CAS # 38083-17-9
III/310 Product Type: Rinse-off anti-dandruff shampoo
Maximum concentration in ready for use preparation: 2,0 % - For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.
Annex/Ref # V/32
Product Type, body parts (a) Hair lotions; (b) Face creams; (c) Foot care products; (d) Rinse-off shampoo. Maximum concentration in ready for use preparation: (a) 0,2 %; (b) 0,2 %; (c) 0,2 %; (d) 0,5%
CONCLUSION SCCS/1600/18: In light of the new margin of safety data provided, the SCCS consider safe the use of Climbazole (CAS 38083-17-9) as a cosmetic preservative in face cream, hair lotion and foot care with a maximum concentration of 0.2 % and as anti-dandruff agent in shampoo with a maximum concentration of 2.0% under an aggregate exposure scenario for cosmetics. The use of Climbazole (CAS 38083-17-9) as a cosmetic preservative in hair lotion and foot care with a maximum concentration of 0.2 % and in face cream with a maximum concentration of 0.5%, in rinse-off shampoo up to a concentration of 0.5% and as anti-dandruff agent in shampoo with a maximum concentration of 2.0% are, when individually used, safe for human health.
The maximum concentrations of Climbazole considered as safe for human health under an aggregate exposure scenario are as follows: 2% as anti-dandruff agent in rinse-off shampoos and 0.2 % as cosmetic preservative in leave - on formulations (face cream, hair lotion, foot care) with the exception of cosmetics applied on a full body area (body lotion).

Ingredient: Cetearyl Alcohol
Acute Oral Toxicity LD50 >5.0 g/kg; Acute Dermal Toxicity: LD50 >2.0 g/kg
The ocular irritation potential of a cream containing 3.0% Cetearyl Alcohol
was assessed in 9 albino rabbits. One-tenth milliliter of the product was instilled into one eye of each animal. The eyes of 3 animals were rinsed 30 set after instillation.
Ocular reactions were scored at 1, 2, 3, 4, and 7 days postinstillation.
The product was classified as a nonirritant)
Mutagenicity tests for Cetyl Alcohol were conducted with five mutant strains of Salmonella typhimurium LT2. These mutant strains were selected because of their ability to revert to prototrophy in the presence of a broad spectrum of mutagens and their sensitivity to mutagens. Spot tests were performed according to the methods described by Ames et al. (110) Results indicate that Cetyl Alcohol was not mutagenic to any of the strains in the presence or absence of metabolic activation)

Based on the available data included in this report, the Expert Panel concludes that Cetearyl Alcohol, is safe as cosmetic ingredients in the present practices of use.

Ingredient Name: Disodium EDTA /
di-Sodium edetate 2.hydrate (Disodium edetate)
Acute toxicity No data available
Irritating effect on skin / eyes No data available
Sensitization No data available
Carcinogenic, teratogenic effects. No reported adverse effects
Mutagenic effects No reported adverse effects
Reproductive toxicity No reported adverse effects
Specific target organ toxicity (single / repeated exposure) No data available
The maximum consumption of EDTA and its salts in food is defined as 0.4 mg / kg / day
The substance has been shown to be mutagenic in at least one test, or belongs to a chemical family of compounds that damage or alter the production of cellular DNA. NOAEL (rat, orally) = 237 mg / kg bw / day

Ingredient: Methylchloroisothiazolinone, Methylisothiazolinone
Mixture of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-Methylisothiazol-3(2H)-one with magnesium chloride and magnesium nitrate
V/39. Product Type: Rinse-off
Maximum concentration in ready for use preparation:
0.0015% (of a mixture in the ratio 3:1 of 5-Chloro-2-methyl-isothiazol-3(2H)-one and 2-Methylisothiazol-3(2H)-one
On the basis of the data submitted, the SCCS is of the opinion that the mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one in a ratio of 3:1 does not pose a risk to the health of
the consumer when used as a preservative up to a maximum authorised concentration of 0.0015 % in rinse-off cosmetic products, apart from its sensitising potential

