

Avantor Performance Materials, LLC  
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[www.avantorsciences.com](http://www.avantorsciences.com)

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# Sodium Phosphate Dibasic Anhydrous

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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®   | 3804                | Sodium Phosphate, Dibasic, Anhydrous, U.S.P. Multi-Compendial | R                |
| J.T.Baker®   | 3826                | Sodium Phosphate, Dibasic, Anhydrous U.S.P., A.C.S.           | HR               |
| J.T.Baker®   | 3827                | Sodium Phosphate, Dibasic, Anhydrous U.S.P.                   | HR               |
| J.T.Baker®   | 4953                | Sodium Phosphate, Dibasic, Anhydrous, U.S.P. Multi-Compendial | HR               |
| J.T.Baker®   | CH05                | Sodium Phosphate, Dibasic, Anhydrous, U.S.P. Multi-Compendial | R                |

\*MOC = Management of Change

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

The product codes 3826, 3827 and 4953 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 3804, and CH05 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](http://www.askavantor.com) Keyword: Manufacturer Code.

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### **Section 3 – Physical/Chemical Information**

**CAS #:** 7558-79-4

**Manufacturing Process:** Synthesis by chemical reaction

**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 [TGO-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](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) have acknowledged that Sodium Phosphate Dibasic is a Substance Generally Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per 21 CFR part 182.1778.

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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:** 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.

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### **Section 6 – Revision History**

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

Rev. 1; Sept. 24, 2008 – Section 4: updated residual solvents statement

Rev. 2; Jan. 16, 2009 – Section 1: deleted discontinued product code 3807; Section 4: added DMF reference for 3826

& 3827; Section 7: updated Director of Customer Service phone number; Added keywords where Q&A Center of the customer support section of our web site is referenced

Rev. 3; 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. 4; June 23, 2011 – Entire document: new letterhead, and changed all references of "Solv IT Center" or "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 5: Added Nutritional/Supplement Facts Labeling and Organic Status statements; Section 7: updated contact information; minor formatting. PH-MCH.

Rev. 5; Oct 24, 2014 – HDQ address change. Section 1: Update MOC codes for 3826 and 3827 to HR per MOC-QUAL-6749;–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; May 31, 2018 – Updated to new format; Section 1: removed product code 7771; Section 4: removed Residual Metallic Catalysts, added Elemental Impurity Statement; revised GRAS Status. (PT)

Rev. 7; July 11, 2018 – Revised Datasheet Title to Anhydrous; Section 4: changed the EI attachment to the Anhydrous'. (PT)

Rev. 8; November 21, 2018 – Entire Document: New Format. (EC)

Rev 9: December 13, 2018 –Section 1: added products CH05 and 4953. (MCH)

Rev. 10; April 23, 2021 – Entire Document: Minor formatting. Updated website and emails from avantorinc.com to avantorsciences.com; Section 1: Removed F.C.C. from the Product Description for product codes 3826 and 3827 in accordance with MOC-QUAL-9087; Section 2: Specified product codes; Section 4: Updated DMF and Allergen/Hypersensitivities Information statements; Section 5: Nutritional/Supplement Facts Labeling and Organic Status statements removed due to the removal of the F.C.C. specifications for the listed products. (KH)

Rev. 11; November 4, 2022 – product 4953 changed from “R” to “HR” per MOC-QUAL-9461, updated to current EIP document format(SS)

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*This electronic document is valid without a signature.*

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## **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](mailto:Technical.Service@avantorsciences.com)

### Regulatory Support

Email: [regulatory.support@avantorsciences.com](mailto:regulatory.support@avantorsciences.com)

### Trade Compliance

Email: [Trade.Compliance@avantorsciences.com](mailto: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 does not automatically notify customers of updated revisions; Please submit a request to our Technical Service group to confirm current revision number.



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**Material Name:** Sodium Phosphate Dibasic Anhydrous **Product codes:** 3804, 3826, 3827, CH05, 4953 **Date:** September 9, 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   |

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



| 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"/> |  |  |   |
| 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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