

Avantor Performance Materials, LLC
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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®	3717	Sodium Hydroxide, Pellets, N.F., Multi-Compendial	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®	3714	Sodium Hydroxide, Pellets, Multi-Compendial	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
J.T.Baker®	0290	Sodium Hydroxide, Pellets E.P.	R
J.T.Baker®	2644	Sodium Hydroxide Solution, 1M Biotech Reagent	R

J.T.Baker®

0388

Sodium Hydroxide 0.5N Solution

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 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.

For J.T.Baker® and Macron Fine Chemicals™ brand products, 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 the Avantor website. Instructions can be found by visiting the Ask Avantor link under the Resources tab or by directly linking to www.askavantor.com Keyword: Manufacturer Code. Additional information on Avantor suppliers may be available under NDA. Please reach out to the support contact in Section 7 for additional supplier information inquiries.

Section 3 – Physical/Chemical Information

CAS #: 1310-73-2

Manufacturing Process: Synthesis. Additional manufacturing process information may be disclosed under NDA upon request from the support contact in Section 7.

Raw Material Origin: Chemical

Section 4 – Regulatory Information

DMF: Avantor may hold Master File(s) for specified product codes, dependent on the country of interest. Inquire with the support contact in Section 7 for additional details.

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: To the best of our knowledge, the allergens listed in the [US FDA](#), [EU Directive 2003/89/EC](#), and [TG0-91/92](#) are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

Neither Avantor nor the Original Manufacturer do not produce any of the following types of products: antibiotics, aflatoxins, penicillin, semi-synthetic penicillins, cephalosporins, other beta-lactams, cytotoxics, steroids, medicated feeds, or pesticides.

This product is manufactured using cGMP guidelines which provide controls that allow no potential for cross contamination of any allergens or other contaminants. However, this product is not tested for the presence of these or any other allergens by Avantor or the Original Manufacturer, therefore, we do not have confirmation for the absence of any allergens in the product.

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: For J.T.Baker® and Macron Fine Chemicals™ brand products, kosher certification is aligned to the Avantor packaging site as indicated on the product Certificate of Analysis. Please refer to the site-specific kosher certificate available on AskAvantor for our most up to date listing of kosher products at (www.askavantor.com Keyword: kosher).

Halal Status: For J.T.Baker® and Macron Fine Chemicals™ brand products, halal certification is aligned to the Avantor packaging site as indicated on the product Certificate of Analysis. Please refer to the site-specific halal certificate available on AskAvantor for our most up to date listing of halal products at (www.askavantor.com Keyword: halal).

GRAS Status: The United States Food and Drug Administration (FDA) have acknowledged that some chemicals may be considered Substances Generally Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per specific 21 CFR regnums. For the latest information on whether or not an Avantor product is considered GRAS, please visit the [Electronic Code of Federal Regulations](#).

Nutritional/Supplement Facts Labeling: The product codes 3728 and 7680 listed in Section 1 are 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 and are exempt from the Nutrient Content Evaluation and Nutrient Labeling Requirements (21 CFR 101.9(j)(9)).

Organic Status: The product codes 3728 and 7680 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.

Section 5 – Miscellaneous Product Information

Certificate of Analysis Date Format: The Manufactured Date and Expiration/Retest Date on the Certificate of Analysis are reported as YYYY-MM-DD. For example, the Manufactured Date for October 1, 2021 would be reported as 2021-10-01.

Lot Numbering System and Batch Description: For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to Ask Avantor 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 reach out to the support contact in Section 7 for additional stability inquiries.

Management of Change: For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to Management of Change link under the Working with Avantor tab on the Avantor website.

Country of Origin Statement: Country of Origin is indicated on the product Certificate of Analysis. If you require further documentation, please reach out to the Trade Compliance support contact in Section 7.

Storage Requirements: Please refer to the product's Certificate of Analysis or Product Specifications. In the absence of specific storage conditions listed on its specification sheet or Certificate of Analysis, 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's SDS sheet.

Certificates of Analysis: For J.T.Baker® and Macron Fine Chemicals™ brand products, please see the current list of product specifications using the Certificate/SDS Search tool on our website [here](#).

Safety Data Sheet: For J.T.Baker® and Macron Fine Chemicals™ brand products, please see the current product safety information using the Certificate/SDS Search tool on our website [here](#).

Avantor Site Certifications: Please see the current Avantor site certifications on our website [here](#).

Site Quality Overview: Avantor maintains a self-assessment modeled after IPEC guidelines which describes site and quality system information to support the manufacturing activities of this product. Please reach out to the support contact in Section 7 for a current copy of the Site Quality Overview.

Packaging Information: Please reach out to the support contact in Section 7 for current packaging specifications.

