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

NIGHT ANTI-AGING CREAM WITH ALAPTIDE & SQUALANE

Responsible person:

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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	**Ad 100**	-	Solvent
Glycerin (99,5 %)	56-81-5	**3,00 - 5,00**	-	Humectant
Acacia Senegal Gum, Xanthan Gum, Aqua	9000-01-5; 11138-66-2; 7732-18-5	**0,05 -0,50**	-	Binding, Gel Forming, Emulsion Stabilising, Viscosity Controling
Polyglyceryl-3 Rice Branate, Sucrose Stearate, Cetearyl Alcohol.	-, 25168-73-4 / 37318-31-3, 67762-27-0 / 8005-44-5	**1,00 - 5,00**	-	Emulsifier
Cetearyl Alcohol	67762-27-0	**2,00 - 5,00**	-	Viscosity controling, Emulsifying
Squalane	111-01-3	**1,00 - 5,00**	-	Emollient, Skin conditioning
Moringa Oleifera Seed Oil	93165-54-9	**5,00 - 10,00**	-	Skin conditioning, Emollient
Camellia Oleifera Seed Oil	225233-97-6	**1,00 - 3,00**	-	Emollient, Skin conditioning
Dimethicone, Cetearyl Dimethicone Crosspolymer, C30-45 Alkyl Dimethicone, Beeswax	63148-62-9 / 9006-65-9 / 9016-00-6; 756876-51-4; 243137-49-7; 8006-40-4/8012-89-3	**0,05 - 2,00**	-	Skin conditioning
Butyrospermum Parkii Butter, Moringa Oleifera Seed Oil, Limnanthes Alba Seed Oil, Macadamia Integrifolia Seed Oil, Ceramide NP, Phytosphingosine, Glycerin, Hydrogenated Lecithin	91080-23-8; -; 153065-40-8; 159518-86-2; -; 554-62-1; 56-81-5; 92128-87-5	**0,50 -1,00**	-	Skin conditioning
Alaptide	90058-29-0	**2,00**	-	Skin Conditioning
Azelamidopropyl Dimethyl Amine, Aqua, Butylene Glycol.	1272659-40-1; 7732-18-5; 107-88-0/6290-03-5	**0,50 - 2,00**	-	Skin Conditioning, Anti-sebum
Butylene Glycol, Aqua,	107-88-0/6290-03-5, 7732-18-5,	**1,00 -2,00**	-	Skin conditioning

Trifolium Repens Extract	89997-79-5			
Hyaluronic Acid	9067-32-7	**0,02 – 0,05**	-	Humectant
Lauroyl Lysine	52315-75-0	**1,00- 2,00**	-	Skin conditioning
Parfum	-	**0,20**	-	Parfuming
Phenoxyetanol, Glyceryl Laurate, Aqua	122–99 – 6, 142–18 – 7, 7732-18-5	**1,00**	0,750 – 0,850; 0,090 – 0,110; 0,090 – 0,110	Preservative
Triethanolamine	102-71-6	**qs.**	-	Buffering
Lactic Acid	79-33-4	**qs.**	-	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

Ingredience: Demineralised 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
Microbiological specifications: Expected values for bacteria, yeast and moulds <= 100 CFU/g, absent E.coli, P.aurrginosa, 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.

Ingredience: Solagum AX
INCI Name: ACACIA SENEGAL GUM; XANTHAN GUM; AQUA
Description: Acacia Senegal Gum is the dried, gummy exudate of the acacia, Acacia senegal, Leguminosae; Xanthan gum
INN Name: -
Ph. Eur. Name: -; gummi xanthanum
CAS No.: 9000-01-5; 11138-66-2; 7732-18-5
EINECS/ELINCS No.: 232-519-5; 234-394-2; 231-791-2
Chemical/IUPAC Name: -
Cosmetic Restriction: -
Other Restriction(s): -
Functions: FILM FORMING, MASKING; BINDING, EMULSIFYING, EMULSION STABILISING, GEL FORMING, SKIN CONDITIONING, SURFACTANT, VISCOSITY CONTROLLING; SOLVENT
SCCS opinions: -
Physical / chemical characteristics, purity:
Powder

Lightly yellow
Odourless
Composition:
Acacia Senegal Gum – 48 – 55 %, molecular weight 350 00 PM
Xanthan Gum: 40 -45 %, molecular weight 100 000 PM
Aqua: 0-12 %
Water soluble
pH (1% sol.)= 5,0-7,5
Traces of prohibited substances:
Heavy metals: 20 ppm max. according EP method 2.4.8. C
Microbiological specifications:
Expected value for bacteria, yeast and mould <= 100 CFU/g, absent E.coli, P.aureginosa, S.aureus, Salmonella spp.
Toxicological profile:
Primary eye irritation: Non irritant – HETCAM Seppic 3053
Not CMR – Ames protocol OECD (report LCE 09001)
NOAEL (oral, beagle): 250 mg/kg/day (read across Xanthan Gum, Safety Assessment of Microbial Polysaccharide Gums as Used in Cosmetics; October 5, 2012; https://www.cir-safety.org/sites/default/files/microb092012rep.pdf
Exposure: see section 7.

