Avantor Performance Materials, LLC.
3477 Corporate Parkway
Center Valley, PA 18034
U.S.A.
Tel: 1-610-573-2600
Fax: 1-610-573-2610
www.avantormaterials.com

# Trehalose, Dihydrate

**Product Regulatory Data Sheet**

## *Section 1 – Product Information*

**Products Covered**

| Brand | Product Code | Product Description | MOC* code |
|---|---|---|---|
| J.T.Baker® | 6324 | Trehalose, Dihydrate 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 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

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**Manufacturing Process:** Purification, Batch Process

**Raw Material Origin:** Plant

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***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 material is initially manufactured from starch using enzymatic technology. Alpha-amylase is added to the preparation mixture for the saccharification of starch, which is used in the manufacture of Trehalose. Milk-derived casein is used in the fermentation medium of the microorganisms that produces the a-amylase. The manufacturer of the a-amylase states that the casein is manufactured from milk for human consumption in countries, except the UK and Portugal. They meet "the Standards for Biologically Derived Raw Materials" (Announcement No. 210 issued by the Ministry of Health, Labor and Welfare in 2003). The resulting product is further purified chromatographically to yield a high purity, low endotoxin trehalose product.

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

- For Milk and milk derivatives as per EMA/410/01 rev.3, Section 6.6: Current scientific knowledge and irrespective of the geographical origin, bovine milk is unlikely to present any risk of TSE contamination

- No other 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 of this product.

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

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**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.

Eggs, milk, wheat and soy bean are used in the fermentation medium of microorganisms during the production of enzymes, which are used for the production of the initial trehalose product. The product is further purified after production.

**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:** Only the Class 2 solvent Methanol and the Class 3 solvent Ethanol are likely to be present. Each is tested and the concentration reported for each batch.

**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)

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***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)

**Batch Definition**: A "batch" is a homogeneous unit of production; each batch of 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. (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)

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

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## *Section 6 – Revision History*

Rev. 0; March 11, 2014 – IPEC EIP format (MCH)
Rev. 1; Feb. 9, 2016 – Section 1: update product name. (MCH)
Rev 2; February 27, 2017 – Entire document: new letterhead (company name & headquarters address); Section 4:Added BSE/TSE statement to EMa 410/10 Rev.3; Section 5: added Storage Requirement, Batch Definition, and Country of Origin Statements. (MCH)

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***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
CS.Specialist@avantormaterials.com

Technical Service

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