

SAFETY DATA SHEET

Preparation Date: 5/10/2016

Revision Date: 6/14/2018

Revision Number: G2

1. IDENTIFICATION

Product identifier

Product code: T1281
Product Name: LEVOTHYROXINE SODIUM, USP

Other means of identification

Synonyms: 3,3',5,5'-Tetraiodo-L-thyronine, sodium salt, hydrate
 Levothyroxine sodium, hydrate
 Monosodium thyroxine, hydrate
 Monosodium L-Thyroxine, hydrate
 Sodium levothyroxine, hydrate
 Sodium thyroxin, hydrate
 Sodium thyroxinate, hydrate
 Sodium thyroxine, hydrate
 Sodium L-thyroxine, hydrate
 L-Thyroxine sodium, hydrate
 Thyroxine sodium salt, hydrate
 L-Thyroxine sodium salt, hydrate
 L-Thyroxine monosodium salt, hydrate
 Thyroxine sodium, hydrate
 L-Tyrosine, O-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-, monosodium salt, hydrate

CAS #: 25416-65-3
 55-03-8 (CAS number for anhydrous form)

RTECS # XP3583000 (for anhydrous form)

CI#: Not available

Recommended use of the chemical and restrictions on use

Recommended use: Medication.
Uses advised against No information available

Supplier: Spectrum Chemical Mfg. Corp
 14422 South San Pedro St.
 Gardena, CA 90248
 (310) 516-8000

Order Online At: <https://www.spectrumchemical.com>

Emergency telephone number Chemtrec 1-800-424-9300

Contact Person: Martin LaBenz (West Coast)

Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification

This chemical is not considered hazardous according to the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Not classified

Hazards not otherwise classified (HNOC)

Not Applicable

Other hazards

Not available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS-No.	Weight %
Levothyroxine Sodium hydrate	25416-65-3	100

4. FIRST AID MEASURES

First aid measures

General Advice:

National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

Skin Contact:

Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.

Eye Contact:

Flush eyes with water for 15 minutes. Get medical attention.

Inhalation:

Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

Ingestion:

Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

Most important symptoms and effects, both acute and delayed

Symptoms

May cause central nervous system effects
May cause drowsiness or dizziness
May cause headache
May affect the cardiovascular system
Hypertension
Cardiac arrhythmias
Weak, rapid pulse or rapid heart rate (Tachycardia)
May cause changes in appetite (increased or decrease appetite) and weight (weight gain or weight loss)
May cause gastrointestinal disturbances
Ingestion of large amounts may cause nausea, vomiting, abdominal pain
May cause hypermotility, diarrhea
Excessive sweating
May cause hot flashes
Muscle weakness
May cause hyperthyroidism

Indication of any immediate medical attention and special treatment needed

Notes to Physician: Treat symptomatically.

Protection of first-aiders

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

5. FIRE-FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media: Dry chemical. Carbon dioxide (CO₂). Water spray mist or foam.

Unsuitable Extinguishing Media: No information available.

Specific hazards arising from the chemical

Hazardous Combustion Products: Carbon Monoxide, Carbon Dioxide. Nitrogen Oxides. Sodium Oxides.

Specific hazards: May be combustible at high temperatures.

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Use personal protective equipment. Avoid dust formation. Remove all sources of ignition.

Environmental precautions Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Methods for containment Stop leak if you can do it without risk. Cover with plastic sheet to prevent spreading.

Methods for cleaning up Sweep up and shovel into suitable containers for disposal. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions:

Provide sufficient air exchange and/or exhaust in work rooms. Avoid dust formation. All equipment used when handling the product must be grounded. Keep away from incompatible materials.

Safe Handling Advice

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Do not

ingest. Do not breathe dust. Keep away from heat and sources of ignition. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical Measures/Storage Conditions:

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep refrigerated. Keep at temperatures between 2 and 8 °C. Protect from light. Sensitive to light. Store in light-resistant containers. Store away from incompatible materials.

