

Avantor, Inc.
100 Matsonford Rd., Suite 200
Radnor, PA 19087 USA
www.avantorsciences.com

Methylparaben

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>
Macron Fine Chemicals™	6215	Methylparaben NF - GenAR®	R

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

The product in Section 1 is 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 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 #: 99-76-3

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 [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, cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridized strains), milk, eggs, fish (e.g. bass, flounder, cod), crustacean shellfish (e.g. crab, lobster, shrimp) tree nuts (e.g. almonds, hazelnut, cashew, brazil nut, Pistachio nut, Macadamia and Queensland nut, walnuts, pecans) peanuts, wheat, soybeans, celery, mustard, sesame seed, sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/liter or their products thereof 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. Only the Class 2 solvent Methanol is present. Residual concentration is <3000 ppm. No

other 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 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 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](#).

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 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; July 15, 2008 – Section 4: Updated Residual Solvents statement

Rev. 2; Sept. 2, 2008 – Section 4: Updated Residual Solvents statement to include limit of methanol and reference USP Chapter <467>

Rev. 3; Sept. 25, 2008 – Section 4: Changed "Class 4" to "other" in Residual Solvents statement.

Rev. 4; Jan. 8, 2010 – Entire document: new letterhead and changed all references of "Solv IT Center" to "AskMBI."; Section 7: updated TS manager info.; Section 4: added GRAS section (KES)

Rev. 5; August 15, 2011 – Entire document: new letterhead, and changed all references of "AskMBI" to "AskAvantor." Updated website links for new website; Section 1: Mallinckrodt brand name updated to Macron; added MOC codes;

Section 2: added GMP statement; Section 4: expanded Allergens list; added Residual Metallic Catalysts statement;
Section 5: Added Nutritional/Supplemental Facts Labeling and Organic Status statements; Section 7: updated contact information; minor formatting. PH/MCH
Rev. 6; Sept. 7, 2012 – Entire document: updated headquarters address; Section 4: Added add'l allergens as listed in EU Directive 2003/89/EC; Updated Residual Metallic Catalysts statement; Section 5: Added Management of Change information; Section 7: Removed contact list table and added CS/TS contact information. (JLW)
Rev. 7; Jan. 11, 2016 –Section 4: Updated EMEA Residual Metallic statement to reflect current guideline revision, separated Kosher/Halal status and added certification statement; Section 5: Added COA Date Format statement; (MCH)
Rev. 8; July 19, 2017 –Entire document: new letterhead, Section 4: Added Elemental Impurities Statement. (MCH)
Rev. 9; November 15, 2018 - Entire Document: New Format. (EC)
Rev. 10; August 8, 2020 - Entire document: New format and letterhead (company name & headquarters address). Updated email and website address from avantorinc.com to avantorsciences.com; Section 4: Updated format of DMF statement. Updated Elemental Impurity assessment. Updated GRAS Status statement to add regunum 181.23 per the FDA website; Section 5: Corrected Certificate of Analysis Date Format statement. Removed Nutritional/ Supplemental Facts Labeling and Organic Status statements. Statements only applicable to products with F.C.C. monographs. (KH)
Rev. 11; October 10, 2023 – Entire document new template format. Allergen statement aligned in new format with most recent supplier allergen statement. (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

Regulatory Support

Email: regulatory.support@avantorsciences.com

Trade Compliance

Email: 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: Methylparaben **Product codes:** 6215 **Date:** May 27, 2020

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

Other (explain):

Note: < indicates below method 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"/>			
Arsenic (inorganic)	As	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.45 ppm	ICP-MS	Results provided by manufacturer's testing
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.15 ppm	ICP-MS	Results provided by manufacturer's testing
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.9 ppm	ICP-MS	Results provided by manufacturer's testing
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.15 ppm	ICP-MS	Results provided by manufacturer's testing
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1.5 ppm	ICP-MS	Results provided by manufacturer's 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"/>	<6 ppm	ICP-MS	Results provided by manufacturer's testing
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<3 ppm	ICP-MS	Results provided by manufacturer's testing
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<4.5 ppm	ICP-MS	Results provided by manufacturer's testing
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<3 ppm	ICP-MS	Results provided by manufacturer's testing
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<3 ppm	ICP-MS	Results provided by manufacturer's testing
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<3 ppm	ICP-MS	Results provided by manufacturer's testing
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<3 ppm	ICP-MS	Results provided by manufacturer's testing
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<3 ppm	ICP-MS	Results provided by manufacturer's 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"/>			
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<3 ppm	ICP-MS	Results provided by manufacturer's testing
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<3 ppm	ICP-MS	Results provided by manufacturer's testing
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<4.5 ppm	ICP-MS	Results provided by manufacturer's testing
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.24 ppm	ICP-MS	Results provided by manufacturer's testing
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<42 ppm	ICP-MS	Results provided by manufacturer's testing
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<330 ppm	ICP-MS	Results provided by manufacturer's testing
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<90 ppm	ICP-MS	Results provided by manufacturer's testing
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<16.5 ppm	ICP-MS	Results provided by manufacturer's 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"/>			
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<90 ppm	ICP-MS	Results provided by manufacturer's testing
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<36 ppm	ICP-MS	Results provided by manufacturer's testing
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<180 ppm	ICP-MS	Results provided by manufacturer's testing

Reference: ICH Q3D Guideline for Elemental Impurities



David L. Cugini, Sr. QA Analyst



Prepared by the Technical Service Department

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