Ingredience: Supreme
INCI Name: POLYGLYCERYL-3 RICE BRANATE, SUCROSE STEARATE, CETEARYL ALCOHOL.
Description: Emulsifyer
INN Name: -
Ph. Eur. Name: -
CAS No.: -, 25168-73-4 / 37318-31-3, 67762-27-0 / 8005-44-5
EINECS/ELINCS No.: -, 246-705-9 / 253-459-6, 267-008-6 / -
Chemical/IUPAC Name: -
Cosmetic Restriction: -
Other Restriction(s): -
Functions: Emulsifyier; Skin Conditioning
SCCS opinions: -
Physical / chemical characteristics:
Appearance: waxy flakes.
characteristics Colour: from ivory to pale yellow.
Odour: characteristic.
pH (sol. 10%): 6.00-7.50.
Theoretical HLB: 11 ± 1.
Melting point: 60.00-70.00°C.
% H2O (K.F.): max 1.00.
Purity / Active substance content:
Polyglyceryl-3 Rice Branate: 50–60 %
Sucrose Stearate: 10–20 %
Cetearyl Alcohol: 25–35 %

Data from 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:
Product: Not hazardous, not toxic, not irritant to skin/eyes, not sensitizing. (Data from sinerga product information sheet)
Polyglyceryl-3 Rice Branate
NOAEL (oral, rat): 2500 mg/kg bw/day (EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), Younes M, Aggett P, Aguilar F, Crebelli R, Dusemund B, Filipič M, Frutos MJ, Galtier P, Gott D, Gundert-Remy U, Kuhnle GG, Leblanc J-C, Lillegaard IT, Moldeus P, Mortensen A, Oskarsson A, Stankovic I, Waalkens-Berendsen I, Woutersen RA, Wright M, Boon P, Chrysafidis D, Gürtler R, Mosesso P, Parent-Massin D, Tobback P, Rincon AM, Horvath Zs and Lambré C, 2017. Scientific Opinion on the re-evaluation of polyglycerol esters of fatty acids (E 475) as a food additive. EFSA Journal 2017;15(12):5089, 32 pp. https://doi.org/10.2903/j.efsa.2017.5089)
Sucrose Stearate
NOAEL (oarl, rat, male): 3240 mg/kg bw/day (derived from data of Sucrose Laurate, https://echa.europa.eu/cs/registration-dossier/-/registered-dossier/25178/7/6/2)
Cetearyl Alcohol
NOAEL (oral, rat): 1000 mg/kg/day (Cognis. tox. file)
The NOAEL of the mixture was estimated >1000 mg/kg/day
Exposure: see section 7.

Ingredience: Cetearyl Alcohol
INCI Name: CETEARYL ALCOHOL
Description: -
INN Name: -
Ph. Eur. Name: -
CAS No.: 67762-27-0
EINECS/ELINCS No.: -
Chemical/IUPAC Name: -
Cosmetic Restriction: -
Other Restriction(s): -
Functions: EMULSIFYING, VISCOSITY CONTROLLING
SCCS opinions: -
Physical / chemical characteristics, purity:
Solid (20°C) and waxy flakes or beads, white colour, clean when melted, characteristic odour.
Acid value: 0,1 - 0,30 mg KOH.g-1
Saponification value: 0,2 - 1,00 mg KOH.g-1
Iodine value: 0,1 - 1,0 g I2/100 g
Hydroxyl value: 225,0 - 235,0 mg KOH.g-1
Solidification point: 46 - 50°C
Hydrocarbon content: max. 0,5% by wt.
Solubility: in water insoluble / in fats soluble.
Melting point: 48 - 53°C

Flash point: >170°C
Boiling point: >310°C
Character: non-ionic.
Density (70°C): 0,83 g/cm3
Log P(ow): 6,7
Purity:
C14(%): 0,6-3,0 / C16 (%): 49,9-55,0 / C18(%): 48,3-55,0 / C20(%): 0,3-3%
Water content: max. 0,15%
Traces of prohibited substances: Not present
Microbiological specifications: A microbiological contamination can be excluded due to the production parameters (solid and waxy flakes) and due to the water content (max. 0,15%).
Toxicological profile: Toxicological data from Toxicological file by Cognis:
LD50 (oral, rat) > 5000 mg/kg (MSDS)
NOAEL(oral, rat): 1000 mg/kg/day (Cognis. tox. file)
Dermal / Eye irritation: Non-irritant
Sensitization: No sensitizing potencial.
AMES-Test negativ (bacteria)
CMR effects (carcinogenity, mutagenicity and toxicity for reproduction): non – CMR
Exposure: see section 7.

Ingredience: Squalane
INCI Name: SQUALANE
Description: -
INN Name: squalane
Ph. Eur. Name: -
CAS No.: 111-01-3
EINECS/ELINCS No.: 203-825-6
Chemical/IUPAC Name: 2,6,10,15,19,23-Hexamethyltetracosane
Cosmetic Restriction: -
Other Restriction(s): -
Functions: EMOLLIENT, SKIN CONDITIONING
SCCS opinions: -
Physical / chemical characteristics, purity:
Appearance: Liquid
Color: Clear to Colorless
Melting point/freezing point: -38°C (-36.4°F)
Initial boiling point and boiling range: 176°C (348°F) at 0.05 mm Hg; 210-215°C at 1.0 mm Hg
Flash point: 218 °C (424 °F)
Relative density: 0.81 g/mL
Solvent solubility: Soluble in alcohols.
log P(o/w): 12.86 (http://www.chemicalize.org/structure/#!mol=Squalane&source=fp)
Formula: C30H62
Isotope formula: C30H62
Composition: C (85.22 %), H (14.78 %)
Isotope composition: C (85.22%), H (14.78%)

Mass: 422.8133
Exact mass: 422.485151984
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:
Irritation/Corrosion (MSDS):
Squalane is considered a reversible eye irritant. An assessment of existing studies has determined that the chemical is a reversible irritant which does not fully meet the CLP criteria for eye irritation based on weight of evidence of the data and professional judgment.
Sensitization (MSDS):
Squalane is not considered a skin sensitizer (i.e. it does not cause an allergic response from repeated skin contact). Results from an HRIPT with 100 % squalane showed no indication of irritation or sensitization.
NOAEL (oral, dog): 400 g/kg/day (http://www.ncbi.nlm.nih.gov/pubmed/2744688)
Exposure: see section 7.

