

100 Matsonford Rd #200 Radnor, PA 19087 USA Technical Service Department Toll free 1 855 282 6867, select option 5 Outside U.S. 1 610 573 2600, select option 5 technical.service@avantorsciences.com

PRODUCT REGULATORY INFORMATION DATASHEET Non-Botanical Dietary Ingredients

Section 1. PRODUCT INFORMATION	
PRODUCT CODE & NAME:	Macron Fine Chemicals™ 5933 Magnesium Chloride, Hexahydrate F.C.C. Macron Fine Chemicals™ 5954 Magnesium Chloride, Flakes F.C.C. Macron Fine Chemicals™ 7550 Magnesium Chloride, 6-Hydrate F.C.C.
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, LLC. 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:	Extracted through the evaporation of sea water.
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:
Magnesium Chloride	Magnesium chloride, hexahydrate		Chemical	7791-18-6	100%
CURRENT PRODUCT SPECIFICATION SHEET:		Please see the current product specifications on CoAs available at www.avantorsciences.com .			



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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 INFOR	RMATION
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/ HYPERSENSITIVITES/ 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:	For J.T.Baker® and Macron Fine Chemicals [™] brand products, kosher certification is aligned to the Avantor packaging site as indicated on the product Certificate of Analysis. Please refer to the site-specific kosher certificate available on AskAvantor for our most up to date listing of kosher products at (www.askavantor.com Keyword: kosher).
HALAL STATUS:	For J.T.Baker® and Macron Fine Chemicals [™] brand products, halal certification is aligned to the Avantor packaging site as indicated on the product Certificate of Analysis. Please refer to the site-specific halal certificate available on AskAvantor for our most up to date listing of halal products at (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.



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GRAS STATUS:	21 CFR 184.1426 For the latest information on whether or not an Avantor
	product is considered GRAS, please visit the <u>Electronic Code of Federal</u>
	Regulations.
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 <u>www.askavantor.com</u> Keyword: ISO

Section 6. MISCELLANEOUS PI	RODUCT INFORMATION
LOT 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)
BATCH/LOT DEFINITION:	A "batch" is a homogeneous unit of production; each batch of is from one single batch of the source supplier.
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 <u>www.avantorsciences.com</u>
PACKAGING SIZE(S):	Please reach out to the support contact in Section 7 for current packaging specifications.
MANAGEMENT OF CHANGE CONTROL:	For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to Management of Change <u>link</u> on the Avantor website. (https://www.avantorsciences.com/us/en/about/management-of-change)
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.

Section 7. REVISIONS		
REVISION DATE:	REVISION	CHANGES:
	LEVEL:	
July 02, 2010	0	New
August 30, 2011	1	Entire document: new letterhead including headquarters address change; changed all references of AskMBI Q&A Center to AskAvantor"; updated company name from Mallinckrodt Baker, Inc. to Avantor Performance Materials, Inc.; updated website links to new website; Section 3: corrected Cas No; Section 4: Nutritional/Supplement facts labeling statement updated; Section 5: Allergen/Hypersensitivities statement expanded; Gluten and HACCP statements added; Section 6: updated Lot Numbering System, Expiration dating and Management of Change Control statements.



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		(PH/JLW)
January 26, 2015		Section 1: Added MOC code; Section 2: Updated Name and Address of Manufacturing Site statement; Clarified manufacturing process; Section 5: Split Kosher and Halal Status, Updated HACCP statement; Section 6: Updated lot numbering system; Updated expiration dating; Updated Management of Change statement; Section 8: Updated Contact information. (MCH)
March 23, 2020	3	Entire document: new letterhead, updated address, and updated website address from avantormaterials.com to avantorsciences.com; Section 5: Updated Halal status to include additional product code. (KH)
November 15, 2023	4	Entire document: new letterhead; Section 5: Updated Kosher and Halal statements; Section 6: Added batch definition and support contact for packaging specification, updated MOC link. (SP)

This electronic document is valid without a signature.

Section 8. CONTAC	T INFORMATION	
COMPANY NAME:	Avantor Performance Materials, LLC.	
CONTACT NAME:	Technical Support	
CONTACT PHONE:	Toll free 1 855 282 6867, select option 5	
	Outside U.S. 1 610 573 2600, select option 5	
CONTACT EMAILS:	Technical Service	
	<u>Technical.Service@avantorsciences.com</u>	
	Regulatory Support	
	Regulatory.Support@avantorsciences.com	
	Trade Compliance	
	<u>Trade.Compliance@avantorsciences.com</u>	

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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.