# SECTION 1: PRODUCT IDENTIFICATION

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>LEVOTHYROXINE SODIUM, USP</th>
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<tbody>
<tr>
<td>PRODUCT CODE</td>
<td>1657</td>
</tr>
<tr>
<td>SUPPLIER</td>
<td>MEDISCA Inc.</td>
</tr>
<tr>
<td></td>
<td>Tel.: 1.800.932.1039</td>
</tr>
<tr>
<td></td>
<td>661 Route 3, Unit C, Plattsburgh, NY, 12901</td>
</tr>
<tr>
<td></td>
<td>3955 W. Mesa Vista Ave., Unit A-10, Las Vegas, NV, 89118</td>
</tr>
<tr>
<td></td>
<td>6641 N. Belt Line Road, Suite 130, Irving, TX, 75063</td>
</tr>
<tr>
<td></td>
<td>MEDISCA Pharmaceutique Inc.</td>
</tr>
<tr>
<td></td>
<td>Tel.: 1.800.665.6334</td>
</tr>
<tr>
<td></td>
<td>4509 Rue Dobrin, St. Laurent, QC, H4R 2L8</td>
</tr>
<tr>
<td></td>
<td>21300 Gordon Way, Unit 153/158, Richmond, BC V6W 1M2</td>
</tr>
<tr>
<td></td>
<td>MEDISCA Australia Pty Ltd</td>
</tr>
<tr>
<td></td>
<td>Tel.: 1.300.786.392</td>
</tr>
<tr>
<td></td>
<td>Unit 7, Heritage Business Park</td>
</tr>
<tr>
<td></td>
<td>5-9 Rickety Street, Mascot, NSW 2020</td>
</tr>
<tr>
<td>EMERGENCY PHONE</td>
<td>CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300</td>
</tr>
<tr>
<td></td>
<td>NSW Poisons Information Centre: 131 126</td>
</tr>
<tr>
<td>USES</td>
<td>Thyroid hormone</td>
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# SECTION 2: HAZARDS IDENTIFICATION

**GHS CLASSIFICATION**

- Specific Target Organ Toxicity - Repeated Exposure (Category 1) - (thyroid gland)
- Specific Target Organ Toxicity - Single Exposure (Category 1) - (cardiovascular system)
- Toxic to Reproduction (Category 2)

**PICTOGRAM**

**SIGNAL WORD**

Danger

**HAZARD STATEMENT(S)**

Causes damage to organs through prolonged or repeated exposure.

Suspected of damaging fertility or the unborn child.

**AUSTRALIA-ONLY HAZARDS**

Not Applicable.

**PRECAUTIONARY STATEMENT(S)**

**Prevention**

- Do not breathe dust/fume/gas/mist/vapors/spray.
- Do not eat, drink or smoke when using this product.
- Do not handle until all safety precautions have been read and understood.
- Obtain special instructions before use.
- Wash thoroughly after handling.
- Wear protective gloves/protective clothing/eye protection/face protection.

**Response**

IF EXPOSED OR CONCERNED: Call a poison center or doctor

**Storage**

- Store locked up.

**Disposal**

Dispose of contents and/or container in accordance with local regulations.

**HMIS CLASSIFICATION**

- Health Hazard: 1
- Flammability: 0
- Reactivity: 0
- Personal Protection: G

# SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

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Last Revision: 03/2018

LEVOTHYROXINE SODIUM, USP

Page 1 of 7
SAFETY DATA SHEET

CHEMICAL NAME: L-Tyrosine, O-(4-hydroxy-3,5-diiodophenyl)-3,5-diiodo-, monosodium salt, pentahydrate

BOTANICAL NAME: Not applicable

SYNONYM: Monosodium L-thyroxine hydrate

CHEMICAL FORMULA: C₁₅H₁₀I₄NNaO₄ . 5H₂O

CAS NUMBER: 6106-07-6

ALTERNATE CAS NUMBER: 25416-65-3

MOLECULAR WEIGHT: 888.991

COMPOSITION:

<table>
<thead>
<tr>
<th>CHEMICAL NAME</th>
<th>CAS NUMBER</th>
<th>% BY WEIGHT</th>
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<tbody>
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<td>LEVOTHYROXINE SODIUM</td>
<td>6106-07-6</td>
<td>100</td>
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There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

Chemical family: Thyroxine derivative.

