

Cosmetic Product Safety Report

(According to Regulation (EC) n°1223/2009 of the European Parliament and of the Council of November 30th 2009, and Regulations mending annexes, on Cosmetic Products)

SAIN EYE MAKE-UP REMOVER WITH HEMISQUALANE & PORTULACA EXTRACT

Responsible person:

GlobeTech Innovation s.r.o.

Klausova 2541/15

155 00 Prague

Czech Republic

Date of Issue: 20.11.2023

Part A

Cosmetic Product Safety Data

1. Quantitative and qualitative composition of the cosmetic product

INCI	CAS No	% Raw material	% Active substance	Function
Aqua	7732-18-5	Up to 100	-	Solvent
Poloxamer 184	9003-11-6	2,00 - 4,00	-	Emulsifying, Surfactant
Glycerin (99,5 %)	56-81-5	2,00 – 4,00	-	Humectant
Propanediol	504-63-2	2,00 – 4,00	-	Solvent, viscosity controlling
C13-15 Alkane	64742-46-7	0,05 – 1,00	-	Solvent
Glycerin, Aqua, Portulaca Oleracea Extract	56-81-5; 7732-18-5; 90083-07-1	0,05- 2,00	-	Skin conditioning
Aqua, Pentylene Glycol, Sodium Acetylated Hyaluronate, Sodium Hyaluronate, Sodium Hyaluronate Crosspolymer, Hydrolyzed Sodium Hyaluronate, Ethylhexylglycerin	7732-18-5, 5343-92-0, -, 9067-32-7, 105524-32-1, -, 70445-33-9.	3,00 – 5,00	-	Skin conditioning
Aqua, Leuconostoc/Radish Root Ferment Lysate Filtrate	7732-18-5, 1686112-10-6	1,00 - 3,00	-	Antimicrobial
Lonicera Caprifolium Flower Extract, Lonicera Japonica Flower Extract, Aqua	84603-62-3, 223749-79-9, 7732-18-5	0,20 – 0,40	-	Skin conditioning, Antimicrobial
Lactic Acid	50-21-5	0,05 - 0,20	-	Buffering

The company **GlobeTech Innovation s.r.o** has, for each raw material used, according available data from providers, a technical dossier including toxicological data, analytic data... (MSDS, TDS, ECRC, LoA, IFRA51).

All documents are stored at the premises of the responsible person and have been made available to the Safety Assessor for the purpose of drawing up the CPSR for human health.

2. Physical, chemical, microbiological and toxicological properties of the cosmetic ingredients or mixtures

Ingredient: Water

INCI Name: AQUA

Description: -

INN Name: water

Ph. Eur. Name: aqua

CAS No.: 7732-18-5

EINECS/ELINCS No.: 231-791-2

Chemical/IUPAC Name: -

Cosmetic Restriction: -

Other Restriction(s): -

Functions: SOLVENT

SCCS opinions: -

Physical / chemical characteristics, purity:

Liquid, colourless, odourless.

Boiling point: 100°C

Conductivity (20°C): < 4.3 µS/cm

pH: 5,5 - 8,0

Molar mass of H₂O = 18,01528 g/mol

Water hardness: < 1°dH

Total organic carbon (TOC): < 0.5 mg/l

Nitrates content: < 0.2 µg/g

Heavy metals: < 0.1 µg/g

Traces of prohibited substances: Not present

Microbiological specifications: Expected value for bacteria, yeast and moulds <= 100 CFU/g, absent

E.coli, P.aureginosa, S.aureus, Salmonella spp.

Toxicological profile: Non-hazardous substance.

Exposure: see section 7.

Ingredient: MASSOCARE PEL6

INCI Name: POLOXAMER 184

Description: Oxirane, methyl-, polymer with oxirane (13;30)

INN Name: -

Ph. Eur. Name: -

CAS No.: 9003-11-6

EINECS/ELINCS No.: -

Chemical/IUPAC Name:

Cosmetic Restriction: -

Other Restriction(s): -

Functions: EMULSIFYING, SURFACTANT

SCCS opinions: -

Physical / chemical characteristics:

Physical state: Liquid

Colour: light yellow.

Odour: Mild

pH (2,5% m/m aq. solution, 20 °C): 5,0 – 7,5

Density (25 °C): 1,04 g/ml

Viscosity, dynamic: 720 mPa.s (25°C)

Melting point: 16 °C

Boiling point: 250 °C

Auto-ignition temperature: 390 °C

Solidification point point: 16 °C

HLB appr. 15

Molecular weight appr. 2 900 Da

Hydroxyl value: 37,4 – 40,8 mgKOH/g

Cloud point (10% m/m aq. solution): 57 – 61 °C

Colour APHA @ 60°C: 100 Hazen

Freezing point: 57 - 61 (10% H₂O)

Purity / Active substance content:

Poloxamer 184: up to 100 %

Water: max. 0,4 %

Ethylene Glycol: max 310 mg/kg

Data from MSDS, Product Data Sheet.

