



PerfectionPeptide P3

Technical Data Sheet

PerfectionPeptide P3 is a (super-transparent) concentrate of liposomes prepared from soy-phospholipids containing Peptide Hexanoyl-Arg-Ala-Nle-NH₂ Acetate salt

Composition

Hexanoyl-Arg-Ala-Nle-NH ₂ Acetate salt	0.01%
Phospholipids	12.5%
Glycerin	39%
Phenoxyethanol	1%
Deionized Water	ad 100%

INCI (EU-Declaration / PCPC-Declaration)

Hexanoyl Dipeptide-3 Norleucine Acetate (and) Lecithin (and) Glycerin (and) Phenoxyethanol (and) Aqua/Water

Physical properties

Consistency	viscous liquid
Appearance	amber, transparent
Odor	characteristic
Particle size (zAve.)	20 - 130nm

Characteristics

pH-Value (5% aqu. solution)	5.5 ± 1.5
Preservation	1% Phenoxyethanol
Bacteriology	total germ count: < 100 CFU/g

Stability	18 months
Packaging	10 l polyethylene containers
Storage	4 °C - 8 °C, in closed containers

Specification:

0420 PerfectionPeptide P3

18.06.2013

Composition Breakdown / Origin

The product was developed by Mibelle Group Biochemistry, Switzerland in 2005 for cosmetic applications.

Components /INCI (EU/PCPC)	CAS	EC	% w/w	origin
Hexanoyl Dipeptide-3 Norleucine Acetate	860627-90-3	/	0.01	Synthetic
Lecithin	8002-43-5	232-307-2	12.5	Vegetable (soy bean)
Glycerin	56-81-5	200-289-5	39	Vegetable
Phenoxyethanol	122-99-6	204-589-7	1.0	Synthetic
Aqua/Water	7732-18-5	231-791-2	47.49	Natural

We confirm that this cosmetic ingredient was manufactured by Mibelle Group Biochemistry in Switzerland, thus can be considered as Swiss origin.

HS Code (Switzerland): 3824.9999

VOC

This product contains no VOC (volatile organic compound) according to annex 1 of the Swiss regulation SR 814.018 (VOCV) and to 40 CFR 51.100 issued by U.S.Environmental Protection Agency (EPA).

Manufacturing

Manufacturer

Mibelle Group Biochemistry
Bolimattstrasse 1
5033 Buchs, Switzerland
Phone +41 62 836 17 31
Fax +41 62 836 14 05

info@mibellebiochemistry.com
www.mibellebiochemistry.com

Manufacturing Process

Blending of aqueous phase
▼
liposome preparation by high pressure homogenization
▼
Encapsulation and stabilization of the peptide into liposomes
▼
Packaging
▼
Quality control

Certificates

Certificates are available upon request

ISO 9001:2015

ISO norm for quality management systems

ISO 22716:2007

ISO norm for Cosmetic GMP (Good Manufacturing Practice)

ISO 14001:2004

ISO norm for environmental management systems

EFfCI GMP

GMP standard for cosmetic ingredients 2012 of the European Federation for Cosmetic Ingredients (EFfCI)

BRC

Global Standard for Consumer Products Personal Care and Household

RSPO

RSPO/SCCS certified.

Certificate RSPO SCCS, Mibelle AG, Certificate number 7-00284-2017. Supply chain model Mass Balance (MB)

Residues/Impurities

Pathogens

We confirm the absence of pathogenic germs as follows (absent in 1g):

- Yeast / Moulds
- Pseudomonas aeruginosa
- E. coli / Enterococcae
- Candida albicans
- Staphylococcus aureus
- Aspergillus niger

Solvents / Residual solvents

Based upon our knowledge about the raw materials and the production process, we confirm that the product contains no other solvents than specified in the INCI, unless non-intended, technically unavoidable traces, regarding good manufacturing process.

