Global Headquarters:
Avantor, Inc.
100 Matsonford Rd., Suite 200
Radnor, PA 19087 USA
www.avantorsciences.com

Packaging site:
Avantor Performance Materials India Private Limited
Plot No.1, GIDC, Panoli, Ankleshwar
Gujarat Pin: 394116, India

Glycerin

Product Regulatory Data Sheet

Section 1 – Product Information

Products Covered

Brand	Product Code	Product Description	MOC* code
Macron Fine Chemicals™	5270	Glycerin, BP/EP/JP/USP (Multicompendial)	R
Macron Fine Chemicals™	5271	Glycerin, IP	RL
Macron Fine Chemicals™	5272	Glycerin, CP, Multicompendial	R
Macron Fine Chemicals™	5273	Glycerin USP	R

*MOC = Management of Change

Section 2 – Manufacturing, Packaging and Release Site Information

The product code(s) 5270, 5272 and 5273 listed in Section 1 is/are manufactured according to current Good Manufacturing Practices (cGMPs) as set forth by International Pharmaceutical Excipients Council (IPEC) guidelines.

The product code 5271 listed in Section 1 with IP monographs is manufactured under current Good Manufacturing Practices (cGMPs) as set forth by the Drugs and Cosmetics Rule, 1945, Government of India Ministry of Health and Family Welfare.

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 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.

Section 3 – Physical/Chemical Information

CAS #: 56-81-5

Manufacturing Process: Synthesis

Raw Material Origin: Plant

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 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.

According to the Original Manufacturer, *melamine, gluten, latex, aflatoxin, phthalates, dioxin, bisphenol, nitrosamines, diethylene glycol or genotoxin* 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, 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 manufacturer confirms the manufacturing process of the subject materials, does not utilize any material of genetically modified organisms at any stage.

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 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 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.

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-Xyz-DD. For example, the Manufactured Date for October 1, 2021 would be reported as 2021-Oct-01.

Lot Numbering System and Batch Description: For J.T.Baker® and Macron Fine Chemicals™ brand products released from our Panoli site, please refer to Ask Avantor for information concerning our lot/batch numbering system. (www.askavantor.com Keyword: Panoli).

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.

Section 6 – Revision History

Rev. 0; April 21, 2020: IPEC EIP Format New product code added 5272 per MOC-PLT-2850 (MK)Rev. 1; Rev. 1 July 4, 2022 - Section 2: Minor updating to language; Section 4: Removed Compendial Compliance statement. Removed Regulatory email from DMF statement. 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. Updated EI summary (KS)

Rev. 2; September 27, 2023 – updated to current template. Added product 5273 per current site information. Product 5271 MOC code corrected to RL for IP only product. Product code 5273 added to EI report (SS)

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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

Regulatory Support

Email: regulatory.support@avantorsciences.com

Trade Compliance

Email: Trade.Compliance@avantorsciences.com

Global Headquarters:
Avantor, Inc.
100 Matsonford Rd., Suite 200
Radnor, PA 19087 USA
www.avantorsciences.com

Packaging site:
Avantor Performance Materials India Private Limited
Plot No.1, GIDC, Panoli, Ankleshwar
Gujarat Pin: 394116, India

Material Name: Glycerin
Product Code: 5270, 5271, 5272, 5273 (Rev 1)
Source/Type of Excipient: ☐ Mineral; ☐Mineral Derived; ☐ Plant; ☐Plant Derived; ☐Synthetic; ☐Fermentation Derived;
Other (explain): Vegetable source

Elemental Impurity		Class	Likely to be present			If known, please identify the Expected concentration/ unit (or range)	Analytical Method used (Limit of Quantification if available)	Comments regarding source of information (i.e; number of lots tested, frequency of testing; process understanding etc.)
Arsenic	As	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Cadmium	Cd	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Mercury	Hg	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Lead	Pb	1	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Cobalt	Co	2A	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Nickel	Ni	2A	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Vanadium	V	2A	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Silver	Ag	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Gold	Au	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Iridium	Ir	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Osmium	Os	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Palladium	Pd	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Platinum	Pt	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches

Elemental Impurity		Class	Likely to be present			If known, please identify the Expected concentration/ unit (or range)	Analytical Method used (Limit of Quantification if available)	Comments regarding source of information (i.e; number of lots tested, frequency of testing; process understanding etc.)
Rhodium	Rh	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Ruthenium	Ru	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Selenium	Se	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Thallium	Tl	2B	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Barium	Ba	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Chromium	Cr	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Copper	Cu	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Lithium	Li	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Molybdenum	Mo	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Antimony	Sb	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches
Tin	Sn	3	Yes ☐	No ☒	Unknown ☐	<0.05 ppm	ICPMS (<0.05 ppm)	Avg. of 3 batches