

**SAFETY DATA SHEET**

**1. Identification**

**Product Identifier:** Chlorothiazide Sodium for Injection, USP

**Synonyms:** 2H-1,2,4-Benzothiadiazine-7-sulfonamide, 6-chloro-, 1,1-dioxide

**National Drug Code (NDC):** 17478-419-40

**Recommended Use:** Pharmaceutical.

**Company:** Akorn, Inc.  
1925 West Field Court, Suite 300  
Lake Forest, Illinois 60045

**Contact Telephone:** 1-800-932-5676

**E mail:** customer.service@akorn.com

**Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)


**2. Hazard(s) Identification**

**Physical Hazards:** Not classifiable.

**Health Hazards:**

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 1, 2A
Respiratory sensitization	Category 1
Skin corrosion/irritation	Category 1A, 2
Skin sensitization	Category 1
Corrosive to metals	Category 1
Hazardous to the aquatic environment	Category 3



**Symbol(s):** 

**Signal Word:** Danger.

**Hazard Statement(s):** May form combustible dust concentrations in air.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

## SDS: Chlorothiazide Sodium for Injection, USP

### Precautionary Statement(s):

- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- P261 Avoid breathing dust.
- P264 Wash hands, forearms, and other exposed areas thoroughly after handling.
- P272 Contaminated work clothing must not be allowed out of the workplace.
- P280 Wear eye protection, protective clothing, protective gloves, respiratory protection.
- P284 In case of inadequate ventilation wear respiratory protection.
- P302 IF ON SKIN: Wash with plenty of water.  
+  
P352
- P304 IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.  
+  
P340
- P305 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
+  
P351  
+  
P338
- P321 Specific treatment (see Section 4 on this SDS).
- P332 If skin irritation occurs: Get medical advice/attention.  
+  
P313
- P333 If skin irritation or rash occurs: Get medical advice/attention.  
+  
P313
- P337 If eye irritation persists: Get medical advice/attention.  
+  
P313
- P342 If experiencing respiratory symptoms: Call a POISON CENTER, a doctor.  
+  
P311
- P362 Take off contaminated clothing and wash before reuse.
- P362 Take off contaminated clothing and wash it before reuse.  
+  
P364

## SDS: Chlorothiazide Sodium for Injection, USP

P501 Dispose of contents/container in accordance with local, regional, national, and international regulations.

**Hazards Not Otherwise Classified:** Exposure may aggravate those with pre-existing eye, skin, or respiratory conditions. Persons who are hypersensitive to this product or to other sulfonamide-derived drugs may have an allergic reaction to this drug. Symptoms of an allergic reaction include anaphylactic reactions, necrotizing angitis (vasculitis and cutaneous vasculitis), itching, swelling, dizziness, respiratory distress including pneumonitis and pulmonary edema, photosensitivity, fever, hives, rash, and purpura. In addition to diuresis and resultant dehydration, overdosage of thiazides (such as Chlorothiazide Sodium) may produce lethargy, nausea, weakness, and electrolyte imbalance; lethargy may progress to coma within a few hours with minimal depression of respiratory and cardiovascular function and without evidence of dehydration or serum electrolyte change. The mechanism of thiazide-induced CNS depression is unknown. Gastrointestinal irritation and hypermotility may occur, and temporary elevation of the BUN has been reported. Serum electrolyte changes (e.g., hypokalemia, hypochloremia, hyponatremia) may occur, especially in patients with impaired renal function.

**Supplementary Information:** None.

### 3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Chlorothiazide Sodium	58-94-6	2H-1,2,4-Benzothiadiazine-7-sulfonamide, 6-chloro-, 1,1-dioxide	C <sub>7</sub> H <sub>6</sub> ClN <sub>3</sub> O <sub>4</sub> S <sub>2</sub>	317.71	50%
Mannitol	69-65-8	1,2,3,4,5,6-Hexanehexol * Mannite	C <sub>6</sub> H <sub>14</sub> O <sub>6</sub>	182.2	25%

\*The formula also contains Sodium Hydroxide to adjust pH.

