
Ferrous Sulfate Heptahydrate

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>
Macron Fine Chemicals™	5572	Ferrous Sulfate, 7-Hydrate, Granular, U.S.P., F.C.C.	R
J.T.Baker®	2074	Ferrous Sulfate, 7-Hydrate, Crystal U.S.P. - F.C.C.	R
J.T.Baker®	2063	Ferrous Sulfate, 7-Hydrate, Crystal Multi-Compendial	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 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 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.

Section 3 – Physical/Chemical Information

CAS #: 7782-63-0

Manufacturing Process: Synthesis

Raw Material Origin: Chemical

Section 4 – Regulatory Information

Compendial Compliance: The subject materials Meets U.S.P. Requirements. Please also see the current product specifications at www.avantormaterials.com for the specific product code for compendial compliance.

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, 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 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.

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: Certified Kosher – Pareve for year-round use. 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: Macron Fine Chemicals™ 5572 is 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](#))

GRAS Status: The United States Food and Drug Administration (FDA) have acknowledged that the chemical listed in Section 1 is a direct food substances affirmed as Generally Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per 21 CFR parts 184.1315.

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)

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.

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. 13, 2008 – Section 4: updated residual solvents information

Rev. 2; July 13, 2009 – Section 4: Added “Carageenan products, xanthine products, simethicone” to allergens list; Entire document: New letterhead (KES)

Rev. 3; Apr. 1, 2011 – Section 1: added GMP statement, updated Q7A to Q7; Section 4: added GRAS statement; Entire document: new letterhead, Mallinckrodt brand name updated to Macron and changed all references of “Solv IT Center” to “AskAvantor” or to customer support section Updated website links for new website; Section 7: updated contact information. Minor formatting (PH/JLW)

Rev. 4; Oct 11, 2011- Entire document: updated headquarters address; Section 1: added MOC codes; Section 2: added GMP statement; Section 4: expanded Allergens list; Section 5: added Nutritional/Supplement Facts Labeling and Organic Status. Section 7: updated phone numbers to contacts at new HQ's (MCH)

Rev. 5; Oct. 19, 2012 –Section 4: added USP compendial compliance; added add'l allergens as listed in EU Directive 2003/89/EC; added Residual Metallic Catalysts statement; added kosher/halal certified; Section 5: added Management of Change information; Section 7: removed contact list table and added CS/TS contact information. (JLW)

Rev. 6; Nov. 4, 2016 – Section 4: separated Kosher/Halal status and added certification statement; Updated EMEA Residual Metallic statement to reflect current guideline revision Section 5: Added COA Date Format statement; (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