Ingredience: Moringový olej
INCI Name: MORINGA OLEIFERA SEED OIL
Description: Moringa Oleifera Seed Oil is the oil expressed from the seeds of Moringa oleifera, Moringaceae
INN Name: -
Ph. Eur. Name: -
CAS No.: 93165-54-9
EINECS/ELINCS No.: 296-941-1
Chemical/IUPAC Name: -
Cosmetic Restriction: -
Other Restriction(s): -
Functions: Emollient, skin conditioning
SCCS opinions: -
Physical / chemical characteristics, purity:
Sight: Oil
Color: Pale yellow, green to amber
Odor: Characteristic
Refraction index: 1.450 - 1.480
Specific gravity: 0.850 - 0.950
Peroxid: ≤ 15.0 meq O2 / kg
Acid value: ≤ 10.0 mg KOH / g
Iodine value: 60 - 95 g / 100g
Saponification value: 180 - 200 mg KOH / g
Fatty Acid Composition:
Palmitic: 5,0-9,0 %
Oleic acid: ≥ 55,0%
Stearic acid: 3,0-9,0 %
Linoleic: ≤ 5,0 %

Linolenic: ≤ 1,0 %
Eicosenoic: 1,5-5,0 %
Sourse: Specification data sheet Greentech Moringa oil
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: Non-hazardous substance, used in food. Not irritating, not sensitizing, not CRM, expected low skin penetration.
For linar long-chain and branched chain, unsaturated fatty acids (e.g. oleic and linoleic acids) the **NOAEL is expected over 1 000 mg/kg/day**
(http://www.heraproject.com/files/5-HH-04-HERA%20Fatty%20acid%20salts%20HH%20web%20wd.pdf)
Exposure: see section 7., Inc., PO Box 2152, Princeton, NJ 08543,USA. katraul@aol.com)

Ingredience: Kameliový olej
INCI Name: CAMELLIA OLEIFERA SEED OIL
Description: Camellia Oleifera Seed Oil is a fixed oil from the seeds of Camellia oleifera, Theaceae
INN Name: -
Ph. Eur. Name: -
CAS No.: 225233-97-6
EINECS/ELINCS No.: -
Chemical/IUPAC Name: -
Cosmetic Restriction: -
Other Restriction(s): -
Functions: EMOLLIENT, SKIN CONDITIONING
SCCS opinions: -
Physical / chemical characteristics, purity (Specification Sheet):
Aspect: Liquid
Color: Colorless to yellow
Odor: Characteristic
Peroxid value: ≤ 10.0 meq O2 / kg
Acid value: ≤ 5.0 mg KOH / g
Fatty Acids:
C16:0 (Palmitic acid) 3–12 %
C18:0 (Stearic acid) 1–4 %
C18:1 (Oleic acid) assay 70–85 %
C18:2 (Linoleic acid) 5–12 %
C18:3 (Linolenic acid) ≤ 1 %
Traces of prohibited substances: Non present
Microbiological specifications: Expected value for bacteria, yeast and moulds <= 100 CFU/g, absent E. coli, P. aeruginosa, S. aureus, Salmonella spp.
Toxicological profile: Non-toxic
Non-hazardous substance, used in food. Not irritating, not-sensitizing, not CMR, expected low skin penetration rate below 1 %.
For linear long-chain and branched chain, unsaturated fatty acids (e.g. oleic and linoleic acids) the

NOAEL is expected over 1000 mg/kg/day.
Skin sensitisation: Unknown
Skin / Eye irritation: Unknown
Exposure: see section 7.

Ingredience: Velvesil B Magic gel
INCI Name: DIMETHICONE, CETEARYL DIMETHICONE CROSSPOLYMER, C30-45 ALKYL DIMETHICONE, BEESWAX
Description: Silicone mixture containing dimethicone crosspolymer, silicone wax and natural wax.
INN Name: -
Ph. Eur. Name: -
CAS No.: 63148-62-9 / 9006-65-9 / 9016-00-6; 756876-51-4; 243137-49-7; 8006-40-4/8012-89-3
EINECS/ELINCS No.:
Chemical/IUPAC Name:
Cosmetic Restriction: -
Other Restriction(s): -
Functions: SKIN CONDITIONING
SCCS opinions: -
REACH: -
Physical / chemical characteristics, purity:
Physical state: solid
Form: Wax
Color: White to yellowish
Odor: Specific
Density: 0,94 g/cm^3
Cyclotetrasiloxane (CAS 556-67-2) <1000 ppm
Cyclopentasiloxane (CAS 541-02-6) <2000 ppm
Cyclohexasiloxane (CAS 540-97-6) <4000 ppm
Traces of prohibited substances:
Analytical tests have been performed for the elemental impurities Lead (Pb), Mercury (Hg), Chromium (Cr), Cadmium (Cd), Arsenic (As), Silver (Ag), Barium (Ba), Nickel (Ni), Cobalt (Co), Vanadium (V), Manganese (Mn) Beryllium (Be), Copper (Cu), Zinc (Zn), Tin (Sn), Bismuth (Bi), Antimony (Sb), Selenium (Se), and these components were not detected in the product within the capabilities of the tests used (<1ppm)
Microbiological specifications: Microbiological specifications: Expected value for bacteria, yeast and mould <= 100 CFU/g, absent E. coli, P. aureginosa, S. aureus, Salmonella spp.
Toxicological profile:
Dimethicon:
Non-hazardous substance, not classified according to CLP. Not skin irritant, not sensitizing, not CMR.
On contact with eyes: May cause temporary discomfort (slight irritant), but not classified according to CLP.
LD50(oral,rat) > 16000 mg/kg (MSDS)
NOAELderived = 160 mg/kg/d

