

Puritan Products Inc.
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Sodium Hydroxide

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	7660__GMP	SODIUM HYDROXIDE 1.0N SOL'N PharmaPUR GMP	R
PURITAN PRODUCTS	7664__GMP	SODIUM HYDROXIDE 0.1 N SOL'N PharmaPUR GMP	R
PURITAN PRODUCTS	7668__GMP	SODIUM HYDROXIDE 0.5N (+/-0.02%)	R
PURITAN PRODUCTS	7669__GMP	SODIUM HYDROXIDE 0.5N (+/-0.02%)	R
PURITAN PRODUCTS	7670__GMP	SODIUM HYDROXIDE 1.00N SOLUTION PharmaPUR GMP	R
PURITAN PRODUCTS	7671__GMP	SODIUM HYDROXIDE 1.0N (+/-0.025)	R
PURITAN PRODUCTS	7672__GMP	SODIUM HYDROXIDE 5.0 N SOL'N PharmaPUR GMP	R
PURITAN PRODUCTS	7673__GMP	SODIUM HYDROXIDE 8.0N	R
PURITAN PRODUCTS	7674__GMP	SODIUM HYDROXIDE 10.0 N SOL'N PharmaPUR GMP	R
PURITAN PRODUCTS	7675__GMP	SODIUM HYDROXIDE 10.0N PharmaPUR	R
PURITAN PRODUCTS	7676__GMP	SODIUM HYDROXIDE 25%(+/-0.5%)	R
PURITAN PRODUCTS	7677__GMP	SODIUM HYDROXIDE 25%(+/-0.5%)	R
PURITAN PRODUCTS	7678__GMP	SODIUM HYDROXIDE 50% SOL'N PharmaPUR GMP	R
PURITAN PRODUCTS	7679__GMP	SODIUM HYDROXIDE 50%	R
PURITAN PRODUCTS	7680__GMP	SODIUM HYDROXIDE 10%	R
PURITAN PRODUCTS	7681__GMP	SODIUM HYDROXIDE 6N	R
PURITAN PRODUCTS	7682__GMP	SODIUM HYDROXIDE 2.0N SOL'N PharmaPUR GMP	R

PURITAN PRODUCTS	7723__GMP	SODIUM HYDROXIDE 50% SOL'N PharmaPUR GMP	R
PURITAN PRODUCTS	8708__GMP	SODIUM HYDROXIDE 5.0 N SOLUTION PharmaPUR GMP	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 sodium hydroxide, NF pellets from an approved supplier and water purified according to USP requirements for manufacturing. 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. Additional information on Puritan 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 #: 1310-73-2

Manufacturing Process: Synthesis

Raw Material Origin: Chemical

Section 4 – Regulatory Information

Compendial Compliance: NA

Animal origin (BSE/TSE Status) The subject materials do not originate from any component of animal or plant and 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 manufactured with raw materials containing any allergenic products according to Directive 2007/68/EC amending annex IIIa of Directive 2000/13/EC and none of the following substances:

Alcohols, Bisphenol A, Glycol Ethers, Melamine, Sulphites, Antibiotics, Coconut, Hormones, Parabens, Thiuram, Antioxidants, Dioxines, Jatropha, Pesticides, Beeswax, Glutamates, Latex, PreservativesMSG - (Monosodium Glutamate) Grains (including, but not limited to: barley, oats, rice, etc.)Corn (including, but not limited to: maltodextrin, corn starch, corn syrup, etc.)

Colors (including, but not limited to: FD&C Yellow 5 & 6, titanium dioxide, carmine, Tartrazine Dye, synthetic iron oxide, etc.)

Yeast or Yeast Derivatives (including, but not limited to: Autolyzed Yeast Extract, Yeast Extract)
Antioxidants - Specify (including, but not limited to: Tocopherols, BHA, BHT, L-cysteine) Added
Diacetyl, Phenylalanine, Cereals, Buckwheat, Tomatoes, Peaches, Lupine, Pork, Potato

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: No Class 1, 2, 3 or other solvents are used or produced in the manufacturing or purification of the product.

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

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. 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 reach out to the support contact in Section 7 for additional information.

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 (3) 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. If you require further documentation, please reach out to the support contact in Section 7.

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; February, 28, 2022 – Section 1 -added codes for products 7660__GMP, 7664__GMP, 7668__GMP, 7669__GMP, 7671__GMP, 7674__GMP, 7675__GMP, 7677__GMP, 7680__GMP, 7682__GMP, Section 2-5 updated contact instructions (SS)

This electronic document is valid without a signature.

Section 7 – Contact Information

Customer Service

United States

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1-610-573-2600 (outside U.S.)

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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

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