



Purpose:

Ursinus College is committed to operating academic programs in the safest manner possible, with concern for the individual and the protection of the environment in accordance with all applicable Federal and State statutes. This document outlines regulations for handling research generated chemical and substances that are shipped or transported to an off-site location in accordance with the United States Environmental Protection Agency (US EPA) regulations, 29 CFR 720-723, Standards for *Toxic Substance Control Act (TSCA) Research Exempt Chemical Substances*.

Definitions:

PMN - Pre-manufacture Notice

Small quantity (solely for R&D) – quantity of a chemical substance manufactured, imported or processed or proposed to be manufactured, imported or processed solely for research and development that are not greater than reasonably necessary for such purposes.

Research and Development – Activities that are intended solely as scientific experimentation, research or analysis, and can include the synthesis of new chemical substances or the analysis,

Technically qualified individual – Means a person or persons who, because of education, training or experience, or a combination of these factors is capable of understanding the health and environmental risks associated with the chemical substance, which is used under his or her supervision, and who is responsible for enforcing appropriate methods of conducting scientific research to minimize such risks, and who is responsible for the safety assessments and clearances related to the procurement, storage, use and disposal of the chemical substance as may be appropriate or required within the scope of conducting a research and development activity.

TSCA – Toxic Substance Control Act

Introduction:

Section 5(h) of TSCA, 15 USC 2604(h) provides certain exemptions from the section 5(a) Pre-manufacture Notice (PMN) and significant new use notice requirements. Section 5(h)(1) authorized EPA to allow persons, upon application, to manufacture or process a new chemical substance or a chemical substance subject to a significant new use rule for “test marketing” purposes without complying with section 5(a). Section 5(h)(3) exempts substances that are manufactured in **small quantities** solely for research and development (R&D) from the section 5(a) notice requirements. No application is required for the exemption for R&D under section 5(h)(3); however, record-keeping requirements do apply.

Any manufacturer, importer or individual who distributes a chemical substance to persons not in its employ must notify those persons in written form the following:

- Substance(s) is to be used only for R&D purposes
- Notice of health or environmental risks



- Use of substance requires supervision of a technically qualified individual

Recordkeeping:

Requirements to comply with the TSCA PMN R&D exemption require that the College maintain copies of all information on that specific chemical, its hazards, and method of risk notification to the person or persons receiving the chemical substance. An alternative recordkeeping method is to document all laboratory prudent practices in accordance with 40 CFR 720.78(b)(iii). Additional recordkeeping requirements include maintaining the names and addresses of those who received a particular substance, identity of the substance, the amount distributed, and copies of written notification.

At Ursinus College, use of the TSCA form located at the end of this policy shall be used to record any shipment of samples to another location. The original copy of the form will be filed in the Environmental Health & Safety Coordinator's office. These records must be maintained for a minimum of 5 years.

Labeling Requirements:

All **samples** sent out for analysis must have the following words on the sample container:

For R&D Use ONLY

Shipping Label (placed on the outside of outgoing packages) must have the following words:

NOTICE: This package contains

**TSCA Research Exempt Chemical
Substances
(For R&D Use only)**

Read the enclosed "Notification Form"
Use prudent laboratory practices for handling
chemical substances of unknown toxicity.

EPA regulations 40 CFR 720-723