

Product Name: Synthroid Injection
Issued: 12/14/2001



MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name and Address: Abbott Laboratories,
Pharmaceutical Products Division,
200 Abbott Park Road,
Abbott Park, Illinois 60064-3537

Customer Service Telephone: 1- 800 - 441 - 4987

Emergency Telephone: CHEMTREC: 1-800-424-9300

Product Name: Synthroid Injection

Synonyms: Levothyroxine Sodium

List Number: 1014, 2326, 1012, 2327

National Drug Code Number: 0048-1014-99, 0048-1012-99, 0074-2326-01, 0074-2327-01

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
Levothyroxine Sodium 55-03-8	Proprietary	Not Listed	Not Listed	Not Applicable	3 mcg/m ³ TWA	None
Sodium Phosphate Tribasic 7601-54-9	Proprietary	15 mg/m ³ , total dust; 5 mg/m ³ , respirable fraction	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate	5 mg/m ³ TWA (15 min, as TSP dodecahydrate) 5 mg/m ³ STEL (as TSP dodecahydrate, for protection against the irritating effects of TSP dust on the eyes and respiratory tract)	Not Applicable	Skin (AIHA)

Notes: OSHA PEL: US Occupational Safety and Health Administration- Permissible Exposure Limit.
ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value.
AIHA WEEL: American Industrial Hygiene Association - Workplace Environmental Exposure Level.
Abbott EEL: Abbott Laboratories Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.
C: Ceiling Limit.
Abbott : Hazardous per OSHA criteria

3. HAZARDS IDENTIFICATION

Emergency Overview:
Powder.
Odor not determined.

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Potent drug.

Routes of Exposure:

Oral: Yes
Dermal: No
Inhalation: Yes

Hazard Information:

Ingestion Rating: None
Skin Absorption Rating: None
Inhalation Rating: Not determined.
Corrosiveness Rating: Not determined.
Skin Contact Rating: Not determined.
Skin Sensitization Rating: Not determined
Eye Contact Rating: Not determined.
Target Organs: Cardiovascular System , Digestive System , Hormonal System .

Carcinogenicity Rating:

Ingredients	OSHA:	NTP:	IARC:	ACGIH:
Levothyroxine Sodium 55-03-8	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Phosphate Tribasic 7601-54-9	Not Listed	Not Listed	Not Listed	Not Listed

NFPA Rating: Not determined.

Signs and Symptoms: No signs and symptoms from occupational exposure are known. Reported to cause the following: headaches, fast heart rate, increased blood pressure, nausea, diarrhea, sweating, low blood sugar, gastrointestinal upset. Clinical overdose may result in the following: abnormal thyroid function.

Medical Conditions Aggravated by Exposure: No medical conditions aggravated by occupational exposure are known. Data suggest any preexisting ailments in the following organs: cardiovascular system, gastrointestinal system, thyroid. Hypersensitivity to the material and/or similar materials. Concurrent use of medications.

4. FIRST AID MEASURES

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

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FLAMMABILITY:

Flammability Class: Not determined.
Autoignition Temp. (°C): Not determined.

FIRE-FIGHTING INFORMATION:

Suitable Extinguishing Media: Use appropriate medium for the underlying cause of the fire.

6. ACCIDENTAL RELEASE MEASURES

Methods of Cleaning and Collecting: Recover product. Place into appropriate container for disposal. Clean area with suitable cleaning materials. Dispose of as directed in Section 13.

Personal Precautions: Use personal protective equipment identified in Section 8.

Environmental Precautions: Not determined.

7. HANDLING AND STORAGE

Handling: Not determined.

Storage : Store according to label instructions.

Special Precautions: Not applicable.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: No special provisions are required under normal product use conditions.

Respiratory Protection: An approved respirator (i.e. NIOSH, etc.) should be worn when exposures are expected to exceed the applicable limits. Respiratory protection is not needed during normal product use.

Eyes: Eye protection not required during typical product use conditions.

Gloves: Impervious gloves.

