

Puritan Products Inc.  
2290 Avenue A  
Bethlehem, PA 18017  
U.S.: 1-877-778-7482 | Fax: 1-610-866-4270  
Outside U.S.: 1-610-573-2600  
[www.puritanproducts.com](http://www.puritanproducts.com)  
[www.avantorsciences.com](http://www.avantorsciences.com)

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## Sulfuric Acid

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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>
PURITAN PRODUCTS	2828__GMP	SULFURIC ACID 95-98% NF, FCC	R
PURITAN PRODUCTS	2830__GMP	SULFURIC ACID 4.5N SOLUTION PharmaPUR GMP	R
PURITAN PRODUCTS	2832__GMP	SULFURIC ACID 45% GMP	R
PURITAN PRODUCTS	2894__GMP	SULFURIC ACID 1.00N SOL'N PharmaPUR GMP	R
PURITAN PRODUCTS	8382__GMP	SULFURIC ACID 2.0N SOLUTION PharmPUR GMP	R
PURITAN PRODUCTS	8386__GMP	SULFURIC ACID 5.0N SOLUTION PharmaPUR GMP	R
PURITAN PRODUCTS	8388__GMP	SULFURIC ACID 10.0N SOLUTION PharmaPUR GMP	R

\*MOC = Management of Change

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#### 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 sulfuric acid from an approved US Manufacturer 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.

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### Section 3 – Physical/Chemical Information

CAS #: 7664-93-9

Manufacturing Process: Synthesis

Raw Material Origin: Chemical

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### Section 4 – Regulatory Information

**Compendial Compliance:** Please see the current product specifications at [www.avantorsciences.com](http://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:** 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.

The subject materials are not derived from materials identified in the Food Allergen Labeling and Consumer Protection Act of 2004 as major food allergens. The products listed above do not contain cereals containing gluten (i.e. wheat, rye, oats, barley, spelt, kamut or their hybridized strains), malt, triticale, gluten, other grains, corn, soy, soybeans, eggs, yeast, canola, milk, dairy products, fish, crustacean shellfish, seafood products, tree nuts, peanuts, nut products (i.e. Almond (*Amygdalus communis* L.), Hazelnut (*Corylus avellana*), Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut (*Carya illinensis* (Wangenh.) K. Koch), Brazil nut (*Bertholletia excelsa*), Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*)), seed products (sesame seeds and products thereof), natural grape products, natural flavors, artificial flavors, celery, mustard, lactose, sulfites, elemental sulfur, preservatives, lupine and products thereof, MSG, disodium guanylate/inosinate, artificial sweeteners, phenylalanine, additives, colorants, dyes, or natural rubber (latex). These products are manufactured using cGMP guidelines which provide controls that allow no potential for cross contamination of any allergens or other products.

**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.

**Melamine**

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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 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. We have no reason to expect that these substances would be present above the threshold levels in this legislation (>100 ppm for Lead; and concentrations >0.1% for the listed phthalates).

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

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#### **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

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**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.

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## Section 6 – Revision History

Rev. 0; April 30, 2021 – Entire Document new format to align with IPEC EIP and Avantor global quality

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*This electronic document is valid without a signature.*

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## Section 7 – Contact Information

### Customer Service

United States  
U.S.: 1-877-778-7482  
1-610-573-2600 (outside U.S.)  
Fax: 1-610-866-4270  
[info@puritanproducts.com](mailto:info@puritanproducts.com)  
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### Technical Service

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Phone: 1-855-282-6867  
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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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