### 4. First Aid Measures

**Ingestion:** If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves. DO NOT induce vomiting.

## SDS: Chlorothiazide Sodium for Injection, USP

<b>Eye Contact:</b>	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Skin Contact:</b>	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 15 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Inhalation:</b>	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	Please refer to the package insert for more detailed information. Common clinical symptoms include: weakness, low blood pressure, pancreatitis, jaundice, diarrhea, vomiting, inflammation of a salivary gland, cramping, constipation, gastric irritation, nausea, anorexia, aplastic anemia, agranulocytosis, leukopenia, hemolytic anemia, thrombocytopenia, electrolyte imbalance, hyperglycemia, glycosuria, hyperuricemia, muscle spasm, vertigo, paresthesias, dizziness, headache, restlessness, erythema multiforme including Stevens-Johnson syndrome, exfoliative dermatitis including toxic epidermal necrolysis, hair loss, transient blurred vision, yellow vision, renal failure, renal dysfunction, interstitial nephritis, blood in the urine, and impotence.
<b>Symptoms/Injuries After Inhalation:</b>	Potent pharmaceutical - respirable dust may be absorbed through the bloodstream and have adverse effects. May cause an allergic reaction in sensitive individuals.
<b>Symptoms/Injuries After Skin Contact:</b>	May cause an allergic reaction in sensitive individuals. Causes skin irritation.
<b>Symptoms/Injuries After Eye Contact:</b>	Causes serious eye irritation.

## SDS: Chlorothiazide Sodium for Injection, USP

<b>Symptoms/Injuries After Ingestion:</b>	Ingestion is likely to be harmful or have adverse effects. Dizziness, headaches, nausea. Vomiting.
<b>Chronic Symptoms:</b>	Exposure may produce an allergic reaction.
<b>Indication of Any Immediate Medical Attention and Special Treatment Needed:</b>	If you feel unwell, seek medical advice (show the label where possible).
<b>Medical Conditions Aggravated by Exposure:</b>	Not determined.
<b>Notes to Physician:</b>	Treat supportively and symptomatically.

### 5. Firefighting Measures

<b>Suitable Extinguishing Media:</b>	Powder, alcohol-resistant foam, water spray or fog, carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable Extinguishing Media:</b>	Do not use a heavy water stream. Use of heavy stream of water may spread fire.

#### Specific Hazards Arising from the Chemical:

<b>Hazardous Combustion Products:</b>	Not determined.
<b>Other Specific Hazards:</b>	Not determined.
<b>Fire Hazard:</b>	Not considered flammable but will burn at high temperatures.
<b>Explosion Hazard:</b>	Product itself is not explosive but if dust is generated, dust clouds suspended in air can be explosive.
<b>Precautionary Measures Fire:</b>	Exercise caution when fighting any chemical fire.
<b>Firefighting Instructions:</b>	Avoid raising dust. Use water spray or fog for cooling exposed containers. Do not allow run-off from firefighting to enter drains or water courses. Do not breathe fumes from fires or vapors from decomposition.
<b>Protection During Firefighting:</b>	Do not enter fire area without proper protective equipment, including respiratory protection.
<b>Special Protective Equipment/Precautions for Firefighters:</b>	Wear self-contained breathing apparatus and full and protective gear.

6. **Accidental Release Measures**

<b>General Measures:</b>	Avoid contact with skin and eyes. Avoid breathing dust. Avoid generating dust.
<b>Personal Precautions:</b>	Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
<b>Personal Protective Equipment:</b>	For personal protection see section 8.
<b>For Containment:</b>	Contain and collect as any solid.
<b>Methods for Cleaning Up:</b>	Always wear applicable PPE. For small quantities associated with normal therapeutic use, collect spillage by sweeping, vacuum, or sponge and transfer to a closed waste container for disposal, avoid generating dust. Use only non-sparking tools. Large spill: Trained personnel using pre-planned procedures should respond to large or uncontrolled releases. Avoid actions that cause dust to become airborne during clean-up such as dry sweeping or using compressed air. Use HEPA vacuum or thoroughly wet with water to clean-up dust. Use PPE described in Section 8. Finish cleaning the area with small amounts of soap and water on the spill area. Contact competent authorities after a spill.
<b>Environmental Precautions:</b>	Avoid release to the environment.
<b>Reference to Other Sections:</b>	Refer to Sections 8, 12 and 13 for further information.

7. **Handling and Storage**

<b>Hygiene Measures:</b>	This SDS is for a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.
<b>Technical Measures:</b>	Ensure vials are properly labeled. Employees must be trained to properly use this product.
<b>Precautions for Safe Handling:</b>	Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.
<b>Conditions for Safe Storage, Including Any Incompatibilities:</b>	Store in a dry, cool and well-ventilated place. Keep/Store away from direct sunlight, high or low temperatures and incompatible materials.
<b>Specific End Use:</b>	Pharmaceuticals. Intravenous diuretic and antihypertensive.

