Avient Corporation: Quality Response for Manufacturing Facilities in North America, North LATAM, Europe, the Middle East, and Africa

Rev 12-05-2023

Dear Customer,

This Quality Response for Manufacturing Facilities in North America, Europe, the Middle East and Africa, is being provided in response to your request to complete and return your supplier questionnaire / assessment. It provides information on topics frequently evaluated by our customers, including quality management, environmental, health and safety, and sustainability. In addition to the information contained in this document, which is focused on quality systems and management, Avient has prepared a separate summary of Avient's Environmental, Social and Governance (ESG) policies and practices that is available upon request.

Avient is committed to continuous improvement and delivering solutions on the foundation of a quality focus; we conduct our operations in accordance with the applicable laws and regulations. Our internal policies and practices often go beyond compliance as part of our continuing commitment to corporate responsibility and sustainability.

Many customers have asked us to complete their supplier questionnaire. We understand and appreciate your need to have information regarding our products and processes. However, it is not always feasible to respond to each individual questionnaire we receive. Therefore, we prepared this summary, highlighting major initiatives and linking you to more detailed resources to help provide information that is frequently requested from our customers. Our systems have been designed to comply with applicable laws and regulations and offer robust programs for supporting our quality and corporate responsibility initiatives. We believe you will find our programs make us an industry leader in these areas.

Please be informed that Avient does not provide detailed information about buildings and facilities, storage area, staff numbers and union organizations on surveys. While we believe the information contained in this document should be responsive to most inquiries, if you have questions not answered by this document you should reach out to your sales representative, who is your primary contact, and can forward your request to an appropriate person.

We thank you for your understanding, and we look forward to serving your needs.

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Avient Corporation: Overview

The Avient website is your home base for information about the company:
http://www.avient.com/

To find our facility locations:
http://www.avient.com/contact/global-directory-and-contacts

For more information about our management systems certifications, including ISO, go to:
http://www.avient.com/company/sustainability/environmental/global-iso-certificate-library

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Avient Governance (corporate policies and the Avient Code of Conduct):
http://www.avient.com/investors/governance

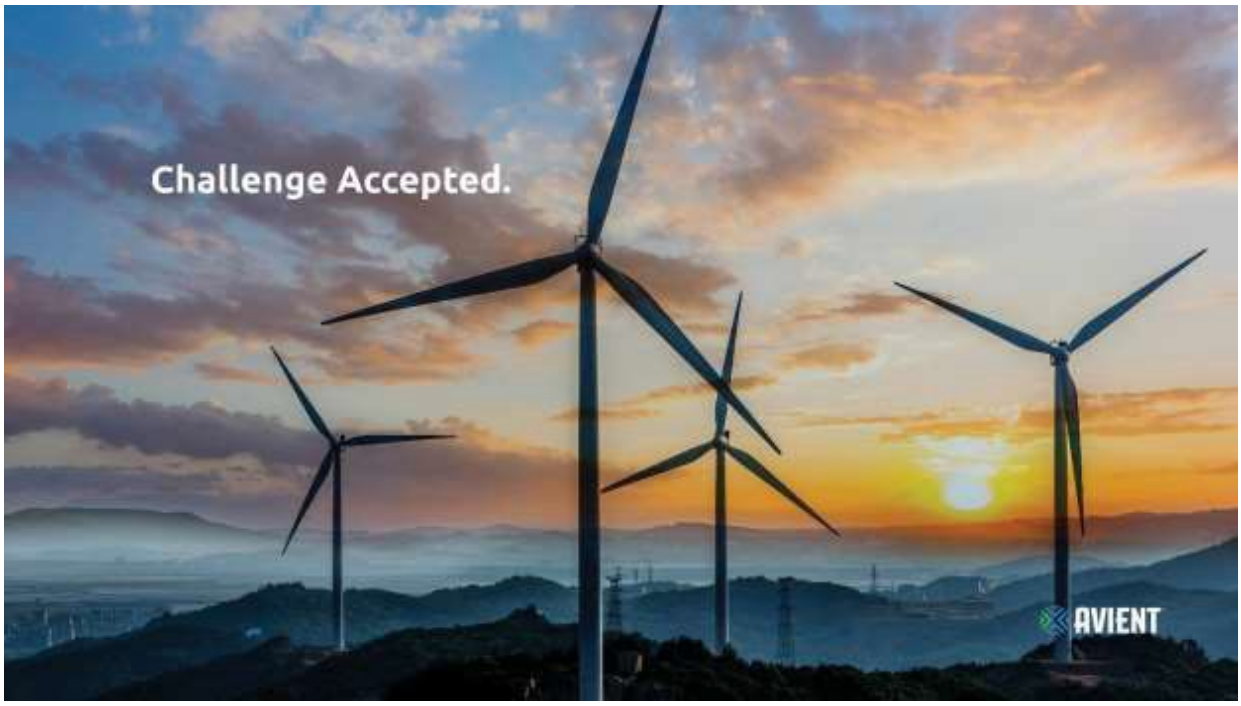
Financial reports:
https://www.avient.com/investors

Avient Sustainability Report:
https://www.avient.com/company/sustainability

Avient Policy for Customer Audits

Avient may permit audits of facilities, subject to:

- Advanced notice and an audit agenda provided at least thirty (30) days in advance or as agreed by the Avient location to be audited for a routine audit.
- Audits must be conducted during normal business hours.
- Audits may require a signed Non-Disclosure Agreement (NDA) prior to the audit. Avient can provide its NDA form upon request.
- All persons attending the audit may be required to sign an individual non-disclosure agreement prior to being permitted into Avient facilities. Additionally, personal protective equipment may be required in certain areas of the facility.
- Audits are at the discretion of Avient and may be limited in content/scope.



