


Section 1: Identification

Common Name/Trade Name	Levothyroxine Sodium	
Supplier Information	Letco Medical, LLC 1316 Commerce Drive NW Decatur, AL 35601 1 (800) 239-5288 +1 (734) 843-4693	IN CASE OF EMERGENCY: Chemtrec 1 (800) 424-9300 (24 hours)
Product Synonym(s)	L-Tyrosine, O-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-, monosodium salt, hydrate	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Specific target organ toxicity, single exposure, Category 1 (cardiovascular system), Specific target organ toxicity, repeated exposure, Category 1 (thyroid gland)	
Signal Word	Danger	
Hazard Statement(s)	H370 H372	Causes damage to organs Causes damage to organs through prolonged or repeated exposure
Pictogram(s)		
Precautionary Statement(s)	P264 P307+P311 P405 P501	Wash hands thoroughly after handling. IF exposed Call a POISON CENTER or doctor/physician. Store locked up. Dispose of contents/container to an approved waste disposal plant.
Hazards Not Otherwise Classified	Not classified.	
Ingredient(s) with Unknown Toxicity	No data available	

Section 3: Composition/Information on Ingredients

Chemical Name	Monosodium L-thyroxine hydrate
Common Name	Levothyroxine Sodium
CAS Number	25416-65-3
Impurities and/or Stabilizing Additives	N/A

Section 4: First Aid Measures

General Advice	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.
If Inhaled	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
In Case of Skin Contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
In Case of Eye Contact	Rinse with water. Get medical attention if irritation develops and persists.
If Swallowed	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most Important Symptoms and Effects	Hyperthyroidism. Indication of immediate medical attention and special treatment needed: Treatment of overdose should be symptomatic and supportive. 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. (Poisindex), (Poisoning and Drug Overdose fourth edition).

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO ₂ .
Special Hazards Arising From the Substance/Mixture	No unusual fire or explosion hazards noted.
Special PPE and/or Precautions for Firefighters	Wear suitable protective equipment. 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.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and Materials Used for Containment	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.
Cleanup Procedures	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

Section 7: Handling and Storage

Precautions for Safe Handling	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. Use of a designated area is recommended for handling of potent materials.
Conditions for Safe Storage	Pack in tight, light resistant container under nitrogen atmosphere. Storage temperature: 2-8°C.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	TWA 1 micrograms/m ³ . Biological limit values No biological exposure limits noted for the ingredient(s).
Appropriate Engineering Controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment. Handle in accordance with good industrial hygiene and safety practice.
PPE - Eye/Face Protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
PPE - Skin Protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.
PPE - Body Protection	For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.
PPE - Respiratory Protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Section 9: Physical and Chemical Properties

Appearance	Light yellow to off-white powder.
Upper/Lower Flammability or Explosive Limits	Not available.
Odor	Odorless.
Vapor Pressure	No data available
Odor Threshold	Not available.
Vapor Density	Not available.
pH	pH in aqueous solution 8.9 (saturated solution)
Relative Density	Not available.
Melting Point/Freezing Point	Not available.
Solubility	Solubility in water Very slightly soluble. Solubility (other) Soluble in alkali hydroxides; slightly soluble in ethanol; insoluble in acetone, in chloroform, and in ether.
Initial Boiling Point and Boiling Range	Not available.
Flash Point	Not available.
Evaporation Rate	Not available.
Flammability (Solid, Gas)	Not applicable.
Partition Coefficient	Not available.
Auto-Ignition Temperature	Not available.
Decomposition Temperature	Not available.
Viscosity	Not available.

