# COSMETIC PRODUCT

# SAFETY REPORT

Ultimate Shampoo

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| | |
|---|---|
| Product: | Ultimate Shampoo |
| | |
| Responsible person: | Hair Cure Polska Sp. z o.o.<br>[redacted]<br>KRS 0000877478<br>NIP 5213917297 |

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

| Ingredients(ICID) | RM or Ingredient % in fla | Ingredients % in RM | Actual Wt(%) | Function | CAS No. |
|---|---|---|---|---|---|
| Sodium C14-16 Olefin Sulfonate | 43.00 | 35.00 | 15.05 | Cleansing Agent | 68439-57-6 |
| Water | | 65.00 | 27.95 | Skin Conditioning Agent | 7732-18-5 |
| Water | 28.28 | 100.00 | 28.28 | Skin Conditioning Agent | 7732-18-5 |
| Water | 10.00 | 70.00 | 7.00 | Skin Conditioning Agent | 7732-18-5 |
| Undaria Pinnatifida Extract | | 4.00 | 0.40 | Skin Conditioning Agent | |
| Laminaria Cloustoni Extract | | 4.00 | 0.40 | Skin Conditioning Agent | 7732-18-5 |
| Glycine Soja (Soybean) Seed Extract | | 3.00 | 0.30 | Skin Conditioning Agent | 90046-11-0 |
| Polygonum Multiflorum Root Extract | | 3.00 | 0.30 | Skin Conditioning Agent | |
| Poria Cocos Extract | | 3.00 | 0.30 | Skin Conditioning Agent | |
| Morus Alba Bark Extract | | 3.00 | 0.30 | Skin Conditioning Agent | |
| Pinus Densiflora Extract | | 2.00 | 0.20 | Skin Conditioning Agent | |
| Artemisia Vulgaris Extract | | 2.00 | 0.20 | Skin Conditioning Agent | |
| Rehmannia Chinensis Root Extract | | 2.00 | 0.20 | Skin Conditioning Agent | 84775-45-1 |
| Thuja Orientalis Extract | | 2.00 | 0.20 | Skin Conditioning Agent | |
| Sesamum Indicum (Sesame) Seed Extract | | 2.00 | 0.20 | Skin Conditioning Agent | |
| Coco-Betaine | 5.00 | 30.00 | 1.50 | Cleansing Agent | 68424-94-2 |
| Water | | 63.00 | 3.15 | Skin Conditioning Agent | 7732-18-5 |
| Sodium Chloride | | 7.00 | 0.35 | Viscosity increasing Agent | 7647-14-5 |
| Decyl Glucoside | 5.00 | 50.00 | 2.50 | Cleansing Agent | 58846-77-8 |
| Water | | 50.00 | 2.50 | Skin Conditioning Agent | 7732-18-5 |
| Glycereth-26 | 3.00 | 100.00 | 3.00 | Skin Conditioning Agent | 31694-55-0 |
| PEG-160 Sorbitan Triisostearate | 0.97 | 100.00 | 0.97 | Cleansing Agent | |
| Menthol | 0.80 | 100.00 | 0.80 | Fragrance | 99-78-1 |
| Biotin | 0.001 | 100.0000 | 0.0010 | Hair Conditioning Agent | 58-85-5 |
| Citrus Nobilis(Mandarin Orange) Peel Extract | 1.00 | 25.00 | 0.25 | Skin Conditioning Agent | 90063-83-5 |
| Water | | 75.00 | 0.75 | Skin Conditioning Agent | 7732-18-5 |
| PPG-3 Caprylyl Ether | 0.70 | 100.00 | 0.70 | Solvent | |
| Fragrance | 0.83 | 100.00 | 0.83 | Fragrance | |
| Panthenol | 0.50 | 100.00 | 0.50 | Skin Conditioning Agent | 16485-10-2 |
| Citric Acid | 0.42 | 100.00 | 0.42 | pH Adjuster | 77-92-9 |
| Polyquaternium-10 | 0.30 | 100.00 | 0.30 | Antistatic Agent | 53568-66-4 |
| Saccharomyces Cerevisiae Extract | 0.100 | 88.0000 | 0.0880 | Skin Conditioning Agent | 84604-16-0 |
| Butylene Glycol | | 10.0000 | 0.0100 | Solvent | 107-88-0 |
| 1,2-Hexanediol | | 2.0000 | 0.0020 | Solvent | 6920-22-5 |
| Copper Tripeptide-1 | 0.100 | 0.1000 | 0.0001 | Skin Conditioning Agent | |
| Water | | 99.4000 | 0.0994 | Skin Conditioning Agent | 7732-18-5 |
| Phenoxyethanol | | 0.5000 | 0.0005 | Solvent | 122-99-6 |

