100 Matsonford Rd., Suite 200
Radnor, PA 19087
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www.avantorsciences.com

Sodium Hydroxide

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered

Brand	Product Code	Product Description	MOC* code
J.T.Baker®	0312	Sodium Hydroxide, 10N Solution Biotech Reagent	R
J.T.Baker®	0328	Sodium Hydroxide, 1.0N Solution Biotech Reagent	R
J.T.Baker®	0329	Sodium Hydroxide, 0.5N Solution Biotech Reagent	R
J.T.Baker®	0338	Sodium Hydroxide, 25% Solution Biotech Reagent	R
J.T.Baker®	0339	Sodium Hydroxide, 50% Solution Biotech Reagent	R
J.T.Baker®	0389	Sodium Hydroxide, 1.0N Solution Biotech Reagent	R
J.T.Baker®	0390	Sodium Hydroxide, 2.0N Solution Biotech Reagent	R
J.T.Baker®	0895	Sodium Hydroxide, 5.0N Solution Biotech Reagent	R
J.T.Baker®	0896	Sodium Hydroxide Solution 40% (w/w) Biotech Reagent	R
J.T.Baker®	0897	Sodium Hydroxide, 50% Solution Biotech Reagent	R
J.T.Baker®	3718	Sodium Hydroxide, Pellets, N.F. Multi-Compendial	R
J.T.Baker®	3728	Sodium Hydroxide, Pellets N.F. - F.C.C.	R
J.T.Baker®	5000	Sodium Hydroxide, 10N Solution Biotech Reagent	R
J.T.Baker®	5668	Sodium Hydroxide, 5N Solution Biotech Reagent	R
Macron Fine Chemicals™	7001	Sodium Hydroxide, N.F., A.C.S.	R
Macron Fine Chemicals™	7680	Sodium Hydroxide, Pellet N.F. - F.C.C.	R
Macron Fine Chemicals™	7772	Sodium Hydroxide, Pellet NF - GenAR®	R

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

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

A number of the cGMP produced products that are sold by Avantor Performance Materials, LLC 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 and cGMP 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.avantorsciences.com.

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

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/Hypersensitivities Information: The products listed do not contain cereals containing gluten (i.e. wheat, rye, oats, barley, spelt, kamut or their hybridized strains), malt, triticale, gluten, other grains, corn, soy, soybeans, eggs,

yeast, canola, milk, dairy products, fish, crustacean shellfish, seafood products, tree nuts, peanuts, nut products (i.e. Almond (Amygdalus communis L.), Hazelnut (Corylus avellana), Walnut (Juglans regia), Cashew (Anacardium occidentale), Pecan nut (Carya illiniesis (Wangenh.) K. Koch), Brazil nut (Bertholletia excelsa), Pistachio nut (Pistacia vera), Macadamia nut and Queensland nut (Macadamia ternifolia)), seed products (sesame seeds and products thereof), natural grape products, natural flavors, artificial flavors, celery, mustard, lactose, sulfites, elemental sulfur, preservatives, lupine and products thereof, MSG, disodium guanylate/inosinate, artificial sweeteners, phenylalanine, additives, colorants, dyes, or natural rubber (latex). These products are manufactured using cGMP guidelines which provide controls that allow no potential for cross contamination of any allergens or other products.

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.

Elemental Impurities:
Please see attached summary for Elemental Impurity information for listed products.

Kosher Status: Pareve for year-round use. Please refer to the customer support section of our website for our most up to date listing of Kosher products. (www.askavantor.com Keyword: Kosher)

Halal Status: Macron Fine Chemicals™ 7680, 7772 and J.T.Baker® 3718, 3728 are Halal Certified. Please refer to the customer support section of our website for our most up to date listing of Halal products. (www.askavantor.com Keyword: Halal)

GRAS Status: The United States Food and Drug Administration (FDA) have acknowledged that the sodium hydroxide is a substance Generally Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per 21 CFR part 184.1763.

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 effective April 30, 2012. For example, the Manufactured Date for October 1, 2012 would be reported as 2012/10/01.

Prior to ERP implementation, the Release Date on the C of A was reported as MM/DD/YYYY. For example, the Release Date for October 1, 2012 would have been reported as 10/01/2012.

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)

Batch Definition: A "batch" is a homogeneous unit of production; each batch of is from one single batch of the source supplier.

