

**Safety Data Sheet**

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification

Product Name Levothyroxine Sodium USP (T4) Pentahydrate
Commercial Name Not available
Product Use Not available
Restrictions On Use Not available
Product Code 55-1877
Company PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: Specific target organ toxicity, single exposure Category 1 (cardiovascular system) Specific target organ toxicity, repeated exposure Category 1 (thyroid gland)
CFR 1910.1200

Signal Word DANGER

Hazard Statement(s) Causes damage to organs (cardiovascular system). Causes damage to organs (thyroid gland) through prolonged or repeated exposure.

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention Not available
Response Not available
Storage Not available
Disposal Not available.

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components {L-}Thyroxine, sodium salt
% By Weight 100
CAS# 25416-65-3
Molecular Weight 888.94g/mole
Chemical Formula C₁₅H₁₀N-Na-O₄.5H₂O
Synonym(s) Levothyroxine, sodium , B.P.; Sodium L-Thyroxine; Sodium L - T h y r o x i n e p e n t a h y d r a t e ; L - T y r o s i n e , O-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-, sodium salt, pentahydrate

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
{L-}Thyroxine, sodium salt	25416-65-3	100	Not available	Not available

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Section 4: First-Aid Measures

Inhalation	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.
Skin Contact	Skin contact flushes the contact area with lukewarm running water. Hazardous skin contact flushes 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.
Eye Contact	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.
Ingestion	Slight inhalation allows the victim to rest in a well ventilated area. Seek medical attention. 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.
Symptoms/Effects	
Acute	Adults rarely experience symptoms with one time ingestions of up to 3 mg, but ingestion of larger amounts can be serious.
Delayed	Adults rarely experience symptoms with one time ingestions of up to 3 mg, but ingestion of larger amounts can be serious.

Immediate Medical Attention

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 T4 to T3.

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**

Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Unsuitable Extinguishing Media

Not available.

Products of Combustion

Fire degradation products these products are carbon oxides (CO, CO₂), nitrogen oxides (NO, NO₂), halogenated compounds.

Firefighters Special Equipment and Precautions

Special fire fighting procedures As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Risks of explosion of the product in presence of static discharger: Fine air borne dust can be ignited by static discharge.

Section 6: Accidental Release Measures

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 a 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

Section 7: Handling and Storage

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. Packaging and Storage condition: Pack in tight, light resistant container under nitrogen atmosphere. Store at 2-8°C.

Section 8: Exposure Controls/Personal Protection**Exposure Limits**

Not available.

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.

Personal Protection

Splash goggles. Full suit with hood, or disposable/washable cover all. Half face piece Air purifying respirator with particulate cartridge P100 (HEPA) (Less than 1g). powdered air purifying respirator (PAPR) with particulate cartridge P100 (HEPA) (greater than 1g). Boots rubber gloves (impervious). chemical fume hood. Personal protective equipment: 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. Have appropriate equipment available for use in emergencies such as spills or fire. If respiratory protection is required, institute a complete respiratory protection program, including selection, fit testing, training, maintenance and inspection. Refer to the CSA standard Z94.4-M1982, "selection care and use of respirators," available from the Canadian standards association, Rexdale, Ontario, M9W 1R3, or equivalent local codes and standards. Respiratory protection guidelines: Where barrier technology or a high degree of process contaminant exists, respiratory protection may not be required. 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. When performing cleaning activities refer to appropriate cleaning solution MSDS. NOTE: barrier technology utilizes physical containment facilities and methods to prevent human contact with a chemical or biological material with hazardous properties. Examples include glove boxes, flexible isolators, robotics or remote operation. EYE/FACE PROTECTION: Safety goggles SKIN PROTECTION: Impervious gloves (eg. Natural or butyl rubber, nitrile, neoprene or PVC). Apotex 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 (eg. Shield 2 or Tyvek brands and/or equivalent resistant protective clothing). Have a safety shower/eye wash fountain readily available the immediate work area. RESISTANCE OF MATERIALS FOR PROTECTIVE CLOTHING: Guidelines: GOOD: natural, butyl or styrene- utadienerubber (SBR), neoprene, nitrile, polyvinyl chloride (PVC), polyurethane, nitrile+PVC, neoprene+SBR, neoprene+natural rubber, SBR, no oprene NOTE: Resistance of specific materials can vary from product to product. Evaluate

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Section 9: Physical and Chemical Properties

Appearance	Light yellow to buff colored powder Solid.		
Odor	Not available.		
Odor Threshold	Not available		
Melting Point	Not available	pH	(0.1% aqueous solution) about 8.9
Freezing Point	Not available	Vapor Pressure	Not applicable.
Boiling Point/Range	Not available	Vapor Density	Not available
Decomposition temperature	Not available	Viscosity	Not available
Partition Coefficient: n-octanol/water	Not available	Evaporation Rate	Not available
Flash Point	Not available	Autoignition temperature	Not available
Flammability	Not available	Flammability or Explosive Limits:	
		Lower	Not available
		Upper	Not available
Solubility(ies)	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.		
Other	Not available.		

Section 10: Stability and Reactivity

Reactivity	Not available
Chemical Stability	the product is stable
Hazardous Polymerization	these products are halogenated compounds
Conditions to Avoid	Not available.
Incompatible Materials	Strong oxidizing agents, strong acids
Hazardous Decomposition Products	Not available

Section 11: Toxicological Information**RTECS** XP3583000**Acute Toxicity**

LD50 Mouse >10000 mg/kg Rat >10000 mg/kg

Skin Corrosion/Irritation

Not available

Serious Eye Damage/Irritation

Not available

Respiratory or Skin Sensitization

Not available

Germ Cell Mutagenicity

Not available

Carcinogenicity

Not listed.

Reproductive Toxicity

Not available

Routes of Entry

eye contact, skin contact, inhalation, ingestion

Symptoms Related to Exposure

Behavior (headache, coma) Cardiac (change in rate) Gastrointestinal (hyper motility, diarrhea). 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

Potential Health Effects

Possible hyper sensitization. Possible eye, skin, gastrointestinal and/or respiratory tract irritation. Possible allergic reaction to material of inhaled, ingested or in contact with skin.

Target Organ(s)**Section 12: Ecological Information****Ecotoxicity**

Not available

Persistence and Degradability

possibly hazardous short term degradation products are not likely, however, long term degradation products may arise.

Bioaccumulative Potential

Not available

Mobility in Soil

Not available

Other Adverse Effects

Not available

Section 13: Disposal Considerations**Waste Disposal**

Collect in sealed containers and place in appropriate labeled pharmaceuticals solid waste class 26IN 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.

Disposal of Container

Not available

Other Considerations

Not available.

Section 14: Transport Information**DOT Classification**

Not a DOT controlled material (United States). This material is not classified dangerous good according to international transportation regulations (ADR/RID-IMDG-ICAO/IATA).

Section 15: Regulatory Information**Regulations**

USA Classifications NATIONAL FIRE PROTECTION ASSOCIATION (NFPA) HAZARD INDEX: NFPA-HEALTH-blue : 1-slightly hazardous to health NFPA-FLAMMABILITY-red: 1-materials that must be preheated before ignition can occur NFPA-REACTIVITY-yellow: 1-normally stable

Other

Not available.

Section 16: Other Information

Not available.