

Puritan Products Inc.
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www.puritanproducts.com
www.avantorsciences.com

Citric Acid

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>
PURITAN PRODUCTS	5049__GMP	CITRIC ACID 10% SOLUTION PharmaPUR GMP REAGENT	R
PURITAN PRODUCTS	5031__GMP	CITRIC ACID 25% SOL'N PharmaPUR	R
PURITAN PRODUCTS	5039__GMP	CITRIC ACID 50% SOLUTION PharmaPUR GMP	R
PURITAN PRODUCTS	5049__GMP	CITRIC ACID 10% SOLUTION GMP REAGENT	R

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

The products in Section 1 are manufactured according to current Good Manufacturing Practices (cGMPs) as set forth by International Pharmaceutical Excipients Council (IPEC) guidelines.

The subject materials prepared by Puritan Products, 2290 Avenue A, Bethlehem, PA 18017 are manufactured from water purified according to USP requirements for manufacturing and cGMP anhydrous citric acid manufactured in the united states of America by an approved supplier. The anhydrous citric acid raw material is manufactured on dedicated equipment using polypropylene components compatible for Citric Acid and the manufacturing environment. The citric acid is derived from corn with no raw materials of animal origin

A number of the cGMP produced products that are sold by Puritan Products Inc. may not be originally manufactured at our sites. However, we perform the analytical 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 responsibility for, the traceability and quality of the finished, packaged product that we offer. For supply chain information, please contact technical service at the address provided in section 7 of this document.

Section 3 – Physical/Chemical Information

CAS #: 77-92-9

Manufacturing Process: Fermentation, purification

Raw Material Origin: Plant, corn (maize)

Section 4 – Regulatory Information

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

Animal origin (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 subject materials are manufactured using cGMP guidelines which provide controls that allow no potential for cross contamination of any allergens or other products.

This product does not contain any of the following allergens listed under the US Food Allergen Labeling and Consumer Protection Act of 2004: cereals containing gluten, crustaceans, mollusks and their products, peanuts and peanut products, egg and egg products, soybean and soy products, fish and fish products, tree nuts, other allergens such as buckwheat, celery, cottonseed, mustard, mustard seed, rice, lupin, sesame seed and sunflower seeds, milk and dairy products, wheat and wheat products.

This product is not manufactured with equipment that comes in contact with the listed allergens, nor are these allergens within the processing areas. Sulfur dioxide, which is considered a sensitizer, can be used in the manufacture of this product, but residual levels will not exceed 10 ppm.

GMO Information: The subject material citric acid may be produced using raw materials from GM corn. The raw material manufacturer confirms GM DNA or proteins are not expected to be present in detectable amounts due to refining and successive processing including physical separation, heating, purification, and filtration. The manufacturer reports samples which were previously tested by a third party provider were found to be non detectable for GM DNA down to 0.1% by PCR testing.

Residual Solvents/Organic Volatile Impurities (OVI) Information: No Class 1, 2, 3, or non-ICH solvents are used in the manufacture of these products. Due to possible organic acid and other carbohydrate reactions that naturally occur in sugars, only Class 3 or non-ICH solvents may be present below 0.1%.

Melamine

The subject materials supplied by Puritan products are not produced or processed with melamine or materials considered to be at risk for melamine contamination. The raw materials used for the subject materials are not considered to be at risk of melamine contamination and the products are not tested for melamine contamination

Phthalates, Metal Catalysts, Conflict minerals

Phthalates are not used in the production of citric acid raw material and are not expected to be found in the finished product. Metal Catalysts are not used in the production of citric acid and Metal Reagents (as listed in the EMEA/CHMP/SWP/4446/2000 guideline) are not added during the manufacturing process. Conflict minerals originating in the Democratic Republic of the Congo or its adjoining countries are not used in the production of the subject materials.

Elemental Impurities: The subject products have not been assessed for Elemental Impurities.

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 MM/DD/YYYY

Lot Numbering System:

All Puritan Products brand chemicals have lot numbers containing 11 digits.

The first four digits of the lot number are the product code

The next three digits of the lot number represent the Julian date

The next two digits represent the last two digits of the year

The last two digits represent the sequence of lot numbers assigned that day

Please refer to the customer support section of our website for more information concerning our lot/batch numbering system. <https://www.puritanproducts.com/resources-support/technical-resources/how-to-interpret-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. Dates are assigned in conformance with Puritan's Product Shelf Life/Expiration Date Policy (<https://www.puritanproducts.com/wp-content/uploads/2018/04/7P10F1-Shelf-Life-Policy-19-FEB-2018-1.pdf>) except where otherwise noted on the product CoA. Shelf life periods are valid for unopened containers only. The expiration date of a product is the shelf life period added to the manufacture date of the product and extended until the end of the month. For products that do not have assigned dates please contact Technical Support through the customer support section of our website

Management of Change: Puritan actively identifies changes both internally (our processes), and externally (our suppliers' processes) and requires our suppliers to have an MOC program, to which we subscribe and are notified when there are changes that impact our supply chain of certain products. We notify the appropriate personnel in your organization who have registered for our MOC program. If your company purchased a Puritan Products brand material directly from us within the past three years, then the notice will be sent directly to the contacts within your organization. If your company purchased an affected Puritan Products brand product through one of our distribution channels, then the key personnel in the distribution channel will be notified. Please refer to our website for additional information <https://www.puritanproducts.com/quality/management-of-change/>

Country of Origin Statement: The subject materials are manufactured in the United States of America.

Storage Requirements: Please refer to the product Certificate of Analysis. In the absence of specific storage conditions listed on the Product Certificate of Analysis, Puritan 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 SDS sheet.

Section 6 – Revision History

Rev. 0; April 19, 2021 – Entire Document new format to align with IPEC EIP and Avantor global quality

This electronic document is valid without a signature.

Section 7 – Contact Information

Customer Service

United States

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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

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