Traces of prohibited substances: Not expected to be present unless specified above

Microbiological specifications: Expected values for bacteria, yeast and moulds ≤ 100 CFU/g, absent E.coli, P.auriginosa, S.aureus, Salmonella spp.

Toxicological profile:

Not classified as hazardous according to Regulation (EC) No. 1272/2008 [CLP], not classified as skin/eye irritant, nor skin sensitiser, CMR not reported.

BASF Pluracare L64 G (MSDS)

Acute toxicity Assessment of acute toxicity:

Of low toxicity after single ingestion. Virtually nontoxic by inhalation.

Experimental/calculated data: LD50 rat (oral): > 2,000 - < 5,000 mg/kg

Toxicological data also available in Safety Assessment of poloxamers, Int. Journal of Toxicology,

<https://www.ncbi.nlm.nih.gov/pubmed/18830866>

NOAEL(derived): 50 mg/kg/day

Exposure: see section 7.

Ingredient: Glycerin Ph.Eur.

INCI Name: GLYCERIN

Description: -

INN Name: glycerol

Ph. Eur. Name: -

CAS No.: 56-81-5

EINECS/ELINCS No.: 200-289-5

Chemical/IUPAC Name: Glycerol

Cosmetic Restriction: -

Other Restriction(s): -

Functions: HUMECTANT

SCCS opinions: -

Physical / chemical characteristics, purity:

Clear liquid (20° C), odourless.

pH (20°C): 6 - 7

Specific gravity: >1,228 g/cm³

Refractive index (20°C): 1,470 – 1,475

Density (20°C): 1,258 -1,268 g/cm³

Boiling point: 133°C

Melting point: -8°C

Flash point: 190°C

log Pow: -2,6 - -2,47

Purity:

Glycerine content: 99,5%

Acid value: 0,1 mg KOH/g

Sulphated ash: <0,1%

Organic chloride: <5%

Heavy metals: max. 5 ppm

Chlorides: max. 10 ppm

Aldehydes: max. 10 ppm

Traces of prohibited substances: Not expected to be present unless specified above

Microbiological specifications: Expected values for bacteria, yeast and moulds ≤ 100 CFU/g, absent
E.coli, P.auriginosa, S.aureus, Salmonella spp.

Toxicological profile: Acute toxicity: IUCLID

LD50 (oral, rat): 10000 - 27200 mg.kg⁻¹

LD50 (dermal, rabbit): >18700 mg.kg⁻¹

Skin sensitisation (human, patch test): not sensitizing

Eye irritation (rabbit): not irritating (OECD 405)

NOAEL (rat, oral, 25 weeks): 2 000 mg/kg/day (SIDS Initial Assessment Report, 2002)

Exposure: see section 7.

Ingredient: Propanediol (Zemea)

INCI name: PROPANEDIOL

Description: -

INN Name: -

Ph.Eur.Name: -

CAS No.: 504-63-2 / 26264-14-2

EINECS/ELINCS No: 207-997-3

Chemical/IUPAC Name: 1,3-dihydroxypropane

Cosmetic Restriction: -

Other Restriction(s): -

Functions: SOLVENT, VISCOSITY CONTROLLING

SCCS opinions: -

Physical /chemical characteristics, purity:

Liquid, colourless, slight odor.

Boiling point (boiling point range): ca 214°C

Melting point (melting point range): ca. -24,6°C

Octanol-water partition coefficient: -

Flash point: ca 129°C

Solubility (20°C in water): >1 000 g/l

Density (at 20°C): ca. 1,053g.cm⁻³

Eur.assay: 99,8%

Heavy metals: ppm max. 5

Traces of prohibited substances: Not present

Microbiological specifications: Not Applicable

Toxicological profile: Non-hazardous substance.

Toxicological profile of substance:

Skin irritation: not classified as skin irritant

Eye irritation: not classified as skin irritant

Sensitization: did not cause sensitization on laboratory animals

LD50 (oral, rat): >15 800 mg/kg (MSDS)

NOAEL (oral, rat): 1 000 mg/kg

http://ec.europa.eu/food/fs/sc/scf/out189_en.pdf

Exposure: see section 7.

Ingredient: Hemisqualane

INCI Name: C13-15 ALKANE

Description: C13-15 Alkane is a mixture of alkanes with 13 to 15 carbon atoms in the alkyl chain

INN Name: -

Ph. Eur. Name: -

CAS No.: 64742-46-7

EINECS/ELINCS No.: 934-954-2

Chemical/IUPAC Name: 2,6,10-Trimethyldodecane

Cosmetic Restriction: -

Other Restriction(s): -

Functions: SOLVENT

SCCS opinions: -

REACH: Registration numbers: 01-211994811-47-0001

Physical / chemical characteristics, purity:

Colorless liquid

Nearly odorless

Purity by GC: 99%

Density @ 20 °C: 0.770 g/cm³

Refractive Index @ 20 °C: 1.431

Iodine Value: < 0.5 g I₂/100 g

Acid Value: < 0.01 mg KOH/g

Saponification Value: < 0.2

Viscosity @20°C: 2.7 cP

Surface Tension @20°C: 25.5 mN/m

Flash Point: 110 °C

Pour Point: < 57 °C

Solubility: oil soluble; water insoluble

Toxicological profile:

LC50 Inhalation Rat >2.19 mg/L

LD50 Oral Rat > 5000 mg/kg

LD50 Dermal Rabbit > 5000 mg/kg

NOAEL (oral, rat, male): 3 000 mg/kg/day (read across C15-19 Alkan, ECHA)

Exposure: see section 7.

