

**Safety Data Sheet**

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification**Product Name** TAMOXIFEN CITRATE USP MICRONIZED**Commercial Name** N/A**Product Use** N/A**Restrictions On Use** N/A**Product Code** 30-5076**Company** PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300**Section 2: Hazard(s) Identification****OSHA Haz Com:** Acute toxicity, oral Category 4 Carcinogenicity Category 1A Reproductive toxicity Category 1
CFR 1910.1200**Signal Word** DANGER**Hazard Statement(s)** Harmful if swallowed. May cause cancer. May damage fertility or the unborn child. MAY CAUSE HARM TO BREAST-FED CHILDREN**Pictogram(s) or Symbol(s)****Precautionary Statement(s):**

Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If exposed or concerned: Get medical advice/attention.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations

Section 3: Composition/Information on Ingredients

Substance/Mixture	Substance
Components	Tamoxifen citrate
% By Weight	100
CAS#	54965-24-1
Molecular Weight	N/A
Chemical Formula	N/A
Synonym(s)	N/A

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Tamoxifen citrate	54965-24-1	N/A	N/A	N/A

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Section 4: First-Aid Measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin Contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye Contact	Rinse with water. Get medical attention if irritation develops and persists.
Ingestion	Rinse mouth. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell
Symptoms/Effects	
Acute	Central nervous system effects. Cardiovascular effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Delayed	Central nervous system effects. Cardiovascular effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Immediate Medical Attention

Provide general supportive measures and treat symptomatically. Overdose treatment may include the following: Administer activated charcoal as a slurry. This is most effective when administered within one hour of ingestion. Consider gastric lavage if it can be performed soon after ingestion, unless contraindicated. Control seizures prior to initiation and protect airway. For seizures: Administer intravenous benzodiazepines. Consider phenobarbital if seizures are uncontrollable or recur. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. For Torsades des pointes: Electrical cardioversion may be necessary if patient is hemodynamically unstable. If patient is stable, administer magnesium, isoproterenol, and/or atrial overdrive pacing. Correct electrolyte abnormalities

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**

Water. Foam. Dry chemical or CO₂. Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable Extinguishing Media

N/A

Products of Combustion

No unusual fire or explosion hazards noted.

Firefighters Special Equipment and Precautions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials.

Section 6: Accidental Release Measures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS. Methods and materials for containment and cleaning up: Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS. Environmental precautions: Avoid discharge into drains, water courses or onto the ground.

Section 7: Handling and Storage

Handling: As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

Exposure Limits	TWA 0.5 micrograms/m ³
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Engineering Controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Personal Protection

Eye/face protection: Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available. Skin protection Hand protection: Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Other: Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Respiratory protection: Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls. Thermal hazards: Wear appropriate thermal protective clothing, when necessary. General hygiene consideration: Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

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Section 9: Physical and Chemical Properties**Appearance** White. Off-white crystalline powder**Odor** Odorless**Odor Threshold** N/A**Melting Point** 284 - 287.6 °F (140 - 142 °C)**Freezing Point** N/A**Boiling Point/Range** N/A**Decomposition temperature** N/A**Partition Coefficient:**
n-octanol/water 3.9 - 4.5**pH** N/A**Vapor Pressure** n/a**Vapor Density** N/A**Viscosity** N/A**Evaporation Rate** N/A**Flash Point** N/A**Flammability** N/A**Autoignition temperature** N/A**Flammability or Explosive Limits:****Lower** N/A**Upper** N/A**Solubility(ies)** Very slightly soluble in water.**Other** Acetone: Very slightly soluble. Chloroform: Very slightly soluble. Methanol: Soluble. Ethanol: Very slightly soluble. Chemical family Stilbene derivative; triphenylethylene derivative. Molecular formula C₂₆H₂₉NO . C₆H₈O₇ Molecular weight 563.65 g/mol**Section 10: Stability and Reactivity****Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport**Chemical Stability** Material is stable under normal conditions**Hazardous Polymerization** No dangerous reaction known under conditions of normal use**Conditions to Avoid** Contact with incompatible materials**Incompatible Materials** Strong oxidizing agents**Hazardous Decomposition Products** NO_x. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.**Section 11: Toxicological Information****RTECS** N/A**Acute Toxicity**Oral LD₅₀ Rat 1190 mg/kg Acute Oral LD₅₀ Mouse 3100 mg/kg Rat 1190 mg/kg**Skin Corrosion/Irritation**

