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## L-Cysteine Hydrochloride, Monohydrate

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### Product Regulatory Data Sheet

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#### Section 1 – Product Information

##### Products Covered

<u>Brand</u>	<u>Product Code</u>	<u>Product Description</u>	<u>MOC* code</u>
J.T.Baker®	2072	L-Cysteine Hydrochloride, Monohydrate, U.S.P. Multi-Compendial	HR
J.T.Baker®	2071	L-Cysteine Hydrochloride, Monohydrate, U.S.P. Multi-Compendial	R

\*MOC = Management of Change

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#### Section 2 – Manufacturing, Packaging and Release Site Information

The product(s) listed in Section 1 with the MOC code "HR" is manufactured under current Good Manufacturing Practices (cGMPs) as set forth by ICH Q7 and International Pharmaceutical Excipients Council (IPEC) guidelines.

The product(s) in Section 1 with the MOC code "R" is 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](http://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.

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### **Section 3 – Physical/Chemical Information**

CAS #: 7048-04-6

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

**Raw Material Origin:** Animal

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### **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 DO contain animal parts, products, and/or by-products.

NO animal origin materials listed as "Specified risk materials" in Commission Decision 97/534/EC are used.

Neither source materials nor any materials used during production processes as defined in Section 2 of the "Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products" (EMA/410/01 rev. 3) are used in the manufacture.

This product is manufactured by hydrolysis of proteins (human hair and/or poultry feathers).

The hydrolysis conditions are as follows:

- Acid: Hydrochloric Acid
- pH: Not more than 1
- Temperature: about 110°C
- Time: about six hours.

**Allergen/Hypersensitivities Information:** To the best of our knowledge, the allergens listed in the [US FDA](#), [EU Directive 2003/89/EC](#), and [TG0-91/92](#) 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 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:** 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](http://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](http://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](#).

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## **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](http://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.

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## **Section 6 – Revision History**

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

Rev. 1; Oct. 14, 2008 – Section 4: updated residual solvents information

Rev. 2; Nov. 6, 2009 – Section 4: updated addition statement to BSE/TSE section and added Residual Metallic Catalysts statement; Entire document: new letterhead and changed all references of "Solv IT Center" to "AskMBI."; Section 7: updated Director of CS and TS manager info. (JLW)

Rev. 3; July 27, 2011 – Entire document: new letterhead, and changed all references of "AskMBI" to "AskAvantor." Updated website links for new website; Section 1: added MOC codes; Section 2: added GMP statement; Section 4:

expanded Allergens list, added Residual Metallic Catalysts and GRAS statements; Section 5: Added Nutritional/Supplement Facts Labeling and Organic Status statements; Section 7: updated contact information; minor formatting. (PH/MCH)

Rev. 4; Oct. 8, 2012– Entire document: updated headquarters address and minor formatting; Section 4: Updated BSE/TSE statement; Added add'l allergens as listed in EU Directive 2003/89/EC; Updated Residual Metallic Catalysts

statement; Section 5: Added Management of Change information; Section 7: removed contact list table and added CS/TS contact information. (MCH)

Rev. 5; Jan. 19, 2016 – – Section 4: separated Kosher/Halal status and added certification statement, Updated EMEA

Residual Metallic statement to reflect current guideline revision; Section 5: Added COA Date Format statement. (MCH)

Rev. 6; December 29, 2017 - Updated document to new format. Section 4: Removed Residual Metallic Catalysts and added Elemental Impurity Statement. (PT)

Rev. 7; March 23, 2018 - Section 1: added code 2072; Section 4: updated DMF. (PT)

Rev. 8; November 15, 2018 - Entire Document: New Format. (EC)

Rev. 9; February 7, 2020 – Entire document: Updated email and website addresses from avantorinc.com to avantorsciences.com. Added website link for AskAvantor; Section 2: Formatted Manufacturing, Packaging and Release Site Information; Section 3: Updated Raw Material Origin; Section 4: Updated DMF statement. Updated BSE/TSE Status statement to align with manufacturer's documentation. Updated GRAS Status statement to align with CAS number; Section 5: Updated Certificate of Analysis Date Format statement. (KH)