Management Responsibility

The following information describes minimum requirements in place at all ISO 9001 certified manufacturing facilities identified at http://www.avient.com/company/sustainability/environmental/global-iso-certificate-library

Some additional certified management systems are described in the annex to this document.

Certificate of Product Liability Insurance

Provided upon request, contact your sales representative.

Ethics - Code of Conduct

Avient has its own ethics policy – The Avient Code of Conduct which establishes a clear set of ethical and behavioral standards for business conduct by all Avient associates. The Avient code of conduct is available here.

Modern Slavery Statement

For our Policy on Modern Slavery and Human Rights click here.

Conflict Mineral Policy

The Conflict Mineral Policy is available here.

Environmental Performance

Our Environmental Management System establishes internal performance and audit/review standards for all our facilities comparable to ISO 14001 standards. Certain facilities have also received official certification to the ISO 14001 by third-party ISO representatives. Please check our certificate library here.

Safety Data Sheets

For selected products, click here, or contact your sales representative.

Technical Data Sheets

For selected products, click here, or contact your sales representative.

Regulatory Requests and Certificates (FDA certificate, Absence declaration, REACH, SDS)

Available upon request, please contact your sales representative.

Safety Performance

Safety is Avient's first priority. A safety management system is in place in all our locations to analyze, reduce risk, and improve safety performance. For more detailed information click here.

Energy Management

To continuously track progresses made toward achieving environmental goals, Avient has implemented a reporting program that can be found here.

Business Continuation Plan

Backup plans have been established in some facilities in case of production site/line disruption to ensure service continuity to customers.

Preventive - Predictive Maintenance

Each manufacturing location has a preventive and predictive maintenance schedule.

Financial Report

Our most recent Financial Report can be found here.

Information that Avient considers as confidential and will not communicate through questionnaires:	
• **Building and facilities figures** • **Workforce effective** • **Organization charts** • **Shift organization** • **Unions affiliations** • **Customers**	• **Suppliers** • **Procedures** • **Work instructions** • **Quality Manuals** • **FMEA/CCP** • **Control plans**

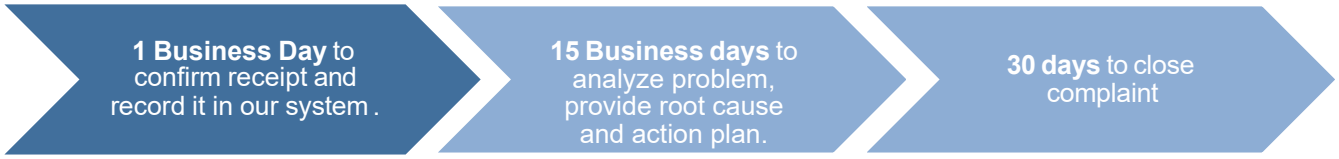
Quality Management

3rd Party Certifications

All manufacturing facilities are certified to the ISO 9001 standard. Some have additional certifications such as ISO 13485, ISO 14000, ISO 22000 and other third-party certified standards such as Responsible Care® and IATF. Detailed information on a site specific basis can be found in Avient's Global Certificate Library here.

Product Complaint Timeline

In the event you have a quality issue or concern with an Avient product, please contact your sales representative, provide as much detail as possible, and records, data, and other supporting information. Standard handling time frame:



The overall processing times may vary depending on the complexity of the issue and resources needed.

Continuous Improvement

Avient primarily uses a Lean Six Sigma approach in our responsive investigation. We use a set of formal quality tools and systems in evaluating and tracking quality complaints.

Traceability

Our Enterprise Resource Planning (ERP) system allows us to have full traceability from raw material to finished goods linked to production conditions and test results. Information is available on a batch or lot basis.

Record Retention

- Production records are stored for a minimum of **1 year**.
- ERP records are kept for a minimum of **5 years**.

Time frames mentioned above are the standard minimum requirements; longer retention time are defined in plants with specific certifications. Special dispositions are detailed in the annex.

IT Security

Firewall	Critical Data
Firewall systems are in place on our network.	Avient has set a system to backup critical data.

IT Disaster Recovery

Avient has a documented crisis management process. The plan covers all locations where services are provided and covers fire, water, storm, bomb threat, site security, and information systems security failure scenarios.

IT Systems of Use Policy

This Policy is available here.


Challenge Accepted.
AVIENT

Annex 1 - ISO 13485 certification for Mevopur manufacturing sites North America & EMEA.

