

## U of L Requirements for Possession of Permissible Quantities of Select Toxins

This document outlines U of L'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 toxins
- Compliance with federal regulations

### Exempt Quantities of CDC Select Toxins

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

Permissible Quantities of CDC Select Toxins	
Toxin	Maximum Quantity (per PI)
Abrin	100 mg
Botulinum neurotoxins	0.5 mg
Short, paralytic alpha conotoxins	100 mg
Diacetoxyscirpenol	1000 mg
Ricin	100 mg
Saxitoxin	100 mg
Staphylococcal Enterotoxins (Subtypes A, B, C, D, and E)	5 mg
Tetrodotoxin	100 mg
T- 2 toxin	1000 mg

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 quantity limits at all times for exemption from 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 for these toxins. DEHS will contact these labs annually to verify inventories.

**Warning: 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).**

## **U of L Requirements for Possession of Permissible Quantities of Select Toxins**

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

- Obtain approval from the Institutional Biosafety Committee.
- Develop Standard Operating Procedures for the use of select toxin.
- Provide initial lab-specific safety training to staff on toxin-involved processes, with updates as necessary. Best practices recommend that the PI maintains documentation of training. The following topics should be covered during the training:
  - Toxin-associated hazards
  - Engineering controls used to minimize exposure (e.g., fume hood use)
  - Personal protective equipment (PPE) to be used when handling toxin
  - Safe handling and storage
  - Proper decontamination, inactivation and disposal
  - Administrative requirements (recordkeeping, inventory, security)
- Provide appropriate personal protection (e.g., gloves, safety goggles, lab coat or disposable lab coat). NOTE: If respirators are necessary, contact Sheila Emerson at 502-852-6670 for appropriate fit-testing and training.
- Use of fume hood, biological safety cabinet or glove box with toxin-associated procedures.
- Use accepted inactivation procedures. Contact DEHS if you need to discuss inactivation methods.



<b>Chemical Inactivation of Toxins</b>				
<b>Toxin</b>	<b>2.5% NaOCl + 0.25 N NaOH</b>	<b>2.5% NaOCl</b>	<b>1% NaOCl</b>	<b>0.1% NaOCl</b>
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 minutes exposure to various concentrations of sodium hypochlorite with and without sodium hydroxide.  
Key: Yes- complete inactivation; Yes(?)-assumed inactivation.  
Wannemacher, 1989.

- Storage/Security: Items must be:
  - Stored with compatible materials within secondary containment
  - Provided one layer of physical security (e.g., Select Toxin should be secured within a locked freezer, or secured within a permanently fixed lockbox)
- List of PI-Approved Users: A documented list shall be maintained of PI-approved toxin users (including those having access to toxin materials). The lab must keep track of who uses the stock (and who has access to the freezer). Before becoming an approved user, the PI must ensure that each person has received training, as discussed above.
- Inventory Maintenance: Inventory must be kept on the [Select Toxin Inventory and Usage Log](#). To prevent inadvertently exceeding exempt quantity levels of select toxins, researchers are required to promptly update inventories after every container of select toxin is:
  - Acquired (by purchase/intra-campus transfer)
  - Depleted (by consumption/intra-campus transfer)
  - Inactivated
- Documented Security Inspection: Self-Inspections should be performed annually and documentation of inspections must be kept for one year or the duration of Select Toxin possession, whichever is longer. Inspection should include:

- Review of approved users list to verify authorized access to toxins
- Verification of appropriate labeling, storage, secondary containment, security measures
- Comparison of physical inventory with what is accounted for on the usage log

In addition, DEHS will perform at a minimum annual laboratory visits to review compliance with institutional requirements on possession of select toxins.