



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.

ATTENTION !

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

HYDROCHLOROTHIAZIDE

Catalog Number: 1314009

Revision Date:

August 24, 2006

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Hydrochlorothiazide

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

Mailing Address: 12601 Twinbrook Parkway, Rockville, MD 20852 USA

Phone: 301-816-8129

Hours: 8 a.m. to 5 p.m. EST Mon. - Fri.

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

Adverse Effects: Adverse effects of thiazide diuretics are usually dose-related and may include increased urination, confusion, convulsions, muscle cramps or pain, dry mouth, increased thirst, irregular heartbeat, mood or mental changes, nausea, vomiting, unusual tiredness or weakness, weak pulse, loss of appetite, decreased sexual ability, diarrhea, dizziness, upset stomach, fever, increased sensitivity of skin to sunlight, and skin eruptions and rash. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

Overdose Effects: Overdose effects may include adverse effects above, leading to difficulty breathing and coma.

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

Chronic: Possible hypersensitization.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, anuria, hyperuricemia or gout, impaired liver (severe) or kidney function, hypercalcemia, lupus erythematosus, porphyria, diabetes mellitus, and Addison's disease.

Cross Sensitivity: Persons sensitive to other sulfonamide-type medications, bumetanide, furosemide, or carbonic anhydrase inhibitors may be sensitive to this material also.

Target Organs: Kidneys, heart, central nervous system

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

HYDROCHLOROTHIAZIDE

Catalog Number: 1314009

Revision Date:

August 24, 2006

Common Name: Hydrochlorothiazide

Formula: C7H8ClN3O4S2

Synonym: Chlorosulthiadil

Chemical Name: 2H-1,2,4-Benzothiadiazine-7-sulfonamide, 6-chloro-3,4-dihydro-, 1,1-dioxide

CAS: 58-93-5

RTECS Number: DK9100000

Chemical Family: Benzothiadiazine

Therapeutic Category: Diuretic

Composition: Pure Material

SECTION 4 - FIRST AID MEASURES

Inhalation: May cause irritation. Remove to fresh air.

Eye: Causes mild irritation. Avoid contact. Flush with copious quantities of tepid water for at least 15 minutes.

Skin: May cause irritation. Flush with copious quantities of water.

Ingestion: May cause irritation and slightly bitter taste. Flush out mouth with water. This material is readily absorbed from the gastrointestinal tract. Its onset of action is within 2 hours; duration of action is 6 to 12 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 thiazide diuretic overdose should be symptomatic and supportive and may include the following:

1. Administer activated charcoal as a slurry.
2. Cathartics may potentiate fluid and electrolyte disturbances and should be AVOIDED.
3. For dysrhythmias, first correct electrolyte imbalance. If dysrhythmia persists despite correction, treat with standard advanced cardiac life support protocols.
4. Monitor fluid and electrolyte balance carefully. [Meditext 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: 500 micrograms/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 or almost white crystalline powder; odorless or nearly odorless.

Odor Threshold: n/f

pH: n/f

Melting Range: 273 - 275° C ; also reported as 268° C (decomposes)

Boiling Point: n/f

Flash Point: n/f

Autoignition Temperature: >500° C

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: Slightly soluble

Fat Solubility: n/f

Other Solubility: Freely soluble in sodium hydroxide solution, in n-butylamine, and in dimethylformamide; sparingly soluble in methanol; insoluble in ether, in chloroform, and in dilute mineral acids

Partition Coefficient: n-octanol/water: -0.07

Percent Volatile: n/f

Reactivity in Water: n/f

Explosive Properties: n/f

Oxidizing Properties: n/f

Formula: C₇H₈ClN₃O₄S₂

Molecular Weight: 297.74

HYDROCHLOROTHIAZIDE

Catalog Number: 1314009

Revision Date:

August 24, 2006

SECTION 10 - STABILITY AND REACTIVITY

Conditions to Avoid: Avoid exposure to moisture.

Incompatibilities: n/f

Decomposition Products: When heated to decomposition material emits very toxic fumes of SO_x, NO_x, and Cl₋. Emits toxic fumes under fire conditions.

Stable? Yes **Hazardous Polymerization?** No

SECTION 11 - TOXICOLOGICAL PROPERTIES

Oral Rat: LD50: 2750 mg/kg

Oral Mouse: LD50: 1175 mg/kg

Other Toxicity Data: n/f

Irritancy Data: n/f

Corrosivity: n/f

Sensitization Data: n/f

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

Other Carcinogenicity Data: This material is not classifiable as to its carcinogenicity in humans. Two-year feeding studies in mice and rats revealed no evidence of carcinogenic potential of hydrochlorothiazide in female mice at doses up to 600 mg/kg/day or in male and female rats at doses up to 100 mg/kg/day. There was equivocal evidence for hepatocarcinogenicity (increased incidence of hepatocellular neoplasms) in male mice.

Mutagenicity Data: Hydrochlorothiazide induced gene mutations in mouse lymphoma cells and sister chromatid exchange in Chinese hamster cells. It induced mitotic recombination and nondisjunction in *Aspergillus nidulans*. Hydrochlorothiazide did not induce chromosomal aberrations in Chinese hamster cells in vitro or sex-linked recessive lethal mutations in *Drosophila*, and was not mutagenic to *Salmonella typhimurium* or *E. coli*.

Reproductive and Developmental Effects: The use of thiazides during pregnancy may produce hypoglycemia, hyponatremia, hyperbilirubinemia, decreased birth weight, bone marrow suppression with thrombocytopenia, and fetal death in newborn and fetus. Thiazide diuretics can also cause fetal or neonatal jaundice when used by pregnant women. Nine controlled trials involving almost 7000 individuals showed no evidence birth defects in infants born to mothers exposed to thiazide diuretics during pregnancy. No adverse effects on fertility were seen in mice and rats fed diets including doses of hydrochlorothiazide up to 100 and 4 mg/kg, respectively. No defects in fetuses were observed in the offspring of pregnant rats administered 250 mg/kg on days 9, 10, 11, and 12 of gestation. Mice and rats gavaged with up to 3000 and 1000 mg/kg, respectively, produced no birth defects in their offspring, despite maternal toxicity.

SECTION 12 - ECOLOGICAL INFORMATION

Ecological Information: *Brachydanio rerio*: LC50 (96 hr): >100 mg/L
Daphnia magna: EC50 (48 hr): >100 mg/L
Activated sludge: EC50 (3 hr): >100 mg/L

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

HYDROCHLOROTHIAZIDE**Catalog Number:** 1314009**Revision Date:**August 24, 2006

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 # 200-403-3

SECTION 16 - OTHER INFORMATION

Revision: 24-Aug-06**Previous Revision Date:** 11-Jun-04