Shelf Life Information: If a product has an assigned expiration or retest period, the date will appear on the certificate of analysis. For products that do not have assigned dates please contact Technical Support through the customer support section of our website for our product stability profiles. (www.askavantor.com Keyword: Expiration)

Nutritional/Supplement Facts Labeling: Bulk food chemicals that are intended for the use in manufacturing of finished food products or for products that are to be processed, labeled, and/or repacked at a site other than where it's originally processed or packed, are exempt from the Nutrient Content Evaluation and Nutrient Labeling Requirements. (21 CFR 101.9(j)(9))

Organic Status: The products listed in Section 1 are not certified as organic. However, to the best of our knowledge, the product is not produced using Ionizing Radiation as described in 21 CFR 179.26 or Sewage Sludge as described in 7 CFR Section 205.2.

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)

Country of Origin Statement: Country of Origin is indicated on the product Certificate of Analysis. Please contact our Trade Compliance if you require further documentation (Trade.Compliance@avantorsciences.com).

Storage Requirements: Please refer to the product Certificate of Analysis/Product Specifications. In the absence of specific storage conditions listed on the Avantor specification sheet or certificate of analysis, our products are to be stored in ambient conditions of temperature and humidity. We do not formally tie any specific temperature or humidity range with the 'ambient' storage designation, but an example of a common temperature interpretation is 15-30°C. Our products are also packaged to protect from the normal variation in humidity during storage and shipment. Further handling and storage information may be found in Section 7 of the product SDS sheet.

Section 6 – Revision History

Rev. 0; Oct. 1, 2007 – IPEC EIP format
Rev. 1; Jan. 30, 2008 – Added Product Code 0338
Rev. 2; April 24, 2008 – Added Product Code 0895
Rev. 3; July 11, 2008- Added Product Code 7680
Rev. 4; Sept. 12, 2008 – Section 4: updated residual solvents statement
Rev. 5; Oct. 28, 2008 – Section 1: added product codes 0312, 0344 and 0897; grade name changed from BAKER ANALYZED® Reagent to Biotech Reagent
Rev. 6; Jan. 15, 2009 – Section 4: Added Residual Metallic Catalysts statement. Section 7: Updated telephone # for Customer Service Director. Entire Document: added keywords to Solv It Center links. (KES)
Rev. 7: 3/31/09- Added product code B0337; updated letterhead; updated # for Tech. Service director
Rev. 8: 5/13/09- Added product code B0327.
Rev. 9; Jan. 6, 2010 – Entire document: Changed all references of "Solv IT Center" to "AskMBI."; Section 7: updated TS manager info. Section 1: deleted product code B0327; this product was mistakenly added to the datasheet during a previous revision. Section 4: added GRAS statement (KES)
Rev. 10; May 23, 2011 –Entire document: new letterhead, and changed all references of "AskMBI" to "AskAvantor." Updated website links for new website; Section 1: removed discontinued product 0337, 0344; Mallinckrodt brand name updated to Macron; added MOC codes; Section 2: added GMP statement; Section 4: expanded allergen list; Section 5: added Nutrition and Organic statement; Section 7: updated contact information; minor formatting. (PH, JLW)
Rev. 11; Nov. 9, 2012 – HDQ address change and minor formatting; Section 1: removed discontinued product code J.T.Baker 0342 and 0344; Section 4: Added add'l allergens as listed in EU Directive 2003/89/EC; updated Residual Metallic Catalysts statement; separated Kosher/Halal status and added certification statement; Section 5: added Management of Change information; Added COA Date

Format statement; Section 7: removed contact list table and added CS/TS contact information. (MCH/JLW)
Rev. 12; Dec. 11, 2015 – Section 1: Removed delisted code 0388
Rev 13; February 25, 2019 – Entire document: new letterhead (logo & headquarters address, updated email from @avantormaterials.com to @avantorsciences.com; Section 4: Removed Residual Metallic Catalyst statement, replaced with Elemental Impurities reflective of new process material per MOC-PROC-2874 and MOC-PROC-2831. Section 5: added Storage Requirement, Batch Definition, and Country of Origin Statements (MCH)

This electronic document is valid without a signature.

Section 7 – Contact Information

Customer Service

Phone: 1-855-282-6867
1-610-573-2600 (outside U.S.)
Fax: 1-610-573-2650
CS.Specialist@avantorsciences.com

Technical Service

Phone: 1-855-282-6867
1-610-573-2600 (outside U.S.)
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The most current revision of this document is maintained on our website. Reviews and revisions are performed as warranted due to product changes or as part of the supplier audit cycle

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Material Name: Sodium Hydroxide Pellets **Product codes**: : 7680, 7001, 7772, 3728, 3718 **Date**: May 5, 2018

Source/Type of Excipient: ☐ Mineral; ☐ Mineral derived; ☐ Plant; ☐ Plant derived; ☒ Synthetic; ☐ Fermentation derived

Other (explain):

No ICH Q3D elements are intentionally added during production of this material.