Ingredient: Portulaca Extract GN

INCI Name: GLYCERIN, AQUA, PORTULACA OLERACEA EXTRACT

Description: Portulaca Oleracea Extract is an extract of the whole plant of the Purselane, Portulaca oleracea L., Portulacaceae

INN Name: -

Ph. Eur. Name: -

CAS No.: 56-81-5, 7732-18-5, 90083-07-1

EINECS/ELINCS No.: 200-289-5, 231-791-2, 290-201-1

Chemical/IUPAC Name: -

Cosmetic Restriction: -

Other Restriction(s): -

Functions: SOLVENT; HUMECTANT; SKIN CONDITIONING

SCCS opinions: -

Physical / chemical characteristics:

Appearance : Colorless to Light yellow liquid

Odour : Characteristic

pH : 4.0 ~ 6.0 (Neat)

Flash point : >160°C (320 F)

Solubility(ies) : Soluble in many organic solvents

Purity / Active substance content:

Glycerin:> 50 %

Aqua: 10–25 %

Portulaca Oleracea Extract: 0,1 – 1,0 %

Data from MSDS, TDS.

Traces of prohibited substances: Not present

Microbiological specifications: Expected value for bacteria, yeast and mould <= 100 CFU/g, absent E.coli, P.aureginosa, S.aureus, Salmonella spp.

Toxicological profile:

Is not hazardous according to Regulation (EC) No 1272/2008, not toxic, not skin/eye irritant, not sensitising, CMR not reported.

Glycerin:

LD50 (oral, rat): 10000 - 27200 mg.kg-1

LD50 (dermal, rabbit): >18700 mg.kg-1

Skin sensitisation (human, patch test): not sensitizing

Eye irritation (rabbit): not irritating (OECD 405)

NOAEL (rat, oral, 25 weeks): 2 000 mg/kg/day (SIDS Initial Assessment Report, 2002)

The ingredient has an estimated NOAEL of 2000 mg/kg/day, derived from toxicological data of Glycerin.

Exposure: see section 7.

Ingredient: Hymagic™-4 D (4 D Hyaluronic Acid)

INCI Name: AQUA, PENTYLENE GLYCOL, SODIUM ACETYLATED HYALURONATE, SODIUM HYALURONATE, SODIUM HYALURONATE CROSSPOLYMER, HYDROLYZED SODIUM HYALURONATE, ETHYLHEXYLGLYCERIN.

Description: -

INN Name: -

Ph. Eur. Name: -

CAS No.: 7732-18-5, 5343-92-0, -, 9067-32-7, 105524-32-1, -, 70445-33-9.

EINECS/ELINCS No.: 231-791-2, 226-285-3, -, -, -, 408-080-2

Chemical/IUPAC Name: -

Cosmetic Restriction: -

Other Restriction(s): -

Functions: SKIN CONDITIONING

SCCS opinions: -

Physical / chemical characteristics, purity:

Appearance: a clear transparent, viscous liquid

Soluble: in water

Colour: Colorless to slight yellow

Odour: Slight characteristic odour

pH: 5.0~7.0

Transparency: ≥97.0%

Kinetic viscosit: ≥500 mPaS

Heavy metals: ≤10ppm

As: ≤2ppm

Data from MSDS a TDS.

Traces of prohibited substances: Not expected

Microbiological specifications: Expected value for bacteria, yeast and mould ≤ 100 CFU/g, absent E.coli, P.aureginosa, S.aureus, Salmonella spp.

Toxicological profile:

Is not hazardous according to Regulation (EC) No 1272/2008, not toxic, not CMR, in concentration 3 % in final product does not represent any risk for skin irritation or sensitization.

Pentylene Glycol

Not skin/eye irritant, not sensitising, not CMR.

Acute toxicity:

LD50 (oral, rat): 10 000 mg/kg bw

Repeated dose toxicity:

NOAEL (oral, rat): 1000 mg/kg/day (Pentane-1,5-diol. Registration Dossier ECHA.

<https://echa.europa.eu/cs/registration-dossier/-/registered-dossier/14818/7/6/1> .)

Sodium Hyaluronate

Not skin/eye irritant, not sensitising, not CMR.

