

Avantor Performance Materials, LLC
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Sodium Phosphate, Monobasic, Monohydrate

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>
J.T.Baker®	3820	Sodium Phosphate, Monobasic, Monohydrate, Crystal U.S.P. - F.C.C.	HR
J.T.Baker®	3821	Sodium Phosphate, Monobasic, Monohydrate, Crystal U.S.P. - F.C.C.	HR
J.T.Baker®	3802	Sodium Phosphate, Monobasic, Monohydrate, U.S.P. Multi-Compendial	HR
J.T.Baker®	3808	Sodium Phosphate, Monobasic, Monohydrate U.S.P., A.C.S.	R
J.T.Baker®	4954	Sodium Phosphate, Monobasic, Monohydrate U.S.P. Endotoxin Tested	HR
J.T.Baker®	CH04	Sodium Phosphate, Monobasic, Monohydrate, U.S.P. Multi-Compendial	R
J.T.Baker®	LP10	Sodium Phosphate, Monobasic, Monohydrate, U.S.P. Multi-Compendial	HR
J.T.Baker®	BS22	Sodium Phosphate, Monobasic, Monohydrate, U.S.P. Multi-Compendial	HR

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

The product codes 3820, 3821, 3802, 4954, LP10, and BS22 listed in Section 1 are manufactured under current Good Manufacturing Practices (cGMPs) as set forth by ICH Q7 and International Pharmaceutical Excipients Council (IPEC) guidelines.

The product code 3808 and CH04 listed in Section 1 is 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 #: 10049-21-5

Manufacturing Process: Synthesis- Chemical Reaction

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 may hold Master File(s) for specified product codes, dependant on the country of interest. Inquire with regulatory.support@avantorsciences.com 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 Performance Materials, LLC does not produce any of the following types of products: Antibiotics, Aflatoxins, Penicillin, Semi-Synthetic Penicillins, Cephalosporins, other Beta-Lactams, Antibiotics, 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 Performance Materials, LLC, 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: Certified Kosher – 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: The subject materials are not 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) has assessed sodium phosphate monobasic as a phosphate salt and indicated a conclusion Type 1: "There is no evidence in the available information on [substance] that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current or might reasonably be expected in the future." There is no CFR reference for sodium phosphate monobasic with regard to GRAS status. Refer to Database of Select Committee on GRAS Substances (SCOGS) Reviews report number 32.

Nutritional/Supplement Facts Labeling: The product codes 3820 and 3821 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, are exempt from the Nutrient Content Evaluation and Nutrient Labeling Requirements. (21 CFR 101.9(j)(9))

Organic Status: The product codes 3820 and 3821 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.askavantort.com Keyword: Lot Number). For other branded products, please reach out to the support contact in Section 7 for the certificate, if available.

Product numbers for J.T. Baker® and Macron Fine Chemicals™ products consist of 6 characters* in the format "XXXX-XX". The first 4 characters ("XXXX") form the root product code and are followed by a 2 character suffix ("-XX") which identifies the package size. The first 4 characters identify individual material which has the same specifications, MOC (Management of Change) code and, for GMP products, the same source manufacturer. The suffix denotes different packaging sizes only. When products are identified by only the four-digit product code without the package size, all package sizes for that product are intended to be included in the reference.

*Note, the product number may be alphanumeric, e.g. V078-04, and may be 5-digits for bulk product codes, e.g. 3628-R.

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. For other branded products, please reach out to the support contact in Section 7 for information on the applicable management of change process.

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](#). For

other branded 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](#). For other branded products, please see the current list of product specifications 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; Sept. 11, 2008 – Section 4: Updated Residual Solvents statement to reference USP Chapter <467>

Rev. 2; Oct. 1, 2008 – Section 4: updated residual solvents information

Rev. 3; Jan. 26, 2010 – Entire document: new letterhead and changed all references of "Solv IT Center" to "AskMBI."; Section 7: updated TS manager info. Section 4: added Residual Metallic Catalysts statement and GRAS information. (KES)

Rev. 4; May 5, 2011 – Entire document: new letterhead and changed all references of "AskMBI" to "AskAvantor." Updated website links for new website; Section 1: Mallinckrodt brand name updated to Macron; added MOC codes; Section 2: added GMP statement; Section 6: added Nutrition and Organic statement; Section 7: updated contact information; minor formatting. (PH, JLW)

Rev. 5; March 12, 2013 – HDQ address change, minor formatting; Section 2: Updated GMP statements; 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. 6; April 9, 2014 – Section 4: Updated EMEA Residual Metallic statement to reflect current guideline revision. (MCH)

Rev. 7; Dec. 4, 2014 – Section 1: Added code 3808. (MCH)

Rev. 8; November 30, 2018 – Entire document: new letterhead (logo & headquarters address, updated email from @avantormaterials.com to @avantorinc.com ; Section 1: Removed delisted codes 7774, 7868, added code CH04; Section 4: Removed Residual Metallic Catalyst statement, updated with Elemental Impurities; Section 5: added Storage Requirement, Batch Definition, and Country of Origin Statements (MCH)

Rev 9; July 21, 2021- Entire Document: Minor formatting. Changed website and email addresses from avantorinc.com to avantorsciences.com; Section 1: Added product codes BS22 and LP10; Section 2 Specified product codes for guidelines; Section 4: Updated DMF and Allergen/Hypersensitivities Information statements. Updated Elemental Impurity report to include added product codes. Moved Nutritional/Supplement Facts Labeling and Organic Status statements and specified product codes (previously in Section 5); Section 7: Added email addresses to Contact Information. (KH)
Rev 10; October 22, 2022- CH04 changed "HR" to "R" MOC code per MOC-QUAL-9317 Added product 4954(SS)
Rev 11; added 4954 to EI report, updated to current format with contacts and corrected typo from document tracking.(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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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.



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Material Name: Sodium Phosphate Monobasic Monohydrate

Date: November 3, 2022 Rev. 2

Product codes: 3802, 3808, 3820, 3821, 4954, CH04, LP10, BS22

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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
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)	Avg. of 3 batches
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)	Avg. of 3 batches
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)	Avg. of 3 batches
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)	Avg. of 3 batches
Nickel	Ni	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.1 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.)
			Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>			
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)	Avg. of 3 batches
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)	Avg. of 3 batches
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)	Avg. of 3 batches
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)	Avg. of 3 batches
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)	Avg. of 3 batches
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)	Avg. of 3 batches
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)	Avg. of 3 batches
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)	Avg. of 3 batches
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)	Avg. of 3 batches
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)	Avg. of 3 batches
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)	Avg. of 3 batches
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)	Avg. of 3 batches
Chromium	Cr	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.3 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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.07 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
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)	Avg. of 3 batches
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
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)	Avg. of 3 batches
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)	Avg. of 3 batches

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



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

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