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Calcium Phosphate, Tribasic

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>
Macron Fine Chemicals™	4280	Calcium Phosphate, Tribasic, Powder N.F. - F.C.C.	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 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 #: 1306-06-5

Manufacturing Process: Synthesis

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: According to the Original Manufacturer, allergenic substances as specified in the U.S. Food Allergen Labeling and Consumer Protections Act of 2004 (FALCPA) which include: milk (and milk products), eggs, fish, crustacean shellfish, tree nuts, wheat (or other cereal grains), peanuts, soybeans (and soy products) in addition to allergens of concern in other world regions or countries including: gluten, sesame seeds, mustard (or mustard seeds), celery, sulfites, molluscan shellfish, and lupin are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

Neither Avantor nor the Original Manufacturer 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 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 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: This product has not been assessed for Elemental Impurities.

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.askavantort.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.askavantort.com Keyword: Halal)

GRAS Status: CAS # 1306-06-5 has not been assessed as GRAS under CFR parts 181, 182, 184 or 186.

Nutritional/Supplement Facts Labeling: 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 products 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 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.askavantort.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.askavantort.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.askavantort.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. 9, 2008 – Section 4: updated residual solvents information

Rev. 2; Nov. 18, 2011 – Entire document: new letterhead (company name & headquarters address); changed all references of "Solv IT Center" to "AskAvantor"; updated website links to new Avantor website; minor formatting; Section 1: Mallinckrodt brand name changed to Macron; added MOC codes; Section 2: added GMP statement; Section 3: changed Cas No from 12167-74-7 to 1306-06-5 to be aligned with Avantor's documentation; Section 4: expanded Allergens list; added GRAS statement; Section 5: Added Nutritional/Supplemental Facts Labeling and Organic Status statements; Section 7: updated contact information. (PH/JLW)

Rev. 3; June 17, 2013 –Section 4: added add'l allergens as listed in EU Directive 2003/89/EC; Added Residual Metallic Catalysts statement; separated Kosher/Halal status and added certification statement; Section 5: added Management of Change information; Added COA Date Format statement; added Phthalate statement. Section 7: removed contact list table and added CS/TS contact information. (MCH)

Rev. 4; January 14, 2020 - Entire document: New format and letterhead (company name & headquarters address). Updated website address from avantormaterials.com to avantorsciences.com. Added website link for AskAvantor; Section 4: DMF statement updated. Removed Residual Metallic Catalyst statement, replaced with Elemental Impurities (optional until 2018). GRAS Status statement updated to reflect CAS number; Section 5: Added Batch Definition, Country of Origin Statement, and Storage Requirements statements; Section 7: Added email addresses to contact information. (KH)

Rev. 5; January 18, 2021 – Entire Document: Minor formatting; Section 4: Updated Allergen/Hypersensitivities Information statement; Section 5: Moved Nutritional/Supplement Facts Labeling and Organic Status statements to Section 4. Removed Phthalate Statement. (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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