
Barium Sulfate

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>
J.T.Baker®	1040	Barium Sulfate, USP	R
J.T.Baker®	1041	Barium Sulfate, USP, Multi-Compendial	R
Macron Fine Chemicals™	4518	Barium Sulfate, For Formulation, USP	R
Macron Fine Chemicals™	8821	Barium Sulfate, USP	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, Inc. 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 the International Pharmaceutical Excipients Council (IPEC) guidelines and it meets cGMP requirements. For instructions to decipher the manufacturer reference code please consult our website, directions may be found in the Q&A Center of the customer support section of our web site (www.AskAvantor.com Keyword: Manufacturer Code).

Section 3 – Physical/Chemical Information

CAS #: 7727-43-7

Manufacturing Process: Synthesis

Raw Material Origin: Chemical

Section 4 – Regulatory Information

Compendial Compliance: Please see the current product specifications at www.AvantorMaterials.com

DMF: Avantor Performance Materials, Inc. does not carry a Drug Master File for these products

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: The products listed do not contain cereals containing gluten (i.e. wheat, rye, oats, barley, spelt, kamut or their hybridized strains), malt, triticale, gluten, other grains, corn, soy, soybeans, eggs, yeast, canola, milk, dairy products, fish, crustacean shellfish, seafood products, tree nuts, peanuts, nut products (i.e. Almond (*Amygdalus communis* L.), Hazelnut (*Corylus avellana*), Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut (*Carya illiniesis* (Wangenh.) K. Koch), Brazil nut (*Bertholletia excelsa*), Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*)), seed products (sesame seeds and products thereof), natural grape products, natural flavors, artificial flavors, celery, mustard, lactose, sulfites, elemental sulfur, preservatives, lupine and products thereof, MSG, disodium guanylate/inosinate, artificial sweeteners, phenylalanine, additives, colorants, dyes, or natural rubber (latex). These products are manufactured using cGMP guidelines which provide controls that allow no potential for cross contamination of any allergens or other products.

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.

Residual Metallic Catalysts: No metal catalysts or metal reagents, as defined by EMEA Guideline on the Specification Limits for Residues of Metal Catalysts or Metal Reagents (CPMP/SWP/QWP/4446/00), are used in the production of the above subject materials.

Kosher Status: The subject materials are not Kosher Certified. 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 support section of our website for our most up to date listing of Halal products. (www.askavantor.com Keyword: [Halal](#))

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.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 please contact Technical Support through the customer support section of our website for our product stability profiles. (www.askavantor.com Keyword: Expiration)

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.

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 6 – Revision History

Rev. 0; Oct. 1, 2007 – IPEC EIP format

Rev. 1; Oct. 3, 2008 – Section 4: updated residual solvents information

Rev. 2; October 4, 2011 –Entire document: new letterhead, and changed all references of “Solv IT Center” to “AskAvantor.” Updated website links for new website; Section 1:

Mallinckrodt brand name updated to Macron; added MOC codes; Section 2: added GMP statement; Section 4: expanded Allergens list; added Residual Metallic Catalysts statement; Section 7: updated contact information; minor formatting. PH/MCH

Rev. 3; Dec. 5, 2012 –Section 4: added add'l allergens as listed in EU Directive 2003/89/EC; updated Residual Metallic Catalysts statement; separated Kosher/Halal status and added certification statement; Section 5: added Management of Change information; added COA Date Format statement; Section 7: removed contact list table and added CS/TS contact information. JDR

This electronic document is valid without a signature.

Section 7 – Contact Information

POSITION/TITLE	PHONE NUMBER
Research & Technology:	
Director of R & T – Bio/Pharmaceuticals	908-213-6720
Director of R & T - Microelectronics	908-859-9337
Production:	
Director of Manufacturing	908-859-9345
Phillipsburg Plant Manager	908-859-9456
Paris Plant Manager	859-987-9400
Packaging:	
Senior Packaging Engineer	908-859-9668
Quality Control/Quality Assurance:	
Global Director of Quality Assurance	908-859-6926
Director of Regulatory Affairs	908-859-9466
Quality Manager, Paris Plant	859-987-9459
Other Key Personnel:	
EH&S Phillipsburg Plant	908-329-9976
EH&S Paris Plant	859-987-9423
Director of Marketing North America	908-859-9413
Manager, Customer Services	908-859-9314
Manager, Technical Support	908-329-9915