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# Calcium Pantothenate

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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®	1443	Calcium Pantothenate U.S.P.	R

\*MOC = Management of Change

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

The product listed in Section 1 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 #: 137-08-6

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

Raw Material Origin: Chemical

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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 regulatory 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 No 1169/2011](#), and [TG0-91/92](#) 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 product does not contain allergenic substances as listed in Annex II of Regulation (EU) No 1169/2011.

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, 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 2 solvents (Methanol, Dichloromethane) are likely to be present. All are below Option 1 limits. No other Class 1, 2, 3 or other solvents are used or produced in the manufacturing or purification of the product.

**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 ([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. (<https://avantor-prod.cxoneexpert.ai/> 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; Jan. 2, 2009 - Section 4: Residual Solvents statement updated to mention "other" solvents and specifically reference USP chapter <467>; Section 7: updated telephone # for Customer Service Director; Entire Document: added keywords to Solv It Center links. (KES)

Rev. 2; August 26, 2011 –Entire document: new letterhead, and changed all references of "Solv IT Center" 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 7: updated contact information; minor formatting. PH/MCH

Rev.3 March 5, 2018-Entire document: new letterhead (company name & headquarters address); Section 5: added Storage Requirement Statement. (SR)

Rev. 4; November 12, 2018 - Entire Document: New Format

Rev. 5; September 3, 2021- Entire Document: Minor formatting. Updated website and email address from avantorinc.com to avantorsciences.com; Section 4: DMF, Allergen/Hypersensitivities Information, and Residual Solvents/Organic Volatile Impurities (OVI) Information statements. Removed Aflatoxin statement. It is not part of the Allergen/Hypersensitivities Information statement; Section 5: Corrected Certificate of Analysis Date Format statement with missing information. (KH)

Rev. 6; September 18, 2024-Reviewed current documents and updated allergens according to current statements, updated link for lot numbering information (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.