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# Magnesium Stearate

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## Product Regulatory Data Sheet

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### Section 1 – Product Information

#### Products Covered

<u>Brand</u>	<u>Product Code</u>	<u>Product Description</u>	<u>MOC* code</u>
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

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### 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 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.

For J.T.Baker® and Macron Fine Chemicals™ brand products, 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 the Avantor website. Instructions can be found by visiting the Ask Avantor link under the Resources tab or by directly linking to [www.askavantor.com](http://www.askavantor.com) Keyword: Manufacturer Code. Additional information on Avantor suppliers may be available under NDA. Please reach out to the support contact in Section 7 for additional supplier information inquiries.

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### Section 3 – Physical/Chemical Information

CAS #: 557-04-0

**Manufacturing Process:** Synthesis. Additional manufacturing process information may be disclosed under NDA upon request from the support contact in Section 7.

**Raw Material Origin:** Plant

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#### **Section 4 – Regulatory Information**

**DMF:** Avantor may hold Master File(s) for specified product codes, dependent on the country of interest. Inquire with the support contact in Section 7 for additional details.

**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:** To the best of our knowledge, the allergens listed in the [US FDA](#), [EU Directive 2003/89/EC](#), and [TGO-91/92](#) are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

According to the Original Manufacturer allergens listed by the FDA, which include: Crustacean shellfish (and products thereof), egg (and products thereof), fish (and products thereof), gluten (wheat/rye/barley), milk (and products thereof), tree nuts/coconut/peanut (and products thereof), and Soy/Soybeans (and products thereof). In addition, the following common allergens/materials/additives which include: Alcohols (Synthetic/Grain), Animal products (including Porcine), Antibiotics, Apples, Artificial Colors and/or Flavors, Aspartame, Beans, Beets, Benzoate, Caffeine or derivatives thereof, Canola Oil, Carrot, Casein, Cauliflower, Celery (and products thereof), Cereals containing gluten (and products thereof), Cereals Used For Making Alcoholic Distillates Including Ethyl Alcohol or Agricultural Origin, CFC (Chlorofluorocarbon), Cobalt, Colophony, Coloring Agents, Corn/Maize and products thereof, Corn Starch, Cottonseed, Dairy (Milk Derivatives), DEHP, Diethylene Glycol, Diluents, Dried Fruit, Dyes, Eggplant, Flax, Fleshy fish, Flavoring/Sweetener (including nut flavor), Fluorescent Agents or Substances, Fruit, Galactose, Gelatin, Glucose Syrups based on Barley, Glutamate, Glycerin, Glycol, Honey, Hormones, Hydrolyzed plant protein, Hydroxybenzoic Acid Esters, Guaiac Gum, Iodine, Kamut or their hybridized strains, Lactalbumin, Lactose, Latex or latex contaminants, Lemon/Citrus, Lentils, Lupin, Mercury, Molluscs (and products thereof), MSG, Mustard (and products thereof), Nitrites/Nitrates, Nitrofurazone, Oats, Odor, Olive Oil, Parabens, Parsley, Parthenolide, Peach, Peas, Penicillin, Phenylalanine, Phthalates, Pineapple, Plasticizers, Pollen, Polyethylene Glycol, Pine Resin, Porcine, Potassium Salts, Potato, Preservatives, Potassium Salts, Propolis, Propylene, PVC, Rice, Royal Jelly, Saccharin, Salicylates, Seeds (other than sesame), Seed Oils, Sesame (or products thereof), Sesame Seeds, Sodium Salts, Sorbates, Sorbitol, Spelt, Starch/Carbohydrate/Sugar (including sucralose, sucrose, sugar alcohols, fructose, invert sugar, glucose, maltose), Sulfa/Sulfonamides, Sulfites, Sulphur, Sulphur Dioxide, Sunflower, Talc, Tomato, Tartrazine, Wheat Based Glucose Syrups including Dextrose, Wheat Based Maltodextrins, Whey, Xanthan Gum, Yeast, and Zinc are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

Neither Avantor nor the Original Manufacturer produce any of the following types of products: antibiotics, aflatoxins, penicillin, semi-synthetic penicillins, cephalosporins, other beta-lactams, cytotoxics, steroids, medicated feeds, or pesticides.

