
Sodium Chloride

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®	3627	Sodium Chloride, Granular, U.S.P., Multi-Compendial	R
J.T. Baker®	3628	Sodium Chloride, Granular, U.S.P. - F.C.C.	R
J.T. Baker®	3629	Sodium Chloride, Granular, U.S.P. - F.C.C.	R
Macron Fine Chemicals™	7532	Sodium Chloride, Granular, U.S.P. - F.C.C.	R
Macron Fine Chemicals™	7540	Sodium Chloride, Powder, USP - GenAR®	R
Macron Fine Chemicals™	7713	Sodium Chloride, Granular, USP - 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 QA Center of the support section of our web site or by directly linking to Ask Avantor Keyword: Manufacturer Code.

Section 3 – Physical/Chemical Information

CAS #: 7647-14-5

Manufacturing Process:

Synthesis

Raw Material Origin:

Chemical

Section 4 – Regulatory Information

Compendial Compliance: Please see the current product specifications at www.AvantorInc.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 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, 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:

Certified Kosher – Pareve for year-round use.

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:

J.T. Baker® 3627 is 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 sodium chloride is a substance Generally Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per 21 CFR parts 182.70.

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)

Nutritional/Supplement Facts Labeling: Bulk food chemicals that are intended for use in manufacturing of finished food products or for products that are to be processed, labeled, and/or repacked at a site other than where it's originally processed or packed are exempt from the Nutrient Content Evaluation and Labeling Requirements. (21 CFR 101.9(j)(9)).

Organic Status:

The products listed in Section 1 are not certified as organic. However, to the best of our knowledge, the product is not produced using Ionizing Radiation as described in 21 CFR 179.26 or Sewage Sludge as described in 7 CFR Section 205.2.

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.

Section 6 – Revision History

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

Rev. 1; Oct. 1, 2008 – Section 1: added product code 3626; Section 4: updated residual solvents information

Rev. 2; Jan. 14, 2008 – Section 4: added Residual Metallic Catalysts statement; Section 7: Updated telephone # for Director Customer Service; Entire document: added “keywords” to Solv It Center links. (KES)

Rev. 3; Jan. 26, 2010 – Entire document: new letterhead and changed all references of “Solv IT Center” to “AskMBI.”; Section 7: updated TS manager info. Section 4: added GRAS information. (KES)

Rev. 4; Mar. 7, 2011 – Section 1: changed brand name from “Mallinckrodt” to “Macron;” Entire document: new letterhead and changed all references of “AskMBI” to “AskAvantor.” Updated website links for new website; Section 7: updated contact information. (JLW)

Rev. 5; Sept. 11, 2011 – Entire Document: headquarters address changed; Section 1: added MOC code; omitted discontinued code 7576; Section 2: added GMP statement; Section 4: added add'l allergens as listed in EU Directive

2003/89/EC; updated Residual Metallic Catalysts statement; Section 5: added Nutritional, Organic, and Management of Change statements; Section 7: removed contact list table and added CS/TS contact information. (JLW)
Rev. 6; Sept. 18, 2015 - Section 1: Removed codes 3626 and 4577; Section 4: added additional 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 COA Date Format statement; (MCH).
Rev. 7; Nov. 13, 2017 - Update document to new format. Section 4: Removed Residual Metallic Catalysts and added Elemental Impurity Statement. (PT)
Rev. 8; November 16, 2018 - Entire Document: New Format. (EC)

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@AvantorInc.com

Technical Service
Phone: 1-855-282-6867
1-610-573-2600 (outside U.S.)
Fax: 1-610-573-2650
Technical.Service@AvantorInc.com

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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: Sodium Chloride **Product codes:** : 3628, 3627, 3628, 7540, 7532, 7713 **Date:** May 3, 2016

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 ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Cadmium	Cd	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Mercury (inorganic)	Hg	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Lead	Pb	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Cobalt	Co	2A	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Nickel	Ni	2A	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Vanadium	V	2A	Yes ☐	No ☒	Unknown ☐	<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 ☐	No ☒	Unknown ☐			
Silver	Ag	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Gold	Au	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Iridium	Ir	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Osmium	Os	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Palladium	Pd	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Platinum	Pt	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Rhodium	Rh	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Ruthenium	Ru	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Selenium	Se	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Thallium	Tl	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Barium	Ba	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Chromium	Cr	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Copper	Cu	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Lithium	Li	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Molybdenum	Mo	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Antimony	Sb	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Tin	Sn	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches

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



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Prepared by the Technical Service Department
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