

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

078073252

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

078480827



## MATERIAL SAFETY DATA SHEET

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### SECTION 1 - PRODUCT & COMPANY IDENTIFICATION

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1501 East Woodfield Road  
Suite 300 East  
Schaumburg, IL 60173  
(847) 969-2700

Emergency Telephone

(800) 551-7176

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**Product Identifier:** Levothyroxine Sodium for Injection  
**Chemical Name:** Levothyroxine Sodium  
**Category:** Hormone

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### SECTION 2 - COMPOSITION

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<u>Ingredient</u>	<u>CAS Number</u>	<u>Amount</u>
Levothyroxine Sodium	55-03-8	200 mcg and 500 mcg per vial
Mannitol	69-65-8	10 mg per vial
Tribasic Sodium Phosphate Anhydrous	7601-54-9	0.7 mg per vial

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### SECTION 3 - HAZARDS IDENTIFICATION

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**Route of Entry:** Inhalation, eye/skin contact, or ingestion

**Chemical Listing as Carcinogen**

**NTP:** No

**IARC:** No

**OSHA:** No

**Note:** NA

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### SECTION 4 - EMERGENCY & FIRST AID MEASURES

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**Eyes:** Immediately flush eyes with water for at least 15 minutes. Seek medical attention.

**Skin:** Remove contaminated clothing immediately. Flush area with water for at least 15 minutes. Wash exposed area with soap and water. Seek medical attention if pain, redness, or swelling persists.

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## SECTION 4 - EMERGENCY & FIRST AID MEASURES... continued

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<b>Inhalation:</b>	Move exposed subject to fresh air immediately. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required. Seek medical attention.
<b>Ingestion:</b>	Flush mouth out with water immediately. Seek medical attention.
<b>Contact Info:</b>	For Adverse Event Information, please call (800) 551-7176 or (847) 969-2700.

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## SECTION 5 - FIRE FIGHTING MEASURES

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### Fire and Explosion Data

<b>Closed Cup Flash Point:</b>	200.0
<b>Open Cup Flash Point:</b>	NE
<b>Fire Point:</b>	NE
<b>Autoignition:</b>	NE
<b>Lower Explosion Limit:</b>	NE
<b>Upper Explosion Limit:</b>	NE
<b>General Hazard:</b>	When heated to decomposition, toxic fumes may be emitted.
<b>Fire Fighting Instructions:</b>	Use water or a type ABC multi-purpose extinguisher.
<b>Fire Fighting Equipment:</b>	Wear self-containing breathing apparatus and protective clothing.
<b>Hazardous Combustion Products:</b>	May emit noxious fumes of iodine, iodine compounds, and nitrogen oxides. As with any burning material, carbon monoxide and carbon dioxide may be produced.

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## SECTION 6 - ACCIDENTAL RELEASE MEASURES

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<b>Clean-Up:</b>	Wear recommended personal protective equipment (See Section 8 - Exposure Controls/Personal Protection). Use absorbent towels or brooms to clean-up spill. Wipe surface area clean with soap and water.
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## SECTION 7 - HANDLING AND STORAGE

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<b>General Handling:</b>	When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.
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**SECTION 7 - HANDLING AND STORAGE...continued**

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**Storage Conditions:** Store dry product at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light.

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION**

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**Engineering Controls:** General room ventilation is usually satisfactory. Use local exhaust ventilation if necessary.

**Personal Protective Equipment**

**Eye Protection:** Safety glasses or goggles recommended.

**Hand Protection:** Disposable latex gloves recommended.

**Respiratory Protection:** With satisfactory ventilation, respiratory protection is usually not required.

**Skin Protection:** Disposable garments if direct skin contact is anticipated.

**Exposure Limits:**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Levothyroxine Sodium	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	Other Limits	0.002 mg/m <sup>3</sup>
Mannitol	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE
Tribasic Sodium Phosphate Anhydrous	OSHA	PEL	NE
	ACGIH	TLV	NE
	---	STEL	NE

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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**Physical Form/  
Appearance:** White, lyophilized powder

**Boiling Point/Boiling  
Range:** NA

**Melting Point/Melting  
Range:** NE

**Freezing Point:** NA

**Vapor Pressure :** NA

**Relative Vapor Density:** NA

**Percent Volatiles:** NA

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES...**continued

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**pH:** NE  
**Molecular Weight:** 798.86  
**Solvent Solubility:** Slightly soluble in water  
**Note:** NA

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**SECTION 10 - STABILITY AND REACTIVITY**

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**Stability:** Stable  
**Conditions to Avoid:** Avoid storage with strong oxidizers. Exposure to light may cause decomposition  
**Hazardous Polymerization:** Does not occur.

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**SECTION 11 - TOXICOLOGY INFORMATION**

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**Signs & Symptoms of Exposure & Overexposure:** This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Possible adverse reactions are due to overdose and induced hyperthyroidism. Occupational exposure has not been fully investigated.

**Medical Conditions Aggravated by Accidental Exposure:** Individuals with cardiovascular diseases, endocrine disorders such as diabetes mellitus, adrenal insufficiency (Addison's disease), hypopituitarism, and diabetes insipidus may be aggravated by accidental exposure. Exposure may potentiate the effects of anticoagulants and the anorectic effects of individuals taking sympathomimetic amines.

