

Avantor Performance Materials, LLC  
100 Matsonford Rd., Suite 200  
Radnor, PA 19087 USA  
[www.avantorsciences.com](http://www.avantorsciences.com)

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# Sodium Phosphate Dibasic Heptahydrate

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## Product Regulatory Data Sheet

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### Section 1 – Product Information

#### Products Covered

<u>Brand</u>	<u>Product Code</u>	<u>Product Description</u>	<u>MOC* code</u>
J.T.Baker®	3803	Sodium Phosphate, Dibasic, 7-Hydrate U.S.P.	HR
J.T.Baker®	3816	Sodium Phosphate, Dibasic, 7-Hydrate, Crystal U.S.P.	HR
J.T.Baker®	3817	Sodium Phosphate, Dibasic, 7-Hydrate, Crystal U.S.P.	HR

\*MOC = Management of Change

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### Section 2 – Manufacturing, Packaging and Release Site Information

The products 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.

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](http://www.askavantor.com) Keyword: Manufacturer Code.

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### Section 3 – Physical/Chemical Information

CAS #: 7782-85-6

**Manufacturing Process:** Synthesis- Chemical Reaction, batch process, not dedicated

**Raw Material Origin:** Chemical

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#### **Section 4 – Regulatory Information**

**Compendial Compliance:** Please see the current product specifications at [www.avantorsciences.com](http://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](mailto: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, 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](http://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](http://www.askavantor.com) Keyword: Halal)

**GRAS Status:** The United States Food and Drug Administration (FDA) has assessed sodium phosphate dibasic 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 dibasic with regard to GRAS status. Refer to Database of Select Committee on GRAS Substances (SCOGS) Reviews report number 32.

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#### ***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](http://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](http://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](http://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](mailto: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.

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### **Section 6 – Revision History**

Rev. 0; Oct. 1, 2007 – IPEC EIP format

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

Rev. 2; Jan. 27, 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 and GRAS information. (KES)

Rev. 3; June 17, 2011 – Entire document: new letterhead and changed all references of "Solv IT Center" or "AskMBI" to "AskAvantor." Updated website links for new website; minor formatting; Section 1: added MOC codes; Section 2: added GMP statement; Section 5: added Nutritional/Supplement Facts Labeling and Organic Status statements; Section 7: updated contact information. MCH.

Rev. 4; March 12, 2013 – HDQ address change, minor formatting; 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; June 6, 2017 – Entire document- updated to new format. Section 1: Removed delisted product codes 7393 and 7896; Section 4: Replaced Residual Metallic Catalysts with elemental Impurities. (MCH)

Rev. 6; November 21, 2018 – Entire Document: New Format. (EC)

Rev. 7 July 15, 2021 – Entire Document Minor formatting. Updated website and email addresses from avantorinc.com to avantorsciences.com; Section 4: Updated DMF and Allergen/Hypersensitivities Information statements. (KH)

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*This electronic document is valid without a signature.*

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### **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](mailto: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](mailto: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:** Sodium Phosphate Dibasic Heptahydrate **Product codes:** 3803, 3816, 3817 **Date:** October 7, 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 type="checkbox"/>	Unknown <input type="checkbox"/>	0.09 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.)
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"/>	0.1 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 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





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