Section 10: Stability and Reactivity

Reactivity	No reactivity hazards known.
Chemical Stability	Material is stable under normal conditions.
Possibility of Hazardous Reactions	No dangerous reaction known under conditions of normal use.
Conditions to Avoid	None known.
Incompatible Materials	None known.
Hazardous Decomposition Products	I-. Na2O. NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	Based on available data, the classification criteria are not met. LD50 Mouse Oral > 10000 mg/kg. Rat > 10000 mg/kg
Acute Toxicity - Inhalation	Due to lack of data the classification is not possible.
Acute Toxicity - Dermal	Due to lack of data the classification is not possible.
Acute Toxicity - Eye	Due to lack of data the classification is not possible.
Skin Corrosion/Irritation	Due to lack of data the classification is not possible.
Serious Eye Damage/Irritation	Due to lack of data the classification is not possible.
Respiratory or Skin Sensitization	Due to lack of data the classification is not possible.
Germ Cell Mutagenicity	Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found. Mutagenicity In vitro assay with human peripheral lymphocytes in whole blood Result: No increase in chromosome aberrations or chromosome breakage. In vitro comet assay with purified human lymphocytes Result: Increased sister chromatid exchange; no increase in multinucleii frequency.
Carcinogenicity IARC	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Carcinogenicity ACGIH	Due to lack of data the classification is not possible. No data available.
Carcinogenicity NTP	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Carcinogenicity OSHA	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Reproductive Toxicity	Due to lack of data the classification is not possible. Reproductivity 0.25 - 0.3 mg/day Reproductivity 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 (thyroid gland) through prolonged or repeated exposure.
Aspiration Hazard	Based on available data, the classification criteria are not met.

Section 12: Ecological Information

Toxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and Degradability	No data is available on the degradability of this product.
Bio-accumulative Potential	Not available.
Mobility in Soil	Not available.
Other Adverse Effects	Not available.

Section 13: Disposal Considerations

Waste Treatment Methods Product	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.
Waste Treatment Methods Packaging	Dispose of in accordance with local regulations. 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). Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.
Special Precautions Landfill or Incinerations	No data available
Other Information	No data available

Section 14: Transport Information

UN Number	Not dangerous goods.
UN Proper Shipping Name	N/A
Transport Hazard Class(es)	N/A
Packaging Group	N/A
Environmental Hazards	No data available

Section 15: Regulatory Information

US federal regulations All components are on the U.S. EPA TSCA Inventory List. CERCLA/SARA Hazardous Substances - Not applicable. Superfund Amendments and Reauthorization Act of 1986 (SARA) Hazard categories Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No SARA 302 Extremely hazardous substance No SARA 311/312 Hazardous chemical No Other federal regulations Safe Drinking Water Act (SDWA) Not regulated. Food and Drug Administration (FDA) Not regulated. US state regulations This product does not contain a chemical known to the State of California to cause cancer, birth defects or other reproductive harm. 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 Country(s) or region Inventory name On inventory (yes/no)* Australia Australian Inventory of Chemical Substances (AICS) Yes Canada Domestic Substances List (DSL) No Canada Non-Domestic Substances List (NDSL) Yes China Inventory of Existing Chemical Substances in China (IECSC) No Country(s) or region Inventory name On inventory (yes/no)* Europe European Inventory of Existing Commercial Chemical Substances (EINECS) Europe European List of Notified Chemical Substances (ELINCS) No Japan Inventory of Existing and New Chemical Substances (ENCS) Yes Korea Existing Chemicals List (ECL) No New Zealand New Zealand Inventory No Philippines Philippine Inventory of Chemicals and Chemical Substances No (PICCS) United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory Yes *A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

Section 16: Other Information

Additional Information	Symptoms related to the physical, chemical, and toxicological characteristics: Sweating. Heat intolerance. Fever. Fast heartbeat. Palpitations. Chest pain. Shortness of breath. Vomiting. Diarrhea. Increased appetite. Weight loss. Insomnia. Anxiety. Headache. Trembling. Weakness. Seizures. Change in menstrual cycle. Delayed and immediate effects of exposure: Hyperthyroidism. Decreased bone mineral density. Medical conditions aggravated by exposure Cardiovascular disease. Hyperthyroidism. Nodular thyroid disease. Adrenal insufficiency. High blood pressure. Diabetes.
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