NOAEL (dermal, rat) = 1000 mg/kg/day (Safety Assessment of Dimethicone, 2019 - chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.cir-safety.org/sites/default/files/Methicones.pdf)
NOEL (oral, rat) = 1000 mg/kg/day (Safety Assessment of Dimethicone, 2019 - chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.cir-safety.org/sites/default/files/Methicones.pdf)
Other Health Hazard Information:
Product may emit formaldehyde vapour at temperatures above 150°C in the presence of air. Formaldehyde vapour is a suspected carcinogen, toxic by inhalation and irritating to eyes and the respiratory system. Exposure limmits shoud be stricly respected.
Decamethylcyclopentasiloxane:
In the key skin and eye irritation studies (Toxikon Corporation, 1990b and c, respectively), which were conducted using protocols comparable with OECD 404 and 405, respectively, and to GLP, it was concluded that D5 was not irritating to the skin or eyes of rabbits.
There are no studies specific to testing for respiratory tract irritation; however, acute inhalation (RCC Ltd, 1994) and repeated dose inhalation studies, including the key study (RCC Ltd, 2005) generally show signs of respiratory tract irritation.
In a Local Lymph Node Assay (BSL Bioservice Scientific Labs, 2005) conducted using a protocol similar to OECD 429 and to GLP, D5 gave a negative result and is therefore not expected to be a skin sensitiser.
NOAEL: 1000 mg/kg/day. (https://echa.europa.eu/cs/registration-dossier/-/registered-dossier/14807/7/6/1)
Acute oral toxicity: LD50, Rat, male and female, > 24,134 mg/kg (MSDS)
Dodekamethylcyklohexasiloxan:
Acute oral toxicity: LD50, Rat, male and female, > 2,000 mg/kg No deaths occurred at this concentration. (MSDS)
NOAEL: 1000 mg/kg/day. (https://echa.europa.eu/cs/registration-dossier/-/registered-dossier/15811/7/6/1)
The approximated NOAEL of the mixture is 160 mg/kg/d (read across main compound Dimethicone).
Exposure: see section 7.

Ingredience: EcoCeramide LCS
INCI Name: BUTYROSPERMUM PARKII BUTTER, MORINGA OLEIFERA SEED OIL, LIMNANTHES ALBA SEED OIL, MACADAMIA INTEGRIFOLIA SEED OIL, CERAMIDE NP, PHYTOSPHINGOSINE, GLYCERIN, HYDROGENATED LECITHIN
Description: -
INN Name: -
Ph. Eur. Name: -
CAS No.: 91080-23-8; 93165-54-9; 153065-40-8; 438545-25-6/159518-86-2; 34354-88-6/100403-19-8; 554-62-1; 56-81-5; 92128-87-5
EINECS/ELINCS No.: 293-515-7; 296-941-1; 310-127-6; -; -/309-560-3; -; 200-289-5; 295-786-7
Chemical/IUPAC Name:
Cosmetic Restriction: -
Other Restriction(s): -

Functions: SKIN CONDITIONING
SCCS opinions: -
REACH: -
Physical / chemical characteristics, purity:
Appreance: Yellow Cream
Physical state: Cream
Odor: Characteristic Odor
Color: Pale yellow to Dark yellow
Flash point: 199 ℃
Purity / Active substance content:
Butyrospermum Parkii (Shea) Butter: 15,5±2,0 %
Moringa Oleifera Seed Oil: 2,0±1,0 %
Limnanthes Alba (Meadowfoam) Seed Oil: 1,0±0,5 %
Macadamia Integrifolia Seed Oil: 1,0±0,5 %
Phytosphingosine: 1,5±1,0 %
Ceramide NP: 4,0±1,0 %
Glycerin: 74,0±5,0 %
Hydrogenated Lecithin: 1,0±0,5 %
Heavy metals: <20 ppm
Arsenic: <2 ppm
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 (MSDS):
Acute oral toxicity: LD50 (oral, mouse): 23000 mg/kg, bw. ca. OECD GHS
Acute inhalation toxicity: Rat: 4655, 7 hours, mg/min/L; L(Ct)50. OECD GHS
Acute dermal toxicity: LD 50. Guinea pig: 45 ml/kg, bw. OECD GHS
NOAEL (oral, mouse): 230 mg/kg bw/d (derived from LD50, see above)
Exposure: see section 7.

Ingredience: Alaptide
INCI Name: CAS 90058-29-0 (Alaptide)
Description: -
INN Name: -
Ph. Eur. Name: -
CAS No.: 90058-29-0
EINECS/ELINCS No.: -
Chemical/IUPAC Name: -
Cosmetic Restriction: -
Other Restriction(s): -
Functions: SKIN CONDITIONING
SCCS opinions: -
Physical / chemical characteristics:
Physical state: solid
Color: white
Appearance: powder

Purity / Active ingredient content:
Alaptide: up to 100 %
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, non – toxic, CMR not reported. At a concentration of 1 % in the final product, it is not expected to cause skin or eye irritation or sensitisation.
NOAEL (experimental calculation): 286 mg/kg/d
Alaptid – bezpečnostní profil (stanovení alaptidu ve směsích jakožto bezpečného přípravku – přiznání zdravotního tvrzení dle čl. 13.1. direktivy EC/432/2012 z 25.5.2012).
https://www.alaptid.cz/user/documents/upload/bezpecnostny_profil.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: HappiClov
INCI Name: BUTYLENE GLYCOL, AQUA, TRIFOLIUM REPENS EXTRACT.
Description: -
INN Name: -
Ph. Eur. Name: -
CAS No.: 107-88-0/6290-03-5, 7732-18-5, 89997-79-5
EINECS/ELINCS No.: 203-529-7/228-532-0, 231-791-2, 289-716-4
Chemical/IUPAC Name:
Cosmetic Restriction: -
Other Restriction(s): -
Functions: SKIN CONDITIONING
SCCS opinions: -
REACH: -
Physical / chemical characteristics:
Physical state: Liquid
Colour: Light yellow to yellowish brown liquid
Odor: Characteristic odor
Flash point: >93℃ / 200 °F
Solubility: Very soluble in water
Purity / Active substance content:
Butylene Glycol: 49,9 %
Aqua: 49,9 %
Trifolium Repens Extract: 0,2 %
Data from MSDS, Composition sheet.
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:

Not classified as hazardous according to Regulation (EC) No 1272/2008, CMR not reported. At a concentration of 1 % in the final product, it is not expected to cause skin or eye irritation or sensitisation.

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

The NOAEL for the mixture was estimated to be 5,000 mg/kg/day, derived from toxicological data on Butylene Glycol, one of the main constituents.