Acute toxicity:

LD50 (oral, rat): 5280 mg/kg bw

Subchronic toxicity:

NOAEL (oral, rat): 1000 mg/kg bw/d (90 days study) (Safety Assessment of Hyaluronates as Used in Cosmetics. CIR Report Data Sheet. https://www.cir-safety.org/sites/default/files/SLR_HyaluronicAcid_092022.pdf .)

Ethylhexylglycerin

Mild skin irritant, eye irritant, not sensitising, not phototoxic/ photosensitizer, not CMR. (On the Safety Assessment of Alkyl Glyceryl Ethers As Used in Cosmetics. CIR Report Data Sheet. <https://www.cir-safety.org/sites/default/files/ethylh122011finalx.pdf> .)

Acute toxicity:

LD50 (oral, rat) > 2 000 mg/kg bw

Repeated dose toxicity:

NOAEL (oral, rat): 100 mg/kg bw/day (3-(2-ethylhexyloxy)propane-1,2-diol. Registration Dossier ECHA. <https://echa.europa.eu/cs/registration-dossier/-/registered-dossier/16725/7/6/2> .)

The ingredient has an estimated NOAEL of 100 mg/kg/day, derived from dose-response studies.

Exposure: see section 7.

Ingredient: Leucidal® Liquid

INCI Name: AQUA, LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE

Description: Leuconostoc/Radish Root Ferment Lysate Filtrate is a filtrate of a lysate of the product obtained by the fermentation of the roots of *Raphanus sativus* (radish) by the microorganism, *Leuconostoc*. The ingredient is based on an antimicrobial peptide originally derived from the lactic acid bacteria, *Leuconostoc kimchii*.

INN Name: -

Ph. Eur. Name: -

CAS No.: 7732-18-5; 1686112-10-6

EINECS/ELINCS No: 231-791-2; -

Chemical/IUPAC Name: -

Cosmetic Restriction: -

Other Restriction(s): -

Functions: SKIN CONDITIONING; ANTIMICROBIAL

SCCS opinions: -

Physical / chemical characteristics, purity:

Clear to slightly hazy liquid

Yellow to light amber colour

Odor: characteristic

Solubility in water: water, ethanol soluble

Specific Gravity (@ 25 °C): 1.140 – 1.180 6

pH: 4.0 - 6.0 6

log Kow; Kow: -1.92; 0.013

Purity:

Solvent: water

Allergens: none

Preservatives: none

Antioxidants: none

Water: 48-52%

Leuconostoc/Radish Root Ferment Filtrate : 48-52%

Traces of prohibited substances: Heavy Metals < 20 ppm (Max.); Lead < 10 ppm (Max.); Antimony < 5 ppm (Max.); Arsenic < 2 ppm (Max.); Mercury < 1 ppm (Max.); Cadmium < 1 ppm (Max.)

Microbiological specifications:

Expected values for bacteria, yeast and moulds ≤ 100 CFU/g, absent E.coli, P.aeruginosa, S.aureus, Salmonella spp.

Toxicological profile: (data source: Safety Assessment of Radish Root – Derived Ingredients as Used in Cosmetics; 2022)

Non- toxic; Non-hazardous substance, used in food. Not irritating, not-sensitizing, not CMR. GRAS certified.

“According to the US FDA, commercially-produced products of carbohydrates, such as glucose, sucrose, or lactose, which undergo lactic acid fermentation, are generally recognized as safe (GRAS) for their intended use in foods [21CFR § 184.1016]. Leuconostoc is an approved bacterial strain used to produce a butter starter distillate [21CFR § 184.1848].”

Subchronic toxicity:

Raphanus Sativus (Radish) Root Extract

Groups of albino rats were dosed with 0, 150, 250, 350, 450, or **550 mg/kg bw** of methanolic Daikon (vegetable; a Raphanus sativus var.) extract, in the diet, for 90 d. 15 Body weight, as well as various hematological parameters and enzymes, including red blood cell count, hemoglobin, white blood cell count, aspartate aminotransferase (AST), alanine transaminase (ALT), acid phosphatase (ACP), urea, uric acid, and protein were measured and compared at 30 and 90 d of treatment. Upon sacrifice, heart, kidney, liver, spleen, and brain weights were also measured, and those of treated animals were compared to controls. No statistically significant differences were observed between the mean body weights, organ weights, and measured hematological parameters in treated animals, compared to controls, throughout the experiment.

NOAEL expected 550 mg/kg bw (derived from the data of subchronic toxicity study)

Exposure: see section 7.

