Avantor Performance Materials, Inc.
222 Red School Lane
Phillipsburg, NJ 08865
U.S.A.
Tel: 1-908-859-2151
Fax: 1-908-859-9370
www.avantormaterials.com

# Methyl Paraben

**Product Regulatory Data Sheet**

## *Section 1 – Product Information*

### Products Covered

| Brand | Product Code | Product Description | MOC* code |
|---|---|---|---|
| Macron | 6215 | Methyl Paraben, NF, GenAR® | R |

*MOC = Management of Change

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

The products 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 Performance Materials, Inc. 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.

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 the International Pharmaceutical Excipients Council (IPEC) guidelines and it meets cGMP requirements. For instructions to decipher the manufacturer reference code please consult our website. Instructions can be found in the Q&A Center of the customer support section of our web site or by directly linking to www.AskAvantor.com Keyword: Manufacturer Code.

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## *Section 3 – Physical/Chemical Information*

**CAS #:** 99-76-3

**Manufacturing Process:** Synthesis

**Raw Material Origin:** Chemical

## *Section 4 – Regulatory Information*

**Compendial Compliance:** Please see the current product specifications at www.AvantorMaterials.com

**DMF:** Avantor Performance Materials, Inc. does not carry a Drug Master File for these products

**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:** The products listed do not contain wheat, rye, oats, barley, spelt, malt, triticale, gluten, other grains, corn, soy, soybeans, eggs, yeast, canola, milk, dairy products, fish, crustacean shellfish, seafood products, tree nuts, peanuts, nut products, seed products, natural grape products, natural flavors, artificial flavors, celery, lactose, sulfites, elemental sulfur, preservatives, MSG, disodium guanylate/inosinate, artificial sweeteners, phenylalanine, additives, colorants, dyes, or natural rubber (latex). These products are manufactured using cGMP guidelines which provide controls that allow no potential for cross contamination of any allergens or other products.

**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:** Methylparaben is manufactured using methanol, a Class 2 Residual Solvent, as a raw material. However, no other Class 1, 2, 3, or other Residual Solvents, as described in USP <467>, are likely to be present in the finished product.

The product conforms to the acceptable amounts of residual solvents as described in USP <467>:

*Methanol Concentration Level Max. 3000ppm Method: GC*

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**Residual Metallic Catalysts:** No metallic catalysts, as defined by EMEA Guideline on the Specification Limits for Residues of Metal Catalysts (CPMP/SWP/QWP/4446/00), are used in the production of the above subject materials.

**Kosher/Halal Status:** Please refer to the customer support section of our website for our most up to date listing of Kosher and Halal products. (www.AskAvantor.com Keyword: Kosher)

**GRAS Status:** The United States Food and Drug Administration (FDA) have acknowledged that Methylparaben is a Direct Food Substances Affirmed As GRAS in foods when used in accordance with the requirements and limitations per 21 CFR parts 184.1490.

## *Section 5 – Miscellaneous Product Information*

**Lot Numbering System and Batch Description:** Please refer to the customer support section of our website for information concerning our lot numbering system. (www.AskAvantor.com Keyword: Lot Number)

**Shelf Life Information:** If a product has an assigned expiration period the date will appear on the certificate of analysis. For products that do not have assigned dates please contact Technical Support through the customer support section of our website for our product stability profiles. (www.AskAvantor.com Keyword: Expiration)

**Nutritional/Supplement Facts Labeling:** 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, are exempt from the Nutrient Content Evaluation and Nutrient Labeling Requirements. (21 CFR 101.9(j)(9))

**Organic Status:** The products listed in Section 1 are 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 6 – Revision History***

Rev. 0; Oct. 1, 2007 – IPEC EIP format
Rev. 1; July 15, 2008 – Section 4: Updated Residual Solvents statement
Rev. 2; Sept. 2, 2008 – Section 4: Updated Residual Solvents statement to include limit of methanol and reference USP Chapter <467>
Rev. 3; Sept. 25, 2008 – Section 4: Changed “Class 4” to “other” in Residual Solvents statement.
Rev. 4; Jan. 8, 2010 – Entire document: new letterhead and changed all references of “Solv IT Center” to “AskMBI.”; Section 7: updated TS manager info.; Section 4: added GRAS section (KES)
Rev. 5; August 15, 2011 –Entire document: new letterhead, and changed all references of “AskMBI” to “AskAvantor.” Updated website links for new website; Section 1: Mallinckrodt brand name updated to Macron; added MOC codes; Section 2: added GMP statement; Section 4: expanded Allergens list; added Residual Metallic Catalysts statement; Section 5: Added Nutritional/Supplemental Facts Labeling and Organic Status statements; Section 7: updated contact information; minor formatting. PH/MCH

