

# 84679-ANHYDROUS CITRIC ACID

#### 1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.

# 1.1. <u>Identification of the substance or preparation.</u>

Name: Anhydrous citric acid

Bulk code: 84679 Internal code: 405999

Valid from bulk batch: 0117093

# 1.2. Synonyms.

E-330

### 2. <u>DESCRIPTION</u>.

Appearance: Colourless crystals or crystalline powder.

Colour: Colourless or white.

Odour: Odourless.

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

Geographical origin: Austria.

# 3. COMPOSITION/INFORMATION ON COMPONENTS.

Molecular formula: C<sub>6</sub>H<sub>8</sub>O<sub>7</sub>

CAS: 77-92-9

EINECS: 201-069-1

**Method of production:** Citric acid is made via fermentation of a carbohydrate source. The product undergoes several purification processes and is finally obtained in its purest form. No yeast is added in the manufacturing process.

#### 4. PHYSICO-CHEMICAL DATA.

For more information, see the analysis report.

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

# 5. PROPERTIES/USES.

Excipient for pharmaceutical use.

Food use. (Additive)

Feed additive.

Industrial use.

The product may be used in food for children, coeliac patients, diabetics and patients with a fructose intolerance or those who suffer galactosemia or phenylketonuria.



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### 6. DOSAGE.

No information available.

# 7. REMARKS.

The product has been handled in a NON-sterile room; so the product IS NOT sterile.

#### **STORAGE**

Store at room temperature in a cool, dry place in a tightly closed container away from sunlight, heat sources and moisture.

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

### BSE/TSE:

The product is free of BSE/TSE.

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

### GMOs:

The manufacturer does not use genetically modified microorganisms in the product's fermentation stage.

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

There are no labelling requirements for the above-mentioned product, in accordance with Regulations (EC) no. 1829/2003 and 1830/2003

### NANOMATERIALS:

The product has not been manufactured using nanotechnology, nor does it contain materials designed via 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, are not treated with ionising radiation or ethylene oxide. Furthermore, based on the production process as well as on the type of raw materials used, the above mentioned products are 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 concerning 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



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#### PRESERVATIVES/COLOURINGS/ANTIOXIDANTS:

The product does not contain colourings, preservatives, flavourings or antioxidants.

### **RESIDUAL SOLVENTS:**

Only water is used in the manufacturing process.

### **CONTAMINANTS:**

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

# Toxic and/or carcinogenic contaminants:

3-MCPD (3-monochloropropane-1,2-diol) Cyanuric acid Mycotoxins

Acrylonitrile Diethylene glycol (Aflatoxins, Fumonisins, Ochratoxin A, Patulin, T-2 toxin, Zearalenone, Deoxynivalenol etc.)
AOX (Halogenated organic compounds) Dioxins PAHs (Polycyclic aromatic hydrocarbons)

Asbestos Ethyl carbamate PBBs (Polybrominated biphenyls)

BTEX (Benzene, Toluene, Ethylbenzene, Xylenes)

Chloropropanols

CMR substances

Ethylene oxide
Formaldehyde
Formaldehyde
Furan

PCP (Pentachlorophenol)

PFOA (Perfluorooctanoic acid)

PFOS (Perfluorooctane sulfonates)

(carcinogenic, mutagenic or reprotoxic) Genotoxic substances Radionuclides

Cyanogenic glycosides Melamine Vinyl chloride monomer

# Potentially toxic and/or cancerogenic contaminants:

Nitrofuran 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 ISOPTENE (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



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- Nitrosamines: Due to the manufacturing process none are expected to be present. In addition, these are not added at any point in the manufacturing process.

# **ELEMENTAL IMPURITIES:**

In accordance with the ICHQ3D Guidelines on elemental impurities and general chapters <232> and <233> of the USP, no class 1, 2a, 2b or 3 impurities are expected to be present in the end product and are not added intentionally during the manufacturing process.

### **ALLERGENS:**

Food allergens: The product does not present any of the allergens listed in Appendix IIIa of Directive 2000/13/EC and its amendments, Directives 2003/89/EC, 2006/142/EC and 2007/68/EC, nor the Alba List (August 2003), nor do cross-contamination processes with these substances exist. The product does not contain any of the substances listed in Annex II of Regulation (EC) 1169/2011. Corn is not present in the end product.

### **NUTRITIONAL COMPOSITION:**



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

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

# **VEGAN/VEGETARIAN:**

Suitable for vegan/vegetarian use.

# **TESTED ON ANIMALS:**

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

It has however, undergone, general toxicity test on animals in the past, like any other approved food additive or approved cosmetic respectively pharmaceutical excipient.

# **REACH:**

01-2119457026-42-0000