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

CALMING & MOISTURISING SKIN TONIC WITH FOUR TYPES OF HYALURONIC ACID

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
Glycerin (99,5 %)	56-81-5	**2,00 – 4,00**	-	Humectant
Propanediol	504-63-2	**2,00 – 4,00**	-	Solvent, viscosity controlling
Azelamidopropyl Dimethyl Amine, Aqua, Butylene Glycol	1272659-40-1; 7732-18-5; 107-88-0/6290-03-5	**2,00 – 4,00**	-	Skin Conditioning, Anti-sebum
Butylene Glycol, Aqua, Citrus Species Leaf Extract	107-88-0 (i) / 6290-03-5 (ii), 7732-18-5, 94266-47-4	**1,00 - 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.	**1,00 - 3,00**	-	Skin conditioning
Aqua, Leuconostoc/Radish Root Ferment Lysate Filtrate.	7732-18-5, 1686112-10-6	**2,00 - 4,00**	-	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.

Ingredience: 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
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.

Ingredience: 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.

Ingredience: Epi-On
INCI Name: AZELAMIDOPROPYL DIMETHYL AMINE, AQUA, BUTYLENE GLYCOL
Description: -
INN Name: -
Ph. Eur. Name: -
CAS No.: 1272659-40-1; 7732-18-5; 107-88-0/6290-03-5
EINECS/ELINCS No.: -; 231-791-2; 203-529-7/228-532-0
Chemical/IUPAC Name:
Cosmetic Restriction: -
Other Restriction(s): -
Functions: SKIN CONDITIONING, ANTI-SEBUM
SCCS opinions: -
REACH: -
Physical / chemical characteristics, purity (MSDS, TDS):
Physical State: Liquid
Appearance: Liquid
Color: Clear to yellow (APHA 200 Max.)
Odor: Typical
pH value (30% aq.): 5.0-7.0
Active content (%): 48 - 52
Acid value (mg KOH/g): 98 - 108
SOLUBILITY: Water Soluble
Traces of prohibited substances: Not expected to be present unless specified above
Microbiological specifications: Expected value for bacteria, yeast and mould <= 100 CFU/g, absent E.coli, P.aureginosa, S.aureus, Salmonella spp.
Toxicological profile:
Azelamidopropyl Dimethyl Amine:
Not irritant to skin (Pure active Epi-On®), not irritant to eyes (Epi-On® gel (4% A.I.), non mutagenic/non
pro-mutagenic (Pure active Epi-On®)

NOAEL values for the reactants of the synthesis reaction of Azelamidopropyl Dimethyl Amine.
NOAEL (oral, rat) for Azelaic Acid: 1 000 mg/kg bw/day (nominal)
(https://echa.europa.eu/cs/registration-dossier/-/registered-dossier/13411/7/6/2)
NOAEL (oral, rat, female): NOAEL was 250 mg/kg bw/day (for 3-aminopropyldimethylamine;
https://echa.europa.eu/cs/registration-dossier/-/registered-dossier/14823/7/6/2)
Butylene Glycol:
Skin irritation: Human data reveal no or only minimal skin irritating properties of the undiluted substance or a 50% aqueous solution. This is supported by animal studies with neat substance, where no or only minimal signs of skin irritation are documented, which is not.
Eye irritation: relevant with respect to classification. The key study documents a slight irritating effect in the eyes of rabbits, and several further animal studies showed no or only minimal eye irritation. Human data are restricted to a short remark in a handbook, which reports that the substance caused stinging, when it was applicated to the human eye and there was a rapid complete relief after rinsing-off the material.
NOAEL (oral, rat): 5 000 mg/kg bw/day (nominal)
The approximated NOAEL of the mixture is 250 mg/kg/d (read across 3-aminopropyldimethylamine).
Exposure: see section 7.

Ingredience: Mandarin Clear
INCI Name: BUTYLENE GLYCOL, AQUA, CITRUS SPECIES LEAF EXTRACT.
Description: -
INN Name: -
Ph. Eur. Name: -
CAS No.: 107-88-0 (i) / 6290-03-5 (ii), 7732-18-5, 94266-47-4
EINECS/ELINCS No.: 203-529-7 (i) / 228-532-0 (ii), 231-791-2, 304-454-3
Chemical/IUPAC Name: -
Cosmetic Restriction: -
Other Restriction(s): -
Functions: SKIN CONDITIONING
SCCS opinions: -
Physical / chemical characteristics:
Appearance: Light yellow to yellowish brown liquid
Odor: Slightly characteristic
Flash point: > 93 °C
Solubility in water: soluble
Purity / Active ingredient content:
Butylene Glycol: 67,9 %
Aqua: up to 100 %
Citrus Species Leaf Extract: 3,0 %
Heavy methals max. 20 ppm, Arsenic max. 2 ppm
Data from MSDS.
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:

Not classified as hazardous according to Regulation (EC) No 1272/2008, not-sensitising, CMR not reported. At a maximum concentration of 1 % in the final product, it is not expected to cause skin or eye irritation.
Toxicological information MSDS:
Acute toxicity (1-3-butanediol): LD50 (rat): 22 800 mg/kg
Skin corrosion/irritation (1-3-butanediol): not classified
Serious eye damage /irritation (1-3-butanediol): not classified
Respiratory or skin sensitisation (1-3-butanediol): negative
Butylene Glycol
Not skin irritant, mild eye irritant, CMR not reported.
Repeated dose toxicity:
NOAEL (oral, rat): 5 000 mg/kg bw/day (Butane-1,3-diol. Registration Dossier ECHA. https://echa.europa.eu/cs/registration-dossier/-/registered-dossier/14962/7/6/2 .)
An estimated NOAEL of 5000 mg/kg/day was determined based on toxicological data of Butylene Glycol, the main component of the mixture.
Exposure: see section 7.

