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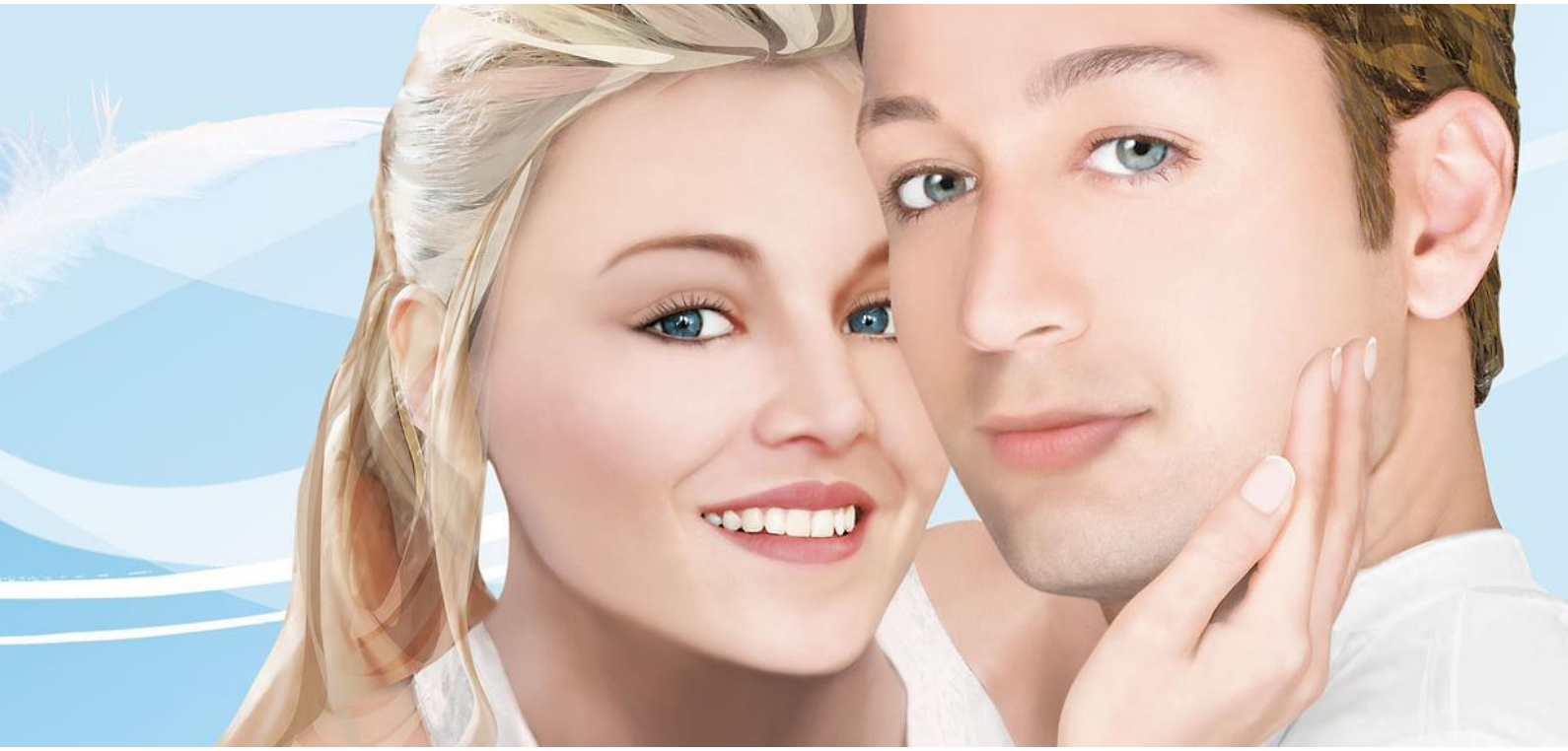

AquaCacteen

Technical Data Sheet

AquaCacteen 0860

AquaCacteen is a water-based extract of Opuntia ficus-indica stems.

