

Levothyroxine sodium hydrate

sc-235497

Material Safety Data Sheet



The Power is Question

Hazard Alert Code Key:

EXTREME

HIGH

MODERATE

LOW

Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Levothyroxine sodium hydrate

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER

Santa Cruz Biotechnology, Inc.
2145 Delaware Avenue
Santa Cruz, California 95060
800.457.3801 or 831.457.3800

EMERGENCY

ChemWatch
Within the US & Canada: 877-715-9305
Outside the US & Canada: +800 2436 2255
(1-800-CHEMCALL) or call +613 9573 3112

SYNONYMS

C15-H10-I4-N-Na-O4, "levothyroxin sodium", "tetraiodothyronine sodium", "thyreoidium sodium", "(-)-thyroxine monosodium", "sodium thyroxinate", "O-(4-hydroxy-3, 5-diiodophenyl)-3, 5-diiodotyrosine sodium", "3-(4-(4-hydroxy-3, 5-diiodophenoxy)-3, 5-diiodophenyl)-L-alanine sodium", "3, 5, 3', 5'-tetraiodo-L-thyronine sodium", "beta-((3, 5-diiodo-4-hydroxyphenoxy)-3, 5-diiodophenyl)-L-alanine sodium", "L-tyrosine, O-(4hydroxy-3, 5-diiodophenyl)-3, 5-diiodo-, monosodium salt", Dathroid, Eferox, Eltroxin, Eutyrox, Laevoxin, Letter, Levaxin, Levoroxine, Oroxine, Synthroid, Thyroxevan

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

		Min	Max
Flammability:	1		
Toxicity:	3		
Body Contact:	2		
Reactivity:	1		
Chronic:	2		

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4



CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW

RISK

May cause SENSITISATION by skin contact.

Harmful by inhalation and in contact with skin.

Repeated exposure may cause skin dryness and cracking.

May cause long-term adverse effects in the environment.

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

■ Accidental ingestion of the material may be seriously damaging to the health of the individual; animal experiments indicate that ingestion of less than 40 gram may be fatal.

EYE

■ Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn).

Slight abrasive damage may also result.

SKIN

■ Skin contact with the material may be harmful; systemic effects may result following absorption.

■ The material is not thought to be a skin irritant (as classified using animal models).

Abrasive damage however, may result from prolonged exposures.

■ Repeated exposure may cause skin cracking, flaking or drying following normal handling and use.

■ Open cuts, abraded or irritated skin should not be exposed to this material.

■ Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.

Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

■ Absorption by skin may readily exceed vapor inhalation exposure.

Symptoms for skin absorption are the same as for inhalation.

INHALED

■ Inhalation of dusts, generated by the material, during the course of normal handling, may be harmful.

■ The material is not thought to produce respiratory irritation (as classified using animal models).

Nevertheless inhalation of dusts, or fume, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.

■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

■ Skin contact with the material is more likely to cause a sensitization reaction in some persons compared to the general population.

Prolonged or repeated skin contact may cause drying with cracking, irritation and possible dermatitis following.

Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

Exposure to the material may cause concerns for humans owing to possible developmental toxic effects, on the basis that similar materials tested in appropriate animal studies provide some suspicion of developmental toxicity in the absence of signs of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not a secondary non-specific consequence of other toxic effects.

Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.

Iodine and iodides, may give rise to local allergic reactions such as hives, rupture of skin blood vessels, pain in joints or diseases of the lymph nodes.

Iodine and iodides cause goiter and diminished as well as increased activity of the thyroid gland. A toxic syndrome resulting from chronic iodide overdose and from repeated administration of small amounts of iodine is characterized by excessive saliva production, head cold, sneezing, conjunctivitis, headache, fever, laryngitis, inflammation of the bronchi and mouth cavity, inflamed parotid gland, and various skin rashes.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
L-thyroxine, sodium salt	55-03-8	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

· Give a slurry of activated charcoal in water to drink. NEVER GIVE AN UNCONSCIOUS PATIENT WATER TO DRINK. · At least 3 tablespoons in a glass of water should be given.

