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# Stearic 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®	0340	Stearic Acid, Powder (Triple Pressed) N.F.	R
Macron Fine Chemicals™	2025	Stearic Acid, 92% N.F.	R
Macron Fine Chemicals™	2216	Stearic Acid 50, Powder NF - GenAR®	R

\*MOC = Management of Change

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

The products listed 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 #: 57-11-4

**Manufacturing Process:** Synthesis, Fermentation, Continuous, Batch, Dedicated, Extraction, Purification, Recrystallization, etc. Additional manufacturing process information may be disclosed under NDA upon request from the support contact in Section 7.

**Raw Material Origin:** Plant and Animal

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### Section 4 – Regulatory Information

**DMF:** Avantor may hold Master File(s) for specified product codes, dependant 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.

According to the Original Manufacturer, severe processing conditions are used in the manufacture of all oleochemical products. These conditions at minimum include hydrolysis at 260 °C and 48 bar for 1.5 to 2 hours and may also include hydrogenation at 200 °C and vacuum distillation at 232 °C. The manufacturing conditions exceed the European Union recommendation of hydrolysis of 200 °C, under an appropriate corresponding pressure for 20 minutes, followed by a purification to remove (insoluble) impurities, endorsed by the Scientific Steering Committee (SSC) of the European Commission.

EU Regulation 1069/2009 [laying down health rules as regards animal byproducts and derived products not intended for human consumption] and its accompanying implementing Regulation Commission Regulation 142/2011 set down controls on the safe use and disposal of animal-by products to safeguard public and animal health.

The products meet the definition set out in Chapter XI of Annex XIII as an end point in the manufacturing chain for oleochemical products, beyond which they are no longer subject to the requirements of Regulation (EC) No 1069/2009.

21CFR189.5 Prohibited cattle materials - Some oleochemical products meet the definition of a Tallow derivative and are NOT considered Prohibited cattle materials.

**Allergen/Hypersensitivities Information:** According to the Original Manufacturer, Highly refined (RBD) soybean oil is used at the facility. No soy protein is used in the manufacturing process, and none is used in the facility. Highly refined (RBD) rapeseed oil is used at the facility. No rapeseed protein is used in the manufacturing process, and none is used in the facility. Additionally, raw materials containing milk, eggs, wheat, fish, shellfish, corn, tree nuts or any derivative thereof, raw materials containing substances listed in Regulation (EU) No 1169/2011; Annex II: Substances or Products Causing

Allergies or Intolerances, which include; Cereals containing gluten, namely: wheat (such as spelt and khorasan wheat), rye, barley, oats or their hybridised strains, and products thereof, Crustaceans and products thereof; Eggs and products thereof; Fish and products thereof, except: Peanuts and products thereof; Soybeans and products thereof, except: (a) fully refined soybean oil and fat (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources; (c) vegetable oils derived phytosterols and phytosterol esters from soybean sources; (d) plant stanol ester produced from vegetable oil sterols from soybean sources; Milk and products thereof (including lactose), except: (a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin; (b) lactitol; Nuts, namely: almonds (*Amygdalus communis* L.), hazelnuts (*Corylus avellana*), walnuts (*Juglans regia*), cashews (*Anacardium occidentale*), pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), pistachio nuts (*Pistacia vera*), macadamia or Queensland nuts (*Macadamia ternifolia*), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin; 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 in terms of the total SO<sub>2</sub> which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers; Lupin and products thereof; Molluscs and products thereof 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, Antibiotics, 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:** According to the Original Manufacturer, Genetically Modified Organism (GMO) is considered to be an organism that contains recombinant DNA elements. The genome of these organisms has been altered by insertion of foreign DNA sequences by means of genetic engineering. They are referred to as transgenic or bioengineered organisms. Determination of the presence of GMOs is currently limited to substances derived from agricultural plants. This facility processes highly refined soy bean oil which is a soy-based material; therefore trace amounts of soy may be present. Since some soy beans are GMO, some products may have derivatives of GMO soy beans. No GMO transgenic or bioengineered organisms are present in our products.

**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:** The subject materials are not Kosher Certified. For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to the certificate available on AskAvantor for our most up to date listing of Kosher products. ([www.askavantor.com](http://www.askavantor.com) Keyword: Kosher). For other branded products, please reach out to the support contact in Section 7 for the certificate, if available.

**Halal Status:** The subject materials are not Halal Certified. For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to the certificate available on AskAvantor for our most up to date listing of Kosher products. ([www.askavantor.com](http://www.askavantor.com) Keyword: Halal). For other branded products, please reach out to the support contact in Section 7 for the certificate, if available.