***This electronic document is valid without a signature.***

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## *Section 7 – Contact Information*

| POSITION/TITLE | PHONE NUMBER |
|---|---|
| **Research & Technology:** | |
| Director of R & T – Bio/Pharmaceuticals | 908-213-6720 |
| Director of R & T - Microelectronics | 908-859-9337 |
| **Production:** | |
| Director of Manufacturing | 908-859-9345 |
| Phillipsburg Plant Manager | 908-859-9456 |
| Paris Plant Manager | 859-987-9400 |
| **Packaging:** | |
| Senior Packaging Engineer | 908-859-9668 |
| **Quality Control/Quality Assurance:** | |
| Global Director of Quality Assurance | 908-859-6926 |
| Director of Regulatory Affairs | 908-859-9466 |
| Quality Manager, Paris Plant | 859-987-9459 |
| **Other Key Personnel:** | |
| EH&S Phillipsburg Plant | 908-329-9976 |
| EH&S Paris Plant | 859-987-9423 |
| Director of Marketing North America | 908-859-9413 |
| Manager, Customer Services | 908-859-9314 |
| Manager, Technical Support | 908-329-9915 |

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# J.T.Baker® and Macron™ Chemicals
# Product Number and Lot Number Systems

## J.T.Baker and Macron Chemicals Product Numbers

Product numbers for J.T.Baker and Macron products consist of six characters that comprise the four digit product code and the two digit package size code.

| **3628** | **-** | **04** |
|---|---|---|
| Four digit product code | | Two digit package size code |

The first four characters designate the product code and identify individual product. The product code is then followed by a hyphen, and the remaining two characters denote the package size.

## J.T.Baker and Macron Chemicals Lot Numbers

J.T.Baker and Macron products display a lot number on the container label. Each lot of product is assigned a unique lot number, consisting of six-characters. The lot number is easy to interpret. The current J.T.Baker and Macron lot numbering system can be explained as follows. In the example shown, Lot Number H26015 corresponds to the 26th week in 2009.

| **H** | **26** | **015** |
|---|---|---|
| A letter is used to denote the year of manufacture. | Two-digit numbers are used to denote the calendar week. | Three-digit manufacturing identifier may be numeric or alphanumeric and represents a unique lot of material. |

- The first digit is a letter, designating the year. The current schedule of letters is:

| | | |
|---|---|---|
| 2000 = T | 2005 = B | 2010 = J |
| 2001 = V | 2006 = C | 2011 = K |
| 2002 = X | 2007 = E | 2012 = L |
| 2003 = Y | 2008 = G | 2013 = M |
| 2004 = A | 2009 = H | 2014 = P |

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- The second and third digits indicate the week of the calendar year in which the lot number was assigned; i.e. all lot numbers assigned in the first week of the year would be 01.
- Calendar weeks begin counting on Sunday. For example, if January 1, 2009 falls on a Thursday then week **02** would begin on Sunday January 4, 2009. Week **03** begins on Sunday January 11, etc.
- The remaining digits represent a manufacturing identifier, assigned sequentially. This three digit identifier can be numeric or alphanumeric; i.e., 015 or C30.

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Prepared by the Technical Service Department
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# Site Quality Overview

## *Section 1 – Facility Overview*

### Sites Covered

***Corporate Headquarters***
Avantor Performance Materials, Inc.
222 Red School Lane
Phillipsburg, NJ 08865 USA

***Phillipsburg Site***
600 North Broad Street
Phillipsburg, NJ 08865 USA

***Paris Site***
7001 Martin Luther King Jr. Blvd.
Paris, KY 40361 USA

### History & General Site Information

Avantor™ Performance Materials, Inc. (formerly Mallinckrodt Baker) has been an integral part of the Phillipsburg community for more than 100 years. The business was originally founded in 1904 as the J.T.Baker Chemical Company, whose mission was to produce chemicals with the "highest degree of purity commercially available." Throughout the years the company has been under the ownership of several different major corporations. Past owners include Richardson Merrill, Proctor & Gamble, Mallinckrodt Inc. and Tyco Healthcare, a division of Tyco International and Covidien. In August 2010, Covidien sold the business to an affiliate of New Mountain Capital. On October 1, 2010, Mallinckrodt Baker changed its name to Avantor™ Performance Materials, Inc.