Ingredient: SALICYLIC ACID
Benzoic acid, 2-hydroxy-
V/3
Substance Salicylic acid and its salts
CAS # 69-72-7[1]/ 824-35-1[2]/ 18917-89-0[3]/ 59866-70-5[4]/ 54-21-7[5]/ 578-36-9[6]/ 2174-16-5[7]. EC # 200-712-3[1]/ 212-525-4[2]/ 242-669-3[3]/ 261-963-2[4]/ 200-198-0[5]/ 209-421-6[6]/ 218-531-3[7]
Repr. 2. Acute Tox. 4. Eye Dam. 1. H361d. H302. H318
Name of Common Ingredients Glossary SALICYLIC ACID, CALCIUM SALICYLATE, MAGNESIUM SALICYLATE, MEA- SALICYLATE, SODIUM SALICYLATE, POTASSIUM SALICYLATE, TEA- SALICYLATE
Maximum concentration in ready for use preparation: Salicylic acid: 0,5 % (acid); Salicylic acid salts: 0,5 % (acid)
Salicylic acid: Not to be used in products for children under 3 years of age. Not to be used in oral products. Not to be used in applications that may lead to exposure of the end-user’s lungs by inhalation.
Salicylic acid salts: Not to be used in products for children under 3 years of age, except for shampoos.
Wording of conditions of use and warnings Salicylic acid:

Not to be used for children under 3 years of age**
**Solely for products which might be used for children under 3 years of age.
Salicylic acid salts: Not to be used for children under 3 years of age***
***Solely for products which might be used for children under 3 years of age and which remain in prolonged contact with the skin.
III/98. Product Type, body parts (a) Rinse-off hair products; (b) Other products except body lotion, eye shadow, mascara, eyeliner, lipstick, roll on deodorant
Maximum concentration in ready for use preparation (a) 3.0%; (b) 2.0%
Other Not to be used in preparations for children under 3 years of age. Not to be used in applications that may lead to exposure of the end- user's lungs by inhalation. Not to be used in oral products. For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.
For purposes other than inhibiting the development of micro-organisms in the product. This purpose has to be apparent from the presentation of the product.
Wording of conditions of use and warnings Not to be used for children under 3 years of age*
* Solely for products which might be used for children under 3 years of age.
SCCS/1601/18: The SCCS considers salicylic acid (CAS 69-72-7) safe when used as preservative at a concentration of 0.5 % in cosmetic products considering its current restrictions in place. This Opinion is not applicable to any oral product (such as toothpaste and mouthwash) with the exception of lipsticks. Sprayable products that could lead to exposure of the consumer's lung by inhalation are also excluded. The provided information shows that salicylic acid is an eye irritant with the potential to cause serious damage to the eye.
Based on the data provided and available literature, the SCCS considers salicylic acid (CAS 69-72-7) safe when used for purposes other than preservative at a concentration up to 3.0 % for the cosmetic rinse-off hair products and up to 2.0 % for other products, considering ts current restrictions in place. However, in body lotion, eye shadow, mascara, eyeliner, lipstick and roll on deodorant applications, salicylic acid is considered safe up to 0.5 %. The SCCS position is that these levels are inclusive of any use of salicylic acid, i.e. should not exceed the stated levels with additional use as a preservative. This Opinion is not applicable to any oral product (such as toothpaste and mouthwash) with the exception of lipsticks. Sprayable products that could lead to exposure of the consumer's lung by inhalation are also excluded. The conclusionsof this Opinion refer only to Salicylic Acid and should not be applied to other salicylates or salicylic acid salts.

