Avantor Performance Materials India Ltd.
Plot No.1, GIDC, Panoli, Ankleshwar
Gujarat Pin: 394116, India
www.avantorsciences.com

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	R

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

The product code 7506 and 7508 in Section 1 is manufactured according to current Good Manufacturing Practices (cGMPs) as set forth by 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

Raw Material Origin: Chemical

Section 4 – Regulatory Information

Compendial Compliance Please see the current product specifications at www.avantorsciences.com.

DMF: Avantor Performance Materials LLC may hold Master File(s) for specified product codes, dependent on the country of interest. Inquire with regulatory.support@avantorsciences.com 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: The products listed 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. 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.

Aflatoxins: Aflatoxins as defined by IPEC (International Pharmaceutical Excipient Council) are a group of structurally related toxic compounds produced by certain strains of the fungi Aspergillus flavus and A. parasiticus. Under favorable conditions of temperature and humidity, these fungi grow on certain foods and feeds, resulting in the production of aflatoxins. The most pronounced contamination has been encountered in tree nuts, peanuts, and other oilseeds, including corn and cottonseed. Aflatoxicosis is poisoning which results from ingestion of aflatoxins in contaminated food or feed.

Avantor does not analyze this product for the presence of aflatoxin content. We can confirm the subject materials do not contain, nor are they manufactured with any product commonly affected by aflatoxins.

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: The subject materials mentioned in section 1 are 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)

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)

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.

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. (Ask Avantor Keyword: Expiration)

Management of Change: Please refer to the customer support section of our website for information concerning our Management of Change program. (Ask Avantor Keyword: MOC)

Batch Definition: A batch is a homogenous unit of production.

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 (Trade.Compliance@Avantorsciences.com).

Storage Requirement: 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, refer to further handling and storage information may be found in Section 7 of the product SDS sheet.

Section 6 – Revision History

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

This electronic document is valid without a signature.

Section 7 – Contact Information

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

Avantor Performance Materials India Ltd.
Plot No.1, GIDC, Panoli, Ankleshwar
Gujarat Pin: 394116, India
www.avantorsciences.com

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.

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/ 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.)
Arsenic	As	1	Yes ☐	No ☒	Unknown ☐	0.03 ppm	ICPOES (0.02 ppm)	Avg. of 3 batches
Cadmium	Cd	1	Yes ☐	No ☒	Unknown ☐	<0.0005 ppm	ICPOES (0.0005 ppm)	Avg. of 3 batches
Mercury	Hg	1	Yes ☐	No ☒	Unknown ☐	0.087 ppm	ICPOES (0.006 ppm)	Avg. of 3 batches
Lead	Pb	1	Yes ☐	No ☒	Unknown ☐	0.026 ppm	ICPOES (0.01 ppm)	Avg. of 3 batches
Cobalt	Co	2A	Yes ☐	No ☒	Unknown ☐	0.110 ppm	ICPOES (0.004 ppm)	Avg. of 3 batches
Nickel	Ni	2A	Yes ☐	No ☒	Unknown ☐	1.026 ppm	ICPOES (0.006 ppm)	Avg. of 3 batches
Vanadium	V	2A	Yes ☐	No ☒	Unknown ☐	0.015 ppm	ICPOES (0.002 ppm)	Avg. of 3 batches
Silver	Ag	2B	Yes ☐	No ☒	Unknown ☐	<0.0009 ppm	ICPOES (0.0009 ppm)	Avg. of 3 batches
Gold	Au	2B	Yes ☐	No ☒	Unknown ☐	0.17 ppm	ICPOES (0.002 ppm)	Avg. of 3 batches
Iridium	Ir	2B	Yes ☐	No ☒	Unknown ☐	<0.004 ppm	ICPOES (0.004 ppm)	Avg. of 3 batches
Osmium	Os	2B	Yes ☐	No ☒	Unknown ☐	<0.002 ppm	ICPOES (0.002 ppm)	Avg. of 3 batches
Palladium	Pd	2B	Yes ☐	No ☒	Unknown ☐	<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 ☐	No ☒	Unknown ☐	<0.02 ppm	ICPOES (0.02 ppm)	Avg. of 3 batches
Rhodium	Rh	2B	Yes ☐	No ☒	Unknown ☐	<0.008 ppm	ICPOES (0.008 ppm)	Avg. of 3 batches
Ruthenium	Ru	2B	Yes ☐	No ☒	Unknown ☐	0.104 ppm	ICPOES (0.006 ppm)	Avg. of 3 batches
Selenium	Se	2B	Yes ☐	No ☒	Unknown ☐	0.145 ppm	ICPOES (0.03 ppm)	Avg. of 3 batches
Thallium	Tl	2B	Yes ☐	No ☒	Unknown ☐	0.031 ppm	ICPOES (0.01 ppm)	Avg. of 3 batches
Barium	Ba	3	Yes ☐	No ☒	Unknown ☐	0.023 ppm	ICPOES (0.0001 ppm)	Avg. of 3 batches
Chromium	Cr	3	Yes ☐	No ☒	Unknown ☐	<0.0009 ppm	ICPOES (0.0009 ppm)	Avg. of 3 batches
Copper	Cu	3	Yes ☐	No ☒	Unknown ☐	<0.002 ppm	ICPOES (0.002 ppm)	Avg. of 3 batches
Lithium	Li	3	Yes ☐	No ☒	Unknown ☐	0.075 ppm	ICPOES (0.00001 ppm)	Avg. of 3 batches
Molybdenum	Mo	3	Yes ☐	No ☒	Unknown ☐	0.005 ppm	ICPOES (0.003 ppm)	Avg. of 3 batches
Antimony	Sb	3	Yes ☐	No ☒	Unknown ☐	<0.03 ppm	ICPOES (0.03 ppm)	Avg. of 3 batches
Tin	Sn	3	Yes ☐	No ☒	Unknown ☐	<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.