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Arsenic (inorganic)	As	1	Yes ☐	No ☒	Unknown ☐	<0.5 ppm	ICP-MS (MRL=0.5 ppm)	Reported by manufacturer. Results of tested 3 batches.
Cadmium	Cd	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Reported by manufacturer. Results of tested 3 batches.
Mercury (inorganic)	Hg	1	Yes ☐	No ☒	Unknown ☐	<0.004 ppm	ICP-MS (MRL=0.004 ppm)	Reported by manufacturer. Results of tested 3 batches.
Lead	Pb	1	Yes ☐	No ☒	Unknown ☐	<0.2 ppm	ICP-MS (MRL=0.2 ppm)	Reported by manufacturer. Results of tested 3 batches.
Cobalt	Co	2A	Yes ☐	No ☒	Unknown ☐	<0.5 ppm	ICP-MS (MRL=0.5 ppm)	Reported by manufacturer.

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
								Results of tested 3 batches.
Nickel	Ni	2A	Yes ☐	No ☒	Unknown ☐	<3 ppm	ICP-MS (MRL=3 ppm)	Reported by manufacturer. Results of tested 3 batches.
Vanadium	V	2A	Yes ☐	No ☒	Unknown ☐	<0.2 ppm	ICP-MS (MRL=0.2 ppm)	Reported by manufacturer. Results of tested 3 batches.
Silver	Ag	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Reported by manufacturer. Results of tested 3 batches.
Gold	Au	2B	Yes ☐	No ☒	Unknown ☐	None	N/A	Not added to production process
Iridium	Ir	2B	Yes ☐	No ☒	Unknown ☐	None	N/A	Not added to production process
Osmium	Os	2B	Yes ☐	No ☒	Unknown ☐	None	N/A	Not added to production process
Palladium	Pd	2B	Yes ☐	No ☒	Unknown ☐	None	N/A	Not added to production process
Platinum	Pt	2B	Yes ☐	No ☒	Unknown ☐	<1 ppm	ICP-MS (MRL=1 ppm)	Reported by manufacturer. Results of tested 3 batches.
Rhodium	Rh	2B	Yes ☐	No ☒	Unknown ☐	None	N/A	Not added to production process
Ruthenium	Ru	2B	Yes ☐	No ☒	Unknown ☐	None	N/A	Not added to production process

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Selenium	Se	2B	Yes ☐	No ☒	Unknown ☐	<5 ppm	ICP-MS (MRL=5 ppm)	Reported by manufacturer. Results of tested 3 batches.
Thallium	Tl	2B	Yes ☐	No ☒	Unknown ☐	<5 ppm	ICP-MS (MRL=5 ppm)	Reported by manufacturer. Results of tested 3 batches.
Barium	Ba	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Reported by manufacturer. Results of tested 3 batches.
Chromium	Cr	3	Yes ☐	No ☒	Unknown ☐	<0.2 ppm	ICP-MS (MRL=0.2 ppm)	Reported by manufacturer. Results of tested 3 batches.
Copper	Cu	3	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS (MRL=0.1 ppm)	Reported by manufacturer. Results of tested 3 batches.
Lithium	Li	3	Yes ☐	No ☒	Unknown ☐	<1 ppm	ICP-MS (MRL=1 ppm)	Reported by manufacturer. Results of tested 3 batches.
Molybdenum	Mo	3	Yes ☐	No ☒	Unknown ☐	<0.5 ppm	ICP-MS (MRL=0.5 ppm)	Reported by manufacturer. Results of tested 3 batches.
Antimony	Sb	3	Yes ☐	No ☒	Unknown ☐	<5 ppm	ICP-MS (MRL=5 ppm)	Reported by manufacturer. Results of tested 3 batches.
Tin	Sn	3	Yes ☐	No ☒	Unknown ☐	<1 ppm	ICP-MS (MRL=1 ppm)	Reported by manufacturer. Results of tested 3 batches.

Reference: ICH Q3D Guideline for Elemental Impurities, Step 5 version.



