

**SAFETY DATA SHEET****1. Identification**

**Product Identifier:** Sodium Diuril® (clorothiazide sodium)

**Synonyms:** 6-Chloro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide

**National Drug Code (NDC):** 76478-711-40

**Recommended Use:** Pharmaceutical.

**Company:** Oak Pharmaceuticals, Inc. (Subsidiary of 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:**

Serious eye damage/ eye irritation	Category 1, 2A
Corrosive to metals	Category 1
Respiratory sensitization	Category 1
Skin corrosion/ irritation	Category 1A, 2
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.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



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<b>Precautionary Statement(s):</b>	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		
P501	Dispose of contents/container in accordance with local, regional, national, and international regulations.	



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**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, hyponatremia, 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
Sodium Diuril (clorothiazide sodium)	58-94-6	6-Chloro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide	C <sub>7</sub> H <sub>5</sub> ClN <sub>3</sub> NaO <sub>4</sub> S <sub>2</sub>	317.71	0.05%
Mannitol	69-65-8	Manna Sugar, Mannite, Mannitol D- * 1,2,3,4,5,6-Hexanhexol	C <sub>6</sub> H <sub>14</sub> O <sub>6</sub>	182.17	0.025%

\*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.

**Eye Contact:** 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



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material(s) involved and are aware of precautions to protect themselves.

### **Skin Contact:**

Basic hygiene and appropriate precautions should prevent skin contact. Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 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.

### **Inhalation:**

The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic; 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.

### **Protection of First-Aiders:**

Use personal protective equipment (see section 8).

### **Signs and Symptoms:**

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.

### **Medical Conditions Aggravated by Exposure:**

There is no information on pre-existing medical conditions that may be aggravated by occupational exposure to this product. With therapeutic use, pre-existing anuria, impaired hepatic function, progressive liver disease, allergy, bronchial asthma, and systemic lupus erythematosus may be aggravated by exposure to this product clinical use of this product.

### **Notes to Physician:**

This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treatment of over dosage is mainly supportive and consists of the following: correct dehydration, electrolyte imbalance, hepatic coma and hypotension by established procedures. If required, give oxygen or artificial respiration for respiratory impairment. The degree to which Chlorothiazide Sodium is removed by hemodialysis has not been established.



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### 5. Firefighting Measures

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

#### Specific Hazards Arising from the Chemical:

- 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.
- Hazardous Combustion Products:** This product is combustible. When involved in a fire, the products of combustion or thermal decomposition can include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides, sulfur oxides, sodium oxides, and hydrogen chloride). Accumulated dusts of this product can create a serious hazard of explosion. If the fire scene includes high levels of airborne dusts from this product, firefighters should take great care as an explosive ignition may occur.
- Other Specific Hazards:** Not determined.
- Special Protective Equipment/Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.
- Firefighting Instruction:** 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.

### 6. Accidental Release Measures

- Personal Precautions:** Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.
- Personal Protective Equipment:** For personal protection see section 8.
- Methods for Cleaning Up:** For small releases of this compound, wear double latex or butyl rubber gloves and safety glasses. Sweep, vacuum, or wipe up spilled material with damp sponge or polypad. Place in a bag and hold for waste disposal. Avoid producing airborne dusts of this product during cleanup. In case of a large spill, clear the affected area and protect people. Trained personnel using pre-planned procedures should respond to large or uncontrolled releases. Proper protective equipment should be used, including double natural rubber, neoprene or nitrile gloves, full body gown, and full-face respirator equipped



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with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator in the event of a large spill. Eliminate all sources of ignition before clean-up operations begin. Use non-sparking tools. Sweep up or vacuum spilled solid (an explosion-proof vacuum should be used). Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Contact competent authorities after a spill.

**Environmental Precautions:**

Avoid release to the environment. Large quantities released to the aquatic and terrestrial environment may have an adverse effect.

**Reference to Other Sections:**

Refer to Sections 8, 12 and 13 for further information.

### 7. Handling and Storage

**Precautions for Safe Handling:**

Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage, Including Any Incompatibilities:**

Store in a dry, cool and well-ventilated place. Keep/Store away from direct sunlight, high or low temperatures and incompatible materials. Store at 20 - 25 °C (68 - 77 °F). See USP controlled room temperature. Store according to label and/or product insert information.

**Specific End Use:**

Pharmaceuticals.

### 8. Exposure Controls/Personal Protection

**Occupational Exposure Guidelines:**

Common or Chemical Name	Employee Exposure Limits
Sodium Diuril (clorothiazide sodium)	OSHA PEL: 15 mg/m <sup>3</sup> TWA – Total dust OSHA PEL: 5 mg/m <sup>3</sup> TWA – Respirable dust OTHER (Inhalable fraction): 4 mg/m <sup>3</sup> TWA (Respirable fraction): 1.5 mg/m <sup>3</sup> TWA
Sodium Hydroxide	OSHA PEL: 2 mg/m <sup>3</sup> TWA US IDLH: 10 mg/m <sup>3</sup> NIOSH REL: 2 mg/m <sup>3</sup> – Ceiling ACGIH: 2 mg/m <sup>3</sup> – Ceiling
Mannitol	Not established.

