



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



THE MANUFACTURING PROCESS OF THE PRODUCT BELOW IS COVERED BY A CERTIFIED FSSC 22000 FOOD SAFETY SYSTEM

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SPECIFICATIONS

SODIUM ACETATE ANHYDROUS USP AGGLOMERATE

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

GENERAL-2

Molecular formula: C₂H₃NaO₂

CAS #: 127-09-3

Molecular weight: 82.03 g/mol

Description

White, odorless, hygroscopic powder that is freely soluble in water.

| <u>Parameters</u> | <u>Methods</u> | <u>Specifications</u> |
|--|-----------------|-----------------------|
| Identification | USP | Passes test |
| pH (3%) | USP | 7.5 to 9.2 |
| Loss on drying | USP | 1.0% Max. |
| Assay (dry basis) | USP | 99.0 to 101.0% |
| Chloride | USP | 350 ppm Max. |
| Sulfate | USP | 50 ppm Max. |
| Potassium compounds | USP | Passes test |
| Calcium and Magnesium | USP | Passes test |
| Insoluble matter | USP | 0.05% Max. |
| 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. |
| <i>E. coli, S. aureus, P. aeruginosa</i> | USP<62> | Absent |

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 tapped density

28 to 32 lbs/cu.ft.

0.45 to 0.51 g/mL

Typical particle size

On 850 µm (US std mesh #20): 1% Max.

Through 75 µm (US std mesh #200): 1% Max.

Packaging

20 kg multiwall (polyethylene and paper) bags.

Storage

Store in a cool and dry place, in tight containers, for up to 18 months.

Bulk pharmaceutical chemical.

Caution: for manufacturing, processing, or repacking

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