Ingredient: CAMPO PLANTSERVATIVE Wsr (Lonicera Flower Extract)

INCI Name: LONICERA CAPRIFOLIUM FLOWER EXTRACT, LONICERA JAPONICA FLOWER EXTRACT, AQUA

Description: active liquid preservative, isolated from herb, suitable for the antimicrobial protection of cosmetic and pharmaceutical applications. Lonicera Caprifolium Flower Extract is an extract of the flowers of the Honeysuckle, Lonicera caprifolium L., Caprifoliaceae. Lonicera Japonica Flower Extract is an extract of the flowers of the japanese honeysuckle, Lonicera japonica, Caprifoliaceae

INN Name: -

Ph. Eur. Name: -

CAS No.: 84603-62-3; 223749-79-9; 7732-18-5

EINECS/ELINCS No.: 283-263-6; - ; 231-791-2

Chemical/IUPAC Name: -

Cosmetic Restriction: -

Other Restriction(s): -

Functions: ANTIMICROBIAL, MASKING, SKIN CONDITIONING

SCCS opinions: -

Physical and chemical characteristics:

Mobile liquid, clear colorless yellowish tint to yellow

Odour: characteristic faint

Refractive index (20°C): 1.300 - 1.450

pH value: 9,0 -12,0 (100% Concentrate.)

Density (20°C): 1.1200 - 1.3200

Boiling point: 100 °C

Solubility: soluble in water and most other cosmetic solvents

Purity:

Preservation -none

100% CO₂ extracted flowers and buds of *Lonicera Caprifolia* (<45%) and *Lonicera Japonica* (<20%) in water carrier (<35%).

CTFA Monograph 8845 – *Lonicera Caprifolium*, 9690 – *Lonicera Japonica*

Traces of prohibited substances: Not present

Microbiological specifications: Total germs < 100 CfU /ml; Total yeasts/mold < 100 CfU /ml

Toxicological profile: (MSDS Comercial Química Massó, S.a.)

Acute toxicity:

Non-Toxic. Edible in small quantity.

LD50 (oral, rat): 3 679 mg.kg⁻¹

Dermal irritation: not-irritant (repeated patch insult test on 50 human volunteers)

Eye irritation: very mild by 10% conc.

Skin sensitizing: not detected (repeated patch insult test on 50 human volunteers 48h)

NOAEL (derived): 36 mg/kg/d (1% from LD50 oral, rat)

Exposure: see section 7

Ingredient: Lactic Acid

INCI Name: LACTIC ACID

Description: organic acid

INN Name: -2-hydroxypropanoic acid, 2-hydroxypropionic acid, Milk acid,

Ph. Eur. Name: -

CAS No.: 79-33-4

EINECS/ELINCS No.: 201-196-2

Chemical/IUPAC Name: C₃H₆O₃ / 2-hydroxypropanoic acid

Cosmetic Restriction: -

Other Restriction(s): -

Functions: BUFFERING

SCCS opinions: 0370/00 - Position paper on the Safety of alpha-Hydroxy Acids

0799/04 - Updated position paper concerning consumer Safety of α-hydroxy acids

Physical / chemical characteristics, purity:

Liquid aqueous solution (80%)

Colorless to pale yellow

Characteristic odour

Molecular weight: 90,077

Boiling point: 120°C

Density: 1,19-1,25 g/cm³

pH (20°C) = 1-2

Solubility: 100% soluble in water

Specific gravity: 1,1

Traces of prohibited substances: Not present

Microbiological specifications: Not applicable

Toxicological profile:

Data sources:

<http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?sid=176255034&viewopt=PubChem>
Cosmetic Ingredient Review Expert Panel; International Journal of Toxicology, 17 (Suppl.1): 1-203 (1998)

„The percutaneous absorption of topically applied 5% [14C]-Lactic Acid in an oil-in-water cream was measured using rats. After 3 days, 50% of the applied Lactic Acid had penetrated the skin.“

Corrosive to skin; [Quick CPC]

A skin and respiratory tract irritant; Corrosive to eyes; [ICSC]

Causes burns to skin and eyes; Vapors cause eye and mucous membrane irritation and can cause coughing and difficulty breathing; [CHRIS]

Safe when used as a flavoring agent in food; [JECFA]

Corrosive to rabbit skin, mildly irritating to guinea pig skin, and not irritating to pig skin;

Not sensitizing in a study of guinea pigs;

A 13-week oral study of rats produced a NOAEL of 500 mg/kg/day (highest tested dose);

Studies on reproductive and developmental toxicity not considered necessary because lactic acid is a product of human intermediary metabolism; [EPA ChAMP]

A skin and strong eye irritant;

LD50(oral,rat): 3 730 mg/kg (Lewis, R.J. Sr. (ed) Sax's Dangerous Properties of Industrial Materials. 11th Edition. Wiley-Interscience, Wiley & Sons, Inc. Hoboken, NJ. 2004., p. 2196)

LOAEL (oral,rat): 886 (US EPA, 2002)

NOAEL : 88 mg/kg/day (extrapolated from LOAEL/10)

Exposure: see section 7.

3. Physical, chemical and microbiological properties of the final cosmetic product

a. Physical and chemical properties

- I. Appearance, texture: Slightly to medium opalescent liquid
- II. Colour: Colourless to slightly yellowish
- III. Odor: Unperfumed – faintly of the raw materials used
- IV. Viscosity: 1,00 – 1,03 g·cm⁻³ [@ 20 °C]
- V. pH: 5,3-5,5

b. Stability

Shelf life /Expiry date: 30 months.

