

84679-ANHYDROUS CITRIC ACID**1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1. Identification of the substance or preparation.**

Name: Anhydrous citric acid

Bulk code: 84679

Internal code: 405999

Valid from bulk lot: 130822

1.2. Synonyms.

E-330

2. DESCRIPTION.

Appearance: colorless crystals or crystalline powder

Color: colorless or white

Smell: Odorless

Origin: Glucose syrup from corn, as well as molasses and sugar from sugar beet.

Geographical origin: Austria.

3. COMPOSITION/INFORMATION OF COMPONENTS.Ingredients: Anhydrous citric acid $\geq 99.7\%$ Molecular formula: $C_6H_8O_7$

CAS: 77-92-9

EINECS: 201-069-1

Method of production: Citric acid is produced by fermentation of a carbohydrate source. The product undergoes several purification processes and is finally obtained in its purest form. No yeasts are added to the manufacturing process.

4. PHYSICAL-CHEMICAL DATA.

For more detailed information, please refer to the analysis bulletin.

Solubility: very soluble in water, also soluble in ethanol (96%), very slightly soluble in ether.

5. PROPERTIES/USES.

Excipient for pharmaceutical use.

Industrial use.

Food use.

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The product can be used in celiac patients, diabetics and patients who are intolerant to fructose or who have galactosemia or phenylketonuria .

6. DOSAGE.

No data available

7. OBSERVATIONS.


The product has been handled in a NON-sterile room, so the product is NOT sterile.

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

NUTRITIONAL INFORMATION:

Nutrition declaration according Regulation (EU) No. 1169/2011
 Typical values based on 100 g of Citric Acid Anhydrous

| | |
|----------------------|--------------------|
| Energy: | 1300 kJ / 300 kcal |
| Fat: | - g |
| of which | |
| - saturates | - g |
| - mono-unsaturates | - g |
| - polyunsaturates | - g |
| Carbohydrate: | - g |
| of which | |
| - sugars | - g |
| - polyols | - g |
| - starch | - g |
| Fibre: | - g |
| Protein: | - g |
| Salt: | |
| - sodium | < 0.3 mg |
| Organic acid: | ~ 99.9 g |
| Moisture content: | ~ 0.1 g |
| Vitamins: | none |
| Minerals: | |
| - Potassium | < 0.1 mg |
| - Chloride | < 0.5 mg |
| - Calcium | < 0.1 mg |
| - Phosphorus | < 0.3 mg |
| - Magnesium | < 0.05 mg |
| - Iron | < 0.05 mg |
| - Zinc | < 0.05 mg |
| - Copper | < 0.05 mg |
| - Manganese | < 0.01 mg |
| - Fluoride | < 1 mg |
| - Selenium | < 0.1 mg |
| - Chromium | < 0.05 mg |
| - Molybdenum | < 0.01 mg |
| - Iodine | - µg |

| | | |
|---|---|-------------|
|  | GUINAMA. Laboratory distributing raw materials for the pharmaceutical and cosmetics sectors . | |
| | Document Type: | |
| | TECHNICAL SHEET | |
| | Revision date: | Version: |
| | 03.10.2024 | 11.0 |
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ALLERGENS:

- **Food allergens:** The product does not contain any of the substances listed in Annex II of Regulation (EC) 1169/2011. Corn is not present in the final product.
 - Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridized varieties, and their products, except
 - Crustaceans and their products
 - Eggs and egg products
 - Fish and fish products
 - Peanuts and derived products;
 - Soybeans and derived products, except:
 - Milk and milk products (including lactose)
 - Nuts, namely: hazelnuts, walnuts, cashews, pecans, Brazil nuts, pistachios, macadamia nuts or Queensland nuts and products thereof
 - Celery and derived products
 - Mustard and its products
 - Sesame seeds and derived products
 - Sulphur dioxide and sulphites in concentrations greater than 10 mg/kg or 10 mg/litre in terms of total SO₂, to be calculated for proposed products ready for consumption or reconstituted according to the manufacturers' instructions
 - Lupins and their products
 - Mollusks and derived products.

SHELF LIFE: 3 years. For more information, see the analysis bulletin .

STORAGE

Store at room temperature, in a cool, dry place, protected from light and with the container tightly closed, away from sources of heat and humidity.

LEGAL REQUIREMENTS:

The product complies with Commission Regulation (EU) No 231/2012 on food additives.

The product complies with Annex II of Regulation (EU) 1169/2011.

BSE/TSE:

The product is BSE/TSE free.

The product does not contain derivatives of animal origin and has never been exposed to derivatives of animal origin.