This product is manufactured using cGMP guidelines which provide controls that allow no potential for cross contamination of any allergens or other contaminants. However, this product is not tested for the presence of these or any other allergens by Avantor or the Original Manufacturer, therefore, we do not have confirmation for the absence of any allergens in the product.

**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.

**Kosher Status:** For J.T.Baker® and Macron Fine Chemicals™ brand products, kosher certification is aligned to the Avantor packaging site as indicated on the product Certificate of Analysis. Please refer to the site-specific kosher certificate available on AskAvantor for our most up to date listing of kosher products at ([www.askavantor.com](http://www.askavantor.com) Keyword: kosher).

**Halal Status:** For J.T.Baker® and Macron Fine Chemicals™ brand products, halal certification is aligned to the Avantor packaging site as indicated on the product Certificate of Analysis. Please refer to the site-specific halal certificate available on AskAvantor for our most up to date listing of halal products at ([www.askavantor.com](http://www.askavantor.com) Keyword: halal).

**GRAS Status:** The United States Food and Drug Administration (FDA) have acknowledged that some chemicals may be considered Substances Generally Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per specific 21 CFR regnums. For the latest information on whether or not an Avantor product is considered GRAS, please visit the [Electronic Code of Federal Regulations](#).

**Nutritional/Supplement Facts Labeling:** The product code 2257 listed in Section 1 is a 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 and are exempt from the Nutrient Content Evaluation and Nutrient Labeling Requirements (21 CFR 101.9(j)(9)).

**Organic Status:** The product code 2257 listed in Section 1 is 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.

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## **Section 5 – Miscellaneous Product Information**

**Certificate of Analysis Date Format:** The Manufactured Date and Expiration/Retest Date on the Certificate of Analysis are reported as YYYY-MM-DD. For example, the Manufactured Date for October 1, 2021 would be reported as 2021-10-01.

**Lot Numbering System and Batch Description:** For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to Ask Avantor for information concerning our lot/batch numbering system. ([www.askavantor.com](http://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 reach out to the support contact in Section 7 for additional stability inquiries.

**Management of Change:** For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to Management of Change link under the Working with Avantor tab on the Avantor website.

**Country of Origin Statement:** Country of Origin is indicated on the product Certificate of Analysis. If you require further documentation, please reach out to the Trade Compliance support contact in Section 7.

**Storage Requirements:** Please refer to the product's Certificate of Analysis or Product Specifications. In the absence of specific storage conditions listed on its specification sheet or Certificate of Analysis, 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's SDS sheet.

**Certificates of Analysis:** For J.T.Baker® and Macron Fine Chemicals™ brand products, please see the current list of product specifications using the Certificate/SDS Search tool on our website [here](#).

**Safety Data Sheet:** For J.T.Baker® and Macron Fine Chemicals™ brand products, please see the current product safety information using the Certificate/SDS Search tool on our website [here](#).

**Avantor Site Certifications:** Please see the current Avantor site certifications on our website [here](#).

**Site Quality Overview:** Avantor maintains a self-assessment modeled after IPEC guidelines which describes site and quality system information to support the manufacturing activities of this product. Please reach out to the support contact in Section 7 for a current copy of the Site Quality Overview.

**Packaging Information:** Please reach out to the support contact in Section 7 for current packaging specifications.

## 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)

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 Catalyst 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)

Rev. 13; October 7, 2016 – Datasheet reviewed- no changes required.

