

Magnesium Sulfate

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered

Brand	Product Code	Product Description	MOC [*] code
J.T.Baker®	2504	Magnesium Sulfate, 7-Hydrate, Crystal, U.S.P. Multi- Compendial	R
J.T.Baker®	2505	, Magnesium Sulfate, 7-Hydrate, Crystal U.S.P.	R
Macron Fine	4200	Magnesium Sulfate, 7-Hydrate U.S.P F.C.C.	R
Chemicals™			
Macron Fine	5053	Magnesium Sulfate, Anhydrous, Powder U.S.P.	R
Chemicals™			
Macron Fine	5054	Magnesium Sulfate, Anhydrous, Powder U.S.P.	HR
Chemicals™			
Macron Fine	5691	Magnesium Sulfate, 7-Hydrate, (For Parenteral Use) USP -	R
Chemicals™		GenAR®	
Macron Fine	6046	Magnesium Sulfate, 7-Hydrate U.S.P F.C.C.	R
Chemicals™			
Macron Fine	6050	Magnesium Sulfate, Dried Powder U.S.P F.C.C.	R
Chemicals™			

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

MOC CODE HR PRODUCTS: The products listed in Section 1 are manufactured under current Good Manufacturing Practices (cGMPs) as set forth by ICH Q7 and International Pharmaceutical Excipients Council (IPEC) guidelines.

MOC CODE R PRODUCTS: 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, LLC 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 <u>www.askavantor.com</u> Keyword: Manufacturer Code.

Section 3 – Physical/Chemical Information

CAS #: 7487-88-9 (anhydrous); 10034-99-8 (hydrate)

Manufacturing Process: Synthesis

Raw Material Origin: Chemical

Section 4 – Regulatory Information

Compendial Compliance: Please see the current product specifications at <u>www.avantorinc.com</u>.

DMF: Avantor Performance Materials, LLC 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.

Elemental Impurities:

Please see attached summary for Elemental Impurity information for listed products.

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: 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. (<u>www.askavantor.com</u> Keyword: <u>Kosher</u>)

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. (<u>www.askavantor.com</u> Keyword: <u>Halal</u>)

GRAS Status: The United States Food and Drug Administration (FDA) have acknowledged that the chemical listed in Section 1 is a substance Generally



Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per 21 CFR parts 184.1443

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)

Batch Definition: A "batch" is a homogeneous unit of production; each batch of is from one single batch of the source supplier.

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. (<u>www.askavantor.com</u> 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 lonizing 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)

Country of Origin Statement: Country of Origin is indicated on the product Certificate of Analysis. Please contact our Trade Compliance if you require further documentation (<u>Trade.Compliance@Avantorinc.com</u>).

Storage Requirements: Please refer to the product Certificate of Analysis/Product Specifications. In the absence of specific storage conditions listed on the Avantor specification sheet or certificate of analysis, our products are to be stored in ambient conditions of temperature and humidity. We do not formally tie any specific temperature or humidity range with the 'ambient' storage designation, but an example of a common temperature interpretation is 15-30°C. Our products are also packaged to protect from the normal variation in humidity during storage and shipment. Further handling and storage information may be found in Section 7 of the product SDS sheet.

Section 6 – Revision History

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

Rev. 2; July 8, 2010 – Entire document: new letterhead and changed all references of "Solv IT Center" to "AskMBI."; Section 7: updated TS manager info. Added Residual Metallic Catalysts and GRAS statements.

Rev. 3; March 21, 2011 – Entire document: new letterhead and changed all references of "Solv IT Center" or "AskMBI" to "AskAvantor." Updated website links for new website; Section 7: updated contact information. Updated Mallinckrodt to Macron. (MCH)

Rev. 4; Oct. 7, 2011 – Entire document: changed headquarters address; minor formatting; Section 1: added MOC codes; Section 3: added hydrate CAS No; Section 4: expanded Allergens list; Section 5: added Nutritional/Supplement Facts Labeling and Organic Status statements; Section 7: updated contact information. (JLW)

Rev. 5; Nov. 1, 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)

Rev. 6- July 22, 2016- Section 4: Updated EMEA Residual Metallic statement to reflect current guideline revision. (MCH)



Rev 7; December 13, 2018 – Entire document: new letterhead (logo & headquarters address, updated email from @avantormaterials.com to @avantorinc.com);Section 1- Removed delisted code 7778, added code 5054; Section 4: Added Elemental Impurities information for limited products; Section 5: added Storage Requirement, Batch Definition, and Country of Origin Statements

Rev. 8: January 11, 2019 Added Elemental Impurity information for products 5053, 5054, 6050.

