SAFETY DATA SHEET

1. Identification

Product identifier: **Levothyroxine**

Other means of identification
- Catalog number: 1365000
- CAS number: 51-48-9
- Synonyms: L-thyroxine * T4
- Chemical name: L-tyrosine, 0-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-

Recommended use: Specified quality tests and assay use only.

Recommended restrictions: Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer
- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway
  Rockville
  MD
  20852-1790
  United States
- Telephone: RS Technical Services 301-816-8129
- Website: www.usp.org
- E-mail: RSTECH@usp.org
- Emergency phone number
  CHEMTREC within US & Canada 1-800-424-9300
  CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards
- Specific target organ toxicity, single exposure: Category 1 (Cardiovascular system)
- Specific target organ toxicity, repeated exposure: Category 1

Environmental hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements

Signal word: Danger

Hazard statement: Causes damage to organs (Cardiovascular system). Causes damage to organs through prolonged or repeated exposure.

Precautionary statement

Prevention: Do not breathe dust. Wash thoroughly after handling.

Response: If exposed: Call a poison center/doctor. Get medical advice/attention if you feel unwell.

Storage: Store locked up.

Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC): This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

Supplemental information: Highly potent pharmacologically active material.

3. Composition/information on ingredients

Substance
### 4. First-aid measures

**Inhalation**
Move to fresh air. 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 ingestion of a large amount does occur, call a poison control center immediately.

**Most important symptoms/effects, acute and delayed**
Cardiovascular effects. Hyperthyroidism Highly potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

**Indication of immediate medical attention and special treatment needed**
Provide general supportive measures and treat symptomatically. Administer activated charcoal with sorbitol to decrease absorption. Use beta-adrenergic antagonists such as propranolol, labetalol, or sotalol for treatment of adrenergic findings associated with hyperthyroidism. Bisoprolol has been used to treat cardiac symptoms of adrenergic overactivity. For seizures, administer a benzodiazepine intravenously, followed by phenobarbital or propofol if the seizures recur. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, hypoxia Large doses of anti-thyroid drugs (methimazole or propylthiouracil) followed by iodine may inhibit synthesis and release of thyroid hormones. Glucocorticoids may be used to inhibit the conversion of T4 to T3. This material is not dialyzable.

**General information**
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

### 5. Fire-fighting measures

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

**Unsuitable extinguishing media**
None known.

**Specific hazards arising from the chemical**
Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

**Special protective equipment and precautions for firefighters**
Wear suitable protective equipment.

**Fire-fighting equipment/instructions**
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.

**Specific methods**
Use standard firefighting procedures and consider the hazards of other involved materials.

**General fire hazards**
No unusual fire or explosion hazards noted.

### 6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
Keep unnecessary personnel away. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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**
For waste disposal, see section 13 of the SDS. 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.

**Environmental precautions**
Avoid discharge into drains, water courses or onto the ground.

### 7. Handling and storage

**Precautions for safe 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. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

**Conditions for safe storage, including any incompatibilities**
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.
8. Exposure controls/personal protection

**Occupational exposure limits**
No exposure limits noted for ingredient(s).

**Biological limit values**
No biological exposure limits noted for the ingredient(s).

**Appropriate engineering controls**
No open handling. For laboratory operations, conduct powder handling operations in an isolator or equivalent. Put powder into solution or a tightly capped container prior to removal from containment. Isolator should be equipped with bag out ports or transfer chamber. 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.

**Individual protection measures, such as personal protective equipment**

**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**
Wear 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 laboratory coat and disposable sleeve covers appropriate to the task, two pairs of gloves, and safety glasses with side shields. An anteroom or transition area is recommended for gowning and degowning. 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. Chose respiratory protection appropriate to the task and the level of existing engineering controls.

**Thermal hazards**
Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**
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.

