

Avantor Performance Materials, Inc. 3477 Corporate Parkway Suite 200 Center Valley, PA 18034 U.S.A.

Tel: 1-610-573-2600 Fax: 1-610-573-2650 www.avantormaterials.com

# **Sodium Acetate Trihydrate**

#### **Product Data Sheet**

### Section 1 – Product Information

#### **Products Covered**

| Brand                  | Product<br>Code | Name                         | Grade           | Compendia    |
|------------------------|-----------------|------------------------------|-----------------|--------------|
| Macron Fine Chemicals™ | 7320-02         | Sodium Acetate<br>Trihydrate | IP              | IP           |
| Macron Fine Chemicals™ | 7320-06         | Sodium Acetate Trihydrate    | IP              | IP           |
| Macron Fine Chemicals™ | 7330-02         | Sodium Acetate Trihydrate    | USP             | USP          |
| Macron Fine Chemicals™ | 7330-06         | Sodium Acetate<br>Trihydrate | USP             | USP          |
| Macron Fine Chemicals™ | 7380-02         | Sodium Acetate<br>Trihydrate | Multicompendial | BP/USP/EP/JP |
| Macron Fine Chemicals™ | 7380-06         | Sodium Acetate Trihydrate    | Multicompendial | BP/USP/EP/JP |

## Section 2 – Manufacturing, Packaging and Release Site Information

The **USP and Multicompendial** grade products in Section 1 are manufactured according to current Good Manufacturing Practices (cGMPs) as set forth by International Pharmaceutical Excipients Council (IPEC) guidelines.

The **IP** grade products in Section 1 are manufactured according to current Good Manufacturing Practices (cGMPs) as set forth in the Drugs and Cosmetics Rules, 1945, Government of India Ministry of Health and Family Welfare.

# Section 3 – Physical/Chemical Information

**CAS** #: 144-55-8

Manufacturing Process: Synthesis

Raw Material Origin: Chemical



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## Section 4 – Regulatory Information

**Compendial Compliance:** Please see the current product specifications at www.avantormaterials.com.

**DMF:** Avantor Performance Materials, Inc. does not carry a Drug Master File for these products.

**BSE/TSE Status:** To the best of our knowledge, the subject materials are manufactured from raw materials that contain NO animal parts, products, and/or by-products nor do they come in contact with animal parts, products, and/or by-products.

**Allergen/Hypersensitivities Information:** To the best of our knowledge, the subject materials are free from allergens and do not come into contact with any allergic substance.

**GMO Information:** To the best of our knowledge, the subject materials, including any raw materials and processing aids, are NOT subject to genetic modification.

Residual Solvents/Organic Volatile Impurities (OVI) Information: To the best of our knowledge, the subject materials (all lots) comply with the requirements of the ICH Q3C Residual Solvents Guideline and USP<467>Residual Solvents. No Class 1, 2, 3 or other solvents are used or produced in the manufacturing or purification of the product.

#### Section 5 – Miscellaneous Product Information

**Management of Change:** Please refer to the customer support section of our website for information concerning our Management of Change program. (<a href="www.askavantor.com">www.askavantor.com</a> Keyword: MOC)

# Section 6 – Revision History

Rev. 0; Effective Date: February 11, 2014 (MCH)



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### Section 7 – Contact Information

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OR

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