
Sodium Phosphate, Monobasic, Monohydrate

Product Data Sheet

Section 1 – Product Information

Products Covered

Brand	Product Code	Name	Grade	Compendia
Macron Fine Chemicals™	7869-02	Sodium Phosphate Monobasic, Monohydrate, USP	Multicompendial	BP/USP
Macron Fine Chemicals™	7869-06	Sodium Phosphate Monobasic, Monohydrate, USP	Multicompendial	BP/USP
Macron Fine Chemicals™	7879-02	Sodium Phosphate Monobasic, Monohydrate, USP	USP	USP
Macron Fine Chemicals™	7879-06	Sodium Phosphate Monobasic, Monohydrate, USP	USP	USP
Macron Fine Chemicals™	7859-02	Sodium Phosphate Monobasic, Monohydrate,	IP	IP
Macron Fine Chemicals™	7859-06	Sodium Phosphate Monobasic, Monohydrate,	IP	IP

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 #: 10049-21-5

Manufacturing Process: Synthesis

Raw Material Origin: Chemical

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: This product has not yet been evaluated for allergen information.

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.

Residual Metallic Catalysts: No metal catalysts or metal reagents, as defined by EMA Guideline EMEA/CHMP/SWP/4446/2000, are used in the production of this material.

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. (www.askavantor.com Keyword: MOC)

Section 6 – Revision History

Rev. 0; Effective Date: August 30, 2013 (TLS/MCH)

Section 7 – Contact Information

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