



SAFETY DATA SHEET

Levothyroxine Sodium Tablets

1. IDENTIFICATION

Manufacturer:

Ascent Pharmaceuticals Inc
400 S. Technology Drive
Central Islip, NY 11722
USP

Emergency Phone:

1-855-221-1622

Common Name: Levothyroxine Sodium Tablets

Synonym(s): Not Applicable

Trade Name(s): Levothyroxine Sodium Tablets, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, 150 mcg, 175 mcg, 200 mcg, and 300 mcg.

2. HAZARDS IDENTIFICATION

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

Health: Levothyroxine sodium tablets are contraindicated in patients with uncorrected adrenal insufficiency.

Environment: No information is available about the potential of this product to produce adverse environmental effects.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration*</u>
Levothyroxine sodium	55-03-8	≈ 0.025 % to 0.3%
Excipients	NA	≈ 99.975-99.700 %

* All Concentrations are percent by weight.

4. FIRST AID MEASURES



Inhalation: If breathing is difficult, move to fresh air, if not breathing give artificial respiration. Get medical attention immediately.

Skin Contact: Wash with soap and water for at least 15 minutes. Get medical attention if symptoms occur.

Eye Contact: Any material that contacts the eye should be washed out immediately with water for at least 15 minutes. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist.

Ingestion: Call a physician or poison control center immediately. Never give anything by mouth to a victim who is unconscious or is having convulsions. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.

5.FIRE-FIGHTING MEASURES

Extinguishing Media: Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area

Unusual Fire & Explosion Hazards: Not Applicable.

Special Fire Fighting Procedures: Wear full protective clothing and self-contained breathing apparatus.

Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6.ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.

Environmental precautions: Do not release in to the environment.

Spill Cleanup methods: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly

7.HANDLING AND STORAGE



Handling: Special handling and storage requirements must be observed to assure compliance with Drug Enforcement Administration regulations. All employees who handle this material should be thoroughly trained to handle it safely. Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly. Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Storage: This material must be stored in a Storage Room, per the requirements of FDA at Controlled Room Temperature: 20° to 25° C (68° to 77° F). Store the medicine in a tight, light resistant container at room temperature, away from heat, moisture, and direct light.

8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Compressed tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.

Protective Measures: Not required when handling tablets or containers. Ventilation should be matched to conditions.

Respiratory Protection: Not required when handling tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.

Hand Protection: Chemical resistant gloves.

Eye Protection: Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and Body Protection: Not required when handling tablets. If containers are compromised or exposure is likely --wear: Goggles, Lab Coat and Gloves

Hygiene Measures: Wash skin thoroughly with soap and water.

9.PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Physical State: Solid

Form: Tablets

Appearance:



Levothyroxine Sodium Tablets ,25 mcg: Orange Color, Capsule Shaped, Biconvex tablets, plain on one side and debossed “score line 1” on the other side.

Levothyroxine Sodium Tablets ,50 mcg: White Color, Capsule Shaped, Biconvex tablets, plain on one side and debossed “score line 2” on the other side.

Levothyroxine Sodium Tablets ,75 mcg: Violet Color, Capsule Shaped, Biconvex tablets, plain on one side and debossed “score line 3” on the other side

Levothyroxine Sodium Tablets ,88 mcg: Olive Color, Capsule Shaped, Biconvex tablets, plain on one side and debossed “score line 4” on the other side.

Levothyroxine Sodium Tablets,100 mcg: Yellow Color, Capsule Shaped, Biconvex tablets, plain on one side and debossed “score line 5” on the other side.

Levothyroxine Sodium Tablets,112 mcg: Rose Color, Capsule Shaped, Biconvex tablets, plain on one side and debossed “score line 6” on the other side.

Levothyroxine Sodium Tablets,125 mcg: Gray Color, Capsule Shaped, Biconvex tablets, plain on one side and debossed “score line 7” on the other side.

Levothyroxine Sodium Tablets, 137 mcg: Turquoise Color, Capsule Shaped, Biconvex tablets, plain on one side and debossed “score line 8” on the other side.

Levothyroxine Sodium Tablets, 150 mcg: Blue Color, Capsule Shaped, Biconvex tablets, plain on one side and debossed “score line 9” on the other side.

Levothyroxine Sodium Tablets, 175 mcg: Lilac Color, Capsule Shaped, Biconvex tablets, plain on one side and debossed “1 score line 0” on the other side.

Levothyroxine Sodium Tablets, 200 mcg: Pink Color, Capsule Shaped, Biconvex tablets, plain on one side and debossed “1 score line 1” on the other side.

Levothyroxine Sodium Tablets, 300 mcg: Green Color, Capsule Shaped, Biconvex tablets, plain on one side and debossed “1 score line 2” on the other side.

10. STABILITY AND REACTIVITY

Possibility of hazardous reactions: Stable under ordinary conditions of use and storage.

Conditions to avoid: Excessive heat & Moisture.

Incompatible materials: Alkalis.

Hazardous Decomposition products: May produce Carbon oxides, Nitrogen oxides (NO_x) & Hydrogen chloride.

11. TOXICOLOGICAL INFORMATION



Carcinogenesis, Mutagenesis, Impairment of Fertility: Standard animal studies have not been performed to evaluate the carcinogenic potential, mutagenic potential or effects on fertility of levothyroxine

12.ECOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

Ecotoxicity: No data available.

Acute toxicity (Aquatic invertebrates): No data available.

Bioaccumulation: No data available.

Mobility: No data available.

13.DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste must be in accordance with all applicable Federal, State and local laws. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations.

14.TRANSPORT INFORMATION

DOT: Not Regulated

IMDG: Not regulated

ICAO/IATA: Not Regulated

15.REGULATORY INFORMATION

Stated regulatory information chosen primarily for possible usage of Ascent Pharmaceutical, Inc. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

16.OTHER INFORMATION

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty,



express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Ascent shall not be held liable for any damage resulting from handling or from contact with the above product.

SDS Sections Revised: New

GLOSSARY:

SDS	Safety Data Sheet
NA	Not Applicable
CAS Number	Chemical Abstract Service Registry Number
NTP	National Toxicology Program
NIOSH	National Institute for Occupational Safety and Health
DOT	Department of Transportation
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association
IMO	International Maritime Organization
TSCA	Toxic Substances Control Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
SARA	Superfund Amendments and Reauthorization Act
OSHA	Occupational Safety and Health Administration

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