
Polysorbate 20

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®	4116	Polysorbate 20, N.F. 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 #: 9005-64-5

Manufacturing Process: Synthesis

Raw Material Origin: Plant

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 wheat, rye, oats, barley, spelt, malt, triticale, gluten, other grains, soy, eggs, yeast, canola, dairy products, seafood products, seed products, natural grape products, natural flavors, artificial flavors, celery, lactose, sulfites, elemental sulfur, preservatives, 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. Please be advised that this product is produced from substances of vegetable origin (corn, coconut).

GMO Information: The raw materials used to manufacture this product (palm, coconut, corn, sunflower, petrochemical) are non-GMO materials.

Residual Solvents/Organic Volatile Impurities (OVI) Information: The subject materials (all lots) comply with the requirements of the ICH Q3C Residual Solvents Guideline and USP<467>Residual Solvents. Of the solvents described as Class 1, 2, 3, and other Residual Solvents in USP <467>: Only Class 2 (1,4 Dioxane, Ethylene Glycol) and Class 3 (acetic acid, 2-propanol) solvents are likely to be present. Class 2 solvents are below the Option 1 limits and any Class 3 solvent is <0.5%.

Solvent	Class	Concentration Level
1, 4 Dioxane	2	≤ 5 ppm
Ethylene Glycol	2	≤ 620 ppm
Acetic Acid	3	≤ 0.5 %
2-Propanol	3	≤ 0.5 %
Ethylene Oxide	--	≤ 1 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 (CHMP/SWP/4446/2000), are used in the production of the above subject materials.

Kosher Status: The subject materials are not Kosher Certified. 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: The subject materials are not 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](#))

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)

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; Jan. 2, 2008 - Section 4: Residual Solvents statement updated to mention “other” solvents and specifically reference USP chapter <467>. Identified the Class 3 solvents; Section 7: updated telephone # for Customer Service Director; Entire Document: added keywords to Solv It Center links. (KES)

Rev. 2; Oct. 1, 2009 - Entire document: new letterhead and changed all references of “Solv IT Center” to “AskMBI.”; Section 4: Added Residual Metallic Catalysts statement;

Rev. 3; June 17, 2011 - Entire document: new letterhead and changed all references of “AskMBI” to “AskAvantor.” Updated website links for new website; Section 1: added MOC codes, removed delisted product J.T. Baker 4034; Section 2: added GMP statement; Section 4: updated Residual Solvents statement; Section 7: updated contact information; minor formatting. MCH

Rev. 4; Jan. 9, 2012 – Entire Document: Headquarters address changed to new location; minor formatting; Section 4: added residual solvents max concentration levels; Section 7: updated titles/phone numbers in contact list. (JLW)

Rev. 5; March 3, 2014 –Section 4: Updated Residual Metallic Catalysts statement; separated Kosher/Halal status and added certification statement; Section 5: separated Kosher/Halal status and added certification statement; added Management of Change information; Section 7: removed contact list table and added CS/TS contact information. (MCH)

This electronic document is valid without a signature.



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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