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 CS.Specialist@avantorinc.com

Technical Service

Phone: 1-855-282-6867 1-610-573-2600 (outside U.S.) Fax: 1-610-573-2650 Technical.Service@avantorinc.com

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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 or as part of the supplier audit cycle

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Material Name: Magnesium Sulfate Heptahydrate Product codes: 2504, 2505, 5691, 6046, 4200 Date: August 7, 2018

Source/Type of Excipient:
Mineral;
Mineral derived;
Plant;
Plant derived;
Synthetic;
Fermentation derived

Other (explain):

No Class 1, 2A, 2B, or 3 elementals are intentionally added to the production process.

Elemental Impurity		Class	Lil	kely to be	Present	If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Arsenic (inorganic)	As	1	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Cadmium	Cd	1	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Mercury (inorganic)	Hg	1	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Lead	Pb	1	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Cobalt	Со	2A	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Nickel	Ni	2A	Yes 🛛	No 🗌	Unknown	<0.05 to 0.08 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested,



Elemental Impurity		Class	Lil	kely to be	Present	If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
								range reported
Vanadium	V	2A	Yes 🛛	No 🗌	Unknown 🗌	0.07 to 0.19 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range reported
Silver	Ag	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Gold	Au	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Iridium	lr	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Osmium	Os	2B	Yes 🗌	No 🛛	Unknown	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Palladium	Pd	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Platinum	Pt	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Rhodium	Rh	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Ruthenium	Ru	2B	Yes 🗌	No 🛛	Unknown	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Selenium	Se	2B	Yes 🛛	No 🗌	Unknown 🗌	<0.05 to 0.25 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range is reported



Elemental Impurity		Class	Lil	kely to be	Present	If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Thallium	ті	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Barium	Ва	3	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Chromium	Cr	3	Yes 🛛	No 🗌	Unknown 🗌	0.07 to 0.15 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range reported
Copper	Cu	3	Yes 🛛	No 🗌	Unknown 🗌	<0.05 to 0.23	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range reported
Lithium	Li	3	Yes 🛛	No 🗌	Unknown 🗌	0.08 to 0.12	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range reported
Molybdenum	Мо	3	Yes 🛛	No 🗌	Unknown 🗌	<0.05 to 0.06ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range reported.
Antimony	Sb	3	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Tin	Sn	3	Yes 🗌	No 🖂	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit

Reference: ICH Q3D Guideline for Elemental Impurities, Step 5 version



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Prepared by the Technical Service Department

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Material Name: Magnesium Sulfate, Anhydrous Product codes: 5053, 5054, 6050 Date: January 10, 2019

Source/Type of Excipient:
Mineral;
Mineral derived;
Plant;
Plant derived;
Synthetic;
Fermentation derived;

Other (explain):

Elemental Impurity		Class	Lił	cely to be	Present	If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Arsenic (inorganic)	As	1	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Cadmium	Cd	1	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Mercury (inorganic)	Hg	1	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Lead	Pb	1	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Cobalt	Со	2A	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL



Elemental Impurity		Class	Lil	kely to be	Present	If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
Nickel	Ni	2A	Yes 🛛	No 🗌	Unknown 🗌	0.36 – 0.63 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, range reported
Vanadium	V	2A	Yes 🛛	No 🗌	Unknown 🗌	0.28 – 0.33 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, range reported
Silver	Ag	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Gold	Au	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Iridium	lr	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Osmium	Os	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Palladium	Pd	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Platinum	Pt	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Rhodium	Rh	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Ruthenium	Ru	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Selenium	Se	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below



Elemental Impurity		Class	Lil	kely to be	Present	If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
								MRL
Thallium	ТІ	2B	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Barium	Ва	3	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Chromium	Cr	3	Yes 🗌	No 🛛	Unknown 🗌	0.42 – 0.61 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, range reported
Copper	Cu	3	Yes 🗌	No 🛛	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Lithium	Li	3	Yes 🛛	No 🗌	Unknown 🗌	<0.05 – 0.09ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, range reported
Molybdenum	Мо	3	Yes 🛛	No 🗌	Unknown 🗌	0.05 - 0.10 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, range reported
Antimony	Sb	3	Yes 🗌	No 🖂	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Tin	Sn	3	Yes 🗌	No 🖂	Unknown 🗌	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL

Reference: ICH Q3D Guideline for Elemental Impurities, Step 4 version, September 2014



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Prepared by the Technical Service Department

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