Avantor, Inc.
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Hydrochloric Acid

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered

Brand	Product Code	Product Description	MOC* code
J.T.Baker®	0319	Hydrochloric Acid, 5.0N Solution Biotech Reagent	R
J.T.Baker®	0322	Hydrochloric Acid, 0.25 N Solution Biotech Reagent	R
Macron Fine Chemicals™	0323	Hydrochloric Acid, 25% Biotech Reagent	R
J.T.Baker®	0325	Hydrochloric Acid, 1.0 N Solution Biotech Reagent	R
Macron Fine Chemicals™	0327	Hydrochloric Acid, 6.0N Solution Biotech Reagent	R
J.T.Baker®	0335	Hydrochloric Acid, 0.5N Solution Biotech Reagent	R
J.T.Baker®	0336	Hydrochloric Acid, 2.0N Solution Biotech Reagent	R
J.T.Baker®	0347	Hydrochloric Acid, 6.0N Solution Biotech Reagent	R
J.T.Baker®	9544	Hydrochloric Acid, N.F. Multi-Compendial	R
Macron Fine Chemicals™	2062	Hydrochloric Acid N.F., F.C.C., A.C.S.	R
J.T.Baker®	2515	Hydrochloric Acid NF - GenAR®	R
Macron Fine Chemicals™	2608	Hydrochloric Acid, Diluted N.F.	R
J.T.Baker®	2612	Hydrochloric Acid (HCl 36.5%-38.0%) N.F., F.C.C., A.C.S.	R
Macron Fine Chemicals™	2626	Hydrochloric Acid NF - GenAR®	R
Macron Fine Chemicals™	V226	Hydrochloric Acid, NF, FCC	R
J.T.Baker®	CH09	Hydrochloric Acid, N.F. Multi-Compendial	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 or EP monograph 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 thefinished, 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 #: 7647-01-0

Manufacturing Process: Synthesis, Distillation. 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 Regulatory 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.

Avantor does not produce any of the following types of products: antibiotics, penicillin, semi-synthetic penicillin, 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 including aflatoxins. However, this product is not tested for the presence of these or any other allergens by Avantor, 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 summaries 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 2062 and 2612 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 2062 and 2612 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 (www.askavantor.com Keyword: Lot Number) for information concerning our lot/batch numbering system.

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; Feb. 15, 2008 – Added product code V226 in Section 1
Rev. 2; Sept. 29, 2008 – Section 4: updated residual solvents information
Rev. 3; Oct. 8, 2008 – Section 4: Added Carrageenan to allergens list
Rev. 4; Oct. 26 2009 – Entire document: new letterhead and changed all references of "Solv IT Center" to "AskMBI."; Section 7: updated Director of CS and TS manager info. (JLW)
Rev. 5; Nov. 20, 2009 – Section 5: added GRAS status. (KES)
Rev. 6; Mar. 15, 2011- Section 1: deleted code 9540 (discontinued), changed Mallinckrodt to Macron. Entire document: new letterhead and changed all references of "AskMBI" to "AskAvantor." Updated website links for new website; Section 7: updated contact information. (JLW)
Rev. 7; April 7. 2011- Section 4: updated DMF statement to Avantor; Added Residual Metallic Catalysts statement. (MCH)
Rev. 8; August 22, 2011 – Entire document: Changed all references of "AskMBI" to "AskAvantor."; Section 1: added MOC codes; Section 2: added GMP statement; Section 4: expanded Allergens list; updated and moved GRAS statement from section 5 to section 4; Section 5: Added Nutritional/Supplemental Facts Labeling and Organic Status statements; Section 7: updated contact information. PH/MCH
Rev. 9; May 22, 2012: Entire document: updated headquarters address. Section 1: Added product 0319. Section 7: updated phone numbers to contacts at new HQ's.(MCH)
Rev. 10; Dec. 3, 2012 – Entire document: minor formatting; Section 1: Added product 0345; 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)
Rev. 11; Dec. 11, 2015 – Section 1: Removed delisted code 0365.
Rev. 12; Dec. 20, 2016 – Section 1: Removed delisted codes 0345, 0326 (Delist-00021),. Added code 0347. (MCH)
Rev. 13: August 3, 2017 – Entire document: new letterhead, new format; Section 4: Replaced Residual Metallic Catalysts with Elemental Impurities statement. (MCH)
Rev. 14; November 14, 2018 - Entire Document: New Format. (EC)
Rev. 15; January 17, 2020 - Entire document: New format and letterhead (company name & headquarters address). Updated email and website address from avantorinc.com to avantorsciences.com. Added website link for AskAvantor; Section 1: Added product code 0322 in

accordance with NPSU-2588; Section 4: Updated DMF statement. Updated Kosher statement to specify product codes; Section 5: Updated Certificate of Analysis Date Format statement. (KH)
Rev. 16; February 18, 2020 – Section 1: Added Product code 0325. Product code was inadvertently omitted during last revision. (KH)
Rev. 17; May 6, 2021- Entire Document: Minor formatting; Section 1: Added product code CH09 in accordance with NPSU-2697; Section 4: Updated Allergen/Hypersensitivities Information statement. Moved the Nutritional/Supplement Facts Labeling and Organic Status statements from Section 5 to Section 4 and specified the product codes supported by this statement. Added CH09 to Kosher statement and Elemental Impurity assessment. (KH)
Rev. 18; August 10, 2023 – Updated to current template. 2608 brand BAKR corrected to "Macron", reviewed for EI report (concentrate solutions only tested), (SS)

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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Material Name: Dilute Hydrochloric Acid **Product codes**: 2608 **Date**: May 18, 2016

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

Other (explain):

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 ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Cadmium	Cd	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Mercury (inorganic)	Hg	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Lead	Pb	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Cobalt	Co	2A	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Nickel	Ni	2A	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches

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.)
Vanadium	V	2A	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Silver	Ag	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Gold	Au	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Iridium	Ir	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Osmium	Os	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Palladium	Pd	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Platinum	Pt	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Rhodium	Rh	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Ruthenium	Ru	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Selenium	Se	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Thallium	Tl	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Barium	Ba	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Chromium	Cr	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches

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.)
Copper	Cu	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Lithium	Li	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Molybdenum	Mo	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Antimony	Sb	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Tin	Sn	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches

Reference: ICH Q3D Guideline for Elemental Impurities, Step 4 version, September 2014

David L. Cugini, Sr. QA Analyst

Prepared by the Technical Service Department

Avantor™ Performance Materials, LLC

Material Name: Hydrochloric Acid **Product codes**: 9544, 2626, 2062, 2612, 2515, CH09 **Date**: April 4, 2016 Rev. 1

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

Other (explain):

No ICH Q3D elements are intentionally added to the manufacturing 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 ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Cadmium	Cd	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Mercury (inorganic)	Hg	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Lead	Pb	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Cobalt	Co	2A	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches

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.)
Nickel	Ni	2A	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Vanadium	V	2A	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Silver	Ag	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Gold	Au	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Iridium	Ir	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Osmium	Os	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Palladium	Pd	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Platinum	Pt	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Rhodium	Rh	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Ruthenium	Ru	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Selenium	Se	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Thallium	Tl	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Barium	Ba	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches

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.)
Chromium	Cr	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Copper	Cu	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Lithium	Li	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Molybdenum	Mo	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Antimony	Sb	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Tin	Sn	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches

Reference: ICH Q3D Guideline for Elemental Impurities, Step 4 version, September 2014

David L. Cugini, Sr. QA Analyst

Prepared by the Technical Service Department

Avantor™ Performance Materials, LLC