

SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product identifier used on the label:

Product Name: **Levothyroxine Sodium Injection RTU**

Other means of identification:

Synonyms: Levothyroxine Sodium Injection

Recommended use of the chemical and restrictions on use:

Product Use/Restriction: Hormone

Chemical manufacturer address and telephone number:

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

SECTION 2 : HAZARD(S) IDENTIFICATION

Classification of the chemical in accordance with CFR 1910.1200(d)(f):

GHS Class: Not classified

Hazards not otherwise classified that have been identified during the classification process:

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

Mixtures:

Chemical Name	CAS#	Ingredient Percent	EC Num.
Sodium Iodide	7681-82-5	0.70 mg/Vial by weight	231-679-3
Levothyroxine Sodium	55-03-8	100, 200, 500 mcg/Vial by weight	200-221-4
Sodium Chloride	7647-14-5	32.4 mg/Vial by weight	231-598-3
Tromethamine	77-86-1	50 mg/Vial by weight	201-064-4

SECTION 4 : FIRST AID MEASURES

Description of necessary 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.

Most important symptoms/effects, acute and delayed:

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

SECTION 5 : FIRE FIGHTING MEASURES

Suitable and unsuitable extinguishing media:

Suitable 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.

Specific hazards arising from the chemical:

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.

Special protective equipment and precautions for fire-fighters:

Protective Equipment: As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

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.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:

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:

Environmental Precautions: Avoid runoff into storm sewers, ditches, and waterways.

Methods and materials for containment and cleaning up:

Methods for containment: Contain spills with an inert absorbent material such as soil, sand or oil dry.

Methods for cleanup: Absorb spill with inert material (e.g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Precautions for safe handling:

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.

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

Conditions for safe storage, including any incompatibilities:

Storage: Store at controlled room temperature 20 to 25C (68 to 77F).

Specific end use(s):

Work Practices: Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

EXPOSURE GUIDELINES:

Sodium Iodide:

Guideline ACGIH: TWA-TLV: 0.01 mg/m³

Appropriate engineering controls:

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.

Individual protection measures:

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 (<http://www.cdc.gov/niosh/npptl/topics/respirators/>) 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.

General Hygiene Considerations: Wash thoroughly after handling. Do not eat, drink, smoke or apply cosmetics while handling the product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Work should be performed in a designated area for working with hazardous drugs. Contaminated waste must be properly handled. Work areas must be regularly decontaminated.

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

PHYSICAL AND CHEMICAL PROPERTIES:

Physical State Appearance: Sterile liquid.

Color: Colorless.

Boiling Point: Not established.

Melting Point: Not established.

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: Not established.

Lower Flammable/Explosive Limit: Not established.

Upper Flammable/Explosive Limit: Not established.

Auto Ignition Temperature: Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:

Chemical Stability: Stable under normal temperatures and pressures.

Possibility of hazardous reactions:

Hazardous Polymerization: Not reported.

Conditions To Avoid:

Conditions to Avoid: No conditions contributing to instability are known to exist for normal handling of this product.

SECTION 11 : TOXICOLOGICAL INFORMATION

TOXICOLOGICAL INFORMATION:

Sodium Iodide :

RTECS Number: WB6475000

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

Sodium Chloride :

RTECS Number: VZ4725000

Tromethamine :

RTECS Number: TY2900000

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:

Ecotoxicity: No ecotoxicity data was found for the product.

Environmental Stability: No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Description of waste:

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

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

Safety, health and environmental regulations specific for the product:

Sodium Iodide :

TSCA Inventory Status: Listed

Canada DSL: Listed

EC Number: 231-679-3

Levothyroxine Sodium :

EINECS Number: 200-221-4

EC Number: 200-221-4

Sodium Chloride :

EC Number: 231-598-3

Tromethamine :

TSCA Inventory Status: Listed

Canada DSL: Listed

EC Number: 201-064-4

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard: 1

HMIS Fire Hazard: 1

HMIS Reactivity: 1

HMIS Personal Protection: X

Health Hazard	1
Fire Hazard	1
Reactivity	1
Personal Protection	X

SDS Creation Date: October 19, 2018

SDS Revision Date: December 23, 2024

SDS Revision Notes: Overall SDS review - no changes to formulation. Added synonym on Section 1. (Note: 'RTU' on the product name means 'Ready to Use').

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. Fresenius-Kabi 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.

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