

PRODUCT REGULATORY INFORMATION DATASHEET

Non-Botanical Dietary Ingredients

Section 1. PRODUCT INFORMATION	
PRODUCT CODE & NAME:	Macron Fine Chemicals™ 7444 Sodium Bisulfite 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: Usually a mixture of NaHSO ₃ (sodium bisulfite) and Na ₂ S ₂ O ₅ (sodium metabisulfite)	SYNONYM:	ORIGIN:	CAS NUMBER:	Typical PERCENT:
Sodium Bisulfite	Sodium acid sulfite; Sulfurous acid, monosodium salt; Sodium hydrogen sulfite, solid	Chemical	7631-90-5	< 0.001%
Sodium Metabisulfite	Pyrosulfurous Acid, Disodium Salt; Sodium Pyrosulfite (Na ₂ S ₂ O ₅)	Chemical	7681-57-4	100%
CURRENT PRODUCT SPECIFICATION SHEET:	Please see the current product specifications at www.avantormaterials.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 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:	This product is not 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 182.3766
HACCP STATUS:	Avantor Performance Materials, Inc. does not operate its facility under a HACCP plan. These products are manufactured under food cGMP guidelines, and our facilities are ISO 9001 certified.

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Section 6. MISCELLANEOUS PRODUCT 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)
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)

Section 7. REVISIONS		
REVISION DATE:	REVISION LEVEL:	CHANGES:
February 20, 2012	0	New (MCH)
August 14, 2014	1	Section 1: Added MOC code; Section 2: Updated Name and Address of Manufacturing Site statement; Section 5: Split Kosher and Halal Status.; Section 6: Updated lot numbering system; Updated expiration dating; Updated Management of Change statement; Section 8: Updated Contact information. (MCH)

This electronic document is valid without a signature.

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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