
POLYSORBATE 80

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered

<u>Brand</u>	<u>Product Code</u>	<u>Description</u>	<u>MOC*</u>
J.T.Baker®	4117	Polysorbate 80, NF, 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 the International Pharmaceutical Excipients Council (IPEC) guidelines and it meets cGMP requirements. For instructions to decipher the manufacturer reference code please consult our website. Instructions to decipher the manufacturer reference code can be found in the 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 #: 9005-65-6

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.

Per confirmation from our supplier:

- NO animal origin materials listed as “Specified risk materials” in Commission Decision 97/534/EC are used in the manufacture of the product

- Neither source materials nor any materials used during production processes as defined in Section 2 of the “Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products” (EMA/410/01 rev. 3) are used in the manufacture.

- There is no possibility of the product to contact or cross-contaminate with animal origin materials, during manufacturing process.

Allergen/Hypersensitivities Information: The products listed do not contain wheat, rye, oats, barley, spelt, malt, triticale, gluten, other grains, soybean, eggs, yeast, canola, dairy products, seafood products, peanuts, 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).

Please be advised that the product is sourced from substances of vegetable (corn, palm, sunflower, or coconut).

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: This product is manufactured from oleic acid of palm, coconut, or sunflower origin, sorbitol from corn, and ethylene oxide from petrochemical origin.

The palm, coconut, sunflower, ethylene oxide are non-GMO materials.

Sorbitol, crystalline and solutions are made by hydrogenation of starch hydrolysates from corn. Our manufacturer's policy is to procure its raw material corn from internationally approved crop sources. The sorbitol products may or may not be produced from GM corn, and could be regarded as a food ingredient produced from GM organisms under the new EU regulations.

Residual Solvents/Organic Volatile Impurities (OVI) Information: 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%. Below are the solvents that are likely to be present at the typical level present.

Solvent	Typical Level Present
Class 2, 1,4-dioxane	≤ 5 ppm
Class 2, ethylene glycol	≤ 620 ppm
Class 3, acetic acid	< 0.1%
Class 3, 2-propanol	< 0.1%

Residual Metallic Catalysts Information: 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: 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: April 11, 2008- Revise Residual Solvents statement.

Rev 2: October 27, 2008- Revise Residual Solvents statement to include 2-propanol.

Rev. 3: March 13, 2009- added product B4500, updated director of customer service data.

Rev. 4: March 16, 2009- removed product B4500 to a separate datasheet (EIP-0178)

Rev. 5: Sept. 24, 2009 – Section 4: added Residual Metallic Catalysts statement; Entire Document: changed references of “Solv IT Center” to “AskMBI” (KES)

Rev. 6; March, 7th 2011 – Updated GMO section to correct conflicting corn origin information. Entire document: new letterhead and changed all references of “Solv IT Center” or “AskMBI” to “AskAvantor.” Updated website links for new website; Section 7: updated contact information. (PH)

Rev. 7; March 30, 2011 – Section 4: Added peanuts to the Allergen list; Corrected residual solvents info for Ethylene glycol; minor formatting. (JLW)

Rev. 8; June 22, 2011 – Section 1: added MOC codes; Section 2: added GMP statement; Section 7: updated contact information minor formatting. PH-MCH

Rev. 9; Oct 9, 2012 HDQ address change, Section 5: added Management of Change information; Section 7: removed contact list table and added CS/TS contact information. (JDR)
Rev. 10; March 12, 2013–Section 4: updated Residual Metallic Catalysts statement; separated Kosher/Halal status and added certification statement; Section 5: Added COA Date Format statement (MCH).
Rev. 11; September 1, 2016–Section 4: Added statement to EMA/410/01 rev. 3; Updated EMEA Residual Metallic statement to reflect current guideline revision. (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