SECTION 4: FIRST-AID MEASURES

IN CASE OF EYE CONTACT: Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT: Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED: Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED: Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES

SPECIFIC HAZARDS ARISING FROM THE CHEMICAL: Not applicable

FLAMMABLE PROPERTIES: May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS: Under fire conditions, hazardous fumes will be present.

EXTINGUISHING MEDIA: Small fire: dry chemical, CO₂ or water spray. Large fire: dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS: Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS: Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT: On land, sweep or shovel into suitable containers. Minimize generation of dust.
SAFETY DATA SHEET

CLEANUP PROCEDURE
Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

SECTION 7: HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING
Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabelled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS
Store in original container, tightly sealed, protected from direct sunlight and moisture. Preserve in tight containers between 2 - 8 °C, protected from light.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: LEVOTHYROXINE SODIUM    CAS #: 6106-07-6

<table>
<thead>
<tr>
<th>OSHA PEL</th>
<th>Ceiling</th>
<th>STEL</th>
<th>REL</th>
<th>IDLH</th>
<th>Remarks</th>
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<td>N/L</td>
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<td>-</td>
<td>-</td>
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<td>ACGIH TLV</td>
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</table>

N/L = Not Listed

EXPOSURE GUIDELINES
Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT
Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA’s eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. Skin: Wear appropriate gloves to prevent skin exposure. Clothing: Wear appropriate protective clothing to minimize contact with skin. Respirators: Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

SPECIFIC ENGINEERING CONTROLS
Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

NOTES
USP: OEL: Industrial: TWA: 1 micrograms/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE
Solid

DESCRIPTION
Light yellow to buff-colored, odorless, hygroscopic powder. Is stable in dry air but may assume a slight pink color upon exposure to light.

SOLUBILITY
Very slightly soluble in water; soluble in solutions of alkali hydroxides and in hot solutions of alkali carbonates; slightly soluble in alcohol; insoluble in acetone, in chloroform, and in ether.

ODOR
Odorless
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<th>Value</th>
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<td><strong>FLAMMABILITY</strong></td>
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<td>ODOR THRESHOLD</td>
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<td>BOILING POINT</td>
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<td>SPECIFIC GRAVITY</td>
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<td>UPPER FLAMMABLE/EXPLOSIVE</td>
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<td>VAPOR DENSITY (AIR = 1)</td>
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<tr>
<td>AUTO-IGNITION TEMPERATURE</td>
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<tr>
<td>pH</td>
<td>8.5 - 9.0 (25°C) (saturated solution)</td>
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<tr>
<td>MELTING POINT</td>
<td>(207-210)°C, (404.6-410)°F</td>
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<tr>
<td>FLASH POINT</td>
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<td>EXPLOSIVE LIMIT</td>
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<td>VAPOR PRESSURE</td>
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<td>DECOMPOSITION TEMPERATURE</td>
<td>&gt;100°C, &gt;212°F</td>
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<td><strong>NOTES</strong></td>
<td>The physical data presented above are typical values and should not be construed as a specification.</td>
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**SECTION 10: STABILITY AND REACTIVITY**

**REACTIVITY**
- Not established

**STABILITY**
- Stable under recommended storage conditions

**MATERIALS TO AVOID**
- Strong oxidants

**HAZARDOUS DECOMPOSITION PRODUCTS**
- Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides and other gases may occur

**HAZARDOUS POLYMERIZATION**
- Will not occur

**POSSIBILITY OF HAZARDOUS REACTION**
- Not established

**CONDITIONS TO AVOID**
- Moisture, sunlight and extreme temperatures

**SECTION 11: TOXICOLOGICAL INFORMATION**

**ACUTE TOXICITY**
- Oral: Rat: LD50: (mg/kg): >10 000
- Dermal: Rabbit LD50: (mg/kg): Not available
- Inhalation: Rat: LD50: (mg/L/4hr): Not available

**SKIN CORROSION/IRRITATION**
- Due to lack of data the classification is not possible.

**SERIOUS EYE DAMAGE/EYE 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**
- Based on available data, the classification criteria are not met.
- Suspected mutagen: The Toolbox profiler Protein binding alerts for Chromosomal aberration by OASIS v1.1 gives an alert for mutagenicity
SAFETY DATA SHEET

LEVOTHYROIDINE SODIUM is not listed.

OSHA

LEVOTHYROIDINE SODIUM is not listed.

NTP

LEVOTHYROIDINE SODIUM is not evaluated.

IARC

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

California Proposition 65

Due to lack of data the classification is not possible.

ADDITIONAL CARCINOGENICITY INFORMATION

REPRODUCTIVE TOXICITY

Suspected of damaging fertility or the unborn child.

