



Material Safety Data Sheet

12601 Twinbrook Parkway,
Rockville, MD 20852 USA

Phone Calls: 301-816-8129
8 a.m. to 5 p.m. EST Mon. - Fri.

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CYCLOBENZAPRINE HYDROCHLORIDE

Catalog Number: 1154503

Revision Date:

April 4, 2006

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Cyclobenzaprine Hydrochloride

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

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Product Use: USP Reference Standards and Authentic Substances are used for chemical tests and assays in analytical, clinical, pharmaceutical, and research laboratories.

SECTION 2 - HAZARD INFORMATION

EMERGENCY OVERVIEW: Toxic. Irritant.

Adverse Effects: Adverse effects may include drowsiness; dry mouth; dizziness or lightheadedness; blurred vision; headache; confusion; excitement or nervousness; numbness, tingling, pain, or weakness in hands or feet; muscle twitching or weakness; trembling; trouble sleeping; unusual tiredness; constipation; frequent or lack of urination; stomach cramps or pain; bloated feeling or gas; diarrhea; indigestion; nausea; vomiting; fast, irregular, or pounding heartbeat; speech problems; unpleasant taste in mouth; swelling of face, tongue, or lips; severe skin rash or hives; and seizures. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: Overdose effects include fast or irregular heartbeat; low or high blood pressure; troubled breathing; severe confusion; delirium; convulsions; severe drowsiness; hallucinations; severe restlessness; dry, hot, flushed skin; vomiting; unexplained muscle stiffness; and an increase or decrease in body temperature.

Acute: Possible eye, skin, gastrointestinal and/or respiratory tract irritation.

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, active alcoholism, heart problems (including recent heart attack, arrhythmia, congestive heart failure, or heart block), impaired liver function, and hyperthyroidism.

Cross Sensitivity: n/f

Target Organs: Central nervous system.

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS**Common Name:** Cyclobenzaprine Hydrochloride**Formula:** C₂₀H₂₁N . HCl**Synonym:** n/f**Chemical Name:** 1-Propanamine, 3-(5H-dibenzo[a,d]cyclohepten-5-ylidene)-N,N-dimethyl-, hydrochloride**CAS:** 6202-23-9**RTECS Number:** HP0875000**Chemical Family:** Dibenzo-cycloheptane derivative**Therapeutic Category:** Relaxant (muscle)**Composition:** Pure Material**SECTION 4 - FIRST AID MEASURES****Inhalation:** May cause irritation. Remove to fresh air.**Eye:** Causes irritation. Avoid contact. Flush with copious quantities of water for at least 15 minutes.**Skin:** May cause irritation. Flush with copious quantities of water.**Ingestion:** May cause irritation and toxicity. Flush out mouth with water. This material is slowly but almost completely absorbed from the gastrointestinal tract. Effects begin in 1 hour and may last between 12 and 24 hours.**General First Aid Procedures:** Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing give artificial respiration. If breathing is difficult give oxygen. Obtain medical attention.**Note to Physicians**

Overdose Treatment: Treatment of cyclobenzaprine overdose should be symptomatic and supportive and may include the following:

1. Empty the stomach and decrease absorption via gastric lavage or activated charcoal.
2. For severe or life-threatening anticholinergic effects use physostigmine salicylate. Repeat dose as required if symptoms persist. Physostigmine is only recommended for severe cases due to its toxicity.
3. For cardiac arrhythmia administer neostigmine, pyridostigmine, or propranolol.
4. For cardiac failure consider a short acting digitalis preparation. Close monitoring of cardiac function for at least five days is recommended.
5. For convulsions administer an appropriate anticonvulsant. Benzodiazepines are most often used; however, this is recommended only in a medical setting with respiration and resuscitation support available.
6. Supportive measures include maintaining open airway, maintaining adequate fluid intake, regulating body temperature, and treating circulatory shock, convulsions, and metabolic acidosis as necessary.
7. Dialysis is probably of no value in removing cyclobenzaprine hydrochloride from the body. [USP DI 2006]

SECTION 5 - FIREFIGHTING MEASURES**Extinguisher Media:** Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.**Fire and Explosion Hazards:** This material is assumed to be combustible. As with all dry powders it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential buildup of static electricity.**Firefighting Procedures:** As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.**SECTION 6 - ACCIDENTAL RELEASE MEASURES****Spill Response:** Wear approved respiratory protection, chemically compatible gloves and protective clothing. Wipe up spillage or collect spillage using a high efficiency vacuum cleaner. Avoid breathing dust. Place spillage in appropriately labelled container for disposal. Wash spill site.

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. Wash thoroughly after handling.

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 CONTROL / PERSONAL PROTECTION

Engineering Controls: Engineering controls such as exhaust ventilation are recommended.

Respiratory Protection: Use a NIOSH approved respirator, if it is determined to be necessary by an industrial hygiene survey involving air monitoring. In the event that a respirator is not required, an approved dust mask should be used.

Gloves: Chemically compatible

Eye Protection: Safety glasses or goggles

Protective Clothing: Protect exposed skin.

Exposure Limits: Industry: TWA: 0.08 mg/m³

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

Appearance and Odor: White to off-white crystalline powder; odorless.

Odor Threshold: n/f

pH: n/f

Melting Range: 216 - 218°C

Boiling Point: n/f

Flash Point: n/f

Autoignition Temperature: n/f

Evaporation Rate: n/f

Upper Flammability Limit: n/f

Lower Flammability Limit: n/f

Vapor Pressure: n/f

Vapor Density: n/f

Specific Gravity: n/f

Solubility in Water: Freely soluble

Fat Solubility: n/f

Other Solubility: Freely soluble in alcohol and in methanol; sparingly soluble in isopropanol; slightly soluble in chloroform and in methylene chloride; insoluble in hydrocarbons

Partition Coefficient: n-octanol/water: n/f

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: C₂₀H₂₁N · HCl

Molecular Weight: 311.85

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SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: n/f

Incompatibilities: n/f

Decomposition Products: When heated to decomposition material emits toxic fumes of NO_x and HCl. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: 425 mg/kg

Oral Mouse: LD50: 250 mg/kg

Other Toxicity Data: n/f

Irritancy Data: Animal (species not specified)/eye: severe; Animal (species not specified)/skin: non-irritant

Corrosivity: n/f

Sensitization Data: n/f

Listed as a Carcinogen by: **NTP:** No **IARC:** No **OSHA:** No

Other Carcinogenicity Data: Cyclobenzaprine did not show evidence of carcinogenicity in an 81-week study in mice or in a 105-week study in rats.

Mutagenicity Data: Male rats receiving up to 20 times the human dose of cyclobenzaprine showed no evidence of mutagenicity.

Reproductive and Developmental Effects: Studies in rats, mice and rabbits have not shown that cyclobenzaprine has adverse effects on the fetus when given doses up to 20 times the human dose. There was no evidence of impaired fertility in male or female rats receiving up to 10 times the human dose of cyclobenzaprine.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: Very toxic to freshwater and marine organisms.

SECTION 13 - DISPOSAL CONSIDERATIONS

Disposal: Dispose of waste in accordance with all applicable Federal, State and local laws.

SECTION 14 - TRANSPORT INFORMATION

Shipping Name: n/f

Class: n/f

UN Number: n/f

Packing Group: n/f

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: n/f

International Regulatory Information: EINECS # 228-264-4
Hazard Code: Xn
Risk Phrases: R20/21/22, R36
Safety Phrases: S36

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SECTION 16 - OTHER INFORMATION

Revision: 04-Apr-06

Previous Revision Date: 03-Nov-03