

# University of Louisville

## Requirements for Possession of Permissible Quantities of Select Toxins

This document outlines the University of Louisville's institutional requirements on possession of permissible quantities of Centers for Disease Control and Prevention Select Toxins. These requirements have been established to ensure:

- Safe laboratory handling, use, and storage procedures.
- Effective tracking and security of the regulated toxin.
- Compliance with federal regulations.

### Exempt Quantities of CDC Select Toxins

Per federal regulations, each Principal Investigator (PI) may possess a permissible amount of Select Toxin(s) without triggering CDC registration and approval. Specified below is a list of Select Toxins and the maximum quantities per PI. (<http://www.selectagents.gov/PermissibleToxinAmounts.html>)

Toxin	Maximum Quantity (per PI)
Abrin	1,000 mg
Botulinum neurotoxins	1 mg
Short, paralytic alpha conotoxins	100 mg
Diacetoxyscirpenol	10,000 mg
Ricin	1,000 mg
Saxitoxin	500 mg
Staphylococcal enterotoxins (subtypes A, B, C, D, E)	100 mg
Tetrodotoxin	500 mg
T-2 toxin	10,000 mg

\*Updated Feb 2022

Additionally, the following Select Toxins are exempt:

- Any Select Toxin that is in its naturally occurring environment provided it has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.
- Non-functional Select Toxins.
- An animal inoculated with or exposed to a Select Toxin.

It is important to ensure that the total amount of Select Toxin per PI in a laboratory is maintained below these permissible quantities at all times for exemption from the Select Agent and Toxin regulation and registration. Due to the severe penalties associated with non-compliance with the Select Agent and Toxin rules, it is imperative that each laboratory using and storing Select Toxins maintains current and accurate inventory information. The Department of Environmental Health and Safety (DEHS) will contact and visit these labs annually to verify inventories.

Failure to register a select agent is a criminal offense, punishable by up to five years in prison and/or \$500,000 in fines per the Public Health Security & Preparedness Response Act of 2002, s. 231(c).

## Requirements for Possession of Permissible Quantities of Select Toxins

The PI is responsible for ensuring the following items are in place before obtaining and/or using Select Toxins:

- Approval from the Institutional Biosafety Committee.
- Development of Standard Operating Procedures for the use of the Select Toxin.
- Initial lab-specific safety training for lab personnel on processes involving Select Toxins, with updates as necessary. Best practice recommends the PI maintain documentation of training. The following topics should be covered during training:
  - Toxin-associated hazards
  - Engineering controls used to minimize exposure (such as chemical hoods)
  - Personal protective equipment (PPE) for handling Select Toxin
  - Safe handling and storage
  - Proper decontamination, inactivation, and disposal
  - Administrative requirements (recordkeeping, inventory, security)
- Appropriate PPE (gloves, eye protection, lab coat). If respirators are necessary, contact DEHS 852-6670 for appropriate fit-testing and training.
- Use of chemical hood, biological safety cabinet, or glove box with toxin-associated procedures.
- Use of accepted inactivation procedures. Contact DEHS 852-6670 for further assistance.

### Chemical Inactivation of Select Toxins

Toxin	2.5% NaOCl + 0.25 N NaOH	2.5% NaOCl	1% NaOCl	0.1% NaOCl
T-2 mycotoxin	Yes	No	No	No
Tetrodotoxin	Yes	Yes	Yes	No
Saxitoxin	Yes	Yes	Yes	Yes
Ricin	Yes	Yes	Yes	Yes
Botulinum	Yes	Yes	Yes	Yes
Staphylococcal enterotoxin	Yes (?)	Yes (?)	Yes (?)	Yes (?)

\*30-minute exposure to various concentrations of sodium hypochlorite with and without sodium hydroxide.

Yes: complete inactivation

Yes(?): assumed inactivation

- Storage and security, including:
  - Stored with compatible materials within secondary containment.
  - Provided one layer of physical security (within a locked freezer, permanently fixed lockbox).
- List of PI-approved users
  - A documented list of who has access to and uses the stock.
- Inventory maintenance
  - Updated inventory after Select Toxin is acquired, depleted (used/transferred), and inactivated.
- Documented security inspection
  - Self-inspection including review of approved users, verification of labeling, storage, and security measures, and comparison of physical inventory to usage log.