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 HAZARDS

Based on available data, the classification criteria are not met.

SIGNS AND SYMPTOMS OF EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms related to the physical, chemical, and toxicological characteristics:
Thyroid hormones: Central nervous system stimulation. Cardiovascular effects. Anxiety.

May cause tachycardia, palpitations, cardiac arrhythmias, increased in blood pressure, anginal pain, headache, restlessness, excitability, insomnia, tremors, muscle weakness and cramps, heat intolerance, sweating, flushing, fever, weight loss, menstrual irregularities, diarrhoea, and vomiting. Ingestion or prolonged inhalation of dust may cause hyperthyroidism.

POTENTIAL HEALTH EFFECTS

Inhalation
May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion
May be harmful if swallowed.

Skin
May be harmful if absorbed through skin. May cause skin irritation

Eyes
May cause eye irritation.

SECTION 12: ECOLOGICAL INFORMATION

TOXICITY

EC50: 48 Hr: Crustacea: (mg/L): Not available

LC50: 96 Hr: Fish: (mg/L): 1-10*

IC50: 72 Hr: Algae: (mg/L): Not available

PERSISTENCE AND DEGRADABILITY

Suspected persistent in the environment: The Danish QSAR database contains information indicating that the substance is predicted as non readily biodegradable.

BIOACCUMULATIVE POTENTIAL

High: LogPow: 4.099 (Levothyroxin)

MOBILITY IN SOIL

Water solubility: 0.15 g/L (25°C)

OTHER ADVERSE EFFECTS

Water danger class 3 (German Regulation) (Self-assessment): extremely hazardous for water.

Do not allow product to reach ground water, water bodies or sewage system, even in small quantities.

This product is not intended to be released into the environment

NOTES

*Suspected hazardous to the aquatic environment: Fish toxicity classification (SarPy/IRFMN) model in VEGA (Q)SAR platform precision(moderate reliability)

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL

Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment.
SECTION 14: TRANSPORT INFORMATION

UNITED STATES & CANADA
UN PROPER SHIPPING NAME
Not dangerous good
UN NUMBER
Not applicable
CLASS
Not applicable
PACKING GROUP
Not applicable

AUSTRALIA
UN PROPER SHIPPING NAME
Not dangerous good
UN NUMBER
Not applicable
CLASS
Not applicable
PACKING GROUP
Not applicable

HAZCHEM
Not applicable

ENVIRONMENTAL HAZARDS
Not available

SPECIAL SHIPPING INFORMATION
Not applicable

SECTION 15: REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Chemical Name &amp; CAS</th>
<th>CERCLA 40 CFR Part 302.4</th>
<th>SARA (Title III) 40 CFR Part 372.65 Appendix A</th>
<th>EPA 40 CFR Part 355 Appendix B</th>
<th>Pennsylvania</th>
<th>Right-to-know New Jersey</th>
<th>Massachusetts</th>
<th>California Prop 65</th>
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N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

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<tr>
<th>Chemical Name &amp; CAS</th>
<th>Poisons and Therapeutic Goods Regulation</th>
<th>Therapeutic Goods Act</th>
<th>Code of Practices - Illicit Drug Precursors</th>
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SECTION 16: OTHER INFORMATION

REFERENCES
Available upon request
ABBREVIATIONS AND ACRONYMS

- CAS – Chemical Abstract Service
- GHS – Global Harmonized System
- OSHA PEL – Occupational Safety & Health Administration Permissible Exposure Limits
- TWA – Time Weighted Average
- HSIS – Hazardous Substances Information System
- STEL – Short Term Exposure Limit
- AIHA WEEL – American Industrial Hygiene Association Workplace Environment Exposure Levels
- LD50 – Lethal Dose, 50%
- IARC – International Agency for Research on Cancer
- NTP – National Toxicology Program
- WHMIS – Workplace Hazardous Materials Information System
- SARA – Superfund Amendments and Reauthorization Act
- EPA – Environmental Protection Agency
- CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act
- HMIS – Hazardous Materials Information System
- NIOSH – National Institute for Occupational Safety and Health
- MSHA - Mine Safety and Health Administration
- ACGIH - American Conference of Governmental Industrial Hygienists
- IDHL - Immediately Dangerous to Health or Life
- TLV – Threshold Limit Value
- HSE – Health and Safety Executive
- REL - Recommended Exposure Limit

LAST REVISION
03/2018

SUPERSEDES
03/2015

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.