**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](#).

**Nutritional/Supplement Facts Labeling:** The product code 2216 listed in Section 1 is bulk food chemicals that are intended for the use in manufacturing of finished food products or for products that are to be processed, labeled, and/or repacked at a site other than where it's originally processed or packed and are exempt from the Nutrient Content Evaluation and Nutrient Labeling Requirements (21 CFR 101.9(j)(9)).

**Organic Status:** The product code 2216 listed in Section 1 is not certified as organic. However, to the best of our knowledge, the product is not produced using Ionizing Radiation as described in 21 CFR 179.26 or Sewage Sludge as described in 7 CFR Section 205.2.

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### **Section 5 – Miscellaneous Product Information**

**Certificate of Analysis Date Format:** The Manufactured Date and Expiration/Retest Date on the CofA are reported as YYYY-MM-DD. For example, the Manufactured Date for October 1, 2021 would be reported as 2012-10-01.

**Lot Numbering System and Batch Description:** For J.T.Baker® and Macron Fine Chemicals™ brand products, please refer to AskAvantor for information concerning our lot/batch numbering system. ([www.askavantor.com](http://www.askavantor.com) Keyword: Lot Number). For other branded products, please reach out to the support contact in Section 7 for the certificate, if available.

**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, 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 Working with Avantor tab on the Avantor website. For other branded products, please reach out to the support contact in Section 7 for information on the applicable management of change process.

**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 our Certificate/SDS Search tool on our website [here](#). For other branded 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 our Certificate/SDS Search tool on our website [here](#). For other branded products, please see the current list of product specifications 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. 22, 2008 – Changes to Section 1, added the following products:

Mallinckrodt

2025 Stearic Acid, 92% N.F.

Rev. 2; Apr. 23, 2008 – Section 4: updated BSE/TSE information

Rev. 3; July 9, 2008 – Section 1: corrected 2216 description  
Rev. 4; July 16, 2008- Section 4: removed soy from allergen list  
Rev. 5; Aug. 8, 2008 – Section 4: added processing condition details to BSE/TSE statement  
Rev. 6; Sept. 12, 2008 – Section 4: updated residual solvents statement  
Rev. 7; Sept. 15, 2008 – Section 4: Updated reference to 9 CFR in BSE statement  
Rev. 8; March 17, 2011 – Entire document: new letterhead and changed all references of “Solv IT Center” or “AskMBI” to “AskAvantor.” Updated website links for new website; Section 7: updated contact information. Macron brand name updated. Residual Metallic Impurities added. (MCH)  
Rev. 9; Feb. 11, 2013 – Entire document: updated headquarters address. Section 1: Added MOC codes; Section 2: Updated GMP statement; Section 4: separated Kosher/Halal status and added certification statement; Added GRAS statement; Section 5: Added COA Date Format statement; added Management of Change information, Nutritional/Supplement Facts Labeling and Organic Status; Section 7: removed contact list table and added CS/TS contact information. (MCH)  
Rev. 10; June 3, 2013– Section 4: Updated Residual Metallic Catalysts statement. (MCH)  
Rev. 11; November 29, 2016– Section 4: added add'l allergens as listed in EU Directive 2003/89/EC. (MCH)  
Rev. 12 ; March 18, 2019– Entire document: new letterhead (logo & headquarters address, updated email from @avantormaterials.com to @avantorsciences.com ;Section 4: Removed Residual Metallic Catalyst statement, replaced with Elemental Impurities. (MCH) Section 5: added Storage Requirement, Batch Definition, and Country of Origin Statements  
Rev. 13; December 3, 2021 - No Changes. Revision initiated to align with document control system current revision (KH)  
Rev. 14; December 3, 2021 - No Changes. Revision initiated to align with document control system current revision (KH)  
Rev. 15; December 3, 2021 – Entire Document: Minor formatting; Section 2: Minor updating to language; Section 4: Removed Compendial Compliance statement. Updated DMF statement. Updated BSE/TSE Status, Allergen/Hypersensitivities, and GMO statements to align with original manufacturer’s most current statement information. There are no changes to the material origin. Specified certificate availability for different branded products for Kosher and Halal Status statements. Generalized GRAS Status statement. Moved Nutritional/Supplemental Facts Labeling and Organic Status statements from Section 5 to Section 4 and specified applicable product code; 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)

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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:** Stearic Acid **Product codes:** 2216, 2236, 0340, 2025 **Date:** June 30,, 2016

**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.)
			Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>			
Arsenic (inorganic)	As	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches

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"/>			
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches

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"/>			
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Unknown <input type="checkbox"/>	<0.05 ppm	ICP-MS (MRL=0.05 ppm)	Avg. of 3 batches

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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