[redacted]

Allergens above 0,01% to be declared on the label:

| Ingredients | % | CAS |
|---|---|---|
| Limonene | 0,0713 | 5989-27-5 |
| Benzyl Benzoate | 0,0706 | 120-51-4 |
| Hexyl Cinnamal | 0,0291 | 101-86-0 |
| Linalool | 0,0142 | 78-70-6 |

# 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 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 Ultimate Shampoo meet requirements of internal standard:

| Parameter | Requirements |
|---|---|
| Appearance | Light brown, transparent liquidTo Match Standard |
| Color | To Match Standard |
| Odor | To Match Standard. Characteristic for the fragrance composition used and for the raw materials used, menthol |
| Density | 0.9141 ~ 1.1173 / [20 ºC] |
| Viscosity | 8460 ~ 10340cP (63rod,6rpm,1min) |
| pH [20 ºC] | 4,95-5,95 |
| Microbiological quality | $\leq 10^2$ cfu/g<br>Absence of: Pseudomonas aeruginosa – in 1g<br>Staphylococcus aureus – in 1g<br>Candida albicans - in 1g<br>Escherichia coli – in 1g |

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

Ultimate 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 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 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.

Ultimate 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 Ultimate 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 Ultimate 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 Ultimate Shampoo. MoS value for substances with available NOAEL was also calculated.

| INCI | SED | NOAEL | MOS |
|---|---|---|---|
| Sodium C14-16 Olefin Sulfonate | 0,2273 | --- | --- |
| Undaria Pinnatifida Extract | 0,0060 | --- | --- |
| Laminaria Cloustoni Extract | 0,0060 | --- | --- |
| Glycine Soja Seed Extract | 0,0045 | --- | --- |
| Polygonum Multiflorum Root Extract | 0,0045 | --- | --- |
| Poria Cocos Extract | 0,0045 | --- | --- |
| Morus Alba Bark Extract | 0,0045 | --- | --- |
| Pinus Densiflora Extract | 0,0030 | --- | --- |
| Artemisia Vulgaris Extract | 0,0030 | --- | --- |
| Rehmannia Chinensis Root Extract | 0,0030 | --- | --- |
| Thuja Orientalis Extract | 0,0030 | --- | --- |
| Sesamum Indicum Seed Extract | 0,0030 | --- | --- |
| Coco-Betaine | 0,0227 | --- | --- |
| Sodium Chloride | 0,0053 | --- | --- |
| Decyl Glucoside | 0,0038 | 250 | 66 225 |
| Glycereth-26 | 0,0453 | --- | --- |
| PEG-160 Sorbitan Triisostearate | 0,0146 | --- | --- |
| Menthol | 0,0121 | 200 | 16 556 |
| Biotin | 0,0000 | --- | --- |
| Citrus Nobilis Peel Extract | 0,0038 | --- | --- |
| PPG-3 Caprylyl Ether | 0,0106 | --- | --- |

| | | | |
|---|---|---|---|
| Parfum | 0,0125 | --- | --- |
| Limonene | 0,0011 | 30 | 27 866 |
| Benzyl Benzoate | 0,0011 | 100 | 93 870 |
| Hexyl Cinnamal | 0,0004 | 30 | 68 391 |
| Linalool | 0,0002 | 50 | 233 302 |
| Panthenol | 0,0076 | 237 | 31 391 |
| Citric Acid | 0,0063 | 1200 | 189 215 |
| Polyquaternium-10 | 0,0045 | --- | --- |
| Saccharomyces Cerevisiae Extract | 0,0013 | --- | --- |
| Butylene Glycol | 0,0002 | 2500 | 16 556 291 |
| 1,2-Hexanediol | 0,0000 | --- | --- |
| Copper Tripeptide-1 | 0,0000 | --- | --- |
| Phenoxyethanol | 0,0000 | 357 | 47 284 768 |