EYE

■ If this product comes in contact with the eyes: · Immediately hold eyelids apart and flush the eye continuously with running water. · Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

SKIN

■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

INHALED

· If fumes or combustion products are inhaled remove from contaminated area. · Lay patient down. Keep warm and rested.

NOTES TO PHYSICIAN

■ Treat symptomatically.

for poisons (where specific treatment regime is absent):

-----BASIC TREATMENT

· Establish a patent airway with suction where necessary.
· Watch for signs of respiratory insufficiency and assist ventilation as necessary.
In acute overdose empty the stomach by aspiration and lavage or emesis.
The appearance of symptoms may be delayed.

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not available
Specific Gravity (water=1):	2.381
Lower Explosive Limit (%):	Not available

EXTINGUISHING MEDIA

· Foam.
· Dry chemical powder.

FIRE FIGHTING

· Alert Emergency Responders and tell them location and nature of hazard.
· Wear full body protective clothing with breathing apparatus.

When any large container (including road and rail tankers) is involved in a fire, consider evacuation by 800 metres in all directions.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

· Combustible solid which burns but propagates flame with difficulty.
· Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.
Combustion products include: carbon monoxide (CO), carbon dioxide (CO₂), hydrogen iodide, nitrogen oxides (NO_x), other pyrolysis products typical of burning organic material.
May emit poisonous fumes.

FIRE INCOMPATIBILITY

■ Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION

Glasses:
Gloves:
Respirator:
Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

■ Environmental hazard - contain spillage.
· Clean up waste regularly and abnormal spills immediately.
· Avoid breathing dust and contact with skin and eyes.
· Wear protective clothing, gloves, safety glasses and dust respirator.
· Use dry clean up procedures and avoid generating dust.
· Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).
· Dampen with water to prevent dusting before sweeping.
· Place in suitable containers for disposal.

MAJOR SPILLS

■ Environmental hazard - contain spillage.
· DO NOT touch the spill material.
· Clear area of personnel and move upwind.
· Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

- Avoid all personal contact, including inhalation.
 - Wear protective clothing when risk of exposure occurs.
- Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.
- Do NOT cut, drill, grind or weld such containers.
 - In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS

- Glass container.
- Lined metal can, Lined metal pail/drum
- Plastic pail.

For low viscosity materials

- Drums and jerricans must be of the non-removable head type.
- Where a can is to be used as an inner package, the can must have a screwed enclosure.

All inner and sole packagings for substances that have been assigned to Packaging Groups I or II on the basis of inhalation toxicity criteria, must be hermetically sealed.

STORAGE REQUIREMENTS

- Store in original containers.
- Keep containers securely sealed.

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

Source	Material	TWA ppm	TWA mg/m³	STEL ppm	STEL mg/m³	Peak ppm	Peak mg/m³	TWA F/CC	Notes
US ACGIH Threshold Limit Values (TLV)	L-thyroxine, sodium salt (Particles (Insoluble or Poorly Soluble) [NOS] Respirable particles)		3						See Appendix B current TLV/BEI Book
US ACGIH Threshold Limit Values (TLV)	L-thyroxine, sodium salt (Particles (Insoluble or Poorly Soluble) [NOS] Inhalable particles)		10						See Appendix B current TLV/BEI Book
Canada - Ontario Occupational Exposure Limits	L-thyroxine, sodium salt (Specified (PNOS))		3 (R)						
Canada - British Columbia Occupational Exposure Limits	L-thyroxine, sodium salt (Particles (Insoluble or Poorly Soluble) Not Otherwise Classified (PNOC))		10 (N)						
Canada - Quebec Permissible Exposure Values for Airborne Contaminants (English)	L-thyroxine, sodium salt (Particulates Not Otherwise Classified (PNOC))		10						
US - Washington Permissible exposure limits of air contaminants	L-thyroxine, sodium salt (Particulates not otherwise regulated - Respirable)		5		10				

	fraction)			
US - Washington Permissible exposure limits of air contaminants	L-thyroxine, sodium salt (Particulates not otherwise regulated - Total particulate)	10	20	
Canada - Nova Scotia Occupational Exposure Limits	L-thyroxine, sodium salt (Particles (Insoluble or Poorly Soluble) [NOS] Respirable particles)	3		See Appendix B current TLV/BEI Book
Canada - Nova Scotia Occupational Exposure Limits	L-thyroxine, sodium salt (Particles (Insoluble or Poorly Soluble) [NOS] Inhalable particles)	10		See Appendix B current TLV/BEI Book

