



## MACCO ORGANIQUES INC.

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THE MANUFACTURING PROCESS OF THE PRODUCT BELOW IS COVERED BY A REGISTERED ISO 9001 QUALITY SYSTEM AND A FSSC 22000 FOOD SAFETY SYSTEM

Date: June 19, 2017

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Ref #: S36274-A-G

DC #: **17-115**

### SPECIFICATIONS SODIUM ACETATE TRIHYDRATE PHARMA HEMODIALYSIS

*For non-sterile uses only*

#### GENERAL

Molecular formula:  $C_2H_3NaO_2 \cdot 3H_2O$

CAS #: 6131-90-4

Molecular weight: 136.08

#### Description

White or almost white, crystalline powder or colorless crystals.

#### Parameters

#### Specifications

Identification	Passes test
Appearance of solution	Clear and colorless
pH (5%)	7.5 to 9.0
Assay (dry basis)	99.0 to 101.0%
Loss on drying	39.0 to 40.5%
Chloride	200 ppm Max.
Sulfate	50 ppm Max.
Calcium and Magnesium	Passes test / 50 ppm Max. (as Ca)
Potassium	Passes test
Insoluble matter	0.05% Max.
Iron	10 ppm Max.
Heavy metals (as Pb)	10 mg/kg Max.
Reducing substances	Passes test
Arsenic	2 ppm Max.
Aluminum	0.2 ppm Max.
Bacterial endotoxins	3.9 EU/mg Max.
Total aerobic microbial count	100 CFU/g Max.

**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.*

#### Typical bulk density (tapped)

56 to 60 lbs/cu.ft.  
0.90 to 0.96 g/mL

#### Typical particle size

On 2000  $\mu$ m (US std mesh #10): 1% Max.  
Through 45  $\mu$ m (US std mesh #325): 2% Max.

#### Packaging

25 kg multiwall paper bags.

#### Storage

Store in a dry place, in tight containers, for up to 2 years.

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