## 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 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 Ultimate 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 Sodium C14-16 Olefin Sulfonate
68439-57-6. Alkenes, C14-16, sulfonated, sodium salts
Sulfonic acids, C14-16-alkane hydroxy and C14-16-alkene, sodium salts
Acute oral toxicity: LD50 6.314 mg / kg oral rat
Acute dermal toxicity: LD50 6,300 - 13,500 mg / kg / dermal, rabbit
Skin corrosion / irritation: irritating (rabbit) OECD Guideline 404 (Acute Dermal Irritation / Corrosion)
Respiratory or skin sensitization: non-sensitizing guinea pig test / OECD Guideline 406 (Skin Sensitisation)
Germ cell mutagenicity: negative bacterial reverse mutation assay (e.g Ames test) with and without OECD Guideline 471

Ingredient: Coco-Betaine
Betaines, coco alkyldimethyl
Skin irritation Category 2; H315. Skin contact: Irritating to skin.

Eye damage Category 1; H318. Eye contact: Severely irritating to eyes. Risk of serious damage to eyes.
Ingestion**:** Irritating to mouth, throat and stomach.
Acute oral toxicity (Mouse): LD50:>2000 mg/kg bw (Equivalent or similar to OECD Guideline 401) Read-across approach
Acute dermal toxicity (Rat): LD50:> 2000 mg/kg bw /(OECD Guideline 402 / EU Method B.3) Read-across approach
Not sensitizing: (OECD Guideline 406 / EU Method B.6)
Germ cell mutagenicity: Bacterial reverse mutation assay (in vitro): Negative/(OECD Guideline 471 / EU Method B.13/14)/ Mammalian cell gene mutation assay (in vitro): Negative/(OECD Guideline 476)
In vitro mammalian chromosome aberration test: Negative/(OECD Guideline 473)
Toxicity to reproduction (Rat): NOAEL (systemic): 50 mg/kg bw/day
NOEL (reproduction/developmental): 150 mg/kg bw/day
NOAEL (systemic): 150 mg/kg bw/day (OECD Guideline 422 / other guideline: EPA OPPTS 870.3650)/ Read-across approach
Developmental toxicity/teratogenicity (Rat): NOEL (maternal toxicity): 330 mg/kg bw/day
NOEL (developmental toxicity): 990 mg/kg bw/day
NOEL (external, skeletal or soft tissue malformations and variations): 3300 mg/kg bw/day/(OECD Guideline 414)Read-across approach
STOT-repeated exposure : Not classified
Repeated dose toxicity: Oral (Rat): NOEL: 250 mg/kg bw/day; NOAEL: ≥ 500 mg/kg bw/day (Equivalent or similar to OECD Guideline 408) /Read-across approach

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: 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 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: 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: Decyl GLUCOSIDE
Acute oral toxicity: D-Glucopyranose, oligomeric, C10-16-alkyl glycosides
LD50> 2.000mg / kg / ral / rat / EU Method B.1 (Acute Toxicity (Oral))
Acute dermal toxicity: LD50> 2.000 mg / kg / dermal / rabbit / OECD Guideline 402 (Acute Dermal Toxicity)
Skin corrosion / irritation: moderately irritating / 4 h / rabbit / OECD Guideline 404 (Acute Dermal Irritation / Corrosion)
Serious eye damage / eye irritation: irritating / 24 h / rabbit / OECD Guideline 405 (Acute Eye Irritation / Corrosion)
Respiratory or skin sensitization: not sensitizing / guinea pig test / OECD Guideline 406 (Skin Sensitisation)
Germ cell mutagenicity: negative / bacterial reverse mutation assay (e.g Ames test) / with and without / OECD Guideline 471 (Bacterial Reverse Mutation Assay)
Repeated dose toxicity: 250 mg / kg orally: gavage / 90 days once daily, 5 times a week / rat / EU Method B.26 (Sub-Chronic Oral Toxicity Test: Repeated Dose 90-Day Oral Toxicity Study in Rodents)
Carcinogenicity: Not classified as a human carcinogen.

It can support the transepidermal penetration of other ingredients. These compounds have been found safe by CIR in current practice and concentrations.