Exposure: see section 7.

Ingredience: Oligo HA

INCI Name: HYALURONIC ACID

Description: -

INN Name: -

Ph. Eur. Name: -

CAS No.: 9004-61-9

EINECS/ELINCS No.: -

Chemical/IUPAC Name: (1→4) -(2-Acetamido-2-deoxy-D-gluco)-(1→3)-D-glucuronoglycan

Cosmetic Restriction: -

Other Restriction(s): -

Functions: HUMECTANT, SKIN CONDITIONING, MOISTURIZING

SCCS opinions: -

Physical / chemical characteristics, purity:

Appearance: White/Light yellow powder

Appearance of 0,5 % solution: Colorless clear liquid

Water Content (KF): Not more than 10,0 %

* Uronic Acid Content 45 ~ 51,3 %

* Hyaluronic Acid Content 88 ~ 100 %

Other Acidic Mucopolysaccharides: Not Detected

Molecular Weight (GPC): 3.0 ~ 10.1 Kda

Traces of prohibited substances (Specification):

Heavy Metals: Not more than 20ppm

Arsenic: Not more than 2ppm

Microbiological specifications:

Total Plate Count: Not more than 1×102cfu/g

Hemolytic Streptococci: Not Detected
Toxicological profile: Not classified as dangerous according to the Regulation No. 1907/2006 (REACH), not classified according to the Regulation No. 1272/2008 (CLP).
Sub-chronic toxicity: **NOAEL (oral, rat) 1000 mg/kg bw/d** (Oesser S, Seifert J. Cell Tissue Res. 311, 3, 2003)
Acute toxicity:
Not skin/eye irritant, not senzitizing / not fototoxic / not fotosenzitizing / not CMR.
LD50 (oral, rat) >0,4 $g.kg^{-1}$
LD50 (mouse) >5000 $mg.kg^{-1}$
Exposure: see section 7.

Ingredience: AMIHOPE®LL (Lauroyl Lysine)
INCI Name: LAUROYL LYSINE
Description: an amino-acid derivative made from L-Lysine and a fatty acid. Being barely soluble either in water or organic solvents, can be used as a powdery texture modifier for various cosmetic applications.
INN Name: -
Ph. Eur. Name: -
CAS No.: 52315-75-0
EINECS/ELINCS No.: 257-893-4
Chemical/IUPAC Name: -
Cosmetic Restriction: -
Other Restriction(s): -
Functions: SKIN CONDITIONING
SCCS opinions: -
REACH reg.: 01-2120769333-51-0000
Physical and chemical characteristics:
Solid, powder, white to pale yellow
Slightly characteristic odor
Relative density: No data available.
Solubility: insoluble; soluble under strong alkaline condition. [pH >12]
Partition coefficient: n-octanol/water No data available.
Decomposition temperature: 230°C
Purity:
Traces of prohibited substances: Not expected to be present unless specified above
Microbiological specifications:
Expected values for bacteria, yeast and moulds ≤ 1000 CFU/g, absent E.coli, P.aeruginosa, S.aureus, Salmonella spp. Pathogene organisms not to be expected.
Toxicological profile: (data source REACH dossier: https://echa.europa.eu/registration-dossier/-/registered-dossier/24853)
Acute toxicity:
Not CLP classified. Not skin, eye irritant.Not sensitizing.
In an acute oral toxicity study with ICR mice the dosing with up to 3000 mg/kg bw caused no adverse effects, i.e. the oral LD50 value of the test item is > 3000 mg/kg bw. A Draize test comparable to OECD Guideline 404 gave no indication for adverse systemic effects and there was also no indication

for a skin irritating potential of the test item. Also in a GPMT comparable to OECD Guideline 406 the test item caused no adverse effects and gave no indication for a skin sensitisation potential.
Repeated dose toxicity:
The aim of this repeated dose toxicity study was to obtain information on the toxicity of Famex LL T administered once daily by oral administration via gavage to rats for 28 consecutive days. The animals were treated with 100, 300 or 1000 mg Famex LL T/kg b.w./day. The control animals received the vehicle (0.5% Methylcellulose 400). None of the animals died or had to be sacrificed prematurely. No test itemrelated changes were observed for the behaviour or external appearance of the animals, the detailed clinical observations, the neurological screening, the body weight, body weight gain and body weight at autopsy, the food and drinking water consumption, for any of the haematological and clinical chemical parameters, the eyes or optic region, the auditory acuity, the relative and absolute organ weights, and at macroscopic inspection at necropsy at any dose level. The histopathological examination did not reveal any test item-related morphological changes. The experimental no-observed-effect level ***(NOEL) was above 1000 mg Famex LL T/kg b.w./day, by daily oral administration****.*
NOAEL : 1000 mg/kg/day (data source: REACH dossier on N6-(1-oxododecyl)-L-lysine)
Exposure: see section 7

Ingredience: SOZIO Celestial Fragrance (SO049893)
INCI Name: PARFUM
Description: Parfum is a term for ingredient labelling used to identify that a product contains a material or a combination of materials normally added to a cosmetic to produce or to mask a particular odour. According to Article 19 of the Cosmetics Regulation, 'Perfume and aromatic compositions and their raw materials shall be referred to by the terms ‘parfum’ or ‘aroma’. '
INN Name: -
Ph. Eur. Name: -
CAS No.: -
EINECS/ELINCS No.: -
Chemical/IUPAC Name:
Cosmetic Restriction: -
Other Restriction(s): -
Functions: PARFUMING, FRAGRANCE
SCCS opinions: -
REACH: -
Physical / chemical characteristics, purity:
Aspect: Liquid
Colour: Pale yellow to dark yellow
Odour: Characteristic
Flash point (in °C): >100
Boiling point (ethanol): 86 – 114 °C
Solubility: Alcohol
Refractive index @ 20°C: [1.478; 1.498]
Specific gravity@20°C: [1.001; 1.021]
Data from MSDS, TDS.
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:

List of allergens:

This allergen list shall apply to the placing of products on the market with the original labelling **until 31 July 2028**.

