

## Microbiological Data

### Citric Acid Anhydrous

Food & Pharmaceutical Grade

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Product name	Citric acid anhydrous	C <sub>6</sub> H <sub>8</sub> O <sub>7</sub>
EC No.	201-069-1	
CAS No.	77-92-9	
E-No.	E 330	

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Total Aerobic Microbial Count (TAMC)	max. 10 <sup>3</sup> CFU / g
Total Combined Yeasts / Moulds Count (TYMC)	max. 10 <sup>2</sup> CFU / g
Staphylococcus Aureus	negative / 1 g
Escherichia Coli	negative / 5 g
Salmonella	negative / 10 g
Bile-Tolerant Gram-Negative Bacteria	negative / 5 g

Jungbunzlauer has voluntarily set a microbiological specification for citric acid anhydrous in order to comply with the Ph. Eur. Requirements on the Microbiological Quality of Non-Sterile Pharmaceutical Preparations and Substances for Pharmaceutical use. Jungbunzlauer guarantees to meet the limits of the corresponding Ph. Eur. Monograph 5.1.4. The test methods have been adopted and validated for our products according to Ph. Eur. 7.0:2011. The microbiological testing is performed once per quarter by an external accredited laboratory. However, these parameters are not release criteria and they do not appear on the Certificate of Analysis of our standard materials.

## Shelf Life and Storage Conditions Citric Acid, Trisodium Citrate

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This information refers to following Jungbunzlauer products:

- Citric acid anhydrous
- Citric acid monohydrate
- Trisodium citrate anhydrous
- Trisodium citrate dihydrate

### Storage Conditions

Citric acid and trisodium citrate should be stored in original packaging or tight containers in a cool and dry place.

Recommended temperature: max. 30°C  
Recommended relative humidity: max. 70 %

Prolonged storage at higher temperatures and/or higher humidity should be avoided in order to prevent caking.

### Shelf Life

A shelf life of 3 years (till end of the month) from the date of manufacturing has been defined for above mentioned products. This shelf life is guaranteed if the product is stored in the originally closed bag or tight containers under the above described storage conditions.

In the calculation of the shelf life, short-term excursions during transport of the product have been taken into consideration. The shelf-life is conditional upon compliance at all times by the customer with the above mentioned storage conditions.

Physical properties may change on prolonged storage, thus a retest is recommended after the mentioned shelf life period.

### Expiry Date

The expiry date is consequently 3 years (till end of the month) after the date of production.

On the packaging of citric acid anhydrous, citric acid monohydrate, trisodium citrate dihydrate and trisodium citrate anhydrous the production and expiry date are mentioned as follows:

- Production date (YY/MM/DD)
- Expiry date (YY/MM)

## Food Safety and Suitability

### Citric Acid and Citrates

- Citric Acid Anhydrous
- Citric Acid Monohydrate
- Trimagnesium Citrate Anhydrous
- Trimagnesium Citrate Nonahydrate
- Trisodium Citrate Anhydrous
- Trisodium Citrate Dihydrate
- LIQUINAT® Citric Acid Solution
- Monosodium Citrate
- Tricalcium Citrate
- Tripotassium Citrate
- Zinc Citrate

**Statement with regard to the Annex II of Regulation (EU) 1169/2011\* (substances or products causing allergies or intolerances), the ALBA-list, other (allergenic) substances and dietetic suitability.**

**\*supersedes Annex IIIa of Directive 2000/13/EC on 13 December 2014**

Do above mentioned products contain allergenic or other substances, respectively possible traces thereof (cross-contamination)?

Products of animal origin	Yes	No	Comments
Beef and products thereof		X	BSE free
Chicken and products thereof		X	
Crustaceans and products thereof		X	
Dairy products and products thereof (incl. milk constituents, caseinate, whey etc.)		X	
Eggs (chicken's egg) and products thereof (albumin, yolk etc.)		X	
Fish and products thereof		X	
Gelatine		X	
Hydrolysed animal protein (HAP)		X	
Insect derivatives		X	
Milk (cow's milk protein) and products thereof (incl. lactose, milk powder etc.)		X	
Molluscs and products thereof		X	
Pork and products thereof		X	
Royal jelly		X	
Seafood		X	
Shellfish		X	
Other products of animal origin		X	

Seeds	Yes	No	Comments
Cotton		X	
Poppy		X	
Rape		X	
Sesame seeds and products thereof		X	
Sesame oil		X	
Sunflower kernels		X	
Other seeds		X	