Ingredient: Glycereth-26
Poly(oxy-1,2-ethanediyl)], .alpha.,.alpha.',.alpha."-1,2,3-propanetriyltris[.omega.-hydroxy-
Is 26 mole ethylene oxide adduct of glycerine
Acute oral toxicity: LD50(Rat):>2,000mg/kg/ Remarks: Information given is based on data obtained from similar substances.
Skin corrosion/irritation: Method: In vitro study. Result: No skin irritation
Serious eye damage/eye irritation: Result: No eye irritation /Remarks: Information given is based on data obtained from similar substances.

Ingredient: PEG-160 sorbitan triisostearate
Sorbitan, poly(oxy-1,2-ethanediyl) derivs. triisooctadecanoates, (160 mol EO average molar ratio)
Rat, LD50: >5g/kg (Data on similar product)
SKIN CORROSION / IRRITATION: Draize test, undiluted, intact and abraded skin: P.I.I. = 0.21 (Data on similar product)
SERIOUS EYE DAMAGE / IRRITATION: Draize test, undiluted, washed eyes or unwashed eyes: Mildly irritating /(Washed eyes or Unwashed eyes, Kay and Calandra's classification) (Data on similar product)
SKIN SENSITIZATION: Guinea pig, Maximization Test: Negative / (Data on similar product)
MUTAGENICITY (GERM CELL MUTAGENICITY): Ames test (TA98,TA100,TA1535,TA1537, WP2uvrA): Negative. (Data on similar product)
Not listed as a carcinogen by IARC, EU, NTP, OSHA
Photosensitization, Adjuvant-Strip-AA : Negative (Data on similar product)
The CIR Expert Panel concluded that the polysorbates listed below are safe in cosmetics when formulated to be non-irritating.

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: PPG-3 Caprylyl Ether
There is polypropylene glycol (3mol) and caprylic alcohol ether
PPG-3 Caprylyl Ether is the polypropylene glycol ether of caprylic alcohol; Poly (oxy-1-methyl-1,2-ethandiyl), alpha-octyl-omega-hydroxy- (3 mol PO average molar ratio)

Non-ionic conditioning substance
Suggested dosage: 0.3% -1%.

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: Saccharomyces Cerevisiae Extract
is an extract of the yeast cells of Saccharomyces Cerevisiae /Yeast extract
Acute toxicity estimate: > 2,000 mg/kg (Calculation method)
Saccharomyces cerevisiae: LD50 Oral Rat >5000 mg/kg
Product recognized as safe
No skin irritation (human)
Acute Toxicity: Oral / inhalation / dermal
Not harmful if swallowed.Not harmful after dermal exposure
Irritation: Sin / eye / respiratory tract.Not irritating to skin.Not irritating to eyes
Sensitisation Not sensitizing to skin
Toxicity after repeated exposure.Oral / inhalation / dermal: No considered to be toxic after repeated oral exposure
Genotoxicity / mutagenicity Not genotoxic / not mutagenic
Carcinogenicity Not expected to be carcinogenic
Toxicity for reproduction Not expected to be toxic for reproduction

Not listed as a carcinogen or potential by the NTP, IARC Monographs or OSHA

Ingredient: Butylene Glycol

Substance considered low toxic. The following were determined in the acute toxicity tests:
$LD_{50}$ (a rat, oral exposure): 22,800 mg/kg; $LD_{50}$ (a mouse, subcutaneous exposure); 12,980 mg/kg
$LD_{50}$ (a guinea pig, oral exposure): 11,460 mg/kg; $LD_{50}$ (a rabbit, dermal exposure): > 20,000 mg/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.

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|---|---|
| Acute toxic effect | $LD_{50}$ (oral exposure, rat): 22,800 mg/kg<br>$LD_{50}$ (dermal exposure, rat): no data<br>$LD_{50}$ (inhalation exposure, rat): 290 mg/l (4 hours' exposure)<br>Chronic toxicity: NOAEL: 5,000 mg/kg/day (a rat) |
| Irritating /Corrosive effect on skin | No irritating effect on skin (a rabbit) |
| 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<br>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)<br>LOAEL: 12,000 mg/kg/day (a rat, oral exposure)<br>Development toxicity:<br>Maternity toxicity: NOAEL 2,500 mg/kg/day (a rat, oral exposure)<br>Teratogenicity: NOAEL 12,000 mg/kg/day (a rat, oral exposure)<br>Fetus toxicity:<br>NOAEL : 2,500 mg/kg/day (a rat, oral exposure)<br>LOAEL: 5,000 mg/kg/day (a rat, oral exposure)<br>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 | No data |

| | |
|---|---|
| organs - repeated exposure | |
| Threat caused by aspiration | No data |