CMR

Based upon our knowledge about the raw materials and the manufacturing process, we confirm that the product does not contain any substances that are carcinogenic, mutagenic or toxic for reproduction (CMR substances) according to Annex VI of (CLP) Regulation (EC) No 1272/2008, unless non-intended technically unavoidable traces regarding good manufacturing process.

Heavy metals

	mg/kg (ppm)
• Arsenic (As)	<0.5
• Cadmium (Cd)	<0.1
• Lead (Pb)	<1.0
• Mercury (Hg)	<0.1
• Antimony (Sb)	<0.5
• Chromium (Cr)	<1.0
• Nickel (Ni)	<1.0

Total heavy metals:

Technically unavoidable traces of heavy metals, in accordance with good manufacturing process < 20 ppm

Pesticides

The product was screened for the content of pesticides and does not contain pesticides above the concentration limit according to the regulation (EC) No 396/2005.

Thus, the product can be considered as "Pesticide Free".

Phthalates

Based upon our knowledge about the raw materials and the manufacturing process we do not expect phthalates (incl. DBP, DMP, Diethyl-Phthalate DEP) to be present.

Proposition 65 (California)

To the best of our knowledge, we confirm that the product does not contain any contaminants or bi-products, known to the State of California to cause cancer or reproductive toxicity as listed under Proposition 65 State Drinking Water and Toxic Enforcement Act (current list), unless non-intended technically unavoidable traces regarding good manufacturing process.

Other Impurities

Based upon our knowledge about the raw materials and the production process, the product should not contain any impurities or residues which are not mentioned in the INCI, caused by the manufacturing process, unless non-intended technically unavoidable traces regarding good manufacturing process.

Due to the manufacturing processes of the components glycerin and phenoxyethanol the following technical unavoidable traces of residual impurities can be present:

- diethylene glycol (DEG, CAS 111-46-6) \leq 0.04%. As specified by our supplier, the glycerin was tested conforming to the standards of the European Pharmacopeia (EP), for the content of diethylene glycol.
- phenol (CAS 108-95-2) max. 0.1 ppm
- ethylene oxide (CAS 75-21-8) max. 0.02 ppm

Preservative System

Contains 1% phenoxyethanol, preservative according to EU Cosmetic Regulation (EC) 1223/2009, Annex V.

Regulatory

Admission status of the raw material or its components / Restrictions

EU

Not specifically regulated under EU Cosmetic Regulation (EC) 1223/2009. No restrictions.

Meets the legal standards of Regulation (EC) No 1223/2009 of the European Parliament and the council of 30 November 2009 on cosmetic products and does not contain any substances listed under annexes II or III.

We hereby confirm that the product does not contain any nanoparticles according to the definition of nanomaterial given in Article 2 (§1k) of the European Cosmetics Regulation (EC)1223/2009.

Furthermore, we declare that to the best of our knowledge we do comply with the French decree 2012-232. The above-mentioned product does not contain nanoparticles, which are regulated by this decree.

ASEAN

To the best of our knowledge we hereby confirm, that we are not aware of any restrictions for the use of this product as a cosmetic ingredient in cosmetic products at the recommended concentrations and it conforms to the ASEAN Cosmetic Directive. Additional country specific requirements have to be considered.

Australia (NICNAS)

The component Hexanoyl Dipeptide-3 Norleucine Acetate is not listed on AICS.
Please consider NICNAS exemptions for notification.

Canada

The component Hexanoyl Dipeptide-3 Norleucine Acetate is not specified on DSL/ NDSL (CEPA Environmental Registry). Given the recommended use level, it is exempted by the low volume importation regulation.

China

The Chinese Chemical Substance legislation and the Chinese 'Hygiene Supervision over Cosmetics' legislation have to be respected.

The INCI of this product has not been listed on the the latest Chinese approved INCI list (IECIC 2015 version) published by CFDA (China Food and Drug Administration) and is therefore not considered as China okay.

Japan

Authorised. Not specifically regulated according to the New Cosmetic Standards, enforced on April 1st 2001, by the ministry of Health and Welfare (MHW).

