

## Managed Substances Policy

### 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), compliant with all applicable regulations, and based upon responsible chemistry.

The objective of the Managed Substances Policy is to ensure rigor is applied to evaluate specific chemicals of interest to drive proactive, risk-based, responsible chemical management. This emphasis is beyond routine evaluation of products for safety and regulatory compliance. As Solventum employees, we will continually improve our chemical management processes and procedures with the interest of our communities and protection of the environment as top priorities.

### Requirements

Solventum employees including Product Stewardship, Environmental Health & Safety (EHS), Research & Development, Manufacturing, Regulatory, Sourcing, and others are responsible for abiding by this Policy.

Solventum will maintain processes to enable responsible chemical management. This includes consideration throughout the life cycle of a product, and extends to new, existing, or developmental products. Requirements are facilitated as integrated aspects of the Solventum Life Cycle Management (LCM) process and, where appropriate, and other facility chemical introduction processes, such as Management of Change (MOC).

To support compliance to this Policy, procedures will be maintained to:

- Manage Formulation and Composition Information:
  - Gather, validate, and maintain formulation and composition information of products, intermediates, raw materials, and developmental products using designated processes and repositories.
  - Consider the impact of processing aids on formulation and composition.
  - Comply with Solventum record retention and information management expectations for all associated data and documents.
- Designate specific chemicals of interest into categories of a Managed Substances List (MSL):
  - Prohibited Substances: Substances that cannot be added to Solventum products.
  - Restricted Substances: Substances that must be further scrutinized in Solventum products. Solventum's goal is to reduce our reliance on these substances.
- Identify when chemicals included on the MSL are present in Solventum Products.
- Review and approve or disapprove use of the identified MSL listed chemical(s) in subject Products.
  - Prohibited Substances. Our operating principle is that these substances will not be approved.
  - Restricted Substances. Our operating principle is that authorization for use may be given on a case-by-case basis after confirming the use meets the criteria of regulatory compliance, human health safety, environmental safety, and considering the EU definition of essential use<sup>1</sup>.

- For chemistries not specifically identified on the MSL, Solventum will continue the practice of selecting lower hazard materials, when possible, in alignment with our Code of Conduct and corporate values.

Specific details, including the MSL list and relevant procedures, can be found in Solventum Product Stewardship Global Compliance Standard and associated Standard Operating Procedures outlined in the Solventum Quality Management System.

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

## Definitions

**Composition:** The identities and relative quantities of the chemical compounds that make up the particular mixture or material.

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

**Essential Use:** A use that is “necessary for health, safety, or is critical for the functioning of society and if there are no alternatives that are acceptable from the standpoint of environment and health” (EU, 2020<sup>1,2</sup>). It is consistent with the U.S. State of Maine<sup>4</sup> position that the use of some chemicals of interest is “currently unavoidable.” The concept was originally proposed in the 1989 Montreal Protocol<sup>5</sup> on substances that deplete the ozone layer.

**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.

**Managed Substances List:** A list of restricted and prohibited substances as defined in Product Stewardship Standard Operating Procedures for which approval by the Managed Substances Committee is required for use in Solventum new, existing, and developmental products.

**Processing Aid:** Processing aids can include adhesives, in-process liners, mold cleaning agents, mold releasing agents, sterilization chemicals, etc.<sup>3</sup> that may contact the product. Chemicals and materials used in the facility that do NOT contact the product are not processing aids, e.g., floor cleaners, worker coveralls, etc.

**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.

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

## Other References

1. European Commission. 2020. "Chemicals strategy for sustainability towards a toxic-free environment." COM(2020) 667. Accessed from: [Chemicals strategy - European Commission \(europa.eu\)](#)
2. Wood E&S GmbH, Ramboll, and the European Commission. 2022. "Supporting the Commission in developing an essential use concept." EC Document: 807740-WOOD-RP-OP-00011\_1\_Final Workshop. Accessed from: [Essential Use Workshop Report final.pdf \(europa.eu\)](#)
3. US FDA. 2023. Guidance for Industry: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."
4. Maine, United States of America. An Act to stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution. 2021; Vol. 477. <http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=HP1113&item=5&snum=130>.
5. UN Environment Programme. 1989. Montreal Protocol on Substances that Deplete the Ozone Layer. Accessed from: [The Montreal Protocol on Substances that Deplete the Ozone Layer | Ozone Secretariat \(unep.org\)](#).