

Principal Investigator Working with Exempt Quantities of Select Agent Toxins

1. Purpose of this Document:

This document is to ensure that each Principal Investigator (PI) who possesses exempt quantities of CDC Select Agent Toxins understands the allowable maximum exempt quantities that s/he can possess, as specified by the federal regulations on Select Agents (42 CFR Part 73).

The toxins and their exempt quantity limits are listed below:

Toxin	Max. Allowable per PI for exemption
Abrin	100 mg
Botulinum neurotoxins	0.5 mg
Short, paralytic alpha conotoxins	100 mg
Diacetoxyscirpenol (DAS)	1000 mg
Ricin	100 mg
Saxitoxin	100 mg
Staphylococcus enterotoxins (Subtypes A, B, C, D, – E)	5.0 mg
Tetrodotoxin	100 mg
T-2 Toxin	1000 mg

A Principal Investigator (PI) Working with Exempt Quantities of Select Agent Toxins is Responsible for:

1. Preparing written Standard Operating Procedures (SOPs) for toxin-involved research procedures.
2. Providing initial lab-specific safety training to staff on toxin-involved processes, with updates as necessary. The PI must maintain documentation of that training.
3. Training topics should include, but are not limited to:
 - Toxin-associated hazards
 - Engineering controls used to minimize exposure, such as use of a fume hood, biosafety cabinet, or glove box
 - Personal protective equipment (PPE), to be used when handling the toxin, such as gloves, safety goggles, and a lab coat
 - Safe handling and storage
 - Proper decontamination and disposal
 - Administrative requirements (recordkeeping, inventory, security)
4. Completing the written hazard assessment and providing and training all staff in the use of appropriate PPE.
5. Ensuring proper use of the fume hood, biosafety cabinet, or glove box with toxin-associated procedures.
6. Ensuring proper storage/security. Items must be
 - Stored with compatible materials within secondary containment; and
 - Provided with one layer of physical security (e.g., toxin secured within a locked freezer or a lockbox securely attached to a wall, floor, etc.).

7. Ensuring that each staff member who uses the toxin has received training and records any addition or removal of the toxin in the inventory records, prior to initiating any research with the toxin.
8. Using accepted inactivation procedures prior to disposal of remaining toxin stock and/or empty containers (see Select Agent Toxin Inaction Information).
9. Disposing of residual wastes, after inactivation, as follows:
 - Liquids: can be disposed of in a red plastic biowaste tub, provided there is no other characteristic of the waste that makes it a hazardous waste, such as heavy metals, flammability, etc.
 - Stock vials and other materials: Deface container labeling. Collect in non-leaking container and place in a red plastic biowaste tub, with the same condition as above.
10. Maintaining a current inventory of toxins; the online chemical inventory system may be used for this purpose. In order to ensure that the exempt quantity limits are not unintentionally exceeded, inventories are to be promptly updated after every container of toxin is:
 - Acquired (by purchase/intra-campus transfer)
 - Depleted (by consumption /intra-campus transfer)
 - Inactivated
11. Properly document the transfer of any quantity of exempt quantities of toxin to provide due diligence that the receiver has a legitimate need to handle or use the toxin(s): [Select Agent and Toxin exclusions website](#). This form and records should be kept for a minimum three year period.

2. Toxin Inactivation Information:

Use of Chemical/Heat Inactivation of Toxins

Toxin	For Inactivation by Chemical Treatment	For inactivation by Autoclaving 1hour @ 121C, liquid exhaust
Abrin	1:10 bleach 30 minutes	Yes
Botulinum neurotoxins	1:10 bleach 30 minutes	Yes
Short, paralytic alpha conotoxins	Contact EH&S for details	
Diacetoxyscirpenol (DAS)	1:10 bleach + 0.25N NaOH 30 minutes	No
Ricin	1:5 bleach 30 minutes	Yes
Saxitoxin	1:10 bleach 30 minutes	No
Staphylococcus enterotoxins (Subtypes A, B, C, D, – E)	1:10 bleach 15 minutes	Yes
Tetrodotoxin	1:10 bleach 30 minutes 1:10 bleach + 1N NaOH	No
T-2 Toxin	1:10 bleach 4 hours 1:10 bleach + 0.25N NaOH	No

Protocol for Conotoxin

Conotoxin inactivation depends on the presence or absence of disulfide bonds.

- For conotoxins with disulfide bonds, incubate with an excess of dithiothreitol (DTT) (usually 10-20mM buffered solution, pH8.7) for at least 1 hour at room temperature or 30 minutes at 50°C. Add an equal volume of 50-100mM solution of iodoacetamide (buffered solution, pH8.7) and incubate for 1 hour at room temperature.
- For conotoxins without disulfide bonds, incubate in a closed glass vial with 6N HCl for 24 hours at 90-110°C.

For skin contaminated with conotoxin, use soap and water to remove toxin burden. Mycotoxins are dermally active; however, washing even 1 hour after contact with T-2 can prevent dermal toxicity.

- For complete inactivation of T-2 mycotoxin and brevetoxin, all liquid samples, accidental spills, nonburnable waste, and cages and bedding from animals exposed to these toxins, soak in 2.5% NaOCl + 2.25%N NaOH for 4 hours.
- All toxins wastes should be incinerated at temperatures in excess of 1500°F (815°C), contact EH&S Hazardous Waste Pick-up: [EHS Waste management](#)

3. Important Notice/Recommendations:

- Prior to possessing select agent toxins in quantities above the maximum allowable limits for exempt quantities, a Principal Investigator must contact Nasr Gergis Campus Biosafety Officer, (Ext: 2-2648), in order to submit all appropriate information to the CDC and FBI, and receive CDC approval to conduct the work in an approved facility
- **Failure to register a Select Agent toxin is a criminal offense, punishable by up to five years in prison and/or \$500,000 in fines (Public Health Security & Preparedness Response Act of 2002).**

For any questions regarding the CDC Select agent Program, Contact the Campus Biosafety Officer at 951-827-2648

References:

CDC Select Agent Program: <http://www.selectagents.gov/>