Korea (KCA)

All components are listed on the KCID.

Switzerland

No restrictions under the FDHA Ordinance of 16. December 2016 on Cosmetics (CosmO), for the use as a cosmetic ingredient at the recommended concentrations.

USA

No restrictions for the use as a cosmetic active ingredient at the recommended concentrations in conventional cosmetic products.

Not listed as OTC drug (FDA)

Other Countries

To the best of our knowledge we hereby confirm, that we are not aware of any restrictions for the use of this product as a cosmetic ingredient at the recommended concentrations and it conforms to the cosmetic regulations.

REACH

Meets the regulation (EC) 1907/2006 (REACH) as all substances it is composed of,

- are excluded from registration and /or
- are exempted from registration, and/or
- have been registered by our suppliers

The product does not contain any Substances of Very High Concern (SVHC) as listed under Annex XIV of the REACH legislation.

CITES

We hereby confirm, that the vegetable components are not subject of the Cites regulation.

Statements

Allergens

We hereby confirm that the product was screened for the content of fragrance allergens. This product does not contain allergenic substances above the concentration limits according to EU Cosmetic Regulation (EC) 1223/2009, Appendix III.

Animal Test

We hereby confirm that the product has not been tested on animals by or on behalf of our company. To the best of our knowledge we confirm that the component parts, as defined by the INCI nomenclature, are in compliance with the requirements on ingredients as stated in Regulation 1223/2009/ EC and have not been the subject of animal testing or retesting for cosmetic purposes since March 11th, 2009 at the latest.

Animal Free /Pork Free

We hereby confirm that the production of this product does not involve the use of any animal originating or animal derived components.

The term "animals" refers to the entire animal kingdom, that is all vertebrates and all multicellular invertebrates.

BSE /TSE Hazard

We hereby confirm that the product does not contain components originating from animal sources. Thus, the product can be considered as "BSE/TSE Free".

Cyclosiloxanes D4, D5 and D6

Based upon our knowledge about the raw materials and the manufacturing process, we confirm that neither octamethylcyclotetrasiloxane, CAS -Nr. 555-67-2 (D4), decamethylcyclopentasiloxane, CAS-Nr. 541-05-6 (D5) nor dodecamethylcyclohexasiloxane, CAS-Nr. 540-97-6 (D6), are used in the manufacture of the product.

Formaldehyde/ Formaldehyde Releasers

Based upon our knowledge about the raw materials and the manufacturing process, we hereby confirm that the product does not contain formaldehyde and/or formaldehyde releasers.

GMO

GMO free (component lecithin PCR neg.)

The component lecithin (originating from soy) is measured batch wise for GMO content by PCR. Only PCR negative lecithin is used for the manufacturing of this product.

Gluten

Based upon our knowledge about the raw materials and the manufacturing process, we hereby confirm that the product does not contain impurities or residues of gluten containing ingredients or proteins thereof nor are such components present during manufacturing. Thus, the product should not contain any impurities or residues of gluten and can be considered as "Gluten Free".

Halal

We hereby confirm that the product does not contain animal derived components and/or ethyl alcohol as a component. In addition, the equipment used to manufacture the product is not used at any time to process animal derived materials or components. The product is stored separately from products of animal origin or products containing such ingredients.

Therefore, the product is never in contact with any kind of animal sources and can therefore be regarded as halal.

Latex

We hereby confirm that the product and packaging material are free of latex.

Microplastics

We hereby confirm that the product does not contain microplastic. 'Microplastic' means particles with a size of below 5 mm of insoluble macromolecular plastic. Including (Acrylates Copolymer (AC), Acrylates Crosspolymer (ACP), Nylon-12, Nylon-6, Polyacrylate (PA), Polyethylene (PE), Polyethyleneterephthalate (PET), Polymethyl methacrylate (PMMA), Polypropylene (PP), Polyquaternium (P), Polystyrene (PS) and Polyurethan (PUR).