Ingredience: HymagicTM-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.

Ingredience: 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 ºC): 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.

Ingredience: 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% CO_2 extracted flowers and buds of Lonicera Caprifolia (<45%) and Lonicera Japonica (<20%) in water carier (<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: $C_3H_6O_3$ / 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 miroorganisms: max. 1.10^2 cfu/g
Total count of moulds and yeasts: 1.10^2 cfu/g

Escherichia coli	not detected in 0,1 ml
Pseudomonas aeruginosa	not detected in 0,1 ml
Staphylococcus aureus	not detected in 0,1 ml
Candida albicans	not detected in 0,1 ml
Aspergillus Brasiliensis	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 december 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. Challange test was conducted on the product Sain Eye make-up remover, which can be considered a group product due to its composition.

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 (200 ml) – PET
           Manufacturer/supplier: Vexel/Mandario
    II. Secondary packaging:
        1. Paper box – C/PAP
           Manufacturer/supplier: REP Tisk spol s.r.o.

The used 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 – Skin tonic (Make up remover - closest reference product)

Product name and instructions for use:

SAIN
CALMING & MOISTURISING SKIN TONIC WITH FOUR TYPES OF HYALURONIC ACID

Ingredients: Aqua, Leuconostoc/Radish Root Ferment Lysate Filtrate, Pentylene Glycol, Sodium Acetylated Hyaluronate, Sodium Hyaluronate, Sodim Hyaluronate Crosspolymer, Hydrolyzed Sodium Hyaluronate, Ethylhexylglycerin, Glycerin, Propanediol, Azelamidopropyl Dimethyl Amine, Butylene Glycol, Citrus Species Leaf Extract, Lonicera Caprifolium Flower Extract, Lonicera Japonica Flower Extract, Lactic Acid.

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

200 ml

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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 – leave on (closest reference product)	
Skin surface area involved	565	cm^2
Area of aplication	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 g, tj. 83,3 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:

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

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

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 absorbtion 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% absorbtion).

MOS (Margin Of Safety) is futher 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.

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

Ingredience	C [%]	DA_P [%]	SED [mg/kg bw/day]	NOAEL [mg/kg/d]	MOS	
Aqua	CONFIDENTAL					
Glycerin (95,5 %)						
Propanediol						
Azelamidopropyl Dimethyl Amine, Aqua, Butylene Glycol.						
Butylene Glycol, Aqua, Citrus Species Leaf Extract.						
Aqua, Pentylene Glycol, Sodium Acetylated Hyaluronate, Sodium Hyaluronate, Sodium Hyaluronate Crosspolymer, Hydrolyzed Sodium Hyaluronate, Ethylhexylglycerin.						
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 CALMING & MOISTURISING SKIN TONIC WITH FOUR TYPES OF HYALURONIC ACID**", i.e. as skin tonic and skin cleansing product (leave on). 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, LEUCONOSTOC/RADISH ROOT FERMENT LYSATE FILTRATE, PENTYLENE GLYCOL, SODIUM ACETYLATED HYALURONATE, SODIUM HYALURONATE, SODIM HYALURONATE CROSSPOLYMER, HYDROLYZED SODIUM HYALURONATE, ETHYLHEXYLGLYCERIN, GLYCERIN, PROPANEDIOL, AZELAMIDOPROPYL DIMETHYL AMINE, BUTYLENE GLYCOL, CITRUS SPECIES LEAF EXTRACT, LONICERA CAPRIFOLIUM FLOWER EXTRACT, LONICERA JAPONICA FLOWER EXTRACT, 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 healths. 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 protocol 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_025

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CV and assessor´s credentials and aproval are included in this Safety Assessment Report.

Privacy statement:
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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 Instiute of Prague,** Dept. Of Dairy, Fat and Cosmetics
Completed a bachelor's degree program, achieved title „Bc.“.

2010 **The Chemical Instiute 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.**
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2011 – 2012 **Cormen s.r.o.**
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2013 – 2018 **RYOR, a.s.**
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position: „R&D Formulator“

2014 – 2016 **Czech Technical University in Prague,** Faculty of Biomedical Engineering
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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/jí uděluje

akademický titul **inženýr** ve zkratce **„Ing."** uváděné před jménem.

V Praze dne 3. června 2010

L.S.

