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www.avantorsciences.com

Zinc Chloride

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered

Brand	Product Code	Product Description	MOC* code
J.T.Baker®	4320	Zinc Chloride, Granular U.S.P.	RL
J.T.Baker®	4326	Zinc Chloride, Granular, USP Multi-Compendial	RL

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

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 #: 7646-85-7

Manufacturing Process: Synthesis

Raw Material Origin: Chemical

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: 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, the following allergens: milk and products thereof (including lactose), fish and products thereof (including roe), crustaceans and products thereof, soybeans and products thereof, peanuts and products thereof, lupines and products thereof, mustard and products thereof, natural rubber latex, eggs and products thereof, molluscs and products thereof, sesame seeds and products thereof, celery and products thereof, cereals containing gluten (namely: wheat, rye, barley, oats, spelt, kamut or their hybridized strains, and products thereof), nuts (namely: almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia or Queensland nuts, and products thereof), and sulfur dioxide and sulfites at concentrations of more than 10 mg/kg or 10 mg/litre are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

According to the Original Manufacturer, latex containing material (rubber) might be used in technical components like gaskets or inliners for processing and handling the product.

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: 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. (www.askavantor.com Keyword: Kosher)

Halal Status: J.T.Baker® 4320 is 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 Zinc Chloride (CAS # 7646-85-7) is a Substance Generally Recognized as Safe (GRAS) in foods when used in accordance with the requirements and limitations per 21 CFR parts 182.8985.

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. 4, 2008 – Section 4: updated residual solvents information
Rev. 2; Jan. 12, 2010 – Entire document: new letterhead and changed all references of "SolvIT Center" to "AskMBI."; Section 7: updated TS manager info. Section 4: added GRAS section. (KES)
Rev. 3; Aug. 30, 2011 – Entire document: new letterhead; changed all references of "AskMBI" to "AskAvantor"; updated website links for new website; minor formatting; Section 1: added MOC codes; removed discontinued Product Number 8772; Section 2: added GMP statement; Section 4: expanded Allergens list; Section 7: updated contact information. PH/JLW
Rev. 4; Oct 18, 2012– HDQ address change, minor formatting. Section 4: Added add'l allergens as listed in EU Directive 2003/89/EC; Section 5: Added Management of Change information; Section 7: Removed contact list table and added CS/TS contact information. (MCH)
Rev. 5; Oct 22, 2013– Section 1: Updated MOC status per MOC-QUAL-6193; Section 4: separated Kosher/Halal status and added certification statement; Section 5: Added COA Date Format statement. (MCH)
Rev. 6; Dec. 29, 2016 – Section 4: added Residual Metallic Catalysts statement. (MCH)
Rev 7: December 10, 2018 – Entire document: new letterhead (logo & headquarters address, updated email from @avantormaterials.com to @avantorinc.com ;Section 4: Removed Residual Metallic Catalyst statement, replaced with Elemental Impurities. Section 5: added Storage Requirement, Batch Definition, and Country of Origin Statements (MCH)
Rev. 8; June 25, 2020- Entire Document: Minor formatting. Updated website and email addresses from avantorinc.com to avantorsciences.com; Section 2: Corrected Manufacturing, Packaging and Release Site Information statement and removed IPEC portion of statement due to requirements of MOC code; Section 4: DMF statement format updated. Added Elemental Impurity Data. Added CAS # to GRAS Status statement and added regnum. (KH)
Rev. 9; February 9, 2021 – Entire Document: Minor formatting; Section 4: Updated Allergen/Hypersensitivities Information statement. Updated GRAST Status statement in accordance with FDA website. (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

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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: Zinc Chloride **Product codes**: 4326, 4320 **Date**: September 14, 2018

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

Other (explain):

No Class 1, 2A, 2B, or 3 elementals are intentionally added to the production 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.)
Arsenic (inorganic)	As	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Cadmium	Cd	1	Yes ☒	No ☐	Unknown ☐	0.06 to 0.16 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range reported
Mercury (inorganic)	Hg	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit

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.)
Lead	Pb	1	Yes ☒	No ☐	Unknown ☐	0.18 to 0.31 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range reported
Cobalt	Co	2A	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Nickel	Ni	2A	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Vanadium	V	2A	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Silver	Ag	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Gold	Au	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Iridium	Ir	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Osmium	Os	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Palladium	Pd	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit

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.)
Platinum	Pt	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Rhodium	Rh	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Ruthenium	Ru	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Selenium	Se	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Thallium	Tl	2B	Yes ☒	No ☐	Unknown ☐	0.18 to 0.48ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range reported
Barium	Ba	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Chromium	Cr	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Copper	Cu	3	Yes ☒	No ☐	Unknown ☐	0.11 to 0.13 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, range reported
Lithium	Li	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit

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.)
Molybdenum	Mo	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Antimony	Sb	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit
Tin	Sn	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	3 commercial batches tested, all below detection limit

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



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Prepared by the Technical Service Department

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