

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* code</u>
J.T.Baker®	3618	Sodium Chloride, Granular, U.S.P.	R
J.T.Baker®	3625	Sodium Chloride Multi-Compendial	R
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
J.T.Baker®	LP09	Sodium Chloride, Granular, U.S.P. Multi-Compendial	R
J.T.Baker®	CH22	Sodium Chloride, Granular, U.S.P. Multi-Compendial	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
Macron Fine Chemicals™	BR19	Sodium Chloride USP - GenAR®	R
Macron Fine Chemicals™	BS19	Sodium Chloride 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)

A number of the cGMP produced products that are sold by Avantor 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.

For J.T.Baker® and Macron Fine Chemicals™ brand products, 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 the Avantor website. Instructions can be found by visiting the Ask Avantor link under the Resources tab or by directly linking to www.askavantor.com Keyword: Manufacturer Code. Additional information on Avantor suppliers may be available under NDA. Please reach out to the support contact in Section 7 for additional supplier information inquiries.

Section 3 – Physical/Chemical Information

CAS 7647-14-5

Manufacturing Process: Recrystallization. Additional manufacturing process information may be disclosed under NDA upon request from the support contact in Section 7.

Raw Material Origin: Mineral Derived

Section 4 – Regulatory Information

DMF: Avantor may hold Master File(s) for specified product codes, dependent on the country of interest. Inquire with the support contact in Section 7 for additional details.

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: To the best of our knowledge, the allergens listed in the [US FDA](#), [EU Directive 2003/89/EC](#), and [TGO-91/92](#) are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

Avantor 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 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, 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: For J.T.Baker® and Macron Fine Chemicals™ brand products, kosher certification is aligned to the Avantor packaging site as indicated on the product Certificate of Analysis. Please refer to the site-specific kosher certificate available on AskAvantor for our most up to date listing of kosher products at (www.askavantor.com Keyword: kosher). 3628-65_FIN that is packaged out of Gliwice and Singapore code 3627-67 are NOT Kosher Certified.

Halal Status: For J.T.Baker® and Macron Fine Chemicals™ brand products, halal certification is aligned to the Avantor packaging site as indicated on the product Certificate of Analysis. Please refer to the site-specific halal certificate available on AskAvantor for our most up to date listing of halal products at (www.askavantor.com Keyword: halal). 3628-65_FIN that is packaged out of Gliwice and Singapore code 3627-67 are NOT Halal Certified.

GRAS Status: The United States Food and Drug Administration (FDA) have acknowledged that some chemicals may be considered Substances Generally Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per specific 21 CFR regnums. For the latest information on whether or not an Avantor product is considered GRAS, please visit the [Electronic Code of Federal Regulations](#).

Nutritional/Supplement Facts Labeling: The product codes 3628, 3629, and 7532 listed in Section 1 are bulk food chemicals that are intended for the 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 and are exempt from the Nutrient Content Evaluation and Nutrient Labeling Requirements (21 CFR 101.9(j)(9)).

Organic Status: The product codes 3628, 3629, and 7532 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.

Section 5 – Miscellaneous Product Information

Certificate of Analysis Date Format: The Manufactured Date and Expiration/Retest Date on the Certificate of Analysis are reported as YYYY-MM-DD. For example, the Manufactured Date for October 1, 2021 would be reported as 2021-10-01.

Lot Numbering System and Batch Description: For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to Ask Avantor 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 reach out to the support contact in Section 7 for additional stability inquiries.

Management of Change: For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to Management of Change link under the Working with Avantor tab on the Avantor website.

Country of Origin Statement: Country of Origin is indicated on the product Certificate of Analysis. If you require further documentation, please reach out to the Trade Compliance support contact in Section 7.

Storage Requirements: Please refer to the product’s Certificate of Analysis or Product Specifications. In the absence of specific storage conditions listed on its specification sheet or Certificate of Analysis, 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’s SDS sheet.

Certificates of Analysis: For J.T.Baker® and Macron Fine Chemicals™ brand products, please see the current list of product specifications using the Certificate/SDS Search tool on our website [here](#).

Safety Data Sheet: For J.T.Baker® and Macron Fine Chemicals™ brand products, please see the current product safety information using the Certificate/SDS Search tool on our website [here](#).

Avantor Site Certifications: Please see the current Avantor site certifications on our website [here](#).

