

PRODUCT REGULATORY INFORMATION DATASHEET

Non-Botanical Dietary Ingredients

Section 1. PRODUCT INFORMATION	
PRODUCT CODE & NAME:	Macron Fine Chemicals™ 7132 Potassium Sulfate FCC, Purified
MANAGEMENT OF CHANGE(MOC) CODE	RL- REGULATED LIMITED

Section 2. MANUFACTURING INFORMATION	
NAME AND ADDRESS OF MANUFACTURING SITE:	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. 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.
MANUFACTURING, PACKAGING AND RELEASE SITE INFORMATION:	A number of the food cGMP produced products that are sold by Avantor Performance Materials, Inc. may not be originally manufactured at our sites. However, we perform analytical testing, repackaging where applicable and product release from our facility (Paris, KY and/or Phillipsburg, NJ).
MANUFACTURING PROCESS:	Chemically Synthetic
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.

Section 3. PHYSICAL/CHEMICAL INFORMATION				
INGREDIENT(S)				
COMMON OR USUAL NAME:	SYNONYM:	ORIGIN:	CAS NUMBER:	Typical PERCENT:
Potassium Sulfate	Sulfuric acid dipotassium salt; Sal polychrestum	Chemical	7778-80-5	100%
CURRENT PRODUCT SPECIFICATION SHEET:	Please see the current product specifications at www.avantormaterials.com .			

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))

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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):	The products listed do not contain wheat, rye, oats, barley, spelt, malt, triticale, gluten, other grains, corn, soy, soybeans, eggs, yeast, canola, milk, dairy products, fish, crustacean shellfish, seafood products, tree nuts, peanuts, nut products, seed products, natural grape products, natural flavors, artificial flavors, celery, lactose, sulfites, elemental sulfur, preservatives, MSG, disodium guanylate/inosinate, artificial sweeteners, phenylalanine, additives, colorants, dyes, or natural rubber (latex). These products are manufactured using Food cGMP guidelines which provide control of potential cross contamination of any allergens or other products.
GLUTEN STATUS:	This product does not contain gluten.
KOSHER STATUS:	This product is considered Kosher certified. Please refer to the Ask Avantor Q&A Center for our most up to date listing of Kosher Certificate (www.askavantor.com Keyword: Kosher)
HALAL STATUS:	Product Macron 7132 is considered Halal. Please refer to the Ask Avantor Q&A Center for our most up to date listing of Halal Certificate (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 184.1643
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

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Section 6. MISCELLANEOUS PRODUCT INFORMATION	
LOT/BATCH NUMBERING SYSTEM:	Please refer to the customer support section of our website for information concerning our lot/batch numbering system. (www.askavantor.com Keyword: Lot Number)
EXPIRATION DATING:	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)
RECOMMENDED STORAGE CONDITIONS:	Please refer to the MSDS, Section 7. Handling and Storage.
MSDS:	MSDS are available at www.avantormaterials.com
PACKAGING SIZE(S):	Packaging sizes and container type can be obtained from our online Product Catalog at www.avantormaterials.com .
MANAGEMENT OF CHANGE CONTROL:	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)
CERTIFICATE OF ANALYSIS DATE FORMAT:	<p>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.</p> <p>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.</p>

Section 7. REVISIONS		
REVISION DATE:	REVISION LEVEL:	CHANGES:
October 22, 2010	0	New (JLW)
February 10, 2011	1	Corrected website address; added code 7128; Added Gluten Status & HACCP; Updated MOC; Lot numbering – provided additional explanation. (JLW)
August 22, 2011	2	Brand name change, Updated allergen list to include soybeans, milk, fish, crustacean shellfish, tree nuts, peanuts; added hyperlinks to standard documentation; added USA before lot number; Update URL links to correspond to actual answer link; Added “Electronic Signature” line. (MCH)
April 22, 2013	3	Change HQ address; Split Kosher and Halal Status.; Updated lot numbering system; Updated expiration dating; Updated Contact information. (MCH)
October 12, 2015	4	Section 1: Removed product code 7128(delisted); Added MOC code; Section 2: Updated Name and Address of Manufacturing Site statement; Section 5: Updated HACCP statement; Section 6: Updated Management of Change statement, Certificate of Analysis Format.(MCH)

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Section 8. CONTACT INFORMATION	
COMPANY NAME:	Avantor Performance Materials, Inc.
CONTACT NAME:	Technical Support
CONTACT PHONE:	1-855-282-6867 (1-610-573-2600 outside of U.S.)

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