

# SODIUM HYDROXIDE

## Product Regulatory Data Sheet

### Section 1 – Product Information

#### Products Covered

<u>Brand</u>	<u>Product Code</u>	<u>Product Description</u>	<u>MOC<sup>*</sup> code</u>
J.T.Baker®	2632	Sodium Hydroxide Solution 17%, Biotech Reagent	R
J.T.Baker®	2615	Sodium Hydroxide Solution 20%, Biotech Reagent	R
J.T.Baker®	2613	Sodium Hydroxide Solution 25%, Biotech Reagent	R
J.T.Baker®	2616	Sodium Hydroxide Solution 45%, Biotech Reagent	R
J.T.Baker®	2617	Sodium Hydroxide Solution 30%, Biotech Reagent	R
J.T.Baker®	2622	Sodium Hydroxide Solution 50%, Biotech Reagent	R
J.T.Baker®	2650	Sodium Hydroxide Solution 10N, Biotech Reagent	R

\*MOC = Management of Change

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

The product in Section 1 are manufactured according to current Good Manufacturing Practices (cGMP) as set forth by International Pharmaceutical Excipients Council (IPEC) guidelines.

A number of the R 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 #:** 1310-73-2

**Manufacturing Process:** Synthesis

**Raw Material Origin:** Chemical

---

### ***Section 4 – Regulatory Information***

**Compendial Compliance:** Please see the current product specifications at [www.avantorinc.com](http://www.avantorinc.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.

**Melamine absence:** No melamine is added to the product(s) mentioned above. Furthermore no melamine is used in the production process, as starting material or has been added to a starting material.

**Bisphenol A:** Product(s) mentioned in this document does not contain bisphenol A (BPA) and other endocrine disrupters.

**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.

**GMO Information:** The subject materials, including any raw materials and processing aids, are NOT subject to genetic modification.

**Gluten:** To the best of our knowledge, this product does not contain gluten.

**Kosher Status:** The subjected materials is Kosher Certified. Please refer to the customer support at [www.avantorinc.com](http://www.avantorinc.com)

**Halal Status:** The subjected materials are Halal Certified. Please refer to the customer support at [www.avantorinc.com](http://www.avantorinc.com)

---

### ***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 YYYY/MM/DD from our ERP system. For example, the Manufactured Date for October 1, 2012 would be reported as 2012/10/01.

**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).

---

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

Rev. 1; May 05, 2017

Rev. 2; May 15, 2017

Rev. 3, May 23, 2017

Rev. 4, May 29, 2017



Avantor Performance Materials Poland Spółka Akcyjna  
ul. Sowińskiego 11  
44-101 Gliwice, Poland  
Tel: +48 32 2392 000  
avantor.pl@avantorinc.com  
www.avantorinc.com

---

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

---

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

European Customer Service  
Phone: +31570687500

Technical Service Department  
Avantor™ Performance Materials, Inc.  
3477 Corporate Parkway Suite #200  
Center Valley, PA 18034  
1-800-669-8230

---