After this date, products shall be required to bear an **extended list of allergens**, indicating whether the product contains any of the **more than 80 fragrance allergens at concentrations exceeding 10 ppm**, as listed in **Annex III of Regulation (EC) No 1223/2009 of the European Parliament and of the Council**, as amended by **Commission Regulation (EU) 2023/1545 of 26 July 2023**.

Name of common ingredients glossary	CAS-Number	% in raw material	% in product
Alpha-Isomethyl Ionone	**127-51-5**	**1,87500**	**0,00375**
Anisyl Alcohol	105-13-5	0,00280	0,00001
Benzyl Alcohol	100-51-6	0,00690	0,00001
Benzyl Salicylate	**118-58-1**	**4,00000**	**0,00800**
Citral	5392-40-5	0,08160	0,00016
Citronellol	**106-22-9 / 26489-01-0 / 7540-51-4 / 1117-61-9**	**0,65870**	**0,00132**
Farnesol	4602-84-0	0,00150	0,00000
Geraniol	106-24-1	0,38020	0,00076
Hydroxycitronellal	**107-75-5**	**3,20000**	**0,00640**
Isoeugenol	97-54-1	0,00160	0,00000
Limonene	**138-86-3**	**3,62280**	**0,00725**
Linalool	**78-70-6**	**1,83470**	**0,00367**

Classified as hazardous substance according to Regulation (EC) No. 1272/2008 (CLP). Although individual perfume subcomponents exhibit skin/eye irritation or sensitisation properties, the perfume concentration 0,2 % in the finished product does not represent any toxicological risk for consumers. The amount of Benzyl Alcohol in final product is complient with Regulation (EC) 2013/344 Annex V/34.

NOAELs for selected substances:

Alpha-Isomethyl Ionone: NOAEL (oral, rat (male), 90 d): 3,55 mg/kg/day (Log Kow: 4,29) (https://echa.europa.eu/cs/registration-dossier/-/registered-dossier/18602/7/6/2)
Benzyl Salicylate: NOAEL (oral, rat (male)): 177 mg/kg/day (Log Kow: 4,0) (https://echa.europa.eu/cs/registration-dossier/-/registered-dossier/16100/7/6/2)
Citronellol: NOAEL: 50 mg/kg/day (US EPA) (Log Kow: 3,41)
Hydroxycitronellal: NOAEL (oral, rat (female)): 492 mg/kg/day (https://echa.europa.eu/cs/registration-dossier/-/registered-dossier/12695/7/6/1)
D-Limonene: NOAEL: 250 mg/kg/day (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.4053)
Linalool: NOAEL: 50 mg/kg/day (Log Kow: 2,9) (http://www.efchemicalconsulting.co.uk/lavender-mos.pdf)

Exposure: see section 7.

Ingredience: Sensicare 1000
INCI Name: PHENOXYETANOL, GLYCERYL LAURATE, AQUA.
Description: -
INN Name: -
Ph. Eur. Name: -
CAS No.: 122-99-6, 142-18-7, 7732-18-5
EINECS/ELINCS No.: 204-589-7, 205-526-6, 231-791-2
Chemical/IUPAC Name: -
Cosmetic Restriction: V/29
Other Restriction(s): -
Functions: PRESERVATIVE
SCCS opinions: -
Physical / chemical characteristics, purity:
Appearance: Clear transparent liquid
Odour: Mild characteristic.
Density (20ºC): 1.06 ± 0,02
pH (100%): 7.5 ± 0,02
Refractive index (20ºC): 1.507
Viscosity Brookfield (20ºC): 22 cps
Water solubility (1%): Milky dispersion
Purity / Active substance content:
Phenoxyethanol: 75,0 -85,0 %
Glyceryl Laurate: 9,0 -11,0 %
Aqua: 9,0 – 11,0 %
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: NOAEL of mixture read across Phenoxyethanol:
Phenoxyethanol:
Approved preservative according to the Regulation 1223/2009, Annex V/29, max. 1%
LD50 (oral, rat/rabbit): 1260 mg/kg
LD50 (dermal, rat/rabbit):> 2000 mg/kg
NOAEL (oral, rat): 80 mg/kg/d (Draft Interim REL; March 2010)
Glyceryl Laurate:
Not hazardous (CLP), not skin/eye irritant, not skin sensitising, CMR not reported.
NOAEL (oral, rat): 10 000 mg/kg bw/day (https://echa.europa.eu/cs/registration-dossier/-/registered-dossier/13112/7/6/2)
Exposure: see section 7.

Ingredient: Triethanolamine
INCI Name: TRIETHANOLAMINE
Description: Trialkylamines, trialkanolamines and their salts
INN Name: -

Ph. Eur. Name: -
CAS No.: 102-71-6
EINECS/ELINCS No.: 203-049-8
Chemical/IUPAC Name: -
Cosmetic Restriction: III/62
Other Restriction(s): -
Functions: BUFFERING
SCCS opinions: -
Physical / chemical characteristics, purity:
Appearance: Colorless liquid
Molecular Weight: 149.2 g/mol
Melting point: 20,5 °C
Boiling point: 336,1 °C at 1013.25 hPa
Vapour pressure: 0,00029 hPa at 21 °C
Dissociation constant (pKa): 7.86 at 25 °C
log Pow: -2.3 at 25 °C
Solubility: miscible with water
(2,2',2''-nitrilotriethanol - Registation Dossier - Echa. https://echa.europa.eu/cs/registration-dossier/-/registered-dossier/15134/7/2/1 .)
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. aeruginosa, S. aureus, Salmonella spp.
Toxicological profile:
Is classified as hazardous substance according to Regulation (EC) No. 1272/2008 (CLP). At the concentration used in the final product, Triethanolamine does not pose a risk of irritation or sensitization to the skin, eyes, or respiratory tract. Although allergic reactions to TEA have been reported, the substance is judged to have a very low sensitisation potential. Expected low skin penetration rate below 10 %.
NOAEL (oral, rat): 1000 mg/kg bw/day (2,2',2''-nitrilotriethanol - Repeated dose toxicity: oral. Registation Dossier - Echa. https://echa.europa.eu/cs/registration-dossier/-/registered-dossier/15134/7/2/1 .)
Exposure: see section 7.

