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Delentigo

Technical Data Sheet

Delentigo™ 0879

Delentigo™ is a liposomal preparation of garden cress sprout extract with a liposomal preparation containing pure isoflavone aglycones from soy. Delentigo™ is a cosmetic ingredient to treat age spots or uneven skin tone.

Composition

Lepidium Sativum Sprout Extract:	37%
Dry Matter 0.3%	
Aqua/Water 99.7%	
Lecithin	2.8%
Genistein	0.14%
Tween 80	10%
Alcohol	8.5%
Glycerin	3.0%
Phenoxyethanol	1.0%
Aqua/Water	ad. 100%

INCI (EU/PCPC) Declaration

Lepidium Sativum Sprout Extract (and) Lecithin (and) Soy Isoflavones (and) Polysorbate 80 (and) Alcohol (and) Glycerin (and) Phenoxyethanol (and) Aqua/Water

Physical Properties

Consistency	liquid
Appearance	amber, transparent
Odor	characteristic
Particle size (zAve.)	<190nm

Characteristics

pH-Value	4.0 - 7.0
Density 20°C	0.98 - 1.02 g/ml
Bacteriology	total germ count:<100 CFU/g
Preservation	1% Phenoxyethanol

Stability	18 months
Packaging	10 L polyethylene containers
Storage	25°C, in closed containers at a dark place

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Origin / % Breakdown

The product was developed by Mibelle Group Biochemistry, Switzerland in 2009 for cosmetic applications.

Components /INCI (EU/PCPC)	CAS	EC	% w/w	origin
Lepidium Sativum Sprout Extract	90063-43-7	290-001-4	0.11(dry matter)	Vegetable
Lecithin	8002-43-5	232-307-2	2.8	Vegetable (soy)
Alcohol	64-17-5	200-578-6	8.5	Vegetable (mixed)
Soy Isoflavones	446-72-0	207-174-9	0.14	Vegetable (soy)
Polysorbate 80	9005-65-6	500-019-9	10.0	Vegetable derived / synthetic
Glycerin	56-81-5	200-289-5	3.0	Vegetable (mixed)
Phenoxyethanol	122-99-6	204-589-7	1.0	Synthetic
Aqua/Water	7732-18-5	231-791-2	74.45	Natural

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

VOC

Ethanol is considered as VOC (volatile organic compound) according to annex 1 of the Swiss regulation SR 814.018 (VOCV) , EC Directive 1999/13/EC (Solvent Emissions Directive) and to 40 CFR 51.100 issued by US Environmental Protection Agency (EPA).
The VOC content of this product is 8.5%.

Manufacturing

Manufacturer

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Manufacturing Process

Multiple aqueous extraction of cress (Lepidium sativum) sprouts

▼

Maturation

▼

Filtration

▼

UHT processing

▼

Filtration

▼

Encapsulation of cress sprout extract into liposomes by high pressure homogenization

▼

Preparation of soy isoflavones premix

▼

Filtration

▼

Addition of polysorbate 80

▼

Encapsulation and stabilization of soy isoflavones into liposomes

▼

Blending of liposomes

▼

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 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 of residual methanol below 9 ppm, in accordance with 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

Pesticides
The product was screened for the content of pesticides (method ASU 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 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), the United States Pharmacopeia (USP) and the Food Chemicals Codex (FCC) 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 Delentigo is ≤0.003%.

Due to the manufacturing process of the component polysorbate 80 and/or phenoxyethanol, technical unavoidable traces of residual ethylene oxide (<0.12 ppm) , ethylene glycol (<62 ppm) 1,4 dioxane (<1 ppm) and phenol (CAS 108-95-2) at a maximum level of 10 ppm, can be present.

The concentration of methanol in ethanol was specified ≤max. 100 ppm by our supplier.
Thus the methanol concentration in Delentigo is max. 9 ppm.

Preservative System

1% phenoxyethanol. Cosmetic 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.

Australia (NICNAS)

The components Soy Isoflavones and Lepidium Sativum Sprout Extract are not listed on AICS.
Please consider NICNAS exemptions for notification.

Canada

The component Lepidium Sativum Sprout 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 (IECIC 2015 version) published by CFDA (China Food and Drug Administration) 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.

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

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, have not been the subject of animal testing or retesting for cosmetic purposes since September 11th 2004 at the latest.

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.

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".

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".

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.

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

Parabens
We hereby confirm that the product is paraben free.

Gluten
The component polysorbate 80 (vegetable portion originating from wheat/ maize/ olive) was measured on gluten content by PCR. Based on this result and upon our knowledge about the raw materials and the manufacturing process, Delentigo can be regarded as gluten free (gluten <1ppm).

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 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 with undiluted product 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 at 100% (undiluted). 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 Guidelines

Optimal pH Range	4.0 – 8.0
Recommended use level	2 -6 %
Proven efficacy	4%
Thermostability	Homogenization and temperatures of up to 60 °C over a short time do not affect the stability of Delentigo ™.
Incompatibilities	No further incompatibilities detected.
Solubility	Water soluble.
Incorporation	Delentigo be incorporated into most formulations, emulsions and gels. For cold processes, Delentigo into the aqueous phase. In hot/cold processes, add during the cooling phase below 40 °C.
Remarks	High concentrations of electrolytes may affect the stability of Delentigo ™.

Authorized by Dr. Cornelia Schürch, Head of Development & Compliance
Valid without signature

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