Laboratory-Specific Standard Operating Procedures

TITLE: SOP for the safe use of Tamoxifen

Date: Review Date: Revised:

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This SOP must be kept on file for all laboratory employee training and review.

Section 1: (Check One)
There are three methods that can be used to write SOPs. They are: by process (distillation, synthesis, chromatography, etc.); by individual hazardous chemical (benzene, phenol, arsenic, etc.); and by hazardous chemical class (flammable, corrosive, oxidizer, etc.).

_____ Process _X_____ Chemical ____ Hazard Chemical Class

Section 2: Describe Process, Hazardous Chemical or Hazard Class
Provide a general description of what activities are covered under this SOP.

- Tamoxifen (CAS# 10540-29-1) is a white, odorless, crystalline solid powder with a melting point of 140-144 degrees Celsius. It is an antineoplastic agent used to treat breast cancer and is used in campus laboratories and animal facilities for cancer research studies.
- Tamoxifen is an antagonist of the estrogen receptor(ER) and is used in the treatment of ER(+) breast cancer. Tamoxifen is metabolized in the liver into its active form which causes cell arrest. Due to its various effects, tamoxifen is the subject of much research.
- Tamoxifen is water insoluble and should be dissolved in methanol, ethanol, propanol, propylene glycol, DMSO, or chloroform.

Section 3: Potential Hazards
Describe the potential hazards for each process, hazardous chemical or hazard class. Include physical and health hazards.

Tamoxifen is a known carcinogen (IARC Group 1), toxic, and is considered a reproductive Hazard. Pregnant women should not work with, be exposed to, or be allowed to handle this chemical in any form, as, it may cause harm to the unborn child. Breast-fed children may be harmed by Tamoxifen.
Oral LD50 for Tamoxifen is 4,100 mg/kg.
Acute effects: Eyes and Skin: Irritation
Ingestion: Harmful if swallowed
Inhalation: Irritation of the respiratory tract
Chronic effects: Carcinogen, Teratogen, Reproductive hazard.

Section 4: Personal Protective Equipment
Identify the required PPE. If a respirator is required, contact EH&S before using.

- A lab coat, double Nitrile gloves, safety glasses and closed-toed shoes.
- Wear goggles and/or a face shield when splashes may occur.
- Respirators when dust cannot be contained with Engineering Controls.

Section 5: Engineering Controls
Describe engineering controls that will be used to prevent or reduce employee exposure to hazardous chemicals.

- Tamoxifen must be handled and weighed in a closed scale with a "wind shield" or a functioning chemical fume hood.
- Dosing of animals with Tamoxifen solutions should occur in a designated area of the lab, under a chemical fume hood, biological safety cabinet or ventilated cage changing. See LSUHSC Animal Care SOP # 606.

Section 6: Special Handling and Storage Requirements
List storage requirements for hazardous chemicals involved with the SOP, including specific area, and policies regarding access to chemicals. Special procedures such as dating peroxide formers are appropriate here. Is a special "designated area" required?

- Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.
- Signage is required for the container, designated work area and storage location. Sign wording must state the following: "DANGER, CANCER HAZARD, CARCINOGEN"
- Designate benchtop space with a colored tape.

Section 7: Spill and Accident Procedures
Indicate how spills or accidental release will be handled. List the location of appropriate emergency equipment. Any special requirements for protection of personal from exposure should be identified here.

- For Accidents:
  Avoid breathing dust and provide adequate ventilation. Wear a respirator and personally protect with rubber boots, safety goggles, and heavy rubber gloves.
- For Spills:
  Chemical spill kit is located in cabinet under the sink. For all spills, large or small, refer to the EHS 200.002, Chemical Spill Response Procedures (See attachment for spill response procedures). For large spills and accidents, place absorbent material on the spill, evacuate, and contact University Police (568-8999) or EH&S (952-1337).

Section 8: Decontamination Procedures

Specify decontamination procedures to be used for equipment, glassware, and clothing: including equipment such as hoods, lab benches, and controlled (special "designated area") areas within the lab.

No waste streams containing tamoxifen shall be disposed of in sinks. Decontaminate work space with 70-75% ethanol. Wash hands and arms with soap and water after finished. Contaminated pipet tips, Eppendorf tubes, and gloves should be discarded as hazardous waste.

Section 9: Waste disposal Procedures
Waste must be disposed in accordance with LSUHSC EHS 200.04, Chemical Waste Management Procedures.

- Waste storage – Handle waste for disposal without creating dust. Keep in suitable, closed containers for disposal. Label containers with "HAZARDOUS WASTE – TAMOXIFEN" and the date collection began.
- Disposable supplies with trace amounts of carcinogenic residues may be disposed of as regulated medical waste in the biohazard waste streams. If dissolved with a chemical, it must be disposed of as hazardous waste.
- To schedule a waste pick-up by EH&S, use the bob.lsuhsc.edu service request system.