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

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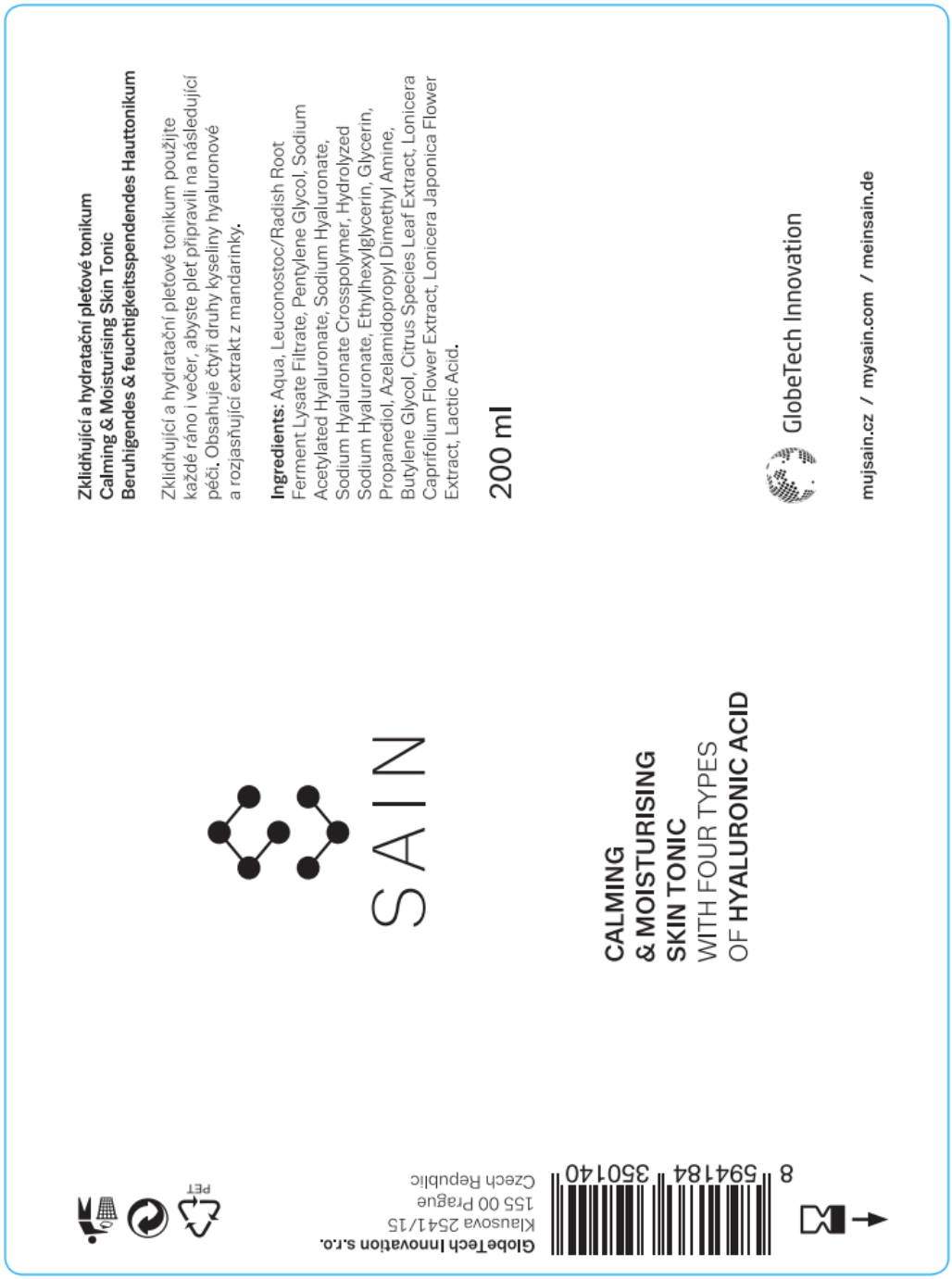
Annexes to this CPSR:

1) Product label
2) Challenge test protocol
3) Active ingredients studies:
    a) HymagicTM-4D (4D Hyaluronic Acid)
    b) Epi-On
    c) Mandarin Clear

Primary packaging:



Secondary packaging (box):


SAIN
ZKLIDŇUJÍCÍ
& HYDRATAČNÍ
PLEŤOVÉ TONIKUM
SE ČTYŘMI DRUHY
KYSELINY
HYALURONOVÉ
SAIN
CALMING
& MOISTURISING
SKIN TONIC
WITH FOUR TYPES
OF HYALURONIC ACID
Zklidňující a hydratační pleťové tonikum
Calming & Moisturising Skin Tonic
Beruhigendes & feuchtigkeitsspendendes Hauttonikum
Ingredients: Aqua, Leuconostoc/Radish Root Ferment Lysate Filtrate, Pentylene Glycol, Sodium Acetylated Hyaluronate, Sodium Hyaluronate, Sodium Hyaluronate Crosspolymer, Hydrolyzed Sodium Hyaluronate, Ethylhexylglycerin, Glycerin, Propanediol, Azelamidopropyl Dimethyl Amine, Butylene Glycol, Citrus Species Leaf Extract, Lonicera Caprifolium Flower Extract, Lonicera Japonica Flower Extract, Lactic Acid.
200 ml
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