
Acetic 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>
J.T.Baker®	9522	Acetic Acid, Glacial U.S.P. - F.C.C.	R
J.T.Baker®	9526	Acetic Acid, Glacial, U.S.P. Multi-Compendial	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.

A number of the cGMP produced products that are sold by Avantor Performance Materials, Inc. 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.

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 our website. Instructions can be found in the Ask Avantor Q&A Center of the customer support section of our web site or by directly linking to www.askavantor.com Keyword: Manufacturer Code.

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.avantormaterials.com.

DMF: Avantor Performance Materials, Inc. does not carry a Drug Master File for these products.

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 products listed 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 illiniesis* (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: The above glacial acetic acid 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 with the following exceptions: *Only Class 3 Solvents are likely to be present. Residual concentration of all Class 3 Solvents is <0.35%.* The class 3 solvents that may be present are formic acid and methyl acetate which are typically < 5 ppm.

Residual Metallic Catalysts: No metal catalysts or metal reagents, as defined by EMEA Guideline on the Specification Limits for Residues of Metal Catalysts or Metal Reagents (CPMP/SWP/QWP/4446/2000), are used in the production of the above subject materials.

Kosher Status: Certified Kosher – Pareve for year-round use. Please refer to the customer support section of our website for our most up to date listing of Kosher products. (www.askavantor.com Keyword: [Kosher](#))

Halal Status: < J.T.Baker® 9526 is Halal Certified.> Please refer to the customer support section of our website for our most up to date listing of Halal products. (www.askavantor.com Keyword: [Halal](#))

GRAS Status: The United States Food and Drug Administration (FDA) have acknowledged that the chemical listed in Section 1 is a Direct Food Substances Affirmed As Generally Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per 21 CFR parts 184.1005.

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 YYYY/MM/DD from our ERP system effective April 30, 2012. For example, the Manufactured Date for October 1, 2012 would be reported as 2012/10/01.

Prior to ERP implementation, the Release Date on the C of A was reported as MM/DD/YYYY. For example, the Release Date for October 1, 2012 would have been reported as 10/01/2012.

Lot Numbering System and Batch Description: Please refer to the customer support section of our website for information concerning our lot/batch numbering system. (www.askavantor.com Keyword: Lot Number)

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 contact Technical Support through the customer support section of our website for our product stability profiles. (www.askavantor.com Keyword: Expiration)

Nutritional/Supplement Facts Labeling: Bulk food chemicals that are intended for the use in manufacturing of finished food products or for products that are to be processed, labeled, and/or repacked at a site other than where it's originally processed or packed, are exempt from the Nutrient Content Evaluation and Nutrient Labeling Requirements. (21 CFR 101.9(j)(9))

Organic Status: The products listed in Section 1 are not certified as organic. However, to the best of our knowledge, the product is not produced using Ionizing Radiation as described in 21 CFR 179.26 or Sewage Sludge as described in 7 CFR Section 205.2.

Management of Change: Please refer to the customer support section of our website for information concerning our Management of Change program. (www.askavantor.com)
Keyword: MOC)

Section 6 – Revision History

Rev. 0; Oct. 1, 2007 – IPEC EIP format

Rev. 1: April 30, 2008 – Section 4: Aligned Residual Solvents statement with product Certificate of Analysis

Rev. 2: June 9, 2008 – Section 4: Added detail to Residual Solvents statement

Rev. 3; Jan. 2, 2009 – Section 1: Deleted product 0320; Section 4: Residual Solvents statement updated to mention “other” solvents and specifically reference USP chapter <467>. Added sentence specifically for the acetic acid solutions; Section 7: updated telephone # for Customer Service Director; Entire Document: added keywords to Solv It Center links. (KES)
Rev. 4; Mar. 2, 2009 – Entire Document: New Letterhead; Section 4: Residual Solvents statement: changed “Residual concentration of all...” to “Residual concentration of each...” (KES)

Rev. 5; Apr. 15, 2009 – Section 4: Residual Solvents statement: Per MOC-QUAL-3791 residual solvents limit changed from 0.5% to 0.35%; Changed “Residual concentration of each...” to “Residual concentration of all...”; Section 7: Updated telephone # for Technical Services Manager. (K. Sebring)

Rev. 6; Nov. 23, 2009 – Section 1: Removed product code 0321 (see Acetic Acid M datasheet). Section 4: removed reference to product code 0321 in Residual Solvents section with minor formatting. Added residual metallic catalysts statement; Entire document: new letterhead and changed all references of “Solv IT Center” to “AskMBI.” (JLW)

Rev. 7; May 16, 2011 – Entire document: new letterhead and changed all references of “AskMBI” to “AskAvantor.” Updated website links for new website; minor formatting; Section 1: added MOC codes; Section 2: added GMP statement; Section 4: expanded Allergens list; added GRAS statement; Section 5: added Nutrition and Organic statement; Section 7: updated contact information. (JLW)

Rev. 8; Dec. 8, 2011 – Headquarters address updated; Section 7: updated contact list. (JLW)

Rev. 9; Dec. 11, 2012 – Section 4: added add'l allergens as listed in EU Directive 2003/89/EC; updated Residual Metallic Catalysts statement; separated Kosher/Halal status and added certification statement; Section 5: added Management of Change information; added COA Date Format statement; Section 7: removed contact list table and added CS/TS contact information. JDR

Rev. 10; March 13, 2013 – Section 4: updated Residual Metallic Catalysts statement. (MCH)

Rev. 11; May 7, 2015 – Section 4: Updated Halal statement. (MCH)

This electronic document is valid without a signature.

Section 7 – Contact Information

Customer Service

Phone: 1-855-282-6867
1-610-573-2600 (outside U.S.)
Fax: 1-610-573-2650

Technical Service

Phone: 1-855-282-6867
1-610-573-2600 (outside U.S.)
Fax: 1-610-573-2650