Avantor™ Performance Materials is a global chemical company that offers high purity specialty chemical products for use in the laboratory, biopharmaceutical, microelectronic and industrial markets. The company's headquarters is located in Phillipsburg (Lopatcong Township), NJ and has facilities worldwide, with manufacturing sites located in Phillipsburg, NJ; Paris, Kentucky; Deventer, The Netherlands; and Mexico City, Mexico. The Phillipsburg manufacturing plant is situated just a few miles away from its headquarters along the Delaware River at the original founding site of the company. Growing from humble beginnings of approximately 20 employees and 6 buildings, the Phillipsburg site now occupies 70 acres of property, with 40 separate buildings, and employs approximately 400 individuals.

In total, Avantor™ now employs over 1100 employees worldwide. Worldwide sales offices and an extensive distributor network allow Avantor to conduct business in over 80 countries. The principal packaging plant is our Paris, KY facility, where over 250 dedicated people work to distill, blend, sample, analyze, package, label, and ship the finest performance chemistries.

## Facility Size

### *Paris, KY Facility*

Facility Size: 290,000 Sq. Ft.
Production Department Size: 40,000 Sq. Ft.
Quality Control Laboratories and Print Shop Size: 10,000 Sq. Ft.
Warehousing and Distribution Size: 200,000 Sq. Ft.
Administrative Offices: 40,000 Sq. Ft.

This concrete and steel facility was constructed in 1978 and had major expansions in 1996 and 2003. It consists of a one-story building with approximately 290,000 square feet of floor space. Concrete block walls provide separation of different manufacturing and packaging operations. The dry product areas are further isolated in separate packaging cubicles, with only one product being packaged at a time. The QC Lab has its own separate area. A 60,000 square foot addition was completed in 1996 to expand warehousing and production capabilities. An aqueous solution facility with 4 manufacturing tanks for solutions blending and a WFI quality water production unit was put in place in 2003.

### *Phillipsburg, NJ Facility*

Facility Size: 470,000 Sq. Ft.
Production Department Size: 170,000 Sq. Ft.
Quality Control Laboratories and Administrative Offices Size: 50,000 Sq. Ft.
Warehouse/Storage Size: 250,000 Sq. Ft.

Buildings are constructed with steel frames, block walls, and concrete floors. Acid brick is used in a number of buildings where exposure to corrosive materials requires such construction. More than 30 separate buildings are employed in making, handling, and testing products. This separation provides good prevention of cross-contamination. In most instances, equipment is totally enclosed. Equipment is multi-purpose, well-documented and validated cleaning procedures are used to prevent cross-contamination.

## Staff Levels

### Phillipsburg, NJ

| DEPARTMENT | TOTAL STAFF | FULL TIME | TEMP |
|---|---|---|---|
| Operations | 263 | 259 | 4 |
| Quality Unit | 38 | 38 | 0 |
| R&T / Tech Support | 53 | 51 | 2 |
| Admin / Other | 132 | 130 | 2 |
| **Total Staff** | 486 | 478 | 8 |

### Paris, KY

| DEPARTMENT | TOTAL STAFF | FULL TIME | TEMP |
|---|---|---|---|
| Operations | 194 | 178 | 16 |
| Quality Unit | 44 | 44 | 0 |
| R&T / Tech Support | 3 | 3 | 0 |
| Admin / Other | 16 | 16 | 0 |
| **Total Staff** | 257 | 241 | 16 |

## Union Background

The United Steel Workers Union (Formerly PACE) represents the employees at our Phillipsburg facility. The current contract expires March 27, 2014.

The Paris facility is a non-union operation.

## Insurance

Avantor maintains business interruption insurance; various insurance carriers are used for comprehensive coverage.

