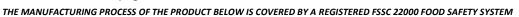


## MACCO ORGANIQUES INC.

100 McArthur, suite 112, Salaberry-de-Valleyfield, Quebec, Canada, J6S 4M5 Tel: (450) 371-1066, Fax: (450) 371-5519

Web page address: www.macco.ca, Email: macco@macco.ca



Date: January 26, 2021 Supersedes: May 28, 2020 Ref #: S36274-A-G Page: 1/1 DC #: 20-278

## **SPECIFICATIONS** SODIUM ACETATE TRIHYDRATE PHARMA

For non-sterile uses only, not intended for injectable use unless further processed for that purpose.

## **GENERAL**

Molecular formula: C2H3NaO2·3H2O CAS #: 6131-90-4

Molecular weight: 136.08 g/mol

## **Description**

White or almost white, crystalline powder or colorless crystals.

<u>Parameters</u>	<u>Methods</u>	<u>Specifications</u>
Identification	USP, EP	Passes test
Appearance of solution	EP	Clear and colorless
pH (5%)	EP	7.5 to 9.0
Assay (dry basis)	EP	99.0 to 101.0%
Loss on drying	EP	39.0 to 40.5%
Chloride	EP	200 ppm Max.
Sulfate	USP	50 ppm Max.
Calcium and Magnesium	EP	50 ppm Max. (as Ca)
Potassium	USP	Passes test
Insoluble matter	USP	0.05% Max.
Iron	EP	10 ppm Max.
Reducing substances	EP	Passes test
Aluminum	ICP (QER-10-38)	0.2 ppm Max.
Bacterial endotoxins	USP<85>	2.5 EU/g Max.
Total aerobic microbial count	USP<61>	100 CFU/g Max.
Total combined yeasts and molds count	USP<61>	100 CFU/g Max.
E. coli, S. aureus, P. aeruginosa	USP<62>	Absent

Complies with the USP and EP requirements. Suitable for hemodialysis.

OVI and RS: This material conforms to the USP/NF limits for organic impurities. Based on our knowledge of the manufacturing process and on controlled handling and storage of the material, we acknowledge that there is no potential for introduction of residual solvents (RS) or organic volatile impurities (OVI) in the material, because, when used, the only solvent in our inorganic synthesis process is water.

56 to 60 lbs/cu ft

Typical tapped density	56 to 60 lbs/cu.ft.	
	0.90 to 0.96 g/mL	
	0 2000 /US 1 1 1/4	

Typical particle size On 2000 µm (US std mesh #10): 1% Max. Through 45 µm (US std mesh #325): 2% Max.

**Packaging** 25 kg multiwall paper bags.

Store in a dry place, in tight containers, for up to 36 months. Storage

Liability: The information submitted in this document is based on current knowledge and experience. The information contained herein is furnished without warranty of any kind. Macco Organiques Inc. does not accept any liability whatsoever in respect of the use of this information nor in respect of use, application, adaptation or processing of the product described herein. The recommended times presented in this document may vary greatly depending on storage conditions.