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)**
Distributor Name	Bella Corp Trading Pty Ltd 6/34 Dominions Road, Ashmore QLD 4214, Australia Telephone: 07 5597 4169 Email: bellacorp@bellacorp.com.au	
Product Synonym(s)	L-3,3',5,5'-tetraiodothyronine sodium salt; L-Tyrosine, O-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-, monosodium salt, hydrate; Sodium (2S)-2-amino-3-[4-(4-hydroxy-3,5-diiodophenoxy)-3,5-diiodophenyl]propanoate	
Relevant Use(s) of Product	Manufacture or Compounding of Substances	

Section 2: Hazards Identification

Classification of Substance or Mixture	Acute toxicity, inhalation (Category 4), Acute toxicity, dermal (Category 4), Acute toxicity, oral (Category 4)	
Signal Word	Warning	
Hazard Statement(s)	H302 H312 H332	Harmful if swallowed Harmful in contact with skin Harmful if inhaled
Pictogram(s)		
Precautionary Statement(s)	P261 P264 P270 P271 P280 P301+P312 P302+P352 P304+P340 P312 P330 P363 P501	Avoid breathing dust/fume/gas/mist/vapours/spray. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing/eye protection/face protection. IF SWALLOWED Call a POISON CENTER or doctor/physician if you feel unwell. IF ON SKIN Wash with soap and water. IF INHALED Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. Wash contaminated clothing before reuse. 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	L-3,3',5,5'-tetraiodothyronine sodium salt
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	Slight inhalation allows the victim to rest in a well-ventilated area. Seek medical attention. Hazardous inhalation, remove source of contamination or move victim to fresh air. If breathing has stopped, cardiopulmonary resuscitation (CPR) immediately (use protective mask with one way valve). If breathing is difficult give oxygen. Seek medical attention.
In Case of Skin Contact	Flush the contact area with lukewarm running water for at least 15 minutes. Remove contaminated clothing, taking care not to spread the chemical. Seek medical attention if irritation persists.
In Case of Eye Contact	Immediately flush eyes with running water for at least 15 minutes, keeping eye lids open. Take care not to rinse contaminated water into the non-affected eye. Always seek medical attention for accidents involving the eyes.
If Swallowed	Slight ingestion may cause irritation. Flush out mouth with water. Hazardous ingestion Never give anything by mouth if victim is rapidly losing consciousness or is unconscious convulsing. Rinse mouth thoroughly with water. If breathing has stopped, trained personnel should begin artificial respiration (use protective mask with one way valve), or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention. Adults rarely experience symptoms with one-time ingestions of up to 3 mg, but ingestion of larger amounts can be serious. Overdose treatment includes the following. 1. For recent ingestions, empty the stomach by induced vomiting. Charcoal instillation may be useful up to 3 to 4 hours following ingestion. 2. Administer cardiac glycosides if congestive heart failure develops. 3. Use appropriate measures to control fever, hypoglycemia, fluid loss. 4. Give ant adrenergic agents such as propranolol for treatment of increased sympathetic activity. 5. Intravenous hydrocortisone can be used to partially inhibit conversion of T 4 to T 3.
Most Important Symptoms and Effects	Short term effects and signs & symptoms of over exposure Possible eye, skin, gastrointestinal and/or respiratory tract irritation. The usual oral adult dose of Levothyroxine (as the sodium salt) is 0.05mg as a single daily dose, which may be gradually increased up to 0.15 mg. NOTE: signs of toxicity may be delayed as long as 5 to 11 days after ingestion of Levothyroxine. Possible allergic reaction to material of inhaled, ingested or in contact with skin. Effects from overdose can be delayed for several days and may include changes in appetite, changes in menstrual periods, sensitivity to heat, weight loss, palpitations, rapid and irregular pulse, headache, dizziness hand tremors nervousness or irritability, insomnia, delirium, leg cramps, shortness of breath, chest pain, sweating, high fever, vomiting, diarrhea, seizures, collapse and coma.

