
SODIUM HYDROXIDE, EP

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered

<u>Brand</u>	<u>Product Code</u>	<u>Product Description</u>	<u>MOC* code</u>
Macron Fine Chemicals™	7066	Sodium Hydroxide, EP	RL

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

The product in Section 1 is 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 Keyword: Manufacturer Code.

Section 3 – Physical/Chemical Information

CAS #: 1310-73-2

Manufacturing Process: Synthesis

Raw Material Origin: Chemical

Section 4 – Regulatory Information

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

BSE/TSE Status: According to the CPMP/CVMP Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agent via Medicinal Products and Veterinary Medicinal Products (EMA/410/01- FINAL, Rev. 03- July 2011) 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.

Phthalate Information: The subject materials, including any raw materials do NOT contain Phthalates.

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 YYDDDXXXX 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 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 Keyword: MOC)

Section 6 – Revision History

Rev. 0; March 21, 2014
Rev. 1; October 17, 2014
Rev. 2; May 12, 2015

This electronic document is valid without a signature.

Section 7 – Contact Information

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