

## 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

<b>Flash Point:</b>	200
<b>Flash Point Method:</b>	Closed cup
<b>Auto Ignition Temperature:</b>	Not established.
<b>Lower Flammable/Explosive Limit:</b>	Not established.
<b>Upper Flammable/Explosive Limit:</b>	Not established.
<b>Fire Fighting Instructions:</b>	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.
<b>Extinguishing Media:</b>	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>Protective Equipment:</b>	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
<b>Hazardous Combustion Byproducts:</b>	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

<b>Personnel Precautions:</b>	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.
<b>Environmental Precautions:</b>	Avoid runoff into storm sewers, ditches, and waterways.
<b>Methods for containment:</b>	This material will settle out of the air.
<b>Methods for cleanup:</b>	Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

## SECTION 7 : HANDLING and STORAGE

<b>Handling:</b>	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.
<b>Storage:</b>	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.
<b>Work Practices:</b>	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
<b>Hygiene Practices:</b>	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

## SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

<b>Engineering Controls:</b>	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>Eye/Face Protection:</b>	Chemical splash goggles. Wear a face shield also when splash hazard exist.
<b>Skin Protection Description:</b>	Protective laboratory coat, apron, or disposable garment recommended.
<b>Hand Protection Description:</b>	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
<b>Respiratory Protection:</b>	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.
<b>Other Protective:</b>	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

## EXPOSURE GUIDELINES

## SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

<b>Physical State Appearance:</b>	Lyophilized powder. (May appear as a lyophilized solid or film)
<b>Color:</b>	White
<b>Boiling Point:</b>	Not established.
<b>Melting Point:</b>	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/m <sup>3</sup> /4H [Endocrine - Changes in adrenal weight Blood - Changes in other cell count (unspecified)] Inhalation - Rat TCLO: 0.1 mg/m <sup>3</sup> /4H [Cardiac - EKG changes not diagnostic of specified effects Liver - Other changes Biochemical - Metabolism (Intermediary) - Other] Inhalation - Rat TCLO: 0.56 mg/m <sup>3</sup> /4H [Endocrine - Other changes Blood - changes in serum composition (e.g. TP, bilirubin, cholesterol)] Inhalation - Rat TCLO: 1.43 mg/m <sup>3</sup> /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:

### Disclaimer:

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