

Product Stewardship and Environmental Testing 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 our products are safe for their intended use(s), compliant with all applicable regulations, and based upon responsible chemistry.

This standard sets the requirements for non-clinical safety and environmental testing for products, intermediates, raw materials, and developmental products.

Requirements

Overall responsibility for ensuring compliance with this document is assigned to the Product Stewardship and the Environmental, Health, and Safety (EHS) organizations.

Prior to initiating non-clinical safety and environmental testing for products, intermediate, raw materials, and developmental products, coordination with the Product Stewardship and/or the EHS Organization is required. In scope testing includes toxicity (including biocompatibility), product exposure, ecotoxicity, environmental fate, hardgoods safety, and electromagnetic compatibility. This coordination is necessary to ensure consistent oversight and execution of the testing process including study planning, internal/external laboratory selection, protocol or General Project Outline (GPO) approval, study monitoring, data review, final report approval, and centralized storage of study-related information. This coordination enables:

- Regulatory reporting obligations are met.
- Appropriate and approved laboratories are used.
- Appropriate testing guidelines and methods are followed.
- Data is appropriately evaluated and interpreted.
- Duplicative or unnecessary testing is not performed.
- Records are easily located and retrievable.

Definitions

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

Environmental Testing: Experimental studies performed to evaluate the potential ecotoxicology effects or environmental fate of a substance or product.

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.

Non-clinical safety testing: Experimental studies performed to evaluate the safety of a substance or product including potential toxicology effects (e.g., biocompatibility testing), electrical safety and



electromagnetic compliance. This testing is “non-clinical” testing, because it does not include clinical trials in humans.

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.