Standard Operating Procedure
For
Tamoxifen

PURPOSE:
Tamoxifen is a white, odorless, crystalline solid with a melting point of 140-144°C. It is an antineoplastic agent used to treat breast cancer and is used in campus laboratories and animal facilities for cancer research studies. This document establishes procedures for the safe handling and use of Tamoxifen (CAS# 10540-29-1).

HEALTH EFFECTS:
Tamoxifen is a known carcinogen (IARC Group 1), toxic, and is considered a reproductive hazard. Pregnant women should not be exposed to or handle this chemical in any form. The Oral LD50 for Tamoxifen is 4,100 mg/kg.

Acute effects:
- Eyes: Irritation
- Skin: Irritation
- Ingestion: Harmful if swallowed
- Inhalation: Irritation of the respiratory tract

Chronic effects: Carcinogen, Teratogen, Reproductive hazard.

REGULATORY LIMITS:
There are no current established occupational exposure limits for Tamoxifen.

REQUIREMENTS:
Based on the risk associated with the use of Tamoxifen, the safety procedures outlined below are required by all research staff.
Administrative Controls:

- IACUC protocols that include Tamoxifen should reference this SOP to verify that the standard operating procedures are being followed.
- Anyone who handles Tamoxifen is required to review this SOP and the attached Safety Data Sheet (SDS) prior to work.
- Lab surfaces or equipment contaminated with Tamoxifen should be cleaned using dilute bleach or another appropriate disinfectant. Any rinsate or debris should be collected for EHS waste pickup.
- Glassware and other non-porous materials may be decontaminated by soaking them in bleach.
- An emergency eyewash station should be located inside lab spaces and a safety shower should be accessible nearby where Tamoxifen is handled.
- Tamoxifen use in animals must follow the DLAM SOP – *Handling Cages Dosed with Chemical Hazards*. Notify the DLAM Facility Manager prior to use.

Engineering Controls:

- When preparing solutions, Tamoxifen powder must be handled and weighed in a functioning chemical fume hood. Dosing of animals with Tamoxifen solutions should occur under a chemical fume hood, biological safety cabinet or ventilated cage changing station.

Personal Protective Equipment (PPE):

- When working with Tamoxifen in laboratories, PPE should include, at a minimum, a lab coat, double Nitrile gloves, and safety glasses. Wear goggles and/or a face shield when splashes may occur.
- When in DLAM facilities, PPE use must be consistent with the facility policy.

Waste Disposal:

- All Tamoxifen waste, including dilute solutions and contaminated solid waste may be disposed through EHS ([https://ehs.cloudapps.unc.edu/HazMat_Pickup/](https://ehs.cloudapps.unc.edu/HazMat_Pickup/))
- Needles used for Tamoxifen injections should be properly disposed of in a Sharps container and should never be bent, sheared or recapped.

Accidents or Injuries:

- If Tamoxifen exposure occurs, flush the affected area for 15 minutes with copious quantities of water and contact the University Employee Occupational Health Clinic (919-966-9119).
- Spill procedures:
  - Do not attempt to clean-up if you feel unsure of your ability to do so or if you perceive the risk to be greater than normal laboratory operations.
  - If a small spill occurs within a chemical fume hood, clean up with dilute bleach. Collect spilled material and clean up material into appropriately labeled, non-metallic waste container. All spill clean-up material should be disposed of as hazardous waste.
  - If a large spill occurs, notify others in the area and evacuate room immediately. Contact EHS (919-962-5507) during working hours and 911 if after hours.
1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product name: Tamoxifen
Product Number: T5648
Brand: Sigma
CAS-No.: 10540-29-1

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses: Laboratory chemicals, Manufacture of substances

1.3 Details of the supplier of the safety data sheet

Company: Sigma-Aldrich
3050 Spruce Street
SAINT LOUIS MO  63103
USA
Telephone: +1 800-325-5832
Fax: +1 800-325-5052

1.4 Emergency telephone number

Emergency Phone #: (314) 776-6555

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)
Carcinogenicity (Category 1B), H350
Reproductive toxicity (Category 1B), H360
Effects on or via lactation, H362

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 GHS Label elements, including precautionary statements

Pictogram

Signal word: Danger
Hazard statement(s)
H350: May cause cancer.
H360: May damage fertility or the unborn child.
H362: May cause harm to breast-fed children.