The expiry date is established on the base of internal operating procedure.

The product is stable min. 30 months from the production date under reasonably foreseeable storage conditions (at temperature not exceeding 30°C, protected from sunlight).

c. Microbiological challenge test results

Total viable count of aerobic microorganisms: max. 1.10² cfu/g

Total count of moulds and yeasts: 1.10² cfu/g

<i>Escherichia coli</i>	not detected in 0,1 ml
<i>Pseudomonas aeruginosa</i>	not detected in 0,1 ml
<i>Staphylococcus aureus</i>	not detected in 0,1 ml
<i>Candida albicans</i>	not detected in 0,1 ml
<i>Aspergillus Brasiliensis</i>	not detected in 0,1 ml

Microbiological challenge test was made by the Evonik **COMERCIAL QUIMICA MASSO, S.A.**

Based on the provided results of microbiological testing from October 2023 this cosmetic product can be approved **as microbiologically safe.**

Challenge test results **are in accordance with the A criterion of the of PhEur. 2011-5.1.3 and EN ISO 11930:2012.** The final Challenge test Protocol is deposited at the seat of Responsible person and added to this CPSR.

4. Impurities, traces of prohibited materials and informations about the packaging material

a. Impurities, traces of prohibited materials and other specifications of ingredients / mixtures see 2.

b. Specification of packaging material:

I. Primary packaging:

1. Disk top cap, white – PP
2. Bottle, white (100 ml) – PET

Manufacturer/supplier: Vexel/Mandario

II. Secondary packaging:

1. Paper box – C/PAP

Manufacturer/supplier: REP Tisk spol s.r.o.

The used plastic components of packaging complies with requirements of the Regulation (EC) No 10/2011 of 14 January 2011 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.

Declaration of conformity and drawings related to the used packaging material are deposited at the seat of Responsible person.

5. Normal and reasonably foreseeable use of the cosmetic product

Leave on product – Make up remover

Product name and instructions for use:

SAIN

EYE MAKE-UP REMOVER WITH HEMISQUALANE & PORTULACA EXTRACT

Ingredients: Aqua, Poloxamer 184, Leuconostoc/Radish Root Ferment Lysate Filtrate, Pentylene Glycol, Sodium Acetylated Hyaluronate, Sodium Hyaluronate, Sodium Hyaluronate Crosspolymer, Hydrolyzed Sodium Hyaluronate, Ethylhexylglycerin, Glycerin, Propanediol, Portulaca Oleracea Extract, Lonicera Caprifolium Flower Extract, Lonicera Japonica Flower Extract, C 13-15 Alkane, Lactic Acid.

Batch number / Best before: printing on the secondary packaging (box) near the hourglass symbol

100 ml

GlobeTech Innovation s.r.o.

Klausova 2541/15

155 00 Prague

Czech Republic

+ multilingual variants

A preview of both the primary and secondary packaging is attached to this report.

6. Exposure to the cosmetic product

Cosmetic product		
Product type	Make up remover – rinse off (closest reference product)	
Skin surface area involved	565	cm ²
Area of application	the face	
Estimated daily amount applied	5,0	g/den
Duration and frequency of application	1	den
Retention factor	1,0	
Normal and reasonably foreseeable way of exposure	dermal, skin	
Targeted (or exposed) population	adults	

SED classified according to SCCS'S Notes Of Guidance For Testing Of Cosmetic Substances And Their Safety Evaluation 12th Revision, the SCCS plenary meeting, 15.05. 2023, Table 3A, 3B.

$$SED = 5,0 \text{ g, tj. } 83,3 \text{ mg/kg/day}$$

7. Exposure of substances with regard to their toxicological profile

SED value (**Systemic Exposure Dose**) for toxicologically relevant ingredients is calculated according the following formula:

$$SED = A \left(\frac{mg \text{ bw}}{kg \text{ day}} \right) \times \frac{C(\%)}{100} \times \frac{DA_p(\%)}{100}$$

$$SED \left[\frac{mg \text{ bw}}{kg \text{ day}} \right]$$

SED of certain ingredient is the amount that can penetrate the circulation and may have a systemic effect. System availability depends on dermal absorption. The absorption of the ingredient depends on its physical-chemical properties (polarity, molecular shape, molecular weight). If no data is available on the absorption of particular ingredient and regarding the method of its structural analysis can not be the absorption approximated safely, it is assumed

conservative toxicological view, ie. The substance is absorbed 100% (despite the fact that no substance penetrates into the skin in 100% absorption).

MOS (Margin Of Safety) is further calculated for toxicologically relevant ingredients. Generally, it can be argued that if

$$MOS \geq 100,$$

it can be assumed that it is safe to use the ingredient. To calculate the MOS only relevant toxicological data must be used. Use is made of values of the systemic toxicity dose for that was observed no adverse effect level (NOAEL, No Observed Adverse Effect Level). If the data on short-term or subchronic toxicity are not available the premise will be based on the assumption that the NOAEL is 1% of the acute oral LD50. When the substance is not classified as acutely toxic or harmful (eg., In plant extracts), then according to the criteria for the classification of dangerous substances is considered LD50 value ≥ 2000 mg / kg and the NOAEL is assumed 20 mg / kg / d. MOS is count according to the following formula.