Rev. 10; April 14, 2023 – updated to current template format. Removed additional allergens (SS)

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*This electronic document is valid without a signature.*

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## **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](mailto:Technical.Service@avantorsciences.com)

### Regulatory Support

Email: [regulatory.support@avantorsciences.com](mailto:regulatory.support@avantorsciences.com)

Trade Compliance

Email: [Trade.Compliance@avantorsciences.com](mailto: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:** L-Cysteine Monochloride Monohydrate    **Product codes:** 2071, 2072    **Date:** July 6, 2017

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

Other (explain): Extraction from human hair

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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.45 ppm	ICP-MS (MRL=0.45 ppm)	Max. of 3 batches – testing provided by supplier
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.06 ppm	ICP-MS (MRL=0.06 ppm)	Max. of 3 batches – testing provided by supplier
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.09 ppm	ICP-MS (MRL=0.09 ppm)	Max. of 3 batches – testing provided by supplier
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.15 ppm	ICP-MS (MRL=0.15 ppm)	Max. of 3 batches – testing provided by supplier
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.15 ppm	ICP-MS (MRL=0.15 ppm)	Max. of 3 batches – testing provided by supplier
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.6 ppm	ICP-MS (MRL=0.6 ppm)	Max. of 3 batches – testing provided by supplier

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"/>			
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.3 ppm	ICP-MS (MRL=0.3 ppm)	Max. of 3 batches – testing provided by supplier
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.3 ppm	ICP-MS (MRL=0.3 ppm)	Max. of 3 batches – testing provided by supplier
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<3 ppm	ICP-MS (MRL=3 ppm)	Max. of 3 batches – testing provided by supplier
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.3 ppm	ICP-MS (MRL=0.3 ppm)	Max. of 3 batches – testing provided by supplier
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.3 ppm	ICP-MS (MRL=0.3 ppm)	Max. of 3 batches – testing provided by supplier
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.3 ppm	ICP-MS (MRL=0.3 ppm)	Max. of 3 batches – testing provided by supplier
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.3 ppm	ICP-MS (MRL=0.3 ppm)	Max. of 3 batches – testing provided by supplier
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.3 ppm	ICP-MS (MRL=0.3 ppm)	Max. of 3 batches – testing provided by supplier
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.3 ppm	ICP-MS (MRL=0.3 ppm)	Max. of 3 batches – testing provided by supplier



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.)
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<2.4 ppm	ICP-MS (MRL=2.4 ppm)	Max. of 3 batches – testing provided by supplier
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.6 ppm	ICP-MS (MRL=0.6ppm)	Max. of 3 batches – testing provided by supplier
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<21 ppm	ICP-MS (MRL=21 ppm)	Max. of 3 batches – testing provided by supplier
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<33 ppm	ICP-MS (MRL=33 ppm)	Max. of 3 batches – testing provided by supplier
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<9 ppm	ICP-MS (MRL=9 ppm)	Max. of 3 batches – testing provided by supplier
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<7.5 ppm	ICP-MS (MRL=7.5 ppm)	Max. of 3 batches – testing provided by supplier
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<45 ppm	ICP-MS (MRL=45 ppm)	Max. of 3 batches – testing provided by supplier
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<2.7 ppm	ICP-MS (MRL=2.7 ppm)	Max. of 3 batches – testing provided by supplier
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<18 ppm	ICP-MS (MRL=18 ppm)	Max. of 3 batches – testing provided by supplier

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

\* Supplier defines MRL as result reported at <30% of ICH Q3D Option 1 limit parenteral values.

Note: No ICH Q3D Class 1,2A, 2B or 3 elements are intentionally added during the manufacturing of this material..

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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