

Chlorothiazide Sodium for Injection, USP

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Revision Date: 01/30/2015 Date of issue: 01/30/2015

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Chlorothiazide Sodium for Injection, USP

Product Code: 1820-01

1.2. Intended Use of the Product

Use of the Substance/Mixture: Intravenous diuretic and antihypertensive

1.3. Name, Address, and Telephone of the Responsible Party

Distributor

PharmaForce, Inc.

6610 New Albany Road East

New Albany, OH 43054

T 614-436-2222

www.pharmaforceinc.com

1.4. Emergency Telephone Number

Emergency Number : 1-800-424-9300 CHEMTREC

SECTION 2: HAZARDS IDENTIFICATION

Classification (GHS-US)

Comb. Dust

Skin Irrit. 2 H315

Eye Irrit. 2A H319

Resp. Sens. 1 H334

Skin Sens. 1 H317

Full text of H-phrases: see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



Signal Word (GHS-US)

: Danger

Hazard Statements (GHS-US)

: May form combustible dust concentrations in air.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary Statements (GHS-US) : 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+P352 - IF ON SKIN: Wash with plenty of water.
P304+P340 - IF INHALED: Remove person to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P321 - Specific treatment (see Section 4 on this SDS).
P332+P313 - If skin irritation occurs: Get medical advice/attention.
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER, a doctor.
P362 - Take off contaminated clothing and wash before reuse.
P362+P364 - Take off contaminated clothing and wash it before reuse.

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

2.3. Other Hazards

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, hyponatremia, hypochloremia) may occur, especially in patients with impaired renal function.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	Classification (GHS-US)
2H-1,2,4-Benzothiadiazine-7-sulfonamide, 6-chloro-, 1,1-dioxide	(CAS No) 58-94-6	67	Resp. Sens. 1, H334 Skin Sens. 1, H317
D-Mannitol	(CAS No) 69-65-8	33	Comb. Dust
Sodium hydroxide*	(CAS No) 1310-73-2	> 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

* Added to QS for pH.

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label if possible).

First-aid Measures After Inhalation: The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

First-aid Measures After Skin Contact: Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

First-aid Measures After Eye Contact: The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

First-aid Measures After Ingestion: Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention. DO NOT induce vomiting.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: 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.

Symptoms/Injuries After Inhalation: Potent pharmaceutical- respirable dust may be absorbed through the bloodstream and have adverse effects. May cause an allergic reaction in sensitive individuals.

Symptoms/Injuries After Skin Contact: May cause an allergic reaction in sensitive individuals. Causes skin irritation.

Symptoms/Injuries After Eye Contact: Causes serious eye irritation.

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Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects. Dizziness, headaches, nausea. Vomiting.

Chronic Symptoms: Exposure may produce an allergic reaction.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Powder, alcohol-resistant foam, water spray or fog, carbon dioxide (CO₂).

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but will burn at high temperatures.

Explosion Hazard: Product itself is not explosive but if dust is generated, dust clouds suspended in air can be explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: 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.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Other Information: Refer to Section 9 for flammability properties.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid contact with skin and eyes. Avoid breathing dust. Avoid generating dust.

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Use appropriate personal protection equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel. Stop leak if safe to do so. Eliminate ignition sources. Ventilate area.

6.2. Environmental Precautions

Avoid release to the environment.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain and collect as any solid.

Methods for Cleaning Up: 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.

6.4. Reference to Other Sections

See heading 8, Exposure Controls and Personal Protection. Concerning disposal elimination after cleaning, see item 13.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Hygiene Measures: 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.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Ensure vials are properly labeled. Employees must be trained to properly use this product.

Storage Conditions: Store in a dry, cool and well-ventilated place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Storage Temperature: Store at 20 - 25 °C (68 - 77 °F). See USP controlled room temperature.

Special Rules on Packaging: Examine the vial for particulate matter and discoloration prior to administration. If the solution is discolored or contains solid particles (precipitate) upon rehydration, do not use.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

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Pharmaceutical. Intravenous diuretic and antihypertensive

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), NIOSH (REL), or OSHA (PEL).