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)

Rev 14; April 16, 2019 – Section 4: Updated Kosher statement. Reviewed materials to MOC-PROC-3131 and MOC-PROC-3125. Reviewed Elemental Impurities data. (MCH)

Rev. 15; February 26, 2020 – Entire Document: Minor formatting; Section 4; Fixed website address in Compendial Compliance statement. Updated DMF statement. Updated Elemental Impurity data for pellet products per MOC-PROC-3125. (KH)

Rev. 16; January 28, 2021 – Entire Document: Minor formatting; Section 1: Added product code 3717 in accordance with NPSU-2713 and NPSU-2714; Section 4: Updated Allergen/Hypersensitivities Information statement. Updated Elemental Impurities report for product code 0897 and 3717. Kosher Status statement updated to specify product codes. GRAS Status statement updated to specify CAS #; Section 5: Nutritional/Supplement Facts Labeling and Organic Status statements moved to Section 4 and products with FCC specifications specified. (KH)

Rev. 17; October 12, 2023 – Section 4: Updated Elemental Impurities table results as per CM-2023-000281. (EM)

Rev. 18; February 2, 2024- Added Product Code 3714 (KS)

Rev. 19; February 13, 2024- Entire Document: Adjusted formatting, grammar, and spelling errors. Removed references to other branded products in multiple statements; Section 1: Added product codes 0290, 2644, 0388 Section 3: Updated Manufacturing Process information; Section 4: Removed Compendial Compliance information, Updated Kosher and Halal statements and GRAS Status information; Section 5: Updated Certificate of Analysis Date Format information, Added Certificates of Analysis, Avantor Site Certifications, Site Quality Overview and Packaging Information; Section 7: Updated contact information (KS)

This electronic document is valid without a signature.

Section 7 – Contact Information

Technical Service

Phone: 1-855-282-6867 and 1-610-573-2600 (outside U.S.), select option 5

Email: Technical.Service@avantorsciences.com

Regulatory Support

Email: regulatory.support@avantorsciences.com

Trade Compliance

Email: Trade.Compliance@avantorsciences.com

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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 and managed under a validated document control system.

Avantor Performance Materials, LLC
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Material Name: Sodium Hydroxide Pellets **Product codes:** 7680, 7001, 7772, 3728, 3718, 3717 **Date:** October 12, 2023; Rev. 1

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

Other (explain):

No Class 1, 2A, 2B or 3 elements are intentionally added to the 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.)
Arsenic (inorganic)	As	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Nickel	Ni	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	1.09 - 1.34 ppm	ICP-MS (MRL=0.05 ppm)	Range of 3 batches
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL

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.)
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Range of 3 batches
Chromium	Cr	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.21 – 0.22 ppm	ICP-MS (MRL=0.05 ppm)	Range of 3 batches
Copper	Cu	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Molybdenum	Mo	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL

Reference: ICH Q3D Guideline for Elemental Impurities

A handwritten signature in black ink that reads 'David L. Cugini'.

David L. Cugini, Sr. QA Analyst

While the above information is provided in good faith and believed to be accurate as of the date provided, Avantor Performance Materials ("Avantor") makes no representations or warranties as to the accuracy or completeness of such information. All Avantor products are subject to Avantor's terms and conditions of sale including the limitations of liability contained therein and any contrary terms and conditions are expressly rejected. As Avantor has no control over purchasers' uses of its products, Avantor expressly disclaims all liability with respect to same.

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, 3717 **Date:** October 12, 2023; Rev. 1

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

Other (explain):

No Class 1, 2A, 2B or 3 elements are intentionally added to the 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.)
Arsenic (inorganic)	As	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Nickel	Ni	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	1.09 - 1.34 ppm	ICP-MS (MRL=0.05 ppm)	Range of 3 batches
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Range of 3 batches
Chromium	Cr	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.21 – 0.22 ppm	ICP-MS (MRL=0.05 ppm)	Range of 3 batches
Copper	Cu	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL

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.)
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Molybdenum	Mo	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches, all below MRL

Reference: ICH Q3D Guideline for Elemental Impurities



David L. Cugini, Sr. QA Analyst

Prepared by the Technical Service Department
Avantor™ Performance Materials, LLC

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

Date: April 12, 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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.5 ppm)	Calculated from NaOH pellets used in solution makeup
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.004 ppm)	Calculated from NaOH pellets used in solution makeup
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.2 ppm)	Calculated from NaOH pellets used in solution makeup
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.5 ppm)	Calculated from NaOH pellets used in solution makeup
Nickel	Ni	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.36 to 0.42 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 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.)
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.10 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Chromium	Cr	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.12 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS on solid pellets (MRL=0.05 ppm)	Calculated from NaOH pellets used in solution makeup

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



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