### Contamination Potential

Neither plant produces any of the following types of products: Penicillin, Semi-Synthetic Penicillins, Cepahalosporins, Other Beta-Lactams, Antibiotics, Cytotoxics, Steroids, Medicated Feeds, Pesticides.

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# *Section 2 – Evidence of Compliance*

## Government Inspections/ Government Relations

Avantor Performance Materials, Inc. products are manufactured according to current ICH Q7 and IPEC Good Manufacturing Practices (cGMPs), where applicable. The facilities are inspected by local/national health inspection agencies including the FDA and these facilities have been found in compliance.

| Inspection Date | Site | Reason | FDA-483 Issued?* |
|---|---|---|---|
| 12/09/10-12/10/10 | Paris | General GMP | No |
| 01/06 & 01/10-01/11/11 | Phillipsburg | General GMP | No |
| 04/14/09-04/15/09 | Paris | General GMP | No |
| 06/25-06/26/09 & 07/01-07/02/09 | Phillipsburg | General GMP | No |
| 08/09-8/10/07 | Paris | General GMP | No |
| 03/09 & 03/12-03/13/07 | Phillipsburg | General GMP | No |
| 03/16/06 | Paris | General GMP | No |
| 01/10/2005 | Phillipsburg | General GMP | Yes |
| 08/27-8/29/03 | Paris | General GMP | No |
| 06/30/2003 | Phillipsburg | General GMP | Yes |
| 06/27/2002 | Phillipsburg | General GMP | No |

*For additional information, please reference the FDA Freedom of Information Act at www.fda.gov.

Avantor has not received any Warning Letters from the FDA or equivalent agency nor has Avantor been subject to the FDA's Application Integrity Policy (AIP) Program , been placed on FDA's Import Alert Lists, or otherwise been prevented from selling product in the United States at any time.

The following are the FDA Registration Numbers for the manufacturing facilities

| Plant Site | FDA Registration Number |
|---|---|
| Phillipsburg, NJ | 2220077 |
| Paris, KY | 1045125 |

## Quality Systems

During the past three years, Avantor Performance Materials, Inc. manufacturing facilities have been involved with "Quality Management Systems", with ISO 9001 or an equivalent system.

| Site | Registration or Inspection Body | Registered As | Date of First Certification | Date of Last Certification | Certificate Number |
|---|---|---|---|---|---|
| Paris, KY | BV, Houston, TX | ISO 9001:2008 | September 15, 1994 | August 19-20, 2010 | US 09000627 |
| Phillipsburg, NJ | Quality Systems Registrars, Herndon, VA | ISO 9001:2008 | March 2, 1993 | October 8, 2009 | QSR-078 |
| Phillipsburg, NJ | Quality Systems Registrars, Herndon, VA | ISO 14001:2004 | December 18, 2000 | January 21, 2010 | QSR-EMS-005 |

- ✧ Please visit www.avantormaterials.com to view our current certificates by site.

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# *Section 3 – GMP compliance Details*

This section is covered by our Quality Policy Manual (POL-00001).

**Quality Management Systems-Excipient Quality Systems (4)**

- **General Requirements (4.1)** Avantor Performance Materials, Inc. has established, documented, implemented and maintained the quality management system and continually improves and manages it in accordance with the requirements of ISO 9001: 2008. The Site Management Representative is responsible for evaluating the quality management system through internal audits and documentation reviews. Reports of the results of the evaluation, as well as the status, adequacy, and effectiveness of the system, are presented at a management review meeting annually.

Where Avantor chooses to outsource any processes that affect product conformity with requirements, we ensure control over such processes through inspection of product supplied or audits of the supplier. (see section 7.4 Purchasing)

- **Documentation Requirements (4.2)** Procedure PRO-00061 Control of Records describes the process for controlling records. Controlled, electronic procedures are used wherever possible. Changes to documentation are maintained in Master Control, a 21 CFR Part 11 compliant computerized document control system. Master Control is used to generate, maintain, and control the following types of documentation: Raw Material Specifications, Production SOPs, Validation Protocols, Policies, Finished Product Specifications, Laboratory SOPs, Stability Protocols, Batch Production and Packaging Records. The system is audited annually.

