

Avantor Performance Materials, LLC
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Radnor, PA 19087 USA
www.avantorsciences.com

Sucrose

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® | 4074 | Sucrose, Crystal, N.F. Multi-Compendial | R |
| Macron Fine Chemicals™ | 7723 | Sucrose NF - GenAR® | R |
| Macron Fine Chemicals™ | 7724 | Sucrose NF - GenAR® | 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 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 #: 57-50-1

Manufacturing Process: Purification

Raw Material Origin: Plant- sugar cane

Section 4 – Regulatory Information

Compendial Compliance: Please see the current product specifications at www.avantorsciences.com.

DMF: Avantor Performance Materials, LLC may hold Master File(s) for specified product codes, dependant on the country of interest. Inquire with regulatory.support@avantorsciences.com for additional details.

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: According to the Original Manufacture the following allergens are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product: Neither crustaceans/shellfish (such as crab, crayfish, lobster, and shrimp), mollusks (oysters, clams, mussels, and scallops) or their products, fish (fresh or saltwater finfish), pork or any other animal, eggs, gluten, sulfites or SO₂ in concentrations above 10 ppm, MSG, milk/dairy, whey, milk byproducts (cheese, curds, lactose, and nougat), butter, peanuts, peanut by-products, chocolate/chocolate derivatives, wheat (bran, bread crumbs, farina, wheat gluten, wheat starch, semolina, malt wheat germ), barley, rye, oats, psyllium, soy, millet, spelt, triticale products, artificial flavorings, caramel color, hydrolyzed protein (vegetable/animal), alcohol,

autolyzed yeast/yeast extracts, tocopherols (vitamin E), celery or its products, mustard or its products, sesame or its products, poppy or its products, latex, iodine, lupin or its products, cocoa, vanilla, legumes/pulses, coriander, umbellifereae, carrots, fruits, tree nuts (including almonds, Brazil nuts, cashews, filberts, hazelnuts, macadamia nuts, chestnuts, pecans, pine nuts, pistachios, and walnuts) nor their derivatives or by-products are present in any of the refined sugars, raw cane sugars, organic sugars, dry rice products, sugarcane molasses and refiners' syrups we manufacture.

Avantor Performance Materials, LLC does not produce any of the following types of products: Antibiotics, Aflatoxins, Penicillin, Semi-Synthetic Penicillins, Cephalosporins, other Beta-Lactams, Cytotoxics, Steroids, Medicated Feeds, or Pesticides.

This product is manufactured and packaged using cGMP guidelines which provide controls that allow no potential for cross contamination of any allergens or other contaminants. However, this product is not tested for the presence of these or any other allergens by Avantor Performance Materials, LLC or the Original Manufacturer, therefore, we do not have confirmation for the absence of any allergens in the product.

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. (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 United States Food and Drug Administration (FDA) have acknowledged that Sucrose (CAS # 57-50-1) 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.

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@avantorsciences.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; Nov. 14, 2008 – Section 4: Removed "soy" from the allergens list; Added "other solvents" to the Residual Solvents statement along with a reference to USP Chapter . Added "This product is not Kosher or Halal certified" to the Kosher/Halal status section.

Rev. 2; March 14, 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 Metallic Impurities statement. Updated Macron brand name. MCH

Rev. 3; Nov. 27, 2012 – Entire document: updated headquarters address, minor formatting; 1: added MOC codes; Section 2: added GMP statement; Section 4: 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. 4; April 19, 2013 – Section 4: added add'l allergens as listed in EU Directive 2003/89/EC; Section 5: Added Nutritional/Supplement Facts Labeling, Organic Status and Phthalate statement. (MCH)

Rev. 5; May 2, 2013 – Section 4: GRAS statement added. (MCH)

Rev. 6; September 1, 2016 – Section 4: Updated EMEA Residual Metallic statement to reflect current guideline revision. (MCH)

Rev. 7; November 6, 2017 – Entire document: new letterhead, new format; Section 4: Replaced Residual Metallic Catalysts with Elemental Impurities statement. (MCH)

Rev. 8; November 20, 2018 – Entire Document: New Format. (EC)

Rev. 9; August 3, 2021- Entire Document: Minor formatting. Updated website and email addresses from avantorinc.com to avantorsciences.com; Section 1: Added product code 7724; Section 4- Updated DMF and Allergen/Hypersensitivities Information statements. (KH)

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@avantorsciences.com

Technical Service

Phone: 1-855-282-6867

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

Fax: 1-610-573-2650

Technical.Service@avantorsciences.com

While the above information is provided in good faith and believed to be accurate as of the date provided, Avantor Performance Materials ("Avantor") makes no representations or warranties as to the accuracy or completeness of such information. All Avantor products are subject to Avantor's terms and conditions of sale including the limitations of liability contained therein and any contrary terms and conditions are expressly rejected. As Avantor has no control over purchasers' uses of its products, Avantor expressly disclaims all liability with respect to same.

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.) |
|--------------------|----|-------|------------------------------|--|----------------------------------|--|--|---|
| | | | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | Unknown <input type="checkbox"/> | | | |
| 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 |

| 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.) |
|--------------------|----|-------|------------------------------|--|----------------------------------|--|--|---|
| 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 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

A handwritten signature in black ink that reads 'David L. Cugini'.

David L. Cugini, Sr. QA Analyst

Prepared by the Technical Service Department

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