David L. Cugini, Sr. QA Analyst

Prepared by the Technical Service Department

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Material: Sodium Hydroxide Solutions **Product codes**: 0312, 0328, 0329, 0338, 0339, 0389, 0390, 0895, 0896, 0897, 5000, 5668

Date: February 25, 2019

Source/Type of Excipient: ☐ Mineral; ☐ Mineral derived; ☐ Plant; ☐ Plant derived; ☒ Synthetic; ☐ Fermentation derived

Other (explain):

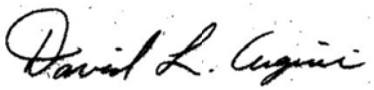
No ICH Q3D elements are intentionally added during production of this material.

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Arsenic (inorganic)	As	1	Yes ☐	No ☒	Unknown ☐	<0.3 ppm	ICP-MS on solid pellets (MRL=0.5 ppm)	Calculated from NaOH pellets used in solution makeup
Cadmium	Cd	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Mercury (inorganic)	Hg	1	Yes ☐	No ☒	Unknown ☐	<0.004 ppm	ICP-MS on solid pellets (MRL=0.004 ppm)	Calculated from NaOH pellets used in solution makeup
Lead	Pb	1	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS on solid pellets (MRL=0.2 ppm)	Calculated from NaOH pellets used in solution makeup

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Cobalt	Co	2A	Yes ☐	No ☒	Unknown ☐	<0.3 ppm	ICP-MS on solid pellets (MRL=0.5 ppm)	Calculated from NaOH pellets used in solution makeup
Nickel	Ni	2A	Yes ☐	No ☒	Unknown ☐	<2 ppm	ICP-MS on solid pellets (MRL=3 ppm)	Calculated from NaOH pellets used in solution makeup
Vanadium	V	2A	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS on solid pellets (MRL=0.2 ppm)	Calculated from NaOH pellets used in solution makeup
Silver	Ag	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Gold	Au	2B	Yes ☐	No ☒	Unknown ☐	None	N/A	Not added to NaOH pellet production process
Iridium	Ir	2B	Yes ☐	No ☒	Unknown ☐	None	N/A	Not added to NaOH pellet production process
Osmium	Os	2B	Yes ☐	No ☒	Unknown ☐	None	N/A	Not added to NaOH pellet production process
Palladium	Pd	2B	Yes ☐	No ☒	Unknown ☐	None	N/A	Not added to NaOH pellet production process
Platinum	Pt	2B	Yes ☐	No ☒	Unknown ☐	<0.5 ppm	ICP-MS on solid pellets (MRL=1 ppm)	Calculated from NaOH pellets used in solution makeup
Rhodium	Rh	2B	Yes ☐	No ☒	Unknown ☐	None	N/A	Not added to NaOH pellet production process

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Ruthenium	Ru	2B	Yes ☐	No ☒	Unknown ☐	None	N/A	Not added to NaOH pellet production process
Selenium	Se	2B	Yes ☐	No ☒	Unknown ☐	<3 ppm	ICP-MS on solid pellets (MRL=5 ppm)	Calculated from NaOH pellets used in solution makeup
Thallium	Tl	2B	Yes ☐	No ☒	Unknown ☐	<3 ppm	ICP-MS on solid pellets (MRL=5 ppm)	Calculated from NaOH pellets used in solution makeup
Barium	Ba	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Chromium	Cr	3	Yes ☐	No ☒	Unknown ☐	<0.1 ppm	ICP-MS on solid pellets (MRL=0.2 ppm)	Calculated from NaOH pellets used in solution makeup
Copper	Cu	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS on solid pellets (MRL=0.1 ppm)	Calculated from NaOH pellets used in solution makeup
Lithium	Li	3	Yes ☐	No ☒	Unknown ☐	<0.5 ppm	ICP-MS on solid pellets (MRL=1 ppm)	Calculated from NaOH pellets used in solution makeup
Molybdenum	Mo	3	Yes ☐	No ☒	Unknown ☐	<0.3 ppm	ICP-MS on solid pellets (MRL=0.5 ppm)	Calculated from NaOH pellets used in solution makeup
Antimony	Sb	3	Yes ☐	No ☒	Unknown ☐	<3 ppm	ICP-MS on solid pellets (MRL=5 ppm)	Calculated from NaOH pellets used in solution makeup
Tin	Sn	3	Yes ☐	No ☒	Unknown ☐	<0.5 ppm	ICP-MS on solid pellets (MRL=1 ppm)	Calculated from NaOH pellets used in solution makeup

Reference: ICH Q3D Guideline for Elemental Impurities, Step 5 version.



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Prepared by the Technical Service Department

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