Avantor Performance Materials, Inc.
3477 Corporate Parkway,
Suite # 200
Center Valley, PA 18034
U.S.A.
Tel: 1-610-573-2600
Fax: 1-610-573-2610
www.avantormaterials.com

Magnesium Stearate

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered

Brand	Product Code	Product Description	MOC code
Macron Fine Chemicals™	2257	Magnesium Stearate, Hyqual®, Vegetable Source NF - GenAR®	R
Macron Fine Chemicals™	5712	Magnesium Stearate, Hyqual®, Vegetable Source NF - GenAR®	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. Instructions can be found in the Q&A Center of the customer support section of our web site or by directly linking to www.AskAvantor.com Keyword: Manufacturer Code.

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Section 3 – Physical/Chemical Information

CAS #: 557-04-0

Manufacturing Process: Synthesis

Raw Material Origin: Plant

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.
This product does not come into contact with any equipment or vessel which could transfer animal related impurities to the product and repackaging of product meets the conditions as cited in "Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMEA/410/01 current version)".

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.

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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/4446/2000), 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)

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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))

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.

Phthalate Statement: To the best of our knowledge, Dibutyl phthalate (DBP) (CAS# 84-74-2), Bis (2-ethyl(hexyl) phthalate (DEHP) (CAS# 117-81-7), and Bisphenol A (BPA) (CAS # 80-05-7) are not known additives, by-products or an intermediate part of the manufacturing process of the following products and are not expected to be present in the product or packaging. However, these products are not tested for the presence of these compounds and no specification is set for these compounds in these products.

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; June 24, 2008- Additional Residual Solvents data added.
Rev. 2; Aug. 5, 2008 – Section 4: updated Residual Solvent information
Rev. 3; Sept. 22, 2008 – Section 4: Updated Residual Solvents statement to include reference to USP Chapter <467>.
Rev. 4; Oct. 17, 2008- Section 7: Updated telephone number for Tech Service Manager; Section 4: Added Residual Metallic Catalysts statement.
Rev. 5; Jan. 19, 2009- Section 4: Updated Residual Solvents statement to match COA.
Rev. 6; April 23, 2009- Entire document: new letterhead; Section 4: Updated Kosher/Halal section to indicate lack of certification. Section 7: Updated telephone numbers for Customer Service Director and Technical Service Manager.
Rev. 7; March 8, 2011 – Entire document: new letterhead and changed all references of "Solv IT Center" or "AskMBI" to "AskAvantor." Updated from Mallinckrodt to Macron. Updated website links for new website; Section 7: updated contact information. MCH
Rev. 8; May 19, 2011- Updated GMP statement, added MOC codes.(MCH)

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Rev. 9; September 20, 2011 - Section 4: expanded Allergens list; added GRAS statement; Section 5: Added Nutritional/Supplemental Facts Labeling and Organic Status statements; Section 7: updated contact information. PH/MCH
Rev. 10; Nov. 27, 2012 – Entire document: updated headquarters address, minor formatting; 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. (MCH)
Rev. 11; April 18, 2013 – Section 4: Added additional allergens; Section 5: Added phthalate statement. (MCH)
Rev. 12; Jan 14, 2014– Section 4: Added EMEA declaration based on supplier documentation; Updated Residual Metallic Catalysts EMEA statement to reflect current guideline revision.(MCH)

This electronic document is valid without a signature.

Section 7 – Contact Information

Customer Service

Phone: 1-855-282-6867
1-610-573-2600 (outside U.S.)
Fax: 1-610-573-2650

Technical Service

Phone: 1-855-282-6867
1-610-573-2600 (outside U.S.)
Fax: 1-610-573-2650