

Product Data Sheet

Monosodium Citrate Anhydrous

Version: PDS Monosodium Citrate Anhydrous Version 08	Issue date: 24/09/2024	Supersedes versions: 2022-02-28
Reason for issue: Some rounding has also been adapted: - colour is shown at 1 decimal place instead of 2 - Assay is shown at 1 decimal place instead of 2. - pH is shown at 1 decimal place instead of 2. - For identification: EP is mentioned as requirement (Note: method has not changed!) - For RCS: FCC is mentioned		PDS-04 12570 Version 07 Monosodium Citrate Anhydrous Granular PDS-04 12562 Version 07 Monosodium Citrate Anhydrous Powder

Appearance

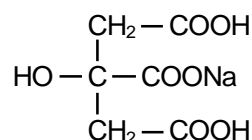
Monosodium Citrate Anhydrous consists of colourless crystals or a white, crystalline powder, practically odourless, with a slightly acid taste.

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
E No:	E 331 (i)
INCI name:	Sodium citrate
Empirical formula:	C ₆ H ₇ NaO ₇
Molecular mass:	214.11 g/mol



Specifications

Odour	odourless	Barium	< 1 ppm
Identification	meets EP requirements	Copper	< 1 ppm
Water (Loss on drying)	0.00 – 0.10 %	Zinc	< 1 ppm
Extraneous matter	passes test	Iron	< 5 ppm
Colour (250 g/L, T at 366 nm, 1 cm)	92.0 – 100.0 %	Calcium	< 50 ppm
Appearance of solution	meets EP requirements (visual test)	Magnesium	< 2 ppm
Clarity of solution	meets USP requirements (colour: %T)	Mercury	< 1 ppm
Colour of solution	meets USP requirements (colour: %T)	Chlorides	< 5 ppm
Readily carbonizable substances RCS	Meets FCC requirements	Sulphates	< 30 ppm

Heavy metals (sum: Cd, Cr, Cu, Pb, Hg, Zn, Ni)	< 1 ppm	Oxalates / oxalic acid	< 10 ppm
Arsenic	< 1 ppm	pH (1% in water)	3.5 – 3.8
Lead	< 1 ppm	Assay	99.5 – 100.5 % (on dry substance)
		Taste	Slightly acid taste

Fineness (ISO standard sieves) / MESH						Product Code
Granular						04 12570
On	No.	40	(425 µm)	max.	10%	
Through	No.	200	(75 µm)	max.	30%	
Powder						04 12562
On	No.	60	(250 µm)	max.	5%	
Through	No.	200	(75 µm)	min.	65%	

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.

Citribel nv

Phone: +32 (0) 16 80.62.11

Fax : +32 (0) 16 80.66.11

E-mail : info@citribel.com