– **Change Control (4.3)** PRO-00101 Management of Change (MOC) document describes the process for documentation, review, approval and implementation of changes to products, processes, or systems. Avantor has implemented a four-tiered MOC program for our chemical products. Each tier offers a different level of change control; every product we offer has been classified into one of these four tiers. The most stringent levels of change control are applied to products suitable to be used as Active Pharmaceutical Ingredients (APIs) or Bulk Pharmaceutical Excipients (BPEs). These products are included in our two highest tiers, HR and R tiers. For the top two tiers we provide notification of critical changes in accordance with industry standards to customers registered in our change notification database and to customers who have purchased the product directly from Avantor in the last three years. The two remaining tiers, NI and N tiers, include food and non-FDA-regulated products. Limited change control information on products in these tiers is available for customers who have requested inclusion in our change notification database. For a complete descriptions of the MOC categories, please visit our web site at www.avantormaterials.com.

**Management Responsibility (5)**

– **Management Commitment (5.1)** It is the policy of Avantor to provide products that meet the requirements of our customers in accordance with our quality policy. Top management drives accountability, this ensures direct management involvement, dedicated capable resources and regular progress review. Management has optimized the culture to continually meet challenges through innovative organizational and systemic changes to emphasize technology, quality, and supporting operational system sharing of best methods and applying globally. System feedback and continuous improvement are pervasively evident throughout, with an emphasis on customer satisfaction. Top management at each site conducts a review of the quality management system at least once per calendar year. Management and employees are committed to achieving this policy through the implementation and maintenance of our quality management system.

– **Customer Focus (5.2)** The Leadership Team ensures that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

- **Quality Policy (5.3)** The quality policy for Avantor is as follows:
  "To strive for total customer satisfaction by meeting all requirements and by continually improving the effectiveness of the quality management system."

- **Planning (5.4)** The Leadership Team is accountable to plan and establish quality objectives at relevant functions and levels of the organization. These objectives are measurable and consistent with the quality policy and Avantor's commitment to continual improvement. All quality objectives are reviewed at least annually during quality management system review.

- **Responsibility, Authority and Communication (5.5)** The responsibilities, authorities, and interrelationships of personnel within Avantor who manage, perform, and verify work affecting quality include the organizational freedom necessary to perform tasks that affect quality. All employees are responsible for the quality of their own work.

- A management representative is appointed at each site by the Plant Manager. In conjunction with the Global Director of Quality, the overall Quality Management representative for Avantor has responsibility and authority that includes ensuring that processes needed for the quality management system are established, implemented and maintained, reporting to top management on the performance of the quality management system and any need for improvement, and ensuring the promotion of awareness of customer requirements throughout the organization.

- The Leadership Team ensures that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

- **Management Review (5.6)** Top management reviews the quality management system at least annually to ensure its continuing suitability, adequacy and effectiveness. This review includes assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. The management review follows the agenda described in procedure PRO-00001, Management Review.

**Resource Management (6)**

- **Provision of Resources (6.1)** Provision of resources within Avantor is the responsibility of the Leadership Team. Provision of resources within departments is the responsibility of department heads. Resources may be classified as personnel, time, equipment, facilities, and finances.

- **Human Resources (6.2)** Personnel are deemed competent on the basis of their education, training, skills, or experience. Specific requirements for each job are defined in the competency document, which may be a job description for that task, advertisement for the position, or other applicable document. Avantor has determined the necessary competency needs for personnel performing work affecting quality. Such

requirements are defined in the job descriptions and/or skill blocks. Avantor has provided training, or taken other action to satisfy these needs, where such training has been deemed necessary and is available. Avantor has evaluated the effectiveness of the training and other actions provided and recorded such on the training record of the employee or appropriate documentation. Avantor has ensured that employees are aware of the relevance and importance of their activities and how they contribute to the department objectives and Avantor objectives. Avantor maintains appropriate records of education, experience, training, and qualifications of employees in Human Resources

- **Infrastructure (Facilities and Equipment) (6.3)** The identification, provision, and maintenance of facilities needed to achieve conformity of product are considered part of Avantor's normal management process and as such are the responsibility of top management.

- **Work Environment (6.4)** Avantor has identified and manages the work environment needed to achieve conformity to product requirements.

**Product Realization (7)**

- **Planning of Product Realization (7.1)** The quality plan followed by Avantor in implementing the quality management system consists of the procedures described in the quality manual and includes any referenced work instructions. As such, the realization processes are consistent with any other requirements of Avantor Performance Materials, Inc.'s quality management system.

