

Product Data Sheet Monosodium Citrate Anhydrous

Version: PDS Monosodium Citrate Anhydrous Version 07	Issue date: 28/02/2022	Supersedes versions: 01/02/2019
Reason for issue: 3-yearly update + new logo		PDS-04 12570 Version 06 Monosodium Citrate Anhydrous Granular PDS-04 12562 Version 06 Monosodium Citrate Anhydrous Powder

Appearance

Monosodium Citrate Anhydrous consists of colourless crystals or a white, crystalline powder, practically odourless, with a slightly acid taste.

Product identification

Chemical name: 2-hydroxy-1,2,3-propanetricarboxylic acid monosodium salt **Synonyms:** monosodium citrate, citric acid, monosodium salt, sodium citrate

CAS No.: 18996-35-5

EINECS No.: 242-734-6 CH_2-COOH E No: E 331 (i) CH_2-COOH INCI name: Sodium citrate $C_6H_7NaO_7$ CH_2-COOH Molecular mass: 214.11 g/mol

Specifications

odourless Barium		< 1 ppm
		<1 ppm
0.00 – 0.10 % Zinc		< 1 ppm
passes test	Iron	< 5 ppm
92.00 – 100.00 % Calcium		< 50 ppm
meets EP requirements (visual test) Magnesium		< 2 ppm
meets USP requirements Mercury		< 1 ppm
meets USP requirements (colour:%T)		< 5 ppm
meets requirements	Sulphates	< 30 ppm
< 1 ppm	Oxalates / oxalic acid	< 10 ppm
	passes test 92.00 – 100.00 % meets EP requirements (visual test) meets USP requirements meets USP requirements (colour:%T) meets requirements	meets requirements 0.00 - 0.10 % passes test 1ron 92.00 - 100.00 % meets EP requirements (visual test) meets USP requirements (colour:%T) meets requirements Chlorides Sulphates Oxalates / oxalic





Arsenic	<1 ppm	pH (1% in water)	3.50 – 3.80
Lead	<1ppm	Assay	99.50 –100.50 % (on dry substance
		Taste	Slightly acid taste

Fineness (ISO standard sieves) / MESH		/ MESH	Product Code	
Granular On No. Through No.		(425 μm) max. (75 μm) max.		04 12570
	60 200	(250 μm) max. (75 μm) min.		04 12562

Solubility

Monosodium Citrate Anhydrous is freely soluble in water, and very slightly soluble in ethanol.

Stability and storage

Monosodium Citrate Anhydrous may be stored for 36 months from the date of manufacture in the unopened original packaging (bags and big bags). A relative humidity of 50% and a temperature range of 10–30 °C are the most suitable conditions for storage.

Temperatures and a relative humidity above recommendation should be avoided in order to prevent caking. Monosodium Citrate Anhydrous has a tendency to compaction. However, possible lump forming can be broken with light to moderate pressure if the problem is detected early. Permitting the product to remain lumpy for long periods could result in irreversible caking.

It is highly recommended to have a low inventory and not to stack the pallets.

Stability tests have shown that monosodium citrate is chemically stable for at least five years in tightly closed packaging under proper storage conditions.

Uses

- Imparts a cool and saline taste to beverages. Acts as a buffer in combination with free acid in beverages and jellies.
- For solid and liquid 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

Monosodium Citrate Anhydrous meets all requirements of DAC and JECFA latest editions and the Commission Regulation (EU) 231/2012.





Safety

This product is safe for the intended use. Avoid ingestion, inhalation of dust or direct contact by applying suitable protective measures and personal hygiene.

For 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.

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