

PRODUCT REGULATORY INFORMATION DATASHEET
Non-Botanical Dietary Ingredients

Section 1. PRODUCT INFORMATION	
PRODUCT CODE & NAME	Macron Fine Chemicals™ 4880 CALTAC™ F.C.C.
MANAGEMENT OF CHANGE(MOC) CODE	RL- REGULATED LIMITED

Section 2. MANUFACTURING INFORMATION	
NAME AND ADDRESS OF MANUFACTURING SITE	For J.T.Baker® and Macron Fine Chemicals™ brand products, 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. Additional information on Avantor suppliers may be available under NDA. Please reach out to the support contact in Section 8 for additional supplier information inquiries.
MANUFACTURING, PACKAGING AND RELEASE SITE INFORMATION	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. Please see the Certificate of Analysis for more details.
MANUFACTURING PROCESS	Synthesis
RAW MATERIAL	Chemical
GMP COMPLIANCE	The food grade chemicals are manufactured in accordance with Food Chemicals Codex (F.C.C.) and Food cGMP standards and are suitable only for food manufacturing. This product meets F.C.C. requirements.
STERILIZATION OR FUMIGATION METHOD(S)	Not Applicable
KNOWN OR POTENTIAL SOURCES OF IMPURITIES AND/OR CONTAMINANTS	Please see the Certificate of Analysis for any trace impurities reported.

PRODUCT REGULATORY INFORMATION DATASHEET

Non-Botanical Dietary Ingredients

Section 3. PHYSICAL/CHEMICAL INFORMATION				
INGREDIENT(S)				
COMMON OR USUAL NAME	SYNONYM	ORIGIN	CAS NUMBER	Typical PERCENT
Calcium Chloride Anhydrous	Calcium Dichloride	Chemical	10043-52-4	93.0-100.5%
CURRENT PRODUCT SPECIFICATION SHEET		Please see the current product specifications at www.avantorsciences.com or contact Technical Service		

Section 4. LABELING INFORMATION	
REQUIRED FINISHED PRODUCT LABEL STATEMENTS	N/A. This is sold as a bulk food chemical.
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))

Section 5. REGULATORY INFORMATION	
COMPENDIAL GRADE	F.C.C.
BSE/TSE INFORMATION	The subject materials are manufactured from raw materials that do not contain animal parts, products, and/or by-products nor do they come in contact with animal parts, products, and/or by-products.
SUITABLE FOR VEGAN OR VEGETARIAN	Yes
ALLERGENS/ HYPERSENSITIVITIES/ PRESERVATIVES (or PROCESSING AIDS)	Our supplier confirmed that this product does not contain applicable ingredients that could cause allergic reactions – including soy products, eggs products, milk and milk products, peanuts, soybeans, wheat, barley, oats, rye, gluten, proteins, fish, shell fish (crustacean or mollusk products), tree nut and tree nut products, mustard, celery, cotton, sesame, sunflower, poppy seeds, Avantor does not produce any of the following types of products: Antibiotics, Penicillin, Semi-Synthetic Penicillins, Cephalosporins, other Beta-Lactams, Cytotoxics, Steroids, Medicated Feeds, or Pesticides. These products are manufactured and packaged using cGMP guidelines which provide controls that allow no potential for cross contamination of any allergens or other contaminants including aflatoxins. However, they are not tested for the presence of any allergens by Avantor therefore, we do not have confirmation for the absence of any allergens in the products.
KOSHER STATUS	This product is considered Kosher Certified. Certified Kosher – Pareve for year-round use and acceptable for Passover. 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

PRODUCT REGULATORY INFORMATION DATASHEET

Non-Botanical Dietary Ingredients

	support section of our website for our most up to date listing of Halal products. (www.askavantor.com Keyword: Halal)
ORGANIC STATUS	The products listed 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.
GMO STATUS	The subject materials, including any raw materials and processing aids, are not subject to genetic modification.
RESIDUAL SOLVENTS INFORMATION	The above 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.
GRAS STATUS	21 CFR 184.1193
HACCP STATUS	Avantor's Phillipsburg, NJ plant is certified under FSSC 22000. These products are manufactured under food cGMP guidelines, and our facilities are ISO 9001 certified. Please refer to the Ask Avantor Q&A Center for our most up to date listing of certificates at www.askavantor.com Keyword: ISO

Section 6. MISCELLANEOUS PRODUCT INFORMATION

LOT NUMBERING SYSTEM	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.askavantor.com Keyword: Lot Number).
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 For products that do not have assigned dates, please reach out to the support contact in Section 8 for additional stability inquiries
RECOMMENDED STORAGE CONDITIONS	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 8 of the product's SDS sheet.
MSDS	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 .
CERTIFICATE 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
CERTIFICATE OF ANALYSIS DATE FORMAT	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.

PRODUCT REGULATORY INFORMATION DATASHEET

Non-Botanical Dietary Ingredients

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 8.
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.
AVANTOR SITE CERTIFICATION	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 8 for a current copy of the Site Quality Overview.
PACKAGING INFORMATION	Please reach out to the support contact in Section 8 for current packaging specifications.

Section 7. REVISIONS

REVISION DATE:	REVISION LEVEL:	CHANGES:
April 13, 2010	0	New
June 13, 2011	1	Corrected website address; Added Gluten Status & HACCP; Updated MOC; Lot numbering – provided additional explanation. Brand name change;
March 25, 2013	2	Change HQ address & ph/fax numbers; Updated allergen list to include soybeans, milk, fish, crustacean shellfish, tree nuts, peanuts; added hyperlinks to standard documentation; Update URL links to correspond to actual answer link; Added "Electronic Signature" line; Split Kosher and Halal Status.; Added Pesticide statement; Updated lot numbering system; Updated expiration dating; Updated Contact information. (MCH)
February 8, 2018	3	Entire document: new letterhead; updated company name from Avantor Performance Materials, Inc. to Avantor Performance Materials, LLC; Section 1: Added product code 3630; Section 2: Updated Name and Address of Manufacturing Site statement; Updated MOC code Section 5: Split Kosher and Halal Status; Section 6: Updated Management of Change statement; (MCH)
March 11, 2020	4	Entire document: new letterhead, updated address, and updated website address from avantorinc.com to avantorsciences.com (KH)
June 8, 2023	5	Revised to new document template. Removed code 3630; revised Manufacturing Process and added Raw Material; removed Packaging Sizes; revised Allergens Statement; added Certificates of Analysis; added Contacts and other items. (PT)
November 6, 2023	6	Entire document: Updated links; Section 5: Updated Allergens/ Hypersensitivities/Preservatives information, Updated Kosher Status language. (EM)

This electronic document is valid without a signature.

PRODUCT REGULATORY INFORMATION DATASHEET

Non-Botanical Dietary Ingredients

Section 8. CONTACT INFORMATION	
CONTACTS	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

Avantor Performance Materials, LLC. provides the information contained herein in good faith but makes no representations or warranties, either expressed or implied, including without limitation any warranties of merchantability or fitness for a particular purpose with respect to the information set forth herein or the product(s) to which the information refers. Accordingly, Avantor Performance Materials, LLC. will not be responsible for damages resulting from the use of or reliance upon this information.

The most current revision of this document is maintained on our website. Reviews and revisions are performed as warranted due to product changes.