

## SAFETY DATA SHEET

### SECTION 1 : IDENTIFICATION

**Product Name:** Chlorothiazide Sodium for Injection, USP  
**Product Use/Restriction:** Diuretic and antihypertensive  
**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:** July 28, 2009  
**SDS Revision Date:** June 10, 2015  
**(M)SDS Format:**

### SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



**Signal Word:** DANGER.

**GHS Class:** Respiratory sensitisation. Category 1.  
 Skin Sensitization. Category 1.  
 Reproductive toxicity. Effects on or via lactation.

**Hazard Statements:** May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
 May cause an allergic skin reaction.  
 May cause harm to breast-fed children.

**Precautionary Statements:** Obtain special instructions before use.  
 Do not breathe dust/fume/gas/mist/vapours/spray.  
 Avoid breathing 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.  
 Contaminated work clothing should not be allowed out of the workplace.  
 Wear protective gloves/protective clothing/eye protection/face protection.  
 In case of inadequate ventilation wear respiratory protection.  
 IF ON SKIN: Wash with plenty of water.  
 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  
 IF exposed or concerned: Get medical advice/attention.  
 Specific treatment (see ... on this label).  
 If skin irritation or rash occurs: Get medical advice/attention.  
 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.  
 Take off contaminated clothing and wash it before reuse.  
 Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

**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. Harmful. May cause sensitization by inhalation and skin contact.

**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.

**Signs/Symptoms:** Other symptoms may include throat, anorexia, muscle spasms, and weakness. Exposure to high concentrations can depress CNS function. Exposure can cause: Dermatitis. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated. Stomach pains, vomiting, diarrhea, nausea, dizziness, and headaches.

**Aggravation of Pre-Existing Conditions:** Individuals with hypersensitivity to any component of this product.

### SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Chlorothiazide sodium equivalent to chlorothiazide	58-94-6	0.5 g/ vial	

Sodium Hydroxide	1310-73-2	As needed to adjust pH
Mannitol	69-65-8	0.25 g/ vial

#### SECTION 4 : FIRST AID MEASURES

<b>Eye Contact:</b>	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.
<b>Skin Contact:</b>	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.
<b>Inhalation:</b>	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
<b>Ingestion:</b>	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.
<b>Other First Aid:</b>	For Adverse Event Information, please call (800) 551-7176.

#### SECTION 5 : FIRE FIGHTING MEASURES

<b>Flash Point:</b>	Not established.
<b>Flash Point Method:</b>	Not established.
<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>	Contain spills with an inert absorbent material such as soil, sand or oil dry.
<b>Methods for cleanup:</b>	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

<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 between 2 to 25°C (36 to 77°F).
<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:</b>	Lyophilized powder.
<b>Color:</b>	White
<b>Odor:</b>	Odorless.
<b>Boiling Point:</b>	Not established.
<b>Melting Point:</b>	Not established.
<b>Solubility:</b>	Not established.
<b>Vapor Density:</b>	Not established.
<b>Vapor Pressure:</b>	Not established.
<b>Percent Volatile:</b>	Not established.
<b>pH:</b>	9 - 10
<b>Molecular Formula:</b>	Mixture
<b>Flash Point:</b>	Not established.
<b>Flash Point Method:</b>	Not established.
<b>Auto Ignition Temperature:</b>	Not established.

### SECTION 10 : STABILITY and REACTIVITY

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

### SECTION 11 : TOXICOLOGICAL INFORMATION

#### Chlorothiazide sodium equivalent to chlorothiazide :

<b>RTECS Number:</b>	DK9450000
<b>Ingestion:</b>	Oral - Mouse LD50: 8 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Rat LD50: 10 gm/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)
<b>Other Toxicological Information:</b>	Intravenous. - Mouse LD50: 940 mg/kg [Peripheral Nerve and Sensation - Spastic paralysis with or without sensory change Behavioral - Convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - Other changes] Intravenous. - Rat LD50: 200 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LD50: 1386 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 1400 mg/kg [Peripheral Nerve and Sensation - Spastic paralysis with or without sensory change Behavioral - Convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - Other changes]

#### Sodium Hydroxide :

<b>RTECS Number:</b>	WB4900000
<b>Eye:</b>	Eye - Rabbit Standard Draize test.: 400 ug Eye - Rabbit Standard Draize test.: 50 ug/24H (RTECS)
<b>Skin:</b>	Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H
<b>Ingestion:</b>	Oral - Rabbit LDLo: 500 mg/kg [Details of toxic effects not reported other than lethal dose value]

#### Mannitol :

<b>RTECS Number:</b>	OP2060000
<b>Ingestion:</b>	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]
<b>Other Toxicological Information:</b>	Intravenous. - Rat LD50: 9690 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50: 7470 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 14 gm/kg [Details of toxic effects not reported other than lethal dose value]

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**SECTION 12 : ECOLOGICAL INFORMATION**

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

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**SECTION 13 : DISPOSAL CONSIDERATIONS**

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

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**SECTION 14 : TRANSPORT INFORMATION**

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**DOT Shipping Name:** Not Regulated.  
**DOT UN Number:** Not Regulated.

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**SECTION 15 : REGULATORY INFORMATION**

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**Chlorothiazide sodium equivalent to chlorothiazide :**

**Canada DSL:** Listed

**Sodium Hydroxide :**

**TSCA Inventory Status:** Listed

**Canada DSL:** Listed

**Mannitol :**

**TSCA Inventory Status:** Listed

**Canada DSL:** Listed

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**SECTION 16 : ADDITIONAL INFORMATION**

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**HMIS Ratings:**

**HMIS Health Hazard:** 2  
**HMIS Fire Hazard:** 1  
**HMIS Reactivity:** 0  
**HMIS Personal Protection:** X

**SDS Creation Date:** July 28, 2009

**SDS Revision Date:** June 10, 2015

**SDS Format:**

**Disclaimer:**

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