	Levothyroxine Sodium for Injection		Safety Data Sheet (SDS)	
	Effective Date: 07DEC2018	SDS No.: SDS028	Revision No: 01	Page 1 of 9


Section 1 - Identification

- (a) **Product Identifier:** Levothyroxine Sodium for Injection
- (b) **Product Code:** 70860-451
70860-452
70860-453
- Common/Trade Name:** Levothyroxine Sodium
- Chemical Name:** Levothyroxine Sodium
- Chemical Family:** Hormone
- (c) **Product Use:** Hormone
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road,
Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

Section 2 - Hazards Identification

- (a) **GHS Classification of substance or mixture:** **US OSHA:**
Reproductive toxicity.
Effects on or via lactation.

(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
GHS Class:	Reproductive toxicity. Effects on or via lactation.
Hazard Statement:	May cause harm to breast-fed children
Precautionary Statements:	Do not breathe dust/fume/gas/mist/vapors/spray. Avoid contact during pregnancy and while using this product. Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. If exposed or concerned: Get medical advice/attention.

	Levothyroxine Sodium for Injection		Safety Data Sheet (SDS)	
	Effective Date: 07DEC2018	SDS No.: SDS028	Revision No: 01	Page 2 of 9

Emergency Overview:	This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed and overdoses are described in the package insert. Reproductive effects.
Route of Exposure:	Inhalation Ingestion Eye contact Skin Absorption. Injection.
Potential Health Effects:	Eye: Contact with eyes may irritation. Skin: May cause skin irritation. Inhalation: May cause irritation of respiratory tract. Ingestion: May cause irritation.


Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Mannitol	D-Mannitol	3 mg/vial	69-65-8	N/A
Levothyroxine Sodium	L-Thyroxine	100, 200, and 500 mcg/vial	55-03-8	N/A
Dibasic Sodium Phosphate, Heptahydrate	Dibasic Sodium Phosphate, Heptahydrate	0.944 mg/vial	7782-85-6	N/A
Sodium Hydroxide	Sodium Hydroxide	Q.S. for pH Adjustment	1310-73-2	N/A

Q.S. – Quantity Sufficient

Section 4 – First Aid Measures

Eye Exposure:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Exposure:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

	Levothyroxine Sodium for Injection		Safety Data Sheet (SDS)	
	Effective Date: 07DEC2018	SDS No.: SDS028	Revision No: 01	Page 3 of 9

Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

Section 5 – Fire-fighting Measures


- (a) **Extinguishing Media** Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- (b) **Hazardous Combustion Products:** Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances maybe formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.
- (c) **Special Protective Equipment / Precautions:** As in any fire, wear Self-Contained Breathing Apparatus (SC BA), MSHA/NIO SH (approved or equivalent) and full protective gear.

Section 6 - Accidental Release Measures

- Personal Precautions:** Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
- Environmental Precautions:** Avoid runoff into storm sewers, ditches, and waterways.
- Methods for Containment:** This material will settle out of the air.
- Method for cleanup:** Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

Section 7 - Handling and Storage

- General Handling:** When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
- Storage Conditions:** Store at 20° to 25°C (68 to 77°F) [See USP control Temperature]. Protect from light. Retain in carton until time of use.
- Work Practices:** Facilities storing or utilizing this material should be equipped with an eyewash facility and safety shower.

	Levothyroxine Sodium for Injection		Safety Data Sheet (SDS)	
	Effective Date: 07DEC2018	SDS No.: SDS028	Revision No: 01	Page 4 of 9

Hygiene Practices: Wash thoroughly. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.


Section 8 - Exposure Controls / Personal Protection

(a) Engineering Controls

General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

(b) Individual Protection Measures

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet/ fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exists
Skin Protection:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor/nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH website (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.

	Levothyroxine Sodium for Injection		Safety Data Sheet (SDS)	
	Effective Date: 07DEC2018	SDS No.: SDS028	Revision No: 01	Page 5 of 9

Other Protective Equipment:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.
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Section 9 - Physical and Chemical Properties

(a)	Physical State Appearance:	Lyophilized powder. (May appear as a lyophilized solid or film)
(b)	Color:	White
(c)	Boiling Point:	Not established
(d)	Melting Point:	Not established
(e)	Solubility:	Soluble in water
(f)	Vapor Density:	Not established
(g)	Vapor Pressure:	Not established
(h)	Percent Volatile:	Not established
(i)	pH:	Not established
(j)	Molecular Formula:	Mixture
(k)	Molecular Weight:	798.856
(l)	Flash Point:	Not established
(m)	Flash Point Method:	Not established
(n)	Auto Ignition Temperature:	Not established

Section 10 - Stability and Reactivity


(a)	Chemical Stability	Stable under normal temperatures and pressures.
(b)	Hazardous Polymerization	Not reported.
(c)	Conditions to Avoid	No conditions contributing to instability are known to exist for normal handling of this product.