<u>Ingredience: Lactic Acid</u>
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

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]
Skin and strong eye irritating.
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: Glossy, thicker, creamy emulsion
ii. Colour: Almost white, with a slight beige tint
iii. Odor: After perfume composition used: Celestial Fragrance SO049893

iv. pH: 5,5 – 6,0
v. Density 0.97 – 1.00 g·cm-3 [@ 20°C]
vi. Termostability: Conforms to the parameters of the designated test.

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 **testing laboratory Chemipol, S.A.**

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

Challenge test results (Reference: S 3523) **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. Jar white 50ml – porcelain
      2. Sealing foil – foamed PE
      3. Oak lid – wood
         Manufacturer/supplier: Thun 1794 a.s. / TVAR výrobní družstvo PARDUBICE
   ii. Secondary packaging:

1. Paper box – C/PAP
   Manufacturer/supplier: REP Tisk spol s.r.o.

iii. Tester

1. Sachet (2ml) Laminate – PET+AL+LDPE
   Manufacturer/supplier: JC-obaly 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 – Face Cream

Product name and instructions for use:

SAIN
NIGHT ANTI-AGING CREAM WITH ALAPTIDE & SQUALANE

Ingredients: Aqua, Squalane, Moringa Oleifera Seed Oil, Polyglyceryl-3 Rice Branate, Sucrose Stearate, Cetearyl Alcohol, Camellia Oleifera Seed Oil, Glycerin, Dimethicone, Cetearyl Dimethicone Crosspolymer, C30-45 Alkyl Dimethicone, Beeswax, CAS 90058-29-0 (Alaptide), Azelamidopropyl Dimethyl Amine, Butylene Glycol, Lauroyl Lysine, Butylene Glycol, Trifolium Repens Extract, Phenoxyethanol, Glyceryl Laurate, Acacia Senegal Gum, Xanthan Gum, Butyrospermum Parkii Butter, Limnanthes Alba Seed Oil, Macadamia Integrifolia Seed Oil, Ceramide NP, Phytosphingosine, Hydrogenated Lecithin, Hyaluronic Acid, Parfum, Lactic acid, Benzyl Salicylate, Limonene, Hydroxycitronellal, Alpha-Isomethyl Ionone, Linalool, Citronellol.

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

50 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	Face Cream	
Skin surface area involved	565	cm^2
Area of aplication	the face	
Estimated daily amount applied	1,54	g/day
Duration and frequency of application	2,0	day
Retention factor	1,0 (leave-on product)	
Normal and reasonably foreseeable way of exposure	dermal, skin	
Targeted (or exposed) population	adults, both women and men	

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 = 1,54 g, tj. 25,7 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 into 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 are 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 (99,5 %)						
Acacia Senegal Gum, Xanthan Gum, Aqua						
Polyglyceryl-3 Rice Branate, Sucrose Stearate, Cetearyl Alcohol.						
Cetearyl Alcohol						
Squalane						
Moringa Oleifera Seed Oil						
Camellia Oleifera Seed Oil						
Dimethicone, Cetearyl Dimethicone Crosspolymer, C30-45 Alkyl Dimethicone, Beeswax						
Butyrospermum Parkii Butter, Moringa Oleifera Seed Oil, Limnanthes Alba Seed Oil, Macadamia Integrifolia Seed Oil, Ceramide NP, Phytosphingosine, Glycerin, Hydrogenated Lecithin.						
CAS 90058-29-0 (Alaptide)						
Azelamidopropyl Dimethyl Amine, Aqua, Butylene Glycol.						
Butylene Glycol, Aqua, Trifolium Repens Extract.						
Hyaluronic Acid						
Lauroyl Lysine						
Parfum						

Phenoxyetanol; **Glyceryl Laurate**	
Triethanolamine	
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 NIGHT ANTI-AGING CREAM WITH ALAPTIDE & SQUALANE**", i.e. face cream. 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. The concentrations of individual allergenic components in the product exceed 0.001 %, and therefore they must be listed as separate ingredients in the composition.

INCI labelling:
INGREDIENTS: AQUA, SQUALANE, MORINGA OLEIFERA SEED OIL, POLYGLYCERYL-3 RICE BRANATE, SUCROSE STEARATE, CETEARYL ALCOHOL, CAMELLIA OLEIFERA SEED OIL, GLYCERIN, DIMETHICONE, CETEARYL DIMETHICONE CROSSPOLYMER, C30-45 ALKYL DIMETHICONE, BEESWAX, CAS 90058-29-0 (ALAPTIDE), AZELAMIDOPROPYL DIMETHYL AMINE, BUTYLENE GLYCOL, LAUROYL LYSINE, BUTYLENE GLYCOL, TRIFOLIUM REPENS EXTRACT, PHENOXYETHANOL, GLYCERYL LAURATE, ACACIA SENEGAL GUM, XANTHAN GUM, BUTYROSPERMUM PARKII BUTTER, LIMNANTHES ALBA SEED OIL, MACADAMIA INTEGRIFOLIA SEED OIL, CERAMIDE NP, PHYTOSPHINGOSINE, HYDROGENATED LECITHIN, HYALURONIC ACID, PARFUM, LACTIC ACID, BENZYL SALICYLATE, LIMONENE, HYDROXYCITRONELLAL, ALPHA-ISOMETHYL IONONE, LINALOOL, CITRONELLOL.