Section 5: Fire Fighting Measures

Suitable Extinguishing Media	Extinguishing media Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials. Special firefighting procedures. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Special Hazards Arising From the Substance/Mixture	Fire degradation products these products are carbon oxides (CO, CO_2), nitrogen oxides (NO, NO_2), halogenated compounds. Emits toxic fumes under fire conditions. Risks of explosion of the product in presence of mechanical impact: Not available Risks of explosion of the product in presence of static discharger: Fine air bone dust can be ignited by static discharge.
Special PPE and/or Precautions for Firefighters	Firefighters should use self-contained breathing equipment and protective clothing.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures	Small spill and leak Vacuum or sweep up spillage. Avoid dust. Place spillage in appropriate labeled solid pharmaceutical waste class 261N container for waste disposal. Wash contaminated clothing before reuse. Ventilate area and wash spill site. Follow appropriate safe work practice. Large spill and leak Use a shovel put the material into an appropriate labeled waste disposal container. Finish cleaning by spreading water on the contaminated surface. Label and dispose as pharmaceutical waste class 261N. Follow appropriate safe work practices. Protective clothing in case of large spill Hooded full suit, Tyvek coveralls or equivalent air purifying respirator with particulate cartridge P100 (HEPA). Boots gloves.
Methods and Materials Used for Containment	Small spill and leak Vacuum or sweep up spillage. Avoid dust. Place spillage in appropriate labeled solid pharmaceutical waste class 261N container for waste disposal. Wash contaminated clothing before reuse. Ventilate area and wash spill site. Follow appropriate safe work practice. Large spill and leak Use a shovel put the material into an appropriate labeled waste disposal container. Finish cleaning by spreading water on the contaminated surface. Label and dispose as pharmaceutical waste class 261N. Follow appropriate safe work practices.
Cleanup Procedures	Small spill and leak Vacuum or sweep up spillage. Avoid dust. Place spillage in appropriate labeled solid pharmaceutical waste class 261N container for waste disposal. Wash contaminated clothing before reuse. Ventilate area and wash spill site. Follow appropriate safe work practice. Large spill and leak Use a shovel put the material into an appropriate labeled waste disposal container. Finish cleaning by spreading water on the contaminated surface. Label and dispose as pharmaceutical waste class 261N. Follow appropriate safe work practices.

Section 7: Handling and Storage

Precautions for Safe Handling	Precautions Use with adequate dust control. In case of insufficient ventilation, wear suitable respiratory equipment. Avoid inhalation, skin and eye contact. Wash thoroughly after handling. Dispose as pharmaceutical waste 261N. Incompatibility strong oxidizing agents, strong acids.
Conditions for Safe Storage	Pack in tight, light resistant container under nitrogen atmosphere. Store at 2-8°C.

Section 8: Exposure Controls/Personal Protection

Components with Workplace Control Parameters	No data available
Appropriate Engineering Controls	Exposure to This material can be controlled in many ways. The measures appropriate for a particular worksite depend on how this material is used and on the extent of exposure. This general information can be used to help develop specific control measures. Ensure that control systems are properly designed and maintained. Comply with occupational, environmental, fire and other applicable regulations. Engineering methods to control hazardous conditions are preferred. Methods include mechanical (local exhaust) ventilation, process or personnel enclosure and control of process conditions. Administrative controls and personnel enclosure and control of process conditions. Administrative controls and personnel protective equipment may also be required. Supply sufficient replacement air to make up for air removed by exhaust system. Remove contaminated clothing promptly. Launder before re wearing. Inform laundry personnel of contaminants hazards. Do not eat, drink or smoke in work areas. Wash hands to thoroughly after handling this material. Maintain good housekeeping. Exposure limits: Not established. Chemical Fume hood.
PPE - Eye/Face Protection	Splash goggles.
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. Impervious gloves (e.g. Natural or butyl rubber, nitrile, neoprene or PVC). Manufacturer standards require that all latex gloves should be medical grade hypoallergenic gloves or those who have type 1 hyper sensitive reaction to latex nitrile gloves are recommended. Hooded full impervious suit and boots (e.g. Shield 2 or Tyvek brands and/or equivalent resistant protective clothing). Have a safety shower/eye wash fountain readily available the immediate work area.
PPE - Body Protection	If engineering controls and work practices are not effective in controlling exposure to this material, then wear suitable personal protective equipment, including approved respiratory protection. Full suit with hood, or disposable/washable cover all. Half-face piece Boots rubber gloves (impervious).
PPE - Respiratory Protection	If engineering controls and work practices are not effective in controlling exposure to this material, then wear suitable personal protective equipment, including approved respiratory protection. Air purifying respirator with particulate cartridge P100 (HEPA) (Less than 1g). powdered air purifying respirator (PAPR) with particulate cartridge P100 (HEPA) (greater than 1g). Chemical fume hood. If respiratory protection is required, institute a complete respiratory protection program, including selection, fit testing, training, maintenance and inspection. Refer to the CSA standard Z 94,4-M1982 selection care and use of respirators, available from the Canadian standards association, Rexadale, Ontario, M9W 1R3, or equivalent local codes and standards. When working with quantities less than 1 kg and in the absence of appropriate local exhaust ventilation (LEV) or other containment, a half-face piece Air purifying respirator with particulate cartridge P100 (HEPA) and goggles is adequate. When working with quantities greater than 1 kg and in the absence of local exhaust ventilation (LEV) or other containment, a powdered Air purifying respirator (PAPR) with particulate cartridge P100 (HEPA) and helmet/hooder supplied air respirator is recommended. The specific respirator selected must be based on contamination levels found in the work place, the specific operation and not exceed the working limits of the respirator.

