



GUINAMA. Laboratory distributor of raw materials for the pharmacy and cosmetics sectors .

Document type:

DATA SHEET

Review date:

11/29/2023

Version:

9.0

88631-COENZYME Q10

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

1.1 Identification of the substance or preparation.

Name: Coenzyme Q10

Bulk code: 88631

Internal code: 46000

Valid from lot: 0123364

1.2 Synonyms.

Ubidecarenone

2. DESCRIPTION

Appearance: crystalline powder

Color: yellow or orange

Origin: Glucose obtained from corn starch.

Geographic origin: China.

3. COMPOSITION/INFORMATION ON COMPONENTS.

Chemical formula: $C_{59}H_{90}O_4$

CAS: 303-98-0

EINECS: 206-147-9

Molecular weight: 863.36 g/mol

Composition:

Coenzyme Q10 (all trans) Min. 99%

Impurities: CIS- Isomer (CIS- Isomer <0.5%)

Obtaining method:

The product is made by fermentation of corn starch glucose by *Rhodobacter . Sphaeroides* (strain free of genetic modifications of origin). The product obtained is filtered and extracted, chromatography is performed and it is crystallized. Finally it is dried, sieved, examined and packaged.

4. PHYSICAL-CHEMICAL DATA.

For more information, consult the analysis bulletin.

Solubility: Coenzyme Q10 is insoluble in water.



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5. PROPERTIES/USES.

Pharmaceutical use excipient.

Suitable for food use.

6. DOSAGE.

No data available.

7. OBSERVATIONS.

STORAGE:

The product should be stored in a cool, dry place, protected from light and humidity, with the container tightly closed and away from heat sources.

The documentation corresponding to the regulatory part of the product that is available for it is what we reflect below

BSE/TSE:

The product is BSE/TSE free.

GMO:

The product is NON-GMO.

CMR:

The product is free of carcinogenic, mutagenic or toxic substances for Reproduction according to EU Regulation 1272/2008.

SVHC:

The product is free of SVHC substances.

NANOPARTICLES:

The product is free of nanoparticles and/or substances generated from nanotechnologies.

VOC:

The manufacturer uses ethanol, ethyl acetate and hexane in the production of coenzyme Q10 and the residual solvents in the finished product are as follows:

Ethanol ≤ 1000ppm

Ethyl acetate ≤ 100ppm

Hexane ≤ 1ppm



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IRRADIATION:

The product has been manufactured without using ionization or irradiation such as gamma rays or electrons.

PESTICIDES:

The product complies with Regulation 396/2005/EC and its amendments.

DYES/PRESERVATIVES/ANTIOXIDANTS:

The product is free of chemical preservatives.

The product is free of dyes.

The manufacturer does not use preservatives in the manufacture of the product and the finished product is free of sorbates , benzoates, esters of hydroxybenzoic acid , paraben and phenylalanine .

RESIDUAL SOLVENTS:

During the manufacturing of the product, ethanol, ethyl acetate and Hexane. The residual solvent in finished products are as follows and comply with ICH Q3C:

Ethanol \leq 1000ppm

Ethyl acetate \leq 100ppm

Hexane \leq 1ppm

CONTAMINANTS/IMPURITIES:

The product is in accordance with and complies with Commission Regulation (EC) No 1881/2006 establishing maximum levels for certain contaminants in foodstuffs and Commission Regulation (EU) No 1259/2011, 2 December 2011 amending Regulation (EC) No 1881/2006 as regards maximum levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs.

- Dioxins: complies with European Regulation 1881/2006 and its amendments.
- Benzo (a) pyrene : complies with European Regulation 1881/2006 and its amendments.
- PAH(4): complies with European Regulation 1881/2006 and its amendments.
- Phthalates : The product complies with DEHP NMT 1ppm, DBP NMT 0.3ppm, DINP NMT 5ppm, BBP NMT 1ppm, DIDP NMT 5ppm

HEAVY METALS:

The product meets the following requirements:

Heavy metals \leq 10ppm

Lead (Pb) \leq 1ppm

Arsenic (As) \leq 1ppm

Mercury (Hg) \leq 0.1ppm

Cadmium (Cd) \leq 1ppm



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CALIFORNIA PROPOSITION 65:

The product contains chemicals known to the State of California to cause cancer or reproductive toxicity, including but not limited to the following heavy metals: mercury, cadmium, lead, and arsenic ("Proposition 65 Chemicals"), however:

- the chemicals are "natural" (for example, they are a natural constituent of the raw material or are present in the raw material only as a result of the absorption or accumulation of the chemical, which are naturally present in the environment in the one from which the raw material is cultivated, or grows or is obtained;
- and
- the presence of the chemical substance(s) in the raw material(s) was not due to any known human activity; and
- the presence of the chemical substance(s) in the raw material(s) could not be avoided by good agricultural practices or good manufacturing practices; and
- The supplier used quality control measures at all times to reduce natural chemical constituents to the lowest level currently feasible.

ALLERGENS:

- **Food allergens:** The product does not contain any of the allergens listed in Regulation (EC) 1169/2011 and its amendments. It is also not possible that it has suffered cross-contamination processes with them.

HALAL:

Halal certified .

KOSHER:

Kosher certified .

NUTRITIONAL COMPOSITION (per 100g of Raw Material):

Compound	Worth
Energy	0 KJ
Proteins	0g
Total fats	0g
Carbohydrates	0g
Sodium	0mg

VEGAN/VEGETARIAN:

The product is suitable for vegans/vegetarians.

TEST ON ANIMALS:

The product has not been tested on animals.



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REACH:

Does not apply.