Avient Colorants Sweden AB in Malmoe and Avient Colorants USA LLC in Lewiston, Maine are Medical Centers of Competence with an external ISO 13485 certification. Core processes that may be additional at the ISO 13485 sites include the following as they relate to the Mevopur medical line of products:

Change control

All changes concerning any Mevopur products are evaluated to determine whether there will be any impact on the product specification or the quality of the product. The category of changes that are evaluated include: raw material, regulatory status, packaging, manufacturing principles, processing equipment, QC methods, manufacturing location, organizational structure, standard operational procedures.

Validation

Avient Colorants Sweden AB and Avient Colorants Lewiston, ME follow the Global Harmonization Task Force guideline GHTF/SG3/N99-10 to define the procedure for process validation. These sites use a global validation program with periodically validation of selected processes such as cleaning validation and software validation defined in the Validation Masterplan.

Control of documents and records

All Mevopur related documents and records are required to be maintained in a legible, readily identifiable and retrievable manner as evidence that these products meet specified requirements. The record retention period for these records is seven (7) years.

Supplier approval and supplier evaluation

Procedures are in place to manage supplier approval as well as a supplier evaluation for new suppliers.

Traceability

The sites have established a traceability system that tracks components from raw material through inspection, test, and final release.

Material management

Raw materials used in Avient healthcare applications must fulfill a minimum set of requirements. New raw materials are selected by Regional Technical Managers in all regions and pre- screened to fulfill all requirements before a request for a new raw material is entered. Some of the raw materials that are used in Mevopur products are tested in accordance with selected parts of ISO 10993, USP. European Pharmacopoeia and ICH 3QD. The tests are done by certified laboratories and declarations are available to customers upon request on product level. A goods receipt inspection with defined tests are mandatory for all raw materials used in Mevopur products.

Release of finished products

Production of Mevopur products are under controlled conditions according to a documented procedure. Records are established and maintained for each batch of medical products that provides traceability and identifies the amount manufactured and amount approved for distribution. All Batch records are reviewed by the assigned manufacturing unit. The Quality Control Record is reviewed by authorized Quality Control personnel before the batch release takes place. The review process confirms that the QC testing results fulfil the established product specification. Batch Certificates (CoC or CoA) are prepared as applicable.

Control of Non-conforming products, complaints handling, recall and CAPA

Avient follows a documented process for control of non-conforming products, complaints handling, recall and CAPA. Non-conforming products are identified, segregated, and evaluated. The established system for complaints tracks a complaint throughout the process of corrective, preventive actions and root cause analysis. Recall exercises are done on a regular basis in accordance with the global SOP.

Annex 2 – ISO 22000 certifications

Avient Colorants Spain S.A, Avient Colorants Santa Clara Coatitla Mexico, and PolyOne Spain SLU have enhanced systems to support food packaging applications with an external ISO 22000 certification adding the following core processes:

Change

All changes concerning any product produced under ISO 22000 conditions are evaluated to determine whether there will be any impact the

specification or in the quality of the product.

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HACCP

Avient Colorants Spain S.A., Avient Colorants Toluca Mexico, and PolyOne Spain SLU follow the structure of HACCP (Hazard Analysis and Critical Control Point) as a system for assessing compliance to food safety standards. These standards are designed to mitigate potential health risks related to food products and or nutraceutical products from their packaging and/or any other material that may come into direct contact with it. A well-defined risk assessment process is in place for all global sites certified according to ISO 22000 requirements.

Control of documents and records

All ISO 22000 related documents and records are required to be maintained in a legible, readily identifiable and retrievable manner as evidence that these products meet specified requirements. The record retention period for these records is three (3) years.

Material management

Raw materials used in food applications must fulfill a minimum set of regulatory requirements according to customer demands. New raw materials are selected by Technical Managers in all selected sites and pre-screened to fulfill all requirements before a new raw material is approved for use. A goods receipt inspection with defined tests are mandatory for all raw materials used in food application products produced under ISO 22000 conditions

Supplier approval and supplier evaluation

Procedures are in place to manage both supplier approval in case of new suppliers and continuing supplier evaluation.

Traceability

The site has established a traceability system that tracks components from raw material through production, inspection, test, and final release operations.

Release of finished products

Production of products produced under ISO 22000 conditions are maintained according to documented procedures. Records are established and maintained for each batch of products that provides traceability to the extent specified and identifies the amount manufactured and amount approved for distribution. All Batch records are reviewed by the assigned manufacturing unit. The Quality Control Record is reviewed by authorized Quality Control Personnel before the batch disposition and release take place. During the review is assured that the QC testing results fulfil the established product specification. Batch Certificates (CoC or CoA) are prepared as applicable.

Control of Non-conforming products, complaints handling, recall and CAPA

Documented process for control of non-conforming products, complaints handling, recall, and CAPA has been established. Non-conforming products are identified, segregated, and evaluated. The established system for complaints tracks the complaint throughout the process of corrective and preventive actions and root cause analysis. Recall exercises are done on a regular basis in accordance with the ISO 22000 requirement.

Sustainable Solutions Live Here.

At Avient, we create specialized and sustainable material solutions that transform customer challenges into opportunities, bringing new products to life for a better world.