- **Customer-Related Processes (7.2)** The customer's verbal or written requirements are documented, verified, reviewed, and approved prior to implementation. Prior to acceptance of an order, Technical Services reviews the specifications and other technical requirements for new orders as well as for amended requirements. Customer Service reviews the commercial requirements for new or revised orders. Reviews are conducted as described in PRO-00005, Order Acceptance (Contract Review) – Domestic and Export. Customer communication is recognized as an important aspect to achieving product satisfaction by Avantor Performance Materials, Inc. If the communication is a customer complaint, it is handled according to procedure PRO-00048, Customer Product Quality Inquiry. If the communication is Avantor based, it is generally issued by Marketing or with Marketing consent.

- **Design and Development (7.3)** Avantor has a documented process for designing, developing and putting into production new products. Avantor's product development process (PDP) incorporates all functions of the business in a stage gate system. The PDP is a stage-gate process that consists of 7 stages where Stage 0 is Pre-concept, Stage 1 is Concept, Stage 2 is Feasibility, Stage 3 is Development, Stage 4 is Qualification, Stage 5 is Launch, and Stage 6 is a Post-Launch review stage.

- **Purchasing (7.4)** Avantor has established and maintains procedures to ensure that purchased raw materials that affect the quality of our products conform to specified purchase requirements and product specifications. Raw material suppliers are

evaluated, selected and approved as per PRO-00024 Supplier Approval. The criteria for the suppliers are based on quantitative evaluation of product samples, requirement for commitment to Management of Change (MOC) and change forecasting, evaluation of statistical quality control data (SQC), cost competitiveness, supplier self-assessment audits and on-site audits.

- An approved supplier list for purchasing is maintained and addressed in WI-00512 Vendor Master Maintenance.

- Supplier performance is monitored using key metrics of quality, service and cost as described in PRO-00088 Supplier Quality Process (SQP).

– **Production and Service Provision (7.5)** Avantor plans and carries out production provision under controlled conditions. The manager of each department processing products is responsible for assuring process control is achieved and maintained. Written procedures have been established which allow for product identification throughout product realization. Each product is identified by a product number, a suffix, and a lot or batch number. Avantor uses a combination of computer systems and physical location labels to identify the inspection and test status of raw materials, work in progress, and finished product, including conformance or non-conformance to defined quality criteria.

– Customer property provided for use or incorporation into a product is handled by the same processes, systems, and procedures used to handle Avantor materials and includes the identification, verification, protection and safeguarding of the customer property.

– Avantor has established and maintains documented procedures for identification, handling, packaging, storage and protection of our raw materials, in-process material, and finished goods. Secure storage areas are provided to prevent damage or deterioration of product pending use or delivery. Receipt and dispatch to and from these areas is controlled by procedures, documented by movement forms or reports, and tracked by computer systems. Products held by Avantor are assigned appropriate storage locations and conditions to preserve their quality and integrity.

– **Control of Measuring and Monitoring Devices (7.6)** Avantor identifies the measurements to be made and the monitoring and measuring devices required to assure conformity of product to specified requirements. Monitoring and measurement devices are used and controlled to ensure that measurement capability is consistent with the measurement requirements. Each manager is responsible for proper calibration and use of their department's monitoring and measurement equipment. All personnel are responsible for ensuring that calibrated equipment with an expired calibration date is not used. If equipment is found to be out of calibration, Avantor assesses and records the validity of the previous measuring results made with that instrument. Appropriate action is taken on the equipment and any product that may be affected. Records of the results of calibration and verification are maintained.

**Measurement, Analysis and Improvement (8)**

- **General (8.1)** Avantor plans and implements the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity of the product, to ensure conformity of the quality management system, and to continually improve the effectiveness of the quality management system.

- **Monitoring and Measurements (8.2)** Customer satisfaction is determined by Avantor through acquisition of customer and end-user information available in written and/or verbal forms, from internal and external sources.

- Avantor conducts periodic internal audits to verify that the quality management system conforms to the planned arrangements documented in section 7.1, Planning of Product Realization and the requirements of ISO 9001:2008, and is effectively implemented and maintained. The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records is defined in procedure PRO-00062, Internal Audits. Follow-up activities include the verification of actions taken and the reporting of verification results. This may be completed by the verification step in the corrective action review process (PRO-00097) or by a follow-up audit.