Ingredient: Parfum
[redacted]
Applied fragrance composition has IFRA Certificate to a maximum concentration of 30,58% for category 9. 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 above 0,01% to be declared on the label: Linalool, Limonene, Hexyl Cinnamal, Citronellol, Hydroxycitronellal, Alpha-isomethyl ionone, Benzyl Salicylate

Ingredient: Linalool
1,6-Octadien-3-ol, 3,7-dimethyl-
III / 84. Potential allergen. The substance must be listed on the label if its concentration in the finished product exceeds 0.01% for flushed products and 0.001% for products remaining on the skin
Linalool; (S,R)-3,7-dimethyl-1,6-octadien-3-ol; dl-linalool [1] Coriandrol; (S)-3,7-dimethyl-1,6-octadien-3-ol; d-linalool [2] Licareol; (R)-3,7-dimethyl-1,6-octadien-3-ol; l-linalool [3]
EC numbers: 201-134-4 [1], 204-810-7 [2], 204-811-2 [3] CAS numbers: 78-70-6 [1], 126-90-9 [2], 126-91-0 [3]
Skin Sens. 1B (H317)
Linalool is autoxidized when exposed to air, giving oxidation products with increased sensitizing properties.
Acute Dermal: Rabbit 2000 mg/kg; Oral: LD50 Rat. 2790 mg/kg
oral-mouse LD50 [sex: M,F] 3918 mg/kg (Hoffman-LaRoche, Inc., 1967b)
oral-mouse LD50 [sex: M,F] 1700 mg/kg (Rhone-Poulenc, Inc., 1992a)
LD50 (mice, orally)> 2200mg / kg bw / day; LD50 (rabbit, dermal)> 5610mg / kg bw / day Skin and eye irritation (100% concentration) was observed in rabbits. In its pure form, it may cause allergic reactions. For chronic or sub-chronic toxicity, NOAEL was determined by oral administration in rats 160 mg / kg bw / day. or 200 mg / kg bw / day (exposure period 28 days), and for dermal exposure 250 mg / kg bw / day. Lack of genotoxic and carcinogenic properties, while NOAEL 1000 mg / kg bw / NOAEL was determined in tests on the effect on embryo development. (OECD Test Guideline 401) - LD50: 3500 mg / kg; (OECD Test Guideline 407) - NOAEL: 160 mg / kg; NOEL (no observed effect level): 15,000 µg / cm²; NESIL: 15,000 µg / cm²; NOAEL Developmental Toxicity of a mother 500 mg / kg; Fetal NOAEL: 1000 mg / kg. NOAEL reproductive toxicity: 500 mg / kg. Genotoxicity (in vivo): negative. Genotoxicity (in vitro): negative
Skin corrosion/irritation Causes skin irritation. guinea pig - Skin irritation - 24 h - Draize Test.rabbit: Irritant. (OECD Guideline 404)
Serious eye damage/eye irritation: Causes serious eye irritation.
rabbit - Moderate eye irritation - Draize Test
rabbit: slightly irritating. (OECD Guideline 405)
Respiratory sensitization Not a respiratory sensitizer.
Skin sensitization: possible
In the LLNA pure linalool was a weak sensitizer with an EC3 of 46.2% (Sköld et al., 2004).
Draize test/guinea pig: Non-sensitizing
no indication that the substance is mutagenic.
Reproductive toxicity: This product is not expected to cause reproductive or developmental effe

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

Ingredient name: Hydroxycitronellal / 7-Hydroxycitronellal
III / 72. Potential allergen. A substance must be listed on the label if its concentration in the finished product exceeds 0.01% for rinse-off products and 0.001% for products remaining on the skin Maximum permissible concentration in ready-to-use preparation: 1% for all products, except for oral cosmetics. LD50 (rat, oral):> 5 g / kg. LD50 (rabbit, dermal) (OECD 402)> 2000 mg / kg NOEL (- HRIPT 5000 µg / cm2; (NESIL) = 5000 µg / cm² May cause sensitization by skin contact. Acute oral toxicity to humans (OECD Guideline 401) - LD50: 260 mg / kg Repeated dose toxicity (OECD Guideline 407) - NOAEL: 100 mg / kg Dermal toxicity (RIFM Institute - Fragrance Research Institute or OECD 407 Guideline): NOEL (level no observed effect): 5612 g / cm² LOEL (lowest observed exposure): 5906 g / cm² NESIL (unexpected induction level): 5000 g / cm² respiratory tract (OECD 403 Guideline): n / Maternal developmental NOAEL: n / a mg / kg; Fetal NOAEL: n / mg / kg for reproduction NOAEL toxicity: n / a mg / kg Genotoxicity (in vivo): negative. Genotoxicity (in vitro): negative Hydroxycitronellal: NOEL – HRIPT 5000 µg / cm2; (NESIL) = 5000 µg / cm².

