

Managed Substance 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 this mission, our code of conduct, values, Quality Policy, and Product Stewardship Policy, the Managed Substance Policy governs risk-based, responsible selection and management of the chemicals used to manufacture Solventum products. This is in addition to routine evaluation of materials and products for safety and regulatory compliance.

Requirements

Overall responsibility for ensuring compliance with this Policy is assigned to the Product Stewardship, EHS, Package Engineering, and Procurement organizations, in close collaboration with other interdependent functions.

Throughout the life cycle of all products, from design to disposal, we are committed to:

- Maintain detailed information on chemicals and components used in our products, product packaging, and as processing aids, to inform responsible chemical management.
- Assign chemicals of interest to categories of a Managed Substance List (MSL):
 - Prohibited Substances: Substances that cannot be added to Solventum products, packaging, processing aids, and/or used in manufacturing processes.
 - Restricted Substances: Substances that require risk-based evaluation for potential use in Solventum products, packaging, processing aids, and/or used in manufacturing processes. Solventum's goal is to reduce our reliance on these substances. Authorization may be given after confirming the use meets the criteria of regulatory compliance, human health safety, environmental safety, and essential use^{1,2}.
- Identify, review, and approve or disapprove the use of MSL chemicals in products, packaging, or as processing aids.
- Select lower hazard materials, when possible.

Specific details on how the above commitments are executed are in the Solventum Product Stewardship Global Compliance Standard and associated Standard Operating Procedures and Work Instructions outlined in the Solventum Quality Management System.

Definitions

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”^{1,2}. It is consistent with the U.S. State of Maine³ position that the use of some chemicals of interest is “currently unavoidable.” The concept was originally proposed in the 1989 Montreal Protocol⁴ on substances that deplete the ozone layer.

Processing Aid: A processing aid is a material used to facilitate manufacturing, improve product quality, or enhance efficiency. Processing aids can include adhesives, in-process liners, mold cleaning agents, mold releasing agents, sterilization chemicals, etc. that may contact the product⁵. Chemicals and materials used in the facility that do NOT contact the product are not processing aids, e.g., floor cleaners, worker coveralls, etc.

Other references

Solventum Code of Conduct

Solventum Quality Policy

Solventum Product Stewardship Global Compliance Standard and associate standard operating procedures outlined in the Solventum Quality Management System

Solventum Quality Management System Master Glossary

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&IS 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. 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>.

4. 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).

5. 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."

Further Information

For further information, contact Solventum Product Stewardship organization