



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

Type of document:

TECHNICAL DATA SHEET

Review date:

26.12.2022

Version:

11.0

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

1.2. Synonyms

Vitamin C; L-Ascorbic acid; Levitamic acid.

2. DESCRIPTION

Appearance: Powder with small crystals.

Colour: White or slightly yellowish.

Odour: Odourless.

Geographical origin: China

Origin: Synthetic

3. COMPOSITION/INFORMATION ON COMPONENTS

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 steps of fermentation of the sorbitol from the corn, before removing the sodium by adding an acid solution. Subsequently the product undergoes evaporation, cooling and crystallisation processes, before it is esterified and converted. Finally, another process of sodium removal, evaporation, cooling, crystallisation and centrifugation takes place to obtain the crude substance. This substance is crystallised, separated, washed and dried so that it can finally be packaged.

4. PHYSICO-CHEMICAL DATA

For more information see the analysis report.

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.

Excipient for food use.

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

The product is compliant with the Food Chemical Codex (FCC), with the IOC (International Oenological Codex) and with Regulation (EU) No 231/2012.

6. DOSAGE

The following is the suggested daily vitamin C intake:

- The UK Food Standards Agency suggests: 40 mg per day
- World Health Organization: 45 mg per day
- US National Academy of Sciences: 60-90 mg per day
- US officials have stated that 25-year-old men should eat 2,000 mg maximum each day.

7. REMARKS

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

STORAGE:

Store in a cool, dry place, away from sunlight, in a tightly closed container (non-metallic) at room temperature container. Protect from sunlight and moisture. It is photosensitive, so if exposed to light it can turn darker.

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

BSE-TSE:

The product does not contain or is a derivative of animal origin, nor has it been exposed to them, therefore it is compliant with Regulation 999/2001.

GMOs:

The product does not contain GMOs and none of these substances are used during the manufacturing process. GMOs do not have to be labelled on the product 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 of the Council. This product has not been genetically modified and thus there is no requirement to label GMOs as defined by the above-mentioned regulations.



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CMR substances:

The product is free of substances classified as CMR substances.

SVHC:

The product is free of SVHCs.

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 manufacturing of the product no nanomaterials are used in the formulation or packaging material of the product.

IRRADIATION:

The product has not been sterilised by ionising radiation at any point in the manufacturing process and is compliant with Directive 1999/2/EC.

ETHYLENE OXIDE:

Ethylene oxide is not used to manufacture the product and it is compliant with Directives 1999/2/EC and 1999/3/EC.

PESTICIDES:

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

RESIDUAL SOLVENTS:

The product is compliant 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 foodstuffs 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).

ALLERGENS:

- **Food allergens:** The product does not contain any of the allergens listed in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council, nor is it possible that the product has been at risk of cross-contamination with them.
- **Cosmetic allergens:** The product does not contain any of the 26 cosmetic allergens listed in Annex III to Regulation (EC) No 1223/2009.

GLUTEN:

The product does not contain gluten.



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KOSHER:

The product is 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 derived from a doping substance.

REACH:

Exempt.