N/A

Serious Eye Damage/Irritation

N/A

Respiratory or Skin Sensitization

N/A

Germ Cell Mutagenicity

N/A

Carcinogenicity

May cause cancer.

Reproductive Toxicity

May damage fertility or the unborn child. Miscarriages, birth defects, fetal deaths and vaginal bleeding have been reported with tamoxifen use by pregnant women. Tamoxifen induces ovulation. It has been reported that this material inhibits lactation.

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Routes of Entry

Ingestion.

Symptoms Related to Exposure

Gastrointestinal disturbances. Swelling. Weight gain. Skin rash. Bone pain. Hair loss. Blurred vision. Dizziness. Confusion. Headache. Sleepiness. Weakness. Depression. Flushing. In females: Vaginal bleeding. Vaginal discharge. Vaginal itching. Pelvic pain. Change in menstrual cycle. In males: Impotence. Decreased sexual desire

Potential Health Effects

N/A

Target Organ(s)

N/A

Section 12: Ecological Information**Ecotoxicity**

Very toxic to aquatic life with long lasting effects. Aquatic Acute Crustacea EC50 Daphnia magna < 1 mg/l, 48 hours Fish LC50 Bluegill (Lepomis macrochirus) 0.23 mg/l, 96 hours (flow through) 0.41 mg/l, Rainbow Trout 96 hours (flow through)

Persistence and Degradability

Minimally biodegradable

Bioaccumulative Potential

Octanol water partition coefficient log Kow 3.9 - 4.5

Mobility in Soil

N/A

Other Adverse Effects

N/A

Section 13: Disposal Considerations**Waste Disposal**

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. The waste code should be assigned in discussion between the user, the producer and the waste disposal company. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Disposal of Container

Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Other Considerations

N/A

Section 14: Transport Information**DOT Classification**

UN number: UN3077 UN proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Tamoxifen Citrate) Transport hazard class(es) Class 9 Subsidiary risk - Packing group III

Section 15: Regulatory Information**Regulations**

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US federal regulations: This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200 TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated. CERCLA Hazardous Substance List (40 CFR 302.4) Tamoxifen Citrate (CAS 54965-24-1) Listed. SARA 304 Emergency release notification Not regulated. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052) Not regulated. SARA 302 Extremely hazardous substance Superfund Amendments and Reauthorization Act of 1986 (SARA) Not listed. YesSARA 311/312 Hazardous chemical Acute toxicity (any route of exposure) Carcinogenicity Reproductive toxicity Classified hazard categories SARA 313 (TRI reporting) Not regulated. Other federal regulations Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Tamoxifen Citrate (CAS 54965-24-1) Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated. Not regulated. Safe Drinking Water Act (SDWA) US state regulations California Proposition 65 This product can expose you to Tamoxifen Citrate, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov. WARNING: California Proposition 65 - CRT: Listed date/Carcinogenic substance Tamoxifen Citrate (CAS 54965-24-1) Listed: September 1, 1996 California Proposition 65 - CRT: Listed date/Developmental toxin Tamoxifen Citrate (CAS 54965-24-1) Listed: July 1, 1990 US. California. Candidate Chemicals List. Safer Consumer Products Regulations (Cal. Code Regs, tit. 22, 69502.3, subd. (a)) Tamoxifen Citrate (CAS 54965-24-1)

Other

N/A

Section 16: Other Information

N/A