

Product Data Sheet

Citric Acid Monohydrate

Version: PDS Citric Acid Monohydrate version 06	Issue date 01/02/2019	Supersedes versions: 01/10/2015
Reason for issue: Adaptation to update of the latest pharmacopoeia and regulations		PDS 04 32768 Version 05 Citric Acid Monohydrate Granular PDS 04 32776 Version 05 Citric Acid Monohydrate Fine Granular

Appearance

Citric Acid Monohydrate consists of colourless crystals or a white, granular to fine powder, practically odourless, with a strong acid taste.

Product Identification

Chemical name: 2-hydroxy-1,2,3-propanetricarboxylic acid monohydrate

Synonyms: citric acid monohydrate

CAS No.: 5949-29-1

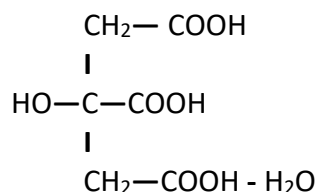
EINECS No.: 201-069-1

E No: E330

INCI name: Citric Acid

Empirical Formula: C₆H₈O₇H₂O

Molecular mass: 210.14 g/mol

**Specifications**

Odour	odourless	Barlum	< 1 ppm
Identification	Meets requirements	Copper	< 1 ppm
Water (K.Fischer)	8.10-8.70%	Zinc	< 1 ppm
Extraneous matter	Passes test	Iron	< 1 ppm
Colour (500 g/L, T at 405 nm, 1 cm)	Min 98%	Calcium	< 10 ppm
Appearance of solution	Meets EP requirements (visual test)	Magnesium	< 1 ppm
Clarity of solution	Meets USP requirements (colour:%T)	Aluminium	< 0,2 ppm
Colour of solution	Meets USP requirements (colour:%T)	Chlorides	< 5 ppm
Readily carbonizable substances RCS	Meets requirements	Sulphates	< 30 ppm
Heavy metals (sum: Cd, Cr, Pb, Hg, Zn, Ni)	< 1 ppm	Oxalates/oxalic acid	< 10 ppm
Arsenic	< 1 ppm	Sulphate ash/ Residue on Ignition	Meets FCC requirements (NMT 0,05% on 4g)
Lead	< 0,5 ppm	Assay	99,80-100,5%
Mercury	< 1 ppm	Tridodecyclamine	Not applicable fo Citrique Belge, only for solvent extracted citric acid

Fineness (ISO standard sieves) / MESH		Product Code
Granular		
On	No. 5 (4000 µm) max 5 %	04 32768
Through	No. 30 (600 µm) max 10 %	
Fine Granular		
On	No. 20 (850 µm) max 5 %	04 32776
Through	No. 100 (100 µm) max 5 %	

Solubility

Citric Acid Monohydrate is very soluble in water, freely soluble in ethanol and sparingly soluble in ether.

Stability and storage

Citric Acid Monohydrate may be stored for 36 months from the date of manufacture in the unopened original container. A relative humidity of 50% and a temperature range of 10-30°C are the most suitable conditions for storage.

Temperatures above 40°C and a relative humidity above 70% should be avoided in order to prevent caking, especially the Fine Granular form. The stocking of the Fine Granular form for long periods is not recommended.

Stability tests have shown that Citric Acid Monohydrate is chemically stable for a least five years in tightly closed containers under proper storage conditions.

Uses

- As an acidulant, flavor enhancer and sequestering agent in food applications and beverages, and as a synergist in antioxidant mixtures.
- For cosmetics and personal care products.
- For pharmaceutical preparations, especially effervescent tablets.
- This product is not intended for use in the manufacture of sterile drug products. The purchaser assumes all responsibility for additional processing, testing, labelling and registration required for such use.

Compendial Compliance

Citric Acid Monohydrate meets all requirements of the USP, FCC, Ph, Eur, and JP and the Commission regulation (EC) No 231/2012 when tested according to these compendia.

Citric Acid Monohydrate is classified as a GRAS (Generally Recognized As Safe) substance following the US Food and Drug Administration (FDA)

Safety

This product is safe for the intended use. Avoid inhalation of dust, contact with eyes and prolonged contact with skin by applying suitable protective measures and personal hygiene.

For a full safety information and necessary precautions, please refer to the respective Material safety Data Sheet.

Legal notice

The information given in this publication is based on our current knowledge and experience, and may be used at your discretion and risk. It does not relieve you from carrying out your own precautions and tests. We do not assume any liability in connection with your product or its use. You must comply with all applicable laws and regulations, and observe all third party rights.

Citrique Belge N.V.

Phone: +32(0) 16 80.62.11

Fax: +32(0) 16 80.66.11

E-mail: Citrique.belge@citriquebelge.com