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Gujarat Pin: 394116, India

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>
Macron Fine Chemicals™	H670	Sodium Chloride USP	R
Macron Fine Chemicals™	H672	Sodium Chloride Multicompndial	R
Macron Fine Chemicals™	H673	Sodium Chloride, Multicompndial	R
Macron Fine Chemicals™	H675	Sodium Chloride IP	RL
Macron Fine Chemicals™	H677	Sodium Chloride, Micronized Multicompndial	R
Macron Fine Chemicals™	H678	Sodium Chloride, CP Multicompndial	R

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

The product codes H670, H672, H673, H677, and H678 listed in Section 1 are manufactured according to current Good Manufacturing Practices (cGMPs) as set forth by International Pharmaceutical Excipients Council (IPEC) guidelines.

The product code H675 in Section 1 with IP monographs is manufactured under current Good Manufacturing Practices (cGMPs) as set forth by the Drugs and Cosmetics Rule, 1945, Government of India Ministry of Health and Family Welfare.

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

Raw Material Origin: Chemical

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.

According to the Original Manufacturer, the products listed do not contain Latex, Phthalates, Gluten, Barley, Kamut, Oat, Rye, Spelt, Wheat, Crustaceans, Egg, Fish, Peanuts, Soybean, Mango, Milk, Celery, Mustard, Sesame Seed, Sulphur Dioxide & Sulfites, Monosodium Glutamate, Sulfites, Lactose, Yellow 5 (tartrazine), Almond, Brazil Nut, Cashew, and Hazelnut 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, penicillin, semi-synthetic penicillins, cephalosporins, other beta-lactams, cytotoxins, 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 including aflatoxins. 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).

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).

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](#).

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-Xyz-DD. For example, the Manufactured Date for October 1, 2021 would be reported as 2021-Oct-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; Effective Date: December 27, 2012 (MCH)

Rev. 1; January 07, 2020: Entire document on new letterhead, updated Section no. 2 MOC codes, updated Section no. 4 for Aflatoxin statement, TSE and BSE statement, Residual solvent statement, added Elemental impurity declaration and removed Residual Metallic catalyst; Section no. 5: Added

COA Date Format statement, Shelf life information, Batch definition, Storage requirement, Kosher Statement and Country of Origin statement. New product code added H678 per MOC-PLT-2850 (MK) Rev. 2; September 15, 2023; Entire document updated to 2023 Template; Section 1: Combined PAN-EIP-0002 information (added product codes H672 and H675), Added product code H670 per Panoli site information list, Changed H675 to MOC Code "RL" – this was a typographical change that is not indicative of a change in quality, therefore we do not have an MOC for it; Section 4: Updates Allergens/Hypersensitivities, Added H670, H672, H675 to Elemental Impurities chart, per the combination with PAN-EIP-0002 – this is a typographical change not a change in quality (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@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.



Material Name: Sodium Chloride

Product Code: H676, H673, H678, H677, H670, H672, H675

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/unit (or range)	Analytical Method used (Limit of Quantification if available)	Comments regarding source of information (i.e; number of lots tested, frequency of testing; process understanding etc.)
Arsenic	As	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	IP/BP/USP Method	Product is analyzed for each batch
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 0.2 ppm	ICP (0.2 ppm)	Avg. of 3 batches
Mercury	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 0.5 ppm	ICP (0.5 ppm)	Avg. of 3 batches
Lead	Pb	1	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Unknown <input type="checkbox"/>	< 5 ppm	IP/BP/USP Method	Product is analyzed for each batch
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	ICP (1 ppm)	Avg. of 3 batches
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 1 ppm	ICP (0.5 ppm)	Avg. of 3 batches



Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	ICP (1 ppm)	Avg. of 3 batches
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	ICP (1 ppm)	Avg. of 3 batches
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	ICP (1 ppm)	Avg. of 3 batches
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<5 ppm	ICP (5 ppm)	Avg. of 3 batches
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<2 ppm	ICP (2 ppm)	Avg. of 3 batches
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<5 ppm	ICP (5 ppm)	Avg. of 3 batches
Elemental Impurity		Class	Likely to be present			If known, please identify the Expected concentration/ unit (or range)	Analytical Method used (Limit of Quantification if available)	Comments regarding source of information (i.e; number of lots tested, frequency of testing; process understanding etc.)
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	ICP (1 ppm)	Avg. of 3 batches
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 5 ppm	ICP (5 ppm)	Avg. of 3 batches
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 5 ppm	ICP (5 ppm)	Avg. of 3 batches
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	ICP (0.5 ppm)	Avg. of 3 batches
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 5 ppm	ICP (5 ppm)	Avg. of 3 batches
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	ICP (0.5 ppm)	Avg. of 3 batches



Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 2 ppm	ICP (0.5 ppm)	Avg. of 3 batches
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<5 ppm	ICP (1 ppm)	Avg. of 3 batches
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 2 ppm	ICP (2 ppm)	Avg. of 3 batches
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	< 2 ppm	ICP (2 ppm)	Avg. of 3 batches
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<1 ppm	ICP (0.5 ppm)	Avg. of 3 batches
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	Complies	USP/EP/BP Method	Avg. of 3 batches

Reference: ICH Q3D Guideline for Elemental impurities, step 4 version, 2014

Authorized Signatory

Avantor Performance Materials India Private Limited.