Site Quality Overview: Avantor maintains a self-assessment modeled after IPEC guidelines which describes site and quality system information to support the manufacturing activities of this product. Please reach out to the support contact in Section 7 for a current copy of the Site Quality Overview.

Packaging Information: Please reach out to the support contact in Section 7 for current packaging specifications.

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)

Rev. 9; March 4, 2020 - Entire Document: Minor formatting. Updated email and website addresses from avantorinc.com to avantorsciences.com; Section 1: Added product code 3625; Section 4: Updated DMF statement. Updated GRAS Status statement to include additional regnums. (KH)

Rev. 10; August 23, 2021 - Entire Document: Minor formatting. Reviewed all statements for product code 3627 in accordance with MOC-QUAL-3534; Section 1: Added product code 3618 in accordance with NPSU-2816, NPSU-2817, NPSU-2818, NPSU-2819, and NPSU-2820. Added product codes LP09, BS19, and BR19; Section 3: Updated Manufacturing Process and Material Origin from Synthesis and Chemical to more accurately align with Original Manufacturer's processes and documentation; Section 4: Updated Allergen/Hypersensitivities Information statement. Updated Elemental Impurities report to include added product codes and changed Source/Type of Excipient from Synthetic to Mineral Derived to more accurately align with Original Manufacturer's processes and documentation. Specified CAS # in GRAS Status statement. Moved Nutritional/Supplement Facts Labeling and Organic Status statements to Section 4 (previously in Section 5) and applicable product codes specified. (KH)

Rev. 11; October 19, 2023 – Entire document updated to 2023 template, changes made in accordance with MOC-PLT-3111 and CM-2023-000658; Section 1: Added new product code CH22; Section 4: Changes made to Kosher and Halal Status verbiage for the new 3628-65_FIN out of Gliwice and new

Singapore code 3627-67, Allergens Statement was modified, Elemental Impurities were added for 3628-65_FIN packaged out of Gliwice as per MOC-PLT-3111, Added F.C.C Grade product codes 3628, 3629, and 7532 to Nutritional/Supplement Facts Labeling and Organic Status (EM).

This electronic document is valid without a signature.

Section 7 – Contact Information

Technical Service

Phone: 1-855-282-6867 and 1-610-573-2600 (outside U.S.), select option 5

Email: Technical.Service@avantosciences.com

Regulatory Support

Email: regulatory.support@avantosciences.com

Trade Compliance

Email: Trade.Compliance@avantosciences.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 and managed under a validated document control system.



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Material Name: Sodium Chloride **Product codes:** 3618, 3625, 3628, 3627, 3629, 7540, 7532, 7713, LP09, BS19, BR19 **Date:** May 3, 2016

Rev. 1

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.)
			Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>			
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 checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
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
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"/>	<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"/>			
Gold	Au	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
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"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Barium	Ba	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
Chromium	Cr	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
Copper	Cu	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
Lithium	Li	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

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"/>			
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"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Tin	Sn	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

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



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Prepared by the Technical Service Department

Avantor™ Performance Materials, LLC



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Material Name: Sodium Chloride **Product codes:** 3628-65_FIN **Date:** October 24, 2023; Rev. 2

Source/Type of Excipient: Mineral; Mineral derived; Plant; Plant derived; Synthetic;
 Fermentation derived

Avantor Performance Materials Poland S.A. Elemental Impurities Checklist

Product Name: Sodium Chloride

Product Number: 3628

Elemental Impurity	Class	Potentially Present (tick the appropriate <input checked="" type="checkbox"/>)		Content measured / range with unit	Analytical Method Used (and Limit of Detection if Available, MRL)	
		Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>			
Arsenic (inorganic)	As	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Nickel	Ni	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	<0.01 ppm	ICP-OES
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA

Print date: 2 June 2022

Elemental Impurity		Class	Potentially Present (tick the appropriate <input checked="" type="checkbox"/>)		Content measured / range with unit	Analytical Method Used (and Limit of Detection if Available, MRL)
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>		NA
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Chromium	Cr	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	<0.01 ppm	ICP-OES
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA	NA

Reference: ICH Q3D Guideline for Elemental Impurities, Step 5 version

02 Jun 2022 *Cherif*
 (Date and Signature)

Print date: 2 June 2022