
α,α -Trehalose, Dihydrate

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®	4226	α,α -Trehalose, Dihydrate Biotech Reagent	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 #: 6138-23-4

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 Allergen/Hypersensitivities status of this product has not been evaluated.

GMO Information: The product is derived from tapioca starch, which is made from cassava. Genetically modified cassava has not been grown commercially. 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 subject materials (all lots) comply with the requirements of the ICH Q3C Residual Solvents Guideline and USP<467>Residual Solvents. No Class 1, 2, or 3 solvents are likely to be present with the following exceptions: Ethanol (Class 3) is NMT 5000 ppm and Methanol (Class 2) is NMT 3000 ppm. Both are tested, quantified, and reported on the Certificate of Analysis.

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](#))

GRAS Status: The US Food and Drug Administration has issued a letter of no objection to the Generally Recognized As Safe (GRAS) status for trehalose. (GRAS Notice No. GRN 000045)

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)

Shelf Life Information: If a product has an assigned expiration 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)

Section 6 – Revision History

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

Rev. 1; Jan. 20, 2009 – Section 4: updated GMO information to change from corn to tapioca starch; added residual solvents information; Section 7: updated phone number for Director of Customer Service; Added keywords where Q&A Center of the customer support section of our web site is referenced.

Rev. 2; Jan. 11, 2010 – Entire document: new letterhead and changed all references of “Solv IT Center” to “AskMBI.”; Section 7: updated TS manager info. Section 4: to GMO statement added “...which is made from cassava. Genetically modified cassava has not been grown commercially.”; To Residual Solvents statement added “Both are tested, quantified, and reported on the Certificate of Analysis.”; Added GRAS section; to Kosher section added “No Kosher certification is available for this product.” (KES)

Rev. 3; August 17, 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 7: updated contact information. (PH/JLW)

Rev. 4; March 25, 2013 – HDQ address change, minor formatting. Section 4: 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. (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

https://avantormaterials.custhelp.com/app/answers/detail/a_id/1226