

Avantor, Inc.  
100 Matsonford Rd., Suite 200  
Radnor, PA 19087 USA  
[www.avantorsciences.com](http://www.avantorsciences.com)

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## L-Lactic Acid

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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®	0200	L-Lactic Acid Multi-Compendial (levorotary)	R
J.T.Baker®	0203	L-Lactic Acid Multi-Compendial (levorotary)	R

\*MOC = Management of Change

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

The product(s) 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](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 #: 50-21-5

**Manufacturing Process:** Dedicated: Continuous batch fermentation and purification. Additional manufacturing process information may be disclosed under NDA upon request from the support contact in Section 7.

**Raw Material Origin:** Plant

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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 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, allergens mentioned in Annex II of Regulation (EU) N° 1169/2011 and European Cosmetic Directive 76/768 EC (27/07/06) are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

Neither Avantor nor the Original Manufacturer produce any of the following types of products: antibiotics, 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 including aflatoxins. 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. Only Class 3 Solvents are likely to be present. Residual concentration of all Class 3 Solvents is <0.5%. No other 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; April 23, 2012 – New product- IPEC EIP format (MCH)

Rev. 1; Sept. 10, 2013 –Section 4: added add'l 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 Management of Change information; Added COA Date Format statement ; Section 7: removed contact list table and added CS/TS contact information. (MCH)

Rev. 2; May 25, 2017- Updated template to reflect new logo information. Section 3: Updated manufacturing information. Section 4: Removed residual metallic catalysts statement; added elemental impurities statement; added aflatoxin statement. Section 5: Added batch definition; added country of origin statement; added storage requirements. Section 7: Updated contact information. (CMG)

Rev. 3; November 20, 2018 - Entire Document: New Format. (EC)

Rev. 4: June 4, 2019– Entire document- Updated email from @avantorinc.com to @avantorsciences.com, Section 3: updated CAS # as per MOC-QUAL-8321 (MCH)

Rev. 5; April 15, 2022 – Entire Document: Minor formatting; Section 2: Minor updating to language; Section 4: Removed Compendial Compliance statement. Updated formatting of DMF and Allergen/Hypersensitivities Information statements. 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) Rev. 6; September 12, 2023 – Section 1: Added product code 0203 in accordance with BoM-008411; Section 4: Updated formatting of Allergen/Hypersensitivities Information statement. No change to the quality of the product. Added 0203 to Elemental Impurity assessment. 0203 is a mirror of 0200. (KH)

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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:** Lactic Acid **Product codes:** 0200, 0203 **Date:** February 6, 2017 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.)
Arsenic (inorganic)	As	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.50 ppm	ICP-OES (MRL=0.50 ppm)	Manufacturer data, periodic testing, all below limit of detection
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.10 ppm	ICP-OES (MRL=0.10 ppm)	Manufacturer data, periodic testing, all below limit of detection
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	AAS, Hydride Generation (MRL=0.05 ppm)	Manufacturer data, periodic testing, all below limit of detection
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.10 ppm	ICP-OES (MRL=0.10 ppm)	Manufacturer data, periodic testing, all below limit of detection
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	N/A	N/A	Not tested; not expected to be present

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"/>	<0.15 ppm	ICP-OES (MRL=0.15 ppm)	Manufacturer data, periodic testing, all below limit of detection
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	N/A	N/A	Not tested; not expected to be present
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	N/A	N/A	Metal not intentionally added to process
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	N/A	N/A	Metal not intentionally added to process
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	N/A	N/A	Metal not intentionally added to process
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	N/A	N/A	Metal not intentionally added to process
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	N/A	N/A	Metal not intentionally added to process
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	N/A	N/A	Metal not intentionally added to 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"/>			
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	N/A	N/A	Metal not intentionally added to process
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	N/A	N/A	Metal not intentionally added to process
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	N/A	N/A	Metal not intentionally added to process
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	N/A	N/A	Metal not intentionally added to process
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	N/A	N/A	Not tested; not expected to be present
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.10 ppm	ICP-OES (MRL=0.10 ppm)	Manufacturer data, periodic testing, all below limit of detection
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.10 ppm	ICP-OES (MRL=0.10 ppm)	Manufacturer data, periodic testing, all below limit of detection
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	N/A	N/A	Not tested; not expected to be present



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"/>	<0.10 ppm	ICP-OES (MRL=0.10 ppm)	Not tested; not expected to be present
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.30 ppm	ICP-OES (MRL=0.30 ppm)	Not tested; not expected to be present
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.20 ppm	ICP-OES (MRL=0.20 ppm)	Not tested; not expected to be present

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



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Prepared by the Technical Service Department



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