- Avantor has identified measurement methodologies for monitoring, and where applicable, measurement of the quality management system processes.

- Avantor has established procedures to monitor and measure the characteristics of the product to verify that product requirements have been met. This is carried out at appropriate stages of the product realization process in accordance with the planned arrangements. Avantor maintains inspection and test records which provide evidence of product conformance.

- **Control of Nonconforming Product (8.3)** Avantor has established procedures to ensure that product not conforming to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities are described in procedure PRO-00044, Control of Nonconforming Material. All nonconforming product is placed on MRB (Material Review Board) status in the inventory control system to prevent its unintended use or delivery. This system also maintains the record of the nonconformity and its disposition. The investigation to document the cause of the nonconformity and the resulting correction action is documented in the CAPA system.

- **Analysis of Data (8.4)** Avantor determines, collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the quality management system can be made. This includes data generated from monitoring and measurement activities such as product testing, internal audits and control of nonconforming product.

- **Improvement (8.5)** Avantor plans and manages the processes necessary for the continual improvement of the quality management system. Avantor facilitates the continual improvement of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive action, and management review.

- The Corrective Action and Preventive Action (CAPA) System has been developed to ensure all non-conformances or deviations are documented and the critical non-conformances or deviations are fully investigated to address identified issues, determine root cause and take action to correct the nonconformity and prevent its recurrence. Corrective and Preventive Action requests are documented in the CAPA system as described in procedure PRO-00097, Corrective and Preventive Action.

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# *Section 4 – Miscellaneous Site Information*

## Quality Unit

The production facility has a defined Quality Unit that is lead by the Quality Manager. The Quality Unit has the responsibility and authority to approve or reject all raw materials, packaging components, intermediates and finished products. In addition, the Quality Unit participates in review and approval of changes within the facilities' Management of Change process.

Avantor maintains a Reserve Sample Program per written SOP.

## Equipment Calibration

Avantor has written procedures detailing the test methods used in calibration. The standards used are traceable to the National Bureau of Standards or equivalent agency. Laboratory, monitoring and measurement equipment is included in the calibration program.

## Raw Materials

Avantor has a Supplier Management Program which includes auditing and maintenance of a list of approved suppliers. A program exists for qualifying certain vendors such that Avantor can minimize incoming raw material testing routines. In the event that Avantor has approved a reduced testing program for a material, Avantor continues to perform full testing of incoming batches every $10^{th}$ lot or 1 lot per year (whichever is more stringent) to assure that the vendor is maintaining performance commitments. In cases where incoming testing is not performed a Certificate of Analysis is required from the supplier to verify the raw material meets acceptance criteria.

Any raw materials that are received without a vendor's Certificate of Analysis must be tested against all specifications prior to approval for use. Our facilities follow a FIFO (First-in-First-Out) procedure.

## Lot Numbering System

All Avantor products display a lot number on the label to assist in keeping the freshest chemicals on your lab shelf. The six-character lot numbers are easy to interpret. Following is an example for Lot Number H26015:

| H | | 26 | 015 |
|---|---|---|---|
| A letter is used to denote the year of manufacture. | | Two-digit numbers are used to denote the calendar week of the year. | Three-digit manufacturing identifier may be numeric or alphanumeric and represents a unique lot of material. |
| Y = 2003 | G = 2008 | | |
| A = 2004 | H = 2009 | | |
| B = 2005 | J = 2010 | | |
| C = 2006 | K = 2011 | | |
| E = 2007 | | | |

In the example shown, Lot Number H26015 was assigned to material produced during the 26th week in 2009.

## Documentation

A computerized document control system is used to generate, maintain, and control the following types of documentation: Raw Material Specifications, Production SOPs, Validation Protocols, Policies, Finished Product Specifications, Laboratory SOPs, Stability Protocols, Batch Production and Packaging Records.

Most documentation is retained for 7 years or as described in the Document Retention Policy.

## Computer Operations

A validated computer system is used as part of the inventory management system. This system is used to monitor material status as to “quarantine”, “release”, or “reject”, however “Reject” labeling is also applied to rejected material. Computer bar coding for container identification is used on finished products. Computers are used in production monitoring and laboratory management (data collection).

