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# Sucrose

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## Product Regulatory Data Sheet

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### Section 1 – Product Information

#### Products Covered

| <u>Brand</u> | <u>Product Code</u> | <u>Product Description</u>   | <u>MOC*<br/>code</u> |
|--------------|---------------------|------------------------------|----------------------|
| J.T.Baker®   | 4005                | Sucrose, NF Multi-Compendial | R                    |

\*MOC = Management of Change

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### 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](http://www.askavantor.com) Keyword: Manufacturer Code.

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### Section 3 – Physical/Chemical Information

**CAS #:** 57-50-1

**Manufacturing Process:** Purification

**Raw Material Origin:** Plant

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## **Section 4 – Regulatory Information**

**Compendial Compliance:** Please see the current product specifications at [www.avantormaterials.com](http://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 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.

**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:** The above subject materials (all lots) are not manufactured with the solvents listed as Class 1, Class 2, Class 3 or other solvents in the International Committee of Harmonization (ICH) Guidelines and USP<467>Residual Solvents with the following exceptions:

Production involves ethanol (Class 3) and methanol (Class 2). Ethanol is a Class 3 solvent (5000 ppm max.) and methanol is a Class 2 solvent (3000 ppm max.). The product has a Loss on Drying @ 105 C specification of 0.1% max.

This product complies with the requirements of the ICH Q3C Residual Solvents Guideline and USP<467> Residual Solvents.

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**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 (CPMP/SWP/QWP/4446/00), 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](http://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](http://www.askavantor.com) Keyword: [Halal](#))

**GRAS Status:** The United States Food and Drug Administration (FDA) have acknowledged that Sucrose is a Direct Food Substances Affirmed as Generally Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per 21 CFR parts 184.1854.

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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](http://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](http://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](http://www.askavantor.com) Keyword: MOC)

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## ***Section 6 – Revision History***

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

Rev. 1; Aug. 16, 2011 – Entire document: new letterhead, and changed all references of “Solv IT Center” to “AskAvantor.” Updated website links for new website; minor formatting ; Section 1: Mallinckrodt brand name updated to Macron; added MOC codes; Section 2: added GMP statement; Section 4: expanded Allergens list; added USP<467> to residual solvents statement; added Residual Metallic Catalysts and GRAS statements; Section 7: updated contact information. (PH/JLW)

Rev. 2; April 2, 2013 – HDQ address change, minor formatting ; Section 4: added add'l allergens as listed in EU Directive 2003/89/EC; updated Residual Metallic Catalysts statement; 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)

Rev. 3: Sept. 10, 2013 – Section 4: Updated Residual Solvents Statement to include “other solvents” . (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

### Technical Service

Phone: 1-855-282-6867  
1-610-573-2600 (outside U.S.)  
Fax: 1-610-573-2650