



PhytoCellTec™ Malus Domestica

Technical Data Sheet

PhytoCellTec™ Malus Domestica is a novel cosmetic active ingredient containing apple stem cell compounds encapsulated in liposomes prepared from soy phospholipids. The ingredient with its viscous appearance is used for skin rejuvenating properties.

Composition

Malus domestica fruit cell culture extract	9%
Phospholipids	0.14%
Glycerin	0.4%
Phenoxyethanol	1.4%
Xanthan Gum	1%
Deionized water	ad 100%

INCI (EU-Declaration / PCPC-Declaration)

Malus Domestica Fruit Cell Culture Extract (and) Xanthan Gum (and) Glycerin (and) Lecithin (and) Phenoxyethanol (and) Aqua/ Water

Physical properties

Consistency	viscous
Appearance	white to yellow, turbid
Odor	characteristic
Density	0.95 - 1.05 g/mL
Viscosity	500 - 2000 mPas

Characteristics

pH-Value	5.0-8.0
Bacteriology	total germ count:< 100 CFU/g

Preservation	1.4% Phenoxyethanol
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Stability	18 months (shelf life can be extended:4°C storage)
Packaging	10 l polyethylene containers
Storage	25°C, in closed containers at a dark place

Specification:

0510 **PhytoCellTec™ Malus Domestica**

19.06.2013

Origin

The product was developed by Mibelle Group Biochemistry, Switzerland in 2008 for cosmetic applications.

Components /INCI (EU/PCPC)	CAS	EC	% w/w	origin
Malus Domestica Fruit Cell Culture Extract	89957-48-2	289-567-5	9.0	Vegetable/ biotechnology
Xanthan Gum	11138-66-2	234-394-2	1.0	Fermentative
Glycerin	56-81-5	200-289-5	0.4	Vegetable
Lecithin	8002-43-5	232-307-2	0.14	Vegetable
Phenoxyethanol	122-99-6	204-589-7	1.4	Synthetic
Aqua/Water	7732-18-5	231-791-2	88.06	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

Mibelle Group Biochemistry
Bolimattstrasse 1
5033 Buchs, Switzerland
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Manufacturing Process

Wounding of Malus domestica plant material to induce callus formation



Harvesting of developed callus on solid media



Cultivation until complete dedifferentiation to obtain stem cells



Transfer of the stem cells into a suspension (liquid media) culture



Disruption of the stem cell walls.

Encapsulation and stabilization of the oil- and water-soluble cell components into liposomes.



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)

Halal

Halal certified by the Halal Certification Services GmbH, 4310 Rheinfelden, Switzerland

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

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

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)	Method
• Arsenic (As)	<0.5	PV 01184
• Cadmium (Cd)	<0.1	PV 01184
• Lead (Pb)	<1.0	PV 01184
• Mercury (Hg)	<0.1	PV 01184

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".

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, unless non-intended technically unavoidable traces regarding good manufacturing process (see other impurities) .

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.

Due to the manufacturing process of the component glycerin (99.5%, Ph. Eur. Grade) , 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 current European Pharmacopeia (EP) and the Food Chemicals Codex (FCC) for the content of diethylene glycol. The concentration of DEG in glycerin was specified $\leq 0.1\%$ by our supplier.

Thus the diethylene glycol concentration in PhytoCellTec™ Malus Domestica is ≤ 4 ppm

Due to the manufacturing process of the component phenoxyethanol, technical unavoidable residues of phenol (CAS 108-95-2) at a maximum level of ≤ 20 ppm and ethylene oxid (CAS 75-21-8) at a maximum level of 0.03 ppm are possible.

Preservative System

1.4% Phenoxyethanol . 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 (NICNAS)

All components are listed on the AICS

Canada

The component Malus Domestica Fruit Cell Culture 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 in 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.

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 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

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".

Additives

We hereby confirm that the product contains no other additives than specified in the INCI, unless non-intended technically unavoidable traces regarding good manufacturing process.

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.

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".

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.

Parabens

We hereby confirm that the product is paraben free.

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 this product is halal certified by the Halal Certification Services GmbH, 4310 Rheinfelden, Switzerland

Latex

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

Microplastics

We hereby confirm that the products does not contain microplastic. 'Microplastic' means particles with a size of below 5 mm of insoluble macromolecular plastic.

Parabens

We hereby confirm that the product is paraben free.

Palm Oil

PhytoCellTec Malus Domestica 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.

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.

Photosensitivity

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 with undiluted product. According to the JORF classification the product was considered as "slightly irritant".

Safety

We hereby confirm, that PhytoCellTec Malus Domestica has been evaluated for its safety as cosmetic ingredient, at recommended use level. PhytoCellTec Malus Domestica 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 full 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 – 9.0
Recommended use level	2 -5 %
Proven efficacy in vivo	2%
Thermostability	Temperatures of up to 60°C for a short time do not affect the stability of PhytoCellTec™ Malus Domestica
Solubility	Water miscible
Incorporation	PhytoCellTec™ Malus Domestica be incorporated into most formulations, emulsions and gels, except water free formulations. For cold processes, dissolve PhytoCellTec™ Malus Domestica into the aqueous phase. In hot/cold processes, add during the cooling phase below 40 °C.

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

Valid without signature

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