Incompatible Materials:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

Components	CAS-No.	OSHA	NIOSH	ACGIH	AIHA WEEL
Levothyroxine Sodium hydrate	25416-65-3	None	None	None	None

Canada

Components	CAS-No.	Canada - Alberta	Canada - British Columbia	Canada - Ontario	Canada - Quebec
Levothyroxine Sodium hydrate	25416-65-3	None	None	None	None

Australia and Mexico

Components	CAS-No.	Australia	Mexico
Levothyroxine Sodium hydrate	25416-65-3	None	None

Appropriate engineering controls

Engineering measures to reduce exposure:

Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Goggles

Skin and body protection: Long sleeved clothing
Chemical resistant apron
Gloves

Respiratory protection: Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust

clouds) , inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

Hygiene measures:

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Solid	Appearance: Powder. Crystalline powder.	Color: Off-white. Light yellow.
Odor: Odorless.	Taste Tasteless.	Formula: C15-H10-I4-N-O4-Na.xH2O
Molecular/Formula weight: 798.85 + xH2O	Flammability: No information available	Flashpoint (°C/°F): No information available.
Flash Point Tested according to: Not available	Autoignition Temperature (°C/°F): No information available	Lower Explosion Limit (%): No information available
Upper Explosion Limit (%): No information available	Melting point/range(°C/°F): 207-210°C/404.6-410 °F	Decomposition temperature(°C/°F): 256-236 °C/455--456.8 °F
Boiling point/range(°C/°F): No information available	Bulk density: No information available	Density (g/cm3): No information available
Specific gravity: No information available	pH: No information available	Vapor pressure @ 20°C (kPa): No information available
Evaporation rate: No information available	Vapor density: No information available	VOC content (g/L): No information available
Odor threshold (ppm): No information available	Partition coefficient (n-octanol/water): No information available	Viscosity: No information available
Miscibility: No information available	Solubility: Insoluble in Benzene Insoluble in Ethanol Slightly soluble in water	

10. STABILITY AND REACTIVITY

Reactivity

May react with strong oxidizers

Chemical stability

Stability: Stable under recommended storage conditions. Sensitive to light. It may turn a slight pink color upon exposure to light.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Avoid dust formation. Exposure to light. Incompatible materials.

Incompatible Materials: Strong oxidizing agents

Hazardous decomposition products: When heated to decomposition it emits toxic fumes. Carbon monoxide. Carbon dioxide. Nitrogen oxides (NOx). Sodium oxides.

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Other Information

Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:

Ingestion. Inhalation.

Acute Toxicity

Component Information

Levothyroxine Sodium hydrate	
CAS-No.	25416-65-3

- LD50/oral/rat = No information available
- LD50/oral/mouse = No information available
- LD50/dermal/rabbit = No information available
- LD50/dermal/rat = No information available
- LC50/inhalation/rat = No information available
- LC50/inhalation/mouse = No information available
- Other LD50 or LC50 information = >10000 mg/kg oral LD50 Rat (for anhydrous form CAS no. 55-03-8)
>10000 mg/kg oral LD50 Mouse (for anhydrous form CAS no. 55-03-8)

Product Information

LD50/oral/rat =
VALUE- Acute Tox Oral = No information available

LD50/oral/mouse =
Value - Acute Tox Oral = No information available

LD50/dermal/rabbit
VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat
VALUE -Acute Tox Dermal = No information available

LC50/inhalation/rat
VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse
VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation.

Eye Contact: May cause eye irritation.

Inhalation May cause irritation of respiratory tract.

Ingestion May cause gastrointestinal disturbances. May cause abdominal pain, nausea, vomiting, hypermotility and diarrhea. May cause thyroid hyperfunction (hyperthyroidism). May cause excessive sweating. May cause headache. May cause fatigue. May affect behavior/central nervous system (tremor, convulsions). May affect behavior/central nervous system (somnolence). May affect behavior/central nervous system (depression or excitement). May affect behavior/central nervous system (dizziness, drowsiness). May affect behavior/central nervous system (hallucinations, insomnia). It may affect behavior/central nervous system (irritability). May affect behavior/central nervous system (ataxia). May affect behavior/central nervous system (confusion). May cause mood disturbances, nervousness, hot flashes. May affect behavior/central nervous system (coma). May cause chest pain. May affect the cardiovascular system (hypertension). May affect the cardiovascular system (weak rapid pulse, tachycardia). May affect the cardiovascular system (cardiac arrhythmias). May cause fainting. May affect the cardiovascular system (palpitations). May affect respiration (shortness of breath). May cause difficulty breathing. May cause decreased appetite or anorexia. May affect metabolism (weight loss). May increase appetite. May cause muscle weakness.

Ingestion: May cause fainting, restlessness, disorientation, lightheadedness, heat intolerance, pain or discomfort in the arms, jaw, back, or neck

Aspiration hazard No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity Prolonged or repeated ingestion may affect the thyroid and result in thyroid hyperfunction. Prolonged or repeated ingestion may cause decreased bone mineral density.

Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

Components	CAS-No.	IARC	ACGIH - Carcinogens	NTP	OSHA HCS - Carcinogens	Australia - Notifiable Carcinogenic Substances	Australia - Prohibited Carcinogenic Substances
Levothyroxine Sodium hydrate	25416-65-3	Not listed	Not listed	Not listed	Not listed	Not listed	Not listed

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA (Occupational Safety and Health Administration of the US Department of Labor)

Reproductive toxicity No data is available

Reproductive Effects: No information available

Developmental Effects: No information available

Teratogenic Effects: No information available

Specific Target Organ Toxicity

STOT - single exposure Respiratory system.
STOT - repeated exposure No information available.
Target Organs: Thyroid.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects: No data available.

Persistence and degradability: No information available

Bioaccumulative potential: No information available.

Mobility: No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods

Waste from residues / unused products:
Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal

Components	CAS-No.	RCRA - F Series Wastes	RCRA - K Series Wastes	RCRA - P Series Wastes	RCRA - U Series Wastes
Levothyroxine Sodium hydrate	25416-65-3	None	None	None	None

14. TRANSPORT INFORMATION

DOT

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Class No information available
Packing group: No information available
Emergency Response Guide Number No information available
Marine Pollutant No data available
DOT RQ (lbs): No information available
Special Provisions No Information available
Symbol(s): No information available
Description: No information available

TDG (Canada)

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant No Information available

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Description: No information available

ADR

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available
Subsidiary Risk: No information available

IMO / IMDG

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant No information available

RID

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

ICAO

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

IATA

UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
ERG Code: No information available
Special Provisions No information available

15. REGULATORY INFORMATION

International Inventories

Components	CAS-No.	U.S. TSCA	KOREA KECL	Philippines (PICCS)	Japan ENCS	CHINA	Australia (AICS)	EINECS-No.
Levothyroxine Sodium hydrate	25416-65-3	Not listed: Levothyroxine Sodium, hydrate(CAS no.25416-65-3)is exempt from TSCA 8(b)Inventory listing since it is a hydrate. However, the anhydrous form (CAS no.	Not present	Not present	Not present	Not present	Not present	Not present

		55-03-8) is listed as ACTIVE on the on the TSCA 8(b) Inventory						
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U.S. Regulations

California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.

Chemicals Known to the State of California to Cause Cancer:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Chemicals Known to the State of California to Cause Reproductive Toxicity:

This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

Components	CAS-No.	Carcinogen	Developmental Toxicity	Male Reproductive Toxicity	Female Reproductive Toxicity:
Levothyroxine Sodium hydrate	25416-65-3	Not Listed	Not Listed	Not Listed	Not Listed

CERCLA/SARA

Components	CAS-No.	CERCLA - Hazardous Substances and their Reportable Quantities	Section 302 Extremely Hazardous Substances and TPQs	Section 302 Extremely Hazardous Substances and RQs	Section 313 - Chemical Category	Section 313 - Reporting de minimis
Levothyroxine Sodium hydrate	25416-65-3	None	None	None	None	None

U.S. TSCA

Components	CAS-No.	TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)	TSCA 8(d) -Health and Safety Reporting
Levothyroxine Sodium hydrate	25416-65-3	Not Applicable	Not Applicable

Canada

WHMIS 2015 - GHS Classifications

WHMIS 2015 Hazard Classification Information: Not a dangerous product according to HPR classification criteria.

Canada Hazardous Products Regulation This product has been classified according to the hazard criteria of the HPR (Hazardous Products Regulation) and the SDS contains all of the information required by the HPR

WHMIS 1988 Hazard Class

Non-controlled

Canada Controlled Products Regulation:

This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

Inventory

Components	CAS-No.	Canada (DSL)	Canada (NDSL)

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Product name: LEVOTHYROXINE
SODIUM, USP

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Levothyroxine Sodium hydrate	25416-65-3	Not Listed	Not Listed
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Components	CAS-No.	CEPA Schedule I - Toxic Substances
Levothyroxine Sodium hydrate	25416-65-3	Not listed
Components	CAS-No.	CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting
Levothyroxine Sodium hydrate	25416-65-3	Not listed

EU Classification

EU GHS - SV - CLP 1272/2008

Components	CAS-No.	EU GHS - SV - CLP (1272/2008)
Levothyroxine Sodium hydrate	25416-65-3	

EU - CLP (1272/2008)

R-phrase(s)

not determined (not applicable)

S -phrase(s)

none

Components	CAS-No.	Classification	Concentration Limits:	Safety Phrases
Levothyroxine Sodium hydrate	25416-65-3		No information	

The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:

None.

16. OTHER INFORMATION

Preparation Date: 5/10/2016
Revision Date: 6/14/2018
Prepared by: Sonia Owen

Disclaimer:

All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet