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Citric Acid Monohydrate

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™	0770	Citric Acid Monohydrate, Multicompential	R
Macron Fine Chemicals™	0771	Citric Acid Monohydrate, IP	RL
Macron Fine Chemicals™	0772	Citric Acid Monohydrate, IP	RL
Macron Fine Chemicals™	0773	Citric Acid Monohydrate USP	R
Macron Fine Chemicals™	0774	Citric acid, Monohydrate, CP, Multicompential	R
Macron Fine Chemicals™	0780	Citric acid Monohydrate Multicompential	R
Macron Fine Chemicals™	0790	Citric Acid Monohydrate BP/EP/JP/USP	R

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

The product code(s) 0770, 0773, 0774, 0780, and 0790 listed in Section 1 are manufactured according to current Good Manufacturing Practices (cGMPs) as set forth by International Pharmaceutical Excipients Council (IPEC) guidelines.

The product code(s) 0771 and 0772 listed in Section 1 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 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 #: 5949-29-1

Manufacturing Process: Synthesis, Batch Process. 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, barley, kamut, oat, rye, spelt, wheat, crustaceans, egg, fish, peanuts, soybean, milk, celery, mustard, sesame seed, sulphur dioxide & sulfite, monosodium glutamate, sulfites, lactose, yellow 5 (tartrazine), almond (*amygdalus communis*), Brazil nut (*bertholletia excelsa*), cashew (*anacardium occidentale*), hazelnut (*Corylus avellana*), bisphenol and other materials containing them, gluten, latex, mango, and monomeric di-esters of ortho-phthalic acid (phthalates) and other materials containing them 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, 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 including aflatoxins. 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.

Product codes 0773 and 0780 have not been assessed for Elemental Impurities.

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-Xyz-DD. For example, the Manufactured Date for October 1, 2021 would be reported as 2021-Oct-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; Effective Date: January 24, 2013 (MCH)

Rev. 1; January 13, 2020: Entire document on new letterhead, updated Section no. 2 MOC codes, updated Section no. 4 for Aflatoxin statement, TSE and BSE statement, Residual solvent statement, added Elemental impurity declaration and removed Residual Metallic catalyst; Section no. 5: Added COA Date Format statement, Shelf life information, Batch definition, Storage requirement, Kosher Statement and Country of Origin statement. New product code added 0794 per MOC-PLT-2850 (MK)
Rev. 2; September 25, 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. Consolidated product codes and their statements in PAN-EIP-0023 into this PRDS; Section 1: Corrected MOC codes of 0771 and 0772 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. (KH)

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

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.



Material Name: Citric acid monohydrate

Date: 29/11/18

Product Code: 0790, 0772, 0774

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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	IP/BP/USP Method	Product is analyzed for each batch
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 0.2 ppm	ICP (0.2 ppm)	Avg. of 3 batches
Mercury	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 0.5 ppm	ICP (0.5 ppm)	Avg. of 3 batches
Lead	Pb	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	< 5 ppm	IP/BP/USP Method	Product is analyzed for each batch
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	ICP (1 ppm)	Avg. of 3 batches
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 1 ppm	ICP (0.5 ppm)	Avg. of 3 batches



Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	ICP (1 ppm)	Avg. of 3 batches
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	ICP (1 ppm)	Avg. of 3 batches
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	ICP (1 ppm)	Avg. of 3 batches
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<5 ppm	ICP (5 ppm)	Avg. of 3 batches
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<2 ppm	ICP (2 ppm)	Avg. of 3 batches
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<5 ppm	ICP (5 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"/>	<1 ppm	ICP (1 ppm)	Avg. of 3 batches
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 5 ppm	ICP (5 ppm)	Avg. of 3 batches
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 5 ppm	ICP (5 ppm)	Avg. of 3 batches
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	ICP (0.5 ppm)	Avg. of 3 batches
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 5 ppm	ICP (5 ppm)	Avg. of 3 batches
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	ICP (0.5 ppm)	Avg. of 3 batches



Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 2 ppm	ICP (0.5 ppm)	Avg. of 3 batches
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<5 ppm	ICP (1 ppm)	Avg. of 3 batches
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 2 ppm	ICP (2 ppm)	Avg. of 3 batches
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 2 ppm	ICP (2 ppm)	Avg. of 3 batches
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	ICP (0.5 ppm)	Avg. of 3 batches
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Complies	USP/EP/BP Method	Avg. of 3 batches

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

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Avantor Performance Materials India Limited.



Material Name: Citric Acid Monohydrate

Product Code: 0770,0771

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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	1.069 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"/>	0.059 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"/>	0.100 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"/>	<0.004 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"/>	<0.006 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"/>	<0.002 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"/>	<0.002 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"/>	0.011 ppm	ICPOES (0.003 ppm)	Avg. of 3 batches
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
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.)
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"/>	0.013 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"/>	1.602 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"/>	<0.01 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"/>	0.068 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"/>	0.301 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"/>	<0.00001 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"/>	<0.003 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"/>	0.086 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"/>	0.592 ppm	ICPOES (0.02 ppm)	Avg. of 3 batches

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

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Avantor Performance Materials India Limited.