

## Magnesium Sulfate

### 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>
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 Chemicals™	4200	Magnesium Sulfate, 7-Hydrate U.S.P. - F.C.C.	R
Macron Fine Chemicals™	5053	Magnesium Sulfate, Anhydrous, Powder U.S.P.	R
Macron Fine Chemicals™	5054	Magnesium Sulfate, Anhydrous, Powder U.S.P.	HR
Macron Fine Chemicals™	5691	Magnesium Sulfate, 7-Hydrate, (For Parenteral Use) USP - GenAR®	R
Macron Fine Chemicals™	6046	Magnesium Sulfate, 7-Hydrate U.S.P. - F.C.C.	R

\*MOC = Management of Change

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

The product code 5054 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 codes listed in Section 1 with MOC code "R" 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.

---

### **Section 3 – Physical/Chemical Information**

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

**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 regulatory 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, 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) 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 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:** 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 products are not produced using Ionizing Radiation as described in 21 CFR 179.26 or Sewage Sludge as described in 7 CFR Section 205.2.

---

## 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. 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.

Rev. 9; March 10, 2023 – Updated format reviewed for MOC-QUAL-8908 (pending), MOC-PROC-3654, Delist-00402: 6050-24 (SS)

---

*This electronic document is valid without a signature.*

---

### **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)

---

While the above information is provided in good faith and believed to be accurate as of the date provided, Avantor makes no representations or warranties as to the accuracy or completeness of such information. All Avantor products are subject to Avantor's terms and conditions of sale including the limitations of liability contained therein and any contrary terms and conditions are expressly rejected. As Avantor has no control over purchasers' uses of its products, Avantor expressly disclaims all liability with respect to same.

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.

Avantor, Inc.  
100 Matsonford Rd., Suite 200  
Radnor, PA 19087 USA  
[www.avantorsciences.com](http://www.avantorsciences.com)

**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	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"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
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)	3 commercial batches tested, all below detection limit
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit

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 checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>			
Nickel	Ni	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 to 0.08 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range reported
Vanadium	V	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.07 to 0.19 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range reported
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit



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.)
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Selenium	Se	2B	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 to 0.25 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range is reported
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Chromium	Cr	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.07 to 0.15 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range reported
Copper	Cu	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 to 0.23	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range reported
Lithium	Li	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.08 to 0.12	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range reported
Molybdenum	Mo	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 to 0.06ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range reported.
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit

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"/>			
Tin	Sn	3				<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



David L. Cugini, Sr. QA Analyst

Prepared by the Technical Service Department

Avantor™ Performance Materials, LLC.

Avantor™ Performance Materials, LLC provides the information contained herein in good faith but makes no representations or warranties, either expressed or implied, including without limitation any warranties of merchantability or fitness for a particular purpose with respect to the information set forth herein or the product(s) to which the information refers. Accordingly, Avantor™ Performance Materials, LLC will not be responsible for damages resulting from the use of or reliance upon this information.



Trademarks are owned by Avantor Performance Materials, LLC. or its affiliates unless otherwise noted.

© 2018 Avantor Performance Materials, LLC.



100 Matsonford Rd., Suite 200  
Radnor, PA 19087  
1 855 282 6867  
[www.avantorinc.com](http://www.avantorinc.com)

**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	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"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
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)	3 batches tested, all below MRL
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Nickel	Ni	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.36 – 0.63 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, range reported
Vanadium	V	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.28 – 0.33 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, range reported
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL

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.)
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL

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.)
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.42 – 0.61 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, range reported
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Lithium	Li	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 – 0.09ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, range reported
Molybdenum	Mo	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	0.05 - 0.10 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, range reported
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 batches tested, all below MRL
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<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

A handwritten signature in black ink that reads 'David L. Cugini'.

David L. Cugini, Sr. QA Analyst

Prepared by the Technical Service Department

Avantor™ Performance Materials, LLC

Avantor™ Performance Materials, LLC provides the information contained herein in good faith but makes no representations or warranties, either expressed or implied, including without limitation any warranties of merchantability or fitness for a particular purpose with respect to the information set forth herein or the product(s) to which the information refers. Accordingly, Avantor™ Performance Materials, LLC will not be responsible for damages resulting from the use of or reliance upon this information.

Trademarks are owned by Avantor Performance Materials, LLC or its affiliates unless otherwise noted.

© 2018 Avantor Performance Materials, LLC