



Polysorbate 80

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered :

<u>Brand</u>	<u>Product Code</u>	<u>Product Description</u>	<u>MOC*</u>
J.T.Baker	4113	Polysorbate 80, N.F., Multi-Compendial	R
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, LLC. 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 QA Center of the support section of our web site or by directly linking to Ask Avantor Keyword: Manufacturer Code.

Section 3 – Physical/Chemical Information

CAS #: 9005-65-6

Manufacturing Process:

Synthesis

Raw Material Origin:

Plant- (Coconut, Palm, or Corn) and Petrochemical Origin.

Section 4 – Regulatory Information

Compial Compliance: Please see the current product specifications at www.AvantorInc.com.

DMF:

Avantor Performance Materials, LLC. 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).

GMO Information:

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

The palm, coconut, 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 %

Elemental Impurities:

Please see attached summary for Elemental Impurity information for listed products.

Aflatoxins:

Aflatoxins as defined by IPEC (International Pharmaceutical Excipient Council) are a group of structurally related toxic compounds produced by certain strains of the fungi *Aspergillus flavus* and *A. parasiticus*. Under favorable conditions of temperature and humidity, these fungi grow on certain foods and feeds, resulting in the production of aflatoxins. The most pronounced contamination has been encountered in tree nuts, peanuts, and other oilseeds, including corn and cottonseed. Aflatoxicosis is poisoning that results from ingestion of aflatoxins in contaminated food or feed.

Avantor does not analyze the product(s) for the presence of aflatoxin content, does not maintain a specification for aflatoxin and cannot provide any guarantee of complete absence in the product(s) due the nature of aflatoxins. However, we can confirm the subject materials do not contain, nor are they manufactured with any product commonly affected by aflotoxins. These include cereals (maize, sorghum, pearl millet, rice, wheat), oilseeds (peanut, soybean, sunflower, cotton), spices (chili peppers, black pepper, coriander, turmeric, ginger), and tree nuts (almond, pistachio, walnut, coconut, Brazil nut).

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. (Ask Avantor 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. (Ask Avantor Keyword: Halal)

GRAS Status:

Not assessed

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

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

Batch Definition: A “batch” is a homogeneous unit of production; each batch of material 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. 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. (Ask Avantor Keyword: Expiration)

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

Country of Origin Statement: Country of Origin is indicated on the product Certificate of Analysis. Please contact our Trade Compliance Department if you require further documentation. (Trade.Compliance@AvantorInc.com)

Storage Requirements: Please refer to the product Certificate of Analysis/Product Specifications. In the absence of specific storage conditions listed on the Avantor specification sheet or certificate of analysis, our 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; 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)

Rev.12; Decemeber 04, 2017- Entire document: new letterhead format (company name and headquarters address);

Section4: Updated Allergen statement, and added Elemental Impurities information, added Aflatoxin Statement;

Section 5: added Storage Requirement, Batch Definition, and Country of Origin Statements (SR)

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

CS.Specialist@AvantorInc.com

Technical Service

Phone: 1-855-282-6867

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

Fax: 1-610-573-2650

Technical.Service@AvantorInc.com

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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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Material Name: Polysorbate 80 **Product codes:** : 4117, 4113 **Date:** May 3, 2016

Source/Type of Excipient: Mineral; Mineral derived; Plant; Plant derived; Synthetic; Fermentation derived

Other (explain):

Elemental Impurity	Class	Likely to be Present	If Known, Please Identify the Expected Concentration /Units (or Range)			Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)	
			Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>			
Arsenic (inorganic)	As	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches

Elemental Impurity		Class	Likely to be Present			If Known, Please Identify the Expected Concentration /Units (or Range)	Analytical Method Used (and Limit of Detection if Available)	Comments regarding source of information (i.e.; number of lots tested, frequency of testing, process understanding, etc.)
			Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>			
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches

Reference: ICH Q3D Guideline for Elemental Impurities, Step 4 version, September 2014



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