8. **Exposure Controls/Personal Protection**

**Occupational Exposure Guidelines:**

Common or Chemical Name	Employee Exposure Limits
Chlorothiazide Sodium	OSHA PEL: 15 mg/m <sup>3</sup> TWA – Total Dust OSHA PEL: 5 mg/m <sup>3</sup> TWA – Respirable Dust
Sodium Hydroxide	ACGIH: 2 mg/m <sup>3</sup> – Ceiling NIOSH REL: 2 mg/m <sup>3</sup> – Ceiling IDLH: 10 mg/m <sup>3</sup> OSHA PEL: 2 mg/m <sup>3</sup> TWA

**Engineering Controls:**

Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

**Respiratory Protection:**

When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

**Eyes Protection:**

In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Hand Protection:**

Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Skin Protection:**

In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

**9. Physical and Chemical Properties**

<b>Physical State/Color:</b>	A white lyophilized cake or powder.
<b>Odor:</b>	Odorless.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	9.2 – 10.0 (Reconstituted).
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	No data available.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

**10. Stability and Reactivity**

<b>Reactivity:</b>	Hazardous reactions will not occur under normal conditions.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	Hazardous polymerization will not occur.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	Direct sunlight, high or low temperatures, and incompatible materials. Avoid creating or spreading dust.
<b>Incompatible Materials:</b>	Strong acids, strong bases, strong oxidizers.
<b>Hazardous Decomposition Products:</b>	Thermal decomposition generates: Carbon oxides (CO, CO <sub>2</sub> ). Nitrogen oxides. Sulfur oxides. Sodium oxides. Hydrogen chloride.

**11. Toxicological Information****Information on the Likely Routes of Exposure:**

<b>Inhalation:</b>	Potent pharmaceutical- respirable dust may be absorbed through the bloodstream and have adverse effects. May cause an allergic reaction in sensitive individuals.
<b>Ingestion:</b>	Ingestion is likely to be harmful or have adverse effects; dizziness, headaches, nausea, and vomiting.
<b>Skin Contact:</b>	May cause an allergic reaction in sensitive individuals. Causes skin irritation.



## SDS: Chlorothiazide Sodium for Injection, USP

**Eye Contact:** Causes serious eye irritation.

**Chronic Symptoms:** Exposure may produce an allergic reaction.

**Symptoms Related to the Physical, Chemical and Toxicological Characteristics:** See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

**Delayed and Immediate Effects of Exposure:** No data available.

**Acute Toxicity:**

Compound	Species	Route	Test Type	Dose
Chlorothiazide	Rat	Oral	LD <sub>50</sub>	10,000 mg/kg
D-Mannitol	Rat	Oral	LD <sub>50</sub>	13,500 mg/kg

**Acute Toxicity – Dermal:** No data available.

**Acute Toxicity – Inhalation:** No data available.

**Corrosivity:** No data available.

**Dermal Irritation:** No data available.

**Eye Irritation:** No data available.

**Respiratory or Skin Sensitization:** May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

**Toxicokinetics/Metabolism:** No data available.

**Target Organ Effects:** No data available.

**Reproductive Effects:** No data available.

**Carcinogenicity:** No data available.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

**Mutagenicity:** No data available.

**Aspiration Hazard:** No data available.

12. **Ecological Information**

**Ecotoxicity**

**Aquatic:** May be toxic to aquatic life. May cause long lasting harmful effects to aquatic life. All work practices must be aimed at eliminating environmental contamination.

Compound	Species	Test Type	Dose
Sodium Hydroxide	Oncorhynchus mykiss	LC <sub>50</sub> (96 hrs)	45.4 mg/l
Sodium Hydroxide	Daphnia	EC <sub>50</sub>	40 mg/l

**Terrestrial:** No data available.  
**Persistence and Degradability:** No data available.  
**Bioaccumulative Potential:** No data available.  
**Mobility in Soil:** No data available.  
**Mobility in Environment:** No data available.  
**Other Adverse Effects:** No data available.

13. **Disposal Considerations**

Dispose of all waste in accordance with Federal, State and Local regulations.

14. **Transport Information**

**UN Number:** Not applicable.  
**UN Proper Shipping Name:** Not applicable.  
**Transport Hazard Class(es):** Not applicable.  
**Packing Group:** Not applicable.

**Department of Transportation:** Not regulated as a hazardous material.

**International Air Transport Association (IATA):** Not regulated as a dangerous good.

**International Maritime Dangerous Good (IMDG):** Not regulated as a dangerous good.

15. **Regulatory Information**

**US Federal Regulations:**

**Toxic Substance Control Act (TSCA):** Chlorothiazide: Listed.  
D-Mannitol: Listed.  
Sodium Hydroxide: Listed.

**CERCLA Hazardous Substance and Reportable Quantity:** Not listed.

**SARA 313:** Immediate (acute) health hazard.  
**SARA 302:** Immediate (acute) health hazard.

## SDS: Chlorothiazide Sodium for Injection, USP

### State Regulations

**Massachusetts:**

**New Jersey:**

**Pennsylvania:**

**Pennsylvania:**

Right to Know List.

Right to Know Hazardous Substance List.

RTK (Right to Know) - Environmental Hazard List.

RTK (Right to Know) List.

### 16. Other Information

**Revision Date:** 05/11/2015

**Revision Number:** 0

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