9. Physical and chemical properties

**Appearance**
Appearance descriptions are general information and not specific to any USP lot.

**Physical state**
Solid.

**Form**
Crystalline powder.

**Color**
Yellow. Off-white.

**Odor**
Odorless.

**Odor threshold**
Not available.

**pH**
Not available.

**Melting point/freezing point**
455 - 456.8 °F (235 - 236 °C)

**Initial boiling point and boiling range**
Not available.

**Flash point**
Not available.

**Evaporation rate**
Not available.

**Flammability (solid, gas)**
Not available.

**Upper/lower flammability or explosive limits**

**Flammability limit - lower (%)**
Not available.

**Flammability limit - upper (%)**
Not available.

**Explosive limit - lower (%)**
Not available.

**Explosive limit - upper (%)**
Not available.

**Vapor pressure**
< 0.0000001 kPa at 25 °C

**Vapor density**
Not available.

**Relative density**
Not available.

**Solubility(ies)**

**Solubility (water)**
Insoluble.

**Solubility (other)**
Alcohol: Insoluble.
Alkali hydroxides: Soluble.
Benzene: Insoluble.
Auto-ignition temperature  > 680 °F (> 360 °C)
Decomposition temperature Not available.
Viscosity Not available.
Other information
Chemical family Thyroxine derivative.
Dust explosion properties
Minimum ignition energy (MIE) - dust cloud > 1 J
Molecular formula C15-H11-I4-N-O4
Molecular weight 776.87 g/mol

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.
Possibility of hazardous reactions No dangerous reaction known under conditions of normal use.
Conditions to avoid Contact with incompatible materials.
Incompatible materials Strong oxidizing agents. Strong bases.
Hazardous decomposition products Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. I-. NOx.

11. Toxicological information
Information on likely routes of exposure
Inhalation Knowledge about health hazard is incomplete.
Skin contact Knowledge about health hazard is incomplete.
Eye contact Knowledge about health hazard is incomplete.
Ingestion Based on information from therapeutic use, this material may cause: Cardiovascular effects. Hyperthyroidism.
Symptoms related to the physical, chemical, and toxicological characteristics Thyroid hormones: Central nervous system stimulation. Cardiovascular effects. Anxiety.

Information on toxicological effects
Acute toxicity Not known.
Skin corrosion/irritation Knowledge about health hazard is incomplete.
Serious eye damage/eye irritation Knowledge about health hazard is incomplete.
Respiratory or skin sensitization
Respiratory sensitization Knowledge about health hazard is incomplete.
Skin sensitization Knowledge about health hazard is incomplete.
Germ cell mutagenicity Knowledge about mutagenicity is incomplete.
Mutagenicity
Mutagenicity, In vitro chromosomal aberration assay (human peripheral lymphocytes) Result: No increase in chromosome aberrations or chromosome breakage.
Mutagenicity, In vitro comet assay (human lymphocytes) Result: Increased sister chromatid exchange; no increase in multinuclei frequency.

Carcinogenicity
IARC Monographs. Overall Evaluation of Carcinogenicity Not listed.
US. National Toxicology Program (NTP) Report on Carcinogens Not listed.

Reproductive toxicity Based on available data, the classification criteria are not met. Therapeutic use of this material during pregnancy has not been associated with adverse reproductive effects.
Reproductivity
0.25 - 0.3 mg/day Developmental study
Result: Cataracts in 38% of the fetuses.
Species: Rat

Specific target organ toxicity - single exposure
Causes damage to organs (Cardiovascular system).

Specific target organ toxicity - repeated exposure
Causes damage to organs through prolonged or repeated exposure.

Aspiration hazard
Based on available data, the classification criteria are not met.

Further information
Highly potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological information

Ecotoxicity
The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability
No data is available on the degradability of this product.

Bioaccumulative potential
No data available.

Mobility in soil
No data available.

Other adverse effects
No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions
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.

Local disposal regulations
Dispose in accordance with all applicable regulations.

Hazardous waste code
The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products
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).

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

14. Transport information

DOT
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable.

General information
It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

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)
Not listed.

SARA 304 Emergency release notification
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
Not listed.
SARA 311/312 Hazardous chemical
Yes

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA)
Not regulated.

US state regulations
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
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<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
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<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
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<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
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<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
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<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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<td>European List of Notified Chemical Substances (ELINCS)</td>
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<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
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<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
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<td>Philippines</td>
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<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>Yes</td>
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</tbody>
</table>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s). A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 04-07-2009
Revision date 04-27-2018
Version # 05
Further information
Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

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