ENDOELTABLE

PERSONAL PROTECTION



RESPIRATOR

Particulate

Consult your EHS staff for recommendations

EYE

- Chemical protective goggles with full seal
- Shielded mask (gas-type)
- Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

■ NOTE: The material may produce skin sensitization in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact.

Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:

- frequency and duration of contact,
- chemical resistance of glove material,
- glove thickness and
- dexterity

Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).

- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
- When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
- Contaminated gloves should be replaced.

Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.

- Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
- Double gloving should be considered.
- PVC gloves.
- Protective shoe covers.
- Head covering.

OTHER

- For quantities up to 500 grams a laboratory coat may be suitable.
- For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
- For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.

- For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
- Eye wash unit.
- Ensure there is ready access to an emergency shower.
- For Emergencies: Vinyl suit.

ENGINEERING CONTROLS

- For potent pharmacological agents:

Powders

To prevent contamination and overexposure, no open handling of powder should be allowed.

- Powder handling operations are to be done in a powders weighing hood, a glove box, or other equivalent ventilated containment system.
- In situations where these ventilated containment hoods have not been installed, a non-ventilated enclosed containment hood should be used.
- Pending changes resulting from additional air monitoring data, up to 300 mg can be handled outside of an enclosure provided that no grinding, crushing or other dust-generating process occurs.
- An air-purifying respirator should be worn by all personnel in the immediate area in cases where non-ventilated containment is used, where significant amounts of material (e.g., more than 2 grams) are used, or where the material may become airborne (as through grinding, etc.).
- Powder should be put into solution or a closed or covered container after handling.
- If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.

Solutions Handling:

- Solutions can be handled outside a containment system or without local exhaust ventilation during procedures with no potential for aerosolisation. If the procedures have a potential for aerosolisation, an air-purifying respirator is to be worn by all personnel in the immediate area.
- Solutions used for procedures where aerosolisation may occur (e.g., vortexing, pumping) are to be handled within a containment system or with local exhaust ventilation.
- In situations where this is not feasible (may include animal dosing), an air-purifying respirator is to be worn by all personnel in the immediate area. If using a ventilated enclosure that has not been validated, wear a half-mask respirator equipped with HEPA cartridges until the enclosure is validated for use.
- Ensure gloves are protective against solvents in use.

Unless written procedures, specific to the workplace are available, the following is intended as a guide:

- For Laboratory-scale handling of Substances assessed to be toxic by inhalation. Quantities of up to 25 grams may be handled in Class II biological safety cabinets*; Quantities of 25 grams to 1 kilogram may be handled in Class II biological safety cabinets* or equivalent containment systems Quantities exceeding 1 kg may be handled either using specific containment, a hood or Class II biological safety cabinet*.
- HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

Solid.

Does not mix with water.

Sinks in water.

State	Divided solid	Molecular Weight	798.9
Melting Range (°F)	404.6- 410 (decomp)	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Immiscible
Flash Point (°F)	Not available	pH (1% solution)	Not applicable.
Decomposition Temp (°F)	Not Available	pH (as supplied)	Not applicable
Autoignition Temp (°F)	Not available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not available	Specific Gravity (water=1)	2.381
Lower Explosive Limit (%)	Not available	Relative Vapor Density (air=1)	>1
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

APPEARANCE

Odourless, white to pale buff, tasteless, hygroscopic, amorphous or crystalline powder. May develop a slight pink tinge on exposure to light. Solubility in water = 0.015%. Soluble in mineral acids, alkali hydroxides and carbonates.

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

- Presence of incompatible materials.
- Product is considered stable.

