



MACCO ORGANIQUES INC.

100 McArthur, Valleyfield, Quebec, Canada, J6S 4M5

Tel: (450) 371-1066, Fax: (450) 371-5519

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



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

Date: September 19, 2016

Supersedes: New

Ref #: S36274-A-G

DC #: 16-027

SPECIFICATIONS

SODIUM ACETATE TRIHYDRATE USP-EP 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 (3%) | 7.5 to 9.2 |
| 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 μ m (US std mesh #10): 1% Max.
Through 45 μ 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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