Parabens

We hereby confirm that the product is paraben free.

Palm Oil / Palm Oil Derivatives

We hereby confirm that the product does not contain palm oil and/or palm kernel oil as a component. The component glycerin is derived from mixed vegetable sources: rape seed, palm, sunflower, coconut oil.

PerfectionPeptide P3 is RSPO certified.

Certificate RSPO SCCS, Mibelle AG, Certificate number 7-00284-2017. Supply chain model Mass Balance (MB)

Vegan

We hereby confirm that

- the development and manufacturing of this product don't involve the use of any animal* originating or animal derived components (unless peptone in culture medium used for microbiological testing)
- the development and manufacturing of this product don't involve the testing of animals by or on behalf of Mibelle Biochemistry.
- The product is stored separately from animal originating or animal derived components, or products containing such ingredients.

*The term "animal" refers to the entire animal kingdom, that is all vertebrates and all multicellular invertebrates.

Irradiation

We hereby confirm that in the production process no gamma irradiation was conducted.

Natural / Natural Origin / Organic / Organic Origin Indexes defined in ISO 16128-1

The international standard ISO 16128 presents guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products. These standards are based on a consensus developed by a panel of international experts to respond to cosmetic market's needs. ISO 16128 is divided in two parts:

Part 1: Definitions for ingredients (edited in February 2016)

Part 2: Criteria for ingredients and products (edited in September 2017)

To the best of our knowledge the calculation according to standard
ISO 16128-1:2016 and ISO 16128-2:2017 are:

Natural Content	Natural Origin Content	Organic Content	Organic Origin Content
48.49%	98.99%	0%	0%
Natural Index	Natural Origin Index	Organic Index	Organic Origin Index
0.4849	0.9899	0	0

Toxicological Review / Physiological Safety

Rat oral LD50 [mg/kg]

No LD50 was conducted. Regarding the composition, a LD50 value of > 2000 mg/kg has to be expected.

Photosensitization

A human photo patch test with undiluted product was conducted on 50 volunteers.

The results showed, that under the test conditions the product showed no reaction at the unirradiated and irradiated side.

On the basis of the test results and under the test conditions, there was no evidence of a primary phototoxic reaction of the product at this concentration.

Mutagenicity (Ames Test)

The product is considered to be non-mutagenic in the conducted screening bacterial reverse mutation assay.

Ocular Irritant Potential (Het-Cam Test)

The ocular tolerance was tested by the Het-Cam method (tested concentration 5% in water). According to the JORF classification the product was considered as "practically not irritant" at this concentration.

Safety

We hereby confirm, that PerfectionPeptide P3 has been evaluated for its safety as cosmetic ingredient, at recommended use level. PerfectionPeptide P3 satisfies, according to the current state of knowledge, the safety requirements for the intended applications, at recommended concentrations under normal and reasonably foreseeable conditions of use.

For additional safety information and necessary precautions, please refer to the Material Safety Data Sheet.

Ecology

General

The product is not considered harmful to aquatic organisms or to cause long-term adverse effects in the environment.

Formulation Guidelines

Optimal pH Range	4.0 – 8.0
Recommended use level	0.5-3.0%
Proven efficacy in vivo	1%, 2%
Thermostability	Temperatures of up to 60° over a short time period will not affect the stability of PerfectionPeptide P3.
Incompatibilities	No further incompatibilities detected.
Solubility (at 2%)	Soluble in water. Soluble in aqueous/ethanolic solution up to 20% ethanol. Not miscible with oil.
Incorporation	PerfectionPeptide P3 can be incorporated into most formulations, emulsions and gels, except water free formulations. Dissolve PerfectionPeptide P3 into the aqueous phase or add during the cooling phase below 40 °C.
Remarks	High concentrations of electrolytes could affect the stability of PerfectionPeptide P3.

Authorized by Dr. Cornelia Schürch, Head of Development & Compliance

Valid without signature

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