STORAGE INCOMPATIBILITY

- Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

L-THYROXINE, SODIUM SALT

TOXICITY AND IRRITATION

L-THYROXINE, SODIUM SALT:

■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY	IRRITATION
----------	------------

Intraperitoneal (rat) LD50: 20 mg/kg Nil Reported

Subcutaneous (rat) LD50: 50 mg/kg

■ Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's edema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Excitement, headache, pulse rate increase, elevation of blood pressure, effects on fertility, specific developmental abnormalities of the respiratory system, effects on newborn recorded.

Section 12 - ECOLOGICAL INFORMATION

May cause long-term adverse effects in the environment.

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

This material and its container must be disposed of as hazardous waste.

Avoid release to the environment.

Refer to special instructions/ safety data sheets.

Ecotoxicity

Ingredient	Persistence: Water/Soil	Persistence: Air	Bioaccumulation	Mobility
L-thyroxine, sodium salt	HIGH		LOW	LOW

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.

! Puncture containers to prevent re-use and bury at an authorized landfill.

Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.

A Hierarchy of Controls seems to be common - the user should investigate:

- Reduction
- Reuse
- Recycling
- Disposal (if all else fails)

This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.

DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.

- Recycle wherever possible.
- Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14 - TRANSPORTATION INFORMATION



DOT:

Symbols: None Hazard class or Division: 6.1

Identification Numbers: UN2811 PG: II

Label Codes: 6.1 Special provisions: IB8, IP2, IP4, T3,

TP33

Packaging: Exceptions: 153 Packaging: Non- bulk: 212

Packaging: Exceptions: 153 Quantity limitations: 25 kg

Passenger aircraft/rail:

Quantity Limitations: Cargo 100 kg Vessel stowage: Location: B aircraft only:

Vessel stowage: Other: None

Hazardous materials descriptions and proper shipping names:

Toxic solids, organic, n.o.s.

Air Transport IATA:

ICAO/IATA Class: 6.1 ICAO/IATA Subrisk: None

UN/ID Number: 2811 Packing Group: II

Special provisions: A3

Cargo Only

Packing Instructions: 615 Maximum Qty/Pack: 100 kg

Passenger and Cargo Passenger and Cargo

Packing Instructions: 613 Maximum Qty/Pack: 25 kg

Passenger and Cargo Limited Quantity Passenger and Cargo Limited Quantity

Packing Instructions: Y613 Maximum Qty/Pack: 1 kg

Shipping Name: TOXIC SOLID, ORGANIC, N.O.S. *(CONTAINS L-THYROXINE, SODIUM SALT)

Maritime Transport IMDG:

IMDG Class: 6.1 IMDG Subrisk: None

UN Number: 2811 Packing Group: II

EMS Number: F-A , S-A Special provisions: 274

Limited Quantities: 500 g Marine Pollutant: Yes

Shipping Name: TOXIC SOLID, ORGANIC, N.O.S.

Section 15 - REGULATORY INFORMATION

L-thyroxine, sodium salt (CAS: 55-03-8,6106-07-6,25416-65-3) is found on the following regulatory lists;

"Canada Non-Domestic Substances List (NDSL)", "US Toxic Substances Control Act (TSCA) - Inventory"

Section 16 - OTHER INFORMATION

ND

Substance CAS Suggested codes L- thyroxine, sodium salt 55- 03- 8 L- thyroxine, sodium salt 6106- 07- 6 L- thyroxine, sodium salt 25416- 65- 3

Ingredients with multiple CAS Nos

Ingredient Name CAS L-thyroxine, sodium salt 55-03-8, 6106-07-6, 25416-65-3

Reasonable care has been taken in the preparation of this information, but the author makes no warranty of merchantability or any other warranty, expressed or implied, with respect to this information. The author makes no representations and assumes no liability for any direct, incidental or consequential damages resulting from its use. For additional technical information please call our toxicology department on +800 CHEMCALL.

■ Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

A list of reference resources used to assist the committee may be found at:

www.chemwatch.net/references.

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

This document is copyright. Apart from any fair dealing for the purposes of private study, research, review or criticism, as permitted under the Copyright Act, no part may be reproduced by any process without written permission from CHEMWATCH. TEL (+61 3) 9572 4700.

Issue Date: Apr-2-2009

Print Date: Jan-19-2011