Section 11 - Toxicological Information

(a) Mannitol:

RTECS Number: OP2060000

Ingestion: Oral – Rat LD50: 13500 mg/kg [Details of toxic effects not reported other than lethal dose value]
Oral – Mouse LD50: 22 gm/kg [Behavioral – Somnolence (general depressed activity); Gastrointestinal – Ulceration or bleeding from

	Levothyroxine Sodium for Injection		Safety Data Sheet (SDS)	
	Effective Date: 07DEC2018	SDS No.: SDS028	Revision No: 01	Page 6 of 9

small intestine]

(b) Levothyroxine Sodium:

RTECS Number: XP3583000

Inhalation: Inhalation – Rat TCLO: 5 mg/m³/4H [Endocrine – Changes in adrenal weight Blood – Changes in other cell count (unspecified)]
 Inhalation – Rat TCLO: 0.1 mg/m³/4H [Cardiac – EKG changes not diagnostic of specified effects Liver – Other changes Biochemical – Metabolism (Intermediary) – Other]
 Inhalation – Rat TCLO: 0.56 mg/m³/4H [Endocrine – Other changes Blood – changes in serum composition (e.g. TP, bilirubin, cholesterol)]
 Inhalation – Rat TCLO: 1.43 mg/m³/4H [Nutritional and Gross Metabolic – Body temperature decrease]

Ingestion: Oral – Mouse LD50: >10000 mg/kg [Behavioral – Somnolence (general depressed activity) Lungs, Thorax, or Respiration – Respiratory stimulation]

Other Toxicological Information: Subcutaneous – Rat LD50 mg/kg [Details of toxic effects not reported other than lethal dose value]
 Intraperitoneal. – Rat LD50: 20 mg/kg [Details of toxic effects not reported other than lethal dose value]


(c) Dibasic Sodium Phosphate, Anhydrous:

RTECS Number: WC4500000

Eye: Eye – Rabbit Standard Draize test.: 500 mg/24H (RTECS)

Skin: Administration onto the skin – Rabbit Standard Draize test. 500 mg/24H [mild]

Ingestion: Oral – Rat LD50: 17000 mg/kg [Details of toxic effects not reported other than lethal dose value (RTECS)]

	Levothyroxine Sodium for Injection		Safety Data Sheet (SDS)	
	Effective Date: 07DEC2018	SDS No.: SDS028	Revision No: 01	Page 7 of 9

Section 12 - Ecological Information

(a)	Ecotoxicity	N/A
(b)	Environmental Stability	N/A

Section 13 - Disposal Considerations

Waste Disposal: Dispose of in accordance with Local, State, Federal and Provincial regulations.

Section 14 - Transport Information

DOT: Not regulated as a dangerous good.
IATA: Not regulated as a dangerous good.
IMDG: Not regulated as a dangerous good.

(a)	DOT Shipping Name	Not Regulated
(b)	DOT UN Number	Not Regulated
(c)	IATA Shipping Name	Not Regulated
(d)	IATA UN Number	Not Regulated
(e)	IMDG UN Number	Not Regulated
(f)	IMDG Shipping Name	Not Regulated

Section 15 - Regulatory Information

Mannitol:


TSCA Inventory Status: Listed
EINECS Number: 200-711-8
Canada DSL: Listed

Levothyroxine Sodium:

TSCA Inventory Status: Listed
Canada DSL: Listed

Dibasic Sodium Phosphate, Anhydrous:

TSCA Inventory Status: Listed
EINECS Number: 231-448-7
Canada DSL: Listed

 Pharmaceutical Division	Levothyroxine Sodium for Injection		Safety Data Sheet (SDS)	
	Effective Date: 07DEC2018	SDS No.: SDS028	Revision No: 01	Page 8 of 9

Section 16 - Other Information


As of the date of effectiveness, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Athenex Pharmaceutical Division
10 N. Martingale Road, Suite 230
Schaumburg, IL 60173
847-886-9515

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application

	Levothyroxine Sodium for Injection		Safety Data Sheet (SDS)	
	Effective Date: 07DEC2018	SDS No.: SDS028	Revision No: 01	Page 9 of 9

NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System