

# DI-SODIUM HYDROGEN PHOSPHATE, DODECAHYDRATE, EP, MICRO PURE

## Product Regulatory Data Sheet

### Section 1 – Product Information

#### Products Covered

<u>Brand</u>	<u>Product Code</u>	<u>Product Description</u>	<u>MOC*</u> <u>code</u>
Macron Fine Chemicals™	P116	di-Sodium Hydrogen Phosphate, Dodecahydrate, EP, MicroPure	RL

\*MOC = Management of Change

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

The products in Section 1 are manufactured or purchased where testing meets pharmacopeia requirements. This applies to European Pharmacopeia (EP) and specific products that a customer requires change notification due to regulatory filings. Product may or may not be manufactured according to cGMP standards.

A number of the RL products that are sold by Avantor Performance Materials, Inc. may not be originally manufactured at our sites. However, we perform the analytical and stability testing for these products and repackage the products where applicable. With ISO procedures in place at our facilities we can ensure, and take complete responsibility for, the traceability and quality of the finished, packaged product that we offer.

The original manufacturer and address will be referenced on the Certificate of Analysis as an alpha or alpha-numeric **manufacturer code** rather than listing the full name and address. This practice is compliant with both ICH Q7 Good Manufacturing Guidance for Active Pharmaceutical Ingredients (APIs) and IPEC guidelines and it meets cGMP requirements. For instructions to decipher the manufacturer reference code please consult our website. Instructions can be found in the Ask Avantor Q&A Center of the customer support section of our web site or by directly linking to [www.askavantor.com](http://www.askavantor.com) Keyword: Manufacturer Code.

### ***Section 3 – Physical/Chemical Information***

**CAS #:** 10039-32-4

**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](http://www.avantormaterials.com).

**BSE/TSE Status:** 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:** 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:** The subject materials, including any raw materials and processing aids, are NOT subject to genetic modification.

**Residual Solvents/Organic Volatile Impurities (OVI) Information:** 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 EMEA Guideline on the Specification Limits for Residues of Metal Catalysts or Metal Reagents (CPMP/SWP/QWP/4446/00), are used in the production of the above subject materials.

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### ***Section 5 – Miscellaneous Product Information***

**Certificate of Analysis Date Format:** The Manufactured Date and Expiration/Retest Date on the C of A are reported as YYDDDDXXXX from our ERP system.

**YY** - two digit numbers identifies the year

**DDD** - three digit numbers identifies the day of the year

**XXXXX** - unique numbers assigned by the system

For example, the Manufactured Date for September 30, 2014 would be reported as 1427301821.

**Lot Numbering System and Batch Description:** Please refer to the customer support section of our website for information concerning our lot/batch numbering system.

([www.askavantor.com](http://www.askavantor.com) Keyword: Lot Number)

**Shelf Life Information:** If a product has an assigned expiration or retest period, the date will appear on the certificate of analysis.

**Management of Change:** Please refer to the customer support section of our website for information concerning our Management of Change program. ([www.askavantor.com](http://www.askavantor.com) Keyword: MOC)

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### ***Section 6 – Revision History***

Rev. 0; November 15, 2013

Rev, 1; June 24, 2014

Rev, 2; February 01, 2017

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***This electronic document is valid without a signature.***

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### ***Section 7 – Contact Information***

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Technical Service Department

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