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Packaging site:  
Avantor Performance Materials India Private Limited  
Plot No.1, GIDC, Panoli, Ankleshwar  
Gujarat Pin: 394116, India

# Magnesium Sulphate Heptahydrate

## Product Regulatory Data Sheet

### Section 1 – Product Information

#### Products Covered

Brand	Product code	Product Description	MOC* code
Macron Fine Chemicals™	7506	Magnesium Sulphate Heptahydrate, Multi-Compendial	R
Macron Fine Chemicals™	7508	Magnesium Sulphate Heptahydrate, ChP	R
Macron Fine Chemicals™	7503	Magnesium Sulphate Heptahydrate, IP	RL

\*MOC = Management of Change

### Section 2 – Manufacturing, Packaging and Release Site Information

The product code 7506 and 7508 listed in Section 1 is manufactured under current Good Manufacturing Practices (cGMPs) as set forth by ICH Q7 and International Pharmaceutical Excipients Council (IPEC) guidelines.

The product code 7503 in Section 1 is manufactured in India with IP monographs are manufactured under current Good Manufacturing Practices (cGMPs) as set forth by the Drugs and Cosmetics Rule, 1945, Government of India Ministry of Health and Family Welfare.

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.

### Section 3 – Physical/Chemical Information

CAS #: 10034-99-8

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

**Raw Material Origin:** Chemical

### 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 TG0-91/92 are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

According to the Original Manufacturer, the products listed in Section 1 do not contain latex, gluten, aspartame, antibiotics, benzoates (including benzoic acid, sodium benzoate), crustacean crab, crayfish, lobster, prawn and

shrimp, egg, ethanol, fish and fish products, galactose, hydroxybenzoic esters, lactose, milk and milk products, Peanut (Arachis Hypogea), Walnut (Juglans nigra), Almond oil, Macadamia nut oil, Prunus dulis, Phenylalanine, Pollen propolis or royal jelly, Potassium and Sodium salts, Saccharin, Soy and soy products, sorbates, sucralose, sugars(fructose, glucose, honey, invert sugar, lactose, maltose, and sucrose), sulfites, tartrazine, sesame seeds and sesame seeds products are not known additives, by-products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

Avantor does not 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 materials.

**Elemental Impurities:** Please see attached summary for Elemental Impurity information for these products.

**Halal 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).

**Kosher 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.

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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-Xyz-DD. For example, the Manufactured Date for October 1, 2021 would be reported as 2021-Oct-01.

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 Requirement:** 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.

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## Section 6 – Revision History

Rev. 0; Jun 03, 2020: IPEC EIP Format (MK)

Rev. 1; Sep 13, 2023: Entire Document- Updated to new template. Verbiage was updated to new formats, but the quality of the product and its statements has not changed unless otherwise noted in this revision history. Section 1: Corrected MOC code for 7503 from MOC R to RL in accordance with Panoli site. This was a typographical error and not a change to the product's MOC code; Section 4: Removed Compendial Compliance statement. Removed Regulatory email from DMF statement. Specified certificate availability for different branded products for Kosher and Halal Status statements. Generalized GRAS Status statement; Section 5: Updated COA Date format statement, Batch Description, Country of Origin Statement, Shelf-Life Information, and Management of Change statements. Added Certificates of Analysis, Safety Data Sheet, Avantor Site Certifications, Site Quality Overview, and Packaging Information statements; Section 7: Added contacts. (SP)

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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.

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**Avantor Performance Materials India Ltd.**

Plot No.1, GIDC, Panoli, Ankleshwar  
Gujarat Pin:394116, India

Material Name: Magnesium Sulfate Heptahydrate

Product Code: 7506, 7503, 7508

Source/Type of Excipient: ☐ Mineral; ☐ Mineral Derived; ☐ Plant; ☐ Plant Derived; ☒ Synthetic; ☐ Fermentation Derived;

Other (explain):

Elemental Impurity		Class	Likely to be present			If known, please identify the Expected concentration/u nit (or range)	Analytical Method used (Limit of Quantification if available)	Comments regarding source of information (i.e; number of lots tested, frequency of testing; process understanding etc.)
Arsenic	As	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.03 ppm	ICPOES (0.02 ppm)	Avg. of 3 batches
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.0005 ppm	ICPOES (0.0005 ppm)	Avg. of 3 batches
Mercury	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.087 ppm	ICPOES (0.006 ppm)	Avg. of 3 batches
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.026 ppm	ICPOES (0.01 ppm)	Avg. of 3 batches
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.110 ppm	ICPOES (0.004 ppm)	Avg. of 3 batches
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	1.026 ppm	ICPOES (0.006 ppm)	Avg. of 3 batches
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.015 ppm	ICPOES (0.002 ppm)	Avg. of 3 batches
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.0009 ppm	ICPOES (0.0009 ppm)	Avg. of 3 batches
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.17 ppm	ICPOES (0.002 ppm)	Avg. of 3 batches
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.004 ppm	ICPOES (0.004 ppm)	Avg. of 3 batches
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.002 ppm	ICPOES (0.002 ppm)	Avg. of 3 batches
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.003 ppm	ICPOES (0.003 ppm)	Avg. of 3 batches

Elemental Impurity		Class	Likely to be present			If known, please identify the Expected concentration/ unit (or range)	Analytical Method used (Limit of Quantification if available)	Comments regarding source of information (i.e; number of lots tested, frequency of testing; process understanding etc.)
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.02 ppm	ICPOES (0.02 ppm)	Avg. of 3 batches
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.008 ppm	ICPOES (0.008 ppm)	Avg. of 3 batches
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.104 ppm	ICPOES (0.006 ppm)	Avg. of 3 batches
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.145 ppm	ICPOES (0.03 ppm)	Avg. of 3 batches
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.031 ppm	ICPOES (0.01 ppm)	Avg. of 3 batches
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.023 ppm	ICPOES (0.0001 ppm)	Avg. of 3 batches
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.0009 ppm	ICPOES (0.0009 ppm)	Avg. of 3 batches
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.002 ppm	ICPOES (0.002 ppm)	Avg. of 3 batches
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.075 ppm	ICPOES (0.00001 ppm)	Avg. of 3 batches
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.005 ppm	ICPOES (0.003 ppm)	Avg. of 3 batches
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.03 ppm	ICPOES (0.03 ppm)	Avg. of 3 batches
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.02 ppm	ICPOES (0.02 ppm)	Avg. of 3 batches

Reference: ICH Q3D Guideline for Elemental impurities, step 4 version, 2014

Authorized Signatory



Avantor Performance Materials India Limited.