Composition

Opuntia Ficus-Indica Stem Extract:	49.5%
Dry Matter 5%	
Aqua/Water 95%	
Glycerin	49.5%
Phenoxyethanol	1%

INCI (EU-Declaration / PCPC-Declaration)

Opuntia Ficus-Indica Stem Extract (and) Glycerin (and) Phenoxyethanol (and) Aqua/Water

Physical properties

Consistency	liquid
Appearance	yellow - brown, clear-transparent
Odor	characteristic
Density	1.12-1.16 g/ml

Characteristics

pH-Value	4.0 -7.0
Preservation	1% Phenoxyethanol
Bacteriology	total germ count < 100 CFU/g

Stability	2 years
Packaging	10 L polyethylene containers
Storage	25°C, in closed containers at a dark place

Specification:
0860 AquaCacteen
23.10.2012

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Origin

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

Components /INCI (EU/PCPC)	CAS	EC	% w/w	origin
Opuntia Ficus-Indica Stem Extract	90082-21-6	290-109-1	2.5	Vegetable,
Glycerin	56-81-5	200-289-5	49.5	Vegetable
Phenoxyethanol	56-81-5	200-289-5	1.0	Synthetic
Aqua/Water	7732-18-5	231-791-2	47	Natural

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

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

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5033 Buchs, Switzerland
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Manufacturing Process

Multiple extraction of Opuntia Ficus-Indica with water/ glycerin

▼

Maturation

▼

Filtration steps

▼

Addition of phenoxyethanol

▼

Packaging

▼

Quality control

Certificates

Certificates are available upon request

ISO 9001:2008
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)

Residues/Impurities

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

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

Solvents / Residual solvents
The product contains no other solvents than specified in the INCI.

CMR
Based upon our knowledge about the raw materials and the manufacturing process , no CMR substance under Annex I of Directive 67/548/EEC, respectively Annex VI of the CLP regulation 1272/2008 is used or expected to be formed in the manufacture of the product.

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
• Cobalt (Co)	<0.5

Total heavy metals < 20 ppm

Pesticides
The product was screened for the content of pesticides (method ASU L00.00-34) 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".

Phtalates
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.

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 process of the component glycerin, technical unavoidable traces of residual diethylene glycol (DEG, CAS 111-46-6) can be present. The glycerin was tested conforming to the standards of the European Pharmacopeia (EP) for the content of diethylene glycol. The concentration of DEG in glycerin was specified ≤ 0.1% by our supplier. Thus the diethylene glycol concentration in AquaCacteen is ≤ 0.05%.

Due to the manufacturing process of the component phenoxyethanol, technical unavoidable residues of phenol (CAS 108-95-2) at a maximum level of 10 ppm and ethylene oxid (CAS 75-21-8) at a maximum level of 0.02 ppm are possible.

Preservation

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

Regulatory

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.

Australia
The component Opuntia Ficus-Indica Stem Extract is not listed on AICS.
Please consider NICNAS exemptions for notification.

Canada
The component Opuntia Ficus-Indica Stem Extract 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.

We confirm that the INCI of this product has been listed on the latest Chinese approved INCI list published by CFDA (China Food and Drug Administration) on 30th May 2014 and is therefore 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.

USA
No restrictions for the use as a cosmetic active ingredient at the recommended concentrations in conventional cosmetic products.
Not listed as drug or OTC (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 active 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 pre-registered 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 the 26 fragrance allergens, additionally atranol and chloratranol (components of oak moss and tree moss extract).
This product does not contain allergenic substances above the concentration limits according to EU Cosmetic Regulation (EC) 1223/2009, Appendix III.
Thus the product can be considered as "Allergen Free".

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.

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".

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.

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".

GMO
GMO free

Halal
We hereby confirm that the product does not contain any 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.

Parabens
We hereby confirm that the product is paraben free.

Palm Oil
We hereby confirm that the product does not contain palm oil and/or palm kernel oil as a component.

The product contains glycerin derived from mixed vegetable sources: rape seed, palm, sunflower, coconut oil, RSPO Mass Balance Quality (Certificate CU-RSPO SCC-820321).

Vegan
We hereby confirm that this product does not contain any animal originating or animal derived components. Therefore this product can be considered as "vegan".

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

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 (at10%) was conducted on 50 volunteers.
On the basis of the test result and under the test conditions, there was no evidence of a primary photo toxic reaction.

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 with a 10% aqueous solution. According to the JORF classification the product was considered as “moderately irritant”.

Ecology

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

Formulation

Optimal pH Range	4.0 – 9.0
Recommended use level	0.5 -2.0 %
Proven efficacy (in vivo)	0.1 %, 0.5%, 2.0%
Thermostability	Homogenization and temperatures of up to 60 °C over a short time do not affect the stability of AquaCacteen.
Incompatibilities	No further incompatibilities detected.
Solubility	Water miscible
Incorporation	AquaCacteen be incorporated into most formulations, emulsions and gels. For cold processes, dissolve AquaCacteen into the aqueous phase. In cold / hot processes, add during the cooling phase below 40° C.
Remarks	No further remarks.

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

Valid without signature