

## Product Stewardship Information Management Standard

### **Applies To**

This document applies to all Solventum operations worldwide.

#### Introduction

Solventum is committed to enabling better, smarter, safer healthcare to improve lives. Consistent with our mission, code of conduct, and values, Solventum is dedicated to ensuring products are safe for their intended use(s), compliance with all applicable regulations, and based upon responsible chemistry.

To enable these commitments, this Standard sets the data requirements for formulation, composition, and design information, with the objective of ensuring consistent documentation and alignment across Solventum. These data requirements allow Product Stewardship to assess, manage, and communicate potential hazards.

#### Requirements

Responsibility for ensuring compliance with this document is assigned to all functions including, but not limited to, Product Stewardship, Research & Development, Business Groups, Product Engineers, Sourcing, Manufacturing Locations, Sustainability, Enterprise Supply Chain, and others. These functions must support gathering, validating, and maintaining Product Stewardship information for the following material types to which this Standard applies.

- Solventum products (including new, existing, and acquired products)
- Chemicals
- Raw materials
- Intermediates
- Hardgood products and components
- Article products
- Developmental products

Product Stewardship information includes formulation, composition, and design information. This information must be maintained in designated repositories (e.g. CDMS, PLM, SAP, etc.) in conformance with this Standard. All above material types must be identified with a unique identification number represented in the appropriate repositories.

To support compliance with this standard, procedures will be maintained to support the specific requirements as follows:

- **Gather** A reasonable, good faith, and on-going effort must be used to collect new and updated Product Stewardship information about materials. Information sources may include a Safety Data Sheet (SDS), a material specification, a certificate of analysis, a certification letter, a certification test report, a declaration of conformity, a Raw Material Information Form (RMIF), a Purchased Finished Goods Information Form (PFGIF), a Hardgoods Material Information Form (HMIF), and/or a supplier letter or contract.
- Validate Product Stewardship information received from a supplier must be assessed by product stewardship to ensure that the information is complete and reliable. Consideration must be given to the relationship and history with a supplier. In some cases, testing may be needed if a



supplier cannot or will not supply requested Product Stewardship information. Documentation of validation is implied by uploading material data into the designated repositories.

• **Maintain** - Assigned personnel must ensure that Product Stewardship information for the abovestated material types is recorded and actively managed in designated repositories (e.g. CDMS, PLM, SAP, etc.) to reflect all updated information and to keep current with legal and regulatory requirements for their specific markets and geographic locations.

Failure to comply with these requirements may result in discipline, up to and including termination of employment.

#### Definitions

**Article:** A manufactured object formed to a particular shape, surface or design and that has end-use functions that are dependent on that shape or design.

**Chemical Data Management System (CDMS):** CDMS is a software system to manage chemical environmental, health, and safety information. One of its primary uses is to create Safety Data Sheets (SDSs) and warning statements for product labels. It is the current designated repository for formulation and composition information for products, semi-finished goods, and raw materials.

**Composition:** The base chemicals and biological agents (e.g. Chemical Abstract Service (CAS) Number or specific chemical name or a trade secret identifier) found in a product or material, including known residuals, impurities and by products. The percentage of each base chemical and biological agent must be included to the level of measurement required by applicable law, regulations, or accepted customer requirements.

**Design Information:** The complete set of plans, drawings, documents, and electronic files that are necessary to specify the requirements to build, service, and use a hardgood from individual components (commercial or created) to the finished good.

**Developmental Product:** A product during formulation development and prior to launch (e.g., experimental material, New Technology Introduction (NTI), New Product Introduction (NPI), etc.).

**Formulation:** The substances or materials that go into the process of manufacturing another material. Formulations are described in terms of raw materials and intermediates.

**Hardgood:** An article or system that incorporates electrical, electronic, mechanical, or other energy functions, and is typically durable.

**Intermediate:** A material that is purchased or manufactured to a Solventum specification and is intended to be subject to further manufacturing or conversion operations. Examples include a jumbo roll and a bulk chemical mixture. An intermediate may also be referred to as a semi-finished good.

**Life Cycle Management:** The process of managing product stewardship considerations including human health and environmental safety, compliance, and responsible chemical management throughout the life cycle of a product, from design and development through end of life.

**Product:** A finished good material which is manufactured by Solventum, acquired by Solventum, outsource manufactured on behalf of Solventum, or a purchased finished good that may or may not be private labeled as Solventum. Examples could be a chemical product, article product, or hardgood product.

**Product Life Cycle Management (PLM):** Global PLM, also known internally as eMatrix or by its marketed trade name ENOVIA<sup>™</sup>, is a suite of applications for managing product life cycle information,

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including design information, raw material specifications, engineering specifications, and bills of materials (BOMs). This is the current designated repository for design and composition information of hardgoods.

**Raw Material:** Materials obtained from sources outside of Solventum that are ingredients or components for the production of intermediates and products.

Raw Material Information Form (RMIF); Purchased Finished Goods Information Form (PFGIF); a Hardgoods Material Information Form (HMIF): Forms used to gather Product Stewardship and related information on various material types from vendors for entry into Solventum systems of record.

**System Analysis Program (SAP):** Central data management software for enterprise resource planning. It is the current designated repository for specific regulatory indicators.