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** 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.: 2013_028

Date of revision: 10.1. 2026 (new extended list of allergens)

Ing. Lenka Průšová
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CV and assessor´s credentials and aproval 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 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.**
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
Nám. Sítná 3105, 272 01 Kladno
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ČESKÁ REPUBLIKA

VYSOKÁ ŠKOLA CHEMICKO-TECHNOLOGICKÁ V PRAZE

Číslo diplomu HN 0006482 Číslo protokolu 6369

DIPLOM

Bc. Lenka Průšová
(Jméno a příjmení)

18. březen 1986, Kladno
(Datum a místo narození)

získal/získala vysokoškolské vzdělání studiem v magisterském studijním programu
Technologie potravin kód N2904
ve studijním oboru Technologie mléka a tuků kód (KKOV) 2901T012
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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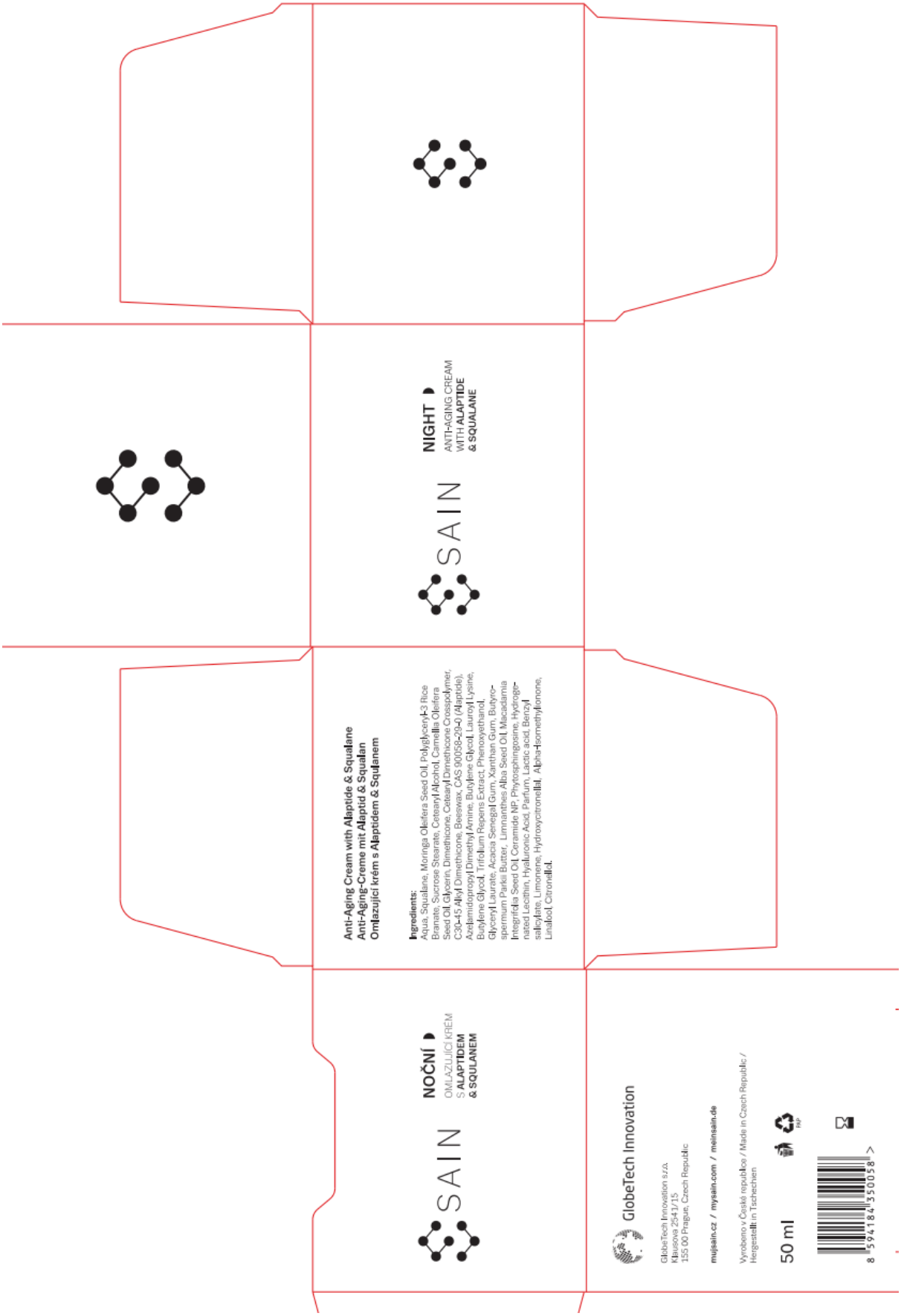
Annexes to this CPSR:

1) Product label
2) Challenge test protocol
3) Dermal test protocol
4) Active ingredient efficiency studies
   A. EcoCeramide LCS
   B. Squalane
   C. Oligo HA
   D. Epi-On
   E. HappiClov
   F. Alaptide

Primary packaging

Secondary packaging (box)



Tester – sachet

SAIN® Omlazující krém s Alaptidem & Squlanem
SAIN® Anti-Aging Cream with Alaptide & Squalane
SAIN® Anti-Aging-Creme mit Alaptid & Squalan

Ingredients: Aqua, Squalane, Moringa Oleifera Seed Oil, Polyglyceryl-3 Rice Branate, Sucrose Stearate, Cetearyl Alcohol, Camellia Oleifera Seed Oil, Glycerin, Dimethicone, Cetearyl Dimethicone Crosspolymer, C30-45 Alkyl Dimethicone, Beeswax, CAS 90058-29-0 (Alaptide), Azelamidopropyl Dimethyl Amine, Butylene Glycol, Lauroyl Lysine, Butylene Glycol, Trifolium Repens Extract, Phenoxyethanol, Glyceryl Laurate, Acacia Senegal Gum, Xanthan Gum, Butyrospermum Parkii Butter, Limnanthes Alba Seed Oil, Macadamia Integrifolia Seed Oil, Ceramide NP, Phytosphingosine, Hydrogenated Lecithin, Hyaluronic Acid, Parfum, Lactic acid, Benzyl salicylate, Limonene, Hydroxycitronellal, Alpha-Isomethylionone, Linalool, Citronellol.

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