

**93116-DL-ALPHA-TOCOPHEROL ACETATE****1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION****1.1 Identification of the substance or preparation**

Name: DL-alpha-Tocopherol acetate

Bulk code: 93116

Internal code: 405277

**1.2 Synonyms**

No information available.

**2. DESCRIPTION**

Appearance: Viscous oil.

Colour: Colourless or slightly yellow or yellow-green.

Origin: Synthetic.

Geographical origin: China

**3. COMPOSITION/INFORMATION ON COMPONENTS**Formula:  $C_{31}H_{52}O_3$ 

CAS: 7695-91-2

EINECS/ELINCS: 231-710-0

Molecular weight: 472.75 g/mol

Composition:

Name	CTFA/INCI	%
DL-alpha-Tocopherol acetate	Tocopheryl acetate	≥98.0

**Method of production:** The product is obtained by a mixture of trimethylhydroquinone isophytol, diethyl carbonate, NB, hydrobromic acid and zinc powder, which is condensed and extracted, to be dissolved with toluene and butanone. After a washing process, an esterification process with acetic anhydride, zinc powder and zinc chloride is performed. The resulting product is again washed, recycled, degassed and rectified. Finally, it is mixed, filtered and packaged.

**4. PHYSICO-CHEMICAL DATA**

For more information see the analysis report.

**Solubility:** Soluble in ethanol, insoluble in water. Miscible with acetone, ether, methylene chloride, chloroform and plant oils.

## 93116-DL-ALPHA-TOCOPHEROL ACETATE

### 5. PROPERTIES/USES

Excipient for pharmaceutical use.

Cosmetic use.

Oral use.

Not suitable for the manufacture of food supplements or foods.

### 1. DOSAGE

No information available.

### 2. REMARKS

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

#### **STORAGE:**

Store at room temperature in a cool, dry place in a tightly closed container away from sunlight and moisture. It is sensitive to light and alkalis.

The documentation available related to the product's regulatory compliance is included below.

#### **BSE/TSE:**

The product does not contain any ingredients of animal origin and thus is free of the risk of bovine spongiform encephalopathy (BSE) and transmissible spongiform encephalopathy (TSE) and is compliant with Regulation (EC) 999/2001.

#### **GMOs:**

According to the manufacturer's information:

(1) The product is not a genetically modified organism and does not contain any genetically modified organisms.

(2) The product is not manufactured from or using genetic organisms.

(3) All individual components used to produce the above-mentioned product meet points (1) and (2).

The product is compliant with Regulations 1829/2003/EC and 1830/2003/EC and amendments.

#### **CMR substances:**

The manufacturer uses toluene as an unavoidable technological adjuvant to produce DL-alpha-Tocopherol acetate, which is obtained following good manufacturing practices.

Since the maximum limit of toluene in this product is 890 mg/kg, which is below the 0.1% limit as per the CLP regulation, it is not necessary to classify/label it as a CMR substance.

**93116-DL-ALPHA-TOCOPHEROL ACETATE****SVHC:**

The product does not have any of the substances of very high concern (SVHCs) published by the ECHA in December 2011 and last updated on 8 July 2021.

**NANOMATERIALS:**

The product is not a nanomaterial according to the definition of nanomaterial in Regulation (EC) 1169/2011. Nanomaterials are not used during the formulation process or in the product packaging.

**VOCs:**

The volatile organic compounds in the product (residual solvents) are as follows:

RESIDUAL SOLVENT	ICH CLASSIFICATION	CONCENTRATION LIMIT
Toluene	Class 2	≤890 ppm
Butanone	Class 3	1000 ppm
Diethyl carbonate	Unregulated	≤580 ppm

**RADIATION:**

The product has not been treated with ionising radiation or ethylene oxide during production and is compliant with Directives 1999/2/EC and 1999/3/EC.

**PRESERVATIVES:**

The product does not contain preservatives (parabens, BHT/BHA) nor other additives since it is a pure product.

**RESIDUAL SOLVENTS:**

The product may contain the following residual solvents:

RESIDUAL SOLVENT	ICH CLASSIFICATION	CONCENTRATION LIMIT
Toluene	Class 2	≤890 ppm
Butanone	Class 3	≤1000 ppm
Diethyl carbonate	Unregulated	≤580 ppm

The residual solvents meet the requirements of the USP and EP.

**IMPURITIES/CONTAMINANTS:**

Any impurities in the product are derived from the manufacturing process and meet pharmacopoeial standards.

The product is free of

- Latex
- Nitrosamines
- Alkyl-azoxy chemicals

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- Aflatoxins
- Halogenated compounds
- Phthalates (including diethyl phthalate)
- Cyclic siloxanes
- UV filters
- Bisphenol A
- Microplastics
- Quaternary ammonium compounds
- Melamine
- Silicones
- Synthetic polymers
- Mineral oils, paraffin or petroleum derivatives.
- Formaldehyde or its donors.
- PEG/PEG derivatives
- PVC/PVDC
- Sodium lauryl sulfate

The product has a dioxin content max. 500 pg/kg, and the sum of dioxin and dioxin as PCB max. 850pg/kg, non-PCB-like dioxins max. 10 µg/kg.

**HEAVY METALS:**

The elemental impurities in this product have the following standards:

Heavy metals ≤ 10 ppm

- Pb ≤ 0.5 ppm
- As ≤ 1.0 ppm
- Cd ≤ 0.5 ppm
- Hg ≤ 0.1 ppm

**CALIFORNIA PROPOSITION 65:**

The product does not contain any components regulated under the California Proposition 65 list.

**ALLERGENS:**

- **Food allergens:** The product may contain soyabean oil. The product does not contain any other allergens than those listed in Regulation 1169/2011 in its latest version/amendment. The product does not contain gluten.
- **Cosmetic allergens:** The product is free of the risk of cosmetic allergens regulated in Annex II to EU Regulation 1334/2008. The product does not contain any of the prohibited substances.

**VEGAN/VEGETARIAN:**

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The product does not contain or use any material of animal origin and is suitable for vegan/vegetarian use.

**KOSHER:**

The product is Kosher.

**HALAL:**

The product meets the Halal requirements of Islamic laws.

**NUTRITIONAL COMPOSITION:**

Calories		0
Calories from Fat		0
Protein		0
Carbohydrate		0
Total fiber		0
Soluble fiber		0
sugars		0
Complex Carbohydrates		0
Total fat		0
Saturated Fat		0
Monounsaturated fat		0
Polyunsaturated fat		0
Trans fat		0
Cholesterol		0
Sodium		0
Potassium		0
Calcium		0
Iron		0

**TESTED ON ANIMALS:**

The product has not been tested on animals for cosmetic purposes since December 1990.

**WADA:**

The production chain is free of the risk of any doping substance.

**RSPO:**

The product does not contain palm oil.

**REACH:**

01-2119457641-38



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

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