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

Ingredient	C [%]	DA _p [%]	SED [mg/kg bw/day]	NOAEL [mg/kg/d]	MOS	
Aqua						
Poloxamer 184						
Glycerin (95,5 %)						
Propanediol						
C13-15 Alkane						
Aqua, Glycerin, Portulaca Oleracea Extract						
Aqua, Pentylene Glycol, Sodium Acetylated Hyaluronate, Sodium Hyaluronate, Sodium Hyaluronate Crosspolymer, Hydrolyzed Sodium Hyaluronate, Ethylhexylglycerin.						CONFIDENTAL
Aqua, Leuconostoc/Radish Root Ferment Filtrate						
Lonicera Caprifolium Flower Extract, Lonicera Japonica Flower Extract, Aqua						
Lactic Acid						

8. Toxicological properties of the cosmetic ingredients

Specified in the Paragraph 2.

9. Undesirable effects and serious undesirable effects

The company has established a system for the registration and management of adverse effects in cosmetic products. Side effects in the cosmetic product are not anticipated since the products of a similar composition are in the market for several years without reporting any side effects.

10. Other informations about the cosmetic product

Part B

Cosmetic Product Safety Assessment

1. Assessment conclusions:

On the basis of all accessible informations and with the use of generally recognised toxicological criteria it is possible to claim the product **as safe for human health** when used in the declared way and when following mandatory instructions on the products packaging according to contemporary requirements of the valid regulations for cosmetic products. **The product complies with requirements on cosmetic product safety specified in the Regulation (EC) No. 1223/2009 on cosmetic products.** This conclusion can be applied only to those products whose composition and qualities conform to the presented documents and results of the laboratory tests.

2. Labelled warnings and instructions for use

According to the Regulation (EC) No.1223/2009 there are not any special mandatory warnings needed on the product label. The intended and reasonably foreseeable way of use is covered by the product extended name „**SAIN EYE MAKE-UP REMOVER WITH HEMISQUALANE & PORTULACA EXTRACT**“, i.e. as make-up remover and skin cleansing product. The declared function of the product is justified by the composition of the product and qualities of the used ingredients. Text for consumers should be indicated on the packaging using the national language(s) of countries where the product is marketed.

INCI labelling:

INGREDIENTS: AQUA, POLOXAMER 184, LEUCONOSTOC/RADISH ROOT FERMENT LYSATE FILTRATE, PENTYLENE GLYCOL, SODIUM ACETYLATED HYALURONATE, SODIUM HYALURONATE, SODIUM HYALURONATE CROSSPOLYMER, HYDROLYZED SODIUM HYALURONATE, ETHYLHEXYLGLYCERIN, GLYCERIN, PROPANEDIOL, PORTULACA OLERACEA EXTRACT, LONICERA CAPRIFOLIUM FLOWER EXTRACT, LONICERA JAPONICA FLOWER EXTRACT, C 13-15 ALKANE, LACTIC ACID.

3. Reasoning:

Based on the documents provided with the product, reports on laboratory and clinical examinations and other accessible information the chemical composition of the product, the toxicological profile of the ingredients and the **level of exposure** according to the purpose of use and the way of application were assessed. The cosmetic product contains ingredients whose general toxicological profile does not endanger the user's health when used in given concentration and for the purpose specified, i.e. as cosmetic treatment for the health underarm skin. Margins of safety for ingredients and their components, where relevant and available, exceed 100, see section A/7.

The use of the product by healthy people under normal or reasonably foreseeable conditions does not represent any risk of irritation, sensitisation or other local or system undesirable effects.

Ingredients which are classified as skin and/or eye irritants are employed in the product formula in concentrations that do not represent any hazards for human health. The composition of the product is in compliance with requirements of the contemporary valid regulations for cosmetic products.

The **microbiological and challenge tests** confirm the health safety. The test protocols are attached in the supplement.

This expert opinion is elaborated in compliance with generally binding valid regulations on cosmetic products and is used solely as an assessment of their safety for human health. It has been made out in accordance with current legislative, scientific and technical knowledge. Changes in the formulation or in legal requirements require a renewed assessment. This expert opinion may be reproduced only as a whole. Otherwise written consent of the person responsible for the safety assessment of the cosmetic products for human health is required.

Date: 20.11.2023

Protocol Nr.: 2023_024

Ing. Lenka Průšová

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CV and assessor's credentials and approval are included in this Safety Assessment Report.

Privacy statement:

This file includes trade secrets and commercial information that are privileged or confidential and shall be disclosed only if such disclosure is required by applicable laws or regulations. In any case, the person to whom the information is disclosed, has to be informed that the information is privileged or confidential and may not be disclosed to other parties. These limitations on disclosure will also apply to all future information that will be marked as privileged or confidential.

