

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

Acetic Acid

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered

Brand	Product Code	Product Description	MOC* code
PURITAN PRODUCTS	2499__GMP	ACETIC ACID 0.1 N SOLUTION PharmaPUR GMP	R
PURITAN PRODUCTS	2500__GMP	ACETIC ACID 1.0M Solution 0.9-1.1M PharmaPUR®	R
PURITAN PRODUCTS	2517__GMP	ACETIC ACID 80%	R
PURITAN PRODUCTS	2518__GMP	ACETIC ACID GLACIAL USP MultPUR GMP	R
PURITAN PRODUCTS	2519__GMP	ACETIC ACID 80% SOL'N PharmaPUR GMP	R
PURITAN PRODUCTS	2520__GMP	ACETIC ACID 4.0 N SOL'N PharmaPUR GMP	R
PURITAN PRODUCTS	2521__GMP	ACETIC ACID GLACIAL USP/EP/JP	R
PURITAN PRODUCTS	2524__GMP	ACETIC ACID 50% SOLUTION PharmaPUR GMP	R
PURITAN PRODUCTS	2526__GMP	ACETIC ACID 36% SOLUTION PHARMAPUR 200L	R
PURITAN PRODUCTS	2560__GMP	ACETIC ACID 50% w/v SOL'N PharmaPUR®	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 glacial acetic acid from an approved supplier and water purified according to USP requirements for manufacturing. The products do not originate from any component of animal or plant.

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 information regarding supply chain, please contact technical service at the address provided in section 7 of this document.

Section 3 – Physical/Chemical Information

CAS #: 64-19-7

Manufacturing Process: Synthesis

Raw Material Origin: Chemical

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 not derived from the following materials identified in the Food Allergen Labeling and Consumer Protection Act of 2004 as major food allergens: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts and soybeans.

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. GMP processes are followed in the production of the material to prevent any potential cross contamination however no testing for specific allergens is performed on this material.

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:

Based on knowledge of the manufacturing processes and raw materials, the manufacturer confirms the following: There are no Class 1, Class 2, or Class 3 residual solvents used.

Only one other solvent (propionic acid) is likely to be present at or below the level of 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

The manufacturer confirmed the subject materials have not been analyzed for the following substances: Lead, Di-iso-nonyl phthalate (DINP); Di(2-ethylhexyl) phthalate (DEHP); Dibutyl phthalate (DBP); Di-iso-decyl phthalate (DIDP); Di-n-octyl phthalate (DNOP); Butylbenzyl phthalate (BBP). However, these substances are not used as a raw material, nor are they added to the manufacturing process or the end product, and are not expected to be present above the threshold levels (>100 ppm for Lead; and concentrations >0.1% for the listed phthalates) for the Consumer Product Safety Improvement Act of 2008

No esters of phthalic acid (also known as ortho-phthalic acid or diesters of 1,2-benzenedicarboxylic acid) are used in the manufacture of this product.

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

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. 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. Shelf life periods are valid for unopened containers only. 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
Rev. 1; October 6, 2022 – Added product code 2526. Revised Phthalate statement to reference originating regulation, edit language of Allergen statement, reviewed other statements for current information,

This electronic document is valid without a signature.

Section 7 – Contact Information

Customer Service
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Technical Service

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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.