Product Data Sheet
Monosodium Citrate Anhydrous

Version: PDS Monosodium Citrate Anhydrous Version 05
Issue date: 01/10/2015
Supersedes versions: 2010-12-01

Reason for issue:
Adaptation to update of the latest pharmacopoeia and regulations

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 requirements
Copper
< 1 ppm
Loss on drying
< 0.10 %
Zinc
< 1 ppm
Extraneous matter
passes test
Iron
< 5 ppm
Colour (250 g/L, T at 366 nm, 1 cm)
min. 92 %
Calcium
< 50 ppm
Appearance of solution
meets EP requirements (visual test)
Mercury
< 2 ppm
Clarity of solution
meets USP requirements
Magnesium
< 1 ppm
Colour of solution
(visual test)
meets USP requirements
Chlorides
< 5 ppm
Readily carbonizable substances RCS
meets requirements
Sulphates
< 30 ppm
Heavy metals
< 1 ppm
Oxalates / oxalic acid
< 10 ppm
Arsenic
< 1 ppm
pH (1% in water)
3.50 – 3.80
Lead
< 1 ppm
Assay
99.50 – 100.50 % (on dry substance)
Taste
Slightly acid taste

\[
\begin{align*}
\text{CH}_2 & \text{― COOH} \\
\text{HO} & \text{― C ― COONa} \\
\text{CH}_2 & \text{― COOH}
\end{align*}
\]
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 container. 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 containers 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 the USP, FCC, Ph. Eur. and JP and the Commission regulation (EC) No 231/2012 when tested according to these compendia.

Monosodium Citrate Anhydrous meets all requirements of JECFA.

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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