Other Personal Protection Data: Not determined.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Powder.
Odor: Odor not determined.
Boiling Point @ 760 mm Hg (°C): Not determined.
Melting/Freezing Point (°C): Not determined.
Vapor Pressure (mm Hg) Not determined.
Bulk Density at 20°C: Not determined.
Solubility: Not determined.
Specific Gravity: Not determined.
pH: Not determined.
Viscosity (centipoise): Not determined.

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10. STABILITY AND REACTIVITY

Chemical Stability: Not determined.
Self-Heating Tendency: Not determined.
Materials to Avoid: Not determined.
Hazardous Decomposition Products: Not determined.
Hazardous Polymerization: Not determined.
Conditions to Avoid: Not determined.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Oral: Not determined. Data for component (s) given below.

Ingredients	Acute Test	Value	Units	Species
Levothyroxine Sodium 55-03-8	ALD =	2400	mg/kg	Dogs
Sodium Phosphate Tribasic 7601-54-9	LD50 =	6500-7400	mg/kg	Rats

Acute Toxicity - Dermal: Not determined. Data for component (s) given below.

Ingredients	Acute Test	Value	Units	Species
Sodium Phosphate Tribasic 7601-54-9	LD50 >	7940	mg/kg	Rabbits

Acute Toxicity - Inhalation: Not determined.

Other Toxicology Data: Other Toxicology data for component(s) listed below:

Ingredients	Test Type	Value	Units	Species	Comments
Levothyroxine Sodium 55-03-8	LD50 (ip) =	20	mg/kg	Rats	None.
	LD50 (sc) =	50	mg/kg		

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Not determined.

Sensitization: Not determined.

Target Organ Effects: Clinical dose is less than (<) 10 mg/day. In clinical use, target organs include: thyroid, endocrine system.

Ingredients	Target Organs:	Species	Dosage	Units	Route	Duration
Levothyroxine Sodium 55-03-8	Thyroid Gastrointestinal Tract Cardiovascular System Kidney Fetus	Rats Rabbits	> = 200	mcg/kg	Oral	Variable exposure periods

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Reproductive Effects: In animals adverse reproductive effects include: fetal abnormalities, maternal toxicity, reduced fetal growth, fetal toxicity.

Ingredients	Reproductive Effects	Species	Dosage	Units	Route	Duration
Levothyroxine Sodium 55-03-8	Fetal Toxicity Fetal Abnormalities	Rats Rabbits	120	mcg/kg	Oral	During Gestation

Carcinogenicity: Not determined.

Mutagenicity: Negative in the Ames test.

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

12. ECOLOGICAL INFORMATION

Aquatic Toxicity: Not determined.

Biodegradation: Not determined.

General Notes: None.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods: Incineration recommended in approved incinerator according to federal, state, and local regulations. This material is not a RCRA hazardous waste.

14. TRANSPORT INFORMATION

DOT:

Status: Not Regulated.

ICAO/IATA:

Status: Not Regulated.

IMDG:

Status: Not Regulated.

TDG (Canada):

Status: Not determined.

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15. REGULATORY INFORMATION

SARA 313 Information

Ingredients	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Levothyroxine Sodium 55-03-8	No	Not Applicable	Not applicable
Sodium Phosphate Tribasic 7601-54-9	No	final RQ = 5000 pounds (2270 kg) (Listed under 'Sodium phosphate, tribasic')	Not applicable

SARA 311/312 Hazard Categories:

Immediate Health: No
Delayed Health: No
Fire: No
Sudden Pressure: No
Reactivity: No

TSCA Inventory Status: Exempt.

CERCLA Status: Not regulated.

RCRA Status: Not a hazardous waste.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

EC HAZARD CLASSIFICATION:

Category of Danger: Exempt.
Indication of danger: Exempt.

ICH Classification: Not determined.

CANADIAN REGULATIONS:

Canadian Inventory: Not determined.
Canadian NDSL: Not determined.
WHMIS Hazard Class: Exempt

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. ICH = International Committee for Harmonization.

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16. OTHER INFORMATION

Document Authored By: Richard Prodans
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