Rev.14; November 08, 2017- Entire document: new letterhead format (company name and headquarters address); Section4: Updated GMO statement, added Elemental Impurities information, added Aflatoxin Statement; Section 5: added Storage Requirement, Batch Definition, and Country of Origin Statements(SR)

Rev. 15; November 15, 2018 - Entire Document: New Format. (EC)

Rev 16; June 20, 2019– Entire document- Updated email from @avantorsciences.com to @avantorsciences.com; Section 4: corrected formatting for Aflatoxin statement (MCH)

Rev. 17; January 21, 2021 – Entire Document: Minor formatting; Section 4: Corrected website link in Compendial Compliance statement. Updated DMF and Allergen/Hypersensitivities Information statements. Removed Aflatoxin statement. Statement is now included in the Allergen/Hypersensitivities Information statement. Added Nutritional/Supplement Facts Labeling and Organic Status statements for product code 2257. (KH)

Rev. 18; February 27, 2024 - Entire Document: Updated letterhead, new format; Section 5: Added Certificates of Analysis, Safety Data Sheet, Avantor Site Certifications, Packaging Information statements; Section 7: Updated contact information; Elemental Impurity Report: Per manufacturer statement Cr is now included, Se and Mo removed. Range and MRL of Ni also changed to  $\leq 0.8$  ppm from  $\leq 0.07$  ppm and  $\leq 0.5$  ppm from  $\leq 0.05$  ppm (CR)

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*This electronic document is valid without a signature.*

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#### **Section 7 – Contact Information**

##### Technical Service

Phone: 1-855-282-6867 and 1-610-573-2600 (outside U.S.), select option 5

Email: [Technical.Service@avantorsciences.com](mailto:Technical.Service@avantorsciences.com)

##### Regulatory Support

Email: [regulatory.support@avantorsciences.com](mailto:regulatory.support@avantorsciences.com)

##### Trade Compliance

Email: [Trade.Compliance@avantorsciences.com](mailto:Trade.Compliance@avantorsciences.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 and managed under a validated document control system.

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**Material Name:** Magnesium Stearate **Product codes:** 5712, 2257 **Date:** February 27, 2024 (Rev. 2)

**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 manufacturing process of this material.

Elemental Impurity		Class	Likely 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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.2 ppm	ICP-MS (MRL=0.2 ppm)	Manufacturer information – production batch testing
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Manufacturer information – production batch testing
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.4 ppm	ICP-MS (MRL=0.4 ppm)	Manufacturer information – production batch testing
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.3 ppm	ICP-MS (MRL=0.3 ppm)	Manufacturer information – production batch testing
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.5 ppm	ICP-MS (MRL=0.5 ppm)	Manufacturer information – production batch testing



Elemental Impurity		Class	Likely 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.)
			Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>			
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	≤0.8 ppm	ICP-MS (MRL=0.5 ppm)	Manufacturer information – production batch testing
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1.0 ppm	ICP-MS (MRL=1.0 ppm)	Manufacturer information – production batch testing
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable	Not applicable	Element not intentionally added to mfg. process
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable	Not applicable	Element not intentionally added to mfg. process
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable	Not applicable	Element not intentionally added to mfg. process
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable	Not applicable	Element not intentionally added to mfg. process
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable	Not applicable	Element not intentionally added to mfg. process
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable	Not applicable	Element not intentionally added to mfg. process



Elemental Impurity		Class	Likely 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.)
			Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>			
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable	Not applicable	Element not intentionally added to mfg. process
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable	Not applicable	Element not intentionally added to mfg. process
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable	Not applicable	Element not intentionally added to mfg. process
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable	Not applicable	Element not intentionally added to mfg. process
Barium	Ba	3	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>	Not applicable	Not applicable	Not tested, not intentionally added
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<250 ppm	ICP-MS (MRL= 250ppm)	Manufacturer information – production batch testing added
Copper	Cu	3	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>	Not applicable	Not applicable	Not tested, not intentionally added
Lithium	Li	3	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>	Not applicable	Not applicable	Not tested, not intentionally added

Elemental Impurity		Class	Likely 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.)
			Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>			
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable	Not applicable	Element not intentionally added to mfg. process
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>	Not applicable	Not applicable	Not tested, not intentionally added
Tin	Sn	3	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Unknown <input checked="" type="checkbox"/>	Not applicable	Not applicable	Not tested, not intentionally added

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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