

Avantor Performance Materials, LLC
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Radnor, PA 19087 USA
www.avantorsciences.com

Potassium Phosphate Dibasic

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®	3222	Potassium Phosphate, Dibasic U.S.P., A.C.S.	R
J.T.Baker®	3250	Potassium Phosphate, Dibasic, U.S.P. Multi-Compendial	HR
J.T.Baker®	3251	Potassium Phosphate, Dibasic U.S.P.	R
J.T.Baker®	3255	Potassium Phosphate, Dibasic, Anhydrous Multi-Compendial	HR
J.T.Baker®	325A	Potassium Phosphate, Dibasic, U.S.P. Multi-Compendial	HR

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

The product codes 3250, 3255, and 325A, 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 codes 3222 and 3251, listed 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 #: 7758-11-4

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, Cytotoxics, Steroids, Medicated Feeds, or Pesticides.

This product is manufactured and packaged 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 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: 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) have acknowledged that Potassium Phosphate Dibasic (CAS # 7758-11-4) is a Substance Generally Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per 21 CFR parts 182.6285.

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)

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; Oct. 22, 2008 – Section 4: updated residual solvents information

Rev. 2; Jul. 22, 2009 – Section 1: added product number 7787; Section 7: reviewed and updated contact information; Entire Document: new letterhead, added 'keywords' to Q&A Center of the customer support section of our web site references. (KES)

Rev. 3; Jul. 22, 2011 – Entire document: new letterhead and changed all references of "AskMBI" to "AskAvantor." Updated website links for new website; minor formatting; Section 1: changed Mallinckrodt to Macron brand; added MOC codes; Section 2: added GMP statement; Section 4: expanded Allergens list; added GRAS statement; Section 7: updated contact information. (PH, JLW)

Rev. 4; June 24, 2013 – Entire document: updated headquarters address; 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. 5- March 13, 2014- Updated EMEA statement to reflect current guideline revision. (MCH)

Rev. 6- Dec. 4, 2014 – Section 1: Added code 3222. (MCH)

Rev. 7; November 14, 2018 – Entire document: new letterhead (logo & headquarters address, updated email from @avantormaterials.com to @avantorinc.com. Section 1: Removed product code 7787. updated MOC code from R to HR for 3250; Section 4: Updated DMF statement Replaced Residual Metallic Catalyst statement with Elemental Impurities statement. Section 5: added Storage Requirement, Batch Definition, and Country of Origin Statements (MCH)

Rev. 8; April 5, 2021 – Entire Document: Minor formatting. Changed website and email address from avantorinc.com to avantorsciences.com; Section 1: Added product codes 3255 per NSPU-2644 and 325A per NPSU-2797; Section 2: Updated language to specify guideline used for the manufacture of each product code; Section 4: Updated DMF and Allergen/Hypersensitivities Information statements Updated Elemental Impurity report to include new product codes; Section 5: Removed Nutritional/Supplement Facts Labeling and Organic Status statements. Products are not F.C.C. (KH)

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.)
Fax: 1-610-573-2650
Technical.Service@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

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Material Name: Potassium Phosphate Dibasic **Product codes:** 3250, 3222, 3251, 3255, 325A **Date:** September 28, 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 <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 checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.5 ppm	ICP-MS (MRL=0.05 ppm)	Avg. 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)	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"/>			
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"/>	0.6 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Copper	Cu	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

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"/>			
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 checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.14 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



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