

Avantor, Inc.  
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# Ethanol

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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®	0395	Ethanol, 96% E.P.	RL
J.T.Baker®	0396	Ethanol 99% Absolute E.P.	RL

\*MOC = Management of Change

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

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 [Ask Avantor](#) 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 #: 64-17-5

**Manufacturing Process:** Distillation/Rectification. 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:** According to the Original Manufacturer, crustaceans and products thereof, eggs and products thereof, fish and products thereof, peanuts and products thereof, soybeans and products thereof, milk and products thereof (including lactose), nuts i.e. almond (*Amygdalus communis* L.), hazelnut (*Corylus avellana*), walnut (*Juglans regia*), cashew (*Anacardium occidentale*), pecan nut (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nut (*Bertholletia excelsa*), pistachio nut (*Pistacia vera*), macadamia nut and Queensland nut (*Macadamia ternifolia*) and products thereof, celery and products thereof, mustard and products thereof, sesame seeds and products thereof, sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO<sub>2</sub>, and lupin and products thereof are not known additives, by products, intermediate parts, or otherwise intentionally added during the manufacturing processes of the product.

According to the Original Manufacturer in accordance with European Directive 2007/142/EC of the European Parliament and the Council, cereals\* containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof are present in the product.

\*cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages

Neither Avantor 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 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:** These products have not been assessed to the requirements of the ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.

**Elemental Impurities:** This product has not been assessed for Elemental Impurities.

**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 ([Ask Avantor](#) 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 ([Ask Avantor](#) 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. ([Ask Avantor](#) 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; Apr. 29, 2021 – New document (JK)

Rev. 1; Jun. 17, 2021 – Product name was changed (JK)

Rev. 2; September 12, 2022 – Section 2: Updated statement; Section 3: Corrected Raw Material Origin according to the manufacturer statement; Section 4: Removed Compendial Compliance statement. Updated GRAS Status Statement and Allergen Statement according to the manufacturer statement; Section 5. Updated Certificate of Analysis Date Format information; Section 7: Updated Contact Information. (KS)

Rev. 3; October 10, 2025 – Entire document: All hyperlinks for Ask Avantor have been updated to the current webpage; Harmonized the product name in document title and footer; Section 1: Added product code 0396 from GLI-PRDS-103; Section 4: Updated Residual solvents information to align with the product's certificate of analysis, Updated the Kosher and Halal statements; Section 5: Updated Country of Origin support contact; Section 7: Updated the Trade Compliance contact information. (SP)

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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: [fta@avantorsciences.com](mailto:fta@avantorsciences.com)

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