Ingredient name: 1,2-Hexanediol
Acute toxicity: no data available. Irritating product
Skin corrosion / irritation: May cause skin irritation.
Serious eye damage / eye irritation: Irritating to eyes.
Respiratory or skin sensitization: May cause respiratory irritation. Sensitization is unknown
Mutagenic effect on reproductive cells: 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
Toxic effect on target organs - single exposure
Inhalation - May cause respiratory irritation.
Specific target organ toxicity - repeated exposure: no data available
Aspiration hazard: no data available
Additional information: RTECS: no data available
To the best of our knowledge, the chemical, physical and toxicological properties are not carefully examined., prolonged or repeated exposure may cause: nausea, headache, vomiting

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: Citrus Nobilis Peel Extract / Citrus Nobilis (Mandarin Orange) Peel Extract
Citrus Nobilis Peel Extract is an extract of the peel of the Mandarin Orange, Citrus nobilis, Rutaceae /Citrus reticulata / Citrus clementine
Acute toxicity: Mandarin oil acute oral LD50 rats>5g/kg; acute dermal LD50 rabbits>5g/kg (Opdyke&Letizia1982)
Hazards: Skin sensitization if oxidized.Cautions: Old or oxidized oils should be avoided. Contains Limonene. Non-volatile compounds: Bergamottin 0–0.001%; Bergapten 0–0.0003%. In Europe, essential oils containing furanocoumarins must be used so that the total level of bergapten will not exceed: (a) 15 ppm in finished cosmetic products intended for application to skin areas likely to be exposed to sunshine, excluding rinse-off products; or (b) 1 ppm in sun protection and in bronzing products.

Ingredient name: Biotin
Acute toxicity LD50 (rat, oral)> 20,000 mg / kg
LD50 (mouse, oral)> 10,000 mg / kg
Skin corrosion / irritation Not irritating to rabbit skin (OECD, 404, 4 hours)
Serious eye damage / eye irritation Not irritating to rabbit eyes (OECD, 405, 72 hours)

Dust - can lead to mechanical irritation.
Sensitization Not sensitizing laboratory animals (guinea pig, OECD, 406)
It does not lead to photosensitization of the skin (guinea pig).
Genotoxicity In vitro - negative (Ames test)
Reproductive toxicity No positive effects (female fertility test in rats)
Teratogenicity Does not show teratogenic effects.
Aspiration hazard Not classified
Specific target organ toxicity - single / repeated exposure Not classified
Specific target organ toxicity - repeated exposure Not classified
Human studies No known negative effects.
RDA = 0.15mg (daily allowable dose)
Chronic and subchronic toxicity
Biotin: TDL0 orally, rat = 9 mg / kg / 30D-I and 6.3 mg / kg / 21D-I.
Skin irritation intradermal injection of 0.1 ml into guinea pig skin did not cause skin irritation (IJT 20 (4), 2001). Eye irritation at 0.1%, pH 7.3 produced a slight, short-term eye irritation in the rabbit (IJT 20 (4), 2001). Skin sensitization: subcutaneous injection of 0.1 ml to guinea pigs did not cause irritation (IJT 20 (4), 2001). Mutagenicity: not mutagenic in bacterial tests (IJT 20 (4), 2001). Reproductive toxicity: TDL0 (subcutaneous, rat) = 200 mg / kg, female, 14-15 days after fertilization; TDL0 (s.c., rat) = 100 mg / kg, 1 day of mating.
The CIR Panel determined to not reopen this safety assessment and reaffirmed the original conclusion that Biotin is safe as used in cosmetic products:
Max Conc of Use (%): Leave-On 0.1 , Rinse-Off-0.1% the Panel recognized that data on the irritation and sensitization potential of Biotin are absent. However, the lack of case reports indicates that Biotin does not have a strong potential to cause skin irritation or sensitization. Biotin is a water-soluble vitamin used as a hair-conditioning agent and a skin-conditioning agent in many cosmetic products at concentrations ranging from 0.0001% to 0.6%. Although Biotin does absorb some ultraviolet (UV) radiation, the absorption shows no peaks in the UVA or UVB region. Biotin is rapidly metabolized and excreted in urine. Little acute oral toxicity is seen in animal tests. Short-term and subchronic toxicity studies likewise found no evidence of toxicity. Although intradermal injection of a small quantity of Biotin (0.1 ml) into guinea pig skin did not produce skin irritation, Biotin (0.1% at pH 7.3) did produce slight, transient ocular irritation in rabbit eyes. Biotin was not mutagenic in bacterial tests, but positive results were found in a Tradescantia micronucleus test. There was evidence of an increase in the number of resorptions in rats receiving Biotin by subcutaneous injection, with concomitant decreases in fetal, uterine, and placental weights. Another study of mice receiving Biotin orally or by subcutaneous injection found no differences between control and treatment groups. Although there is one case study reporting an urticarial reaction in the literature, there are a very large number of individuals exposed to Biotin on a daily basis, and there is not a parallel appearance of irritation, sensitization, or other adverse reactions. Based on these available data, it was concluded that Biotin is safe as used in cosmetic formulations.