**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.



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<b>Respiratory Protection:</b>	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
<b>Eyes Protection:</b>	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.
<b>Hand Protection:</b>	Wear chemically compatible gloves. 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.
<b>Skin Protection:</b>	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

### 9. Physical and Chemical Properties

<b>Physical State/Color:</b>	White lyophilized 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>	Soluble in water.
<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.



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<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 not a significant route of occupational overexposure. Acute ingestion of large quantities of this product may cause dizziness, lightheadedness, blurred vision, loss of appetite, itching, stomach upset, headache, weakness, muscle cramps, weakness, pain, nausea, vomiting.
<b>Skin Contact:</b>	May cause an allergic reaction in sensitive individuals. Causes skin irritation.
<b>Eye Contact:</b>	Causes serious eye irritation.
<b>Injection:</b>	If accidentally injected, symptoms of acute injection overexposure can include an abnormally low concentration of potassium ions in the blood, an abnormally low concentration of chloride ions in the blood, a deficiency of sodium in the blood, and dehydration.

#### **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:**

**ACUTE:** The primary health effects that may be experienced by medical personnel exposed to this product is irritation of contaminated tissues or symptoms described under "Ingestion". In the event of acute exposures to therapeutic doses of this product, effects described in "Other Potential Health Effects" may result.

**CHRONIC:** Persons who are hypersensitive to this product or to other sulfonamide-derived drugs may have an allergic reaction to this drug. In the event of chronic exposures to therapeutic doses of this product, effects described in "Other Potential Health Effects" may result.



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### Acute Toxicity:

Compound	Species	Route	Type	Dose
Clorothiazide	Rat	Oral	LD <sub>50</sub>	10,000 mg/kg
Clorothiazide	Mouse	Oral	LD <sub>50</sub>	8 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:**

Not corrosive.

**Dermal Irritation:**

Not irritating.

**Eye Irritation:**

May cause mechanical irritation.

**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:**

Blood system, metabolic system, kidneys.

**Reproductive Effects:**

No reproductive effects have been reported in humans. Chlorothiazide had no adverse effects on fertility in female rats at doses up to 60 mg/kg/day and no adverse effects on fertility in male rats at doses up to 40 mg/kg/day. These doses are 1.5 and 1.0 times the recommended maximum human dose, respectively, when compared on a body weight basis.

**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 adequate animal studies have been conducted to determine mutagenic effects. No mutagenic effects have been reported in humans. Chlorothiazide was not mutagenic in vitro in the Ames microbial mutagen test (using a maximum concentration of 5 mg/plate and Salmonella typhimurium strains TA98 and TA100) and was not mutagenic and did not induce mitotic nondisjunction in diploid-strains of Aspergillus nidulans.

**Aspiration Hazard:**

No data available.



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**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.

### 12. Ecological Information

**Ecotoxicity**

**Aquatic:**

Release of this product to an aquatic environment may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities. All work practices must be aimed at eliminating environmental contamination.

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

**Terrestrial:**

This product may be harmful to contaminated plant and animal life especially in large quantities.

**Persistence and Degradability:**

No data available.

**Bioaccumulative Potential:**

No data available.

**Mobility in Soil:**

No data available.

**Mobility in Environment:**

The chemical (medicinal) components of this product will slowly degrade in the environment and form a variety of organic materials.

**Other Adverse Effects:**

Large quantities released to the aquatic and terrestrial environment may have an adverse effect.

### 13. Disposal Considerations

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



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### 14. Transport Information

<b>UN Number:</b>	Not applicable.
<b>UN Proper Shipping Name:</b>	Not applicable.
<b>Transport Hazard Class(es):</b>	Not applicable.
<b>Packing Group:</b>	Not applicable.
<b>Department of Transportation:</b>	Not regulated as a hazardous material.
<b>International Air Transport Association (IATA):</b>	Not regulated as a dangerous good.
<b>International Maritime Dangerous Good (IMDG):</b>	Not regulated as a dangerous good.

### 15. Regulatory Information

#### US Federal Regulations:

<b>Toxic Substance Control Act (TSCA):</b>	Clorothiazide: Listed. D-Mannitol: Listed Sodium Hydroxide: Listed
<b>CERCLA Hazardous Substance and Reportable Quantity:</b>	Not listed.
<b>SARA 313:</b>	Not listed.
<b>SARA 302:</b>	Not listed.

#### State Regulations

<b>Massachusetts:</b>	Sodium Hydroxide: Listed
<b>New Jersey:</b>	Sodium Hydroxide: Listed
<b>Pennsylvania:</b>	Sodium Hydroxide: Listed
<b>California Proposition 65:</b>	Not listed.

### 16. Other Information

<b>NFPA Rating:</b>	
Flammability:	1
Instability:	0
Health:	1

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