Ingredient Name: Hexyl Cinnamal
(Hexyl Cinnamaldehyde / 2-Benzylideneactanal)
III / 87. Potential allergen. A substance must be listed on the label if its concentration in the finished product exceeds 0.01% for rinse-off products and 0.001% for products remaining on the skin
Hexyl cinnamic aldehyde; Alpha-Hexylcinnamaldehyde; Hexylcinnamaldehyde; 101-86-0;
2E) -2-benzylideneacetal, α-Hexyl cinnamic aldehyde
LD50 (rat, orally): 3100 mg / kg; LC50 (rat, inhalation)> 2.12 mg / L (4h, adult male) LD50> 3,000 mg / kg, adult rat, male.
The substance is allowed to be used in cosmetics in small amounts. It may cause allergies in high concentrations. May cause eye and skin irritation. It shows no mutagenic and genotoxic properties. May cause allergy in contact with skin.
It shows no mutagenic and genotoxic properties. May cause allergy in contact with skin. Acute oral toxicity for men (OECD Guideline 401) -LD50: 496mg / kg Oral Subacute Toxicity (OECD 407) -NOAEL: 0.074 mg / kg Dermal toxicity (RIFM Institute - Fragrance Research or OECD Guideline 407): NOEL (no observed effect): 23,622 mg / cm2 LOEL (lowest observed exposure level): n / mg / cm2 NESIL not expected level of induction of sensitization): 23,600 mg / cm2 Acute. Inhalation (OECD Guideline 403): n / Developmental maternal NOAEL: n /

mg / kg; Fetal NOAEL: n / mg / kg for reproduction NOAEL toxicity: n / a mg / kg Genotoxicity (in vivo): negative. Genotoxicity (in vitro): negative.

Ingredient: Citronellol
Human Data: NOEL – HRIPT (induction) 29528 (µg/cm2)
NOEL – HMT (induction) 4138 (µg/cm2)
WoE NESIL 29500 (µg/cm2)
LLNA (Data derived from HRIPT or Human Max Tests) 10875 (µg/cm2)
Irritating to skin and eyes.
May cause sensitisation by skin contact. May cause an allergic skin reaction.
Not a respiratory sensitizer
This product is not expected to cause reproductive or developmental effects
Specific target organ toxicity - single exposure: Not classified.
Specific target organ toxicity - repeated exposure: Not classified.
Not an aspiration hazard.

Ingredient Name: Benzyl Salicylate
III / 75. Potential allergen. A substance must be listed on the label if its concentration in the finished product exceeds 0.01% for rinse-off products and 0.001% for products remaining on the skin
SALICYLIC ACID, BENZYL ESTER. CAS: 118-58-1
Acute toxicity studies determined: LD50 (rat, orally): 2227 mg / kg (OECD Test Guideline 401), in another study: 3339 mg / kg; LD50 (rat, dermal): 14150 mg / kg; LD50 (rabbit, dermal)> 2000 mg / kg. In chronic toxicity studies in rats, the NOAEL was determined by oral administration: 360 mg / kg bw / day. The substance does not cause skin irritation (studies on rabbits), may cause temporary eye irritation in the form of conjunctival redness. It shows allergenic properties. Lack of genotoxic activity and negative influence on reproductive capacity (NOAEL for rats 180 mg / kg bw / d) and development of embryos (NOAEL: 360 mg / kg bw / d). Benzyl Salicylate: NOEL - HRIPT 17717 µg / cm2; (NESIL) = 17700 µg / cm² OECD Test Guideline 407) - NOAEL: 360 mg / kg; LOAEL: n / a mg / kg
NOEL (no observed effect level): 20,690 µg / cm²; Developmental toxicity maternal NOAEL: 360 mg / kg; Fetal NOAEL: 360 mg / kg; Reproductive Toxicity NOAEL: 180 mg / kg No genotoxic effect. (in vivo) / (in vitro)
Skin Sens. 1B, Eye Irrit. 2, Aquatic Chronic 3. Warning: GHS07, GHS08, Wng
NOEL–HRIPT 17717 µg/cm2; (NESIL)= 17700 µg/cm²
CAS: 118-262-9 – INCI: Benzyl Salicylate – Concern: potential endocrine disruptor