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: Citric Acid
Irritation to the skin
Local effects of citric acid to the skin (rabbit) are reported as slightly irritating in two studies and as not irritating in a third study using a 30% aqueous solution.
Irritation to the eye
Two nonstandard studies on eye irritation using presumably neat citric acid applied for 24hours respectively a 2% aqueous solution for 30 minutes found severe and permanent injury to rabbit eyes. In a recent study the application of 0.1 ml of a 30% solution of citric acid to one eye for one second resulted in a well-defined to moderate conjunctival irritation which disappeared in two of the three treated rabbits within 14 days; additionally, a short-lasting superficial lesion of the conjunctival epithelium was noted,
but no macroscopical alteration of the cornea. In an acute eye irritation/corrosion test in rabbits according to OECD 405 citric acid was highly irritating.
Irritation to the respiratory tract
Citric acid (concentration and application not stated) caused brochoconstriction in dogs with nonspecific airway hyperreactivity. Coughing is reported for guinea pigs exposed for 30 minutes to atmospheric citric acid concentrations of 81 mg/m3 (aerosolised 6% solution). Coughing was also produced in guinea pigs exposed to 75 mg citric acid/ml as an aerosol for 3 minutes. Coughing was also caused by instillation of 1 ml of an approx. 5.2% solution to the lower trachea in lambs, but not by instillation to the mid-trachea or laryngeal area. According to current criteria, pure citric acid and aqueous solutions must be judged as irritant to the eyes but not to the skin.
Repeated dose toxicity
Groups of 10 male and 10 female rats were given 2 g to 16 g/kg/d orally by gavage during 5 days. A NOEL of 4000 mg/kg/d and an LD50 of 5600 mg/kg/d were determined. Groups of 10 male rats being fed up to 4.8% citric acid in feed (corresponding to approx. 4.67 g/kg/d) for 6 weeks showed slight growth reduction and, in the highest-dose group, mild blood and urine parameter changes and slight degeneration of the thymus gland and spleen. In 9 rats being fed 2% citric acid (approx. 0.13 g/kg/d) no effect on food consumption or body weight was noted nor were the absorption and urinary excretion of calcium and magnesium affected, however, urinary zinc excretion was found to be temporarily elevated.
In male mice being fed 5% citric acid (approx. 7.5 g/kg/d; in the range of published acute LD50) for an unspecified time, decreased growth and lower survival times (11–13 vs. 16–17 months in controls) were reported. In guinea pigs fed 1–5% citric acid (approx. 0.4– 2 g/kg/d) for 60 days, a reduced packed

