



KeraGuard
Technical Data Sheet

InfraGuard / KeraGuard is an extract of *Caesalpinia spinosa* and sunflower sprouts.

Composition

Tara (<i>Caesalpinia Spinosa</i>)	1.5%
Sunflower Sprout Extract	0.39% (dry matter)
Sodium Benzoate	0.12%
Propylene Glycol	30%
Phenoxyethanol	1%
Deionized Water	ad 100%

INCI

Caesalpinia Spinosa Fruit Pod Extract / Caesalpinia Spinosa Fruit Extract (and) Helianthus Annuus (Sunflower) Sprout Extract (and) Propylene Glycol (and) Phenoxyethanol (and) Sodium Benzoate (and) Aqua/Water

Physical Properties

Consistency	liquid
Appearance	amber, transparent
Odor	characteristic

Characteristics

pH-Value	3.0-4.0 (1% product in water)
Density	1.010-1.050 g/ml

Bacteriology total germ count: < 100 CFU/g

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

Specification:

0825 **InfraGuard / KeraGuard**

10.01.2018

Origin / % Breakdown

The product was developed by Mibelle Group Biochemistry, Switzerland in 2016 for cosmetic applications.

Components /INCI	CAS	EC	% w/w	origin
Caesalpinia Spinosa Fruit Pod Extract/ Caesalpinia Spinosa Fruit Extract	39300-88-4	254-409-6	1.5	Vegetable
Helianthus Annuus (Sunflower) Sprout Extract	8001-21-6	232-273-9	0.39 (dry)	Vegetable
Propylene Glycol	57-55-6	200-338-0	30	Synthetic
Phenoxyethanol	122-99-6	204-589-7	1	Synthetic
Sodium Benzoate	532-32-1	208-534-8	0.12	Synthetic
Aqua/Water	7732-18-5	231-791-2	66.99	Natural

The component "Caesalpinia spinosa extract", has two valid INCI names, "Caesalpinia Spinosa Fruit Pod Extract" and "Caesalpinia Spinosa Fruit Extract".

Therefore for the INCI declaration of final products containing KeraGuard, either of the INCI names could be chosen.

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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Manufacturing Process

Multiple aqueous extraction of sunflower sprouts
▼
UHT processing
▼
Maturation and filtration of sunflower sprout extract
▼
Extraction of tara powder in water/ propylene glycol
▼
Maturation and filtration of tara extract
▼
Blending of extracts
▼
Maturation and filtration of extract mix
▼

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

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 (Propylene oxide < 0.3 ppm).

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

Glycol Ethers

Based upon our knowledge about the raw materials and the production process, the following glycol ethers are not likely to be present:

- Butyldiglycol (CAS 112-34-5)
- Ethyldiclycol (CAS 111-90-0)
- 2-Butoxyethanol (CAS 111-76-2)

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 (Propylene oxide < 0.3 ppm).

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 phenoxyethanol, technical unavoidable residues of phenol (CAS 108-95-2) at a maximum level of 0.1 ppm and ethylene oxide (CAS 75-21-8) at a maximum level of 0.02 ppm are possible.

Due to the manufacturing process of the component propylene glycol, technical unavoidable residues of propylene oxide (CAS 75-56-9) at a maximum level of 0.3 ppm ppm are possible.

Preservative System

Contains 0.12% sodium benzoate and 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 component Caesalpinia Spinosa Fruit Pod Extract/ Caesalpinia Spinosa Fruit Extract is not listed on AICS. Please consider NICNAS exemptions for notification.

Canada

All components are specified on DSL/ NDSL (CEPA Environmental Registry).

China

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

The underneath mentioned INCI states the components as listed on the Chinese approved INCI list (IECIC 2015 version) published by CFDA (China Food and Drug Administration). KeraGuard is therefore considered as China okay.

China INCI (CFDA) Declaration:

Caesalpinia Spinosa Fruit Extract (and) Helianthus Annuus (Sunflower) Sprout Extract (and) Propylene Glycol (and) Phenoxethanol (and) Sodium Benzoate (and) Aqua/Water

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

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

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 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.

Palm Oil / Palm Oil Derivatives

We hereby confirm that the product does neither contain palm oil based ingredients nor palm oil derivatives.

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 at 20% 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 20%. According to the JORF classification the product was considered as "slightly 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	3.0 – 7.0
Recommended use level	0.5-2.0 %
Proven efficacy	0.5%
Thermostability	Temperatures of up to 40°C for a short time will not affect the stability of KeraGuard.
Incompatibilities	Strong acids, strong bases. May change colour as function of pH (pH >7.5). Adjust pH of formulation before adding KeraGuard. In combination with non-ionic surfactants, irreversible colour changes may occur.
Solubility	Water miscible
Incorporation	KeraGuard can be incorporated into most formulations, emulsions and gels, except water free formulations. For cold processes, dissolve KeraGuard into the aqueous phase. In hot/cold processes, add during the cooling phase below 40 °C.
Remarks	Slight precipitation of tannins may occur after maturation (in aqueous formulations of low viscosity)

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

Valid without signature

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