



# Material Safety Data Sheet

12601 Twinbrook Parkway,  
Rockville, MD 20852 USA

Phone Calls: 301-881-0666  
8 a.m. to 5 p.m. EST Mon. - Fri.

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## TIAGABINE HYDROCHLORIDE

Catalog Number: 1667280

Revision Date:

March 1, 2005

### SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

**Common Name:** Tiagabine Hydrochloride

**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 may include difficulty concentrating; blue or purple spots on skin; clumsiness or unsteadiness; confusion; mental depression; burning, numbness, or tingling; itching; speech or language problems; unusual tiredness or weakness; diarrhea; dizziness; chills; fever; headache; muscle aches, pain, or weakness; sore throat; drowsiness; tremor; vomiting; abdominal pain; impaired vision; cough; increased appetite; insomnia; mouth ulcers; nausea; and flushing. Possible allergic reaction to material if inhaled, ingested or in contact with skin.

**Overdose Effects:** Overdose effects may include severe agitation or confusion, hostility, lethargy, weakness, seizures, severe muscle twitching or jerking, and coma.

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

**Chronic:** Possible hypersensitization.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to material and impaired liver function.

**Cross Sensitivity:** n/f

**Target Organs:** n/f

**For additional information on toxicity, see Section 11.**

### SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

**Common Name:** Tiagabine Hydrochloride

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**Formula:** C<sub>20</sub>H<sub>25</sub>NO<sub>2</sub>S<sub>2</sub> . HCl . H<sub>2</sub>O

**Synonym:** n/f

**Chemical Name:** 3-Piperidinecarboxylic acid, 1-[4,4-bis(3-methyl-2-thienyl)-3-butenyl]-, hydrochloride, (R)- monohydrate

**CAS:** 145821-59-6 (anhydrous)

**RTECS Number:** TM6128245 (base)

**Chemical Family:** Nipecotic acid derivative

**Therapeutic Category:** Anticonvulsant

**Composition:** Pure Material

## SECTION 4 - FIRST AID MEASURES

**Inhalation:** May cause irritation. Remove to fresh air.

**Eye:** May cause 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. Flush out mouth with water. This material is well absorbed from the gastrointestinal tract.

**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 overdose should be symptomatic and supportive and may include the following:

1. To decrease absorption, induce vomiting or perform gastric lavage, if indicated; usual precautions to maintain the airway should be taken.
2. Monitor vital signs.
3. Since tiagabine is primarily metabolized by the liver and highly protein-bound, dialysis is not likely to be beneficial. [USP DI 2005]

## 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, light-resistant container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity. Store in a refrigerator.

## SECTION 8 - EXPOSURE CONTROL / PERSONAL PROTECTION

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

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**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:** n/f

<b>SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES</b>
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Properties as indicated on the MSDS are general and not necessarily specific to the USP Reference Standard Lot provided.

**Appearance and Odor:** White powder.

**Odor Threshold:** n/f

**pH:** n/f

**Melting Range:** n/f

**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:** Sparingly soluble

**Fat Solubility:** n/f

**Other Solubility:** Insoluble in heptane

**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:** C<sub>20</sub>H<sub>25</sub>NO<sub>2</sub>S<sub>2</sub> . HCl . H<sub>2</sub>O

**Molecular Weight:** 430.0

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## SECTION 10 - STABILITY AND REACTIVITY

**Conditions to Avoid:** Avoid exposure to light and heat.

**Incompatibilities:** n/f

**Decomposition Products:** When heated to decomposition material emits toxic fumes. Emits toxic fumes under fire conditions.

**Stable?** Yes      **Hazardous Polymerization?** No

## SECTION 11 - TOXICOLOGICAL PROPERTIES

**Oral Rat:** LD50: n/f

**Oral Mouse:** LD50: n/f

**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:** A carcinogenicity study in rats receiving 200 mg of tiagabine per kg of body weight a day for 2 years resulted in small but statistically significant increases in the incidences of hepatocellular adenomas in female rats and Leydig cell tumors of the testis in male rats. The no effect dosage for induction of tumors in this study was 100 mg/kg a day. No statistically significant increases in tumor formation were noted in mice at dosages of up to 250 mg/kg a day. [USP DI 2005]

**Mutagenicity Data:** Tiagabine produced an increase in structural chromosome aberration frequency in human lymphocytes in vitro in the absence of metabolic activation; no increase in chromosomal aberration frequencies was demonstrated in this assay in the presence of metabolic activation. No evidence of genetic toxicity was found in the in vitro bacterial gene mutation assays, the in vitro HPRT forward mutation assay in Chinese hamster lung cells, the in vivo mouse micronucleus test, or an unscheduled DNA synthesis assay. [USP DI 2005]

**Reproductive and Developmental Effects:** Tiagabine has been shown to have adverse effects on embryo-fetal development, including birth defects, when administered to pregnant rats and rabbits at doses greater than the human therapeutic dose. Adverse reproductive effects included decreased maternal weight gain, increased resorption of embryos, increased incidence of fetal variations and malformations, decreased fetal weight, increase in stillbirth, and decreased offspring viability and growth.

## SECTION 12 - ECOLOGICAL INFORMATION

**Ecological Information:** n/f

## 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

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**SECTION 15 - REGULATORY INFORMATION**

**U.S. Regulatory Information:** n/f

**International Regulatory Information:** n/f

**SECTION 16 - OTHER INFORMATION**

**Revision:** 01-Mar-05

**Previous Revision Date:** None