



Black BeeOme™
Technical Data Sheet

Specification Black BeeOme™

0601

Fermented honey extract.

Composition

Honey extract	5%
Zymomonas Ferment Extract	45%
Ethanol abs.	15%
Deionized Water	35%

INCI (EU/PCPC) Declaration

(Honey + Zymomonas Ferment) Extract (and) Alcohol (and) Aqua/Water

Physical Properties

Consistency	liquid
Appearance	colorless to amber, transparent
Odor	characteristic

Characteristics

pH-Value	3.5 - 7.5
Density (20°C)	0.9 - 1.0
Bacteriology	total germ count < 100 CFU/g

Stability	1.5 years
Packaging	10 l polyethylene containers
Storage	25°C, in closed containers at a dark place

Specification:

0601 Black BeeOme™

19.12.2018

Composition Breakdown / Origin

The product was developed by Mibelle Group Biochemistry, Switzerland in 2017 for cosmetic applications.

Components /INCI (EU/PCPC)	CAS	EC	% w/w	origin
Honey Extract	91052-92-5	293-255-4	5	Bee / fermentative
Zymomonas Ferment Extract	1375969-44-0	/	45	Fermentative
Alcohol	64-17-5	200-578-6	15	Vegetable (mixed sources)
Aqua/Water	7732-18-5	231-791-2	35	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

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 15%.

Manufacturing

Manufacturer

Mibelle Group Biochemistry
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Manufacturing Process

Cultivation of *Zymomonas mobilis*

▼

Inoculation of honey with *Zymomonas mobilis*

▼

Fermentation

▼

Addition of ethanol

▼

UHT Treatment

▼

Ethanol extraction

▼

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)

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 15ppm, 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
• Antimony (Sb)	<0.5
• Chromium (Cr)	<1.0
• Nickel (Ni)	<1.0
• Cobalt (Co)	<0.5

Total heavy metals < 20 ppm

PAH
Based upon our knowledge about the raw materials and the production process, no polycyclic aromatic hydrocarbons (PAH's) are used or expected to be formed in the manufacture of the product.

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.

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.

- Methanol (CAS No. 67-56-1) <50 ppm

EG/ DEG
Based upon our knowledge about the raw materials and the production process, the product should not contain any impurities or residues of ethylene glycol (EG; CAS 107-21-1) or diethylene glycol (DEG; CAS 111-46-6).

Preservative System

Contains no preservatives 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 Zymomonas Ferment Extract is not listed on AICS.
Please consider NICNAS exemptions for notification.

Canada
The component Zymomonas Ferment 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

Application in process

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.

Patent rights have to be respected.

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 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.

But it contains the following allergenic substance below the concentration limit: **Limonen ~ 2ppm**

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 apart from honey from honey bee.

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.

BSE /TSE Hazard

We hereby confirm that the product does not contain components originating from animal sources apart from honey from honey bee. 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.

GMO

GMO 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 animal derived components* 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 origin*.

*apart from honey from honey bee.

The vegetable based alcohol used is produced through fermentation. The alcohol is an industrial grade and is used as a solvent in the manufacturing process. This alcohol is no longer natural and hence, cannot be consumed.

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.

Parabens

We hereby confirm that the product is paraben free.

Palm Oil / Palm Oil Derivatives

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

Petrochemicals / Petrochemical Derivatives/ Mineral Oils

Based upon our knowledge about the raw materials and the manufacturing process, we confirm that no mineral oils, petrochemicals or substances of petrochemical origin are used in the manufacture of the product.

D4, D5

Based upon our knowledge about the raw materials and the manufacturing process, we confirm that neither octamethylcyclotetrasiloxane (D4) nor decamethylcyclopentasiloxane (D5) are used in the manufacture of the product (according to Commission Regulation (EU) 2018/35)

Vegan

Black BeeOme™ contains honey extract and can therefore not be regarded 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.

Photosensitivity

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 20% in water). According to the JORF classification the product was considered as "practically non-irritant irritant" at this concentration.

Safety

We hereby confirm, that Black BeeOme™ has been evaluated for its safety as cosmetic ingredient, at recommended use level. Black BeeOme™ 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	3.0 – 11.0
Recommended use level	1.0 -2.0 %
Proven efficacy in vivo at	Skin improvement: Test performed with 2.0% Black BeeOme™ Recolonization of the Skin Microflora: Test performed with 2.0% Black BeeOme™ pwd. Skin regeneration: Test performed with 1.0% Black BeeOme™ pwd.
Thermostability	Temperatures of up to 40° over a short time period will not affect the stability of Black BeeOme™
Incorporation	Black BeeOme™ can be incorporated into most formulations, emulsions and gels, except water free formulations. For cold processes and 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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