

94452 - ASCORBIC ACID**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1. Identification of the substance or preparation.**

Name: Ascorbic acid

Bulk code: 94452

Internal code: 405029

Valid from batch: 0130045

1.2. Synonyms.

Vitamin C; L-Ascorbic acid; levitamic acid

2. DESCRIPTION.

Appearance: powder with small crystals

Color: white or slightly yellowish

Smell: odorless

Geographical origin: China

Origin: synthetic

3. COMPOSITION/INFORMATION OF COMPONENTS.

Ingredients: Ascorbic acid >99.0%

Formula: $C_6H_8O_6$

CAS No.: 50-81-7

EC No: 200-066-2

Molecular weight: 176.12 g/mol

Method of production: The product is obtained from successive fermentation steps of sorbitol from corn, followed by the removal of sodium by adding an acid solution. The product then undergoes evaporation, cooling and crystallization processes, before being esterified and converted. Finally, another process of sodium removal, evaporation, cooling, crystallization and centrifugation occurs to obtain the raw substance. This substance is crystallized, separated, washed and dried so that it can be packaged at the end.

4. PHYSICAL-CHEMICAL DATA.

For more detailed information, please consult the analysis bulletin.

Solubility: The product is soluble in water and ethanol and insoluble in ether and chloroform.

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5. PROPERTIES/USES.

Excipient for pharmaceutical use.

Excipient for cosmetic use.

Food use.

It is used to reduce the oxidative stress of ascorbic acid peroxidase base. Vitamin C also plays an important role in many biological synthesis processes. It is an antioxidant.

6. DOSAGE.

No data available.

7. OBSERVATIONS.

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

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

NUTRITIONAL INFORMATION:

Energy/Nutrient	Typical values per 100g
Caloric value	400Kcal
Total carbohydrates (of which)	100g
<ul style="list-style-type: none"> - Sugars - Polyols - Starch 	
Dietary fiber	<0.1g
Sodium	0mg
Potassium	0mg
Calcium	0mg
Ashes	<.01g
Humidity	0g
Vitamin A	0g

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Vitamin B	0g
Vitamin C	99.9g
Vitamin D	0 IU
Vitamin E	0UI

ALLERGENS:

- **Food allergens:** The product does not contain allergenic ingredients according to Annex II of Regulation (EU) No 1169/2011.

Allergens	Added as a base raw material or in a derivative form		Cross contamination ⁽¹⁾	
	Yes	No	Yes	No
Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof, except (*): (a) wheat-based glucose syrups including dextrose ; (b) wheat-based maltodextrins ; (c) glucose syrups based on barley; (d) Cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.		✓		✓
Crustaceans and products thereof.		✓		✓
Eggs and products thereof.		✓		✓
Fish and products thereof, except (*): (a) Fish gelatine used as carrier for vitamin or carotenoid preparations; (b) Fish gelatine or Isinglass used as fining agent in beer and wine.		✓		✓
Peanuts and products thereof.		✓		✓
Soybeans and products thereof, except (*): (a) fully refined soybean oil and fat (And products thereof, insofar as the process that they have undergone is not likely to increase the level of allergenicity assessed by the EFSA for the relevant product from which they originated) (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources; (c) vegetable oils derived phytosterols and phytosterol esters from soybean sources; (d) plant stanol ester produced from vegetable oil sterols from soybean sources.		✓		✓
Milk and products thereof (including lactose), except (*): (a) whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages; (b) lactitol.		✓		✓

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Allergens	Added as a base raw material or in a derivative form		Cross contamination ⁽¹⁾	
	Yes	No	Yes	No
Nuts, i.e. almonds (<i>Amygdalus communis</i> L.), hazelnuts (<i>Corylus avellana</i>), walnuts (<i>Juglans regia</i>), cashews (<i>Anacardium occidentale</i>), pecan nuts (<i>Carya illinoensis</i> (Wangenh.) K. Koch), Brazil nuts (<i>Bertholletia excelsa</i>), pistachio nuts (<i>Pistacia vera</i>), macadamia nuts and Queensland nuts (<i>Macadamia ternifolia</i>), and products thereof, except (*): (a) nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.		✓		✓
Celery and products thereof.		✓		✓
Mustard and products thereof.		✓		✓
Sesame seeds and products thereof.		✓		✓
Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO ₂ .		✓		✓
Lupin and products thereof.		✓		✓
Molluscs and products thereof.		✓		✓

STORAGE:

Store in a cool, dry place, protected from light and with the container (non-metallic) tightly closed, at room temperature. Protect from light and moisture. It is photosensitive, so if exposed to light it may darken.

SHELF LIFE: 36 months. For more detailed information, please consult the analysis bulletin.

LEGAL REQUIREMENTS:

- The product mentioned complies with Regulation (EU) No 178/2002 laying down the general principles and requirements of food law and establishing the European Food Safety Authority and laying down procedures in the field of food safety and Regulation (EC) No 852/2004 on the hygiene of foodstuffs.
- The product complies with Annex II of Regulation (EU) 1169/2011.
- The product complies with Regulation (EU) No 231/2012 and its amendments.

BSE-TSE:

The product does not contain or is not a derivative of animal origin, nor has it been exposed to them, and is in compliance with legislation 999/2001.

94452 - ASCORBIC ACID**GMO:**

The product does not contain GMOs, nor are any of these substances used during the manufacturing process. The product does not require any mention of GMOs on its labelling, in accordance with Commission Regulations (ECC) No 49/2000 of 10 January and (ECC) No 1829/2003 and (ECC) No 1830/2003 of the European Parliament and Council. This product has not been genetically modified, so there is no obligation for GMO labelling as defined by the above-mentioned regulations.

CMR:

The product is free of substances classified as CMR.

SVHC:

The product is free of SVHC.

NANOMATERIALS:

According to the definition of “ nanomaterials ” in EU Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, during the manufacture of the product no nanomaterials are used in the formulation or in the packaging material of the product.

IRRADIATION:

The product has not been sterilized by ionizing radiation at any point in the manufacturing process and complies with Directive 1999/2/EC.

ETHYLENE OXIDE:

No ethylene oxide is used in the manufacture of the product and it complies with Directives 1999/2/EC and 1999/3/EC.

PESTICIDES:

Based on the manufacturing process and starting materials, the product complies with the pesticide requirements for Ph.Eur . 2.8.13 and with Regulation (EC) No 396/2005.

RESIDUAL SOLVENTS:

The product complies with Directive E 2010/59/EU of 26 August 2010 and its amendments Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the member states on extraction solvents used in the manufacture of food and food ingredients.

CONTAMINANTS:

Contaminants such as phthalates , dioxins , melamine , PAHs , and PCBs are not expected to be present in the final product. (Regulation 2015/1933/EC and amendments Regulation 1881/2006/EC).

94452 - ASCORBIC ACID**ALLERGENS:**

- **Cosmetic allergens:** The product does not contain any of the 26 cosmetic allergens listed in Annex III of Regulation (EC) No 1223/2009.

GLUTEN:

The product does not contain gluten.

KOSHER:

kosher certified .

ANIMAL TESTING:

The product has not been tested on animals.

DOPING SUBSTANCES:

The product is not a doping substance and is not a combination of doping substances. The product does not contain any doping substances. The product is not the result of a doping substance.

REACH:

Exempt.