



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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LEVOTHYROXINE

Catalog Number: 1365000

Revision Date:

September 16, 2005

SECTION 1 - PRODUCT AND COMPANY IDENTIFICATION

Common Name: Levothyroxine

Manufacturer: U. S. Pharmacopeia

Responsible Party: Reference Standards Technical Services

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

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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 - Poison.

Adverse Effects: Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

Overdose Effects: Excessive doses of levothyroxine may cause hyperthyroidism. Symptoms may include changes in appetite, changes in menstrual periods, sensitivity to heat, sweating, flushing, fast or irregular heartbeat, increased blood pressure, hair loss, headache, dizziness, hand tremors, nervousness, irritability, leg cramps, shortness of breath, chest pain, sweating, fever, vomiting, diarrhea, trouble sleeping, and weight loss. Effects may not occur at once and may be delayed for as long as 11 days. A massive overdose may cause "thyroid storm" effects, including confusion, fever, jaundice, mood swings, muscle wasting, psychosis, extreme restlessness, marked weakness, convulsions, cardiac arrhythmias, heart failure, coma, and death.

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

Chronic: Possible hypersensitization, hyperthyroidism, and decreased bone mineral density.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, adrenocortical insufficiency, cardiovascular disease, thyroid problems, and pituitary insufficiency.

Cross Sensitivity: n/f

Target Organs: Heart

For additional information on toxicity, see Section 11.

SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS

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Common Name: Levothyroxine

Formula: C₁₅H₁₁I₄NO₄

Synonym: L-thyroxine; T₄

Chemical Name: L-tyrosine, 0-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-

CAS: 51-48-9

RTECS Number: YP2833500

Chemical Family: Thyroxine derivative

Therapeutic Category: Thyroid hormone

Composition: Pure Material

SECTION 4 - FIRST AID MEASURES

Inhalation: May cause irritation. Avoid inhalation. Remove to fresh air.

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

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

Ingestion: May cause irritation. Avoid ingestion. Flush out mouth with water. This material is incompletely and variably 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: Overdose treatment may include the following:

1. Following an acute massive oral overdose (greater than 2 to 5 mg), empty the stomach to reduce gastrointestinal absorption. Activated charcoal may be useful for up to four hours following ingestion.
2. Administer cardiac glycosides if congestive heart failure develops.
3. Use appropriate measures to control fever, hypoglycemia, or fluid loss. Administer oxygen if necessary.
4. Give beta-adrenergic blocking agents such as propranolol for treatment of increased sympathetic activity.
5. Intravenous hydrocortisone can be used to partially inhibit conversion of T₄ to T₃. [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 labeled 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.

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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 goggles or glasses

Protective Clothing: Protect exposed skin.

Exposure Limits: n/f

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: Off-white or light yellow to buff-colored, hygroscopic, crystalline powder; odorless.

Odor Threshold: n/f

pH: n/f

Melting Range: 235 - 236° C (decomposes)

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: Insoluble

Fat Solubility: n/f

Other Solubility: Soluble in alkali hydroxides.

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: C₁₅H₁₁I₄NO₄

Molecular Weight: 776.87

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SECTION 10 - STABILITY AND REACTIVITY

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: No

Mutagenicity Data: n/f

Reproductive and Developmental Effects: Clinical experience in humans has shown that appropriate therapeutic use of thyroid hormones does not cause adverse effects on the fetus.

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: Toxic solid, organic, n.o.s. (Levothyroxine)

Class: 6.1

UN Number: UN2811

Packing Group: III

Additional Transport Information: n/f

SECTION 15 - REGULATORY INFORMATION

U.S. Regulatory Information: n/f

International Regulatory Information: EINECS#: 200-101-1

SECTION 16 - OTHER INFORMATION

Revision: 16-Sep-05

Previous Revision Date: 03-Jun-02