Section 9: Physical and Chemical Properties

Appearance	Physical state: Solid. Appearance: Light yellow to buff colored powder.
Upper/Lower Flammability or Explosive Limits	No data available.
Odor	No data available
Vapor Pressure	Not applicable.
Odor Threshold	Not available.
Vapor Density	Not applicable.
pH	pH (0.1% aqueous solution) about 8.9
Relative Density	No data available.
Melting Point/Freezing Point	Not available.
Solubility	Soluble in solutions of sodium hydroxide and in hot solutions of sodium carbonate, slightly soluble in ethanol, very slightly soluble in water, insoluble in acetone, chloroform and in ether.
Initial Boiling Point and Boiling Range	Not applicable.
Flash Point	No data available.
Evaporation Rate	Not available.
Flammability (Solid, Gas)	No data available
Partition Coefficient	Not available.
Auto-Ignition Temperature	No data available.
Decomposition Temperature	No data available.
Viscosity	Not available.

Section 10: Stability and Reactivity

Reactivity	No data available.
Chemical Stability	The product is stable at 2-8°C.
Possibility of Hazardous Reactions	Hazardous decomposition products these products are halogenated compounds
Conditions to Avoid	No data available.
Incompatible Materials	Reactivity/Incompatibility Strong oxidizing agents, strong acids
Hazardous Decomposition Products	These products are halogenated compounds

Section 11: Toxicological Information

Acute Toxicity - LD50 Oral	Oral LD50 Mouse >10000 mg/kg Rat >10000 mg/kg
Acute Toxicity - Inhalation	No data available.
Acute Toxicity - Dermal	Possible skin irritation.
Acute Toxicity - Eye	Possible eye irritation.
Skin Corrosion/Irritation	No data available
Serious Eye Damage/Irritation	Possible eye irritation.
Respiratory or Skin Sensitization	Possible respiratory tract irritation.
Germ Cell Mutagenicity	No information available.
Carcinogenicity IARC	This product is not listed in IARC monographs, the NTP annual reports or the current ACGIH TLVs as a carcinogen or potential carcinogen. It is not regulated by OSHA as a carcinogen.
Carcinogenicity ACGIH	This product is not listed in IARC monographs, the NTP annual reports or the current ACGIH TLVs as a carcinogen or potential carcinogen. It is not regulated by OSHA as a carcinogen.
Carcinogenicity NTP	This product is not listed in IARC monographs, the NTP annual reports or the current ACGIH TLVs as a carcinogen or potential carcinogen. It is not regulated by OSHA as a carcinogen.
Carcinogenicity OSHA	This product is not listed in IARC monographs, the NTP annual reports or the current ACGIH TLVs as a carcinogen or potential carcinogen. It is not regulated by OSHA as a carcinogen.
Reproductive Toxicity	Teratogenicity pregnancy category: A clinical experience humans has shown that appropriate therapeutic use of thyroid hormones does not cause adverse effects the fetus.
Specific Target Organ Toxicity - Single Exposure	No data available
Specific Target Organ Toxicity - Repeated Exposure	No data available.
Aspiration Hazard	No data available.

Section 12: Ecological Information

Toxicity	Not available.
Persistence and Degradability	Possibly hazardous short-term degradation products are not likely however, long term degradation products may arise.
Bio-accumulative Potential	Degradation is as toxic as the product itself.
Mobility in Soil	Not available.
Other Adverse Effects	Not available.

Section 13: Disposal Considerations

Waste Treatment Methods Product	Collect in sealed containers and place in appropriate labeled pharmaceuticals solid waste class 261N container according to internal and external standards and procedures. Follow all appropriate safe work procedures and federal, provincial and local regulations for disposal. Use only licensed disposal and waste hauling companies.
Waste Treatment Methods Packaging	No data available
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

Safety, health and environmental regulations/legislation specific for the substance or mixture: EU regulations: No REACH Annex XVII restrictions Levothyroxine sodium is not on the REACH candidate list Levothyroxine sodium is not on the REACH Annex XIV List National regulations: No additional information available Chemical safety assessment: No additional information available

Section 16: Other Information

Additional Information	N/A
Prepared By	Scarlotte Smith
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