

Avantor, Inc.  
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[www.avantorsciences.com](http://www.avantorsciences.com)

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## CITRIC ACID, MONOHYDRATE, EP, E330

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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™	P101	Citric Acid, Monohydrate, EP, E330	RL
Macron Fine Chemicals™	P102	Citric Acid, Monohydrate, EP, E330, MicroPure	RL

\*MOC = Management of Change

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

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 #: 5949-29-1

**Manufacturing Process:** Fermentation. 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, dependant 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:** According to the Original Manufacturer, Cereals containing gluten and products thereof, Crustaceans and products thereof, Eggs and products thereof, Fish and products thereof, Peanut and products thereof, Soybeans and thereof, Milk and dairy products, including lactose, Nuts, Celery and products thereof, Mustard and products thereof, Sesame seeds and products thereof, Sulphur dioxide and sulphites at concentrations <10ppm, Lupin and products thereof, Molluscs and 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 or Avantor produces any of the following types of products: Antibiotics, Aflatoxins, Penicillin, Semi-Synthetic Penicillins, Cephalosporins, other Beta-Lactams, Antibiotics, 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:** The subject materials are not Kosher Certified. For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to the certificate available on AskAvantor for our most up to date listing of Kosher products. ([www.askavantor.com](http://www.askavantor.com) Keyword: Kosher). For other branded products, please reach out to the support contact in Section 7 for the certificate, if available.

**Halal Status:** The subject materials are not Halal Certified. For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to the certificate available on AskAvantor for our most up to date listing of Kosher products. ([www.askavantor.com](http://www.askavantor.com) Keyword: Halal). For other branded products, please reach out to the support contact in Section 7 for the certificate, if available.

**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 CofA 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 AskAvantor for information concerning our lot/batch numbering system. ([www.askavantor.com](http://www.askavantor.com) Keyword: Lot Number). For other branded products, please reach out to the support contact in Section 7 for the certificate, if available.

**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 contact, 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 Working with Avantor tab on the Avantor website. For other branded products, please reach out to the support contact in Section 7 for information on the applicable management of change process.

**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 our Certificate/SDS Search tool on our website [here](#). For other branded 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 our Certificate/SDS Search tool on our website [here](#). For other branded products, please see the current list of product specifications 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; April 24, 2014

Rev. 1; May 22, 2014

Rev. 2; November 25, 2014

Rev. 3; July 13, 2016

Rev. 4; February 01, 2017

Rev. 5; March 26, 2018

Rev. 6; November 18, 2019

Rev. 7; November 04, 2021 - Header: Updated company name from Avantor Performance Materials Poland Spółka Akcyjna to Avantor, Inc.; Section 2: Minor updating to language; Section 3: Revised CAS number, Manufacturing Process and Raw Material Origin; Section 4: Updated Allergen Information; Section 5: Updated Certificate of Analysis Date Format statement. Updated contact information directions for Lot Numbering System and 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; 7: Updated contact information. (KS)

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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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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.

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### Avantor Performance Materials Poland S.A. Elemental Impurities Checklist

Product Name: Citric Acid Monohydrate

Product Number: P101, P102

Elemental Impurity		Class	Potentially Present (tick the appropriate <input checked="" type="checkbox"/> )		Content measured / range with unit	Analytical Method Used (and Limit of Detection if Available, MRL)
Arsenic (inorganic)	As	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Cadmium	Cd	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Mercury (inorganic)	Hg	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Lead	Pb	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Cobalt	Co	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Nickel	Ni	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Vanadium	V	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Gold	Au	2B	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Iridium	Ir	2B	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Osmium	Os	2B	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Palladium	Pd	2B	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Platinum	Pt	2B	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Rhodium	Rh	2B	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Ruthenium	Ru	2B	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,5 ppm	ICP-OES
Selenium	Se	2B	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Thallium	Tl	2B	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES

Elemental Impurity		Class	Potentially Present (tick the appropriate <input checked="" type="checkbox"/> )		Content measured / range with unit	Analytical Method Used (and Limit of Detection if Available, MRL)
Silver	Ag	2B	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Barium	Ba	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Chromium	Cr	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Copper	Cu	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Lithium	Li	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Molybdenum	Mo	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Antimony	Sb	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES
Tin	Sn	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,7 ppm	ICP-OES

Reference: ICH Q3D Guideline for Elemental Impurities, Step 5 version

Quality Assurance Specialist  
 18 Nov 2019   
 Joanna Kaczmarczyk  
 (Date and Signature)