A gap analysis and risk assessment have been performed to determine computer systems compliance with 21 CFR Part 11(U.S. Federal law for electronic signatures and technical systems handling data like PC, computers, and PLC for example). Avantor has completed remediation and is compliant.

## *Section 5 – Revision History*

Rev. 0 – Effective 2/19/03
Rev. 1 – Skipped this revision number in sequence in error
Rev. 2 – Effective 5/5/03 – Amended names on page 5 and added ISO document number to pages 17 and 23
Rev. 3 – Effective 7/1/03 – Added 1c and 1d to Analytical Methodology Profile
Rev. 4 – Effective 9/17/03 – Added newest FDA inspection date to table on page 8 and amended Table of Contents page for Equipment Calibration
Rev. 5 – Effective 8/3/06 – Revised entire document
Rev. 6 - Revised entire document to IPEC Site Quality Overview Format - March 2008
Rev. 7 – Updated Staff Levels; Revised FDA & ISO tables; added new year to Lot Number System section; Updated contact information – January 2010
Rev. 8 – Changed company name and logo throughout. Changed first paragraph of History. Changed from Q7A to Q7. Updated web address. Added current year to Lot Number section. Updated Contact Information.– December 2010
Rev. 9 – Updated FDA inspection information and ISO certification information.
Rev. 10 – Updated union contract date in Section 1; Clarified GMP references in Section 2; Added detailed information in Section 3; Updated contact information in Section 6

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## *Section 6 – Contact Information*

| POSITION/TITLE | PHONE NUMBER |
|---|---|
| **Research & Technology:**<br>Director of R & T- Bio/Pharm | <br>908-859-6720 |
| Director of R & T - Microelectronics | 908-859-9337 |
| **Production:**<br>Phillipsburg Plant Manager | 908-859-9456 |
| Paris Plant Manager | 859-987-9400 |
| **Packaging:**<br>Senior Packaging Engineer | <br>908-859-9668 |
| **Quality Control/Quality Assurance:**<br>Global Director of Quality Assurance<br>Director of Regulatory Affairs | <br>908-859-6926<br>908-859-9466 |
| Quality Manager, Phillipsburg Plant | 908-859-6926 |
| Quality Manager, Paris Plant | 859-987-9459 |
| **Other Key Personnel:**<br>EH&S Phillipsburg Plant | <br>908-329-9976 |
| EH&S Paris Plant | 859-987-9423 |
| Director of Marketing, North America | 908-859-9319 |
| Manager, Technical Support Services | 908-329-9915 |
| Manager, Customer Services | 908-859-6968 |

November 28, 2011

Dear Valued Customer:

Our records indicate that you have requested notification of change by registering in the Avantor™ Performance Materials change notification database or you have purchased the product(s) listed in Appendix A within the last three years.

| | |
|---|---|
| Classification | R - Regulated |
| Change Type | Packaging |
| Tracking | MOC-PKG-0564 |
| Notification Type | Preliminary |
| Product(s) | See Appendix A |

Description of Change
This change pertains to a clean out process enhancement associated with our package supplier's liner manufacturing.

The clean out process will include a non-abrasive, non-chemical thermoplastic, which thoroughly loosens carbonized and degraded resin, allowing it to be flushed out of the system.

Reason for Change
Avantor is confident our customers will find value in this clean out process enhancement because it will reduce the introduction of black carbon specs into the finished good product.

This is a preliminary notification only. A secondary notification and associated data will be provided to you upon completion of the change qualification. At that time, a lot number will be provided. Currently, we estimate that the change will be put into effect in May 2012. However, this date may change based on our testing/qualification results.

According to Avantor change control policies and procedures, this product has been classified as R - Regulated IPEC Level 2 Change. (For additional information on the classifications and their meanings, please refer to http://www.avantormaterials.com/threecolumnwireframe.aspx?pageid=2147561697&terms=management%20of%20change).

Please contact your Avantor™ representative if you have any questions regarding this change.
We appreciate your continued confidence and interest in Avantor™ products.

Sincerely,

Lakeicha K Frinzi

Lakeicha Frinzi
Product Manager

If you wish to update your contact information or are currently receiving this notification via mail and would prefer to receive these notifications electronically, please provide us with your e-mail address by contacting us at E-Mail: info@avantormaterials.com

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