Chlorothiazide Sodium for Injection, USP		
USA OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ (Total Dust)
USA OSHA	OSHA PEL (TWA) (mg/m ³)	5 mg/m ³ (Respirable Dust)
Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
USA NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³
USA IDLH	US IDLH (mg/m ³)	10 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³

8.2. Exposure Controls

Appropriate 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.
Personal Protective Equipment	: Not generally required. The use of personal protective equipment may be necessary as conditions warrant.
Hand Protection	: Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.
Eye Protection	: In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety goggles are recommended.
Skin and Body Protection	: In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.
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.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: A white lyophilized cake or powder
Odor	: Odorless
Odor Threshold	: No data available
pH	: 9.2 - 10.0 (Reconstituted)
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

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9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. Reactivity:** Hazardous reactions will not occur under normal conditions.
10.2. Chemical Stability: Stable under normal conditions.
10.3. Possibility of Hazardous Reactions: Hazardous polymerization will not occur.
10.4. Conditions to Avoid: Direct sunlight, extremely high or low temperatures, and incompatible materials. Avoid creating or spreading dust.
10.5. Incompatible Materials: Strong acids, strong bases, strong oxidizers.
10.6. Hazardous Decomposition Products: Thermal decomposition generates : Carbon oxides (CO, CO₂). Nitrogen oxides. Sulfur oxides. Sodium oxides. Hydrogen chloride.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

2H-1,2,4-Benzothiadiazine-7-sulfonamide, 6-chloro-, 1,1-dioxide (58-94-6)	
LD50 Oral Rat	10000 mg/kg
D-Mannitol (69-65-8)	
LD50 Oral Rat	13500 mg/kg

Skin Corrosion/Irritation: Not classified pH: 9.2 – 10 (Reconstituted)

Serious Eye Damage/Irritation: Not classified pH: 9.2 – 10 (Reconstituted)

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

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Potent pharmaceutical- respirable dust may be absorbed through the bloodstream and have adverse effects. May cause an allergic reaction in sensitive individuals.

Symptoms/Injuries After Skin Contact: May cause an allergic reaction in sensitive individuals. Causes skin irritation,

Symptoms/Injuries After Eye Contact: Causes serious eye irritation.

Symptoms/Injuries After Ingestion: Ingestion is likely to be harmful or have adverse effects. Dizziness, headaches, nausea. Vomiting.

Chronic Symptoms: Exposure may produce an allergic reaction.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : 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.

Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 Daphnia 1	40 mg/l

12.2. Persistence and Degradability No additional information available

12.3. Bioaccumulative Potential No additional information available

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

No additional information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Sewage Disposal Recommendations: Do not empty into drains; dispose of this material and its container in a safe way.

Waste Disposal Recommendations: Dispose of waste material in accordance with all local, regional, national, and international regulations.

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SECTION 14: TRANSPORT INFORMATION

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

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SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
2H-1,2,4-Benzothiadiazine-7-sulfonamide, 6-chloro-, 1,1-dioxide (58-94-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
D-Mannitol (69-65-8)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2 US State Regulations

Sodium hydroxide (1310-73-2)
U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Revision Date	: 01/30/2015
Other Information	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Met. Corr. 1	Corrosive to metals Category 1
Resp. Sens. 1	Respiratory sensitisation Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization Category 1
H232	May form combustible dust concentrations in air
H290	May be corrosive to metals
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H402	Harmful to aquatic life

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The information above is believed to be accurate and represents the best information currently available. The information has not been verified and we cannot, therefore, guarantee its accuracy or completeness or adequacy for all persons and situations or as to the results to be obtained by use of the information. It is the user's obligation to evaluate and use this product safely and to comply with all applicable laws and regulations. WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR USE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED, WITH RESPECT TO SUCH INFORMATION AND WE ASSUME NO LIABILITY RESULTING FROM ITS USE. Users should make their own investigations to determine the suitability of the information for their own particular purposes. The user assumes all risks from use of the product. In no event shall Luitpold, its subsidiaries, its affiliates and its contractors be liable for any claims, losses or damages of any third party, or for lost profits, or for any special, indirect, incidental, consequential or exemplary damages however arising, even if Luitpold has been advised of the possibility of such damages.

SDS US (GHS HazCom)