Precautionary statement(s)
P201: Obtain special instructions before use.
P202: Do not handle until all safety precautions have been read and understood.
P260: Do not breathe dust or mist.
P263: Avoid contact during pregnancy/ while nursing.
P264: Wash skin thoroughly after handling.
P270: Do not eat, drink or smoke when using this product.
P281: Use personal protective equipment as required.
2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>(Z)-1-(p-Dimethylaminoethoxyphenyl)-1,2-diphenyl-1-butene trans-2-[4-(1,2-Diphenyl-1-butenyl)phenoxy]-N,N-dimethylethylamine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formula</td>
<td>C_{26}H_{29}NO C_{26}H_{29}NO</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>371.51 g/mol</td>
</tr>
<tr>
<td>CAS-No.</td>
<td>10540-29-1</td>
</tr>
<tr>
<td>EC-No.</td>
<td>234-118-0</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>Classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tamoxifen</td>
<td>Carc. 1B; Repr. 1B; Lact.; H350, H360, H362</td>
<td>&lt;= 100 %</td>
</tr>
</tbody>
</table>

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

**General advice**
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

**If inhaled**
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

**In case of skin contact**
Wash off with soap and plenty of water. Consult a physician.

**In case of eye contact**
Flush eyes with water as a precaution.

**If swallowed**
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed
No data available

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

**Suitable extinguishing media**
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture
Carbon oxides, Nitrogen oxides (NOx)

5.3 Advice for firefighters
Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information
No data available
6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures
Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.
For personal protection see section 8.

6.2 Environmental precautions
Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections
For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.
For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities
Keep container tightly closed in a dry and well-ventilated place.
Recommended storage temperature 2 - 8 °C
Light sensitive.

7.3 Specific end use(s)
Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters
Components with workplace control parameters
Contains no substances with occupational exposure limit values.

8.2 Exposure controls
Appropriate engineering controls
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection
Safety glasses with side-shields conforming to EN166 Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Full contact
Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact
Material: Nitrile rubber
Minimum layer thickness: 0.11 mm
Break through time: 480 min
Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

**Body Protection**

Impervious clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

**Respiratory protection**

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

**Control of environmental exposure**

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Information on basic physical and chemical properties**

- **a)** Appearance
  - Form: solid

- **b)** Odour
  - No data available

- **c)** Odour Threshold
  - No data available

- **d)** pH
  - No data available

- **e)** Melting point/freezing point
  - Melting point/range: 97 - 98 °C (207 - 208 °F) - lit.

- **f)** Initial boiling point and boiling range
  - No data available

- **g)** Flash point
  - Not applicable

- **h)** Evaporation rate
  - No data available

- **i)** Flammability (solid, gas)
  - No data available

- **j)** Upper/lower flammability or explosive limits
  - No data available

- **k)** Vapour pressure
  - No data available

- **l)** Vapour density
  - No data available

- **m)** Relative density
  - No data available

- **n)** Water solubility
  - No data available

- **o)** Partition coefficient: n-octanol/water
  - No data available

- **p)** Auto-ignition temperature
  - No data available

- **q)** Decomposition temperature
  - No data available

- **r)** Viscosity
  - No data available

- **s)** Explosive properties
  - No data available

- **t)** Oxidizing properties
  - No data available
9.2 Other safety information
No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity
No data available

10.2 Chemical stability
Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions
No data available

10.4 Conditions to avoid
Light.

10.5 Incompatible materials
Strong oxidizing agents

10.6 Hazardous decomposition products
Other decomposition products - No data available
In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity
LD50 Oral - Rat - 4,100 mg/kg
Inhalation: No data available
Dermal: No data available
No data available

Skin corrosion/irritation
No data available

Serious eye damage/eye irritation
No data available

Respiratory or skin sensitisation
No data available

Germ cell mutagenicity
No data available

Carcinogenicity
This is or contains a component that has been reported to be carcinogenic based on its IARC, OSHA, ACGIH, NTP, or EPA classification.
Possible human carcinogen

IARC: 1 - Group 1: Carcinogenic to humans (Tamoxifen)
ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
NTP: Known to be human carcinogen (Tamoxifen)
OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity
Effects on or via lactation
Presumed human reproductive toxicant
May cause reproductive disorders.
Specific target organ toxicity - single exposure
No data available

Specific target organ toxicity - repeated exposure
No data available

Aspiration hazard

Additional Information
RTECS: KR5919600
Liver - Irregularities - Based on Human Evidence
Liver - Irregularities - Based on Human Evidence

12. ECOLOGICAL INFORMATION

12.1 Toxicity
No data available

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential
No data available

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product
Offer surplus and non-recyclable solutions to a licensed disposal company. Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging
Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)
Not dangerous goods

IMDG
Not dangerous goods

IATA
Not dangerous goods

15. REGULATORY INFORMATION

SARA 302 Components
No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards
Chronic Health Hazard
Massachusetts Right To Know Components
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components
Tamoxifen
CAS-No. 10540-29-1
Revision Date

New Jersey Right To Know Components
Tamoxifen
CAS-No. 10540-29-1
Revision Date

California Prop. 65 Components
This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.
Carc. Carcinogenicity
H350 May cause cancer.
H360 May damage fertility or the unborn child.
H362 May cause harm to breast-fed children.
Lact. Effects on or via lactation
Repr. Reproductive toxicity

HMIS Rating
Health hazard: 1
Chronic Health Hazard: *
Flammability: 0
Physical Hazard 0

NFPA Rating
Health hazard: 0
Fire Hazard: 0
Reactivity Hazard: 0

Further information
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The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

Preparation Information
Sigma-Aldrich Corporation
Product Safety – Americas Region
1-800-521-8956
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