GMO:

The manufacturer does not use genetically modified microorganisms for the fermentation step of the product.

The product is not a genetically modified organism as such and does not contain genetically modified organisms.

There are no labelling requirements for the above mentioned product according to Regulations (EC) No. 1829/2003 and 1830/2003

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NANOMATERIALS:

The product has not been manufactured using nanotechnology, nor does it contain materials designed by nanotechnology in accordance with Regulations 1169/2011 and 1223/2009.

RADIATION:

The material that the manufacturer uses to make the product, As well as the product itself, it is not treated with ionizing radiation or ethylene oxide. Furthermore, depending on the production process and the type of raw materials used, the product is free of radioactive contamination.

Therefore, the following directives do not apply:

- Directive 1999/2/EC on the approximation of the laws of the Member States relating to foods and food ingredients treated with ionising radiation
- Directive 1999/3/EC on the establishment of a Community list of foods and food ingredients treated with ionising radiation

PRESERVATIVES/COLORINGS/ANTIOXIDANTS:

The product does not contain colorants, preservatives, flavorings, antioxidants.

RESIDUAL SOLVENTS:

Only water is used in the manufacturing process.

CONTAMINANTS:

Due to the manufacturing process and materials used, the product does not contain any of the following substances:

Toxic and/or carcinogenic contaminants:

3-MCPD (3-monochloropropane-1,2-diol)

Acrylonitrile

AOX (Halogenated organic compounds)

Asbestos

BTEX (Benzene, Toluene, Ethylbenzene, Xylenes)

Chloropropanols

CMR substances

(carcinogenic, mutagenic or reprotoxic)

Cyanogenic glycosides

Cyanuric acid

Diethylene glycol

Dioxins

Ethyl carbamate

Ethylene oxide

Formaldehyde

Furan

Genotoxic substances

Melamine

Mycotoxins

(Aflatoxins, Fumonisin, Ochratoxin A, Patulin, T-2 toxin, Zearalenone, Deoxynivalenol etc.)

PAHs (Polycyclic aromatic hydrocarbons)

PBBs (Polybrominated biphenyls)

PCP (Pentachlorophenol)

PFOA (Perfluorooctanoic acid)

PFOS (Perfluorooctane sulfonates)

Radionuclides

Vinyl chloride monomer

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Potentially toxic and/or cancerogenic contaminants:

| | | |
|--------------------------------|--|----------------------------------|
| Nitrofurán | Aromatic amines | PBDE |
| Acetaldehyde | DEHP (Diethylhexylphthalat) | (Polybrominated diphenyl ethers) |
| Acrylamide | Dimethyl fumarate | PCB (Polychlorinated biphenyl) |
| Alkylphenol | MOAH / MOSH | Phthalates |
| APEO (Alkylphenol ethoxylates) | (mineral oil aromatic / saturated hydrocarbon) | |

Other contaminants:

| | | |
|--------------------------|------------------------------------|---------------------------|
| Antibiotics | Hormones | Phytates |
| Azodicarbon amide | Isocitric | Phytoestrogens |
| Bisphenol A, F & S | Isoprene (2-Methyl-buta-1,3-diene) | Propionaldehyde |
| BHA (Butylhydroxyanisol) | Kaolinite | Propylene glycol |
| BHT (Butylhydroxytoluol) | Latex | PVC (Polyvinylchlorid) |
| Calcium silicate | Mesylates | Semicarbacide |
| Chlorofluorocarbons | Nitrate | Silicones |
| Colophonium | Parabens | Sodium aluminium silicate |
| Dehydroacetic acid | PBT (Polybutylene terephthalate) | Steroids |
| Diacetyl | Peptides | Tosylates |
| Glycol ether | Perchlorate | Triclosan |
| Herbicides | Pesticides | Veterinary drugs |
| Histamine | Phenoxyethanol | |

- Nitrosamines: Due to the manufacturing process, they are not expected to be present. Furthermore, they are not added at any time during the manufacturing process.

ELEMENTAL IMPURITIES:

According to ICHQ3D Guidelines on Elemental Impurities and USP General Chapters <232> and <233>, none of the Class 1, 2a, 2b, or 3 impurities are expected to be present in the final product and are not intentionally added during the manufacturing process.

VEGAN/VEGETARIAN:

Suitable for vegan/vegetarian consumption.

TESTED ON ANIMALS:

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

They have however been subjected to general toxicity tests in the past, like any other approved food additive, approved cosmetic respectively or pharmaceutical excipient.

REACH:

01-2119457026-42-0000