<b>Fruits and vegetables</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Almond and products thereof ( <i>Amygdalus communis</i> L.)		X	
Brazil nut and products thereof ( <i>Bertholletia excelsa</i> )		X	
Carrot		X	
Cashew and products thereof ( <i>Anacardium occidentale</i> )		X	
Celery and products thereof		X	
Chestnut		X	
Cocoa		X	
Coconut		X	
Hazelnut and products thereof ( <i>Corylus avellana</i> )		X	
Hydrolysed vegetable protein (HVP)		X	
Macadamia nut, queensland nut and products thereof ( <i>Macadamia ternifolia</i> )		X	
Mustard and products thereof		X	
Nuts or nut oil		X	
Peanuts and products thereof (incl. peanut oil etc.)		X	
Pecan nut and products thereof ( <i>Carya illinoiesis</i> (Wangenh.) K. Koch)		X	
Pistachio nut and products thereof ( <i>Pistacia vera</i> )		X	
Sugar beet		X	1)
Walnut and products thereof ( <i>Juglans regia</i> )		X	
Other fruits and products thereof		X	
Other vegetables and products thereof		X	

<b>Spices and herbs</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Anise		X	
Caraway		X	
Chervil		X	
Cinnamon		X	
Coriander		X	
Curry		X	
Dill		X	
Fennel		X	
Garlic		X	
Lovage		X	
Myrrh		X	
Paprika		X	
Parsley		X	
Rosemary extract		X	
Umbelliferea		X	
Vanillin		X	
Other spices or herbs		X	

1) Sugar from sugar beet is a fermentation raw material, but is not contained in the end product anymore.

<b>Legumes/pulses</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Beans		X	
Guar gum		X	
Gum tragacant		X	
Locust bean gum		X	
Lupin and products thereof		X	
Peas		X	
Soybeans and products thereof (incl. soy oil, soy flour, soy meal, soy protein, soy lecithin etc.)		X	
Tofu		X	
Other legumes/pulses		X	

<b>Cereals and cereal products</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Barley or its hybridised strains		X	
Bakery products (bread crumb)		X	
Cereals containing gluten		X	
Gluten (gliadin, avenin, hordein)		X	
Kamut or its hybridised strains		X	
Maize		X	2)
Millet		X	
Oats or its hybridised strains		X	
Rice		X	
Rye or its hybridised strains		X	
Spelt or its hybridised strains		X	
Starch		X	
Wheat or its hybridised strains		X	
Wheat flour, wheat meal or wheat starch		X	
Other cereals or cereal products		X	

<b>Starch, sugars and sweeteners</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Aspartame		X	
Cyclamate		X	
Dextrin		X	
Fructose		X	
Galactose		X	
Glucose		X	2)
Invert sugar		X	
Lactose		X	
Maltodextrin		X	
Maltose		X	
Mannitol		X	
Saccharose		X	
Sorbitol		X	
Starch		X	
Sucrose		X	
Other starches, sugars or sweeteners		X	

2) Glucose syrup from maize is a fermentation raw material, but is not contained in the end product anymore.

<b>Preservatives</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Benzoic acid and salts (E210 – E213)		X	
Parabenes, hydroxybenzoic acid and salts (E214 – E219)		X	
Sorbic acid and salts (E200, E202, E203)		X	
Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO <sub>2</sub>		X	No added SO <sub>2</sub>
Sulfite (E220 – E228)		X	
Other preservatives		X	
<b>Antioxidants</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
BHA (E320)		X	
BHT (E321)		X	
Gallate (E310 – E312)		X	
Other antioxidants		X	
<b>Colours, flavours and flavour enhancers</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Artificial or natural colours		X	
Azo dye		X	
Flavours or flavour enhancers		X	
Disodium inosinate		X	
Disodium ribonucleotide		X	
Glutamate and glutamic acid (E 620 - 632)		X	
<b>Others</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Biogenic amines		X	
Caffeine		X	
Cholesterol		X	
Latex		X	
Lecithin		X	
Peru balsam		X	
Phenylalanin		X	
Purin and purin derivates		X	
Yeast		X	No added yeast
<b>Suitability for dietetic food</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Baby/infant food	X		
Patients with celiac disease	X		
Diabetics	X		
Patients with fructose-intolerance	X		
Patients with galactosemia	X		
Patients with phenylketonuria	X		
<b>Vegetarism</b>	<b>Yes</b>	<b>No</b>	<b>Comments</b>
Suitable for vegans	X		
Suitable for vegetarians	X		