Assessor's credentials and approval

(in compliance with Annex I of the Regulation (EC) No. 1223/2009)

Lenka PRŮŠOVÁ

Date of Birth: 18.3. 1986

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Education:

- 2008** **The Chemical Institute of Prague**, Dept. Of Dairy, Fat and Cosmetics
Completed a bachelor's degree program, achieved title „Bc.“.
- 2010** **The Chemical Institute of Prague**, Dept. Of Dairy, Fat and Cosmetics
Completed a master's degree program, achieved title „ Ing.“.
- 2014** **Vrije Universiteit Brussel**, Dept. Toxicology
Accreditation - Expert evaluator safety of cosmetic products – “Safety Assessor”

Working experience:

- 2010 – 2011** **Qalt Rakovník s.r.o.**
Zavidov 72, 270 35 Petrovice
manufacturer of household products
position: „R&D Manager“
- 2011 – 2012** **Cormen s.r.o.**
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Manufacturer of household products, desinfecions and cosmetics
position: „Product Manager of Cosmetic Division“
- 2013 – 2018** **RYOR, a.s.**
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manufacturer of cometic products
position: „R&D Formulator“
- 2014 – 2016** **Czech Technical University in Prague**, Faculty of Biomedical Engineering
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position: „External Teacher“
- 2018 – still** **Research & Development Specialist, self employed**

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(Jméno a příjmení)

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(Datum a místo narození)

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na Fakultě potravinářské a biochemické technologie

Podle § 46 odst. 4 zákona č. 111/1998 Sb., o vysokých školách a o změně a doplnění dalších zákonů (zákon o vysokých školách),
se mu/ji uděluje akademický titul **inženýr** ve zkratce „**Ing.**“ uváděné před jménem.

V Praze dne 3. června 2010


Doc. Ing. Josef Koubek, CSc.

rektor





Prof. Ing. Karel Melzoch, CSc.

děkan

SEVT - 92 516 5

B.N.B. 1021 2009



Vrije Universiteit Brussel

CERTIFICATE

The Undersigned declare that

Lenka PRUSOVA

Has attended the course and has successfully passed the exam of the

"Safety Assessment of Cosmetics in the EU - Training Course 2014"

from Monday the 3th of February to Saturday the 8th of February 2014
organized at the Vrije Universiteit Brussel

Brussels, March 17th, 2014

Prof. Dr. Pharm. V. Rogiers
Course organizer

Prof. Dr. Paul De Knop
Rector of Vrije Universiteit Brussel

Annexes to this CPSR:

- 1) Product label
- 2) Challenge test protocol
- 3) Active ingredients studies:
 - a) HymagicTM-4D (4D Hyaluronic Acid)
 - b) Bioland Portulaca Extr.

Primary packaging:

Odličovač očního make-upu
Eye Make-Up Remover
Augen-Make-up-Entferner

Odličovač očního make-upu naneste na vatový tampon, přiložte na zavřená oční víčka a nechte pár sekund působit. Jemnými tahy odstraňte veškerý oční make-up. Obsahuje hemiskvalan, zklidňující extrakt z Portulacy a čtyři druhy kyseliny hyaluronové.

Ingredients: Aqua, Poloxamer 184, Leuconostoc/Radish Root Ferment Lysate Filtrate, Pentylene Glycol, Sodium Acetylated Hyaluronate, Sodium Hyaluronate, Sodium Hyaluronate Crosspolymer, Hydrolyzed Sodium Hyaluronate, Ethylhexylglycerin, Glycerin, Propanediol, Portulaca Oleracea Extract, Lonicera Caprifolium Flower Extract, Lonicera Japonica Flower Extract, C 13-15 Alkan, Lactic Acid.

100 ml

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Klausova 254 1/15
155 00 Prague
Czech Republic

**EYE MAKE-UP
REMOVER
WITH HEMISQUALANE
& PORTULACA
EXTRACT**

8 594184 350157

PET

Secondary packaging (box):



**ODLIČOVAČ
OČNÍHO MAKE-UPU
S HEMISKVALANEM
& EXTRAKTEM
Z PORTULACY**



**EYE MAKE-UP
REMOVER
WITH HEMISQUALANE
& PORTULACA
EXTRACT**



**Odličovač očního make-upu
Eye Make-Up Remover
Augen-Make-up-Entferner**

Ingredients: Aqua,
Poloxamer 184,
Leuconostoc/Radish Root
Ferment Lysate Filtrate,
Pentylene Glycol, Sodium
Acetylated Hyaluronate,
Sodium Hyaluronate,
Sodium Hyaluronate
Crosspolymer, Hydrolyzed
Sodium Hyaluronate,
Ethylhexylglycerin,
Glycerin, Propanediol,
Portulaca Oleracea Extract,
Lonicera Caprifolium
Flower Extract, Lonicera
Japonica Flower Extract,
C 13-15 Alkan, Lactic Acid.

100 ml



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