

Avantor, Inc.
100 Matsonford Rd., Suite 200
Radnor, PA 19087 USA
www.avantorsciences.com

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®	3301	Sodium Chloride, Granular U.S.P. - F.C.C.	HR (US)
J.T.Baker®	3301	Sodium Chloride Multi-Compendial	R (Poland)
J.T.Baker®	3302	Sodium Chloride, Granular U.S.P. - F.C.C.	HR

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

The US product code 3301 listed in Section 1 is manufactured under current Good Manufacturing Practices (cGMPs) as set forth by ICH Q7 and International Pharmaceutical Excipients Council (IPEC) guidelines.

The product code 3302 and 3301 Poland code 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 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: Purification, Crystalization, Close System, Dedicated Equipment. Additional manufacturing process information may be disclosed under NDA upon request from the support contact in Section 7.

Raw Material Origin: Mineral- Solution mined brine

Section 4 – Regulatory Information

DMF: Avantor may hold Master File(s) for specified product codes, dependant 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: According to the Original Manufacturer, allergens as listed in Annex II of Regulation (EU) 1169/2011, which include, but are not limited to gluten, lactose, and molluscs, in addition to aluminium, latex, and Sodium Nitrite, are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

Neither Avantor Performance Materials, LLC nor the Original Manufacturer 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. For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to the certificate available on AskAvantor for our most up to date listing of Kosher products. (www.askavantor.com Keyword: Kosher). For other branded products, please reach out to the support contact in Section 7 for the certificate, if available.

Halal Status: The subject materials are not Halal Certified. For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to the certificate available on AskAvantor for our most up to date listing of Kosher products. (www.askavantor.com Keyword: Halal). For other branded products, please reach out to the support contact in Section 7 for the certificate, if available.

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 regnuns. 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 3301 (US) and 3302 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 3301 (US) and 3302 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 CoFA are reported as YYYY-MM-DD. For example, the Manufactured Date for October 1, 2021 would be reported as 2012-10-01.

Lot Numbering System and Batch Description: For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to AskAvantor for information concerning our lot/batch numbering system. (www.askavantor.com Keyword: Lot Number). For other branded products, please reach out to the support contact in Section 7 for the certificate, if available.

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, 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 Working with Avantor tab on the Avantor website. For other branded products, please reach out to the support contact in Section 7 for information on the applicable management of change process.

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 our Certificate/SDS Search tool on our website [here](#). For other branded 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 our Certificate/SDS Search tool on our website [here](#). For other branded products, please see the current list of product specifications 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; January 17, 2017 – New product creation. Supplier Number P0005200.(MCH)

Rev. 1; December 17, 2018 – Entire document: – Entire document: new letterhead (logo & headquarters address, updated email from @avantormaterials.com to @avantorinc.com Section 1: Added product code 3302 ; Section 4: DMF statement updated, Removed Residual Metallic Catalyst statement, replaced with Elemental Impurities. (MCH)

Rev. 2; September 27, 2021 – Entire Document: Minor formatting. Updated website and email addresses from avantorinc.com to avantorsciences.com; Section 3: Updated the Manufacturing Process description to align with the information provided on the supplier's process flow diagram. No change to the manufacturing process in accordance with Avantor's MOC program; Section 4: Updated formats of the DMF and Allergen/Hypersensitivities Information statements. Removed the Aflatoxin statement. Information is now included in the Allergen/Hypersensitivities Information statement. Moved the Nutritional/Supplement Facts Labeling and Organic Status statements which were previously in Section 5. (KH)

Rev. 3; December 10, 2021 - Header: Updated company name from Avantor Performance Materials, LLC to Avantor, Inc.; Section 1: Added and differentialted Poland and US 3301 product codes; Section 2: Minor updating to language; Section 4: Removed Compendial Compliance statement. Removed Regulatory email from DMF statement. Specified certificate availability for different branded products for Kosher and Halal Status statements. Generalized GRAS Status statement; Section 5: Updated Certificate of Analysis Date Format statement. Updated contact information directions for Lot Numbering System and Batch Description, Country of Origin Statement, Shelf Life Information, and Management of Change statements. Added Certificates of Analysis, Safety Data Sheet, Avantor Site Certifications, Site Quality Overview, and Packaging Information statements; Section 7: Removed Fax number and Customer Service contact information. Added contacts. (KH)

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@avantorsciences.com

Regulatory Support

Email: regulatory.support@avantorsciences.com

Trade Compliance

Email: Trade.Compliance@avantorsciences.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:** : 3301, 3302 **Date:** July 14, 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.)
			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"/>	<0.1 ppm		Manufacturer declaration based on process knowledge
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.1 ppm		Manufacturer declaration based on process knowledge
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.1 ppm		Manufacturer declaration based on process knowledge
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.1 ppm		Manufacturer declaration based on process knowledge
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.1 ppm		Manufacturer declaration based on process knowledge

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"/>			
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.1 ppm		Manufacturer declaration based on process knowledge
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.1 ppm		Manufacturer declaration based on process knowledge
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable		Not used in process
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable		Not used in process
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable		Not used in process
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable		Not used in process
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable		Not used in process
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable		Not used in process
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable		Not used in process
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable		Not used in process
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable		Not used in process
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Not applicable		Not used in process

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"/>			
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.1 ppm		Manufacturer declaration based on process knowledge
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.1 ppm		Manufacturer declaration based on process knowledge
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.1 ppm		Manufacturer declaration based on process knowledge
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.1 ppm		Manufacturer declaration based on process knowledge
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.1 ppm		Manufacturer declaration based on process knowledge
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.1 ppm		Manufacturer declaration based on process knowledge
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.1 ppm		Manufacturer declaration based on process knowledge

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
Avantor™ Performance Materials, LLC

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Avantor Performance Materials Poland S.A. Elemental Impurities Checklist

Product Name: Sodium Chloride, Multi-Compendial

Product Number: 3301

Elemental Impurity	Class	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"/>	N/A	N/A
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Nickel	Ni	2A	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,1 ppm	ICP-OES
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A

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"/>	N/A	N/A
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Chromium	Cr	3	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	< 0,1 ppm	ICP-OES
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	N/A	N/A

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

30 Jan 2020 
 (Date and Signature)