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## Sucrose

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### 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®	4074	Sucrose, Crystal, N.F., Multi-Compendial	R
Macron Fine Chemicals™	7723	Sucrose, NF - GenAR®	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, 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.

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### **Section 3 – Physical/Chemical Information**

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

**Manufacturing Process:**

Purification

**Raw Material Origin:**

Plant-Sugar cane.

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### **Section 4 – Regulatory Information**

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

**DMF:**

Avantor Performance Materials, Inc. does not carry a Drug Master File for these products.

**BSE/TSE Status:**

Sucrose is not derived from animal-based raw materials. However, the sucrose DOES come into contact with animal bone charcoal (bone char) during the refining process.

The use of natural charcoal in the sugar refinement process is approved and certified safe by both the FDA and USDA, and all materials used in the refining process are fully approved as required by the federal government's strict manufacturing standards. The bone char, or natural charcoal, is sterile material used to remove color, impurities and certain naturally occurring minerals from the sugar during the refining process. It acts as an adsorbent to physically remove the impurities.

The manufacturing process of the bone char is such that virtually all organic matter is destroyed, leaving only the inert granular substance called natural charcoal. During manufacturing of the bone char, the bone char supplier confirms that clean, sun dried crushed cattle bone is heated to at least 800°C. The production of bone char uses only raw materials (bovine) sourced from one, or a combination, of the following regions: Brazil and Mexico.

Per our supplier, based on above and on their knowledge of the raw materials and processes used in the manufacture of the above cane sugar products, BSE is not an issue for any of the finished 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 illinensis* (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 subject materials (all lots) comply with the requirements of the ICH Q3C Residual Solvents Guideline and

USP<467>Residual Solvents. No Class 1, 2, 3 or other solvents are used or produced in the manufacturing or purification of the product.

**Elemental Impurities:**

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

**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:**

The United States Food and Drug Administration (FDA) have acknowledged that the chemical listed in Section 1 is a substance 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

**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.

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## **Section 6 – Revision History**

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

Rev. 1; Sept. 25, 2008 – Section 4: Updated BSE statement to include “The bones are sourced from bovine, ovine, and caprine slaughter houses where the animals were healthy and fit for human consumption. Fallen animals are not used.” and clarified the countries of origin. Updated Residual Solvents statement to reference USP Chapter <467> and “other solvents.”

Rev. 2; March 22, 2011 – 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. Added GRAS statement. Updated Mallinckrodt to Macron. (MCH)

Rev. 3; March 23, 2012 - Entire document: updated headquarters address; updated website links to new Avantor website; minor formatting; Section 1: added MOC codes; Section 2: added GMP statement; Section 4: Updated EMEA/410/01 Rev. 3 –(July 2011) reference; expanded Allergens list; Section 7: updated contact information, (MCH)

Rev. 4; April. 2, 2013 –Section 4: added add’l allergens as listed in EU Directive 2003/89/EC; Added 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. 5; Aug. 7, 2014 –Section 4: Updated BSE/TSE information to reflect information per MOC-PROC-2140.(MCH)

Rev. 6; July 21, 2017 – Entire document: Updated to new format, letterhead; Section 4: Updated BSE/TSE information to reflect current supplier statement(no change in status), added Elemental Impurities statement(MCH).



**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@AvantorInc.com

Technical Service

Phone: 1-855-282-6867

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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:** Sucrose **Product codes:** : 4074, 7723, 7724 **Date:** January 3, 2017

**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.)
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 type="checkbox"/>	Unknown <input checked="" type="checkbox"/>		N/A	Not tested. Manufacturer indicates not used in the manufacturing process.
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

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.)
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
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>		N/A	Not intentionally used in the manufacturing process. Not expected to be present.
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>		N/A	Not intentionally used in the manufacturing process. Not expected to be present.
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"/>		N/A	Not intentionally used in the manufacturing process. Not expected to be present.
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>		N/A	Not tested. Manufacturer indicates not used in the manufacturing process.
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	0.08 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"/>	0.14 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"/>		N/A	Not tested. Manufacturer

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.)
								indicates not used in the manufacturing process.
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"/>		N/A	Not tested. Manufacturer indicates not used in the manufacturing process.
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>		N/A	Not tested. Manufacturer indicates not used in the manufacturing process.

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



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