Ingredient Name: Alpha-isomethyl ionone
III / 90. Potential allergen. A substance must be listed on the label if its concentration in the finished product exceeds 0.01% for rinse-off products and 0.001% for products remaining on the skin
(3-Methyl-4 (2,6,6-trimethyl-2-cyclohexen-1-yl) -3-buten-2-one (Methyl Ionone)) / Methyl-gamma-ionone; gamma-Methylionone. Isoraldeine. α-Cetone
Used in raspberry, strawberry, blueberry and cranberry flavors
The toxicity of this substance is considered to be low. For chronic exposure (90 days), the NOAEL of 3.55-4.10 mg / kg / day was determined for mice. No maternal or fetal toxic effects were observed (NOAEL: 30 mg / kg / day). No genotoxic activity (in vitro studies). LD50 (rat, orally)> 5000 mg / kg bw / day (OECD Test Guideline 401); Repeated dose toxicity (OECD Test Guideline 407) - NOAEL: 500 mg / kg; LOAEL: 500 mg / kg. Dermal (human)

toxicity (RIFM-Research Institute for Fragrance Materials or OECD Test Guideline 407): NOEL (no observed effect level): 70 µg / cm²; LOEL (lowest observed effect level): n.a. µg / cm²; NESIL (no expected sensitization induction level): 70 µg / cm²; Inhalation toxicity (OECD Test Guideline 403): n.a. mg / m3. Developmental toxicity maternal NOAEL: 100 mg / kg; Fetal NOAEL: 300 mg / kg. Reproductive Toxicity NOAEL: 120 mg / kg. Genotoxicity (in vivo): negative. Genotoxicity (in vitro): negative
Log P: 4.84. NOEL – HRIPT 70,866 µg / cm2; WoE NESIL 70,000 µg / cm².
May cause allergy in contact with skin.

[redacted]
Coumarin, Benzyl Alcohol, Geraniol, Eugenol, Citral, Benzyl Benzoate, Benzyl Cinnamate, Methyl 2-octynoate in concentration range below 0,01%.

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 Absolute Shampoo, intended for Hair and scalp care and cleansing, 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 Absolute Shampoo 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 kosmetycznegoAbsolute Shampoo, 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 Absolute Shampoo 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 Absolute Shampoo, 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 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/
Regulation (EC) No 1223/2009 Dec 2020
SCCS Opinions. http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/
https://ec.europa.eu/health/scientific_committees/consumer_safety/docs/
ScienceDirect. https://www.sciencedirect.com/science/article/abs/
The Risk Assessment Information System. https://rais.ornl.gov/tox/profiles/
Therapeutic Goods Administration (TGA). https://www.tga.gov.au/sites/default/files/
Toy Directive. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009L0048-20191118&from=EN
USDA. https://dietarysupplementdatabase.usda.nih.gov/conversions.html
WHO. http://www.euro.who.int/__data/assets/pdf_file/
Commission Decision 2006/257/EC of 9 February 2006 amending Decision 96/335/EC establishing an inventory and a common nomenclature of ingredients employed in cosmetic products
Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
Commission Directive 95/45/EC of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs
SCCS Notes of Guidance for Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation SCCS, SCHER and SCEN1HR, Opinion on Use of the Threshold of Toxicological Concern (TTC) Approach for Human Safety Assessment of Chemical Substances with focus on Cosmetics and Consumer Products, SCCP/1171/08
toxnet.nlm.nih.gov
ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm
ec.europa.eu/consumers/cosmetics/cosing/
ijt.sagepub.com
kosmopedia.org

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