**Acute Toxicity:**

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dosage</u>
Levothyroxine Sodium	TD <sub>Lo</sub>	Oral	Woman	117 mcg/kg/60D-I
	LD <sub>50</sub>	IV	Rat	20 mg/kg
	LD <sub>50</sub>	SC	Rat	50 mg/kg
	LD <sub>50</sub>	IP	Rat	20 mg/kg

**Other:** NA

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**SECTION 12 - TRANSPORTATION INFORMATION**

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**UN/NA Number:** NA  
**U.S. DOT Hazard Class:** NA  
**Proper Shipping Name:** NA  
**Shipping Label:** NA

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## SECTION 13 - DISPOSAL INFORMATION

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**Disposal Procedure :** Treatment, storage, transportation, and disposal must be in accordance with applicable federal, state, and local regulations.

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## SECTION 14 - OTHER

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**Key to Abbreviations:** ACGIH - American Conference of Governmental Industrial Hygienists  
HEPA - High Efficiency Particulate Air  
IARC - International Agency for Research on Cancer  
NA - Not Applicable  
NE - Not Established  
NG - Not Given  
NIOSH - National Institute for Occupational Safety and Health  
NTP - National Toxicology Program  
OEL - Occupational Exposure Limit  
OSHA - Occupational Safety and Health Administration  
PEL - Permissible Exposure Limit  
PPM - Parts Per Million  
QS - Quantity Sufficient  
RCRA - Resource Conservation and Recovery Act  
STEL - Short Term Exposure Limit  
TLV - Threshold Limit Value  
USP - United States Pharmacopeia

**Disclaimer:** The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Abraxis BioScience, Inc. assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.

## SAFETY DATA SHEET

### SECTION 1 : IDENTIFICATION

**Product Name:** **Levothyroxine Sodium for Injection**  
**Product Use/Restriction:** Hormone  
**Manufacturer Name:** Fresenius Kabi USA, LLC  
**Address:** Three Corporate Drive  
Lake Zurich, Illinois 60047  
**General Phone Number:** (847) 550-2300  
**Customer Service Phone Number:** (888) 386-1300  
**Health Issues Information:** (800) 551-7176  
**SDS Creation Date:** October 12, 2011  
**SDS Revision Date:** June 10, 2015  
**(M)SDS Format:**

### SECTION 2 : HAZARD(S) IDENTIFICATION

**GHS Class:** Reproductive toxicity. Effects on or via lactation.  
**Hazard Statements:** May cause harm to breast-fed children.  
**Precautionary Statements:** Obtain special instructions before use.  
Do not breathe dust/fume/gas/mist/vapours/spray.  
Avoid contact during pregnancy and while nursing.  
Wash hands thoroughly after handling.  
Do not eat, drink or smoke when using this product.  
IF exposed or concerned: Get medical advice/attention.  
**Emergency Overview:** This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses 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 cause irritation.  
**Skin:** May cause skin irritation.  
**Inhalation:** May cause irritation of respiratory tract.  
**Ingestion:** May cause irritation.

### SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Mannitol	69-65-8	3 mg/vial	
Levothyroxine Sodium	55-03-8	100 , 200, and 500 mcg/vial	
Dibasic Sodium Phosphate, Anhydrous	7558-79-4	0.5 mg/vial	

### SECTION 4 : FIRST AID MEASURES

**Eye Contact:** 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 Contact:** 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.  
**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.  
**Other First Aid:** For Adverse Event Information, please call (800) 551-7176.

## SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	200
Flash Point Method:	Closed cup
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
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.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

## SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personnel 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.
Methods for cleanup:	Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

## SECTION 7 : HANDLING and STORAGE

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:	Store at refrigerated temperatures 2 to 8°C (36 to 46°F). [See USP Controlled Room 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 a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

## SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

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 exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	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 web site ( <a href="http://www.cdc.gov/niosh/npptl/topics/respirators/">http://www.cdc.gov/niosh/npptl/topics/respirators/</a> ) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

### EXPOSURE GUIDELINES

## SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State Appearance:	Lyophilized powder. (May appear as a lyophilized solid or film)
Color:	White
Boiling Point:	Not established.
Melting Point:	Approximately 256 °C



Solubility:	Soluble in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	Not established.
Molecular Formula:	Mixture
Molecular Weight:	798.86
Flash Point:	200
Flash Point Method:	Closed cup
Auto Ignition Temperature:	Not established.

## SECTION 10 : STABILITY and REACTIVITY

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

## SECTION 11 : TOXICOLOGICAL INFORMATION

### 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 small intestine]

### 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: 50 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]

### 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)

## SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

## SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.
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## SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.
IATA Shipping Name:	Non regulated.
IATA UN Number:	Non regulated.

IMDG UN Number : Non regulated.

IMDG Shipping Name : Non 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

## SECTION 16 : ADDITIONAL INFORMATION

### HMIS Ratings:

HMIS Health Hazard: 1

HMIS Fire Hazard: 1

HMIS Reactivity: 1

HMIS Personal Protection: X

SDS Creation Date: October 12, 2011

SDS Revision Date: June 10, 2015

MSDS Revision Notes: Version 0

SDS Format:

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