cell volume in the blood was the only effect noted. No adverse effects were seen in both rabbits and dogs fed approx. 1.5 resp. 1.4 g/kg/d for 150 resp. 120 days. Body weight gain was unaffected in young pigs fed a cadmium-enriched diet containing 5% citric acid (approx. 4 g/kg/d), but elevated cadmium in the liver and kidneys and decreased zinc levels in muscle were found.
A 2-year chronic oral study in rats being given 5% or 3% citric acid in feed (approx. 2 resp. 1.2 g/kg/d) found slightly decreased growth in the higher dosage group but no tissue abnormalities in the major organs. From the lower dosage a NOAEL of 1200 mg/kg/d results. Similarly, NOAELs of 1500 mg/kg/d (rabbit) and of 1400 mg/kg/d (dog) have been determined. No adverse effects, with the possible exception of slight changes of tooth structure, were found when two successive generations of rats were fed 1.2% citric acid (approx. 600 mg/kg/d; duration not stated, probably about one year).
Mutagenicity
In several in vitro and in vivo tests citric acid was not mutagenic. The substance was not mutagenic either in bacterial tests with Salmonella typhimurium (Ames test, 2 studies) and Escherichia coli, with and without metabolic activation. Citric acid was shown to reduce the activity of a recognised chemical mutagen in S. typhimurium. No clear indication of mutagenicity was reported from studies with S. typhimurium or the yeast Saccharomyces cerevisiae living in the body cavity of an unspecified laboratory animal nor in S.cerevisiae cell cultures with or without metabolic activation. Neither was chromosomal
damage caused by citric acid in human and hamster cell cultures. A dominant lethal assay with male rats being treated with up to 3 g/kg/d for 5 days was negative; no chromosomal damage occurred in the bone marrow cell of these male rats.
Reproduction and developmental toxicity
In a two-generation 90 days study with male and female rats fed 1.2 % citric acid no adverse effect on reproductive parameters nor any teratogenicity of dietary citric acid was seen. There were no indications of teratogenic or other adverse effects in three short term reproductive studies in rats with dietary dosage of either 5% citric acid (approx.2.5 g/kg/d) previous, during and after mating (NOEL = 2500 mg/kg/d), or 295 mg/kg/d (route unspecified) during days 6–15 of pregnancy. Similar findings of no effects were reported for two reproductive and teratogenicity studies in mice receiving either 5 % citric acid (approx. 7.5 g/kg/d; in the range of published acute LD50) previous, during and after mating (NOEL = 7500 mg/kg/d) or 241 mg/kg/d during days 6–15 of pregnancy. Further, there were no indications of teratogenicity or other adverse effects in female hamsters receiving 272 mg citric acid/kg (presumably daily) during days 6–10 of pregnancy nor in female rabbits receiving up to 425 mg/kg/d during days 6–18 (NOEL = 425 mg/kg/d).
Carcinogenicity: In a study with only 20 male rats receiving op to 5% citric acid in the feed (approx. 2g/kg/d) for 2 years no evidence of carcinogenicity was reported. In a further study with rats fed 1.7% sodium citrate (approx. 0.74 g/kg/d) for 8 weeks no increase in DNA synthesis, a measure of cell proliferation, in the bladder epithelium was found. In contrast, several nonstandard studies report an increased incidence of tumours in rats treated with known carcinogens and receiving citric acid or citrate (between 1.4 and 2.6 g citric acid equivalents/kg/d for 20–45 weeks) at the same time. In at least one of the studies with sodium citrate in feed and the carcinogen given in drinking water the observed tumorigenic effect was not attributed to the citrate anion but to the sodium cation causing increased water (and thereby carcinogen) intake; in this and another study, citric acid was judged not to have a tumour-promoting effect, respectively not to be a potent tumour promoter. Based on wide spectrum of data relating to experimental animals and on human experience citric acid has a low acute

toxicity; only one case of near fatal human intoxication was found. In a repeated dose study with rats a NOAEL of 1200 mg/kg/d and a LOAEL of 2000 mg/kg/d have been determined.

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: 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: Parfum
[redacted]
Applied fragrance composition has IFRA Certificate (amendment 48 of 2015) to a maximum concentration of 5% for category 9a. 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 0,01%:

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: Benzyl Benzoate
III / 85. 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. CAS no.:120-51-4
Benzoic acid benzyl ester. NOAEL for rats 100 mg / kg bw / day Benzyl benzoate has low toxicity to laboratory animals. It rapidly hydrolyzes to benzoic acid and benzyl alcohol, which is then metabolized to benzoic acid. Benzoic acid conjugates are rapidly excreted in the urine. When administered in high doses to laboratory animals, benzyl benzoate may cause hyperactivity, incoordination, ataxia, seizures and respiratory paralysis. Benzyl benzoate is irritating to the skin. NOEL – HRIPT 59050 µg / cm2; WoE NESIL 59,000 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: 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 effects.

## 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 Ultimate 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 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 Ultimate 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 kosmetycznego Ultimate 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 Ultimate 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 Ultimate 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 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

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**Agency for Toxic Substances and Disease Registry** https://www.atsdr.cdc.gov/toxprofiles/
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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
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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)
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